DAVID ROBERT BROWN, Sc.D.

PROFESSIONAL HISTORY

Southwest Pennsylvania Environmental Health Project 2012 to present Fairfield University, Adjunct Professor 2000 –2017 Environment and Human Health Inc. 2000 - present Health Risk Consultants, Inc. 8/97 - 2008 Northeast States for Coordinated Air Use Management (NESCAUM) 10/96 – 8/04 Agency for Toxic Substance Disease Registry (ATSDR) 1993-1996 Connecticut Department of Public Health (CT DPH) 1985-1993 Northeastern University 1979-1985 American Cyanamid Company 1977-1979 Stauffer Chemical Company 1975-1977 University of Maryland 1970-1975

EDUCATION

Sc.D. (Physiology and Toxicology) Harvard School of Public Health (1970)
M.S. (Environmental Health Sciences) University of California, Berkeley School of Public Health (1967)
B.S. (Biochemistry) Cornell University (1958)

AFFILIATIONS

National Academy of Sciences American Conference of Government Industrial Hygienists Society of Risk Analysis Boston Risk Assessment Group (*Past-President*) Society of Toxicology American Public Health Association American Association for the Advancement of Science American Association of Colleges and Pharmacy

RELEVANT EXPERIENCE

- 2011 to 2912: Designed a Public Health Project to address health impacts from Natural Gas extraction in Southwestern Pennsylvania. The project funded by the Pittsburgh Foundation the Chaneil Foundation and the Heinz Endowments established an Environmental Health Center on February 2012. It is staffed by 3 health professionals and supported by 9 scientific and technical experts.
- Assessed potential health effects (cancer, asthma, etc.) associated with existing and proposed modifications to an asphalt plant in the Hudson Valley region.
- Provided toxicological expertise on possible health effects associated with hypothetical community exposure to blowing agent used in a Firestone building products manufacturing facility. Evaluated current literature on active ingredient as well as structurally-related compounds. Assessed exposure parameters and health implications associated with several hypothetical catastrophic events for both emergency responders and the immediately surrounding residents. Presented findings in several public meeting settings as well as with the local press.

11

- Support on-going toxicological assessment for litigation in a variety consumer product cases in the context of the California Safe Drinking Water and Toxics Act (Proposition 65). Evaluate and quantify exposures stemming from reasonable use scenarios for both carcinogens and non-carcinogens. (on-going project work)
 - Assisted Hamden Board of Education in addressing environmental issues that arose as
 part of a renovations proposal for its Middle School. Worked in concert with engineers and
 regulatory officials to rapidly evaluate and remediate the impact from surface soils containing
 polycyclic aromatic hydrocarbons. Presented findings at public meetings and press
 conferences. Met with parents, staff and teachers of the Hamden Middle School community
 to discuss concerns and describe the science behind environmental findings, health concerns,
 and short- and long-term implications of the cleanup.
- Evaluated health impact of air emissions produced by a proposed oil-fired "peaker plant" on a neighborhood in New Haven, CT. Worked in concert with air modelers to predict air dispersion patterns of SO_x, NO_x, and PM-10. Reviewed epidemiological literature for morbidity and mortality patterns associated with adverse air pollution conditions. Testified before judge on behalf of the Connecticut Fund for the Environment regarding the association between increased particulate matter emissions and adverse health effects for the potentially impacted community.
- Evaluated air quality data associated with a fire in a composting facility. Provided support in developing subsequent air sampling strategy. Compounds of concern included polychlorinated dibenzo-p-dioxins and polychlorinated dibenzo-p-furans, volatile organic compounds, and metals. Advised client on potential exposures and their health implications.
- Conducted risk assessment on arsenic-containing soils of a former railroad bed. Assisted client in developing risk-based cleanup goals in order to facilitate the re-use of the property into a rails-to-trails site.
- Evaluated health and environmental effects of methyl mercury in fish for Northeast Canadian Province Mercury Study project. Identified public health responses for government officials based on study results.

NATIONAL ACTIVITIES

- 1. Human and Ecological Risk Assessment--Editorial Board ('96-Present)
- 2. Scientific Advisory Board-National Pediculosis Association--Member ('80-Present)
- 3. Air Toxics Advisory Board--Chair, State of Vermont ('93-'00)
- Graduate Advisory Committee to the Toxicology Program--Member, University of Georgia at Athens ('93-Present)
- 5. Connecticut Committee on Low Level Nuclear Waste Disposal--Advisor ('91-'93)
- 6. National Academy of Sciences--Chair, Committee on Toxicology Information ('90-'93)
- 7. NESCAUM--Co-chair of committee on Air Toxics ('90-'93)
- 8. ACGIH Committee on Emergency Guidelines--Member ('89-'93)
- US Department of Labor/Occupational Safety and Health Administration--Consultant, Quantitative Risk Assessment Workgroup on Ethylene Dibromide ('82-'84)
- Massachusetts Air Toxics Advisory Committee--Chair, Sub-committee for Chemical Evaluation ('82-'84)

PUBLICATIONS:

Fifty six publications available on request.

November 2017

STATE OF NEW MEXICO

DEPARTMENT OF ENERGY, MINERALS AND NATURAL RESOURCES

OIL CONSERVATION COMMISSION

IN THE MATTER OF PROPOSED AMENDMENT TO THE COMMISSION'S RULES TO ADDRESS CHEMICAL DISCLOSURE AND THE USE OF PERFLUOROALKYL AND POLYFLUOROALKYL SUBSTANCES AND IN OIL AND GAS EXTRACTION, 19.15.2, 19.15.7, 19.15.14, 19.15.16 AND 19.15.25 NMAC

CASE NO. 23580

DIRECT TECHNICAL TESTIMONY AND EXHIBITS

OF

DAVID BROWN, Sc.D

ON BEHALF OF WILDEARTH GUARDIANS

October 21, 2024

1	I am David R. Brown Sc.D., a Public Health Toxicologist. (Cornell University BS
2	Biochemistry, University of California at Berkeley MS Environmental Health, and Harvard
3	University ScD in Physiology Toxicology). I organized and chaired the Toxicology programs at
4	the University of Maryland School of Pharmacy and at Northeastern University. I was
5	responsible for public health follow up while at the Center for Disease Controls' Agency for
6	Toxic Substances and Disease Registry. I also taught Ethics and the Environment at Fairfield
7	University. My career has focused on public health and environmental exposures. My work has
8	included analysis of the interactions between pathways of exposure and health. My Curriculum
9	Vitae is attached as WG Ex. 56.
10	I worked in southwest Pennsylvania with the Southwest Pennsylvania Environmental
11	Health Project ("the Health Project") from its inception and continued for nine years. My
12	testimony will focus on how the Health Project came into being, the work we did, and the
13	lessons we learned about oil and gas chemical exposures and the need for chemical disclosure
14	from fracking sites. Last, I will provide testimony about the toxicity and health effects of
15	exposure to perfluoroalkyl and polyfluoroalkyl substances ("PFAS").
16	Introduction
17	Since 2012, the Health Project has worked to protect the health of people living in the
18	shadow of shale gas development. We have provided guidance to global partners, extending

19 outward from southwest Pennsylvania and across the United States to India and beyond. We

20 have produced first-in-the-nation data on health symptoms associated with shale gas

21 development and have presented our findings to residents, healthcare professionals and

22 researchers, and policymakers at the local, state, and federal levels. We are also a model and

23 featured resource at the Center for Disease Control's Agency for Toxic Substances and Disease

Registry (ATSDR) as "an example of how public health and environmental professionals can
 address the physical and mental health impacts of contamination, including by providing
 extensive resources to local physicians" in areas affected by unconventional oil and gas
 development.¹

5 At the Health Project, we began by evaluating the health effects of the development of 6 shale gas extraction in the region. Our work focused on the assessment of health effects and their 7 causes. This report of our work is focused on the failure to disclose chemical exposures and 8 health risks created when the public is misinformed.

9 At the beginning, health professionals were recruited into the Health Project to meet with 10 residents, their doctors, and consultants on nearby fracking and natural gas processing sites. A 11 major goal of the Health Project was to understand the pathways of human exposure to 12 chemicals used throughout the fracking process. Although the Health Project observed health 13 damages in the residents near the oil and gas extractions sites from the beginning, lack of 14 disclosure about the chemicals present and their use blocked efforts to understand the exact 15 hazards the residents were exposed to. Lack of disclosure presented difficulties in determining 16 risks to local communities, diagnosis of affected people, and impacts to groundwater. For 17 example: the industry publicly asserted that only typical household chemicals were present in 18 fracking, such as those used in toothpaste. Years later, studies revealed that the industry used 19 different cocktails of other, highly toxic materials in large amounts. Studies have also since 20 demonstrated that the ultimate pathways of human exposure are contaminated drinking water and 21 air emissions.²

¹ See WG Ex. 58 Agency for Toxic Substances and Disease Registry's Community Stress Resource Center, Southwest Environmental Health Project webpage.

² WG Ex. 59 Weinberger, Greiner, Walleigh, Brown; Health symptoms in residents living near shale gas activity: A retrospective record review from the Environmental Health Project; *Preventive Medicine Reports* 8 (2017) 112–115.

WG Ex. 57

1	We at the Health Project published some of the earliest scientific papers showing human
2	exposure through water and inhalation of contaminated air. ³ Notably, even given the intense
3	research done, it only became revealed in recent years that PFAS has also been used in fracking
4	fluids in Pennsylvania. ⁴
5	WildEarth Guardians has asked that I describe our early experiences responding to the
6	human health risks from those chemical exposures encountered by residents in communities near
7	oil and gas extraction. Ours was a public health investigation modeled after ATSDR's Health
8	Assessment Format. There are different phases to understanding the public health risks. They
9	are:
10	• 1) Determination of community concerns
11	• 2) Determine the chemicals of concern
12	• 3) Determine the pathways of exposures
13	• 4) Health outcome evaluation
14	• 5) Substance specific information
15	• 6) Conclusions and recommendations
16	
17	

³ See e.g. WG Ex. 60 Lewis C, Greiner LH, Brown DR (2018) Setback distances for unconventional oil and gas development: Delphi study results. PLoS ONE 13 (8): e0202462.; WG Ex. 59 Weinberger, Greiner, Walleigh, Brown; Health symptoms in residents living near shale gas activity: A retrospective record review from the Environmental Health Project; *Preventive Medicine Reports* 8 (2017) 112–115.; WG Ex. 61 Blinn HN, Utz RM, Greiner LH, Brown DR (2020) Exposure assessment of adults living near unconventional oil and natural gas development and reported health symptoms in southwest Pennsylvania, USA. PLoS ONE 15(8): e0237325.; WG Ex. 62 David R. Brown, Celia Lewis & Beth I. Weinberger (2015) Human exposure to unconventional natural gas development: A public health demonstration of periodic high exposure to chemical mixtures in ambient air, *Journal of Environmental Science and Health*, Part A, 50:5, 460-472.; WG Ex. 63 Rosmarin, Curtis Brown, Weather-based evaluation of exposure to airborne toxins to nearby residents, *Environmental Advances* 13 (2023) 100415.

Physicians for Social Responsibility (Oct. 2023).

1	Beginning
2	When the chemicals and the risks are not known by either local public health officials or
3	by those residents, the exposure and health effects cannot be understood.
4	Background
5	In the case of fracking in Pennsylvania, residents near extraction sites observed
6	deaths to livestock, wild animals, and pets. Those who obtained water for domestic use from
7	wells and springs experienced taste, smell, and appearance changes in drinking water, and
8	unexplained headaches, rashes, and other sensory symptoms. Neither the causes or responsible
9	chemicals were known. Specific information was not obtainable due to trade secrets, industrial
10	practices, and public policies. The Health Project went to health departments, but they had no
11	information. State policy dictated that all questions about health effects associated with fracking
12	be directed to the Governor's office or state health department, but after questions were recorded
13	in a file, no answers were provided. When companies were asked for information about
14	chemicals directly, they withheld information as "trade secrets." When companies applied for
15	permits, only limited water testing was done. No air testing was required. Except for explosions
16	and fires, the residents in Pennsylvania were not even aware of the scope of unusual industrial
17	activities in their rural neighborhoods.
18	It was not until 2011 that Pennsylvania required that hydraulic fracturing chemicals be
19	reported to the state. ⁵ Even then, only partial information about chemicals in use was available to
20	residents or their health providers. There was minimal involvement by the local or state health

21 departments.

22

Occasionally, an academic scientist would come by residents' homes asking questions

⁵ See WG Ex. 64 58 Pa.C.S.A. § 3222.1 https://www.legis.state.pa.us/WU01/LI/LI/CT/HTM/58/00.032.022.001..HTM

<u>WG Ex. 57</u>

1	about health or the environment as part of a study. The scientists would collect water samples
2	and health data, but residents rarely heard from them again. In some cases the findings from
3	those inquiries would appear in published academic journals two to three years later. ⁶
4	Impacted residents were "Doctor Shopping" as far as Chicago attempting to find
5	treatments for their children's emerging health conditions. When links between fracking and
6	health problems were found, non-disclosure agreements were negotiated by the industry. These
7	agreements prevented residents from sharing their experience or reaching out to health officials
8	or to neighbors with similar exposures and health effects. Non-disclosure agreements also
9	prevented the Health Project from further investigating the problem.
10	Other NGOs
11	About three or four years after the beginning of fracking, community-level Non-
12	Governmental Organizations (NGO's) were being formed within impacted communities. The
13	NGOs tried to lobby the governments for information and relief. Some national level NGO's
14	also began to take interest. The Southwest Pennsylvania Environmental Health Project was
15	formed with assistance of major funders in the Pittsburgh area with the expectation that the
16	health issues would be identified and ameliorated if public health agencies obtained factual data
17	about public exposures to pollution from fracking sites. The Health Project developed an internal
18	public health plan to address human health effects and chemical exposures. Reduction of
19	exposures through community education was a central component of the initial Health Project
20	approach.
21	Lessons learned by The Health Project

⁶ See WG Ex. 65 Rabinowitz, et al., Proximity to Natural Gas Wells and Reported Health Status: Results of a Household Survey in Washington County, Pennsylvania, *Environmental Health Perspectives*, Volume 123, Number 1, January 2015.

- 1 A systematic Public Health Investigation conducted over several years identified the scope of human health risks and fracking in Southwest Pennsylvania.
- 2

3 **Community Concerns**

4 The project began with a Determination of Community Concerns. It quickly found a 5 pattern of health effects in those living closest to fracking. Persons who drank from groundwater 6 wells reported more clinical signs and symptoms. The health effects were consistent with higher 7 exposures. It appeared as if persons who showered in rural well water were having high 8 exposures from inhalation of chemicals that had contaminated their water supplies and become 9 airborne during showering. This suggested both potential water and air pathways of exposure. 10 Although the specific signs and symptoms were not unique, the patterns of symptoms observed 11 were unusual with respect to the percentage of persons reporting health effects and the range of 12 health effects.

13 The table on page 9 shows a comparison of health complaints between fracking 14 communities in Pennsylvania and a similar population in New York where gas activity was 15 planned but had not yet begun. The range of increased symptoms in the Pennsylvania 16 communities suggested exposures to several different chemical agents. However, interpretation 17 was complicated by the lack of information on which chemicals could be in the water or air 18 exposures. Because industry was not required to disclose all chemicals used in the fracking 19 process, the public health professionals working with the Health Project did not have the data 20 needed to provide public health guidance to protect the communities in areas where fracking 21 occurred.

22 The public health method was applied using a process called a Needs Assessment. In that 23 step, a survey was made of community members and agencies to determine the health effects

1 observed by clinicians and determine the capability of community resources.⁷ The health

2 providers shared the following information on the health of residents: children experienced a

3 'failure to thrive' as well as skin rashes, repeated nosebleeds at night, and other health effects.

4 Some people mentioned that the water from faucets could be set on fire. At that time, other

5 researchers observed an unusual level of birth issues (low birth weights and small size for

6 gestational age) in the regions near fracking.⁸

7 A systematic survey of the health of residents identified several health conditions present

8 in the community. Air and water testing showed a pattern of chemicals present. Subsequent

9 reports have shown a complex combination of fracking and other chemicals at the sites.⁹

10 Unexpectedly, there was no health or exposure information publicly available for workers in the

11 shale gas extraction industry that could be used for comparisons.

12 Determination of the chemicals of concern

13 The Health Project next focused on identification of likely chemical exposures needed for

14 linkage with health findings. However, incomplete chemical disclosures prevented the Health

15 Project from making needed comparisons. Instead, the Health Project itself had to conduct

16 literature research and its own sampling of air and water.¹⁰ These measures slowly yielded the

⁹ WG Ex. 59 Weinberger, Greiner, Walleigh, Brown; Health symptoms in residents living near shale gas activity: A retrospective record review from the Environmental Health Project; *Preventive Medicine Reports* 8 (2017) 112–115.

⁷ See WG Ex. 65 Rabinowitz et al, Proximity to Natural Gas Wells and Reported Health Status: Results of a Household Survey in Washington County, Pennsylvania, *Environmental Health Perspectives*, Volume 123, Issue 1 Pages 21 - 26 (2015).

⁸ See WG Ex. 66 Elaine L. Hill, "Shale Gas Development and Infant Health: Evidence from Pennsylvania," *Journal of Health Economics* 61 (2018): 134–50.

¹⁰ WG Ex. 62 David R. Brown, Celia Lewis & Beth I. Weinberger (2015) Human exposure to unconventional natural gas development: A public health demonstration of periodic high exposure to chemical mixtures in ambient air, Journal of Environmental Science and Health, Part A, 50:5, 460-472.; WG Ex. 61 Blinn HN, Utz RM, Greiner LH, Brown DR (2020) Exposure assessment of adults living near unconventional oil and natural gas development and reported health symptoms in southwest Pennsylvania, USA. PLoS ONE 15(8): e0237325.; WG Ex. 59 Weinberger, Greiner, Walleigh, Brown; Health symptoms in residents living near shale gas activity: A retrospective record review from the Environmental Health Project; *Preventive Medicine Reports* 8 (2017) 112–115.

information needed to begin to understand the risks and indicated ways that a resident might
 reduce their family's exposures.

3	The Health Project developed a list of chemical classes that appeared to be involved. The
4	list is based on chemical analyses, human health responses, and the scientific literature.
5	Subsequently, researchers have confirmed that chemicals in those classes are correct. ¹¹ It is not
6	yet known whether the chemical lists are complete. Chemicals in the PFAS category were only
7	found to also be present recently through the work of Physicians for Social Responsibility. ¹²
8	Today, in October 2024, there is more information about the chemicals used or formed in
9	fracked oil and gas. ¹³ However, there are still many chemicals we don't know because of
10	nondisclosure and uncertainty about how those chemicals react with each other to produce new
11	chemicals. For the chemicals we do know, it is reasonably clear what health effects are present at
12	different dose levels for each of those chemicals. But how the chemicals act on the body when
13	inhaled or consumed as mixtures is still not known. There are 5 to 8 different classes of
14	chemicals shown to be present in shale or oil and gas extraction and processing. ¹⁴ They are:
15	• Aromatic Hydrocarbons (Benzene toluene, xylene, ethylbenzene)
16	• Short chain aliphatic hydrocarbons, (hexane, ethane, etc.)

¹¹ WG Ex. 67 Davis, C. D., Frazier, C., Guennouni, N., King, R., Mast, H., Plunkett, E. M., & Quirk, Z. J. (2023). Community health impacts from natural gas pipeline compressor stations. *GeoHealth*, 7, e2023GH000874..

¹² See WG Exs. 13-19

¹³ Health risks associated with certain oil and gas fracking chemicals are shown in the document prepared by the Health Project – WG Ex. 68 Environmental Health Project Summa Canister Chemical Sampling Guide 2021. Detailed academic publications have confirmed findings. *See* WG Ex. 62 David R. Brown, Celia Lewis & Beth I. Weinberger (2015) Human exposure to unconventional natural gas development: A public health demonstration of periodic high exposure to chemical mixtures in ambient air, *Journal of Environmental Science and Health*, Part A, 50:5, 460-472.; WG Ex. 60 Lewis C, Greiner LH, Brown DR (2018) Setback distances for unconventional oil and gas development: Delphi study results. PLoS ONE 13 (8): e0202462.; WG Ex. 61 Blinn HN, Utz RM, Greiner LH, Brown DR (2020) Exposure assessment of adults living near unconventional oil and natural gas development and reported health symptoms in southwest Pennsylvania, USA. PLoS ONE 15(8): e0237325.

¹⁴ WG Ex. 59 Weinberger, Greiner, Walleigh, Brown; Health symptoms in residents living near shale gas activity: A retrospective record review from the Environmental Health Project; *Preventive Medicine Reports* 8 (2017) 112–115.

1	• Aldehydes irritants. (formaldehyde, acetaldehyde)
2	• Halogenated aliphatic and aromatics (Chlorobenzene, dichloromethane)
3	• Glycols (ethylene Glycol, propylene glycol)
4	• Other unspecified. (radioisotopes. radon, radium)
5	Pathways of exposure
6	The primary exposure pathways to oil and gas chemicals were groundwater and surface
7	water contamination ¹⁵ and airborne exposures. ¹⁶ There are two types of exposures, those that
8	take place every day and the periodic episodes of extreme exposures which occur several hours a
9	week or due to blow downs or accidents. The components of mixtures in the exposures differ
10	depending on sources. Exposed populations range from healthy men to highly susceptible
11	children and elderly.
12	Even now, health workers are unable to obtain real time specific exposure information, or
13	yearly amounts of releases in tons/year or any information at all about some chemicals such as
14	PFAS. Lack of and misleading information is the main problem blocking determination of safety
15	to residents and the workers.
16	
	Health outcome evaluation
17	Because of limited and undisclosed information about specific exposures, it is difficult to
17 18	
	Because of limited and undisclosed information about specific exposures, it is difficult to

¹⁵ WG Ex. 34 U.S. EPA. Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States (Final Report). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-16/236F, 2016

¹⁶ WG Ex. 69 Garcia-Gonzales et al., Hazardous Air Pollutants Associated with Upstream Oil and Natural Gas Development: A Critical Synthesis of Current Peer-Reviewed Literature, *Annu. Rev. Public Health* 2019. 40:283–304.

1 inhalation, ingestion or dermal contacts, the chemical must be transported to a site sensitive to 2 toxic injury, such as the lung, kidneys, or brain, for example. Chemical toxicity is usually 3 understood at the level of cells and tissues and how the chemical actually acts on cells at each 4 site. Primary actions occur at two or more locations, first on receptors by release of bioactive 5 cellular transmitters or by interfering with a cell function such as membrane fluidity. In some 6 cases, a critical biologic reaction is blocked. Some chemicals also bioaccumulate in lipids and 7 other sites eventually reaching concentrations that cause injury. The chemicals frequently block 8 actions involved with normal functions. Generally, the toxic effects stop when the chemical is 9 removed from the body, usually eliminated thru the lung or as metabolites in urine. Some toxic 10 effects are permanent.

When reliable information about chemicals used at an oil and gas site is available, it is possible to characterize exposures and health hazards and to establish appropriate quantitative public health safety guidance. The pharmacokinetics¹⁷ of shale exposures offers a logical approach to determining the risk. Primary actions are determined by estimation of concentration at the likely receptor sites, such as eye, lungs, brain or energetics (liver metabolism). When there is no reliable information about chemicals used at an oil and gas site, you cannot characterize the risk.

18 Steps in characterization of risk

For example: Reliable data exists for particulate matter, which allows characterization of
risk. PM 2.5 and smaller particles exacerbate asthma through a receptor mechanism in which PM
2.5 increases transport of Volatile Organic Compounds (VOCs) to the deep lung and higher
absorption, thus affecting upper and lower respiratory damage.

¹⁷ Pharmacokinetics refers to the quantitative stages in exposure, uptake, actions and elimination of drugs or chemicals in the body.

1	Calculations of risk need to consider:
2	• The number of exposures
3	• The duration of the exposures
4	• Time between exposures
5	• The concentration of chemicals present in the mixture
6	• The baseline of exposures
7	Table of health symptoms
8	The following table from The Health Project studies shows that people near oil and gas
9	wells have disproportionate symptoms than people in other areas. The likely explanation for
10	difference in the rates of certain symptoms, such as headache and sore throat, suggest proximity
11	to oil and gas wells. Other symptoms, such as ringing in the ears and numbness, appear not to be
12	symptomatic of proximity. The following health effects, which have been reported by residents,
13	are characteristic of the chemicals found. A location in New York State is shown for
14	comparison. The Health Project and others have conducted similar comparisons that demonstrate
15	a link between certain health effects and proximity to oil and gas operations. ¹⁸

¹⁸ WG Ex. 65 Rabinowitz, et al., Proximity to Natural Gas Wells and Reported Health Status: Results of aHousehold Survey in Washington County, Pennsylvania, *Environmental Health Perspectives*, Volume 123, Number 1, January 2015.

Symptoms	Exposed population All SWPA average all cases N (77)	Non exposed population New York Pre construction N (88)
headache	42.90%	14.80%
Sore throat	39.00%	5.70%
cough	29.90%	5.70%
Short of breath	28.60%	5.70%
Sinus problems	27.30%	13.60%
wheeze	22.10%	4.50%
nausea	22.10%	3.40%
Abdominal pain	19.50%	1.10%
Eye irritation	16.90%	12.50%
Ring ear	16.90%	15.90%
Skin rashes	16.90%	8.00%
weakness	14.30%	9.10%
Speaking problems	14.30%	1.10%
dizziness	14.30%	2.30%
Heart palpitations	13.00%	6.80%
numbness	13.00%	12.50%
Nose bleed	11.70%	0.00%
Joint pain	11.70%	15.90%
Chest pain	10.40%	3.40%
Hair loss	10.40%	0.00%
Muscle ache	9.10%	11.40%
Skin irritation	9.10%	4.50%
Weight change	7.80%	4.50%
Skin cysts	7.80%	3.40%
vomiting	2.60%	0.00%

Each of the actions on this list were reported to a health professional working with the Health Project. The effects of the chemicals listed from the scientific literature are similar to the effects identified by the Health Project: irritation of eyes, skin; headache, lassitude, central nervous system depression, poor equilibrium; dermatitis; cardiac arrhythmias; liver damage.¹⁹

¹⁹ WG Ex. 68 Environmental Health Project Summa Canister Chemical Sampling Guide 2021.

1 In contrast to the health effects found, monitoring data from government and industrial 2 sources assured the public that untoward exposures are not occurring.²⁰ Health findings and air monitoring reports are in conflict with these governmental and industry sources. Specifically, 3 4 reports of acute onset sequelae in residents (respiratory, neurologic, dermal, vascular bleeding, 5 abdominal pain, nausea, and vomiting) contrast with the assurances made by government and 6 industry based on air monitoring data: Burnet Shale Texas (Bunch et al. 2013), Marcellus 7 Shale Ambient Air sampling (Pennsylvania DEP 2010), City of Fort Worth Gas Air Quality 8 Study (ERG 2011).

9 Cancer

10 Finally, Ewing sarcoma is a rare type of cancer that occurs in bones or in the soft tissue 11 around the bones that has been identified at several sites in southwest Pennsylvania where 12 fracking is present. Ewing sarcoma is more common in children and teenagers, but it can occur at 13 any age. Ewing tumors (sarcomas) are not common. About 1% of all childhood cancers are 14 Ewing tumors. Because only about 200 children and teens are diagnosed with Ewing tumors in 15 the United States each year, multiple cases appearing in southwest Pennsylvania around the sme 16 time did not seem reasonable to the public. Ewing sarcoma is one of the rarest cancers, but 17 families in southwest Pennsylvania experienced frequent cases. About the same time, radium was found to be present in surface water downstream of facilities treating oil and gas waste.²¹ 18 19 Radium is known to cause bone cancers, and southwest Pennsylvania has a cluster of these 20 facilities. A study conducted by the Health Department and the University of Pittsburgh School

²⁰ See WG Ex. 70 Report 1 of the Forty-Third Statewide Investigating Grand Jury (2020)

²¹ WG Ex. 71 Lauren M. Badertscher, et al. Elevated sediment radionuclide concentrations downstream of facilities treating leachate from landfills accepting oil and gas waste, *Ecological Indicators*, Volume 154, 2023, 110616, ISSN 1470-160X, https://doi.org/10.1016/j.ecolind.2023.110616.

1	of Public Health did not confirm a statistical link between fracking and Ewing sarcoma, but it did
2	find a link between fracking and leukemia. ²²
3	PFAS
4	How do these chemicals fit into the shale gas public health story? Use in fracking, unknown
5	until recently, thus not included in health evaluations.
6	Per- and polyfluoroalkyl substances (PFAS) are stable in the environment, including
7	groundwater, and enter the body where they bioaccumulates due to the chemical stability and
8	resistance to metabolic elimination. These chemicals are highly toxic in the parts per trillion
9	range compared to parts per million for most toxic compounds.
10	Health actions
11	In recent years, it was revealed that the oil and gas industry has used PFAS in fracking
12	operations. ²³ It has also been confirmed that exposure to PFAS can cause hepatotoxicity,
13	neurotoxicity, reproductive toxicity, immune toxicity, thyroid disruption, cardiovascular toxicity
14	in humans and pulmonary toxicity, and renal toxicity in laboratory animals. ²⁴
15	In May 2016, EPA established drinking water lifetime health advisories of 70 parts per
16	trillion (0.07 micrograms per liter (μ g/L)) for the combined concentrations of PFAS. ²⁵
17	Subsequently, in April 2024, EPA established drinking water standards for 5 PFAS compounds
18	as follows:

²² WG Ex. 72 University of Pittsburgh School of Public Health, Hydraulic Fracturing Epidemiology Research Studies: Childhood Cancer Case-Control Study, August 3, 2023.

²³ See e.g., WG Ex. 13 Dusty Horwitt. Fracking with "Forever Chemicals." Physicians for Social Responsibility (July 2021).

²⁴ WG. Ex. 73-A Fenton et al., Human health toxicity of per- and polyfluoroalkyl substances - *Environmental Toxicology and Chemistry*, 2021;40:606–630.; WG Ex. 73-B Betts, A Measure of Community Exposure: PFOA in Well Water Correlates with Serum Levels, *Environmental Health Perspectives*, Volume 119, Issue 1 Page A35 (2011).

²⁵ WG Ex. 74 Federal Register, Vol. 81, No. 101 Wednesday, May 25, 2016.

1	Individual Maximum Contaminant Levels (MCLs)
2	a. Perfluorooctanoic acid (PFOA) MCL = 4.0 nanograms per liter or parts per
Z	a. Perhuoroocianoic acid (PFOA) MCL -4.0 hanograms per inter or parts per
3	trillion (ng/L or ppt)
4	b. Perfluorooctane sulfonic acid (PFOS) MCL = 4.0 ng/L
5	c. Perfluorohexane sulfonic acid (PFHxS) MCL = 10 ng/L
6	d. Perfluorononanoic acid (PFNA) MCL = 10 ng/L
7	e. Hexafluoropropylene oxide dimer acid (HFPO-DA) MCL = 10 ng/L^{26}
8	These levels are extremely low compared to other health advisories and drinking water
9	standards, an indication of very potent chemicals. Often, such highly toxic chemicals directly act
10	on critical biocontrol systems in the body and bind tightly to receptors. There is accumulation in
11	the body over time. PFAS's presence in the fracking fluid and the flowback water was not
12	apparent when healthcare workers in Pennsylvania were trying to reduce the health effects for
13	people who were consuming water near or in the gas extraction fields. But two of three PFAS
14	related actions were apparent, in the early screening for health effects: low birth weights and
15	immune problems.
16	PFAS compounds were introduced into commerce in the 1940s. Only recently, studies
17	found that every person studied has been exposed, carrying serum PFOS levels of 2.5 PPT. In
18	states where there have been PFAS controls introduced, the serum levels decrease but the half
19	life is 2.5 years. Persons studied near major sources of PFAS are at higher risks.
20	Health concerns
21	The National Health and Nutrition Examination Survey (NHANES) has measured PFAS

22 levels in blood in the U.S. population since 1999. NHANES is a program of studies designed by

²⁶ WG Ex. 75 Federal Register, Vol. 89, No. 113 Tuesday, June 11, 2024.

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1	the Centers for Disease Control and Prevention (CDC) to evaluate the health and nutrition of
2	adults and children in the United States. NHANES data are publicly released in two-year cycles.
3	Some toxins remain in the body for days or weeks, but PFAS remains in the body for
4	years. As the use of some PFAS have declined, some blood PFAS levels have gone down as
5	well. For example, since 2002 the production and use of PFOS and PFOA in the United States
6	has declined. And, according to NHANES:
7	• From 1999-2000 to 2017-2018, blood PFOS levels declined by more than 85%.
8	• From 1999-2000 to 2017-2018, blood PFOA levels declined by more than 70%. ²⁷
9	However, as PFOS and PFOA are phased out and replaced, people may be exposed to
10	other PFAS.
11	The average half-lives in humans for some PFAS were estimated to be 2.7 years for
12	PFOA, 3.4 years for PFOS, and 5.3 years for PFHxS, with marked interindividual variation (Li et
13	al. 2018). ²⁸ The estimates were in the same range as reported by others. ²⁹ Some PFOS
14	compounds that contain additional branches from their main carbon backbone have a half-life
15	that stretch into decades within the human body. In water, however, they can linger even longer.
16	Some studies have suggested that PFOA has a half-life of more than 90 years, while for PFOS it
17	is more than 41 years.

²⁷ WG. Ex. 76 ATSDR Website PFAS in the US population. Available at: <u>https://www.atsdr.cdc.gov/pfas/health-</u> effects/us-population.html#print ²⁸ WG Ex. 77 Li Y, Fletcher T, Mucs D, et al., Half-lives of PFOS, PFHxS and PFOA after end of exposure to

contaminated drinking water, Occupational and Environmental Medicine 2018;75:46-51.

²⁹ See e.g., Brede E, Wilhelm M, Göen T, Müller J, Rauchfuss K, Kraft M, et al. 2010. Two-year follow-up biomonitoring pilot study of residents' and controls' PFC plasma levels after PFOA reduction in public water system in Arnsberg, Germany. Int J. Hyg Environ Health 213(3):217-223.; and Olsen GW, Burris JM, Ehresman DJ, Froehlich JW, Seacat AM, Butenhoff JL, et al.2007. Half-life of serum elimination of perfluorooctanesulfonate, perfluorohexa-nesulfonate, and perfluorooctanoate in retired fluorochemical production work-ers. Environ Health Perspect 115(9):1298-1305.

1 Health implications and limitations

Exposure to sufficiently elevated levels of certain PFAS may cause a variety of health effects including developmental effects in fetuses and infants, effects on the thyroid, liver, kidneys, certain hormones, and the immune system. Some studies suggest a cancer risk may also exist in people exposed to higher levels of some PFAS. Scientists and regulators are still working to study and better understand the health risks posed by exposures to PFAS.

Failure to disclose PFAS chemicals in oil and gas means that public health tools, such as warning and reducing pathways of exposure, and human testing have not been considered. Yet studies in other areas have established that toxic effects occur at the extremely low parts per trillion range. PFAS that enter the body through drinking water can stay in the body for years, affecting sensitive periods of development, reducing birth weights of children, and interfering with the immune system. Longer exposures produce other serious health effects.

In the face of such uncertainties, the standing Public Health Guidance is to "Break the Chain of Transmission" – stop the exposures because you don't know what they are exposed to, i.e. leave the home. In contrast, for oil and gas the argument is to comply with exposure standards and, when no standards exist, to ignore health concerns completely while waiting for peer reviewed evidence of a link between the exposure and a specific disease.

When documenting health effects in Pennsylvania, the Health Project was unaware that PFAS was present in oil and gas operations and therefore didn't consider those specific chemical exposures. If there had been chemical disclosure, we would have known about the presence of PFAS, and we would have considered them specifically.

- 22
- 23

1 Community notification

A core belief of the Health Project and most departments of health is respect for the autonomy of the residents exposed. In order to support the autonomy imperative, careful and timely (one month) constructed 'Notifications' are sent to each resident and to other persons placed at risk. Local media are included. Community meetings are an important component of community notification.

PFAS releases into communities are notable because of the levels of risk indicated by high toxicity of trace amounts of the chemicals and the gaps in the expected information needed, as well as the long duration (years) the chemicals persist in soil and water. Moreover, in some cases, the people placed at high risk will not be conceived or born for decades. However, their safety is a critical part of the public health process, so data and related notifications should be accessible as long as the chemicals are present.

13 Conclusion

In summary, the human health risks from chemical exposures encountered by residents in communities near oil and gas extraction have raised widespread concerns. There appear to be two pathways of exposure, water contamination and air contamination. Until the Environmental Health Project, there was not a systematic attempt to determine the public health risks in the region. There are now specific studies published in the academic literature that document health hazards in populations exposed to shale gas and other activities. Some residents have purchased monitors to test their own air and are drinking bottled water.

It is my opinion, based on work in southwest Pennsylvania and other sites in the
Northeast, that there are air and water exposures to a suite of chemicals that have actions
consistent with those reported by residents. Exposure to the chemicals have and will continue to

1	be a public health hazard for nearby residents. Lack of and misleading information is the main
2	problem blocking determination of safety to residents and the workers.
3	I have reviewed the proposed rule submitted by WildEarth Guardians. My understanding
4	is that it bans the use of both PFAS and undisclosed chemicals in downhole oil and gas
5	operations in New Mexico. Additionally, it requires community notification of chemicals used
6	downhole in oil and gas operations.
7	In Pennsylvania, we didn't know the chemicals people were exposed to and therefore
8	could not fully employ public health practices and procedures. It is my opinion, from a public
9	health perspective, that without chemical disclosure you are in the same position in New Mexico.
10	If you do not have thorough data from chemical disclosure, public health professionals are in the
11	position of relying on incomplete data.
12	This concludes my testimony, which is accurate to the best of my knowledge.
13 14	<u>/s/ David Brown</u> October 20, 2024 David R. Brown ScD. Date

15 Westport, Connecticut.





Community Stress Resource Center

Southwest Pennsylvania Environmental Health Project

Description:

Developed in the context of unconventional oil and gas development in Southwest Pennsylvania, this website offers an example of how public health and environmental professionals can address the physical and mental health impacts of contamination, including by providing extensive resources to local physicians.

Target Situation:

Community members or local health care providers living in a community affected by unconventional oil and gas development who want to understand some of the potential health and stress impacts; or public health professionals who seek an example of how to develop a comprehensive response and public-facing website page that addresses local contamination.

Additional Reading:

Documents available on the website that may be of interest include:

- 1. A medical toolbox for health care providers \square
- 2. A summary pamphlet providing information about the mental health impacts of unconventional oil and gas development for health care providers 📙 [PDF 330 KB] 🖸
- 3. Proceedings from a community-facing webinar series dealing with health impacts of unconventional oil and gas development 📕 [PDF 734 KB] 🖸
- 4. A presentation that serves as an example of how to conduct focus group research on stress and resilience in a contamination-impacted community [PDF 1.19 MB]

VIEW THIS RESOURCE >>

Resource Type: Website

Source:

Southwest Pennsylvania Environmental Health Project

Publication Year:

2020

Target Audience(s):

Community members, physicians, public health professionals, environmental professionals

3 Keys Framework

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Short communication

Health symptoms in residents living near shale gas activity: A retrospective record review from the Environmental Health Project

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ABSTRACT

Increasing evidence demonstrates an association between health symptoms and exposure to unconventional natural gas development (UNGD). The purpose of this study is to describe the health of adults in communities with intense UNGD who presented for evaluation of symptoms. Records of 135 structured health assessments conducted between February 2012 and October 2015 were reviewed retrospectively. Publicly available data were used to determine proximity to gas wells. Analysis was restricted to records of adults who lived within 1 km of a well in Pennsylvania and denied employment in the gas industry (n = 51). Symptoms in each record were reviewed by a physician. Symptoms that could be explained by pre-existing or concurrent conditions or social history and those that began or worsened prior to exposure were excluded. Exposure was calculated using date of well drilling within 1 km. The number of symptoms/participant ranged from 0 to 19 (mean = 6.2; SD = 5.1). Symptoms most commonly reported were: sleep disruption, headache, throat irritation, stress or anxiety, cough, shortness of breath, sinus problems, fatigue, nausea, and wheezing. These results are consistent with findings of prior studies using self-report without physician review. In comparison, our results are strengthened by the collection of health data by a health care provider, critical review of symptoms for possible alternative causes, and confirmation of timing of exposure to unconventional natural gas well relative to symptom onset or exacerbation. Our findings confirm earlier studies and add to the growing body of evidence of the association between symptoms and exposure to UNGD.

1. Background

The public's health should be a consideration when there is widespread adoption of new industrial activity such as extraction of natural gas through hydraulic fracturing, commonly referred to as "fracking". Hydraulic fracturing, the injection of pressurized water, chemicals and sand into a well bore to increase production of oil or gas, was first used in conventional vertical wells drilled into discrete oil or gas reservoirs. In recent years, the development of high volume, high pressure hydraulic fracturing, combined with directional drilling, has facilitated the extraction of oil and gas from unconventional reservoirs, such as shale and other "tight" geologic formations, where the oil and gas is distributed throughout the formation rather than in defined reservoirs. Proponents of hydraulic fracturing cite benefits such as reduced dependence on foreign oil and job creation in local communities. Public health professionals and others have raised concerns about short- and long-term health and environmental impacts. Hydraulic fracturing is part of a larger process of extracting, processing and transporting natural gas. Taken together, it is referred to as unconventional natural gas development (UNGD). UNGD sites include well pads, where the hydraulic fracturing occurs, compressor stations, metering stations, and processing plants, all of which release emissions.

Air and water monitoring near well pads have documented the presence of multiple compounds with known human health effects, both short- and long-term. Compounds of concern are volatile organic compounds including benzene, associated with short-term effects of headache and dizziness and long-term effects of aplastic anemia and leukemia (ATSDR, 2015); toluene, associated with headaches, sleepiness, confusion, and possible permanent neurological damage (ATSDR, 2011a) ethylbenzene, associated with symptoms of eye and throat irritation and a possible carcinogen (ATSDR, 2011b) and xylene, associated with eye, nose, throat, and skin irritation and possible long-term neurologic effects (CCOHS, 2017).

Other compounds with documented adverse health outcomes

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include particulate matter, associated with asthma attacks, acute bronchitis, and reduced lung function (OSHA, 2013), methylene chloride, associated with cancer (ATSDR, 2011c), and hydrogen sulfide, associated with eye, nose, and throat irritation and asthma (ATSDR, 2011d). Our understanding of the human health impacts of exposure, however, is hampered by the absence of human toxicity information on 75–80% of the chemicals used in this process (Elliott et al., 2016). In addition to chemical emissions, UNGD produces noise and light exposures at levels that may increase the risk of adverse health outcomes, including annoyance, sleep disturbance, and cardiovascular symptoms (Hays et al., 2017).

Self-report studies have consistently documented skin irritation and rash: respiratory symptoms including difficulty breathing; nose, throat, and sinus problems; gastrointestinal disturbances; headache; sleep disruption; and psychological symptoms including stress (Saberi, 2013; Ferrar et al., 2013; Rabinowitz et al., 2015; Steinzor et al., 2013). These studies relied on self-report of symptoms, obtained either through a survey "check-list" that was self-administered (Saberi, 2013; Steinzor et al., 2013) or administered by a research assistant (Rabinowitz et al., 2015). In one study a semi-structured interview was used (Ferrar et al., 2013). With the exception of the study conducted by Rabinowitz and colleagues (Rabinowitz et al., 2015), these studies used convenience samples that ranged in size from 33 to 108. Rabinowitz et al. used randomized subject selection and did not refer explicitly to UNGD in the survey process. Two studies included an estimate of exposure. Steinzor et al. demonstrated compounds with known human health effects in air and water samples; symptoms reported by participants were consistent with these effects. Rabinowitz et al. found increased prevalence of skin and respiratory symptoms was associated with increased proximity to natural gas wells.

Limitations of the self-report studies include the use of convenience samples and possible recall bias on the part of the participant. Onset and/or exacerbation of self-reported symptoms may be subject to recall bias on the part of the participant, particularly if the participants have a high level of awareness of the risks associated with exposure and/or understand the purpose of the study. None of the self-report studies incorporated review of data by a health care provider.

More recently, several population-based studies using publicly available or health system data have documented an association with poor birth outcomes (Casey et al., 2015; McKenzie et al., 2014; Stacy et al., 2015) asthma exacerbation (Rasmussen et al., 2016), infant mortality (Busby and Mangano, 2017), and childhood acute lymphocytic leukemia.(McKenzie et al., 2017) One other study demonstrated an association with migraine, chronic rhinosinusitis, and fatigue, symptoms previously documented in the other self-report studies. (Tustin et al., 2016)

The purpose of the present study is to describe the symptoms reported in a sample of Pennsylvania residents who lived in close proximity to unconventional gas wells. We conducted a retrospective review of 135 health assessment records of individuals who live in the Marcellus Shale region of the United States. The health assessments had been conducted by family nurse practitioners in collaboration with an occupational medicine physician. Because available evidence suggests that health impacts are related to proximity to wells, with symptoms more likely in individuals who live in closer proximity to gas wells (Rabinowitz et al., 2015; Casey et al., 2015; McKenzie et al., 2014; Stacy et al., 2015; Rasmussen et al., 2016; McKenzie et al., 2017; Tustin et al., 2016), this review was restricted to the records of individuals who lived within 1 km of at least one gas well. The study was reviewed and approved by the Duquesne University Institutional Review Board.

2. Method

Family nurse practitioners at the Southwest Pennsylvania Environmental Health Project (EHP) have been systematically collecting health data from residents of communities located near UNGD sites since 2012. This service was developed to meet the needs of residents who were concerned about health impacts and who sought evaluation by a health care professional. Services are advertised on the EHP website, local media, community meetings, and word-of-mouth and are offered at no charge. The health records of these clients provide a dataset of health symptoms reported by those living in proximity to UNGD sites.

Between February 1, 2012 and October 31, 2015, 135 children and adults completed the standardized health assessment, typically conducted face-to-face by a family nurse practitioner. The health assessments were conducted according to standard clinical practice for collecting a medical history and included current problems, review of systems, past medical history, family history, and social history. When indicated by the interview, a targeted physical examination was conducted. Individuals who completed this health assessment did so for their own personal health information.

All 135 records were reviewed by a team of health care providers that included a physician who is board certified occupational medicine (LW) and at least one nurse practitioner. Records were excluded if they were incomplete at the time of the review (n = 2); the client was < 18 years of age (n = 21); the client reported employment in the gas industry (n = 7); client resided in a state other than Pennsylvania (n = 28); client did not report any symptoms at the time of the health assessment (n = 3). After these exclusion criteria were applied, 74 records remained.

2.1. Proximity to unconventional natural gas wells

One author (BW) used publicly available data to determine the number of unconventional natural gas wells located within 1 km of each residence for the 74 records. Publicly available data includes location and "SPUD" date, or date drilling began. Using ArcGIS, the home address was used to calculate the distance from the home to the nearest well(s). Records were excluded if it was not possible to verify at least one gas well within 1 km of the residence (n = 23). After this criterion was applied, 51 records remained.

2.2. Symptom inclusion criteria

Prior to review of the records, the physician (LW) and nurse practitioner developed and implemented the symptom inclusion criteria. Each symptom recorded in the health assessment was reviewed in the context of past medical and surgical history, concurrent medical conditions, family and social history, and environmental exposures unrelated to UNGD. If a plausible cause for the symptom was identified, the symptom was not included in the analysis. For example, if the social history indicated a ½ pack/day smoking history, the symptom of "difficulty breathing" was not included. Symptoms were included only when there was no possible cause evident in the health assessment record. The records were not reviewed with the intent of establishing or confirming a diagnosis, but to determine if a plausible explanation for the symptom could be identified.

Independently, BW determined timing of the exposure for each symptom that met the inclusion criteria, using the SPUD date for each unconventional natural gas well within 1 km. The earliest SPUD date for wells within 1 km of the residence was considered the beginning of exposure to UNGD. The date of onset/exacerbation of each symptom was available in the health assessment record. If the date of onset/exacerbation of a symptom occurred prior to the earliest SPUD date for wells within 1 km, that symptom was not included in the analysis. Symptoms were included only if the onset/exacerbation occurred after the date of first exposure, estimated by the earliest SPUD date.

Descriptive statistics were used to determine frequency, distribution, and variance.

Table 1

Symptoms meeting inclusion criteria that were reported between February 2012 and October 2015 by 51 adults who lived within 1 km of an unconventional natural gas well in Pennsylvania.

Symptoms	# Reporting	% Reporting
Sleep disruption	22	43.1%
Headache	21	41.2%
Throat irritation	20	39.2%
Stress/anxiety	19	37.3%
Cough	17	33.3%
Shortness of breath	15	29.4%
Sinus problems	15	29.4%
Fatigue	12	23.5%
Nausea	12	23.5%
Wheezing	11	21.6%
Itchy eyes	11	21.6%
Weak/drowsy	9	17.6%
Abdominal pain	9	17.6%
Irritable moody	9	17.6%
Painful/dry eyes	8	15.7%
Painful joints	8	15.7%
Rash	8	15.7%
Dizziness	8	15.7%
Nose bleeds	7	13.7%
Tinnitus	7	13.7%
Aches	7	13.7%
Memory - short term	7	13.7%
Numbness	7	13.7%
Chest pain	6	11.8%
Hair loss	6	11.8%
Itchy skin	6	11.8%
Worry	6	11.8%
Palpitation	5	9.8%
Skin lesions/blisters	5	9.8%

3. Results

The 51 adults included in this record review had reported at least one symptom on their health assessment, denied occupation exposure related to natural gas extraction and lived in Pennsylvania within 1 km of an unconventional natural gas well. The average age of this sample was 57 (SD = 12.3), with a range of 24–85. More than half (56.8%) were female and the majority (83%) were married. Each individual lived within 1 km of a gas well; the number of wells ranged from 1 to 16, (mean 5.7, SD 3.6). A total of three counties in Pennsylvania are represented in this sample: Washington (n = 47), Butler (n = 3), and Bedford (n = 1) counties.

In this sample, all individuals reported at least one symptom at the time of the health assessment. The number of symptoms reported ranged from 1 to 19, with an average of 7.2 (SD = 4.9). Not all of the symptoms reported met the inclusion criteria (i.e., symptoms began or worsened after exposure to UNGD and could not be explained by a preexisting or concurrent health condition). Some symptoms reported by 19 individuals (37%) did not meet inclusion criteria and were excluded, although the individuals remained in the analysis. The number of symptoms excluded/individual ranged from 1 to 7, with an average of 2.4 symptoms. For five of the 19 individuals, all reported symptoms were excluded.

The number of symptoms meeting inclusion criteria ranged from 0 to 19 with a mean of 6.2 (SD = 5.1) symptoms/individual. The most frequently reported symptoms that met inclusion criteria were sleep disturbance, headache, throat irritation, stress/anxiety, cough, shortness of breath, sinus, fatigue, wheezing, nausea (> 20% of sample).

Symptoms shown in Table 1 were reported by at least 10% of the sample. Symptoms not shown on Table 1, reported by < 10% of the sample were: weight change, hearing loss, vomiting, burning skin, and depression.

4. Discussion

The symptoms reported by residents of southwestern Pennsylvania who live within 1 km of an unconventional natural gas well are consistent with those reported in other self-report studies. The most commonly reported symptoms in this sample of adults were sleep disruption, headache, throat irritation, stress/anxiety, cough, shortness of breath, sinus problems, fatigue, nausea, and wheezing.

Limitations of this study include use of self-report data and a convenience sample. However, our methodology mitigates some of the limitations typically associated with this type of data and strengthens our results. Reported symptoms were abstracted from health records obtained by a nurse practitioner in consultation with a physician. Each symptom was evaluated using criteria to establish onset or exacerbation of the symptom relative to exposure to UNGD and to rule out other plausible explanations for the symptom. Only those symptoms that could not be explained by evidence in the health record (i.e., medical, surgical, or social history) and had a date of onset or exacerbation after exposure to UNGD began were included in the analysis.

Both the collection of symptom data, and the inclusion criteria used, distinguish this study from others that rely only on self-report. In comparison to such studies, our results are strengthened by the collection of health assessment data by a health care provider, critical review of symptoms for possible alternative causes, and confirmation of timing of exposure relative to symptom onset or exacerbation.

Health care providers whose clients live or work in communities where unconventional techniques are used to extract natural gas and/or oil should be alert to the possibility of environmental exposures. Symptoms, particularly those that are unexplained by concurrent medical conditions, may be related to environmental exposures.

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Conflict of interest

The authors declare no conflict of interest.

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Data Availability Statement: All relevant, deidentified data are available within the paper and its Supporting Information files. The de-identified dataset is shared as supporting documents. It has been uploaded with the manuscript as one PDF of Round one responses and two excel spreadsheets for Rounds two and three responses; see S1–S3 Datasets.

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Setback distances for unconventional oil and gas development: Delphi study results

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Abstract

Emerging evidence indicates that proximity to unconventional oil and gas development (UOGD) is associated with health outcomes. There is intense debate about "How close is too close?" for maintaining public health and safety. The goal of this Delphi study was to elicit expert consensus on appropriate setback distances for UOGD from human activity. Three rounds were used to identify and seek consensus on recommended setback distances. The 18 panelists were health care providers, public health practitioners, environmental advocates, and researchers/scientists. Consensus was defined as agreement of \geq 70% of panelists. Content analysis of responses to Round 1 questions revealed four categories: recommend setback distances; do not recommend setback distances; recommend additional setback distances for vulnerable populations; do not recommend additional setback distances for vulnerable populations. In Round 2, panelists indicated their level of agreement with the statements in each category using a five-point Likert scale. Based on emerging consensus, statements within each category were collapsed into seven statements for Round 3: recommend set back distances of $<\frac{1}{4}$ mile; $\frac{1}{4}$ mile; $1-1\frac{1}{4}$ mile; and > 2 mile; not feasible to recommend setback distances; recommend additional setbacks for vulnerable groups; not feasible to recommend additional setbacks for vulnerable groups. The panel reached consensus that setbacks of < ¼ mile should not be recommended and additional setbacks for vulnerable populations should be recommended. The panel did not reach consensus on recommendations for setbacks between 1/4 and 2 miles. The results suggest that if setbacks are used the distances should be greater than 1/4 of a mile from human activity, and that additional setbacks should be used for settings where vulnerable groups are found, including schools, daycare centers, and hospitals. The lack of consensus on setback distances between 1/4 and 2 miles reflects the limited health and exposure studies and need to better define exposures and track health.

Introduction

In the oil and gas extraction industry hydraulic fracturing, the injection of a mixture of water, chemicals, and sand under high pressure, has increased rapidly since the late 1990s. Critics

in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

PLOS

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have voiced concerns about long-term potential impacts on air, water, and soil quality that may accompany hydraulic fracturing and all stages of the processes associated with the development and transport of produced oil and gas (i.e. unconventional oil and gas development or UOGD) [1–9]. Additional concerns include the significant impact on surrounding communities caused by increased traffic, light, noise, and social disruption from this type of industrial development [10–13]. The entire process of UOGD, including oil and gas discovery, drilling, production, processing, waste management, and transport, includes many sources of air and water pollution, presenting risk factors for the environment, human health and community social structure.

Health and proximity to UOGD activity

Several recent studies have documented health outcomes related to closer proximity to UOGD activity. Steinzor, et al. [14], in their descriptive community study, documented increasing numbers of symptoms reported by residents as proximity to any type of UOGD facility decreased. Rabinowitz et al. [15] conducted a cross-sectional study to investigate the relationship between proximity to unconventional gas wells and reported health symptoms in a random sample of 429 residents of 180 households that had ground-fed water wells. GPS readings were taken at each household as residents completed a health survey. ArcGIS was used to calculate the distance of the home from natural gas wells. In this study, the number of symptoms reported per individual increased with household proximity to wells. Within 1 kilometer (km) of wells, residents reported more skin and respiratory symptoms compared to residents who lived at a greater distance.

Mckenzie et al. [16] estimated health risks for two populations in the Garfield County, Colorado gas fields: residents living less than or equal to 1/2 mile away from gas wells and those greater than ½ mile. They found that the populations living closer to gas wells were at higher risk of respiratory, neurological, and other health impacts and had a higher lifetime risk for cancer than those who lived at farther distances. For this study ambient air samples were collected from a fixed monitoring station located near unconventional natural gas development and residences, and from locations at the perimeters of four well pads. Methodology used by the Environmental Protection Agency were used to estimate non-cancer Hazard Indexes and excess lifetime cancer risks for exposures to hydrocarbons.

In a retrospective cohort study of 124,842 births in Colorado between 1996 and 2009, Mckenzie and colleagues [17] found an association between congenital heart defects and proximity and density of unconventional natural gas wells within 10 miles of maternal residence, using inverse distance weighted natural gas well counts as a measure of proximity and density. Results also suggested a possible association between neural tube defects and proximity and density. In another retrospective cohort study, Casey et al. [18] examined the relationship between exposure to unconventional gas development and birth outcomes in 10,946 births in Pennsylvania between 2009 and 2013. Unconventional gas development was modeled using distance from residence; dates of well pad preparation, drilling and hydraulic fracturing; and amount of production during pregnancy. Results showed an association between increased exposure and preterm birth, but no association between low APGAR scores, small for gestational age, or low term birthweight. Stacy and colleagues [19] also used an inverse distance weighted gas well count to examine the relationship of exposure to birth outcomes in their retrospective cohort study of 15,451 births in southwestern Pennsylvania between 2007 and 2010. Results showed increased exposure was associated with low birth weight and small for gestational age; it was not associated with preterm birth.

Tustin et al. [20] used self-reported symptoms to investigate associations between chronic rhinosinusitis, migraine, and fatigue, three conditions frequently reported in communities

exposed to UOGD. Responses to self-report questionnaires were reviewed using standard criteria. Exposure was estimated using an "activity index" [18] derived from four exposure metrics to account for different phases of well construction and production: distance from the residence; timing of well pad development, drilling, and hydraulic fracturing; and volume of gas produced. Results of the case-control analysis indicated that the highest quartile of the activity index was associated with increased odds of all three outcomes, when compared with the lowest quartile.

McKenzie et al. [21] investigated the relationship between acute lymphocytic leukemia and non-Hodgkin's lymphoma in children ages 0–24 and residential proximity to unconventional oil and gas development in Colorado. Cases and controls (i.e., children diagnosed with nonhematologic cancers) were diagnosed between 2000 and 2013 during rapid expansion of UNGD. Exposure was calculated using an inverse distance weighted (IDW) approach, first described by McKenzie et al. [17], to count all active oil and gas wells within 16.1 miles of each residence, giving greater weight to those that are closer. In the adjusted model, acute lymphocytic leukemia cases age 5–24 were 4.3 times likely to live in the highest well-count tercile as controls, with a monotonic increase across IDW tertiles (p for trend = 0.035). No such relationship was seen in leukemia cases 0–4 years or in non-Hodgkin's lymphoma cases of any age.

Rasmusen and colleagues [22] conducted a nested case-control study to investigate the relationship between asthma exacerbations and exposure to unconventional natural gas development. Using the Geisinger Clinic electronic health records, they identified cases of mild (i.e., new medication prescribed), moderate (i.e., emergency department visit), and severe (i.e., hospitalization) asthma exacerbations (n = 20,749; 1,870; and 4,782 respectively) treated at Geisinger between 2005 and 2012. Exposure was measured using the activity metric previously described by Casey [18]. In the adjusted model, mild, moderate, and severe asthma exacerbations were associated with high scores in each activity metric when compared to referents.

Setback distances and UOGD

A 2013 review of state setback distances for shale gas development shows the broad range of regulations in place at the time [23]. Of the 31 states in the review, 20 had setback restrictions specifically from buildings, 11 had none related to buildings. The restricted distances ranged from 100 feet (NY) to 1,000 feet (MD). California required setbacks, not from buildings but between wells and public roads. For this type of land-based restriction, the American Petroleum Institute recommended that "... the wellsite and access road should be located as far as practical from occupied structures and places of assembly" [24], offering a simple discretionary guideline. Setback restrictions for water sources were found in 12 states; 18 had none and one state had a discretionary standard. The regulated distance from water sources varied from 50 feet (OH) up to 2,000 feet (NY). A review of setback distances in urban areas of the Texas Barnett Shale showed a similarly broad range of regulations [25]. While the State permitted drilling within 200 feet of a dwelling, most municipalities employed longer distances; in Denton County these ranged from 300 to 1500 feet. Fry also found that 12 out of the 26 city setback ordinances reviewed had increased the distance over time-and none had been decreased. The author found that setback restrictions appeared to be politically rather than technically-based decisions and recommended greater reliance on "advanced emissions monitoring" to minimize discrepancies in determining appropriate setback distances.

Several authors have examined potential exposures related to existing setback distances. McCawley [26] conducted a study of air, noise and light impacts using the West Virginia state setback distance of 625 feet from the center of well pads. Measurable levels of dust and volatile organic chemicals, including one or more of benzene, toluene, ethylbenzene, and xylene, were found at all seven drilling sites where measurements were taken. Some benzene concentrations were above the "minimum risk level" for no health effects. Dispersal patterns were influenced by factors including multiple sources of emissions located throughout the well pad, local weather, topography, and wide fluctuation in levels of contaminants. Light levels, measured as skyglow, were zero during night time; ionizing radiation levels measured from filtered airborne particulate were near zero as well. While average noise levels calculated for the duration of work at each site were not above the 70 dBA level recommended by the EPA, the noise at some locations was above that allowed by EPA regulation for vehicles engaged in interstate commerce and local noise ordinances. McCawley concluded that a setback distance of 625 feet cannot assure that nearby residents would not be exposed to drill site contaminants.

Haley et al. [27] reviewed current regulations and other aspects of setback distances used within the Marcellus, Barnett, and Niobrara shale plays. The most common setback distances from buildings were 300 and 500 feet, with a range of 150 to 1500 feet. The authors concluded that current setback distances are inadequate to protect residents in the case of explosions, radiant heat, toxic gas clouds, and air pollution from hydraulic fracturing activities; and that setback distances cannot provide absolute measures of safety, especially for vulnerable populations.

There is an increasing number of peer-reviewed articles addressing air quality impacts from UOGD (see for instance Physicians, Scientists and Engineers for Healthy Energy database) [28]. While these studies provide valuable science-based data that can support the rationale for regulating or not regulating setback distances, there remains a concern about the adequacy of health-based standards used to determine impacts from pollutant exposures.

In a critique of current methods of collecting air emissions data, Brown et al. [29] found that data collection and analysis of air pollution impacts from unconventional natural gas development cannot accurately assess human health impacts near UOGD sites. Specific findings were that "1) current protocols used for assessing compliance with ambient air standards do not adequately determine the intensity, frequency or durations of the actual human exposures to the mixtures of toxic materials released at UOGD sites; 2) the typically used periodic 24 hour average measures can underestimate actual exposures by an order of magnitude; 3) reference standards are set in a form that inaccurately determines health risk because they do not fully consider the potential synergistic combinations of toxic air emissions; 4) air dispersion modeling shows that local weather conditions are strong determinates of individual exposures." The authors recommend protocols that provide continuous chemical monitoring to show variations in exposure; modeling of local weather conditions to identify periods of high exposures; and sampling for chemical mixtures to identify the major components.

Two examples of air modeling studies provide context for assessing the need for setback distances. Olaguer [30] used a neighborhood scale dispersion model to simulate ozone formation resulting from emissions from UOGD in the Barnett Shale, focusing on both routine and nonroutine emission events (flares). The model predicted that both types of UOGD operations can have a significant impact on local ambient ozone levels. Modeled ozone levels increased at an approximate distance of 2km or more, at enhancement levels greater than 3 parts per billion (ppb). Modeled flare events could cause greater increases at distances >8km downwind. Ozone causes respiratory health effects including asthma and chronic obstructive pulmonary disease (COPD).

In another study, Brown et al. [31] describe a hypothetical case that demonstrates the direct effect of weather on exposure patterns of particulate matter (specifically $PM_{2.5}$) and volatile organic chemicals (VOCs) from unconventional natural gas infrastructure. The authors modeled the frequency and intensity of exposures to $PM_{2.5}$ and VOCs at a residence surrounded by

three UOGD facilities. The hypothetical well pad, compressor and processing plant are 1 km, 2 km and 5 km distant from the residence. Modeled peak $PM_{2.5}$ and VOC exposures (defined as 2 standard deviations above the mean) during 14 months of well development occurred 83 times. Modeled compressor station emissions created 118 peak exposure levels and a gas processing plant produced 99 peak exposures over one year. The authors emphasize that local weather patterns combined with episodic emissions drive local exposure profiles.

While there is emerging evidence that proximity to UOGD activities is associated with chemical exposures and health outcomes, there is intense debate about "How close is too close?" The Delphi is an accepted method for reaching convergence of expert opinion about a specific topic, particularly when available data are inconclusive [32]. We conducted this Delphi study to arrive at expert consensus on two closely related questions: 1) the relationship between health outcomes and UOGD activities; and 2) appropriate setback distances for UOGD from human activity including residences, schools, work places, and farms. This paper reports the expert consensus on the question of appropriate setback distances; expert consensus on the question of appropriate setback distances and UOGD activities will be presented in a subsequent report. Portions of this report on setback distances have been issued as a technical report by Southwest Pennsylvania Environmental Health Project www. environmentalhealthproject.org

Methods

Study design

This study used a conventional Delphi procedure [32-35], which can be viewed as a series of rounds. In each round, the participants (called "panelists") respond anonymously to a set of questions and then receive information about the responses of all other participants, including their own. Panelists are encouraged to re-assess their own responses on subsequent rounds with a goal of reaching consensus. The first round consists of a set of open-ended questions. Subsequent rounds consist of a set of statements to which panelists indicate their level of agreement on a five-point Likert scale. Three rounds are usually sufficient to reach consensus [35]. For this study consensus was defined as agreement of 70% of panelists, a decision point that is frequently used in Delphi studies [36–38].

Expert panel

There are few generally accepted criteria for inclusion on a Delphi panel [34] or agreement about the number of panelists required for a Delphi [39]. Early researchers who used this technique suggested the following criteria for inclusion: background and experience with the topic, capability to contribute, and willingness to revise their judgment to reach consensus [40]. More recent researchers suggest identifying stakeholders with interest in the topic: positional leaders, authors of publications in the scientific literature, and those with first-hand experience [41,42]. As Keeney et al. point out in their critical review of the technique, the definition of "expert" ranges from informed individuals to experts in the field [43]. The number of panelists required varies with the focus of the Delphi and the characteristics of the panelists. Generally, the more similar the members and the more narrow the focus of the investigation, the smaller the number, with 10–15 generally considered acceptable if the group is homogeneous; 15–30 if it is heterogeneous [43].

For this Delphi panel, selection criteria included: researchers whose work has been published in peer-reviewed journals and/or presented at national scientific meetings; scientists employed in regulatory agencies; and leaders in public policy and environmental advocacy who have been published in the grey literature. Potential panelists included representatives of federal and state agencies, environmental advocacy groups, health care providers, public health practitioners, and a range of researchers in areas including environmental science, toxicology, and social science. Invitations were sent via e-mail or the US Postal Service if no e-mail address was publicly available. The invitation included a consent to participate and the first round questions, along with an estimate of time commitment for participation. The study was reviewed and approved by the Duquesne University Institutional Review Board.

A total of 57 experts were invited to participate in this Delphi; 18 agreed to be panelists and returned the completed Round 1 questionnaire and consent form. Of those who did not participate, 23 simply did not respond to the invitation. A total of 18 provided a reason for declining, citing lack of time (n = 7), lack of expertise (n = 8), and no longer working in UOGD (n = 2).

Round 1

In the first round, panelists were asked to respond to the open-ended questions shown in Table 1, following these instructions:

"We are interested in both gas and oil and know that the multiple steps in the production of these products differ. We understand that a panelist may have more expertise in one area than the other, so have constructed questions to allow for those differences. Where possible in your responses, please address all steps in the process from drilling site construction through delivery of the product to the consumer (e.g., well pad construction, well drilling, hydraulic fracturing, compressor stations, pumping stations, processing plants, impoundments, pipelines, and other steps in the process). In the questions below, the steps in this process are referred to as 'related activities'."

Panelists were asked to return their responses within two weeks. Non-responders were sent a reminder at the end of two weeks. For those who requested additional time due to workload, travel, etc. the deadline was extended two weeks. The same procedure was followed in subsequent rounds.

Round 1 data analysis and development of Round 2 structured questionnaire

Content analysis was conducted on the qualitative responses to the open-ended questions in Round 1, with all responses independently coded by two members of the research team (CL

Table 1. Open-ended questions used in Round 1.

- 1 What do you believe are appropriate set-back distances for hydraulic fracturing and related activities from places where people live, including single homes, multiple family dwellings, etc.? Please specify if your response is related to oil or gas extraction.
- 2 What do you believe are appropriate set-back distances for hydraulic fracturing and related activities from indoor places where people work including offices, hospitals, and schools? Please specify if your response is related to oil or gas extraction.
- 3 What do you believe are appropriate set-back distances for hydraulic fracturing and related activities from outdoor places where people work such as farms? Please specify if your response is related to oil or gas extraction.
- **4** What do you believe are appropriate set-back distances for hydraulic fracturing and related activities from places where people recreate or play such as parks? Please specify if your response is related to oil or gas extraction.
- 5 Should set-back distances differ for settings that include groups of vulnerable individuals, such as schools, day care centers, long- term care facilities, and if so, how? Please specify if your response is related to oil or gas extraction.

Five open-ended questions were sent to all prospective panelists for their responses to initiate Round 1 of the Delphi study.

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and LG). Coding was compared for congruence. Similar responses were grouped into categories, for example, "Recommended setback distances" and "Cannot recommend setback distances" as shown in the Results section. Within the category "Recommended setback distances" responses were grouped into mutually exclusive sub-categories. Responses to the question concerning vulnerable populations were grouped into two categories; both are shown in the Results section. All responses in each category were included on the structured questionnaire used for Round 2 and 3.

The structured questionnaire for Round 2 included all responses so that each panelist was able to see the complete range of responses in each category, with his/her own responses highlighted. Panelists were asked to indicate their level of agreement with each statement using a 5-point scale: strongly agree, agree, not sure, disagree, and strongly disagree and to provide a rationale for their decisions for those statements for which they strongly agreed or agreed.

Round 2 data analysis and development of Round 3 structured questionnaire

Responses to Round 2 were used to revise the structured questionnaire for Round 3. Statements within categories were collapsed to reflect emerging consensus within the panel. The Round 3 questionnaire provided the aggregated panelists' responses for each statement and the rationales provided by the individual panelists for their responses. For this final round, panelists were asked to review the distribution of responses and rationales provided and then indicate their level of agreement with each statement.

Results

Characteristics of panelists

The 18 panelists who agreed to participate and completed Round 1 self-identified as researchers/scientists, health care providers, environmental advocates, and public health practitioners. Self-reported areas of expertise included: medicine/health care, air quality, water quality, toxicology, environmental science, environmental health, public health, epidemiology, social science, policy, and risk analysis. The majority (83%) of the panelists hold earned doctoral degrees and reported working in their respective fields for a mean of 17.6 years (SD = 10), with a range of 4–35 years. In the area of UOGD specifically, they reported a mean 4.3 years (SD = 1.2), with a range of 2–6 years. The panelists represented a range of geographic regions throughout the United States; 50% were women. None of the authors participated as panelists. Of the 18 panelists, 14 (78%) participated in Round 2 and18 (100%) participated in Round 3.

Round 1

Responses to Questions #1- #4 were similar, with 9 panelists providing word-for-word the same response to all four open-ended questions. An additional four panelists provided the same response to three of the four questions. Only two panelists provided a different response to each of the four questions of setback distances from home, places of work, and places of recreation. Thus, all responses to these questions were considered together in the content analysis; two categories of responses, shown in Table 2, emerged.

There were 17 statements that included recommendations for specific setback distances from homes; places of work such as schools, office buildings, and farms; and recreational areas. Table 2 shows recommended distances ranged from 1/10 of a mile (0.1 km) to 2 miles (3.2 km). There were 18 statements that did not include recommendations for specific setback

Table 2. A comparison of exemplar statements recommending setback distances and exemplar statements not recommending setback distances from homes, places of work, or recreation areas.

Recommended setback distances

I defer to existing regulation: Center of well pads may not be located within 1/10 mile (0.1 km) of an occupied dwelling structure.

2/10 mile (0.3 km) for gas operations based on industry studies of blowouts, explosions and fires from drill rigs, compressor stations and pipelines.

Set-backs of at least 1/3 mile (0.5km) would be needed to prevent flow through documented pathways of subsurface contamination.

¹/₂ mile (0.8 km) for oil or natural gas extraction from office buildings and other indoor areas.

Minimum of 1 mile (1.6 km) for gas extraction

1 ¼ mile (2 km) from natural gas wells

At least 2 miles (3.2 km), maybe more

Cannot recommend setback distances

Due to our inability, with current information, to predict dispersal pathways accurately, I do not think safe set-back distances can be determined.

This is something that is difficult to determine because it depends on the hydrology and air currents.

My response applies to both oil and gas...do not take a position on specific distances, in large part because there is no scientifically definitive distance beyond which health impacts would never occur. However, we believe that current setbacks from residential areas are much too short in all states.

I do not have an opinion on an appropriate set-back distance because I don't believe there is enough evidence to inform an opinion.

Again the distinction between oil and gas is not important. I think there are appropriate, science based setbacks that could be developed. I agree with the position that the ones that exist are not science based at all...and are based on political compromises.

There are no appropriate set-back distances for recreation areas near oil production. Ambient air quality is affected by VOCs. We have no proof of what constitutes a safe set-back distance. Cumulative effects have yet to be studied.

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distances. The exemplar statements in the Table 2 section "Cannot recommend setback distances" reflect panelist's perspectives that there is insufficient information available to make recommendations. As one panelist pointed out, his lack of a specific recommendation did not imply that setback distances were not needed, just that he did not think it was possible to make a recommendation. All statements in each category were included on the structured questionnaire used for Round 2.

The content analysis revealed that responses to the question concerning setback distances for vulnerable populations differed from those to the first four questions. As shown in <u>Table 3</u>, panelist's responses fit into one of two categories: responses that argued for additional setback distances and responses that focused on the difficulties of establishing setback distances for vulnerable populations.

Eleven statements recommended additional setback distances for vulnerable populations. Vulnerable populations were defined by panelists to include: children, neonates, fetuses, embryos, pregnant women, elderly individuals, those with pre-existing medical or psychological conditions, and those with pre-existing respiratory conditions. Panelists included the following settings as places where vulnerable populations might be concentrated: schools, day care centers, hospitals, and long-term care facilities. Five statements focused on the difficulties of setting additional setback distances. As shown on Table 3, the panelists focused on the distribution of vulnerable individuals throughout the population, making the determination of setback distances to protect all vulnerable members of society difficult if not impossible.

The four categories of responses described above, and all statements within each, were used to create a structured questionnaire for Round 2. Panelists were asked to indicate their level of agreement on a 5-point Likert-type scale to a total of 51 statements and to provide a rationale

Table 3. A comparison of exemplar statements recommending additional setback distances for vulnerable populations and exemplar statements not recommending additional setback distances for vulnerable populations.

Panelists recommend additional considerations for vulnerable populations

Populations that are particularly sensitive to the toxins known and suspected to be associated with fracking activities should have special protections; this includes children, neonates, fetuses, embryos, pregnant women, elderly individuals, and those with pre-existing medical or psychological conditions.

I would consider this a case where additional restrictions would be important. Oil and/or gas operations near hospitals and schools should simply not be allowed...

Yes, greater setback distances are warranted for schools, daycare centers, long-term care facilities, etc. for both oil and gas extraction.

Larger setback distances in gas extraction are critical to larger vulnerable groups because one must take into consideration evacuation time and route in case of a catastrophic well or related infrastructure event.

Setbacks (gas) should definitely be farther from schools, day care centers where children are located and long-term facilities where people who already have compromised health don't need it further compromised by poor air quality from unconventional gas development.

Panelists do not recommend additional considerations for vulnerable populations

I am really unsure as to how to answer this because if air plumes travel and contribute to quality degradation of an entire region, it is likely that it would impact vulnerable populations regardless of physical proximity.

Regarding different set-backs for settings with vulnerable populations: Probably not. It appears that the most vulnerable populations are pregnant women and those with asthma, neither of which would necessarily be concentrated in specific facilities.

Vulnerable populations are distributed throughout the environment. This is therefore an inadequate calculation to consider.

The distances mentioned above are set to protect vulnerable persons as they are all a significant part of every society.

It makes sense to start with...longer setbacks on places used or inhabited by people with known vulnerabilities. However, there may be vulnerable individuals living, working, and spending time outdoors even in locations that are not specifically geared toward that population (for example, individuals with compromised immune systems, a history of cancer, or asthma).

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when they agreed with a statement. Their own statements from the first round were highlighted.

Round 2

Based on panelist's responses to the structured questionnaire, statements within categories were collapsed to reflect emerging consensus.

<u>Recommended setback distances</u>: In this category, the 17 statements were collapsed into four: less than $\frac{1}{4}$ mile; $\frac{1}{4}$ — $\frac{1}{2}$ mile; 1–1 $\frac{1}{4}$ miles; and 2 or more miles. (See <u>Table 2</u> for exemplar statements.) All statements fit into one of these four groups, and emerging consensus in panelists' responses determined the cut-points used. These four statements were included on the structured questionnaire for Round 3.

<u>Cannot recommend setback distances</u>: Fourteen of the 18 statements were collapsed into one category which was restated as "It may not be feasible to recommend set back distances for the general population" to more accurately reflect the content of the 14 statements. (See <u>Table 2</u> for exemplar statements.) For these 14 statements, the proportion of panelists who agreed ranged from 54% to 92%. Four statements were excluded because they did not reflect emerging consensus.

<u>Panelists recommend additional considerations for vulnerable populations</u>: Ten of the 11 statements were collapsed into one category which was restated as "Recommend additional consideration for vulnerable groups" to more accurately reflect the content of the 10 statements. (See <u>Table 3</u> for exemplar statements.) The proportion of panelists who agreed with the 10 statements ranged from 58% to 83%, indicating emerging consensus. One statement was excluded because it did not reflect emerging consensus.

<u>Panelists do not recommend additional considerations for vulnerable populations</u>: Three of the five statements were collapsed into one category which was restated as "It may not be feasible to recommend additional considerations (i.e., members of vulnerable populations are distributed throughout the population)" to more accurately reflect the content of the three statements. (See <u>Table 3</u> for exemplar statements.) The proportion of panelists who agreed with the three statements ranged from 25% - 41%. Two statements were excluded because they did not differ from the panelist's responses to questions #1-#4.

The structured questionnaire for Round 3 included seven statements which are shown on Table 3. The questionnaire also included the distribution of panelist's responses and their rationales offered in Round 2. Panelists were asked to review the statements and rationales and then indicate their level of agreement/disagreement with each statement on the Round 3 questionnaire.

Round 3

The distribution of panelists' responses to the structured questionnaire in Round 3, along with the mean and standard deviation for each statement is shown in Table 4.

To determine consensus, we combined responses of "agree" and "strongly agree" to determine the % of panelist agreement with a statement and responses of "disagree" and "strongly disagree" to determine the % panelist disagreement with a statement. Within the category "recommended setback distances", panelists reached consensus on the statement "less than ¼ mile". A total of 89% of panelists disagreed with that statement (i.e., 11% disagreed plus 78% strongly disagreed for a total of 89%), reaching the 70% set for consensus in this Delphi.

Panelists did not reach consensus on the statement "¼—½ mile". For this statement, 66% of panelists disagreed with the statement, 22% were unsure, and only 11% of panelists agreed. Panelists did not reach consensus on the statement "1–1¼ miles", 50% agreed, 28% were unsure, and 22% disagreed. Panelists did not reach consensus on the statement "at least 2 miles"; 34% agreed, 44% were unsure, and 22% disagreed. For the statement "It may not be feasible to recommend setback distances for the general population", 67% of panelists agreed, 6% were unsure, 28% disagreed.

Regarding setback distances for vulnerable populations, panelists reached consensus on the statement "Recommend additional consideration for vulnerable groups" with 87% agreeing. Panelists did not reach consensus on the statement "It may not be feasible to recommend additional considerations for vulnerable groups", with panelists nearly equally divided between agreement and disagreement with the statement. See <u>S1 Chart</u> for a visual representation of Delphi results.

	1	2	3	4	5	Mean (SD)
Recommend less than ¼ mile setback	0%	0%	11%	11%	78%	4.67 (0.65)
Recommend ¼—½ mile setback	0%	11%	22%	22%	44%	4.0 (1.03)
Recommend 1–1¼ miles setback	6%	44%	28%	11%	11%	2.78 (1.05)
Recommend at least 2 miles setback	17%	17%	44%	11%	11%	2.83 (1.14)
It may not be feasible to recommend setback distances for the general population	28%	39%	6%	22%	6%	2.17 (1.09)
Recommend additional consideration for vulnerable groups	67%	22%	11%	0%	0%	1.44 (0.67)
It may not be feasible to recommend additional considerations for vulnerable groups	6%	33%	6%	33%	22%	3.17 (1.26)

1 = strongly agree; 2 = agree; 3 = not sure; 4 = disagree; 5 = strongly disagree.

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Discussion

There is significant public and scholarly debate about the relationship between proximity to these industrial activities and human health. The Delphi provides a unique tool to learn how experts on a particular topic apply their knowledge and experience to a complex problem, and to determine whether a convergence of opinion can be established [32–35, 41–43]. In this study we used the Delphi method to address the issue of appropriate setback distances for UOGD from places where humans live, work, and play. The intent of this Delphi was to reach expert consensus on appropriate setback distances from homes, workplaces, and recreation areas in general, and for vulnerable populations in particular.

The responses to the open-ended questions in Round 1 generated a set of statements that expanded the question of setback distances. The panelist's responses reflected their opinions about the adequacy of both the evidence available to answer the question and the ability of setback distances to protect the health of the public, rather than providing simple statements of specific distances. Accordingly, their responses were grouped into four categories: recommendations for specific setback distances from places of human activity; no recommendations for specific setback distances for polaces of human activity; recommendations for additional setback distances for vulnerable populations; no recommendations for additional setback distances for vulnerable populations.

Round 2 responses were collapsed into seven statements, based on panelists' responses to the individual statements and emerging consensus. Four statements focused on specific setback distances from places where people live, work, or play: Recommend </br/> 4/4 mile; Recommend 1–11/4 mile; Recommend 2 miles or more. Three additional statements focused on feasibility and vulnerable populations: It may not be feasible to recommend setback distances; Recommend additional considerations for vulnerable populations; It may not be feasible to recommend additional considerations for vulnerable groups.

Setbacks of <¼ mile are not sufficient

Panelists reached consensus that setback distances of $< \frac{1}{4}$ mile were not sufficient but were not able to reach consensus for the longer setback distances suggested by panelists (i.e., $\frac{1}{4} - \frac{1}{2}$ mile, 1–1¹/₄ mile, and 2 miles or more). A total of 67% of panelist agreed with the statement that it may not be feasible to establish setback distances, very nearly reaching consensus. Taken together, these results suggest that while these panelists agreed that $\frac{1}{4}$ of a mile is "too close" they did not feel able to recommend a specific distance that would protect the health of the public. Failure to reach consensus about setback distances between $\frac{1}{4}$ and 2 miles reflects published studies that have identified a variety of health effects and evidence of exposure at various points within that range [14, 15, 17–22]. Nevertheless, panelists were clear that current setback regulations of less than $\frac{1}{4}$ mile are not adequate.

Recommend additional setbacks for vulnerable populations or settings

Panelists reached consensus that additional setback distances should be established for vulnerable populations or settings. Vulnerable groups were defined by the panelists as children, neonates, fetuses, embryos, pregnant women, elderly individuals, those with pre-existing medical or psychological conditions, and those with pre-existing respiratory conditions. Vulnerable settings were defined as schools, day care centers, hospitals, and long-term care facilities. At the same time, panelists were split as to whether such consideration was actually feasible, recognizing that since vulnerable people are distributed throughout the general population it would be difficult if not impossible to give them extra consideration. Yet some suggested that where vulnerable individuals gather, such as in schools and playing fields, setbacks may be useful.

Limitations and further research

The results of this Delphi should be interpreted with caution, as they reflect the expert opinion of one panel. It is possible that another panel would reach a different consensus, and further research is warranted. In addition, using 70% as the decision-point for consensus means that some portion of the panel is not in agreement. Therefore, we included in the results section the percentage of agreement and the mean and standard deviation of the Likert score for each statement in an effort to be as transparent as possible. While the panel had a broad range of relevant expertise in public and environmental health and many years of experience in a variety of professional activities, the panel would have been strengthened by representation from the petroleum industry. Future research should purposefully include such scientists, researchers, and practitioners. Not all panelists participated in all rounds, however, all panelists who participated in Round 1 participated in Round 3.

Conclusion

In conclusion, the results of this Delphi study suggest that if setbacks are used the distances should be greater than ¼ of a mile from any area where human activity takes place, and that additional setbacks should be used for settings where vulnerable groups are found, including schools, daycare centers, and hospitals. The panel did not reach a consensus on setback distances between ¼ and 2 miles. While both health effects and exposures have been reported in the literature and are consistent with scientific reports, there is uncertainty with respect to levels and types of exposures and the health responses further from the wells. One report has suggested that site-specific air measures are needed. Levels of exposure have been documented based on analysis and air modeling in both air and water within ¹/₄ of a mile. Although air modeling indicates air exposures in the ¹/₄ to 2-mile range, it is difficult to measure due to localized weather variability. Health effects are reported in the peer-reviewed literature for respiratory disease and dermatologic effects, however the health effects could be related to the presence of other sources of pollution. Thus, failure to achieve consensus on the range of setback distances appears to reflect uncertainties based on limited data on real-time emissions from UOGD, the limited scientific studies available and the presence of periods of potential high exposures.

Supporting information

S1 Chart. Flow chart of results of Rounds 1–3 for statements that recommend setbacks for UOGD infrastructure. Consensus = 70%. (PDF)

S1 Dataset. Round 1 responses. (PDF)

S2 Dataset. Round 2 responses. (XLSX)

S3 Dataset. Round 3 responses. (XLSX)

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Data Availability Statement: Gas well location and emissions data is hosted on a PowerBI report and controlled by the PA Department of Environmental Protection. To view only gas well data, filter by RESEARCH ARTICLE

Exposure assessment of adults living near unconventional oil and natural gas development and reported health symptoms in southwest Pennsylvania, USA

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Abstract

Recent research has shown relationships between health outcomes and residence proximity to unconventional oil and natural gas development (UOGD). The challenge of connecting health outcomes to environmental stressors requires ongoing research with new methodological approaches. We investigated UOGD density and well emissions and their association with symptom reporting by residents of southwest Pennsylvania. A retrospective analysis was conducted on 104 unique, de-identified health assessments completed from 2012–2017 by residents living in proximity to UOGD. A novel approach to comparing estimates of exposure was taken. Generalized linear modeling was used to ascertain the relationship between symptom counts and estimated UOGD exposure, while Threshold Indicator Taxa Analysis (TITAN) was used to identify associations between individual symptoms and estimated UOGD exposure. We used three estimates of exposure: cumulative well density (CWD), inverse distance weighting (IDW) of wells, and annual emission concentrations (AEC) from wells within 5 km of respondents' homes. Taking well emissions reported to the Pennsylvania Department of Environmental Protection, an air dispersion and screening model was used to estimate an emissions concentration at residences. When controlling for age, sex, and smoker status, each exposure estimate predicted total number of reported symptoms (CWD, p<0.001; IDW, p<0.001; AEC, p<0.05). Akaike information criterion values revealed that CWD was the better predictor of adverse health symptoms in our sample. Two groups of symptoms (i.e., eyes, ears, nose, throat; neurological and muscular) constituted 50% of reported symptoms across exposures, suggesting these groupings of symptoms may be more likely reported by respondents when UOGD intensity increases. Our results do not confirm that UOGD was the direct cause of the reported symptoms but raise concern about the growing number of wells around residential areas. Our approach presents a novel method of quantifying exposures and relating them to reported health symptoms.

Facility Type. We additionally filtered by year, county, and and pollutant as described in our methods. Data can then be exported to a .csv file: http://www.depgreenport.state.pa.us/ powerbiproxy/powerbi/Public/DEP/AQ/PBI/Air Emissions Report Climate data was retrieved from NOAA's local climatological database. To use the tool, you need to select the state and county of where the airport is located. We used data from the Pittsburgh Allegheny County Airport in Allegheny County, PA. Once the airport has been added to your cart, you can determine the data range you wish to download and request a .csv of the data: https://www.ncdc.noaa.gov/cdo-web/datatools/lcd Health data cannot be shared publicly because some of the data we collect is in rural areas with sparse population. In areas of sparse population, it may be possible to identify participants using data such as GIS coding. Data are available from the Environmental Health Project Institutional Data Access / Ethics Committee (contact via Environmental Health Project, Sarah Rankin 724.260.5504) for researchers who meet the criteria for access to confidential data.

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Introduction

Unconventional oil and natural gas development (UOGD) may represent a health risk due to exposure to chemicals used during the hydraulic fracturing process, on-site emissions, and/or a lack of strict regulations [1–4]. The UOGD process involves a combination of horizontal drilling across shale formations and the use of a heterogeneous fracturing fluid injected into wells at high pressure to fracture shale and release trapped oil and gas. Evidence suggesting associations between UOGD activity and adverse health effects has emerged from multiple studies. UOGD activity has been associated with adverse birth outcomes [5–7], increased rates of hospital use [8–10], asthma [11,12], and upper respiratory and neurologic symptoms [13–15]. These studies have used a variety of approaches to estimate exposure to UOGD, including inverse distance weighting (IDW), cumulative well count, cumulative well density (CWD), well activity metrics, spatiotemporal models, and direct water sampling [6–8,13,16,17].

Given the associations between UOGD development and adverse health outcomes, but lack of resolution on questions pertaining to safe proximity of residency to wells, we sought to determine which variables related to UOGD are associated with a higher number of reported symptoms. For this study, two proximity metrics and one exposure variable constitute our exposure estimates and are referred to as exposure measures throughout this paper. This study was conducted to address the following questions: 1) Which exposure measure(s) best predicts the of number of symptoms reported? and 2) Which individual symptoms are associated with increasing exposure as estimated by each exposure measure? Unlike prior studies, this analysis compares three estimates of exposure: CWD, an IDW measure, and annual emission concentrations (AEC) derived from estimated well emissions within 5 km of a residence. CWD is defined as the count of wells divided by a spatial scale in km² [8], while IDW, a similar measure, weights wells according to distance from a residence [6,7]. The AEC measure used publicly available data on wells to estimate concentrations of emission pollution at a residence. Bamber at al. [18] notes that exposure to UOGD is poorly characterized, and this analysiscomparing three estimates of exposure-attempts to address this concern. Though frequently used proximity and density metrics are included in this analysis, the methodological approach taken here has not been used to model emission concentrations at the home nor to predict symptom outcomes associated with increasing levels of exposure. The use of two methodologies applied here (i.e., statistical modeling to analyze the influence of different exposures on symptom reporting, and a technique to identify specific symptoms that might be indicative of exposure) suggests new techniques for studying relationships between health and exposure.

Materials and methods

Study sites & health outcomes

The Southwest Pennsylvania Environmental Health Project (hereafter referred to as EHP) is a nonprofit public health organization in Washington County, Pennsylvania (PA). Between February 1, 2012 and December 31, 2017, 135 children and adults completed health assessments at EHP. Individuals self-selected and approached EHP because of their concerns about exposure to UOGD. Health data were abstracted as described in Weinberger et al. [19] and the same data were used in this analysis.

As described by Weinberger et al. [19] the 135 de-identified health assessments were reviewed retrospectively by a team of health-care providers, including a board-certified occupational-health physician and at least one nurse practitioner. Records were excluded if the respondent was under 18 years old, worked in the oil-and-gas industry, lived outside of PA, or did not fully complete the assessment form (17 excluded). The remaining 118 health

assessments were reviewed. Each symptom recorded in the assessment was reviewed and those symptoms that could be plausibly explained by co-occurring medical conditions, medical history, or work and/or social history were excluded. For this analysis, symptoms that remained were grouped into nine categories: general; lung and heart; skin; eyes, ears, nose, and throat (EENT); gastrointestinal (GI); nerves and muscle; reproductive; blood system; and psychological. For this analysis, we restricted the sample to residents of southwest PA with known latitude and longitude data for their residence (14 individuals excluded). The study population included individuals from eight counties: Washington, Greene, Beaver, Butler, Allegheny, Bedford, Fayette, and Westmoreland (Fig 1). This resulted in a convenience sample of 104 adults. This study was approved by the New England Institutional Review Board and the Chatham University Institutional Review Board.

Exposure measures

Cumulative well density and inverse distance weighting. Home address was collected at the time of the health assessment. For this analysis, the address was used to determine the latitude and longitude coordinate of the residence of each respondent [21].

The PA Department of Environmental Protection (PA DEP) publishes active well locations and reported emissions on an open-access online portal [22]. The emissions inventory provides well location data in latitude and longitude coordinates and emissions data by pollutant

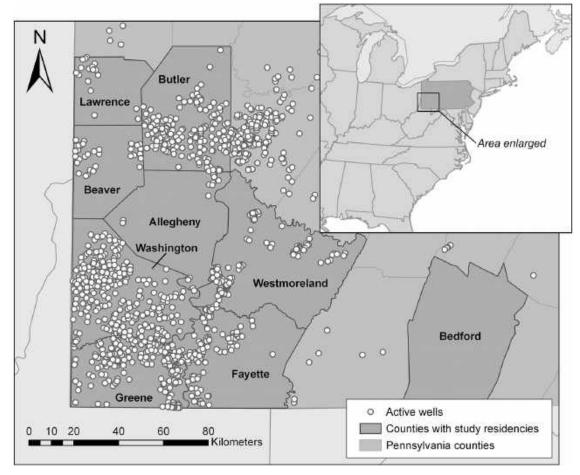


Fig 1. Study area and active well locations. Southwestern PA study location and active wells in 2016. No respondents lived in Lawrence County; however, a respondent in Butler County lived near the county border. Map was made with ArcGIS Desktop [20].

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type for each well. For assessments completed between February 1, 2012 and December 31, 2017, ArcGIS ArcMap 10.3 [20] was used to plot the latitude and longitude of each respondent's residence alongside all active, unconventional wells within a 5-km radius around the residence during that year. A CWD was calculated for each respondent by dividing the number of wells in a 5-km radius around the home by the area of the radius.

An IDW calculation was also applied as a second method for quantifying exposure intensity. This measure applies more weight to wells located closer to a residence than to those located farther away. The inverse distance of each well within a 5-km radius of a residence was calculated, and those values were summed into one IDW score per residence as shown in the following equation:

$$IDW \ density = \sum_{i=1}^{n-1} /_{d_i} \tag{1}$$

where distance (*d*) is kilometers between the well (*i*) and respondent's residence, and *n* is the number of wells within the 5-km radius [5,13]. For this analysis, only wells located within PA state lines were included in the calculations due to a lack of data availability from neighboring states. Four residences' 5-km radius crossed into neighboring West Virginia. For these sites, the radius percentages outside of Pennsylvania were 0.6%, 4.4%, 10.7%, and 14.3%.

Annual emissions concentration. Annual emissions inventories for 2012 through 2017 were exported from the PA DEP's database. Sources reported on the emissions inventory included venting and blowdown, dehydration units, drill rigs, stationary engines, pneumatic pumps, fugitive emissions, and emissions produced during the well completion stage. Sources of emissions that are not represented in the inventory include flaring, off-gassing from contaminated water, and truck traffic. A review of the PA DEP's emissions-inventory data revealed six compounds had the highest reported volume expressed in tons/year: carbon monoxide, nitrogen oxides, particulate matter (PM_{2.5}), aggregated volatile organic compounds (VOCs), methane, and carbon dioxide [22]. To estimate emissions at the residence, we used carbon monoxide, nitrogen oxides, PM_{2.5}, and VOCs because they had known health effects at the expected level of exposure; methane and carbon dioxide did not so were not included despite being two of the top six compounds emitted. For this study, tons/year was converted to grams/hour.

A complete explanation of how concentrations at a residence were estimated can be found in Brown et al. [23] and will briefly be described here. To estimate emissions concentration at a respondent's residence, an atmospheric dispersion box model was used to determine air dilution downwind from emission sources (wells) and estimate the concentration of compounds at a residence. The model assumes a theoretical box, or volume, of air carries emissions downwind from a well. As the box moves away from the source, the size of the box increases, and the concentration of pollutants is proportionally diluted. The initial concentration is inversely proportional to the rate of speed with which the box moves over the source. The vertical and lateral expansion of the box as it moves downwind is determined by weather and wind speed. This screening model estimates the level of air dilution during dispersion using three parameters: 1) cloud cover, 2) wind speed, and 3) time of day. These parameters are taken from Pasquill [24]. His report identifies six stability classes and five wind speeds that characterize the meteorological conditions that define these classes [25,26]. Using these conditions, we applied hourly cloud cover and wind speed data retrieved from the National Oceanic and Atmospheric Administration (NOAA) for the years 2012 through 2017. To ensure a complete set of weather data for each year of the study, we chose to use data from one major airport in southwest PA, the Pittsburgh Allegheny County Airport in West Mifflin, PA, in the model [27]. We were able to establish hourly conditions over a year and apply the estimates to each residence in our

sample, to determine an annual level of exposure for each residence. Estimates of annual average exposures were based on weather patterns for each year over the entire region.

After our screening model was established, we used the weather data to calculate hourly concentrations from a reference well, estimated to emit 300 grams of a compound per hour, to standardize the formula when calculating how other wells deviate from a given reference [23]. Once hourly concentrations were computed for the reference case, we calculated a 90th percentile emissions concentration value (μ g/m³) for distances of 0.5 km, 1 km, 2 km, 3 km, and 5 km in the four directional quadrants around the reference well. The resulting values represent varying exposure levels experienced at a given residence living between 0.5–5 km from the reference. Using the PA DEP data for the year corresponding to the respondent's health assessment, the emissions of carbon monoxide, nitrogen oxides, PM_{2.5}, and VOCs in grams/hour were summed into one total for each well.

Well sites are ubiquitous around residences in these counties, so we used the model to first calculate a residence's exposure for the four directional quadrants. Within a quadrant, the distance of each well from the residence was determined and, depending on the distance, the 90th percentile concentration value was assigned to that well. Then, the total emissions from the well, in grams/hour, was multiplied by the 90th percentile concentration value and divided by 300 grams/hour to derive the deviance from the reference in each quadrant. The outputs give $\mu g/m^3$ per well for each directional quadrant in a 5-km radius. The estimated emission concentrations from each well, across all quadrants, were added together into an annual total exposure value per residence. The total exposure value was used as the AEC measure in the analysis.

Statistical analysis

All statistical analyses were executed in the R Project for Statistical Computing [28]. Model comparisons were made using glmutli version 1.0.7.1 [29], and TITAN analyses with TITAN2 version 2.1 [30].

The analysis consisted of two approaches to address the research questions: generalized linear models (GLMs) to test the association between the number of symptoms reported and the intensity of each exposure, and Threshold Indicator Taxa Analysis (TITAN) to predict which specific symptoms were most likely to be reported with increasing intensity of each exposure measure. Each individual symptom reported in the health assessment was binomially coded per respondent with 1/0 for yes/no. An alpha level of < = 0.05 was used as a threshold for significance in both tests.

Because the dependent variable followed a Poisson distribution, GLMs were used for modeling. For each exposure GLM, a tool was used to automate statistical model selection by generating all possible unique combinations of our demographic variables with each exposure measure to identify the best-fit statistical model for each exposure measure against total number of symptoms. Our demographic variables included: age, sex, smoking status, and water source. All demographic variables were included in the selection tool and, by default, 100 potential models were generated *a priori* to determine the best fitting models. To choose our model, Akaike information criterion (AIC) values, with a correction for small sample sizes, and number of terms for each output model were compared [31]. Lower AIC values are associated with simpler models that exclude irrelevant terms, so when comparing models, the model with the lowest AIC is considered optimal [32,33]. The best model is the one with the lowest or second-lowest AIC score and then statistically assessed for each exposure variable [34]. Interactions between variables were excluded from the best model to increase model parsimony

and only explore main effects. Zero-inflation was not required for our data as only 15% of the sample reported no symptoms. To determine our radius distance around the home, we applied GLM analyses using three spatial scales of cumulative well density: 1, 2, and 5 km. AIC criterion was used to determine which scale to study.

To assess how individual symptoms were related to changing density (CWD and IDW) and AEC, we applied the TITAN methodology. TITAN is a non-parametric analysis traditionally applied in the ecological sciences, but increasingly applied in environmental science [35], where the presence/absence of a species (also referred to as taxon) among different samples of communities is used to assess nonlinear community-scale responses, both positive and inverse, to changes in their environment. Environmental gradients are used in this process to express how an exposure is increasing in the studied environment. The primary goal in TITAN is to determine if there are levels of exposure along the gradient that influence a statistically significant positive or inverse response and are associated with the presence or absence of one or more specific species. The relationship of each species is assessed via an indicator value that ranges from 0 to 100, with 100 representing a perfect indication of species-specific association with the gradient. The TITAN analysis allows for the consideration of species that have low occurrence frequencies to identify those that possess high sensitivity to the environmental gradient. For example, Khamis et al. used the TITAN methodology to determine how reductions in glacier melting influence the presence and absence of certain aquatic species in rivers and lakes [36-38].

For this study, we defined communities as individual respondents and species as the specific symptoms reported to identify the degree to which each symptom represented a statistically significant indicator of UOGD exposure (CWD, IDW, and AEC). To remove symptoms with frequencies too low to detect a pattern, we only included symptoms reported five or more times into the TITAN analysis (n = 50) [39]. Indicator values were considered statistically significant at an α of 0.05, and resulting symptoms were organized by those having a frequency greater than 10 and a z-score greater than or equal to 1. To our knowledge, this is the first use of TITAN methodology in public health research (S1 Appendix).

Results

Symptom reporting characteristics

In this convenience sample of 104 adults who presented health concerns about UOGD, 59% were female with a median age of 57. In this predominantly rural area, only a third reported using municipal water for household use with the majority relying on private wells, cisterns, or springs. Smoking status was available for 78 of the 104; of those, 40% reported either current or former smoking. The number of individual symptoms reported by individuals ranged from 0 symptoms to 36, with mean of 7 symptoms and a standard deviation of \pm 7.7 symptoms per person. Table 1 shows the most frequently reported symptoms.

Generalized linear models: Symptom total

Initial GLMs to test the three spatial scales against symptom total showed that models using 5 km as the radius had the lowest AIC value and were therefore selected in our study (1 km: AIC = 1095.26, 2 km: AIC = 1039.73, 5 km: AIC = 1027.65). Between the three exposure measures, Pearson correlation coefficients ranged from 0.03 to 0.60; thus, all three were tested independently against total reported symptoms. Final GLMs for each exposure measure included sex and smoker status as statistically significant individual predictors, while age was not found to be statistically significant. Sex and smoker status were modeled as categorical

Symptom	n	n (%)
Sore Throat	34	33
Headache	34	33
Difficulty Speaking	34	33
Cough	32	31
Itchy or Burning Eyes	30	29
Stress	30	29
Shortness of Breath/Difficulty Breathing	26	25
Anxiety/Worry	26	25
Fatigue	21	20
Sinus Infection	20	19

Table 1. Ten most frequently reported symptoms by number and percent of respondents (n = 104).

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variables, while age was treated as continuous. Water source was excluded during the model selection process and was not included in the final models.

When controlling for age, sex, and smoker status the exposure measures produced the following results: CWD, IDW, and AEC predicted total reported symptoms (p<0.001, p<0.001, p>0.001, p>0.0

Model	Variable	Estimate	Std. Error	Z statistic	P value
CWD					
	Intercept	1.339	0.257	5.220	< 0.001
	Ever Smoked	0.520	0.088	5.921	< 0.001
	Sex	0.486	0.094	5.156	< 0.001
	CWD	0.840	0.102	8.267	< 0.001
	Age	-0.002	0.004	-0.605	0.545
	Residual degrees of freedom	73			
	AIC	780.91			
IDW Score					
	Intercept	1.407	0.253	5.563	< 0.001
	Ever Smoked	0.492	0.088	5.615	< 0.001
	Sex	0.487	0.094	5.184	< 0.001
	IDW Score	0.015	0.002	6.245	< 0.001
	Age	-0.002	0.004	-0.461	0.645
	Residual degrees of freedom	73			
	AIC	803.13			
AEC					
	Intercept	1.508	0.250	6.029	< 0.001
	Ever Smoked	0.544	0.087	6.252	< 0.001
	Sex	0.550	0.094	5.855	< 0.001
	AEC	5.74 x10 ⁻⁶	2.35x10 ⁻⁶	2.444	< 0.05
	Age	-0.003	0.004	-0.758	0.449
	Residual degrees of freedom	73			
	AIC	831.95			

https://doi.org/10.1371/journal.pone.0237325.t002

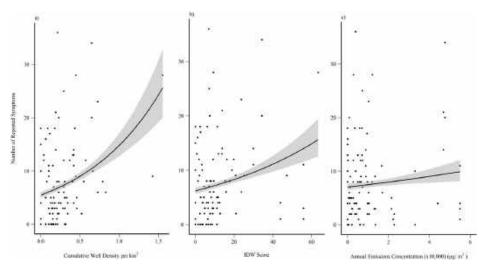
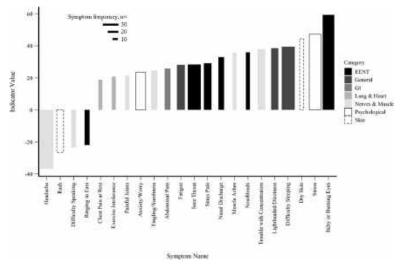


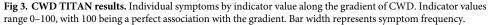
Fig 2. Exposure model plots. Poisson distributed generalized linear model for total symptoms and a) CWD, b) IDW score, and c) AEC as the exposure measure. A 95% confidence interval was applied around the regression line.

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TITAN analysis

The TITAN analysis identified multiple statistically significant symptoms along gradients of CWD, IDW, and AEC ($\alpha < = 0.05$). The higher the indicator value, the more likely the symptom is to be seen with an increase in exposure. Twenty-wo symptoms were associated with the gradient of CWD (Fig 3) with itchy or burning eyes as the strongest, positive indicator value along the gradient (indicator value = 59.31), followed by stress (indicator value = 47.17) and dry skin (indicator value = 44.44). Headache, difficulty sleeping, sore throat, stress, and itchy or burning eyes were the five most frequent symptoms in this gradient. Of the twenty-two statistically significant symptoms, approximately, 27% were categorized as EENT symptoms, followed by nerve and muscle symptoms at 27% as well. Four symptoms were inversely associated with the gradient. Although this is counterintuitive, given that 50 symptoms were





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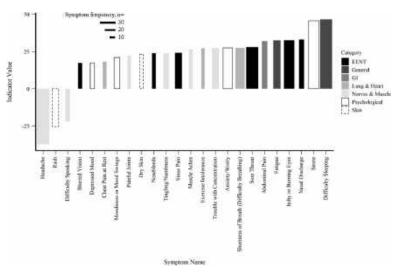


Fig 4. IDW TITAN results. Individual symptoms by indicator value along the gradient of IDW. Indicator values range 0–100, with 100 being a perfect association with the gradient. Bar width represents symptom frequency.

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assessed along each gradient, one would expect a small number of symptoms be statistically significantly associated with gradients as type-I errors.

Twenty-four symptoms were statistically significantly associated with the gradient of IDW (Fig 4), with difficulty sleeping as the strongest, positive indicator (indicator value = 46.6), followed by stress (indicator value = 45.58), and headache (indicator value = 37.7), though this particular symptom was inversely associated with the gradient. In addition to headache, difficulty speaking, and rash were also inversely associated with the gradient. The top five most frequent symptoms were the same as those in the gradient of CWD. Of the twenty-four statistically significant symptoms, approximately 25% were EENT; 25% were nerves and muscle symptoms; 17% were psychological symptoms.

Seventeen symptoms were statistically significantly associated with the gradient of AEC (Fig 5). Difficulty sleeping represented the strongest, positive indicator value (indicator

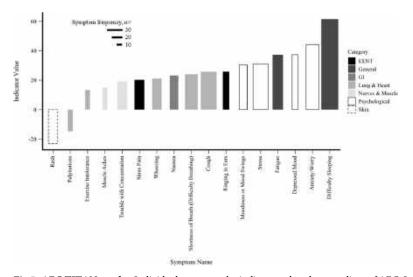


Fig 5. AEC TITAN results. Individual symptoms by indicator value along gradient of AEC. Indicator values range 0–100, with 100 being a perfect association with the gradient. Bar width represents symptom frequency.

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value = 61.58), followed by anxiety/worry (indicator value = 44.29), and depressed mood (indicator value = 37.36) which were both positively associated. Two symptoms were significantly inversely associated with the gradient of AEC. The top five most frequent symptoms of this gradient were: difficulty sleeping, anxiety/worry, cough, stress, and shortness of breath (difficulty breathing). Of the seventeen significant symptoms, roughly 29% were lung and heart symptoms; 29% were psychological.

Discussion

Despite a high degree of inherent complexity in associations between health and UOGD, a growing body of evidence, including our findings, suggests that the impacts of UOGD are heterogeneous and consistently detectable even at distances considered safe by some regulations. Determining the best method for quantifying UOGD intensity from a health standpoint is still unknown; however, we detected links between each exposure measure and total symptoms reported, including effects detected at a farther range (5 km) than reported in other studies [15,19]. Variation in UOGD operations can include the size, operation duration, and heterogeneity in chemicals used which adds complexity when attempting to relate operations to health symptoms. Discerning other influences on health that are not UOGD related or interact with UOGD in ways that have not yet been studied is an additional challenge. Other environmental stressors compounded with UOGD, or the inclusion of other UOGD infrastructure like pipelines and compressor stations, further such complexity. The use of amended IDW metrics, such as employed in Koehler et al. [40], attempts to expand IDW by including well development phases to better define exposure. Regardless, the consensus of studies reporting on health impacts around UOGD infrastructure suggests consistency between variables. The aggregate of these analyses suggests that regardless of how exposure to UOGD intensity is quantified, the impacts may occur at broad spatial scales and using distance to just the nearest UOGD facility may underrepresent risks to health.

The method of estimating UOGD intensity appears to affect the strength of associations between exposure and health outcomes in our study, but overall, a positive relationship was found between CWD, IDW, and AEC and total reported health symptoms within a 5-km radius of respondent homes. Brown et al. [23] did not find an association with the median AEC. This apparent inconsistency may be explained by their use of the median AEC, rather than the 90th percentile AEC used in this study.

Our model accounts for variation in the results that may be linked to our demographic variables. By doing so, our model terms related to exposure can account for the weight of UOGD after the variability of our demographic variables has been factored out. Relative to AEC and IDW measures, our findings indicate that CWD in proximity to residences, which constitutes a more simplistic measure, was more closely linked to total symptom reporting (Fig 2A). Exposure measures like CWD and IDW are considered proximity metrics and do not define an exact exposure pathway from source to residence; however, we hypothesize that adverse health symptoms could occur through inhalation of chemicals in UOGD emissions and that an increase in the density of wells would, together, create an exposure route. Given that both proximity and a better-defined exposure measure of AEC were significant, future studies should explore links between these measures on their own.

Our challenge to predict adverse health symptoms may reflect the general challenge of condensing well operations into a single, simple metric due to variation in each operation. Studies often apply only one metric for exposure, which could potentially overlook effects that may be seen if the measure were more precise and if more detailed UOGD data were readily available. Regardless of our findings, additional inquiries that compare health outcomes associated with exposure magnitude coupled with real-time live air monitoring are needed to determine which measure best quantifies exposure.

Our results also caution against limiting investigations of UOGD impacts on health within symptom categories due to the mixed suite of effects reported by respondents. For example, our model assessing the relationship between total symptoms and IDW, and total symptoms with AEC, suggested relatively limited predictability (Fig 2B & 2C). However, the respective TITAN analyses included nearly as many significant symptom associations compared to the CWD model (24 and 17 statistically significant indicators, respectively). Other studies have limited analyses to symptom categories, which may lead to underreporting of impacts to health across the literature, as individual symptoms have been classified under different categories [13,15,41]. A closer look at category composition in other studies revealed that itchy or burning eyes, sinus pain, fatigue, stress, and anxiety/worry are specific symptoms reported by individuals, consistent with our findings in the TITANs [14,15,42,43]. Psychological symptoms, such as stress and anxiety/worry, were included in the top five symptoms either together or separately in each of our models, with the highest percentage of psychological symptoms found in the gradient of AEC. Studies have found that increased air pollution can be linked to psychological distress, while others have found that increased stress, depression, and anxiety can be experienced by people living in communities with UOGD [14,15,42-44]. Furthermore, Albrecht [45] notes that environmental change can cause human distress, which is supported by Lai [46] who found that negative perceptions of UOGD were associated with negative psychological states. The individual symptom counts increased along exposure gradients (Figs 3-5), suggesting subtler effects when compared to aggregate symptom total (Fig 2).

Our results also caution against emphasizing a single symptom to represent detrimental health in association with UOGD. Given the suite of various chemicals applied in UOGD operations and statistically significant interactions between UOGD exposures and demographic variables as highlighted by our GLM models, substantial weight of evidence is needed to conclude that a single symptom is likely to increase with UOGD intensity. The TITAN analyses identified four, three, and two symptoms that were statistically inversely related to the gradients of CWD, IDW, and AEC. Regardless of these anomalies, 18 out of 22, 21 out of 24, and 15 out of 17 statistically significant indictor symptoms were positively associated with the gradients of CWD, IDW, and AEC which contributes further evidence that UOGD impacts health in a heterogeneous manner.

Limitations & recommendations

As with any work attempting to relate the severity of health impacts to an environmental stressor, our study findings must be considered in the context of the study limitations. Our convenience sample consisted of individuals who presented to EHP because they had concerns about health effects associated with exposure to UOGD, limiting generalizability. Additionally, the health records lacked detailed information about symptoms onset, duration, and severity, or the nature of the symptom (i.e., episodic or chronic). Our lack of detailed information in our symptom data is a limitation of this study. The health records are also subject to recall bias, with the potential for over-reporting of symptoms particularly since respondents presented due to concern about health impacts of UOGD. One mitigating factor is that at the time of reporting their symptoms the respondents did not know their records would be reviewed for this study, nor did they know the exposure measures that would be used. Future studies should collect detailed symptom data and exposure measures in real-time to address these issues.

A further limitation of our study concerns available exposure data. Not all sources of emissions are included in data released by regulatory agencies, and activities such as flaring, off-gassing from contaminated water, and truck traffic may contribute to total emission rates, but are not currently reported [47-49]. In addition, we were limited by available emissions data, which is reported on an annual basis. Some studies suggest that of the development and production stages, the hydraulic fracturing phase of development and the flowback phase of production account for the highest levels of emissions [3,40,50] and future work should include developing exposure measures that capture and isolate these stages.

The air-and-exposure screening model may have also underestimated actual emission concentrations because the model assumes emissions are constant over a year for all sources and does not factor in varying levels of emissions associated with well development phase. Furthermore, our model treats the trajectory of each well's emissions plume equally when summed into one AEC value. Future work should factor wind direction into the model to estimate and correct for the influence wind direction plays on plume movement and concentration to improve upon the AEC value. Additionally, the box model does not correct for influences of topography [25], so we could not compare emission concentrations of various elevations. Regarding weather data, one limitation was that weather data was only taken from one airport for our sample.

Conclusion

This study was unique in its attempt to use an analytical tool taken from ecological research to determine specific symptom sensitivity to changes in CWD, IDW, and AEC from UOGD. The consistency in relationships between UOGD operations, regardless of how UOGD is quantified, and adverse health outcomes across the literature suggests that increases in symptoms could be related to higher exposure to emissions or chemicals used on the well pad [3,5,11,50]. The impact of fracking on health requires ongoing research because of continued industry growth, the relatively young age of the field, and the potential for chronic or latent illness, like cancer or developmental health impacts, to result from long-term exposure [1,51]. Our results do not confirm direct causal links between UOGD exposure and reported symptoms. Our findings suggest that an estimation of exposure that relies only on proximity may be simplistic, particularly in communities with increasing density of wells at 5-km scales, and that a deeper understanding of emissions composition and potency at the residence level is warranted. Future research should examine the question of how the aggregation of exposure affects health.

Supporting information

S1 Appendix. TITAN example code and explanation. Lines 7–13 prepare a sample dataset of twenty potential symptoms and fifty individual respondents to mimic a subset of the data used in this study. For each respondent, 1s and 0s were used randomly for each symptom. A 1 means they did have that symptom, 0 means they did not. Now we have a dataset of fifty respondents and what symptoms they did or did not have. Line 16 creates a randomized list of exposure, one for each of the fifty respondents. In our study, each respondent had a measure of cumulative well density (CWD), an inverse distance weighting (IDW) score, and a measure of estimated annual emissions concentration (AEC). Line 16 creates an exposure variable that ranges from 0 to 50 (no units), with 0 being no exposure and 50 being representative of high exposure, though in our sample there was no limit to how high an exposure measure could go. Line 19 uses titan() to run the TITAN analysis, taking the reported symptoms and exposure values to determine if certain symptoms occur more or less at different levels of exposure. For

example, when the exposure measure reaches 12, the model is looking for any symptoms that stand out as occurring more frequently at that exposure level. Indicator values (range 0-100) are used to score each symptom's relationship to that exposure level, or gradient. A high indicator value shows a strong relationship with the gradient at a certain level. Then, the model determines if that relationship is positive or inverse. In ecological studies, one might study how changes in dissolved oxygen (DO) in a pond ecosystem cause certain species to die off or thrive as levels of DO change. When we begin to see a certain species appear in the pond, we can hypothesize that there may also be a change in DO as well since that species is an indicator of a certain threshold, or level of DO. Lines 22–29 takes information from the TITAN analysis and creates a table. For this table, the rows each represent the different symptoms, while columns are information pertaining to Indicator Value, the frequency of the symptom, p-values, whether the symptom is positively or inversely associated with the gradient, and the z-score. Using these parameters, we begin to filter out symptoms that were infrequent (line 25) and can also filter out insignificant symptoms or symptoms with low z-scores (lines 40–41). The latter two were done in our study but did not make sense for this sample data. Lines 34-36 construct the final plot we used to visualize the results of the TITAN analysis. In the plot, there are ten symptoms positively associated with the gradient with indicator values ranging from 32 to 71. The same goes for the inversely associated symptoms. For the plots in our study, we added additional characteristics like colors to group symptoms into categories and using the width of each bar to represent the frequency of symptoms being reported. (R)

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Author Contributions

Conceptualization: Hannah N. Blinn, Ryan M. Utz. Data curation: Lydia H. Greiner, David R. Brown. Formal analysis: Hannah N. Blinn. Investigation: Hannah N. Blinn. Methodology: Hannah N. Blinn, Ryan M. Utz, Lydia H. Greiner, David R. Brown. Project administration: Hannah N. Blinn. Software: Hannah N. Blinn, Ryan M. Utz. Supervision: Ryan M. Utz. Validation: Hannah N. Blinn. Visualization: Hannah N. Blinn, Ryan M. Utz. Writing – original draft: Hannah N. Blinn, Ryan M. Utz. Writing – review & editing: Ryan M. Utz, Lydia H. Greiner, David R. Brown.

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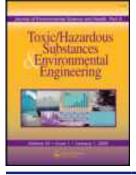
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Human exposure to unconventional natural gas development: A public health demonstration of periodic high exposure to chemical mixtures in ambient air

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Directional drilling and hydraulic fracturing of shale gas and oil bring industrial activity into close proximity to residences, schools, daycare centers and places where people spend their time. Multiple gas production sources can be sited near residences. Health care providers evaluating patient health need to know the chemicals present, the emissions from different sites and the intensity and frequency of the exposures. This research describes a hypothetical case study designed to provide a basic model that demonstrates the direct effect of weather on exposure patterns of particulate matter smaller than 2.5 microns (PM_{2.5}) and volatile organic chemicals (VOCs). Because emissions from unconventional natural gas development (UNGD) sites are variable, a short term exposure profile is proposed that determines 6-hour assessments of emissions estimates, a time scale needed to assist physicians in the evaluation of individual exposures. The hypothetical case is based on observed conditions in shale gas development in Washington County, Pennsylvania, and on estimated emissions from facilities during gas development and production. An air exposure screening model was applied to determine the ambient concentration of VOCs and $PM_{2.5}$ at different 6-hour periods of the day and night. Hourly wind speed, wind direction and cloud cover data from Pittsburgh International Airport were used to calculate the expected exposures. Fourteen months of daily observations were modeled. Higher than yearly average source terms were used to predict health impacts at periods when emissions are high. The frequency and intensity of exposures to PM_{2.5} and VOCs at a residence surrounded by three UNGD facilities was determined. The findings show that peak PM_{2.5} and VOC exposures occurred 83 times over the course of 14 months of well development. Among the stages of well development, the drilling, flaring and finishing, and gas production stages produced higher intensity exposures than the hydraulic fracturing stage. Over one year, compressor station emissions created 118 peak exposure levels and a gas processing plant produced 99 peak exposures over one year. The screening model identified the periods during the day and the specific weather conditions when the highest potential exposures would occur. The periodicity of occurrence of extreme exposures is similar to the episodic nature of the health complaints reported in Washington County and in the literature. This study demonstrates the need to determine the aggregate quantitative impact on health when multiple facilities are placed near residences, schools, daycare centers and other locations where people are present. It shows that understanding the influence of air stability and wind direction is essential to exposure assessment at the residential level. The model can be applied to other emissions and similar sites. Profiles such as this will assist health providers in understanding the frequency and intensity of the human exposures when diagnosing and treating patients living near unconventional natural gas development.

Keywords: Diagnostic tools, dispersion air model, exposure patterns, health impacts, unconventional natural gas.

Introduction

Technological advances in directional drilling and hydraulic fracturing have spawned the shale gas boom across the United States and around the globe. Progress in the oil and gas industry has brought industrial activity in close proximity to residences, schools, day care centers and other places where people spend their time. The short, and even not-so-short, distances between unconventional natural gas development (UNGD) and everyday human activity allow for emissions from natural gas extraction, processing, and transport to reach individuals in the areas where UNGD activities take place.

The emissions that occur within several miles of residences (sometimes less than 500 feet) pose challenges for health care providers seeing patients from these areas. Health care providers (as well as patients

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themselves) have very little information on the contents of UNGD emissions and the concentration of toxics that could be reaching people where they live or work. Currently patients go to physicians with health concerns but are unable to identify chemical or particulate exposures, if they exist. Physicians unfortunately often find themselves with similarly imprecise exposure conceptualizations. Guidance provided by public agencies is often insufficient to protect the health of individuals, yet, there is an increasing amount of data collected on UNGD emissions; and there is existing research on the toxicological and clinical effects of *some* substances emitted by UNGD activities.

In the present study we consider estimates of emissions from well pads, compressor stations and processing plants to gauge individuals' possible exposures and the health risks those exposures pose. This is necessary because much of the publicly accessible emissions data has been collected to provide average exposures over a lengthy period of time and because the data collection is intended to document compliance with regional air quality standards. To assess health impacts, it is, therefore, necessary to look at human exposures in the short term. What matters from a health perspective is the content and intensity of exposures at the individual level. The critical questions are: What is a person, in a given household, exposed to? How high do those exposures climb? How often is that resident exposed to these high levels? What happens physiologically when a particular toxic comes in contact with the body? This set of questions pertains to individuals living in shale gas regions across the country and is at the core of the public health problem of UNGD.

The objective of this article is to provide a structure for understanding patterns of air exposures resulting from shale gas activity. Our aim is to provide a method for understanding the fluctuations and degree of predictability of peaks in exposure. It is not to achieve precise emissions estimates. Current emission data is too sparce to do that level of modeling. To illustrate the patterns, we present a case study of a hypothetical residence located in southwestern Pennsylvania. The residence is situated near a well pad, a compressor station and a processing plant.

The Southwest Pennsylvania Environmental Health Project's ground-level experience with individuals, along with continual assessment of the literature on UNGD emissions, leads us to propose several essential criteria for evaluating individual exposures. These are: 1) proximity of well pads, compressor stations, production facilities or other operations associated with UNGD; 2) varied stages of operations occurring at the just the well pads; 3) the presence of chemical mixtures in air emissions; 4) the role of weather in dispersion of air pollutants; 5) the resulting chemical composition and concentrations exposing the individual; 6) the frequency and duration of exposures.¹

The present study demonstrates that households near UNGD sites are subjected to variable particulate and chemical air exposures that may reach potentially dangerous levels. Furthermore, it broadens the concern to the whole lifetime of shale gas development rather than primarily focusing on hydraulic fracturing as the predominant polluter. Hydraulic fracturing itself occurs over a matter of weeks, while compressor stations and gas processing plants, also located near people's homes, pollute 24 hours a day for as long as gas is flowing through the pipeline. These parts of the process produce significant air contaminants and deserve more attention than they have received thus far.

Background

Emissions and the process of gas extraction and post-extraction activities. There are numerous stages to the natural gas extraction and development process. They begin with the development of a well site and end with the transport of natural gas to its final destination. The well pad itself includes multiple activities that occur prior to the gas production phase. Once natural gas (and other substances) flow up the well and into on-site tanks, several more stages follow. These stages involve an array of machinery and facilities including pipelines, condensate tanks, compressor stations, dehydrators, and processing plants.^[1] During these stages gas is moved, filtered, compressed, and treated. Emissions – fugitive, smokestack and accidental – are released into the air at every stage of UNGD.

Documented air emissions from UNGD sources. As a group, emissions from one part of the process differ from those produced by another. The particular mix of emissions from a processing plant is different in kind and quantity, from that of a compressor station, which is different from emissions produced by the drilling of a well. That said, there are certain contaminants that are common across many, if not all, parts of the process; two of the most notable being VOCs and particulate matter.

Six air pollutants whose regional ambient air levels are regulated by the Environmental Protection Agency (EPA), are generally found at UNGD sties and are frequently discussed in the literature and identified by public agencies. These are: ozone, particulate matter (PM), carbon

¹The Southwest Pennsylvania Environmental Health Project is a nonprofit public health organization established to respond to individual and community needs for access to accurate health information and health services associated with UNGD. The southwest region of the state is among the fastest growing areas for this industry because it lies over the Marcellus shale deposits.

	Ma	May 18		May 19		May 20	
Chemical	Morning	Evening	Morning	Evening	Morning	Evening	3-day Average
Ethylbenzene	No detect	No detect	964	2015	10,553	27,088	13,540
n-Butane	385	490	326	696	12,925	915	5,246
n-Hexane	No detect	536	832	11,502	33,607	No detect	15,492
2-Methyl Butane	No detect	230	251	5137	14,271	No detect	6,630
Iso-butane	397	90	No detect	1481	3,817	425	2070

Table 1. Variation in ambient air measurements of five VOCs near a compressor station in Hickory, PA, reported in ug m^{-3^*} .

*The PA DEP collected data on many more chemicals than those listed above; the authors selected these chemicals specifically to highlight variation in emissions. See Reference 12, Appendix A. p. 31.

monoxide (CO), nitric oxides (NOx), sulfur oxides (SOx), and lead. Also frequently discussed in the emerging literature on UNGD are volatile organic compounds (VOCs) which include aromatic hydrocarbons, halogenated compounds, aldehydes, alcohols, and glycols.^[2-4] VOCs are released into the atmosphere during the production and processing of natural gas and as a component of diesel and exhaust.^[5] They also are released from gasoline, solvents, paints and other industrial and domestic products.

The Pennsylvania Department of Environmental Protection (PA DEP) inventory of emissions from natural gas facilities includes CO, NOx, PM10 (particulate matter less than 10 microns), PM_{2.5} (less than 2.5 microns), SOx, the VOCs, Benzene, Ethyl Benzene, Formaldehyde, n-Hexane, Toluene, Xylenes (isomers and mixture), and 2,2,4-Trimethylpentane.^[6] In Washington County, Pennsylvania, the PA Department of Environmental Protection (PA DEP) has collected data on 214 natural gas facilities. The highest levels of emissions reported were of benzene, PM2.5, NOx, formaldehyde, trimethyl pentene, and ethyl benzene.^[7] Additionally, a study conducted for the City of Fort Worth, Texas found acetaldehyde, butadiene 1,3, carbon disulfide, carbon tetrachloride, and tetrachloroethylene.^[8] The Texas Commission on Environmental Quality collects data on NOx, VOCs and HAPs (hazardous air pollutants regulated based on emissions rather than regional air levels).^[9] There are many other known, suspected, and as yet unknown air emissions from UNGD.^[1,8,10,11]

Fluctuations in emissions and ambient air dispersal. Well pad emissions vary in content and concentration over time. In the lead up to a producing well, different activities occur: drilling, hydraulic fracturing, flowback, flaring and, finishing. In contrast other UNGD facilities operate in a more uniform way over time (such as compressor stations and processing plants) but still emissions measured nearby also vary (see Findings section). In addition to differing releases of contaminants, emissions disperse from their sources in varied patterns due to weather and atmospheric conditions. Characterizing these variations– their intensity, frequency, and duration – is critically important from a public health perspective. Little attention has been paid to these fluctuations, particularly the high spikes in exposures.

Three short-term air reports from the PA DEP provide a set of compounds found at well sites, impoundment ponds and compressor stations.^[12-14] The PA DEP developed its list of air contaminants after consulting with the Texas Commission on Environmental Quality, New York Department of Environmental Conservation, data from research in Dish, TX, the Federal Register, and TERC.^[12] As seen in Table 1, measurement data reveal the variation in emissions even from a single source over only three days. Such variability makes accurate exposure estimates difficult. An examination of the compressor station measurements below also illustrates the seriousness of the problem posed by averaging out emissions data.

Table 1 illustrates the information lost when combining and averaging emissions over time. Looking at ethylbenzene, for instance, we see that its detection varies from zero to over 20,000 ug m^{-3} in just 3 days.

Residential VOC exposures. A small number of studies have been published documenting UNGD-generated air exposures near residences. McKenzie et al.,^[15,16] analyzing data from Garfield County, CO, documented concentrations of benzene, ethylbenzene, toluene, and m-xylene/pxylene 2.7, 4.5, 4.3, and 9 times higher within 0.8 km of sites near well completion activities than were concentrations further out. Also in Garfield County, Colorado, Colborn et al.^[16] sampled air outside a residence 1.1 km from UNGD in 2010 and 2011 (and where there was no other nearby industrial activity). Detected in 60% to 100% of the samples were VOCs including methane, ethane, propane, toluene, isopentane, n-butane, isobutene, acetone, n-pentane, n-hexane, methylcyclohexane, methylene chloride, m/p-xylenes: and carbonyls, including formaldehyde, acetaldehyde, crotonaldehyde, 2-butanone (MEK) and butyraldehyde.

Human exposure to unconventional natural gas development

Researchers working with Earthworks sampled air near residences in nine counties in Pennsylvania during 2011 and 2012. For households between 0.1 km and 8 km from gas facilities 94% of the samples that were tested for 2-butanone detected it; 88% of those tested for acetone and 79% of those tested for chloromethane detected it. Also frequently but not as consistently found were 1,1,2-Tri-chloro-1,2,2-trifluoroethane, carbon tetrachloride and trichlorofluoromethane.^[17]

In 2009, Wolf Eagle Environmental, a consulting firm working for the town of Dish, Texas, sampled air on seven residential properties near compressor stations. Chemicals identified in the samples drawn included a number that were found above Texas's Effective Screening Levels (levels which cause concern for health effects). These included benzene, dimethyl disulfide, naphthalene, m & p xylenes, carbonyl sulfide, carbon disulfide, methyl pyridine, and dimethyl pyridine.^[11]

Health problems identified in the literature. The onset of the acute actions of VOCs and PM_{2.5} can be very brief, within days, hours or minutes.^[18] Many of the studies listed below find illnesses reported that appear to be short term but recurring (Table 2). For instance, burning eyes and throat irritation were found in the research of Bamberger,^[19] Steinzor et al.,^[17] and Subra.^[20,21] Episodic nausea was reported by residents in studies by Ferrar et al.,^[22] Subra,^[20] and Bamberger and Oswald.^[19] Rabinowitz et al. documents reports of dermatologic and upper respiratory symptoms close to well sites.^[23]

Rationale. To understand the potential health effects and risks to residents, it is necessary to conceptualize the intensity and patterns of residential exposures to UNGD air emissions. To do this source term estimates needed to be developed and then applied to a pollution dispersion model. There is little measurement data providing emission rates for the central UNGD operations: four stages of well development at the well pad, compressor stations, and processing facilities. Further, there is great variability in emissions over time and among activities and between sites that is not captured by existing research or by the PA DEP. The model provides estimates of exposures at different distances from UNGD sites. The emissions estimates used here are provisional; when accurate measurements and estimates-which reflect the variability-are available those could be used.

Materials and methods

Development of the case study. A model is presented for a hypothetical residence in southwest Pennsylvania. The residence has one well pad with five wells 1 km to the west, a compressor station 2 km to the south and a processing station 5 km to the north. This "typical" scenario is based on

a dataset of 276 households in Washington County, Pennsylvania.^{[28] 2} It includes two common UNGD facilities – a well pad with multiple wells and a compressor station. We chose to include a processing plant at the furthest distance (5 km) because they are less common yet large enough to pose potentially significant health risks.

Assumptions. To move forward with a basic screening model, we have made several assumptions:

I. Compressor stations and processing plants are assumed to emit at constant rates and concentrations.

II. Each phase of the drill pad development is assumed to emit at a constant rate. That is, the drilling phase is assumed to generate constant emissions, the hydrofracking phase is assumed to generate constant emissions, etc.

III. Terrain is assumed to be flat.

IV. Pollutants such as $PM_{2.5}$ and VOCs are assumed to travel in the same manner.

EHP exposure model. Considering a hypothetical residence with three different sources at 1 km, 2 km and 5 km, we model the movement and dilution of emissions from each point source to the residence over a period of 14 months. We applied weather conditions reported from the Pittsburgh International Airport from February 2011 through March 2012. The rates of dilution, based on known weather effects and distance from the source, are calculated in 6-h increments. Six-h increments capture the four time periods that are generally responsive to diurnal weather-based dilution patterns. The 6-h increments are designated Night: 12 midnight - 6:00 am; Morning: 6:00 am – 12 noon; Afternoon: 12 noon – 6:00 pm; Evening: 6:00 pm - 12 midnight. The short time intervals also reflect our interest in capturing the short time periods in which onset of health reactions can occur.

Calculation of weather/diurnal effects. The exposure model is intended to be of use to health care providers and residents living in shale development areas. It is a basic "box" air pollution dispersion model, based on the seminal work of Pasquill.^[29] Much more complex, accurate air dispersion models are available to use. Highly accurate data on UNGD emissions is not yet available and our data is based on estimates. The simple box model best fits our purpose of providing a simple conceptual model that describes

²Two hundred and fourteen of these residences were found to have between 1 and 77 UNGD well pads at a distance of 2–5 km. Eighty-five residences had from 1 to 17 well pads located between 1–2 km. Thirty-one homes had from 1 to 7 well pads within 1k km. Two hundred and sixty residences had between 1 and 5 compressor stations 2–5 km distant. Fifteen homes had 1– 2 compressor stations within 1–2 km. Five residences had one to two compressor stations less than 1 km distant. Washington County currently has two processing stations.

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Table 2. Evidence for health effects from UNGD found in the literature.

Category	Researcher/author
Behavioral/mood/stress	Steinzor et al. ^[17]
	Ferrar et al. ^[22]
	Perry ^[24]
	Resick et al. ^[26]
	Subra ^[20]
Birth outcomes	Hill ^[26]
	McKenzie et al. ^[27]
Cancer risk	McKenzie et al. ^[15]
Dermal	Steinzor et al. ^[17]
	Rabinowitz et al. ^[23]
	Subra ^[33]
Ear, nose, mouth, throat	Steinzor et al. ^[17]
	Subra ^[21]
	Subra ^[20]
Eye	Bamberger and Oswald ^[19]
5	Steinzor et al. ^[17]
	Subra ^[21]
	Subra ^[20]
Gastrointestinal	Bamberger and Oswald ^[19]
	Steinzor et al. ^[17]
	Ferrar et al. ^[22]
High blood pressure	Subra ^[21]
Muscle/joint pain	Steinzor et al. ^[17]
5 1	Subra ^[21]
	Subra ^[20]
Neurological	Bamberger and Oswald ^[19]
e	Subra ^[21]
	Subra ^[20]
Respiratory	Bamberger and Oswald ^[19]
	Steinzor et al. ^[17]
	Rabinowitz et al. ^[23]
	Subra ^[20]

in general how residents near UNGD are at risk of episodic exposures. See Appendix A for full discussion of the calculation of effects.

The model posits that the emissions at the source are released into a defined volume of air (the theoretical "box"). We use a "box" 100 meters at the base. The length is determined by wind speed (meters per minute) The height is dependent on weather and other atmospheric conditions. The box increases in volume as the air flow carries it away from the site, raising the height of dilution and the width of the plume. A new volume calculation and emission concentration is made at each distance point reported (in this case, at 1 km, 2 km and 5 km). The larger the volume of the "box" the more dispersed the pollution. In the model, emissions are assumed to be constant within every stage. The terrain is assumed to be flat.

Cloud cover, wind speed, wind direction, and portion of the day (day or night) are factored into the model and affect the dilution of the contaminants and the intensity of exposures at different distances. Pasquill categorized these atmospheric variations into six "stability classes" A, B, C, D, E and F, with class A being the most unstable or most turbulent class, and class F the most stable or least turbulent class (Table 3).^[29] The more stable the atmosphere, the less likely emissions will mix and dilute with the ambient air and the greater the risk that higher ambient concentrations will lead to exposure at the residence.

One stability class is assigned to each 6-h period. This determines the mixing of the pollutant in the air column at the relevant distance between a source and the residence. For the well pad, which is 1km west of the residence, days with winds from the west or with calm conditions are expected to carry emissions toward the home. Winds from the south and north are relevant for emissions moving from the compressor and processing station, respectively. Winds reported as zero at the airport are calculated at 0.2 mph since air movement is always present. Further information on the EHP exposure model can be found on the Southwest Pennsylvania Environmental Health Project website.^[30]

Development of source terms used in the case study

Table 4 shows the emissions estimates (in grams per minute) developed for this case study. The values from the literature are adjusted to avoid underestimating the day-today high levels. To develop more precise source terms it would be necessary to collect site specific short term emissions. The model is designed to be conservative in terms of health protection and may represent an upper bound of what is emitted.

Table 3. Air stability classes as related to wind speed, cloud cover, day and night.*

Wind Speed	Day	Day	Day	Day	Night	Night
	Clear or just a few clouds	< 50% cloud cover	>50% cloud cover	Overcast >80% cloud cover	>50% cloud cover	< 50% cloud cover
< 5 mph	А	AB	В	D	Е	F
5 to 7 mph	AB	В	С	D	E	F
7 to 11 mph	В	BC	С	D	D	Е
11 to 13 mph	С	CD	D	D	D	D
>13 mph	С	D	D	D	D	D

*Adapted from Pasquill.^[29]

Table 4. Estimated emissions in grams/minute used in the EHP exposure model.

Source	VOCs Estimate	$PM_{2.5}Estimate$
Drilling stages	400	125
Hydraulic fracturing	160	50
Flares and finishing	300	100
Producing well pad	80	25
Compressor Station	300	100
Processing Station	1500	500

Two of the air contaminants produced by UNGD, particulate matter ($PM_{2.5}$) and volatile organic compounds (VOCs), are used to gauge risk for an individual in the hypothetical residence. The two pollutants pose risks, both individually and synergistically, and they serve as surrogates demonstrating how other hazardous air pollutants resulting from UNGD activity may be dispersed.

Modeling. A short averaging time, (6 h) was used as opposed to 24-h averages. Short averaging times over long periods allowed time specific peak concentrations of exposures to be identified.

To demonstrate the impact of weather on exposure to UNGD emissions we model the exposures from four stages of well pad development, a compressor station, and a processing plant using estimated source terms chosen by EHP based on a review of UNGD emissions monitoring research. Appendix C provides an explanation of EHP's choice of source terms and a table of data from the research EHP reviewed to develop estimated emissions. As valid and reliable emissions data become available the source terms could be adjusted.

Modeled well pad stages using EHP estimated emissions rates

The 11 months after the first well on a pad begins to be drilled encompass four stages of development. We model the first 5 months as "drilling stages"; vertical drilling (small rig) followed by vertical drilling (large rig), horizontal drilling, and preparation for hydraulic fracturing. The next activity is hydraulic fracturing, followed by flaring and finishing processes. Well production, when natural gas is flowing up the well, is then modeled for three months.³ We base these stages on data provided by the industry to

New York State (Table 5).^[1] For the 14-month case study, the stages are shown in Figure 1.

For each well pad stage, the source terms for $PM_{2.5}$ and VOCs are applied to the air screening model using weather data for the corresponding number of days and over a distance of 1 km. The same method is applied to the compressor station and processing plant emissions data for 12 months over distances of 2 km and 5 km, respectively.

Results and discussion

The findings show how exposures to VOCs at a residence will vary, in the short-term and over the course of a year or more, due to weather and diurnal conditions. Results for $PM_{2.5}$ emissions mimic the pattern of VOC emissions at scaled levels based on the emission rates presented in Table 4. Not all results are presented.

Results using EHP estimated emissions source terms

Well pad development. Figures 2–5 show the patterns of 6-hour exposures to VOCs at the residence 1 km from the well pad for four stages of development: drilling stage February–June 2011 (Fig. 2): hydraulic fracturing stage July 1–15, 2011 (Fig. 3): flaring and finishing stage August – December 2011 (Fig. 4): and producing well stage January–March 2012 (Fig. 5). (Note that the values on the vertical axis for Fig. 3 vary from the vertical axis values on Figs. 2, 4 and 5). Inspection of the charts shows 6-h periods of high exposures during all four stages. Differences in intensity of exposures are related to the type of activity at the well pad in conjunction with weather conditions for the specified time period.

Figures 2–5 depict the ambient air concentration of well pad emissions that reach the residence on days with west winds or during times when the wind is calm. The figures show that maximum VOC peaks for hydraulic fracturing (the stage of development that often draws the most attention) reached 186 ug m⁻³, compared to 465, 349 and 425 ug m⁻³ for drilling, flaring and finishing, and production. Low values are also found at each stage. However some level of exposure is always present albeit low compared to peaks.

A "peak" in exposure is defined as two standard deviations above the 6-h mean for the exposure, averaged over the time period of each stage of development. A comparison of average and maximum peaks of exposure levels is found in Table 8. The results show that the drilling, flaring and finishing, and producing stages release higher pollutant concentrations than the hydraulic fracturing stage (Figs. 2, 4, 5).

Compressor station and processing plant. Unlike well pad development, compressor station emissions are assumed to be relatively constant over a 1-year period, operating 24 h a day and seven days a week. The varied patterns of 6-h

³The very first stage of well pad development, access road and well pad construction, is omitted from this case study, although there are public health implications for this stage because of truck traffic, diesel exhaust emissions and particulate matter (PM) effects on air quality.

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Stage of Well Pad Development	Number of Days or Months *	VOC Source Term ug m^{**}	<i>PM</i> _{2.5} Source Term ug m ^{**}
Drilling stages	5 months	400	125
Hydraulic fracturing	15 days	160	50
Flares and finishing processes	5 months	300	100
Producing well pad	Indefinite	80	25
Compressor station	Indefinite	300	100
Processing station	Indefinite	3,000	1,000

Table 5. Estimated length of time per stage of development^{*}.

*Based on NY Revised Draft SGEIS 2011.^[1]

**see Table 4.

exposures to VOCs at the residence 2 km from the compressor station are shown in Figures 6 and 7. Figure 6 shows the variability in exposures experienced over the period of one year (2011) and Figure 7 shows the results for a representative month (May 2011) to provide a closer look at the day-to-day variability. The maximum peak exposure value for the compressor station was 169 ug m⁻³. Low values are also found throughout the year.

Similar to compressor stations, processing plants are assumed to have relatively constant emissions, although there is variation depending on, among other things, the type of gas (wet vs. dry). We use a high estimate for VOCs to reflect an uncertainty factor we associate with the processing facility. The gas processing plants are known to have multiple, frequent, and large scale flaring. In addition, there are more opportunities for fugitive emissions over and above those at the smaller compressor stations. The source term we use for the processing plant is the most complicated and potentially problematic. See Appendix C for a full discussion of the reasoning behind our emissions estimate.

The varied patterns of 6-h exposures to VOCs at the residence 5 km from the processing station are shown in Figures 8 and 9. Although this source is further away than the compressor station, exposure values are higher, with maximum peaks reaching 450 ug m⁻³. These findings, along with those of the compressor station, show that even with relatively constant emissions from a source there will be high variability in the frequency, duration and intensity of exposures at a nearby residence. The results also indicate that processing station emissions will impact a broader geographic range than well pads or compressor stations.

Frequency of peaks. Examining frequency of peaks (two standard deviations above the mean for each stage), Table 6 shows that during the 15-day hydraulic fracturing stage, there would be two 6-h periods with peak exposures at the residence. From the compressor station there would



Fig. 1. Stages of well pad development modeled in the case study and corresponding dates for each stage.

be 118 6-h peak periods – or 708 h of peak exposures – over the 1-year period modeled. From the processing plant there would be 99 6-h peak periods – or 594 h. These findings suggest that the residence could experience as many as 300 6-hour peaks of VOC exposure over the course of the modeled 14-month period. They also indicate that average intensity over the course of a year is a poor measure for risks to individuals near facilities and operations. Table 7 summarizes peak exposures for PM_{2.5}.

Diurnal variation. Residents tend to be more at risk at night when they are also less likely to be aware of the exposures. At night there is usually less mixing within the air column than during the day. The two 6-h periods at night (6:00 pm – 12 midnight and 12 midnight – 6:00 am) tend to carry higher exposure values. For example, in May 2011 the average values of exposure from a producing well pad for evening, night, morning and afternoon periods were 51 ug m⁻³, 58 ug m⁻³, 12 ug m⁻³ and 10 ug m⁻³, respectively. This pattern indicates that residents may be most at risk at night when they are also less likely to be aware of the exposures.

Discussion

The findings of the case study show that residents are exposed to air contaminants at different intensities over

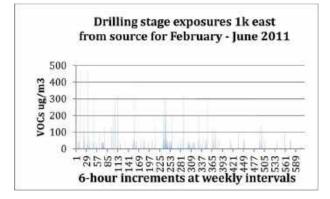


Fig. 2. Changes in the modeled ambient air levels of VOCs from the drilling stage of well pad development.

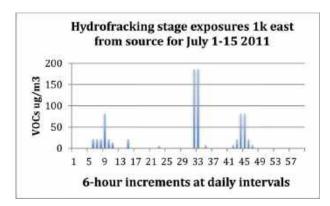


Fig. 3. Changes in the modeled ambient air levels of VOCs from the hydrofracking stage of well pad development. Note variation in vertical axes.

time. Predicting and monitoring these exposures provides important information to residents, health care providers, and policymakers on local health impacts from UNGD. The study shows that it is necessary to consider all nearby sites and the activities at those sites. The effects from one site are compounded by those of another. By bringing together estimates of UNGD emissions, the timing of activities, and weather patterns over a year, a more plausible prediction about an individual's exposures to airborne pollutants can be made.

Health care providers evaluating patients in shale development regions are faced with complex environmental exposures, capable of inducing multiple physiological responses, and non-specific health complaints. It is important for patients and providers to understand that exposure levels and patterns vary predictably and, moreover, exposures can sometimes reach levels that are immediately dangerous to human health.

The study further suggests that the approach commonly taken to estimate average exposures, based on intermittent 24-h sampling, underestimates the hazard at residences near the sites and can mislead the health care provider.

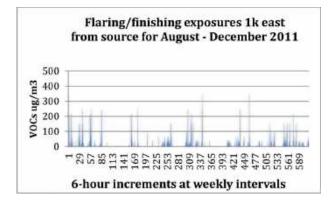


Fig. 4. Changes in the modeled ambient air levels of VOCs from the producing well pad.

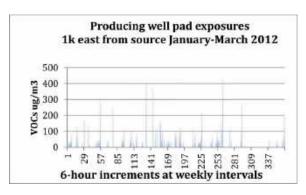


Fig. 5. Changes in the modeled ambient air levels of VOCs from the flaring/finishing stage of well pad development.

Implications of the Model and Findings

Intensity and variability of exposure. The intensity of exposures during UNGD activity at the well pad is determined by 1) the process underway (e.g., drilling, hydraulic fracturing, flaring, producing); 2) wind speed and direction; diurnal and seasonal air dilution; and 3) emission rate from the source.

Fourteen months of modeled data using 2011-12 weather conditions reported from the Pittsburgh airport show that the exposures to PM and VOCs at the hypothetical residence are highly variable and that the variability is predictable with regard to weather patterns.

Periods and patterns of peak exposures. The modeled data show that exposure levels increase most often during night-time hours when there is usually less mixing within the air column. Residents appear to be most at risk at night when they are also less likely to be aware of the exposures. This is consistent with anecdotal reports from residents who often think that nighttime air is *less* polluted than daytime air. They are often inclined to open windows at night before going to bed. Poorer air quality at night, however, may in part explain why people complain of waking up feeling sick, but improve as the day goes on.^[31]

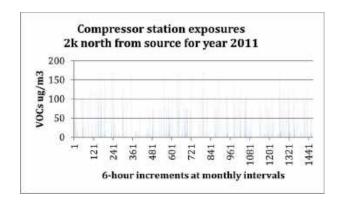


Fig. 6. Changes in the modeled ambient air levels of VOCs from a compressor station over a year.



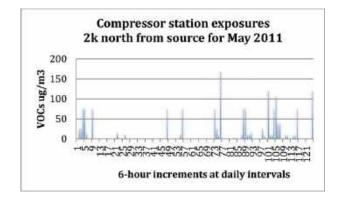


Fig. 7. Changes in the modeled ambient air levels of VOCs from a compressor station over one month.

Tables 8a and 8b show evidence of episodic extreme exposures. In fact, Tables 8a and b and the earlier figures show that 10% of the time or less a peak exposure could occur. The episodic nature of peak exposures points out the difficulty of adequately measuring and documenting exposures at residences and why, anecdotally, residents note odors and symptoms of exposures but air samples days later reveal nothing. Although there may be peaks present, a random air sample has a 75% or more chance of showing little impact of emissions at a residence.

VOC and PM exposures vary with the source

Well pad (Figs. 2–5). Drilling stage emissions are characterized by frequent 6-h episodes of low to moderate VOC exposures and instances of extreme exposures. The hydraulic fracturing stage is similar but is less frequently intense. Flaring and finishing produce high level exposures which continue at lower levels during production. These profiles are consistent with residents' reports of periodic odors and sensory and respiratory irritation. A patient

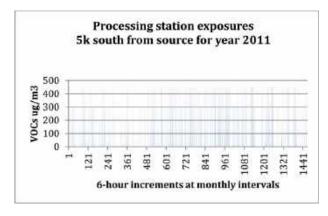


Fig. 8. Changes in the modeled ambient air levels of VOCs from a processing plant over a year.

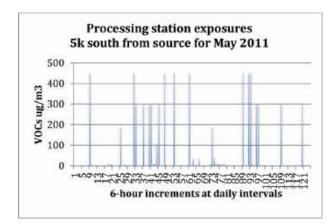


Fig. 9. Changes in the modeled ambient air levels of VOCs from a processing plant over one month.

near a well pad would have periods of low exposure some weeks, but higher, more dangerous exposures other weeks.

Compressor station (Figs. 6 and 7). In contrast to well pads, compressor stations more consistently produce emissions. Thus, variability in exposures is largely, but not entirely, due to weather and air stability.

Processing plant (Figs. 8 and 9). The gas processing plant, despite its being five kilometers north from the residence, produced exposures consistently higher than those produced by well development activities or the compressor station, which are closer. The plant has the largest toxic footprint of the three sites and poses the most danger to residents.

Physicians who understand the fundamental aspects of the route of exposures will be able to communicate risks or reassurances to the resident, explaining that he or she is not exposed to high levels all the time. Some days are better, some are worse. Those days that are 'worse' deserve attention and over time they are numerous.

Exposures occur from multiple sources at overlapping times

Figure 10 provides a 1-week snapshot of exposures at the hypothetical residence in September 2011. In the week featured the highest residential exposures are from the well pad during its flaring/finishing stage. As this occurs, however, the residence is also receiving lower but still significant emissions from the other two facilities.

Health implications of episodic exposures to shale emissions

It is important to consider the toxic actions of periodic exposures to high doses of these chemicals.

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UNGD Source	Average Intensity	Threshold of Peak Value [*]	Maximum 6-h Peak Value	Frequency of 6-h Peaks
Drilling	19	125	465	26/5 months
Hydraulic fracturing	13	88	186	2/15days
Flaring/finishing	19	118	349	30/5 months
Producing	21	130	425	25/3 months
Compressor	10	69.3	169	118/1 year
Proc. Station	56	318	450	99/1 year

Table 6. Average intensities and peak values of VOCs in 6-hour increments.

*This represents the minimum value that is considered a "peak" – defined as 2 standard deviations above the mean. Maximum peak values represent the highest peaks found in the analysis. All values are in ug m^{-3} .

Effects from high exposures to VOCs. VOCs are a varied group of compounds which can range from having no known health effects to being highly toxic. Short-term exposure can cause eye and respiratory tract irritation, headaches, dizziness, visual disorders, fatigue, loss of coordination, allergic skin reaction, nausea, and memory impairment. Long-term effects include loss of coordination and damage to the liver, kidney, and central nervous system. Some VOCs, such as BTEX (benzene, toluene, ethylbenzene and xylene, which are often emitted together), have been detected near natural gas development and specifically noted by Wolf Eagle, McKenzie et al., Colborn et al., and Steinzor et al.^[12,16-18] Acute exposures to high levels of BTEX have been associated with skin and sensory irritation, central nervous system depression, and negative effects on the respiratory system. The case for elevated risk of cancer from UNGD VOC exposure has been made by McKenzie et al.^[15]

Effects from high exposure to particulate matter. Exposure to $PM_{2.5}$, in conjunction with other emissions, is of core concern. Fine particulates interact with the airborne VOCs increasing their absorption into the lung. Reported clinical actions resulting from $PM_{2.5}$ inhalation affect both the respiratory and cardiovascular systems. Inhalation of $PM_{2.5}$ can cause decreased lung function, aggravate asthma symptoms, cause nonfatal heart attacks and high blood pressure.^[32] Research reviewing health effects from highway traffic, which, like UNGD, has especially high particulates, concludes, "[s]hort-term exposure to fine particulate pollution exacerbates existing pulmonary and cardiovascular disease and long-term repeated exposures increases the risk of cardiovascular disease and death."^[33] PM_{2.5}, it has been suggested, "appears to be a risk factor for cardiovascular disease via mechanisms that likely include pulmonary and systemic inflammation, accelerated atherosclerosis and altered cardiac autonomic function. Uptake of particles or particle constituents in the blood can affect the autonomic control of the heart and circulatory system."^[33]

High levels of diesel exhaust from engines during well pad activity. Health consequences of diesel exposures include immediate and long-term health effects. Diesel emissions can irritate the eyes, nose, throat and lungs, and can cause coughs, headaches, lightheadedness and nausea. Exposure to diesel exhaust also causes inflammation in the lungs, which may aggravate chronic respiratory symptoms and increase the frequency or intensity of asthma attacks. Long-term exposure can cause increased risk of lung cancer.^[34-37]

Mixtures increase the hazards. Mixtures of pollutants are a critically important topic in addressing the public health implications of UNGD. While this report has focused separately on two pollutants, in fact, a very large number of chemicals are released together. Moreover many of the chemicals have little or no tested health data – alone or in conjunction with others. In fact, medical reference values do not take the complex nature of the shale environment,

Table 7. Average intensities and peak values of PM peaks are defined as 2 standard deviations above the mean, in 6-h increments.

UNGD Source	Average Intensity	Threshold of Peak Value [*]	Maximum 6-h Peak Value	Frequency of 6-h Peaks
Drilling	6	37	140	26/5 months
Hydr. fracturing	4	26	56	2/15days
Flaring/finishing	6	39	116	30/5 months
Producing	6	39	128	25/3 months
Compressor	3	23	56	118/1 year
Proc. Station	19	106	150	99/1 year

*This represents the minimum value that is considered a "peak" – defined as 2 standard deviations above the mean. Maximum peak values represent the highest peaks found in the analysis. All values are in ug m^{-3} .

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a). PM _{2.5}			
UNGD Source	75th Percentile	90th Percentile	Threshold of Peak
Drilling	3	16.5	37
Hydraulic fracturing	2	7	26
Flaring/finishing	5	14	39
Producing	8	19	39
Compressor	0	9	23
Proc. Station	2.5	100	106
b). VOCs			
UNGD Source	75th Percentile	90th Percentile	Threshold of Peak
Drilling	10	55	125
Hydraulic fracturing	8	22	88
Flaring/finishing	15	41	118
Producing	35	81	130
Compressor	0	26	69
Proc. Station	7.5	300	318

Tables 8a and b. Comparison of 75th and 90th percentiles for 6-h levels of VOCs and PM_{2.5} in ambient air at the modeled residence.

All values are in ug m^{-3} .

the multiple emissions and interactions, into full consideration.^[38] The shale gas industry is not alone in emitting multiple pollutants simultaneously, but this industry is unusual in doing so as close as 500 feet from residences.

Children and pregnant women are vulnerable. Children and pregnant women are especially sensitive to pollution and are of high public health concern. Many studies confirm a range of adverse effects of air pollution on children's lung function and respiratory symptoms, especially for asthmatics. Studies often point, specifically, to fine particles as having an association with respiratory symptoms.^[39]

Research on $PM_{2.5}$ suggests that in pregnant women, the high particulate highway pollution (which has many commonalities with shale gas pollution) "may provoke oxidative stress and inflammation, cause endocrine disruption, and impair oxygen transport across the placenta, all of which can potentially lead to or may be implicated in some low birth weight ... and preterm births." These are immediate consequences in infancy, but further on "low birth weight and preterm birth can affect health

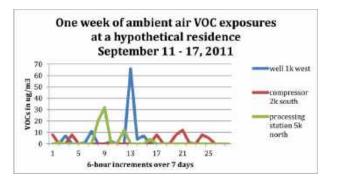


Fig. 10. One week of estimated ambient air exposures from three UNGD sources during a 7-day period.

throughout childhood and in adulthood."^[40] Two studies on birth outcomes and UNGD exposures find correlations between exposures and risk to newborns. Hill found an association between proximity to wells and low birth weight, small for gestational age, and reduction in APGAR scores.^[26] McKenzie et al. found an association between proximity and density of nearby wells and congenital heart defects and possibly neural tube defects.^[27]

Limitations of the research

The study of shale gas activity emissions and their possible health consequences is in its early stages. Thus the case study presented has limitations. These include:

1. There is a need for comprehensive source term data based on measurements, especially at processing stations. EHP's source terms were in response to the small number of measurements currently available. Further, the limited source data available are averaged over one year which underestimate the peak emissions that are of particular public health concern.

2. Full assessment of health effects is hindered by emissions uncertainties in the identification of emissions, their mixtures and consequent health impacts. We chose to look at $PM_{2.5}$ and VOCs because they are consistently found in UNGD emissions and because there are known health effects from human exposure. These contaminants, however, are emitted with a wide and not entirely identified mix of other chemicals whose combined effects cannot be determined.

3. The basic screening model was designed to be straightforward and understandable to the public. More complex models would reveal more precise estimates of periods of dangerous levels of exposure.

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4. In providing a basic rather than more sophisticated model, we held topography constant, flat surfaces. Failure to account for topography may result in an underestimate of exposures under certain circumstances.

5. We did not incorporate background levels of PM and VOCs in our study. In the future, with precise emissions levels, models should account for the additional background levels of air contaminants.

6. For some acute health assessments it may be necessary to model for less than 6 h. Even shorter averaging times would reveal the highest peak exposures, which might be lost in 6-h averaging time.

7. The exposure model, as applied, does not account for intermediate weather conditions nor does it account for vacillating winds within the 6-h periods. While the model could be extended to account for further variability, the findings hold as the emissions reaching the residence are still proportional to the wind direction and speed.

Conclusions

Exposures must be understood to be time- and locationdependent; and it is important to convey this perspective to residents and health care providers. An exposure model of pollution dispersion provides the opportunity to evaluate the intensity and frequency of exposures that are high enough to produce acute health effects at some residences. Moreover, assessing air quality over long stretches of time reveal days when weather conditions are favorable for contaminants to rise and be diluted.

In addition to weather conditions, it is important to consider the time frame for Unconventional Natural Gas Development, which begins with the clearing of land for a well pad and can go on indefinitely as wells produce gas which is transported, separated, pressurized, vented, and treated. Each stage of natural gas development produces its own emissions and a given household can be subjected to exposures from more than one part of the gas development process at once.

The model and findings provide a possible explanation for the episodic nature of health complaints and symptoms in gas drilling and processing areas. From this conclusion, we generate three recommendations: Our strongest recommendation to the research community is to measure emissions in very short time intervals while also measuring over a long period of time. Our strongest recommendation to the health care community is to consider the possibility that a patient is suffering from intermittent industrial exposures, some of which can be estimated when they live or work near UNGD sites. And, lastly, our strongest recommendation to individuals living in shale gas areas is to monitor weather conditions to understand when the air is likely to be particularly polluted and when it is likely to be less polluted. This can provide some small measure of control and warning.

The public health, medical and regulatory communities must be vigilant in assessing risk across time, distance, and activity.

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Supplemental material

Supporting information for this paper can be viewed at environmentalhealthproject.org.

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Weather-based evaluation of exposure to airborne toxins to nearby residents

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ABSTRACT

Industrial sources emit airborne pollutants that impact health. Concentrations of these pollutants near emitting facilities vary according to local weather conditions but can frequently be high—especially at night. This study's methodology used historical hourly weather data and Pasquill air dispersion calculations to quantitatively model the dispersion and hourly concentrations of toxins at discreet distances and directions relative to the emitting source. The example used in this study is a natural gas compressor station's VOCs. This weather-based analytical methodology is applicable to almost any type of polluting site emitting any mix of airborne toxins. The objective was to estimate hourly concentration levels of airborne toxins, frequency of health-hazardous concentrations and therefore frequency of health risk to residents of varying sensitivities at discreet distances near an emitting source. A continuous air monitor confirmed the weather model's results. Based on EPA methodology and NIOSH data, this study provides charts that tabulate risk levels and frequency for individuals with varying sensitivities. Key findings include:

- 1. People in close proximity to toxin-emitting facilities are frequently exposed to health-hazardous air.
- 2. EPA's National Ambient Air Quality Standards (NAAQS) do not separately identify the high levels of toxins in close proximity to emitting facilities and therefore do not adequately protect the tens of millions of nearby residents.
- 3. A weather-based model can estimate exposure levels and the health-hazardous frequency for those in close proximity to most polluting facilities where emissions information is available.

1. Introduction

There is a need to protect the tens of millions of residents in the US who live, work or study near facilities with toxic emissions. According to the FracTracker Alliance this includes an estimated 17.3 million people within 1/2 mile of oil and gas facilities, of which 5.7 million are people of color (Oil and Gas Threat Map 2022). Another study estimated that 17.6 million people in the US live within 1.0 mile of just active gas producing facilities (Czolowski et al., 2017). Many more live 1/2 mile or further from other facilities that also emit large quantities of toxins into the air and are frequently exposed to concentrations of toxins at levels hazardous to their health.

This study investigates the frequency of health risk to people in close proximity to an emitting source and illustrates the impact of weather conditions on levels of airborne toxic concentration. Given that the methodology can be used for any location and almost any polluting point source, it can be a valuable tool to help residents in their efforts to reduce exposures.

1.1. Limitations of the EPA's NAAQS pollution assessments

The EPA's NAAQS are the basis for the federal government and most states' emissions regulations but congressional directives limit them. While the NAAQS have reduced criteria pollutants and the EPA has

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established an environmental risk ranking for VOCs, the EPA does not have a health ranking for VOCs (USEPA 2021; Bachmann, 2007; Owens et al., 2017; USEPA). Therefore, NAAQS VOC focus is on average regional air concentration levels of emissions ("emissions") of 8 or 24 hours (USEPA). Because the NAAQS set standards based on average regional air pollution averaged over time they do not reflect the toxicity of the air for people living in close proximity to emitting facilities. NAAQS' measurements underestimate those acute health risks and thereby fail to identify the need to protect nearby residents and the need to reduce the amount of VOCs emitted. Consequently, the NAAQS and emission regulations based on them do not adequately protect the health of millions of people.

1.2. Acute and chronic health effects of VOCs

Experts have identified a statistically significant positive association between exposure to air pollution such as $PM_{2.5}$, NO_2 , and VOCs and incidence, severity and mortality of Covid-19 resulting both from health impacts due to long term exposure as well as from level of current exposure (Curtis, 2021; Zang et al., 2021). One large study in 33 European nations linked higher outdoor VOCs with significantly higher rates of Covid-19 incidence and mortality (Lembo et al., 2021).

VOC exposures are also associated with health effects impacting cancer, respiratory system including asthma, immune system, endocrine system, nervous system, circulatory system, reproductive system, eve, ear and mastoid process, digestion, skin and subcutaneous, genitourinary: urinary, pelvis, genitals and breasts, congenital malformations and chromosomal abnormalities. (Liu et al., 2022; Russo and Carpenter, 2019; Wickliffe et al., 2020; Ware et al., 1993; Brown et al., 2015; Martin et al., 2021; Zielinska et al., 1995). A review of VOC studies (Liu et al., 2022) reported that 1 µg/m3 of many VOCs including benzene, toluene, xylene, acetaldehyde, and p-dichlorobenzene are associated with significantly increased risk of specific adverse health effects including asthma, leukemia, cardiovascular diseases, and adverse birth outcomes (Liu et al., 2022). One study of three homes located from 0.8 to 1.7 km from a natural gas compressor station reported that levels of many VOCs including benzene, toluene, xylenes, ethyl benzene and 1,2, 4 trichlorobenzene were significantly elevated above the 1 μ g/m³, a threshold of unhealthy levels (Martin et al., 2021).

Exposures to high concentrations of VOCs have been shown to produce immediate respiratory, neurological and cardiovascular effects. A study of fifth grade children in Kanawha County, West Virginia reported that increased levels of outdoor volatile chemicals as low as 2 μ g/m3 were associated with significant increases in chronic respiratory symptoms (Ware et al., 1993).

Statistical studies show exposures to low to moderate concentrations of VOCs are also associated with adverse health effects including respiratory symptoms, neuropsychiatric symptoms and increased risk of cancer (Alford and Kumar, 2021). A number of studies have noted that low level concentrations of VOCs can worsen asthma and other breathing problems. A representative study of 550 US adults reported that low level exposure of many VOCs including benzene, ethylbenzene, 2,4 dichlorobenzene, and MTBE (methyl tetra butyl ether) were associated with significantly higher asthma rates (Arif and Shah, 2007).

Indoor exposures are also problematic. A meta-analysis of 49 published studies links low level indoor VOC levels to increased risk of asthma and wheezing (Alford and Kumar, 2021). A case-control study reported that indoor exposure to many VOCs such as benzene, toluene, xylene and total VOCs were significantly higher in 88 young children (six months to three years) with asthma as compared to 104 controls (Rumchev et al., 2007). A study of indoor VOCs in Louisiana reported that levels of VOCs can affect pulmonary function in asthmatics and may cause unacceptable lifetime cancer risks (Wickliffe et al., 2020).

Those who are within a few miles of the emitting facility are most at risk because, as this study shows, the concentration of pollutants is typically higher closer to the source. While there are limited health studies concerning health risk to high peak exposures lasting an hour or less, the Harvard Six Cities study and the American Cancer Society study (Dockery et al., 1993; Krewski et al., 2005) of particulate air pollution and mortality indicate that such exposures occur frequently and that people who live near sites emitting VOCs and other toxins and who are highly sensitive to short term exposures, such as those with asthma and COPD, are at risk.

Although the health effects of mixtures of air pollutants including VOCs, NO₂, PM_{2.5} have not been as extensively studied as studies analyzing health effects of individual chemicals (Peng et al., 2022), the synergistic health impacts of multiple toxins are established (Vardoulakis et al., 2020). It is probable that the health risks of mixtures of chemicals are greater than suggested by the majority of studies which only analyze one pollutant.

Outdoor air quality has improved in many parts of the US in the 50 years since the passing of the Clean Air Act, however, current pollutant levels still present major localized health risks (Fleischman and Franklin, 2017). In 2020, it was estimated that outdoor air pollution caused from between 100,000 and 200,000 premature deaths a year in the US (Thakrar et al., 2020). The following pollutants are estimated to be associated with total US premature pollution-related deaths: $PM_{2.5}$ 41%, NO₂ 19%, NH₃ 17%, VOCs 12%, and sulphur oxides 10% (Thakrar et al., 2020). The economic cost from fossil fuel air pollution in the US is estimated at \$600 billion per year (Farrow et al., 2020).

1.3. Health concerns and exposures associated with natural gas facilities

Natural gas production, transportation and use are major sources of airborne pollutants. VOCs and other pollutants are emitted into the air in large quantities annually from the power plants, compressor stations, processing plants, well pads, and leaking pipelines, as well as from industrial and manufacturing facilities that span the nation in urban, suburban and rural locations (Russo and Russo, 2017). Conventional and non-conventional gas production are major producers of VOCs and other air pollutants including CO2, PM2.5, NO2, and at least 39 known human carcinogens including arsenic, lead and numerous polycyclic aromatic hydrocarbons (PAHs) (Russo and Russo, 2017; Allen, 2014; Fann et al., 2018; Field et al., 2014; Moore et al., 2014). Studies have reported significant levels of many pollutants including VOCs located in gas producing regions and near natural gas facilities including compressor stations (Brown et al., 2015; Martin et al., 2021; Zielinska et al., 1995; Field et al., 2014; Bamber et al., 2019; Carpenter, 2016; Wollin et al., 2020). Major air pollutants produced by fracking include PM_{2.5}, methane, VOCs, NO₂, as well as other hazardous air pollutants including benzene, toluene, ethyl benzene, xylenes, formaldehyde, hydrogen sulfide, and polycyclic aromatic hydrocarbons (Rumchev et al., 2007). McKenzie reported that levels of VOCs were significantly increased near fracking well sites - especially within 1/2 mile. Exposure to some VOCs such as 1-3 butadiene and benzene exceeded 1 per million lifetime cancer risk (McKenzie et al., 2012). Air emissions of polycyclic aromatic PAHs are often considerable (Paulik et al., 2016).

The chemicals in the emissions from natural gas infrastructure are linked to 19 of 20 major categories of disease states including pulmonary, cardiovascular, endocrine and neurological conditions, birth defects and cancer (Russo and Russo, 2017). Studies have linked indoor or outdoor air exposure in areas near fracking operations to a number of adverse health effects (Bamber et al., 2019; Carpenter, 2016). A 2019 review of 20 epidemiological studies reported significant positive associations with adverse health conditions and fracking in 15 studies (Bamber et al., 2019). This review reported positive associations between fracking and adverse birth outcomes, leukemia, and tumors CNS, bladder and thyroid, cardiovascular hospitalization, psychological problems and asthma (Bamber et al., 2019). Brown reported that in southwest Pennsylvania proximity to unconventional natural gas developments reported proximity-related respiratory symptoms, cough, and shortness of breath (Brown et al., 2019). Bushong also reported a significant association between unconventional gas production and increased asthma hospitalizations in Pennsylvania counties (Bushong et al., 2022). A southwest Pennsylvania study indicated that some symptoms (eyes, ears, nose, throat; neurological and muscular) may be associated with proximity to fracking operations (Blinn et al., 2020). Unconventional natural gas production has been associated with a wide range of negative health effects including adverse birth outcomes (Casey et al., 2016; McKenzie et al., 2014; Stacy et al., 2015; Whitworth et al., 2017), childhood blood cancers (McKenzie et al., 2017), sinusitis/headache/ fatigue (Tustin et al., 2016), depression and disordered sleep (Casey et al., 2018), and increased hospitalization rates (Jemielita et al., 2015).

1.4. Study objectives and hypothesis

The hypothesis of this study is that certain local weather conditions determine the dispersion of airborne toxins and therefore the frequency of unhealthy exposure to people of different sensitivities. Thus, local weather patterns can be used to determine conditions that lead to high exposures and consequently, to potential risk to nearby residents.

The objective of this study was to estimate the hourly concentration levels of airborne toxins, identify the frequency of disproportionately high exposures of over one hour and quantify the impact on residents of varying sensitivities to acute health effects at discreet distances near an emitting source. An additional objective was to provide a clear and readily understandable analysis for regulatory purposes.

2. Materials and methods

When pollutants are released into outdoor air, in addition to the amount of the pollutant emitted, five key factors determine the concentration of the toxins in nearby air and the resulting inhalation exposures at downwind locations:

- 1. The amount of time the air mass is over the source
- 2. The amount of dilution that occurs downwind at various wind speeds
- 3. The degree of dilution due to vertical mixing which is determined by degree of cloud cover and subsequent surface temperature differentials
- 4. Wind direction
- 5. Distance from the source of the emission

To calculate the number of hours, days and nights that local weather conditions were such that VOC mixtures from an emitting facility would contaminate the air 0.1 km to 10 km from that facility, we utilized hourly 2020 weather data from the National Oceanic and Atmospheric Association (NOAA) (Table S1). That data was then overlaid onto air dispersion charts based on Pasquill air dispersion graphs (Kahl, 2018; Pasquill, 1962) that calculate toxin concentration at discreet distances. To develop the charts that specify the frequency at the discreet distances that the toxin concentration exceeds acceptable risk for people of varying health conditions and therefore varying sensitivities to toxins, we compared the weather analysis results to the health effects from the mixture of VOCs emitted. The Pasquill airborne chemical dispersion graphs that we used were developed in World War 2 so troops could assess the toxic concentration of chemical warfare (Pasquill, 1962; Wikipedia 2022). Currently they are the seminal logic extensively used by the nuclear, coal/gas power stations and many other industries to evaluate emissions' safety (Pasquill, 1962; Wikipedia 2022). The EPA uses Pasquill's information as the basis for their air quality measurements.

A natural gas compressor station on the New York-Connecticut border was chosen as the sample source for this study. The study analyzed historical weather data for Danbury Airport (NOAA 2022), which is 3 1/2 miles E-SE from the Southeast Compressor Station ("compressor station") in Brewster, NY. It plotted annual emissions of 40,000 lbs of VOCs — the amount that this mid-sized Title V fracked gas compressor station emitted in 2020 (New York State) and also plotted annual emissions of 20,000 lbs to evaluate the extent of exposure to toxins from facilities with less emissions. Using the same emissions data, the authors also quantified the exposure frequency for a location in Albuquerque, NM with its very different weather patterns.

This study presents the data in table format because, while there exist many excellent spatial air toxin dispersion models, the authors are not aware of any that provide hyper-local, hourly data in a format that would as clearly illustrate the exposure frequencies for the different populations.

In a related analysis, the hours that the study identified as meeting the criteria for being unhealthy were compared to the hours that showed peak levels of VOCs as determined by a PurpleAir PA-II Bosch BME680 sensor VOC continuous air monitor (PurpleAir).

2.1. Exposure guidance for VOC risk

To calculate the health risk to residents, a VOC mixture health risk exposure ranking is needed. The objective of EPA regulatory limits on VOCs, however, is to establish VOC air levels that limit concentrations of ground level ozone for regulatory actions rather than to evaluate direct VOC impact on human health. Well-referenced occupational exposure standards and some indoor air risk standards for specific VOCs exist. This information was used to develop the risk ranking for exposures to the actual mixture of VOC emissions evaluated in this study. (See Section 2.6).

2.2. Weather model basis

In order to determine frequency of acute risk, this study calculated the number of times the concentration of VOCs in the air would exceed the health recommendations for people of varying sensitivities based on EPA methodology and NIOSH data for the specific mixture of VOCs present. We conducted the analysis utilizing publicly available hourly 2020 weather data. The analysis indicated the number of times in a year during the day and separately during the night that the weather conditions were such that a person living near a natural gas compressor station, power plant or other natural gas toxin-emitting facility at that location annually emitting 40,000 lbs and 20,000 lbs of VOCs could be breathing air that is hazardous to their health. Because the facility had low stacks, (New York State 2023) our analysis assumed ground-level emissions (USEPA). This study assumed an identical hourly emissions rate for the year. Actual emissions fluctuate with some hours resulting in a higher concentration of toxins in the air and some hours a lower concentration.

2.3. Developing exposure frequency charts

Utilizing information from Pasquill graphs (Kahl, 2018; Pasquill, 1962), this study's analysis categorized in its charts the actual frequency of high VOC concentrations. Risks levels are expressed by color-code in the charts to reflect risk by resident sensitivity level. The risks are consistent with air quality index criteria for VOC pollution and integrate wind direction, wind speed, cloud cover, day-part and distance from the emitting facility to estimate the toxin concentration in the air. The analysis categorized the hourly NOAA data by the factors listed in the Table 1.

For each wind direction and day-part two charts show the study's Exposure Frequency Risk. One chart reflects dispersion with less than 50% cloud cover and one reflects dispersion with greater than 50% cloud cover. Since both charts are so similar and essentially tell the same story, except for daytime clear, the amount of cloud cover was not integrated into the data. Instead it was reflected by applying the data to the two charts for each direction and day part. Pasquill's graphs also reflect the decreased dispersion of toxins when there is greater than 80% daytime cloud cover. The exposure numbers in our analysis for daytime greater than 50% cloud cover, however, do not reflect the increased exposure from greater than 80% cloud cover. Therefore, the actual

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Table 1

Weather factors used to quantify toxic concentrations lists the factors in the analysis.

Wind Direction	North	South	East	West
Wind Speed Cloud Cover Day-part Date/Time	<5 mph Clear Day 6am-6pm Actual date/time	5-7 mph <50% Night 6pm-6am	8-11 mph >50%	>11 mph

Note: When there is no wind, (0 wind direction), the air is somewhat stagnant. Consequently, for those hours, the data were applied to all four directions. At night it was applied to those less than 1 km (0.6 miles) away from the emitting source. During the day when there was at least some cloud cover it similarly was applied in all four directions to those less than 1 km away from the source. During the day when it was clear and sunny, the toxins were assumed to dilute vertically and so those hours were not included in the analysis. For hours when wind direction data was identified by NOAA as variable, the wind direction and speed in the hours before and after were examined visually and the variable hour's wind direction was manually attributed to the direction that appeared to reflect the predominant wind direction.

daytime exposure numbers are higher.

For each of the four directions and day-part (night, day), the analysis calculated the number of hours that the data from two or more consecutive hours reached the threshold for the weather conditions identified in the chart and the number of days and the number of nights there was at least one alert-hour downwind of the emitting facility. Two consecutive hours with weather conditions that reach the threshold for an unhealthy impact is identified as one alert-hour. Using two consecutive hours to define an alert hour ensures that there is a minimum of 61 minutes meeting the exposure risk threshold. Three consecutive hours with weather conditions that reach the threshold is identified as two alert-hours; four consecutive hours with weather conditions that reach the threshold is identified as three alert-hours, etc.

The charts in this study show the amount of toxins from a source annually emitting 40,000 lbs and 20,000 lbs of VOCs at various distances from the source and at various wind speeds and cloud cover. To adapt Pasquill's airborne toxin concentration analyses to VOC dispersion, a base case was calculated showing the expected concentration of VOCs during the day and during the night at less than 50% and at greater than 50% cloud cover at four wind speeds for seven locations ranging from 100 meters to 10 km downwind from a pollution source.

2.4. Sensitivity classes and frequency of short-term serious health risk

By color-coding (Fig. 1) by level of an individual's sensitivity, Tables 2 and 3, Fig. 2 and Appendix A-C show the frequency of exposure to an unhealthy concentration of VOCs. The numbers in the colored boxes indicate the number of alert-hours and the number of days or nights that someone of that color's sensitivity or where noted on the charts someone more sensitive, living at that distance from the facility could be breathing air that exceeds the health recommendations for their sensitivity group.

The numbers in the Impact by Sensitivity Group charts (Tables 2 and 3) show the number of hours, days and nights that a person of a particular sensitivity group should be aware of and cautioned about the expected concentration of toxins. For each wind direction, the numbers on one line indicate greater than 50% cloud cover and the numbers on the other line indicate less than 50% cloud cover (which includes clear). The colored box for each direction is a weighted average of the frequency in that wind direction that the cloud cover was greater than or less than 50%. The bottom line of the chart is the average of the numbers in the colored wind direction boxes.

2.5. Estimation profiles of residential exposures and weather factors

Hourly residential exposure estimates in this study are based on our reference air model chart and the 40,000 lbs of VOC emissions reported to New York State. The level, timing and frequency of the local exposures

Levels of Risk for VOC emissions

(in micrograms/meters³) Colors and health guidance are consistent with those used by the EPA's Air Quality Index

Risk ranking specific to natural gas VOC emissions for acute health impacts				
Green 0-99 ug/m ³	Good			
Yellow 100-299 ug/m ³	Moderate Unhealthy for Very Sensitive Groups such as People with Asthma and COPD			
Orange 300-599 ug/m ³	Unhealthy for Sensitive Groups			
Red 600-1199 ug/m ³	Unhealthy (for all)			
Purple 1200 and above ug/m ³	Very Unhealthy (for all)			

Fig. 1. Risk ranking specific to natural gas VOC emissions for acute health impacts shows the concentration of VOCs that impact people of varying sensitivities.

were determined over a one-year period based on hourly NOAA weather data for the location. The weather data on percent cloud cover, wind speed and wind direction each hour day or night was used to determine stability class and direction of plume impacts. The 40,000 lbs of emissions was compared to the reference emissions to adjust the levels of local residential exposures for each of the 112 categories (boxes) on each wind direction's Exposure Frequency Risk chart. These were based on the source and the air stability category. Air stability is a function of wind speed and mixing due to heating by the sun or night cooling of the earth.

The number of hours and days that the emissions would impact the residents were calculated at each of five hazard levels (green, yellow, orange, red, purple) and shown in Tables 2 and 3, Fig. 2 and Appendix A-C. The hazard level calculated for VOCs was patterned after the EPA hazard categories and are described below.

2.6. Process for ranking exposure risks for the mixtures of VOCS in peak air exposures

This study focuses on the non-cancer health effects elicited by short inhalation exposures to mixtures of VOCs, with exposures of a minimum of two consecutive hours. The health effects elicited by the mixture are a function of the proportion of each chemical in the mixture and its potency. This study used as its basis, the mix of VOCs emitted at fracked gas extraction, storage and transport sites. Four categories of VOCs were found in the emissions: straight and branched chains that do not contain substitutions of active groups, substituted alkanes such as acids, aldehydes, glycols and ketones, halogenated compounds, and aromatic hydrocarbons such as benzene, toluene and PAHs. The short chain, c1 to c10 carbon chemicals predominate in the mixtures.

A scale of human toxic potency for each of the chemicals in such mixtures has been developed for workers and current standards for both long-term exposures and immediate acute impact from short-term exposures are published by NIOSH in the Guide to Chemical Hazards (Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health 2007). This study used as its basis NIOSH's short-term exposure guidelines. Qualitative and other quantitative lists of the chemicals in the emissions were reviewed. NIOSH's target organ and potency recommendations for each of the four categories of chemicals in the mixture were examined. Chemicals with similar target organs and potencies were grouped together. These groups included acute risks to the eyes, ears, nose and throat, the respiratory system, cardiovascular system and central nervous system. The potencies for each of the compounds in the NIOSH handbook range from air concentrations of 1200 ug/m³ down to 10 ug/m³ with toxic potencies clustered between 100 and 300 ug/m³.

Based on this finding, a risk ranking was constructed for the different short-term exposures to the mixture. Chloromethane, the most toxic commonly identified chemical was used as a guide and surrogate. Its threshold guidance for workplace exposures is 100 ppm or 202 ug/m³. The risk was adjusted for children, the elderly and other susceptible persons by dividing this number by two. The scaling system used is similar to that used by EPA for criteria pollutants. Reference to actions of higher exposures to chloromethane was used to guide ranking for the higher exposures to the mixtures.

Fig. 1 shows the risk ranking using EPA's format and descriptions for air quality exposure categories of individual chemicals. Thus a table was constructed to evaluate the immediate and short-term health risks from peak exposures to the specific mixture of compounds. The risk follows the federal workplace and indoor air guidance standards. The Exposure Frequency Risk charts are based on the five chemicals that according to the NYS DEC make up 95% of VOC emissions. There are other chemicals in the emissions for which this study does not account.

2.7. Comparison of weather model estimates with actual emissions

To determine the accuracy of the weather model results, this study compared the day and hour of peak VOC exposures for the four months March through June 2022 from a PurpleAir monitor, 1/2 km southwest of the compressor station, with day and hour exposures identified in the study's weather model.

3. Results

This study's Impact by Sensitivity Group charts (Tables 2 and 3) and its VOC Exposure Frequency Risk charts (Fig. 2 and Appendix A-C) show risk frequencies for individuals with varying sensitivities.

Table 2

Impact by Sensitivity Group – 40,000 lbs VOCs shows the 2020 frequency of unhealthy exposure by sensitivity level at 0.1 and 1.0 km from the emitting site for a natural gas compressor station annually emitting 40,000 lbs of VOCs.

Impact by Sensitivity Group - 40,000 lbs VOCs								
2020 Frequency - Danbury Night								
	Unhealthy for Very Sensitive @ 1 km Very Unhealthy for Everyone @ 0.1 km		Very Unhealthy for Everyone @ 1 km		Unhealthy for Everyone @ 1 km		Unhealthy for Sensitive People @ 1 km	
	hrs	nights	hrs	nights	hrs	nights	hrs	nights
North								
>50% cloud cover	1558	283	1160	244	1324	263	1492	280
<50% cloud cover	1558	283	1324	263	1492	280	1558	283
Est. average*	1558	283	1274	257	1441	275	1538	282
East								
>50% cloud cover	1486	273	1156	245	1353	266	1464	272
<50% cloud cover	1486	273	1353	266	1464	272	1486	273
Est. average*	1486	273	1283	259	1425	270	1478	273
South								
>50% cloud cover	1601	281	1231	248	1431	268	1558	277
<50% cloud cover	1601	281	1431	268	1558	277	1601	281
Est. average*	1601	281	1370	262	1519	274	1588	280
West								
>50% cloud cover	2223	307	1429	255	1894	291	2131	304
<50% cloud cover	2223	307	1894	291	2131	304	2223	307
Est. average*	2223	307	1772	282	2069	301	2199	306
All directions Est. average*	1717	286	1425	265	1613	280	1701	285

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Table 3

Impact by Sensitivity Group – 20,000 lbs VOCs shows the 2020 frequency of unhealthy exposure by sensitivity level at 0.1 and 1.0 km from the emitting site for a natural gas compressor station annually emitting 20,000 lbs of VOCs.

Impact by Sensitivity Group - 20,000 lbs VOCs									
2020 Frequency - Danbury Night									
	Unhealthy for Very Sensitive @ 1km Very Unhealthy for Everyone @ 0.1 km		for Ev	nhealthy ⁄eryone 1 km	Eve	althy for ryone 1 km	Unhealt Sensitive @ 1	People	
	hrs	nights	hrs	nights	hrs	nights	hrs	nights	
North						-			
>50% cloud cover	1558	283	0	0	1160	244	1324	263	
<50% cloud cover	1558	283	1160	244	1324	263	1492	280	
Est. average*	1558	283	810	170	1274	257	1441	275	
East									
>50% cloud cover	1486	273	0	0	1156	245	1353	266	
<50% cloud cover	1486	273	1156	245	1353	266	1464	272	
Est. average*	1486	273	747	158	1283	259	1425	270	
South									
>50% cloud cover	1601	281	0	0	1231	248	1431	268	
<50% cloud cover	1601	281	1231	248	1431	268	1558	277	
Est. average*	1601	281	856	172	1370	262	1519	274	
West									
>50% cloud cover	2223	307	0	0	1429	255	1894	291	
<50% cloud cover	2223	307	1429	255	1894	291	2131	304	
Est. average*	2223	307	1053	188	1772	282	2069	301	
All directions Est. average*	1717	286	866	172	1425	265	1613	280	

* The estimated average is based on the % of alert hours in each wind direction for all wind speeds that there was >50% cloud cover.

The short-term health impacts for exposure to natural gas VOCs are described in Fig. 1, the risk guideline chart. The following charts show frequency of short-term health hazardous exposures from a facility in New York annually emitting 40,000 lbs of VOCs. Although VOCs can cause cancer, birth defects, neurological damage and chronic health impacts those conditions are not considered in these short-term acute health effect charts.

Tables 2 and 3 show the number of hours and nights that people in different sensitivity groups (very sensitive, sensitive, everyone) living different directions and distances from a gas facility annually emitting 40,000 lbs of VOCs and 20,000 lbs of VOCs would be exposed to VOCs in concentrations considered unhealthy for them. The yellow/purple column shows the number of hours and nights that the emissions would be Unhealthy for a Very Sensitive person living 1 km from the emitting facility and the number of hours and nights it would be Very Unhealthy

for Everyone living 0.1 km from the emitting facility. The purple column shows the number of hours and nights it would be Very Unhealthy for Everyone living 1 km from the emitting facility. The red column shows the number of hours and nights it would be Unhealthy for Everyone living 1 km from the emitting facility and the orange column shows the number of hours and nights it would be Unhealthy for Sensitive Groups 1 km away.

As shown in Tables 2 and 3, if the compressor station were to reduce annual VOC emissions from 40,000 lbs to 20,000 lbs, residents 1 km from the site would still be exposed to an unhealthy amount of toxins over about 250 to 280 nights and over 1270 to 1770 nighttime hours depending on direction relative to the emitting facility. This reduction would reduce frequency of risk that the nighttime air is very unhealthy for everyone at 1 km by about 35% but would have only a minor risk reduction for people who are more sensitive. When the study's toxic concentration model, using as the source term 40,000 lbs of gas compressor station VOCs, was applied to a comparison site in the southwest, Albuquerque, the findings were site specific but exposures were also frequent.

3.1. Exposure frequency risk charts

The Exposure Frequency Risk charts, Fig. 2 (west wind) and Appendix A-C (north, east and south wind), show the effect of wind speed, cloud cover, day part (day/night) and dilution distance on frequency and intensity of exposures for emissions of 40,000 lbs of VOCs to people with different health conditions living at distances 0.1 km to 10 km from

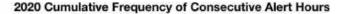
the emitting facility. The colored boxes reflect the impact to each sensitivity level. The charts present the number of alert hours a year in each direction.

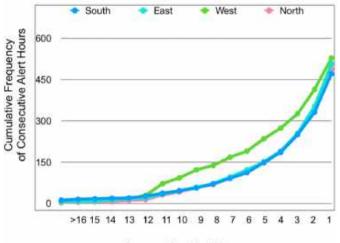
3.2. Multiple hour exposures

As shown in Fig. 3, in addition to brief exposures, there are frequent exposures lasting multiple hours. For example, when the wind was coming from the west, there were 138 times that there were eight or more consecutive alert hours of toxic concentrations that posed a health risk. When the wind was coming from the east, south and north, there were about 70 times for each direction that there were eight or more

		Expo	sure Freque	ncy Risk - Dan	bury West		
		Comp	pressor Station	VOC emissions 40	0,000 lbs/yr		
			0-99 1140-200 3	00-599 600-1199 1	200+ ug/m³		
	100 yds	360 yds	0.6 miles	1.2 miles	1.8 miles	3.1 miles	6.2 miles
	0.1 km	0.5 km	1 km	2 km	3 km	5 km	10 km
Wind speed	Day all cloud co	over except clear <	5 mph shown on	<50% cloud cover c	hart; no wind att	tributed to all direct	tions ≤1 km
<5 mph							
5-7 mph							
8-11 mph		and the second					
>11 mph	Y. O. R. P: 347 alert hrs 116 days	Y: 347 alert hrs 116 days O: 146 alert hrs 50 days	146 alert hrs 50 days				
	Day all cloud co	over except clear <	5 mph shown on	>50% cloud cover c	hart; no wind att	tributed to all direct	tions ≤1 km
<5 mph			40 plant hus				
5-7 mph			48 alert hrs 31 days				
8-11 mph							
>11 mph	Y. O, R, P: 347 alert hrs 116 days	Y.O: 347 alert hrs 116 days R: 104 alert hrs 52 days	347 alert hrs 116 days				
	Night all cloud	cover shown on >5	0% cloud cover c	hart; no wind attribu	ted to all direction	ons ≤1 km	
<5 mph			1429 alert hrs 255 nights	70 alert hrs 51 nights			
5-7 mph		1894 alert hrs 291 nights	1894 alert hrs 291 nights	384 alert hrs 138 nights	384 alert hrs 138 nights	384 alert hrs 138 nights	
8-11 mph			2131 alert hrs 304 nights	610 alert hrs 155 nights			
>11 mph	Y, O, R, P: 2223 alert hrs 307 nights	Y,O,R: 2223 alert hrs 307 nights	2223 alert hrs 307 nights	and a substances of			
	Night all cloud	cover shown on <5	0% cloud cover o	chart; no wind attribu	ted to all direction	ons ≤1 km	
<5 mph		1			70 alert hrs 51 nights	70 alert hrs 51 nights	70 alert hrs 51 nights
5-7 mph			1894 alert hrs 291 nights	384 alert hrs 138 nights	384 alert hrs 138 nights	384 alert hrs 138 nights	or rights
8-11 mph		2131 alert hrs 304 nights	2131 slert hrs 304 nights	Y,O: 610 alert hrs 155 nights	610 alert hrs 155 nights		
>11 mph	Y, O, R, P: 2223 alert hrs 307 nights	Y,O,R: 2223 alert hrs 307 nights	Y,O: 2223 alert hrs 307 nights				

Fig. 2. Exposure Frequency Risk – Danbury West shows frequency of unhealthy exposure to people of varying sensitivities at varying distances from a compressor station annually emitting 40,000 lbs of VOCS when wind is from the west.





Consecutive Alert Hours

Fig. 3. 2020 Cumulative Frequency of Consecutive Alert Hours shows cumulatively the frequency that there are multiple consecutive alert hours

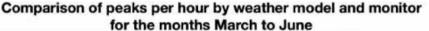
consecutive alert hours. The greater than 16 consecutive alert hour data point includes 15 periods with 17-19 consecutive alert hours; nine periods with 20-29 consecutive alert hours; three periods with 30-31 consecutive alert hours; and, one period of 45 consecutive alert hours.

3.3. Comparison of weather-based hourly predictions and the monitored data for wind from the northeast

The high nighttime frequency of unhealthy pollution is confirmed by the hour-specific frequency of peak concentrations from three PurpleAir VOC monitors positioned 0.5 km to 3.4 km southwest of the compressor station. The hourly observed peak emissions from the closest monitor 0.5 km from the compressor station was compared with the weather model's hours meeting the exposure threshold for March to June. Data from this monitor continuously recording VOCs was used to identify hourly periods that were three times over baseline level. Three standard deviations over baseline level was used to separate the peaks from the average background level.

Fig. 4 shows the observed peak frequency from the monitor (blue) and frequency of high exposure hours based on the weather model (orange). Fig. 5 compares the number of daily hourly peaks by weather model and monitor.

An hour-by-hour analysis of the weather model's alert-hours and no



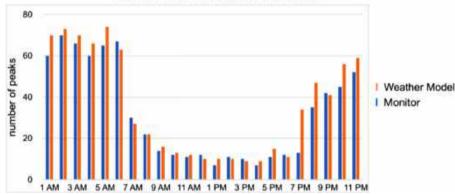


Fig. 4. Comparison of peaks per hour by weather model and monitor for the months March to June shows how closely on an hourly basis the weather model and monitor indicate peaks.

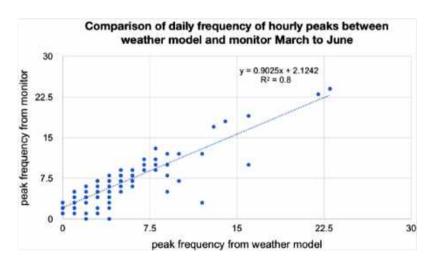


Fig. 5. Comparison of daily frequency of hourly peaks between weather model and monitor March to June compares the number of daily hourly peaks. Its R² value is 0.8.

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alert hours indicated that they were the same hours as the monitor's peak and no peak hours 87% of time.

4. Discussion

The findings from this study show that residences up to, and possibly over, 5 km from a gas compressor station emitting 40,000 lbs of VOCs experience multiple periods of high exposures to a mixture of VOCs both outside and inside their homes over one year. While this study used the VOC emissions from a natural gas compressor station in New York State as the basis for its analysis, this methodology can be applied to other pollutants or polluting facilities.

As illustrated in the Exposure Frequency Risk charts (Fig. 2, Appendix A-C), those who live closer to an emitting site typically will more frequently be exposed to unhealthy air. The periods of high exposure are due to the five conditions, wind direction, wind speed, cloud cover, distance from the sources and time of day or night. Substantial cloud cover and low wind speeds reduce the dilution and increase the concentrations of pollutants at locations close to the emitting source. The greater concentration of pollutants in the air near the emitting facility is because they have not yet been dispersed by the wind and/or the sun's heat. In most cases as the wind blows stronger, the density of the emissions in the air become more diluted. However, when the daytime wind blows stronger, for nearby locations the reverse occurs because more pollutants are carried from the emitting facility. During the day, cloud cover increases toxic concentration while at night there is higher toxic concentration when there is less cloud cover. The charts indicate that at night the high exposures extend further from the source than during the day and that the hazard is higher at low wind speeds and during calms. The charts also show that individuals who are more sensitive are affected at distances farther from the source than those who are less sensitive.

The findings in the charts show:

- For people living close to these emitting facilities, the projected toxic concentration of the air at night from facility emissions frequently exceeds acceptable VOC risk.
- Most nights both sensitive and non-sensitive people who are 1 km (0.6 miles) or less from a facility with 40,000 lbs/year of VOC emissions are exposed to an unhealthy amount of toxins regardless of wind speed or cloud cover. During the day there is greater dilution so unhealthy exposures are reduced in frequency and distance.
- At night when the wind is not strong, many of those who are farther from the emitting site frequently are exposed to an unhealthy amount of toxins.
- At night toxic concentration of air 1 km or less from facilities annually emitting only 20,000 lbs of VOCs exceeds acceptable VOC risk guidance for these chemicals for both sensitive and non-sensitive people the vast majority of nights.

The analysis found that at night both sensitive and non-sensitive people who are 1 km from the compressor station used in this study or a comparable facility at this location are exposed to an unhealthy amount of toxins over 270 nights/year (5 out of 7 nights) and for over 1400 to 2000 nighttime hours depending on direction relative to the emitting facility.

The data used in this study on the components and amounts in the emissions mixture is available to the public from New York State Department of Environmental Conservation. NOAA provides the weather data. Risk-ranking scales needed to determine the acute health hazards from the exposure to the VOCs in mixtures are based on the NIOSH Guide to Chemical Hazards and peer reviewed reports. (See Section 2.6).

The compressor station used in this study reported emitting 40,000 pounds of VOCs in 2020. Classes of VOCs in the pollutants emitted included light weight alkanes, aldehydes, halogenated hydrocarbons,

aromatics and PAHs. Overall there were 18 different VOCs reported in the mixtures. These VOCs are associated with five major acute health conditions: asthma, COPD, sensory and cognitive health effects and cardiovascular attacks. In addition, these VOCs can cause chronic effects including cancer, birth defects, pulmonary and endocrine system conditions. The risk ranking used was based on relative concentrations, potencies and actions of the five predominate VOCs. PMs, CO and NOx were also present in the mixtures emitted but were not included in the risk evaluation. The weather would impact the concentration of those toxins and others in the same way it impacts VOCs. Consequently, the toxicity of the air for nearby residents is greater than that shown in the Exposure Frequency Risk charts.

The Impact by Sensitivity Group chart (Table 2) shows that everyone at 1 km or less from the compressor station could have experienced air that was unhealthy for them an average of 1425–2069 nighttime hours and 270–301 nights depending on direction relative to the emitting source. Sensitive people at 1 km or less would have had a risk of a health response 1478–2199 nighttime hours in 2020.

Although less frequent, the model results show that periods of high exposures can occur up to 10 km from the compressor station, usually these exposures occur at night due to low air dilution. Relative to night, there are far fewer days and hours exceeding acceptable risk limits (Fig. 2 and Appendix A-C).

In 2020 there were 3042 residents within one mile (1.2 km) of the compressor station and 283 within 1/2 mile who were frequently exposed to high levels of toxins. Nationally, there are over 17 million people who live within a mile of active natural gas facilities as well as many millions more who live near other polluting facilities who also experience high exposures.

If the compressor station were to reduce emissions to only 20,000 lbs of VOCs annually, residents 1 km from the site would still be exposed to an unhealthy amount of toxins over about 250 to 280 nights and for over 1270 to 1770 nighttime hours depending on direction relative to the emitting facility. Reducing emissions from 40,000 lbs to 20,000 lbs reduces nighttime frequency of risk at 1 km from 0% to 35% depending on sensitivity category.

Acute health risks to residents near natural gas compressor stations and other toxin-emitting facilities have been reported (Blinn et al., 2020). The current outdoor air quality health risk assessments under-estimate the acute risks. The EPA's NAAQS are not designed to evaluate exposures to residents in close proximity to emitting facilities and thereby fail to recognize the need to protect them and the need to reduce the amounts of VOCs and other toxins emitted. The EPA's NAAQS are the basis for the federal government and most states' emissions regulations. NAAQS average the VOCs regionally and over time so do not reflect the toxicity of the air for people living in close proximity. Averaging over multiple hours and regionally masks the potentially toxic peaks that are shown in this study.

The EPA has established an environmental risk ranking for VOCs, but has not established a health risk ranking for VOCs. While different mixtures in the emissions have different component chemicals, it is possible to systematically evaluate the risks of mixtures if the relative quantity and hazard of each VOC component were considered. The EPA recognizes the necessity of using NO₂ and SO₂ hourly measurements. The authors believe hourly measurements of VOCs are also needed. The EPA, however, is limited in what they can do by congressional direction.

High exposures within houses occur due to intrusion of the VOC emissions from hourly exchange of outside and inside air, at a typical rate of about one half to two air changes per hour, which after three hours will approach outside concentrations (EPA, 2011). There are many times when the high concentration exposures last more than three hours (Fig. 3). In those cases, the toxic concentration inside the home becomes an issue. At a rate of one air change of outside and inside air per hour, after one hour, the concentration inside the home is 1/2 the concentration outside the home. After two hours, the inside concentration rises to 75% of that of the outside air. After three hours the inside

concentration is nearly 88% or nearly the same as the outside. As shown in Fig. 3, there are multiple periods of sequential hours with high VOC concentrations thereby causing the inside air concentration to equal outside concentration and therefore being a health hazard.

4.1. Modeled high exposures compared with monitor peak concentrations

An air monitor 1/2 km southwest of the compressor station continuously measured VOCs from March through June 2022. The PurpleAir monitor measures a reference VOC. While a direct quantitative comparison would require the monitor to measure the exact chemicals in the emitted mixture, the air dilutions should be the same and show when same peaks occur. Consequently, it was possible to compare the times when peaks occurred and the number of peaks per day. A comparison of hours when modeled high exposures occurred show similar hourly patterns as the monitor's findings (Fig. 4). The peaks per day (Fig. 5) illustrate the high percent of times that the high exposures predicted by the model and the peaks observed on the monitor occurred on the same day. When the rate of emissions is relatively constant, this would be expected since high toxic concentrations are driven by weather components. A comparison of the specific hours when the weather model indicated a high exposure and the monitor indicated a peak and when neither indicated one, had a correlation of 87%.

4.2. Limitations

- 1. The Pasquill graphs used to design this study assume flat terrain. Hills and valleys can modify the airflow resulting in a shift regarding exposure location with, for example, increased exposure at 3 km and less at 1 km; or, increased exposure to those living south-southeast and less to those living south when the wind is from the north.
- 2. This study assumed identical hour emissions rate for the year. Actual emissions fluctuate with some hours resulting in a higher concentration of toxins in the air and some hours a lower concentration.
- 3. The study does not compare actual values for the monitor, only peaks.
- 4. The study quantifies outdoor air exposure and notes the typical exchange rate for outdoor to indoor air. Many residences, however, have HVAC and air filters which reduce indoor toxin concentrations and the impact of this equipment was not integrated into the findings.
- 5. The study used one monitor at one site for validation.
- 6. Providing the data in graph form rather than spatially may be a drawback for some.

4.3. Future directions

More sites need to be validated. The authors are in conversation with several organizations to use this weather-based methodology to quantify unhealthy exposures from other emitting sources and compare the findings to continuous monitor data at those locations.

Use this weather-based methodology to provide hourly unhealthy exposure data for other sites to regulatory agencies and environmental justice organizations since polluting facilities tend to be in lower income communities.

The algorithm used in this study was based on a stack height that would result in ground level emissions. Since the dispersion pattern of chemicals differ depending on stack height and because the stack heights of emitting sources differ, analysis for various stack heights would be useful.

5. Conclusion

1. This study shows that archived local weather information can be used to characterize and show the frequency of exposure health risks both past and future near point sources such as compressor stations.

- 2. This study shows that the frequency of high concentrations of VOCs in the air near an emitting facility vary with time of day and weather conditions.
- 3. This study shows the high frequency that people living near the midsized NY compressor station evaluated would be exposed to unhealthy air. Everyone 1 km or less from the station would have been exposed to air that was unhealthy for them an average of 1425 - 2069 nighttime hours and 270 - 301 nights depending on direction of their home relative to the emitting source. People sensitive to lower concentrations who live at 1 km or less would have had a risk of a health response 1478 - 2199 nighttime hours in 2020 (Table 2).
- 4. As noted in the references referred to in this study, on-going and short-term exposures to airborne toxins can cause many health impacts including asthma, COPD and other pulmonary and cardiovascular diseases.
- 5. Currently, the predominantly used methodology for assessing exposures and guiding regulations is the EPA's NAAQS. The NAAQS' methodology, however, averages VOC toxins regionally rather than hyper-locally and over multiple hours instead of hourly so it does not identify the frequent high exposures to residents near emitting sources and therefore does not adequately protect the millions of Americans who live in close proximity to these sources.

CRediT authorship contribution statement

Amy Rosmarin: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Luke Curtis:** Funding acquisition, Writing – review & editing. **David R. Brown:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.

Declaration of Competing Interest

Luke Curtis received financial support from The Heinz Endowments (www.heinz.org) for preparation of the manuscript. The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. While authors Amy Rosmarin and David Brown have a patent pending on the methodology used in this study, the authors declare it does not present a conflict of interest and would not affect their objectivity.

Data availability

Data will be made available on request.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.envadv.2023.100415.

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Purdon's Pennsylvania Statutes and Consolidated Statutes Title 58 Pa.C.S.A. Oil and Gas (Refs & Annos) Part III. Utilization Chapter 32. Development (Refs & Annos) Subchapter B. General Requirements

58 Pa.C.S.A. § 3222.1

§ 3222.1. Hydraulic fracturing chemical disclosure requirements

Effective: April 16, 2012 Currentness

(a) Applicability.--This section applies to hydraulic fracturing of unconventional wells performed on or after the effective date of this section.

(b) Required disclosures.--

(1) Except as provided under subsection (d), a service provider who performs any part of a hydraulic fracturing treatment and a vendor who provides hydraulic fracturing additives directly to the operator for a hydraulic fracturing treatment shall furnish the operator with the information required under paragraph (2) not later than 60 days after the commencement of the hydraulic fracturing.

(2) Within 60 days following the conclusion of hydraulic fracturing, the operator of the well shall complete the chemical disclosure registry form and post the form on the chemical disclosure registry in accordance with regulations promulgated under this chapter in a format that does not link chemicals to their respective hydraulic fracturing additive.

(3) If the vendor, service provider or operator claims that the specific identity of a chemical or the concentration of a chemical, or both, are a trade secret or confidential proprietary information, the operator of the well must indicate that on the chemical disclosure registry form, and the vendor, service provider or operator shall submit a signed written statement that the record contains a trade secret or confidential proprietary information. If a chemical is a trade secret, the operator shall include in the chemical registry disclosure form the chemical family or similar description associated with the chemical.

(4) At the time of claiming that any of the following are entitled to protection under paragraph (3), a vendor, service provider or operator shall file a signed written statement that the record contains a trade secret or confidential proprietary information:

- (i) A hydraulic fracturing additive.
- (ii) A chemical.
- (iii) A concentration.

(iv) Any combination of subparagraphs (i), (ii) and (iii).

(5) Unless the information is entitled to protection as a trade secret or confidential proprietary information, information submitted to the department or posted to the chemical disclosure registry shall be a public record.

(6) By January 1, 2013, the department shall determine whether the chemical disclosure registry allows the department and the public to search and sort Pennsylvania chemical disclosure information by geographic area, chemical ingredient, chemical abstract service number, time period and operator. If the department determines that there is no reasonable assurance that the registry will allow for searches by geographic area, chemical ingredient, chemical abstract service number, time period and operator, at a date acceptable to the department, the department shall investigate the feasibility of making the information under paragraph (2) available on the department's Internet website in a manner that will allow the department and the public to search and sort the information by geographic area, chemical ingredient, chemical abstract service number, time period and operator and shall report to the General Assembly whether additional resources may be needed to implement the searches and sorting.

(7) A vendor shall not be responsible for any inaccuracy in information that is provided to the vendor by a third-party manufacturer.

(8) A service provider shall not be responsible for any inaccuracy in information that is provided to the service provider by the vendor.

(9) An operator shall not be responsible for any inaccuracy in information provided to the operator by the vendor or service provider or manufacturer.

(10) A vendor, service company or operator shall identify the specific identity and amount of any chemicals claimed to be a trade secret or confidential proprietary information to any health professional who requests the information in writing if the health professional executes a confidentiality agreement and provides a written statement of need for the information indicating all of the following:

(i) The information is needed for the purpose of diagnosis or treatment of an individual.

(ii) The individual being diagnosed or treated may have been exposed to a hazardous chemical.

(iii) Knowledge of information will assist in the diagnosis or treatment of an individual.

(11) If a health professional determines that a medical emergency exists and the specific identity and amount of any chemicals claimed to be a trade secret or confidential proprietary information are necessary for emergency treatment, the vendor, service provider or operator shall immediately disclose the information to the health professional upon a verbal acknowledgment by the health professional that the information may not be used for purposes other than the health needs asserted and that the health professional shall maintain the information as confidential. The vendor, service provider or operator may request,

and the health professional shall provide upon request, a written statement of need and a confidentiality agreement from the health professional as soon as circumstances permit, in conformance with regulations promulgated under this chapter.

(c) Disclosures not required.--Notwithstanding any other provision of this chapter, a vendor, service provider or operator shall not be required to do any of the following:

(1) Disclose chemicals that are not disclosed to it by the manufacturer, vendor or service provider.

(2) Disclose chemicals that were not intentionally added to the stimulation fluid.

(3) Disclose chemicals that occur incidentally or are otherwise unintentionally present in trace amounts, may be the incidental result of a chemical reaction or chemical process or may be constituents of naturally occurring materials that become part of a stimulation fluid.

(d) Trade secrets and confidential proprietary information.--

(1) Notwithstanding any other provision of this chapter, a vendor, service company or operator shall not be required to disclose trade secrets or confidential proprietary information to the chemical disclosure registry.

(2) The following shall apply:

(i) If the specific identity of a chemical, the concentration of a chemical or both the specific identity and concentration of a chemical are claimed to be a trade secret or confidential proprietary information, the vendor, service provider or operator may withhold the specific identity, the concentration, or both the specific identity and concentration, of the chemical from the information provided to the chemical disclosure registry.

(ii) Nothing under this paragraph shall prohibit any of the following from obtaining from a vendor, service provider or operator information that may be needed to respond to a spill or release:

(A) The department.

- (B) A public health official.
- (C) An emergency manager.

(D) A responder to a spill, release or a complaint from a person who may have been directly and adversely affected or aggrieved by the spill or release.

(iii) Upon receipt of a written statement of need for the information under subparagraph (ii), the information shall be disclosed by the vendor, service provider or operator to the requesting official or entity authorized under subparagraph (ii) and shall not be a public record.

(e) **Disclosure prevented.--**The department shall prevent disclosure of trade secrets or confidential proprietary information under this section pursuant to the requirements of the Right-to-Know Law¹ or other applicable State law.

(f) Well reporting.--Notwithstanding any other provision of law, nothing in this section shall be construed to reduce or modify the disclosure requirements for conventional well operators contained in 25 Pa. Code Ch. 78 Subch. E^2 (relating to well reporting).

Credits

2012, Feb. 14, P.L. 87, No. 13, § 1, effective in 60 days [April 16, 2012].

Editors' Notes

VALIDITY

<For validity of subsections (b)(10) and (b)(11), see Robinson Tp. v. Com., 147 A.3d 536, 637 Pa. 239, Sup.2016.>

Notes of Decisions (10)

Footnotes

1 65 P.S. § 67.101 et seq.

2 25 Pa. Code § 78.121 et seq.

58 Pa.C.S.A. § 3222.1, PA ST 58 Pa.C.S.A. § 3222.1 Current through Act 95 of the 2024 Regular Session. Some statute sections may be more current, see credits for details.

End of Document

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Proximity to Natural Gas Wells and Reported Health Status: Results of a Household Survey in Washington County, Pennsylvania

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BACKGROUND: Little is known about the environmental and public health impact of unconventional natural gas extraction activities, including hydraulic fracturing, that occur near residential areas.

OBJECTIVES: Our aim was to assess the relationship between household proximity to natural gas wells and reported health symptoms.

METHODS: We conducted a hypothesis-generating health symptom survey of 492 persons in 180 randomly selected households with ground-fed wells in an area of active natural gas drilling. Gas well proximity for each household was compared with the prevalence and frequency of reported dermal, respiratory, gastrointestinal, cardiovascular, and neurological symptoms.

RESULTS: The number of reported health symptoms per person was higher among residents living < 1 km (mean ± SD, 3.27 ± 3.72) compared with > 2 km from the nearest gas well (mean ± SD, 1.60 ± 2.14 ; p = 0.0002). In a model that adjusted for age, sex, household education, smoking, awareness of environmental risk, work type, and animals in house, reported skin conditions were more common in households < 1 km compared with > 2 km from the nearest gas well (odds ratio = 4.1; 95% CI: 1.4, 12.3; p = 0.01). Upper respiratory symptoms were also more frequently reported in persons living in households < 1 km from gas wells (39%) compared with households 1-2 km or > 2 km from the nearest well (31 and 18%, respectively) (p = 0.004). No equivalent correlation was found between well proximity and other reported groups of respiratory, neurological, cardiovascular, or gastrointestinal conditions.

CONCLUSION: Although these results should be viewed as hypothesis generating, and the population studied was limited to households with a ground-fed water supply, proximity of natural gas wells may be associated with the prevalence of health symptoms including dermal and respiratory conditions in residents living near natural gas extraction activities. Further study of these associations, including the role of specific air and water exposures, is warranted.

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Introduction

Unconventional methods of natural gas extraction, including directional drilling and hydraulic fracturing (also known as "fracking"), have made it possible to reach natural gas reserves in shale deposits thousands of feet underground (Myers 2012). Increased drilling activity in a number of locations in the United States has led to growing concern that natural gas extraction activities could contaminate water supplies and ambient air, resulting in unforeseen adverse public health effects (Goldstein et al. 2012). At the same time, there is little peer-reviewed evidence regarding the public health risks of natural gas drilling activities (Kovats et al. 2014; McDermott-Levy and Kaktins 2012; Mitka 2012), including a lack of systematic surveys of human health effects.

The process of natural gas extraction. Natural gas extraction of shale gas reserves may involve multiple activities occurring over a period of months. These include drilling and casing of deep wells that contain both vertical and horizontal components as well as placement of underground explosives and transport and injection of millions of gallons of water containing sand and a number of chemical additives into the wells at high pressures to extract gas from the shale deposits (hydraulic fracturing) (Jackson RE et al. 2013). Chemicals used in the hydraulic fracturing process can include inorganic acids, polymers, petroleum distillates, anti-scaling compounds, microbicides, and surfactants (Vidic et al. 2013). Although some of these fluids are recovered during the fracking process as "flowback" or "produced" water, a significant amount (as much as 90%) (Vidic et al. 2013) may remain underground. The recovered flowback water-which may contain chemicals added to the fracking fluid as well as naturally occurring chemicals such as salts, arsenic, and barium and naturally occurring radioactive material originating in the geological formations-may be stored in holding ponds or transported offsite for disposal and/or wastewater treatment elsewhere.

Potential water exposures. Although much of the hydraulic fracturing process takes place deep underground, there are a number of potential mechanisms for chemicals used in the fracturing process as well as naturally occurring minerals, petroleum compounds (including volatile organic compounds; VOCs), and other substances of flowback water (Chapman et al. 2012) to enter drinking-water supplies. These include spills during transport of chemicals and flowback water, leaks of a well casing (Kovats et al. 2014), leaks through underground fissures in rock formations, runoff from drilling sites, and disposal of fracking flowback water (Rozell and Reaven 2012). Studies have reported increased levels of methane in drinking water wells located < 1 km from natural gas drilling, suggesting contamination of water wells from hydraulic

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Research

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Supplemental Material is available online (http://dx.doi.org/10.1289/ehp.1307732).

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P.M.R. and J.D.D. had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

The contents are solely the responsibility of the authors and do not necessarily represent the official views of NIH.

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Received: 17 October 2013; Accepted: 20 August 2014; Advance Publication: 10 September 2014; Final Publication: 1 January 2015. fracturing activities (Jackson RB et al. 2013; Osborn et al. 2011), although natural movement of methane and brine from shale deposits into aquifers has also been suggested (Warner et al. 2012). If contaminants from hydraulic fracturing activities were able to enter drinking water supplies or surface water bodies, humans could be exposed to such contaminants through drinking, cooking, showering, and swimming.

Potential air exposures. The drilling and completion of natural gas wells, as well as the storage of waste fluids in containment ponds, may release chemicals into the atmosphere through evaporation and off-gassing. In Pennsylvania, flowback fluids are not usually disposed of in deep injection wells; therefore surface ponds containing flowback fluids are relatively common and could be sources of air contamination through evaporation. Flaring of gas wells, operation of diesel equipment and vehicles, and other point sources for air quality contamination around drilling activities may also pose a risk of respiratory exposures to nitrogen oxides, VOCs, and particulate matter. Release of ozone precursors into the environment by natural gas production activities may lead to increases in local ozone levels (Olaguer 2012). Well completion and gas transport may cause leakage of methane and other greenhouse gases into the environment (Allen 2014). Studies in Colorado have reported elevated air levels of VOCs including trimethylbenzenes, xylenes, and aliphatic hydrocarbons related to well drilling activities (McKenzie et al. 2012).

Human health impact. Concerns about the impact of natural gas extraction on the health of nearby communities have included exposures to contaminants in water and air described above as well as noise and social disruption (Witter et al. 2013). A published case series cited the occurrence of respiratory, skin, neurological, and gastrointestinal symptoms in humans living near gas wells (Bamberger and Oswald 2012). A convenience sample survey of 108 individuals in 55 households across 14 counties in Pennsylvania who were concerned about health effects from natural gas facilities found that a number of self-reported symptoms were more common in individuals living near gas facilities, including throat and nasal irritation, eye burning, sinus problems, headaches, skin problems, loss of smell, cough, nosebleeds, and painful joints (Steinzor et al. 2013). Similarly, a convenience sample survey of 53 community members living near Marcellus Shale development found that respondents attributed a number of health impacts and stressors to the development. Stress was the symptom reported most frequently (Ferrar et al. 2013).

Here we report on the analysis of a crosssectional, random-sample survey of the health of residents who had ground-fed water wells in the vicinity of natural gas extraction wells to determine whether proximity to gas wells was associated with reported respiratory, dermal, neurological, or gastrointestinal symptoms.

Methods

Selection of study area. The Marcellus formation, a principal source of shale-based natural gas in the United States, is a Middle Devonian-age black, low-density, organically rich shale that has been predominantly horizontally drilled for gas extraction in the southwestern portion of Pennsylvania since 2003 [Pennsylvania Spatial Data Access (PASDA) 2013]. In this study we focused on Washington County in southwestern Pennsylvania, an area of active natural gas drilling (Carter et al. 2011). At the time of the administration of the household survey during summer 2012, there were, according to the Pennsylvania Department of Environmental Protection, 624 active natural gas wells in Washington County. Of these natural gas wells, 95% were horizontally drilled (Pennsylvania Department of Environmental Protection 2012). The county has a highly rural classification with nearly 40% of the

land devoted to agriculture (U.S. Department of Agriculture 2007). Washington County has a population of approximately 200,000 persons with 94% self-identified as white, 90% having at least a high school diploma, and a 2012 median household income of \$53,545 (Center for Rural Pennsylvania 2014). We selected a contiguous set of 38 rural townships within the center of Washington County as our study site in order to avoid urban areas bordering Pittsburgh, which would be unlikely to have ground-fed water wells, and areas near the Pennsylvania border, which might be influenced by gas wells in other states (Figure 1).

Survey instrument. We designed a community environmental health assessment of reported health symptoms and health status based on questions drawn from publicly available surveys. Symptom questions, covering a range of organ systems that had been mentioned in published reports (Bamberger and Oswald 2012; Steinzor et al. 2013), asked respondents whether they or any household members had experienced each condition during the past year (see Supplemental Material, "Questionnaire"). The health assessment also asked a number

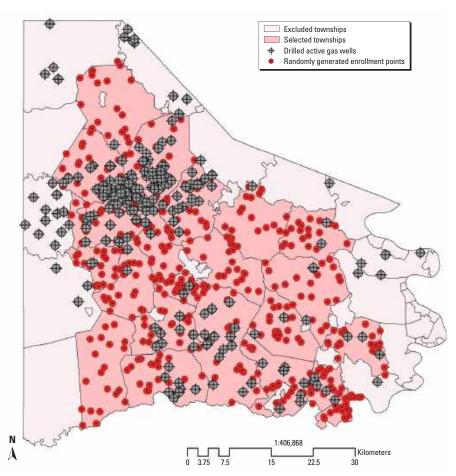


Figure 1. Distribution of drilled active Marcellus Shale natural gas wells (*n* = 624) and randomly generated sampling sites (*n* = 760) for eligible municipalities of Washington County, Pennsylvania.

of general yes/no questions about concerns of environmental hazards in the community, such as whether respondents were satisfied with air quality, water quality, soil quality, environmental noise and odors, and traffic, but did not specifically mention natural gas wells or hydraulic fracturing or other natural gas extraction activities. The survey was pretested with focus groups in the study area in collaboration with a community based group and revised to ensure comprehensibility of questions.

Selection and recruitment of households. Using ArcGIS Desktop 10.0 software (ESRI, Inc., Redlands, CA), we randomly selected 20 geographic points from each of 38 contiguous townships in the study county (Figure 1). We identified an eligible home nearest to each randomly generated sampling point, and visited each home to determine which households were occupied and had groundfed water wells. We selected households with ground-fed water wells to assess possible health effects related to water contamination. From the original 760 points identified (i.e., 20 points in each of the 38 townships), we excluded 12 duplicate points and 64 points found not to correspond to a house structure (see Supplemental Material, Figure S1). After site visits by the study team who spoke to residents or neighbors, we excluded house locations determined not to have a groundfed well or spring. Additional points were excluded if the structure was not occupied (n = 5) or inaccessible from the road (n = 4). During visits to eligible households, a study member invited a responding adult at least 18 years of age to participate in the survey, described as a survey of community environmental health that considered a number of environmental health factors. Three households were excluded when the respondent was unable to answer the questionnaire due to language or health problems. Eligible households were offered a small cash stipend for participation.

The Yale University School of Medicine Human Research Protection Program determined the study to be exempt from Human Subjects review. Respondents provided oral consent but were not asked to sign consent forms; their names were not recorded.

Of the 255 eligible households, respondents refused to complete the survey in 47 households, and we were not able to contact residents in another 26 households. Reasons for refusal included "not interested" (n = 8), "no time/too busy" (n = 3), "afraid" (n = 1), and 35 gave no reason. The rate of refusal varied by distance category, with 12 of 74 (16%) of households < 1 km from a gas well, 10 of 67 (15%) of households 1–2 km from wells, and 25 of 86 (25%) of eligible households > 2 km from a gas well refusing to participate, but the differences were not statistically significant. At the consenting 180 households (71% of eligible households), an adult respondent completed the survey covering the health status of the 492 individuals living in these households.

Administration of survey at residence. Trained study personnel administered the survey in English. The responding adult at the participating household reported on the health status of all persons in the household over the past year. A study team member recorded the global positioning system (GPS) coordinates of the household using a Garmin GPSMAP^{*} 62S Series handheld GPS device (Garmin International, Inc., Olathe, KS). Survey personnel were not aware of the mapping results for gas well proximity to the households being surveyed.

Household proximity to nearest active gas well and age of wells. A map of 624 active natural gas wells in the study area, and their age and type, was created by utilizing gas well permit data publicly available at the PASDA (2013). Ninety five percent of the gas wells had "spud dates" (first date of drilling) between 2008 and 2012, with more than half of spud dates occurring in 2010 and 2011. We used ArcGIS to calculate the distance between each household location (as defined by the GPS reading taken during the site visit) and each natural gas well in the study area. We then classified households according to their distance from the nearest gas well with distance categories of < 1 km, 1-2 km, or > 2 km. We used 1 km as the initial cut point for distance to a nearest gas well because of the reported association of higher methane levels in drinking-water wells located < 1 km from natural gas wells (Osborn et al. 2011), and 2 km as the second cut point because it was close to the mean of the distances between households and nearest gas wells. The mean and median distance between a household and the nearest natural gas well were 2.0 km and 1.4 km, respectively. We classified the age of each gas well as the time interval between spud date and the date that the household survey was conducted during summer, 2012.

Statistical analysis. Demographic variables were analyzed for differences among individuals between distance categories using chi-square, analysis of variance, or generalized linear mixed-model statistics as appropriate. Reported occupation was classified as either blue collar, office sales and service, management/professional, or not working, using classifications of the U.S. Bureau of Labor Statistics (2014).

The prevalence of each outcome and the number of symptoms reported for each household member included in the study were calculated according to the distance of each household (< 1, 1-2, or > 2 km)

from the nearest gas well. To test the association between household distance from a well and the overall number of symptoms as well as the presence or absence of each of six groups of health conditions (dermal, upper respiratory, lower respiratory, gastrointestinal, neurological, and cardiovascular), we used SAS 9.3 in a generalized linear mixed model (GLMM) analysis (SAS Institute Inc., Cary, NC). The analysis used maximum likelihood estimation with adaptive quadrature methods (Schabenberger 2007) including a random effect for household to account for the clustering of individuals within a household. The model was adjusted for age of individual (continuous), sex (binary), average adult household education (continuous), smoker present in household (yes/no), awareness of environmental hazard nearby (yes/no), employment type (four categories), and whether animals were present in the home or backyard (yes/no). Given the exploratory nature of this study, no adjustments were made for multiple comparisons and significance was established at the two-sided 0.05 level. Statistical analyses were conducted using SAS 9.3.

Results

Demographics. Individuals living in households < 1 km from gas wells were older (mean, 46.9 ± 21.9) compared with individuals in households > 2 km from a gas well (mean, 40.0 ± 23.5 years, p = 0.03) (Table 1). There was a higher proportion of children in the households > 2 km from a gas well compared with those < 1 km from a gas well (27% vs. 14%, p = 0.008). Families had lived in their homes an average of 22.8 ± 17.2 years at the time of the interview. Thirty-four percent of individuals had blue-collar jobs and 38% of the subjects were nonworkers (e.g., unemployed, students). Sixty-six percent reported using their ground-fed water (well or natural spring) for drinking water, and 84% reported using it for other activities such as bathing. The age of the nearest gas well was significantly greater for households < 1 km from a gas well (mean, 2.3 ± 1.6) compared with those 1–2 km or > 2 km from a well $(1.5 \pm 1.3 \text{ and } 1.1 \pm 0.9)$, respectively, p < 0.05). Reported smoking was less common in households near gas wells, whereas reported respondent awareness regarding environmental health risks was higher, although these differences were not statistically significant.

Reported health symptoms. The average number of reported symptoms per person in residents of households < 1 km from a gas well (3.27 ± 3.72) was greater compared with those living > 2 km from gas wells $(1.60 \pm 2.14, p = 0.0002)$.

Individuals living in households < 1 km from natural gas wells were more likely to report having any of the queried skin conditions over the past year (13%) than residents of households > 2 km from a well (3%; $\chi^2 = 13.8$, p = 0.001) (Table 2). Reported upper respiratory symptoms were also more frequent among households < 1 km (39%) compared with households > 2 km from gas wells (18%; $\chi^2 = 17.9$, p = 0.0001).

In a hierarchical model that adjusted for age, sex, household education level, smokers in household, job type, animals in household, and awareness of environmental risk (Table 3), household proximity to natural gas wells remained associated with number of symptoms reported per person < 1 km (p = 0.002) and 1–2 km (p = 0.05) compared with > 2 km from gas wells, respectively. In similar models, living in a household < 1 km from the nearest gas well remained associated with increased reporting of skin conditions [odds ratio (OR) = 4.13; 95% confidence interval (CI): 1.38, 12.3] and upper respiratory symptoms (OR = 3.10; 95% CI: 1.45, 6.65) compared with households > 2 km from the nearest gas well.

For the other grouped symptom complexes examined, there was not a significant relationship in our adjusted model between the prevalence of symptom reports and proximity to nearest gas well. In the multivariate model, however, environmental risk awareness was significantly associated with report of all groups of symptoms.

Age of the nearest gas well was found to be negatively correlated with distance (r = -0.325; p < 0.0001): Gas wells < 1 km from households tended to be older than the nearest wells in other distance categories. When age of wells was added to the multivariate model, proximity to gas wells remained significantly associated with respiratory symptoms, but the association between proximity and dermal symptoms lost statistical significance.

Discussion

This spatially random health survey of households with ground-fed water supply in a region with a large number of active natural gas wells is to our knowledge the largest study to date of the association of reported symptoms and natural gas drilling activities. We found an increased frequency of reported symptoms over the past year in households in closer proximity to active gas wells compared with households farther from gas wells. This association was also seen for certain categories of symptoms, including skin conditions and upper respiratory symptoms. This association persisted even after adjusting for age, sex, smokers in household, presence of animals in the household, education level, work type, and awareness of environmental risks. Other groups of reported symptoms, including cardiac, neurological, or gastrointestinal

symptoms, did not show a similar association with gas well proximity. These results support the need for further investigation of whether natural gas extraction activities are associated with community health impacts.

These findings are consistent with earlier reports of respiratory and dermal conditions in persons living near natural gas wells (Bamberger and Oswald 2012; Steinzor et al. 2013). Strengths of the study included the larger sample size compared with previously published surveys, and the random method of selecting households using geographic information system methodology, which reduces the possibility of selection bias (although only a subset of households, those with ground-fed water supply, were sampled).

A limitation of the study was the reliance on self-report of health symptoms. On one hand, symptoms in other household members may have been underreported by the household respondent; on the other hand, awareness bias in individuals concerned about the presence of an environmental health hazard would be more likely to increase reporting of illness symptoms, leading to recall bias of the results. We did not collect data on whether individuals were receiving financial compensation for gas well drilling on their property, which could have affected their willingness to report symptoms. It is possible that differential refusal to participate could have introduced potential for selection bias; for example, individuals who were receiving compensation for gas drilling on their property might be less willing to participate in the survey. We found instead that the refusal rate, though < 25% overall, was higher among households farther from gas wells, suggesting that such households may have been less interested in participating because they had less awareness of hazards. The study questionnaire did not include questions about natural gas extraction activities, in order to reduce awareness bias. At the same time, it is likely that household residents were aware of gas drilling activities in the vicinity of households; and the fact that reported environmental awareness by respondents was associated with the prevalence of all groups of reported health symptoms suggests a correlation between heightened awareness of health risks and reported health conditions. Nevertheless, the observed association between gas well proximity and reported dermal and upper respiratory symptoms persisted in the multivariate model even after adjusting for environmental awareness. Future studies should attempt to medically confirm particular diagnoses and further assess and control for the effect of awareness on reported health status.

Characteristic	< 1 km	1–2 km	> 2 km	All
Individuals				
п	150	150	192	492
Sex				
Male	80 (53)	78 (52)	92 (48)	250 (51)
Female	70 (47)	72 (48)	100 (52)	242 (49)
Children	21 (14)*	27 (18)	52 (27)	100 (20)
Education (years)	13.4 ± 2.0	13.5 ± 1.9	13.3 ± 2.0	13.4 ± 1.9
Age (years)	46.9 ± 21.9**	45.5 ± 22.7	40.0 ± 23.5	43.8 ± 23.0
Occupation ^a				
M/P	29 (19)	34 (23)	33 (17)	96 (19)
0/S	17 (11)	11 (7)	14(7)	42 (9)
BC	60 (40)	51 (34)	56 (29)	167 (34)
NW	44 (29)	54 (36)	89 (46)	187 (38)
Households				
п	62	57	61	180
Smoking ^b	7 (11)	12 (21)	14 (23)	33 (18)
Years in household (n)	23.7 ± 16.6	23.5 ± 16.4	21.2 ± 18.6	22.8 ± 17.2
Body mass index (kg/m ²)	27.9 ± 5.1	27.5 ± 5.4	27.9 ± 6.1	27.8 ± 5.5
Use ground-fed water				
Drinking	39 (63)	41 (72)	38 (62)	118 (66)
Other	54 (87)	51 (89)	46 (75)	151 (84)
Water has unnatural appearance	13 (21)	7 (12)	6 (10)	26 (14)
Taste/odor prevents water use	14 (23)	10 (18)	19 (31)	43 (24)
Dissatisfied with odor in environment	7 (11)	1 (2)	1 (2)	9 (5)
Environmental risk awareness ^c	16 (25)	16 (28)	9 (15)	41 (23)
Years since spud date of closest well (years)	2.3 ± 1.6#	1.5 ± 1.3	1.1 ± 0.9	1.6 ± 1.4

Values are n (%) or mean \pm SD.

^aParticipant occupation was categorized into six main industries according to the U.S. Bureau of Labor Statistics (2014), and presented here in four main groups: M/P, management or professional; O/S, office, sales, or service; BC, blue collar (fishing, farming, and forestry; construction, extraction, maintenance, production, transportation, and material moving); NW, nonworker (student, disabled, retired, or unemployed). ^bHousehold smoking was determined when respondents were asked if they or at least one member of their household smoked cigarettes in the house at the time of the survey. ^cHousehold respondents were asked if they were aware of any environmental health risks near their residence (yes/no), to approximate potential sources of expectation or awareness bias. *p = 0.008 compared with > 2 km households. **p = 0.03 compared with > 2 km households. [#]p < 0.05 compared with 1–2 km and > 2 km households. A further study limitation was the fact that our analysis includes multiple comparisons between groups of households, and the consequent possibility that random error could account for some of our findings. We limited such comparisons by grouping individual symptoms into organ system clusters. However, we acknowledge that the multiple comparisons used in the methodology mean that any such particular findings should be viewed as preliminary and hypothesis generating.

Our use of gas well proximity as a measure of exposure was an indirect measure of potential water or airborne exposures. More precise data could come from direct monitoring and modeling of air and water contaminants, and correlating such measured exposures with confirmed health effects should be a focus of future study. Biomonitoring of individuals living near natural gas wells could provide additional information about the role and extent of particular chemical exposures.

There are several potential explanations for the finding of increased skin conditions among inhabitants living near gas wells. One is that natural gas extraction wells could have caused contamination of well water through breaks in the gas well casing or other underground communication between ground water supplies and fracking activities. The geographic area studied has experienced petroleum and coal exploration and extraction activities in the past century, and such activities may increase the risk of chemicals in fracking fluid or flowback water entering ground water and contaminating wells. If such contamination did occur, several types of chemicals in fracking fluid have irritant properties and could potentially cause skin rashes or burning sensation through exposure during showers or baths. There are published reports of associations between the prevalence of eczema and other skin conditions with exposure to drinking water polluted with chemicals including VOCs (Chaumont et al. 2012; Lampi et al. 2000; Yorifuji et al. 2012) as well as changes in water hardness (Chaumont et al. 2012; McNally et al. 1998).

A second possible explanation for the skin symptoms could be exposure to air pollutants including VOCs, particulates, and ozone from upwind sources, such as flaring of gas wells (McKenzie et al. 2012) and exhaust from vehicles and heavy machinery.

A third possibility to explain the clustering of skin and other symptoms would be that they could be related to stress or anxiety that was greater for households living near gas wells. In this study, awareness of environmental risk was independently associated with overall reporting of symptoms as well as reporting of skin problems. However, in multivariate models, proximity to gas wells remained a significant predictor of symptoms even when adjusting for such awareness. These results argue for possible air or water contaminant exposures, in addition to stress, contributing to the observed patterns of increased health symptoms in households near gas wells. A fourth possibility would be the role of allergens or irritant chemicals not related to natural gas drilling activities, such as exposure to agricultural chemicals or household animals. We did not see a correlation between skin conditions and either the presence of an animal in the household or agricultural occupation, making this association less likely. At the same time, it is possible that other confounding could be present but not accounted for in our models.

Table 2. Prevalence of selected health conditions reported by individuals by proximity to the nearest gas well (2011–2012).^{*a*}

	< 1 km	1–2 km	> 2 km
Symptoms	(<i>n</i> = 150)	(<i>n</i> = 150)	(<i>n</i> = 192)
Total number of symptoms per individual	3.27 ± 3.72	2.56 ± 3.26	1.60 ± 2.14
Dermal [n (%)]	19 (13)	7 (5)	6 (3)
Rashes/skin problems	10 (7)	7 (5)	6 (3)
Dermatitis	6 (4)	5 (3)	2 (1)
Irritation	6 (4)	2 (1)	1 (1)
Burning	8 (5)	4 (3)	1 (1)
Itching	9 (6)	5 (3)	2 (1)
Hair loss	2 (1)	0 (0)	1 (1)
Upper respiratory [n (%)]	58 (39)	46 (31)	35 (18)
Allergies/sinus problems	35 (23)	27 (18)	27 (14)
Cough/sore throat	10 (7)	3 (2)	2 (1)
Itchy eyes	19 (13)	22 (15)	10 (5)
Nose bleeds	13 (9)	8 (5)	4 (2)
Stuffy nose	16 (11)	8 (5)	4 (2)
Lower respiratory [n (%)]	29 (19)	29 (19)	27 (14)
Asthma/COPD	16 (11)	21 (14)	15 (8)
Chronic bronchitis	8 (5)	2 (1)	2 (1)
Chest wheeze/whistling	6 (4)	9 (6)	7 (4)
Shortness of breath	8 (5)	7 (5)	8 (4)
Chest tightness	4 (3)	6 (4)	5 (3)
Cardiac [<i>n</i> (%)]	46 (31)	39 (26)	37 (19)
High blood pressure	38 (25)	33 (22)	29 (15)
Chest pain	8 (5)	5 (3)	6 (3)
Heart palpitations	10 (7)	7 (5)	4 (2)
Ankle swelling	11 (7)	5 (3)	5 (3)
Gastrointestinal [n (%)]	15 (10)	13 (9)	11 (6)
Ulcers/stomach problems	11 (7)	7 (5)	8 (4)
Liver problems	4 (3)	0(0)	1 (0.5)
Nausea/vomiting	1 (1)	3 (2)	1 (0.5)
Abdominal pain	4 (3)	2(1)	2 (1)
Diarrhea	5 (3)	2(1)	2 (1)
Bleeding	4 (3)	4 (3)	0 (0)
Neurologic [n (%)]	48 (32)	37 (25)	39 (20)
Neurologic problems	1 (0.7)	5 (3)	0 (0)
Severe headache/migraine	24 (16)	14 (9)	18 (9)
Dizziness/balance problems Depression	11 (7) 4 (3)	12 (8) 3 (2)	11 (6) 2 (1)
1			
Difficulty concentrating/remembering Difficulty sleeping/insomnia	9 (6)	9 (6)	6 (3) 10 (5)
Anxiety/nervousness	18 (12)	19 (13)	10 (5) 11 (6)
Seizures	11 (7) 2 (1)	4 (3) 2 (1)	1 (0.5)
06120169	2(1)	۷.۱۱	1 (0.0)

COPD, chronic obstructive pulmonary disease.

^aSix categories representing major health conditions of *a priori* interest chosen to ascertain symptom prevalence among individuals living in proximity to the nearest gas well in 2011–2012.

Table 3. Associations of nearest gas well proximi	ty and symptoms.
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	< 1 km	< 1 km			
Outcome	OR (95% CI)	<i>p</i> -Value	OR (95% CI)	<i>p</i> -Value	> 2 km
Dermal	4.13 (1.38, 12.3)	0.011	1.44 (0.42, 4.9)	0.563	Ref
Upper respiratory	3.10 (1.45, 6.65)	0.004	1.76 (0.81, 3.76)	0.148	Ref
Lower respiratory	1.45 (0.67, 3.14)	0.339	1.40 (0.65, 3.03)	0.387	Ref
Cardiac	1.67 (0.85, 3.26)	0.135	1.28 (0.65, 2.52)	0.473	Ref
Gastrointestinal	2.01 (0.49, 8.18)	0.328	1.79 (0.43, 7.41)	0.417	Ref
Neurological	1.53 (0.89, 2.63)	0.123	1.04 (0.59, 1.82)	0.885	Ref

Ref, reference. Results are from hierarchical logistic regression that adjusted for age, household education level, sex, smokers in household, job type, animals in household, and awareness of environmental risk.

Our findings of increased reporting of upper respiratory symptoms among persons living < 1 km from a natural gas well suggests that airborne irritant exposures related to natural gas extraction activities could be playing a role. Such irritant exposures could result from a number of activities related to natural gas drilling, including flaring of gas wells and exhaust from diesel equipment. Because other studies have suggested that airborne exposures could be a significant consequence of natural gas drilling activity, further investigation of the impact of such activities on respiratory health of nearby communities should be investigated. Future studies should collect such data.

Since most of the gas wells in the study area had been drilled in the past 5–6 years, one would not yet expect to see associations with diseases with long latency, such as cancer. Furthermore, if some of the impact of natural gas extraction on ground water happens over a number of years, this initial survey could have failed to detect health consequences of delayed contamination. However, if the finding of skin and respiratory conditions near gas wells indicates significant exposure to either fracking fluids and chemicals or airborne contaminants from natural gas wells, studies looking at such long-term health effects in chronically exposed populations would be indicated.

Conclusions

The results of this study suggest that natural gas drilling activities could be associated with increased reports of dermal and upper respiratory symptoms in nearby communities; these results support the need for further research into health effects of natural gas extraction activities. Such research could include longitudinal assessment of the health of individuals living in proximity to natural gas drilling activities, medical confirmation of health conditions, and more precise assessment of contaminant exposures.

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Shale Gas Development and Infant Health: Evidence from Pennsylvania

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Abstract

This research exploits the introduction of shale gas wells in Pennsylvania in response to growing controversy around the drilling method of hydraulic fracturing. Using de- tailed location data on maternal addresses and GIS coordinates of gas wells, this study examines singleton births to mothers residing close to a shale gas well from 2003–2010 in Pennsylvania. The introduction of drilling increased low birth weight and decreased term birth weight on average among mothers living within 2.5 km of a well compared to mothers living within 2.5 km of a future well. Adverse effects were also detected using measures such as small for gestational age and APGAR scores, while no effects on gestation periods were found. These results are robust to other measures of infant health, many changes in specification and falsification tests. In the intensive margin, an additional well is associated with a 7 percent increase in low birth weight, a 5 gram reduction in term birth weight and a 3 percent increase in premature birth. These findings suggest that shale gas development poses significant risks to human health and have policy implications for regulation of shale gas development.

Keywords

infant health; shale gas development; air pollution; water pollution; low birth weight

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 $^{^{6}}$ To date, there are no estimates in Pennsylvania of how many properties are "split estate"- the condition where surface owners do not own the mineral rights.

¹⁶ I also test whether drilling activity has affected these characteristics directly by changing fertility and/or the composition of families living near shale gas development and I find few economically significant changes.

¹⁷ Johnson and Schoeni (2011) use national data from the US and find that low birth weight increases the probability of dropping out of high school by one-third, lowers labor force participation by 5 percentage points, and reduces earnings by almost 15 percent. More recently, Figlio et al. (2014) use linked birth and schooling records in Florida and find that birth weight has a significant impact on schooling outcomes for twin births.

²⁴ Only one maternal characteristic shows a significant change with drilling: mothers observed after drilling are more educated than those observed prior to drilling (results not shown). Increased college completions among mothers would potentially improve observed infant health in these communities. However, this does suggest some selection and so I include these and other controls in all the subsequent results. The time frame of interest is during the onset of the Great Recession. It may indicate that the opportunity cost of going to college, or becoming a mother, has reduced and so more educated mothers are having children. Other research has linked recessions to improved infant health outcomes, so it is unlikely to be the driver of impacts reported in the next section (Chay and Greenstone, 2003b; Dehejia and Lleras-Muney, 2004).

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The United States (US) holds large unconventional gas reserves in relatively impermeable media such as coal beds, shale, and tight gas sands, which together with Canada account for virtually all commercial shale gas produced in the world (IEA, 2012).¹ New technologies, such as hydraulic fracturing and directional drilling, have made it economically and practically feasible to extract natural gas from these previously inaccessible geological formations.² In 2010, unconventional gas production was nearly 60% of total gas production in the US (IEA, 2012). Natural gas from the Marcellus formation, particularly in Pennsylvania, currently accounts for the majority of this production (Rahm et al., 2013).³ A recent assessment by The Wall Street Journal estimates that over 15 million Americans live within 1 mile of an oil or gas well drilled since 2000 in 11 of the 33 states where drilling is taking place (Gold and McGinty, 2013). With this expansion, it is becoming increasingly common for shale gas development to take place in close proximity to where people live, work and play.

The expansion of shale gas development (SGD) in the US has brought with it a national debate that seemingly lacks a consensus over its economic, environmental, health and social implications. There is growing evidence that shale gas development creates jobs and generates income for local residents in the short run (Allcott and Keniston, 2014; Bartik et al., 2016; Feyrer et al., 2017; Hausman and Kellogg, 2015; Mason et al., 2015). In addition to its economic benefits, many claim that a move to natural gas (and away from petroleumor coal-based energy) will support U.S. energy independence and national security. Shale gas provides an attractive source of energy because it emits fewer pollutants (e.g., carbon dioxide, sulfur dioxide, nitrogen oxides, carbon monoxide and particulate matter) when burned than coal and other fossil-fuel energy sources per unit of heat produced (Chen et al., 2017). Globally, the shale boom has improved ambient air quality and displaced coal-based electricity, especially for areas with coal-fired power plants (Johnsen et al., 2016). However, these benefits may come with local costs associated with drilling activity in communities where it takes place. These costs may include reduced environmental quality through local air pollution (Colborn et al., 2012; Litovitz et al., 2013; Witter et al., 2013), water contamination (Warner et al., 2012; Olmstead et al., 2013; Hill and Ma, 2017), increased truck traffic (Graham et al., 2015) and health. Concerns over perceived ground water contamination have caused a discount of housing prices to compensate for the risk and an approximately \$19 million increase in bottled water purchases in 2010 in response to SGD in Pennsylvania (Muehlenbachs et al., 2015; Wrenn et al., 2016). This is further supported by a recent cost-benefit analysis that found substantial environmental costs associated with health damages from air pollution emitted by SGD totaling \$27.2 billion (Loomis and Haefele, 2017).

In utero exposure to air pollution has been linked to adverse birth outcomes, lower educational attainment, labor market outcomes and future health problems (See Currie and

¹The International Energy Agency (IEA) defines unconventional gas as sources of gas trapped in impermeable rock deep underground. ²Hydraulic fracturing (popularly known as "fracking" or "fracing") stimulates the well using a combination of large quantities of

water ("high-volume"), fracturing chemicals ("slick water") and sand that are injected underground at high pressure. This process fractures the rock and causes the resource to be released. ³Pennsylvania experienced very rapid development of shale gas, with 4,272 shale gas wells drilled from 2007–2010 (PADEP, 2010a).

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Schmieder (2009); Currie (2009); Currie et al. (2014b) for summaries of this research). In particular, a large literature has linked air pollution (e.g. particulate matter (PM), carbon monoxide (CO), sulfur dioxide (S0₂), nitrogen oxide (NO_x)) from coal-fired power plants with low birth weight, premature birth and infant mortality both within the US and in the developing world.⁴ With natural gas touted as a transition fuel between coal-based electricity and renewable options, infant health is one way to compare costs across alternative options. While coal is undeniably worse than natural gas with respect to resource extraction and energy generation, concerns regarding emissions associated with shale gas should be studied (Chen et al., 2017).

The impact of shale gas development on health has become the focus of a growing body of literature. To my knowledge, Hill (2012) is the first study to assess the impact of shale gas development on infant health. Concurrent health studies include case studies (Bamberger and Oswald, 2012), health impact assessments (McKenzie et al., 2012), toxicological assessments of specific chemicals (Colborn et al., 2011), self-reported health symptoms (Ferrar et al., 2013) and studies exploiting administrative records such as birth certificates, hospital records or electronic medical records (EMR) to study asthma, pneumonia, fatigue, migraine, sinus effects, and birth outcomes (Hill, 2013; McKenzie et al., 2014; Stacy et al., 2015a; Rasmussen et al., 2016; Casey et al., 2016; Tustin et al., 2017; Currie et al., 2017; Whitworth et al., 2017; Peng et al., 2018).⁵ All but one of the infant health studies find a positive association between drilling and poor birth outcomes measured by premature/ preterm birth (PTB) or low birth weight (LBW). Due to a lack of consistency in outcomes, proximity, and exposure metrics used, it is challenging to compare findings across these studies.

To assess the impact of shale gas development on infant health, I build a unique database that contains the longitude and latitude of all shale gas wells, the street address (geocoded) of all new mothers, and data on whether the mother's address falls within public water service areas. To define a treatment variable, I exploit both the timing of drilling activity (using the "spud date," or the date the drilling rig begins to drill a well) and the exact locations of well heads relative to residences. I then use as a comparison group mothers who live in proximity to future wells, as designated by well permits. The exact locations of both wells and mothers' residences allow me to exploit variation in the effect of shale gas drilling within small, relatively homogeneous socio-economic groups, and the timing of the start of drilling allows me to confirm the absence of substantive pre-existing differences. Through this method, I am able to provide robust estimates of the impact of maternal exposure to shale gas development during pregnancy on birth outcomes.

The main results suggest both statistically and economically significant effects on infant health. I find that shale gas development increased the incidence of low birth weight and

⁴See Chay and Greenstone (2003a); Currie and Neidell (2005); Jayachandran (2009); Tanaka (2015); Knittel et al. (2015); Sanders and Stoecker (2015); Clay et al. (2016); Arceo Eva et al. (2016); Yang et al. (2017); Yang and Chou (2017); Severnini (2017); Jha and Muller (2017). For example, Yang et al. (2017) found that after a power plant in PA closed down, low birth weight declined by 15 percent and premature birth by 28 percent due to reductions in PM2.5 and S02.
⁵See Colborn et al. (2011) regarding health effects of fracturing chemicals; see McKenzie et al. (2012) for a review of studies

³See Colborn et al. (2011) regarding health effects of fracturing chemicals; see McKenzie et al. (2012) for a review of studies investigating the effects of inhalation exposure; see Vengosh et al. (2014) for a review of the likely effects of water contamination from SGD; see Werner et al. (2015), Stacy (2017), and Balise et al. (2016) for recent reviews of SGD and health related studies.

small for gestational age in the vicinity of a shale gas well by 25 percent and 18 percent, respectively. Furthermore, term birth weight and birth weight were decreased by 49.6 grams (1.5 percent) and 46.6 grams (1.4 percent), on average, respectively and the prevalence of APGAR scores less than 8 increased by 26 percent. Results for premature birth were mixed and sensitive to specification. The difference-indifferences research design, which relies on the common trends assumption, is tested by examining the observable characteristics of the mothers in these two groups before and after development, testing for pretrends in the outcome variables using the sample before drilling, permit dates only, and future wells only, and using a random date to define treatment. The research design is robust to these tests as well as a range of specifications. I examine mobility using the group of mothers with more than one birth and find that there is little evidence of moms moving in response to drilling. I perform a back of the envelope calculation on the costs of these activities using my estimates and the estimated population within 1 mile of drilling from the Wall Street Journal (e.g. 15 million Americans) and estimate that drilling costs more than \$230 million per year in the 11 out of 33 gas producing states. This estimate is likely to be a lower bound given that this assessment doesn't include all states with development and that I use a lower bound estimate of the costs associated with low birth weight.

This paper contributes to the literature using a quasi-experimental design and is a combination of the strengths of both the epidemiologic and economic literature described above. First, I improve upon the epidemiologic literature by employing a difference-indifferences design. In particular, I exploit the exogeneity of drilling conditional on leasing and permitting, which results in statistically homogenous treated and comparison groups. This provides a more stable comparison group than in Currie et al. (2017) that compares to those living within 3–15km. Second, I improve upon the economics literature by using the strengths of the epidemiologic literature by looking at multiple measures of adverse infant health outcomes which may be indicative of different aspects of drilling exposure. Preterm birth is indicative of preterm premature rupture of membranes, which can result from genetics, stress or low socio-economic status (SES) (Goldenberg et al., 2008). Low birth weight and small for gestational age (SGA) are more related to intrauterine growth restriction (IUGR), which is more consistently related to air pollution (Stieb et al., 2012b; Sun et al., 2015; WHO, 2005). Congenital abnormalities indicate exposure to a teratogen during pregnancy. Given the inconsistency in measured outcomes in existing studies, I simultaneously estimate impacts for all outcomes within the same sample and identification strategy. This is particularly useful for policy given the mixed findings in the existing studies and that none of these studies directly test exposure mechanisms. Third, I improve upon the economics literature by thoroughly controlling for predictors of infant health and estimating the extensive and intensive margins of drilling. I include controls for insurance status, WIC, previous risky pregnancy, parity, and smoking status. I also measure heterogeneity across SES subgroups and test whether moms are moving in response to drilling. Importantly, I contribute to the literature by measuring the effect of an additional well on birth outcomes, which is perhaps more relevant to policy-making than simple binary measurements of exposure.

The rest of the paper proceeds as follows: section I presents background and context and section II describes the data. Section III presents graphical evidence and section IV describes

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the estimation strategy. Sections V and VI presents results and robustness checks. Section VII provides interpretation and discussion of the results. Section VIII concludes.

I Background

I.I A Brief Shale Gas Overview for Pennsylvania

In Pennsylvania, shale gas development involves primarily high-volume hydraulically fractured horizontal wells drilled into the Marcellus Shale and more recently, the Utica Shale. Hydraulic fracturing is a process to stimulate a well that uses water to fracture the rock or shale beneath the ground. On average, in Pennsylvania, it involves injecting approximately 4-8 million gallons of water mixed with sand and fracturing chemicals into the well and using pressure to fracture the shale about 6,500–7,500 ft below the surface (Chen and Carter, 2016). Shale plays are heterogeneous and so the distance drilled and quantity of water required differ across varied geological formations. The entire process of completing a natural gas well takes, on average, 3–9 months to finish: access road and well pad construction occurs for a month (0-4 weeks) prior to the spud date, drilling the well takes about 30 days (vertical drilling for 0–2 weeks and horizontal drilling for 4–8 weeks), preparation for hydraulic fracturing takes 1–2 months, hydraulic fracturing takes about 7 days, flowback occurs for 2–8 weeks and clean up and testing takes about a month before the well goes into production (Casey et al., 2015; Graham et al., 2015). During the first few months, diesel trucks bring in materials required for the drilling process, averaging 1500-2000 truck trips per well completion in Pennsylvania. During the first 30 days after well stimulation, it is estimated that approximately 30-70% of the water used during the drilling process returns to the surface (called flowback) and is collected in ground level water impoundments and then taken to be treated at a waste water facility (Kondash et al., 2017).

Most wells are drilled on private property that has been leased to oil and gas companies. ¹After the land is leased by the mineral owner, a company applies for a permit to drill on that property. The state government approves permits and once a company has a permit, the drilling often commences quickly thereafter. There are many layers of decision-making independent of the mineral owner that determine exactly which leases become permits and which permits become a well. This research uses only those locations that are permitted by the state to reduce selection bias in the estimates that follow.

The identification strategy used in this paper depends on the assumption that drilling is exogenous relative to locations that are permitted but not yet drilled. However, areas that are permitted but not drilled may be different from areas that experience active drilling. For example, areas without active drilling may not have as many property owners willing to lease mineral rights or the industry may prioritize leasing in areas with the most productive shale. Appendix Figure A1 overlays the parcels with leases from Drillinginfo with the strata of shale depth from EIA. For counties where we have lease data, the extent of leasing is densest along the deepest contours and more sparse along the shallower contours, except in the northeastern part of the state such as Bradford County. To examine this further, I linked the lease and depth data to the wells and permits used in these analyses to test whether there are substantial differences.⁷ There are no differences in leasing defined by the proportion of acres leased within Census block groups between permitted and drilled wells. The average

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Shale Gas Development As A Potential Pollution Source 1.11

Preliminary evidence indicates that shale gas development may produce waste that could contaminate the air, aquifers, waterways, and ecosystems that surround drilling sites or areas where water treatment facilities treat the waste water from the drilling process. Below I review the current state of the scientific evidence.

I.II.1 Water Pollution—There are a number of mechanisms by which shale gas development might contaminate ground and surface water sources and thereby impact either public or private drinking water. According to a recent assessment by EPA, these mechanisms include: spills of hydraulic fracturing (HF) fluids prior to mixing with large quantities of water or produced water after hydraulic fracturing has taken place, injection of hydraulic fracturing fluids into wells with inadequate mechanical integrity (e.g. faulty well casings), injection of HF fluids directly into groundwater sources, discharge of inadequately treated hydraulic fracturing wastewater to surface water, and disposal or storage of hydraulic fracturing wastewater in unlined pits (EPA, 2016; Osborn et al., 2011; Jackson et al., 2013; Olmstead et al., 2013; Warner et al., 2013).⁸ The EPA report identified 1,084 chemicals reported to be used in hydraulic fracturing fluids and 599 chemicals detected in produced water(EPA, 2016). Of the 599 chemicals detected in produced water, only 77 were also reported to be used in hydraulic fracturing fluid- which is not a great match. The report found that chemicals used in HF fluid varied greatly across regions, which limits external validity(EPA, 2016).⁹ Elliott et al. (2017) provides a review of these chemicals for reproductive and developmental toxicity.¹⁰

The lack of reliable information about what chemicals are used leaves the scientific community testing many different chemicals across regions, with little overlap among detected chemicals. Studies of groundwater contamination have primarily used private drinking water wells and assessed proximity to shale gas wells to assess contamination (e.g. within 5 km of gas wells versus larger distances) (Hildenbrand et al., 2016; Osborn et al., 2011; Jackson et al., 2013). Studies have found increases in organics (many naturally occurring such as chlorides, bromides and iodides, arsenic, selenium, manganese, strontium, barium, heavy metals, beryllium), volatile and semivolitile organic compounds (e.g. BTEX, 2-Butanone), diesel range organic compounds, solvents (e.g. methanol, dichloromethane), and methane (Drollette et al., 2015; Hildenbrand et al., 2015, 2016; Yan et al., 2016;

⁷Available upon request.

⁸Scientists face challenges in assessing the potential for contamination due to limited baseline data on water quality, lack of publicly available data regarding the chemicals used in fracturing uid, the sheer number of chemicals use and naturally occurring contaminants returning to the surface in the process of drilling and hydraulic fracturing.

See Chen et al. (2017) for more information about specific chemicals of concern. The EPA Report has a large appendix characterizing each chemical with citations. ¹⁰Toxicity information was lacking for 781 (76%) chemicals. Of the remaining 240 substances, toxicological studies suggested

reproductive toxicity for 103 (43%), developmental toxicity for 95 (40%), and both for 41 (17%). Of these 157 chemicals, 67 had or were proposed for a federal water quality standard or guideline.

Alawattegama et al., 2015; Burton et al., 2016). Some studies have not found any evidence of contamination, leaving whether SGD impacts water quality a hotly debated question (Li et al., 2016). One study assessing groundwater-sourced public water systems' water quality found that SGD wells were associated with an increase in SGD-related chemicals for wells drilled within 1 km of the groundwater source (Hill and Ma, 2017).

Surface water impacts are more likely to be associated with the handling of shale gas waste. Waste water treatment and discharge is associated with elevated levels of barium, strontium, bromides, chlorides, benzene, and total dissolved solids exceeding the maximum contaminant level for drinking water (Olmstead et al., 2013; Vengosh et al., 2014; Hladik et al., 2014; Lester et al., 2015; Ferrar et al., 2013). Treated produced water (containing naturally occurring bromide and iodide) are potential sources of toxic disinfection byproducts (DBPs): iodinated trihalomethanes (THMs) and brominated haloacetonitriles (HANs) in surface water (Parker et al., 2014).¹¹ Endocrine disrupting chemicals measured in surface water near waste effluent in Colorado and West Virginia are of concern for reproductive health (Kassotis et al., 2015).

I.II.2 Air Pollution—Despite less attention in the media, air pollution is gaining more recent attention by researchers. All stages of shale gas development have the potential to produce hazardous air pollution emissions (Kargbo et al., 2010; Schmidt, 2011). Air pollution has become a more immediate concern following studies in Colorado that discovered higher levels of volatile organic compounds (VOCs), methane and other hydrocarbons near drilling sites (Colborn et al., 2012; Pétron et al., 2012). Other emissions associated with combustion include particulate matter, poly-cyclic aromatic hydrocarbons, sulfur oxides and nitrogen oxides (Colborn et al., 2012). More recent studies have also assessed the air pollution contribution of the many truck trips necessary to build and fracture a well (McCawley, 2017; Goodman et al., 2016).

Studies of air pollution in Pennsylvania are suggestive of increased emissions associated with shale gas development, but have produced inconsistent results. For example, the Pennsylvania Department of Environmental Protection (PA DEP) has conducted three short-term (1 week) air pollution studies in three regions of the state but found little evidence of air pollution concentrations that would likely trigger air-related health issues associated with Marcellus Shale drilling activities (PADEP, 2010b, 2011b, a). But the air emissions inventory for the unconventional natural gas industry, starting in 2011, indicates modest emissions of CO, NO_x, PM₁₀, SO_x and VOCs (PADEP, 2013a).¹² These results were verified by a recent RAND study that used the PA DEP data and other sources to estimate the emissions from shale gas in Pennsylvania (Litovitz et al., 2013). The most significant pollutants, according to the authors, were NO_x and VOCs, which were equivalent to or larger than some of the largest single emitters in the state and the low-end estimates of nitrogen oxide emissions were 20–40 times higher than the level that would be defined as a "major" emissions source. During the same time period, due to the conversion of electricity

¹¹This is also true for groundwater public drinking water systems that treat their water prior to distribution.

¹²According to this emissions inventory, shale gas wells emit carbon monoxide, NOx, PM10, PM2.5, SOx, volatile organic compounds (VOCs), Benzene, ethylbenzene, formaldehyde, hexane, toulene, xylene, trimethylbenzene, CO2, and Methane (Author's calculations of wells drilled 2011–2016).

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from coal to natural gas in the state, the overall pollution for all the criteria pollutants measured decreased substantially and more than outweighed the new pollution related to shale gas development. These data, however, indicate a more nuanced picture of air emissions from drilling activities and show that shale gas development is now a significant source of air pollution in rural counties with few other point-sources of pollution. For example, the 2,600 tons and 2,440 tons of shale-related NO_x emitted in Bradford County and Susquehanna County, respectively in 2011 make up one-third of the statewide shale-related NO_x of 16,500 tons (PADEP, 2013b). These levels surpass the singlelargest industrial source of NO_x pollution in the 11-county northeast region, a coal-fired power plant in Northampton County that emitted 2,000 tons in 2011 (Legere, 2013).

As mentioned above, Pennsylvania DEP began requiring companies drilling Marcellus shale gas wells to report annual estimates of air emission to an inventory starting in 2011. In Table 1, I estimate the intensive margin of the number of wells in a zip code on the annual tons of each pollutant aggregated to that zip code from 2011 to 2015. I also estimate tertiles of wells to capture intensity. Each additional well contributes an average of 0.5 tons of CO, 2 tons of NO_x , 0.07 tons of PM₂ 5, 0.03 tons of SO_x, and 0.17 tons of VOCs per year. The average zip code in 2011 experienced 14 tons of CO, 41 tons of NO_x, 1.4 tons of PM_{2.5}, 0.5 tons of SO_x, and 8 tons of VOCs. In the subset of wells that were spudded prior to 2011, the average well produced 2 tons of CO, 4.7 tons of NO_x, 0.14 tons of PM_{2.5}, 0.04 tons of SO_x, and 0.63 tons of VOCs in 2011. The top tertile (14–213 wells) of zip codes experience an average of 28 tons of carbon monoxide (CO), 90 tons of NO_x , 2.6 tons of $PM_{2.5}$, 1.8 tons of SO_x , and 9 tons of volatile organic compounds (VOC) per year. Babies exposed to shale gas development within 10 km face an average of 24 wells (max of 240) in 2010 and is fairly similar to the tertiles used in Table 1 Although there isn't a direct way to measure the contribution of these emissions to ambient air quality, they do represent a modest and potentially significant amount of emissions for these rural areas.

Of interest is whether wells continue to produce emissions after drilling and entering into production. To test this, I estimate the amount of reported emissions per year per pollutant using years since spud date as the regressors for all wells reported in the emissions inventory from 2011–2015 (Appendix Table A1). For the most part, emissions are largest for the year of the spud date and the first year after drilling occurred, but emissions continue for most pollutants out to years 4 or 5. Due to this evidence, I estimate models using wells drilled from 2006–2010 and determine exposure by wells drilled prior to birth as opposed to restricting just to drilling activity during gestation.

I.III Pollution and Health Literature

Stillerman et al. (2008) review the epidemiological literature and find associations between low birth weight and maternal exposures to PM, SO_2 , CO, NO_x , VOCs and ozone. Most of the studies cited looked at these pollutants in isolation, but with shale gas development mothers are likely exposed to many at the same time and there is little research that examines any compounding effects.¹³ All of the air pollutants emitted by shale gas

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¹³See Currie et al. (2009); Shah and Balkhair (2011); Stieb et al. (2012a); Glinianaia et al. (2004); Sram et al. (2005) for other reviews of past literature related to air pollution and birth outcomes.

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development described above have been associated with adverse birth outcomes (see Online Appendix for more detail). Unfortunately, many of the epidemiological studies do not take into account socio-economic status and so the observed relationships could reflect unobserved factors that may be correlated with pollution and infant health outcomes (i.e. urban areas). The epidemiological literature relating water pollution to reproductive health is more limited (see Quansah et al. (2015) and Nieuwenhuijsen et al. (2013) for recent reviews).

There is a growing literature within health economics that addresses the most common air pollutants associated with SGD described above utilizing quasi-experimental designs and rich controls for potential confounders to identify the infant health effects of ambient air pollution. See Currie et al. (2014b) for a review of the economics literature on short and long term impacts of early life exposure to pollution. For example, Currie and Walker (2011) estimate that reductions in air pollution from E-Z Pass result in reductions of low birth weight (LBW) between 8.5–11.3 percent and Zahran et al. (2012) utilize the natural experiment of benzene content in gasoline from 1996 to 1999 in the US and found exposure to benzene reduces birth weight by 16.5 g and increases the odds of a very low birth weight event by a multiplicative factor. Lavaine and Neidell (2013) use the natural experiment of a strike that affected oil refineries in France to explore the temporary reductions in SO₂ and find that the reductions increased birth weight by 75 grams, on average (2.3 percent increase) and reduced low birth weight by 2 percentage points for residences within 8 km of the air pollution monitor.

With natural gas touted as a transition fuel between coal-based electricity and renewable options, infant health is one way to compare costs across alternative options. To date, even within the epidemiological literature, studies of the effects of living near coal mining (underground or mountain top) on birth outcomes are extremely limited. All three studies focus on WV: one found an increased risk of low birth weight (16 percent increase in most intensive areas) and one study found an increased risk of congenital anomalies with mountain top removal mining associated with worse outcomes, but was later refuted by the third study when the authors controlled for hospital of birth (Ahern et al., 2011b, a; Lamm et al., 2015). See Hendryx (2015) and Boyles et al. (2017) for systematic reviews of the public health literature. However, recent papers in the economics literature have exploited plant openings and closings or being downwind from a plant to identify the causal impact of coalfired power plants on infant health and have found adverse birth outcomes: a 5 percent reduction in continuous birth weight as the grid transitioned from nuclear to coal in Tennessee (Severnini, 2017), a 6 percent increase in low birth weight for infants 20 miles downwind of a power plant (Yang et al., 2017), 15 percent decreased risk for low birth weight once the plant closed (Yang and Chou, 2017), and 3,500 infant deaths per year as of 1962 associated with the expansion of the power grid between 1938 and 1962 (Clay et al., 2016). A recent paper focused on storage of coal at power plant locations found that a 10 percent increase in PM2.5 from coal storage increased infant mortality rates by 6.6 percent (Jha and Muller, 2017).

I.III.1 SGD and Health Literature—Most of the studies to date that address potential health impacts of shale gas development measure pollutants at drilling sites or in drilling

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fluids and then identify the health implications based upon expected exposure to these chemicals (e.g. toxicological assessment). For example, Colborn et al. (2011) find that more than 75% of the chemicals could affect the skin, eyes, and other sensory organs, and the respiratory and gastrointestinal systems. Chronic exposure is particularly concerning because approximately 40-50% could affect the brain/nervous system, immune and cardiovascular systems, and the kidneys; 37% could affect the endocrine system; and 25% could cause cancer and mutations. These may have long-term health effects that are not immediately expressed after a well is completed. Recent studies have found increased hospitalizations for cardiac conditions (Jemielita et al., 2015), increased risk of three types of asthma measures (Rasmussen et al., 2016), increased risk of hospitalization for pneumonia (Peng et al., 2018), and increased prevalence of fatigue, migraine and sinus effects for residents living near development (Tustin et al., 2017).

A growing body of literature has attempted to address the potential reproductive health effects of shale gas development. All of these studies are retrospective analyses of birth certificate records or electronic medical record data and focus on proximity to maternal residences as the definition of "exposure." In Colorado, McKenzie et al. (2014) find an increased risk of congenital heart defects with the highest quartile of exposure compared with the absence of any gas wells within a 10-mile radius of the maternal residence. They also found a reduction in premature birth and low birth weight for the highest quartile of exposure. Hill (2013) finds an increase in the latter two measures of around 30 percent for oil, natural gas and coalbed methane wells. Using a similar research design in Texas, Whitworth et al. (2017) finds an increase in premature birth of 14 percent and an increase in fetal death upwards of 50 percent. Using a case-control analysis, Whitworth et al. (2199) find a 20 percent increase and 15 percent increase in preterm birth for any wells and producing wells within 0.5 miles of the maternal residence, respectively.

Focusing on the three studies in Pennsylvania, Stacy et al. (2015a) study three counties in Southwestern Pennsylvania from 2007-2010 and Casey et al. (2016) study two hospitals in the Geisinger Health System from 2009–2013.¹⁴ Currie et al. (2017) study birth records from Pennsylvania from 2004–2013. Stacy et al. (2015a) use inverse distance weighted number of wells within 10 miles of the maternal residence and create quartiles to define exposure (compare 4th to 1st quartiles; omitting mothers with no wells within 10 miles). Casey et al. (2016) create an "activity index" and use quartiles of the index (compare 4th (average 124 wells, median 8) to 1st quartile (average 6 wells, median 0), but include those with no wells within 20 km). ¹⁵Currie et al. (2017) utilize a difference-in-difference study design comparing close (e.g. 0-1, 1-2, 2-3km) versus further away (e.g. all PA or 3-15km) in Pennsylvania using county fixed effects. Stacy et al. (2015a) find a reduction in birth weight and an increase in small for gestational age (SGA) of 34 percent. Casey et al. (2016) find an increase in premature birth that ranges from 40 to 90 percent and an increase in the prevalence of risky pregnancies. Currie et al. (2017) find a 25 percent increase in low birth weight for the 0-1km group. The 2-3km buffer suggests a 16 percent increase in low birth

¹⁴Both of these study populations are contained within the population studied in this paper.

¹⁵According to the authors, the index does not distinguish between pregnant women living near several producing wells versus well pads under development.

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weight. The 1–2km buffer is not as consistent or statistically precise as the 0-1 or 2-3km buffers. Other measures studied include continuous birth weight and a health index. Currie et al. (2017) further estimate their models using maternal fixed effects but these models are not statistically significant, nor are they consistent with all of their primary findings.

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In the discussion section (Section VII), I compare and contrast my results with those cited above and also provide discussion of interpretation.

Ш Data

My analysis is based upon a data set acquired from the Pennsylvania Department of Environmental Protection (PA DEP) that contains GIS information for all of the wells drilled in the state of Pennsylvania since 2000 and define whether it is a Marcellus shale well. For the analysis that follows, the spud date (date when the drilling rig begins drilling the well) is used as the temporal identification of treatment. In total, the analysis uses 2,459 natural gas wells spudded between 2006 and 2010. In addition to the existing gas well data, this study also makes use of the permit data on the PA DEP website. This allows for the identification of permits that do not become a well during the sample time frame; approximately 40 percent of permits do not become a well (author calculation from PA DEP data). This information is used to define a potential control group for those infants born to residences close to existing gas wells. The assumption is that these residences are a potential counterfactual group: those who have the potential to live close to a gas well in the future, but have not yet had a well drilled as of the timing of the data collection. Figure 1 shows drilled and permitted wells through 2010 along the strata of shale depth. For the most part, wells that are drilled are clustered along the deepest shale strata and permitting is more random.

My second source of data comes from restricted-access vital statistics natality and mortality data from Pennsylvania for the years 2003 to 2010. The restricted-access version of these birth certificate records contain residential addresses geocoded to latitude and longitude and unique identifiers for the mother, father and infant. This precision is essential to my identification strategy because the consequences of drilling are highly localized. To construct the analysis data set, I combine the spatially identified wells and maternal residences and calculate proximity to the nearest wells.

The vital statistics contain important maternal characteristics such as race, education, age, marital status, WIC status, insurance type, previous risky pregnancy and whether the mother smoked during her pregnancy. In the empirical analyses that follow, I control explicitly for these, as well as month of birth, year of birth, the interaction, and gender of the child.¹I exclude multiple births in all analyses because plural births are more likely to have poor reproductive health independent of exposures to environmental pollution.

I focus on low birth weight (LBW), premature birth and term birth weight (TBW) as the primary outcomes of interest. Low birth weight, defined as birth weight less than 2500 grams, and premature birth, defined as gestation length less than 37 weeks, are commonly used as key indicators of infant health and have been shown to predict adult health and well-

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being.¹ I also present the continuous measure of term birth weight, defined as birth weight for infants who reach full term at 37 weeks gestation, to study whether there is an average effect on the birth weight distribution as opposed to these more extreme health outcomes. Other birth outcomes that I examine include the continuous measure of birth weight, gestation (measured in weeks), small for gestational age (SGA; defined as 10th percentile of weight distribution for the gestational week of birth), an indicator for whether the APGAR score is less than 8 to predict an increased need for respiratory support, congenital anomalies, an infant health index and infant mortality (death in the first year).¹⁸

Table 2 provides summary statistics for the universe of births in Pennsylvania from 20032010. The first column reports characteristics of all births and the second column reports average characteristics of births for mothers' residences within 2.5 km of where a shale gas well has been drilled or will be drilled. The localized data I use in this analysis is actually quite similar to the characteristics of the rest of the state. Mothers who live close to shale gas development are less likely to be African American and Hispanic, slightly better off in terms of health outcomes, younger, better educated and more likely to be married at the time of birth compared with the state average. The mothers in the analysis sample are also more likely to smoke than the average for the state. Columns (3) and (4) provide summary statistics for the primary difference-in-difference (DD) analysis sample; the sample is restricted to those mothers' residences within 2.5 km of a gas well or permit and I compare residences before and after drilling. Most of the statistically significant differences between these two samples are arguably not very economically important. Mothers with infants born after drilling are less likely to be over the age of 35, more likely to receive WIC, and more likely to receive Medicaid, on average, likely to do with the shale gas boom coinciding with the Great Recession. However, Table 3 suggests no changes in these economic variables after shale gas development.¹⁹

Ш **Graphical Evidence**

If living close to a drilled well has a negative impact on infant health, we should see average prevalence of low birth weight for mother's residences in close proximity to wells increase subsequent to when drilling begins. Moreover, we should observe larger impacts for homes closest to drilling activity (e.g. dose response). Figure 2 shows the low birth weight (LBW) and premature birth gradients of distance to closest well before and after drilling. LBW prevalence is on average higher for those residences close to drilled wells, compared with those who are close to permitted wells. The primary effect appears to be within 2.5 km but

the standardized outcomes, weighting them equally. ¹⁹ An examination of fertility over time suggests a consistent number of births within 2.5 km of the well head. Muchlenbachs et al. (2015) do not end any changes in neighborhood composition using Census data at the tract level from 2000-2012 in Pennsylvania.

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¹⁸Small for gestational age (SGA) is used to determine the immediate health care needs of the infant and is used increasingly to predict long-term adverse health outcomes and potential exposure to environmental pollution (Callaghan and Dietz, 2010). This paper uses the World Health Organization weight percentiles calculator (WHO, 2011). Another potential measure of reproductive health is the 5 minute American Pediatric Gross Assessment Record (APGAR) score. The physician rates the infant a 0, 1, or 2 on each of 5 dimensions (heart rate, breathing effort, muscle tone, reex initiability, and color), and then sum the scores, giving an APGAR score of 0-10, where 10 is best. This discrete measure is highly correlated (when the score is low) with the need for respiration support at birth (Almond et al., 2005). Most of these outcomes has been previously examined in both the epidemiological and economics literature (e.g., Currie and Walker (2011)). Following Currie et al. (2014a), I also construct a single standardized measure to address examining multiple outcomes and multiple hypothesis tests. I first convert each birth measure so that an increase is "adverse" and then standardize the measure to a mean of zero and standard deviation of 1. I then construct the summary measure by taking the mean over

persists out to almost 5 km (consistent with regression results). In contrast, we do not see a clear trend in premature birth over distance (regression results are mixed depending on extensive or intensive measures).

In Figure 3, I explore pre-trends in these two outcomes across treatment (e.g. drilled wells) and control (e.g. permitted wells) groups, which addresses the validity of my difference-indifference design. Prior to drilling in 2008, trends appear parallel and indicate a diverging trend once drilling begins.

A primary threat to my identification strategy is that the population of mothers may change in response to drilling. One way to test this is to graph the gradient in observable maternal characteristics. In Figure 4, I graph this gradient out to 20 km.²⁰ The gradient is very similar within 5 km of the nearest gas well before and after drilling. If anything, moms after drilling may be more college educated, which is consistent with my regression results. However, the characteristics change meaningfully beyond 5 km, and moms who live more than 5 km from a gas well before or after drilling are more likely to be college educated, less likely to have their birth paid for by Medicaid, less likely to participate in WIC and less likely to smoke. This suggests selection into living very close to drilling/future drilling and that those who live closer may have lower SES than those who live 15–20 km away. This could drive adverse outcomes related to living very close to drilling, which is why I use permitted locations that are similarly close to mothers' residences since these groups are more homogeneous and statistically similar.

IV Empirical Strategy

I exploit the variation over time and across space in the introduction of shale gas wells in Pennsylvania during 2003–2010. Combining gas well data and vital statistics allows the comparison of infant health outcomes of those living near a gas well and those living there before drilling began. Rather than compare aggregated areas, I know specific locations where shale gas drilling has taken place and the dates of when drilling began. The specific location data allow me to compare reproductive health within very small areas in which mothers are likely to be more homogeneous in observable and unobservable characteristics than in aggregate comparisons.

Relying on cross-sectional variation alone, however, would be problematic if mother characteristics vary within the small radius of interest that are unobservable to the researcher. If, for example, the location of gas drilling occurs where the neighborhoods are already economically distressed, then the variation in health outcomes may reflect socioeconomic status, as opposed to living in close proximity to shale gas development. I therefore examine localized reproductive health outcomes before and after shale gas development exploiting permitted but not-yet-drilled wells as a comparison. I use 2.5 km (approximately 1.5 miles) as the primary distance of interest for the main specifications that

 $^{^{20}}$ This is the largest distance used as a treated group in related studies. McKenzie et al. (2014) use 10 miles, Stacy et al. (2015b) use 10 miles, Casey et al. (2016) uses 20km, Whitworth et al. (2017) use 10 miles and Currie et al. (2017) use 15 km.

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follow due to my graphical analyses as well as due to the precision of the effect at this distance for robustness checks.²¹

My primary model is a difference-in-difference model – in which mothers living within 2.5 km from a shale gas well or permit before drilling are used as a control for those exposed after drilling began – to estimate the impact of exposure to shale gas development on birth outcomes. Thus, the counterfactual change in infant health for mother's residences close to a shale gas well is estimated using births prior to drilling at the same distance from the well bore location or permitted location (e.g. those permits that become a well by 2011 are treated differently than those permits that are not drilled by 2011). These models take the following form:

$$Outcome_{it} = \beta_1 [Well \le X]_{it} + \beta_2 [Post]_{it} + \beta_3 [Well \le X]_{it} * [Post]_{it} + \beta_4 X_{it} + \gamma_t + \chi_c + \epsilon_{it}$$

(1)

where *Outcome*_{it} is either low birth weight, prematurity and other measures of reproductive health for each infant *i* born in month-year t. [Well X]_{it} is either an indicator for any gas well or the number of gas wells within Xkm of the mother's residence. $[Post]_{it}$ is an indicator for whether the birth occurs after the spud date of the nearest well of the maternal residence. The estimated impact of shale gas development on infant health is given by the coefficient β_3 and is the difference-indifferences estimator comparing before and after drilling holding the distance Xkm fixed for wells, future wells and permits.²² The vector X_{ict} contains mother and child characteristics including indicators for whether the mother is African American, Hispanic, four mother education categories (less than high school (left out category), high school, some college, and college or more), mother age categories (teen mom (left out category), 19–24, 25–34 and 35+), indicators for smoking during pregnancy, an indicator for receipt of Women, Infants, and Children (WIC), three health care payment method categories (Medicaid, private insurance, and self-pay), mother's marital status, parity, previous risky pregnancy and an indicator for sex of the child. Indicators for missing data for each of these variables were also included. γ_t are indicators for the year, month and year*month to allow for systematic trends. χ_c are indicators for each mother's county of residence. Standard errors are clustered at the county.²³

²¹In Appendix Tables A3 and A4, I report different proximities to gas wells for the definition of treatment and show that for distances up to 5 km, the results are fairly robust. ²²By including permitted wells not drilled, this estimation strategy becomes more than just a pre-post analysis. This identification

strategy assumes that infants born within a similar distance to a permit that is a potential future ²³Due to the localized nature of this estimation strategy, there is little variation within zip codes to allow for zip code fixed effects.

Models with zip code fixed effects are qualitatively similar but less precisely estimated. Results available upon request.

V.I Differences in Characteristics of Mothers Close to a Well

To test the validity of my research design, I estimate equation (1) and use the differenceindifference estimator to see if there are any changes in mother characteristics after drilling began well would face similar ex ante conditions as those born close to a permit that did become a well during the period I have gas well data for (2003–2011). Infants born to mothers who reside close to potential wells are likely to be the most similar comparison group when it comes to family, geological formation and community characteristics. The decision for which permits become a well is arguably exogenous to the families in these locations. This should account for both observable characteristics, as well as unobservable characteristics, such as economic factors that promote gas drilling in a community and the unobserved geology of the shale underneath these communities. I test these assumptions and do not find any observable differences in the characteristics of mothers who live close to a future well versus a permitted and not yet drilled well.

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(e.g. replace birth outcomes with indicators for maternal characteristics). In Table 3: Panel B, I do not find any indication that maternal characteristics are changing in response to shale gas development. In Appendix Table A2, I show that there are no statistically significant differences in maternal characteristics for any potential proximities (e.g. 2km-3.5km).

V.II The Impact of Shale Gas Development on Birth Outcomes

Table 4 shows the results from estimating (equation 1) on low birth weight, term birth weight and premature birth. Distance to a well, including future and permitted, is held fixed at 2.5 km for these models. Each coefficient represents an estimate of β_3 – the difference-indifference estimator – from a separate regression. Columns (1), (3) and (5) show a model that controls only for month and year of birth, month*year and county fixed effects. Adding controls for observable characteristics of the mother should only reduce the sampling variance while leaving the coefficient estimates qualitatively unchanged. Columns (2), (4) and (6) add maternal characteristics and show that controlling for maternal characteristics has controlling for maternal characteristics has little effecton the estimated coefficients for low birth weight and term birth weight. I find a statistically significant increase in low birth weight of 1.36 percentage points and a reduction in term birth weight of 49.58 grams, on average. I do not find any statistically significant effect for premature birth. Thus, mothers who give birth after drilling are more likely to have reduced weight babies, but they come to term. This difference indicates an overall increase in low birth weight of 24 percent (base of 5.7 percent) and a decrease in term birth weight of 1.5 percent (base of 3416 grams), on average.25

The results are qualitatively similar when I estimate equation (1) for other distances up to 5 km from a gas well or permit (See Appendix Table A3). As the buffer of exposure expands, the point estimates become smaller, indicating a dose response relationship, with effects dissipating beyond 3.5 km. The advantage of using permits as the counterfactual is that I can

 $^{^{25}}$ Overall prevalence is calculated as follows: 0.0136/0.057=23.9 percent low birth weight and 49.6/3416 = 1.5 percent reduction in term birth weight.

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look at only residences that are going to be very close to gas wells at some point in the observable future, which should account for the economic benefits for households receiving lease royalties from the industry.²⁶

Table 5 presents estimates of (equation 1) for changes in birth weight, 5 minute APGAR scores less than 8, gestation (weeks), small for gestational age (SGA), congenital anomaly, and an index for infant health due to having multiple outcomes of interest.²⁷ As before, each column presents estimates from a separate regression, comparing outcomes before and after drilling at 2.5 km from a well head or permit. I present results with maternal controls due to there being little appreciable difference for the models without these controls (results available upon request). Looking across all reproductive health measures, these estimates are consistent with shale gas development being detrimental to infant health. The introduction of shale gas development reduced birth weight by 46.6 grams (1.4 percent reduction), which is consistent with the findings for term birth weight. Five minute APGAR scores were also affected by drilling; drilling increased scores less than 8 by 2.51 percentage points or an overall increase of 26 percent. Small for gestational age (SGA), a strong indicator of intrauterine growth restriction (IUGR), increased by 1.81 percentage points or an increase of 18 percent from the mean. Perhaps surprisingly, given that low birth weight is often correlated with premature birth, gestation shows no difference with the introduction of SGD (similar to the findings for premature birth). I do not find any impact on congenital anomaly, despite McKenzie et al. (2014) finding an increase in Colorado. A drilled shale gas well has a small and statistically significant effect on the summary index, increasing the probability of an adverse reproductive health outcome by 0.026 standard deviations. This result is consistent with the finding that living within 1 mile of an operating toxic plant increased the probability of a poor health outcome by 0.016-0.017 standard deviations (Currie et al., 2014a).

V.III Well Density

Given the finding that the introduction of shale gas development adversely affects birth outcomes in a binary or extensive margin framework, it follows to consider how the density of well development might impact the main outcomes of interest. For the primary sample used in Table 4, the average number of wells drilled at 2.5 km prior to birth is 0.6 wells (s.d. 2.12) with a range of 0 to 35. When limited to those who have at least one well drilled within 2.5 km prior to birth (the "treatment group") the average increases to 2.98 wells (s.d. 2.62). In Table 6, I present findings that regress infant health on well density. I find that for each additional shale gas well drilled prior to birth within 2.5 km, low birth weight increases by 0.3 percentage points and term birth weight is reduced by 5 grams. Unlike the previous

 $^{^{26}}$ Permitted wells must have already gone through the leasing process and households that lease their mineral rights will have received signing bonuses previously. These benefits can only reach an approximate 3km buffer where horizontal drilling can reach minerals and would result in royalties. At very close proximities (e.g. < 1km), I see some indication that birth outcomes are improved by drilling. There is a large and growing literature that suggests positive income shocks can have a positive effect on birth outcomes (Almond et al., 2011; Hoynes et al., 2015) and so this ending would be consistent with that hypothesis. Royalties may mitigate the risks of close exposure.

exposure. ²⁷Following Currie et al. (2014a), I address the issue of precision using a summary index measure of infant health. I first convert each birth measure so that an increase is "adverse" and then standardize the measure to a mean of zero and standard deviation of 1. I then construct the summary measure by taking the mean over the standardized outcomes, weighting them equally.

specification, I also find that each additional well increases premature birth by a similar 0.3 percentage points.²⁸

As before, these findings are consistent across proximity buffers from 2 to 5 km, as shown in Appendix Table A4, and also show some degree of dose response for low birth weight and premature birth. At 2 km, estimates for LBW and preterm birth are about 0.4 percentage points and drop to about 0.02 percentage points at 5 km. The relationship for term birth weight shows less of a dose response, but peaks at 2.5 km with 5 grams and drops to < 1 gram at 5 km.

VI Robustness Checks and Heterogeneity of Impacts

VI.I Heterogeneity by Maternal Characteristics

The economics literature measuring health effects of pollution considers avoidance behavior to be an important factor to explore (Currie (2009); Neidell (2004); Currie et al. (2014b)). If families engage in avoidance behavior (e.g. move, use water purification or purchase bottled water (Wrenn et al., 2016), avoid going outside during drilling), then the health effects measured could be a lower bound. To assess this, the literature tests heterogeneity across characteristics to determine whether there are differential impacts by SES (Currie et al., 2013b; Sanders and Stoecker, 2015). This would not reflect a biological difference, but would provide evidence for or against maternal behavioral responses to shale gas. Table 7 contains estimates of heterogeneity for three primary measures of infant health: low birth weight, term birth weight, and premature birth (each reported as a separate panel). Each column and coefficient represents an estimate of β_3 in equation (1) from a separate regression to explore whether the effects of exposure to shale gas drilling are the same for different subgroups of the population. For the most part, the results for low birth weight and term birth weight indicate that there is not much heterogeneity of impacts across demographic groups-shale gas development has detrimental impacts on all subgroups. However, high school dropouts and moms on Medicaid do experience larger impacts with increases in low birth weight of about 4 percentage points and college educated mothers have slightly smaller impacts of about 1 percentage point.²⁹ No subgroups have statistically significant impacts for prematurity and similar to before, the signs of the coefficients are not consistently positive or negative.

In Hill (2012), I also report estimates of maternal mobility for the sample of mothers who have multiple singleton births and those who have ever resided within 2.5 km of a well or future well during 2003–2010. I found that moms may be moving in response to shale gas development (an increase of 2.2. percentage points), but it was not statistically significant. Despite some potential increased mobility of these mothers, I found that the results are

 $^{^{28}}$ I also estimate models using tertiles of wells and find that the top tertile (> 3 wells) has a similar sized effect as the extensive margin results for low birth weight and term birth weight, however, the top tertile increases premature birth by 2 percentage points, in contrast to the null finding in the extensive margin results. 29 The pre-drilling mean for these three groups are substantially different from the overall average. The percentchanges relative to the

²⁹The pre-drilling mean for these three groups are substantially different from the overall average. The percentchanges relative to the mean for both HS dropouts and Medicaid reect a 50 percent increase, while the effect for college educated moms reects a 25 percent increase, which is the same as the main effect. I tested the differences between these and the main results and only the results for Medicaid are statistically different [pvalue=0.01]

qualitatively similar for those who stay as those who move and indicate that the main results are not driven by maternal mobility.

VI.II Sensitivity Analyses

Additional robustness checks were performed to make sure the main specifications are robust to different counterfactual groups, additional controls and subsets of counties associated with production and drilling. These results are reported in Appendix Table A6. First, I limit the sample to mothers who were born in Pennsylvania to test whether migration from out of state is driving the main findings. The results are very similar for the 83 percent of moms who were born in PA.³⁰

Next, I report the estimates using the 10 most drilled counties and the 10 most producing counties (these are not the same) and find similar results indicating that it is not just drilling or production driving these findings.³¹

Another difference-in-difference model commonly used in the environmental health literature is to compare observed health close to a pollution source versus slightly further away. For example, (Currie and Walker, 2011) compared mothers within 2 km of a toll plaza to mothers who are 2–10 km from a toll plaza, before and after the adoption of E-Z Pass in Pennsylvania and New Jersey. In Hill (2012), I compared residences close to a well (a range of proximities as before of 2–3.5km) and residences a little further away (5, 10 and 15km), before and after drilling.³² The results are consistent with the main findings for low birth weight and term birth weight, but as described in the graphical evidence section, there may be selection into proximity and so this in not a preferred specification.

VI.III Falsification Tests

My analysis shows little evidence of any preexisting differences in communities located close to drilled wells relative to communities close to permits or future wells. It is theoretically possible that the increase in low birth weight after drilling is driven by differential trends in fertility or migration post-drilling among mothers who do not have multiple births during the sample. I investigate this possibility by estimating equation (1) using permit dates to define exposure, instead of spud dates. I also create a placebo test using a random date for the closest well. In these specifications, I find no evidence of a

³⁰This does not perfectly address this question since migration can also occur within PA.

³¹Other robustness checks were reported in Hill (2012). First, I showed the results for restricting the sample to infants born within 2 years (before and after) of the spud date for the closest well. This specification is designed to address any possible concerns about unequal prior and post observation periods for each location or concerns about unobserved and differential sorting in the mothers living close to drilled versus permitted wells. The point estimates are somewhat smaller, but qualitatively similar to the estimates in Tables 4 and 5. Next I showed the results using the sample of births from 2008 to 2010, when most of the shale gas development took place during the sample frame. This point estimate is slightly larger for low birth weight (LBW) indicating a 1.89 percentage point increase. Finally, I reported the results from adding the continuous distance to the closest well, as well as the number of wells drilled within 5 km of the maternal residence. Again, the point estimates are very similar to those reported in Tables 4 and 5 and suggest most of the effect is driven by proximity to the closest well.

³²In Hill (2012), I used up to 15 km as the comparison group and reported it as a lower-bound estimate; shale gas development increases the overall prevalence of low birth weight by 12.5 percent and reduces term birth weight by 0.6 percent, on average. Depending on the scale of shale gas development, it is possible that other aspects of drilling activity will inuence infant health within 15 km of a well and could explain these smaller estimates. For example, communities with shale gas development are exposed to increased truck trafic, pipelines, water storage, compressor stations and general increased localized economic activity. These community level effects are less likely to inuence the estimates in the main results of the paper that use permitted/future wells as the comparison group.

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VII Discussion

My results suggest that shale gas development can have adverse effects on the health of people living nearby, namely that of prenatal infants. For the extensive margin, babies born of mothers who lived within 2.5 km of at least one gas well during pregnancy experienced adverse birth outcomes. I find supportive evidence that these effects persist out to 3.5 km of a mother's address and are consistent across multiple specifications. For the intensive margin, or estimating the impact of well density, I find that each additional well drilled within 2.5 km of the mother's residence increases low birth weight and premature birth by 0.4 percentage points and reduces term birth weight by 5 grams.

These results are reasonable for three reasons. First, most areas with shale gas development in Pennsylvania are rural areas with relatively low prevalence of low birth weight (5.7 percent) compared to the state average of 7 percent (for singleton births only).³³ The studies cited in this paper that assess low birth weight impacts of air emissions from other sources (e.g. EZ-Pass, mountain-top coal mining) report baseline average prevalence of low birth weight of 9 or more percent (Currie and Walker, 2011; Ahern et al., 2011b) and therefore mechanically lower relative effect sizes. However, the average birth weight in this population is almost identical to the state average and is 1.5 percent relative to the mean, which is not large, and is very similar or smaller than the average impact on birth weight of exposure to air emissions in other studies (Severnini, 2017; Lavaine and Neidell, 2013; Yang and Chou, 2017). Second, most of the existing literature has studied the effects of air pollution on infant health on a pollutant-by-pollutant basis. In this case, I am identifying the health effects of exposure to the disamenity itself, which according to the air emissions inventory emits a wide variety of pollutants. Some, such as NO_x, are much higher than the largest pre-drilling emitter in the region.³⁴ Each of these contaminants have been separately associated with the birth outcomes measured in this paper, while SGD increases exposure to all of these during active drilling and production. Thus, it is not surprising that my estimates are larger than some of those found in the literature, especially those that are studying one pollutant. Finally, these results are smaller than or similar in magnitude to the existing literature studying the infant health impacts of shale gas development (Stacy et al., 2015b; Casey et al., 2016; Currie et al., 2017; Whitworth et al., 2017, 2199).

My study builds upon the existing literature measuring the infant health impacts of shale gas development. Due to inconsistency in measures used across existing studies, it is challenging to compare and interpret measured impacts. My results are consistent with Currie et al. (2017) for low birth weight and Stacy et al. (2015a) for small for gestational age. While I do

³³Using the pre-drilling mean of low birth weight for the analysis sample, the effect size is 24 percent relative to the mean, whereas the effect size is 19 percent relative to the state average. ³⁴As mentioned in the background section of the paper, the largest industrial source of NOx in the 11-county region is a power plant

that produces 2,000 tons per year. Shale wells in 2011 produced 16,000 tons of NOx in aggregate.

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not find an impact on premature birth in the extensive margin, my intensive margin results indicate that premature birth may be impacted, especially at the highest tertile of exposure. This most closely relates to the inverse distance weighted quartile measures used in the epidemiologic literature and is consistent with Casey et al. (2016) and Whitworth et al. (2017). Although exact mechanisms are difficult to ascertain with the data currently available, the increase in small for gestational age and low birth weight in the extensive margin without a symmetric increase in premature birth indicates that infants born to mothers exposed to any drilling are coming to full term, but are small, as would be the case where drilling persistently increases local air or water pollution. Whereas, preterm labor may be induced by air pollution or stress at higher intensities of drilling and therefore explain the symmetric intensive margin impacts on preterm birth and low birth weight (Dole et al., 2003; Stieb et al., 2012b; Sun et al., 2015).

These results suggest that requiring air and water pollution monitoring of drilling sites could assist researchers and public health officials in efforts to ascertain exposure pathways for residents living nearby and inform policies to mitigate any risks that are likely to be very localized. In 2011, PA DEP began requiring the shale gas industry to report emissions of these pollutants into an emissions inventory so that policy makers can better address these exposures in the future.

The effects of gas drilling are larger for lower SES children. There is prior evidence that in some cases this is explained by the fact that lower SES women take fewer measures to avoid pollution. I do not, however, detect heterogeneous responses as measured by mothers moving. As previously mentioned, early shocks to a child's health can persist for many years, hence if poorer families are unable to mitigate the risks of drilling activity their children's health is likely to suffer, which is reflected in literature that finds pollution to be one potential mechanism by which SES affects health (Neidell, 2004). Given the wealth of studies that identify a causal link between birth weights and long-run outcomes, these impacts are likely to persist throughout these children's lives.

VII.I Cost Estimates

While the economic benefits and costs of shale gas development are quantifiable, the public health benefits and costs might be more difficult to assess. This paper provides evidence that maternal exposure within at least 1.5 miles of SGD is detrimental to fetal development. Due to shale gas development occurring only recently in Pennsylvania, the number of infants observed close to existing wells is quite small relative to other more populated areas with SGD. This translates to a cost of \$4.1 million.³⁵ As a back-of-the envelope estimate, there are more than 2.8 million American women of reproductive age with a well within a mile of their homes (Gold and McGinty, 2013; Howden and Meyer, 2010).³⁶ Using the current fertility rate of 64 per 1,000 women in this age group nationally (Martin et al., 2012), there

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³⁵Combining hospital costs attributable to low birth weight (\$15,100 in additional hospital costs)(Russell et al., 2007), estimates for special education services (\$5,200)(Chaikind and Corman, 1991; Augenblick et al., 2007) and decreased earnings (\$76,800)(Currie et al., 2013a), an arguably conservative estimate is \$96,500 in added cost for each low birth weight child. This figure excludes medical bills after the first year, parental lost earnings and other costs and is, hence, a lower bound estimate of costs. ³⁶Using The Wall Street Journal estimate that over 15 million Americans live within 1 mile of an oil or gas welldrilled since 2000,

and using a rough estimate that half of those people are women and forty percent of them are ages 18-44.

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VIII Conclusions

My study seeks to understand and quantify the impacts of shale gas development on infant health. As a first step, I assembled a unique data set with the latitude and longitude of new mothers' residences and the locations of shale gas wells and permits in Pennsylvania. I examine the impacts of living in close proximity to shale gas development on low birth weight, term birth weight and other measures of infant health.

These results suggest that shale gas wells are associated with reduced average birth weight among infants born to mothers living within a 2.5 km radius from a shale gas well; this implies a monetized cost of \$4.1 million. The impacts associated with shale gas studied in this paper are large but not implausible given the estimates found in the literature for air pollution impacts on low birth weight and term birth weight. The strength of this approach is in exploiting a natural experiment that controls for unobservable characteristics and the results are robust across a variety of specifications, providing evidence on the credibility of the research design.

It is clear from these results that policies intended to mitigate the risks of shale gas development can have significant health benefits. I find detectable effects of shale gas development on low birth weight and term birth weight more than 3.5 km from the well head (more than 2 miles or over 11,000 ft). This finding is of significant independent interest and an important contribution of this paper.

Current required set back distances (distance between well head and nearby residences, hospitals and schools) range from 300 ft to 800 ft across the 33 states where shale gas development is taking place. With detectable infant health effects up to 2 miles away, these set back distances may be deemed insufficient to protect human health. The impacts of shale gas development estimated in this paper are independent of drinking water source and suggest that the mechanism by which shale gas development adversely affects reproductive health is through the pathway of air pollution. This finding also adds impetus for regulators to increase regulations that reduce air pollution emissions from drilling operations and for industry actors to increase voluntary action to reduce air pollution emissions.

Since I have focused on only the infant health effects of shale gas development, the total health effects of drilling exposure are likely to be much greater. Further research on the longer term health impacts of shale gas development on all members of our society –as well as the probable mechanisms and how best to mitigate them– is warranted.

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Appendices

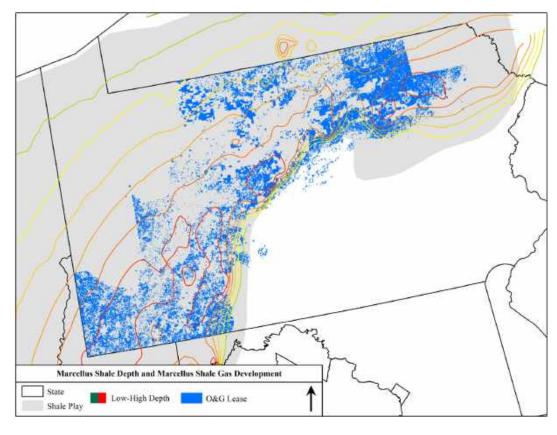


Figure A1: Map of Leasing through 2010

Table A1:

Emissions from Shale Gas Wells First 5 Years after Spud Date

	(1)	(2)	(3)	(4)	(5)	(6)
	co	nox	pm10	pm25	SOX	voc
Year of Spud	2.188***	7.938***	0.282***	0.259***	0.107***	0.585***
	(0.0517)	(0.136)	(0.00614)	(0.00537)	(0.00538)	(0.0463)
One Year Since Spud	2.241***	6.709***	0.225***	0.202***	0.0656***	1.008***
	(0.0532)	(0.140)	(0.00632)	(0.00552)	(0.00558)	(0.0473)
Two Years Since Spud	0.595***	1.351***	0.0612***	0.0550***	0.00860	0.719***
	(0.0577)	(0.152)	(0.00685)	(0.00596)	(0.00607)	(0.0501)
Three Years Since Spud	0.378***	0.661***	0.0289***	0.0256***	0.00985	0.427***
	(0.0603)	(0.158)	(0.00715)	(0.00622)	(0.00628)	(0.0523)
Four Years Since Spud	0.321***	0.438**	0.0213**	0.0172**	0.00334	0.502***
	(0.0737)	(0.193)	(0.00874)	(0.00760)	(0.00765)	(0.0648)
Five Years Since Spud	0.178*	0.250	0.0107	0.00882	0.00101	0.731***
	(0.100)	(0.264)	(0.0119)	(0.0104)	(0.0104)	(0.0892)
Observations	13,650	13,650	13,610	13,555	13,472	14,073
Observations	13,650	13,650	13,610	13,555	13,472	

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	(1) co	(2) nox	(3) pm10	(4) pm25	(5) sox	(6) voc
R-squared	0.215	0.299	0.204	0.218	0.038	0.067
Dep. Var Mean	1.242	3.805	0.136	0.123	0.0436	0.675

Table A2:

Differences in characteristics for analysis sample using DD estimator by Distance

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Teen Mom	Dropout	Black	Smoked	WIC	Medicaid	Born PA	Moved
Within 2km * post-drilling	0.00464	-0.00150	0.00181	-0.00366	-0.0195	-0.0288	-0.0198	-0.0012
	(0.00704)	(0.00927)	(0.00457)	(0.0254)	(0.0276)	(0.0273)	(0.0133)	(0.0124)
Observations	14,131	14,131	14,131	14,131	14,026	14,131	14,131	14,060
R-squared	0.015	0.046	0.022	0.031	0.072	0.098	0.025	0.043
Within 2.5 km [*] post- drilling	0.000550	-0.0132	0.00343	0.00277	-0.00501	-0.0204	-0.0222	0.0191
	(0.00666)	(0.0118)	(0.00308)	(0.0196)	(0.0246)	(0.0282)	(0.0163)	(0.0131
Observations	21646	21646	21646	21646	21469	21646	21646	21511
R-squared	0.012	0.039	0.016	0.026	0.061	0.078	0.020	0.042
Within 3km * post-drilling	-0.00351	-0.0206	0.00443	-0.0210	-0.0221	-0.0426	-0.0209	0.0159
	(0.0108)	(0.0193)	(0.00550)	(0.0234)	(0.0304)	(0.0371)	(0.0139)	(0.0123
Observations	28,910	28,910	28,910	28,910	28,655	28,910	28,910	28,741
R-squared	0.010	0.032	0.016	0.025	0.061	0.073	0.017	0.041
Within 3.5km post-drilling	-0.0140	-0.0258	-0.000432	-0.0234	-0.0451	-0.0451	-0.0160	0.0120
	(0.0108)	(0.0217)	(0.00694)	(0.0266)	(0.0349)	(0.0419)	(0.0173)	(0.0112
Observations	36,447	36,447	36,447	36,447	36,100	36,447	36,447	36,228
R-squared	0.009	0.029	0.015	0.024	0.057	0.069	0.015	0.040

Notes: See Table 3 for specification details.

Significance:

* p<0.10,

** p<0.05,

*** p<0.01.

Table A3:

The Effect of Shale Gas Development on Infant Health by Distance

	(1) <i>d</i> < 2 km	(2) <i>d</i> < 2:5 km	(3) <i>d</i> < 3 km	(4) <i>d</i> < 3:5 km	(5) <i>d</i> < 4 km	(6) <i>d</i> < 4:5 km	(7) <i>d</i> < 5 km
		Panel	A: Low Birth	n Weight			
Well in 'd' km [*] post-drilling	0.0127 **	0.0136**	0.0115 **	0.00912**	0.00533	0.00288	0.00194
	(0.00512)	(0.00511)	(0.00510)	(0.00391)	(0.00406)	(0.00415)	(0.00428
Observations	14,113	21,610	28,865	36,393	44,690	52,325	59,369
R-squared	0.023	0.021	0.019	0.019	0.018	0.018	0.017
Pre-drilling Mean	0.0584	0.0571	0.0579	0.0579	0.0576	0.0574	0.0575
		Panel	B: Term Birtl	n Weight			
Well in 'd' km [*] post-drilling	-38.05*	-49.58 ***	-30.84 **	-29.69**	-15.34	-10.25	-7.311
	(21.49)	(14.04)	(14.20)	(12.59)	(9.781)	(11.56)	(9.457)
Observations	13028	19978	26637	33572	40,277	47,105	53,391
R-squared	0.077	0.075	0.078	0.077	0.078	0.076	0.075
Pre-drilling Mean	3415	3416	3415	3412	3412	3415	3415
		Pa	anel C: Prema	iture			
Well in 'd' km [*] post-drilling	-0.00962**	0.000354	0.00460	-0.00184	-0.000704	0.000242	0.00273
	(0.00403)	(0.00664)	(0.00455)	(0.00483)	(0.00564)	(0.00503)	(0.00446
Observations	13,843	21,189	28,309	35,661	43,741	51,139	57,981
R-squared	0.017	0.012	0.010	0.010	0.009	0.009	0.008
Pre-drilling Mean	0.0802	0.0785	0.0791	0.0791	0.0782	0.0783	0.0786

Notes: See Table 4 for specification details.

Significance:

* p<0.10,

** p<0.05,

p<0.01.

Table A4:

Impact of Number of Wells by Proximity

	(1) <i>d</i> < 2 km	(2) <i>d</i> < 2:5 km	(3) <i>d</i> < 3 km	(4) <i>d</i> < 3:5 km	(5) <i>d</i> < 4 km	(6) <i>d</i> < 4:5 km	(7) <i>d</i> < 5 km
		Pa	nel A: Low Bir	th Weight			
Wells in 'd' km * post-drilling	0.00410*	0.00306***	0.00232***	0.00122**	0.000266	0.000194	0.000209
	(0.00231)	(0.000931)	(0.000758)	(0.000509)	(0.000433)	(0.000302)	(0.000260)

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	(1)	(2)	(3)	(4)	(5)	(6)	(7)
	<i>d</i> < 2 km	<i>d</i> < 2:5 km	<i>d</i> < 3 km	<i>d</i> < 3:5 km	<i>d</i> < 4 km	<i>d</i> < 4:5 km	d < 5 km
Observations	14,049	21,524	28,756	36,241	44,442	51,994	58,976
R-squared	0.023	0.021	0.020	0.019	0.018	0.018	0.017
Pre-drilling Mean	0.0583	0.0570	0.0578	0.0578	0.0575	0.0573	0.0575
		Pa	nel B: Term Bi	rth Weight			
Wells in 'd' km [*] post-drilling	-3.857	-5.386 ***	-4.716***	-3.152 ***	-2.429 ***	-1.438**	-0.930**
	(2.609)	(1.632)	(1.331)	(0.818)	(0.644)	(0.570)	(0.415)
Observations	12,694	19,463	25,969	32,692	40,067	46,822	53,049
R-squared	0.080	0.076	0.078	0.077	0.079	0.076	0.075
Pre-drilling Mean	3415	3416	3415	3412	3412	3415	3415
			Panel C: Prer	nature			
Wells in 'd' km [*] post-drilling	0.00366*	0.00257 **	0.00212**	0.000889	0.000281	0.000235	0.000406
	(0.00210)	(0.00123)	(0.000889)	(0.000718)	(0.000602)	(0.000398)	(0.000331
Observations	13,784	21,109	28,206	35,519	43,506	50,825	57,606
R-squared	0.017	0.011	0.010	0.010	0.009	0.008	0.008
Pre-drilling Mean	0.0803	0.0785	0.0790	0.0789	0.0781	0.0781	0.0786

Notes: See Table 6 for specification details.

Significance:

p<0.10,

** p<0.05, *** p<0.01.

Table A5:

Robustness Check: Future Number of Wells by Proximity

	(1) <i>d</i> < 2 km	(2) <i>d</i> < 2.5 km	(3) <i>d</i> < 3 km	(4) d < 3.5 km
	Panel A: Lov	w Birth Weight		
Wells in 'd' km [*] future	-0.000223	-0.000133	8.19e-05	6.12e-06
	(0.000449)	(0.000341)	(0.000172)	(0.000139)
Observations	14,049	21,524	28,756	36,241
R-squared	0.023	0.021	0.020	0.019
	Panel B: Terr	m Birth Weigh	t	
Wells in 'd' km [*] future	0.977	0.318	0.410	0.730***
	(1.342)	(0.588)	(0.359)	(0.272)
Observations	12,694	19,463	25,969	32,692

	(1) <i>d</i> < 2 km	(2) <i>d</i> < 2.5 km	(3) <i>d</i> < 3 km	(4) <i>d</i> < 3.5 km
R-squared	0.080	0.076	0.078	0.077
	Panel C:	Premature		
Wells in 'd' km [*] future	0.000394	0.000172	0.000352	0.000290
	(0.000412)	(0.000476)	(0.000273)	(0.000227)
Observations	13,784	21,109	28,206	35,519
R-squared	0.017	0.011	0.010	0.010

Notes: See Table 6 for specification details. Instead of existing wells, this table looks at future wells.

Significance:

* p<0.10,

** p<0.05,

*** p<0.01.

Table A6:

Robustness Checks

	(1)	(2)	(3)
	Low Birth Weight	Term Birth Weight	Premature Birth
	Panel A: Mom Born	n in Pennsylvania	
Within 2.5 km * post	0.0128 ***	-50.87 ***	-0.00523
	(0.00466)	(15.99)	(0.00645)
Observations	17,491	15,814	17,155
R-squared	0.022	0.081	0.012
Pre-drilling Mean	0.0576	3415	0.0791
]	Panel B: Top 10 Major	Production Counties	
Within 2.5 km * post	0.0160*	-44.52 ***	-0.00303
	(0.00726)	(12.03)	(0.0104)
Observations	15,052	13,627	14,789
R-squared	0.025	0.081	0.017
Pre-drilling Mean	0.0573	3415	0.0790
	Panel C: Top 10 Majo	or Drilling Counties	
Within 2.5 km * post	0.0175 **	-46.66***	0.000296
	(0.00576)	(12.36)	(0.00978)
Observations	13,208	11,951	12,957
R-squared	0.024	0.076	0.016
Pre-drilling Mean	0.0559	3423	0.0783

Notes: Each coefficient is from a different regression. The sample is limited to singleton births, the sample with a well/permit within 2.5 km and to the panel headings listed. All regressions include indicators for month and year of birth,

month*year, residence county indicators, an indicator for drilling before birth (defined by closest well), an indicator for residence within 2.5 km of a well or future well and the interaction of interest of Within 2.5km*post-drilling. Maternal characteristics include mother black, mother Hispanic, mother education (hs, some college, college), mother age (19–24,25–34, 35+), female child, WIC, smoking during pregnancy, marital status and payment type (private insurance, medicaid, self-pay, other). Indicators for missing data for these variables are also included. Standard errors are in parentheses and clustered at the mother's residence county.

Significance:

p<0.10,

** p<0.05,

- p<0.05 ***

p<0.01

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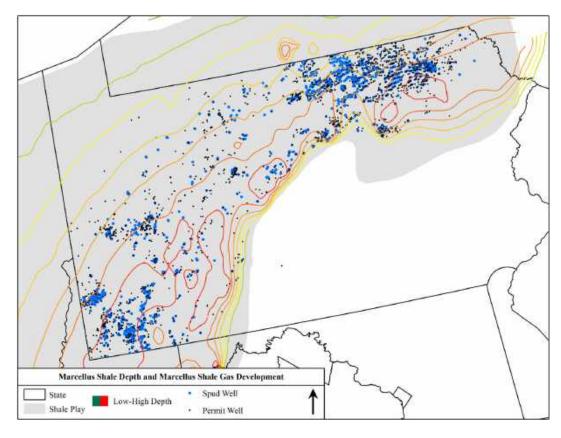
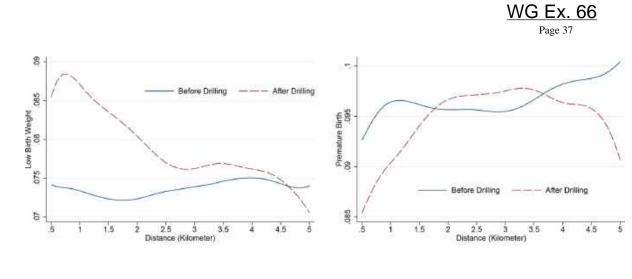


Figure 1:

Map of Shale Gas Development and Permitting through 2010



Low Birth Weight

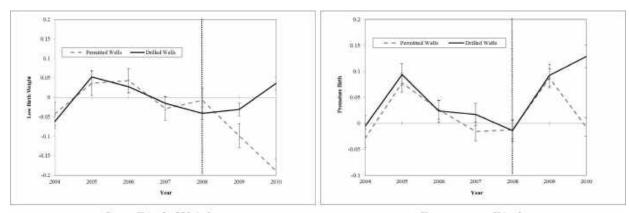
Premature Birth

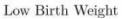
Figure 2:

Distance Gradients of Infant Health by Nearest Well Results from a local polynomial regressions of low birth weight on distance from closest well's future/current location or on days before/after spud date. Observations within 5 km of a well.

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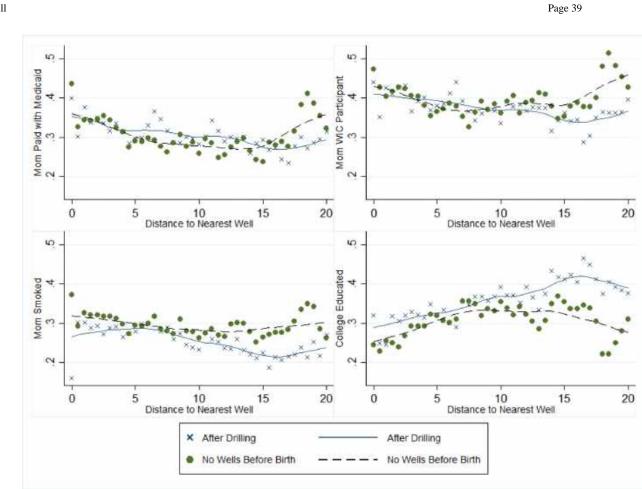
Premature Birth

WG Ex. 66

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Figure 3:

Time Trends of Infant Health Within 2.5 km of Drilled and Permitted Wells Results are from a regression with an interaction term for drilled well * year including county, birth month and year fixed effects. Observations are the main difference-in-differences sample or those mothers within 2.5 km of a drilled well or permitted well.



<u>WG Ex. 66</u>

Figure 4:

Distance Gradients of Maternal Characteristics by Nearest Well Distance bins are 0.5 km, smoothed using "lpoly" (degree 0, bandwidth 15).

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Table 1:

Pollution Per Well and Tertiles Aggregated to Zip Code 2011–2015

	C 9	CO (2)	NO_x	(1)	(C) PM2.5	(0) PM2.5	(7) SO _x	(8) <i>SO_x</i>	(9) VOC	VOC
# wells	0.526***		2.048 ***		0.0639***		0.0325***		0.172 ***	
	(0.0567)		(0.171)		(0.00543)		(0.00500)		(0.0597)	
3-5 wells		3.271		13.28		0.395		0.514 **		1.074
		(2.928)		(090.60)		(0.289)		(0.256)		(3.042)
6-13 wells		13.30^{***}		45.02 ***		1.472 ^{***}		1.271^{***}		3.835
		(3.305)		(10.23)		(0.326)		(0.289)		(3.434)
14-213 wells		27.47 ***		89.83 ***		2.630 ***		1.777 ***		9.023 **
		(3.934)		(12.17)		(0.388)		(0.344)		(4.087)
log prod	0.552^{***}	0.443 **	1.806^{***}	1.627 ***	0.0633 ***	0.0598 ***	0.0336^{**}	0.0241	0.281	0.247
	(0.193)	(0.202)	(0.580)	(0.626)	(0.0185)	(0.0200)	(0.0170)	(0.0177)	(0.203)	(0.210)
Observations	1,172	1,172	1,172	1,172	1,172	1,172	1,172	1,172	1,172	1,172
R-squared	0.697	0.688	0.730	0.707	0.724	0.699	0.500	0.494	0.651	0.650
Dep. Var Mean	15.35	15.35	45.85	45.85	1.482	1.482	0.507	0.507	8.742	8.742

gregated to zip code-year. Regressions include year and zip code fixed effects. First column for each pollutant is number of reported wells in that zip code-year. Second column provides tertile estimates.

Significance:

*p<0.10,

** p<0.05, *** p<0.01.

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Table 2:

Summary Statistics by Sample

		Residenc	es within 2.5	km of well	T-Stat
	All Births	Total	Before	After	for difference
Characteristics of birth					
Birth weight (grams)	3321	3340	3343.23	3310.30	2.70**
Term birth weight (grams)	3407	3415	3418.39	3383.15	3.30***
Gestation in weeks	38.77	38.76	38.76	38.71	1.33
Premature	0.08	0.08	0.076	0.077	-0.09
Low birth weight (LBW)	0.07	0.06	0.055	0.063	-1.52
Small for gestational age (SGA)	0.11	0.10	0.098	0.106	-1.25
APGAR 5 minute	8.81	8.89	8.886	8.885	0.07
Female	0.49	0.49	0.485	0.495	-0.95
Mother's Characteristics					
Drop Out	0.164	0.113	0.112	0.118	-0.88
High School	0.270	0.296	0.297	0.288	0.93
Some college	0.260	0.299	0.299	0.293	0.64
College plus	0.298	0.290	0.289	0.299	-1.07
Teen Mom	0.057	0.048	0.047	0.049	-0.34
Mom Aged 19-24	0.265	0.268	0.267	0.274	-0.65
Mom Aged 25-34	0.527	0.547	0.545	0.559	-1.31
Mom Aged 35 and older	0.150	0.137	0.140	0.117	3.03 **
Mom Black	0.156	0.025	0.025	0.024	0.15
Mom Hispanic	0.092	0.011	0.011	0.010	0.57
Married at time of birth	0.575	0.632	0.633	0.626	0.71
Mom Smoked While Pregnant	0.227	0.299	0.299	0.300	-0.13
Received WIC	0.385	0.398	0.395	0.427	-2.94 **
Medicaid	0.272	0.326	0.320	0.376	-5.45 ***
Private Insurance	0.576	0.567	0.569	0.549	1.84
Wells within 2.5 km					
# of wells before birth	0.000	0.333	0.000	2.89	-19.30 ***
# of wells during gestation	0.000	0.188	0.000	1.714	-93.13 ***
Observations	1098884	21610	19246	2364	

Notes: The samples described here include only singleton births.

Significance:

*p<0.10,

** p<0.05,

*** p<0.01.

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Table 3:

Post- Drilling Differences in Average Characteristics of Mothers Close to Wells

	(1) Teen Mom	(2) Dropout	(3) Black	(4) Smoked	(5) WIC	(6) Medicaid	(7) Born PA	(8) Moved
		Differences	in character	istics for ar	nalysis samp	le using DD	estimator	
Within 2.5 km [*] post-drilling	0.000550	-0.0132	0.00343	0.00277	-0.00501	-0.0204	-0.0222	0.0191
	(0.00666)	(0.0118)	(0.00308)	(0.0196)	(0.0246)	(0.0282)	(0.0163)	(0.0131)
Observations	21646	21646	21646	21646	21469	21646	21646	21511
\mathbb{R}^2	0.012	0.039	0.016	0.026	0.061	0.078	0.020	0.042
Pre-drilling Mean	0.0496	0.117	0.0243	0.307	0.404	0.323	0.815	0.0756

Notes: Each coefficient is from a different regression. Pre-drilling (post-drilling) refers to births that occur before (after) the spud date of the closest well. Robust standard errors are clustered at the mother's residence county. All regressions include indicators for month and year of birth, birth*year and residence county fixed effects.

Significance:

* p<0.10,

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** p<0.05,

*** p<0.01.

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Table 4:

Impact of Well Location on Birth Outcomes

	(1) Low Birth	(2) Weight	(3) Term Birth	(4) Weight	(5) Prem	(6) ature
Within 2.5 km [*] post-drilling	0.0144 **	0.0136**	тм47.82***	тм49.58***	0.00118	0.000354
	(0.00537)	(0.00511)	(15.12)	(14.04)	(0.00597)	(0.00664)
Observations	21610	21610	19978	19978	21,189	21,189
R-squared	0.008	0.021	0.013	0.075	0.008	0.012
Pre-drilling Mean	0.057	0.057	3416	3416	0.079	0.079
Maternal Characteristics	No	Yes	No	Yes	No	Yes

Notes: Each coefficient is from a different regression. The sample is limited to singleton births and to the sample with a well/permit within 2.5 km. All regressions include indicators for month and year of birth, month*year, residence county indicators, an indicator for drilling before birth (defined by closest well), an indicator for residence within 2.5 km of a well or future well and the interaction of interest of Within 2.5km*postdrilling. Maternal characteristics include mother black, mother Hispanic, mother education (hs, some college, college), mother age (19–24,25–34, 35+), female child, WIC, smoking during pregnancy, marital status and payment type (private insurance, medicaid, selfpay, other). Indicators for missing data

Significance:

^rp < 0.10,

** p < 0.05,

*** p < 0.01.

Table 5:

Difference-in-Difference Estimates of the Effect of Drilling on Alternative Health Measures

	(1) Birth Weight	(2) APGAR < 8	(3) Gestation	(4) SGA	(5) Congenital Anomaly	(6) Summary Index	(7)
Within 2.5 km [*] post-drilling	-47.02 ***	0.0251 **	-0.0143	0.0181 **	-0.00193	0.0264 **	
	(12.16)	(0.0101)	(0.0664)	(0.00764)	(0.00189)	(0.0101)	
Observations	21,583	21646	21,631	21524	21,646	21646	
R-squared	0.061	0.029	0.020	0.040	0.008	0.045	
Pre-drilling Mean	3340	0.104	38.74	0.0993	0.00562	-0.0372	

Notes: Each coefficient is from a different regression. See Table 4 for details about included covariates.

Significance:

* p<0.10,

** p<0.05,

*** p<0.01. .

Table 6:

Impact of Well Density on Birth Outcomes

	(1) Low Birt	(2) h Weight	(3) Term Birt	(4) th Weight	(5) Prem	(6) ature
Wells within 2.5 km * post	0.00308 ***	0.00306***	тм4.864 *** (1.783)	тм5.386 ^{***} (1.632)	0.00266**	0.00257**
Observations	21610	21610	19978	19978	21,189	21,189
R ²	0.009	0.021	0.013	0.076	0.008	0.011
Pre-drilling Mean	0.057	0.057	3416	3416	0.079	0.079
Maternal Characteristics	No	Yes	No	Yes	No	Yes

Notes: Each coefficient is from a different regression. The sample is limited to singleton births and to having a well or permit within 2.5 km. All regressions include an indicator for drilling before birth (defined by closest well), number of wells within 2.5km (including future wells) and the interaction of interest: number of wells within 2.5km *post-drilling. See Table 4 for details about other included covariates.

Significance:

* p<0.10,

** p<0.05,

*** p<0.01.

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Table 7:

Shale Gas Development on Maternal Subgroups

	(1) High School dropout	(2) Smoker	(3) Nonsmoker	(4) Medicaid	(5) WIC	(6) College
	-	Panel A: Lo	w Birth Weight			
Within 2.5 km * post	0.0432	0.0186	0.0122 **	0.0413 ***	0.0138**	0.0105
	(0.0268)	(0.0132)	(0.00470)	(0.0120)	(0.00645)	(0.00995)
Observations	2,434	6,465	15,145	7,047	8,541	6,260
R-squared	0.072	0.034	0.018	0.029	0.024	0.029
Pre-drilling Mean	0.0847	0.0830	0.0456	0.0747	0.064	0.0414
		Panel B: Ter	m Birth Weight			
Within 2.5 km *post	-42.09	-56.15	-51.36**	-62.97*	-38.30	-49.61*
	(41.26)	(37.10)	(19.04)	(36.70)	(29.02)	(28.45)
Observations	2,191	5,773	13,763	6,375	7,748	5,699
R-squared	0.131	0.064	0.042	0.077	0.076	0.055
Pre-drilling Mean	3305	3272	3479	3325	3349	3494
		Panel C:	Premature			
Within 2.5 km [*] post	0.0181	-0.00393	-0.000441	-0.00579	-0.00160	0.000744
-	(0.0233)	(0.00950)	(0.00753)	(0.0136)	(0.0142)	(0.0134)
Observations	2,409	6,338	14,851	6,973	8,418	6,122
R-squared	0.070	0.026	0.015	0.027	0.021	0.030
Pre-drilling Mean	0.0896	0.0867	0.0749	0.0859	0.0782	0.0713

Notes: Each coefficient is from a different regression. See Table 4 for details about included covariates.

Significance:

* p<0.10,

** p<0.05,

*** p<0.01.

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Table 8:

Falsification Tests on Impact of Well Location

	(1)	(2)	(3)	(4)	(5)	(6)
		Permit Date			Random date	
	Low Birth Weight	Term Birth Weight	Premature	Low Birth Weight	Term Birth Weight	Premature
Within 2.5 km [*] post	-0.000106	-5.03	-0.00149	0.00103	-1.152	-0.00654
	(0.00682)	(12.382)	(0.00897)	(0.00303)	(11.5)	(.00789)
Sample Size	19246	17795	18854	21610	19978	21204
R ²	0.009	0.013	0.009	0.021	0.075	0.012

Notes: See Table 4 for included covariates. Each panel is a separate regression. All regressions include controls for maternal characteristics and time trends and county fixed effects. Columns (1)- (3) use permit date to define "treatment" and the coefficient reported is the interaction between an indicator for whether the permit was within 2.5 km from the mother's residence and whether the birth occurred after (post) the permit date. Columns (4)-(6) use a random date to define post birth.

Significance:

* p<0.10,

**p<0.05,

***p<0.01.

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GeoHealth

POLICY PAPER

10.1029/2023GH000874

Key Points:

- The impacts of compressor stations fall most heavily on the local communities around the stations, which are often socially vulnerable
- The current National Ambient Air Quality Standards are not sufficient to fully protect human health and vulnerable communities
- There is a severe need for more thorough air quality monitoring to understand the full impact of chemical emissions on community health

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Community Health Impacts From Natural Gas Pipeline Compressor Stations

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Abstract Compressor stations maintain pressure along natural gas pipelines to sustain gas flow. Unfortunately, they present human health concerns as they release chemical pollutants into the air, sometimes at levels higher than national air quality standards. Further, compressor stations are often placed in rural areas with higher levels of poverty and/or minority populations, contributing to environmental justice concerns. In this paper we investigate what chemical pollutants are emitted by compressor stations, the impacts of emitted pollutants on human health, and local community impacts. Based on the information gained from these examinations, we provide the following policy recommendations with the goal of minimizing harm to those affected by natural gas compressor stations: the Environmental Protection Agency (EPA) and relevant state agencies must increase air quality monitoring and data transparency; the EPA should direct more resources to monitoring programs specifically at compressor stations; the EPA should provide free indoor air quality standards to better protect communities and assess cumulative impacts; and decision-makers at all levels must pursue meaningful involvement from potentially affected communities. We find there is substantial evidence of negative impacts to strongly support these recommendations.

Plain Language Summary Compressor stations allow natural gas to run smoothly through long pipelines. Compressor stations release several different types of pollutants; we discuss in this paper what each pollutant does to the human body and to communities as a whole. Compressor stations are often near socially vulnerable communities that are poor, non-white, or elderly, which means they more often bear the burden of the pollution. We examine the shortcomings of current policies and regulations surrounding compressor stations and offer solutions to help protect vulnerable communities. Some of these solutions include better testing of air quality near compressor stations, free indoor air quality testing in homes near compressor stations, and better air quality standards to protect all communities from air pollution.

1. Introduction

1.1. What Are Compressor Stations, and Why do They Matter?

To maintain gas flow in natural gas pipelines, over 1,200 compressor stations pressurize natural gas every 50–100 miles along pipeline routes in the United States (Messersmith, 2015; U.S. EIA Office of Oil and Gas, 2007). We reviewed over 100 peer-reviewed academic articles to synthesize a complete review of chemical emissions from compressor stations and the associated community health impacts. In this paper, we present a complete list of known pollutants emitted by compressors, evaluate the pollution in the context of currently available data and air quality standards, assess associated community impacts, and conclude with policy recommendations for state and federal agencies. Although necessary for natural gas pipelines, we find compressor stations significantly affect the well-being of local communities and thus must be regulated accordingly.

Air pollution released by compressors is known to have significant negative health and environmental impacts to neighboring communities. Exhaust from combustion within compressor units is the major source of the air pollution, emitting chemicals that include volatile organic compounds (VOCs), nitrogen oxide compounds (NO_x), and particulate matter (PM) (D. R. Brown et al., 2015; Green & Crouch, 2021; Hendryx & Luo, 2020; Johnson

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et al., 2015; Olaguer, 2012; Russo & Carpenter, 2017; van der A et al., 2020; Walter, 2020; White et al., 2019). Exposure to these air pollutants can be harmful to human respiratory, cardiovascular, and neurological systems and increase human mortality rates (Hendryx & Luo, 2020; WHO, 2021). Additionally, NO_x and VOCs react in the atmosphere to produce ozone, which aggravates human respiratory conditions like asthma (Grulke & Heath, 2020; U.S. EPA, 2020). While pollutants from compressor stations are widely known to be harmful to human health, there are few studies that directly link compressor station emissions to specific local community health outcomes (Green & Crouch, 2021; Hendryx & Luo, 2020).

Compressor stations are also significant sources of methane, a potent greenhouse gas and contributor to global warming (Strizhenok & Korelskiy, 2019). The majority of the methane is emitted during blowdowns, when compressor units are depressurized for maintenance and release large amounts of high-pressure gas to the atmosphere (White et al., 2019). In the U.S. in 2020, compressors were estimated to have released 420,000 metric tons of methane, mainly during blowdowns, which is about 10% of the methane emitted from U.S. landfills in the same year (U.S. EPA, 2022b).

Although compressor station air pollution can be difficult to regulate, several federal laws apply to these emissions. Foremost, the Clean Air Act of 1970 (abbreviated CAA; see 42 U.S.C. §7401 et seq.) established National Ambient Air Quality Standards (NAAQS) to regulate air pollution from all sources, including compressor stations (U.S. EPA, 2021c). However, a lack of air quality monitoring near compressor stations has led to numerous violations of NAAQS in nearby communities (Babich, 2018). Compressor stations are also regulated under the National Emission Standards for Hazardous Air Pollutants as chemical emissions sources (Babich, 2018; Environmental Health Project, 2015). While there is a federal permitting process to build compressor stations, the EPA often delegates permitting to the state level. Many states and geographic areas have developed their own guidelines for compressor station permitting standards (Babich, 2018; Mountain Valley Pipeline LLC & Equitrans LP, 2017).

1.2. Compressor Stations and Environmental Justice

Decades of work by grassroot activists and academic researchers have documented the disproportionate placement of pollution-generating infrastructure in historically marginalized communities, including the natural gas industry and compressor stations, which has resulted in high levels of air pollution exposure (Banzhaf et al., 2019; Collins et al., 2016; Emanuel et al., 2021; Mohai et al., 2009). These actions raise environmental justice (EJ) concerns and often result in frontline communities being subject to multiple pollution sources that compound to a higher cumulative exposure than if each source was considered alone.

In this paper, we use a definition of EJ that closely follows that of the Environmental Protection Agency (Environmental Justice, 2023), which defines EJ as: "the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies" (Environmental Justice, 2023). Fair treatment ensures no community bears "a disproportionate share of negative environmental Justice, 2023). Fair treatment ensures no commumental and commercial operations or policies" (Environmental Justice, 2023). Meaningful involvement ensures people have an opportunity to participate in decisions that impact their lives and the decision-making body is influenced by the public's voiced opinion (Environmental Justice, 2023). This definition includes the three core components of EJ: distributive (the distribution of environmental burdens), procedural (the policies and decisions that lead to the distribution), and recognitional (a sense of justice among stakeholders) (Banzhaf et al., 2019; Clough, 2018; Menton et al., 2020; Pearsall & Pierce, 2010; Rigolon et al., 2022; Svarstad et al., 2011).

Notably, compressor stations can contribute to all three EJ components. Emissions and associated human health outcomes contribute to distributive EJ based on where compressor stations are located. Federal and state policies that determine where compressor stations are sited can underlie procedural EJ issues; decision-makers who create policy on fossil fuel infrastructure permits can make these decisions without considering the impacts on community members (Clough, 2018; Paparo, 2021). Although public engagement is required by many state and federal agencies, a lack of incorporation of public opinion into the decision-making process can hinder recognitional EJ (Buckingham v. State Air Pollution Control Board & Atlantic Coast Pipeline, 6 VA. Ct. App. (No. 19-1152), 2020; Daley & Reames, 2015; Wortzel & De Las Casas, 2021).

In addition to higher air pollution exposure, low income populations and communities of color are more likely to have underlying health conditions, driven mainly by social factors, that further increase susceptibility to



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environmental health hazards (Adler & Rehkopf, 2008; American Lung Association, 2023b; Murray et al., 2020). However, the interactions between pollution exposure, community vulnerability, and health outcomes remain under-examined, and there are major unknowns regarding the long term and cumulative impacts of compressor stations on socially vulnerable communities that are less resilient when facing external stresses (ATSDR, 2022). Nevertheless, disproportionate placement of compressor stations in communities with EJ concerns is cause for alarm.

1.3. Scope of Paper

This paper addresses the knowledge gap between compressor station air pollution and specific local community health outcomes. We provide a review of major pollutants emitted by compressor stations and associated health impacts, and then evaluate how these emissions impact relevant policy, data quality, and community health. We conclude the paper with policy recommendations that aim to minimize the community health impacts from compressor stations.

2. Chemical Emissions From Compressor Stations: Specific Pollutants

It is well established that air pollution has negative health effects. Short-term effects include symptoms such as headaches, nausea, and irritation of mucous membranes (WHO, 2021). In the long-term, air pollution exposure is known to increase risk of lung cancer and cardiovascular and respiratory diseases (Thurston et al., 2017; WHO, 2021). Often, increased mortality rates can be directly attributed to higher air pollution exposure (Chen & Hoek, 2020; Hendryx & Luo, 2020; Murray et al., 2020; Orellano et al., 2020; WHO, 2021). Studies have also highlighted a variety of health issues affected by air pollution that may be less well-known, including stroke, hypertension, diabetes, mental health effects, and negative reproductive and birth effects (Downey & van Willigen, 2005; Malin, 2020; Thurston et al., 2017; WHO, 2021).

Natural gas compressor stations emit a variety of airborne pollutants (D. R. Brown et al., 2015; Green & Crouch, 2021; Hendryx & Luo, 2020; Johnson et al., 2015; Olaguer, 2012; Russo & Carpenter, 2017; Strizhenok & Korelskiy, 2019; van der A et al., 2020; Walter, 2020; White et al., 2019). Compressor stations can have a significant effect on local air quality; in some rural environments, emissions from compressor stations can account for 98%–99% of VOC ozone precursors and 57%–61% of NO_x ozone precursors (Adgate et al., 2014). The main chemical emissions discussed below and highlighted in Table 1 are noteworthy because of their roles in two major forms of air pollution: smog and PM.

2.1. Atmospheric Smog

Ozone, a strong oxidant, is primarily responsible for the negative health effects associated with urban smog. Tropospheric ozone is formed through a series of photochemical reactions involving NO and NO₂, collectively referred to as NO_x. This photochemical pathway is the only significant source of ground-level ozone (Baird & Cann, 2005; Seinfeld & Pandis, 2016); many regulations and research studies use concentrations of NO_x or NO₂ as an indicator for overall severity of air pollution where ozone is a concern.

 NO_x are consumed in radical reactions producing ozone, so local NO_x concentrations become depleted over a timescale of a few hours. When highly reactive gas-phase VOCs are present, the VOCs also participate in photochemical reactions generating radicals and producing ozone, thus extending the lifetime of a smog event from a few hours to throughout the day (Baird & Cann, 2005).

2.2. Particulate Matter

PM encompasses a diverse group of atmospheric particles with a vast range of sources (biogenic and anthropogenic), chemical compositions, and sizes. The composition of PM is determined by its source. For example, particulates created from combustion, like those emitted by compressor stations, often have high levels of hazardous polyaromatic hydrocarbons (PAHs) (Baird & Cann, 2005; Lloyd & Cackette, 2001; U.S. EPA, 2019) and may also contain metals (Morajkar et al., 2020; Thiruvengadam et al., 2015; U.S. EPA, 2019).

 PM_{10} , particulates with an average diameter of 10 microns or less, are generally small enough to pass through the nose and throat and enter the lungs (Baird & Cann, 2005; Seinfeld & Pandis, 2016). With an average diameter



Emissions	Health effects	Regulatory exposure limits
Nitrogen oxides (NO _{χ}), including nitric oxide (NO) and nitrogen dioxide (NO ₂)	Respiratory irritation and asthma; enhanced allergic responses. ^a Ground-level smog; reacts to produce ozone. Reacts to produce nitric acid; ^b adverse respiratory effects when inhaled ^c	NAAQS primary standard: 53 ppb per year or 100 ppb per hour; secondary standard: 53 ppb per year. ^{d.e.} CAAQS: 0.18 ppm per hour or 0.030 ppm per year. ^{e.f.} WHO: 5.3 ppb per year or 13 ppb per day ^{e.g.}
Ozone (O ₃)	Respiratory irritation, decreased lung function, and asthma ^{,c,g,h} premature death notably linked to worsening of respiratory disease ^{g,h}	NAAQS primary and secondary standards: 0.070 ppm per 8 hr. ^d CAAQS: 0.070 ppm per 8 hr or 0.09 ppm per hour. ^f WHO: 0.05 ppm per 8 hr or 0.03 ppm in peak season ^g
Volatile organic compounds (VOCs)	Ground-level smog; reacts to produce ozone. Reacts to produce secondary organic aerosols, a type of PM. ⁴ Many have negative respiratory effects, are known or potential carcinogens, and can negatively affect neurological and/or cardiovascular systems ⁴	N/A
Particulate matter smaller than 10 μ m (PM ₁₀)	Respiratory irritation and asthma; cardiovascular diseases; lung cancer, k,l increased respiratory, cardiovascular, and cerebrovascular mortality k,m,n	NAAQS primary and secondary standard: 150 μ g/m ³ per day. ⁴ CAAQS: 50 μ g/m ³ per day or 20 μ g/m ³ per year. ⁶ WHO: 45 μ g/m ³ per day or 15 μ g/m ³ per year ⁸
Particulate matter smaller than 2.5 μ m (PM _{2.5})	Respiratory irritation and asthma; cardiovascular diseases; lung cancer, $k^{\rm d}$ increased respiratory, cardiovascular, and cerebrovascular mortality $k_{\rm m,m}$	NAAQS primary standard: 12.0 μ g/m ³ per year; secondary standard: 15.0 μ g/m ³ per year; or primary and secondary standards: 35 μ g/m ³ per day. ^d CAAQS: 12 μ g/m ³ per year. ^f WHO: 5 μ g/m ³ per year or 15 μ g/m ³ per day ^g
^a U.S. EPA (2016). ^b Seinfeld and Pandis (2016). ^c PubChem dat for NO ₂ . ^f California Ambient Air Quality Standards (CAAQS), EPA (2020). ⁱ Qin et al. (2021). ^j Halios et al. (2022). ^k U.S. EPA (^a U.S. EPA (2016). ^b Seinfeld and Pandis (2016). ^c PubChem database, see Kim et al. (2021). ^d National Ambient Air Quality Standards (NAAQS), see U.S. EPA (202d). ^e Standards are specifically for NO ₂ . ^f California Ambient Air Quality Standards (CAAQS), see California Air Resources Board (2016). ^e World Health Organization (WHO) global air quality guidelines, see WHO (2021). ^h U.S. EPA (2020). ⁱ Qin et al. (2021). ^j Halios et al. (2022). ^k U.S. EPA (2019). ¹ Chen and Hoek (2020). ^m Gray et al. (2015). ⁿ Orellano et al. (2020).	ls (NAAQS), see U.S. EPA (2022d). "Standards are specificall on (WHO) global air quality guidelines, see WHO (2021). ^h U.S 20).

of 2.5 microns or less, $PM_{2.5}$ particulates are small enough to bypass bronchial cilia and other natural respiratory protections and interact directly with lung tissue (Baird & Cann, 2005). Because of this, $PM_{2.5}$ is associated more strongly with negative health effects than PM_{10} (U.S. EPA, 2019) and thus is generally targeted more often in research and policy.

Due to the complexity of PM, it has proven difficult to isolate specific properties that contribute to or correlate with the most significant toxicity (Gray et al., 2015; Hime et al., 2018; WHO, 2021). Despite this, the broad effects of PM exposure are well-understood and proven by decades of research (Chen & Hoek, 2020; Orellano et al., 2020; U.S. EPA, 2019; WHO, 2021). Notably, short-term exposure, even on the time scale of hours to days, is associated with increased respiratory, cardiovascular, and cerebrovascular mortality (Gray et al., 2015; Orellano et al., 2020), likely representing deaths within the most vulnerable groups of the population. This is of particular importance given the tendency to place natural gas infrastructure in communities with EJ concerns (Emanuel et al., 2021).

3. Chemical Emissions From Compressor Stations: Evaluating the Context of Atmospheric and Health Data

3.1. Availability and Quality of Data

Prediction and quantification of health impacts from air pollution is complicated by many factors. Generally, a lack of data leads to challenges for establishing baseline levels of air composition and health factors in a community (D. Brown et al., 2014; Nathan et al., 2015). Potential chronic health effects require years of data to track and are therefore widely under-examined (Hendryx & Luo, 2020). Point-source emitters like compressor stations are also difficult to track with regards to accurate spatial and temporal fluctuations in pollutant concentrations. For instance, a study investigating air quality data from the Pennsylvania Department of Environmental Protection found that data averaged over long periods of time do not accurately capture short, high-intensity chemical emissions events, such as compressor station blowdowns (D. R. Brown et al., 2015). Due to low sampling frequency and suboptimal siting, existing air quality monitoring may not always be representative of actual exposure for nearby community members (D. R. Brown et al., 2015; Transcontinental Gas Pipe Line Company LLC, 2019).

3.2. Degree of Exposure and Cumulative Health Impacts

A pollutant's mechanism of toxicity and degree of exposure are factors that affect the nature and severity of the pollutant's adverse health effects. The degree of exposure depends on the local concentration and atmospheric lifetime of a pollutant, two behaviors that are difficult to predict. Physical factors such as local geography and weather patterns can significantly impact pollutant concentrations (Baird & Cann, 2005; D. R. Brown et al., 2015; Mukerjee et al., 2019; WHO, 2021). For example, even the direction of wind can have additive or depleting effects on air pollution levels (Mukerjee et al., 2019).

The lifetime of an airborne pollutant also plays a role in the length of exposure. The atmospheric lifetime of a pollutant is terminated when the pollutant reacts to turn into a different chemical or deposits out of the atmosphere. Atmospheric reactions are typically complex and may vary considerably depending on the exact composition of the local chemical environment (Seinfeld & Pandis, 2016). In some cases, pollutants may undergo reactions to form other hazardous products. Additionally, PM can be created or modified when airborne chemicals aggregate, deposit onto an existing surface, or react with the chemical components of the PM (Seinfeld & Pandis, 2016). These factors affect the composition, lifetime, and fate of airborne pollutants, and are therefore important to consider when evaluating risks of chemical exposure.

There are many studies on negative health effects from exposure to one single type of pollutant or simple mixtures of common pollutants, but compressor stations emit more complex mixtures. A mixture of chemicals can change how pollutants are taken up by the body, as well as how fast the body can break them down (Löf & Johanson, 1998; Péry et al., 2013; WHO, 2021). This is particularly important because VOCs often react in the atmosphere and form different chemicals as secondary pollutants; when evaluating how a mixture of pollutants can change the severity of health effects, secondary pollutants also need to be considered.

Another complication is the possibility for compounding effects from other nearby polluting sources. Compressor stations are often located near other industrial units and infrastructure due to more convenient zoning and



ease of access (Johns & Howell, 2016; Messersmith, 2015; Miles, 2016). These other infrastructure elements also contribute to airborne pollution (HEI Panel on the Health Effects of Traffic-Related Air Pollution, 2010; Henneman et al., 2021; Lloyd & Cackette, 2001; Wang et al., 1999). Further, pollutants can travel up to hundreds of miles depending on geographic and weather conditions, such that rural communities can be exposed to significant amounts of urban pollutants (Baird & Cann, 2005; Mukerjee et al., 2019). It is apparent that the health risks of pollution combine, and may compound, with multiple exposures (Chestnut & Mills, 2005), so a complete risk analysis for a community must consider cumulative health risks.

3.3. National Ambient Air Quality Standards

Compressor stations are regulated by both federal and state laws. Although the EPA classifies a compressor station as a minor stationary emission source, numerous examples of NAAQS violations have been documented at compressor stations (Babich, 2018). This is often because the NAAQS specify different timescales of measurement for different pollutants depending on their lifetime in the atmosphere, but these measurement timescales may not be relevant for compressor stations that release a significant amount of emissions in a short time period, especially during blowdowns.

NAAQS are enforced through state-dependent "state implementation plans" (SIPs). These SIPs are EPA-approved documents that define each state's approach to ensure air quality is monitored and is compliant with the NAAQS (42 U.S.C. §7401 et seq.). Under the guidance of the EPA, each SIP outlines the requirements for sources of emissions to self-monitor and self-report controlled pollutants. Under this arrangement, the public must assume these sources will adequately monitor themselves. Although SIPs require self-report data that is unreliable due to poor measurement practices (Babich, 2018). Such concerns highlight the importance of total transparency in the process of collecting, reporting, and analyzing emissions data, as well as actively alerting the public of non-compliance emissions events.

Furthermore, the NAAQS have faced criticism from experts (D. B. Brown & Rajan, 2022; Independent Particulate Matter Review Panel, 2020). For example, an independent EPA scientific advisory board expressed the need for tighter PM standards, claiming the current NAAQS for $PM_{2.5}$ is not stringent enough to protect human health and emphasizing that any exposure to $PM_{2.5}$ is harmful (Independent Particulate Matter Review Panel, 2020). Even the newly revised $PM_{2.5}$ standards are not adequate (American Lung Association, 2023c; WHO, 2021). The American Lung Association also recently urged the EPA to lower its primary ozone standard, particularly emphasizing the health of people at higher risk (D. B. Brown & Rajan, 2022). Therefore, while there are federal regulations on compressor station emissions, we find that those regulations may not be sufficient to protect community health from negative health outcomes, especially for communities with EJ concerns where compounding factors often result in more severe negative effects (Adler & Rehkopf, 2008; American Lung Association, 2023b; Murray et al., 2020; Simoni et al., 2015).

3.4. Indoor Air Quality

On average, Americans spend 60%–95% of their time in their homes (U.S. BLS, 2020). Residential buildings are typically not well ventilated and often recycle air only 0.35 times per hour. This low level of air turnover can lead to an accumulation of pollutants from outside the home (ASHRAE, 2019; U.S. EPA, 2021a). Studies show that homes near compressor stations have VOC levels that exceed NAAQS, and that indoor VOC levels are often higher than levels measured just outside the homes (Caron-Beaudoin et al., 2022; Martin et al., 2021). As suggested by current literature, we concur that current modeling of emission plumes and outdoor pollutants is not enough to ensure that compressor stations do not negatively affect the health of nearby residents, especially when considering the variability caused by weather events and on-site activities (Martin et al., 2021; Payne et al., 2017). Further, Caron-Beaudoin et al. (2022) point out that the environmental burden, and therefore the indoor air quality, of gas infrastructure lays heavily on communities with EJ concerns.

4. Community Impacts of Compressor Station Development

Many communities across the United States have felt the impacts of natural gas infrastructure, illustrating real world impacts of compressor stations on human health. The Marcellus Shale region of Pennsylvania is a hotspot for natural gas development. Within 10 years between 2008 and 2018, 15,939 natural gas wells were drilled in

this region (Jacquet et al., 2018). As of 2019, Pennsylvania contained more than 500 compressor stations (Pennsylvania Department of Environmental Protection (PA DEP), 2019). The monetized damages associated with air pollution from natural gas extraction, including compressor stations, in Pennsylvania during 2011 has been estimated at \$7,000,000–\$32,000,000 (Litovitz et al., 2013).

The Marcellus Shale region has been a model for studies focusing on how compressor stations impact human health. During a study in Washington County PA, the U.S. Agency for Toxic Substances and Disease Registry (ATSDR) and the EPA identified nine pollutants as being above the recommended exposure limit, potentially affecting elderly or asthmatic persons (ATSDR, 2016). Other studies in the Marcellus Shale Region report that proximity to unconventional natural gas activity is associated with higher risk of heart failure (McAlexander, 2019), asthma (Rasmussen et al., 2016), depression and anxiety (Blinn et al., 2020), and disordered sleep (Casey et al., 2018). Despite strong links between natural gas development and disease, compressor station chemical emissions data remains sparse. In order to fully understand the impacts of compressor station emissions, air quality should be measured in more locations with increased frequency (Long et al., 2019).

Analyzing potential health impacts on surrounding communities is an important step in the natural gas development process, but these analyses are at risk of bias and inaccuracy. Mountain Valley Pipeline, LLC (MVP) planned to construct a new compressor station in Pittsylvania County VA, and commissioned Green Toxicology, LLC to conduct an air quality assessment. The MVP air quality permit was denied based on the report's failure to address EJ concerns according to the Virginia Environmental Justice Act (VA Air Pollution Control Board, 2021; Vogelsong, 2021). The report claims that PM from the compressor station would not aggravate asthma symptoms, despite clear evidence that PM irritates the respiratory system and can induce asthma (D. Brown et al., 2014; U.S. EPA, 2016; Volkodaeva & Kiselev, 2017).

Conflicts of interest in the consulting industry may lead to inadequate analyses of community impacts. One of the scientists from the MVP report has been challenged in the past on some of her claims (Wittenberg, 2021). While conflict of interest disclosures are required by the Federal Energy Regulatory Commission (FERC), they do not vet these disclosures, and other regulatory agencies may not have such requirements.

5. Policy Recommendations

The community health risks associated with living near a compressor station warrant stricter oversight by governments at the local, state and federal levels. Below, we describe several policy recommendations to limit air pollution exposure, assess community impacts, and increase transparency in the decision-making process.

5.1. Increase Air Quality Monitoring and Data Transparency

Increased air quality monitoring at compressor stations is an utmost priority to address both acute and long-term exposure effects. Although compressor stations are almost exclusively placed in rural areas, the EPA maintains most of their monitoring stations in urban areas (U.S. EPA, 2022a). Additionally, indoor air quality in homes near compressor stations is a concern (Martin et al., 2021). Natural gas suppliers in Pennsylvania, Ohio, and Louisiana have faced heavy fines for CAA violations at compressor stations, but a lack of consistent emission reporting makes it challenging to certify compliance at all sites (Russo & Carpenter, 2019; U.S. EPA, 2022c; Wright, Jr, 2022). Although emissions can be modeled, previous monitoring shows that where direct air quality measurements are taken, pollutant levels often exceed those produced by modeling techniques (Babich, 2018).

Ideally, monitoring should be continuous to capture the variability in air pollution emissions and blowdown periods when emissions are released in concentrated bursts. Without continuous monitoring, NAAQS violations will likely be missed in the data record (Babich, 2018). Continuous monitoring would also provide data for long term exposure studies, as prolonged exposure to lower levels of air pollution can also lead to negative health outcomes (Independent Particulate Matter Review Panel, 2020).

We recommend the EPA direct more resources toward monitoring programs at compressor stations and encourage states to incorporate monitoring into their CAA state implementation plans. Since natural gas infrastructure is concentrated in communities with EJ concerns, increased monitoring can also help federal and state agencies contribute to EJ initiatives such as Justice40 at the federal level (Emanuel et al., 2021; The White House, 2023). Pennsylvania has made recent progress in this area and can be a model for other states (Wolf & McDonnell, 2017).



The EPA should also require that data collected in air quality monitoring near compressor stations is accessible and transparent to the public, ideally in easy-to-read maps with downloadable files containing the full data time series. There are existing tools, such as the EPA's AirData Air Quality Monitors application, but these tools should be comprehensive, including all data available to the EPA. We also recommend that the EPA conducts free indoor air quality tests upon request for homes that are within about 10 miles of a compressor station to make sure that community members are aware of health hazards they may face.

5.2. Stricter NAAQS

Even if monitoring improves and NAAQS are more consistently met by compressor stations, these standards do not adequately protect human health from exposure to air pollutants (American Lung Association, 2023a; American Lung Association et al., 2020; D. B. Brown & Rajan, 2022; Independent Particulate Matter Review Panel, 2020). Moving forward, air quality standards need to change to reflect the reality of cumulative exposures to air pollutants that many communities with EJ concerns face (Behles, 2011). We recommend that EPA adjusts the following standards to match the World Health Organization (WHO) (see Table 1 and Figure 1): NO₂ (5.3 ppb per year; 13 ppb per day), O₃ (0.03 ppm in peak season; 0.05 ppm per 8 hr), PM_{2.5} (5 μ g/m³ per year; 15 μ g/m³ per day). We also recommend that NAAQS more strongly consider cumulative health impacts by evaluating a realistic mixture of air rather than a single pollutant on its own (Behles, 2011). Recognizing that changing the NAAQS is a challenging process, the EPA should at least incorporate cumulative impacts into its risk assessments. Cumulative impacts are often an issue in communities with EJ concerns, which makes proper evaluation all the more important.

5.3. Assess Community Impacts and Promote Community Engagement

Air pollutants often disproportionately impact communities with EJ concerns, yet air quality standards are not set with these communities in mind. Very little is understood about the cumulative impacts of exposure to air pollutants and regulations are developed assuming each exposure occurs independently when this is not often the case (Adgate et al., 2014). It appears that the Air Quality Index is the only metric that considers multiple exposure sources (U.S. EPA, 2021b). This index is based on regulation; it alerts residents of a particular area when one or all of the six core air pollutants exceeds recommended thresholds for human health (U.S. EPA, 2021b), but it is not related to control of industry emissions.

Community engagement has been recognized as a ladder of citizen participation, where at the lowest rung community members have little control over the decision-making process (Arnstein, 1969). These lower levels of engagement allow for citizens to speak their views, but with little to no impact. Others have suggested more meaningful forms of engagement wherein the community actively works with the decision-makers to reach a mutually beneficial agreement (Bidwell, 2016; Hagget, 2011). With this context in mind, we recommend that proposed compressor station activities require meaningful involvement from potentially affected community members. We define meaningful involvement based on the Virginia Environmental Justice Act (§2.2–234); this would require that decision-makers actively seek out feedback from affected community members. Although meaningful involvement may take many forms, examples include community advisory boards or workshops for community members; these items are explored in more detail elsewhere (Hagget, 2011; Innes & Booher, 2007; Luyet et al., 2012). Any actions taken to improve community involvement should be thoroughly critiqued to ensure adequate citizen participation (Rowe et al., 2004). Community involvement will help to ensure that the community's needs are met during the development process, and that citizens are actively included in future decision-making processes.

Digital rights and data transparency play important roles in ensuring meaningful community engagement in the decision-making process. Although open government data initiatives have been deployed across the United States in order to increase emissions and air quality data transparency, many state governments may lack commitment to implementing these initiatives for EJ policymaking (Fusi et al., 2022). Although recent work in this area has focused on developing user friendly data visualization (Valencia et al., 2020) and setting guidelines for Indigenous data sovereignty (Carroll et al., 2020), the reality of data governance in the United States reveals underlying challenges that may hinder efforts to expand EJ policymaking (Dosemagen & Tyson, 2020; Dosemagen et al., 2022; Vera et al., 2019). As part of the effort to improve data transparency in the compressor station



GeoHealth

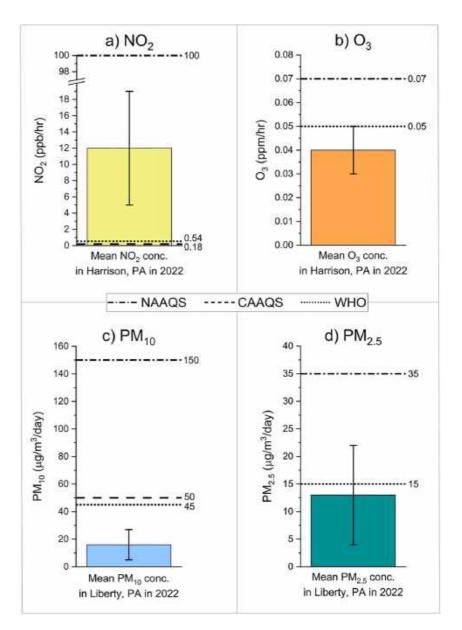


Figure 1. Mean pollutant concentrations are shown here to give a better understanding of the differences between the National Ambient Air Quality Standards (NAAQS), the California Ambient Air Quality Standards (CAAQS), and the World Health Organization (WHO) global air quality guidelines. Data shown are the arithmetic means and standard deviations of measurements taken throughout 2022, sourced from the EPA Air Quality System database. Both measurement locations are within 25 mi of Pittsburgh, PA in the Marcellus Shale region. Data from compressor station blowdowns are not readily available, but these activities increase one-time concentrations significantly. Note that in (a), the WHO guideline for NO₂ exposure per hour is estimated from the 24 hr guideline, and in (b), the CAAQS for O₃ is the same as the NAAQS.

development process, we recommend that developers maintain data transparency regarding emissions and air quality during the review process and environmental data reporting. We suggest that data be published in an accessible manner that may be clearly understood by the affected communities. We recommend, however, that developers must respect the data sovereignty of any affected Indigenous groups, according to the CARE principles for Indigenous data governance (Carroll et al., 2020). To ensure complete transparency, we recommend that FERC vets conflict of interest disclosures to ensure their accuracy. We also recommend that contractors who have worked with pipeline companies in the past should be barred from working on FERC's behalf.

Virginia Department of Environmental Quality's (VA DEQ) Tidewater Air Monitoring Evaluation (TAME) Project provides an excellent example of fostering community involvement in the air monitoring process (VA

DEQ, 2023). As part of this project, the VA DEQ deployed air monitors in two communities with EJ concerns in the Tidewater area to track how nearby coal storage and transportation affects air quality. Real time air quality data is available publicly online. The data collected during this project will be used by the VA Department of Health to communicate potential air quality risks to community members and develop strategies to combat health challenges. For these reasons, the TAME Project serves as a model for programs actively involving communities in the decision-making process and using data transparency to facilitate public knowledge of health impacts.

It is crucial to ensure the community's health and wellbeing during compressor station development and planning. Implementing more stringent air quality standards and considering cumulative exposure risks will help to protect EJ communities that may face air quality concerns from a variety of sources. Community members should be well-informed regarding potential health risks, have easy access to accurate air quality data, and have the opportunity to be an active part of the decision-making process. With these changes, affected communities will have more power to protect citizens' health and advocate for their own needs.

Conflict of Interest

The authors declare no conflicts of interest relevant to this study.

Data Availability Statement

The pollutant concentration data used for Figure 1 in the paper are available through the EPA's AirData website (see U.S. EPA, n.d.), which sources information primarily from the EPA's AQS (Air Quality System) database. On the AirData website, concentration data can be obtained through the interactive AirData Map App by selecting a specific air monitor of interest, or through downloading pre-generated data files.

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This Table shows list of chemicals identified by the EPA TO-15 method of analyzing VOCs in ambient air. The "EHP adjusted value" is EHP's recommended health protective threshold. *Exposure limits from NIOSH and OSHA are for an 8-hr workday schedule. EHP computes lower thresholds for residential areas for 24 hours of exposure, and also includes a calculation for vulnerable individuals including children, the elderly and others who may be more susceptible to these contaminants. This is done by dividing the NIOSH threshold by 30.

Air Test Parameter	Threshold Source	Daily 8-hour Standard in ppm	EHP Adjusted Value* in ppm	Potential Health Effects of Parameter	Potential Carcinogen
1,1,1-Trichloroethan e	NIOSH/ OSHA	350	11	irritation eyes, skin; headache, lassitude, central nervous system depression, poor equilibrium; dermatitis; cardiac arrhythmias; liver damage	
1,1,2,2-Tetrachloroet hane	NIOSH/ OSHA	5	0.16	nausea, vomiting, abdominal pain; tremor fingers; jaundice, hepatitis, liver tenderness; dermatitis; leukocytosis and kidney damage	V
1,1,2-Trichloroethan e	NIOSH/ OSHA	10	0.3	irritation eyes, nose; central nervous system depression; liver, kidney damage; dermatitis	v
1,1-Dichloroethane	NIOSH/ OSHA	100	3.3	irritation of skin; central nervous system depression; liver, kidney, lung damage	
1,1-Dichloroethene	OSHA	1	0.03	irritation eyes, skin, throat; dizziness, headache, nausea, breathing difficulty.	~
1,2,4-Trichlorobenze ne	NIOSH	5	0.16	risk of eye, throat, and dermal irritation associated with exposure to this substance	
1,2,4-Trimethylbenz ene	NIOSH/ OSHA	25	0.83	irritation of respiratory system; bronchitis; hypochromic anemia; headache, drowsiness, lassitude, dizziness, nausea, incoordination; vomiting, confusion; chemical pneumonitis	
1,2-Dibromoethane	NIOSH OSHA	0.045 20	0.0015	irritation eyes, skin, respiratory system; dermatitis with vesiculation; liver, heart, spleen, kidney damage; reproductive effects;	V
1,2-Dichlorobenzene	NIOSH/ OSHA	50	1.66	irritation eyes, nose; liver, kidney damage; skin blisters	
1,2-Dichloroethane	NIOSH OSHA	1 50	0.03	irritation eyes, corneal opacity; depression; nausea, vomiting; dermatitis; liver, kidney, cardiovascular system damage	~
1,2-Dichloropropane	OSHA	75	2.5	irritation eyes, skin, respiratory system; drowsiness, dizziness; liver, kidney damage.	~

Air Test Parameter	Threshold Source	Daily 8-hour Standard in ppm	EHP Adjusted Value* in ppm	Potential Health Effects of Parameter	Potential Carcinogen
1,3,5-Trimethylbenz ene	NIOSH	25	0.83	irritation skin and respiratory system; bronchitis; hypochromic anemia; headache, drowsiness, weakness, exhaustion, dizziness, nausea, incoordination; vomiting, confusion.	
1,3-Butadiene	OSHA	1	0.03	irritation eyes, nose, throat; drowsiness, dizziness; liquid: frostbite; teratogenic, reproductive effects	~
1,3-Dichlorobenzene	NIOSH OSHA	50	1.67	Skin and eye irritation	
1,4-Dichlorobenzene	OSHA	75	2.5	Eye irritation, swelling periorbital; profuse rhinitis; headache, anorexia, nausea, vomiting; weight loss, jaundice, cirrhosis	~
1,4-Dioxane	NIOSH OSHA	1 100	0.03	irritation eyes, skin, nose, throat; drowsiness, headache; nausea, vomiting; liver damage; kidney failure	~
2-Butanone	NIOSH/ OSHA	200	6.67	irritation eyes, skin, nose; headache; dizziness; vomiting; dermatitis	
2 Hexanone	NIOSH OSHA	1 100	0.03	irritation eyes, nose; peripheral neuropathy, weakness, exhaustion, paresthesia; dermatitis; headache, drowsiness	
2 Propanol	NIOSH/ OSHA	400	13.33	irritation eyes, nose, throat; drowsiness, dizziness, headache; dry cracking skin.	
4-Methyl-2-pentano ne	NIOSH OSHA	50 100	1.67	irritation eyes, skin, mucous membrane; headache, narcosis, coma; dermatitis; In Animals: liver, kidney damage	
Acetone	NIOSH OSHA	250 1000	8.33	irritation eyes, nose, throat; headache, dizziness, central nervous system depression; dermatitis	
Benzene	NIOSH OSHA	0.1 0.2 1	0.003	Eye nose and skin irritation, respiratory problems, headache, nausea, dermatitis, bone marrow reduction.	~
Benzyl chloride	NIOSH/ OSHA	1	0.03	irritation eyes, skin, nose; weakness, exhaustion; irritability; headache; skin eruption.	
Bromodichlorometh ane	NIOSH	0.5	0.02	irritation eyes, skin, respiratory system; central nervous system depression; liver, kidney damage	~
Bromoform	NIOSH/ OSHA	0.5	0.02	irritation eyes, skin, respiratory system; central nervous system depression.	
Bromomethane	OSHA	20	0.67	irritation respiratory system; incoordination, visual disturbance, dizziness; nausea, vomiting, headache; malaise; hand tremor; convulsions; dyspnea; skin vesiculation; liquid: frostbite	~

Air Test Parameter	Threshold Source	Daily 8-hour Standard in ppm	EHP Adjusted Value* in ppm	Potential Health Effects of Parameter	Potential Carcinogen
Carbon desulphate	NIOSH	1 20	0.03	dizziness, headache, poor sleep, anxiety, anorexia, weight loss; coronary heart disease; gastritis; kidney, liver injury; eye, skin burns; dermatitis;	
Carbon tetrachloride	NIOSH	1	0.03	reproductive effects Eye irritation, nausea, vomiting, drowsiness, dizziness, skin irritation, liver and kidney problems, central	
	OSHA	10		nervous system problems, incoordination	
Chlorobenzene	OSHA	75	2.5	irritation eyes, skin, nose; drowsiness, incoordination; central nervous system depression;	
Chloroethane	OSHA	1000	33.33	incoordination, inebriation; abdominal cramps; cardiac arrhythmias, cardiac arrest; liver, kidney damage	
Chloroform	NIOSH	2	0.07	irritation eyes, skin; dizziness, mental dullness, nausea, confusion; headache, lassitude, enlarged liver.	~
Chloromethane	OSHA OSHA	50 100	3.33	dizziness, nausea, vomiting; visual disturbance, stagger, slurred speech, convulsions, coma; liver, kidney damage; liquid: frostbite;	~
cis-1,2-Dichloroethe ne	OSHA	200	6.67	irritation eyes, respiratory system; central nervous system depression	
cis-1,3-Dichloroprop ene	NIOSH	1	0.03	irritation eyes, skin, respiratory system	
Cumene	NIOSH/ OSHA	50	1.67	irritation eyes, skin, mucous membrane; dermatitis; headache, narcosis, coma	
Cyclohexane	NIOSH/ OSHA	300	10	irritation eyes, skin, respiratory system; drowsiness; dermatitis; narcosis, coma	
Dibromochlorometh ane	EPA	0.7	0.02	Liver and kidney cancer	~
Dichlorodifluoromet hane	NIOSH/ OSHA	1000	33.33	dizziness, tremor, unconsciousness, cardiac arrhythmias, cardiac arrest; liquid: frostbite	
Ethyl acetate	NIOSH/ OSHA	400	13.33	irritation eyes, skin, nose, throat; narcosis; dermatitis	
Ethyl Benzene	NIOSH/ OSHA	100	3.33	Eye and skin irritation, headache, dermatitis, and respiratory problems.	
Freon 113	OSHA	1000	33.33	irritation skin, throat, drowsiness, dermatitis; central nervous system depression.	
Freon 114	NIOSH/ OSHA	1000	33.33	irritation respiratory system; asphyxia; cardiac arrhythmias, cardiac arrest; liquid: frostbite	
Heptane	NIOSH/ OSHA	85 500	2.83	dizziness, stupor, incoordination; loss of appetite, nausea; dermatitis; unconsciousness	

Air Test Parameter	Threshold Source	Daily 8-hour Standard in ppm	EHP Adjusted Value* in ppm	Potential Health Effects of Parameter	Potential Carcinogen
Hexachlorobutadien e	NIOSH	0.02	0.0006	irritation eyes, skin, respiratory system	~
Hexane	NIOSH/ OSHA	50 500	1.67	irritation eyes, nose; nausea, headache; peripheral neuropathy: numb extremities, muscle weakness; dermatitis; dizziness;	
p-Xylene	NIOSH/ OSHA	100	3.33	irritation eyes, skin, nose, throat; dizziness, drowsiness, incoordination, anorexia, nausea, vomiting, abdominal pain; dermatitis	
Methylene chloride	OSHA	25	0.83	irritation eyes, skin, , exhaustion, drowsiness, dizziness; numb, tingle limbs; nausea	~
MTBE	ACGIH	40	1.33 pm	respiratory tract irritation, headache, nausea, and dizziness	
Naphthalene	NIOSH/ OSHA	10	0.33	irritation eyes; headache, confusion, excitement, malaise; nausea, vomiting, abdominal pain; irritation bladder; profuse sweating; jaundice; hematuria, renal shutdown; dermatitis, optical neuritis, corneal damage.	
o-Xylene	NIOSH/ OSHA	100	3.33	irritation eyes, skin, nose, throat; dizziness, excitement, drowsiness, incoordination, staggering gait; corneal vacuolization; anorexia, nausea, vomiting, abdominal pain; dermatitis	
Propene	OSHA	100	3.33	irritation eyes, skin, respiratory system; skin blisters, burns	~
Styrene	NIOSH/ OSHA	50 100	1.67	irritation of respiratory system; headache, dizziness, confusion, malaise, drowsiness, unsteady gait; narcosis; defatting dermatitis; possible liver injury; reproductive effects	
Tetrachloroethene	OSHA	100	3.33	Irritation of skin and respiratory system; nausea; flush face, neck; dizziness, incoordination; headache, drowsiness.	~
Tetrahydrofuran	NIOSH/ OSHA	200	6.67	Irritation respiratory system; nausea, dizziness, headache, central nervous system depression	
Toluene	NIOSH/ OSHA	100 200	3.33	Eye and nose irritation, exhaustion, confusion, dizziness, watery eyes, anxiety, insomnia, dermatitis, liver and kidney damage	~
trans-1,3-Dichloropr opene	NIOSH	1	0.03	irritation eyes, skin, respiratory system; eye, skin burns; lacrimation; headache, dizziness.	~
Trichloroethene	OSHA	100	3.33	irritation eyes, skin; headache, visual disturbance, lassitude, dizziness, tremor, drowsiness, nausea, vomiting; dermatitis; cardiac arrhythmias, paresthesia; liver injury	4

Air Test Parameter	Threshold Source	Daily 8-hour Standard in ppm	EHP Adjusted Value* in ppm	Potential Health Effects of Parameter	Potential Carcinogen
Trichlorofluorometh ane	NIOSH/ OSHA	1000	33.33	incoordination, tremor; dermatitis; cardiac arrhythmias, cardiac arrest.	
Vinyl acetate	NIOSH	4	0.13	irritation eyes, skin, nose, throat; hoarseness, cough; loss of smell; eye burns, skin blisters	
Vinyl chloride	OSHA	1	0.03	abdominal pain, gastrointestinal bleeding; enlarged liver; pale extremities.	~
Formaldehyde	NIOSH OSHA	0.016 0.75	0.0005	Irritation of the respiratory system	~
Hydrogen Sulfide	NIOSH	10	0.33	Irritation of the respiratory system	~

To convert ppm (parts per million) to ppbV (parts per billion by volume) multiply by 1000 (ALS unit of measurement in summa reports).

Exposure limits mentioned in the table above are for an 8-hour workday schedule. *EHP adjusted threshold to consider action (24-hour value for susceptible groups). This is calculated by dividing the NIOSH value by 30.

EHP recommends using NIOSH values as this is the United States federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness

Threshold Sources

ACGIH: The American Conference of Governmental Industrial Hygienists OSHA: Occupational Safety and Health Authority NIOSH: National Institute for Occupational Safety and Health EPA: Environmental Protection Agency

Acronyms

ppm: Parts per million

A ANNUAL REVIEWS

Annual Review of Public Health Hazardous Air Pollutants Associated with Upstream Oil and Natural Gas Development: A Critical Synthesis of Current Peer-Reviewed Literature

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Keywords

hazardous air pollutants, volatile organic compounds, oil and natural gas, air quality, oil and gas development

Abstract

Increased energy demands and innovations in upstream oil and natural gas (ONG) extraction technologies have enabled the United States to become one of the world's leading producers of petroleum and natural gas hydrocarbons. The US Environmental Protection Agency (EPA) lists 187 hazardous air pollutants (HAPs) that are known or suspected to cause cancer or other serious health effects. Several of these HAPs have been measured at elevated concentrations around ONG sites, but most have not been studied in the context of upstream development. In this review, we analyzed recent global peer-reviewed articles that investigated HAPs near

ONG operations to (*a*) identify HAPs associated with upstream ONG development, (*b*) identify their specific sources in upstream processes, and (*c*) examine the potential for adverse health outcomes from HAPs emitted during these phases of hydrocarbon development.

1. INTRODUCTION

Over the past several decades, as energy demands have increased contemporaneously with innovations in upstream oil and natural gas (ONG) extraction technologies, the United States has become the world's top producer of petroleum and natural gas hydrocarbons (34). The US Energy Information Administration (104) reported that US petroleum and other liquid fuel production reached 9.3 million barrels per day, and dry natural gas production averaged 73.6 billion cubic feet per day in 2017, with increases projected for 2018 and 2019. In some areas, including Pennsylvania, Colorado, Texas, and California, ONG extraction and development have expanded closer to residential communities, increasing risks of population exposures to air, water, soil, noise, and light pollution. Research suggests that current setback standards—or distances in which the ONG industry can develop from water sources, residential structures, and other facilities-may not be sufficient to reduce potential risks to human health from ONG activities (12, 53). A growing, yet still relatively small body of studies has investigated the relationship between the proximity of these facilities and human health impacts (21, 22, 31, 60, 78, 79, 96, 97, 99). With a dearth of scientific data characterizing exposure risks, it is difficult to offer scientific guidance on specific adequate setback requirements, despite the fact that an estimated 18 million people live within 1,600 m (\sim 1 mile) from an active ONG well (32). Special disclosure exemptions from the federal Emergency Planning and Community Right-to-Know Act allow the ONG industry to withhold information regarding chemical constituents used, produced, and emitted, further compounding the difficulty in identifying chemical-related hazards and their associated exposure pathways (106).

The current body of scientific literature suggests that upstream ONG development processes emit numerous air pollutants, including methane, nonmethane-volatile organic compounds (VOCs), particulate matter (PM), aliphatic and aromatic hydrocarbons, aldehydes, and nitrogen oxides, some of which are also precursors to tropospheric ozone and secondary organic aerosol (SOA) production (18, 41, 89, 95, 111, 115, 122). Upstream ONG development includes all phases and processes necessary to extract ONG hydrocarbons from subsurface reservoirs, excluding the transportation, transmission, storage, refinement, and wholesale of refined products. Upstream processes consist of four broad phases of operation: (a) exploration and well pad and infrastructure construction; (b) well drilling and construction of associated surface and subsurface equipment and facilities; (c) application of well stimulation or secondary oil and gas recovery techniques (e.g., water flooding and steam injection) and completion, or both; and (d) hydrocarbon production and processing. Various attempts to identify and classify all products and chemicals used or emitted during the upstream ONG development process have resulted in disparate lists ranging from 343 to 1,177 unique chemicals, some classified as HAP compounds with known carcinogenic and noncarcinogenic toxicological properties (26, 38, 82, 108). Current research on oil and gas development provides conflicting evidence over the concentrations of various pollutants in the air across geographic, regulatory, and corporate spaces; however, a consensus exists regarding the presence of air pollutants that can pose human health hazards around ONG sites (19, 27, 48, 56, 68, 73, 79, 88).

Emissions of hazardous air pollutants (HAPs) from ONG are of particular concern because they are known or suspected to cause cancer or other serious noncancer health effects. The US Clean Air Act currently lists 187 HAPs for regulation (107), some of which have been associated with ONG activities. The Committee on Energy and Commerce and the Endocrine Disruption Exchange have identified more than 20 different HAPs, which have been associated with upstream ONG activities or processes (101, 109). While the number of studies examining the human health impacts of ONG development is growing, limited information exists on the role of HAPs in the upstream process and the health impacts of HAP-related emissions (18, 44, 80, 114).

The purpose of this review is to summarize the research conducted to date on the associations between HAPs and upstream ONG development. Specifically, this article aims to (*a*) identify HAP compounds that have been investigated near upstream operations within the peer-reviewed literature; (*b*) determine which of these compounds has been traced to a specific upstream phase, process, or source; and (*c*) examine the potential health hazards attributable to these HAPs. Our synthesis of the science is intended to inform future research priorities and to assist in public health protection. A list of ONG industry terms can be found in the sidebar titled Terms and Definitions.

TERMS AND DEFINITIONS

Anthropogenic: originating from human activities. With air pollution, these activities include those related to transportation (or mobile), agriculture, or industry sources.

BTEX: the group of compounds, including benzene, toluene, ethylbenzene, and total xylenes. These compounds occur naturally in petroleum and are released primarily through motor vehicle emissions, but they are also emitted naturally via volcanoes and forest fires.

Condensate: broadly defined as a liquid formed by condensation. With oil and natural gas, condensate is a gas that condenses into a liquid hydrocarbon mixture after being liberated from the high-pressure environment within a well.

Hazardous air pollutant (HAP): the US EPA defines HAPs as pollutants that are known or suspected to cause cancer or other serious health effects, such as reproductive effects or birth defects, or adverse environmental effects.

Oil and natural gas (ONG): describing both liquid and gas fossil fuel products. Oil refers to crude oil hydrocarbon mixtures that exist in liquid form, whereas natural gas consists mainly of methane (CH₄), a small amount of hydrocarbon gas liquids, and nonhydrocarbon gases. Oil, gas, and liquid gas hydrocarbons can be found in underground reservoirs, sedimentary rocks, or tar sands and can be recovered in the near absence of the other forms or simultaneously.

Polycyclic aromatic compounds (PAHs): a class of organic compounds composed of multiple aromatic rings that occur naturally in crude oil. More than 100 different PAHs exist, including benzo[a]pyrene, benz[a]anthracene, and chrysene, with varying degrees of toxicity.

Petrogenic: originating from hydrocarbons formed by the decomposition of organic matter. In regard to petrogenic air pollutants, these may be released when fuel oil and crude oil are exposed during upstream oil and natural gas operations.

Polycyclic organic matter (POM): defines a broad class of compounds that generally includes structures containing 2–7 fused aromatic rings and are present in the atmosphere mostly in particle form. PAHs are a subset of POMs.

Proppant: a material (often sand) used to prop open cracks within fractured shale rocks to harvest oil, natural gas, or other targeted materials. Proppant is often mixed with a chemical liquid mixture and forced into shale formations at high pressure.

Reference effect level (REL): a reference exposure level from the Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency (Cal/EPA). The REL is a concentration of a single chemical at or below which adverse noncancer health effects are not anticipated to occur for a specified exposure duration. RELs have been developed for a limited number of compounds for acute, eight-hour, and chronic exposures.

Repository for Oil and Gas Energy Research (ROGER) database: PSE's nearly exhaustive database of peer-reviewed literature on shale gas development, which can be found on the PSE website (http://www.psehealthyenergy.org).

Wet gas: a natural gas that contains less than $\sim 85\%$ methane and increased amounts of ethane and other hydrocarbons, as opposed to dry gas, which occurs in the near absence of condensate or liquid hydrocarbons.

2. MATERIALS AND METHODS

2.1. Scope

We began with the inclusion of all 187 HAPs listed by the US Environmental Protection Agency (EPA). Hydrogen sulfide (H_2S) was removed from the official US EPA list in 1991 but was included in our review owing to its toxic properties, detection at low concentrations (0.03–0.05 ppm), and prevalence in oil and gas development operations. From this point forward, when referring to HAPs, we include all 187 compounds listed by the US EPA, plus H_2S for a total of 188 compounds. Given the rapid expansion of ONG development activities over the past few years, only peerreviewed articles published between January 1, 2012, and February 28, 2018, were included in the current review. Many HAPs have been measured and monitored near ONG operations as primary pollutants; however, some HAPs—including, for example, formaldehyde and acetaldehyde—are also secondary pollutants formed from the atmospheric transformation of HAP formation and atmospheric concentrations, HAP precursors fall outside the scope of this review.

2.2. Keyword Search

We developed a list of keywords to assist in a comprehensive literature search of all upstream ONG processes and target pollutants. Owing to the inconsistency of the terminology surrounding the upstream ONG development process, we cast a wide net to be inclusive of possible iterations when building the keyword search. These keywords included, but were not limited to, the terms "fracking," "fracturing," "hydraulic fracturing," "oil and natural gas development," and common acronyms including "UNGD" and "ONG." In all, we incorporated 18 iterations and acronyms. Additionally, we included keywords for transport media to ensure that search results encompassed airborne compounds. We erred on the side of being overly inclusive and integrated broad group names, including volatile organic compounds (VOCs), nonmethane hydrocarbons (NMHCs), and hazardous air pollutants (HAPs) during the search process. Keywords and search queries are provided in **Supplemental Table 1**.

Supplemental Material >

2.3. Electronic Database Search

We searched peer-reviewed journal articles within three electronic search databases in March 2018. First, we searched the Clarivate Analytics Web of Science database (http://www.webofknowledge.com) using their Advanced Search query tool. Boolean operators were

used to narrow English language article search results by topic and by publication timeframe. We also searched PubMed (http://www.ncbi.nlm.nih.gov) to ensure our literature review included a comprehensive search of peer-reviewed journal articles focused on the human health dimensions of upstream ONG development. Results were narrowed by text words and publication timeframe. Search queries resulted in 639 and 1,146 peer-reviewed journal articles in the Web of Science and PubMed, respectively. After comparing databases and eliminating duplicate articles, search results were then compared with PSE Healthy Energy's Repository for Oil and Gas Energy Research (ROGER) database (https://www.psehealthyenergy.org/our-work/shale-gas-research-library/). Articles found in the ROGER database that were not included in searches from the electronic databases were added to the collection, for a final count of 1,833 journal articles. These articles were then collected, organized, and evaluated using the inclusion/exclusion criteria.

2.4. Inclusion and Exclusion Criteria

A Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart shows how the inclusion/exclusion criteria resulted in the final article count (**Figure 1**). We first scanned titles to remove papers from our review on the bases of whether a paper met the following criteria: (*a*) not written in English; (*b*) was a review, commentary, or response paper and not a primary study; and (*c*) did not investigate air quality near ONG development. After reviewing the abstracts and content of the remaining papers, we excluded studies that did not collect primary, modeled, or estimated HAP emissions and concentrations or did not conduct other primary HAP analyses from secondary data sources. We focused on papers that described ground-level or local-level pollutant concentrations and papers that focused on source attribution of HAPs to upstream ONG operations. Several articles using concentrations of HAP compounds to model the formation of secondary non-HAP air pollutions were excluded if they did not directly investigate impacts of local-scale HAP compounds or their emission sources.

3. RESULTS

A total of 37 peer-reviewed journal articles, published between January 1, 2012, and February 28, 2018, met our inclusion/exclusion criteria (**Supplemental Table 2**). One peer-reviewed article focused on ONG operations in Poland, and the rest of the articles focused on operations within the United States. Thirty-one articles (84%) included primary HAP measurements within eight states, including Arkansas, Colorado, Ohio, Oklahoma, Pennsylvania, Texas, Utah, and Wyoming. The remaining articles included primary data analyses from secondary data sources or publicly accessible data sets.

3.1. HAPs Identified Within Review

To enable generalization of results across all studies, we extracted the reported HAP concentrations from the article content, tables, or supporting information; we did not extract concentrations from graphs or figures. HAPs that were not found in the atmosphere above the sample limit of detection (LOD) were labeled as "Not Detected" (for additional information on the metric of interest, see the sidebar titled Metric of Interest: Sample Limits of Detection versus Health-Based Comparison Values). Of the 37 studies we reviewed, a total of 61 unique HAP compounds were measured near upstream ONG or investigated from secondary data sources. Forty-four HAPs Supplemental Material >

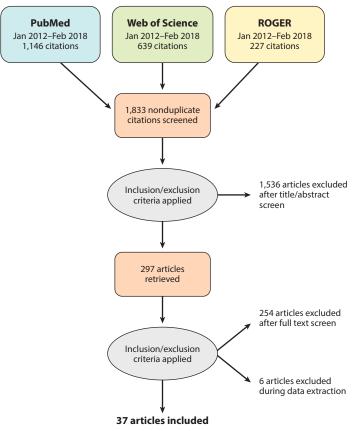


Figure 1

A Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram for hazardous air pollutant (HAP) emissions near upstream oil and natural gas (ONG) development. Abbreviation: ROGER, PSE Healthy Energy's Repository for Oil and Gas Energy Research.

Supplemental Material >

were collected and reported in more than one article as primary or in-situ data, of which 32 were found above the sample LOD. **Supplemental Figure 1** provides the full inventory of HAP compounds investigated within the collected literature. HAPs collected from primary data sources were further listed by the state in which they were investigated and included in **Supplemental Table 4**.

Many of the peer-reviewed studies investigated a broad range of target analytes in ambient air, several of which are ubiquitous in the environment and are sourced not only in upstream ONG operations. While some of the HAP compounds listed in **Supplemental Figure 1** and **Supplemental Table 4** may have a source in upstream ONG, without point source or source attribution methodologies, their association is speculative. Therefore, in the following sections, we have further assessed the 61 HAP compounds identified within the peer-reviewed literature to classify pollutants assessed for contributing sources and to determine their potential association with upstream ONG development.

METRIC OF INTEREST: SAMPLE LIMITS OF DETECTION VERSUS HEALTH-BASED COMPARISON VALUES

The sample limit of detection (LOD) expresses the lowest concentration of the targeted analyte that can be distinguished within a given sample, instrument, or method. We use the sample LOD as our metric of interest instead of commonly referenced health-based comparison values for several reasons. First, the heterogeneity of sampling methodologies prevents direct comparison between concentration results (6). Second, it is difficult to select a single health-based standard exposure timeframe that adequately represents the variety of sampling durations present in the reviewed literature (**Supplemental Table 3**). Finally, many health-based standards are derived from limited data sets and inadequate conversion factors that do not appropriately define the risk threshold of sensitive populations nor do they address the risks of exposure to multiple HAPs concurrently and, thus, may inappropriately imply the absence of health risks.

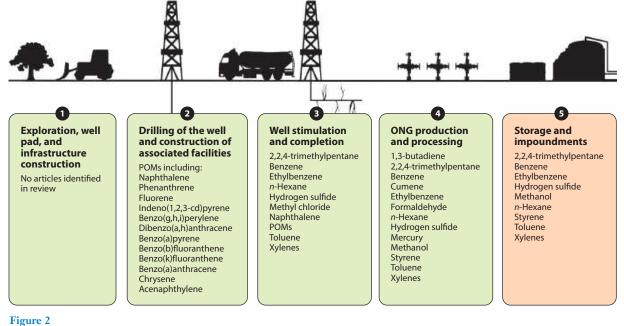
Despite these advantages, an LOD above health-based standards may erroneously imply low exposure risk when concentrations are not detected within the sample. To address these issues, we advise researchers to include LODs within the results to avoid misleading the reader. Failure to supply sample LODs encumbers accurate descriptions of atmospheric concentrations, leading to underestimations of exposure, an issue we have found rife in the ONG literature.

Supplemental Material >

3.2. Sources of HAP Emissions

The range of air pollutant emission sources identified in the reviewed literature includes equipment (e.g., dehydrators, condensate tanks), activities (e.g., flashings, gauging flowback tanks), development phases (e.g., drilling, well stimulation), and facilities (e.g., flowback and produced water treatment and recycling center, oil storage facility). To simplify these broadly categorized emission sources, we recategorized equipment, activities, and facilities into one of the four most appropriate upstream ONG phases: (*a*) exploration and well pad and infrastructure construction; (*b*) well drilling and construction of associated facilities; (*c*) well stimulation, enhanced oil recovery, and completion; and (*d*) ONG production and processing. For example, air quality measurements collected from flowback were recategorized into the third phase (well stimulation, enhanced oil recovery, and completion) because flowback is a fluid often recovered as a result of well stimulation (e.g., hydraulic fracturing). Storage tanks and impoundments can be present at the well pad through multiple phases or can be transported off-site via trucks or pipeline networks. Since the location of storage-related equipment and associated activities varies by location, HAP compounds identified from these sources have been recategorized into a separate storage and impoundment phase and described in Section 3.2.4.

Point source data are collected from stationary, identifiable locations and equipment that release pollutants into the atmosphere. Studies that included the collection of on-site primary point source air quality data, including Brantley et al. (15), Esswein et al. (39), and Hildenbrand et al. (58), provided detailed information about the equipment and activities that occurred during their sampling periods. On the basis of these detailed descriptions, we collected and recategorized the reported data into one of our five phases. In the absence of identifiable emission points, source attribution methods are important to estimate probable sources or categories of sources. Examples of source attribution methods employed in the reviewed literature include factor analyses (1, 43, 90), distance decay gradients (125), and sourcing ratios (45, 46, 50, 54, 85, 99), among others. Additional studies, including Macey et al. (73) and Colborn et al. (27), collected samples off-site and provided information about potential emission sources by detailing the most proximate upstream



Hazardous air pollutant (HAP) compounds collected through primary measurements and recategorized. Abbreviations: ONG, oil and natural gas; POMs, polycyclic organic matter.

> ONG equipment or activities during the data collection timeframe but did not specifically apply commonly used source attribution techniques. Recognizing the limitations of off-site activity reporting in the absence of well-established source attribution analyses, we cautiously used these descriptions as a guide for recategorization but used our best discretion for inclusion.

> A complete summary of recategorized HAP emissions from primary measurements within the reviewed literature is provided in Figure 2. We did not identify any HAPs that were sourced to emissions during the first phase of development (exploration and well pad and infrastructure construction).

> 3.2.1. HAP emissions from well drilling and construction of subsurface infrastructure.

After the site has been cleared and a well pad is established, a vertical well is drilled often using gas-powered rigs and other ancillary equipment to reach depths of several hundred meters below the surface. If necessary, operators will continue to drill directionally (e.g., horizontally) to increase the surface area of the target petroleum geologic zone (e.g., in the case of shale gas development). Drilling through intermediate geological formation on the way to the target formation may release trapped hydrocarbons that can migrate to the atmosphere (23, 51). Thus, both ancillary drilling equipment and subsurface pockets of gaseous fluids within intermediate geologic formation are a source of various HAP emissions into the ambient environment during the drilling and well construction phase (17).

Colborn et al. (27) measured the most elevated chemical concentrations in the ambient air from a stationary monitoring site located 1.1 km from a well pad during drilling activities in rural Colorado. Samples identified twelve different polycyclic aromatic hydrocarbon (PAH) compounds, a subset of polycyclic organic matter (POM) compounds, during a timeframe dominated by drilling activities. Elevated carbonyl and VOC concentrations were also detected; however,

the individual VOC species were not detailed within the paper and, thus, are not included in this section. Source attribution using temporal patterns of PAH concentrations in the ambient environment without supplementary sourcing analyses is difficult to interpret, especially for PAHs that lack chemical disclosures or inventories as well as PAHs commonly formed from combustion or other anthropogenic sources. Yet, analyses of similar PAH compounds found evidence of petrogenic sources during a range of upstream ONG activities in Ohio (85); thus, we have included these within the current section. Additional mobile measurements in Pennsylvania detected acetaldehyde, acetonitrile, benzene, methanol, and toluene downwind from a drilling rig; however, concentrations were not elevated above background, suggesting that the rig was not operating at full capacity, the emissions from this activity in this particular geographic and geologic area did not have high emissions, or the activities and equipment associated with the drilling phase were not the source of these pollutants and thus were not included in our sourcing analyses (51).

3.2.2. HAP emissions from well stimulation, secondary recovery, and completion. The well completion phase encompasses all processes associated with preparing a newly drilled well for the production of oil and gas. This phase is relatively short in duration (3-15 days) but can include a variety of activities, including flowback collection, flaring, workovers, and completion venting. Once the well is drilled, cement and casing are installed to stabilize the wellbore and provide zonal isolation to minimize subsurface migration of liquid and gaseous fluids. This step is followed by the perforation of the casing in the target hydrocarbon reservoir to allow for the stimulation and other injected fluids to gain access to the petroleum reservoir and then subsequently for the flow of hydrocarbons into the well. In low-permeability reservoirs, where hydraulic fracturing and other stimulation are required to extract hydrocarbons, between 0.25 and 50 million gallons of water, chemicals, and proppant are injected down the well at a pressure high enough to increase the permeability of the target geology. The return of these stimulation fluids to the wellhead is referred to as "flowback." Although chemical constituents from the geological formation are present in this flowback, these fluids are often opaquely distinguished from "produced" water, which surfaces shortly thereafter and often throughout the lifetime of active hydrocarbon production (13). Because flowback is limited mostly to the current phase, we include emissions associated with flowback, and not produced water, which is reviewed in subsequent sections. It should be noted, however, that scientific distinctions between the flowback and produced water phases of oil and gas development are not specific and vary considerably across geological and regulatory spaces (70).

BTEX, 1,3-butadiene, n-hexane, cumene, styrene, and 2,2,4-trimethylpentane were identified around the perimeter of five well pads in Colorado during completion activities and, with the exception of styrene, cumene, and 1,3-butadiene, median concentrations were higher than background in ONG area samples (79). Field sampling downwind of a well pad in Pennsylvania during flaring activities measured benzene, toluene, and n-hexane above the sample LOD and at concentrations higher than the upwind direction (76). Occupational and off-site measurements identified POMs (including naphthalene) and H_2S near flowback and workover rigs (39, 73).

BTEX compounds and n-hexane are found in diesel combustion emissions from equipment and vehicles used in ONG, drilling fluids, and fracturing additives. BTEX compounds, in particular, occur naturally in oil and gas geological formations, and emissions of these compounds during oil and gas development are likely attributable to various processes, including those that provide an opportunity for gas compounds to migrate to the surface and volatize into the ambient air. Therefore, many of the HAPs identified in ambient air near ONG operations during well stimulation and completion could be direct emissions from ancillary well pad equipment, loss of wellbore integrity, improper handling of flowback fluids, and volatilization from the chemical mixtures used

for stimulation fluids or completion activities (61, 101, 108, 109). With the current evidence, we cannot identify the specific source activity or equipment, although ONG development appears to be a likely source of these compounds identified at elevated concentrations in the ambient air.

3.2.3. HAP emissions from oil and gas production and processing. During the production phase, ONG is collected from the well and processed with various ancillary equipment, including wellhead compressors, pneumatic devices, separators, and dehydrators. The production phase is the longest of all the upstream phases with the potential to emit maximum peak values that exceed the stimulation and completion phase (17), and it was linked to the most varied number of HAPs within our review. While a given shale well may be depleted within 1–5 years, migrated oil reservoirs may produce for decades. Hydrocarbon production in geological zones richer in oil and wet gas may be associated with HAPs and other larger-molecular-weight hydrocarbon emissions during the production and processing phase when target alkanes are separated from heavier compounds. Operational practices, the spud date, the petroleum geology, and production volumes can also heavily impact emissions from producing wells within the same shale play (51, 98). Therefore, without insight into reservoir composition and well pad operations, it is difficult to predict the geography and magnitude of HAP emissions or to extrapolate results to larger areas.

Wellheads, dehydrators, and separators are important sources of elevated HAP emissions during production and processing in regions rich in oil, wet gas, and condensate (43, 112). Dehydration units account for an estimated 40% of HAP emissions (36). Point source measurements collected on a well pad in Colorado identified BTEX compounds, styrene, n-hexane, and 2,2,4trimethylpentane near producing wellheads, dehydrators, and separator units (15). Off-site measurements in Texas and Wyoming identified similar emissions with an addition of cumene and H_2S near wellheads, separators, and produced water tanks and discharge canals (35, 73). Compressors used to maintain hydrocarbon flow were associated with emissions of BTEX compounds, 1,3-butadiene, methanol, formaldehyde, mercury, and n-hexane (35, 51, 65, 73, 75, 90). With the exception of mercury, these compounds are commonly emitted from continuously reciprocating natural gas-fired engines, and their presence within the collected samples was not unexpected. A report analyzing point source emissions data from 58 compressor stations found formaldehyde to be the fourth largest chemical released by compressors by total pounds, just after total VOCs (92). Mercury, a trace component in natural gas condensate, is removed from the compressor process; thus, its emission may actually be a result of ineffective mercury removal systems and therefore is included in this phase (65).

Abnormal process conditions including control failures, design failures, and malfunctions upstream of the point of emission occur in only a small fraction of facilities, yet they may be responsible for a significant portion of ONG-related air pollution (16, 30, 59, 123). Flyover measurements in the Haynesville and Marcellus Shale gas production regions found that only ~10% of facilities were responsible for up to ~40% of the total CH₄ emissions emitted from these operations (120). Although these measurements might not be representative of all associated HAP emissions, enhancement ratios and correlations between CH₄ and benzene suggest a similar source. Furthermore, mobile measurements in the Barnett Shale area found that only 4% of measured ONG facilities were responsible for a relatively large amount of the measured atmospheric mercury (65). Within the current review, few air quality samples were reported as collected during abnormal ONG development process conditions, yet it is possible that off-normal events occurred without operator knowledge or public disclosure. For example, samples collected near production phase equipment described as "rusty" recorded HAP concentrations up to 47 times higher than those described as being in "good" operating condition, yet neither were identified as abnormal processes (15). In the instance where infrared video captured a clear example of a leaking natural gas wellhead, elevated concentrations of benzene, xylenes, n-hexane, and toluene were detected onand off-site and near residential homes (40).

3.2.4. HAP emissions from storage tanks and impoundments. Storage tanks and impoundments are often used to hold production and maintenance chemicals or condensate and recovered fluids collected and separated during various phases. Chemicals stored at upstream ONG sites include chemical additives and mixtures for well stimulation and various well and equipment maintenance needs. Condensate is different from stored chemicals, flowback, and produced water in that it has been separated from extracted crude oil or natural gas matrices in preparation for additional processing or disposal. Emissions from storage and condensate tanks have been associated with H_2S , BTEX, n-hexane, styrene, methanol, and 2,2,4-trimethylpentane (15, 67, 112). Many of the stored liquids are volatile and enter a gaseous phase as a result of increases in temperature and decreases in pressure. Workers in the upstream ONG industry, especially those working with flowback and condensate tanks, are at increased risk of exposure during routine gauging, measurement, and oil flashing activities, which provide an opportunity for stored liquids to volatilize and escape into the atmosphere. A number of occupational deaths have been reported among workers taking volume measurements of condensate tanks (55).

Such condensate tank emission events, even if brief, can be significant, which may have a substantial impact on local air quality (46), especially in oil-producing areas (72). Storage tanks can be housed at the well site that provide additional emissions source points during the associated phase; however, they can also be sited at different locations, far from the well pad, or piped off-site through transmission pipeline networks (45). Many of the listed HAPs in this section were found at well pads during production, but they were recategorized into the current separate group as the location of storage equipment and related activities varies by well site.

3.3. Summary of Health Impacts from HAP Compounds

HAP compounds are associated with multiple cancer and noncancer health outcomes and have, in some studies, been detected near ONG sites at levels that exceed health-based standards and reference concentrations. The current ONG literature offers limited insights into specific etiological agents and health outcomes because granular measurements of exposure have largely not been undertaken. To better understand health risks and impacts from HAP exposures near upstream ONG development, we further evaluated the studies that included a health component in the analysis. Although exposure to any of the 188 listed HAP compounds may pose reason for concern, we identified several HAPs that were consistently found to be above sample LODs or above health benchmarks or that posed the highest risk from inhalation exposures. A summary of some of the key findings is provided in the following sections.

3.3.1. HAPs of highest concern. BTEX compounds are associated with several serious human health impacts, including neurological damage, birth defects, some cancers, and hearing loss (117). Ubiquitous in the environment, these compounds commonly exceed sample LODs in urban areas as a result of transportation and industrial processes (11); however, many of the reviewed samples were collected near ONG activities in rural regions, where urban emission sources are likely to have minimal impact on local and regional ambient air quality. Several of the studies included in this review found rural BTEX concentrations to exceed those measured in dense urban areas and at concentrations that exceed health-based standards, with some concentrations over 2,900 ppb (parts per billion) (37, 43, 45, 46, 48, 51, 54, 73, 88, 91, 99, 102, 112). For reference, the Office of Environmental Health Hazard Assessment (OEHHA) acute reference effect level (REL)

in nonoccupational settings for benzene is 8 ppb, and the 8-hour and chronic RELs for benzene are 1.0 ppb (29). Studies that report ambient BTEX concentrations below existing health-based standards have implied that upstream ONG emissions of these compounds may not have a substantial impact on human health, yet ambient BTEX concentrations, below health benchmarks, have been associated with adverse health outcomes in numerous epidemiological studies (2, 3, 7, 33, 47, 63, 64, 69, 71, 74, 87, 119, 121, 124).

While health-based air quality standards provide a guide on which to base regulatory thresholds, many standards are extrapolated from in vivo or in vitro animal studies or human-based occupational studies that may not be appropriate for the protection of sensitive populations such as children and pregnant women (42, 110, 113). Recognizing the possible inadequacies of existing uncertainty factors for benzene, the OEHHA in California recently applied a stricter REL to include additional protections to sensitive populations (29), yet questions remain over whether these updated standards are protective enough. On the basis of the existing evidence of exposure risks from chronic, low-level concentrations, current noncancer health benchmarks, such as the OEHHA RELs, may be insufficient for estimating health impacts from benzene-related exposures near upstream ONG development. Recognizing the cancer risks associated with benzene exposures, the World Health Organization states that "no level of exposure can be recommended," implying that there is likely no safe lower threshold of exposure as implied by the RELs (116).

Formaldehyde and acetaldehyde were found to be the most abundant carbonyl species when sampling ambient air near ONG facilities. The chronic OEHHA nonoccupational RELs for acetaldehyde and formaldehyde are 80 ppb and 7 ppb, respectively (84). While many of the observed concentrations around ONG operations were below health standards, the International Agency for Research on Cancer has classified formaldehyde as a group 1 carcinogen, meaning it causes cancer in humans (8) and, generally, does not have a threshold below which there is a safe level of exposure. Furthermore, simplified health risk assessments and modeling estimates near ONG activities have suggested that formaldehyde and acetaldehyde are the dominant contributors to cancer risks (25, 99). The abundance of formaldehyde detection in ambient collected samples may actually indicate secondary atmospheric formation as the dominant source and not primary emissions may actually lead to underreporting if secondary atmospheric formation is the dominant pollutant source.

The natural gas and crude oil impurity H_2S is a colorless and flammable toxicant easily identifiable by its rotten egg odor. H_2S becomes detectable at concentrations as low as 0.5 ppb (10), becomes chronically toxic at 8 ppb (83), and has a National Institute for Occupational Safety and Health (NIOSH) immediately dangerous to life or health (IDLH) concentration of 100 ppm (24). Within the current review, H_2S has been measured in ambient air at various phases of upstream ONG development, including during separation, in storage tanks, and in discharge canals at concentrations exceeding those known to be safe (35, 39, 67, 73). Concentrations of H_2S above the odor threshold were measured just beyond the fence line in 8% of natural gas production sites in Texas during mobile measurements (35).

The simplest unsaturated aldehyde, acrolein, is fairly ubiquitous throughout the environment at concentrations above chronic noncancer benchmarks (77, 81, 100, 118). Used as a biocide additive and H_2S scavenger in ONG operations, acrolein is also emitted from more common sources, including incomplete combustion of petroleum products, tobacco smoke, and cooking activities. Owing to the current health burden of exposure in the ambient environment, the OEHHA identified acrolein as one of the top five most important pollutants of concern in California (4), and an additional exposure from ONG operations could compound the existing public health burden.

Acrolein is difficult to measure accurately, and controversy over prevailing sampling methods persists (49, 57, 62). Exposure to acrolein may cause adverse health effects, including eye, nose, and throat irritation, chest pain, and difficulty breathing (9). In California underground natural gas storage facilities, acrolein is reported as the eighth highest emitted air pollutant in California and was found at elevated levels in indoor environments near the site of the Aliso Canyon natural gas storage blowout (66, 94). Acrolein plays a substantial role in the upstream ONG process, and yet methodological constraints limit the availability of reliable industry-related emissions estimates and, consequently, obscure the understanding of the potential impact to human health.

3.3.2. Gaps in health research. Recent health-based studies have uncovered a spatial relationship between upstream ONG and a range of health outcomes. Epidemiological and health-based studies have found increased risk and incidence of adverse birth outcomes near ONG activity compared with further away (22, 31, 60, 96). Similarly, studies that utilize distance metrics as proxies of exposure reported increased health risks for individuals living near ONG activity compared with further away (21, 79, 99). These findings are corroborated by symptom surveys that found that the number of reported symptoms was higher among residents living closer to well pads compared with those living further away (97). Moreover, McKenzie et al. (78) paired insitu air quality measurements with distance and cancer risk assessment. The study found that within 152 m (\sim 500 feet) of active oil and gas development, the cancer risk estimate was 8.3 cases per 10,000 individuals, greatly exceeding the US EPA's upper threshold for acceptable risk (1 excess case in 10,000).

Despite findings of a spatial dimension of health data near upstream ONG development, measured pollutant concentrations, including concentrations of HAPs, were generally below healthbased standards. It is unclear why ambient air samples have failed to capture concentrations above health benchmarks while the majority of epidemiological studies continue to find incidence of poor health outcomes increasing as distance from these operations decreases. Recent literature provides insights into methodological shortcomings that make investigations more prone to null air pollutant concentration findings. First, in-situ measurements of emissions collected at a distance from well pad activities are prone to effects of atmospheric degradation, dispersion, and deposition (86), and yet they are commonly, and inappropriately, extrapolated to describe local exposures. Studies that utilize data from standard air monitoring networks, such as the Texas Commission on Environmental Quality (19, 40, 93), may fail to capture concentrations that pose actual exposure risks as a result of such methodological biases.

Second, samples collected with short collection timeframes (e.g., "grab samples") are capable of detailing only conditions at a particular—and short—moment in time and often fail to capture the episodic peaks commonly associated with many of the upstream ONG development processes (17). Similarly, integrated concentrations derived from longer sampling timeframes may dilute elevated concentrations during peak emission events and, thus, underestimate the full range of potentially recurring acute exposures (54). Recent evidence suggests that abnormal process conditions or uncontrolled emission events from a small proportion of wells or associated ancillary infrastructures may better explain the complex exposure environment from local to regional scales (123). Studies that estimate exposures on the basis of modeled emission masses and rates may miss peak exposures from abnormal process conditions that are more accurately characterized via field sampling. Air quality studies that focus on granular geographic estimates of exposures via continuous, local-level monitoring better characterize ambient concentrations during brief peak emission episodes, common in upstream ONG development, that may be missed using intermittent sampling methods at select stages (28, 54).

Third, the current state of toxicological data and exposure science may not adequately address potential risks associated with long-term, chronic, lower levels of exposure, particularly when multiple air pollutants might be implicated (18, 20, 52). Thus, available health standards developed from inadequate uncertainty factors may not provide protection for human populations and especially for sensitive subpopulations, including infants, children, pregnant mothers, and people with preexisting medical conditions. Using OEHHA's conservative list of approved risk assessment health values as a guide to understand the current state of available health benchmarks (5), we found that fewer than 40% of all HAP compounds had inhalation cancer risks or noncancer health-based exposure levels. Several compounds that lack reference values were detected in air near, and are likely associated with, ONG sites. Other contaminants with health benchmarks, such as benzene, may still elicit health effects at concentrations lower than the REL. Furthermore, many HAP compounds are associated with cancer end points that, even at low atmospheric concentrations, generally do not have a threshold below which there is a safe level of exposure. Therefore, health studies that provide only comparisons to noncancer benchmarks may be misleading in their estimates of actual long-term health impacts.

Finally, health studies that use single pollutant health-based standards may fail to provide accurate risk estimates from concurrent or close-succession exposures to multiple pollutants that may act biologically antagonistic, synergistic, or additive (105). This situation of potential exposures to multiple air pollutants is particularly relevant for upstream ONG development where emission inventories and air quality monitoring have identified a wide range of pollutants that are often coemitted. Without knowledge of a specific etiological agent or exposure pathway, investigators may find that these studies fail to sample and analyze the full range of biologically relevant ONG pollutants or determine the most appropriate exposure pathways.

4. DISCUSSION

We identified 37 peer-reviewed journal articles that met our inclusion/exclusion criteria, of which all but one focused on ONG operations within the United States. In our review, we found a lack of peer-reviewed literature from outside the United States, likely owing to the growing concerns about human health and environmental impacts, which may have slowed adoption of novel extraction methods in other countries. With the exception of Russia, the United States produced at least twice as much natural gas compared with all other regions in the world (103). In Europe, most exploratory shale gas extraction has occurred in Poland and the United Kingdom, but France and Norway have some of the most promising reserves that remain largely unexploited (44). Within the collected literature, we identified 61 HAPs, of which only 32 were collected during in-situ monitoring. Hydraulic fracturing has received the greatest attention for its potential impact to human and environmental health (14). In the context of HAPs, however, we did not find evidence to support the common assumption that the discrete hydraulic fracturing phase itself is associated with the highest risk of exposure. Instead, we found that the production phase—with its lengthy operation timeframe, episodic peak emission events, and largest number of HAPs sourced to the various equipment and operations—has the potential to emit the highest concentrations and the most varied mixture of HAPs over the longest time period, especially in regions rich in oil, wet gas, and condensate. Our review of the literature further suggests that exposure risks can be much higher if production equipment is colocated with condensate storage and wastewater impoundments. ONG development does not necessarily involve hydraulic fracturing but may include a myriad of different oil and gas development techniques, many that were not investigated within the collected literature.

In general, in-situ air pollutant measurements were found to be below health benchmarks, and yet multiple health-based studies found evidence of a spatial relationship between concentrations of HAPs and incidence of cancer and noncancer health end points in the context of proximity to oil and gas development operations. These findings suggest several possible explanations: (*a*) Spatial sampling methodologies fail to properly characterize exposures prior to atmospheric degradation, dispersion, and disposition of sampled pollutants; (*b*) ambient air sampling timeframes are inappropriate for capturing the episodic peak emission events characteristic of upstream ONG; and (*c*) prevailing health benchmarks are inadequate to identify exposures to chronic, low levels of pollutants, multiple chemical exposures or from multiple exposure pathways.

This review has several limitations. First, some HAPs targeted for this review include broadrange categories (e.g., POM) that contain multiple constituents of varying degrees of toxicity, of which some may have been overlooked during the inclusion/exclusion review. Second, some activities and equipment are used in both upstream and midstream (e.g., hydrocarbon transport) processes, and it was not always clear which was being measured when in-situ monitoring data was being collected. For example, compressors can be used to transport hydrocarbons and other compounds off the well pad during upstream activities, but the act of transportation would classify associated releases as midstream emissions. We used our best judgment when collecting and recategorizing HAP compounds; however, without clarification from the studies' authors, we may have included some midstream processes in our reclassification efforts. Third, several studies included in our review suffered from methodological limitations resulting in over- or underestimated concentrations of summary findings. Although we attempted to recognize and address these inadequacies we may not have adjusted for all possible shortcomings in the reviewed literature. Fourth, we used sample LODs as the most appropriate metric of interest because the heterogeneity of sampling methodologies limited direct comparisons of measured or estimated concentrations across studies (for more information, see the sidebar titled Metric of Interest: Sample Limits of Detection versus Health-Based Comparison Values). While it would be helpful to consider sample LODs when evaluating nondetected HAPs, we identified a consistent failure to supply sample detection limits within the peer-reviewed literature in this review. Finally, our review was limited to constituents classified as HAPs; non-HAP compounds were beyond the scope of this article. Similarly, HAP compounds that were excluded from the collected literature were not extensively discussed here. By design, this review was limited to a select group of compounds that have been previously studied within the peer-reviewed literature. However, non-HAP compounds, HAP compounds not measured, and HAP compounds found under the sample LOD may still have a significant role in upstream ONG development and should be investigated in future studies.

Through our synthesis of the peer-reviewed literature, we have identified the following research priorities: (*a*) Increase research of HAPs near upstream ONG development with an emphasis on those that have not been extensively measured or reported on in the peer-reviewed literature, especially those that overlap with chemicals identified in state inventories or disclosures; (*b*) undertake detailed source attribution investigations of emissions using spatially and temporally appropriate measurements; (*c*) conduct detailed health studies that focus on granular estimates of exposures near upstream ONG development via personalized and community-based monitoring; and (*d*) implement additional research on health impacts from chronic, low-level ambient HAP exposures. Adoption and implementation of these research priorities will help guide future policy aimed to implement appropriate upstream ONG development emission control measures that will protect human and environmental health and decrease the adverse impacts of upstream oil and gas development.

DISCLOSURE STATEMENT

The authors are not aware of any affiliations, memberships, funding, or financial holdings that might be perceived as affecting the objectivity of this review.

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Report 1 of the Forty-Third Statewide Investigating Grand Jury

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IN THE COURT OF COMMON PLEAS ALLEGHENY COUNTY, PENNSYLVANIA

IN RE:	: SUPREME COURT OF PENNSYLVANIA
	: 71 W.D. MISC. DKT. 2017
THE FORTY-THIRD STATEWIDE	:
	: ALLEGHENY COUNTY COMMON PLEAS
INVESTIGATING GRAND JURY	: CP-02-MD-5947-2017
	:
	: NOTICE NO. 42

ORDER ACCEPTING AND FILING INVESTIGATING GRAND JURY REPORT NO. 1

On February 27, 2020, this Court accepted Investigating Grand Jury Report No. 1, finding that said report, within the scope of the Grand Jury's authority, proposed recommendations for legislative, executive or administrative action in the public interest based upon stated findings, and further finding that said report was based upon facts received in the course of an investigation authorized by the Investigating Grand Jury Act, 42 Pa.C.S. § 4541 *et seq.* and was supported by the preponderance of the evidence. Prior to the report being made public, however, this Court exercised its discretion to permit responses to be submitted pursuant to 42 Pa.C.S. § 4552(e). The time period for submitting responses has now ended.

AND NOW, this <u>11</u> day of June, 2020, it is hereby **ORDERED** that:

- Pursuant to 42 Pa.C.S. § 4552(e), the responses of the Pennsylvania Department of Environmental Protection, the Pennsylvania Department of Health, Michael Krancer and Scott Perry to Investigating Grand Jury Report No. 1 shall be attached to the report as part of the report, before the report is made part of the public record;
- Investigating Grand Jury Report No. 1, having been accepted by the Court on February 27, 2020 pursuant to 42 Pa.C.S. § 4552(b), along with the responses of the Pennsylvania Department of Environmental Protection, the Pennsylvania Department

of Health, Michael Krancer and Scott Perry, shall be filed as a public record with the Washington County Court of Common Pleas and the Susquehanna County Court of Common Pleas pursuant to 42 Pa.C.S. § 4552(b),(e); and

- 3. The Attorney for the Commonwealth shall deliver copies of the Report to:
 - A. The Members of the Pennsylvania House of Representatives;
 - B. The Members of the Pennsylvania Senate; and
 - C. The Governor of the Commonwealth of Pennsylvania

BY THE COURT:

THE HONORABLI NORMAN A. KRUMENACKER, III Supervising Judge The Forty-Third Statewide Investigating Grand Jury

IN THE COURT OF COMMON PLEAS ALLEGHENY COUNTY, PENNSYLVANIA

: SUPREME COURT OF PENNSYLVANIA
: 71 W.D. MISC. DKT. 2017
: ALLEGHENY COUNTY COMMON PLEAS
: CP-02-MD-5947-2017
: NOTICE NO. 42

ORDER ACCEPTING INVESTIGATING GRAND JURY REPORT NO. 1 AND DIRECTING FURTHER ACTION PRIOR TO THE REPORT BEING MADE PART OF THE PUBLIC RECORD

AND NOW, this 27 day of February, 2020, upon examination of Investigating Grand Jury Report No. 1, and finding that said report, within the scope of the Grand Jury's authority, proposes recommendations for legislative, executive or administrative action in the public interest based upon stated findings, and further finding that said report is based upon facts received in the course of an investigation authorized by the Investigating Grand Jury Act, 42 Pa.C.S. § 4541 *et seq.*, and is supported by the preponderance of the evidence, it is hereby **ORDERED** that:

- 1. Investigating Grand Jury Report No. 1 is accepted by the Court;
- Investigating Grand Jury Report No. 1 shall be made part of the public record with the court of common pleas of Washington County and the court of common pleas of Susquehanna County, as these counties are the subject of Investigating Grand Jury Report No. 1. See 42 Pa.C.S. § 4552(b).
- 3. Pursuant to 42 Pa.C.S. § 4552(e), the Court finding that the report may be construed as offering constructive or critical guidance on matters implicating the operation of the Pennsylvania Department of Environmental Protection and the Pennsylvania Department of Health, and neither the Departments nor its employees being

charged with any criminal offenses, the Court hereby exercises its discretion to allow THE SECRETARY OF THE PENNSYLVANIA DEPARTMENT OF ENVIRONMENTAL PROTECTION AND THE SECRETARY OF THE PENNSYLVANIA DEPARTMENT OF HEALTH, OR THEIR DESIGNEES, to submit a response to the allegations in the report that may be construed as offering constructive or critical guidance on matters implicating the operation of their respective Departments;

- 4. The Attorney General, or his designee, is directed to disclose the entirety of the report to THE SECRETARY OF THE PENNSYLVANIA DEPARTMENT OF ENVIRONMENTAL PROTECTION AND THE SECRETARY OF THE PENNSYLVANIA DEPARTMENT OF HEALTH, OR THEIR DESIGNEES, who may share the entirety of the report with counsel for their respective Departments;
- 5. The limited disclosure of the report for purposes of submitting a response shall be accompanied by an Order of this Court advising that the content shall not be publicly disclosed until further Order of Court;
- 6. Upon receipt of the report, THE SECRETARY OF THE PENNSYLVANIA DEPARTMENT OF ENVIRONMENTAL PROTECTION AND THE SECRETARY OF THE PENNSYLVANIA DEPARTMENT OF HEALTH, OR THEIR DESIGNEES, may file a response within 21 days should they elect to do so. By Order of this Court, the response shall be submitted under seal to the Honorable Norman A. Krumenacker, III at the Cambria County Courthouse, 200 South Center Street, Ebensburg, Pennsylvania 15931; and

 Upon receipt of any response, the Court shall then consider whether the responses shall be attached to the report before it is made part of the public record. See 42 Pa.C.S. § 4552(e).

BY THE COURT:

THE HONORABLE MORMAN A. KRUMENACKER, III Supervising Judge The Forty-Third Statewide Investigating Grand Jury

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IN THE COURT OF COMMON PLEAS ALLEGHENY COUNTY, PENNSYLVANIA

IN RE:	: SUPREME COURT OF PENNSYLVANIA
	: 71 W.D. MISC. DKT. 2017
THE FORTY-THIRD STATEWIDE	:
	: ALLEGHENY COUNTY COMMON PLEAS
INVESTIGATING GRAND JURY	: CP-02-MD-5947-2017
	•
	NOTICE NO. 42

INVESTIGATING GRAND JURY REPORT NO. 1

We, the members of the Forty-Third Statewide Investigating Grand Jury, duly charged to inquire into offenses against the laws of the Commonwealth of Pennsylvania, have received facts and evidence during the course of an investigation pursuant to Notice of Submission of Investigation No. 42 and have proposed recommendations for legislative, executive or administrative action in the public interest. So finding, by preponderance of the evidence, with no fewer than twelve concurring, we do hereby adopt this Report for submission to the Supervising Judge.

Foreperson The Forty-Third Statewide Investigating Grand Jury

DATED: February 27, 2020

Introduction

The people have a right to clean air, pure water, and to the preservation of the natural, scenic, historic and esthetic values of the environment. Pennsylvania's public natural resources are the common property of all the people, including generations yet to come. As trustee of these resources, the Commonwealth shall conserve and maintain them for the benefit of all the people.

Pennsylvania Constitution, Article 1, Section 27: the Environmental Rights Amendment

This Grand Jury Report assesses impacts on Pennsylvania of a new, lucrative but often destructive enterprise – the unconventional oil and gas industry, commonly known as "fracking." Unconventional oil and gas drilling began its explosive growth in this state more than a decade ago. We, the 43rd Pennsylvania Statewide Investigating Grand Jury, find by a preponderance of the evidence and in many instances by clear and convincing evidence, and that after comprehensive study in the course of our investigative duties, conclude that government oversight of this activity was for many years poor, and has only more recently shown signs of improvement. As a result, officials often did not do enough to properly protect the health, safety and welfare of the thousands of Pennsylvania citizens who were affected by this industry.

The Grand Jury began this investigation based on evidence that private companies engaged in unconventional oil and gas activities have committed criminal violations of Pennsylvania's environmental laws. We found such violations and we are issuing several presentments recommending the filing of criminal charges. And we believe investigation of additional crimes should, and will, continue beyond the term of this Grand Jury. In the course of our work, we found something else as well. We saw evidence that government institutions often failed in their constitutional duty to act as trustee and guardian "of all the people," as Article 1,

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Section 27 provides. We issue this Grand Jury Report to document our findings, and to make recommendations for improvements going forward.

We are not "anti"-fracking. The purpose of this Report is to present an account of the impacts of an industry that will affect Pennsylvanians for decades to come. We are aware that unconventional drilling brings significant economic benefits. But if the activity is to be permitted, it still must be regulated appropriately, in ways that prevent reckless harms. Instead, we believe that our government often ignored the costs to the environment and to the health and safety of the citizens of the Commonwealth, in a rush to reap the benefits of this industry.

At the same time, we recognize that some progress has been made in recent years. Our investigation engaged extensively with the Pennsylvania Department of Environmental Protection (DEP) and the Pennsylvania Department of Health (DOH), the two agencies whose responsibilities encompass oversight of unconventional oil and gas activity. We heard testimony from dozens of current and former employees of these departments, and learned that at least some of their failings are being somewhat addressed. But we strongly believe we have to examine and expose those failings, past and present, in order to illustrate the need for further improvement and to ensure that the mistakes of the past do not continue into the future.

We are also aware of continuing debate about the nature and degree of health impacts related to unconventional drilling. We do not believe, however, that such uncertainty could ever be an excuse for inaction. The risks of this new industry should fall on the industry and the regulatory agencies, not on the public. As we see it, the purpose of government agencies like DEP and DOH is to proactively prevent harm, not to wait and see if the worst really happens. There has already been too much of that.

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<u>Human impact</u>

We heard, from witness after witness, about what happens when you find yourself living next to a fracking site. To understand, we had to spend a great deal of time over the last two years hearing testimony from experts and learning about the process. Unconventional oil and gas activity is heavy industry, requiring heavy construction, heavy trucks, and heavy traffic. Wells are drilled thousands of feet down into the ground, through water tables, and then drilled laterally for thousands more feet. The drills are lubricated with hazardous chemical compounds. When the holes are drilled, gas doesn't just flow up on its own. In order to release the gas, shale rock has to be fractured – "fracked" – using explosives and even more chemicals. There are thousands of wells around the state, and each one produces thousands of gallons of "flowback" or "produced water" – chemical-filled water that comes back up out of the well along with the gas. The fluid, as well as the drill cuttings, present unique issues for storage and disposal.

What is most concerning about this industry is that it doesn't happen in out-of-the-way industrial parks. It happens wherever there is a deep seam of shale rock – under houses, and farms, and woodlands. It's a geological crapshoot. Landowners who sell their mineral rights often have no idea what it really involves, and people who buy property after rights have already been sold, or who live next to someone else who sold, have no choice in the matter.

Wells can be drilled as close as 500 feet from your front door. Once construction of a well pad begins, life changes. We heard about the clouds of dust, the grimy film, the booming and the blinding lights, day and night. The construction phase of the process is still just the beginning. Next comes the drilling and the hydraulic fracturing of the wells. These parts of the process bring their own nuisances, some of which are similar to what homeowners experienced during the construction phase. Oftentimes, the noise is far worse than it was during the

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construction phase and can occur 24 hours a day. Some people had to sleep in a corner of the basement trying to get away from it. The vibrations from drilling and fracking were sometimes so intense that all the worms were forced up out of the ground.

Aside from the nuisances of the process, some people, as we learned from testimony, began to notice changes to their water. In many areas where unconventional oil and gas activity is common, there is no public water line. People rely entirely on water wells drilled on their own property. When the oil and gas operators spilled products used to fracture a well, or the storage facilities that held the waste water leaked, the chemicals made their way into the aquifers that fed those water wells. The water started smelling like sulfur, or tasting like formaldehyde. It burned the skin. There was a black sludge in the toilet. Some people hauled in "water buffaloes" – giant tanks of clean water – but the monthly cost could be more than a mortgage payment.

Then there was the air. The smell from putrefying waste water in open pits was nauseating. Airborne chemicals burned the throat and irritated exposed skin. One witness had a name for it: "frack rash." It felt like having alligator skin. At night, children would get intense, sudden nosebleeds; the blood would just pour out. But you can't buy a water buffalo to replace the air you breathe.

Many of those living in close proximity to a well pad began to become chronically, and inexplicably, sick. Pets died; farm animals that lived outside started miscarrying, or giving birth to deformed offspring. But the worst was the children, who were most susceptible to the effects. Families went to their doctors for answers, but the doctors didn't know what to do. The unconventional oil and gas companies would not even identify the chemicals they were using, so that they could be studied; the companies said the compounds were "trade secrets" and "proprietary information." The absence of information created roadblocks to effective medical treatment. One family was told that doctors would discuss their hypotheses, but only if the information never left the room.

Regulatory reaction

Contamination of water and air is not supposed to happen, of course. Environmental laws and regulations are supposed to prevent these very things. The agency responsible to enforce those requirements is DEP. Our investigation, however, convinced us that DEP did not take sufficient action in response to the fracking boom, and even now, more than a decade after it began, must do more to fully address the special challenges posed by the industry.

Unconventional oil and gas activity uses completely different processes than classic oil drilling, or any other industry that DEP had previously regulated. New rules were required to cope with these issues. But it took the agency years to promulgate regulations specifically targeting this industry, and some crucial areas still haven't been covered. The Department says formal regs are subject by law to an inherently slow review process beyond DEP's control. But we've seen the agency issue and enforce informal rules, when it elected to do so; and on many occasions it hasn't availed itself of that option either. As a consequence, companies were free to continue environmentally hazardous activities that DEP had the power to stop.

DEP employees didn't just need new rules; they needed new knowledge. The Department was faced with novel extraction technologies that no one knew anything about. In the early days of the industry, DEP endeavored to better understand aspects of the process by performing its own study. And yet, the agency did not effectively share the information among its own staff once it was acquired. We learned that expert training is available that could assist DEP employees in their ability to effectively regulate this industry. In spite of its availability, the agency hasn't found a way to avail itself of many of these training opportunities.

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More concerning, though, were the Department's failures to enforce its existing powers. DEP was charged with protecting water quality. One of the mechanisms to do so was to conduct water testing when a homeowner complained of contamination. However, we learned that DEP was relying on old, pre-fracking criteria – meaning DEP employees weren't even looking for the new compounds used in unconventional drilling, and therefore couldn't accurately say whether it was causing contamination. And the Department sometimes failed to take advantage of the law's most powerful feature: the "zone of presumption." If water sources near a gas well showed contamination in the period soon after drilling and hydraulic fracturing, the burden was on the operator to disprove responsibility. But that presumption was not consistently enforced.

We were also troubled by other practices. We learned, for example, that DEP employees often elected not to inspect reported violations; some employees would just call the well's operator, and rely on his version of events. And even in cases where investigation did show that a violation had occurred, and that ground water had been tainted, DEP employees typically chose not to notify neighboring landowners, who would have had no way to know there was a problem. Even today, there is apparently no policy that requires DEP to notify unsuspecting neighbors that a nearby resident's water was found to be contaminated, and therefore that their water could be contaminated as well.

The goal of regulatory oversight, moreover, is not only to discover past violations of environmental requirements, but to deter new ones. And the way to do that is to punish violators once they are identified. Administrative action begins with a Notice of Violation (NOV). But especially in the early years, there just weren't very many NOVs issued for fracking violations. In fact, in 2011, the Department issued a directive prohibiting oil and gas NOVs unless they were personally reviewed and approved by the Secretary himself, the top official in the Department.

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The message to employees, intended or otherwise, was to leave fracking alone. That message was reinforced by the Department's failure to use another powerful tool at its disposal: referral of cases for possible criminal prosecution. Even in recent years, when things have gotten better in some other respects, the number of criminal referrals for fracking infractions has been close to zero.

We believe that some DEP employees saw the job more as serving the industry than the public. We heard too many stories of complaints unanswered, or cavalierly dismissed. Some employees refused to consider evidence of problems presented by citizens, while at the same time readily accepting and believing information supplied by operators. Even when homeowners went to the trouble and expense of hiring their own experts, some DEP employees did not listen. We appreciate that not every complaint is founded. But, in areas of this Commonwealth where fracking has taken a toll, many people do not believe that DEP is an honest broker. Work remains to win back that trust.

Public health response

In some ways, the Department of Health should have had an easier time dealing with the shale gas boom than DEP did. Unconventional oil and gas activity was a revolutionary development. Public health crises, on the other hand, were nothing new for DOH. The Department, like other public health agencies, had seen plenty of newly arising health conditions, such as HIV, that demanded concerted action from health care officials: reaching out to doctors and hospitals in the affected area to gather information, tracing pathways of transmission, educating the public to recognize warning signs and prevent their spread.

Yet somehow it was different with fracking. When reports started coming in from homeowners suffering the symptoms of exposure to frack-contaminated air and water, DOH was

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suddenly hands off. There was no special training for public health center staff in affected communities; no public education alerting people to the potential problem; no centralized collection of data that might help pin down what was making people feel sick.

Instead, staff were directed, in effect, to leave fracking-related complaints alone. The agency actually constructed a list of approximately 20 words related to health complaints arising from unconventional drilling activity. Staff were instructed that if anyone called in, and used one of those words, the staff member should end the call and direct the caller to a central office at headquarters. After that, nothing happened. Callers who had been transferred to the central office never got anywhere. They would call back to their district office asking what happened. Meanwhile, DOH employees who could see that something was going on in their communities, and who were trying to educate themselves about it, were instructed that they could not attend meetings or events related to fracking without applying for and receiving special permission that was not required in other areas.

It didn't have to be that way. We know, because we heard from other entities about how they handled these health issues. We heard evidence about a non-profit health organization active in southwestern Pennsylvania, and a federal agency working on this issue throughout Pennsylvania. Professionals from these organizations actually investigated to try to find out what was happening. They used tools to collect air specimens and to detect patterns. They discovered that exposure levels varied considerably by various factors, such as distance from the well, time of day or night, elevation, and weather conditions. DOH could, and should, have been doing the same kind of work, but never did.

Now the agency tells us they are enhancing their response to fracking-related health complaints. They have a new centralized database, although few people call to report

information, because DOH has little to provide in return. The Department says it is changing that; it is embarking on a new, three-year study, at a cost of one million dollars per year, to examine possible links between health and unconventional oil and gas activity. We are pleased to hear that. But the study is retrospective, meaning it will attempt to gather and analyze already existing data from prior complaints. And because DOH effectively discouraged such complaints in the past, there may be little data to review.

We believe the Department is still in a state of denial about the potential effects of fracking-generated substances on human beings. We asked DOH to share with us its opinion on whether fracking posed a risk to public health. The answer was that definitive causation "has not been proven." Well, yes; you can't prove what you don't examine, and DOH has gone out of its way in the past not to look at connections between fracking and health effects. The circumstantial evidence is compelling and we think it was the Department's job to look at it. The new study is a start, but is still far from the proper response of a public health agency.

Recommendations

We urge the executive and legislative branches of Pennsylvania's government to seriously consider the findings of this Report, and to act in favor of the common good of Pennsylvania and its citizens. We think there is more that can and must be done to minimize the hazards arising from unconventional drilling. Some of it is science; but it's not rocket science. These are practical and available responses to the problem.

1. Expand the no-drill zones

Everything we've seen confirms that all the impacts of fracking activity are magnified by proximity. The closer you live to a gas well, compressor station or pipeline the more likely you are to suffer ill effects. Yet the state law minimum "set-back" for well construction is only 500 feet. That is dangerously close. An increase in the setback, to 2500 feet, is far from extreme, but would do a lot to protect residents from risk.

2. Stop the chemical cover-up

Oil and gas companies use huge quantities of complex, man-made chemical compounds, which then get released into the environment. Some of them are subject to disclosure requirements, but only after they've been used. Some have no reporting requirement at all. And some are kept hidden based on "trade secret" claims. Let's end this camouflage, provide transparency to the public, and mandate disclosure of all chemicals used in any aspect of unconventional drilling, so their possible hazards can be properly considered.

3. Regulate the pipelines

Fracking requires special pipelines that pose special environmental risks. When they travel through less-populated areas, though, the network of smaller pipes, called "gathering lines," is almost completely unregulated. This is yet another undeserved exemption for elements of the unconventional drilling system. Close that loophole.

4. Add up the air pollution sources

Fracking equipment regularly releases gasses into the atmosphere. One of the culprits is the so-called "pigging station," where pipeline valves are opened up for cleaning. DEP generally considers individual pigging stations as too small to require attention. But these stations are often located near each other, and so they have a cumulative effect that is significant. Start adding together all the emissions producing sources in a specific area and treat them as one pollution source, so that the true impact on local residents can be properly addressed.

5. Transport the toxic waste more safely

The industry uses hazardous chemicals in drilling and hydraulically fracturing unconventional wells. These chemicals return to the surface as waste. This waste is transported around the Commonwealth in trucks labeled as non-hazardous "residual waste." That means when the public and first responders encounter this waste, they do not know it could be highly dangerous. To mitigate this risk, Pennsylvania should require trucks carrying waste containing chemicals used in the drilling and fracturing process display signage specifically identifying the source of the waste they carry.

6. Deliver a real public health response

Let's release DOH from its self-imposed constraints and require it to treat fracking like any other public health crisis. Send out the nurses and doctors to interview health care professionals. Advertise in affected areas. Collect sophisticated data and conduct sophisticated analysis.

7. End the revolving door

DEP employees, once trained about fracking at government expense, are often poached away to much higher-paying jobs in the oil and gas industry. That creates a potential conflict of interest for government workers whose duty is to regulate the people who may well be their future employers. A revolving door rule would reduce that potential conflict by requiring a period of delay before taking a new job in the regulated industry.

8. Use the criminal laws

DEP won't use its most powerful weapon against frackers who break the rules: criminal prosecution. But there's no reason it should only be DEP's call to make. Extend jurisdiction to the Office of Attorney General, so that its environmental crimes section can follow the evidence and make appropriate decisions about criminal charges, without leaving it all up to DEP.

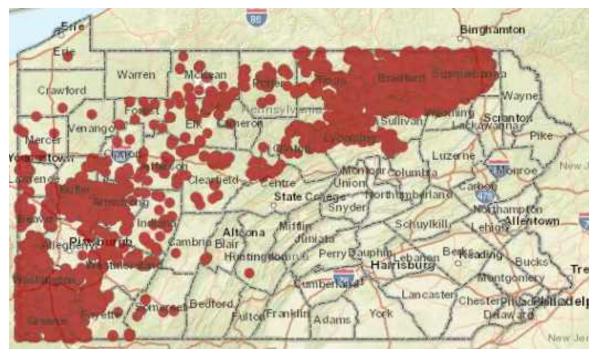
If we ignore history, we're bound to repeat our mistakes. That is why we are issuing this

Report. We've been here before in Pennsylvania. First, we allowed the timber in our Commonwealth to be plundered. Then it was our coal. Now it's shale. Other industries will certainly come our way, for some new natural resource to exploit. This is the time to learn our lesson for the future: who will bear the inevitable risks? We say it should be those who exploit the resources, not those who live among them. That means let industry pay the price of harm reduction, and let government take the time to get it right before we hand over the keys. And for the present, let us at least do all we can to catch up.

The Realities of Shale Gas Operations

Pennsylvania has experienced an extraordinary oil and gas boom since the first unconventional well was drilled in Washington County in 2004. Today, approximately 12,500 unconventional oil and gas wells have been drilled in Pennsylvania, and around 10,500 are actively producing natural gas. Hydraulically fracturing a well is a heavy industrial operation. Even under ideal conditions, these operations significantly affect the environment and communities where they occur.

Fracking technology has enabled the extraction of once unobtainable oil and gas deposits in shale rock formations thousands of feet below the surface of Pennsylvania. In the Commonwealth, unconventional drilling has targeted the Marcellus shale formation, a 575-mile long deposit of flat lying shale rock running beneath West Virginia, Pennsylvania, Ohio, and New York. As shown in the depicted map, in Pennsylvania, the Marcellus runs from the southwest of the Commonwealth in an arc toward the northeastern region of the state, with drilling concentrated in the southwestern corner and northeast.



The ability to access gas deposits in shale formations through unconventional drilling has revolutionized energy production in the United States, and Pennsylvania is at the center of this revolution. While unconventional drilling and recovery involves impressive feats of engineering, it is an industrial enterprise. It has in many cases been undertaken within a few hundred feet of homes and water supplies. This close proximity between industry operations, homeowners, and communities results in unavoidable risks and problems.

The fracking industry is still in its infancy. Experts anticipate that there will be another 30,000 to 40,000 unconventional wells drilled in the Marcellus shale in the coming years. These estimates do not reflect the drilling potential of other shale formations lying beneath Pennsylvania, such as the Utica shale, which also contain substantial gas deposits. Understanding how fracking has developed in Pennsylvania up to the present day is important because we are concerned about Pennsylvania's future. We must act now, with a clear and honest understanding of the reality of this industry, to avoid potentially devastating consequences to our environment and the health and well-being of Pennsylvania residents.

The drilling process

The first stage requires clearing and leveling the drilling site and preparing the drilling infrastructure, including a well pad, an access road to the well pad, and any other required equipment. Once the necessary infrastructure and large machinery are in place, drilling begins. The industry utilizes fluids and chemicals throughout the drilling process to manage friction, allow drill cuttings to move vertically up and out of the well, and to cool and lubricate the drill bit. Drill cuttings can be contaminated with hazardous chemicals used in the drilling process, as well as naturally occurring metals previously trapped beneath the earth's surface, which can be harmful and even radioactive.

Drilling an unconventional well occurs in stages. As each section is drilled, a metal pipe called a "casing" is inserted into the ground to stabilize the hole. Cement is then pumped under pressure inside the casing and when it reaches the bottom of the drilled hole, is pushed up the outside of the casing to fill the area between the casing and surrounding rock and soil. Once the cement hardens, the intended result is a metal casing surrounded by cement that has completely filled and sealed any space between the well and its surroundings. The process is repeated with progressively narrower casings as the well is drilled.

The Marcellus formation lies from 7,000 to 9,000 feet underground and is around 100 to 350 feet thick. At around 1,000 feet of the targeted shale deposit, drilling goes from vertical to horizontal at a slight curve. Once lateral, the well is drilled out through the shale rock for upwards of 25,000 feet, or approximately five miles.

The hydraulic fracturing process

Once an unconventional well is drilled and casings are in place, "perforating guns" are lowered into the horizontal extension of the well. Perforating guns allow explosives to be placed and detonated in order to puncture hundreds of dime-size holes through the production casing and cement and out into the rock formation. This is followed by hydraulic fracturing, which uses a high-pressure injection of fluid (generally water), "proppant" (sand or silica), and chemicals to fracture the shale and stimulate production. The fracturing process requires the use of extraordinary amounts of fluid.

All of those fluids do not remain underground. A portion of the fluid used in the fracking process returns to the surface as "flowback." Flowback consists of the chemical composition of the fracking fluid plus naturally occurring substances it mixed with during the fracking process, such as chloride and strontium.

Once the flowback has exited, natural gas begins flowing upward and out of the well. At this point, the well is in production. In addition to gas, wells expel "produced water," which consists of fracking fluid that did not initially exit the well as flowback, but steadily exits a well during production. Because produced water has remained in the subsurface far longer than flowback, it is more contaminated, and will typically contain high levels of sodium chloride (salt), bromide, lithium, boron, iron, manganese, arsenic, and radioactive radium. An unconventional well can produce from half a million to over three and a half million gallons of flowback and produced water over the first five to ten years of production.

<u>Pipelines</u>

In Pennsylvania, natural gas is transported from well sites via a series of pipelines. From the wellhead, gas first travels through "gathering lines," which are around four-to-six inches in diameter and can be highly pressurized at around 1,000 psi. Gathering lines are not subject to safety regulations in less populated areas. Despite the proliferation of gathering lines throughout the Commonwealth and the fact that they commonly leak, in underpopulated areas (less than 10 residences within 1 linear mile of pipeline) they are not regulated or otherwise monitored by the federal government or the Commonwealth for safety.

Gas transfers from gathering lines to "transmission lines," which are 36-to-42 inches in diameter and travel for hundreds to thousands of miles. Transmission lines ultimately arrive at a "city gate," where gas is decompressed, odorized, and distributed to end use consumers through narrow, low-pressure "distribution lines."

"Compressor stations" are strategically placed along gathering and transmission lines to add and maintain pressure in the pipeline, as well as to clean, cool, and otherwise facilitate movement of natural gas through the pipeline network. It is necessary to release gas from compressor stations through "blowdowns," which are required to ensure the pipeline can be depressurized in case of emergency. Transmission lines, as well as gathering lines, employ "pigging stations," where devices called "PIGs" (pipeline inspection gadgets) are inserted and removed from pipelines to clean out debris and gather data to ensure the pipeline is operating properly. Each time a pig is inserted or removed from a pigging station, the pipeline has to be depressurized and gas released through a blowdown. As with blowdowns at compressor stations, release of gas from a pigging station can have an impact on the environment and those in the vicinity of where the blowdown occurs.

Disclosure of chemicals used in drilling and hydraulic fracturing

Approximately 1,600 different chemicals have been detected in fracking wastewater. We have high quality toxicity data on only about 10% of these, however. Among the most common of these chemicals are petroleum distillates, which are like diesel fuel, and act as "friction reducers" to sustain pressure in a pipe. Hydrochloric acid is frequently used to keep the holes in a production casing clear and open to allow gas to flow into a well. Corrosion inhibitors protect the inside of the casing from corroding. We were particularly concerned to learn that petroleum distillates are commonly used in the fracking process because they contain "BTEX" chemicals like benzene, toluene, ethylbenzene, and xylene. BTEX chemicals are extremely toxic and can cause serious health effects in very small doses, including cancer, neurotoxicity, kidney damage, liver toxicity, changes to blood chemistry, and harm to the immune system.

A sophisticated nationwide system, referred to as "SARA Title III," governs the treatment of hazardous industrial chemicals in the workplace. This system requires businesses to directly report dangerous chemicals they store on site to "Local Area Emergency Planning Committees," local fire departments, and Hazmat teams. The information is also available to the

public. Notifying first responders of dangerous chemicals in their communities allows them to prepare for a fire or emergency at a facility where these chemicals are present. Businesses are required to maintain "Safety Data Sheets" to identify the chemicals on site and allow first responders to quickly determine the specific risks associated with them in emergencies. When dealing with dangerous chemicals such knowledge is essential – firefighters and Hazmat teams can only do their jobs if they know what they are dealing with.

Remarkably, the shale gas industry, despite using and transporting dangerous chemicals in their everyday operations, is largely excused from SARA Title III's oversight regime. No other industry enjoys such comparable exemptions.

Because of these federal exemptions, the states almost exclusively govern the fracking industry's obligations to publicly disclose the dangerous chemicals it uses. In Pennsylvania, the industry self-reports and publicly posts the chemicals used in hydraulically fracturing an unconventional well on a website called "FracFocus." Via FracFocus, anyone can look up any shale gas well in Pennsylvania and see what chemicals the operator reported using in fracturing the well. Operators are required to provide this information only after completing a fracturing job, however, with the DEP receiving notification 30 days after and a public posting occurring within 60 days.

There is a significant gap in reporting, however, because the industry is not obligated to identify or provide information about chemicals they classify as proprietary trade secrets. While the industry must disclose trade secret chemicals to the DEP, the public and first responders cannot access them. Keeping these proprietary chemicals secret leaves firefighters and Hazmat teams incapable of effectively or safely responding to emergencies at unconventional gas sites.

Communities, industry employees, and others who find themselves in close proximity are likewise kept in the dark. This risk is unacceptable. Only full public disclosure is sufficient.

In addition, the industry is only required to disclose chemicals used in the hydraulic fracturing process, but not the drilling process. This is a serious problem because chemicals used in the drilling stage can come into direct contact with the water table. We have learned that water contamination most frequently occurs when a well is drilled. Yet the drilling stage, when water supplies are most at risk, is largely unregulated.

The industry argues that maintaining the confidentiality of trade secret chemicals is necessary to protect their competitive advantages. We find any competitive interest of the industry outweighed by the need for Pennsylvanians to know all chemicals used in fracking operations. In addition, we have learned that full disclosure of trade secret chemicals can occur without harming oil and gas operators' economic interests.

In 2014, a United States Department of Energy task force unanimously recommended full disclosure of all constituents used in hydraulic fracturing, including those containing trade secret information. The task force concluded that complete disclosure can occur with nominal risk of revealing proprietary information if it is "organized by the <u>chemicals</u> rather than the <u>additives</u> of products to the fluid." In the words of one witness, "it is like the back of the Kentucky Fried Chicken box Ingredients do not make a recipe."

Pennsylvania should require full public disclosure of all chemicals, including trade secret chemicals, used in both drilling and hydraulically fracturing an unconventional well. These disclosures should occur before drilling commences, and an operator should update its disclosures if different chemicals are used during a fracking job. Anything other than complete disclosure poses an unacceptable risk to communities and first responders.

Hauling fracking waste

The dangerous chemicals used to drill and hydraulically fracture unconventional wells end up in drill cuttings and millions of gallons of wastewater produced by each individual well. Managing the millions of gallons of wastewater generated by unconventional oil and gas operations, in particular, presents an extremely challenging problem. The fracking industry has never had a good solution for this problem, and it persists today.

For years following the fracking boom, the DEP permitted the industry to dispose of flowback and production water at municipal wastewater facilities. However, these facilities could not process the various metals, chemicals, radioactive materials, and extreme salinity of these fluids. Therefore, in 2012, a voluntary ban on accepting fracking fluids at wastewater facilities was instituted, and Pennsylvania later formally banned the practice.

Fracking wastewater can be permanently disposed of by pumping it into decommissioned oil and gas wells called "deep injection wells," or "underground injection control wells." There are currently around a dozen permitted deep injection wells in Pennsylvania, and only a few of these operate commercially; meaning they can accept wastewater from any operator. Rigorous permitting requirements, local opposition and litigation, and the fact that Pennsylvania's geology is not conducive to these wells means they are not a viable local option to the fracking industry's wastewater problem.

There are over 200 deep injection wells in Ohio, however, so 90% to 95% of Pennsylvania's fracking wastewater disposed of in deep injection wells goes to Ohio. Given the cost and logistical burden of shipping wastewater to these out-of-state injection wells, this is not a viable solution to the industry's wastewater problem.

The industry primarily employs on-site tanks to store flowback and produced water, which is later "recycled" to frack other wells. In Pennsylvania, around 90% of flowback and produced water is recycled, and 20% to 30% of fracturing fluids are composed of recycled wastewater. This practice entails storing fluids in a series of interconnected "frac tanks," which hold around 20,000 gallons and are roughly the size of a shipping container. More recently, companies have begun using "modular aboveground storage structures," which are temporary holding tanks that store massive amounts of wastewater.

Before flowback and produced water can be recycled, it has to be treated. Operators use on-site mobile treatment units or ship their waste to the approximately 20 treatment plants around the Commonwealth. Treating fracking wastewater is its own distinct industry, with costs ranging from \$2.00 to \$10.00 a barrel (42 gallons) depending on the degree of treatment performed.

Both "recycling" wastewater and disposing of it in deep injection wells requires hauling it around the Commonwealth and neighboring states in tanker trucks. This wastewater may be composed mostly of brine and relatively harmless constituents, or it may be full of extremely dangerous chemicals or highly radioactive. There is no way to tell, however, because the industry is not required to identify or manage its wastewater for what it actually contains. Due to exemptions under federal law, trucks carrying fracking wastewater in Pennsylvania are not placarded as hauling hazardous waste, even though they may be carrying hazardous waste. Rather, they display signage indicating they are carrying "residual waste," which fails to account for the serious health and environmental risks posed by fracking wastewater.

Hauling fracking wastewater as "residual waste" poses a serious risk to the public and first responders because if there is an accident and the driver of a truck hauling fracking waste is

incapacitated, the public and first responders at the scene won't know that whatever may have spilled all over the roadway came from a fracking site. Pennsylvania should require that trucks hauling solid and liquid waste containing chemicals from shale gas operations display signage indicating the source of the waste in question. While this signage may not clearly state exactly what is in the waste in question, the public will know it came from a fracking site and can handle the matter appropriately given the risk that it may contain extremely dangerous chemicals.

Our government and the shale gas industry currently have no long-term sustainable solution to managing the toxic waste generated by fracking operations. At the very least, the industry should be required to more safely and responsibly transport this waste around the Commonwealth.

The Effects of Shale Gas Operations on Pennsylvania Families

We heard testimony of the experiences of over 70 households with the shale gas industry. This sampling represents the limited number of complaints we as a grand jury had jurisdiction to investigate. While the number of homeowners we heard from is far less than the total number of Pennsylvanians who have experienced harm from fracking operations, their stories provided us with a sound and detailed understanding of the realities of this industry and the problems associated with fracking in our Commonwealth.

We are deeply grateful to the homeowners who shared their stories with us. We were moved by the profoundly emotional experiences many have endured. Often, their pain was still raw, but they nevertheless testified and taught us about the sometimes harsh reality of shale gas operations. While we cannot truly capture what it was like to witness their testimony, all those reading this report should understand that we find the testimony of these homeowners credible and compelling.

While each homeowner's experience was unique, they were in many ways similar, regardless of whether they lived in the same township or hundreds of miles from one another. Indeed, many of their accounts were remarkably consistent. Dozens of people experienced the same medical symptoms in association with the same oil and gas activity. Parents invariably feared what exposure to fracking operations posed to their children's health and future, as any parent would. There are simply too many people who have suffered similar harms in communities throughout Pennsylvania where fracking occurs to disregard the damage caused by this industry's operations. This reality necessitates laws and regulations capable of protecting those put at risk by fracking, and a government willing to enforce them. For too long, Pennsylvania has failed to live up to its responsibility to its people in both respects.

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Fracking is a heavy industrial operation. It requires hundreds or even thousands of trips by heavy trucks, coming and going from a well pad, 24 hours a day, for months. Drilling and fracturing requires the use of dangerous chemicals – some known and some unknown, because the industry refuses to disclose them. The use of these chemicals produces contaminated solid waste and hundreds of thousands of gallons of liquid waste. The industry is exempt from treating the dangerous byproducts of its operations as hazardous. Spills and accidents happen. Emissions are inevitable. We examined evidence and heard testimony showing that when all this industrial activity occurs within a few hundred feet of someone's home, as our laws have allowed, harm to public health and significant disruption to people's lives result.

We do not claim to have an easy solution that would allow fracking operations and residents to coexist in perfect harmony. However, the recommendations we do offer are necessary and obvious. Extensive testimony, hundreds of exhibits containing records, and technical data from leading experts and dozens of DEP and DOH employees support what we propose. Ultimately, the recommendations in this Report are rooted in and validated by the experiences of everyday Pennsylvanians who shared with us the real world effects unconventional oil and gas operations can have on people's lives. Confronting and fixing the legal, regulatory, and executive-level norms that enabled the harms experienced by the homeowners will go a long way toward restoring some balance between fracking operations, public health, and the constitutional right to "clean air, pure water, and the preservation of the natural, scenic, historic and esthetic values of the environment."

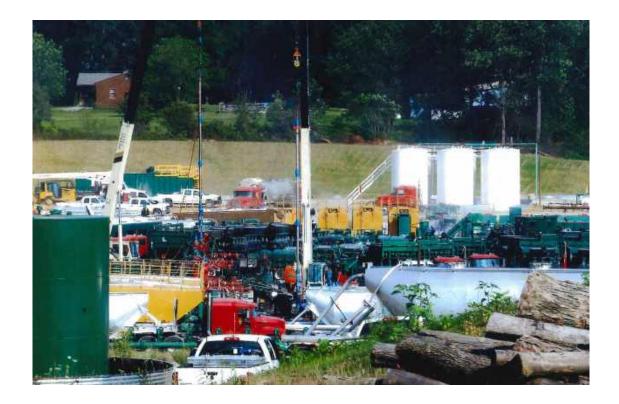
The vast majority of homeowners we heard from lived in rural, agricultural areas. Some deliberately sought an escape from the noise of urban or suburban life when they bought property and built their dream homes. They lived on small plots of land as well as on farms

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spanning hundreds of acres. Some entered into oil and gas leases, often under false pretenses or lacking a full understanding of what fracking operations would entail. As one homeowner told us,

> The land manager told us that when they were finished, all that would be in there were a few green tanks, but we had no idea that it was going to be a three-year ordeal of 24-hour lights, back-up beepers, digging, my wall vibrating in my house. Just had no idea.

Many did not sign leases, but that did not insulate them from the life-altering disruption of industry activities. Extraction may occur on a neighboring property, or an oil and gas company might have obtained the mineral rights to the land from a prior owner, allowing the company to access the property to extract the oil and gas lying below. So long as the operation was not within 500 feet of their home – the only limitation under Pennsylvania law – residents had no control.



Families that once lived in peaceful agrarian communities suddenly found themselves

living in something resembling an oil refinery. As one witness described it,

It has made it an industrial zone. There is no country living out there anymore. Getting out of our driveway alone is dicey at best. We have a lot of fracking trucks. We have a lot of sand trucks. We have a lot of construction vehicles And there is - you know, when we first started building, there was one small compressor station. There is two very large compressor stations. There are two cryogenic plants. There are several wells, pigs, of course, and that is all within less than a mile from our house. Most is I would say less than three quarters of a mile. . . . So, yeah, it is - it is worrisome.

For homeowners who did not own the mineral rights beneath their property, the

realization that an oil and gas operator had the right to come onto their land and set up operations

could be traumatic:

A: I just got a chill. You kind of forget some of those things. But when it first happened, it was devastating to have somebody knock on your door and tell you we're going to come on your land, we have the right to do it, and we're going to use – I don't even know how many acres they said. I don't even know if they knew at the time. You know, beautiful wooded land, places I take trail horses with old tree lines with trees covered and old fence lines. It was a nightmare. I remember [my husband] and I both – I don't think I slept through the night for a month. It was like a nightmare. You just can't imagine somebody knocking on your door saying we have the right to come on your land and do such and such to the land. It was like a living nightmare really.

Q: Ultimately, did they come on the land to start constructing well pads?

A: Ultimately, they did, yeah.

Once an operator has secured leases for mineral rights in and around the area of the proposed well pad, their next step would be to acquire all necessary permits. Once the permits are in hand, the operator would begin the actual construction of the well pad. The heavy industrial nature of fracking becomes evident to property owners from the very outset of constructing the well pad. Many homeowners described the extreme disruption this process

caused to their lives. Heavy truck traffic caused clouds of dust to circulate around their properties, blanketing their homes inside and out. They kept their windows shut. They stopped spending time outdoors. Their children could not play in their yards. A grimy film would accumulate on glass surfaces as dust and particulate matter invaded the interior of their homes. These sort of problems were a direct result of our laws permitting shale gas sites in such close proximity to people's homes.

The industrial nature of fracking operations is apparent from just looking at a typical well pad.



Construction of the pad is only the beginning. Next comes the drilling of the gas wells. This part of the process can continue for weeks on end, day and night, with the drilling pad lit up with blinding lights, creating extraordinary noise and vibrating the Earth around it. The closer a homeowner lived to these operations, the more traumatic they were to their previously peaceful lives. Homeowners described sleeping in corners of their basements in an effort to escape the bright lights and noise. They could not sleep. Their children could not sleep. They could not escape the industrial activity happening so close to where they lived.

When they sought help from local authorities, their pleas often fell on deaf ears. For example, we heard testimony that when residents complained that industry operations were in violation of noise ordinances, local governments changed the ordinances to accommodate the industry rather than responding to the needs of their citizens. In addition to finding no help from the local authorities, we heard from homeowners who sought help elsewhere and were equally frustrated. One witness recounted calling DEP to register her complaints and being told to call 9-1-1 instead. When she called 9-1-1 as instructed, they did not understand why she was calling and were equally unhelpful. The lack of response from agency after agency led to feelings of hopelessness, despair, and distrust toward the government.

Many homeowners reported that they first experienced contamination of their drinking wells during the drilling process. Drilling through the water table would turn their well water brown and rust-colored and fill it with sediment. Sometimes after drilling was complete, their well water would eventually return to normal after constituents in the aquifer resettled or contaminants introduced during the drilling process dissipated or moved along in the aquifer. For others, contamination of their water supply was just beginning. In some cases, homeowners experienced a complete loss of their water supply.



Below is a photo of contaminated tap water from a homeowner's well:

For many Pennsylvanians living in rural areas, such as where shale gas drilling proliferates, clean drinking water is available only from wells. Most of us take for granted the safe, municipally supplied water we use every day. In rural parts of the Commonwealth, public water is the exception to the rule, and well water is the only option. Thus, if industry operations contaminate a family's water supply, they cannot simply hook up to a public system. When their water suddenly changes in taste, smell, or appearance, they can either continue drinking it and hope for the best or begin hauling clean water to their homes.

Many resort to using large water tanks called "water buffalos." Sometimes an oil and gas operator alleged to have contaminated a family's well will supply them with a water buffalo, at least temporarily, while other homeowners are left to cover the cost of an alternative water source themselves. One homeowner testified that paying for an alternative water supply cost her family \$650 per week, which can easily exceed a family's monthly mortgage payment. We heard testimony from some homeowners who felt that oil and gas operators would remove their water buffalo in direct response to additional or continuing complaints that they made. We find this behavior, if true, unconscionable.

The next stage in the process of extracting natural gas is known as hydraulic fracturing. During this stage of the process, many homeowners described over 200 trucks coming and going from a well site in a single 24-hour cycle. This traffic goes on for weeks as a well is fracked. These numbers are not exaggerated. They reflect the millions of gallons of fluids, sand, and chemicals necessary to hydraulically fracture a well. We heard the following account of what fracking-related truck traffic is like:

It was horrific. It was constant. The amount of trucks going in and going out of there, I've never seen anything like it in my life. You couldn't pull out without being behind, between or trying to maneuver with the trucks. . . . [T]hey made the roads go like a washboard. It was rough.

Below is a screenshot from a video of fracking-related truck traffic that captures to some degree what such traffic looks like.



Hydraulic fracturing entails pumping millions of gallons of fluid into the earth under enormous pressure. This causes powerful vibrations to resonate through the earth. These vibrations shake homes and crack foundations. Several homeowners described how the earth around their homes would vibrate so intensely that worms would crawl out from the ground in their yards and basements. A fleet of heavy trucks coming and going, day and night, to provide millions of gallons of fluid to the well pad, accompanies all of this fracturing activity. The noise would be overwhelming.

Descriptions of the effects of fracking on peoples' well water were remarkably similar across the Commonwealth. Many described a "black film" or "black sheen" appearing in their water, particularly when it would sit idly in their toilets. Some would have "cloudy" water. "Black sludge" or "black slime" would clog and damage the pumps and filters used to treat their well water. They would find sandy, particulate matter in their water and filters. They described a "sulfur" or "rotten eggs" smell. Homeowners detailed a variety of chemical smells, as "sweet," "like a chemical lab," "plastic," or "like formaldehyde." Those who ventured to taste their water often described it as "foul" and "metallic." None of these conditions occurred prior to fracking operations near their homes.

Homeowners' water became unusable for not only drinking and cooking, but bathing, hand washing, and other basic household purposes. Some came to realize their water was contaminated not because of perceptible changes such as smell or color, but through illnesses and health effects. Accounts of red, itchy, burning rashes from exposure to contaminated water were widespread. When people were away from their residence, their skin problems subsided. They were unable to safely wash their hands or bathe in their own homes. Often these symptoms

would manifest without their water exhibiting noticeable problems such as intense smells or discoloration. As one homeowner described her family's experience,

We started getting sores all over us. And we were sick to our stomachs and having problems with breathing whenever we were in the shower. And it would burn our eyes, nose, and throat; and it just -- it was putrid. It was embarrassing. If we had anyone coming to our home, we would have to shower and air the house out and then try to spray air fresheners to get rid of the smell. It was bad.

We learned that part of what complicates well water testing and determinations of contamination is that subsurface waters are dynamic, and chemicals in an aquifer may not appear at detectable levels in a water supply at the same time. Nor do they necessarily remain indefinitely. This means that contaminants may be in someone's water and affecting their health, but they are initially unaware of it at the time, but when symptoms manifest those chemicals may have washed out or dissipated in the water table and been replaced by some other contaminants. Often a homeowner will take action to test their water only when it becomes highly salty, or when some other noticeable problem manifests, without realizing they have been exposed to contaminants over the prior months. When testing then occurs, it may not reflect the totality of their exposure, and the links between their health condition and possible causes are more difficult to determine.

Water analysis is an imperfect science that cannot always provide the answers homeowners need. This complexity of water testing is compounded by the fact that operators are not required to disclose all the chemicals used to fracture any particular well, or any chemicals used in the drilling process. That makes it impossible to analyze a homeowner's water for sources of contamination properly, because the tester does not know what to look for.

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Homeowners frequently described a lingering fear that analysis of their water was not showing a full and accurate picture of what was happening. When they turned to DEP for answers, they were often left unsatisfied because DEP's standard water analysis was too narrow and would not account for the full range of potential contaminants in their water. When results were provided they were difficult for the layman to understand. Turning to the industry operator would bring equally unsatisfying answers. In the midst of this anxiety-inducing situation, homeowners often concluded that no one was taking their concerns seriously. They were ultimately left to decide whether to pay the hefty cost of an alternative water supply or complex treatment systems to clean their water of unknown chemicals and fracking byproducts or continue using their suspect well water.

Different homeowners described different ways in which the industry's operations affected their lives. We heard many accounts of impoundments; man made ponds, several acres in size, where oil and gas operators stored millions of gallons of fluids. In some instances the DEP permitted the use of an impoundment to hold fresh water for use in fracturing wells in the surrounding area. Over time, however, the industry sometimes would use these impoundments to store contaminated wastewater, even though they were not designed to store toxic fluids. Such impoundments lacked features like double liners and leak detection zones capable of detecting leaks. As a result some of these ponds of liquid waste failed, with devastating consequences. Dangerous chemicals and contaminants invaded the environment and affected public health.

Families came to realize that wastewater impoundments not only contaminated their water, but the air they breathed. As enormous open toxic pits, some of which were acres in size, impoundments would release harmful chemicals into the air. The smell of sulfur and intense

chemicals smells would inundate nearby homes. Property owners would sense a metallic taste in their mouths. Contamination in the air would overwhelm homeowners with nausea, dizziness, and a feeling that they would pass out. They would vomit. Their eyes, nose, skin, and throat would burn.

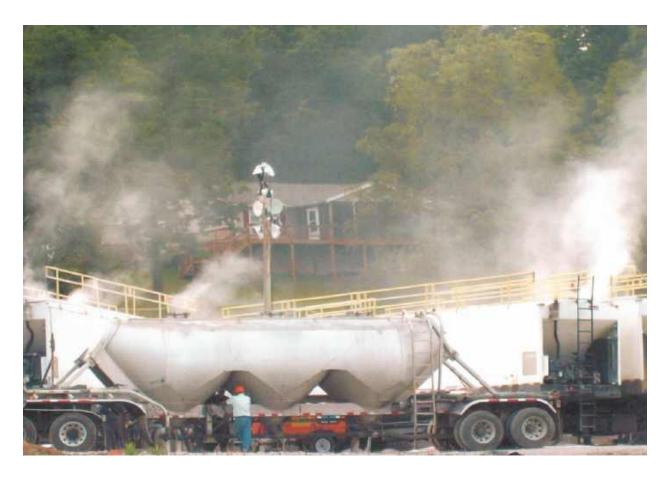
These were not fleeting episodes. The air in their homes would cause persistent sores, nosebleeds, mouth ulcers, unexplained bruises, and extreme fatigue. Visitors would grow ill. Children would become frighteningly lethargic. Homeowners stopped going outside from fear of exposure. Their children could no longer play in their yards or explore the previously bucolic farmland where they lived. Nor did the inside of their homes offer an escape. We learned that air quality testing inside residences confirmed the presence of dangerous chemicals that would not normally be in people's homes, like benzene, toluene, methylbenzene, chlorobenzene, xylenes, acrylonitrile, cyclohexane, and three different types of trimethylbenzene. One homeowner described what it was like to live near a wastewater impoundment:

My property had a fence around it and they put the frack pit in 200 feet behind my property which was the size of a football field. Then they started filling it with chemicals. It constantly smelled like gasoline and kerosene, constantly.

Homeowners processed their experiences in different ways. In telling their stories, some seemed haunted and freshly traumatized, while others were stoic. The common theme from every homeowner who testified before us was an all-encompassing, debilitating anxiety that comes from so many unknowns. This was especially the case in the early days of the fracking boom, when there were more questions than answers. While this was partially due to the newness of the activity, it was also a consequence of the industry having no obligation to provide information to families living within a stone's throw of a well pad. Homeowners were not informed that toxic chemicals were used during the drilling or fracturing of a well. They were

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not told that toxic waste was stored in impoundments. They had no idea if these giant ponds of wastewater were leaking. They smelled foul odors, but did not know the cause, or if the mere act of inhaling could cause them to become ill. They did not know if their water was safe to drink or bathe in. Almost every normal daily activity suddenly posed unknown risks. There was little to no transparency.



When families would turn to the medical community their problems would often remain unresolved. We heard from several homeowners who attempted to find answers to their ongoing health concerns and received troubling responses from medical professionals. Too often, they recounted their doctors expressing reluctance to overtly link their symptoms to fracking operations, while also telling them it was not safe to stay in their homes. For instance, one parent described receiving test results confirming that chemicals used in an adjacent fracking site were poisoning her family. When she visited a toxicologist with this information, the doctor told her his office could not confirm the gas industry was responsible because his practice may lose its government funding, but that if he were in her situation, he would leave the family home.

This type of account was not an anomaly. Another homeowner described a similar experience with the medical community:

... [W]e've kind of hit a brick wall there as well trying to relate it. We go to the doctor's with him and they're not allowed to talk about anything. You mention one word, drilling or fracking or any of the key words, then you're kind of shut down. At one point we met with the doctors at UPMC and they took us into an emergency room and brought a couple chairs in and shut the door and whatever happens in this room has to stay in this room. What they told us is they can't put a direct link to it. It's just that the only thing they can do is process of elimination, take one thing out of the mix at a time until they determine what's wrong. They sent us to a specialist. Then it just kind of went nowhere either.

Another homeowner recounted the struggle faced when trying to find answers to what

was making her children so sick:

...our other doctors, like our family doctor and the pulmonologist and the gastroenterologist that my son saw, I mean basically, they were just trying to help us figure this out along with us. I mean, no one had any experience or expertise in this area. ... And so it just – it was hard trying to put two and two together. And, you know, [the operator] wouldn't tell us what they were using up there. You know, they have their proprietary chemicals, which we fought hard to try to get those, and so we didn't even know what else to test for. I mean, it was – if they would have at least given us what they were using, then we could have – you know, I could have had my kids tested for other things. We were just trying to figure things out on our own, find out information from the people in Texas, who had already been through a lot of this. It was – it was just hard, and there was no cooperation whatsoever.

For many, determining what industry operation was causing them to get sick was elusive.

The most obvious pathway of contamination seemed to be well water, so people initially focused

on their water. Many would obtain alternative water sources once the quality of their well water

was ruined or they started getting sick. Even though they were no longer exposed to contaminated water, their health would not improve, and many found themselves and their children getting sicker.

Families would then turn to the next most likely pathway of contamination: air. Wastewater impoundments would release repugnant airborne smells and toxins so intense property owners would pass out, become sick or vomit, or so overwhelming that they would have to be rushed to the hospital. Many other components of this industry's operations release airborne contaminants as well, which can be particularly harmful to those living close to sources of these emissions. Emissions from well pads, pigging stations, compressor stations, and other industry operations can all contaminate the surrounding air. Sometimes the way homeowners experienced emissions from well sites would change over the course of a day, with the air smelling "sweet and sulfur-like" at night, and like "burning hair" during the day. We heard of smells like "hair dye at a salon" and "burnt electrical components."

We heard of the industry performing "blowdowns" or wellhead "flaring"; or the rapid release of gas due to maintenance, a malfunction, emergency, or as part of regularly mandated safety testing. Many homeowners described these events as sounding like a "jet engine," vibrating nearby homes and windows, and releasing plumes of gas that would, in some instances, settle like fog in the surrounding area. One homeowner described awakening at 4:00 in the morning, without notification, to the "jet engine" sound of a wellhead flaring natural gas. The industry employees overseeing these operations wore protective headgear, but she was not, and was left with a loud hissing sound in her ears.

Various homeowners all described emissions from compressor stations smelling like chlorine. Noxious gases generated from compressor stations would permeate the interior and

exterior of peoples' homes, causing burning eyes, headaches, and sores in their mouths, and the development of serious illnesses. Blood tests would confirm the presence of contaminants in people who had been exposed to these gaseous emissions.

Health symptoms related to exposure to routine emissions were numerous and deeply troubling. Respiratory problems, headaches, dizziness, and burning eyes were commonplace. Children in particular experienced nosebleeds and extreme stomach pain. People told us that after the industry came into their lives they experienced weight loss, neuropathy (nerve pain), tremors and shaking, nose and throat pain.

Linking the wide variety of health issues homeowners have associated with air contamination to specific industry operations can be difficult. The absence of testing and lack of access to industry data substantially impede understanding. What we do know is that upon installation of an industry operation close to a family's home, they would begin to detect smells associated with the gases and chemicals emitted from these operations. At the same time, they started experiencing various symptoms indicative of airborne contamination and getting sick. Environmental testing at their homes, when properly conducted, would confirm the presence of airborne contaminants. Medical testing would likewise reveal that chemicals associated with industry operations were inside of their bodies.

One homeowner eventually saw a specialist who told him his blood revealed "chronic benzene exposure." His wife also had benzene levels in her blood. But he was particularly concerned for his children. As he told us,

Q. How does it make you feel that your children were being exposed?

A. Well, the same thing. The worst thing about it is if you read the toxicologist's report, one of the last statements he makes is now you need to be concerned about cancer sometime in the future.

For many families, exposure to contaminated air results in health anxieties and requisite

medical monitoring becoming a routine part of their children's lives:

A: So there was blood work, urinalysis; and it is hard to take kids to have their blood taken all the time. It is pretty terrifying. How much do you torture them through that; but yet, there were things found in their blood.

Q: Okay. And do you have any recollection sitting here today what those things were or would you have to look back at the actual medical records?

A: They said it had something to do with the ethyl benzene.

We heard the same account from witness after witness about the rashes their families would get from exposure to air contaminants. These rashes would appear on the frequently exposed parts of their bodies – their hands and arms, necks and faces – and would go away when they were away from home for a long enough period of time. While a rash may not seem like a particularly distressing ailment, one parent's description of a rash his son continually had captures the disturbing nature of this condition:

> Yes. We all call it a frack rash. He gets like an alligator skin after that and becomes really sensitive after a while. He's moved out of the house a couple times, moved back in. As he moves away, he's gone for a month and it goes away. If he's back in, it acts up right away.

Another near constant account was of children frequently waking at night with sudden,

severe nosebleeds. As one parent testified:

Both kids seemed to have [nosebleeds] a lot. My daughter seemed to get them more at night so she would kind of just wake up and panic, you know, something is on my face, screaming. She was, like, four or five years old. So by the time you turn on the light, you see - I know kids get bloody noses. We all do, but it was becoming a chronic thing. And it was getting to the point where I could trace them back to when they were doing maintenance at one of the compressor stations or opened the lines because there was

too much pressure. But it was getting really bad like she had this pretty little – her first princess bedspread and it was just ruined. It was getting to the point where I was using hydrogen peroxide to get the blood out of the carpet. That is not something normal. The doctors couldn't find any reason for it.

Another mother recalled a similar experience:

We had – my daughter had a lot of nosebleeds. It seems like the nosebleeds were worse with her. They would just be standing there and then all of the sudden blood would start pouring out of their noses. It wasn't anything like that they had done anything to prompt it.

A constant theme in the stories we heard was that children suffered health effects from nearby oil and gas operations more than adults. In addition to severe and chronic rashes, headaches, and nosebleeds, we heard accounts of children experiencing lethargy, bruising, intense cramping, difficulty sleeping, and painful stomach problems, including nausea and vomiting. They had eye problems ranging from frequent burning sensations and conjunctivitis to partial blindness. We heard of young people suffering symptoms associated with neurological problems, like twitching and tremors, erratic and uncontrollable eye movements, and neuropathy, which involves weakness, numbness, and stabbing or burning sensations throughout the body.

We heard clear and convincing evidence that leads us to conclude that industry operations in Pennsylvania have made our children sick. That is not a reality we are willing to accept, and the recommendations we propose will help to alleviate this problem.

We learned that kids get sick from airborne contamination not just because of some faulty industry operation, such as a malfunctioning compressor station, or practices that are no longer commonplace, like the use of wastewater impoundments. We know that air contamination is not limited to anomalous, outdated, or unintended industry activities. Indeed, the exact opposite is true. Standard operating procedure under Pennsylvania's current legal and regulatory regime

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exposes those living in close proximity to fracking operations to possible exposure and health risks. Pennsylvania needs to resolve this problem by requiring industry sites be far more distant from where we live and work. The current 500 foot standard is woefully inadequate.

Pennsylvania's laws further aggravate the problem by not accounting for the aggregate effects of fracking operations. When numerous gas sites exist in a relatively small area, their collective effect is not measured or acknowledged in the governing regulatory scheme. Many homeowners described living near a combination of well pads, pigging stations, gas processing plants, compressor stations, and impoundments. The DEP regulates these sites only individually, however, and by each individual company associated with them. Therefore, two oil and gas companies may own and operate adjacent pigging stations, but so long as each is compliant with emissions limits, Pennsylvania law is met. Meanwhile, a nearby homeowner is exposed to the collective effect of the emissions from both pigging stations, in addition to other nearby well pads and industry operations, but there is no recognition of the heightened risk posed by the collective emissions from multiple sites.

When families would escape their homes, whether temporarily or permanently, many of their symptoms would go away. For some the damage was permanent, however, and they continue to struggle with long-term problems like reduced motor faculties and sensitivity to chemicals. Many parents and medical professionals fear for the long-term health of children who have suffered health problems related to industry activities, particularly their ability to have children of their own and the risk of developing cancer. Doctors have advised that children who have suffered persistent health problems related to nearby fracking sites participate in regular cancer screening for decades to come.

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Additionally, we find that while families may implement measures to remediate the risks of living near an industry site inside their homes, such as with high-tech air filtration systems and alternative sources of water, they cannot remedy conditions outside the home. As a result, pets and livestock would continue to face exposure. Often, homeowners' animals first showed symptoms of contamination from industry activity. Even if their owners arranged a safe water supply for their animals, animals instinctively drink from seeps, streams, and ponds and their caretakers can do little to stop this. Family dogs got violently ill and died. Horses were poisoned and died. Many homeowners regularly bred livestock like goats, sheep, and cows. Some animals would become infertile, miscarry, and produce deformed offspring. Postmortem blood testing consistently showed the presence of fracking-related chemicals in animals' bodies. For many homeowners, the loss and harm to their animals was not strictly economic, but caused great emotional anguish.

Industry operations would ruin families' ability to enjoy other aspects of their country homesteads. For many, fishing and swimming in a pond is part of the joy of living in the countryside. Several homeowners described chemical spills, impoundment failure, or well bore breakdowns ruining their once thriving freshwater ponds. We heard about fish kills, ponds turning black, natural gas bubbling around the surface of the water, and plants and animals living around ponds dying off. Trees and massive patches of grass would die on people's land. While these effects of fracking may not seem as profound or life altering as other events we have learned about, such as someone's child becoming terribly ill, they nevertheless constitute a serious impact on homeowners' lives and are indicative of the variety of ways industry operations can harm the environment in which they occur.



Additionally, we heard testimony from individuals concerned about the possible effects of producing food on their property in close proximity to shale gas operations. Well pads in rural areas of Pennsylvania means there is a lot of industry activity near farming. We heard from a homeowner whose property was surrounded by multiple well pads who grew tomatoes, grapes, and apples. The owner watered the produce with potentially contaminated water and sold it to a local grocery chain. We heard from another farmer with a well pad on their property who raised and bred livestock that drank from suspected contaminated water. When the livestock failed to breed as anticipated, possibly because of the tainted water they were exposed to, the farmer sold them at auction to be butchered and sold to the public. We have learned that food, like water and

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air, is a possible pathway of contamination, and are concerned that contaminants from fracking may be spreading into the broader community by entering our food supply.

Industry operations also had effects on interpersonal relationships and sense of community. Once close-knit communities unraveled over whether they supported or opposed fracking. The industry perpetuated this division by rallying public support for their work and opposing those who spoke out against their business interests. Formerly cordial neighbors would be openly hostile to one another. People told us they no longer felt comfortable shopping and socializing in their own communities because of the animosity they felt. Friendships and community bonds were broken. We heard testimony from a witness who spoke about how life in her community changed:

... I got some incidents where I would go to a grocery store and one time a guy came charging at me. The woman with him pulled him back. Other times I would be pushed pretty close to the edge of the road. I had a gas tanker beep loudly their air horn every time they go by my house. I went up to the [supermarket] one day and walked in and they had a table set up where you could get a subscription to the [local newspaper]. I thought about it. I said maybe I should. Then a guy came up behind me and said, you should, you're in it all the time. People felt free just to say things to me. Some of the neighbors that were talking to me just had to tell me how badly I was being spoken of. It was very hostile. I actually stopped shopping in my hometown. My family all lives a short distance away in [a nearby town] and I do all my shopping there or elsewhere. Once in a while, I have to run over to [the supermarket]. I have a beautiful home in a community that is not my home.

As these experiences compounded, some homeowners eventually reached a breaking point and were left with no choice but to leave the homes they loved. Medical professionals and others told them it was unsafe to stay; an obvious fact given what was happening to their family. They could not sell their home, however, because it was unsafe, but also could not afford the cost of maintaining their mortgage and paying to live somewhere else. Thus, they were stuck with the option of financial ruin or trying to carry on living in a home where they feared for their health and the long-term wellbeing of themselves and their children. These were decisions born from desperation, and several homeowners shared with us the heartbreaking moment they realized they had no option but to leave:

> One day I was unpacking the car from Costco, I realized I'm now buying the double pack of hydrogen peroxide at Costco because this is strictly just to clean the carpet. This is it for me. I am done. This is not how kids live. So we left.



Protecting one's children is fundamental to a parent, and the realization that your own kids cannot experience a healthy, happy childhood is too much for anyone to bear. A parent described learning from someone else that her own son would hide the fact that he was feeling the effects of airborne contamination from his parents just so he could play outside:

...And she was sitting in the sandbox with him and she came back down with tears in her eyes and literally said to me that he told her

that he doesn't always tell me when he is outside and gets headaches and dizzy and can smell it because mommy won't let him come out and play with his new trucks in the sand box.

Some homeowners were able to obtain financial relief by entering into settlement

agreements with industry operators. This, however, brought additional issues in the form of non-

disclosure agreements that prevented homeowners from discussing with their neighbors the fact

that their community had been contaminated by industry activity. One homeowner described the

way a non-disclosure agreement impacted her ability to answer her neighbors' questions:

And the people that just purchased the [] house down below. . . [S]he says tell me about your water situation and I said I'm not allowed. And she says we just bought this place. I need to know So I told them, I said you need to get in touch with the DEP and EPA as well and that is all I can tell them.

Some homeowners found themselves with no choice other than to stay where they were.

We heard from one homeowner who testified as follows:

I took my son [] to the doctor and he referred me to Children's Hospital for his rash. . . . I went in there and after several times of going to [the doctor's] office, she said that there was nothing she could do for me. Then she said her advice was to get an attorney or move.

And then that's when I thought, I can't live – why is this happening? And that's when I thought, I can't move. I'm going to sell this house to somebody else and let this happen to somebody else or somebody else's kid? I couldn't do it. So that's when we just decided we really have to, as a family, just watch out for one another and my two neighbors and just not go outside.

* * * * *

Knowing what we know, and having heard so many Pennsylvania families experiencing terrifying health problems in relation to unconventional oil and gas operations, we cannot accept the status quo in our Commonwealth that facilitates these harms. Every Pennsylvanian should ask themselves how they would feel if a fracking operation suddenly commenced near their

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home. Imagine waking up in the morning and knowing that when you step into the shower, it fills the house with a smell of rotten eggs and burns your skin. You try to shower as quickly as possible with the windows open to mitigate the effects. You try to increase the number of days between bathing your children to minimize their exposure to this harmful water.

To protect friends and family and out of embarrassment, you never allow visitors to come over because of the way your water looks and smells when it comes out of the tap. You can't help but wash your clothes in your now contaminated water. You just hope you can air dry your clothes long enough that the odor diminishes before you have to wear them, all the while hoping that wearing clothes washed in unknown chemicals isn't going to exacerbate any symptoms you or your children have developed since your water changed.

And you do have symptoms that tell you that something is wrong: headaches and nose bleeds and rashes that don't go away. Your children are tired and nauseous all the time and frequently sick. You fear that something isn't right with your water, in spite of being told it is safe and so you begin to spend money to buy bottled water. You have animals to care for, but there is no way you can afford to give them bottled water to drink, so you continue to let them drink the potentially contaminated water. You watch as some of your livestock and pets become sick and die.

You become more and more concerned for your health and the health of your children. You cannot get straight answers from the gas company about what chemicals might be in your water because they're not required to tell you, so you're left to try to figure it out for yourself. DEP tests your water but only for a handful of compounds – and not the ones you really want to know about.

You worry that it's not just the water that is to blame, but the air that your family is breathing. You can't buy clean air at the grocery store. You make more frequent trips to the doctor. You scour the internet for information. You and your children do more blood tests. The symptoms persist.

You try to spend more time away from your house than you do in it. But you cannot leave permanently because your house is worthless without potable water, so you cannot sell it. You cannot afford to keep paying a mortgage on a house that has no value and so you just wait for the bank to foreclose or possibly declare bankruptcy. No matter what, your credit is ruined, which makes it almost impossible to find another place to live. You struggle to work because you're feeling sick and you're taking more time off to care for your sick children. And even if you do finally manage to get away from the house and you find a new place to live, even when you have the opportunity to breathe clean air and drink clean water again, you are left waiting for a diagnosis that you hope never comes. Because you know that the impact of drinking contaminated water or breathing contaminated air can show up slowly over time as a multitude of diseases.

This reality is not something that should be tolerated. We find it unacceptable that, for many living in close proximity to unconventional oil and gas operations, their health is jeopardized and their constitutional right to "clean air" and "pure water" has been rendered a fiction.

The Pennsylvania Department of Environmental Protection

DEP Mission Statement

The Department of Environmental Protections's mission is to protect Pennsylvania's air, land and water from pollution and to provide for the health and safety of its citizens through a cleaner environment. We will work as partners with individuals, organizations, governments and businesses to prevent pollution and restore our natural resources.

The Grand Jury heard extensive evidence about the response of the Pennsylvania Department of Environmental Protection (DEP) to the fracking boom. More than 30 witnesses from the department testified. They included retired and current employees, ranging from the ground-level inspectors up through various managers, to the people at the very top of the agency. We heard from water quality specialists, water quality specialist supervisors, oil and gas inspector supervisors, air quality specialists, air quality specialist supervisors, environmental program managers, environmental protection specialists, geologists, engineers, bureau directors, Deputy Secretaries and even former Secretaries – the top officials who ran the Department.

We conclude from this evidence that DEP was initially unprepared for and at times overwhelmed by the challenges resulting from the new technologies of unconventional drilling – or, as it is known in the general public, "fracking." To some extent, this was not the fault of Department employees. They were not the people who opened the Commonwealth's shale resources to industrial exploitation, or who permitted aggressive expansion before an appropriate regulatory framework could be enacted. Nonetheless, we were disturbed by what we heard. We believe that many DEP employees were doing the best job possible with the limited resources they had. We also believe there were others who appeared to show undue deference to the fracking industry, and undue indifference to citizens with serious complaints about appalling effects they were suffering.

In more recent years, it appears progress has been made. The current administration has responded to our requests for information, and has documented improvements. We believe, however, that it remains important to highlight the past history of DEP's management of this new industry, both to explain the public distrust that has built up over time, and to ensure that the Department's actions going forward will fulfill its mission – to protect the environment, for all the citizens of Pennsylvania.

At the outset, we feel obligated to note concern about the role that industry influence may have played in DEP's delayed reaction to the arrival of unconventional drilling. We realize, of course, that government bureaucracy is inherently slow. But we heard enough testimony during the course of our investigation to believe that more may have been at work. Two former DEP Secretaries voiced similar opinions before the Grand Jury. Both felt an obligation under Article 1, Section 27 of the Constitution of the Commonwealth of Pennsylvania, known as the Environmental Rights Amendment. That provision, adopted by the voters in 1971, gives citizens the right to clean water and air, and makes the Commonwealth the trustee of the environment for present and future generations. Yet both Secretaries felt that the oil and gas industry had its own pipeline to elected officials, and both felt pressure to permit production of shale gas.

As our investigation progressed, we learned of a joke circulated in Harrisburg that there was an oil and gas industry lobbyist for every member of the General Assembly. We assume that is hyperbole. But the concern would explain a lot of what we saw, and what we heard from DEP employees at both high and low levels.

Failure to regulate

When the shale gas "boom" began in Pennsylvania, DEP was still working from administrative regulations that were geared to a different era. The only regulations in place were

those created to oversee conventional drilling – *e.g.*, old-fashioned oil wells. When the U.S. oil industry first began in the 1800s – ironically, in Pennsylvania – operators only had to dig down 100 feet or so in the right spot, and the oil spouted up by itself. Fracking requires an entirely different and more complex approach. As one witness described it to the Grand Jury, the comparison was like riding in a horse and buggy while the unconventional operators were flying to the moon and back.

• Impoundments

A prime example of the outmoded regulatory approach was the use of "impoundments," or pits for storing liquids at the well site. While pits certainly existed at old-fashioned conventional well sites, the impoundments that were springing up around fracking sites dwarfed anything DEP had seen previously. These impoundments were now being used to store tens of thousands of gallons of fracking fluid, which contained varieties of exotic, complex chemical compounds, many of which may have serious health consequences.

The Grand Jury heard testimony about consideration of new rules for such impoundments that would have required permits like those for landfills. In the end, DEP decided to let operators build impoundments as part of the well pad, making them exempt from permit requirements under the Solid Waste Management Act.

In the mid-2010s, DEP recognized that impoundments were not safe, and they were phased out in favor of more secure storage methods. But by that time, DEP had years of knowledge about impoundment failures. The Grand Jury heard extensive testimony about leaks from impoundments that contaminated springs and wells which had served as the only source of water for many Pennsylvania families. We also heard about the effects on neighbors' living standards caused by the intense, rancid odors generated by the impoundments. The consequences

of these under-regulated impoundments ruined property values, family finances and water supplies in many areas, and impacts on physical health are still being assessed. DEP's new regulatory approach is welcome, but for many Pennsylvanians it came too late.

We heard from current DEP Deputy Secretary Scott Perry, who was also with the agency in those early fracking days. He testified that an initial decision made by DEP management to exempt impoundments from regulation under the Solid Waste Management Act was "wrong," but that his position was rejected. A former DEP employee testified that, based on his experience with the agency, the impoundment decision was likely made in deference to the oil and gas industry: "if they had to go through waste management, they were concerned that there were going to be delays in getting these permits issued.... [W]hat was consequential for [the industry] was time, not so much money.... They had a lot of resources. They could spend the money."

• Pigging stations

We saw another example of failure to regulate in the case of pigging stations. At these junctions along a gas pipeline where the gas is treated and the lines are cleaned, methane and other pollutants are regularly released into the air. We know DEP knew about the issue, because it sent out a preliminary notice to the industry in 2011. Yet it did not follow up for five more years, until 2016, when it finally began to require emissions reporting for pigging stations. In the meantime, the lack of regulatory oversight in this area made it possible for operators to build multiple stations in close proximity, sometimes right next to a school or someone's backyard.

The net result, for some unlucky homeowners, has been high exposure to the kind of danger DEP is tasked to help protect us against. Health data presented to the Grand Jury have made clear that, although fracking has caused severe water contamination in certain parts of the Commonwealth, we should be equally concerned about the contaminants the industry releases into our air. DEP regulation concerning pigging stations has been, in our view, insufficient and untimely.

Ask the family we heard from in Washington County. They built a home for their three children, and refused to grant an easement for oil and gas development. But the company came anyway, laid down a pipeline next to their property, and constructed a high pressure valve system for "blow-downs" that showered chemical waste into the yard. After a gas release that sounded "like a jet engine," the family developed nosebleeds, dizziness, and a rash of eraser-sized dots on exposed areas of their skin. The family called DEP, but were told no action could be taken. "I assumed by the title of their name, department of environmental, I just thought they were protecting the environment," the mother told us. "Now I really don't know what they do."

• Comprehensive regulations

But the failure to regulate wasn't just in one or two areas. Testimony showed that, early on, people in the agency knew they needed a whole new set of regulations specific to unconventional drilling, and there was much discussion of the issue. DEP helpfully prepared a timeline for us, showing that the Department began "developing concepts" for a comprehensive fracking regulation package as early as 2009-10. But the package wasn't formally proposed until 2013, and it wasn't until 2016 that full regulations were finally adopted. John Hanger, a former DEP secretary, testified that in his view the delay was partly political: "the business community has been very, very successful in making passing regulations or enacting regulations difficult because they don't generally like regulations. So the rules about how you pass a regulation in Pennsylvania are very, very difficult." But another former Secretary, Michael Krancer, testified that "the Department is able to move more nimbly by using policy documents and guidance documents, which are not regulation," but still provide a basis for enforcement. Unfortunately, DEP for a variety of reasons failed to create a comprehensive fracking policy, whether through formal regulations or internal guidance documents, in a timely fashion.

Failure to train

As fracking ramped up in Pennsylvania, DEP was attempting to perform its regulatory responsibilities with employees whose tenures largely predated unconventional drilling, and who knew little about the highly complex methods used to extract natural gas from shale. One employee, for example, told us he had never even seen an impoundment before. The testimony we heard established that agency personnel knew they were playing catch-up; yet many were unsatisfied by DEP's efforts to train employees for the new challenges they would be facing.

Indeed, several employees testified that training opportunities that did arise seemed to be discouraged, both in earlier and in more recent years. One DEP employee testified that he traveled out of state for training on his own initiative, and met scientists (including one from Penn State, which has a Center for Marcellus Shale Research) who offered to provide training and assistance to DEP. The employee brought back the offer to supervisors, but nothing was ever done. Other DEP employees testified that they were told not to participate in training provided by outside entities because attendance would violate the administration's "gift ban" policy. Another employee testified that he tried to institute bi-monthly training sessions within his district office, but that he was transferred after two or three sessions and the training stopped.

The result, once again, was the absence of any comprehensive response to the new circumstances. One employee told us that, when fracking began, he felt his colleagues were "thrown into the fire." Another testified that agency staff received only "on-the-job training" and "an occasional staff meeting." As he pointed out, "[w]hen you learn from someone who

learned from someone who learned from someone, you could have been doing it wrong the whole time."

DEP did provide us with a list of training sessions conducted by the agency over the years. Many of these, however, do not appear to have focused on fracking, and in several years it appears there was little or no training at all. We recognize that most government agencies lack significant funding for training. Indeed, an official DEP representative acknowledged to the Grand Jury that this remained an item of need for the Department. For us the point is that fracking was the new challenge facing DEP, and that was the subject on which agency personnel most required information. As we heard from the employees who testified before us, they didn't get it.

Failure to communicate

Testimony also established that, even when DEP employees did gain useful knowledge about the new industry, they failed to communicate it to others within the agency. Some of this was a structural problem; sections of the Department with overlapping responsibilities did not talk to each other. We learned of one case, for example, in which one DEP section – the Bureau of Waste Management – prepared a cease and desist order against a company that was illegally operating a waste storage unit without the required permit. When inspectors arrived at the scene to serve the order, however, the operator produced a document provided to him by a different DEP section – Oil and Gas – which authorized him to use the waste storage unit without getting a permit. The Oil and Gas employees had never bothered to check with Waste Management about its interpretation of the law it oversaw. Oil and Gas issued similarly improper authorizations throughout the Commonwealth. In general, we learned, DEP showed little interest in cross-training employees with overlapping responsibilities. Instead, the culture was described to us as "stay in your lane." We heard testimony about another very telling case, in which DEP actually did something responsible early on, and yet wound up wasting the effort. In the first days of unconventional drilling, starting in 2008, DEP undertook what should have been a crucial study to identify the precise chemicals the industry was using in frack fluid to open up shale deposits. The environmental engineer who led the investigation appeared before the Grand Jury. Several employees were assigned to the project, as well as interns. They took dozens of samples around the state, which were then analyzed by the Department's Bureau of Labs.

But the results never really went anywhere. The engineer handed off the data, but the study was never published within the agency, and no one received any training on it. We asked other employees what they had learned from the study. It appeared that most had barely even heard of it. This was information that should have advanced DEP's regulation efforts by years. But it didn't.

DEP has assured us that its efforts from the beginning of the fracking boom included internal collaboration, and no doubt there was at least some in some form. But the testimony of the agency's own employees persuaded us that, in the opening years of unconventional oil and gas activity, when the need was greatest, the Department's efforts to coordinate its widespread staff were not sufficient.

Failure to test

We were also disturbed by testimony about how the Department failed to test, or ineffectively tested, water samples to find contamination caused by fracking. The law requires the Department to conduct water quality tests in response to citizen complaints. We learned that DEP performed that obligation by relying on a set list of known parameters to test for, such as chloride and sediment levels. The list was called a "suite code", and could be effective only to the extent that it accurately identified the appropriate factors for which to test in particular situations. One of these lists, suite code 942, had been developed by DEP before fracking, for old-fashioned conventional drilling. Since conventional drilling did not use the same chemicals or techniques as fracking, suite code 942 could not accurately indicate whether water was contaminated; yet many DEP employees relied upon it to the exclusion of any additional investigation. Eventually, a new list was developed, suite code 946, but many employees didn't know about it, and kept on using suite code 942.

Even the new suite code, moreover, was often too narrow to catch contaminants. And once again, it was used without regard to individual circumstances. An operator might be using a particular compound on a specific occasion that is not universally present at fracking sites. If DEP did not check the operator's records to see what he was using when a spill occurred (if the chemicals were fully disclosed), the Department would never know what to test for. Reliance on the standard suite code would actually be detrimental, because it would give a clean bill of health to water that might in fact be dangerously contaminated. And the problem was compounded, we learned, by the fact that DEP did not always fully report all the substances for which it did test. So even those homeowners whose water was tested, and who did receive results, might never know what they really meant.

We were also disturbed to learn about DEP practices concerning "pre-drill" sampling. Experts in the field explained to us that impact assessment relies heavily on comparing the water before and after a company starts drilling in a particular area. Some compounds occur naturally in water, and vary from location to location. Pre-drill samples establish a baseline for a

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particular water supply; if the water changes significantly after fracking operations begin, the reasonable conclusion is that the fracking caused the change. DEP often lacked pre-drill data in the early years of fracking, but nevertheless purported to make determinations about whether a well site had caused contamination. We heard testimony from one water quality specialist supervisor who stated that without pre-drill testing a positive determination would not be possible and that any additional investigation would not be helpful. We shared that assertion with a higher ranking employee in the same section and the response was "that's absurd."

Moreover, even when proper samples did exist, we remained concerned about whether DEP knew how to properly analyze them. We reviewed a DEP policy document from 2015 setting forth guidelines for assessing water quality samples. But the document makes no reference to established federal standards for maximum safe concentrations of various contaminants, nor does it identify the criteria that are most likely to indicate whether water has been compromised by industrial activity. Surprisingly, this policy was adopted in 2015 – long after unconventional drilling began. By that time, DEP's water-testing policies should have been far more advanced.

These concerns may sound technical; but they are not trivial. It is important to keep in mind that, in most of the areas where unconventional drilling became prevalent, there are no public water lines to supply water to landowners. These people rely entirely on wells that are dug on their property to supply their water. So when there is a noticeable change to their water, whether it is a smell or a change in appearance, it is devastating. We heard many accounts of landowners who literally begged and pleaded with operators to provide a temporary water supply so they wouldn't have to drink, cook, clean, bathe or care for their animals using well water they believed was contaminated

We heard much testimony, however, indicating that DEP employees often approached these issues with less gravity than, in our view, they deserved. In many cases, DEP water quality specialists, relying on outmoded or overly restrictive testing parameters, would declare water to be clean and would "close" the investigation in the face of a homeowner's knowledge that something was wrong. We remember one employee in particular who admitted in his testimony that, as he saw it, his duty prevented him from putting a "monetary hit" on an operator unless he could "prove that this water is being impacted by this activity."

As we learned, however, that is not at all how the applicable law works. The Oil and Gas Act establishes a "*zone of presumption*." Within the zone, contamination from oil and gas activity is presumed. DEP need not "prove" that the activity caused the contamination; rather, the operator must prove the opposite. Previously, the zone of presumption was 1,000 feet from an oil or gas well, and applied to any contamination manifesting within six months after completion of drilling or subsequent alterations. In 2012, the zone was enlarged – to 2,500 feet and 12 months after drilling or alteration.

This is an absolutely essential aspect of Pennsylvania's environmental protection system. But testimony established that some DEP employees have simply disregarded this safeguard. One, for example, stated that "I would use probably the same, you know, level of proof regardless" of the zone of presumption. We find it troubling that any DEP employee was unaware of crucial legal guidelines that govern the Department's testing program.

Failure to inspect

We were additionally troubled by testimony concerning the conduct of inspections, such as when a spill was reported. We learned that DEP regulations require well operators to report spills of more than five gallons. Several employees testified that, in order to make determinations in such situations, they would simply take the operator's word for it about the existence or amount of a spill. These employees told us that they trusted the industry to follow the rules and self-report accurately.

We are mindful of concerns that DEP is understaffed and employees cannot spend all their time making inspections. At the same time, we are highly skeptical that operators can fairly or effectively police themselves, given the powerful incentives not to expose their own violations. Yet we learned that it was not uncommon for DEP employees to resolve some cases through an "administrative file review," meaning sitting at their desks, reviewing documentation submitted by the industry, without ever seeing the spill for themselves.

On other occasions, we learned, DEP employees would investigate citizen complaints simply by calling the operator and asking him what happened. "We had so many complaints," testified one employee. "It was impossible for us to respond to every one." So, instead, the first step was often to telephone the well site operator. If the operator sent in a photo purporting to show that no spill had occurred, the matter could be closed without ever leaving the office.

<u>Revolving door</u>

The credence given to oil and gas operators by some DEP employees proved less surprising to us after we learned this fact: that oil and gas operators often *were* DEP employees who had recently left the public sphere for private industry. As is typical with government work, they could make considerably more money by moving on. In fact we learned of an instance in which an operator scooped up seven employees from the same DEP office all at one time. This sort of hiring created an unfortunate talent drain for DEP – but more concerning to us was the potential effect on the integrity of the Department's investigations.

We heard testimony, for example, concerning the improper issuance of two "plugging" certificates that allowed a company to shut down wells without first doing the necessary work to make them safe. When we asked about the identity of the employee who had issued the certificates, we learned he was no longer at DEP; he was hired by the company to whom the certificates had been issued. Such career progression was not uncommon. Industry employees were often former employees of DEP. In our view, this is not a recipe for restoring public confidence in the DEP inspection process.

Failure to notify

We should emphasize that DEP did often perform proper testing and inspection, and in many cases has identified contamination caused by shale gas activity. Yet we were surprised to learn about what often happened, or more accurately didn't happen, next. We would have expected that DEP would have a clear practice, if not a rule, of notifying neighbors in the area once a positive determination had been made that water sources had been tainted. That apparently is not the case.

DEP employees testified repeatedly that notification to neighbors was not the norm, nor required, as far as they were aware. As one put it, employees were reluctant to "poke a hornet's nest." Another explained that, in his view, surrounding homeowners might not *want* to know, "because they're afraid of what it will do to their property value." A third simply said, "[w]e generally do not do that. We address the complaint that's given to us." These employees were not against the idea that it made sense to notify neighbors if DEP determined someone's water supply had been contaminated, they just understood that wasn't the policy. As to why – that was "above [their] paygrade."

We asked Deputy Secretary Perry about this issue. He stated DEP had an obligation to notify neighbors when a contaminating event occurred close to their homes, but that this obligation, and how it is carried out, depends on the circumstance of the particular event. For example, when serious instances of well failure cause stray gas to migrate out of a well bore and into the surrounding aquifer, according to Perry, DEP has a clear half-mile notification policy, which can expand beyond this radius. DEP has also required operators to notify neighbors about serious chemical spills in their area. Ultimately, however, DEP's approach to this issue depends on the "best judgment" of its employees in determining the need to notify nearby homeowners about a contaminating event.

What we know from the DEP employees we asked about this issue – including water quality supervisors and those supervisors' supervisor – is that to the extent there is some policy or practice about notifying homeowners in close proximity to a confirmed case of water contamination from shale gas activity – DEP employees are largely unaware of it. Indeed, their understanding was that the policy is *not* to notify those living nearby.

It is deeply troubling to us that this type of notification isn't routinely happening at DEP. The need is particularly great given that many homeowners enter into non-disclosure agreements (NDA) with operators in order to settle water supply complaints. If DEP doesn't tell neighbors there is a potential problem and their neighbors can't tell them because they entered into an NDA, there may be no way for people to find out. We think that, whether or not DEP believes adjacent landowners "want" to know, they have a *right* to know, so that they can make their own decisions about how to proceed. We recommend DEP take measures to ensure this is occurring—formalizing and standardizing policies and procedures to ensure consistent application by all regions and levels of employees.

Failure to issue violations

Our investigation also revealed evidence of another manner in which DEP was not vigorously enforcing Pennsylvania environmental laws. When the Department discovers that an operator is not in compliance with a regulation, the Department is supposed to issue a Notice of Violation, or "NOV." DEP failed to do much of that in the formative years of fracking, which is when oil and gas violations were much more likely to occur.

We saw this in particular in relation to odor complaints. In the early days of the industry, when impoundments were commonly used to store noxious fluids in open air, neighbors lodged repeated air quality complaints. We think they should not have been that difficult to substantiate; the nose knows. The Department, however, imposed such stringent requirements that violations could rarely be found. A DEP air quality specialist explained, for example, that, in order to vindicate a complaint, the odor had to be smelled at the same time by three unrelated people in three different households, plus an inspector on site. And if the operations around the impoundment tended to produce the odor at a particular time of day that was outside of DEP work hours, no violation could be brought. The inspector testified that, in ten years in his position, he had never once been able to issue a "malodor" NOV.

We heard evidence indicating that in at least some cases DEP staff's reluctance to issue oil and gas NOVs may have been a consequence of policy decisions made at the top of the Department. We reviewed an email from the then-Executive Deputy Secretary of DEP, dated March 23, 2011. The email directed that every single NOV had to be personally approved by the highest official in the agency, then-Secretary Michael Krancer. The email stated emphatically that "I need to repeat no final actions are to be taken unless … with clearance from Mike. Any waiver from this directive will not be acceptable." From: Hines, John Sent: Wednesday, March 23, 2011 9:03 AM To: Aunkst, Dana; Taber, Nels; Jugovic, George; Bedrin, Michael; Burch, Kelly; Perry, Scott Cc: Harris, Alisa; Raphael, David J.; Krancer, Michael Subject: Marcellus Shale NOV and other Actions

Effective immediately, any actions, NOVs and such-must get the approval of Dana and I with final clearance from Mike. Alisa and Dave are to be cc' on all correspondence related to these actions.

I need to repeat no final actions are to be taken unless approval comes from Dana and I with clearance from Mike. Any waiver from this directive will not be acceptable.

Call Dana or I if you want to discuss.

John T. Hines | Executive Deputy Secretary Department of Environmental Protection Rachel Carson State Office Building 400 Market Street | Harrisburg, PA 17101 Phone: 717.787.2815| Fax: 717.705.4980 www.depweb.state.pa.us

Mr. Krancer did come before this Grand Jury, and described the email as "a misunderstanding" based on a miscommunication between the Deputy Secretary and himself. Employees who learned of the email, understandably, did not take it that way. As one put it, he thought the message was clear: "To leave the Marcellus alone.... Don't interfere with their business."

DEP has provided the Grand Jury with statistics showing that, in more recent years, the number of NOVs has dramatically increased. In 2015, for example, the Department issued over 400 unconventional well NOVs, and the numbers have gone up since. We're encouraged to see that. We do note, however, that the Department has begun, in effect, double-counting NOVs in some cases. If the violation is not corrected within the year, it is carried over to the following year but is registered as if it were a new violation. In addition, the Department can't tell us what we would most like to know: how many NOVs have risen to the level of enforcement action? DEP now publishes online the status of each NOV that occurred after 2017, and whether the violation has been corrected or noted on a subsequent report. DEP does *not* track all

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enforcement actions and litigation that may result from an NOV. We also find it concerning that the Department says that while it tracks complaints generally, it is unable to parse out which complaints relate solely to oil and gas activities, so we cannot tell how many citizen complaints in this area have been investigated and acted upon. Still, the situation seems to be improving.

Failure to refer

In a related area, however, we think enforcement is still lagging, and has even been getting worse. The ultimate sanction for an environmental law violation is criminal prosecution. The Pennsylvania Legislature has created several criminal offenses in the environmental field. The Office of Attorney General has a special section dedicated to environmental crimes. But the office does not have the power to initiate such prosecutions on its own. The Attorney General can act only if an outside agency – primarily DEP – refers the case for investigation.

Evidence presented to the Grand Jury, however, established that, in contrast to NOVs, the number of criminal referrals by DEP in fracking-related cases has been *declining* in recent years, to the point where they rarely occur at all. A number of DEP employees testified that they didn't even know about the referral process. Others, who did know, justified the absence of criminal referrals mostly on the grounds that such referrals simply aren't necessary. They testified to their belief that the oil and gas industry wants to do the right thing, and that the threat of civil penalties is sufficient to achieve compliance with the law. As one supervisor put it, "[t]he industry is pretty scared of us."

We don't agree. We did not see anything in this investigation to convince us that oil and gas operators are running scared. The advantages of money and power are on their side. Given that reality, there will be cases on occasion in which appropriate enforcement includes prosecution. DEP witnesses themselves acknowledged that guns, badges, and subpoenas can get

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the attention of people on a drilling site. Decisions about invoking these criminal sanctions should ultimately be made by experienced prosecutors, not oil and gas administrators.

DEP has recently given us new statistics, claiming that it actually has referred hundreds of cases for prosecution, with yearly levels in the double digits. We find those numbers to be irrelevant to the present inquiry. What we are talking about are *fracking*-related referrals, for violations related to unconventional drilling and pipelines. From 2008 to 2018 there were a total of only 17 such referrals. From 2015 to 2018, the grand total was *two*. If DEP is dedicated to effective use of the tools at its disposal, it should start referring appropriate cases for criminal prosecution. Given what we've seen, we feel confident there are more cases out there that deserve prosecutorial review.

<u>Failure to listen</u>

We end with one overriding concern. Our investigation persuaded us that DEP's actions in the past, during the years that defined its reaction to the fracking phenomenon, created significant distrust of the agency among many members of the public. We know that there are and have always been exemplary DEP employees. But we heard of too many times when Department representatives, all too willing to believe operators, dismissed the concerns of citizens who had turned to government for assistance. We hope that is changing, and that this Report, by exposing the behavior, may advance the change.

We heard, for example, from a homeowner who personally observed a spill occurring into the creek near his property. He saw the creek change color. He took video. He called DEP and described what was happening in real time. But nothing he said would convince the employee to come and look for himself. The employee said he had already talked to the operators of the well, that they had assured him there was no danger to the creek, and that he

therefore had no need of the homeowner's evidence. He threatened to have the homeowner prosecuted for filing a false report.

We heard testimony from other citizens who could get nowhere even when they went to the expense of hiring their own consultants to offer scientific analyses to DEP. The Department declined to review third party data from citizens, although we know that employees often accepted evidence from oil and gas operators. We heard from a DEP water quality specialist that he could not consider lab results provided by a homeowner, even when they came from the same lab regularly used by the industry. We heard from another homeowner that DEP not only refused to review her lab report, but also refused to do its own analysis to look for the compounds her report had revealed.

We also heard from a hydrologist at Penn State who had been called in to investigate well water that was milk-colored and frothing. The scientist performed extensive forensic lab testing to confirm that the foam had the same chemical signature as a drilling foam that was then being used at a nearby well site. But even this expert made no progress with DEP.

Ironically, forensic analysis is what one DEP employee expressly disavowed. "[T]hey expect my guys to be NCIS," he testified, referring to a popular crime lab television series. "That's not going to happen in reality."

We don't think the public really expects DEP to be NCIS. We think citizens just want to be listened to, to be taken seriously, and to be informed. We understand that complaints about fracking-related contamination are not always correct. Sometimes the operator is not to blame. But unconventional drilling is different from almost all other heavy duty industrial operations in that it can happen virtually in people's backyards or the playgrounds where they take their children. Fracking can threaten the only water available to them to drink and the only air

available to them to breathe. DEP must respond to these concerns with neutrality and professionalism.

* * * * *

We recognize that certain actions taken by DEP as described in this report were based on legitimate policy decisions. A deliberate policy decision was made to support the fracking industry in Pennsylvania as an important economic driver. However, policy decisions also have consequences, and in this case, one consequence of the decisions made by multiple administrations and DEP was inadequate supervision of an industry which had – and continues to have – significant impacts on the Commonwealth's citizens. While it may not have been intentional or malicious, ultimately, DEP failed to meet its mission "to protect Pennsylvania's air, land and water from pollution and to provide for the health and safety of its citizens."

The Pennsylvania Department of Health

DOH Mission Statement The mission of the Pennsylvania Department of Health is to promote healthy behaviors, prevent injury and disease, and to assure the safe delivery of quality health care for all people in Pennsylvania.

For years following the outset of the fracking boom, Pennsylvania failed to sufficiently recognize or respond to the public health consequences of fracking. We failed to train or empower our public servants to educate and help those reaching out to their government when they believed their health was suffering because of industry operations. Our government devoted woefully insufficient resources toward gathering public health data associated with industry activities. It failed to implement executive-level policies that could have improved public health data collection. This absence of data crippled potential regulatory, legal, and enforcement actions aimed at addressing industry practices harmful to public health.

Things have improved under the current gubernatorial administration. Inheriting a legacy of inaction, the administration made a deliberate effort to gather health data associated with fracking operations more effectively, but the inadequate resources put toward this effort doomed it to failure. Just recently, the administration has directed greater effort and resources toward the problem, but in our view, more should be done. Most significantly, our government -- including its Department of Health (DOH) -- does not recognize that fracking operations harm public health, citing insufficient research on the issue. However, the absence of such research, at least in part, is due to DOH's own failure to inquire into the matter over the past decade. This "wait and see" approach facilitates placing the health risks of the shale gas industry's operations on everyday Pennsylvanians. We find this status quo unacceptable. The recommendations we

propose are in recognition of the public health risks posed by the fracking industry and seek to strike the right balance going forward.

DOH at the beginning of the fracking boom

We heard from a public health nurse who worked for the Pennsylvania Department of Health in Fayette County, in southwest Pennsylvania, for 36 years. In 2011 and 2012, State Health Centers in southwest Pennsylvania began receiving complaints from people in the community who believed they were experiencing health problems due to shale gas activity. Fracking was a new phenomenon, however, and DOH employees had not received training on how to respond to these complaints. As a result, they were unequipped to help members of the community reaching out to DOH for help.

This was not the first time the Department of Health was confronted with an emergent public health event. In such instances when communities were experiencing a broad public health phenomenon, such as the HIV crisis or hepatitis outbreaks, DOH responded by educating its staff through in-service and out-service programs. DOH staff would then implement a Department-directed public education, outreach, and treatment program. DOH would refer the public to resources and medical professionals for treatment and testing. As we were told, one of the "ten essential services of public health" is "informing and educating and empowering people regarding health issues."

When DOH began receiving health complaints linked to fracking activity, however, no such collective public outreach and education response occurred. Rather, the Department of Health strictly limited its employees' activities in relation to fracking. For instance, the public health nurse we heard from explained that she and her colleagues received a list of 15 to 20 words related to the fracking industry they were to keep next to their telephones. If someone

called with a health complaint and referenced these terms, they could not answer any of the caller's questions. Rather, they were to take the caller's name and information and pass it on to a supervisor. While they were under the impression that someone higher up in DOH would respond, she and her colleagues frequently received calls from frustrated citizens who never received a follow-up response from DOH to their fracking-related health complaints. The witness we heard from testified that in her 36 years as a public health nurse, the Department had never handled any other public health complaints in this manner.

At the same time DOH employees received instructions on how to process frackingrelated health complaints, the Department imposed other limitations on their freedom to engage with the public. DOH employees were instructed that in order to participate in conferences, boards, task forces, or public meetings, they first had to channel a request through their supervisor, which would ultimately require approval from the DOH Bureau of Community Health in Harrisburg. These requests entailed filling out a form specifying the date of the event, who would be attending, the agenda and what would be discussed, and if they would be taking an active or speaking role. Staff was obligated to sign a document confirming they understood the limitations DOH had placed on public engagements. Thus, although a public-facing office, DOH policies restrained public health employees from engaging with the public or from participating in events where they could learn about fracking, health concerns related to industry operations, or otherwise carry out the Department's public health mission.

The Department's blanket muzzling of its employees at the outset of the fracking boom and general failure to meaningfully address the public health consequences of fracking operations was unprecedented. As the witness before us confirmed, the Department had never

before imposed comparable restrictions on its employees in response to any other public health issue during her 36-year career.

DOH continued to ignore the public health effects of fracking

The absence of any meaningful public health response from our government to the fracking phenomenon continued for years. We heard testimony from a witness who served as the District Executive Director for the Southwest District of DOH's Bureau of Community Health Services from January 2012 through April 2014 (District Director). This District Director oversaw the State Health Centers in ten southwest Pennsylvania counties at the center of the fracking boom.

DOH provides public health services to local communities through its State Health Centers, such as those the District Director oversaw. During his tenure with DOH, all phone calls or complaints involving unconventional oil and gas activity were forwarded to the Bureau of Epidemiology in Harrisburg. The District Director confirmed these referrals did not go to some team of public health professionals specially equipped to respond to fracking-related issues. Rather, they went into a proverbial "black hole." There was no protocol, there was no plan, and there was no meaningful response from DOH. The practice implemented at the beginning of the fracking boom continued for years thereafter.

DOH's approach to fracking-related health issues stood in stark contrast to the usual way State Health Centers respond to health outbreaks. The District Director described how DOH carries out its mission when communities experience a public health event. For instance, when he worked at DOH there were 74 diseases, conditions, and infections the Department was required to monitor and address as part of the National Electronic Disease Surveillance System, or "PA-NEDSS." The PA-NEDSS is integrated with local health providers and the federal

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Centers for Disease Control and Prevention, and is part of a nation-wide system for monitoring outbreaks and risks to public health. When a public health issue included in the PA-NEDSS arises, DOH takes action to address the problem.

The Department's public health nurses, who work out of DOH State Health Centers, are its "boots on the ground" points of contact with the community. DOH nurses carry out their duties according to training and protocols developed by the Department for a wide variety of health issues, including those in the PA-NEDSS. These protocols include providing public health nurses with questionnaires to gather pertinent information from the community in response to an emergent health problem. When such a problem arises, DOH does not sit idly by, but goes out into the community to directly figure out what is happening. Once DOH acquires an understanding of the problem, it equips its staff with direction on how to advise the public accordingly, with the ultimate goal to figure out the source of the health issue in question and then execute a plan to stop the problem from continuing or spreading.

Despite DOH's capacity to address a wide variety of public health problems, nothing was developed to address the health effects of fracking. There were simply no resources or policies implemented to do so. Early versions of Act 13 included \$2 million to address the public health risks of fracking. When the Act ultimately passed, however, it allocated no money for public health. The District Director testified that he attended quarterly meetings in Harrisburg with the DOH Secretary and Department of Epidemiology leadership. A response to fracking was never discussed at these meetings. Thus, DOH's failure to take meaningful action in response to fracking was established as policy from the outset of the unconventional oil and gas boom and continued for years, despite persistent and widespread reports and public outcry about the harms to health industry operations were causing to so many Pennsylvanians.

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Throughout our investigation, we heard Pennsylvanians express a sense that their government failed to acknowledge what they were experiencing because of shale gas operations occurring near their homes and in their communities. Accompanying this lack of acknowledgment was a lack of action, which fostered a feeling of hopelessness and distrust in their government. We find that DOH's response – or rather lack of response – during the rapid expansion of the fracking industry contributed significantly to the pervasive sense of despair felt by so many people whose lives were upended, and health damaged, as a result of industry activities. While better efforts by DOH are now underway, this legacy continues to pose substantial obstacles to mounting an adequate response to the public health implications of fracking.

<u>The current administration's approach</u>

• The "enhanced" oil and gas health registry

Our government's first deliberate response to the public health harms caused by unconventional oil and gas operations was the development of a so-called "enhanced" oil and natural gas public health registry. The development of this registry began in 2015 with the current administration devoting \$100,000 to address the public health effects of fracking, which ultimately went to the enhanced registry. "Enhancing" DOH's fracking-related health registry did not mean much, however, since from 2011 on, the Department logged citizen complaints involving shale gas activity on a Microsoft Word document. When the current administration assumed office in 2015, this Word document log was the totality of what DOH received in terms of fracking-related data or programs from prior administrations.

During our investigation, the Office of Attorney General shared evidence with DOH and the administration and welcomed feedback on this evidence. DOH accepted this opportunity by

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submitting written submissions and live testimony for our consideration. The Office of Attorney General "ceded the floor" to the administration and allowed it to present its own evidence directly to us. With respect to the administration's public health approach to the shale gas industry, we heard from Dr. Rachel Levine, the current DOH Secretary.

Dr. Levine explained the circumstances surrounding the creation of the enhanced registry. Dr. Levine, who previously served as Pennsylvania's Physician General, testified she was tasked by her predecessor as DOH Secretary with developing a proposal for how to most effectively use the \$100,000 budgeted toward the administration's public health response to fracking. DOH developed two proposals. The money could be used for an enhanced oil and gas health registry, which was ultimately selected, or as "seed money" toward a more comprehensive health study, which would be done in partnership with a research university. Such a comprehensive study, if ultimately funded, would cost millions, however. Because there was no certainty more money would be budgeted toward this public health issue in the future, the administration opted to spend the \$100,000 toward the enhanced registry.

Virtually all of the \$100,000 in funding for the enhanced registry went toward paying the contract employee who administered it. This contractor initially worked with others in the DOH toward developing a more detailed questionnaire for collecting health complaint data involving shale gas operations. Once collected, the data is entered into a free software program provided by the Centers for Disease Control (CDC).

The CDC software used for the enhanced registry is an information repository capable of generating reports, which DOH issues quarterly. The software does not analyze data. The dataset in the registry includes only that self-reported by a citizen complainant. The program does not incorporate medical data and DOH does not engage with health providers in developing

the registry. While a letter sent in response to oil and gas complaints welcomes the recipient to have their doctor contact DOH, the contractor stated that had never occurred. In addition, Dr. Levine stated, "data reported by a doctor would be anecdotal and therefore not really useful." Assuming contaminants are found in the complainant's water at elevated levels indicative of a health risk, the contractor informs the complainant accordingly and describes the risks associated with the chemicals in question. A toxicologist is available to assist the contractor in that regard. Otherwise, the Department does not follow-up with complainants or doctors.

DOH has received an average of one complaint per month since establishing the enhanced registry in 2017. As of DOH's last report issued for 2019, the registry includes 164 inquiries related to fracking since March 2011. Of these 164 inquiries, only around 120 constitute specific complaints of fracking activity affecting someone's health. Most of these registered complaints carried over from the Word document dataset maintained by prior administrations, which gathered less data than the current registry. So, over three years the enhanced registry gathered around three dozen complaints.

The amount of complaints received by the enhanced registry fell far below the Department's expectations, which was partly a consequence of DOH failing to meet community expectations. As Dr. Levine acknowledged, despite DOH's concerted efforts to encourage those with fracking-related health complaints to participate in the enhanced registry, it was difficult to convince people to do so because the Department was not offering answers or solutions to their problems. People were not eager to spend upwards of an hour completing a detailed health survey when DOH had little assistance to provide them in return. We find that DOH's response, or in reality lack of response, contributed to citizens' feelings of hopelessness and created a lack of trust in the government that should have been interested in protecting them.

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When Governor Wolf commenced his first term in 2015, he selected John Quigley to serve as DEP Secretary. The Senate confirmed Quigley as Secretary in June 2015 and he remained in that position until May 2016. Quigley testified that he also participated in the administration's discussions on developing a fracking-related public health registry.

Quigley had significant concerns about the harm to public health posed by shale gas operations. However, he understood that without data substantiating the connections between fracking and public health, DEP, the administration, and other actors were hamstrung in asserting the need for regulatory or government action to address this problem. In Quigley's view, the \$100,000 a year budgeted for such a registry was inadequate, and it would cost millions of dollars to build a sufficient registry. We find it self-evident that this level of funding was inadequate and did not rise to the level of importance of the problem at hand.

• Failure to work together

The administration's failure to gather public health data effectively in relation to industry activities was further undermined by its own agencies' inability to work effectively together toward that end. DOH relies primarily on DEP referrals for oil and gas related health complaints. As the contractor who administers the enhanced registry testified, it was "perplex[ing]" how DEP had received thousands of complaints in relation to fracking activity, while DOH had registered only around 120 total health complaints. While under the current administration DOH and DEP have made some effort to collaborate and address this data gap, these efforts have fallen short.

At the outset of the current administration, DEP and DOH initiated monthly meetings aimed at getting DEP and DOH to work together to gather better public health data. The general approach developed during these meetings was to include health-related questions among those

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asked when DEP takes an environmental complaint. If someone contacted DEP to report their belief that fracking operations were contaminating their water, air, soil, etc., they would also be asked whether they were experiencing any health problems. If so, that information could be shared and registered with DOH, and DOH could follow-up accordingly.

Efforts at incorporating health questions into DEP's environmental complaints culminated in a November 7, 2018 meeting between high-ranking DOH and DEP officials and policy experts. DOH had proposed adding an "active" box to DEP's water quality complaint form, which would require a DEP employee registering a complaint to ask the complainant whether they had any health concerns. DEP, principally through Scott Perry, the Deputy Secretary of the Oil and Gas Management Program, opposed this request because it would constitute a "leading question" and was outside the area of DEP's expertise. Ultimately, DEP agreed to a "passive" box on the complaint form; meaning if the complainant mentioned a health issue, unprompted, a notation to that effect would occur and be passed to DOH.

Additionally, DOH and DEP were only discussing adding a health question to water quality complaints, but health complaints regularly pertained to air quality, truck traffic, and other effects of unconventional oil and gas operations. DOH was interested in developing ways they could gather information about these health issues as well. So, while DEP was somewhat receptive to incorporating public health issues into its complaint processes, in DOH's view, there was a lot more it could do. DOH representatives continued to push DEP to take further action aimed at gathering public health information, including adding an "active" question on health. Ultimately, however, Scott Perry refused to agree to more than adding the passive box to the water quality complaint form, and the meeting, which was contentious at times, ended.

After the November 2018 meeting, DEP cancelled all future regularly scheduled meetings with DOH. There was no discussion about this; DEP simply deleted the meetings from a shared Outlook calendar.

When Dr. Levine testified before us in January 2020, she informed us that DEP and DOH had recently begun meeting again. That was not the case when Scott Perry testified in November 2019, however. Mr. Perry shared his view on the above-described meetings with DOH. According to Perry, it was important that DEP only provide information to DOH with the consent of the complainant because not all homeowners trusted the government or would welcome another agency reaching out to them following their interaction with DEP. Perry believed DEP's engagement with DOH accomplished that end because DEP now refers health complaints to DOH. Otherwise, at the time of his testimony, Perry was open to meeting with DOH again, but said he would want to see what agenda they had because he saw nothing more on the policy development side for them to discuss.

DOH saw a slight increase in complaint referrals from regional DEP field staff following the November 2018 meeting. While the creation of the enhanced registry and DEP agreeing to transmit some information to DOH was an improvement over nothing, the financial resources devoted to this enhanced registry and collaborative effort between DEP and DOH were grossly inadequate and did not constitute a legitimate public health response to the realities of fracking.

We learned that the current administration recently budgeted \$1 million a year to fund a study, in collaboration with a research university, of trends and clusters of acute health harms and cancer rates in southwest Pennsylvania. The administration anticipates dedicating \$1 million each year for three years. Once gathered, this data can be analyzed to determine whether public health trends correlate to unconventional oil and gas activity. While the administration has

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finally budgeted funds sufficient to gathering and studying public health data associated with fracking, we are disturbed by the long-standing approach by our government to ignore or reject information that substantiates the health and environmental harms of shale gas operations.

Further, we understand that developing sound data on the health consequences of the unconventional oil and gas industry is important to implementing polices aimed at addressing this issue. The current \$1 million in funding to engage in a study of this issue may finally bring about some meaningful results. We fear that the unwillingness to gather data over the past decade, and years it will take to develop data under the currently-envisioned plan, have and will continue to allow further harm to Pennsylvanians.

We asked DOH its position on whether unconventional oil and gas operations harm public health. As the question was phrased, "Is it the DOH and administration's view that there is insufficient evidence proving that unconventional oil and gas operations, whether in the past or as they currently exist under the governing legal and regulatory scheme, harm public health?" DOH responded by stating, "[T]he science in this area is developing, and it is fair to say that it has not been proven that fracking harms public health." The Department further noted that "association' is not the equivalent to 'causation,'" and that further research was required to substantiate a causal connection between fracking and harms to public health.

We do not contend that we are qualified to dispute medical professionals over whether there is a sufficient body of epidemiological research establishing a connection between fracking and public health. Indeed, officials at DOH co-authored a study in 2019 in which they reviewed the prevailing scientific literature on the issue and found it lacking. However, we also learned about studies concluding that health harms increase based on how close one lives to a fracking operation, and that the only dispute was over how far away from the site was far enough.

Regardless of which view is the correct one, we reject DOH and the administration's view on this issue for two primary reasons.

First, DOH, prior gubernatorial administrations, and our government as a whole failed to acknowledge or inquire into the public health effects of fracking since shale gas operations commenced in the Commonwealth years ago. No resources were put toward addressing this issue and executive level polices were implemented that prevented data gathering or a legitimate public health response. Recently, the current Administration made some effort, but the \$100,000 per year put toward the enhanced registry was inadequate and that endeavor was destined to fail, despite efforts by those at DOH to make the most with what they were given.

Only now, after a decade of fracking and the drilling of over 12,000 unconventional wells, has our government devoted resources to study the issue that may actually bring about some meaningful results. These results, assuming they do come about, are still years away. Thus, the absence of data and research DOH points to in saying there is insufficient evidence to find a connection between fracking operations and harms to public health is, in part, a consequence of DOH and our government's failure to look into this issue in the first place. In other words, our government made no effort to gather the data and points to the lack of data as a reason for not concluding there is a problem.

Meanwhile, we know that Pennsylvania families have been crying out to their government, and anyone who will listen, that fracking operations have made them sick. We heard many of their stories, and we find them credible.

Second, we do not accept that perceived inadequacies in available scientific research on the risks to public health posed by industry operations should result in placing those risks on Pennsylvania families. Under the status quo, the industry operates in close proximity to family

homes without those families knowing what is happening at the industrial site next door. They are exposed to harmful emissions and chemicals while we wait and see if research will definitively prove, and in what way, the harms to their health that may be occurring. We are not guinea pigs in an epidemiological study. If further research is necessary to understand this issue fully, so be it. In the meantime, our laws should protect Pennsylvania families. The recommendations we propose seek to impose some sanity and safety to how this industry operates in Pennsylvania.

Others actors fill the void

Given our government's failure to mount a meaningful public health response to the fracking phenomenon in Pennsylvania, concerned organizations have tried to fill this void. We heard testimony from Dr. David Brown, a public health toxicologist with the Southwest Pennsylvania Environmental Health Project (EHP), a nonprofit public health organization that offers services to southwestern Pennsylvanians who believe their health has, or could be, affected by unconventional oil and gas development. We learned from Dr. Brown's testimony what a typical, on-the-ground public health response looks like.

In approximately 2010, a philanthropic organization voicing community concerns about the health impacts of fracking contacted Dr. Brown. They flew him in to meet with physicians and residents in Greene and Washington Counties who believed they were experiencing health problems because of shale and gas operations. Dr. Brown met with multiple people living near unconventional gas sites who described illnesses befalling their animals and similar health problems they were experiencing personally; most notably headache symptoms associated with methane exposure. He saw no indication these people were colluding in describing their similar ailments and experiences. Dr. Brown was particularly concerned upon seeing reports signed by DEP employees informing people their water was safe, rather than such assurance coming from a public health or medical professional, which he described as a "sin." In the doctor's view, the scenario looked like "a public health outbreak," and he put together a plan to mount a public health response, received immediate funding from a philanthropic organization, and the project commenced.

Dr. Brown had overseen responses to public health outbreaks before, for instance while working at the Centers for Disease Control and as the Director of Epidemiology for the Connecticut Department of Health. He educated us on how a public health response is carried out. The first step is to perform a "needs assessment," which entails finding out what is going on in the local population and whether the population has the resources to deal with the problem. That means gathering as much information as possible from local medical professionals, the Department of Health, and the community. To achieve that end, Dr. Brown hired a nurse practitioner and a professional to do environmental assessments at peoples' homes. They used a standardized questionnaire in an effort to develop a sound dataset to understand what was going on and develop possible solutions to the problem.

The chief obstacle at the outset of this public outreach effort was the sense of hopelessness felt by many suffering the health effects of oil and gas activities. Their government was not recognizing what they were experiencing or trying to offer some meaningful help, the industry continued to operate unabated, and they felt let down and abandoned as a result. For these and other reasons, there was significant distrust of anyone from outside of Washington County. To overcome this barrier, Dr. Brown's team brought on Raina Rippel, a local environmentalist and health organizer, who helped build trust with the community. Ms. Rippel insisted a social worker accompany medical and technical experts on home visits because the

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focus of the organization was to help people. That is and remains the mission of EHP: to "do what public health organizations do," which is to look at health data, come up with solutions to the problem at hand, and educate the public on ways they can protect themselves.

Informing people on how to protect themselves from contaminants harmful to health requires determining the pathways of exposure. Cutting off these pathways is how a public health outbreak is stopped. In this instance, there were three possible pathways: (1) groundwater, which was the most frequent mechanism; (2) air; and (3) contamination through plants and food. What EHP learned about how oil and gas activity results in contamination via air pathways was of particular interest to us.

Consistent with the evidence we heard from homeowners living in close proximity to industry operations, people living near oil and gas operations regularly complained to EHP of repeated nosebleeds. These nosebleeds most often occurred at night. Children were affected most frequently. While kids getting nosebleeds is not unusual, they would also develop stomach distress and frequent headaches. Local doctors could not explain what was going on. People were traveling as far as the Cleveland Clinic for help. These complaints came from those with both well and public water supplies, so EHP looked to air emissions as a source.

EHP used meters to measure air quality in affected areas and determined that while emissions from unconventional gas sites may have been relatively constant, at night contamination levels would "peak," resulting in increased exposure. This was explained by "vertical mixing," which refers to the upward or downward movement of air because of temperature differences between the surface of the Earth and overlying air. At night, when there is no sunlight hitting the ground, there is less vertical mixing and air is stagnant and low-lying. On cloudy nights without wind, air was even more likely to stagnate and settle on the ground.

Under this combination of circumstances exposure levels would peak, contaminated air would enter homes, and symptoms like nosebleeds, stomach problems, and headaches would result. EHP confirmed this was occurring by monitoring air quality meters placed inside and outside of peoples' homes along with the health complaints experienced by those living in monitored homes.

Meanwhile, DEP's air monitoring program, which conformed to EPA's, was concerned with overall air emissions compliance over 24-hour periods. While overall emission reduction targets were reached under this program, it did not account for how peak contamination levels affected health in localized instances. As a result, when people complained to DEP about health problems – headaches, nosebleeds, burning eyes, etc. – they believed were caused by emissions from a nearby compressor station or impoundment, DEP would conclude there was no problem based on testing focused on emissions over 24-hour periods. DEP would deny the claim, but the health problems would persist.

Over the decade or so EHP has operated, it has identified 77 compounds emitted from the approximately 350 compressor stations, gas processing plants, and well pads operating in Washington County. Of these 77 compounds, five made up 90% of emissions. The most frequent was nitrogen oxide, which is an eye irritant that also causes cardiovascular problems and damage deep in the lungs and upper respiratory system. Carbon monoxide, which causes "anoxia," or reduced oxygen to the brain, headaches, and brain pain, is also common. In Dr. Brown's opinion, however, detected carbon monoxide levels – which were comparable to smoking three cigarettes a day – were not high enough to cause the reported health problems.

The most frequent compounds also include microscopic particulate matter, which moves like a gas, releases proteins in the blood called "kinins" that cause inflammation and affect blood

pressure, damage the lungs, and cause heart conditions. Particulate matter is also problematic because water-soluble compounds in the air can attach to it, causing it to act as a vector by which other toxins can travel deep into the lungs where they are far more damaging. Among the compounds that can attach to particulate matter are volatile organic compounds (VOC), like toluene, benzene, and xylene, which are also frequently found in gas emissions. These cause neurological and cardiovascular effects and intense fatigue. Also, when VOCs like iodine, chlorine, and bromine attach to a chemical like methane, they become even more toxic. Finally, formaldehyde, a carcinogen and irritant that results from methane as it breaks down, is also among the top five contaminants in oil and gas emissions.

The potential health risks of the remaining 72 compounds identified by EHP emitted by oil and gas operations are, in many cases, unknown.

Factors determinative of exposure risks to people living near oil and gas operations are necessarily nuanced and site-specific. For instance, EHP found that in Washington County, the particular chemicals emitted from any one oil and gas site would vary by a factor of 10; meaning chemicals from one well could be 10 times greater than that emitted by another. Whether someone lives uphill or downhill from oil and gas operations affects exposure. The number of peak exposures experienced within a short time-period is significant because if the body has not processed contaminants from one exposure before another occurs, the health effects can compound.

Health impacts also increase the closer someone lives to an oil and gas operation and as the density of pads around their property increases. The general range where exposure can be problematic is within two kilometers, or a mile-and-a-quarter, of a gas site. And the rates of emissions from well pads are not the same. Well pads emit contaminants from degassing tanks,

<u>WG Ex. 70</u>

condensate tanks, and dehydrating tanks, which can emit periodically. These inconsistent emission events, both in frequency and volume, add additional unpredictability. Meanwhile, weather can be varied, with cloud cover, temperature, wind, and vertical mixing all having a significant influence on exposure risk. All these factors make reaching some comprehensive, uniform approach to understanding airborne exposure risks from oil and gas operations difficult, if not impossible, to determine. Risk is determined by location and constantly changing interactive factors.

Once EHP developed an understanding of the paths of airborne exposure from oil and gas operations and the factors influencing risk, they implemented means of educating the public on how to avoid these risks. EHP can identify a Washington County homeowner's exact latitude and longitude and determine their grams per hour exposure risk depending on their distance from the source and weather patterns. EHP developed an informational magnet people keep on their refrigerators that help them predict risk levels based on weather patterns. These are particularly useful to asthmatics because of their sensitivity to airborne contaminants and those with young children who need to avoid playing outside when the air is compromised.

Air quality monitoring techniques employed by EHP include providing homeowners with "SUMMA" canisters, which collect air over 24-hour periods for testing inside and outside of peoples' homes. Testing from SUMMA canisters has confirmed high levels of contamination inside residences. EHP recommends such minor approaches as not wearing shoes in the house to prevent dust from oil and gas activity tracking inside to recommending installation of advanced home filtration systems. Children are a particular concern with respect to airborne contamination because chemicals associated with oil and gas emissions can block development in their rapidly growing bodies, causing permanent damage. However, health data on the long-term effects of

oil and gas operations to children's health are incomplete, and likely will not be clear for years to come. In instances where air contamination levels are particularly high in a home, EHP has recommended that families with young children move. Dr. Brown confirmed it would be unethical for a public health organization, like EHP, to advise families that consistently exposing their children to airborne fracking contaminants is acceptable.

We find that EHP's actions stand in stark contrast to DOH's: the government agency charged with protecting public health. We further find it remarkable that a newly created organization like EHP swiftly gathered data and provided guidance to Pennsylvanians on how they could protect themselves from the effects of industry operations, while a long-established government entity, DOH, did not.

In addition to Dr. Brown's testimony on the work of EHP, we learned of efforts by the federal government to provide public health services to Pennsylvanians who suffered adverse health effects from fracking operations. We heard testimony from Dr. Karl Markiewicz, a Senior Toxicologist from the Agency for Toxic Substances and Disease Registry (ATSDR), which is a federal public health agency within the Centers for Disease Control. ATSDR partners with EPA and other agencies to provide public health oversight and responses to significant instances of environmental pollution or contamination.

As a public health agency, ATSDR works much like EHP. When assigned to look at a particular incident, usually via a referral from EPA, they first perform a public health assessment. In understanding the situation at hand, ATSDR most often gets data from states in which they work, medical records from patients, and other sources, although they gather their own data as well. Dr. Markiewicz repeatedly emphasized how critically important access to comprehensive, quality data is to understanding the possible health risks to a community in

relation to an incident of contamination. Like EHP, ATSDR tries to determine exposure pathways, with groundwater being the most likely path of exposure, but air as well, and then a means of interrupting that pathway to prevent ongoing harm from the given source of contamination.

ATSDR's first contact with the fracking phenomenon in Pennsylvania was in response to a stray gas migration incident that resulted in the contamination of numerous drinking water wells. DEP investigated the incident and determined the problem was resolved and drilling operations could continue. Meanwhile, EPA and ATSDR were brought in out of concern over possible ongoing health risks. ATSDR did its own independent water testing and recommended people not drink local groundwater pending further testing. They were the only agency advising the public as such.

According to Dr. Markiewicz, the divergence between ATSDR's recommendation and DEP's reflected, at least in part, the agencies' respective missions. DEP is a regulatory agency that performed testing according to the governing protocols of DEP. DEP is not specifically tasked with protecting public health or addressing public concerns outside its perceived regulatory mission. ATSDR is a public health agency with a different perspective, and their focus on public health led them to view the same phenomenon in a different light. There were apparent, serious risks to public health present, and ATSDR could not accept or disregard these risks without further understanding what was going on. These differences in perspective illustrate how the absence of any meaningful involvement by the Pennsylvania Department of Health in the fracking phenomenon has resulted in an ineffective response by our government to the realities of unconventional oil and gas operations experienced by many of its citizens.

<u>WG Ex. 70</u>

ATSDR's inability to get data from DEP and industry operators frustrated efforts at mounting a public health response to the stray gas migration incident in question. ATSDR works most frequently with Superfund sites, where the norm is an open door policy with private companies and the government in sharing all available data and information. The fracking industry is different, however. The fracking industry resisted sharing information about its practices with ATSDR and legal mechanisms obstruct the sort of routine oversight other industries are subject to. Meanwhile, DEP's failure to collect data, and resistance to sharing what data they have, coupled with their narrow approach to testing when determining whether contamination has occurred, enables the industry to ignore residents' claims that oil and gas activity has contaminated their environment, air, or water supply. DEP's failure to adequately respond to homeowners' concerns builds distrust between the community and the government. That distrust has become entrenched in Pennsylvania, which further impedes a meaningful response to the problem.

With respect to the Pennsylvania Department of Health, ATSDR experienced the same disengaged, hands-off response consistently shown by DOH in relation to the fracking phenomenon. Pennsylvania has professionals capable of doing the same work ATSDR does and Dr. Markiewicz was in contact with DOH employees during their work involving fracking operations. While DOH employees wanted to know what was going on, "they were not allowed to work on it," and did not engage in an on-the-ground response to what was happening, despite being welcome to participate. Dr. Markiewicz could not verify whether there was any specific directive within DOH preventing its employees from working with ATSDR on a public health response to fracking-related contamination, but he frequently heard complaints from residents about DOH's absence from their community.

Like EHP, ATSDR also worked on air quality contamination from fracking operations. They used SUMMA canisters to collect data, but emphasized a significant lack of air quality data in Pennsylvania on oil and gas activity. They investigated emissions from a pigging station in collaboration with the criminal division of EPA, and found that when a pigging station releases rapidly at around 1000 psi, as opposed to gradually at 100 psi, there are significantly higher methane and benzene emissions. Using high-tech cameras, they observed the massive amount of emissions from when a PIG was removed at the station, and the plume of gas that would waft over nearby residents' homes.

Dr. Markiewicz expressed concerns that DEP was not looking into the combined impact of pigging stations, gas condensing units, and the combined effect of transporting gas from well pads through pipelines. Again, more data is needed to understand the reality of how fracking operations affect air quality and public health.

Testing must reflect how oil and gas operations impact air quality and the pathways of contamination that can result in harm to public health. Similar to the testimony we heard from Dr. Brown, Dr. Markiewicz recognized how air contamination occurs in "peaks" through a combination of factors, and that testing needs to reflect that reality. ATSDR was asked to review data gathered by DEP pursuant to a long-term air-monitoring project conducted at four locations in Washington County in 2012 and 2013. They found that because of where DEP placed airmonitoring devices in relation to wind and weather, the devices collected pertinent data only 20% of the time. Again, more data is essential, and testing must account for the inherently localized nature of air contamination from oil and gas operations.

Dr. Markiewicz's testimony also reflected Dr. Brown's concern over DEP informing people that based on its test results, it was safe to drink their well water. In his view, by

providing such assurances without consulting with medical or public health experts, they are putting peoples' health at risk. Moreover, you do not need to be an expert to see the wisdom of this view. As Dr. Markiewicz described an interaction he had with a homeowner who was told by DEP that his water supply was safe to drink:

> He kind of looked at me and he stood up and his kids are sitting around. And he went over to the kitchen sink and he took a glass tumbler and filled it up and I mean, it looked like swamp water. And he said, you are telling me that I can drink this? And he didn't say, go ahead and drink it but he was holding it in front of me. And I said, [], I agree with what you are saying but based on the data -and that is how I started the conversation. I said, based on the data, there wouldn't be any restrictions on this. It would be okay. He said would you drink this or give it to your kids? I said, no, I wouldn't.

> > * * * * *

We appreciate DOH engaging with us in this investigation. We found their input extremely helpful, and the Department deserves credit for the efforts it has made in recent years given its available funding. For instance, in addition to the initiatives discussed above, in 2015 DOH hired an expert with a background in environmental health to head its Bureau of Epidemiology. It brought on additional staff over the past few years, most of whom were responsible for overseeing the enhanced registry. The Department also indicated it received funding in 2019-2020 for ten new positions dedicated to environmental health. It has engaged in direct outreach to communities and stakeholder organizations in an effort to encourage participation in the health registry. It provides useful information to the public via a website devoted to oil and gas activities. When DOH comes in direct contact with people who believe fracking operations have affected their health, it offers to review any available sampling results to identify potential health risks, and provides referral information for environmental health physicians.

In our view, however, more can be done. We would like to see DOH not only fund research and provide feedback and referrals to those who reach out to the Department, but actively go out into communities and try to find solutions to the problems people are experiencing right now – not wait on the research. We learned that public health work is all about identifying pathways of contamination and cutting off these pathways so that people stop getting sick. This is what EHP has endeavored to do in Washington County, and they have had some success. We know DOH does this with other public health issues, and we would like to see DOH put forth the type of on-the-ground effort others are making in response to the public health consequences of fracking. Such an approach would provide Pennsylvanians with the kind of help they are looking for from their government.

We also understand DOH may not have the resources to do the sort of work we would like to see. Perhaps the increased staffing it expects will enable it to do more. Regardless, we remain troubled by the Department's belief "that it has engaged in an appropriate response to the potential health effects associated with fracking." Again, DOH's perspective appears rooted in its view that a connection between shale gas operations and public health remains "unknown," and "that it has not been proven that fracking harms public health." We know from our investigation what too many Pennsylvanians know from personal experience: that industry operations have made Pennsylvanians sick, and that the legal and regulatory regime governing shale gas extraction in the Commonwealth puts people's health at risk. Our proposed recommendations account for this risk as we develop a better understanding and approach to managing the relationship between public health and fracking.

Recommendations of the Forty-Third Statewide Investigating Grand Jury

We, the 43rd Statewide Investigating Grand Jury, based on a preponderance of the evidence before us and in some cases clear and convincing evidence, make the following recommendations. Our recommendations, though relevant to all living in the Commonwealth, are focused on the oil and gas industry, the Commonwealth of Pennsylvania's Department of Environmental Protection, the Department of Health, and the General Assembly.

One: Expand the No-Drill Zones

For all the arguments about the effects of fracking, we believe, and the evidence we gathered confirms, that there is one point that is impossible to deny. The closer people happen to live to a massive, industrial drilling complex, the worse it is likely to be for them. The more of a chance that their drinking, cooking, and bath water will be contaminated. The more harmful emissions they will breathe into their lungs. The more truck traffic and machinery they will have to hear, at all hours of the day and night. The more the effect on the health, safety, and welfare of their family and children.

And yet, under current law, an unconventional oil and gas company can drill a well as close as 500 feet from a person's home. That's only about 200 steps away. That means the well itself can be that close; the well pad and its accompanying equipment can come even closer. No one expects, when they find a place to settle, raise a family, live a life, that a steel mill might be constructed right next door, or a power plant. And local zoning laws will normally make sure that doesn't happen. When it comes to unconventional drilling, though, people have seen rigs sprout up almost in their backyard, along with all the equipment necessary to service them. In many parts of the state, local zoning practices have simply been inadequate to prevent such

development. There has to be a *statewide* minimum "set-back" – and the current minimum, 500 feet, just isn't high enough.

We therefore recommend that the set-back statute be changed. Considering the size and scale of a fracking site, the no-drill zone should be at least 2,500 feet, not 500. Even that distance is still only a short stroll, within sight and sound of residences. We do not believe such a modest buffer zone is too much to ask when it comes to people's health and homes.

But our concern is not just for residential settings. We were astonished to learn that the drilling set-back is no different even when it comes to sensitive sites, like a hospital, or an elementary school playground. It is the same 500 feet. We think the no-drill zone for schools and hospitals should be even bigger – 5,000 feet. We understand that fracking has its benefits. We just want to give it some separation from the places we eat and sleep, treat the sick, and educate our children.

Two: Stop the Chemical Cover-up

We heard repeatedly during this investigation the claims that there is no real danger from the use of complex chemical compounds manufactured for the fracking process – or at least that the risk is "unproven." The time has come to provide for proof, one way or another; and the only way that can happen is to require disclosure.

We learned that under existing law, the oil and gas companies don't have to say what chemicals they are using *until after they have already used them*. And even that disclosure rule only applies to chemicals used in the fracturing phase of the process – the stage after the well has been drilled, when the companies use high-pressure water and chemicals to break up underground rock formations in order to extract the gas. What goes down the hole, though, must

come up – much of the chemical-filled fluid that is used for fracturing makes its way, sooner or later, back to the surface.

But the companies also use potentially dangerous chemicals during the drilling process itself, before they even start the fracturing. And *those* chemicals don't have to be publicly disclosed at all – even though they often drill directly through water tables, where the chemicals may mix with water that someone is using and drinking.

In addition, every time these fracking chemicals are moved there is a risk of leaks or spills or escape onto the ground, into the water, and into the air. And if there is any kind of accident, the first people at risk are the first responders, followed by everyone else in the vicinity.

But in addition to these lax rules about disclosure, there is another problem. Companies also get an exception to the disclosure requirements for "trade secrets." So if they say they have created some special chemical compound that gives them a competitive advantage over other gas companies, they don't have to reveal publicly what it is.

We find that unacceptable. The corporate bottom line does not outweigh the lives and health that may be at stake. We want the public to know the identity of all these chemicals being released into the environment, so their effects can be studied, and so government or individual citizens can choose to protect against them if they deem it necessary. We recommend that all chemicals employed in any stage of the unconventional oil and gas process must be publicly disclosed before they can be used.

Three: Regulate All Pipelines

With all the attention on pipeline problems in different parts of Pennsylvania, one would expect that government must have some role in how the system is operated. And it does – up to

a point. We were surprised to learn, however, that as of now regulations focus primarily on the *big* pipelines, the major "highways" that transport gas over long distances.

As with the road system, though, those gas highways are *not* the only pipelines. The gas has to have some way to get to the pipeline highways from the well. They don't use tank trucks. They use a system of smaller pipelines, called "gathering lines."

And those gathering lines are hardly regulated at all in the rural and semi-populated areas where most fracking takes place. In effect, it is a remnant of history: they didn't need regulation for gathering lines in conventional drilling days, because those lines were low pressure, low volume, and no real hazard. Modern gathering lines are very different. Yet only the gas highways get full government oversight.

This deficiency is not defensible. These gathering lines operate under high pressure and can span hundreds of miles. They are subject to leaks, erosion, and even explosion, much like the bigger lines. And yet, outside of higher-population areas of the state, the companies are largely free to lay down whatever gathering lines they want.

We say the Commonwealth must start regulating gathering lines from unconventional drilling wells. *All* pipelines in *all* parts of Pennsylvania.

Four: Add Up the Air Pollution Sources

Fracking does not entail big belching smokestacks, like some factories. So we don't think of it as a source for air pollution.

But it is. Fracking operations mean frequent releases of gas, not just accidental but intentional. The pipes must be cleaned out regularly, and every time that is done, billowing but invisible clouds of gas escape into the atmosphere. That gas can be hazardous in itself, and in

addition can be tainted with the man-made chemicals used to extract it from the ground, and with naturally occurring chemicals released from deep in the earth.

The problem is that most of the fracking industry air pollution comes from smaller cleanout stations, known as "pigging stations," and other sources that, *individually*, slip under the air pollution thresholds at which regulation would kick in. And that is true even though these oiland-gas industry pollution sources are often clustered together; if aggregated, they would trigger requirements for pollution control. But they are not aggregated, and so they are frequently not regulated.

The solution is to stop looking in isolation at air pollution caused by unconventional drilling sources. The state has to begin using more common sense and logical standards for evaluating these sources. If air-polluting fracking facilities are stationed in close proximity, treat them as one source, and regulate accordingly. After all, if people live anywhere nearby, their lungs aren't going to care whether the chemicals in the air came from one large source or from many smaller sources all next to each other. It is reasonable to expect our regulatory agencies to take that into account.

Five: Transport the Toxic Waste More Safely

Among the many troubling aspects of unconventional oil and gas drilling is this one: its waste. Simply put, the fracking industry generates enormous quantities of noxious by-products. We learned that unconventional drilling creates two categories of waste requiring special disposal. The first is a significant problem; the second is an even more significant problem.

First, there are the drill cuttings – the rock and mud that is ground up and brought out to create the well. The drill cuttings are mixed in with the sludge of industrial chemicals used for the drilling processes. This is not just normal rubbish that can be tossed onto a regular garbage

dump. The chemicals in drill cuttings are potentially hazardous even beyond the standards of landfill sites used for municipal trash.

Second, there is the wastewater – which is not just water at all. The fluid injected into a fracking well cannot perform its function with mere H₂0. Frack fluid is an elaborate and, as we mentioned, secret chemical cocktail of lubricants, biocides, solvents, and other agents. And the issue isn't just the composition, but the *quantity*. A single well may create *millions* of gallons of contaminated water over its lifetime.

Yet this hazardous material is not treated as such. We learned of a striking example of the problem. When toxic chemicals are initially transported to a well, the tanker trucks are labeled as carrying hazardous material. But after these chemicals are injected into the ground, and then return to the surface in wastewater, the contaminated water is transported *from* the well as if any danger had ceased to exist. The very same chemicals that were identified as hazardous before they were used are now identified as non-hazardous "residual waste," although their composition has not changed. Thus, the transportation of fracking-generated wastewater in Pennsylvania does not account for the toxic nature of this waste being hauled all over the Commonwealth.

This creates a serious problem. Fracking wastewater can be a relatively harmless briny concoction, an extremely dangerous combination of chemicals, or highly radioactive. Because it is labeled as "residual waste" – a classification that includes many sources of waste other than from fracking – there is no way to know whether a tanker came from a shale gas site or carries something that does not carry the same potential risk. If one of these trucks overturns and spills all over a roadway, the signage on the truck will not provide adequate notice to those at the scene about what they are dealing with. This system puts the public and first responders at risk.

Presently, there is no easy long-term solution for permanently disposing of waste generated from shale gas operations. And operators perform an elaborate shell game, moving fluid from one well to the next to fracture more shale. The movement of this waste presents a risk to the public. While regulators sort that out, at a bare minimum, Pennsylvania should require that trucks carrying waste from fracking sites display signage specifically identifying that which they are hauling as unconventional oil and gas waste.

Six: Deliver a Real Public Health Response

Our investigation showed that, for the better part of a decade, there were Pennsylvania citizens who suffered ill effects after fracking moved into their neighborhoods, and who basically received a cold shoulder from their government's official medical establishment. Now we have learned that in recent years the Department of Health has made more of an effort to address the problem, and has allocated a million dollars a year for a three-year study. That is encouraging. But it is not enough.

We understand the nature of the challenge. There are many potential health issues that fall under the "fracking" label, and many conflicting claims about what is or is not dangerous. That, however, is usually the case with public health issues. It is not always obvious up front, in any health crisis, what the real causes are, or what the consequences will be. But lack of knowledge should be a reason to do *more*, not less.

Consider the attention being paid to vaping, which the Pennsylvania Secretary of Health wants declared as a public health emergency. Consider the resources marshaled to study the spread and effects of a group of harmful substances known as PFAS from the former Willow Grove air base outside of Philadelphia. Consider the state government's call to arms over spotted lanternflies.

These are all significant issues, and we have no intention of minimizing them. But fracking has been going on for over a decade in Pennsylvania now. It has potentially affected the short- and long-term health of tens of thousands of people. By this point, we should know more than we do. It was as if our government didn't *want* to know.

Several other of our recommendations will serve to address the public health consequences of fracking, such as expanding the no-drill zone and requiring full disclosure of chemicals used in industry operations. We also call on DOH to unleash the full force of the public health apparatus in order to gather all the data and figure out the best medical responses. Don't just wait for people to report; they might not, or they might have tried repeatedly and given up because no one listened. Put boots on the ground and go out into the community. Mobilize health centers. Make public service announcements. Build a better website, and advertise the hotline. Reach out to doctors and hospitals in the affected areas. Issue declarations. Do what we do with other public health crises.

Seven: End the Revolving Door

We saw staffing issues at DEP that caused us concern. But among the most troubling was the fact that DEP employees were frequently lured away to work for the oil and gas operators they were supposed to be regulating. In a way, this should be no surprise. The industry is far better funded than government, and can offer far better compensation to state employees who have developed, at state expense, an expertise in this regulatory field. But the resulting potential for conflict of interest cannot be ignored. If DEP employees know there may be a big paycheck waiting for them on an operator's payroll, they may be reluctant, consciously or otherwise, to bring to bear the full force of the law. The solution is to do what Pennsylvania has done in other areas: impose a "cooling-off" period that would prohibit DEP employees from jumping directly into a job with an oil and gas company.

To be clear, this would not be a complete solution to the personnel issues we saw at DEP. We believe the agency has been understaffed and undertrained; even the Department's own representative testified to the need for more resources. DEP must have an appropriate, sustainable funding source in order to ensure that it can hire, train, and retain the people necessary to perform the challenging tasks required to regulate this complex industry.

In the meantime, however, a revolving door rule would be a simple and straightforward means of addressing at least one part of the problem. The Ethics Act provides that former public employees must wait one year after leaving state government before they can engage in lobbying before their former agency. And the Gaming Act provides an even more pertinent provision. A former employee of the Gaming Control Board cannot accept employment, for a period of two years, with any company that has applied to the Board for a license. The prohibition is particularly prudent in an industry awash in money, as is gambling. We have some of the same concern regarding the oil and gas industry. While energy prices may rise and fall, the profits in the good years are plentiful, and thus enhances the industry's ability to pluck talent from the Department. We propose that a cooling-off period, as under the Gaming Act, will protect the Department's work force and at the same time enhance integrity.

Eight: Use the Criminal Laws

Pennsylvania has a series of special environmental statutes that make it a *crime* for people to pollute the Commonwealth's air or water, or dispose of industrial waste improperly. And yet, when it comes to unconventional drilling, these criminal statutes in effect do not exist; they are virtually never invoked. We wondered why.

As it turns out, the lack of criminal prosecution is not because no such crimes have been committed. As we learned during our investigation, most of this criminal conduct cannot go forward unless the Department of Environmental Protection refers it to law enforcement for criminal investigation. Local D.A.s have the authority to prosecute these environmental laws, but seldom the resources. The Attorney General's Office, on the other hand, has a special environmental crimes section for exactly this purpose – but it lacks the legal authority to prosecute unless DEP asks it to do so.

Yet, in recent years DEP has seldom asked. DEP employees testified to various explanations for this lack of criminal referrals for oil and gas violations. Some said they don't need to seek criminal prosecutions, because their own internal regulations provide sufficient deterrence. Some said they would refer more cases, if only prosecution didn't take so long. Some said they wanted to send out cases for prosecution, but supervisors didn't always approve.

Whatever the story, there is a simple fix. The legislature should amend the environmental laws, in particular the Solid Waste Management Act and the Clean Streams Law, to give the Attorney General direct jurisdiction over environmental crimes. That way the office will not have to wait for DEP to refer or not refer; it can begin an investigation on its own, whenever it has proper cause to do so. There are already a number of other specialized areas, such as child predator and computer crimes, where the Attorney General's Office has been given special jurisdiction. It would be a straightforward matter to do the same here.

We think, in appropriate cases, criminal charges can provide an effective way to help carry out the constitutional mandate of article 1, section 27: to conserve and maintain the people's right to clean air, pure water, and a healthy environment. The three presentments issued by this Grand Jury serve as a first step.

Response of the Pennsylvania Department of Environmental Protection

IN THE COURT OF COMMON PLEAS ALLEGHENY COUNTY, PENNSYLVANIA

IN RE:	SUPREME COURT OF PENNSYLVANIA
:	71 W.D. MISC. DKT. 2017
THE FORTY-THIRD STATEWIDE	
	ALLEGHENY COUNTY COURT OF COMMON
:	PLEAS CP-02-MD-0005947-2017
INVESTIGATING GRAND JURY	
:	NOTICE NO. 42

RESPONSE OF THE PENNSYLVANIA DEPARTMENT OF ENVIRONMENTAL PROTECTION TO REPORT 1 OF THE FORTY-THIRD STATEWIDE INVESTIGATING GRAND JURY

The Pennsylvania Department of Environmental Protection ("DEP"), by and through its counsel, Pietragallo Gordon Alfano Bosick & Raspanti, LLP, submits this response to Report 1 of the Forty-Third Statewide Investigating Grand Jury. The report was served upon DEP pursuant to an order by Supervising Judge Norman A. Krumenacker, III. DEP requests that this response be attached as an exhibit to the report prior to public disclosure and/or publication.

I. INTRODUCTION

A. The Boom of Unconventional Gas Well Development in Pennsylvania

The development of the unconventional gas industry posed a unique challenge for the Department of Environmental Protection. DEP rose to the challenge through the efforts of its dedicated staff of professional geologists, engineers, and biologists who were committed to creating a regulatory program that protected the citizens of Pennsylvania and their environment, while allowing responsible development of the resource. It is important for Pennsylvania's citizens to know that these DEP employees care about, are engaged in, and have expertise in protecting the environment and public health and safety from the impacts of unconventional gas development. Citizens also need to know that the oversight of this industry now in place is comprehensive, responsive and protective.

In 2008, when the industry began significant development of the Marcellus Shale, an unconventional natural gas formation, DEP had in place a regulatory program for addressing the impacts of the historic conventional oil and gas industry that existed in rural areas of northwestern and southwestern Pennsylvania. That regulatory program, which has never had a federal counterpart, derived largely from the 1984 Oil and Gas Act. DEP quickly identified the need for an updated regulatory program for unconventional gas development.

Although the techniques used to produce natural gas from unconventional formations were not new to Pennsylvania - horizontal drilling had been used for years prior to the Marcellus Shale boom to stimulate coalbed methane wells, and hydraulic fracturing and the chemicals used in that process have been standard operating procedures for virtually every conventional oil and gas well in Pennsylvania for decades – the sheer scale of this new development was unprecedented. From the total acreage of the play across Pennsylvania (the productive area of the geologic formation) to the size of the well sites, the time it took to drill and hydraulically fracture each well, the amount of water used, and the amount of residual waste generated by developing these wells, this was a significantly different industry. The increased scale and rate of unconventional gas development resulted in new field practices which required DEP to develop new approaches to regulating the industry and to update DEP's existing regulatory program for conventional oil and gas development.

DEP's task was to adapt the existing regulatory program as this large and impactful industry grew exponentially, changing its methods and techniques as it grew. At every critical juncture, the environmental professionals at DEP committed themselves to doing the job right and created a regulatory program that ensures the public receives all the protections afforded them by Pennsylvania's strong environmental statutes. The cornerstones of the new regulatory program are the 2012 Oil and Gas Act (an updated 1984 Oil and Gas Act) and Pennsylvania's other

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environmental statutes, including the Clean Streams Law, Solid Waste Management Act, Air Pollution Control Act, Dam Safety and Encroachments Act, and Radiation Protection Act, along with the regulations that implement these statutes, many of them amended in new rulemakings to address the potential risks and hazards presented by today's unconventional gas development.

To better administer this new program, DEP made changes within the agency, including restructuring the Oil & Gas Program, creating a new district office to serve northcentral and northeast Pennsylvania, increasing its staff, and training all staff members. DEP also made changes to ensure its regulation of this industry is transparent, participative, and collaborative. The agency enhanced the public's access to accurate factual and scientific information regarding its oversight of the industry, engaged the public's participation in a massive rulemaking process, and collaborated with many stakeholder organizations in developing its new program.

The regulatory program which DEP has developed, continuously improved, and implemented for this complex industry is recognized nationally and internationally for its features, which protect citizens and the environment while allowing responsible development. Over the past several years, representatives and officials from many countries have traveled to Pennsylvania to meet with DEP staff and learn more about its program and practices. As part of the Unconventional Gas Technical Engagement Program, the U. S. Department of State has sent DEP staff to other countries, including Mongolia, Poland, Lithuania, Argentina, and Columbia, to assist these countries in creating effective regulatory programs for this industry.

Of no small note, DEP accomplished this work at the same time the federal government was reducing its involvement, oversight, and support of state environmental protection programs , the state legislature was focused on limiting DEP's budget and regulatory authority, and critics were shaping public opinion with fear and inaccurate information without respect for facts, law or science. Moreover, DEP has achieved this success as Pennsylvania has become the second largest producer of natural gas in the U.S., behind only Texas. In 2019, 6.2 trillion cubic feet of natural gas was produced from unconventional wells in Pennsylvania, the largest volume of natural gas on record produced in Pennsylvania in a single year.

For certain, there have been and will continue to be concerns related to the impacts of unconventional gas development on the health and safety of the Commonwealth's citizens and our environment. DEP shares these concerns and is committed to continually improving the regulatory program to better protect and serve the citizens of the Commonwealth.

B. The Grand Jury Investigation

DEP's regulation of the unconventional gas industry recently has come under the scrutiny of a Statewide Investigating grand jury requested by the Pennsylvania Office of Attorney General ("OAG"). The grand jury was convened two years ago with the stated purpose of investigating whether private companies engaged in unconventional well development activities had committed criminal violations of Pennsylvania's environmental laws. In mid-December of 2019, 22 months into the grand jury's 2-year term, the OAG advised DEP, for the first time, that it had prepared a draft report that was critical of how DEP regulated the unconventional gas industry. The OAG agreed to share summaries of excerpts of the draft report applicable to DEP and to give DEP a limited time period to respond in writing and present testimony before the grand jury. Upon reading those excerpts, DEP was surprised by the extent of the factual inaccuracies and confused articulation of the relevant law in the excerpts of the draft report and submitted three written statements on the issues and purported facts in the short summaries. DEP also received a limited opportunity to present testimony by one DEP employee, Kurt Klapkowski, Director of the Bureau of Oil & Gas Planning and Program Management, based solely on the topics and contents of the short summaries provided by the OAG.

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In the full report, which DEP obtained only after it sought court intervention, the grand jury made no findings of criminal wrongdoing by DEP. However, it presents an inaccurate and incomplete picture of Pennsylvania's regulatory program and how it is being implemented today. The report relies upon unidentified witness snapshots, in some cases from 10-15 years ago. It is critical of today's DEP regulatory program while demonstrating little knowledge or understanding of it. DEP respects the work of and the mission of the grand jury. However, accuracy is necessary before criticisms can be fairly made. Likely because of the limited information presented to them by OAG during the confidential grand jury investigation, the grand jurors were not able to develop an understanding of the current regulatory program or the related law and, consequently, made recommendations that are ultimately unproductive and/or inappropriately directed to DEP.

This false picture of DEP does a disservice to the citizens of the Commonwealth, generally, and to the dedicated employees of DEP, specifically. It undermines the public's right and ability to understand whether they are receiving the protections afforded them by law and erodes the public's trust in DEP. For this reason, DEP respectfully requests this Honorable Court attach this response as an exhibit to the report prior to public disclosure and/or publication.

DEP's response below consists of two sections. The first section, "Creation of a Modern Natural Gas Regulatory Program" describes DEP's regulatory program. It examines distinctions between the statutes, regulations, and policies; describes requirements of DEP's regulatory program; provides a timeline of critical events in the development of that program; describes organizational changes made in the Oil & Gas Program; and reviews the Program's successes. The second section, "DEP's Responses to the grand jury's Conclusions and Recommendations" identifies factual and legal inaccuracies in the report and presents DEP's responses to the individually articulated recommendations of the grand jury.

II. CREATION OF A MODERN NATURAL GAS REGULATORY PROGRAM

A. Governmental Authority to Regulate

The report starts by quoting the "Environmental Rights Amendment" of the Pennsylvania Constitution, which enshrines the peoples' rights to a clean environment and creates a constitutional "trust" in Pennsylvania's public natural resources. The Pennsylvania Constitution is the starting point for understanding Pennsylvania's structure of government and the basic relationships between citizens and business and government. It is important to recognize however, that the Constitution also limits the power of the government by making clear that governmental "police power" must be spelled out in laws written by the Legislature. Unfortunately, the report stops at the Constitution and does not do the hard and complicated work of examining Pennsylvania's laws that define governmental authority to regulate industry. It is easy to point to the Pennsylvania Constitution's unique and powerful Environmental Rights Amendment, and then simply say the government and specifically, DEP, should have done more. This oversimplified approach is misleading and ultimately unhelpful.

If the objective of this report – which does not find any unlawful behavior by DEP – is to produce improvements to governmental policing of the industry, OAG should have first explained the rules, starting with the identification of the laws that give an agency specific "police powers" to regulate how industries operate. In addition to the laws, examination of policy statements and approval mechanisms are also relevant to understand whether the agency is doing its job. Once rules are explained, then the investigation should gather facts related to the agency's performance under all of these requirements. No such effort is reflected in this report.

Despite the seriousness of the allegations in the report, there is no discussion of the environmental laws that establish – and in important ways limit – the scope of governmental oversight of the industry. There is no acknowledgment of the fundamental "checks and balances"

principle of government that the Legislature writes the laws, and the Governor and his agencies implement those laws. It is important to understand that the Environmental Rights Amendment cited at the beginning of the report does not give the Governor or the agencies the power to expand their authority beyond the laws passed by the Legislature.

Also absent from the report is any discussion of the regulations developed under the laws written by the Legislature. In fact, since the start of the unconventional gas boom in Pennsylvania, DEP and the Environmental Quality Board (also within the executive branch) have shepherded seven different regulatory packages through the Pennsylvania "regulatory rulemaking" process. This achievement is significant because the process agencies must follow, which was established by the Legislature in the Regulatory Review Act, the Commonwealth Documents Law, the Commonwealth Attorneys Act, and the Administrative Code is detailed and prescriptive, in order to ensure that the agencies do what the Legislature intended. DEP's regulatory development process typically takes at least two years and includes public hearings, consultation with numerous advisory committees, public notice, public comment, DEP's response to public comments, review by the Independent Regulatory Review Commission, review by the Legislative Committees, and review and approval by the Attorney General. At each step in the process, proposed regulations are scrutinized for consistency with the laws they are intended to implement, and regulatory rulemakings that are found to go "too far" and to exceed the statutory authority are not approved. Once a regulation makes it through the entire process, it does have the "force of law" - which means that it can be enforced like a statute passed by the Legislature, and agencies have the power to issue orders or take "enforcement action" when someone violates the regulation.

The report does discuss policies, but mistakenly implies that policies are interchangeable with statutes or regulations. On pages 52-53, the report suggests that DEP could have regulated the industry more quickly *by policy*, because agencies can write these themselves and no approval

is needed. The report cites the testimony of former Environmental Hearing Board Chief Judge and former DEP Secretary, Michael Krancer, as supporting this idea. In fact, the testimony quoted on page 52 of the report appears to have been taken out of context and should not be interpreted to support the conclusion that DEP on its own could have "created a comprehensive fracking policy" to regulate the industry. Pennsylvania law is clear that policies do not function like laws that can be enforced. An agency may not create binding rules to limit activities of individuals or industry without having been given the power to do so by the Legislature through statutes, and without having gone through the regulatory rulemaking process. In fact, it is unlawful for DEP to apply a policy to an industry as though it were a statute or promulgated regulation. Rather, policies, or "technical guidance documents" as they are often referred to by DEP, can only be used to explain an agency's interpretation of the statutes and regulations and to make recommendations for how a party can demonstrate compliance with the laws.

Because the report does not provide a description of the statutory and regulatory framework, this section of DEP's Response provides an overview of the current legal framework of DEP's regulatory program, provides a timeline of the transformation of that program, and discusses some of the program's successes, including the Pennsylvania courts' conclusion that DEP's regulation of the unconventional gas industry satisfies its constitutional duties under the Environmental Rights Amendment.

B. Pennsylvania's Current Regulatory Program is Comprehensive

Under several Pennsylvania environmental statutes, DEP is empowered with permitting and inspecting unconventional gas development. The current program framework comprehensively anticipates a broad spectrum of potential environmental impacts and ensures protection of public health, safety and the environment. Specifically, the statutes and regulations that DEP administers address the potential impacts to land, water, air and natural resources during

each phase of the unconventional gas development: 1) planning and construction; 2) well drilling and hydraulic fracturing; 3) operation; and 4) plugging and restoration. (See Exhibit A for a complete list of laws, regulations, policies, and permitting forms relied on by DEP to oversee the unconventional gas industry). Key elements of the regulatory program, based in the statutory provisions and regulations, are briefly identified below.

1. Planning and Construction

Unconventional gas well operators must obtain several different permits or approvals from DEP before they can conduct any construction associated with unconventional gas well development. These applications require planning and investigation by the applicants and must include information related to geology, groundwater, surface waters, nearby structures and natural resources, soil information, stormwater runoff patterns and features in the area, as well as information regarding species that are protected under state and federal laws and past land uses. The applications must be prepared by licensed professionals. DEP reviews the applications, coordinates with other resource agencies as necessary, coordinates internally regarding other associated permit applications, considers comments from the public and local governments, and issues authorizations only if the applications satisfy all the requirements, and DEP is satisfied that the project will not cause unreasonable diminution, depletion or degradation of Pennsylvania's public natural resources. The permits or authorizations needed before commencement of unconventional well development activity are:

i. Well Permits

Under the 2012 Oil and Gas Act and the Chapter 78a regulations, to drill a new unconventional gas well, the operator must obtain a well permit from DEP and post a bond. The permit application must identify the well location and its proximity to buildings, water supplies, workable coal seams, gas storage reservoirs and landfills. An operator must comply with all

applicable laws, including requirements for site construction, drilling, water use, wastewater management, notification, spill reporting, and spill remediation.

ii. Water Withdrawals

Large volumes of water are required for drilling and hydraulic fracturing of an unconventional gas well. An operator withdrawing water for use in drilling or hydraulic fracturing must obtain approval of a Water Management Plan from DEP in accordance with the 2012 Oil and Gas Act, the Clean Streams Law, the Chapter 78a regulations, and approvals from the Susquehanna or Delaware River Basin Commissions if applicable.

iii. Earth Disturbance and Stream Crossings

Unconventional gas well development involves extensive earth disturbance, including roads, well sites and gathering, transmission and distribution pipelines, that can result in accelerated erosion and sedimentation. Under the Clean Streams Law and Chapter 102 regulations, an Erosion and Sediment Control General Permit authorization is required before construction. To obtain coverage under this general permit, the applicant must submit an application and detailed site-specific plans for review and approval.

Additionally, unconventional gas construction activities that are in or along wetlands and streams, also require a "water obstruction or encroachment" permit or approval from DEP before the operator may commence construction under the Clean Streams Law, the Dam Safety and Encroachments Act, and Chapter 105 regulations.

2. Drilling and Hydraulic Fracturing

After construction of the well site, drilling and hydraulic fracturing of unconventional gas wells must comply with permit conditions and regulatory requirements including those described below.

i. Well Casing and Cementing

Properly constructed and operated wells are critical to protecting water supplies and public safety. Under the 2012 Oil and Gas Act and the Chapter 78a regulations, operators must meet specific casing and cementing requirements tailored to unconventional well construction to protect groundwater from the fluids and natural gas that will be contained inside the well and to keep water from the surface and other geologic strata from mixing with and contaminating groundwater.

ii. Air Quality

In Pennsylvania, air emissions from unconventional gas development are regulated under the Pennsylvania Air Pollution Control Act, the 2012 Oil and Gas Act, the federal Clean Air Act, and the related air quality regulations. Prior to commencing construction of the air contamination sources, approval must be secured under either General Permit-5 or General Permit-5a, an individual permit, or undertaken in accordance with specific regulatory requirements.

iii. Wastewater

Large volumes of wastewater are generated during the drilling and hydraulic fracturing phases and during operation of unconventional wells. This wastewater is classified as a residual waste in Pennsylvania and is regulated by the 2012 Oil and Gas Act, the Solid Waste Management Act, the Clean Streams Law, and the Chapters 78a, 95, and 287 regulations. An unconventional gas well operator must identify in its Water Management Plan where wastewater will be stored, treated, and disposed. Wastewater must be recycled and treated at an authorized wastewater treatment facility or disposed at an authorized waste disposal facility. Operators must also provide monthly reports to DEP documenting wastewater generation, management and/or disposal.

iv. Disclosure to DEP of Chemicals Used

Under the 2012 Oil and Gas Act and the Chapter 78a regulations, unconventional gas well operators must submit to DEP all chemical information, including any designated trade secrets or

confidential proprietary information after the well is hydraulically fractured. Unconventional operators must also complete a chemical disclosure registry and post it on the publicly available website FracFocus.

v. Water Supply Restoration or Replacement

Disruption of water quality or flow in nearby water wells from drilling activities can occur. The 2012 Oil and Gas Act and the Chapter 78a regulations require operators to replace or restore affected water supplies. DEP investigates all complaints and issues orders as necessary to replace or restore impacted water supplies. Unconventional gas well operators are presumed responsible for any water supply impacts that occur within 2,500 feet of the vertical wellbore within a year of completion, drilling, stimulation, or alteration of the well. The presumption of liability may be rebutted by pre-drill survey or samples proving the operator's drilling did not cause the water supply impacts, or by the landowner's refusal to allow a pre-drill survey to be performed.

vi. Prevention of Spills and Releases and Remediation

Under the 2012 Oil and Gas Act, the Clean Streams Law, and the Chapter 78a regulations, before bringing chemicals to or generating waste at a well site, an operator must prepare and implement a Preparedness, Prevention and Contingency Plan, and must plan for the control and disposal of the waste generated and managed at the well site. Unconventional gas well sites must be completely lined so that wastes or fuels are always managed within competent secondary containment and operators must develop a containment plan for chemicals and fluids including fuels, drilling muds and additives and flowback. Among other reporting requirements, a person responsible for a spill or release causing or threatening pollution of waters of the Commonwealth must immediately notify DEP. When DEP concludes that a private water supply owner may be impacted by a spill, the agency provides notice to the owner and may gather additional information, including sampling water supplies potentially impacted by a spill, and may take enforcement

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action. DEP oversees remediation of an area affected by a spill or release at a well site based on scientific criteria that are applicable to all contaminated sites in Pennsylvania.

vii. Air Monitoring

All unconventional gas operators must report air emission data annually to DEP, consistent with the 2012 Oil and Gas Act and the Chapter 135 regulations. DEP's air monitoring activities include operation of the Commonwealth of Pennsylvania Air Monitoring System to continuously monitor pollutant levels statewide. DEP continues to establish new monitoring sites in unconventional gas producing counties across the Commonwealth.

3. Operation and Well Integrity

After construction of the well and hydraulic fracturing, mechanical integrity testing is required quarterly, including the collection and submission of information on wellhead pressures, annular pressures and flows, leaks and severe corrosion in accordance with the 2012 Oil and Gas Act and the Chapter 78a regulations. Operators must take corrective actions to repair or replace defective equipment or casing or mitigate the excess pressure on casings.

4. Plugging and Restoration

Once a well is no longer producing gas, the operator must plug the well as prescribed by the 2012 Oil and Gas Act and the Chapter 78a regulations to stop vertical flow of fluids or gas within the well bore and must restore the well site within nine months of plugging the well.

5. **DEP Monitoring and Inspections**

DEP inspects unconventional gas well sites from construction to restoration after plugging to ensure that the site has proper erosion controls in place, the operator sites and drills the wells according to permit requirements and applicable laws, and any waste generated in drilling and completing the well is properly managed and disposed. Unconventional gas well operators are required to submit to DEP a variety of notices and reports regarding well drilling, completion, production, waste disposal, and well plugging. DEP staff investigate complaints from the public that an unconventional gas activity may be causing environmental or public safety concerns. If necessary, DEP employs aggressive enforcement against operators to ensure that facilities are brought into compliance.

C. Timeline of Unconventional Gas Regulation in Pennsylvania

Much of the inaccuracy in the report stems from a failure to anchor events in time. The report does not differentiate between DEP's oversight of the industry as unconventional gas exploration started in 2004 subject to rules created in 1984 for a different industry versus the current oversight more than fifteen years later. In fact, since the beginning of unconventional gas well development in the Commonwealth, DEP has transformed the regulatory program, prioritizing updates around four categories: 1) safety concerns such as emergency planning, well construction and staffing; 2) health concerns, for example from wastewater and air emissions; 3) environmental impacts like those from increased erosion and water withdrawals; and finally 4) overall administration of the program including improvements to transparency and reporting associated with permitting and enforcement. To fully understand that transformation, DEP provides the following timeline which summarizes critical developments in the oversight of unconventional gas development in Pennsylvania:

Jan. 2003 – 2010 Governor Ed Rendell

2004-2007 Unconventional gas well industry conducts exploratory drilling in PA subject to DEP's 1984 regulatory requirements for the conventional oil and gas industry.

2008 Unconventional gas well development boom begins.

- 2008 DEP creates PA Clean Streams Law-based General Permit, "ESCGP-1," continuing the requirement that PA gas developers obtain erosion and sediment control permits after Congress passes exemptions at federal level.
- 2009 DEP opens Williamsport Oil & Gas Program Office.
- 2009 EQB promulgates final regulations to increase permit application fees to hire additional technical staff to handle increased workload.
- 2009-2011 DEP hires approximately 137 new staff for the Oil & Gas Program.
- 2009 DEP initiates a new regulatory package to modernize well construction standards.
- 2010 EQB promulgates final regulations to codify requirement for erosion and sediment control permit in wake of federal exemptions, amending 25 Pa. Code Ch. 102.
- 2010 EQB promulgates final regulations to address Total Dissolved Solids pollution from natural gas well wastewater, amending 25 Pa. Code Ch. 95.
- 2010 DEP initiates a new rulemaking package addressing surface activities associated with both conventional and unconventional gas development (Surface Activities Rulemaking), proposing to amend 25 Pa. Code Ch. 78.
- 2010 Gov. Rendell issues Pa. Exec. Order No. 2010-05, placing a moratorium on additional leasing for gas development on lands owned and managed by the DCNR.

Jan. 2011 – 2014 Governor Tom Corbett

- 2011 DEP begins to receive electronic reporting of data from well operators.
- 2011 DEP establishes a new deputate, the Office of Oil & Gas Management, with direct oversight of both central office and district office operations.

- 2011 EQB promulgates final regulations to update well construction standards to address, inter alia, gas migration risks, amending 25 Pa. Code Ch. 78.
- 2012 General Assembly enacts Act 13 of 2012, (2012 Oil & Gas Act), updating DEP's oversight authority of oil and gas well development and preempting municipal authority to zone unconventional gas development activities.
- 2012 General Assembly enacts Act 9 of 2012 directing DEP and PA Emergency Management Agency (PEMA) to adopt emergency regulations requiring unconventional gas operators to plan and prepare for emergency response.
- 2012 DEP finalizes ESCGP-2, updating the permit for erosion and sediment control of earth disturbances associated with oil and gas activities.
- 2013 EQB promulgates final regulations authorized by Act 9 of 2012, related to emergency planning and response, amending 25 Pa. Code Ch. 78.
- 2013 DEP publishes Technical Guidance "Addressing Spills and Releases at Oil & Gas Well Sites or Access Roads," Document No. 800-5000-001.
- 2013 DEP announces new online oil and gas mapping tool to provide access to statewide data related to well location, status and permitting information.
- EQB proposes new oil and gas rulemaking package for conventional and unconventional gas well development ("Surface Activities Rulemaking"), which included a 90-day public comment period; 9 public hearings in all regions of the state with testimony from approximately 300 individuals; and 23,213 written comments.

- 2013 PA Supreme Court finds portions of Act 13 of 2012 unconstitutional, including the provision preempting municipal zoning of unconventional gas development.
- 2013 DEP finalizes amendments to the Air Quality General Permit (GP-5) for natural gas compression and processing facilities establishing emission limitations, and including leak detection and repair, emission control, recordkeeping and reporting requirements.
- EQB promulgates final regulations to increase permit application fees for gas wells, for DEP to hire additional staff in light of declining revenues and increasing workloads.
- 2014-2015 DEP hires approximately 24 new staff to Oil & Gas Program.
- 2014 Gov. Corbett issues Pa. Exec. Order No. 2014-03, allowing additional leasing for oil and gas development on DCNR lands rescinding Pa. Exec. Order No. 2010-5.
- 2014 General Assembly enacts Act 126 requiring regulations under the 2012 Oil & Gas Act to differentiate between conventional and unconventional wells. DEP bifurcates proposed Surface Activities Rulemaking into two chapters: Ch. 78 (conventional wells) and 78a (unconventional wells).
- 2014 DEP launches e-Well permit to streamline oil and gas permitting process and allow the information to be accessed on DEP's webpage.
- 2014 General Assembly enacts Act 173 of 2014, the Unconventional Well Report Act, requiring operators to report production on a monthly basis.

Jan 2015 – Present Governor Tom Wolf

- 2015 Gov. Wolf issues Pa. Exec. Order No. 2015-03, reinstating the moratorium on additional gas leasing on DCNR lands rescinding Pa. Exec Order No. 2014-03.
- 2015 DEP updates Technical Guidance: "Standards and Guidelines for Identifying, Tracking and Resolving Oil and Gas Violations," Document No. 820-4000-001.
- 2015 DEP publishes the TENORM report, analyzing the naturally occurring levels of radioactivity associated with unconventional gas development, leading to radioactive material action plan requirements to be included in the Surface Activities Rulemaking.
- EQB publishes the draft final Surface Activities Rulemaking for a second time, providing an additional 45-day public comment period; 3 additional public hearings, in the three oil and gas district office territories with testimony from 129 individuals; and 4947 additional written comments.
- 2015 DEP and DCNR fund expansion of a state seismic station network to record seismicity, in association with the Pennsylvania State University (PSU), in response to public concerns regarding induced seismicity from hydraulic fracturing and underground injection of oil and gas wastes. DEP's and DCNR's construction of the network expansion is completed in August 2016. PSU monitors network and maintains associated website.
- 2016 Gov. Wolf announces Methane Reduction Strategy, which includes new requirements for oil and gas operators to reduce air emissions.

- 2016 Independent Regulatory Review Commission approves Ch. 78 and 78a rulemaking after full day hearing; House and Senate standing committees issue resolutions disapproving the rulemaking; General Assembly's Joint Committee on Documents holds hearing on the propriety of the regulatory process.
- 2016 General Assembly enacts Act 52 abrogating the Surface Activities Rulemaking -Ch. 78 (conventional wells); OAG directs DEP to strike Ch. 78 amendments.
- 2016 DEP releases eSubmission system for electronic submission of forms required from unconventional operators. eSubmission data is publicly available and searchable.
- 2016 DEP publishes interim final Technical Guidance "Guidelines for Implementing Area of Review Regulatory Requirement for Unconventional Wells," Document No. 800-0810-001, to address the potential risks of hydraulic fracturing in proximity to other wells.
- 2016 DEP publishes interim final Technical Guidance "Policy for the Replacement or Restoration of Private Water Supplies Impacted by Unconventional Operations," Document No. 800-0810-002, to inform DEP staff, industry and the public how to comply with the water supply restoration and replacement requirements in the 2012 Oil and Gas Act, The Clean Streams Law, and 25 Pa. Code Chapter 78a.
- 2016 EQB promulgates as final regulations the Ch. 78a Surface Activities Rulemaking for unconventional well development, modernizing and strengthening environmental protection for these activities.
- 2016 One week after EQB promulgates final Ch. 78a Surface Activities regulations, the Marcellus Shale Coalition files a lawsuit to enjoin portions of the new regulations.

- 2016 PA Commonwealth Court temporarily enjoins DEP's enforcement of portions of the Surface Activities regulations in response to the Marcellus Shale Coalition's lawsuit.
- 2016 Gov. Wolf and the Governors of New York and Delaware pass a Delaware River Basin Commission proposed resolution to permanently ban hydraulic fracturing for oil and gas in the Delaware River Basin.
- 2017 DEP publishes interim final Technical Guidance "Guidelines for Chain Pillar Development and Longwall Mining Adjacent to Unconventional Wells," Document No. 800-0810-004, to facilitate appropriate unconventional well inactivation and re-entry procedures before and after longwall panel removal.
- 2017 DEP establishes "The Pipeline Portal" on DEP webpage providing public access to pipeline permit application and enforcement information.
- 2018 DEP finalizes ESCGP-3, updating the permit for erosion and sediment control of earth disturbances associated with oil and gas activities.
- 2018 DEP establishes the Office of Regional Permit Coordination as the lead office related to pipeline environmental permitting and enforcement.
- 2018 PA Supreme Court lifts portions of 2016 preliminary injunction of Ch. 78a Surface Activities Rulemaking, allowing DEP to implement most of the new regulations.
- 2018 DEP updates the Air Pollution Control Act General Permit GP-5 and finalizes a new General Permit GP-5a regulating emissions from unconventional gas well site operations and remote pigging operations.

- 2018 DEP releases Mechanical Integrity Assessment dataset (thousands of well assessments dating back to 2014) and an accompanying report.
- EQB approves proposed regulations to control and reduce Volatile Organic Compound emissions (and thereby reduce methane emissions) from oil and gas development activities, amending 25 Pa. Code Ch. 127.
- 2020 EQB approves final regulation to increase permit application fees for unconventional wells to fund retention of DEP staff complement in light of decreasing revenues and increasing workloads.

This timeline details DEP's persistent efforts from 2008 to the present to create a more robust and modern regulatory scheme to address and minimize new and different impacts from unconventional gas development and to make information available and accessible to the public. It counters the report's allegations that DEP did very little to make needed changes in the Oil and Gas Program until recently.

D. DEP Made Internal Changes to Support Its Modern Regulatory Program

While an updated regulatory framework was critical to DEP's regulating the unconventional gas industry more effectively and better protecting the public, DEP could not have accomplished its goals without also making organizational changes to expand and restructure the Oil & Gas Program, in terms of physical capital and human resources, and to enhance the transparency of the activities of both the agency and the industry.

Prior to 2008, the Oil & Gas Program had three offices, a small central office in Harrisburg and two regional offices in northwestern and southwestern Pennsylvania. There was no DEP Oil & Gas Program presence in northcentral or northeastern Pennsylvania, the location of the heaviest unconventional gas development. In 2008, DEP created a third regional Oil & Gas office in

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Williamsport, which allowed inspectors and technical staff to more effectively inspect and address problems at well sites in that region and gave the people most affected by that well activity greater access to DEP.

DEP's next priority was to increase staff dedicated to the Oil & Gas Program and to train them. The dramatic increase in the number of wells drilled required correspondingly greater numbers of permit reviewers and inspectors to handle oversight activities. Using funds generated by increasing the application fees for unconventional well permits, DEP enlarged the Oil & Gas Program staff from 64 to 202 employees. The new employees were allocated among the four Oil & Gas Offices. Approximately 80 percent of the new employees became inspectors or were assigned to engineering or scientific-related work for permitting; the remaining 20 percent were assigned to clerical, administrative, or legal work to support the program.

All inspectors and permitting staff received on-the-job training by shadowing experienced employees and participated in formal in-house training on unconventional industry practices and identifying and addressing the environmental and health and safety impacts of gas development. Between 2009 and 2012, over 34 training classes were held. Class instructors included representatives of DEP's Oil & Gas and Water Programs, U.S. E.P.A., and PA Department of Conservation and Natural Resources. In later years, DEP expanded staff training by accessing the educational opportunities presented by the many stakeholder and professional organizations with which the Oil & Gas Program collaborated, including the PA Groundwater Association, American Association of Petroleum Geologists, NELAC Institute, North American Coalbed Methane Forum, Interstate Oil and Gas Compact Commission, TOPCORP, and the Shale Network. Between 2014 and 2019, Oil & Gas Program staff attended 73 different educational trainings.

The physical growth of the Oil & Gas Program magnified the need for a restructuring. Before 2011, the Oil & Gas Program was split between two DEP management units whose Deputy

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Secretaries reported to the DEP Secretary. Oil & Gas Program planning had been part of the Mineral Resources deputate, but the three regional Oil & Gas offices were part of the Field Operations deputate. In 2011, DEP created a new management unit, the Office of Oil & Gas Management, to unify the planning and program management staff with the permitting, inspection and enforcement staff under one Deputy Secretary. The Office of Oil & Gas Management, which is responsible for administrative, policy and regulatory development functions, and the Bureau of District Oil & Gas Operations, which consists of the three district offices and performs all permitting, inspection and enforcement tasks. The 2011 restructuring gave the Oil & Gas Program a more substantial DEP Central Office presence, centralized management of O&G personnel, and streamlined collaboration between the two Bureaus. The reorganization also advanced development of a core group of technical staff with industry-specific expertise.

To accomplish its goal of creating a program that balanced the need for resource development by private industry with the need to protect citizens and the environment, it was important for DEP to be as transparent as possible about how the regulatory program worked and whether the industry was complying with the law. The citizens needed to know that their interests mattered and were being protected. Locating Oil & Gas district offices in each of the three regions of unconventional gas development and expanding DEP's field staff was the first step.

Next, DEP responded by making information about its regulation of the industry as accessible to the public as possible. In addition to the permit file information available for review at the three district offices and information DEP provides in response to requests under the Pennsylvania Right to Know Law, DEP recognized that the public needed even greater accessibility to information regarding this industry and created a webpage that includes the numbers and locations of issued well permits, dates when wells are drilled, dates when wells are

completed, the identity of chemicals used to hydraulically fracture each well, the volume of gas produced at each well, the volume of waste produced, quarterly reports on well integrity, data on air emissions, emergency response plans for well sites, inspection reports, results of water supply impact investigations, water samples collected and analyzed by DEP, Notices of Violations, and enforcement actions taken by DEP. In 2013, DEP's Oil & Gas Program migrated to an electronic well permitting platform to increase efficiency, improve data integrity, and improve DEP's ability to quickly locate records and provide timely responses to information requests.

Over the last twelve years, the webpage has been expanded and improved and now includes more information regarding oversight of this industry than has ever been publicly available, such as links to other DEP data management systems that provide compliance information (eFACTS), as well as a report generator for inspections and violations; a notice service (eNotice) to receive emails of each permit application submitted to DEP; and eMapPA, which shows where wells are located using detailed and specific Geographic Information System tools. As part of the 2016 Surface Activities rulemaking, DEP developed an eSubmission system for electronic submission of most required forms, which system is also publicly available and searchable. In addition to links to all the applicable laws, forms, policies and Technical Guidance Documents, also posted are the Office of Oil & Gas Management's Annual Reports which analyze much of this information. In 2017, DEP added the "Pipeline Portal" to its website, which contains detailed information on the status of major gas pipeline permit application reviews, compliance and enforcement matters. And, in 2018, DEP released a new mobile inspection application and a new inspection view report tool, which enables the agency to publish its inspection reports on line in real time. All these developments have enhanced the transparency of this regulatory program and help the public to better understand how they are being protected.

E. DEP Has Successfully Implemented Its Modern Regulatory Program

By repeatedly adapting its strategies to meet the new challenges this industry presents and strengthening its organizational capacity, DEP has successfully implemented a modern regulatory program. Important progress has been made in permitting and enforcement activities and DEP has shaped the overall program to be transparent, participative and collaborative.

1. The Oil and Gas Permitting Program Satisfies the Environmental Rights Amendment

DEP's protective permitting procedures for unconventional wells have been validated by Pennsylvania's courts. In the case of *Brockway Borough Municipal Authority v. DEP*, 2015 EHB 221, the Pennsylvania Environmental Hearing Board ("EHB") not only dismissed an administrative challenge to DEP's issuance of a drilling permit located near a water well of a public water supply but expressly found that DEP had satisfied its trustee obligations under the Environmental Rights Amendment in its review of the permit application. The EHB noted that it was appropriate for DEP to first determine whether the application satisfied all applicable regulations pertaining to the drilling of unconventional gas wells because the regulations were specifically designed to minimize the risks associated with the drilling. The EHB further approved of DEP's imposing special permit conditions relating to drilling techniques and the casing and cementing plan because they gave additional protection to the water well and of requiring supplemental monitoring because it ensured that any problem that did arise could be quickly identified and corrected. On appeal, the Pennsylvania Commonwealth Court affirmed the EHB's ruling. *Brockway Borough Municipal Authority v. DEP*, 131 A.3d 578 (Pa. Cmwlth. 2016).

2. The Oil and Gas Enforcement Program is Driving Compliance

DEP has been vigorously enforcing the law. By increasing staff, providing them with appropriate training, and creating clear enforcement protocols, such as the Technical Guidance Document "Standards and Guidelines for Identifying, Tracking, and Resolving Oil and Gas Violations," Document No. 820-4000-001, DEP has conducted more monitoring activities and pursued significant and impactful enforcement. The metrics alone tell a positive story. Over the past two years, DEP has conducted record numbers of inspections, responses to complaints, and water samplings, as set forth below. All these investigations give DEP important information about the industry's compliance with the law and whether enforcement action is needed.

2018 and 2019 Inspection Numbers:

- In 2018, DEP's Office of Oil & Gas Management conducted 36,907 inspections;
- In 2019, DEP's Office of Oil & Gas Management conducted 35,371 inspections;
- In 2018, DEP's Office of Oil & Gas Management received and responded to 879 complaints;
- In 2019, DEP's Office of Oil & Gas Management received and responded to 815 complaints;
- In 2018, DEP's Office of Oil & Gas Management collected and analyzed 1,372 water samples; and
- In 2019, DEP's Office of Oil & Gas Management collected and analyzed 1,686 water samples.

DEP has continued to successfully use Notices of Violation and civil penalty assessments to address many of the more straightforward violations which DEP identifies, as reflected in the chart below.

2018 and 2019 Notices of Violation ("NOV") and Civil Penalties

- In 2018, DEP's Office of Oil & Gas Management issued 575 NOVs;
- In 2019, DEP's Office of Oil & Gas Management issued 407 NOVs;

- In 2018, DEP's Office of Oil & Gas Management collected \$4,140,382 in fines and penalties related to non-compliance at oil and gas sites; and
- In 2019, DEP's Office of Oil & Gas Management collected \$4,097,545 in fines and penalties related to non-compliance at oil and gas sites.

Complementing the metrics are the complex enforcement actions which DEP takes to address more egregious conduct. Two cases from the last several years stand out. In 2014, EQT Production Company allowed an impoundment full of production and flowback fluids to leak into and degrade the groundwater, a wetland, and a stream. Fortunately, the incident was identified by careful inspection/surveillance by the field staff in DEP's Williamsport Office, and DEP filed a complaint for civil penalties under the Clean Streams Law against EQT. EQT challenged DEP's claim for civil penalties, and the litigation that ensued was contentious and resource-intensive. It included a ten-day evidentiary hearing, at which seven expert witnesses testified about the hydrogeologic aspects of the site, the impact of the pollutional discharge on surface and groundwaters, and the impact of the degraded surface and groundwater on aquatic communities. In 2018, DEP prevailed and the EHB assessed, and the Commonwealth Court affirmed, a civil penalty in the amount of \$1,137,295.76 against EQT. DEP v. EQT Production Company, 2017 EHB 439; EQT Production Company v. DEP, 181 A.3d 1128 (Pa. Cmwlth. 2018) Of note, while this litigation was pending, DEP banned the practice of these onsite impoundments, in the Surface Activities Rulemaking.

More recently, DEP took an unprecedented civil enforcement action against Energy Transfer Corporation ("ETC"), one of the largest oil and gas companies in the world which is building an extensive gas transportation pipeline through Pennsylvania. ETC provided inaccurate information in its permit application concerning the slide-prone nature of the soils at a portion of the pipeline site. The permit was issued and once the pipeline was installed it became compromised and exploded. DEP imposed a civil penalty of \$31 million against the company for this violation, one of the largest civil penalties in state history. But, more importantly, DEP imposed a permit bar statewide on ETC and all its subsidiaries for one year, preventing them from receiving any permits from DEP during that time period. For an extractive industry which is dependent upon receiving a steady stream of permits, such as the unconventional gas and associated pipeline industries, a bar on the receipt of permits has a far greater deterrent effect on future behavior than any single penalty ever could.

All of DEP's enforcement actions together drive compliance with the law, which is the primary objective of the enforcement program. DEP is now seeing the raw numbers of violations and "violations per inspection" decrease over time even as the regulations have become more stringent and more requirements have been placed on the unconventional operators. This fact speaks more to the success of DEP's enforcement program than any other consideration. These activities collectively describe an agency that is actively and aggressively enforcing the law.

3. The Oil & Gas Program is Transparent, Participative and Collaborative

Although there is a strong tendency to measure a regulatory program which is very data oriented, such as the Oil & Gas Program, exclusively by metrics, there is another measure of success that is equally important. That is the ability of the Program to embrace the values of transparency, participation, and collaboration. Those values focus on the relationships which the agency has with its stakeholders and can greatly affect the agency's ability to be trusted, to be deemed credible, and to grow and improve, all of which impact the agency's effectiveness. The stakeholders of the Oil & Gas Program include the industry, residential communities located near well sites, environmental consultants, municipal governments, environmental groups, academia and other research institutions, other Pennsylvania state agencies, and other state oil and gas

regulatory agencies. The Oil & Gas Program has made significant strides in building professional relationships with its stakeholders from which it can learn and teach and explore solutions to the difficult issues it must address.

DEP's commitment to making its regulation of the unconventional gas industry transparent is discussed above. All stakeholders benefit from the agency's transparency, but particularly those who experience the impacts of the industry directly. In its annual plan for 2020, the Oil & Gas Program has committed to continued improvements related to data collection and transparency including: 1) adding functionality to the mobile GIS applications that staff use while conducting field investigations; 2) continued enhancements to the eSubmission system; and 3) continued improvement to electronic data collaboration tools related to gas storage fields and underground mines. DEP's insistence on continual improvements in data collection, management and access speaks to the integrity and openness of the agency. The credibility and value of DEP's electronic data systems was recently acknowledged in a Memorandum Opinion by the U.S. District Court for the Eastern District of Pennsylvania. In the case of Delaware Riverkeeper Network, et al. v. Sunoco Pipeline, L.P., Civ. No. 18-447, Judge Diamond, in ruling on a motion for summary judgment concerning the environmental permitting needed by Sunoco to construct its Mariner East II Pipeline, relied upon DEP's Pipeline Portal to support important facts concerning Sunoco's compliance with DEP's regulations for pipeline construction. (Slip Opinion of 4/16/2020 at p.13).

Public participation is also an agency priority. DEP's success in encouraging the public's participation was borne out during the 2016 Surface Activities Rulemaking which proposed significant changes to modernize the regulatory program. DEP was able to finalize this rulemaking in part due to the very engaged participation of the general public, which balanced the strong opposition from industry and two separate legislative enactments to thwart DEP's efforts. The public participation process was unprecedented and featured 135 days of public comment, 12

public hearings held across the Commonwealth, at which many individuals presented oral testimony, and the submission of almost 28,000 written comments. The individuals who participated were well-informed, mirroring DEP's extraordinary outreach and the significant volume of information provided by the agency to support and explain the proposed regulation. Many citizens argued for enhanced protection of their safety, their water supplies, their communities, and the public resources. Many of the changes made to the regulations after the two public comment periods were in response to and specifically implemented changes requested by the public, which is explained in the Preamble to the rulemaking. 46 Pa. B. 6431. The written Comment and Response document and other supporting documents for the final rulemaking can be found on the Environmental Quality Board's 2016 webpage.

As to collaboration, the Oil & Gas Program has developed an extensive network of professional relationships with a broad range of technical, scientific, regulatory, and academic organizations. Some of these collaborations are more established, such as the Oil and Gas Technical Advisory Board, which has a specific structure, statutory mandate, and scheduled meetings with the Oil & Gas Program to consult with and advise the Program. Others are less formal and are convened to address a particular problem, such as the Coal-Gas Industry-Agency Stakeholder Committee, which consists of representatives of DEP District Oil and Gas Operations, DEP Division of Subsurface Activities, DEP Bureau of Mine Safety, National Institute of Occupational Safety and Health ("NIOSH"), U.S. Mine Safety and Health Administration ("MSHA"), coal and unconventional gas operators, and West Virginia and Ohio regulatory agencies, which was formed to identify best practices for coordinating the intersection of the coal and natural gas industries. All these collaborative relationships enlarge the expertise of the Oil & Gas Program by bringing in a broader range of knowledge and experiences to inform the Program's decision-making. These collaborative relationships also have served to formally and informally

educate the Oil & Gas Program's scientists and experts, thereby strengthening the Program's capacity to address the difficult science and technology issues that arise on a daily basis. These many relationships have played a significant role in helping the Oil & Gas Program to create a modern, proactive, and protective regulatory program.

III. DEP'S RESPONSES TO THE GRAND JURY'S CONCLUSIONS AND RECOMMENDATIONS

A. The Grand Jury Report Is Not Reliable

DEP respects the time-consuming work of the grand jury and recognizes the importance of the grand jury investigation. DEP shares the grand jury's goal of ensuring that the oil and gas industry is appropriate regulated. However, in many aspects the grand jury report is both factually and legally inaccurate. If the grand jury had been presented with complete and credible evidence, as well as the applicable law, it likely would never have written the report in its current form. The citizens of Pennsylvania need to know the report is unreliable and does not support the grand jury's recommendations. This section identifies numerous factual and legal errors in the report and discusses DEP's responses to the recommendations.

1. The Report Relies Upon Hearsay and Anecdotes

The report asserts that its findings are based on evidence meeting the legal standard of "a preponderance of the evidence," and, in some instances, the standard of "clear and convincing evidence." The evidence cited, however, consists of untested anecdotal accounts from a limited group of witnesses. However, even these accounts cannot and do not support the report's broad sweeping statements about legally complex and nuanced scientific issues. There are no dates, places, or times identified, no references to sampling or testing data, no corroborating testimony from medical professionals, no evidence of chemical disclosure requests denied to medical professionals, and no evidence that the complaints recounted to the grand jury were provided to

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DEP staff for resolution. The timing of events, which is critical to substantiating any of the claims, is obscured such that events that may have occurred fifteen years ago seem to have occurred yesterday. Some examples that exemplify the unreliability of the information in the report are:

a. Vibrations

On pages 3 and 30, the report states that vibrations from hydraulic fracturing were so intense that "worms were forced up out of the ground" or that "worms would crawl out from the ground" into people's yards and basements. There is no testimony or other evidence verifying this statement – no photos, no dates, times, nor locations. There is no evidentiary support from biologists or engineers addressing whether such incidents are a cause for concern or associated with pollution or indicative of some type of environmental harm. Since 2011, DEP staff have been on more than 250,000 site inspections, including inspections during hydraulic fracturing, and have never witnessed this phenomenon nor heard anything about this sort of occurrence.

b. Undocumented Health Effects

The report contains accounts of rashes and other concerning health problems that witnesses believed were connected with living in close proximity to unconventional gas well sites. These stories are distressing and serious, but unsubstantiated by names, dates, times, places, air or water sample results, medical tests, or any testimony of medical professionals. While the report states that the evidence was clear and convincing, there is no documentation of these occurrences nor any evidence to associate these health effects with unconventional gas development. DEP further notes that the report does not include medical testimony regarding the reported health problems. DEP is certainly concerned with the potential health impacts of unconventional drilling, but this report does not contribute to a scientific or medical understanding of whether there was, is, or possibly could be an association between unconventional gas development and observed health problems.

c. Collaboration Between Department of Health and Department of Environmental Protection

Another concerning mischaracterization in the report, at pages 77-78, relates to the coordination and collaboration of the PA Department of Health ("DOH") and DEP regarding public health complaints. The descriptions of DEP and DOH interactions are plainly incorrect. DEP and DOH in fact closely collaborated on how best to gather public health information and agreed upon the associated operational policies put in place in 2018. In particular, the report was critical of Scott Perry, the Deputy Secretary of the Oil and Gas Management Program, for "opposing requests" and refusing to make changes to DEP's inspection procedures to collect health-related information for DOH. The report does not tell the whole story, and had the OAG asked, DEP would have provided the documentation of the agencies' informal 2018 agreement, which is attached in **Exhibit B**.

d. Public Notifications

On page 60, in the "Failure to notify" section of the report, unidentified representatives of DEP are cited for general and non-specific incidents of failing to notify landowners of pollution incidents that could impact them. No specific instances or details are provided. DEP Deputy Secretary Perry is the only witness identified by name, and is quoted under oath describing DEP's practice, which is to give notice to landowners who could be affected. It is simply not true that the DEP policy is not to conduct case-specific investigations and notify or to require notification to potentially impacted landowners.

e. Impoundments

The discussion of impoundments on pages 50-51 of the report implies that no permit was required for centralized impoundments which held flowback or produced waters. That is incorrect. Permits for centralized impoundments were required starting in 2008 under the authority of the

Dam Safety and Encroachments Act. DEP later decided to eliminate the permit and instead require these facilities to be properly closed or permitted under DEP's residual waste regulations in the Chapter 78a rulemaking, at 25 Pa. Code § 78a.59c. The new Chapter 78a regulations for impoundments provide a higher level of environmental protection than the prior centralized impoundment requirements. These new impoundment rules have been challenged by industry before the Commonwealth Court and DEP continues to defend and protect the new standards against the industry attack.

f. Photos

There are numerous photos in the report and none of them have any identifying information, prompting many questions. Who took the photos? Where were the photos taken? When were the photos taken? Have the photos been altered electronically? Are the photos true and accurate representations of what specifically identified witnesses (testifying under oath) observed in Pennsylvania? For the civil investigations that DEP staff routinely undertake, simple protocols are in place and routinely followed regarding photographic evidence documentation, to ensure reliability if used in actions to enforce Pennsylvania's environmental laws. DEP and the public should expect no less from the OAG when undertaking a criminal investigation.

These examples of false or incomplete information in the report are particularly troubling because it would have been easy for the OAG to obtain current information about DEP's regulatory program and about the performances of both DEP and the industry. As discussed above, much of this information is publicly available, consistent with Governor Wolf's overarching goal of full transparency for all state government activities. There is no reference in the report to the voluminous information on DEP's webpage regarding oversight of the industry, including links to applicable law, well development data, DEP's enforcement activities, and the Oil & Gas Program's Annual Reports. It appears that none of the objective and publicly available data and information

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was shared with the grand jury. Moreover, the lack of supporting, verified, and contextual information, otherwise required in court proceedings, makes it impossible to respond to the allegations in a meaningful way.

2. The Report Is Legally Erroneous, Which Compromises its Conclusions Apart from the factual inaccuracies in the report, three important legal errors re-occur throughout the report and prevent readers from reaching a clear understanding of DEP's assigned responsibilities for oversight of unconventional gas development. Two of these issues are discussed above but bear a brief mention here. First, there is the lack of information about what each statute and regulation requires. The absence of that information leaves the readers of the report to guess at the legal framework and to assume that DEP has ignored the law when something unfavorable occurs. The second error is ignoring the constraints on DEP as a regulatory agency to function within the authority given to it by the General Assembly through statute. Several requirements of the regulatory program which the grand jury criticizes, such as setbacks for wells, are established by statute and can be changed only through new legislative action by the General Assembly.

Finally, the report fails to acknowledge the roles of other agencies and commissions in regulating the unconventional gas industry. While DEP has one of the larger roles in regulating the industry, other agencies and commissions also have responsibilities. Unconventional gas development in Pennsylvania is conducted with oversight by numerous Pennsylvania agencies and commissions, including the Department of Conservation and Natural Resources, Department of Health, PA Emergency Management Agency, PA Public Utility Commission, PA Fish and Boat Commission, and PA Game Commission and municipalities. In addition, the Federal Energy Regulatory Commission and other federal agencies regulate the safety of interstate natural gas

pipelines. Each agency, commission, and municipality has a distinct set of responsibilities regarding the unconventional gas well development.

Together, these errors create a confusing picture of exactly what DEP is charged with doing by statute, what it has the authority to do through the rulemaking process, what it has the ability to do through policies and permits, and what it is prohibited from doing because the General Assembly has established the basic boundaries of the law (such as how close a well site can be to a building) or given it to another agency (such as the Public Utility Commission, designated as the authority to regulate the safety of intrastate gas pipelines). These errors set the stage for the grand jury's recommendations.

B. The Grand Jury's Recommendations Miss the Mark As to DEP

DEP has carefully evaluated the recommendations in the Report. The recommendations are generally directed to the industry, DEP, DOH, and the General Assembly, and it is unclear to which entity each recommendation is specifically directed. DEP is responding to recommendations one, two, three, four, five, seven, and eight, but not recommendation six, which appears to be directed at DOH.

The fact that the grand jury was not provided with clear or accurate information about the regulatory requirements for the unconventional gas industry is evident from the recommendations which DEP reviewed. Several of the recommendations make the case for a change in statutes, many of which DEP might support, but is a task beyond the authority of the agency. Several other recommendations are based on a mischaracterization of existing law, and when the existing law is examined, it is clear that it already provides what the grand jury now recommends. Other recommendations urge policy positions that are unwise.

1. Recommendation One: Expand the No-Drill Zones DEP's Response: Only the General Assembly Can Expand No-Drill Zones

Recommendation One addresses the established setbacks, or distances that an operator must maintain between an unconventional well and buildings, private water supplies and public water supplies. These setbacks were established by the General Assembly when it amended the 1984 Oil and Gas Act in 2012 and are set forth in Section 3215 of the statute. The setback provision specifically mandates that: 1) No unconventional well may be drilled within 500 feet of a building or private water well, and 2) No unconventional well may be drilled within 1000 feet of a public water supply well, surface water intake, reservoir or other water supply extraction point used by a water purveyor, without the consent of the building or water well owner. The grand jury proposes enlarging the setbacks because it believes that unconventional well development activities occur too close to where citizens live, attend school, and recreate.

Before examining the merits of the recommendation, it is important to remember that DEP has no authority to enact or modify a statute. Only the General Assembly can modify or eliminate these statutory limitations, and this recommendation should be re-directed exclusively to the General Assembly. To the extent that the report blames DEP for these setbacks, the report is erroneous and misleading.

As to the merits of the recommendation, the grand jury proposes to create a setback of 2,500 feet (from what, is not identified) and a 5,000-foot setback from schools. The proposed setbacks are not supported with any information that establishes that these particular distances afford an appropriate level of protection and appear to have been chosen arbitrarily. Any proposal for new setbacks should include a scientific or technical rationale for the distances chosen.

DEP also notes that local governments have the authority under the Municipalities Planning Code to zone areas within their boundaries where natural gas facilities can and cannot be located and can play a role in the siting of natural gas facilities.

2. Recommendation Two: Stop the Chemical Cover-up DEP's Response: There is No Chemical Cover-Up; Operators are Required to Provide All Chemical Information to DEP and Maintain That Information Onsite

Recommendation Two is based on the premise that the law does not require all chemicals used in the development of unconventional wells to be disclosed. This premise is wrong. An unconventional well operator is required by Section 3222 of the 2012 Oil and Gas Act to disclose to DEP all chemicals, and all amounts of those chemicals, used to hydraulically fracture a well. Under Section 3222.1 of the statute, unconventional operators must also complete a chemical disclosure registry of that same information and post it on the publicly available website FracFocus. Separately, an operator is required by both state and federal law to maintain onsite Safety Data Sheets which identify all chemicals and their amounts used and located at the well site. All information regarding fracking fluids used in Pennsylvania is available to the agency.

The one limitation on public disclosure of these chemicals pertains to the operator's ability under both the 2012 Oil and Gas Act and the Pennsylvania Right to Know Law to designate information as a trade secret. If an operator claims that part of the chemical information is a trade secret and requests DEP to treat it as confidential, DEP must treat it as confidential. Any recommendation to eliminate the trade secret provision must be re-directed exclusively to the General Assembly.

Moreover, contrary to the allegations in the report, DEP regulations related to disclosure and use of chemicals are not lax. The report alleges that there are hazardous chemicals used in drilling a well, that water contamination occurs most frequently during drilling when water supplies are most at risk, and that this activity is largely unregulated. This is all incorrect. The 2011 well-construction rulemaking at 25 Pa. Code Chapter 78a, Subchapter D, was specifically aimed at protecting groundwater and preventing gas migration and set standards of performance for how a well is to be drilled and hydraulically fractured. The regulations prohibit the use of chemicals in well drilling in the shallower depths where the drilling could come into contact with fresh groundwater and prescribe the specifications that must be met related to casing and cementing of wells. DEP's regulations concerning disclosure and use of chemicals are protective of public health and the environment.

3. Recommendation Three: Regulate All Pipelines DEP's Response: DEP Already Regulates All Pipelines for Environmental Impacts; Only the General Assembly Can Expand the PUC's Oversight of the Safety of Gas Transportation Lines to Include Gathering Lines

In Recommendation Three, the grand jury suggests that gas pipelines are not adequately regulated and that the safety of gathering lines, in particular, should receive greater oversight. Two facts need to be clarified here. The first fact is that DEP comprehensively regulates the environmental impacts of all pipelines in Pennsylvania, including gathering lines, the smaller pipelines which carry natural gas from a well to a transmission pipeline. Construction of all these pipelines requires an erosion and sediment control permit under the Clean Streams Law and 25 Pa. Code Ch. 102 regulations. In fact, Pennsylvania is at the forefront of state and federal regulation of environmental impacts from all pipelines. A similar permit does not exist in many other states. As discussed above in Part II, this permit requirement was established by DEP in the wake of the federal government's 2005 exemptions for oil and gas activities from the federal Clean Water Act's NPDES permit requirements.

In Pennsylvania, the environmental impacts of construction and operation at all natural gas pipelines including gathering lines are also regulated by permits for hydrostatic testing, wetland

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and stream crossings, air emissions, as well as the cleanup of spills and releases, under the Oil and Gas Act, Clean Streams Law, Dam Safety and Encroachments Act, Air Pollution Control Act, Solid Waste Management Act, and the associated regulations. For example, 25 Pa. Code § 78a.68, imposes specific requirements for gathering pipelines.

The second fact is that DEP has no responsibility for regulatory authority regarding the *safety* of gas pipelines. By the decision of the General Assembly, the responsibility to address the safety of Pennsylvania's intrastate natural gas pipelines largely falls to the Pennsylvania Public Utility Commission. Responsibility for the safety of the large interstate natural gas pipelines lies with the Federal Energy Regulatory Commission ("FERC"), the Pipeline and Hazardous Materials Safety Administration ("PHMSA"), or one of the other federal agencies with jurisdiction over the transportation of natural gas.

DEP agrees that the oversight of pipeline safety and the approval process for what can be transported in pipelines and where they may be located could be improved and clarified and that it would be useful for the General Assembly to expand the PUC's oversight authority on safety issues to include gathering lines.

4. Recommendation Four: Add Up the Air Pollution Sources DEP's Response: Air Emissions from Sources Which Are Not Under Common Control Cannot Be Aggregated; DEP's Air Requirements Are Among the Most Stringent in the Nation

In the Fourth Recommendation, the grand jury expresses concerns with what it perceives as uncontrolled air emissions from the natural gas industry, particularly from small equipment such as pigging stations (devices for cleaning pipes which convey natural gas). Concerned that these small devices may escape regulation under Pennsylvania's Air Pollution Control Act, because of their size, the grand jury recommends that DEP alter its regulatory requirements by not treating those small devices individually, and instead treat a group of them situated in some close proximity

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as a single facility and require them to comply with stringent emission limits. While this approach may have some facial appeal, it is unworkable: one party cannot be held responsible for controlling emissions when it has no control over the source of the emissions. Put another way, DEP cannot impose liability or duties on one person because of the emissions of another person, who the first person cannot control. Moreover, the law does not support this approach. Each pigging location is an "air contamination source" as defined in the Air Pollution Control Act. A "facility" is a collection of sources that are "on contiguous or adjacent properties" and are under "common control," that are regulated as a unit. 25 Pa. Code 121.1. Absent common control, regulating multiple air contamination sources as a single facility would not be lawful.

That being said, it appears that DEP's goals with regard to the control of emissions from the natural gas industry align with those of the grand jury. Following the early years of unconventional gas development, DEP's goal has been to comprehensively regulate all air emission sources associated with the industry, and it is working aggressively toward that goal. Since unconventional well development began in Pennsylvania DEP has updated and revised its regulatory and permitting requirements for the industry to reflect its understanding of the air quality impacts of the industry. In 2013, DEP t established regulatory requirements for air emission sources at unconventional well sites, including leak detection and repair, emission controls, recordkeeping and reporting requirements for sources that had previously been unconditionally exempt from emission controls under the air quality regulations. In 2018, DEP revised those requirements, in part, to update the leak detection and repair requirements. Also, in 2018, DEP revised one existing General Permit, GP-5, and created a new General Permit, GP-5a, for the unconventional gas industry so that the General Permits address all types of natural gas facilities and require the use of best available technology to control emissions from each source. GP-5 applies to larger facilities such as mid-stream gas processing, and gas transmission facilities,

and any pigging devices and other equipment associated with those facilities that cause emissions. GP-5a, on the other hand, regulates air emissions from well site operations and remote pigging operations, i.e., those not associated with a larger facility. These permits are the first of their kind in the U.S. and are innovative in controlling air emissions which have often escaped control in the past. Large facilities may also be regulated through individual case-by-case permitting, under 25 Pa. Code Chapter 127. Well sites which have emissions below the threshold in GP-5a are still required to comply with the regulatory requirements, which include emission controls, leak detection and repair, recordkeeping and reporting.

Although DEP has made important strides in regulating air emissions it continues to assess the overall effectiveness of the air quality regulatory program to determine how it can improve the program. Further refinements depend in significant part on a better understanding of the impacts of the various controlled emissions from the gas industry on ambient air quality. To this end, DEP is gathering information through a variety of data collection and air monitoring activities. Since 2012, in accordance with the Oil and Gas Act, and 25 Pa. Code Ch. 135, all unconventional well operators must report air emission data on a quarterly basis to DEP. DEP operates the Commonwealth of Pennsylvania Air Monitoring Network, a Pennsylvania statewide ambient air monitoring network. DEP is conducting short-term and long-term studies of a suite of constituents from oil and gas operations, including benzene emissions, as well as a two-phase study of methane emissions assisted by a grant from the U.S. Environmental Protection Agency ("EPA").

DEP has even used its enforcement authority to obtain additional data about the impact of air emissions from the unconventional industry. In 2018, DEP and EPA entered into a landmark settlement of numerous violations related to pigging emissions at several MarkWest Liberty Midstream & Resources, LLC sites. In the Consent Decree, DEP and EPA waived a portion of their claims for civil penalties in exchange for MarkWest's undertaking a "Supplemental Environmental Project" to study air quality in the vicinity of its Harmon Creek Station gas processing plant. Harmon Creek Station is located in Smith Township, Washington County where many different types of natural gas facilities are concentrated, a prime location for evaluating the ambient impacts of natural gas emissions. The design and details of this multi-year study were reviewed by DEP and EPA experts and will employ state of the art monitoring equipment, which will be given to DEP at the end of the study for its continued use. This unique study, in combination with several other ongoing and planned research and data projects will advance DEP's understanding of the cumulative ambient air impacts of natural gas development in Pennsylvania and facilitate the development of additional measures to address natural gas impacts and protect the citizens of Pennsylvania.

5. Recommendation Five: Transport the Toxic Waste More Safely DEP's Response: Unconventional Well Wastes Must Be Transported in Compliance with the Residual Waste Regulations Which Provide for Safe Transportation

Recommendation Five implies that the transportation of unconventional gas related waste and wastewater, specifically drill cuttings and flowback and produced waters, is not safe because the vehicles are marked as carrying "residual waste" and not as "hazardous" or as "unconventional oil and gas waste." The discussion contains factual mistakes and misstates the existing law and existing permitting requirements related to management and transportation of wastes generated in unconventional gas drilling. This waste is exempt by definition from the federal hazardous waste requirements under the Resource Conservation and Recovery Act and the corresponding state hazardous waste requirements under the Pennsylvania Solid Waste Management Act. Under Pennsylvania's regulatory framework, this waste constitutes residual waste. Contrary to what the report suggests, the classification of waste as residual waste does not mean that the waste is handled carelessly or could be disposed of at a municipal waste landfill. In fact, Pennsylvania's

residual waste regulations are among the most robust and protective non-hazardous waste management regulations in the nation. The residual waste regulations, among other things, require specified transportation signage and include provisions related to the special handling and disposal of radioactive waste. In short, waste transported in compliance with Pennsylvania's residual waste regulations is being transported safely.

Recommendation Five also references "an elaborate shell game" whereby operators move waste fluids from one well to another to reuse the fluids in fracturing a new well. While it is true that operators do move waste fluids from one well to another for reuse, there is no shell game involved. The 2010 TDS rulemaking (mentioned above) requires operators to develop a plan for maximizing the recycling of wastewater to fracture other wells. In fact, recycling wastewater is one of the solutions to disposal issues and recycling minimizes freshwater withdrawals thereby protecting surface water and groundwater sources. Significantly, the 2016 Surface Activities Rulemaking imposes additional and more stringent requirements related to storage, transportation, use, and disposal of waste from unconventional well development, as well as new requirements related to preventing and responding to spills and releases. These regulations fully regulate management of drill cuttings and unconventional gas wastewater. As a result, virtually all unconventional well wastewater is now recycled in the next hydraulic fracturing operation or taken to disposal wells out of state.

DEP notes that portions of this section of the rulemaking are being challenged by the Marcellus Shale Coalition in Commonwealth Court.

6. Recommendation Seven: End the Revolving Door DEP's Response: There Is No Revolving Door; Dedicated DEP Employees Developed and Implemented This Comprehensive Regulatory Program

Recommendation Seven suggests that DEP has not properly managed the employees who have worked in the Oil & Gas Program and recommends a legislative response. Recommendation Seven suggests there is "a revolving door" whereby DEP employees who are trained to work in the Oil & Gas Program, take advantage of their position to favor the industry in some way, thereby paving their way into lucrative employment with the industry. To address this, the grand jury suggests enactment of legislation prohibiting former employees from working in the industry for a period of time after leaving DEP.

Before examining the merits of the recommendation, it is important to remember that DEP has no authority to enact or modify a statute. Only the General Assembly can legislate. This recommendation must be re-directed exclusively to the General Assembly.

As to the merits, there is no evidence of any such revolving door at DEP, nor is the proposed legislation supported by any information that establishes that it will have the effect that the grand jury is seeking. With regard to all individuals across the agency who have left the Commonwealth's employment, DEP has responsibly enforced the Pennsylvania Public Official and Employee Ethics Act, including Section 1103(g), which prohibits a former public official or public employee from representing a person, with promised or actual compensation, on any matter before DEP for one year after that official or employee leaves DEP.

What all Pennsylvanians should know about DEP's employees is that the Oil & Gas Program has been developed and implemented largely by a handful of dedicated individuals, most of whom have worked with the agency since the arrival of the industry in Pennsylvania and are career employees who choose to remain in public service because they believe in the mission of the agency. Together they have fought battle after battle, before the General Assembly, in the regulatory review process, before the courts, and with the industry to craft and implement an effective regulatory program that protects the environment and the public health and safety. Those individuals should be recognized for their work and not indirectly denigrated by this investigation.

7. Recommendation Eight: Use the Criminal Laws

DEP's Response: DEP Has Consistently and Appropriately Referred Criminal Matters to the OAG for Many Years; the Referral Process Is Not Broken and Does Not Need to Be Fixed

In Recommendation Eight, the grand jury proposes a significant change to a long-standing division of authority between the Governor and the Attorney General. Since 1980, the Commonwealth Attorneys Act has defined the powers and duties of the Governor and the OAG and gives the OAG jurisdiction to prosecute criminal charges referred by a Commonwealth agency as part of its duty to enforce statutes or by a county District Attorney. The grand jury now recommends that the OAG be given *concurrent* jurisdiction to investigate and prosecute matters involving environmental violations without the required referral from a Commonwealth agency or District Attorney. DEP believes that recommendation is unwise, and notes, again, that only the General Assembly can legislate.

The limitation on the OAG's jurisdiction to prosecute a matter involving the responsibilities of a Commonwealth agency reflects the General Assembly's understanding that a Commonwealth agency implementing a regulatory statute is best suited to decide when to seek a criminal prosecution for a violation of that statute. Leaving this decision to the regulatory agency avoids selective enforcement, which could occur when a prosecuting agency lacks sufficient experience with a regulatory program and a complex body of law to make prudent decisions to prosecute. Leaving the decision to the regulatory agency also avoids the risk of inconsistent interpretations of substantive law, which can arise when two agencies have concurrent jurisdiction.

DEP believes that criminal prosecution plays an important role in implementing Pennsylvania's environmental statutes. However, as a government agency, DEP must use, and does use, appropriate discretion and does not misuse the legal system by referring matters for criminal prosecution where facts and circumstances do not warrant it. To do otherwise would constitute an abuse of power.

Throughout several Gubernatorial administrations and DEP Secretaries, DEP has approached the criminal referral process consistently. Both the evaluation process and the referral procedures have remained the same, and the number of referrals made by DEP has varied little from year to year and from administration to administration. The referrals have involved violations of a broad array of environmental statutes, including the Solid Waste Management Act, Clean Streams Law, Oil and Gas Act, Surface Mining Conservation and Reclamation Act, Bituminous Mine Subsidence and Land Conservation Act, Bituminous Coal Mine Safety Act, Air Pollution Control Act, Radiation Protection Act, Safe Drinking Water Act, Waste Tire Recycling Act, Waste Transportation Safety Act, and Water and Wastewater Systems Operators' Certification Act. Included in these referrals are several matters involving the development/operation of unconventional wells and the construction/operation of natural gas pipelines.

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DEP has exercised judgment and discretion in all its referral decisions. DEP regards the decision to refer a matter as an important one for both the public and the subject of the referral. DEP has always made decisions to refer a matter on a case by case basis and with the belief that a criminal prosecution is an extraordinary remedy which should be limited to cases where there is a strong indication of serious misconduct. DEP never refers a matter without conducting its own investigation and determining there is a solid basis in fact and law for a referral. As to Pennsylvania environmental law, DEP is undeniably the expert and is in the best position to decide if the law and the facts will support a prosecution.

The OAG can accept referrals of environmental matters from sixty-seven county District Attorneys' Offices, all Executive branch agencies, the PA Fish and Boat Commission and PA Game Commission, as well as referrals from citizens and environmental groups across the Commonwealth through referrals from District Attorneys Of all the parties authorized to refer criminal environmental matters to the OAG, DEP has referred the most environmental matters and likely the most materially significant environmental matters. Because DEP best understands how to use its statutes in different legal contexts, DEP can be most successful in identifying environmental cases for criminal prosecution and the OAG can be most successful in accepting the DEP referrals.

DEP's extensive experience in deciding when to refer a matter to the OAG, coupled with the General Assembly's considered decision to give the OAG jurisdiction to prosecute a matter only upon a referral from an agency should not be changed based on undocumented, unsubstantiated and unchallenged accusations in a grand jury report. This is particularly true where a grand jury report reflects substantial misunderstanding of the underlying law and of what constitutes probative evidence. The criminal referral process has satisfied the legislature, DEP, and the numerous prior gubernatorial administrations and Attorneys General. DEP administers all statutes within its authority evenhandedly, as the public should expect. The referral system is not broken and should not be changed.

V. CONCLUSION

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The grand jury report fails as an exposé of a government agency ignoring its statutory duties and constitutional obligations. In this regard, it is important to remember that the OAG did not find any wrongdoing on the part of DEP. The report also fails as a meaningful tool for improving the regulation of the unconventional gas industry, because the report is not at all informed by the applicable law or facts. Had the jurors been provided with accurate information about the existing laws, the scientific and policy underpinnings of the regulations, and the commitment of DEP staff to create and implement a comprehensive and effective regulatory program that protects the citizens and environmental resources from the impacts of natural gas development in Pennsylvania, the report would likely never have been written the way it was.

Although the grand jury believed it was advancing the public good in preparing and planning to publicize its report, it actually does the public a disservice. The inaccuracies in the report provide Pennsylvania's citizens with a false picture of DEP and encourage them to believe their government is incompetent and/or places the economic well-being of various corporations above their health and well-being and that of the Commonwealth's public natural resources. Perhaps Kurt Klapkowski put it best when he appeared before the grand jury in January 2020, after the grand jury had already drafted its report through the Office of Attorney General. Mr. Klapkowski testified that in 26 years of working for DEP, through six Governors and 9 Secretaries, he has never worked with anyone at the DEP who did not believe in the Department's mission. To carelessly erode the citizens' trust and confidence in their government threatens the foundation of our democratic society and should not be tolerated. Pennsylvania's citizens deserve and have been provided regulation based on sound facts, science and public policy. They are entitled to know this.

Respectfully submitted,

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP

Seete A. Alfan / Frs By:

GAETAN J. ALFANO Pa. Attorney ID No. 32971 DOUGLAS K. ROSENBLUM Pa. Attorney ID No. 90989 1818 Market Street, Suite 3402 Philadelphia, PA 19103 (215) 320-6200 gja@pietragallo.com dkr@pietragallo.com

Dated: May 7, 2020

<u>WG Ex. 70</u>

EXHIBIT A

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STATUTES, REGULATIONS, TECHNICAL GUIDANCE DOCUMENTS, AND PERMITTING PROGRAMS BY WHICH PENNSYLVANIA REGULATES THE UNCONVENTIONAL NATURAL GAS INDUSTRY

The Department of Environmental Protection regulates unconventional well development activities under the following Pennsylvania oil and gas laws and environmental protection laws and their implementing regulations as well as a framework of technical guidance documents and applicable permitting programs.

Statutes

2012 Oil and Gas Act, 58 Pa.C.S. §§ 3201-3274 Air Pollution Control Act, 35 P.S. §§ 4001–4005 Clean Air Act, 42 U.S.C. § 7401 et seq. Coal and Gas Resource Coordination Law, 58 P.S. §§ 501-518 Dam Safety and Encroachments Act, 32 P.S. §§ 693.1-693.27 Delaware River Basin Compact, 32 P.S. §§ 815.1010815.106 Environmental Laboratory Accreditation Act, 27 P.S. §§ 4101 Land Recycling and Environmental Remediation Standards Act, 35 P.S. §§ 6026.101-6026-901 Noncoal Surface Mining Conservation and Reclamation Act, 52 P.S. §§ 3301-3326 Oil and Gas Conservation Law, 58 P.S. §§ 401-419 Pennsylvania Grade Crude Development Act, 58 P.S. §§ 1201-1208 Pennsylvania Public Official and Employee Ethics Act, 65 Pa.C.S. §§ 1101-1113 Pennsylvania Safe Drinking Water Act, 35 P.S. §§ 721.1-721.17 Radiation Protection Act, 35 P.S. §§ 7110.101-7110.703 Right-to-Know Law, 65 P.S. §§ 67.101-67.3104 Solid Waste Management Act, 35 P.S. §§ 6018.101-6018.1003 Susquehanna River Basin Compact, 32 P.S. §§ 820.1-820.8 The act of February 2, 2012, P.L. 67, No. 9, 35 P.S. § 7321 The act of July 10, 2014, P.L. 1053, No. 126, 72 P.S. § 1741.1-E The act of July 13, 2016, P.L. 664, No. 85, 72 P.S. § 1690-E The act of November 7, 2019, P.L. 634, No. 85, 58 P.S. § 34.2 The Administrative Code of 1929, 71 P.S. §§ 232, 510-20 The Clean Streams Law, 35 P.S. §§ 692.1-691.1001 The Commonwealth Attorneys Act, 71 P.S. §§ 732.101-732.506 Commonwealth Document Law, 45 P.S. §§ 1102-1208 Water Resources Planning Act, 27 Pa.C.S. 3101-3136 Unconventional Well Report Act, 58 P.S. §§ 1001-1003

Regulations

25 Pa. Code Chapter 77 (relating to Non-coal Mining)

25 Pa. Code Chapter 78a (relating to Unconventional Wells)

25 Pa. Code Chapter 79 (relating to Oil and Gas Conservation)

25 Pa. Code Chapter 91 (relating to Water Resources-General Provisions)

25 Pa. Code Chapter 95 (relating to Wastewater Treatment Requirements)

25 Pa. Code Chapter 102 (relating to Erosion and Sediment Control)

25 Pa. Code Chapter 105 (relating to Dam Safety and Waterway Management)

25 Pa. Code Chapter 109 (relating to Safe Drinking Water)

- 25 Pa. Code Chapter 110 (relating to Water Resource Planning)
- 25 Pa. Code Chapter 121 (relating to Air Resources–General Provisions)
- 25 Pa. Code Chapter 127 (relating Air Resources–Construction, Modifications, Reactivation and Operation of Sources)
- 25 Pa. Code Chapter 135 (relating to Air Resources–Reporting of Sources)
- 25 Pa. Code Chapter 129 (relating to Standards for Sources)
- 25 Pa. Code Chapter 250 (relating to Administration of Land Recycling Program)
- 25 Pa. Code Chapter 287 (relating to Residual Waste Management-General Provisions)
- 25 Pa. Code Chapter 299 (relating to Storage and Transportation of Residual Waste)

Technical Guidance Documents

- Addressing Spills and Releases at Oil & Gas Well Sites or Access Roads, Document No. 800-5000-001
- Standards and Guidelines for Identifying, Tracking, and Resolving Oil and Gas Violations, Document No. 820-4000-001
- Stormwater Management at Oil and Gas Well Sites, Document No. 800-2100-008
- Guidelines for Implementing Area of Review (AOR) Regulatory Requirement for Unconventional Wells, Document No. 800-0810-001
- Policy for the Replacement of Private Water Supplies Impacted by Unconventional Operations, Document No. 800-0810-002
- Policy for Implementing the Department of Environmental Protection Permit Review Process and Permit Decision Guarantee, Document No. 021-2100-001
- Policy for Pennsylvania Natural Diversity Inventory (PNDI) Coordination During Permit Review and Evaluation, Document No. 021-0200-001

Permit and Authorization Packages

- *Affidavit Request for Unconventional Well Permit Renewal*, Document No. 8000-PM-OOGM0109B
- *Application and Instructions for Transfer of Erosion and Sediment Ctrl GP ESCGP Approval*, Document No. 8000-PM-OOGM0012
- Application for Coal Pillar Permit, Document No. 8000-PM-OOGM0007
- *Application for a Permit to Drill or Alter an Oil or Gas Well*, Document No. 8000-PM-OOGM0001
- *Application for Transfer of Well Permit or Registration*, Document No., Document No. 5500-PM-OG0010
- Authorization of Coverage Under the Erosion and Sediment Control General Permit (ESCGP-3), Document No. 8000-PM-OOGM0006
- *Co-Permittee Liability Release Form*, Document No. 8000-PM-OOGM0160
- Conditional Chain Pillar and Well Pillar Plan in Association with Longwall Mine, Document No. 8000-PM-OOGM0012 & 112A
- Coordination of a Well Location with Public Resources (Unconventional Operations Only), Document No. 8000-PM-OOGM0076U
- Environmental Good Samaritan Project Proposal for Abandoned Well Plugging, Document No. 8000-PM-OOGM0111
- Post-Plugging Well Site Restoration Report (Unconventional Operations Only), Document No. 8000-PM-OOGM0075U

- *Proposed Alternative Method of Casing, Plugging, Venting, or Equipping*, Document No. 8000-PM-OOGM0024
- Request for Approval of Waste Management Practices Unconventional Operations Only, Document No. 8000-PM-OOGM0071U
- Water Management Plan Approval Renewal Request Unconventional Operations Only, Document No. 8000-PM-OOGM0087U
- *Well Location Plat*, Document No. 8000-PM-OOGM0002
- *Well Pillar Plan*, Document No. 8000-PM-OOGM0007A
- Well Site Restoration Report, Document No. 8000-PM-OOGM0075
- GP-05 AND GP-05A and Supporting Documents, Document No. 2700-PM-BAQ0269
- GP-05, Compliance Certification Forms, Document No. 2700-PM-BAQ0205
- *GP-05, Natural Gas Compression Stations, Processing Plants, and Transmission Stations*, Document No. 2700-PM-BAQ0267
- *GP-05A, Unconventional Natural Gas Well Site Operations and Remove Pigging Stations*, Document No. 2700-PM-BAQ0268
- Form U Request to Process or Dispose of Residual Waste, Document No. 2540-PM-BWM0395
- Form 26R Chemical Analysis of Residual Waste Annual Report by the Generator, Document No. 2540-PM-BWM0347
- Processing & Beneficial Use of Gas Well Wastewater from Hydraulic Extraction of Natural Gas, Document No. 2540-PM-WMGR123
- 05 GP-5 Utility Line Stream Crossings, Document No. 3150-PM-BWEW0505
- 07 GP-7 Minor Road Crossings, Document No. 3150-PM-BWEW0507
- 08 GP-8 Temporary Road Crossings, Document No. 3150-PM-BWEW0508
- 11 GP-11 Maintenance, Testing, Repair, Rehabilitation or Replacement of Water Obstructions and Encroachments, Document No. 3150-PM-BWEW0511

<u>WG Ex. 70</u>

EXHIBIT B

Note: Stephanie Hasanali, Anil Nair, Sharon Watkins and Farhad Ahmed were employees of the Pennsylvania Department of Health in 2018 and were involved in the discussions surrounding notification from DEP to DOH of oil and gas-related health complaints.

From: Ryder, John <jryder@pa.gov>

Sent: Wednesday, May 2, 2018 1:37 PM

To: Lobins, Craig <slobins@pa.gov>; Lichtinger, Joseph <jlichtinge@pa.gov>; Dudzic, Scott <sdudzic@pa.gov>; Neville, Richard <rneville@pa.gov>; Means, Jennifer <jenmeans@pa.gov>; O'Donnell, Michael <miodonnell@pa.gov>; Wharton, Stephanie <swharton@pa.gov>; Counahan, Daniel <dcounahan@pa.gov>; McDermott, David <davmcdermo@pa.gov>; Milcic, Kareen <kmilcic@pa.gov> Cc: Hasanali, Stephanie <c-shasanal@pa.gov>; Nair, Anil <annair@pa.gov>; Watkins, Sharon <shawatkins@pa.gov>; Ahmed, Farhad <fahmed@pa.gov>; Perry, Scott (DEP) <scperry@pa.gov>; Klapkowski, Kurt E <kklapkowsk@pa.gov>; Brokenshire, Stephen <sbrokenshi@pa.gov>; Wallace, Todd twallace@pa.gov

Subject: DEP Oil and Gas Complaint Investigations and Pennsylvania Department of Health Coordination **Importance:** High

All,

When DEP Oil & Gas staff are investigating a water supply complaint and encounter a complainant with human health concerns, our current practice (in accordance with the C&E Policy, Doc# 820-4000-001 and the Final Interim Water Supply Replacement TGD, Doc# 800-0810-001) is to provide that complainant / citizen with the appropriate Pennsylvania Department of Health (PA DOH) contact information so the complainant may contact that agency at their discretion. Oil & Gas staff have done a great job with this, and I ask that all staff continue this practice.

In addition, at the time that the Oil & Gas staff encounter a complainant with human health concerns, the Oil & Gas staff will now provide the following information about the complainant to both Stephanie Hasanali and Anil Nair with the PA DOH:

- Name
- Phone number
- Email
- Street address and county
- Initial date of complaint to DEP

This is a change from our past practice of first notifying PA DOH when O&G program staff make a positive determination (in accordance with the TGDs mentioned above).

PA DOH has indicated to us that Name, Phone number, and Email are the only fields absolutely needed. If staff encounter complainants without email address contact information, name and phone number will suffice. It is appropriate for Oil & Gas staff to let the complainant know they will be sharing this contact information with the PA DOH. It is important to note that any time an Oil and Gas employee encounters a complainant with health concerns during the course of a complaint investigation, the employee should forward that individuals contact information to PA DOH, not just when a water supply investigation is being conducted. Only complaints involving human health concerns should be forwarded to PA DOH. All other complaints received and investigated by the Department's Oil & Gas Program should be handled using current Department practices.

It is also important that Oil & Gas staff document that the complainants contact information has been provided to PA DOH. Please provide this information to Stephanie (c-shasanal@pa.gov) and Anil (annair@pa.gov) via e-mail (they are also both copied above) and be sure to CC the appropriate District Oil and Gas Manager as well as supervisor / manager. A copy of the email notification should be uploaded to CTS as part of the investigation documentation.

Please share this important message with the appropriate program field staff.

John

John Ryder | Bureau Director Department of Environmental Protection Bureau of District Oil and Gas Operations 208 West Third Street Suite 101 | Williamsport PA 17701 Phone: 570.327.0533 | Fax: 570.327.3420 www.dep.pa.gov

Response of the Pennsylvania Department of Health

<u>WG Ex. 70</u>

IN THE COURT OF COMMON PLEAS ALLEGHENY COUNTY, PENNSYLVANIA

IN RE:	: SUPREME COURT OF PENNSYLVANIA
	: 71 W.D. MISC. DKT. 2017
THE FORTY-THIRD STATEWIDE	:
	: ALLEGHENY COUNTY COURT OF COMMON
	: PLEAS CP-02-MD-0005947-2017
INVESTIGATING GRAND JURY	:
	:
	: NOTICE NO. 42

Response on behalf of the Pennsylvania Department of Health

The Pennsylvania Department of Health ("DOH") has reviewed Report 1 of the Forty-Third Statewide Investigating Grand Jury ("the Report" or "the Grand Jury Report") and respectfully submits this response and requests that it be attached to the Grand Jury Report.

I. <u>Introduction</u>

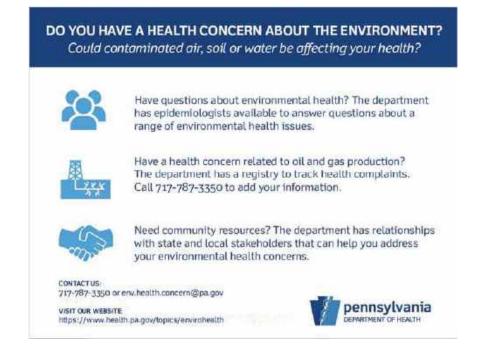
DOH respects the comprehensive work performed by the grand jury. DOH has studied the grand jury's report carefully and will continue to do so, and takes all of its observations and recommendations with the utmost seriousness. In that regard, DOH appreciates the observations that "things have improved under the current gubernatorial administration," and that "the Department deserves credit for the efforts it has made in recent years given its available funding."

The grand jury also recognizes the challenges that limited state resources present. This is made all the more challenging by the absence of any meaningful federal action, funding, studies or response to the many environmental and health questions raised by fracking. That said, DOH must always strive to do better in realizing its vision of "a healthy Pennsylvania for all."

As such, DOH welcomed the opportunity to engage in the grand jury process with the aim that the Report would be accurate and the Report's recommendations and observations would be a useful tool in examining and improving DOH's work related to fracking. To that end, when offered the opportunity by the Office of Attorney General, DOH provided written statements and exhibits to the grand jury. In addition, the Secretary of Health welcomed the opportunity to testify before the grand jury, testified extensively, and answered all of the questions asked her by the grand jury.

Unfortunately, the secret nature of the grand jury process has resulted in a Report that contains some factual errors and (in some instances) erroneous conclusions. Further, DOH has not been provided with the transcripts of testimony or the documents or other materials presented to the grand jury. These troubling times have underscored many things, including that transparency, objectivity, facts and science will always be among the critical pillars of effective public health. It is in that spirit that the following observations are provided. But, the ensuing comments are not intended in any way to detract from the important work performed by the grand jury here.

In the current administration DOH has listened and will continue to listen, with even greater intensity, to the concerns of Pennsylvanians who express health concerns related to fracking. As evidenced by the Report, fracking is a challenging and complex topic that requires a thoughtful, coordinated approach. DOH therefore would like to take this opportunity to once more encourage Pennsylvanians to contact DOH and report their health concerns related to fracking by telephone at 717-787-3350 or e-mail at <u>env.health.concern@pa.gov</u> :



This is not an empty invitation. DOH relies on these submissions to gather health data that is vital its work to study this topic and ensure an informed and effective approach.

To the degree that the Grand Jury Report suggests that DOH does not share the grand jury's concerns and is not invested in solutions, that is neither fair nor accurate. While DOH is constantly seeking ways in which to improve its response to fracking, DOH under the current administration has always been committed to understanding and responding to the potential health effects associated with fracking. As such, DOH would like to provide additional information about its programming and strategy, particularly as it relates to fracking.

II. Overview of DOH's Public Health Response to Fracking

A. Background

DOH is an agency comprised of medical professionals, policy experts, scientists, and staff who work to achieve DOH's mission to: "promote healthy behaviors, prevent injury and disease, and to assure the safe delivery of quality health care to all people in Pennsylvania." DOH is currently led by the Pennsylvania Secretary of Health, Dr. Rachel Levine. Dr. Levine first joined the Wolf administration in 2015 as Physician General. In July 2017, Governor Wolf named Dr. Levine the Acting Secretary of Health. She was confirmed as Secretary of Health in March 2018.

Of course, currently, DOH is deeply engaged in addressing one of its paramount responsibilities – to address acute public health emergencies. It is, therefore, coordinating Pennsylvania's comprehensive response to the COVID-19 pandemic, a public health emergency the like of which has not been experienced since the influenza pandemic of 1918. Additionally, DOH operates many ongoing programs related to a multitude of significant public health issues. Among these are programs addressing environmental health issues (including fracking), the opioid epidemic, HIV, quality care in health care facilities, school health, emergency preparedness, maternal and child health, obesity, sexual violence, and many more.

Funding for DOH programming comes from a combination of sources. Approximately one-third of DOH's budget comes from state government funding, which, by necessity, is allocated based on a consideration of a variety of competing needs. The remaining two-thirds of DOH's budget comes from the federal government through specific program grants. Unfortunately, there has not been a single grant from federal sources to address the health effects of fracking.

By contrast, there are federal grants provided to study health effects associated with other environmental concerns, such as "PFAS" (or "poly-fluoroalkyl substances" which are manufactured chemicals included in many household products). The Report highlights DOH's health work on PFAS in an effort to contrast that work to fracking. Specifically, the Report directs readers to compare DOH's fracking-related program to "the resources marshaled to study the spread and effects of a group of harmful substances known as PFAS." (Report at p. 99.) For

its PFAS-related program, however, DOH received funding through the Centers for Disease Control and Prevention ("CDC"), as well as the Association of State and Territorial Health Officials. With this funding, DOH was able to implement three PFAS-related studies – the testing of a response toolkit, an exospore assessment project, and a multisite health study. However, while DOH has federal funding available for its PFAS work, there is no federal funding for fracking, an absence of resources which necessarily impacts DOH's capabilities with regard to fracking.

Despite these and other resource constraints, since the beginning of Governor Wolf's Administration in January 2015, DOH sought to markedly change the prior administration's approach, and to bring a much greater focus to bear on both fracking and environmental health issues more generally.¹ And these efforts are ongoing. For example, at Dr. Levine's request, in 2019, the Administration granted DOH funding of over \$1 million per year for three years to study the health effects associated with fracking.

B. Environmental Health Program Development

Beginning in 2015, DOH brought in new staff to the Bureau of Epidemiology to reassess needs, including those related to environmental health. Since then, DOH has continued to build its staff and expertise to better address existing and emerging issues in environmental health, such as fracking, lead, and PFAS. Thus, DOH hired Dr. Sharon Watkins as its Director

¹ DOH notes that much of the discussion in the Report relates to conduct that occurred before January 2015 under the prior Administration,. The current DOH Administration is not able to fully comment on the circumstances surrounding that purported conduct. However, DOH does understand generally that, prior to 2015, DOH focused its epidemiology resources on disease investigations with an emphasis on pandemic flu, anthrax, emergency response, and food and water borne disease. While the Report makes some distinction between the prior Administration and the current Administration, it largely conflates time periods. For example, certain comments and opinions voiced by Karl Markiewicz from the Agency for Toxic Substances and Disease Registry ("ATSDR") and Dr. David Brown from the Southwest Pennsylvania Environmental Health Project ("SPEHP") may have related in part or in whole to activity prior to 2015. However, as DOH was not present for their testimony and has not had the opportunity to ask questions, DOH does not have sufficient information to fully respond to their observations.

of the Bureau of Epidemiology. Dr. Watkins is a nationally-recognized epidemiologist who previously served as the Chief of the Bureau of Epidemiology for the State of Florida, and who is currently the president of the Council of State and Territorial Epidemiologists. Dr. Watkins has a strong background in environmental health.

DOH hired Dr. Anil Nair as the Director of the Environmental Health Division of the Bureau of Epidemiology. A PhD-level consultant also has been retained by DOH to focus specifically on fracking. Moreover, DOH hired a full-time toxicologist with expertise in reviewing environmental testing samples and assessing the associated health risks.

Currently, the Environmental Health Division is comprised of five staff members and two contractors, as well as one intern and one annuitant. DOH has requested and received approval for funding in the 2019-2020 year for ten new positions dedicated to environmental health, including fracking. Eight of those positions are in the Bureau of Epidemiology and two are in the Bureau of Laboratories. DOH is currently recruiting for those positions.

C. <u>Development of the Fracking Questionnaire and Data Registry</u>

Starting in 2015, DOH developed a complaint questionnaire to gather and analyze information from individuals with health concerns related to fracking.² DOH then contracted with a PhD-level consultant to be the Department's point person on fracking. The consultant refined the questionnaire so that it would gather more useful and standardized information, and developed the data registry so that the information can be stored and analyzed. (See the questionnaire template at **Exhibit A**). DOH uses this information to improve its understanding of the causal links that may exist between fracking and specific health effects.

² DOH receives \$100,000 per year in state funding to develop and operate this registry. In 2019, the Administration budgeted a much larger amount, over \$1 million per year for the next three years, for DOH to work with an academic partner to conduct two comprehensive studies on health effects associated with fracking.

DOH routes all health complaints related to fracking to the Bureau of Epidemiology. Once routed to the Bureau of Epidemiology, staff members contact every person who reports a fracking-related health concern to gather additional data as well as to respond to the individual concern.³ DOH does not take a "wait and see" approach to fracking. Instead, DOH proactively seeks to gather the information by encouraging individuals impacted by fracking to participate and report their concerns. DOH's proactive approach has taken many forms. For example, DOH spoke directly with individuals within concerned communities about the data registry at public meetings. DOH also met with the Southwest Pennsylvania Environmental Health Project to seek their assistance in referring complaints to DOH for purposes of the data registry. DOH created flyers to publicize the data registry, and placed the flyers at each of DOH's six Bureau of Community Health district offices, and all 60 state health centers, as well as the district offices of the Department of Environmental Protection ("DEP"). (Flyer attached as **Exhibit B**). DOH publicized the data registry on its website and publicly invited individuals to contact DOH to report concerns by email, phone, fax or mail. (See Exhibit C; available at: https://www.health.pa.gov/topics/envirohealth/Pages/Contact-Environmental-Health.aspx). DOH set up regular meetings with DEP to facilitate coordination between the agencies and to receive health complaint referrals. The health complaint reporting information was also included on DEP's website, and the information was shared with the Agency for Toxic Substances and Disease Registry and environmental health physicians to whom DOH refers individuals. Additionally, DOH regularly conducts statistical analyses of the

³ These complaints do not go to a "black hole" as alleged in the Report. (Report at p. 71). That allegation appears to refer to policies under the prior Administration rather than the current Administration. Nonetheless, DOH is providing information about its current policies and practices.

public health data it collects, and publishes reports of that data on an anonymized basis. These reports are made available on DOH's website and provide the public with information on the reported health effects associated with fracking. This includes data on the number of complaints, location of the complaints and wells (by county), the environmental source of concern (such as water or air), health symptoms reported (such as cardiovascular or dermatological), and demographic and other information. (See **Exhibit D**; available at

https://www.health.pa.gov/topics/Documents/Environmental%20Health/Q32019_ONGP.pdf). Pennsylvania is one of the few states that maintains a data registry of fracking-related health concerns and reports that data publicly.

Despite these measures, the number of reports DOH received for the data registry was less than anticipated or desired. As of December 2019, DOH received 125 formal health complaints relating to 263 individuals. The Grand Jury Report acknowledges that DOH publicized its registry and encouraged participation through a variety of means (Report at p. 91), yet it suggests that the reason individuals did not report their concerns to DOH was because "the Department was not offering answers or solutions to their problems." (Report at p. 75).

That conclusion is not correct. As Secretary Levine explained in her testimony, DOH's process for collecting scientifically useful information for the registry necessarily depended on individuals providing information in response to a detailed survey. That information provides significant value to the public, as it is used by DOH to study the issue and to inform the public at large. However, individuals may have been deterred from participating in the survey because it did not provide an immediate tangible benefit to the person on the phone. Rather the information gleaned from the survey was meant to provide useful data for DOH to study and educate the public. Dr. Levine further explained that, in response to low participation

rates, DOH has since evolved its strategy, and will be conducting two comprehensive studies using health data maintained by an academic partner.

D. <u>Support and Referrals for Individuals</u>

In addition to gathering health information for purposes of analysis, DOH also directly responds to individuals who report health concerns. When DOH receives a complaint, a staff member of the Bureau of Epidemiology contacts the individual. The staff member gathers information about the complaint and obtains any environmental sampling results in that person's possession. DOH also seeks any available sampling results from DEP. DOH's toxicologist reviews those results to determine if any potential health risks are identified. DOH informs the complainant of the results, including the toxicologist's interpretation of the results related to health risks, and refers the individual to physicians with particular expertise in environmental health issues. Additionally, DOH provides educational resources through FAQs on fracking issues and the contact information to make a report related to Pennsylvania's drinking water. Finally, where needed, DOH will request that DEP do further sampling.

E. Other Public Information-Sharing, Research, and Education

DOH has also continued to engage in scholarship, education, and informationsharing on fracking. Like most government agencies, DOH requires that its employees seek approval before attending conferences or participating in speaking engagements. Such rules are in place to ensure that resources are used wisely and that employees do not violate the Commonwealth-wide ban on gifts to public employees (such as free admission to conferences, compensation for speaking engagements, or other items that could be considered gifts). It would be irresponsible not to have them. However, the rules apply across the board and are neither

specific to fracking, nor in any way designed or utilized to chill participation in fracking related programs.⁴

Furthermore, since 2016, DOH has been presenting fracking data at state and national conferences, and discussing fracking issues in connection with other state programs. For example, DOH staff attends the annual conference of the Council of State and Territorial Epidemiologists, including participating in roundtables and workshops related to fracking. From 2016 to 2018, DOH personnel attended the annual Shale in Public Health Conference hosted by the Pennsylvania League of Women Voters. In 2017 and 2018, DOH staff attended the Shale Network Conference at Penn State and, in 2018, participated in a fracking-related workshop by the National Academy of Science. These efforts help keep DOH up to date on the latest developments in public health related to fracking, and provide an opportunity for DOH attendees to educate others.

DOH staff also engage in research to advance the understanding of health effects associated with fracking. For example, in 2019, under Dr. Levine's direction, DOH and the State of Colorado published a study titled "A Systematic Review of the Epidemiologic Literature Assessing Health Outcomes in Populations Living near Oil and Natural Gas Operations: Study Quality and Future Recommendations."⁵ This piece surveyed the most in-depth peer-reviewed literature on health effects associated with fracking to date. Additionally, DOH is currently completing a report evaluating the occurrence of a rare form of cancer, Ewing's Sarcoma, in communities experiencing fracking issues.

⁴ The Grand Jury Report alleged that DOH "muzzles" its staff in relation to fracking, which was clearly a reference to the prior administration. (See Report at p. 70). Since the new administration, DOH has never muzzled its staff, but has engaged in the numerous efforts to educate itself and the public about ongoing fracking concerns, as detailed in the Response.

⁵ The paper can be found at: <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6616936/#</u>

In Spring 2019, DOH began to develop a new initiative for fracking-related research, which was approved by the Administration in November 2019. This initiative involves two studies based in southwestern Pennsylvania, where the most fracking activity occurs. The first study will focus on the potential acute effects of fracking (i.e. asthma and birth defects). The second study will focus on incidents of cancer in these areas. For both studies, instead of relying on data that DOH collects from individual complainants, DOH will work with an academic partner and with existing health system databases, including the Pennsylvania Cancer Registry and data from regional healthcare systems. DOH will use that data to analyze health trends in proximity to fracking sites. This initiative is budgeted at just over \$3 million for three years (approximately \$1 million per year). DOH has requested to receive this funding in its 2020-2021 budget.

The Grand Jury Report incorrectly claims that these upcoming studies "will attempt to gather and analyze already existing data from prior complaints. And because DOH effectively discouraged such complaints in the past, there may be little data to review." (Report at p. 9). To the contrary, these studies will not rely on the fracking-related health data that has been collected by DOH thus far. As detailed above, the studies will rely on robust existing healthcare system data, which is not limited to individuals who made complaints related to fracking. This misunderstanding causes the Report to erroneously imply that the studies will not be sufficiently useful.

To the contrary, these studies will accomplish many of the goals for DOH outlined in the Report. For example, the Report recommends that DOH "[s]end out the nurses and doctors to interview health care professionals. Advertise in affected areas. Collect sophisticated data and conduct sophisticated analysis." (Report at p. 10). The studies described

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above will accomplish those aims even more effectively by gathering medical data from health care professionals in a much more comprehensive manner, rather than through anecdotal interviews that may vary in accuracy or opinion. The studies will also allow DOH to conduct sophisticated analyses of detailed data that will be published and made available to the general public.

III. The Science of Health Effects Associated with Fracking

A fundamental criticism of DOH in the Report is that DOH is in a "state of denial" about the health effects associated with fracking and that it has taken a "wait and see" approach to the issue. (See Report at p. 2, 9). As explained above, that criticism is unfounded. DOH has proactively invited people to report health concerns related to fracking, collected scientifically-useful data, conducted research, collaborated with DEP, published data to inform the public, referred individuals to doctors expert in environmental health, made available other resources, and more. While DOH has improved its response to fracking over time, and will continue to do so, it is wrong to suggest that DOH is sitting idly by or, worse, purposefully ignoring evidence of the health effects associated with fracking. That suggestion is both untrue and damaging to the public interest.

The Report cites the following question posed by the grand jury to DOH:

Is it the DOH and administration's view that there is insufficient evidence proving that unconventional oil and gas operations, whether in the past or as they currently exist under the governing legal and regulatory scheme, harm public health?

In response, DOH explained that "the science in this area is developing, and it is fair to say that it has not been proven that fracking harms public health." That is true, and no amount of grand jury investigating will change the science. Importantly, however, what the Report omits is the remaining portion of DOH's response on this point. Immediately after this

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statement, DOH explained: "That said, the number of peer-reviewed epidemiological studies in

this area has increased in recent years, and studies have shown some association between

fracking and a limited number of health-related effects in select areas, though the strength and

the nature of the association still requires further research." DOH further explained that it had

conducted a detailed review of the existing studies, and provided a copy of that review to the

grand jury. (See "A Systematic Review of the Epidemiologic Literature Assessing Health

Outcomes in Populations Living near Oil and Natural Gas Operations: Study Quality and Future

Recommendations" attached as Exhibit E). That review concluded:

There currently exists limited research and conflicting scientific information on the health risks for those living next to these operations.

Twenty (20) studies met our criteria of a human health epidemiologic study evaluating the potential health effects associated with living near ONG [oil and natural gas] operations in the United States. Weight-of-evidence conclusions were developed for a total of 32 different health effects, and ranged from insufficient evidence to limited evidence. Across all health outcomes, four of the 20 studies received a moderate level of certainty rating. All others received a rating of low certainty.⁶

In further contradiction of the erroneous conclusion of the Grand Jury Report that

DOH is "in denial" about fracking, DOH provides a summary of what is known about the

potential health effects associated with fracking on its public website:

Recently there has been increased interest in UONGD by academic researchers. When most people think of unconventional oil and natural gas development (UONGD) they only think of wells and well pads, but there is an entire network of compressor stations, natural gas processing plants and pipelines in addition to the drill rigs and accompanying access roads that make for several points of

⁶ "A Systematic Review of the Epidemiologic Literature Assessing Health Outcomes in Populations Living near Oil and Natural Gas Operations: Study Quality and Future Recommendations" at pp.1 and 6 (references omitted).

concern from a health perspective. UONGD may negatively impact water, air and soil quality. It may also involve excessive noise, light and vibrations from seismic testing and cause vehicular injuries from increased truck traffic or other injuries or emergencies from well explosions or flooding. What is more are the mainly mental health impacts related to the disruption of rural communities and the influx of young male workers. Together these factors may directly impact health or indirectly impact health through increased stress, anxiety and reduced sleep. For workers and their families and sensitive populations (e.g., pregnant women, children and elderly), the health consequences of UONGD may be more severe.

Most epidemiologic research to this point has compared the health outcomes of those living varying distances from unconventional well sites as a substitute for exposure to UONGD. There have been very few studies that have measured exposure directly. Overall, epidemiologic work has found some limited evidence of relationships between living near UONGD and poor infant health and worsening respiratory symptoms. Infant health is unique in that the timing of exposure can be pinpointed (within a 9-month period) more precisely than for other health symptoms or outcomes.

(available at: https://www.health.pa.gov/topics/envirohealth/Pages/OilGas.aspx)

There is no doubt that DOH relies on scientific methods and evidence to shape its policies and programs. But this does not lead to inaction by DOH. Instead, it is the reason that DOH's multi-prong strategy for fracking has included a particular focus on improving the research and public understanding of the health effects associated with fracking. It is also the reason that the Administration agreed to spend \$1 million per year for three years to conduct two comprehensive studies on the health effects associated with fracking.

DOH does not address every public health concern with a one-size-fits-all approach. DOH's responses differ depending on the specific disease, infection or condition, how deadly it is, how quickly and easily it spreads, and what is known about the causes of the disease. For example, DOH takes a different approach to highly-infectious diseases than it does for a disease that is not infectious. Similarly, DOH takes a different approach to diseases where the cause or method of transmittal is known versus one that is that is subject to evolving scientific and medical understanding. DOH is committed to serving the interests of Pennsylvanians, and addressing the many public health issues that Pennsylvanians face including those related to fracking. DOH's response to fracking has continued to evolve and improve, and DOH will continue this trend into the future.

Respectfully submitted,

By:

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Dated: May 8, 2020

CERTIFICATE OF SERVICE

I hereby certify that I am this day serving one copy of the foregoing Response on behalf of

the Pennsylvania Department of Health upon the below by electronic mail:

Rebecca S. Frantz Chief Deputy Attorney General Office of Attorney General Environment Crime Section rfranz@attorneygeneral.gov

Carson B. Morris Deputy Attorney General Office of Attorney General Environmental Crime Section cbmorris@attorneygeneral.gov

Dated: May 8, 2020

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EXHIBIT A

Oil and natural gas production health complaints registry: A project of the Pennsylvania Department of Health, Bureau of Epidemiology, Division of Environmental Health Epidemiology

The Division of Environmental Health Epidemiology at the Department of Health evaluates possible connections between the environment someone lives in and their health outcomes. The Division compares medical information it collects with environmental data provided by other state and federal agencies, like the Department of Environmental Protection. While the Division and our toxicologist who evaluate concerns are not able to provide specific medical advice and/or medical care, we are able to collaborate with constituents' medical providers and federal, state, county and local officials to address environmental health issues and protect communities.*

It is also important to note that the information you provide and the records we keep related to constituent reports will be kept confidential subject to the provisions of both the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Pennsylvania's Right to Know Law (RTKL).

* Note as of July 15, 2017: Before the interview, please obtain verbal consent from constituents to discuss case with PADEP or ATSDR, if applicable, Also, please obtain written (through email) consent from constituents following the interview.

Verbal consent received Written consent received

Staff member who initiated repo	ort Date of initial report	2011-2016 "drilling log" case number(s
][
Name of Complainant (perso	n or organization)	Ever presence of a patient advocate
	Non Household	×.
Referral source: How did you re	ach us? If other, specify:	
	~	ATSDR DCS case only
General complaint type		
Incident/event related	Describe incident/event	Incident code (ICODE)
	~	
—Source of concern (Check all I	that apply)	7
Air pollution	Soil pollution Truck traffic	If other, specify:
Water pollution	🗌 Naise 📄 Other	
—Which of the following aspects	of oil and natural gas production are you concer	ned about? (Check all that apply)
Oil or gas well	Compressor station	If other, specify:
🗌 Pipeline	Impoundment, wastewater storage	
Processing plant	C Other	
Please provide brief summary o	fcomplaint	

Complaint specific to conventional oil and natural gas production Complaint misspecified

ent Contact Information		<u></u>
Cell Phone	Home Phone	Work Phone
Email Address		
Mailing Address		
]	
City	J	Zip Code
,]	
ess Corresponding to Health Co	amplaint	
Street Address	7	
City	Zip Code	
Township/Borough/Municipality		
	7	
County	County FIPS	
-		
Is this a home, school, work, or o	ther address?	
How many people are included/in	voived in your nealth complaint? (i T	i.e., number of people with health symptoms, etc.)
	e	
If N/A, explain:		
14 and discuss 10 and the second second second		
Would you like to report on anima		
	5	

Confirm number of people in household		<u>WG Ex. 70</u>
Confirm number of people in household	with health symptoms	
Respondent 1 Demographics		different from date of initial report
First Name	Person deceased at i Last Name	time of initial report
Date of Birth	Age	Race/Ethnicity
Relationship to Interviewee		
Self Spouse Child	Other If other, specify:	
Educational Attainment	Occupation	Industry
~		~ ·
Health Insurance Status	General Health Status	Smoking Status
~ ·	~	~
Respondent 2 Demographics		f different from date of initial report
First Name	Person deceased at Last Name	time of initial report
Date of Birth	Age	Race/Ethnicity
Relationship to Interviewee	Occupation	Industry
~		×
Health Insurance Status	General Health Status	Smoking Status
~	~	~ ·
Respondent 3 Demographics	Person deceased at	f different from date of initial report
First Name	Last Name	Sex
Date of Birth	Age	Race/Ethnicity
Relationship to Interviewee	If other, specify:	
Self Spouse Child [Other	
Educational Attainment	Occupation	Industry
2		~
Health Insurance Status	General Health Status	Smoking Status
	~	~ ·

Remandent & Democrathics	······	WG Ex. 70
Respondent 4 Demographics —		if different from date of initial report
First Name	Last Name	Sex
		~
Date of Birth	Age	Race/Ethnicity
		Ý
Relationship to Interviewee	If other, specify:	
Self Spouse Child	Other	
Educational Attainment	Occupation	Industry
~		~
Health Insurance Status	General Health Status	Smoking Status
~	~ ~	
Respondent 5 Demographics		if different from date of initial report at time of initial report [] Sex
Date of Birth	Age	Race/Ethnicity
Relationship to Interviewee	If other, specify:	
Self Spouse Child	Other	
Educational Attainment	Occupation	Industry
		~
Health Insurance Status	General Health Status	Smoking Status
	×	

-Health Symptoms believed	to be (potential	lly) related to	UONGD	
····Neurological	Frequency	Date of onset	Respiratory	FrequenWG Exat70 onset
🗌 Headache/migraine	~ ~		🗌 Allergies/sinus problems	~
🗌 Dizziness/balance	\sim		🗌 Nosebleeds	~
🗌 Memory loss	~		🗌 Nose congestion/runny	2
Difficulty concentrating	~		🗌 Sneezing	
Numbness/tingling	~		🗌 Sore throat	5
Confusion	~		Dry/irritated mouth	~
Psychological				
Anxiety/stress			🗌 Cough	~
🗌 Irritability			Shortness of breath	4
Depressed	~		🗌 Wheezing	
Ey e			Exacerbation/asthma	~
🗌 Trouble seeing			Exacerbation/COPD	~
 Itchiness	1.4		Exacerbation/Bronchitis	
			Gastrointestinal	
			🗌 Nausea	10 E
Pain/discomfort	×.		🗌 Vomiting	~
Ear	0.03		Diarrhea	
🗌 Hearing loss			🗖 Abdominal pain	
Ringing			Exac./ulcer/reflux/GERD	
Pain/discomfort			☐ Indigestion	
General Systemic	5174		Dermatological	
Sleep disturbance				
E Fatigue/malaise			Rash	~
Fever	~		Hives	~
Chills	÷		Skin irritation	<u> </u>
Night sweats	<u></u>		🗌 Hair Ioss	\sim
☐ Shaking	. v.		Cardiovascular	
Weight loss/gain	v.		Chest pain/tightness	¥
Decreased appetite	4		High blood pressure	
Muscle aches/cramps			🗌 Irregular heartbeat	~
Joint pain	~		Notes on symptoms:	
Loss of consciousness				
Swelling				
🗌 Urogenital problem	4			
Diagnosed Health Conditio	ns believed to b	e (potentially) related to UONGD	
Arthritis Date diagr	tosed		Kidney disease/fail Date dia	gnosed
Asthma/COPD Date diagr	2	- 8	Liver disease Date dia	50H(1950)
Cancer Date diagr	112221	- 0	Mental health Date dia	CALLY SAN YOU
and subspace	000000		Neurological disease Date dia	Zeste L. C. C. C.
Cancer site			Thyroid condition Date dia	
Heart disease and/or hype	rtension	Medi	cations taken (tyne, frequency, bo	and the second se
Date diagr	losed			
Health Care				
Sought medical care for conce	area Have vor	u had any toxic	ological tests done?	
	×.		Notes on health care	
Did you receive a diagnosis?	Describe	diagnosis		
	~			
	<u> </u>		[

Health Symptoms believed		TO TODO A CARDENE TO THE	UONGD	
Neurological	Frequency	Uate of onset	Respiratory	FrequenWG Exet70 onset
Headache/migraine	~		🗌 Allergies/sinus problems	
Dizziness/balance	~		🗌 Nosebleeds	~
Memory loss	~		🗌 Nose congestion/runny	2
Difficulty concentrating	34		🗌 Sneezing	~
Numbness/tingling	4		🗌 Sore throat	0
Confusion	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		Dry/irritated mouth	~
Psychological				
Anxiety/stress			🗌 Cough	
1rritability	÷		Shortness of breath	4
Depressed	~		🔲 Wheezing	~
Eye			🗌 Exacerbation/asthma	~
Trouble seeing	· ~ :		Exacerbation/COPD	~
1 Itchiness			Exacerbation/Bronchitis	
Watery			Gastrointestinal	
Dry			🗌 Nausea	
Pain/discomfort	×.		U Vomiting	~
Ear	1165		Diarrhea	10 I
Hearing loss			 Abdominal pain	10 C
Ringing			Exac./ulcer/reflux/GERD	
Pain/discomfort	~		Indigestion	~
General Systemic	5174		Dermatological	
Sleep disturbance			Rash	
Fatigue/malaise			Hives	
Fever	~		Skin irritation	
Chills	<u></u>		☐ Hair loss	0
Night sweats			Cardiovascular	55
Shaking			Chest pain/tightness	201
Weight loss/gain	. v.		High blood pressure	~
Decreased appetite	4		🗌 Irregular heartbeat	0
Muscle aches/cramps			Notes on symptoms:	
] Joint pain			Notes on symptoms.	
Loss of consciousness				
Swelling	2			
Contraction of the second second second				
🗌 Urogenital problem	2.90			
Diagnosed Health Conditio	ons believed to l	e (potentially)	related to UONGD	
Arthritis Date dia	anosed		Kidney disease/fail Date diag	nosed
Asthma/COPD Date dia	The state of the s		Liver disease Date diag	
Cancer Date dia	5 01		Mental health Date diag	
	attraction of the		Neurological diseaseDate diag	
Cancer site			Thyroid condition Date diag	
Heart disease and/or hype	ertension	Me	dications taken (type, frequency, f	
Date dia	gnosed			
-Health Care				
Sought medical care for conc	ern? Have vo	u had any toxic	ological tests done?	
		- nee ony toxit	Notes on health care	2
Did you receive a diagnosis?	Describe	e diagnosis		
	*			
L				

-Health Symptoms believed	to be (potentially	y) related to L	IONGD	_
Neurological	Frequency L)ate of onset	Respiratory	FrequenWG Exat70 onset
🗌 Headache/migraine	\sim		Allergies/sinus problems	~
🔲 Dizziness/balance	~		🗌 Nosebleeds	~
🗌 Memory loss	~		Nose congestion/runny	2
Difficulty concentrating	~		🗌 Sneezing	2
Numbness/tingling	~		🗌 Sore throat	2
Confusion	~		Dry/irritated mouth	~
Psychological				
Anxiety/stress			🗌 Cough	~
🔲 Irritability	4		Shortness of breath	3
Depressed	~		🗌 Wheezing	
Eye			🗌 Exacerbation/asthma	2
🗌 Trouble seeing			Exacerbation/COPD	~
🗌 Itchiness	4		🗌 Exacerbation/Bronchitis	÷
🔲 Watery			Gastrointestinal	
Dry			🗌 Nausea	
Pain/discomfort	1		🗌 Vomiting	~
Ear			🔲 Diarrhea	~
🗌 Hearing loss	14		🗌 Abdominal pain	
🔲 Ringing			Exac./ulcer/reflux/GERD	2
Pain/discomfort	1.1		🗌 Indigestion	~
General Systemic			Dermatological	
Sleep disturbance			🗌 Rash	200
🗌 Fatigue/malaise			— Hives	2.5
Fever	· *.		Skin irritation	~
Chills	4		🗌 Hair Ioss	~
Night sweats	· \v		Cardiovascular	
Shaking	· Y :		🗌 Chest pain/tightness	2
Weight loss/gain			🗌 High blood pressure	4
Decreased appetite	~		🗌 Irregular heartbeat	~
Muscle aches/cramps	~		Notes on symptoms:	
🔲 Joint pain	~			
Loss of consciousness				
Swelling	14 C			
🗌 Urogenital problem	<u></u>			
Diagnosed Health Conditio	ns believed to be	(potentially)	related to UONGD	
Arthritis Date diag	noted	r	Kidney disease/fail Date diagn	osed
Asthma/COPD Date diag		—— F	Liver disease Date diagn	
Cancer Date diagn		—— F	Mental health Date diagn	
	1942		Neurological diseaseDate diagn	
Cancer site			Thyroid condition Date diagno	osed
Heart disease and/or hypert	100.5 S56 A	Medi	cations taken (type, frequency, ho	w used, date started)
Date diag	nosed			
Health Care				
Sought medical care for conce		had a set		
	Have you	nad any toxico	logical tests done? Notes on health care	:
	×.]
Did you receive a diagnosis?	Describe o	diagnosis		
	÷			

F Health Symptoms believed to be (potentially) related to UONGD

····Neurological	Frequency	Date of onset	Respiratory	FrequenWG ExatZQ onset
Headache/migraine	~		🗌 Allergies/sinus problems	
Dizziness/balance	~			
Memory loss	~		Nose congestion/runny	
Difficulty concentrating			Sneezing	
Numbness/tingling	~		Sore throat	
			Dry/irritated mouth	
Psychological				
Anxiety/stress	~		🗌 Cough	
			Shortness of breath	<u> </u>
			Wheezing	<u> </u>
-Eye	~		Exacerbation/asthma	~
Trouble seeing	~ ~		Exacerbation/COPD	<u> </u>
Itchiness	~		Exacerbation/Bronchitis Gastrointestinal	~
Watery	~ ~			
Dry	~			~ <u> </u>
Pain/discomfort	~			~
Ear			🗌 Diarrhea	~
Hearing loss	×		🗌 Abdominal pain	
🗌 Ringing	×		Exac./ulcer/reflux/GERD	~
Pain/discomfort	<u> </u>		🔲 Indigestion	~
General Systemic			Dermatological	
🔲 Sleep disturbance			[Rash	~ ~
🔲 Fatigue/malaise	~			~ ~
🗌 Fever	~		Skin irritation	~
🗌 Chills	~		Hair loss	<u> </u>
Night sweats	~		Cardiovascular	
☐ Shaking	~		Chest pain/tightness	~
Weight loss/gain	~		High blood pressure	~
Decreased appetite	~		🗌 Irregular heartbeat	~
Muscle aches/cramps	~		Notes on symptoms:	
☐ Joint pain	~]
Loss of consciousness				
Swelling				
Urogenital problem	~			
Diagnosed Health Conditio	ns believed to k	e (potentially)	related to UONGD	
Arthritis Date diagnos	and l		Kidney disease/fail Date diagnos	
	1.2.1.1		Net 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 19	
Asthma/COPD Date diagnos	1.		Liver disease Date diagnos	STRV. L
Cancer Date diagnos	e o		Mental health Date diagno:	2006.1
Cancer site		The second se	Neurological disease Date diagno:	
Heart disease and/or hypert	ension	the second se	Thyroid condition Date diagno:	and the second sec
Date diagnos	and the second se	Medical	ions taken (type, frequency, how s	ised, date started)
wave undgited				
Health Care				
Sought medical care for conc	ern? Have vo	u had any toxic	ological tests done?	
		a nea briy toxici	Notes on health care	
	100		Y Notes of fleater care	
Did you receive a diagnosis?	Describe	diagnosis		

[—] Health Symptoms believed	to be (potentia	lly) related to l		
····Neurological	Frequency	Date of onset		FrequenWG Ex. 70 anset
🗌 Headache/migraine	1		🗌 Allergies/sinus problems	~
Dizziness/balance	~		Nosebleeds	~
🗌 Memory loss	~		Nose congestion/runny	2
Difficulty concentrating	34		Sneezing	24
Numbness/tingling	4		Sore throat	5
Confusion			Dry/irritated mouth	~
Psychological				
Anxiety/stress			🗌 Cough	~
🗍 Irritability	<u></u>		Shortness of breath	0
			Wheezing	5
 Eye			Exacerbation/asthma	2
Trouble seeing			Exacerbation/COPD	~
Titchiness	1.0		Exacerbation/Bronchitis	10 I
Watery			Gastrointestinal	
			🗌 Nausea	
Pain/discomfort	×.		Use Vomiting	~
Ear	0.65		Diarrhea	
Hearing loss			🗌 Abdominal pain	
			Exac./ulcer/reflux/GERD	201
Pain/discomfort	~		Indigestion	~
General Systemic	5174		Dermatological	
Sleep disturbance				
🔲 Fatigue/malaise			 Hives	
Fever	~		Skin irritation	~
	~		 ∏ Hair loss	<u> </u>
Night sweats	- C.		Cardiovascular	
			Chest pain/tightness	300 E
Weight loss/gain	. V.		High blood pressure	~
Decreased appetite	14		🗌 Irregular heartbeat	
Muscle aches/cramps			Notes on symptoms:	
🔲 Joint pain	~			
Loss of consciousness	· · · ·			
Swelling	4			
🗌 Urogenital problem	· •			
Diagnosed Health Conditio	as holioused to I	a (natontially)		
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Asthma/COPD Date dia	ignosed		Liver disease Date diag	nosed
Cancer Date dia	ignosed		Mental health Date diag	inosed
100000000000000000000000000000000000000			Neurological disease Date diag	nosed
Cancer site	14 F.	VAG	Thyroid condition Date diag	
Heart disease and/or hype	rtension	Med	fications taken (type, frequency, h	ow used, date started)
Date dia	ignosed			
Health Care				
Sought medical care for conce	rn? Have you	had any toxicol	ogical tests done?	
			Notes on health care:	
L	~]
Did you receive a diagnosis?	Describe	diagnosis		
	2			

I

Pregnancy	WG Ex. 70
	rths in the household (can go back as far as 2004)
Pregnancy/baby #1	Out of household
Respondent number of pregnant	t/recently pregnant woman
Estimated date of delivery (if bal	by already born, use birth date) Miscarriage
Birth weight lbs	oz 5 minute APGAR score
Gestational age at birth	completed weeks Birth defect? Describe
Pregnancy/baby #2	
Respondent number of pregnant	
Estimated date of delivery (if bal	by already born, use birth date)
Birth weight lbs	or 5 minute APGAR score
Gestational age at birth	completed weeks Birth defect? Describe
Pregnancy/baby #3	
Respondent number of pregnant	t/recently pregnant woman Dut of household
Estimated date of delivery (if ba	by already born, use birth date) Miscarriage
Birth weight lbs	5 minute APGAR score
Gestational age at birth	completed weeks Birth defect? Describe
Housing	
-	
How long in this home?	
Seasonal residence	If yes, how much of the year do you spend in this home?
Year home built	Describe any remodeling or renovations (e.g., area of home, date, etc.)
Size of lot (in acres)	
Badaa kastina	Date of test Test result
Radon testing	
Ý	
Do you have central heating?	If no, describe heating system
*	
Pesticide or insecticide use	If so, describe (e.g., type of pesticides/insecticides, domestic or farm-related, etc.)
~	
Have you changed residences follow	ving health concern? Date of move
~	
Do/did you have an oil & gas lease (on your property? Effective date of lease

Water Date data entered if different from date of initial from the pole x. 70 Primary source of water for ingestion Treated or not? Primary source of water for bathing Treated or not? Date treatment system installed Describe treatment system Change in taste, appearance, odor? Date first noticed change in water	
Primary source of water for bathing Treated or not? Date treatment system installed Describe treatment system	
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Date treatment system installed Describe treatment system	
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Any water tests?	
Number of water tests completed	
Three most recent water test results (list most recent first)	
OCD	
Date Laboratory name obtained Contaminants of concern effects suspect	
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Notes on water testing:	
Unusual odor? Date first noticed odor	
Describe odors (include frequency)	
Describe visible emissions, if any	
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			- WG Ex. 70
in the soil on your p	roperty?		
duce? Describe con	cerns		
own in the soil on yo	ur property?		,
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CED			Adverse health effects suspected
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ory, digestive, skin,	eyes, neurologic, other)		
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Documented complaint, no further action required Documented complaint, no further action required Decorbe requests: (Include date requested, type of sample or record requested, etc.) Decorbe request: (Include date requested, type of sample or record requested, etc.) Decorbe what was obtained: (Include date samples collected and date received, type of samples collected, etc.) Decorbe what was obtained: (Include date records, laboratory results, etc. Decorbe what was obtained: (Include date samples collected and date received, type of samples collected, etc.) Decorbe what was obtained: (Include date of review, conclusion reached, if further action is necessary, etc.) Decorbe process: (Include relevant date, parties involved, etc.) Decorbe action(s): (Include relevant date, parties involved	Documented complaint, no further action recuired Requested environmental testing results, medical records, laboratory (blood, urine) results, etc. Desorbe request: (Include date requested, type of sample or record requested, etc.) Waiting for aforementioned results? Busche environmental testing results, medical records, laboratory result, etc. Desorbe what was obtained: (Include date samples collected and date received, type of samples collected, etc.) Reviewed environmental samples, medical records, lab results, etc. Desorbe process: (Include date of review, conclusion reached, if further action is necessary, etc.) Cother action(s): (Include relevant date, parties involved, etc.) Further steps needed: List all DOH employees who contributed to investigation: Dest of Environmental Protection Dest of Enviro	actions Taken by the Department of Health	
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List all DOH employees who contributed to investigation:	List all DOH employees who contributed to investigation:		
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Medical professional(s)	Medical professional(s) Image: Constraint of the second	Occupational Safety and Health Admin	
Other	Other	DOH-approved Environmental Medicine affiliates	
		Medical professional(s)	
Referral notes:	Referral notes:		
		Referral notes:	

ase Summary							<u>WG Ex. 70</u>
State ID	County	ID	Household #	Case	#	Unique ID	
Please fill out 'Case Open = awaiting fur Closed = communica Never open = compl	th <mark>er</mark> commun ated to comp	lication from	t outcome of inv	estigation, no fur	ther actio	in planned at thi	is time e
Case Outcome		022					
-If applicable, case	outcome co	mmunicated	to complainant s	ia:			
🗌 Mail 🛛 Date lo	etter sent:						
Email Date e	mail sent:						
🗌 Phone - Date o	f phone call:						
iriefly list what hard	l copy files a	nd/or digital	media we have	at DOH:			

	Date data entered if diff	erent from date of initiaWeGor <mark>Ex. 70</mark>
Number of active wells < 1/2 mile	Number of active wells < 2 miles]
ame of closest UONGD well of concern	Distance to closest well of concern	Current stage of closest well of concern
Date pad development began:	Date drilling began ("spud date"):	Date stimulation began:
Date production began:	Date well plugged:	
ame of closest pipeline	Distance to closest pipeline	Date of onset
ame of closest compressor station	Distance to closest station	Date of onset
ame of closest impoundment, H2O storage	Distance to closest impoundment	Date of onset
lame of closest processing plant	Distance to closest processing plant	Date of onset
ame of trucking company	Distance to truck traffic	Date of onset
otes on nearby drilling infrastructure:		
)ther industries/companies close by that cou	uld contribute to health concerns?	
ame of closest superfund site	Distanc	te to closest superfund site

EXHIBIT B

DO YOU HAVE A HEALTH CONCERN ABOUT THE ENVIRONMENT? *Could contaminated air, soil or water be affecting your health?*

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Have questions about environmental health? The department has epidemiologists available to answer questions about a range of environmental health issues.



Have a health concern related to oil and gas production? The department has a registry to track health complaints. Call 717-787-3350 to add your information.



Need community resources? The department has relationships with state and local stakeholders that can help you address your environmental health concerns.

CONTACT US: 717-787-3350 or env.health.concern@pa.gov

VISIT OUR WEBSITE: https://www.health.pa.gov/topics/envirohealth



EXHIBIT C

Contact Environmental Health

Ways to Contact Us Report an Environmental Health ConcernONGP Health Registry

The Division of Environmental Health Epidemiology is part of the Bureau of Epidemiology in the Pennsylvania Department of Health. All programs within the division – the Health Assessment Program, Environmental Public Health Tracking Program, Adult Blood Lead Epidemiology and Surveillance Program and Unconventional Oil and Natural Gas Development Program – can be contacted at the bureau office.

Ways to Contact

Mail: Pennsylvania Department of Health Division of Environmental Health Epidemiology Bureau of Epidemiology Room 933, Health and Welfare Building 625 Forster Street Harrisburg, Pennsylvania 17120-0701

Phone: 717-787-3350 Fax: 717-346-3286 <u>env.health.concern@pa.gov</u> Email: (mailto:env.health.concern@pa.gov)

Hours: Monday-Friday, 8 a.m. to 4 p.m.

Reporting an Environmental Health Concern

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The Division of

Environmental Health Epidemiology is part of the Bureau of Epidemiology in the Pennsylvania Department of Health (DOH). Pennsylvania residents are encouraged to report environmental health concerns to the Division, where they will be evaluated and referred to an appropriate program area for potential investigation and follow-up. If applicable, we will analyze environmental sampling data and/or clinical (i.e., toxicological) data. If environmental sampling data are not available, we will work with the Department of Environmental Protection (DEP) to collect data, when indicated and as appropriate. Lack of environmental sampling data may limit the department's ability to conduct a thorough investigation.

While we do not offer primary health care services, we can provide advice based on the nature of the complaint and work closely with the individual who filed the complaint and, if applicable,

their healthcare providers to address health concerns. Depending on the nature of the concern, DOH environmental health staff members will collaborate with federal, state <u>Weguery</u> **an** d local officials, healthcare providers and the public on a regular basis to address environmental health issues throughout the commonwealth.

Before Contacting Us

If you have an environmental health concern, the tips below are intended to help us address your concern in the most efficient way possible. Please be patient, as it takes time to investigate the many variables at play in environmental health concerns and to conduct a health evaluation. You can expedite the department's response by having the following things in place before you file a complaint:

- Visit your healthcare provider or doctor first.
- Have environmental test results available.
- Be prepared to speak about your family's current health and health history.
- Be prepared to talk about your health symptoms.

Difference between DOH and DEP

Both DOH and DEP receive and respond to environmental complaints. Citizens should know that, in matters of environmental concern, DOH is an advisory agency, not a regulatory one. Environmental regulation concerns are primarily managed by DEP or, on a national level, the EPA. The following is a rough guide for when to contact DEP versus DOH. It is possible that you would contact both departments.

DEP works to protect the state's air, land and water from pollution and ensure a clean environment. DEP is the agency to which you primarily direct your complaint or questions if your concern involves drinking water or the waterways, air quality issues or potential soil pollution believed to be related to UONGD. Additionally, DEP takes reports of spills, accidents and other releases of hazardous substances and contaminants. DEP will test the air, water or soil to determine if there is a problem.

DOH examines how different environments affect a person's well-being. The health effects of breathing air, drinking water and more are researched in relation to specific sites where they are reviewed and investigated. Your complaint should also be directed to DOH's Division of Environmental Health Epidemiology if you have an environmental concern that is specific to your health or the health of a family member or friend, which may be caused by the air, water or soil.



ONGP Health Registry

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The Division of Environmental Health Epidemiology manages the oil and natural gas (ONG) health complaints registry. If you have a health concern related to the oil and gas industry in your area, please contact the division to be included in the registry. DOH environmental health staff are also available to answer general questions about health impacts of the oil and gas industry.

Mail: Pennsylvania Department of Health Division of Environmental Health Epidemiology Bureau of Epidemiology Room 933, Health and Welfare Building 625 Forster Street Harrisburg, Pennsylvania 17120-0701

Phone: 717-787-3350 Fax: 717-346-3286 <u>env.health.concern@pa.gov</u> Email: (mailto:env.health.concern@pa.gov) Hours: Monday-Friday, 8 a.m. to 4 p.m.

EXHIBIT D

Oil and Natural Gas Production (ONGP) Health Concerns

ONGP in Pennsylvania

ONGP is a significant industry in Pennsylvania. The latest wave of ONGP activity in the state began in 2005 with the start of unconventional oil and natural gas development (UONGD). Unconventional wells are distinct from conventional wells by the geologic formation being tapped. They use horizontal and vertical drilling and hydraulic fracturing ("fracking") to access traditionally unavailable reservoirs of oil and natural gas.

As of Dec. 31, 2019, the Pennsylvania Department of Environmental Protection (DEP) reported there were 10,819 active unconventional wells in the state. Thirtyfour of Pennsylvania's 67 counties had active unconventional wells, with Washington (1,772), Susquehanna (1,601) and Greene (1,367) counties having the greatest numbers of active unconventional wells.*

ONGP Health Registry

In response to growing concerns about UONGD, the Pennsylvania Department of Health (DOH) developed a confidential health registry to better track and respond to public health complaints related to ONGP.

As of Dec. 31, 2019, DOH received 164 ONGP-related health complaints, with Washington (41), Susquehanna (31) and Bradford (22) counties having the most health complaints.

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Figure 1. Total Health Complaints Logged by DOH Division of Environmental Health Epidemiology Since 2011 (N=164)

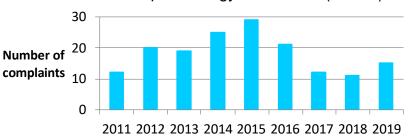


Table 1. Reason for Contact (N=164)

Reason	Q4 2019	2019 YTD	Total since 2011	% of Total since 2011
General inquiry	0	0	24	14.6%
News update/alert	0	0	3	1.8%
Information sharing	0	0	12	7.3%
Formal health complaint ^a	2	15	125	76.2%

^aGeneral inquiries, news updates/alerts and information sharing cases were no longer logged in the health complaints registry effective March 2017.

Table 2. Environmental Source of Concern^a (N=164)

Source	Q4 2019	2019 YTD	Total since 2011	% of Total since 2011
Water	2	14	115	70.1%
Air	0	5	96	58.5%
Soil	1	7	31	18.9%
Noise	0	2	54	32.9%
Truck traffic	0	2	50	30.5%
Other ^b	2	3	48	29.3%
Missing	0	0	9	5.5%

^aMore than one environmental source of concern may be selected per complaint.

^bOther category includes light, drilling mud or solid waste, vibrations or seismic testing, etc.

Referrals

One hundred % of Q4 2019 health complaints were referred by DEP.

Warren McKean Tioga Potter Crawford Wayne Womi Sullivan Elk Lycoming Pik Mercel Clinton outsolumbi Monroe wrene Clearfield Centre Union Butlet rthumb Carbor Armstrong Snyde Nathampto Schuylkill Beaver Indiana Aittin Number of wells ehiat Allegheny Perry Øa Berks 0 101-500 ebanon Buck Westmoreland toomerv umberland 1-30 501-1000 Lancaster Phyladelphia Chester Bedford 31-100 Some 1001+ Fayette Fulton Franklin York Adams Figure 2. Active Unconventional Oil and Natural Gas Wells in Pennsylvania,

as of Dec. 31. 2019

*Based on the number of active wells from DEP Spud Data Report, Wells Drilled by County

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Table 3. Demographic Information of Individuals in ONGP Registry With a Formal Health Complaint (N=125 formal health complaints, 263 individuals*)

Characteristic	Q4 2019	2019 YTD	Total since 2011	% of Total since 2011
Female	1	11	136	51.7%
Male	2	15	123	46.8%
Missing	0	0	4	1.5%
Non-Hispanic white	3	22	109	41.4%
Non-Hispanic black	0	0	0	0.0%
Hispanic	0	0	0	0.0%
Other	0	2	3	1.1%
Missing	0	2	151	57.4%
0-17 years old	0	4	43	16.3%
18-64 years old	3	16	130	49.4%
65+ years old	0	4	41	15.6%
Missing	0	2	49	18.6%
Any private insurance	3	20	79	30.0%
Public only insurance	0	3	28	10.6%
Uninsured	0	1	6	2.3%
Missing	0	2	150	57.0%

Demographic Summary This table summarizes the demographic and health insurance information of individuals included in the formal health complaints received for Q4 2019, YTD 2019 and total since 2011. This does not necessarily reflect the demographic characteristics of the entire community.

*Table excludes general inquiries, news updates and information sharing complaints. Each health complaint may pertain to more than one individual. Race/ethnicity, age and health insurance were not systematically collected until March 2017. Percentages within each group may not sum to 100% due to rounding.

Table 4. Health Information of Individuals in ONGP Registry With a Formal Health Complaint (N=125 formal health complaints, 263 individuals*)

Symptom Group	Q4 2019	2019 YTD	Total since 2011	% of Total since 2011	Symptom Summary
Cardiovascular	1	2	42 (11)†	16.0%	This table summarizes the symptoms
Dermatological	2	10	100	38.0%	reported by individuals for Q4 2019,
Ear	0	2	32	12.2%	YTD 2019 and total since 2011.
Eye	1	5	54	20.5%	
Gastrointestinal	0	9	93	35.4%	
General systemic ^a	2	10	95	36.1%	
Neurological	2	10	115 (6)†	43.7%	
Psychological	0	4	60 (8)†	22.8%	
Respiratory	0	10 (2)†	140 (22)†	53.2%	
Urogenital	0	1	26 (6)†	9.9%	
Missing	0	0	36	13.7%	

*Table excludes general inquiries, news updates and information sharing complaints. Each health complaint may pertain to more than one individual.

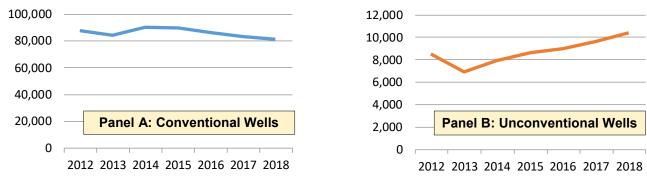
^aIncludes sleep disturbance, fatigue, fever, chills, night sweats, shaking, weight loss/gain, decreased appetite, muscle aches/cramps, joint pain, fainting and swelling [†]Numbers in parentheses correspond to newly diagnosed conditions relevant to that symptom group: heart disease and/or hypertension (cardiovascular group), neurological disease (neurological), psychological disease (psychological), asthma or COPD (respiratory), kidney disease or failure (urogenital). They do not represent pre-existing conditions. Therefore, someone could report that UONGD exacerbated their asthma (noted in the respiratory count) but was diagnosed before UONGD activity started in their area (not reflected in number of parentheses).

Health Overview 2019 Year-to-Date Based on Formal Health Complaints (N=15 complaints, 26 individuals)

- 42% of individuals reported being in poor or fair health.
- **8%** of individuals reported being disabled.
- **O**% of individuals reported being diagnosed with cancer since the beginning of 2019.
- 65% of individuals visited the doctor for their health concerns.
- Five (33%) of 2019 YTD complaint cases had concerns about animal health (livestock or pets).

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Figure 3. Total Number of Active Oil and Natural Gas Wells in Pennsylvania, 2012 to 2018



The tables below show data for counties with more than 500 active unconventional oil and natural gas wells as of Dec. 31, 2019.

Washington (1,772) Susquehanna (1,601) Greene (1,367) Bradford (1,326) Lycoming (919) Tioga (769) Butler (576)

Table 5. Environmental Source of Concern by County (All Complaints Since 2011)

Source	Washington	Susquehanna	Greene	Bradford	Lycoming	Tioga	Butler
Water	24	26	7	20	2	4	3
Air	32	17	4	6	4	2	2
Soil	9	5	2	4	0	1	0
Noise	21	10	4	4	0	1	1
Truck traffic	21	9	3	4	1	2	1
Other ^a	21	10	2	5	0	0	1
Missing	3	0	0	0	1	0	0

County-specific numbers of complaint cases are as follows: 41 (Washington), 31 (Susquehanna), 8 (Greene), 22 (Bradford), 6 (Lycoming), 4 (Tioga) and 3 (Butler). More than one environmental source of concern may be selected per complaint.

^aOther category includes light, drilling mud or solid waste, vibrations or seismic testing, etc.

Table 6. Health Symptoms by County (Individuals With a Formal Health Complaint Since 2011)

Symptom Group	Washington	Susquehanna	Greene	Bradford	Lycoming	Tioga	Butler
Cardiovascular	6	8	3	12	0	1	0
Dermatological	23	26	10	11	6	1	0
Ear	7	5	0	3	2	1	0
Eye	15	11	2	5	3	2	0
Gastrointestinal	22	23	6	14	0	3	2
General systemic ^a	24	19	9	10	0	3	2
Neurological	29	19	6	15	1	5	3
Psychological	22	13	2	4	3	0	2
Respiratory	37	29	12	15	4	6	2
Urogenital	6	6	2	4	3	0	1
Missing	16	2	3	8	0	0	1

County-specific numbers of individuals are as follows: 66 (Washington), 59 (Susquehanna), 20 (Greene), 34 (Bradford), 8 (Lycoming), 8 (Tioga) and 5 (Butler).
^aIncludes sleep disturbance, fatigue, fever, chills, night sweats, shaking, weight loss/gain, decreased appetite, muscle aches/cramps, joint pain, fainting and swelling

By far, most oil and natural gas-related complaints received by DOH have been related to UONGD. We have received four complaints related to conventional oil and natural gas development since 2011.

Figures in this report may slightly differ from previous reports due to the potential for ongoing data collection. Please contact the Division of Environmental Health Epidemiology for more details at 717-787-3350 or env.health.concern@pa.gov.



EXHIBIT E



International Journal of Environmental Research and Public Health

Review





A Systematic Review of the Epidemiologic Literature Assessing Health Outcomes in Populations Living near Oil and Natural Gas Operations: Study Quality and Future Recommendations

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Abstract: A systematic method was used to review the existing epidemiologic literature and determine the state of the scientific evidence for potential adverse health outcomes in populations living near oil and natural gas (ONG) operations in the United States. The review utilized adapted systematic review frameworks from the medical and environmental health fields, such as Grading of Recommendations, Assessment, Development and Evaluations (GRADE), the Navigation Guide, and guidance from the National Toxicology Program's Office of Health Assessment and Translation (OHAT). The review included 20 epidemiologic studies, with 32 different health outcomes. Studies of populations living near ONG operations provide limited evidence (modest scientific findings that support the outcome, but with significant limitations) of harmful health effects including asthma exacerbations and various self-reported symptoms. Study quality has improved over time and the highest rated studies within this assessment have primarily focused on birth outcomes. Additional high-quality studies are needed to confirm or dispute these correlations.

Keywords: oil and natural gas; hydraulic fracturing; fracking; unconventional oil and gas; environmental health; epidemiology; systematic literature review

1. Introduction

The United States has significantly increased its capacity for oil and natural gas (ONG) development through the technological advancements of directional drilling and hydraulic fracturing, with natural gas production reaching a high in 2017 and 2018 [1]. In 2016, more than two-thirds of the 977,000 producing ONG wells in the U.S. used these technologies to access energy reserves in shale and tight oil sands [2]. In places like the Colorado Front Range and Dallas-Fort Worth, Texas, ONG operations are occurring directly alongside population growth. It is estimated that 17.6 million people in the U.S. live within 1 mile of an active ONG well [3].

There currently exists limited research and conflicting scientific information on the health risks for those living next to these operations. The industry surrounding ONG expanded faster than evidence-based epidemiologic research could respond [4,5]. Early community health assessments and surveys of health symptoms in people living near ONG operations raised concerns about the potential chemical hazards, including exposures to air and water pollution [6–8]. Additional studies pointed

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to non-chemical stressors, including psychosocial stress, from living near ONG operations [9–11]. These early hypothesis-generating studies gave way to a growing body of observational epidemiologic literature that has quantified associations between residential proximity to ONG operations and the potential for certain adverse human health effects. Several review articles published within the last five years summarize this literature [5,12–14].

Our study is the first of its kind to systematically review the entirety of existing epidemiologic literature on the associations between living near ONG development and the potential for harmful health effects. We weigh the level of evidence for each health outcome and aim to present a clear assessment of the methodological rigor, study strengths, and weaknesses, to identify approaches to future research. The scholarship published to date varies in the types of ONG operations studied, the populations of interest (e.g., based on their geography, time period, or demographic characteristics), the health outcomes measured, and the quality of the methods used. While Saunders and colleagues do raise important methodological concerns about many of the articles they review [14], no existing review addresses study quality in a systematic way. In research on the health effects of potential environmental contaminants, where randomized controlled trials are neither ethical nor appropriate, study quality, or certainty in the study aligning with its stated objectives, is integral to interpreting scientific results and extrapolating them for regulatory and other science-based decisions.

The need for public health scientists to systematically evaluate the body of a literature base for an important issue, with limited resources, is necessary to assist in science-based regulatory decision making. Often, these issues are not entirely characterized and may include multiple chemical stressors (which are typically unknown) and variable health outcomes. The current established systematic review frameworks focus on an in-depth evaluation of the toxicological and epidemiological literature for a specific chemical and/or health outcome, however, this approach is unable to be applied directly to the epidemiological literature surrounding ONG development. Therefore, we have adapted these approaches to better answer this environmental health question.

The steps used to conduct the review were adapted from various established systematic review frameworks for the medical and public health fields, including as Grading of Recommendations, Assessment, Development and Evaluations (GRADE) [15] and Meta-analyses Of Observational Studies in Epidemiology (MOOSE for observational studies) [16], and emerging methods in environmental health as outlined by the Navigation Guide [17], and Office of Health Assessment and Translation (OHAT) [18] guidance (Figure 1). Each study was evaluated using 14 study evaluation questions to assess the level of certainty in, or scientific plausibility of, the study findings. The overall weight of evidence was determined for each health outcome separately. This review is not intended to replicate any previous frameworks nor is it to be the single word on study quality in this area of research. Our aim is to be objective and transparent, in a way that can be understood by community members, government and non-government public health and environmental officials and policymakers.

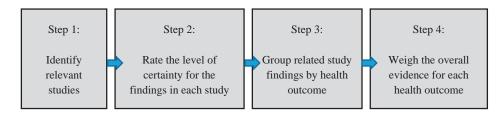


Figure 1. Steps in the current systematic review of epidemiologic literature.

2. Materials and Methods

2.1. Scope of Analysis

The scope of this literature review is defined by a PECO (populations, exposures, comparators, and outcomes) question [19]: "In humans (including unborn fetuses) living in the U.S., is exposure to

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chemicals emitted from ONG operations, compared to people who are not exposed (or who are exposed at lower levels), associated with adverse changes in health?" (Figure 2). Unborn fetuses were included as a population of interest to account for the possibility of ONG activities affecting fetal development within the mother's womb. The term "oil and natural gas operations" (or development) was defined to include all upstream processes involved in the extraction of ONG resources using any combination of vertical drilling, directional/horizontal drilling, and hydraulic fracturing to access energy reserves from conventional and unconventional geologic formations. This review does not include studies evaluating mid- and downstream processes. Since October 2011, the majority of new ONG wells in the U.S. overall have been hydraulically fractured horizontal wells, typically referred to as unconventional wells [2]. Study authors will often use a variety of these terms, and the distinction between conventional and unconventional wells—in source rock, depth, or drilling technique—is muddled in practice [20]. We sought to look across a range of comparators since exposures to ONG-associated chemicals occur along a continuum and it may not always be clear what the pathway of exposure is, how far that pathway reaches, or whether multiple exposure pathways produce synergistic effects on health [5,19]. We then considered whether any and all adverse changes in health occur with these exposures. While it is plausible that ONG may impact health through indirect pathways such as income (e.g., from monetary gains from leasing land or mineral rights), or investment in community infrastructure such as healthcare services [10,21,22], indirect effects were not included in this paper.

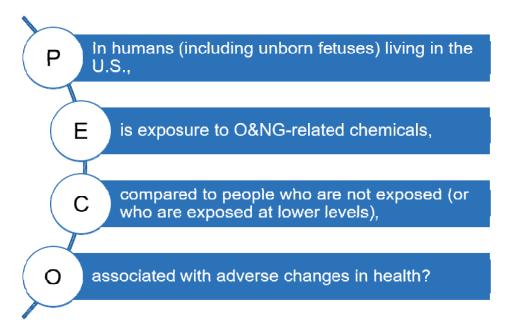


Figure 2. Populations, exposures, comparators, and outcomes (PECO) statement.

The PECO question informed our exclusion criteria and studies were excluded if one or more of the following five criteria were met: (1) exposure to ONG chemicals was not directly measured in, or estimated for, study subjects (i.e., excluded studies focused on indirect health effects including community stressors such as degradation of rural life, sexually transmitted infections from newly arrived young male workers, and traffic accidents from increased heavy truck traffic); (2) the study failed to quantify associations between exposures and a specific health outcome (i.e., excluded studies did not measure odds ratios, relative risk, etc.); (3) the study did not include original data or observations (e.g., review articles, commentaries); (4) the study did not define ONG operations to include any or all processes associated with the upstream development and production of ONG, including but not limited to horizontal drilling and hydraulic fracturing; or (5) the study did not take place in the U.S.

2.2. Data Search

PubMed was the primary research database used to obtain articles. We identified relevant records using the following PubMed search terms: (("Oil and Gas Industry" [Mesh] OR "Natural Gas" [Mesh]) AND (epidemiolog* or symptom*)) OR ((oil OR natural gas) AND (epidemiolog* OR health OR symptom*) AND (unconventional OR drilling OR shale OR coal OR production OR development) NOT ("Occupational Health" [Mesh] OR "Animal Experimentation" [Mesh]) AND ("2013/01/01" [PDAT]: "2018/10/01" [PDAT])) AND Humans [Mesh]. We verified that no relevant study was published before 2013, and any studies published after our search date of October 1, 2018 were not included in the assessment. In total, 1253 articles were returned by the search and all were screened for eligibility (Figure 3). Review articles, risk assessments, and included studies were also screened for references and identified six additional studies. The majority of articles (98%) did not meet our study inclusion criteria because they were related to the fields of environmental engineering, geology, hydrology or biomedical topics such as plant-based oil extracts/lipids. We kept the search terms broad in an effort to capture the wide variety of terminology that has been used within the interdisciplinary ONG health effects field.

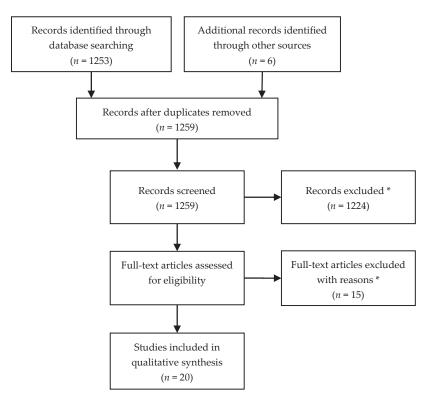


Figure 3. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram for study inclusion. * Exclusion criteria is detailed within the methods.

2.3. Level of Certainty Rating and Level of Evidence Conclusions for Individual Studies

A modified systematic review framework was used to rate the level of certainty (or the certainty in an estimate of effect) for each health outcome (Figure 4). We developed our framework based on established methods of systematic reviews for the medical, public health and environmental health fields. These frameworks incorporate, either explicitly or implicitly, most of Bradford Hill's criteria for causation such as studies with specificity and biological plausibility and that were temporal and consistent [23]. We consulted these classic criteria to develop a meaningful scope of review (as reflected in the PECO question) and determine criteria for study certainty and weight of evidence [24].

<u>WG Ex. 70</u>

1. Establish Init	tial Level of Certainty		2. Consider Raising Level of Certainty		3. Final Level of Certainty Rating
Study design	Initial certainty in an estimate of effect		Higher certainty if:		Certainty in an estimate of effect
Randomized control trials *	High certainty		Percentage of study		High
	Moderate certainty	⇔	evaluation questions adequately addressed	⇔	Moderate
Observational studies	Low certainty		in the study		Low

Figure 4. The approach used for developing level of certainty ratings for each study outcome. * No randomized control trials were identified in this review.

We rated study findings as having low, moderate, or high certainty that the estimated effect was close to that of the true effect. The findings of observational epidemiologic studies were initially ranked as low certainty and were upgraded according to fourteen (14) study evaluation questions that assessed various domains (Table 1). These criteria were based on established frameworks which specify the domains, questions, or study limitations used to evaluate individual studies for use in a systematic review [17,18,25–27]. We categorized the study evaluation questions into five groups: population and sample, exposure, health outcomes, confounders, and reporting. Two or more authors reviewed each study evaluation question with a yes-or-no response for each study (Supplementary Tables S1–S20). Conflicting responses were resolved through discussion and additional review of the study. Studies with greater than 50% "yes" answers (i.e., 8 "yes" answers out of 14) were considered for potential upgrade of their findings to moderate certainty; studies with greater than 75% "yes" answers (i.e., 11 "yes" answers out of 14) were considered for potential upgrade to high certainty [28]. All findings of each study were ascribed the same level of certainty after evaluations were complete.

Table 1. Key study evaluation questions to determine the level of certainty ratings for health outcomes.

Study Evaluation Questions
Population and Sample1. Does the control group match the exposed group?2. Is the sample generalizable to the population of interest?3. Did the study a priori quantify sample and power?4. Were missing data addressed and tested?
Exposure5. Was exposure directly measured and quantified?6. Was the exposure or proxy/surrogate of exposure measured from a point location?7. Does the proxy/surrogate adequately estimate exposure?8. Was there a temporal relationship between exposure and outcome?
Health Outcomes 9. Was the health outcome determined by a medical provider? 10. Was a dose-response relationship seen in any outcome?
Confounders 11. Did the study design or analysis account for important confounding and modifying variables? 12. Did the study design or analysis adjust or control for other environmental exposures that were anticipated to bias results? 13. Were sensitivity analyses attempted for population, outcome, or exposure?
Reporting 14. Did the study conclusions match the results?
Final level of certainty rating: Low/Moderate/High

We derived weight-of-evidence conclusions using standards outlined in GRADE [29], the Cochrane Handbook [30], and developed by the Institute of Medicine [31]. For each health outcome, relevant

findings from individual studies were grouped and evaluated to derive one of the following weight-of-evidence levels: substantial, moderate, limited, mixed, failing to show an association, or insufficient (Table 2).

Evidence Level	Definition
Substantial	Strong scientific findings that support an association between oil and gas exposure and the outcome, with no credible opposing scientific evidence.
Moderate	Strong scientific findings that support an association between oil and gas exposure and the outcome, but these findings have some limitations.
Limited	Modest scientific findings that support an association between oil and gas exposure and the outcome, but these findings have significant limitations.
Mixed	Both supporting and opposing scientific findings for an association between oil and gas exposure and the outcome, with neither direction dominating.
Failing to show an association	Body of research failing to show an association—indicates that the topic has been researched without evidence of an association; is further classified as a limited, moderate or substantial body of research failing to show an association.
Insufficient	The outcome has not been sufficiently studied.

3. Results

Twenty (20) studies met our criteria of a human health epidemiologic study evaluating the potential health effects associated with living near ONG operations in the United States (Table 3, Supplementary Table S21). Weight-of-evidence conclusions were developed for a total of 32 different health effects, and ranged from insufficient evidence to limited evidence (Table 4).

Across all health outcomes, four of the 20 studies received a moderate level of certainty rating. All others received a rating of low certainty. The majority of the studies were retrospective cohort (six studies) or ecological (six studies) study designs. There were five cross sectional studies, two nested case controls, and two case-controls. The average score across all studies was 6, with a score range from 2 to 9 (Supplementary Table S22).

3.1. Birth Defects and Birth Outcomes

This review identified nine studies comprising 12 low to moderate certainty findings that identified the relationship between women who lived near ONG operations and the likelihood that their child was born with birth defects or other types of adverse health outcomes at birth.

Two studies evaluated birth defects (congenital heart defects, oral clefts, and neural tube defects) in infants of mothers who lived at varying proximities to ONG development during pregnancy [32,33]. These low-certainty studies resulted in insufficient evidence to determine if living near ONG operations during pregnancy is associated with birth defects since there was only one study per outcome.

Eight studies evaluated adverse birth outcomes [32,34–40]. These studies examined commonly used indicators of infant health status such as preterm birth, gestational age, Apgar score, birth weight, infant mortality, and fetal death. Overall, there are conflicting findings across studies resulting in either mixed or insufficient evidence of adverse birth outcomes associated with living near ONG operations during pregnancy (Table 4). Three of the eight studies and their findings were upgraded to a moderate level of certainty rating due to strength in their study designs that reduced risk-of-bias [35,37,38]. These studies demonstrated both positive and null associations for multiple health outcomes. All three were retrospective cohort studies that demonstrated evidence of a dose-response relationship and included a valid exposure surrogate as taken from a point location. All other studies were ranked as low certainty because of limitations within the study design or missing key elements. For example, most studies failed to adequately quantify exposure either directly, or through a proxy/surrogate estimate. In many cases, this measure of exposure was limited to either presence or absence of wells in a county or was

solely proximity-based. Although some studies calculated inverse distance-weighted well counts, they failed to quantify other metrics such as well development phase or total natural gas volume [39].

Birth outcomes have received the most scholarly attention for this topic, due to the relatively easy access to birth certificate or birth health records data, and the ability to pinpoint exposures to ONG operations during the 40-week gestation period [36]. While the overall evidence is rated as mixed or insufficient for various outcomes, the most recently published studies on ONG and birth outcomes have used innovative methodologies that improve or alleviate some of the weaker assumptions in early work. For example, Hill in 2018 took advantage of the little assumed difference between pregnant women living near permitted but not yet drilled wells and those living near active wells to define a better comparison or control group [37]. Additionally, three of the four moderate certainty studies evaluated birth outcomes and have identified positive associations between living near ONG operations and these adverse health outcomes.

ONG operations can emit volatile organic compounds (VOCs) into the air and contribute to increased particulate matter 10 micrometers or less in diameter ($\leq PM_{10}$) during upstream development activities. Some of these VOCs have the potential to cause developmental effects in test animals following high levels of exposure—generally at much higher levels than what has been observed for individual VOCs at ONG operations [41]. Systematic reviews of a broad set of data have identified positive associations between maternal exposures to fine particulate matter in ambient outdoor air pollution in urban areas and adverse birth outcomes. Other studies have documented adverse developmental and reproductive health outcomes in animals exposed to ONG-related chemicals used as fracturing fluids in the hydraulic fracturing process [42–45]. Although these substances may be released from operations, the exposure concentrations and complete routes of exposure have not been well characterized.

3.2. Cancer

We identified seven low certainty study outcomes from three studies that assessed the relationship between living near ONG operations and the likelihood of developing cancer [46–48]. The studies examined various types of both adult-onset and childhood cancers. Specifically, they looked at the incidence of cancers of the urinary bladder and thyroid, leukemia, all childhood cancers, childhood leukemia (and specifically acute lymphocytic leukemia), childhood non-Hodgkin's lymphoma, and childhood central nervous system tumors. Overall, the weight of evidence is insufficient for all but one of the cancer outcomes since there is only one study for each. There is mixed evidence for childhood leukemia owing to conflicting study findings.

None of the three cancer studies and their findings were upgraded to a moderate level of certainty rating. Two of the studies were ecological, conducted at the county level in Pennsylvania, and did not control for potential confounding variables [46,47]. For example, it is probable that there are social characteristics of county populations (e.g., race or ethnicity, occupation, smoking status, etc.), differing access to medical care and screening, and other environmental exposures (e.g., major roadways, particularly in a place like Allegheny County where Pittsburgh is located) that would explain some of the study findings. Fryzek et al. also incorrectly interpreted their standardized incidence ratio results, as has been noted by Saunders et al. [14]. McKenzie et al. used a case-control design to study childhood cancers in rural Colorado [48]. However, their data source was exclusively the state's cancer registry and therefore there was no comparison group made up of children without cancer. Additional research on this topic might consider incorporating a more appropriate comparison group from household surveys [49]. For studies of cancer, it is crucial for researchers to consider what would be an appropriate time frame from exposure to ONG operations to the potential development of cancer. ONG operations began in earnest in the late 2000s in Pennsylvania, but Fryzek et al. used data only through 2009; this truncated period between community exposure and cancer endpoint is a major limitation [47]. As noted elsewhere [50], the study period was not matched to the theoretical lag period or latency period for adult carcinogenesis.

ONG operations may release chemicals into the air and water, such as benzene, polycyclic aromatic hydrocarbons, and diesel exhaust [51]. Although long-term exposure to these substances, such as benzene, may increase the risk of developing certain types of cancer, the development of cancer is complex because many other non-environmental influences, such as genetics and lifestyle behaviors, also contribute to cancer risk.

3.3. Respiratory Health Outcomes

There were three low to moderate rated health outcomes from six studies evaluating the associations between living near ONG and respiratory health effects [52–57]. A single moderate certainty study with one study outcome indicated a limited weight of evidence for an association with asthma exacerbations [56]. The current literature provides a link between regulated air pollutants (ozone and particulate matter) and lung, heart disease and other respiratory health effects [58]. The influence, specifically, of ONG contributing to respiratory health outcomes is not fully understood, particularly within the context of other behavioral/lifestyle influences (e.g., smoking) exacerbating the deleterious effects of air pollutants. Additionally, there may be many other environmental sources of emissions for air pollutants including vehicles and wildfires.

Five other low-rated studies evaluated the occurrence of respiratory effects (various self-reported symptoms and hospitalizations) and found conflicting evidence for both categories. The two hospitalization studies used ecological study design, which is limited since the estimation of exposure is based on an average in the population. The three other studies documented self-reported symptoms. Health outcomes were not determined by a medical provider.

3.4. Neurological Health Outcomes

We identified four studies that assessed the relationship between living near ONG development and the likelihood of neurological health effects [52,53,55,57]. Three studies identified self-reported neurological symptoms (Elliott et al. [52]: severe headaches, dizziness; Rabinowitz et al. [55]: neurologic problems, severe headache/migraine, dizziness/balance problems, depression, difficulty concentrating/remembering, difficulty sleeping/insomnia, anxiety/nervousness, seizures; Tustin et al. [57]: migraine headache, fatigue) and yielded a limited weight of evidence for a null association with neurological health effects. The other outcome, neurological hospitalizations, had insufficient evidence, with only one positive study published [53]. VOCs are known to produce neurological effects, such as central nervous system damage, headaches, dizziness, visual disorders, loss of coordination, and memory impairment in test animals and humans [59].

ciations Level of Certainty	. Low (3)	small for age, term Moderate (9) eight	d sleep ses) Low (6)	. Low (5)	ttory, çical b, al, Low (6) estinal onted)	cancer, Low (2) nia	d cancer e and Low (2) nia
Null Associations	NA	Apgar score, small for gestational age, term birth weight	s Disordered sleep (diagnoses)	t, NA nt	Respiratory, neurological ^b , dermal, gastrointestinal symptoms (self-reported)	r Thyroid cancer, leukemia	n All childhood cancer incidence and leukemia
Positive Associations	Early infant mortality	Preterm birth and high-risk pregnancy ^a	Depression symptoms (self-reported)	Low birth weight, decreased birth weight, decreased score on infant health index	General symptoms (stress, fatigue, muscle or joint pain, any other self-reported health symptoms)	Urinary bladder cancer	Central nervous system tumors
Health Finding Category	Birth outcomes	Birth outcomes	Self-reported symptoms and diagnoses	Birth outcomes	Self-reported symptoms	Cancer	Cancer (child)
Study Type	Ecological	Retrospective cohort	Case-control and cross-sectional	Retrospective cohort	Cross-sectional	Ecological	Ecological
State	Pennsylvania	Pennsylvania	Pennsylvania	Pennsylvania	Ohio	Pennsylvania	Pennsylvania
Publication	Journal of Environmental Protection	Epidemiology	Scientific Reports	Science Advances	Cross-sectional	Public Health	Journal of Environmental Medicine
Title	There's a World Going on Underground—Infant Mortality and Fracking in Pennsylvania	Unconventional Natural Gas Development and Birth Outcomes in Pennsylvania, USA	Associations of Unconventional Natural Gas Development with Depression Symptoms and Disordered Sleep in Pennsylvania	Hydraulic Fracturing and Infant Health: New Evidence from Pennsylvania	A Community-based Evaluation of Proximity to Unconventional Oil and Gas Wells, Drinking Water Contaminants, and Health Symptoms in Ohio	Shale Gas Development and Cancer Incidence in Southwest Pennsylvania	Childhood Cancer Incidence in Pennsylvania Counties in Relation to Living in Counties with Hydraulic Fracturing Sites
Year	2017	2016	2018	2017	2018	2016	2013
First Author	Busby [34]	Casey [35]	Casey [60]	Currie [36]	Elliott [52]	Finkel [46]	Fryzek [4 7]

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				Tal	Table 3. Cont.				
First Author	Year	Title	Publication	State	Study Type	Health Finding Category	Positive Associations	Null Associations	Level of Certainty
Jemielita [53]	2015	Unconventional Gas and Oil Drilling is Associated with Increased Hospital Ufilization Rates	PLOS ONE	Pennsylvania	Ecological	Hospitalizations	Cardiology and neurology hospitalizations	Hospitalizations for various medical categories, including pulmonary hospitalizations	Low (7)
Ma [33]	2016	Time Series Evaluation of Birth Defects in Areas with and without Unconventional Natural Gas Development	Journal of Epidemiology and Public Health Reviews	Pennsylvania	Interrupted time series	Birth defects	NA	Birth defects prevalence	Low (5)
McKenzie [32]	2014	Birth Outcomes and Maternal Residential Proximity to Natural Gas Development in Rural Colorado	Environmental Health Perspectives	Colorado	Retrospective cohort	Birth outcomes and birth defects	Congenital heart defects and neural tube defects	Oral clefts, preterm birth +, term low birth weight +, decreased term birth weight +	Low (6)
McKenzie [48]	2017	Childhood Hematologic Cancer and Residential Proximity to Oil and Gas Development	PLOS ONE	Colorado	Case-control	Cancer (child)	Childhood acute lymphocytic leukemia	Childhood non-Hodgkin's lymphoma	Low (8)
Peng [54]	2018	The Health Implications of Unconventional Natural Gas Development in Pennsylvania	Health Economics	Pennsylvania	Ecological	Hospitalizations	Pneumonia hospitalizations	Hospitalizations for acute myocardial infarction, chronic obstructive pulmonary disease (COPD), asthma, upper respiratory infections	Low (6)
Rabinowitz [55]	2015	Proximity to Natural Gas Wells and Reported Health Status: Results of a Household Survey in Washington County, Pennsylvania	Environmental Health Perspectives	Pennsylvania	Cross-sectional	Self-reported symptoms	Dermal and upper respiratory symptoms (self-reported)	Lower respiratory, cardiovascular, gastrointestinal, neurological symptoms (self-reported)	Low (7)
Rasmussen [56]	2016	Association Between Unconventional Natural Gas Development in the Marcellus Shale and Asthma Exacerbations	JAMA Intern Med.	Pennsylvania	Nested case-control	Respiratory diagnoses	Asthma exacerbations	NA	Moderate (8)

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Table 3. Cont.

First Author	Year	Title	Publication	State	Study Type	Health Finding Category	Positive Associations	Null Associations	Level of Certainty
Stacy [38]	2015	Perinatal Outcomes and Unconventional Natural Gas Operations in Southwest Pennsylvania	PLOS ONE	Pennsylvania	Retrospective cohort	Birth outcomes	Decreased birth weight and small for gestational age	Premature birth+	Moderate (8)
Steinzor [61]	2013	Investigating Links Between Shale Gas Development and Health Impacts Through a Community Survey Project in Pennsylvania	New Solutions	Pennsylvania	Cross-sectional	Self-reported symptoms	Throat irritation, sinus problems, nasal irritation, eye burning, persistent cough, frequent nose bleeds, loss of sense of smell, severe headaches, skin rashes, swollen painful joints symptoms (self-reported)	Joint pain, sleep disturbances, shortness of breath, forgettulness, sleep disorders, feeling weak and tired, increased fatigue, lumbar pain, muscle aches or pain, diarrhea symptoms (self-reported)	Low (3)
Tustin [57]	2016	Associations between Unconventional Natural Gas Development and Nasal and Situs, Migraine Headache, and Fatigue Symptoms in Pennsylvania	Environmental Health Perspectives	Pennsylvania	Cross-sectional	Self-reported symptoms	Chronic rhinosinusitis (CRS), migraine headache, and fatigue symptoms in combination (self-reported): CRS and fatigue, migraine headache and fatigue, and all three symptoms together	NA	Low (5)
Whitworth [39]	2017	Maternal Residential Proximity to Unconventional Gas Development and Perinatal Outcomes among a Diverse Urban Population in Texas	PLOS ONE	Texas	Retrospective cohort	Birth outcomes	Preterm birth and fetal death	Small for gestational age and term birth weight	Low (7)
Whitworth [40]	2018	Drilling and Production Activity Related to Unconventional Gas Development and Severity of Preterm Birth	Environmental Health Perspectives	Texas	Nested case-control	Birth outcomes	Preterm birth	NA	Low (9)

Health				Number o	Number of Studies Per Certainty Rating	er Certaiı	nty Rating		
Outcome	Total Number of Studies	Health Outcomes	Reference	Positive Association	ion	Z	Null Association	u	Weight of Evidence
Categories				High Moderate	Low	Low	Moderate	High	
		Congenital heart defects	McKenzie [32]		1				Insufficient
Birth defects	C	Oral clefts	McKenzie [32]			1			Insufficient
	I	Neural tube defects	McKenzie [32]		1				Insufficient
		Birth defects prevalence	Ma [33]			1			Insufficient
		Decreased term birth weight or low birth weight	Casey [35]; Currie [36]; Hill [37]; McKenzie [32]; Stacy [38]; Whitworth [39]	И	-	7	1		Mixed
		Early infant mortality	Busby [34]		1				Insufficient
		Fetal death	Whitworth [39]			1			Insufficient
Birth outcomes	œ	Gestation period	Hill [37]				1		Insufficient
		Low infant health index	Currie [36]		1				Insufficient
		Low APGAR score ^a	Casey [35]; Hill [37]	1			1		Mixed
		Preterm/premature birth	Casey [35]; Hill [37]; McKenzie [32]; Stacy [38]; Whitworth [39,40]	1	ę		1		Mixed
		Small for gestational age	Casey [35]; Hill [37]; Stacy [38]; Whitworth [39]	2			1		Mixed
		Cancer incidence (childhood)	Fryzek [47]			1			Insufficient
		Leukemia (childhood non-specific and acute lymphocytic leukemia)	Fryzek [47]; McKenzie [48]		1	-			Mixed
Cancer	б	Non-Hodgkin's lymphoma (childhood)	McKenzie [48]						Insufficient
		CNS tumors ^b (child)	Fryzek [47]		1				Insufficient
		Urinary bladder	Finkel [46]		1				Insufficient
		Thyroid	Finkel [46]			1			Insufficient
		Leukemia	Finkel [46]			-			Insufficient
Cardiovascular	¢	Hospitalizations	Jemielita [53]; Peng [54]		1	1			Mixed
)	Self-reported symptoms	Rabinowitz [55]			1			Insufficient
Dermal	2	Self-reported symptoms	Elliott [52]; Rabinowitz [55]		1	1			Mixed
Gastrointestinal	c	Salf-monoted commone	Elliott [52]. Rahinowitz [55]			ç			Limited-failing to show

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Table 4. Cont.

Outcome Definition CategoriesTotal Number of StudiesHath OutcomeReferencePositive AssociationNull AssociationWeight of EvidenceActionation CategoriesdistunctioninterventioninterventioninterventioninterventioninterventioninterventionNeurological Unuber4Ellerported symptomsjenelite [53]jenelite [53]interventioninterventioninterventionNeurological Unuber4Self-reported symptomsElliot [52]; Rusin [57]jjinterventioninterventionNeurological Unuber2Self-reported symptomsCasey [36]; Tustin [57]jjjinterventionSelf-reported symptomsElliot [52]; Rusin [57]jjjjjinterventionSelf-reported symptomsElliot [52]; Rusin [57]jjjjjinterventionSelf-reported symptomsElliot [52]; Tustin [57]jjjjjjSelf-reported symptomsInterventionRanusen [56]jjjjjjSelf-reported symptomsElliot [52]; Tustin [57]jjjjjjSelf-reported symptomsInterventionRanusen [56]jjjjjSelf-reported symptomsElliot [52]; Tustin [57]jjjjjjSelf-reported symptomsElliot [52]; Tustin [57]jjjjjjSelf-rep	Health				2	Number of Studies Per Certainty Rating	tudies Per	Certain	y Rating	
$eq:high_high_high_high_high_high_high_high$	Outcome	Total Number of Studies	Health Outcomes	Reference	Positive	Association	-	N	II Association	Weight of Evidence
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	Categories			1		foderate				
$ \begin{array}{c c c c c c c c c c c c c c c c c c c $			Hospitalizations	Jemielita [53]			1			Insufficient
$ \begin{array}{c cccc} & & \label{eq:constraint} & eq:con$	Neurological	4	Self-reported symptoms	Elliott [52]; Rabinowitz [55]; Tustin [57]				e		Limited-failing to show an association
	Pevcholomical	c	Self-reported symptoms	Casey [36]; Tustin [57]			1	1		Mixed
Self-reported symptoms Elliott [52]; Rabinowitz [55], Tustin [57] 1 2 6 Hospitalizations Jemelita [33]; Peng [54] 1 1 7 Asthma exacerbation Rasmussen [56] 1 1 1 2 Self-reported symptoms (multiple) Elliott [52]; Tustin [57] 2 1 2 4 Hospitalizations (all) Jemelita [53] 1 2 1	in openion de t	٧	Diagnosed sleep disturbances	Casey [36]			1			Insufficient
6 Hospitalizations Jemielita [53]; Peng [54] 1 1 7 Asthma exacerbation Rasmussen [56] 1 1 2 Self-reported symptoms (multiple) Elliott [52]; Tustin [57] 2 Hospitalizations (all) Jemielita [53] 1			Self-reported symptoms	Elliott [52]; Rabinowitz [55]; Tustin [57]			1	2		Mixed
Asthma exacerbation Rasmussen [56] 1 2 Self-reported symptoms (multiple) Elliott [52]; Tustin [57] 2 Hospitalizations (all) Jemielita [53] 1	Respiratory	6	Hospitalizations	Jemielita [53]; Peng [54]			1	1		Mixed
2 Self-reported symptoms (multiple) Elliott [52]; Tustin [57] 2 Hospitalizations (all) Jemielita [53] 1			Asthma exacerbation	Rasmussen [56]		1				Limited
- Hospitalizations (all) Jemielita [53] 1	Other	c	Self-reported symptoms (multiple)	Elliott [52]; Tustin [57]			2			Limited
		I	Hospitalizations (all)	Jemielita [53]				1		Insufficient

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3.5. Other Health Outcomes

We found limited evidence of a positive association between general multiple self-reported symptoms and living near ONG development, with two studies assessing this relationship [52,57]. The two studies however characterized symptoms differently: Elliott and her colleagues combined feeling stress, fatigue, muscle or joint pain, or any other health symptom into a "general health symptom" grouping [52]; while Tustin and his co-authors found significant effects only when at least two of the three symptoms they considered—chronic rhinosinusitis, migraine, and fatigue—were experienced jointly [57].

Two epidemiologic studies evaluated a variety of indicators of psychological well-being, including depression, anxiety and sleep disturbances [60,61]. Measures of mental health are not necessarily a result of direct exposure to substances emitted from oil and gas operations but could be indirectly associated with non-chemical environmental stressors such as noise, light, odors, or social stress of living near a hotly debated, politicized, and potentially risky industry. For example, studies have shown associations between living in areas with increased noise and traffic, such as by airports, with increased psychological symptoms [62–65].

There was mixed evidence for self-reported dermal symptoms, self-reported psychological symptoms, and cardiovascular hospitalizations. Other health effects, including neurological and all hospitalizations, diagnosed sleep disturbances, and self-reported cardiovascular symptoms, had insufficient evidence due to a single low-rated study per outcome. There was a demonstrated lack of evidence (no association) for gastrointestinal self-reported symptoms. Three studies evaluated self-reported dermal symptoms, such as rash, irritation, burning, itching, and hair loss, in relation to ONG in Pennsylvania, resulting in mixed evidence [52,55,61]. Skin-related health effects may be possible due to direct exposure to soil or water. However, the routes of exposure to ONG-related chemicals were not well characterized in these studies and encounters with other skin irritants were not documented, making it difficult to interpret these conclusions.

4. Discussion

In this paper, we summarized the observational epidemiologic literature on the health effects of populations living near ONG operations and assessed the methodological rigor of the studies published to date. Specifically, we used a modified systematic review framework, adapted from GRADE, the Navigation Guide, and guidance from OHAT, to determine the level of certainty that the study findings represent the true effect of exposures to ONG-related substances, and to make overarching weight-of-evidence determinations for a variety of health outcomes.

The strength of our review lies in its transparency and objectivity. We adapted previous systematic review guidelines to make the criteria for evaluating studies as clear as possible. We considered a wide variety of study evaluation questions to represent those domains. Our review framework can also be applied to other research questions in environmental health. For researchers, policymakers, and public health practitioners, this type of review can swiftly help elucidate key findings and gaps in the knowledge base that need to be addressed.

We found 20 published epidemiologic studies that evaluate potential associations between ONG operations and health outcomes. These studies assessed 32 different health outcomes ranging from self-reported symptoms to confirmed disease diagnoses. Since only a few outcomes were covered by multiple studies, there was insufficient weight of evidence for most health outcomes. We found studies of populations living near ONG operations provide limited evidence (modest scientific findings that support the outcome, but with significant limitations) of harmful health effects including asthma exacerbations and various self-reported symptoms. For all other health outcomes, we found conflicting evidence (mixed), insufficient evidence, or in some cases, a lack of evidence of the possibility for harmful health effects.

There are important limitations to our approach. First, it is not a meta-analysis as the current line of inquiry, including different exposure measures (and surrogates), health outcomes, and

geographic/geologic locations, is not suited to conducting a meta-analysis. Second, although we clearly stated our criteria for upgrading a study to a moderate or high level of certainty ranking, the number of study evaluation questions and the ranking cutoffs may still be viewed as arbitrary since Rooney et al. (2016) compares these systematic review methods and notes that the scoring of studies may be influenced by the number of elements and may not account for the differences in relative importance across the risk of bias domains [66]. Study certainty is difficult to quantify, but we used a quantifiable framework and did not allow factors such as media coverage or other publicity (positive or negative) to color our ranking system.

The majority of findings from the studies were ranked as low certainty, primarily due to limitations of the study designs that make it difficult to establish clear links between exposures to substances potentially emitted directly from ONG operations and the health outcomes evaluated. These limitations are inherent to observational epidemiologic studies and include indirect exposure measurements, confounding bias, and subjective methods to determine health outcomes. The field of environmental health incorporates these types of studies along with exposure and risk assessments to inform public health and policies. In addition to these factors, differences in the observational epidemiologic study types (e.g., retrospective cohort, case-control, ecological) make it difficult to compare results across studies with various health outcomes. These epidemiologic studies may also reflect the interactions of non-chemical or chemical stressors that may or may not be related to ONG operations that can contribute to adverse health outcomes in a population. Study quality has improved in recent years with better exposure measures and more thorough methods to account for possible confounders.

Although these observational epidemiologic studies alone are not sufficient to determine causality, they provide helpful information to direct further investigation into the public health implications of ONG activity near residential areas. Taken together, these studies make it clear that the identities and exposure levels of substances people are exposed to when living, working, or going to school near ONG development have not been well characterized. Epidemiologic studies that include more controlled designs with direct measurement of exposure and diagnosed health outcomes are needed to confirm or dispute the associations published in the literature. Incorporating a health impact assessment framework within an epidemiologic study may be useful. One such framework, developed by the Agency for Toxic Substances and Disease Registry (ATSDR) can be used to assess the health impacts of multiple chemicals and stressors [67].

Additionally, we have little empirically driven understanding of the factors (biological, geological, meteorological, and social) that drive ONG-related exposure patterns and vulnerability to such exposures. For example, there may be regional differences across the U.S., with varying technological controls or regulatory environments. Researchers should integrate community members [68–70] and concepts of health equity and environmental justice [69] into their research approaches. They should also consider using policy as a starting point rather than the conclusion in order to evaluate policies and ONG industry practices that have been implemented thus far (e.g., setback distances, number of wells drilled per well pad, etc.). Having an understanding and familiarity with the populations at risk for health effects from ONG development across states and regions within states is also important to prioritize evidence-based health-protective policy interventions and to improve public health prevention strategies [52,68–71].

ONG regulatory policy has not been informed by robust epidemiologic research literature. Now, 15–20 years since the widespread application of hydraulic fracturing and horizontal drilling in states as diverse as Colorado, Pennsylvania, Texas, and Kansas, the epidemiologic literature on the potential health effects of ONG operations is still inadequate to definitively guide policy, as evidenced by the mainly low certainty and conflicting studies reviewed here. Regulators and policymakers, then, should work with public health researchers to pose specific questions that need to be answered, and partner with public health officials to evaluate the public's concerns. Public health officials should continue to monitor health concerns in areas with substantial ONG operations through centralized data collection and analysis. Multi-state collaborations should be considered to collect consistent data from differing

oil and gas basins across the United States with the aim to more comprehensively evaluate the potential for adverse health effects.

Supplementary Materials: The following materials are available online at http://www.mdpi.com/1660-4601/16/12/2123/s1, Tables S1–S20: Study evaluation individual assessments, Table S21: Full summary details of epidemiologic studies included in systematic review, Table S22: Summary of answers to study evaluation questions.

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Response of Michael Krancer

IN THE COURT OF COMMON PLEAS ALLEGHENY COUNTY, PENNSYLVANIA

IN RE:	: SUPREME COURT OF PENNSYLVANIA
	: 71 W.D. MISC. DKT. 2017
THE FORTY-THIRD STATEWIDE	:
	: ALLEGHENY COUNTY COMMMON PLEAS
INVESTIGATING GRAND JURY	: CP-02-MD-5947-2017
	:
	: NOTICE NO. 42

RESPONSE TO CERTAIN ALLEGATIONS IN INVESTIGATING GRAND JURY REPORT NO. 1

Pursuant to the Court's April 7, 2020 Order, and by his undersigned counsel, respondent Michael Krancer hereby responds to the allegations in the report that may be construed as offering constructive or critical guidance to him. Such allegations are found at pages 6-7 and 62-63 of the report, and state as follows.

Mr. Krancer was the Secretary of the Department of Environmental Protection ("DEP") from January 18, 2011 through April 13, 2013. The gravamen of the allegations is that, based upon a March 23, 2011 email from DEP's then Executive Deputy Secretary John Hines, "any actions, NOVs, and such" required approval of the Executive Deputy Secretary and Dana Aunkst, with "final clearance from" then Secretary Krancer.

The report accurately and fairly states that Mr. Krancer testified before the Grand Jury that this was a "misunderstanding." However, the report unfairly omits reference to an email authored the very next day by Dana Aunkst, an email that was presented to the Grand Jury, in which Mr. Aunkst apologized for the confusion caused by the Hines email of the day before. Although we are unable to have access to that email because it is a Grand Jury document, that email, as Mr. Krancer recalls it, specifically clarified that no such "final clearance" by the Secretary was necessary. Mr. Krancer was shown this email in the Grand Jury; yet no mention of it is made in the report. Given (i) the immediate correction that was made to Hines's email,

WG Ex. 70

and (ii) the fact that the Grand Jury report specifically emphasizes that, although the communication was based upon a misunderstanding, "employees who learned of the email did not take it that way," this omission leaves an unfair, incomplete, inaccurate, and impression. Even if "employees who learned of the email did not take it that way," it was corrected the very next day. In fairness, the next day email (and this Response) should be added to the report.

It is also important for context to note that, at the time of the Hines email, as Mr. Krancer recollects it now, nine years later, the Department was specifically undertaking (or was about to undertake) a formal consistency review regarding the different Regional Offices of DEP for NOVs and enforcement actions in the Oil and Gas program. That accounts for particular attention's being directed toward DEP actions at that time relating to oil and gas operations. The results of that review process were released in November 2011. This, Mr. Krancer believes, is the background and context of the Hines email.

Accordingly, for the foregoing reasons, respondent Krancer respectfully requests that this Response, and the next day Aunkst email, be attached to the report before it is made part of the public record.

Respectfully submitted,

/s/Joseph G. Poluka JAMES T. SMITH Pennsylvania Attorney I.D. 39933 JOSEPH G. POLUKA Pennsylvania Attorney I.D. 42035 **BLANK ROME LLP** One Logan Square 130 North 18th Street Philadelphia, PA 19103 (215) 569-5624

Dated: April 28, 2020

<u>WG Ex. 70</u>

Original Message
 Aunkst, Dana
 Aunkst, Dana
 Sent: Thursday, March 24, 2011 12:30 PM
 To: Taber, Nels; Burch, Kelly; Jugovic, George
 Subject: Clarification on NOV Issue

John asked that I forward this message to you and your staff.

This message is to clarify my directive from March 23, 2011, regarding NOVs related to Marcellus Shale activities. It appears that message has caused significant confusion and consternation, and for that I apologize.

To be clear, we have in place an established MAA process. That process should be continued to be followed, as it provides appropriate notification to the Deputy Secretary and the Secretary regarding high-profile actions proposed by field staff

Field inspections are to continue as they have always been done. When violations are discovered, they should continue to be documented in inspection reports. For Marcellus-related violations that do not rise to the MAA level, however, prior to sending an NOV, that NOV must be forwarded to the Deputy Secretary for Field Operations. Staff will be notified when they may proceed with taking the notice action by sending the NOV.

Thanks for your cooperation.

John Hines

Let me know if you have any questions, guys. Thanks.

Dana





Response of Scott Perry

IN THE COURT OF COMMON PLEAS

ALLEGHENY COUNTY, PENNSYLVANIA

IN RE:	: SUPREME COURT OF PENNSYLVANIA
	: 71 W.D. MISC. DKT. 2017
THE FORTY-THIRD STATEWIDE	:
	: ALLEGHENY COUNTY COMMON PLEAS
INVESTIGATING GRAND JURY	: CP-02-MD-5947-2017
	:
	: NOTICE 42

MOTION FOR INCLUSION OF RESPONSE OF DEPARTMENT OF ENVIRONMENTAL PROTECTION WITNESS SCOTT PERRY TO GRAND JURY REPORT

1. The Forty-Third Statewide Investigating Grand Jury has produced a Report that outlines the Commonwealth's findings on, *inter alia*, the issues that Department of Environmental Protection ("DEP") has had in exercising its regulatory authority against companies that use hydraulic fracturing ("fracking") to harvest natural gas in Pennsylvania. That report has been referred to by this Court in prior orders as Investigating Grand Jury Report No. 1.

2. DEP Deputy Secretary of the Office of Oil and Gas Management, Scott Perry, testified before the grand jury, and his testimony is quoted in Investigating Grand Jury Report No. 1. He is also specifically named in multiple places in the Report.

3. On April 7, 2020, this Court entered an Order stating that pursuant to 42 Pa.C.S. § 4552(e), Mr. Perry would be permitted to prepare and submit a response to allegations made against him in Investigating Grand Jury Report No. 1 that "may be construed as offering constructive or critical guidance to him."

4. On April 20, 2020, this Court entered an Order permitting disclosure of the transcript of Mr. Perry's own testimony in front of the Forty-Third Grand Jury pursuant to 42 Pa.C.S. § 4549 so that he could properly prepare his Response to the Report in accordance with this Court's April 7, 2020 Order.

5. This Court further granted Mr. Perry until May 8, 2020 to file his Response.

6. Mr. Perry has reviewed the Report and his Grand Jury Testimony.

7. Pages 77-78 of the Report do not provide a complete and accurate description of the joint efforts by the Pennsylvania Department of Health (DOH) and the Pennsylvania Department of Environmental Protection (DEP) to incorporate health questions into DEP's forms used when registering complaints from complainants. Accordingly, Mr. Perry, who is specifically identified in an unfavorable light in those paragraphs of the Report, asks that Attachment A (which is the information set forth in ¶¶ 8-13 below) be appended as his Response to any public release of the Report, which to date, has remained under seal.

8. The Grand Jury Report at pp. 77-78 talks about efforts at incorporating health questions into DEP's environmental complaints. At page 77, the Report states that "DOH had proposed adding an 'active' box to DEP's water quality complaint form, which would require a DEP employee registering a complaint to ask the complainant whether they had any health concerns." The Report further states that this idea was opposed by "DEP, principally through Scott Perry, the Deputy Secretary of the Oil and Gas Management Program" because "it would constitute a 'leading question' and [a health complaint] was outside the area of DEP's expertise." The Report then states that DEP agreed to a 'passive' box on the complaint form; meaning if the complainant mentioned a health issue, unprompted, a notation to that effect would occur and be passed to DOH."

9. The Report states at page 77 that "[a]dditionally, DOH and DEP were only discussing adding a health question to water quality complaints, but health complaints regularly pertained to air quality, truck traffic, and other effects of unconventional oil and gas operations[]" and "DOH was interested in developing ways they could gather information about these health issues as well."

10. The Report further states at page 77 that DOH "continued to push DEP to take further action aimed at gathering public health information, including adding an 'active' question on health. Ultimately, however, Scott Perry refused to agree to more than adding the passive box to the water quality complaint form, and the [November 2018] meeting, which was contentious at times, ended." The Report states at page 78 that after the November 2018 meeting, DEP cancelled all future regularly scheduled meetings by DOH without discussion and by deleting meetings from a shared outlook calendar.

11. These allegations of the Report do not accurately reflect what occurred. The decision to include a "passive" box to the DEP water quality complaint form regarding health concerns - as opposed to an "active" box - was not a unilateral decision made by Mr. Perry or by DEP but rather a joint decision by DEP *and* DOH. Mr. Perry and his counterpart at DOH - a DOH Deputy Secretary - discussed this matter and jointly agreed that the best procedure to employ would be the passive box, and not an active box. The DOH Deputy Secretary told Mr. Perry that he did not support adding an "active" box because it would constitute a "leading question." The use of the phrase, leading question, originated with the DOH Deputy Secretary; not with Mr. Perry.

12. DEP did not limit the health question to water quality complaints but expanded it to include all investigations conducted by DEP where the DEP employee encountered a complainant with health concerns. In all such matters, DEP would forward the complainant's contact information to DOH.

13. Moreover, the meetings between DEP and DOH stopped because DOH had not asked for another meeting and also because the objective of the meetings - to make sure there was a flow of information from DEP to the DOH registry - was accomplished. Mr. Perry notes that he would be willing to meet in the future with DOH provided there was an agenda with new matters to discuss.

WHEREFORE, for the reasons set forth above, Scott Perry respectfully requests that the Court include his Response (Attachment A) to the Investigating Grand Jury Report No. 1 if and when such Report is publicly released.

Respectfully submitted,

/s/ Linda Dale Hoffa

LINDA DALE HOFFA DILWORTH PAXSON LLP 1500 Market Street, Suite 3500E Philadelphia, PA 19102 Phone: (267) 767-6275 (mobile) Email: lhoffa@dilworthlaw.com

Dated: 5/8/2020

<u>WG Ex. 70</u>

ATTACHMENT A

RESPONSE OF MR. SCOTT PERRY, DEPUTY SECRETARY, PENNSYLVANIA DEPARTMENT OF ENVIRONMENTAL PRODUCTION. TO GRAND JURY REPORT #1

43rd STATEWIDE INVESTIGATING GRAND JURY

The Grand Jury Report at pp. 77-78 talks about efforts at incorporating health questions into DEP's environmental complaints. At page 77, the Report states that "DOH had proposed adding an 'active' box to DEP's water quality complaint form, which would require a DEP employee registering a complaint to ask the complainant whether they had any health concerns." The Report further states that this idea was opposed by "DEP, principally through Scott Perry, the Deputy Secretary of the Oil and Gas Management Program" because "it would constitute a 'leading question' and [a health complaint] was outside the area of DEP's expertise." The Report then states that DEP agreed to a 'passive' box on the complaint form; meaning if the complainant mentioned a health issue, unprompted, a notation to that effect would occur and be passed to DOH."

The Report states at page 77 that "[a]dditionally, DOH and DEP were only discussing adding a health question to water quality complaints, but health complaints regularly pertained to air quality, truck traffic, and other effects of unconventional oil and gas operations[]" and "DOH was interested in developing ways they could gather information about these health issues as well."

The Report further states at page 77 that DOH "continued to push DEP to take further action aimed at gathering public health information, including adding an 'active' question on health. Ultimately, however, Scott Perry refused to agree to more than adding the passive box to the water quality complaint form, and the [November 2018] meeting, which was contentious at

times, ended." The Report states at page 78 that after the November 2018 meeting, DEP cancelled all future regularly scheduled meetings by DOH without discussion and by deleting meetings from a shared outlook calendar.

These allegations of the Report do not accurately reflect what occurred. The decision to include a "passive" box to the DEP water quality complaint form regarding health concerns - as opposed to an "active" box - was not a unilateral decision made by Mr. Perry or by DEP but rather a joint decision by DEP *and* DOH. Mr. Perry and his counterpart at DOH - a DOH Deputy Secretary - discussed this matter and jointly agreed that the best procedure to employ would be the passive box, and not an active box. The DOH Deputy Secretary told Mr. Perry that he did not support adding an "active" box because it would constitute a "leading question." The use of the phrase, leading question, originated with the DOH Deputy Secretary; not with Mr. Perry.

DEP did not limit the health question to water quality complaints but expanded it to include all investigations conducted by DEP where the DEP employee encountered a complainant with health concerns. In all such matters, DEP would forward the complainant's contact information to DOH.

Moreover, the meetings between DEP and DOH stopped because DOH had not asked for another meeting and also because the objective of the meetings - to make sure there was a flow of information from DEP to the DOH registry - was accomplished. Mr. Perry notes that he would be willing to meet in the future with DOH provided there was an agenda with new matters to discuss.

DATED: 5/8/2020

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Elevated sediment radionuclide concentrations downstream of facilities treating leachate from landfills accepting oil and gas waste

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ARTICLE INFO

Keywords: Oil and Gas Waste Landfills NORM Stream Impacts

ABSTRACT

Management of oil and gas (O&G) waste streams from extraction of unconventional reservoirs challenges the sustainable development of these reservoirs. Landfilling of waste materials is an emerging strategy for unconventional O&G waste disposal. However, the effectiveness of effluent management systems designed for historical landfill waste streams in treating O&G waste is not established. This creates the potential for contamination associated with landfills accepting O&G waste. Yet, tracers of O&G waste are not necessarily included in routine effluent monitoring and environmental surveillance monitoring is too sparse to reliably detect this contamination. This study reviewed administrative records and analyzed grab samples of surface waters and stream sediments near effluent outfalls from facilities accepting O&G waste to evaluate this potential contamination. Administrative records are conflicting and inadequate, with only one landfill out of twenty-five agreeing within a factor of two between waste delivery and receipt volume reporting in 2019. Moreover, total radium was enriched in sediments downstream of effluent discharges, up to 4x relative to upstream values, magnitudes consistent with sediment accumulations downstream of known O&G waste inputs. Water chemistry measurements indicate that the largest upstream to downstream changes are consistent with O&G waste chemistry. These findings suggest landfill effluent influenced by O&G waste should be carefully scrutinized to avoid potential contamination of surface waters.

1. Introduction

The rapid development of unconventional oil and gas (O&G) reserves has increased the flux of both solid and liquid waste, fluxes proportionally much greater than those generated from traditional conventional well development on a per well basis. Solid wastes include materials from pad development and drill cuttings. Drill cutting wastes from unconventional wells may contain more total naturally occurring radioactive materials (NORM) than conventional wells for two reasons. Geochemically, the shale itself contains more NORM as compared to the sandstone and limestone reservoirs holding conventional oil and reserves (Huang et al., 2017). Physically, the horizontal bore is usually much longer than the vertical bore and a larger proportion of the drill cuttings are composed of the NORM rich shale due to the directional drilling. The Pennsylvania Department of Environmental Protection (Pennsylvania Department of Environmental Protection, 2016) reported drill cuttings with the following ranges: ²²⁶Ra (below detection limit to 640 Bq/kg) and ²²⁸Ra (0.37–104 Bq/kg).

In addition, the volumes of fluids used in hydraulic fracturing are orders of magnitude greater than conventional O&G extraction, due to the increased length of the well bore, often exceeding several kilometers, and the substantial volume of water injected during the fracturing process (Stolz and Griffin, 2022). It is estimated that over 1 trillion gallons of waste fluids are now being generated annually in the United States, as a result of drilling and production (i.e., flowback, produced water) (Stolz and Griffin, 2022). The Marcellus Shale formation is one of the richest unconventional gas reservoirs in the world and underlies substantial portions of New York, Pennsylvania, Ohio, and West Virginia (Stolz and Griffin, 2022). Marcellus formation water has some of the highest values of gross alpha, gross beta, and radium (²²⁶Ra) reported for shale production waters (Huang et al., 2017). The PADEP (Pennsylvania Department of Environmental Protection, 2016) reported produced water samples with the following ranges: ²²⁶Ra (2.8–984 Bq/L) and ²²⁸Ra (0.96-70 Bq/L).

The potential for increased fluxes of NORM through shallow terrestrial systems due to increased fluxes of unconventional O&G brines has

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been recognized for more than a decade (Kargbo et al., 2010). Produced water recycling can mitigate some of this increased flux, but eventually fluids, particularly reject materials from reverse osmosis water treatment, need to be disposed of (Scanlon et al., 2020). Dedicated brine treatment facilities accumulate radionuclides at the facilities and in the surface water systems used for wastewater discharge (Lauer et al., 2018). Class II injection well capacity (i.e., deep formation waste disposal capacity) is limited (Lutz et al., 2013) and substantial transport costs can discourage this disposal method. Sanitary landfills in several states (i.e., Pennsylvania (PA), New York (NY)) have accepted the liquids as long as they are "immobilized" using an absorbent such as wood chips or sawdust. Similarly, solid wastes (i.e., drill cuttings), may be buried on site, sent to sanitary landfill, or a hazardous waste facility if necessary (Warner et al., 2022). These wastes, when deposited in a landfill, can leach and be reintroduced to shallow terrestrial systems via landfill leachate discharges. For example, leachate from the Westmoreland Sanitary Landfill (Rostraver, PA) had elevated ²²⁶Ra and ²²⁸Ra content (4.4 and 9.3 Bg/L respectively). When the flux of leachate to the Belle Vernon Publicly Owned Treatment Works (POTW) for treatment is considered (i.e., 400 to 1200 m^3/day) this is a substantial flux of radioactive material.

While there are limited data on the actual ecological impacts of NORM associated with unconventional gas development, O&G brines in offshore and coastal environments impact behavior, growth, reproduction, and immunity in ecological communities (Holdway, 2002). We expect similar ecological impacts in terrestrial fresh water ecosystems. In particular, radium is carcinogenic (Raabe, 1984) and, in freshwater ecosystems, accumulates in mussels (Bollhöfer et al., 2011; Jeffree and Simpsonf, 1984). Therefore, there is strong potential for environmental radium to be introduced to local foodwebs. The limited information on ecological impacts of radium in these ecosystems underlines the need to clarify patterns of radium contamination and to devise strategies to prevent further contamination. This study is meant to address both needs.

Despite this increased flux of O&G waste and the potential for transfer of contaminants to natural systems, there remains limited data available to evaluate potential contamination from O&G waste in treated effluent. This study combines regulatory data and grab samples of sediment and water from surface waters in PA, Ohio (OH), and NY near outfalls of landfill leachate treatment system and POTW discharge outfalls to evaluate 1) the accessibility and accuracy of landfill reporting of O&G wastes fluxes, 2) the total flux of leachate from landfills accepting O&G waste, and 3) potential impacts on surface waters in areas downstream of treated leachate discharge outfalls. This study builds on previous work (Cantlay et al., 2020; Stolz et al., 2022; Stolz and Griffin, 2022) but focuses attention on stream sediments as a potential means to evaluate and detect long-term, accumulative impacts of inadequate O&G waste management.

2. Methods

2.1. Landfill and POTW selection

A list of landfills that had accepted unconventional and conventional O&G waste from Pennsylvania was compiled from the Pennsylvania Department of Environmental Protection's (PADEP) Oil and Gas Well Waste Report between January 2010 and December 2020 (Pennsylvania Department of Environmental Protection, 2022a) (Fig. 1, Table S1). Landfills that did not accept O&G waste were not included in this list. Oil and gas producers are required to report the amount of waste they produce and disposal method to PADEP (liquid waste in barrels and solid waste in tons). These data are made available for each landfill in the Oil and Gas Well Waste Report. While reporting is required, PADEP does not confirm the accuracy of the reported information.

Once these landfills were identified, their National Pollution Discharge Elimination Discharge System (NPDES) permits were obtained to identify landfills permitted to treat and discharge their own effluent. In addition, we examined NPDES permits for publicly owned treatment works (POTWs) handling leachate from the selected landfills. NPDES websites for New York, Ohio, and Pennsylvania (New York Department of Environmental Conservation, 2022a; Ohio Environmental Protection Agency, 2022; Pennsylvania Department of Environmental Protection, 2022b) were used to access final permits. In the case of NY, draft permits were also available. Only five landfills in West Virginia took Pennsylvania O&G waste and the state's NPDES permits are not available online. Therefore West Virginia landfills were excluded from further examination in this study. A subset of facilities in New York, Pennsylvania, and Ohio were selected based on travel logistics dictated by COVID-19 risk mitigation measures in place during the sampling period. Potential sample locations were prioritized by

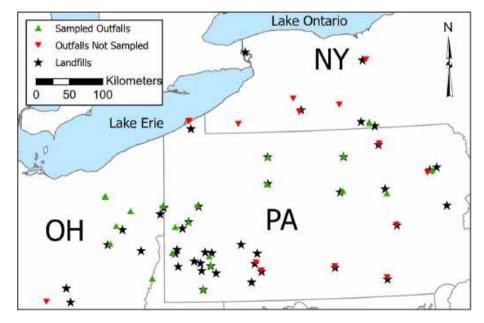


Fig. 1. Location of landfills in Ohio, Pennsylvania, and New York that accepted PA O&G waste between January 2010 and December 2020. Outfalls for either landfills or POTWs treating leachate from these landfills are symbolized based on whether or not they were sampled.

proximity (within a two-hour drive of Duquesne University) and then by the quantity of O&G waste the landfill had accepted according to the PADEP oil and gas waste report.

2.2. Gathering Landfill reports

New York regulations subpart 363-8 Recordkeeping and Reporting require landfills in the state to complete an annual report using an online form (New York Department of Environmental Conservation, 2022b) (6 CRR-NY 363-8.2). Reports include estimates of landfill capacity used in the previous year, remaining capacity, any capacity to be added in the upcoming year, and the remaining life of the landfill. Municipal solid waste, industrial, and ash landfill annual reports include detailed, monthly records of materials accepted with specific categories for O&G drilling waste. In contrast, New York construction and demolition landfill annual reports are less specific with categories only for aggregate/concrete, processed construction/demolition waste, contaminated soils, and other. Information on the origin of waste is also provided (state and county). In these annual reports, both landfill types also document the volume of leachate produced monthly, whether leachate was sent offsite, lists of offsite leachate treatment facilities used during the year, leachate monitoring activities and results, and landfill gas production and use (flared or used to create energy).

Ohio landfills must submit annual reports to the Ohio Environmental Protection Agency through an online form (Ohio Environmental Protection Agency, 2023). Ohio annual reports include remaining landfill capacity, recently added capacity, information on tipping fees, leachate testing results, scrap tire disposal, and details on the waste accepted. Waste accepted is broken down by waste type, as well as by state and county of origin. In Ohio, O&G waste is not a separate waste type on the form. Annual reports in Ohio do provide additional information on leachate management including monthly records of leachate volumes sent to each offsite treatment facility and names and addresses of those facilities.

Pennsylvania landfills submit an annual operations report to the PADEP (Pennsylvania Department of Environmental Protection, 2022c). Information reported includes landfill capacity, the amount and type of waste accepted, any radioactive materials detected and disposal decisions on whether to accept it, acreage revegetated or seeded, groundwater monitoring plans and results, landfill gas production and use, and landfill topography. In order to accept residual waste, including O&G waste, municipal landfills must submit a Form U permit modification. This form is required for every facility and every waste type from that facility the landfill wants to accept. Residual waste producers provide landfills with information on the nature of the waste using the Form U. For each Form U a landfill has, they must report the tons of waste taken under that permit modification in their annual report. That is, a landfill with multiple Form U's from multiple facilities would have to separately report the waste taken under each modification, separately reporting on each type of waste from each facility.

The amount of O&G waste landfills accepted was inferred from landfill annual reports (Table 1). Information on leachate treatment, especially for sites that do not handle their own waste, as well as the quantity of O&G waste the landfill reported taking were also compiled from the landfill reports. These data, when available, were compiled for comparison with data in the Oil and Gas Waste Reports. Annual report acquisition varied by state. New York landfill annual reports are accessed through the New York Department of Environmental Conservation (NYDEC)'s File Transfer Protocol site. New York annual landfill reports were only available online going back to 2017, so the NYDEC was contacted directly for landfill reports 2010-2016. Annual reports for Ohio landfills were accessed online through the Ohio Environmental Protection Agency (OEPA)'s edocuments search webpage. In contrast, Pennsylvania has not made its landfill annual reports available online. Therefore, PADEP Bureau of Waste Management personnel were contacted for information on where landfills taking O&G waste sent their

leachate for treatment. This information was obtained for all of PA, with the exception of the South East Regional Office. Annual reports for Pennsylvania landfills were requested through the PADEP's Informal File Review request system. Because of time limitations on the study and the time it took to receive annual reports from PADEP regional offices (1–4 months), only annual reports for 2019 were requested. Freedom of Information Act avenues were beyond the scope of available resources, particularly given the complicated nature of these requests during COVID risk mitigation periods. Informal file reviews were completed remotely either through file exchange sites or mailed thumb drives for the South West Region, North Central Region, and North East Region Offices. Both the North West Region and South Central Regional Offices refused to do remote file reviews. An in-person file review was completed for the North West Region Office, but the file review was not completed for South Central Region Office due to COVID protocols.

2.3. Field collection details

All landfills in New York, Pennsylvania, and Ohio taking Pennsylvania O&G waste were located using outfall coordinates from NPDES for their landfill or POTW outfall (Fig. 1, Table S1). Some coordinates listed on the NPDES permits were not located in the listed waterway, rather on the treatment facility site or in locations not clearly associated with the facility or the surface water. Upstream and downstream sample sites were selected based on proximity to the outfall, accessibility, and public access. In particular, samples were not taken on private property. Upstream samples were treated as local controls providing a background measurement of sediment/stream water conditions in the absence of leachate inputs.

At the sample site, specific conductivity (μ S/cm) was measured with a YSI Professional Plus handheld multimeter with Quatro cable (Fondriest Environmental Products, Yellowspring OH). The sensor was left in the water for two to five minutes and allowed to stabilize before results were recorded. Total dissolved solids were estimated by multiplying specific conductivity by 0.65. The YSI multimeter was calibrated every two weeks or after twenty samples were collected. Sample coordinates were taken using Garmin GPSmap 62 s (Olathe, KS).

Sediment and water samples were collected at sites upstream and downstream of discharge outfalls (e.g., Figure S1). Water samples for anion analysis were collected in a sterile 1 L French square bottle (VWR International, Bridgeport, NJ). Metal/metalloid samples were collected in a 60 mL glass bottle (VWR International, Bridgeport, NJ) with 8–10 drops of nitric acid (10 M HNO3). Sediment samples were taken where possible; in some instances bed sediments could not be sampled because the slope of the riverbank made the area inaccessible or stream sediments were too coarse. The top 0–5 cm of stream sediments were sampled using a shovel or hand trowel and stored in plastic bags. This sediment interval is part of the hyporheic zone and we interpret Ra content in these sediments to reflect accumulations of Ra over years to decades. Both water samples and sediment samples were stored in coolers with ice packs while in the field, then stored in refrigerators kept at 4C in the Duquesne University lab until analysis was completed.

2.4. Laboratory measurements of water chemistry

Anion (Cl⁻ and SO^{$\frac{2}{4}$}) concentrations were measured on a Dionex ICS-1100 equipped with DS6 heated conductivity cell and DAD-3000 Ulti-Mate 3000 Diode Array programmable UV/VIS detector (Thermo Scientific, Sunnyvale CA). Target analyte anions were separated using the Dionex IonPac AS22A Carbonate Eluent Anion-Exchange Column, 2x250 mm, 6.5-µm particle diameter, with a Dionex IonPac AG22 Guard Column (2x50 mm) coupled to an anion self-regenerating Dionex ASRS 300 suppressor (Thermo Scientific, Sunnyvale CA). A Dionex AS-DV autosampler (Thermo Scientific, Sunnyvale CA) was used for sample processing. Note, the limit of detection for bromide with the UV detector is 0.035 mg/L and water samples measured had concentrations lower

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Table 1

Landfills in Pennsylvania, New York, and Ohio that accepted Pennsylvania O&G waste between 2010 and 2020 according to the PADEP Oil and Gas Waste Report. The quantity of both solid waste in tons and liquid waste in barrels for that 10-year span is shown. Additionally, the amount of solid waste accepted by each facility in 2019 according to the Oil and Gas Waste Report and the facilities annual report are shown. "NA" indicates the information was not available, further detail on availability is found in the notes column. Annual reports for landfills in the South Central region of Pennsylvania were not reviewed as in-person file review was required and not feasible given travel distance complicated by COVID risk mitigation. Landfills were grouped into sampled, water sampled only, and not sampled categories and listed alphabetically by name in each category.

Landfill	Tons sent to Landfill 2010–2020 per the Oil and Gas Waste Report	Barrels sent to Landfill 2010–2020 per the Oil and Gas Waste Report	Tons sent to landfill 2019 per the Oil and Gas Waste Report	Tons received by landfill per 2019 Annual Reports	2019 Net Difference in Tons (sent less received)	Sampled in this project?	Notes
Pennsylvania Advanced Disposal Services Greentree Landfill	313,100	420	5	NA	5	Y	No information in 2019 report
Max Env Tech Inc Yukon Facility Landfill	27,589	46,598	0	3,038	-3,038	Y	
Max Environmental Technologies Inc Bulger Facility	54,912	20,920	0	NA	0	Y	No information in 2019 report
Mckean County Landfill	348,726	14,334	47,703	NA	47,703	Y	No information in 2019 report
Northwest Sanitary Landfill	368,681	7,401	38,138	NA	38,138	Y	No specific category for oil and gas waste in 2019 report
Phoenix Resources Landfill	765,498	8,797	36,879	218,500	-181,621	Y	L
Seneca Landfill (AKA Vogel Landfill)	121,485	417	0	NA	0	Y	No specific category for oil and gas waste in 2019 report
Valley Landfill	15,595	88	1,150	3,719	-2,569	Y	
Wayne Township Landfill	274,395	3,248	28	NA	28	Y	No information in 2019 report
White Pines Landfill	303,821	851	2,199	NA	2,199	Y	No information in 2019 report
Advanced Disposal Service Chestnut Valley Landfill	421,201	0	113	NA	113	Y – Water only	No information in 2019 report
Arden Landfill	249,330	3,261	29,221	269,480	-240,259	Y – Water only	
Keystone Sanitary Landfill	755,199	2,737	10,603	NA	10,603	Y – Water only	No information in 2019 report
Alliance Landfill	216,899	0	14,942	NA	14,942	Ν	No specific category for oil and gas waste in 2019 report
Bradford County Landfill #2	33,230	0	19,271	NA	19,271	Ν	No information in 2019 report
Commonwealth Environmental Systems Landfill	2,536	0	0	NA	0	Ν	No specific category for oil and gas waste in 2019 report
Cumberland County Landfill	6,573	1,449	0	not reviewed	0	Ν	•
Evergreen Landfill	42,583	1,171	255	0	255	Ν	
Grand Central Sanitary Landfill	0	0	0	NA	0	Ν	Requirement to report oil and gas waste added to permit
Greenridge Reclamation Landfill	0	0	0	1,121	-1,121	Ν	
Imperial Landfill	44,487	89	4,455	62,403	-57,948	Ν	
J.J. Brunner, Inc. Landfill	0	0	0	NA	0	Ν	No specific category for oil and gas waste in 2019 report
Kelley Run Landfill	43,410	0	13,997	39,806	-25,808	Ν	<u>.</u> .
Lake View Landfill	33	0	0	NA	0	Ν	No specific category for oil and gas waste in 2019 report
Laurel Highlands Landfill	9,369	2,078	0	0	0	Ν	-
Modern Landfill	3	0	3	not reviewed	3	Ν	
Monroeville Lanfill	32,247	0	16	1,056	-1,040	N	
Mostoller Landfill	13,823	1,048	0	NA	0	N	No specific category for oil and gas waste in 2019 report
Shade Landfill	522	0	0	0	0	N	
South Hills Landfill	34,051	2,370	3,844	8,790	-4,946	Ν	(continued on next page)

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Table 1 (continued)

Landfill	Tons sent to Landfill 2010–2020 per the Oil and Gas Waste Report	Barrels sent to Landfill 2010–2020 per the Oil and Gas Waste Report	Tons sent to landfill 2019 per the Oil and Gas Waste Report	Tons received by landfill per 2019 Annual Reports	2019 Net Difference in Tons (sent less received)	Sampled in this project?	Notes
Southern Alleghenies Landfill	11,453	1,239	0	1,473	-1,473	Ν	
Westmoreland Waste LIC Sanitary Landfill	125,826	3,827	11,574	153,637	-142,063	Ν	
New York Chemung County Landfill (two separate landfills reports at facility):	300,155	0	1,450	1,065	385	Y	
Chemung Construction and Demolition				584			
Chemung Municipal				481			
Allied Waste Hakes C&D Landfill	73,013 140,959	21,763 220	0 0	0 NA	0 0	N N	No information in 2019 report- information on origin of waste, but not
Hyland Facility Association	73,850	797	0	0	0	Ν	oil and gas category
Seneca Meadows Landfill	8,985	0	0	NA	0	Ν	No specific category for oil and gas waste in 2019 report
Ohio Apex Sanitary Landfill	89,120	23,183	8,139	NA	8,139	partial (sends leachate to 4 facilities, water collected at 2 and soil at 1 of those)	No specific category for oil and gas waste in 2019 report
American Landfill, Inc	5,090	6,226	0	NA	0	Y	No specific category for oil and gas waste in 2019 report
Carbon Limestone Landfill	107,143	3,575	863	NA	863	Y	No specific category for oil and gas waste in 2019 report
Kimble Sanitary Landfill	250,842	1,445	0	NA	0	Y	No specific category for oil and gas waste in 2019 report
Mahoning Landfill Inc	12,367	6,992	1,605	NA	1,605	Y	No specific category for oil and gas waste in 2019 report
Suburban Rdf Landfill	29,904	0	0	NA	0	Y	No specific category for oil and gas waste in 2019 report
Tunnell Hill Reclamation Landfill	382,284	54,046	4,270	NA	4,270	Ν	No specific category for oil and gas waste in 2019 report

than this limit. Therefore, Br⁻ concentrations are not reported in this paper. Multielement Ion Chromatography Anion Standard Solution (Certified Reference Material, 10.0 mg/kg, Sigma Aldrich) and spiked samples were run every sequence to ensure correct analyte identification, recovery and repeatability of the IC method.

Multi-element analysis (i.e., Li, Na, Mg, and Ba are reported here) was performed on a Perkin Elmer NexION 300x ICP-MS with Perkin Elmer S10 Autosampler and the NexION 300x ICP-MS software. Analytical method EPA 200.7 was used to analyze samples by ICP-MS. Ground Water ERM CA 615 from the Joint Research Center Institute for Reference Materials and Measurements (IRMM), CRM-SW Certified Reference Material Sea Water, and CWW-TM-H Certified Waste Water (Trace Metals Solutions from High-Purity Standards) were used for instrument performance validation. Ground Water ERM CA 615 from the Joint Research Center Institute for Reference Materials and Measurements (IRMM), CRM-SW Certified Reference Materials and Measurements (IRMM), CRM-SW Certified Reference Materials and Measurements (IRMM), CRM-SW Certified Reference Material Sea Water, and CWW-TM-H Certified Waste Water – Trace Metals Solutions from High-Purity Standards were used for the ICPMS method and instrument

performance validation. A drift sample was run every 10 samples in the sequence to ensure analyte recovery and repeatability of ICPMS data.

Method detection limits (MDLs) for IC and ICPMS target analytes were established using EPA method 40. (EPA, U. 40 CFR part 136 Appendix B, revision 1.11. 1978.).

2.5. Measurement of radium in stream sediments

Stream sediment samples were dried for > 24hrs at 60 °C. Dried sediments were transferred to 500 mL HDPE screw top beakers, sealed with vinyl tape, and allowed to equilibrate for > 21 days. While samples were not sieved, samples were consistent in size between samples and generally less than 2 mm diameter. Radioactivities of the equilibrated samples were measured with a broad energy germanium detector (Canberra BE3825), calibrated using LabSOCS procedures. To avoid uranium interferences, ²²⁶Ra activities were inferred from the ²¹⁴Bi (609 keV) and ²¹⁴Pb (259 keV, 351 keV) energies. ²²⁸Ra activities were inferred from the ²²⁸Ac daughter activity (911 keV). Activity

uncertainties are reported in Table 1. Gamma counter performance was evaluated with regular counts of known standards and background radioactivity.

3. Results

3.1. Waste volumes in landfills

Annual reports were used to calculate the total quantities of O&G waste, by state of origin and overall, for 2019 where the information was available (Table 1). This was compared to the amount of waste O&G producers reported they sent to landfills as detailed in the PADEP Oil and Gas Well Waste Reports. Information on the amount of O&G waste accepted was only available in 14 of the 28 Pennsylvania landfills whose annual reports were accessible for review; the others did not report taking any O&G waste. (Table 1, note: two reports were not included in this analysis because in-person file review was required and not feasible given travel distance complicated by COVID risk mitigation). Landfills were required to add this information to their annual report as a condition of their permit. No data on the amount of O&G waste accepted by landfills in Ohio was found in landfill annual reports or online databases.

There is very little agreement between the PADEP Oil and Gas Well Waste Report and the landfill reports for 2019 (the fourth and fifth columns in Table 1). The closest agreement was Chemung County Landfill where waste reports were within roughly 30%. Valley Landfill, Kelly Run Landfill, and South Hills Landfill were within a factor of four. A substantial part of the time (17 out of 42) waste was reported as sent to or received by and no indication of receipt or shipment was present in the corresponding report. There were seventeen landfills that PADEP Oil and Gas Well Waste Reports had records of shipments to between 2010 and 2020, but no activity reported (either shipment to or receipt of) during 2019. This means there were substantial discrepancies (>100%) between records of shipment to and receipt by in twenty-four of the landfills documented in this study.

3.2. Water chemistry at stations upstream and downstream of facility outfalls

Water chemistry in receiving waters around the sampled outfalls was typical of the region (Table 2). TDS ranged between 40 and 1150 mg/L and [Cl] ranged between 4 and 486 mg/L, with the upper end exceeding the USEPA chronic freshwater criteria (230 mg/L). Sulfate ranged between 6 and 588 mg/L. Both TDS and sulfate concentration ranges are in excess of USEPA secondary drinking water standards (500 mg/L and 250 mg/L, respectively). Sodium concentrations ranged between 4 and 237 mg/L, lithium between 0.001 and 0.062 mg/L, and magnesium between 3 and 50 mg/L. Finally, barium concentrations were between 0.01 and 0.09 mg/L, well below the 2 mg/L drinking water standard. In general, concentrations of solutes were greater downstream of the sampled outfalls than upstream of the outfalls (Table 3).

3.3. Sediment radium content

Radium concentrations in the sediment ranged from 13.2 to 69.4 Bq/kg 226 Ra and 12.4 to 55 Bq/kg 228 Ra (calculated from data in Table 2). On average across all measurements, downstream locations had higher concentrations (Downstream average 226 Ra: 39.0 Bq/kg, 228 Ra: 37.6 Bq/kg, Upstream average 226 Ra: 30.9 Bq/kg, 228 Ra: 32.7 Bq/kg). The mean of all upstream 226 Ra activities was significantly lower than the mean of downstream activities at the p=0.05 level (Student's two-sample T-Test, two tails). However, the differences in upstream/downstream mean 228 Ra activities were not significant at the p=0.05 level.

The enrichment of downstream sediment samples relative to upstream samples for each outfall point were evaluated. In general, this downstream to upstream sediment ratio ranged from 0.6 to 4 (226 Ra) and 0.5 to 2.8 (228 Ra).



4. Discussion

4.1. Comparison of landfill reports and O&G waste reports

One potential avenue for assessing the nature of potential loadings over time is evaluation of the magnitude of O&G waste deposited in the landfill. Data was initially compiled from the PADEP Oil and Gas Well Waste Report, where O&G producers report the amounts of waste they sent to specific facilities. As a check on the reliability of this data, we compared data from the Oil and Gas Well Waste Report to landfill annual reports. However, this information is woefully inadequate. Annual reports were reviewed for 43 of 45 landfills Pennsylvania O&G producers reported sending waste to, only 18 documented the amount of O&G waste the facility accepted. Rates of reporting in annual reports varied by state. Despite a legal requirement to report the mass of O&G waste accepted, only 67% (4 of 6) of New York landfills clearly did so. Additionally, only 47% (14 of 30) of Pennsylvania landfills whose annual reports were reviewed and no Ohio landfills identified the mass of O&G waste they accepted.

Even if these data were complete, it is not at all clear they would be reliable. There were no cases where the O&G Report figures matched the landfill reports (Table 1). The inability to reconcile O&G producers' reports of waste disposal with landfills' reports reveals a fundamental gap in our management of O&G waste. Either the landfills are in error, the O&G operators are in error, or both are incorrect. In any of these cases, this allows ambiguity in the role of O&G waste as a contributor of radium accumulations in downstream sediments. More importantly, it undermines confidence in all reporting of O&G waste disposal.

The list of landfills for this study was compiled from PADEP Oil and Gas Well Waste Reports. With Pennsylvania O&G producers sending waste across state lines, reporting formats and access to reports varied (e.g., central online access in New York to informal file review requests and paper files in Pennsylvania). In all jurisdictions, reporting of O&G waste receipt in landfill reports was inconsistent and incomplete. This leaves a substantial gap in our life cycle understanding of contemporary O&G waste. Without reliable information on O&G waste volumes ending up in landfills, it is extremely challenging to effectively assess the risks this waste creates for both humans and ecosystems downstream of effluent treatment.

4.2. Radium enrichment in downstream sediments

Comparison of these sediments with other studies is challenged by the nature of the approach. The study was designed to be broad spatially and not necessarily coordinated with the facilities of interest. This allowed a relatively large set of sampled locations, but precluded access to near outfall sediments (access to these areas are controlled for security reasons). Therefore, these observations cannot be directly compared to reports of sediments and waters at the outfall reported in the literature. However, these observations are placed in the context of numerous measurements made in downstream sediments (Lauer et al., 2018; Van Sice et al., 2018; Warner et al., 2013a) in this discussion and analysis.

The radium concentrations observed in stream sediments downstream of some outfalls in this study were similar to concentrations observed downstream of centralized waste treatment facilities. Warner et al's (2013b) observations of stream sediment radium concentrations in samples collected between 300 and 2000 m downstream of the Josephine Brine Treatment Facility outfall in Blacklick Creek (PA) were 33–53 Bq/kg ²²⁶Ra and 22–34 Bq/kg ²²⁸Ra. Lauer et al. (2018) collected sediment samples directly at the Josephine facility outfall, making their observations hard to compare to ours (the Josephine outfall sediments are much more concentrated). Van Sice et al. (2018) sampled over much longer spatial domains, but reported increases ~ 1.5x above background for extended distances downstream (~31 km), a similar magnitude of enrichment observed here. In contrast, Skalak et al. (2014) did not observe increased Ra content downstream of publicly owned treatment

Table 2

Sediment radium content and water total chemistries for sampling sites bracketing facilities sampled in this study (Table 1). Upstream and downstream sites are identified by the sample name. If the facility is a POTW receiving landfill leachate, both the landfill and POTW are indicated in the site name.

Sample	SEDIME	EDIMENT RADIUM ACTIVITY							WATER CHEMISTRY					
	Bi 214 (Bq/ kg)	Bi 214 uncertainty (Bq/kg)	Pb 214 (Bq/ kg)	Pb 214 uncertainty (Bq/kg)	Average inferred Ra 226 (Bq/kg)	Ac 228 (Bq/ kg)	Ac 228 uncertainty (Bq/kg)	TDS (mg/ L) based on SpC	Cl (mg/ L)	SO4 (mg/ L)	Na (mg/ L)	Mg (mg/ L)	Ba (mg/ L)	Li (mg/ L)
Max Env Tech Inc Yukon Facility Landfill- downstream	39.8	2.8	42.1	4.9	41.0	39.9	3.8	496	94.2	119.1	57.4	16.2	0.05	0.013
Max Env Tech Inc Yukon Facility Landfill- upstream	27.6	2.5	31	3.7	29.3	32.4	3.5	492	89.7	124.6	58.4	16.3	0.05	0.013
Brush Creek WWTP [Valley Landfill] – downstream	31.1	2.6	35.9	4.2	33.5	32.7	3.4	722	161.4	187.8	99.8	20.6	0.06	0.018
Brush Creek WWTP [Valley Landfill] – upstream	35.3	2.7	39	4.5	37.2	41.7	4.0	718	157.8	200.8	99.1	20.3	0.06	0.018
Northwest Sanitary Landfill – downstream	50.3	3.6	54.6	6.3	52.5	46.0	4.3	201	13.6	88.2	8.7	10.7	0.03	0.006
Northwest Sanitary Landfill – upstream	20.9	1.8	21.9	2.6	21.4	24.7	2.6	106	8.4	37.3	5.8	5.0	0.03	0.00
Dover WWTP – [Kimble Sanitary Landfill]- upstream	54.3	4.7	60	7.1	57.2	52.2	5.7	404	92.6	60.6	53.3	12.5	0.04	0.00
Dover WWTP – [Kimble Sanitary Landfill]- downstream	34.9	2.6	38.6	4.5	36.8	26.7	2.8	406	89.9	58.0	54.2	12.9	0.05	0.00
Canton Water Reclamation Facility [American Landfill]- downstream	65.12	4.5	73.63	8.5	69.4	32.7	3.5	1152	386.4	114.1	236.7	21.7	0.04	0.00
Canton Water Reclamation Facility [American Landfill]- upstream	18.3	1.7	19.129	2.3	18.7	14.7	1.8	603	137.5	65.5	82.7	17.0	0.06	0.00
Sity of Akron Water Reclamation Facility [American Landfill]-	34.7	2.8	37.4	4.4	36.1	31.4	3.4	412	112.7	31.0	63.8	11.1	0.04	0.00
downstream Sity of Akron Water Reclamation Facility [American Landfill]-	31.6	2.6	35.3	4.1	33.5	29.3	3.1	411	108.6	29.7	61.1	10.8	0.04	0.00
upstream Alliance Wastewater Treatment Plant [American	12.839	1.3	13.616	1.7	13.2	12.4	1.7	376	79.1	34.5	46.3	12.6	0.04	0.00

(continued on next page)

					(Bq/kg)	kg)		based on						
								SpC						
Landfill]- upstream														
Alliance	30.858	2.6	34.965	4.1	32.9	35.1	3.6	377	58.6	70.6	37.0	14.9	0.03	0.004
Wastewater														
Treatment														
Plant [American														
Landfill]-														
downstream														
Lowellville	27.7	2.1	29.6	3.4	28.7	22.7	2.4	326	72.4	66.2	46.2	9.9	0.02	0.004
WWTP [Carbon														
Limestone														
Landfill]-														
upstream	10.0													
Lowellville WWTP	49.9	3.7	53.7	6.2	51.8	39.3	3.9	327	87.1	37.5	49.3	9.2	0.02	0.004
[Carbon														
Limestone														
Landfill]-														
downstream Beaver Falls	24.8	2.0	25.3	3.0	25.1	22.1	2.4	355	69.8	56.0	47.0	12.7	0.04	0.005
Sewage	24.0	2.0	23.5	5.0	23.1	22.1	2.4	555	09.8	30.0	47.0	12.7	0.04	0.005
Treatment														
Plant														
[Mahoning Landfill, Inc														
Waste														
Management]-														
upstream Boower Falle	27.7	0.0	21 4	2.7	20.6	<u></u>	2.4	247	60.4	E7 0	1E 6	10.0	0.04	0.005
Beaver Falls Sewage	27.7	2.3	31.4	3.7	29.6	22.2	2.4	347	69.4	57.0	45.6	12.3	0.04	0.005
Treatment														
Plant														
[Mahoning Landfill, Inc														
Waste														
Management]-														
downstream														
Max Environmental	27.8	2.4	29.6	3.5	28.7	32.7	3.4	567	15.1	302.7	35.2	33.0	0.05	0.04
Technologies														
Inc Bulger														
Facility-														
upstream racoon														
Max	45.9	3.4	50.6	5.8	48.3	53.9	5.1	803	199.3	304.1	27.2	34.5	0.05	0.015
Environmental														
Technologies Inc Bulger														
Facility-														
downstream														
little raccon	16.0		51.0		40.1	50.0	5.0	000	105.4	050 5	00.0		0.04	0.000
Max Environmental	46.9	3.4	51.2	5.9	49.1	52.9	5.0	832	185.4	353.7	29.0	44.2	0.04	0.022
Technologies														
Inc Bulger														
Facility-														
upstream little racoon														
Pine Creek	31.9	2.7	37.3	4.4	34.6	34.0	3.5	81	6.7	23.0	6.5	5.3	0.02	0.003
Municipal														
Authority														
Sewage Treatment														
Plant [Wayne														
Township														
Landfill]- upstream														
upoticini												(cont	inued on ne	rt nage)

Average inferred

Ra 226

(Bq/kg)

Ac

228

(Bq/

kg)

Ac 228

(Bq/kg)

uncertainty



Sample

_

SEDIMENT RADIUM ACTIVITY

uncertainty

Pb 214

(Bq/

kg)

Pb 214

(Bq/kg)

uncertainty

Bi 214

(Bq/kg)

Bi 214

(Bq/ kg)



Ba

(mg/

L)

Li (mg/

L)

Mg

(mg/

L)

WATER CHEMISTRY

TDS

(mg/

based

L)

Cl

L)

(mg/

 SO_4

(mg/

L)

Na

L)

(mg/

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Table 2 (continued)

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		NT RADIUM AC						WATER CHEMISTRY					. <u> </u>	
Sample	Bi 214 (Bq/ kg)	Bi 214 uncertainty (Bq/kg)	Pb 214 (Bq/ kg)	Pb 214 uncertainty (Bq/kg)	Average inferred Ra 226 (Bq/kg)	Ac 228 (Bq/ kg)	Ac 228 uncertainty (Bq/kg)	TDS (mg/ L) based on SpC	Cl (mg/ L)	SO4 (mg/ L)	Na (mg/ L)	Mg (mg/ L)	Ba (mg/ L)	Li (mg/ L)
Pine Creek Municipal Authority Sewage Treatment Plant [Wayne Township Landfill]- downstream	35.2	3.0	38.3	4.5	36.8	40.7	4.2	81	5.9	23.0	5.8	5.0	0.03	0.003
Millville Municipal Authority [White Pines Landfill]-	30.3	2.4	32.2	3.8	31.3	35.4	3.5	40	4.4	6.1	4.5	3.1	0.02	<0.001
upstream Millville Municipal Authority [White Pines Landfill]- downstream	22.6	1.9	23.7	2.8	23.2	30.6	3.0	43	6.7	7.1	6.4	3.2	0.01	0.001
Phoenix Resources Landfill- downstream	39.7	3.0	45.5	5.3	42.6	55.0	5.1	419	9.8	434.8	7.9	37.9	0.02	0.052
Phoenix Resources Landfill-	20.6	2.0	23.1	2.8	21.9	28.6	3.1	575	6.2	588.3	5.2	50.4	0.01	0.062
upstream Advanced Disposal Services Greentree Landfill- upstream	33.6	3.0	35.9	4.3	34.8	37.3	4.2	341	11.0	327.8	8.0	28.0	0.02	0.022
Advanced Disposal Services Greentree Landfill - point 1 – downstream	39.6	3.5	42.2	5.0	40.9	45.2	4.8	434	53.7	316.4	46.3	26.5	0.03	0.022
Advanced Disposal Services Greentree Landfill - point 2– downstream	29.2	2.4	32.6	3.8	30.9	37.8	3.8	367	17.7	274.1	18.4	28.5	0.03	0.021
Chemung County Elmira Sewer District (Milton St) [Chemung County Landfill] downstream	41.4	3.8	45.8	5.4	43.6	50.5	5.5	256	56.8	14.8	36.8	9.8	0.09	0.003
Both Chemung County Sewer District No. 1 (Lake St) [Chemung County Landfill] downstream and Chemung County Elmira Sewer District (Milton St) [Chemung	36.5	3.1	40.1	4.7	38.3	40.2	4.3	287	80.4	17.0	48.3	11.6	0.09	0.003

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Table 2 (continued)



	SEDIMENT RADIUM ACTIVITY							WATER CHEMISTRY						
Sample	Bi 214 (Bq/ kg)	Bi 214 uncertainty (Bq/kg)	Pb 214 (Bq/ kg)	Pb 214 uncertainty (Bq/kg)	Average inferred Ra 226 (Bq/kg)	Ac 228 (Bq/ kg)	Ac 228 uncertainty (Bq/kg)	TDS (mg/ L) based on SpC	Cl (mg/ L)	SO ₄ (mg/ L)	Na (mg/ L)	Mg (mg/ L)	Ba (mg/ L)	Li (mg/ L)
County Landfill] downstream Chemung County Sewer District No. 1 (Lake St) [Chemung County Landfill] upstream	26	2.2	29.4	3.5	27.7	35.3	3.4	216	40.1	13.0	26.9	8.0	0.07	0.003

works that had historically processed unconventional O&G brines.

If we assume the decreases in Ra concentrations with distance from the outfall are generally consistent among streams, we can infer information about the nature of the Ra inputs to these stream systems. All samples collected in this study were from relatively similar hydroclimatic and physiographic conditions and are also similar to conditions where these Ra patterns were observed (Lauer et al., 2018; Van Sice et al., 2018; Warner et al., 2013b). A comparison of enrichment (measured over background) vs. distance from the outfall in the Warner et al. (2013b) data (most comparable in terms of spatial scale) and the observations from this study (Fig. 2) suggest Ra loadings from the outfalls are similar in distance/magnitude to the accumulations observed downstream of treatment facility outfalls.

However, these inferences about decreases in Ra concentrations with distance downstream would also require at least similar magnitude and duration of loading. While we have a reasonable handle on fluxes through centralized treatment works in PA since the onset of the Marcellus boom (Van Sice et al., 2018), the Josephine plant was in operation before that period and some of the observed elevated concentrations could result from a longer history of conventional brine treatment. This would be a potential explanation for the observed differences between centralized brine treatment facilities (Warner et al., 2013b) and publicly owned treatment works (Skalak et al., 2014). Therefore, the observed concentrations reported here could also result from a longer history of waste disposal in the landfills. Whether the observed enrichments reported here arose from long, small but consistent releases or more recent but larger fluxes created by the unconventional boom would require more refined sampling beyond the scope of the current study.

In addition, 228 Ra/ 226 Ra activity ratios can indicate Marcellus foundation radium (i.e., ratios less than 0.3) (Lauer et al., 2018). That is, a decrease in this ratio from upstream to downstream indicate contributions of low ratio materials, potentially from the Marcellus Formation. In our observations, as the enrichment in radium increases from upstream to downstream the difference between upstream and downstream ratios increase (R² = 0.53, p ~ 0.001), suggesting an increased contribution from low ratio materials (Fig. 3).

4.3. Comparison of radium enrichments and changes in water chemistry near outfalls

While the incomplete and unconstrained waste stream data preclude evaluation of O&G waste influence on radium accumulation in stream sediments, comparison of water chemistry upstream/downstream of facility outfalls can clarify potential O&G contributions to outfall chemistry. That is, if stream chemistry changes reflect chemistries associated with O&G contributions, and these changes are associated with the observed accumulation of radium, this is an additional, parallel line of evidence that O&G waste is impairing the receiving waters. Simple changes in single parameters are often used as sentinels of O&G contamination. Abrupt increases in dissolved solids are the cornerstone of broad scale monitoring efforts (e.g., Bowen et al (2015)). Proportional upstream to downstream changes in TDS are related to enrichment in sediment ²²⁶Ra content (R² = 0.19, p ~ 0.08, Fig. 4a). This level of association is striking given the small sample size and the strong contrast between characteristic time scales of the two measures. The sediment radium ratio should reflect the integration of radium inputs over time scales of years to decades. In contrast, grab samples collected from the stream waters surrounding the outfall should reflect water chemistry inputs at the scale of hours to days.

Ideally, these relationships should also hold between water chemistry parameters of materials indicative of O&G waste contamination. Bromide is an effective tracer of potential contamination as it is relatively rare in regional surface waters, therefore even a small increase of bromide can be differentiated from background. However, with the exception of the Chemung County Elmira Sewer District (Milton St) [Chemung County Landfill] site, bromide concentrations remain below the detection limit, precluding examination of changes in Br concentrations vs changes in sediment radium concentration. Chloride is a potential parameter to evaluate, occurring at high concentrations in O&G waste, but lower concentrations in most human systems (with the exception of road salt runoff). However, a relationship between increases in sediment radium and dissolved Cl is not apparent ($R^2 = 0.00$, Fig. 4b). Part of this poor goodness of fit measure arises from a single outlier (Advanced Disposal Services Greentree Landfill - point 1 site, Fig. 4b). Regardless, these single element results remain ambiguous given the potential for dilution by higher flows or false positives due to inputs of materials from sources other than the outfalls.

Cantlay et al (2020) lay out a set of constituent ratios that can both differentiate O&G waste from other potential contaminants and diminish the noise introduced by water dynamics (i.e., dilution during elevated flow). These ratios include: Mg/Na; SO₄/Cl, Mg/Li, and Ba/Cl (the Br/SO₄ ratio is not included due to limited Br measurements above the detection limits). When comparing the downstream/upstream difference of ratio values to the downstream/upstream ratio of sediment ²²⁶Ra activities, the direction of evolution is mixed (Fig. 5). There are several cases where waters strongly diverge toward chemistries more characteristic of O&G waste (e.g., low values in Mg/Na and SO₄/Cl). However, in both cases these differences could be driven by NaCl inputs from common practices including road de-icing.

These grab sample measurements of water chemistry suggest that O&G waste like materials may be contributing to water chemistry downstream of the sampled outfalls. The observed shifts are not consistent (Fig. 5), but there are clear cases where observed changes are consistent with O&G waste-like contributions at the outfalls. This ambiguity underlines the potential power of the downstream/upstream radium ratios, as those ratios capture accumulations of releases through

Table 3

11

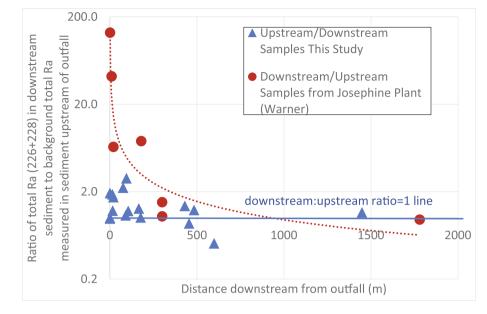
Ratios of Downstream over Upstream values of sediment radium content, total water concentrations, and selected stoichiometric ratios for facilities sampled in this location.

Outfall Sample (waste generator noted with brackets if different from sampled outfall)	Downstream/ Upstream Ratio of ²¹⁴ Bi	Downstream/ Upstream Ratio of ²¹⁴ Pb	Downstream/ Upstream Ratio of Inferred ²²⁶ Ra	Downstream/ Upstream Ratio of ²²⁸ Ac	Downstream sample distance from outfall (m)	Downstream/ Upstream Ratio of TDS based on Specific Conductance	Downstream/ Upstream Ratio of Chloride Concentrations	Downstream/ Upstream Ratio of Mg/Na Ratios (wt/wt)	Downstream/ Upstream Ratio of SO4/Cl Ratios (wt/wt)	Downstream/ Upstream Ratio of Mg/Li Ratios (wt/wt)	Downstream/ Upstream Ratic of Ba/Cl Ratios (wt/wt)
Max Env Tech Inc Yukon Facility Landfill	1.4	1.4	1.4	1.2	483.1	1.0	1.1	1.0	0.9	1.0	1.0
Brush Creek WWTP – [Valley Landfill]	1.1	1.1	1.1	1.3	165.8	1.0	1.0	1.0	0.9	1.0	1.0
Northwest Sanitary Landfill	2.4	2.5	2.5	1.9	14.0	1.9	1.6	1.4	1.5	1.8	0.6
Dover WWTP – [Kimble Sanitary Landfill]	0.6	0.6	0.6	0.5	598.3	1.0	1.0	1.0	1.0	1.0	1.3
Canton Water Reclamation Facility [American	3.6	3.9	3.7	2.2	75.6	1.4	1.8	0.6	0.8	1.0	0.5
Landfill] City of Akron Water Reclamation Facility [American Landfill]	1.1	1.1	1.1	1.1	90.2	1.0	1.0	1.0	1.0	1.0	1.0
Alliance Wastewater Treatment Plant [American Landfill]	2.4	2.6	2.5	2.8	94.2	1.0	0.7	1.5	2.8	0.6	1.0
Lowellville WWTP [Carbon Limestone Landfill]	1.8	1.8	1.8	1.7	19.8	1.0	1.2	0.9	0.5	0.9	0.8
Beaver Falls Sewage Treatment Plant [Mahoning Landfill, Inc Waste Management]	1.1	1.2	1.2	1.0	0.0	1.0	1.0	1.0	1.0	1.0	1.0
Max Environmental Technologies Inc Bulger Facility	1.0	1.0	1.0	1.0	0.0	1.0	1.1	0.8	0.8	1.1	1.2
Pine Creek Municipal Authority Sewage Treatment Plant	1.1	1.0	1.1	1.2	104.9	1.0	0.9	1.1	1.1	0.9	1.7

Table 3 (continued)

Outfall Sample (waste generator noted with brackets if different from sampled outfall)	Downstream/ Upstream Ratio of ²¹⁴ Bi	Downstream/ Upstream Ratio of ²¹⁴ Pb	Downstream/ Upstream Ratio of Inferred ²²⁶ Ra	Downstream/ Upstream Ratio of ²²⁸ Ac	Downstream sample distance from outfall (m)	Downstream/ Upstream Ratio of TDS based on Specific Conductance	Downstream/ Upstream Ratio of Chloride Concentrations	Downstream/ Upstream Ratio of Mg/Na Ratios (wt/wt)	Downstream/ Upstream Ratio of SO4/Cl Ratios (wt/wt)	Downstream/ Upstream Ratio of Mg/Li Ratios (wt/wt)	Downstream/ Upstream Ratio of Ba/Cl Ratios (wt/wt)
[Wayne Township Landfill] Millville Municipal Authority	0.7	0.7	0.7	0.9	454.8	1.1	1.5	0.7	0.8	1.0	0.3
[White Pines Landfill] Phoenix Resources	1.9	2.0	2.0	1.9	0.0	0.7	1.6	0.5	0.5	0.9	1.3
Landfill Advanced Disposal Services Greentree Landfill - point 1	1.2	1.2	1.2	1.2	15.5	1.3	4.9	0.2	0.2	0.9	0.3
Advanced Disposal Services Greentree Landfill - point 2	0.9	0.9	0.9	1.0	176.5	1.1	1.6	0.4	0.5	1.1	0.9
Chemung County Elmira Sewer District (Milton St) [Chemung County Landfill]	1.1	1.2	1.2	1.2	624.0	0.9	0.7	1.1	1.2	0.8	1.4
Chemung County Sewer District No. 1 (Lake St) [Chemung County Landfill]	1.4	1.4	1.4	1.4	848.0	1.3	2.0	0.8	0.6	1.5	0.6

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Fig. 2. Comparison of relative enrichments (total Ra measured in sediments downstream of outfall divided by total Ra measured in stream sediments upstream of outfall) observed in known releases of O&G waste at the Josephine treatment plant (red dots) (Warner et al., 2013b) and enrichments observed in sediments collected below outfalls of landfill leachate discharges (blue triangles). Orange dotted line is a power fit of the Josephine total Ra sediment enrichment as a function of distance below the outfall. This fit is for visualization purposes. The blue solid line is where the ratio between upstream and downstream Ra is equal to one, or the value where there is no enrichment or dilution. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

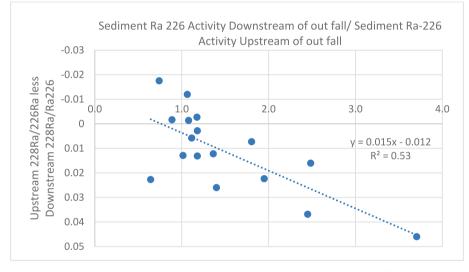


Fig. 3. Comparison between downstream ²²⁶Ra/ upstream ²²⁶Ra ratios and the upstream/downstream differences in ²²⁸Ra/²²⁶Ra ratios. A larger difference suggests more input to the system from a low ratio source, potentially Marcellus sources. Note the y axis is reversed.

time. The water chemistry is inconsistent and cannot be used to rule out O&G waste influence on surface water.

4.4. Water quality regulatory landscape at sampled facilities

Given the observed changes in sediment and water chemistry near these facilities, the case for additional monitoring is strengthened. To evaluate the current regulatory landscape we examined the reported constituents for all NPDES permits associated with these facilities.

One of the most sensitive indicators of O&G contamination is bromide (Wilson et al., 2014). Only four of the 18 facilities sampled are required to monitor Br as part of their discharge permit. Given the fiveyear renewal cycle, this means all of these locations have renewed at least once since 2012, i.e., the peak of the regional unconventional O&G extraction boom. During this period additional relevant solutes were not added to the permit. This suggests a fundamental disconnect in our regulation of waste in the unconventional energy landscape. There are simple, effective means to evaluate the impact of O&G waste on outfall chemistry (e.g., gross alpha, bromide, etc.). The failure to include these constituents in discharge permits for facilities that are permitted to accept waste or treat effluent from facilities accepting O&G waste is a failing in our regulatory system that if left uncorrected, has the potential to result in pockets of radiological contamination across the landscape. It is important to note that one of the four facilities to monitor Br was required to start monitoring Br in 2022, suggesting these changes may be starting.

5. Conclusions

Grab sampling of stream water and sediments in areas bracketing outfalls of facilities treating waste from landfills accepting O&G waste indicate accumulation of NORM in the sediments. Given distance from the outfall, these accumulations are of similar magnitude to those downstream of brine treatment facilities reported in the literature (Warner et al., 2013b) and indicate additions from a low 228 Ra/ 226 Ra activity ratio source, consistent with Marcellus formation sources (Lauer et al., 2018). Examination of water chemistry, including use of characteristic chemical ratios, provides further evidence for contributions from

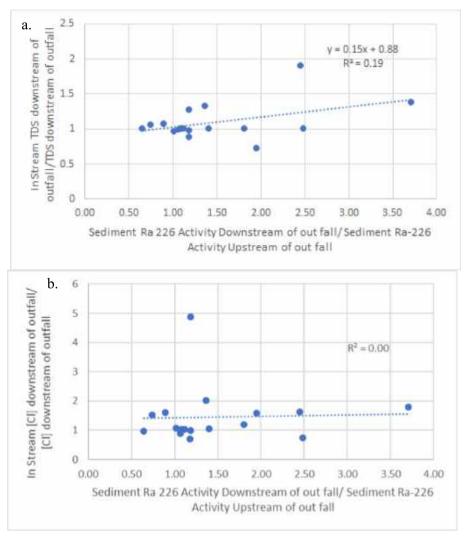


Fig. 4. Comparison of relative enrichments in stream sediment ²²⁶Ra observed in this study with the relative change in water sample chemistry measured (TDS in panel a, [Cl] in panel b) in water samples collected downstream and upstream of the corresponding discharge outfall. The linear fit is shown for both plots.

O&G waste. Access to near outfall sediments and leachate samples curtail more precise evaluation of the impact. The continued treatment and discharge of O&G waste through sanitary landfills and/or landfill leachate by POTWs has the potential to increase radioactive loads that will accumulate in sediment and remain for long periods given characteristic half-lives (e.g., 226 Ra: $t_{\prime_2} \sim 1600$ y).

Examination of administrative records to constrain these material budgets suggest wide discrepancies in mass flux reporting across jurisdiction and across bureaus within the state departments. This precludes our ability to assess the patterns in NORM accumulation relative to the volumes of O&G waste accepted and leaves the mechanisms delivering NORM to the streams ambiguous. These ambiguities limit efforts to identify surface waters at highest risk for contamination.

The abundance of unconventional gas and oil reserves and the expansion of the petrochemical industry in the United States suggest that the development of these plays will continue (Stolz et al., 2022), thus, waste management will also continue to be an issue. Additions of parameters characteristic of O&G waste (e.g., bromide, gross alpha) to discharge permits for all facilities handling these materials would provide early warning of potential breakthroughs. Cross-checking of administration records would quickly uncover sloppy or malicious disposal practices, similar to early efforts to deal with challenges like leaking underground storage tanks.

CRediT authorship contribution statement

Lauren M. Badertscher: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Validation, Visualization, Writing – original draft, Writing – review & editing. Memphis J. Hill: Formal analysis, Project administration, Writing – review & editing. Tetiana Cantlay: Data curation, Formal analysis, Methodology, Project administration, Supervision, Writing – review & editing. John F. Stolz: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Supervision, Validation, Writing – review & editing. Daniel J. Bain: Data curation, Formal analysis, Investigation, Methodology, Supervision, Validation, Visualization, Writing – review & editing.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Daniel Bain reports financial support was provided by Heinz Endowments. John Stolz reports financial support was provided by Heinz Endowments. John Stolz reports financial support was provided by Park Foundation. John Stolz reports financial support was provided by Colcom Foundation.



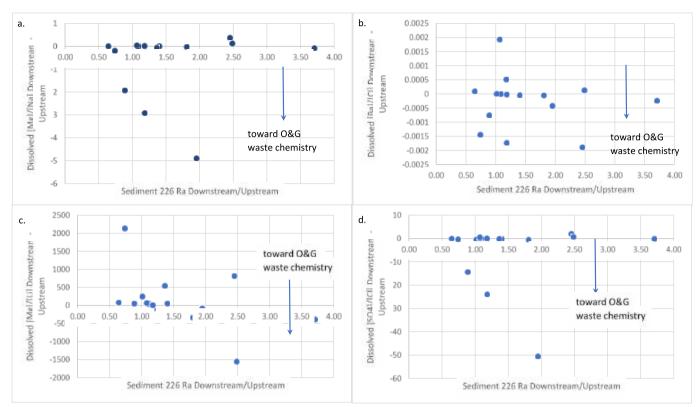


Fig. 5. Plots of the difference between downstream and upstream water chemistry observations of common solute ratios indicative of O&G waste (a) Mg/Na, b) Ba/Cl, c) Mg/Li, d)SO₄/Cl) plotted as a function of downstream/upstream ²²⁶Ra concentrations. Arrows indicate direction toward chemistries characteristic of O&G waste.

Data availability

Data will be made available on request.

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Appendix A. Supplementary data Figure S1 depicting detail in sampling locations around the Chemung landfills (doc); Table S1 relating landfills, treatment plants, and NPDES information (doc).

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ecolind.2023.110616.

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Final Report For

Pennsylvania Department of Health, Bureau of Epidemiology

Hydraulic Fracturing Epidemiology Research Studies: Childhood Cancer Case-Control Study

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Abbreviations

Abbreviation	Definition			
ALL	Acute Lymphocytic Leukemia			
ATSDR	Agency for Toxic Substances and Disease Registry			
CATI	Computer–Assisted Telephone Interviewing			
СНР	Children's Hospital of Pittsburgh			
CI	Confidence Intervals			
CNS	Central Nervous System			
CPDB	Carcinogenic Potency Database			
СТ	Computed Tomography			
EFOT	Ewing Family of Tumor			
EPA	US Environmental Protection Agency			
GIS	Geographic Information System			
HF	Hydraulic Fracturing or fracking			
IARC	International Agency for Research on Cancer			
ICCC	International Classification of Childhood Cancer			
IDW	Inverse Distance Weighting			
IRB	Institutional Review Board			
NCI	National Cancer Institute			
NHL	Non-Hodgkin Lymphoma			
NPL	National Priorities List			
OR	Odds Ratio			
PA	Pennsylvania			
PADEP	Pennsylvania Department of Environmental Protection			
PADOH	Pennsylvania Department of Health			
SEER	Surveillance, Epidemiology, and End Results			
SIR	Standard Incidence Ratios			
TRI	Toxic Release Inventory			
UMTRA	Uranium Mill Tailing Remedial Action			
UNGD	Unconventional Natural Gas Development			
UV	Ultraviolet			
WCS	World Geocoding Service			
WHO	World Health Organization			

CHILDHOOD CANCER CASE-CONTROL STUDY

I. Background

Hydraulic fracturing (or fracking) is a type of unconventional natural gas development (UNGD) used to extract natural gas from underground shale rock formations. After obtaining the necessary permits, the first phase of hydraulic fracturing (HF) is well pad preparation. This includes preparing a site for one or more fracturing wells by building access roads and clearing land to build infrastructure. The next phase is drilling in which a borehole is drilled vertically 1 to 2 miles into the ground then turned horizontally into the shale rock (Deziel et al., 2022). Then the steel casing is installed in the borehole and sealed with cement.

Fracturing fluid consists of 90-97% of a base fluid, which is usually water. A fracturing well uses an average of 1.2 million gallons of water. A proppant, usually sand, composes 2-10% of the fracturing fluid. Chemical additives make up less than 2% of the fracturing fluid, though hundreds of chemicals have been reported (Deziel et al., 2022). More information on the chemical additives and their function in fracturing fluid, as well as common constituents reported by the EPA analysis of FracFocus 1.0 (2015) is shown in **Appendix A**. A number of these chemicals include known and suspected endocrine inhibitors and carcinogens (Deziel et al., 2022).

Workers inject this fracturing fluid into the well under high pressure which 'fractures' the rock and releases the natural gas. Once the pressure is released, a mixture of the gas, fracturing fluid, and other compounds found in the rock flow back through the well to the surface. This mixture is often called flowback or produced water. The production phase refers to the separation of the gas from the flowback water, which is then transported through pipelines to a storage facility or processing plant (Deziel et al., 2022). See **Figure 1**.

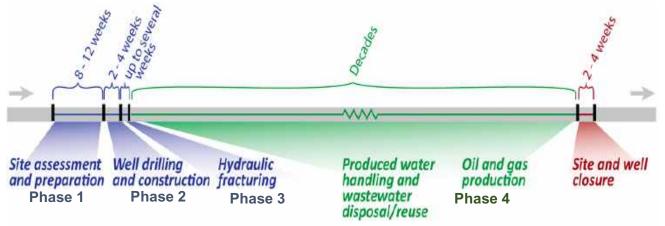
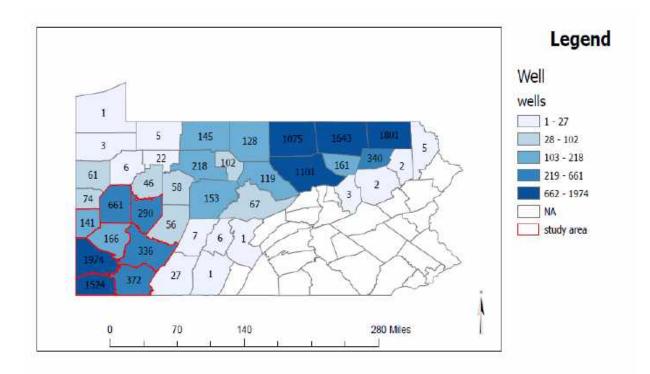


Figure 1. Hydraulic Fracturing Timeline (Adapted from: U.S. EPA 2016)

The first recorded shale gas well in Pennsylvania was drilled in Erie County in 1860, though modern hydraulic fracturing began in earnest in 2005 in Southwestern Pennsylvania (PA). Currently, Washington County has the largest number of UNGD wells in operation in this region. As of December 2020, there were 12,903 unconventional wells active throughout PA and 5,464 in the 8 county Southwestern PA area. See **Figure 2**. The last county to begin with UNGD drilling was Allegheny County in 2008. The highlighted area on the map includes Allegheny, Armstrong, Beaver, Butler, Fayette, Greene, Washington, and Westmoreland counties, where each had >100 active unconventional oil and natural gas wells in 2020.

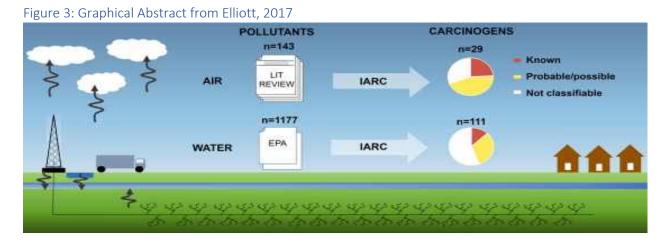
Figure 2. Distribution of Wells in Each PA County, with a Total of 12,903 Wells Throughout PA as of December 2020



UNGD-related chemicals in the environment

A systematic assessment of carcinogenicity of chemicals in fracturing fluid and flowback water was conducted by Xu et al. (2019). The group assessed 1,173 fracturing fluid-related chemicals identified by the US Environmental Protection Agency (EPA) (Xu et al., 2019). They then linked the fracturing fluid chemical data to the agent classification data from the International Agency for Research on Cancer (IARC) at the World Health Organization (WHO), which was evaluated for human carcinogenic risk. Using IARC's database of 998 chemicals, they found information on 104 fracturing fluid-related chemicals with different evidence in carcinogenicity: 14 were carcinogenic to humans, 7 were probably carcinogenic, and 27 were possibly carcinogenic. Some of these carcinogenic compounds include 1,3-butadiene, ethanol, ethylene oxide, and formaldehyde, which are found in fracturing fluids; benzo(a)pyrene, beryllium, cadmium, radium-226 and -228 found in flowback; and arsenic, benzene, and chromium (VI) found in both. Additional assessment of the Carcinogenic Potency Database (CPDB) suggested that 66 fracturing fluid-related chemicals are potentially carcinogenic based on rats and mouse models (Xu et al., 2019). Xu et al.'s evaluation suggests that individuals with exposure to certain chemicals in fracturing fluids and wastewater may be at increased risk of cancer, as these chemicals can make their way into ground water and drinking water.

Elliott (2017) also systematically assessed evidence for potential carcinogenicity of both air and water pollutants from hydraulic fracturing exposures but specific to childhood leukemia and lymphoma risk. They likewise evaluated 1,177 chemicals in fracturing fluids and wastewater, finding similar results as those described by Xu et al. They additionally considered 143 UNGD-related air pollutants by review of scientific papers published through 2015 using both PubMed and ProQuest Database, and assessing carcinogenicity evidence of increased risk of leukemia and lymphoma from these chemicals using the IARC monographs. See **Figure 3**.



Of 143 potential air pollutants, 29 (20%) have been evaluated for carcinogenicity by IARC and the remaining 114 (80%) have not been evaluated (Elliot, 2017). Of the 29 air pollutants evaluated, 7 (24%) were carcinogenic to humans, 2 (7%) were considered probably carcinogenic to humans, 11 (38%) were considered possibly carcinogenic to humans, and the remaining 9 (31%) could not be classified with respect to their carcinogenicity. Of the 20 known, probable, or possible carcinogens, there has been supporting evidence for 11 air pollutants that were associated with an increased risk of leukemia or lymphoma. These included 5 known human carcinogens (1,3-butadiene, benzene, ethanol, formaldehyde, diesel engine exhaust), 2 probable human carcinogens (dibenz[a,h]anthracene, tetrachloroethylene), and 4 possible human carcinogens (carbon tetrachloroethylene, chrysene, indenol[1,2,3-*cd*] *pyrene* and styrene).

Risk Factors for Childhood Cancer

Although cancer in children and adolescents is rare, it is the leading cause of death by disease past infancy among children in the United States, according to the National Cancer Institute (NCI, 2021).

In 2021, it was estimated that 15,590 children and adolescents ages 0 to 19 were diagnosed with cancer and 1,780 died of the disease in the United States (Siegel, 2021). Overall, among children and adolescents (ages 0 to 19) in the United States, the most common types of cancer are leukemias, brain and central nervous system (CNS) tumors, and lymphomas (NCI, 2021). These are also the types of cancers found to be associated with various environmental exposures in both adults and children in the literature (NCI, 2021).

Many childhood cancers are caused by genetic mutations that increase cancer risk. Germline alterations (or variants) associated with an increased risk of cancer can be passed down from parents to their offspring, or somatic mutations in cells can occur spontaneously in cells during development (NCI, 2021). About 6-8% of all cancers in children are caused by an inherited pathogenic variant (harmful alteration) in a cancer predisposition gene (Gröbner et al., 2018, Zhang et al., 2015). For example, children with Li-Fraumeni syndrome, Beckwith-Wiedemann syndrome, Fanconi anemia, Noonan syndrome, and von Hippel-Lindau syndrome, have an increased risk of childhood cancer.

Genomic changes that arise during development of one of the germ cells (sperm or egg) which unite to form the zygote that becomes a child can increase the risk of cancer in that child (NCI, 2021). Genomic changes can include broken, missing, rearranged, or extra chromosomes and gene variants. One such alteration is trisomy 21, or the presence of an extra copy of chromosome 21, which causes Down syndrome. Children with Down syndrome are 10 to 20 times more likely to develop leukemia than children without Down syndrome (Ross, 2005). However, only a small proportion of childhood leukemia is linked to Down syndrome (NCI, 2021).

Genetic changes associated with cancer can also occur in different cells of the body after birth, as the body is actively growing and developing during early childhood (Moore et al., 2021). The extent to which these changes react to environmental exposures is unclear. In adults, exposure to cancer-causing substances in the environment, such as cigarette smoke, asbestos, and ultraviolet (UV) radiation from the sun is known to cause genetic changes that can lead to cancer (NCI, 2021). However, environmental causes of childhood cancer have been particularly difficult to identify, this is partly because cancer in children is rare and because it is difficult to determine what children may have been exposed to early in their development (NCI, 2021).

Nevertheless, several environmental exposures, such as ionizing radiation, can lead to the development of leukemia and other cancers in children and adolescents (NCI, 2021). Children and adolescents who were exposed to radiation from the atomic bombs dropped in Japan during the Second World War had an elevated risk of leukemia (Hsu et al., 2013). Also, children exposed to radiation from the Chernobyl nuclear plant accident had an elevated risk for thyroid cancer (Cardis, 2011).

Exposure of parents to ionizing radiation is also a concern in terms of the development of cancer in their future offspring. Exposure to diagnostic medical radiation from computed tomography (CT) scans by children whose mothers had x-rays during pregnancy (that is, children who were exposed before birth) and children exposed after birth has been linked to a slight increase in risk of leukemia and brain tumors, and possibly other cancers (Pearce et al., 2012). However, genomic analysis of children

born to people exposed to radiation at Chernobyl indicates that this exposure did not lead to an increase in new genetic changes passed from parent to child (Yeager et al., 2021).

Several other environmental exposures have also been associated with childhood cancer; however, it is difficult to draw firm conclusions because of challenges in studying these exposures. For some types of childhood leukemia (particularly acute lymphoblastic leukemia), researchers have identified associations with paternal tobacco smoking (Liu, 2011, Cao, 2020); exposure to certain pesticides used in and around the home (Bailey et al., 2015) or by parents at their workplaces (Van Maele-Fabry, 2010, Vinson, 2011); use of solvents, organic chemicals found in some household products; and outdoor air pollution (NCI, 2021).

Investigations of childhood brain tumors and leukemia and lymphomas have studied associations with exposures to pesticides in and around the home. A meta-analysis of 277 studies found an increased risk of leukemia and lymphomas in children exposed to indoor residential pesticides. A significant increase in the odds of leukemia was also associated with herbicide exposure. Also observed was a positive but not statistically significant association between childhood home pesticide or herbicide exposure and childhood brain tumors. (Chen et al., 2015). Johnson et al, 2014 reported an association of maternal consumption of cured meats and childhood brain tumors. A recent study (Lombardi et al, 2021) used the California cancer registry to identify childhood cases of brain tumors and linked residence to agricultural pesticide exposure. They noted a significant increased risk of CNS tumors and proximity to residences.

Researchers have also identified factors that may be associated with reduced risk of childhood cancer (NCI, 2021). For example, maternal consumption of folate has been associated with reduced risks of both leukemia and brain tumors in children (Chiavarini, 2018). Also, being breastfed and having been exposed to routine childhood infections are both associated with a lowered risk of developing childhood leukemia (Amitay, 2015).

Previous Hydraulic Fracturing and Childhood Cancer Studies

Three studies have been published that examined a possible association between hydraulic fracturing and the risk of childhood cancer. The study populations and main findings are briefly summarized in **Table 1.** Below are more details for each of these three studies.

Fryzek et al. (2013) were the first to investigate a potential relationship between childhood cancer and hydraulic fracturing in Pennsylvania. The study compared cancer incidence rates at the county level before and after hydraulic fracturing to determine if rates increased. The study did not find a significant increase in the incidence of total cancers or leukemia. It did find a slightly elevated incidence rate for central nervous tumors after drilling began. The ecological study design employed has major limitations due to a lack of individual level data. Further studies were required to draw solid conclusions about the relationship between hydraulic fracturing and childhood cancer.

	Fryzek et al., 2013	McKenzie et al., 2017	Clark et al. 2022		
Study area	Pennsylvania	Rural Colorado	Pennsylvania		
Time period	1990-2009 (stopped data collection 2 years after hydraulic fracturing began - latency issues)	2001-2013	2009-2017		
Study population size/design	Standardized incidence rates by county for cases of CNS and leukemia, age 0-20 (N =1,874)	Case-control: aged 0-24, Final sample: 87 ALL, 50 lymphoma and 528 controls diagnosed with non-hematologic cancer sample	Case-control study, N=405 cases of ALL and 2,080 controls		
Data source	PA Cancer Registry, US Census Bureau	Colorado Central Cancer Registry	PA Cancer Registry, PA Vital Records (Bureau of Health Statistics and Registries)		
Exposure metrics	Compared SIRs before and after drilling using spud dates (date drilling operations begin)	Inverse distance weighted oil and gas well counts within a 16.1 km radius of the residence at time of diagnosis	Inverse distance-squared weighted well counts with buffer sizes 2, 5, and 10 km from birth address for the association between residential proximity to UNGD and ALL in primary exposure and perinatal window		
Outcome	Childhood cancer, childhood leukemia, and CNS tumors	ALL and NHL	ALL		
Results	 The observed number of childhood cancers both before and after drilling were as expected (based on SEER cancer incidence rates) No evidence that persons living in counties with HF experienced higher childhood cancer rates overall or for childhood leukemia 	 Children aged 0-24 years diagnosed with NHL were no more likely to live in areas with active oil and gas development than children diagnosed with non- hematologic cancer Children aged 5-24 years diagnosed with ALL were more likely than children diagnosed with non- hematologic cancer to live within 16.1-km of an active oil and gas well 	 Children with at least one UNGD well within 2 km of their birth residence during the primary window had 1.98 (95% Cl: 1.06, 3.69) times the odds of developing ALL in comparison with those with no UNGD wells Children with at least one vs. no UNGD wells within 2 km during the perinatal window had 2.80 (95% Cl: 1.11, 7.05) times the odds of developing ALL 		

Table 1: Comparison of Previous HF and Peer-Reviewed Childhood Cancer Studies

Two case-control studies have been published in the US involving individual data on childhood cancer risk and hydraulic fracturing. The first was conducted between 2001-2013 in Colorado by McKenzie et al. (2017); and the other was conducted between 2009-2017 in Pennsylvania by Clark et al. (2022).

McKenzie et al. (2017) conducted a case-control study in rural Colorado and included participants who were 0-24 years old and diagnosed with cancer between 2001-2013. For each child, they estimated exposure to hydraulic fracturing activity by calculating the distance between the participants' residences and oil and gas wells within a ten-mile radius. Exposure metrics accounted for both the density and proximity of wells to the child. The logistic regression utilized adjusted for age, race, gender, income, and elevation.

Children aged 0-24 with acute lymphoblastic leukemia (ALL) were more likely to live in areas with active wells. For ages 5-24, ALL cases were 4.3 times as likely to be in the highest exposure category. Further adjustment for year of diagnosis increased the association. The study's limitations included the use of non-hematologic cancer cases as a control group, the substantial number of cancer cases that could not be geocoded (28%), and the sole use of residence at cancer diagnosis to calculate exposure, which is not static and can result in misclassification bias.

A more recent case-control study was reported by Clark et al. (2022), which included 405 children aged 2-7 diagnosed with ALL in Pennsylvania between 2009–2017, and 2,080 controls matched on birth year. They calculated a similar exposure metric to the McKenzie study (2017) but used different distance cutoffs to better understand how distance affects exposure levels. They investigated two time-based exposure windows: a primary window (3 months preconception to 1 year prior to diagnosis/index date) and a perinatal window (3 months preconception to birth).

Clark et al. used logistic regression to estimate odds ratios (ORs) and 95% confidence intervals (Cis) for the association between residential proximity to UNGD and ALL in two exposure windows. Children with at least one UNGD well within 2 km (1.2 mile) of their birth residence during the primary window had 1.98 times the odds of developing ALL in comparison with those with no UNGD wells (95% CI: 1.06, 3.69). This result was only based on 7 cases. After adjusting for maternal race and other potential confounders, the OR was no longer statistically significant (OR=1.74, 95% CI: 0.93, 3.27). Similar ORs were produced by models using the water pathway-specific metric.

A major limitation of the Clark et al. study was that a considerable proportion (93-98%) of the study population had no exposure to any UNGD activity within a 10-mile radius. Regulations in metropolitan areas such as Philadelphia and Pittsburgh, or the lack of shale deposits, prohibit hydraulic fracturing activity in sizable portions of Pennsylvania. High proportions of unexposed participants within the study hindered the investigators' ability to identify associations.

In addition to the three peer-reviewed studies, on February 13, 2019, the Pittsburgh-based TV news channel WPXI aired a story regarding a potential cluster of Ewing sarcoma, also sometimes called the Ewing family of tumors (EFOT), a specific type of bone or soft tissue cancer usually occurring in childhood or adolescence. Subsequently, the PA Department of Health received many calls concerning multiple children in the Canon-McMillan School District in Washington County, reporting that they had been diagnosed with EFOT. Several parents came forward to say that their children were also diagnosed with the same disease.

This prompted a cancer incidence survey reported on April 22, 2019 (PADOH, 2019). The PA Department of Health analyzed cancer registry data in three time periods: 1985–1994, 1995–2004 and 2005–2017. These three time periods were used to assess cancer incidence trends over time. This analysis used the mid-time period census population (1990, 2000, and 2010 census data) for age adjustment. Age-standardized SIRs for various childhood cancer types and their 95% CIs for Washington County and Canon-McMillan School District residents were calculated respectively by gender to determine whether the residents experienced a significant excess of cancer incidence compared to the rest of the Pennsylvania population.

Study results for Canon-McMillan School District and incidence of EFOT indicated that there were no cases reported during the first two time periods before hydraulic fracturing. However, there were three cases reported during the 2005-2017 period, which coincided with hydraulic fracturing. The SIRs of Ewing sarcoma estimated based on this small number of cases were considered unstable and difficult to interpret. Overall, total childhood cancer incidence rates were also calculated, and both female and male childhood cancer rates were not appreciably different from the rest of the Commonwealth during any of the three time periods. Moreover, childhood cancer rates in the school district decreased over the last two time periods. The PADOH, however, stated that it would continue to closely monitor EFOT and pediatric cancer incidence in Pennsylvania over the next several years as new data becomes available through the PA cancer registry.

Community concerns persisted, prompting a supplemental analysis reported in March 2020 in addition to advancing other research studies. The present case-control study was initiated by PA Governor Wolf's administration due to concerns about the Ewing sarcoma cluster and a significant rise in hydraulic fracturing and UNGD drilling in western PA since 2005.

Study Aims and Objectives

This study aims to investigate the risk for childhood cancer related to environmental exposures from UNGD hydraulic fracturing in Southwestern Pennsylvania.

Objectives:

- 1) We built upon previous studies of exposure to hydraulic fracturing and risk of childhood cancer by conducting a matched case control study using the entire sample of cancer cases identified within the 8-county study area and identifying one randomly selected age, gender, race, and county matched control. Birth records were used to extract information on the mother's and newborn's residence and their characteristics. This birth record-based /cancer registry study enabled comparison with earlier studies conducted by McKenzie (2017) and Clark (2022).
- An overall UNGD well activity metric was created using each of the individual phases to investigate the childhood cancer risk while controlling for sociodemographic, health history, and behaviors in the year before birth up to the child's cancer diagnosis date.
- 3) This study also sought to collect more detailed residential histories that can be applied to individual phases and overall UNGD well activity in childhood cancer cases and controls.

Study Design: The study examined three populations derived from the 507 childhood cancer cases diagnosed from 2010-2019 in the eight-county Southwestern Pennsylvania area. The study team completed 234 residency interviews for cases and were able to match 213 of these cases with controls born in the same county, and 160 with controls born in different counties (but still in the eight-county area). Of the total of 507 childhood Cancer Cases, a total of 498 cases were matched to a new group of county-matched controls using only birth certificate data. Nine cases were removed from the full list of cases during data verification.

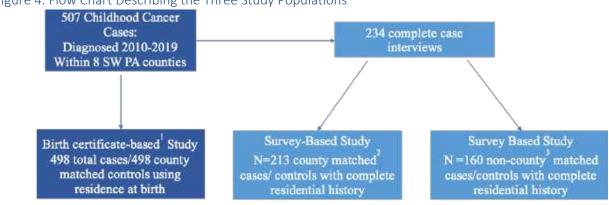


Figure 4. Flow Chart Describing the Three Study Populations

- 1. Birth certificate-based means the exposure is based on the mother's residence at birth.
- 2. County-matched means controls came from the same county as the case.
- 3. Non-county-matched means controls were chosen at random from the eight-county area.

II. Methods

Study Population

All cases and controls were born in one of the eight counties selected for this study, including Allegheny County (except city of Pittsburgh), Armstrong, Beaver, Butler, Fayette, Greene, Washington, and Westmoreland. Case children were diagnosed with any of four types of malignancies described below and had an address within the defined study area at the time of cancer diagnosis between the years of 2010-2019.

Due to restrictions in hydraulic fracturing within city limits of Pittsburgh, it was necessary to exclude any cases or controls whose parents lived in a zip code located in, or part of, the City of Pittsburgh, as indicated on the birth record or at time of cancer diagnosis. Zip codes excluded from the City of Pittsburgh are shown in **Appendix B**.

Case Inclusion Criteria

All cases of childhood cancer in the present study were identified through the PA Cancer Registry diagnosed from 2010-2019. The cancer types were leukemia, lymphoma, CNS tumors, and malignant bone tumors diagnosed at 0-19 years of age. We extended the age range up to 29 years for malignant bone tumors, including EFOT, to increase sample size due to the rarity of the condition and its later presentation. These specific malignancy types were defined according to the <u>International</u> <u>Classification of Childhood Cancer Recode Third Edition (ICD-O-03/IARC 2017)</u>, which is recommended by the NCI Surveillance, Epidemiology, and End Results (SEER) Program. See **Table 2**.

Table 2. Definition of Childhood Cancer Cases for the Case-Control Study in Western PA (International Classification of Childhood Cancer Recode Third Edition, ICD-O-3/IARC 2017)

Cancer type	ICCC Recode 3 rd ICD-O-3/	Behavior	ICD-O-3 primary site code
	IARC 2017 morphology codes	codes	
I. Leukemias, Myeloproliferativ	e, and Myelodysplastic Diseases (0-19 y	/ears of age)	
1. Des sums an and de vita mais	9811-9818, 9837	3	C420, C421, C423, C424, C809
1. Precursor cell leukemia	9835, 9836	3	C000-C809
	9823	3	C420, C421, C423, C424, C809
2.Mature B-cell leukemias	9826, 9832, 9833, 9940	3	C000-C809
3. Mature T-cell and Natural	9827	3	C420, C421, C423, C424, C809
Killer (NK) cell leukemias	9831, 9834, 9948	3	C000-C809
	9591	3	C420, C421, C423, C424
4. Lymphoid leukemia, NOS	9820	3	C000-C809
5. Acute myeloid leukemias	9840, 9861, 9865-9867, 9869-9874, 9891, 9895-9897, 9898, 9910, 9911, 9920, 9930, 9931	3	C000-C809
6. Chronic myeloproliferative diseases	9863, 9875, 9876, 9950, 9960-9964	3	C000-C809
7. Myelodysplastic syndrome and other myeloproliferative diseases	9945, 9946, 9975, 9980, 9982-9987, 9989, 9991, 9992	3	C000-C809
8. Unspecified and other	9800, 9801, 9805-9809, 9860, 9965-	3	C000-C809
specified leukemias II. Lymphoma (0-19 years of ag	9967		
II. Lymphoma (0-19 years of ag		L -	
1. Precursor cell lymphomas	9727-9729	3	C000-C809
	9811-9818, 9837	3	C000-C419, C422, C440-C779
2. Mature B-cell lymphomas (except Burkitt lymphoma)	9597, 9670, 9671, 9673, 9675, 9678-9680, 9684, 9688-9691, 9695, 9698, 9699, 9712, 9731-9735, 9737, 9738, 9761, 9762, 9764-9766, 9769, 9970, 9971	3	C000-C809
	9823	3	C000-C419, C422, C440-C779
3. Mature T-cell and NK-cell	9700-9702, 9705, 9708, 9709, 9714, 9716-9719, 9724-9726, 9767, 9768	3	C000-C809
lymphomas	9827	3	C000-C419, C422, C440-C779
4. non-Hodgkin lymphomas,	9591	3	C000-C419, C422, C440-C779, C809
NOS	9760	3	C000-C809
5. Burkitt lymphoma	9687	3	C000-C809
6. Miscellaneous lymphoreticular neoplasms	9740-9742, 9750, 9751, 9754-9759	3	C000-C809
7. Unspecified lymphomas	9590, 9596	3	C000-C809

Table 2 Continued. Definition of Childhood Cancer Cases for the Case-Control Study in Western F	эА
(International Classification of Childhood Cancer Recode Third Edition, ICD-O-3/IARC 2017)	

Cancer type	ICCC Recode 3 rd ICD-O-3	Behavior	ICD-O-3 primary site code		
	IARC 2017 morphology codes	codes			
III. CNS and Miscellaneous Intra	cranial and Intraspinal Neoplasms (0-19 years	of age)			
1. Ependymomas and choroid plexus tumor	9383, 9390, 9391-9394, 9396	0-1, 3	C000-C809		
	9380	0-1, 3	C723		
2. Astrocytomas	9384, 9400-9411, 9420-9424, 9425, 9440- 9442	0-1, 3	C000-C809		
3. Intracranial and intraspinal	9470-9478, 9480, 9508	0-1, 3	C000-C809		
embryonal tumors	9501-9504	0-1, 3	С700-С729		
4. Other gliomas	9381, 9382, 9385, 9430, 9431, 9444, 9445, 9450, 9451, 9460	0-1, 3	C000-C809		
0	9380	0-1, 3	C700-C722, C724-C729, C751, C753		
5. Other specified intracranial and intraspinal neoplasms	9840, 9861, 9865-9867, 9869-9874, 9891, 9895-9897, 9898, 9910, 9911, 9920, 9930, 9931	3	C000-C809		
	8158, 8290	0-1, 3	C751		
6. Unspecified intracranial and intraspinal neoplasms	8000-8005	0-1, 3	C700-C729, C751-C753		
IV. Malignant Bone Tumor (0-29) years)				
1. Osteosarcoma	9180–9187, 9191–9195, 9200	3	C400-C419, C760-C768, C809		
	9210, 9220, 9240	3	C400-C419, C760-C768, C809		
2. Chondrosarcomas	9211-9213, 9221, 9222, 9230, 9241-9243		C000-C809		
	9231		C400-C419		
	9260	3	C400-C419, C760-C768, C809		
3. Ewing tumor and related sarcomas of bone	9365		C000-C809		
sarcomas of bone	9364		C000-C809		
4 Other specified malignant bone tumors	8810, 8811, 8818, 8823, 8830	3	C400-C419		
	8812, 9262, 9370-9372, 9270-9275, 9280- 9282, 9290, 9300-9302, 9310-9312, 9320- 9322, 9330, 9340-9342, 9250, 9261		C000-C809		
5. Unspecified malignant bone tumors	8000-8005, 8800, 8801, 8803-8805	3	C400-C419		

Exclusion of Ineligible Cases

A total of 593 cancer cases were identified from the PA Cancer Registry between 2010-2019 according to the case eligibility criteria described above. During the data checking and cleaning process, the study team identified the following number of cancer cases were ineligible, and thus were excluded from the final statistical analysis:

- 41 based on the Third Edition ICD-O-3/IARC 2017
- 25 diagnosed within the City of Pittsburgh
- 20 born outside of the eight-county study area.

After these cases were excluded, a total of 507 cancer cases were deemed eligible for the study.

Control Selection

We referenced the birth record registry at PA Bureau of Health Statistics and Registries to select age-, sex- and race-matched controls for either the county-matched or non-county-matched groups. The details of the specific control selection algorithm are provided in Appendix B of this report.

The following steps were followed to obtain a county-matched control:

- A control was selected among children whose mother's residence was recorded on the birth record in the same county as the index case at birth.
- In addition to age, sex, and race, a control without matching on county was selected among children whose mother's residence was <u>within the eight counties</u> of the study area.
- Eligible controls were born within ± 45 days of the index case and were of the same sex and mother's race. For each case, up to 40 county-matched controls and 40 non-county-matched controls were randomly chosen by the PADOH without replacement.
- If the number of eligible controls was fewer than 40 for a given index case, the PA Bureau of Health Statistics and Registries provided information on all eligible controls.
- If a control was matched to multiple cases, a simple random sampling algorithm without replacement was used to determine the matched index case.

We made attempts to locate and update the information of current and past residence history of all cases and 20 of the 40 eligible controls (due to time limitations) through the contact information tracing service Lexis Nexis (described in detail below). Additionally, we used Spokeo, an online tracing service that provides property records, emails, addresses, and phone numbers to confirm residential history and contact information when needed. A unique random number was generated during the control selection process for each of 40 eligible controls per case.

The county-matched control was chosen to help adjust for both urban/rural differences within each county and to assure the greatest similarity of sociodemographic and environmental characteristics to the index cancer case. The non-county match was chosen to limit potential bias from over-matching. The duration of the exposure data collected for the control subject was the same as for the index case, and personal history was obtained up to the index date, which was defined as the date of cancer diagnosis for cases. The same date was applied to matched controls.

Survey

A survey questionnaire was developed based on an ATSDR (Agency for Toxic Substances and Disease Registry) childhood cancer cluster investigation (State of New Jersey Department of Health, 2017) and was modified to include hydraulic fracturing, and industrial and farming activity with an emphasis on residential history. The objective of the survey was to capture the mother's and child's environmental exposure history, residential history, sociodemographic information, health history, and behaviors in the year prior to birth up to the cancer diagnosis date. The survey was then uploaded to a Qualtrics (Provo, UT) software platform. If there were any questions the parent was uncomfortable addressing, they could decline to answer at any time. See **Appendix D**.

As will be described below, the initial response rate from the PADOH recruitment brochure was low (20%) and it was determined that the at least 45 minutes needed to answer the survey questions was negatively affecting the response rate. It became necessary to shorten the questionnaire into a more user-friendly online version, which could be taken at any time. The revised survey included many of the same sections but included fewer questions. See **Table 3**.

Tuble 5. Multi Sections of Cuse control Survey	
1. Parental background and demographics	5. Maternal reproductive history
2. Residential history, home characteristics,	6. Maternal medical procedures that occurred
and environmental risk factors for all	during pregnancy with case/control child
addresses	
3. Occupational and lifestyle histories of	7. Child's medical procedure and infection
the parent(s)	history
4. Familial cancer history	8. Optional questions regarding household
	income, interest in future studies, opportunity
	to share any additional relevant information

Table 3. Main Sections of Case-control Survey

The shortened survey is included in **Appendix D**. The longer survey is available upon request.

Overview of Recruitment and Enrollment Process

The Institutional Review Board (IRB)/consent application for this study (protocol number 21020141) was approved by the University of Pittsburgh IRB on March 16, 2021. The PADOH-specific IRB application was approved on June 17, 2021. The University of Pittsburgh applied for and was granted access to protected health information in a data sharing agreement from the PADOH on April 19, and July 7, 2021, respectively. Parents of case and control children, not the children themselves, were asked to participate in the study. The information collected included residence of the mother, and both parents' occupation and health behaviors, including the pregnancy period and early years of the child's life. There was no assent process for children under 18. IRB materials, the timeline of study events, and outreach and recruitment materials are included in **Appendix C**.

PADOH leadership strongly recommended a government-approved third-party tracing agency, LexisNexis, to provide updated and confirmed contact information for recruitment mailings, phone calls, text messages, and emails. The LexisNexis contract was finalized in August 2021, and updated contact information was provided in September 2021, prior to the dissemination of the first round of case recruitment mailings. The initial case dataset was received from the PADOH in September 2021, with the decedent cases received in April 2022.

The initial case recruitment protocol, beginning in late September 2021, included a letter from the PADOH Secretary of Health inviting families to schedule a 45–60-minute telephone interview, a brochure explaining the study, and an opt-in/opt-out card with a pre-addressed return envelope. The study team's strategy was to prioritize case recruitment given the need for a sample of controls matched on age, race, gender, and county. Participants who did not respond were sent an additional letter.

Telephone interviewers attempted to contact all parents who opted in using a computer– assisted telephone interviewing (CATI) system to manage sample and call attempts. The CATI system was linked to a Qualtrics-based survey which interviewers used to administer the survey instrument. The PADOH protected-access protocol mandated that only one phone call be made to request participation after receipt of the two recruitment mailings.

Due to concern about the initial low response rate (<20%) after the two letters were sent and follow-up calls were made, the study team initiated a briefer questionnaire that included an online 20–25-minute interview facilitated by co-investigator Dr. Todd Bear and the Population Survey Facility in Pitt School of Medicine in March 2022. In addition, in May 2022 the survey team initiated a shortened two-page residential questionnaire that captured a complete residential history. See **Figure 5** for a timeline of recruitment efforts.

To augment the study response rate and enhance communication with families, the study team solicited support from Dr. Jean Tersak, of UPMC Children's Hospital of Pittsburgh, who provided a letter of support for the study which was subsequently included in all study recruitment mailings. Dr. Tersak was added as a study co-investigator in June 2022.

August 2021		ontract finali						n	Monthly USPS Mailing Total	
September 2021	case trac	ing performe	4						Cases: 86	
October 2021	2 rd mailing:	1		ì					Cases: 125	
November 2021		and the second se								Cases: 140
December 2021										Cases: 103
January 2022			-						Cases: 23	
February 2022		and a second second	Phone call follow-ups						Cases: 64	
March 2022		sent out	to cases: 967 attempted,	-					Cases: 58	
April 2022		Treamy	124 successful						Cases: 12	
May 2022			41 refusals	ds					Cases: 74 Controls: 832	
June 2022				All control	Corrected		2-page questionnaires	EventBrite Case Fa	Cases: 8	
July 2022		1	mailings	and the second	addresses for 3 rd case	Email and text	mailed to cases (n=29)	Invitations (n=1,809)	Cases: 142 Controls: 4,097	
August 2022			(n=8.355)	mailing (n=123)	message follow- up for controls (n= 59,897) Cases =800*	Phone call follow- ups to controls. 1,111 attempted, 32 successful, 270 refusals		Cases:0 Controls: 1,582		
September 2022							Survey enrollment	Cases: 0		

Figure 5. Timeline of Recruitment Efforts for Cases and Controls

*in follow-up of phone calls

In summer 2022, the study team worked with community nurses and supervisors at state health centers in Washington and Westmoreland counties to facilitate in-person informational sessions at respective health centers in Washington and Greensburg. The goal of these planned sessions was to make the study team available to answer any questions the invited case families may have had regarding the study and their invitation to participate, as well as to facilitate their participation. The study team utilized the email addresses provided by LexisNexis (up to three addresses per parent, a maximum of six addresses per family) to send e-vites to these events, with RSVP capabilities provided through Eventbrite.

The study team sent 1,809 invitations to unique email addresses, of which 415 emails were found to be undeliverable or incorrect; 1,394 were successfully delivered. While 258 recipients clicked the link to the Eventbrite page, no confirmed responses were received for the events. One case family contacted the study team through the publicly available study email address to posit a question about the events, but no families expressed interest in attending the information sessions or completing the online survey. The lack of interest in attending these events was most likely due to remaining COVID school closures and protocols.

Control families were sent an initial mailing between May-September 2022. The study team was permitted to pivot to electronic methods of contact for the second mailing, and emails were sent September 8-22. Priority was given to contacting matched controls of the cases who had already completed an interview. Once a control for each case and each group had participated, and the survey was deemed eligible (completing the residential history at a minimum), no more controls for that case were contacted. Only a few matched controls were contacted at a time to reduce the number of duplicate controls, and to minimize extraneous recruitment outreach efforts.

Control enrollment was closed on September 27, 2022, to allow the study team sufficient time to clean, analyze, and summarize the data. 8,355 initial recruitment letters were mailed to control families between May-September 2022 and 48,298 reminder letters were sent as emails. Telephone interviewers were given case records of anyone who had not responded to previous mail invitations. These individuals were contacted a maximum of five times in seven days. See **Appendix B** for a summary of activities for recruitment of controls.

Incentives

Incentives were provided for all participants who did not refuse payment. The study team used two University of Pittsburgh-approved incentive programs. Initially, the Vincent Card program was used, which involved sending a payment card loaded with a specified amount of money to the participant after the survey. The participant then called the university, reaching a member of the study team who would activate their card. Participants were followed-up if they did not call to activate their card. A new program, called the Tango Card System, was implemented halfway through the recruitment process to simplify the process and to be more conducive to the new online method of completing the survey independently.

The Tango Card system involved the participants entering an email address at the end of the survey. Upon the survey's completion in the Qualtrics software platform, a link was automatically sent to their provided email address, giving the participants access to a site where a variety of gift cards could be selected. Email addresses could not be used multiple times to receive additional payments. Cases were provided \$25 compensation, and controls were provided \$15. The decrease in incentive for controls was due to the shortening of the survey, which preceded control participation. Case participants who took the shorter survey had their incentives kept at \$25 to align with initial communications about the study. 804 participants completed the study, with 731 accepting and receiving paid incentives.

Final Enrollment Numbers

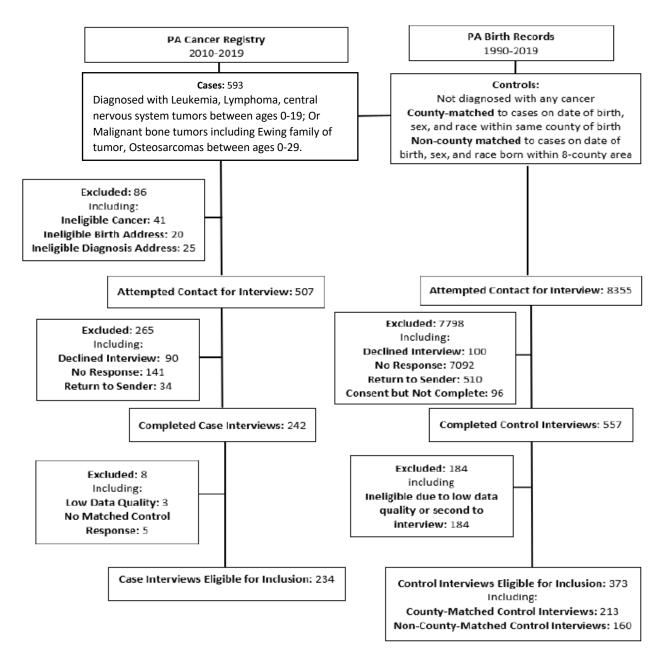
A total of 593 cancer cases were originally identified by the study team. A shift to the use of the ICD-O-3/IARC 2017 coding from an earlier version was recommended by PADOH, leading the study team to reclassify 41 eligible cases to ineligible. Of the 507 remaining eligible cases which the study team attempted to contact, 265 were excluded because 90 refused to participate,141 did not respond to contact attempts, and 34 mailings were "return to sender." An additional 8 cases were excluded from post-data collection; 5 cases were unmatched to a control, and 3 cases were excluded due to low data quality. These exclusions resulted in 234 eligible case interviews.

The research team attempted to contact 8,355 controls, with a priority for interviews with controls whose matched case had already been interviewed. Multiple potential controls for each case were contacted, with the first control who had an eligible response used as the match. 7,798 controls were excluded during recruitment: 7,092 did not respond, 510 were unable to be traced after the letter returned as return to sender, 100 declined interviews, and 96 consented to participate but did not complete the survey. 557 controls were interviewed, but 184 either had low quality data or were second

responses for cases who already had a matched control interview completed for that group (countymatched or non-county-matched). 373 controls were included in the analysis. See **Figure 6** for the final enrollment diagram of the case-control study.

Of the 234 eligible case interviews, 147 cases had both county-match and non-county-match controls. A total of 13 cases only had a non-county-matched control and 66 cases only had a county-matched control. After excluding those who refused and the study team was unable to contact, the cooperation rate was 63%.





Exposure Measures

UNGD Activity Overview

The primary exposure measure for this study was an inverse distance-weighted index of UNGD activity within 5 miles of parent and child residence. The study team also considered additional buffers: 0.5, 1, and 2 miles. There were four phases of UNGD, including well pad preparation, drilling, hydraulic fracturing, and production, which varied in duration and exposures to potential carcinogens. Therefore, the UNGD activity metric was calculated separately for each of the four phases, for each study subject. Additionally, the study team created an overall activity metric structured the same way as the phase specific metrics, but the duration of activity spanned from the start date of well pad construction until the end of the production phase for each relevant well. Due to the way the phase metrics were structured, the overall activity metric was also equivalent to the sum of the 4-phase metrics. Lastly, the study team calculated well count and inverse distance weighting (IDW) well count to measure the density of and proximity to well sites without integrating duration of exposure. These two metrics were used to align with previous studies.

For wells located in Pennsylvania, data required to calculate the UNGD activity metric were obtained from the Pennsylvania Department of Environmental Protection and the Pennsylvania Department of Conservation and Natural Resources. For wells in Ohio and West Virginia, data were obtained from the Ohio Department of Natural Resources and the West Virginia Department of Environmental Protection, respectively. Due to the difference in the reported data in Ohio and West Virginia (provided annually, rather than daily), the study team was unable to incorporate these data into analyses. Although the analyses focus on residences within the bounds of the eight-county study, the study team had to account for residences located on the geopolitical borders of the study region. To account for this, buffer regions that extended five miles into adjacent counties were included and exposure data within these buffer regions were captured. UNGD phase descriptions are below:

- 1. Well pad preparation the process of preparing a site where one or more wells were located. It is defined as the period beginning 30 days before the first well on the pad is spudded and ending when the first well is spudded.
- 2. **Drilling** the creation of the wellbore. This phase begins on the well's spud date and ends on the drilling completion date; the median for the wells was 104 days.
- 3. **Hydraulic fracturing** the process of injecting large volumes of water at high pressure into the wellbore to fracture the shale layer. This period is defined as beginning on the stimulation commencement date and ending on the stimulation completion date. Hydraulic fracturing may be repeated over time for a given well. The median for the wells was 12 days.
- 4. **Production** the process of collecting natural gas or oil that—following hydraulic fracturing—travels through the wellbore to the surface. Production durations are variable. A well was defined as being in production for reporting periods when production was indicated and reported production volume was non-zero. The minimum amount of time in the production phase was 30 days (as per how the data were reported). The maximum number of days was 8,769 days. The mean number of days was 2,239 and the median was 2,193 days. An individual well could have had multiple production periods with gaps in which the well was inactive. Calculations include all production period durations but not the gaps between them.

UNGD Exposure Metrics Calculation

Inverse distance weighting (IDW) is a metric used to account for both the proximity and density of wells within a designated buffer distance from a participant's residence. It is a commonly used metric in environmental epidemiological studies. The metric includes a numerator value which is typically 1 but can also take on other quantifying values, such as daily volume of gas production or well depth, adding further information to the metric. The denominator is a measure of distance, typically the distance measured squared. Then these individual fractions are summed across all wells located within a designated buffer distance. See **Figure 7**.

In previous studies, a well was included in the IDW metric if it was both within the designated buffer and there was at least one day of overlap between the well's activity and the participant's study period of interest. This kind of metric did not account for the duration of overlap. For example, two wells that were equidistant from a participant's residence would have made the same contribution to their exposure metric, even if one well was active for one day, whereas the other for one year during the participant's study period. The study team created this metric because it was commonly used in existing literature. To account for duration of exposure, the study team also created an overall activity metric that integrated both the distance and duration of every active well.

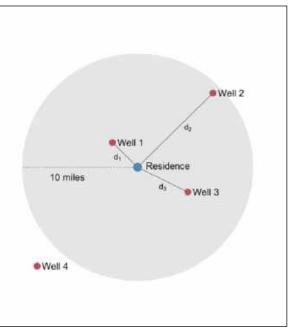
To include a duration element, the numerator for the IDW overall activity metric, as well as the well pad construction, drilling metrics were the sum of days of activity overlap, over the distance squared of each well. This number was summed across all wells within the designated buffer distance. The numerator for IDW hydraulic fracturing and production metrics was well depth in meters and daily average volume of gas production in cubic meters (m³), respectively, summed over the days of overlap between each respective phase and the participant's study period, then summed across all wells within the designated buffer distance. These two metrics were calculated with additional information to examine how well depth and gas production volume contributed to exposure metric for a given participant.

An IDW overall activity metric and well count metric was calculated as the primary exposure variables. Additionally, 4 IDW metrics corresponding to each phase were calculated as secondary exposure variables. An additional metric of well count (without the use of IDW) was calculated. While examining each phase alone may introduce some issues because many individuals can be exposed to more than one phase simultaneously, the analysis can still contribute to the study's overall conclusions. These 7 metrics were calculated for each residence of the case or control subject. Because each participant could move multiple times during the period of exposure, these metrics were first calculated by residence and then aggregated to create one metric per participant. Further description about how metrics were aggregated provided in the Data Processing section.

Figure 7. Inverse Distance Weighting Example

Inverse distance weighting is a method for calculating exposure to nearby locations of interest, such as UNGD wells.

- The resulting IDW metric not only takes into account the number of wells nearby a residence, but also how close the wells are.
- Wells located close to the residence (like Well #1) contribute more to the IDW metric value, while wells farther away (like Well #2) contribute less.
- Often a buffer distance is used as a boundary, beyond which a well (like Well #4) no longer contributes to the IDW metric value.



Definition of Time Periods

A participant's study period of interest included two time periods. Pregnancy (exposure time window 1, or T1) was defined as conception through date of birth. Date of conception was calculated by subtracting gestational age (in weeks) from the date of birth. Total exposure (exposure time window 2, or T2) was defined as date of birth through the index date, which was date of cancer diagnosis for cases. The same date was applied to controls so the period for both cases and controls was identical.

UNGD activities for a given well had 4 phases as described previously. The duration of each phase was defined in **Table 4**. Each of the data was found, or calculated, using datasets from the Pennsylvania Department of Environmental Protection and the Pennsylvania Department of Conservation and Natural Resources. If a phase for well or well pad overlapped with the case's study exposure time windows T1 and/or T2, all or in part, the overlapping portion of that phase contributed to the calculation of the activity metric for that individual case. See **Tables 5a** and **5b** for the equations of these metrics with an explanation of each term.

Metric	Variable name	Definition of Duration			
1	Overall Activity	Production period end date minus start date of the well pad preparation variable minus (if applicable) periods of inactivity between production periods			
2	IDW Well Count	Numerator was 1 if there were any days overlap between spud date until the most recent production period end date (wells can have multiple production periods), and the participant's exposure period			
3	Well Count	Count of 1 if there were any days overlap between spud date until the most recent production period end date (wells can have multiple production periods over time), and the participant's exposure period			
4	Well Pad Preparation	Spud date minus 30 days			
5	Drilling	Stimulation commencement date minus spud date +1 day			
6	Hydraulic Fracturing	Stimulation completion date minus the commencement date + 1 day			
7	Production	Production period end date minus production period start date			
*Spud date	*Spud date is a fracking industry term meaning the first day of drilling.				

Table 4. Definition of UNGD Activity Metric Phase Durations

Metric	Variable	Calculation of phase-specific activity metric
	Name	
1	Overall Activity	Overall well activity for maternal residence $J = \sum_{i=1}^{n} \sum_{k=1}^{l} \frac{I_{A}(K)}{d_{ij}^{2}}$ Where: • <i>n</i> was the number of wells within 0.5, 1, 2, or 5 miles of maternal residence <i>j</i> • <i>k</i> was equal to the date of the beginning of conception and <i>l</i> the date of birth (for T1), or <i>k</i> was equal to date of birth and <i>l</i> the index date (for T2) • $I_{A}(K)$ was equal to 1 when $d_{ij} \le 0.5$, 1, 2, or 5 miles, respectively, and the overall activity (from well pad construction to the end of production not including any inactive periods of production for a given well) overlapped with the defined exposure time window (T1 or T2), or equal to 0 otherwise
2	Well Count IDW	• d_{ij}^2 was the squared distance (m ²) between well <i>i</i> and maternal residence <i>j</i> IDW well count for maternal residence $j = \sum_{i=1}^{n} \frac{I_A(K)}{d_{ij}^2}$
		 Where: <i>n</i> was the number of wells within 0.5, 1, 2, or 5 miles of maternal residence <i>j</i> <i>k</i> was equal to the date of the beginning of gestation and <i>l</i> the date of birth, or <i>k</i> was equal to date of birth and <i>l</i> the index date for maternal residence <i>j</i> <i>I</i>_A(<i>K</i>) was equal to 1 when <i>d_{ij}</i> ≤ 0.5, 1, 2, or 5 miles, respectively, and the activity of a well (between spud date and the end date of the last production period) overlapped with the defined exposure time window (T1 or T2), or equal to 0 otherwise
3	Well Count* *(Results for this metric	• d_{ij}^2 was the squared distance (m ²) between well <i>i</i> and maternal residence <i>j</i> Well count metric for maternal residence $j = \sum_{i=1}^{n} \sum_{k=1}^{l} l_A(K)$
	presented in Supplement)	 Where: <i>n</i> was the number of wells within 0.5, 1, 2, or 5 miles of maternal residence <i>j</i> <i>k</i> was equal to the date of the beginning of gestation and <i>l</i> the date of birth, or <i>k</i> was equal to date of birth and <i>l</i> the index date for maternal residence <i>j</i> <i>I_A(K)</i> was equal to 1 when <i>d_{ij}</i> ≤ 0.5, 1, 2, or 5 miles, respectively, and the activity of a well (between spud date and the last production period end date) overlapped with the defined exposure time window (T1 or T2), or equal to 0 otherwise

Table 5a. Definition of Primary UNGD Activity Metrics

<u>WG Ex. 72</u>

Table 5b. Definition of	f secondary phase specific	UNGD activity metrics
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Phase	Phase name	Calculation of phase-specific activity metric
4	Well pad	
	preparation	Phase 1 metric for maternal residence $j=\sum_{i=1}^n\sum_{k=1}^l\frac{I_A(K)}{d_{ij}^2}$
		Where:
		• <i>n</i> was the number of well pads within 0.5, 1, 2, or 5 miles of maternal residence <i>j</i>
		• <i>k</i> was equal to the date of the beginning of gestation and <i>l</i> the date of birth (T1), or <i>k</i> was equal to
		date of birth and / the index date (T2)
		• $I_A(K)$ was equal to 1 when $d_{ij} \le 0.5$, 1, 2 or 5 miles, respectively, and the phase overlapped with the defined exposure time window (T1 or T2), or equal to 0 otherwise
		• d^{2}_{ij} was the squared distance (m ²) between well pad <i>i</i> and maternal residence <i>j</i>
5	Drilling	Phase 2 metric for maternal residence j = $\sum_{i=1}^n \sum_{k=1}^l \frac{I_A(K)}{d_{ij}^2}$
		Where:
		• <i>n</i> was the number of wells within 0.5, 1, 2, 5 miles of maternal residence <i>j</i>
		• <i>k</i> was equal to the date of the beginning of gestation and <i>l</i> the date of birth (T1), or <i>k</i> was equal to
		 date of birth and / the index date (T2) I_A(K) was equal to 1 when d_{ij} ≤ 0.5, 1, 2, or 5 miles, respectively, and the phase overlapped with the
		• $I_{A}(X)$ was equal to 1 when $u_{ij} \le 0.5$, 1, 2, or 5 miles, respectively, and the phase overlapped with the defined exposure time window (T1 or T2), or equal to 0 otherwise
		• d^2_{ij} was the squared distance (m ²) between well <i>i</i> and maternal residence <i>j</i>
6	Hydraulic	$\sum_{k=1}^{n} \sum_{k=1}^{n} w_{k} \times L(K)$
	fracturing	Phase 3 metric for maternal residence $j = \sum_{i=1}^{n} \sum_{k=1}^{l} \frac{w_i \times I_A(K)}{d_{ij}^2}$
		Where:
		• <i>n</i> was the number of wells within 0.5, 1, 2, or 5 miles of maternal residence <i>j</i>
		 k was equal to the date of the beginning of gestation and / the date of birth (T1), or k was equal to date of birth and / the index date (T2)
		 <i>w_i</i> was the depth in meters of well <i>i</i>
		• $I_A(K)$ was equal to 1 when $d_{ij} \le 0.5$, 1, 2, or 5 miles, respectively, and the phase overlapped with the
		defined exposure time window (T1 or T2), or equal to 0 otherwise
	Due du etiere	• d^2_{ij} was the squared distance (m ²) between well <i>i</i> and maternal residence <i>j</i>
7	Production	Phase 4 metric for maternal residence j = $\sum_{i=1}^n \sum_{k=1}^l \frac{\nu_i \ \times \ I_A(K)}{d_{ij}^2}$
		Where:
		 <i>n</i> was the number of wells within 0.5, 1, 2, or 5 miles of maternal residence <i>j</i>
		 k was equal to the date of the beginning of gestation and / the date of birth (T1), or k was equal to date of birth and / the index date (T2)
		• <i>v_i</i> was the daily average produced gas volume (m ³) of well <i>i</i> , which was calculated as the reported
		produced gas volume during the reporting period divided by the number of days the well was
		 actively producing during that reporting period. <i>I_A(K)</i> was equal to 1 when <i>d_{ij}</i> ≤ 0.5, 1, 2, or 5 miles, respectively, and the phase overlapped with the
		defined exposure time window (T1 or T2), or equal to 0 otherwise
		• d^2_{ij} was the squared distance (m ²) between well <i>i</i> and maternal residence <i>j</i>

Calculating IDW Metrics

Addresses were geocoded using ArcMap 10.6 to calculate distances between the wells and residences. Distances were calculated between every residence and well within the study area in MySQL server. Once distances were calculated, data was filtered to include only those that were closer than, or equal to, each respective buffer distance 0.5, 1, 2, and 5 miles. Unexposed individuals were those who had never lived within 5 miles of any UNGD site. Time spent in each residence was truncated for each person to ensure that the dates were within the study periods of interest for each person (T1 conception to birth, and T2 – birth to the diagnosis/index date). Subsequently, the days that overlapped between time spent in each residence and well activity was calculated. For the hydraulic fracturing and production metrics, the days of overlap were multiplied by well depth and average daily gas volume production, respectively. IDW metrics were built by dividing these numerators by the distance in meters squared for all wells located within each residence's buffer distance. These numbers were then aggregated across all wells for one metric per residence. For those who did not remain consistently within the study area, the study team developed methods to handle lapses in exposure estimation. To aggregate exposure metrics across residences for each case and control, a dataset representing individual participants was used. See Appendix B for in-depth descriptions of the geocoding process and methods used to handle incomplete data, as well as calculation methods.

Other UNGD-Related Exposures

Impoundment Ponds

Impoundment ponds store water and other fluids from the hydraulic fracturing process. Using SkyTruth, a nonprofit that uses satellite imagery to identify the locations of possible environmental exposure sites, locations and proximity measures were located and created using the same process described above.

Compressor Stations

Compressor stations are facilities where natural gas is received, repressurized, and sent back out in pipelines. Compressor station data was obtained from the PADEP. Their database was used to identify locations of compressor stations and create inverse distance-weighted proximity measures described above.

Waste Facilities

Waste facilities store waste from the hydraulic fracturing process. Waste facility data was obtained from the PADEP. Their database was used to identify locations of waste facilities and create inverse distance-weighted proximity measures described above.

Other Environmental Exposures

In addition to the UNGD activity metrics, the study team also considered additional sources of environmental exposures in the study area during the study period. These included additional components of oil and gas-related activity (e.g., impoundment ponds, compressor stations, waste disposal facilities), other industrial activities (e.g., toxic release inventory sites), and water source measures. Inverse distance-weighting and other modeling approaches were used, as appropriate, to quantify exposure to these additional sources using the same defined buffer zones.

The study team utilized the following environmental exposures including Uranium Mill Tailing Remedial Action (UMTRA) sites, Toxic Release Inventory (TRI) sites, and Superfund sites. The exposure variables created for UMTRA, TRI, Superfund sites were IDW metrics where the numerator was 1 and denominator was the distance in meters squared summed across each respective site. There was no duration component included. The same buffer distances for UNGD activity metrics were considered. The water source variable was a dichotomous variable with public or private source of water. Below are detailed descriptions of these environmental exposures.

UMTRA Sites

There were four UMTRA sites in the study area. Mill tailings are defined as the sandy waste material from a conventional uranium mill. Milling is the first step in making fuel for nuclear reactors from natural uranium ore. UMTRA sites are areas designated by the US Department of Energy who monitor the clean-up of these mills and prevent further contamination of ground water. The IDW was calculated for the four sites in the study area, as well as the eleven sites outside of Pennsylvania, in case the participants' residential history included areas near those sites.

TRI Sites

Facilities in the United States must report toxic chemical releases to the EPA through the TRI program. For the present analysis, the study team downloaded the 2015 data on all TRI inventory sites for the eight-county study area and all surrounding counties. The year 2015 was chosen as a representative time-point based on the midpoint of the diagnosis time (i.e., 2010 -2019) of cancer cases included in the study. For more information on TRI, visit <u>https://www.epa.gov/toxics-release-inventory-tri-program</u>.

Superfund Sites

Superfund is an environmental remediation program established by the EPA. The program is designed to investigate, and clean-up sites contaminated with hazardous substances and include seven EPA PA sites within the eight-country area, and several sites within the study area.

Other Covariates

In the present analysis, in addition to matching factors on age, sex, race, and county of residence between cases and controls, the following set of variables were considered as potential confounders derived from birth records. These covariates are included in all of the logistic regression models.

- 1. Maternal age at childbirth
- 2. Maternal education level (a measure of socioeconomical status)
- 3. Maternal smoking status (any time during pregnancy) reported at childbirth
- 4. Gestational age in weeks at birth
- 5. Birth weight of the study subject

Definition of Exposed and Unexposed

IDW metrics are commonly summarized into levels of exposure for increased ability to meaningfully interpret results. Means and standard deviations (SDs), and medians and inter-quartile values were calculated for each of 7 UNGD activities metric for T1 and T2 time periods for all buffer distances. The distributions of all UNGD activity metrics were used to determine dichotomous exposure or exposure by tertiles or quartiles. Cut points in these variables (between exposed and unexposed or between levels of exposure) are set specifically to increase the contrast.

Few participants in any one level of exposure may yield unstable risk estimates with wide 95% Cls. Beyond this practice, there is currently no agreement in the literature on the best way to summarize IDW variables. The study team chose to display results for several distinct kinds of summary variables where appropriate to see how results may have shifted between options. Four different summary variables were provided for all IDW metrics when there were appropriate numbers of participants within exposure levels as described below:

- Dichotomous Exposure This variable takes on values of either an exposed or unexposed category. The exposed category was defined for individuals who had any history of residence that was located within 5 miles of any UNGD activity, whereas unexposed category was those who did not have a history of residence within 5 miles of UNGD activity. The unexposed group was used for all analyses for different UNGD-derived metrics described below.
- 2. Exposure levels within 5-mile or 2-mile buffer zone Exposed individuals were further divided by level of cumulative exposure to UNGD activities over time within the defined buffer zone. The median value among the control group was used to classify individuals into high or low category— tertiles classified individuals into the lowest, middle, and highest-thirds of exposure, and the quartiles classified individuals into the lowest, middle-low, middle-high, and highest-quarters of exposure. In the risk modeling, the unexposed group (defined above) was always used as the reference group.
- 3. Proximity measure of UNGD activity The proximity measure (i.e., buffer zone) was defined as the shortest distance from a residence to any UNGD activity. Conventional cut-off values [0-0.5], (0.5-1], (1-2] and (2-5] miles were used when appropriate. The reference group consisted of individuals who did not have any wells within 5 miles as defined above. When there were too few subjects in each category, the cut points were set as [0-2], and (2-5]. A square bracket indicates that the value was included within the bound, whereas a parenthesis indicates the value was not included within the bound.

4. **Standardized exposure using phase specific z-score values** – IDW metrics for each phase (well pad construction, drilling, hydraulic fracturing, and production) were calculated and standardized by the standard deviation (i.e. the z-score). The phase-specific z-scores were summed using the following formula: $\sum_{ij}^{k} \frac{x_{ij}-\mu_{,j}}{\sigma_{,j}}$, where *i* is for subject; *j*, specific phases of UNGD activities (k=4); *x*, individual measurement of phase-specific UNGD activity; μ , mean; and σ , standard deviation. The summed z-score was another measure of total UNGD activities per individual exposure. The z-score was unitless and accounted for different values and units of all phase-specific UNGD activities.

Statistical Analysis

Primary Strategy

Descriptive statistics were computed and assessed for all outcome and exposure measures, covariates, and characteristics of the study participants. For continuous variables, mean/standard deviation and median/inter quartile range were used; for categorical variables, frequency/percentiles were used. These variables were estimated for the total population and for the birth record-based and survey-based populations separately and stratified by case-control status and various covariates. Chi-square testing was used to compare differences in percentages for social/demographic and maternal characteristics between groups (e.g., cases vs. controls) when categorical; t-tests were used to evaluate differences in means between groups when continuous. When appropriate, nonparametric tests were used.

The study's main aim was to examine the link between UNGD activity and childhood cancer. As such, logistic regression modeling was used to assess this relationship. To preserve the matched study design, conditional logistic regression modeling was done whenever possible. However, some analyses were performed using an unconditional model including the matching variables as covariates.

Separate conditional logistic regression models were used to estimate ORs and the 95% Cls for all four types of cancer combined (i.e., leukemia, lymphoma, CNS tumors, and bone cancer) comparing exposed with unexposed, as well as comparing various levels of exposure by buffer zone and/or levels of overall UNGD activity. The regression analyses were performed, with and without adjustment for additional covariates. In addition to the primary exposure (UNGD metrics) variable, the multivariableadjusted models included the following covariates: maternal age at childbirth (continuous), maternal education level (≤ 8th grade, high school, some college, or college degree or higher), maternal smoking status at childbirth (yes/no), gestational age (continuous in weeks), birthweight (continuous in grams), TRI (delineated as non-exposed or exposed within 5 miles), UMTRA (non-exposed or exposed within 5 miles), as well as for Superfund sites (non-exposed or exposed within 5 miles).

Significance testing was performed for individual ORs, as well for evaluation of linear trend for increasing level of UNGD activities using an ordinal variable (i.e., 0 for non-exposed and 1, 2 and 3 for tertiles or 1, 2, 3, 4 for quartiles) with the risk of disease of interest. Similar logistic models were used for the decreasing buffer zone (non-exposed, 2-5 miles, 1-2 miles, 0.5-1.0 miles, and 0-0.5 miles) with the risk of disease of interest. All ORs in this report are shown with 95% CIs for UNGD activities and other exposure variables with adjustment for additional covariates. These models were used to analyze data for all three study populations (two survey-based and one birth record-based).

Although underpowered, regression modeling was done for each of the four individual cancer types. The study team believed it was important to separately examine them due to their different biological characteristics. For EFOT (n=20), unconditional logistic regression modeling was performed separately from other malignant bone tumor cases by including all controls in both survey- and birth record-based studies with adjustment for matching variables (i.e., age at diagnosis, sex, race/ethnicity, and county of residence).

Primary Study Population: Use of the Birth Record Study

The primary study population for analysis was the 498 cancer cases and their county-matched controls. Information on the mothers' and newborns' residence and characteristics from birth certificates was extracted from both cancer registry and birth certificates. For analyses of all malignancies combined, this samples (i.e., 498 cases and 498 matched controls) has sufficient statistical power (>80%) to detect odds ratio of 1.5 and greater assuming 25% UNGD exposure within the control group; when exposure among controls is 20%, there is high power (>90%) to detect odds ratios of 1.75 and greater. Furthermore, this sample had sufficient power to detect odds ratios of 1.75 and greater when exposure among controls is 10%. **(Table 6A).** For analyses of site-specific cancers, power is shown in **Table 6B-D** can detect odds ratios of 2.0 for leukemia and CNS and 2.25 for lymphoma with 80% power within the exposure ranges shown. Power estimates assume a two-sided test with alpha = 0.05, a value of 0.20 for the correlation of exposure status in the matches. Power estimates were calculated using https://sampsize.sourceforge.net/iface/s3.html#ccp).

Table 6: Estimated Power to Detect a Specified Odds Ratio and Probability of Exposure in the Control Sample: (Based on Sample Size Available for Study)

		00	dds Ratio		
Probability of exposure in controls	1.5	1.75	2.0	2.25	2.5
0.05	0.326	0.582	0.796	0.922	0.977
0.10	0.543	0.841	0.966	0.996	1.0
0.15	0.684	0.935	0.993	1.0	1.0
0.20	0.772	0.970	0.998	1.0	1.0
0.25	0.826	0.983	0.999	1.0	1.0

6A. 498 case control pairs

6B. Leukemia 157 case control pairs for the Birth Record Study of 498 Cancer Cases

	Odds Ratio					
Probability of exposure in controls	1.5	1.75	2.0	2.25	2.5	
0.05	0.129	0.219	0.327	0.447	0.567	
0.10	0.207	0.37	0.546	0.705	0.827	
0.15	0.272	0.483	0.683	0.832	0.922	
0.20	0.323	0.564	0.765	0.893	0.958	
0.25	0.363	0.619	0.814	0.924	0.974	

	Odds Ratio					
Probability of exposure in controls	1.5	1.75	2.0	2.25	2.5	
0.05	0.0988	0.157	0.228	0.31	0.398	
0.10	0.151	0.2599	0.388	0.521	0.646	
0.15	0.195	0.342	0.504	0.655	0.778	
0.20	0.2299	0.405	0.584	0.736	0.846	
0.25	0.2578	0.451	0.637	0.784	0.883	

6C. Lymphoma 105 case control pairs for Birth Record Study of 498 Cancer Cases

6D. CNS 193 case control pairs for the Birth Record Study of 498 Cancer Cases

	Odds Ratio	Odds Ratio					
Probability of exposure in controls	1.5	1.75	2.0	2.25	2.5		
0.05	0.15	0.261	0.394	0.533	0.664		
0.10	0.246	0.441	0.639	0.796	0.899		
0.15	0.324	0.569	0.774	0.903	0.965		
0.20	0.386	0.655	0.848	0.946	0.984		
0.25	0.433	0.712	0.888	0.966	0.991		

In contrast and as shown in **Table 6E**, the resulting sample size of the survey 213 cases and 213 matched controls would not provide sufficient power to consider individual cancer specific sites (e.g. leukemia). For all sites combined, however, the resultant sample size *is powered* to detect an odds ratio 2.00 or greater with 80% power. Power estimates assume a two-sided test with alpha = 0.05, a value of 0.20 for the correlation of exposure status in the matches. Please see **Supplementary Tables S3-5** for the overall four malignancies combined risk estimates involving the survey-based population and a few descriptive tables for this second arm of the study.

	Odds Ratio							
Probability of exposure in controls	1.5	1.75	2.0	2.25	2.5			
0.05	0.162	0.285	0.439	0.577	0.71			
0.10	0.267	0.479	0.684	0.836	0.927			
0.15	0.353	0.612	0.815	0.929	0.98			
0.20	0.419	0.699	0.882	0.964	0.991			
0.25	0.469	0.755	0.917	0.978	0.996			

6E. 213 case control pairs with two-sided test (Survey Sample size) Overall Combined Cancer Risk

The decision to use birth residence as the primary location for determining UNGD activity until diagnosis comes into question if the case or control moves during the time from birth until diagnosis. This can lead to misclassification of the exposure and can affect exposure estimates. We carried out a cross tabulation of the county of birth residence for the 498 cases using birth records and the residence county at time of diagnosis using PA Cancer registry. Shown in **Table 7A**, there is high agreement within this study population in that over 85% of cases' parents remained in SW PA counties and the majority also remained within the same county over this period. Likewise shown in **Table 7B** are the results for the controls interviewed for their residential history as part of the survey study. Similarly, the cross tabulation indicates that there is high concordance of residence of controls remaining in the same county of their child's birth and maternal residence.

Child's Birth County		Child's Diagnosis County								
	Alleghen y*	Armstrong	Beaver	Butle r	Fayet te	Greene	Wash ing ton	West more land	Total	%
Allegheny- **outPGH	188	0	1	8	1	0	6	9	213	88.3
Armstrong	0	13	0	0	0	0	0	3	16	81.3
Beaver	1	1	30	3	0	0	0	0	37	81.1
Butler	0	0	1	55	0	0	0	0	58	94.8
Fayette	2	0	0	0	23	1	2	1	29	79.3
Greene	0	0	0	0	0	9	3	0	12	75.0
Washington	4	0	0	0	0	2	49	0	55	89.1
Westmorelan d	7	0	0	0	1	0	1	78	87	89.7
Total	204	14	32	68	25	12	61	91	507	

Table 7A. County of the mother's residence when giving birth, vs. County at diagnosis for the 498 childhood cancer cases

Table 7B. County of the mother's residence when giving birth vs county at diagnosis for 213 controls

Child's Birth County		Child's Diagnosis County								
	Allegheny	Armstron g	Beaver	Butle r	Fayet te	Greene	Was hing ton	West morela nd	Total	%
Allegheny	92	0	1	1	0	0	4	1	99	92.9
Armstrong	0	4	0	0	0	0	0	0	4	100
Beaver	2	0	14	2	0	0	0	0	18	77.8
Butler	2	0	0	16	0	0	0	0	18	88.9
Fayette	0	0	0	0	6	0	0	1	7	85.7
Greene	0	0	0	0	0	6	1	0	7	85.7
Washington	1	0	0	1	0	0	24	0	26	92.3
Westmorelan d	0	1	0	0	0	0	0	39	40	97.5
Total	97	5	15	20	6	6	29	41	219*	

*Six controls were excluded due to low data quality or did not meet the resident location requirements

<u>WG Ex. 72</u>

III. Results

Birth Record Sample Characteristics

Table 8 presents the distribution of the 507 childhood cancer cases by primary site for the Birth Record Study. These are newly diagnosed cases excluding relapses and secondary diagnoses. CNS and miscellaneous intracranial and intraspinal neoplasms comprised the largest group, with 38.3% of all cases, followed by leukemias and myeloproliferative diseases accounting for 32.5%, lymphomas (20.7%), and malignant bone tumors including EFOT (8.5%). (See **Supplementary Table S1** for more details).

Table 9 presents the number of total childhood cancer cases for the birth record study by county, year of birth, age group and year of diagnosis (2010-2019). Among the 507 childhood cancer cases eligible for the study, Allegheny County, being the most populous, contributed 204 (40.2%) of these cases followed by Westmoreland, Washington, and Butler counties with 90, 68, and 61 cases, respectively. Fewer cases were included in the 1990-1994 birth cohort as some of children "aged out", (i.e., older than 19 years for the period of cancer diagnosis from 2010-2019). The number of cases by year at diagnosis appears to be evenly distributed from 2010 to 2019. The distribution for the four childhood cancers for ages 0 to 19 years was similar within the total study population, as well as for the two survey populations. They were also similar to the national data recorded by the NCI SEER Program (Cronin et al, 2022).

Table 8 Primary Classes of Childhood Cancer Included in the Birth Record Study (2010-2019)

Primary Cancer Classes	All Cases N (%)
I. Leukemias, myeloproliferative	165 (32.5)
diseases, and myelodysplastic	
diseases	
II. Lymphomas and	105 (20.7)
reticuloendothelial neoplasms	
III. CNS and miscellaneous	194 (38.3)
intracranial and intraspinal	
neoplasms	
IV. Malignant bone tumors including	43 (8.5)†
EFOT	
TOTAL	507 (100)

⁺ Including 20 cases of Ewing tumor and related sarcomas of bone.

Table 9. Characteristics of Childhood Cancer Cases in the Birth Record study, South Western PA 2010-2019

	Total cases (N=507)
	N (%)
Year of Birth	
1990-1994	46 (9.1)
1995-1999	107 (21.1)
2000-2004	115 (22.7)
2005-2009	104 (20.5)
2010-2014	96 (18.9)
2015-2018	39 (7.3)
County of Residence	
Allegheny†	204 (40.2)
Armstrong	14 (2.8)
Beaver	32 (6.3)
Butler	68 (13.4)
Fayette	25 (4.9)
Greene	12 (2.4)
Washington	61 (12.0)
Westmoreland	91 (18.0)
Year of Diagnosis	
2010	60 (11.8)
2011	63 (12.4)
2012	45 (8.9)
2013	52 (10.2)
2014	47 (9.3)
2015	51 (10.1)
2016	52 (10.2)
2017	41 (8.1)
2018	51 (10.1)
2019	45 (8.9)
Age Group at Diagnos	sis
0-4	149 (29.4)
5-9	98 (19.3)
10-14	111 (21.9)
15-19	146 (28.8)
20-24‡	2 (0.4)
	· /

⁺ Excluding the City of Pittsburgh where UNGD is not permitted.[‡] Applicable for malignant bone tumors only.

Table 10. Distributions of Sociodemographic Characteristics of Childhood Cancer Cases Using Birth Record Information in the Birth Record-Based Studies with County-Matched Controls

Sociodemographic	ociodemographic Birth Record-Based S		
Characteristic	Cases (%)	Controls (%)	
Total number	498 (100)	498 (100)	
Sex at Birth			
Female	216 (43.4)	216 (43.4)	
Male	282 (56.6)	282 (56.6)	
Maternal Age (years)			
<20	33 (6.6)	25 (5.0)	
20-24	79 (15.9)	83 (16.7)	
25-29	132 (26.5)	124 (24.9)	
30-34	146 (29.3)	160 (32.1)	
≥35	108 (21.7)	106 (21.3)	
Maternal Race			
White	480 (96.4)	480 (96.4)	
Black	12 (2.4)	12 (2.4)	
Other	5 (1)	6 (1.2)	
Maternal Education ¹		· · · ·	
≤ 8 th Grade	2 (0.4)	3 (0.6)	
Some High School	36 (7.2)	25 (5)	
High School Diploma	145 (29.1)	141 (28.3)	
Some College	124 (24.9)	123 (24.7)	
College Degree or Higher	186 (37.4)	198 (39.8)	
Unknown	5 (1)	8 (1.6)	
Number of Prenatal			
Visits			
0-7	41 (8.2)	48 (9.6)	
8-12	241 (48.4)	245 (49.2)	
13-16	177 (35.5)	176 (35.3)	
≥17	20 (4.0)	17 (3.4)	
Unknown	19 (3.8)	12 (2.4)	
Birth weight			
≤2500 g	28 (5.4)	23 (4.6)	
2501- 4000 g	411 (82.5)	426 (85.5)	
>4000 g	60 (12.1)	49 (9.8)	
Unknown	28 (5.4)	23 (4.6)	
Smoking during			
pregnancy ²			
Never	397 (79.7)	408 (81.9)	
Ever	92 (18.5)	89 (17.9)	
Unknown	9 (1.8)	1 (0.2)	
Gestation in weeks			
Mean (±S.D.)	38.7 (1.8)	38.8(1.6)	

¹ p value=.08 survey based education >college; p value<.01 for birth record based> college

 $^{\rm 2}$ p value=.28 survey based ever smoked during pregnancy ; p value<.026 for birth record based smoking

Maternal and Birth Characteristics of Birth Record Based Study

Table 10 presents characteristics of cancer cases and their matched controls for the birthrecord based study. Childhood cancer cases and their matched controls were 56.6% male, and approximately 96% of the maternal study population reported a race of white. Case mothers reported an educational level of some college (24.9%) or completed college degree or higher (37.4%). The control distribution of education was similar (24.7% and 39.8%, respectively). There was also a similar proportion of cases and county-matched controls with a birth weight between 2501-4000g (82.5% and 85.5%, respectively). The proportion of mothers who reported never smoking during pregnancy was similar for cases and county-matched controls (79.7% and 81.9%, respectively). The birth weight of case infants versus control infants between 2501-4000g was also similar (82.3% and 85.6%, respectively). Similarly, 79.7% of mothers of cases and 82% of mothers of controls reported never having smoked cigarettes during their pregnancy. The average gestational age was 38 weeks for both groups.

Supplementary Table S2 presents the distributions of the eight UNGD activities metrics within a 5-mile radius of the residence among all 498 cancer cases and their 498 county-matched birth certificate controls for the two exposure time windows.

Exposure to UNGD Activity and Risk of Childhood Cancer

The study team analyzed the association between UNGD exposures and risk of four childhood malignancies (lymphoma, leukemia, CNS tumor and malignant bone tumor) combined for all 498 cases and their matched controls based on the information on birth records.

In the birth record-based analyses, the study team presented the results for two exposure time windows separately: T1 was mother's pregnancy period and T2 was from birth to the index date. The index date was the date of malignancy diagnosis for cases and the corresponding date for the matched controls. In addition to matching factors (date of birth, sex, and race), results presented were adjusted for maternal age at childbirth, education level, smoking status at childbirth, as well as gestation age, birthweight, TRI, UMTRA, and superfund site.

Four Malignancy Types Combined

Table 11 presents UNGD activities related to the risk of childhood malignancies. During pregnancy, mothers of 39 (18.3%) cases and of 41 (19.2%) county-matched controls in the survey-based study (213 pairs) reported a history of residence within 5 miles of a UNGD site. In the birth record-based study (498 pairs), the corresponding numbers were 94 (18.9%) cases and 99 (19.9%) controls. Compared with non-exposed group, there was no evidence to support an association between exposure to UNGD activity during mother's pregnancy and risk of malignancy in childhood and adolescence.

In the birth record-based analysis (498 case-control pairs), children diagnosed with any of the four malignancies included in the study were about four times more likely to live in a house within 0.5 miles of a UNGD site than controls (OR=3.94, 95% CI [1.66-9.30], P=0.002). There was a statistically significant linear trend for close-proximity and risk of childhood malignancy (p=0.004) When the subjects were divided into quartiles of overall UNGD activities, increasing levels of these were associated with increased risk of the four childhood malignancies. For example, children diagnosed with any of the four malignancies were more than two times more likely to be in the highest quartile of overall UNGD activities within 2 miles (OR=2.16, 95% CI [1.10-4.25], p=0.026) than their matched controls, and the linear trend for the overall UNGD activities with risk of these malignancies was statistically significant (p for trend=0.032).

Table 11. Overall Unconventional Natural Gas Drilling Activities and Risk of Four Childhood/Adolescent Malignances Combined During Two Exposure Periods in Southwestern PA 2010-2019

Overall UNGD activities by exposure period	Birth Record-Based Study with County-Matched Controls (498 case-control pairs)			
	Controls	Controls Cases OR (95% CI) ⁺		
T1: During Mother's Pregn	ancy			
Non-exposed	399	404	1.00	
Exposed*	99	94	0.82 (0.47-1.41)	
By buffer zone				
Non-exposed	399	404	1.00	
(2-5] miles	64	63	0.84 (0.48-1.46)	
(1-2] miles	24	22	0.72 (0.31-1.67)	
(0.5-1] miles	9	7	0.65 (0.19-2.26)	
[0-0.5] miles	2	2	0.81 (0.05-14.62)	
P trend‡			0.3817	
By overall UNGD activities with	nin 5 miles			
Non-exposed	399	404	1.00	
Lowest (1 st) quartile	24	17	0.63 (0.29-1.34)	
Low-middle (2 nd) quartile	25	22	0.77 (0.37-1.64)	
High-middle (3 rd) quartile	25	36	1.40 (0.63-3.14)	
Highest (4 th) quartile	25	19	0.75 (0.31-1.83)	
P trend‡			0.7587	

* Exposed included individuals who lived within 5 miles of any UNGD activity during mother's pregnancy (T1) or from birth to the index date (i.e., date of cancer diagnosis for cases or the same date for matched controls) (T2); non-exposed otherwise.

⁺ All ORs and their 95% CIs for different buffer zones or levels of exposures against non-exposed group were derived from unconditional logistic regression models with adjustment for matching factors (age, sex, race, and county of residence) and the following variables, including maternal age at childbirth (years), maternal education level, maternal smoking status at childbirth (no, yes), gestation age (weeks), birthweight (g), toxics release inventory (TRI) (no, yes), uranium mill tailings remedial action sites {UMTRA} (no, yes), and Superfund site (no, yes). **Odds ratios and confidence ratios which are bolded are significant at P < .05**.

[‡] The same unconditional logistic models were used for linear trend test for the exposure variable in ordinal values (1, 2 for high or low) that also included non-exposed individuals (coded as 0) to maintain the case-control matched pairs.

	Birth Record-based Study with County-matched Controls (498 case-control pairs)				
Overall UNGD activities					
by exposure period					
	Controls	Cases	OR (95% CI)†		
T2: From Birth to Index Date §					
Non-exposed	201	187	1.00		
Exposed*	297	311	1.24 (0.87-1.78)		
By buffer zone					
Non-exposed	201	187	1.00		
(2-5] miles	178	170	1.18 (0.82-1.71)		
(1-2] miles	72	77	1.49 (0.89-2.51)		
(0.5-1] miles	37	38	1.61 (0.85-3.03)		
[0-0.5] miles	10	26	3.94 (1.66-9.39)		
P trend‡			P=0.0041		
By overall UNGD activities with	nin 5 miles				
Non-exposed	201	187	1.00		
Lowest (1 st) quartile	74	86	1.40 (0.91-2.14)		
Low-middle (2 nd) quartile	74	50	0.76 (0.46-1.25)		
High-middle (3 rd) quartile	74	88	1.69 (1.01-2.82)		
Highest (4 th) quartile	75	87	1.79 (1.00-3.19)		
P trend‡			0.0975		
By overall UNGD activities with	nin 2 miles*	*			
Non-exposed	201	187	1.00		
Lowest (1 st) quartile	29	37	1.74 (0.93-3.27)		
Low-middle (2 nd) quartile	30	32	1.48 (0.77-2.84)		
High-middle (3 rd) quartile	30	30	1.41 (0.72-2.77)		
Highest (4 th) quartile	30	42	2.16 (1.10-4.25)		
P trend‡			P=0.0321		

Table 11 Continued. Overall Unconventional Natural Gas Drilling Activities and Risk of Four Childhood/Adolescent Malignances Combined During Two Exposure Periods in Southwestern PA 2010-2019

* Exposed included individuals who lived within 5 miles of any UNGD activity during mother's pregnancy (T1) or from birth to the index date (i.e., date of cancer diagnosis for cases or the same date for matched controls) (T2); non-exposed otherwise.

⁺ All ORs and their 95% CIs for different buffer zones or levels of exposures against non-exposed group were derived from unconditional logistic regression models with adjustment for matching factors (age, sex, race, and county of residence) and the following variables, including maternal age at childbirth (years), maternal education level, maternal smoking status at childbirth (no, yes), gestation age (weeks), birthweight (g), toxics release inventory (TRI) (no, yes), uranium mill tailings remedial action sites {UMTRA} (no, yes), and Superfund site (no, yes). Odds ratios and confidence ratios which are bolded are significant at P < .05.</p>

§ The index date was the date of malignancy diagnosis for cases and the same corresponding date for matched controls.

Lymphoma

An analysis was carried out on the 105 lymphoma cases and their matched controls using the overall UNGD activity metric with consideration by exposure within five miles versus no exposure within five miles. See **Table 12**. The analysis is shown for both T1 (based on residence during pregnancy till birth) and T2 periods (residency from birth till index date). There is no significant relationship between overall UNGD activity and lymphoma risk for the T1 period. However, for the T2 period involving UNGD activity from birth to date of diagnosis, the point estimate for exposure to UNGD activity was (OR=2.24, 95% CI [0.92-5.47], p=0.076). The data were analyzed by buffer zone, the ORs (95% CIs) of lymphoma for the distance of 2-5, 1-2, 0.5-1, and <0.5 miles from residence to a UNGD site were 2.06 (0.83-5.13), 2.45 (0.77-7.83), 5.05 (1.09-23.39), and 7.71 (1.01-59.00), respectively, compared with non-exposed group (p value for trend=0.015). When the subjects were grouped by the overall UNGD activities over time, the ORs for lymphoma increased with greater levels of UNGD activities within both 5 and 2 miles of buffer zones. For example, the ORs (95% CIs) of lymphoma for children with the first, second, and third tertile of overall UNGD activities limited to two miles of radius surrounding their residences were 2.12 (0.51-8.79), 2.66 (0.66-10.72), and 7.73 (1.63-36.87), respectively, compared with non-exposed individuals (p value for trend=0.020).

When the UNGD activities were summed over the number of standard deviations for each of the four phase-specific UNGD activities, ORs (95% CIs) of lymphoma for children in the first, second, third, and fourth quartile of summed scores were 1.39 (0.44-4.37), 1.89 (0.62-5.80), 4.35 (1.26-15.01), and 5.15 (1.35-19.63), respectively (p values for trend = 0.011), compared with the non-exposed group in the birth record-based analysis.

Overall UNGD activities by exposure period	Birth Record-based Study with County-matched Controls (105 Lymphoma case-control pairs)		
	Controls	Cases	OR (95% CI)†
Period T1: During Mother's F	regnancy	-	
Non-exposed	89	90	1.00
Exposed*	16	15	0.91 (0.26-3.12)
By buffer zone			
Non-exposed	89	90	1.00
(2-5] miles	10	9	0.96 (0.27-3.48)
(1-2] miles	3	2	0.77 (0.09-6.34)
(0.5-1] miles	1	2	1.82 (0.11-30.83)
[0-0.5] miles	2	2	2.26 (0.06-85.26)
P trend‡			0.6818
By overall UNGD activities with	in 5 miles		
Non-exposed	89	90	1.00
Lowest (1 st) quartile	5	1	0.28 (0.03-2.60)
Low-middle (2 nd) quartile	5	5	0.82 (0.13-5.06)
High-middle (3 rd) quartile	3	6	4.83 (0.4-58.83)
Highest (4 th) quartile	3	3	3.59 (0.25-50.69)
P trend‡			0.4023

Table 12. Overall Unconventional Natural Gas Drilling Activities and Risk of Childhood Lymphoma During Two Exposure Periods in Southwestern PA 2010-2019

* Exposed included individuals who lived within 5 miles of any UNGD activity during mother's pregnancy (T1) or from birth to the index date (i.e., date of cancer diagnosis for cases or the same date for matched controls) (T2); non-exposed otherwise.

⁺ All ORs and their 95% CIs for different buffer zones or levels of exposures against non-exposed group were derived from unconditional logistic regression models with adjustment for matching factors (age, sex, race, and county of residence) and the following variables, including maternal age at childbirth (years), maternal education level, maternal smoking status at childbirth (no, yes), gestation age (weeks), birthweight (g), toxics release inventory (TRI) (no, yes), uranium mill tailings remedial action sites {UMTRA} (no, yes), and Superfund site (no, yes). Odds ratios and confidence ratios which are bolded are significant at P < .05.</p>

[‡] The same unconditional logistic models were used for linear trend test for the exposure variable in ordinal values (1, 2 for high or low) that also included non-exposed individuals (coded as 0) to maintain the case-control matched pairs.

§ The index date was the date of malignancy diagnosis for cases and the same corresponding date for matched controls.

Overall UNGD activities by exposure period	Birth Record-based Study with County-matched Controls (105 Lymphoma case-control pairs)				
by exposure period	Controls				
Period T2: From Birth to Index Date	§				
Non-exposed	40	32	1.00		
Exposed*	65	73	2.24 (0.92-5.47)		
By buffer zone	•		•		
Non-exposed	40	32	1.00		
(2-5] miles	39	39	2.06 (0.83-5.13)		
(1-2] miles	17	16	2.45 (0.77-7.83)		
(0.5-1] miles	6	12	5.05 (1.09-23.39)		
[0-0.5] miles	3	6	7.71 (1.01-59.00)		
P trend‡			0.0149		
By overall UNGD activities within	5 miles		•		
Non-exposed	40	32	1.00		
Lowest (1 st) quartile	13	15	1.74 (0.53-5.77)		
Low-middle (2 nd) quartile	18	11	1.14 (0.35-3.72)		
High-middle (3 rd) quartile	15	24	5.68 (1.58-20.48)		
Highest (4 th) quartile	19	23	3.96 (1.01-15.49)		
P trend‡			0.0155		
By overall UNGD activities within	2 miles**		·		
Non-exposed	40	32	1.00		
Lowest (1 st) tertile	8	7	2.12 (0.51-8.79)		
Middle (2 nd) tertile	10	12	2.66 (0.66-10.72)		
Highest (3 rd) tertile	8	15	7.73 (1.63-36.67)		
P trend‡			0.0201		

Table 12. Continued. Overall Unconventional Natural Gas Drilling Activities and Risk of Childhood Lymphoma During Two Exposure Periods in Southwestern PA 2010-2019

* Exposed included individuals who lived within 5 miles of any UNGD activity during mother's pregnancy (T1) or from birth to the index date (i.e., date of cancer diagnosis for cases or the same date for matched controls) (T2); non-exposed otherwise.

⁺ All ORs and their 95% (CIs for different buffer zones or levels of exposures against non-exposed group were derived from unconditional logistic regression models with adjustment for matching factors (age, sex, race, and county of residence) and the following variables including maternal age at childbirth (years), maternal education level, maternal smoking status at childbirth (no, yes), gestation age (weeks), birthweight (g), toxics release inventory (TRI) (no, yes), uranium mill tailings remedial action sites {UMTRA} (no, yes), and Superfund site (no, yes). Odds ratios and confidence ratios which are bolded are significant at P < .05.</p>

[‡] The same unconditional logistic models were used for linear trend test for the exposure variable in ordinal values (1, 2 for high or low) that also included non-exposed individuals (coded as 0) to maintain the case-control matched pairs.

§ The index date was the date of malignancy diagnosis for cases and the same corresponding date for matched controls.

Leukemia

During both the mother's pregnancy and postnatal period, there was no elevated risk of childhood leukemia noted with exposure to any UNGD activities (or overall cumulative activities) or proximity to UNGD sites, in the birth record analysis. In the birth record-based analysis, for the postnatal (T2) period overall, any exposure to UNGD was not associated with the risk of leukemia (OR = 0.79, 95% CI = 0.35-1.79, P = 0.574). See Table 13.

	Birth Rec	Birth Record-based Study with County- matched Controls				
Overall UNGD activities						
by exposure period	(157 Le	(157 Leukemia case-control pairs)				
	Controls	Cases	OR (95% CI)†			
Period T1: During Mother's Preg	nancy					
Non-exposed	120	122	1.00			
Exposed*	37	35	0.73 (0.25-2.10)			
By buffer zone	·					
Non-exposed	120	122	1.00			
(2-5] miles	21	25	0.77 (0.27-2.24)			
[0-2] miles	16	10	0.27 (0.05-1.36)			
P trend‡			0.1288			
By overall UNGD activities within	5 miles					
Non-exposed	120	122	1.00			
Lowest (1 st) quartile	8	8	0.89 (0.24-3.27)			
Low-middle (2 nd) quartile	10	6	0.44 (0.10-1.90)			
High-middle (3 rd) quartile	9	14	1.12 (0.24-5.25)			
Highest (4 th) quartile	10	7	0.47 (0.08-2.64)			
P trend‡			0.4337			

Table 13. Overall Unconventional Natural Gas Drilling Activities and Risk of
Childhood Leukemia During Two Exposure Periods in Southwestern PA 2010-2019

* Exposed included individuals who lived within 5 miles of any UNGD activity during mother's pregnancy (T1) or from birth to the index date (i.e., date of cancer diagnosis for cases or the same date for matched controls) (T2); non-exposed otherwise.

+ All ORs and their 95% CIs for different buffer zones or levels of exposures against non-exposed group were derived from unconditional logistic regression models with adjustment for matching factors (age, sex, race, and county of residence) and the following variables, including maternal age at childbirth (years), maternal education level, maternal smoking status at childbirth (no, yes), gestation age (weeks), birthweight (g), toxics release inventory (TRI) (no, yes), uranium mill tailings remedial action sites {UMTRA} (no, yes), and Superfund site (no, yes). Odds ratios and confidence ratios which are bolded are significant at P < .05.
 + The same unconditional logistic models were used for linear trend test for the exposure variable in ordinal values (1, 2 for high or low) that also included non-exposed individuals (coded as 0) to maintain the case-control matched pairs.

§ The index date was the date of malignancy diagnosis for cases and the same corresponding date for matched controls.

	Birth Reco	Birth Record-based Study with Count				
Overall UNGD activities		matched Controls (157 Leukemia case-control pairs)				
by exposure period	(157 Leu					
	Controls	Cases	OR (95% CI) †			
Period T2: From Birth to Index Dat	e§		- -			
Non-exposed	67	69	1.00			
Exposed*	90	88	0.79 (0.35-1.79)			
By buffer zone						
Non-exposed	67	69	1.00			
(2-5] miles	56	50	0.77 (0.34-1.75)			
(1-2] miles	21	20	0.97 (0.28-3.33)			
(0.5-1] miles	12	10	0.92 (0.24-3.46)			
[0-0.5] miles	1	8	7.69 (0.70-83.91)			
P trend‡			0.3203			
By overall UNGD activities within 5	miles					
Non-exposed	67	69	1.00			
Lowest (1 st) quartile	25	31	1.16 (0.46-2.90)			
Low-middle (2 nd) quartile	23	9	0.38 (0.13-1.16)			
High-middle (3 rd) quartile	26	25	0.98 (0.29-3.27)			
Highest (4 th) quartile	16	23	1.51 (0.35-6.42)			
P trend‡			0.7676			
By overall UNGD activities within 2	miles**	·				
Non-exposed	67	69	1.00			
Lowest (1 st) tertile	14	11	0.62 (0.16-2.4			
Middle (2 nd) tertile	14	12	0.77 (0.20-2.92)			
Highest (3 rd) tertile	6	15	3.97 (0.66-23.95)			
P trend‡			0.2648			

Table 13 Continued. Overall Unconventional Natural Gas Drilling Activities and Risk of Childhood Leukemia During Two Exposure Periods in Southwestern PA 2010-2019

* Exposed included individuals who lived within 5 miles of any UNGD activity during mother's pregnancy (T1) or from birth to the index date (i.e., date of cancer diagnosis for cases or the same date for matched controls) (T2); non-exposed otherwise.

† All ORs and their 95% CIs for different buffer zones or levels of exposures against non-exposed group were derived from unconditional logistic regression models with adjustment for matching factors (age, sex, race, and county of residence) and the following variables, including maternal age at childbirth (years), maternal education level, maternal smoking status at childbirth (no, yes), gestation age (weeks), birthweight (g), toxics release inventory (TRI) (no, yes), uranium mill tailings remedial action sites {UMTRA} (no, yes), and Superfund site (no, yes). Odds ratios and confidence ratios which are bolded are significant at P < .05.</p>
‡ The same unconditional logistic models were used for linear trend test for the exposure variable in ordinal values (1, 2 for high or low) that also included non-

Fine same unconditional logistic models were used for linear trend test for the exposure variable in ordinal values (1, 2 for high or low) that also included non exposed individuals (coded as 0) to maintain the case-control matched pairs.

§ The index date was the date of malignancy diagnosis for cases and the same corresponding date for matched controls.

Central Nervous System (CNS) Tumor

Similarly, analyses for the risk of CNS tumor from exposure to UNGD during the mother's pregnancy and the period from birth to the index date were conducted separately. There was no association between any measure of UNGD exposure and risk of childhood CNS among the 193 pairs of cases and county-matched controls studied. **See Table 14**. In this birth record-based analysis, any exposure to UNGD within five miles of the mother's residence at birth was not associated with the risk of CNS tumor either during pregnancy or from birth to the index date, (OR = 0.85, 85% CI = 0.35-2.03) and OR = 1.28, 95% CI= 0.74-2.22), respectively. There was one occurrence of a significant increase in risk of CNS tumor in the T2 period from birth to the index date in the lowest tertile of exposure by overall UNGD activities within two miles (OR = 2.79, 95% CI:1.08-7.24).

Overall UNGD activities by exposure period		Birth Record-based Study with County-matched Controls (193 CNS case-control pairs)			
by exposure period	Controls	Cases	OR (95% CI)†		
Period T1: During Mother's Pregna					
Non-exposed	151	152	1.00		
Exposed*	42	41	0.85 (0.35-2.03)		
By buffer zone					
Non-exposed	151	152	1.00		
(2-5] miles	29	28	0.84 (0.34-2.06)		
(1-2] miles	7	8	1.07 (0.26-4.46)		
[0-1] miles	6	5	0.68 (0.13-3.59)		
P trend‡			0.7712		
By overall UNGD activities within 5 m	iles				
Non-exposed	151	152	1.00		
Lowest (1 st) quartile	9	8	0.77 (0.18-3.30)		
Low-middle (2 nd) quartile	10	10	0.99 (0.28-3.47)		
High-middle (3 rd) quartile	11	14	1.09 (0.34-3.53)		
Highest (4 th) quartile	12	9	0.56 (0.15-2.03)		
P trend‡			0.5827		

Table 14. Overall Unconventional Natural Gas Drilling Activities and Risk of Childhood Central Nervous System Tumor During Two Exposure Periods in Southwestern PA 2010-2019

* Exposed included individuals who lived within 5 miles of any UNGD activity during mother's pregnancy (T1) or from birth to the index date (i.e., date of cancer diagnosis for cases or the same date for matched controls) (T2); non-exposed otherwise.

+ All ORs and their 95% CIs for different buffer zones or levels of exposures against non-exposed group were derived from unconditional logistic regression models with adjustment for matching factors (age, sex, race, and county of residence) and the following variables, including maternal age at childbirth (years), maternal education level, maternal smoking status at childbirth (no, yes), gestation age (weeks), birthweight (g), toxics release inventory (TRI) (no, yes), uranium mill tailings remedial action sites {UMTRA} (no, yes), and Superfund site (no, yes). Odds ratios and confidence ratios which are bolded are significant at P < .05.
 + The same unconditional logistic models were used for linear trend test for the exposure variable in ordinal values (1, 2 for high or low) that also included non-exposed individuals (coded as 0) to maintain the case-control matched pairs.

§ The index date was the date of malignancy diagnosis for cases and the same corresponding date for matched controls.

Table 14 continued. Overall Unconventional Natural Gas Drilling Activities and Risk of Childhood Central Nervous System Tumor During Two Exposure Periods in Southwestern PA 2010-2019

Overall UNGD activities by exposure period		Birth Record-based Study with County-matched Controls (193 CNS case-control pairs)			
by exposure period	Controls	Cases	OR (95% CI)†		
Period T2: From Birth to Index Da					
Non-exposed	83	74	1.00		
Exposed*	110	119	1.28 (0.74-2.22)		
By buffer zone					
Non-exposed	83	74	1.00		
(2-5] miles	62	62	1.23 (0.71-2.16)		
(1-2] miles	28	30	1.54 (0.69-3.47)		
(0.5-1] miles	15	15	1.38 (0.49-3.89)		
[0-0.5] miles	5	8	1.96 (0.53-7.26)		
P trend‡			0.2818		
By overall UNGD activities within 5 r	niles				
Non-exposed	83	74	1.00		
Lowest (1 st) quartile	29	34	1.32 (0.69-2.50)		
Low-middle (2 nd) quartile	24	24	1.06 (0.48-2.33)		
High-middle (3 rd) quartile	24	30	1.55 (0.71-3.35)		
Highest (4 th) quartile	33	31	1.15 (0.47-2.79)		
P trend‡			0.6205		
By overall UNGD activities within 2 r	niles**				
Non-exposed	83	74	1.00		
Lowest (1 st) tertile	13	24	2.79 (1.08-7.24)		
Middle (2 nd) tertile	14	11	0.84 (0.29-2.49)		
Highest (3 rd) tertile	21	18	1.06 (0.39-2.87)		
P trend‡			0.9850		

* Exposed included individuals who lived within 5 miles of any UNGD activity during mother's pregnancy (T1) or from birth to the index date (i.e., date of cancer diagnosis for cases or the same date for matched controls) (T2); non-exposed otherwise.

† All ORs and their 95% CIs for different buffer zones or levels of exposures against non-exposed group were derived from unconditional logistic regression models with adjustment for matching factors (age, sex, race, and county of residence) and the following variables, including maternal age at childbirth (years), maternal education level, maternal smoking status at childbirth (no, yes), gestation age (weeks), birthweight (g), toxics release inventory (TRI) (no, yes), uranium mill tailings remedial action sites {UMTRA} (no, yes), and Superfund site (no, yes). Odds ratios and confidence ratios which are bolded are significant at P < .05.</p>
‡ The same unconditional logistic models were used for linear trend test for the exposure variable in ordinal values (1, 2 for high or low) that also included non-exposed individuals (coded as 0) to maintain the case-control matched pairs.

§ The index date was the date of malignancy diagnosis for cases and the same corresponding date for matched controls.

Malignant Bone tumors

In the birth record-based study (43 case-control pairs), 3 mothers in the cases and 4 in the controls reported a similar exposure to UNGD activities. No risk of malignant bone tumor was associated with exposure to UNGD activities during mother's pregnancy. See **Table 15**. However, the small sample size of malignant bone tumors provided limited statistical power.

Table 15. Overall Unconventional Natural Gas Drilling Activities and Risk of Childhood/Adolescent Malignant Bone Tumor During Two Exposure Periods in Southwestern PA 2010-2019

Overall UNGD activities	Birth Record-based Study with County- matched Controls (43 case-control pairs)				
by exposure period	Controls Cases OR (95% CI)†				
T1: During Mother's P	regnancy				
Non-exposed	39	40	1.00		
Exposed*	4	3	0.22 (0.01-8.58)		
T2: From Birth to Inde	x Date§				
Non-exposed	11	12	1.00		
Exposed*	32	31	1.01 (0.25-4.15)		
By Buffer zone					
(2-5] miles	21	15	1.02 (0.25-4.12)		
[0-2] miles	11	16	3.32 (0.42-26.24)		
P trend			0.2550		
By overall UNGD activities	within 5 miles				
Lowest (1 st) tertile	11	9	1.20 (0.25-5.85)		
Middle (2 nd) tertile	12	9	0.63 (0.1-4.03)		
Highest (3 rd) tertile	9	13	3.52 (0.30-40.73)		
P trend‡			0.5410		

* Exposed included individuals who lived within 5 miles of any UNGD activity during mother's pregnancy (T1) or from birth to the index date (i.e., date of cancer diagnosis for cases or the same date for matched controls) (T2); non-exposed otherwise.

⁺ All ORs and their 95% CIs for different buffer zones or levels of exposures against non-exposed group were derived from unconditional logistic regression models with adjustment for matching factors (age, sex, race, and county of residence) and the following variables, including maternal age at childbirth (years), maternal education level, maternal smoking status at childbirth (no, yes), gestation age (weeks), birthweight (g), toxics release inventory (TRI) (no, yes), uranium mill tailings remedial action sites {UMTRA} (no, yes), and Superfund site (no, yes). **Odds ratios and confidence ratios which are bolded are significant at P < .05**.

[‡] The same unconditional logistic models were used for linear trend test for the exposure variable in ordinal values (1, 2 for high or low) that also included nonexposed individuals (coded as 0) to maintain the case-control matched pairs.

§ The index date was the date of malignancy diagnosis for cases and the same corresponding date for matched controls.

Ewing Family of Tumor

In the birth record-based study, Ewings cases, which numbered only 20 in the present study, were compared using unconditional logistic regression to the total sample of 498 controls. This was done to increase the power to assess the relationship of UNGD activities with adjustment by matching variables, age, race, sex and county of birth as well as the other covariates. There were no significant findings from this analysis. **See Table 16.** Additional analysis did not reveal any dose-response relationships for different buffer zones and overall UNGD activities with risk of EFOT (both p values for trend >0.48). To align with previous studies in UNGD and childhood cancer risk in the literature, similar UNGD exposure metrics were created using well counts and IDW well counts. Overall, the associations between these well count measures and risk of childhood malignancies were like those of the newly created UNGD measurements described above. For example, levels of well counts and IDW well counts were associated with higher ORs for lymphoma, CNS tumor, and malignant bone tumor and EFOT. However, none of the point estimates or linear trend tests were statistically significant.

During Two Exposure Periods in Southwestern PA 2010-2019				
Overall UNGD activities	Birth Record-based Study with County- matched Controls (20 cases vs. 498 controls)			
by exposure period	Controls	Cases	OR (95% CI)†	
T1: During Mother's Pi	regnancy			
Non-exposed	399	18	1.00	
Exposed*	99	2	0.55 (0.10-2.86)	
T2: From Birth to Index Date				
Non-exposed	201	6	1.00	
Exposed*	297	14	1.55 (0.46-5.17)	
By Buffer zone				
Non-exposed	201	6	1.00	
(2-5] miles	178	9	1.50 (0.43-5.21	
[0-2] miles	119	5	1.72 (0.36-8.36)	
P trend			0.4879	
By overall UNGD activities	within 5 miles	6		
Non-exposed	201	6	1.00	
Low (below median)	148	8	1.62 (0.46-5.7)	
High (above median)	149	6	1.39 (0.32-5.96)	
P trend‡			0.6763	

Table 16. Overall Unconventional Natural Gas Drilling Activities and Risk of Childhood/Adolescent Ewing Family of Tumor During Two Exposure Periods in Southwestern PA 2010-2019

* Exposed included individuals who lived within 5 miles of any UNGD activity during mother's pregnancy (T1) or from birth to the index date (i.e., date of cancer diagnosis for cases or the same date for matched controls) (T2); non-exposed otherwise.

⁺ All ORs and their 95% CIs for different buffer zones or levels of exposures against non-exposed group were derived from unconditional logistic regression models with adjustment for matching factors (age, sex, race, and county of residence) and the following variables, including maternal age at childbirth (years), maternal education level, maternal smoking status at childbirth (no, yes), gestation age (weeks), birthweight (g), toxics release inventory (TRI) (no, yes), uranium mill tailings remedial action sites {UMTRA} (no, yes), and Superfund site (no, yes). Odds ratios and confidence ratios which are bolded are significant at P < .05.</p>

[‡] The same unconditional logistic models were used for linear trend test for the exposure variable in ordinal values (1, 2 for high or low) that also included non-exposed individuals (coded as 0) to maintain the case-control matched pairs.

§ The index date was the date of malignancy diagnosis for cases and the same corresponding date for matched controls.

Exposure to Other Environmental Risk Sites and Risk of Childhood Cancer

We examined the association for risk of childhood malignancies with exposures to TRI, UMTRA, and Superfund sites using the case and control mothers' residence for the birth-record study. These analyses were adjusted for age at childbirth, maternal education level, maternal smoking, gestational age, and birth weight. Overall, 86.7% of the children diagnosed with any of the 4 malignancies studied and 84.7% of their matched controls had a birth residence within 5 miles of a TRI site. Compared with non-exposed groups, living close to a TRI site was not associated with an elevated risk of 4 childhood malignancies combined. The malignancy-specific analysis revealed that children with leukemia were no more likely to have lived within 0.5-1 miles of a TRI site, (**Table 17**), and no consistent dose-response relationship was observed for proximity and level of exposure to TRI with risk of leukemia (both *Ps* for trend >0.32). No association with elevated risk of other childhood malignancy types including lymphoma, CNS tumor and osteosarcoma was observed for exposure to TRI site. (**Table 17**).

The proportions of children who were exposed to UMTRA and superfund sites within 5 miles of residence from birth to the index date were low. Overall, 8.4-10.6% of children in the study had a history of residence within 5 miles of UMTRA and superfund site. There was no increased risk in children for the four childhood malignancies combined nor for leukemia, lymphoma, and osteosarcoma. However, the risk of childhood CNS Tumors was significantly elevated **OR=2.68 (1.11-6.44) p=.028)** (**Table 18.)**

The proportions of children who were exposed to a Superfund site within five miles of residence from birth to index date was 8.8% for cases and 7.8% for controls. For the overall combined four malignancies, the odds ratio of 1.12 (95% CI: .71-1.76) was not significant. Moreover, leukemia, lymphoma, and osteosarcoma showed no significant results. However, the risk of CNS associated with proximity to a superfund site was OR=2.16 (0.96-4.86), p=.06 after adjustment for all covariates. **(Table 19).**

Exposure to IDW TRI	Controls	Cases	OR (95% CI)†	Р	P for trend‡
4 Cancer types combined (49	8 Pairs)	-			
Non exposed/[5-10] miles	76	66	1 (reference)	-	.5368
[2-5] miles	194	197	1.23 (.81-1.86)	0.3432	-
[1-2] miles	125	132	1.27 (0.8-2.01)	0.3179	-
[.5-1] miles	72	69	1.15 (0.69-1.92)	0.5845	-
[05] miles	31	34	1.31 (0.71-2.42)	0.3909	-
Leukemia (157 pairs)					
Non exposed/[5-10] miles	20	19	1 (reference)	-	0.3228
[2-5] miles	64	61	1.23 (0.55-2.74)	0.6209	-
[1-2] miles	46	43	1.12 (0.48-2.63)	0.7932	-
[.5-1] miles	17	24	1.86 (0.68-5.05)	0.2252	-
[05] miles	10	10	1.61 (0.47-5.55)	0.4535	-
Lymphoma (105 pairs)					
Non exposed/[5-10] miles	16	15	1 (reference)	-	0.3916
[2-5] miles	38	36	1.14 (0.37-3.44)	0.8226	-
[1-2] miles	30	34	1.45 (0.46-4.51)	0.5237	-
[.5-1] miles	17	10	0.59 (0.14-2.51)	0.4749	-
[05] miles	4	10	3.89 (0.71-21.41)	0.1187	-
CNS tumor (193 pairs)					
Non exposed/[5-10] miles	29	29	1 (reference)	-	0.8641
[2-5] miles	82	78	0.99 (0.52-1.91)	0.9844	-
[1-2] miles	40	44	1.16 (0.54-2.46)	0.7096	-
[.5-1] miles	29	31	1.11 (0.51-2.4)	0.8019	-
[05] miles	13	11	0.92 (0.36-2.34)	0.8564	-
Malignant bone tumor (43 pa	irs)				
Non exposed/[5-10] miles	11	3	1 (reference)	-	0.7340
[2-5] miles	10	22	10.51 (1.47-75.37)	0.0193	-
[0-2] miles	22	18	2.82 (0.52-15.43)	0.2312	-

Table 17. Birth Record Exposure to Inverse-Distanced Weighed (IDW) Toxic Release Inventory (TRI) (US EPA) and Risk of Childhood Malignancies in Western Pennsylvania 2010-2019

⁺ Odds ratios (ORs) were adjusted for maternal age at childbirth, maternal education level, maternal smoking status at childbirth, gestation age, and birthweight.

‡ Linear trend test for the exposure variable in ordinal values (1, 2, 3, 4 for quartile) that also included non-exposed.

Exposure to IDW UMTRA	Controls	Cases	OR (95% CI)†	Р	P for trend‡				
4 Cancer types combined (498 Pairs)									
Non exposed/[5-10] miles	456	445	1 (reference)	-	.1884				
[0-5] miles	42	53	1.37 (0.86-2.2)	.1884	-				
Leukemia (157 pairs)									
Non exposed/[5-10] miles	140	140	1 (reference)	-	.9098				
[0-5] miles	17	17	.95 (.37-2.43)	.9098	-				
Lymphoma (105 pairs)									
Non exposed/[5-10] miles	95	97	1 (reference)	-	0.5978				
[0-5] miles	10	8	0.75 (0.25-2.2)	0.5978	-				
CNS tumor (193 pairs)									
Non exposed/[5-10] miles	184	172	1 (reference)	-	0.0281				
[0-5] miles	9	21	2.68 (1.11-6.44)	0.0281	-				
Malignant bone tumor (43 pa	irs)								
Non exposed/[5-10] miles	37	36	1 (reference)	-	0.6164				
[0-5] miles	6	7	1.40 (0.38-5.13)	0.6164	-				

Table 18. Birth Record Exposure to Inverse-Distance Weighted (IDW) Uranium Mill Tailings Remedial Action (UMTRA) (US DOE) and Risk of Childhood Malignancies in Western Pennsylvania 2010-2019

⁺ Odds ratios (ORs) were adjusted for maternal age at childbirth, maternal education level, maternal smoking status at childbirth, gestation age, and birthweight.

‡ Linear trend test for the exposure variable in ordinal values (1, 2, 3, 4 for quartile) that also included non-exposed.

Table 19. Birth Record Exposure to Inverse-Distance Weighted (IDW) Superfund Site (US EPA) and Risk of
Childhood Malignancies in Western Pennsylvania 2010-2019

Exposure to IDW TRI	Controls	Cases	OR (95% CI)†	Р	P for trend‡				
4 Cancer types combined (498 Pairs)									
Non exposed/[5-10] miles	459	454	1 (reference)	-	0.6403				
[0-5] miles	39	44	1.12 (0.71-1.76)	0.6403	-				
Leukemia (157 pairs)									
Non exposed/[5-10] miles	139	142	1 (reference)	-	0.2679				
[0-5] miles	18	15	0.64 (0.29-1.41)	0.2679	-				
Lymphoma (105 pairs)									
Non exposed/[5-10] miles	97	99	1 (reference)	-	0.7097				
[0-5] miles	8	6	0.82 (0.28-2.4)	0.7097	-				
CNS tumor (193 pairs)									
Non exposed/[5-10] miles	182	172	1 (reference)	-	.0545				
[0-5] miles	11	21	2.16 (0.96-4.86)	.0612	-				
Malignant Bone Tumor (43 pa	iirs)								
Non exposed/[5-10] miles	41	41	1 (reference)	-	0.0612				
[0-5] miles	2	2	0.77 (0.1-6.01)	0.8055	-				

⁺ Odds ratios (ORs) were adjusted for maternal age at childbirth, maternal education level, maternal smoking status at childbirth, gestation age, and birthweight.

‡ Linear trend test for the exposure variable in ordinal values (1, 2, 3, 4 for quartile) that also included non-exposed.

IV. Discussion

The present study performed three separate analyses derived from 507 cases with childhood cancer newly identified throughout eight counties within Southwestern Pennsylvania between 2010 – 2019, a period of extensive hydraulic fracturing activity. The primary analyses were focused on 498 case-control pairs based on birth certificate data.

The following criteria were used to summarize results:

- 1. There are no data to suggest/support an increased risk
 - a. No statistically significantly elevated odds ratios
 - b. Odds ratios at or near 1
 - c. Odds ratios below 1 (with or without statistical significance)
- 2. There are limited data to suggest/support an increased risk
 - a. Statistically significantly elevated odds ratios in a low or moderate tertile
 - b. Not statistically significant elevated odds ratios in multiple tertiles
- 3. There are moderate data to suggest/support an increased risk
 - a. Statistically significantly elevated odds ratios in multiple low or moderate tertiles
 - b. Statistically significantly elevated odds ratios in a high tertile
- 4. There are strong data to suggest/support an increased risk
 - a. Statistically significantly elevated odds ratios in multiple tertiles
 - b. Statistically significantly elevated odds ratios that increase across low, moderate, and high tertiles

Table 20. Summary of Results of Association Between UNGD Activities and Childhood Cancer in Southwestern PA 2010-2019

Analysis	Exposure	Four Malignancy Types Combined	Lymphoma	Leukemia	CNS Tumor	Malignant Bone Tumor	Ewing Family of Tumor
Birth-record based study with county matched controls (498 pairs)	Overall UNGD	Moderate evidence	Moderate evidence	None	Limited evidence	None	None

Four Childhood Malignancies Combined

In the birth record-based analyses with county-matched controls, there was limited to moderate evidence in support of an association between overall UNGD exposure and the combined four malignancies studied. See **Table 20**. No evidence was observed that exposure to other UNGD-related sites (i.e., compressor station, impoundment pond, and wastewater facility sites) or to other environmental risk sites (i.e., TRI, UMTRA and superfund site) was associated with the risk.

Childhood Lymphoma

This study provided moderate evidence suggesting an association between UNGD activity and childhood lymphoma. Analyses revealed statistically significant elevated ORs in multiple higher levels of overall UNGD activities. ORs for lymphoma increased as residential distances from UNGD sites decreased. These odds also increased as overall UNGD activities within both five miles and two miles of

buffer zone increased. respectively. See **Table 12**. Although these positive associations between UNGD activities and risk of lymphoma were stronger in the birth record-based analysis than the survey-based analysis, size of the risk estimates and their direction and magnitude wee similar among the two analyses.

Childhood Leukemia

There was no evidence in support of an association between exposure to UNGD activities and other environmental factors with the risk of childhood leukemia was found in this study. See **Table 13**.

Childhood CNS

Limited data suggesting an association between exposure to overall UNGD activities and risk of childhood CNS was found in this study. See **Table 14**. Analyses revealed a significantly elevated risk of CNS in the lowest tertile of the overall UNGD activities during the primary study period, but no elevated risk estimates were observed for higher exposure levels, nor was there a dose-response relationship.

Malignant Bone Tumor and Ewing Family of Tumor

In this study, no evidence was found to support an association between exposures to UNGD activities and other environmental factors and the risk of malignant bone tumors, including EFOT. Given the small sample size of children with malignant bone tumor, particularly EFOT, additional studies with a larger sample size may be warranted.

Previous Studies

One investigation thus far (McKenzie et al., 2017) considered the association of hydraulic fracturing and the risk of childhood lymphoma and included only non-Hodgkin's lymphoma (N=50) cases which were matched to other cancer controls without "environmentally mediated" cancers.

Within a ten-mile buffer, the researchers observed no statistically significant associations between density of oil and gas development and NHL in either model, based on trend analysis across categorical IDW well counts adjusted for age, race, gender, socioeconomic status, elevation, and year of diagnosis. Of the 50 cases, 18 were unexposed and 32 were within 8 km or a five-mile buffer with UNGD activity exposure. McKenzie et al. noted odds ratios of 1.5 (95% CI; 0.72, 3.3) in the lowest tertile of exposure, 0.91 (95% CI; 0.37, 2.2) in the medium tertile, and 1.6 (95% CI; 0.77, 3.4) in the highest tertile with the closest buffer. They did, however, note an association of increased risk of Leukemia with UNGD in Colorado in ages 5-24, Acute lymphoblastic leukemia cases were 4.3 times as likely to be in the highest exposure category.

The current study team considered all forms of lymphoma (52 Hodgkin's, 22 NHL, 5 Burkitt's lymphoma, 25 miscellaneous lymphoreticular neoplasm, and 5 unspecified), and were able to consider multiple buffer distances and individual hydraulic fracturing phases as well as an overall metric that considered birth residence. In contrast, McKenzie et al. used geocoded addresses at time of cancer diagnosis as the only residence.

Lymphoma is more likely to emerge in the presence of infectious stimuli, chemical toxicity, or an immune system that has lost the ability for self-regulation (Skrabek, 2013). There are several studies investigating possible environmental risk factors for lymphoma in children and adults. Some of the

environmental risk factors investigated include polychlorinated biphenyls, organophosphate and organochlorine pesticides, benzene, nitrogen dioxide, and in utero exposure to smoking. Many of these chemicals are in the IARC carcinogen list and are also found in hydraulic fracturing fluids (Mcnally, 2006). Future studies with biomarkers for exposure to UNGD activities may clarify the current study's observed association between hydraulic fracturing and risk of lymphoma.

Strengths and Limitations

This study has many strengths. It is only the second population-based study on UNGD activities and childhood cancer risk randomly sampling age, race, and sex matched controls from birth records. The study population was restricted to Western Pennsylvania counties which permitted UNGD activities since 2005. As such, the City of Pittsburgh was excluded due to a ban on hydraulic fracturing. This minimized potential confounding and bias due to other environmental risk factors. The rigid matching criteria (less than 45 days of difference in birth dates between a case and matched control) eliminated potential confounding effect by age. The collection of other environmental exposure data through publicly available sources provided additional information on factors (e.g., TRI, UMTRA, Superfund sites, impoundment ponds, compressor stations, and facilities accepting oil and gas waste), which were adjusted for through multivariable logistic models.

In addition to conventionally used well counts and IDW well counts as exposure variables, the study team was able to create a new metric called "overall activity" in estimates to evaluate cancer risk. The challenge in considering the health effects of individual hydraulic fracturing phases is that they may be occurring simultaneously in the background with other co-located wells. This overall metric accounted for the duration of UNGD activity and IDW components for each phase during the period of exposure studied. Moreover, phases of hydraulic fracturing and other potential environmental covariates including proximity to TRI, UMTRA, and Superfund sites were included in the overall analysis. An additional strength was the application of multiple buffers for proximity of residences within < 0.5, 0.5-1.0, 1-2, and 2-5 miles of these sites, which allowed for the assessment of cancer risk with UNGD proximity. The increased risk of childhood cancer with decreasing residential distance from UNGD sites suggests a probable link between UNGD activities and childhood cancer risk.

This comprehensive analysis also revealed consistent associations for various metrics of UNGD activities, which were highly correlated with each other and the risk of childhood cancer outcomes, further strengthening a probable link between UNGD activities in general and risk of childhood cancer.

This is the first study to include the four most common childhood cancers – leukemia, lymphoma, CNS tumors and malignant bone tumors. The inclusion of multiple cancer types provided a larger sample size for the study and allowed for the assessment of cancer-specific risk with UNGD activities. The strongest association was observed between UNGD activities and risk of childhood lymphoma, which are novel findings and warrant assessment by future studies.

The present study also has some limitations. The chief limitation is using distance as a proxy exposure measurement for UNGD activities. Exposure may be affected by many factors such as the nearby topography and geological formations, weather patterns, and water sources, and the behaviors of individuals residing near UNGD activity. It is possible that using distance as a proxy has resulted in

exposure misclassification, which may identify an association where there is not one or vice versa. In addition, although the study team focused much attention on data cleaning and geocoding, the accuracy and completeness of the UNGD activity data used for the calculation of UNGD metrics cannot be certain. In addition, the use of residence from the birth records as a proxy for UNGD exposure from birth until index date to increase sample size also introduces the possibility of misclassification bias. However as shown in previous Table 8, there was an extremely high concordance (85%) with cases' residence at birth compared to their residence at diagnosis remaining in SW PA and an almost 80% of cases remaining in the same county. This adds validity to the use of birth certificates as a proxy for UNGD metrics for this study. Another limitation of the study was the small sample size particularly for Bone Cancer and Ewing Family of Tumor which resulted in large variations in risk estimates and wider confidence intervals.

V. Conclusion

There were no associations between unconventional natural gas development activities and childhood leukemia, brain and bone cancers, including Ewing's family of tumors. Results indicated that children who lived within 1 mile of a well had approximately 5 to 7 times the chance of developing lymphoma, a relatively rare type of cancer, compared to children who lived in a place with no wells within 5 miles. Data suggests that those who lived closer, especially in areas with greater intensity of unconventional natural gas development activities, had the highest risk. There was also a strong dose-response relationship between the overall UNGD activities over the four phases and risk of lymphoma. In addition, the closer the proximity of a residence to an UNGD site, the higher the risk of lymphoma, which further supports a possible link between UNGD activity and risk of childhood lymphoma.

For perspective, the incidence of lymphoma is, on average, 0.0012% in U.S. children under 20 years of age. Our study estimates that rate would be 0.006% to 0.0084% for children living within 1 mile of a well.

No evidence was observed for exposures to other environmental sites (i.e., TRI, UMTRA and Superfund sites), and any childhood cancers.

In this study, no evidence was found to support an association between exposures to UNGD activities and other environmental factors and the risk of leukemia, CNS tumors, and malignant bone tumors, including EFOT. Given the small sample size of malignant bone tumors, due to a very low incidence rate in the population, especially for EFOT, additional studies with a larger sample size are warranted.

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Appendices

Appendix A: Background Reference Materials

Common Hydraulic Fracturing Fluid Constituents (U.S. EPA 2015, Hurley 2015, Wollin 2020)

Additive	Common Chemical	Function
	Constituents	
Acid	Hydrochloric acid	Cleans casing and formation prior to injection; dissolves cement, minerals, and clays to reduce clogging of pore space
Antibacterial agent/biocide	Glutaraldehyde	Controls or eliminates bacterial growth that may reduce well productivity
Breaker	Peroxydisulfuric acid diammonium salt, sodium chloride	Reduces viscosity of gels and foams and promotes recovery of fracturing fluid
Clay controller	Choline Chloride, potassium chloride	Prevents mobilization of formation clays
Corrosion inhibiter	Methanol, propargyl alcohol, isopropanol	Protects steel tubing and other equipment from corrosion
Crosslinker	Ethylene glycol, potassium hydroxide, sodium hydroxide, borate salts	Increases gel viscosity by connecting polymer molecules
Friction reducer	Hydrotreated light petroleum distillates, mineral oil	Minimizes friction when pumping fluids to optimize fluid injection
Gelling agent	Guar gum, hydrotreated light petroleum distillates	Increases fluid viscosity to promote proppant transport and reduce fluid loss
Iron controller	Citric acid	Prevents precipitation of iron compounds
pH control	Carbonic acid, dipotassium salt, potassium hydroxide, sodium hydroxide, acetic acid	Regulates pH of a solution by either inducing a change (pH adjuster) or stabilizing and resisting change (buffer) to achieve desired qualities
Scale controller	Ethylene glycol, methanol	Controls or prevents scale deposits in production conduit or completion system
Solvent	Hydrochloric acid	Controls wettability of contact surfaces or prevents or breaks emulsions
Surfactant	Naphthalene	Decrease fluid surface tension, promote injection, and fluid recovery

Appendix B: Methods Reference Materials

Zip code	All or part City of Pittsburgh	Zip code	All or part City of Pittsburgh	Zip code	All or part City of Pittsburgh
15106	Part City	15212	Part City	15224	All City
15120	Part City	15213	All City	15226	Part City
15201	All City	15214	Part City	15227	Part City
15203	All City	15215	Part City	15230	All City
15204	Part City	15216	Part City	15232	All City
15205	Part City	15217	All City	15233	All City
15206	All City	15218	Part City	15234	Part City
15207	All City	15219	All City	15235	Part City
15208	All City	15220	Part City	15240	Part City
15210	Part City	15221	Part City	15260	All City
15211	All City	15222	All City	15282	All City

City of Pittsburgh Zip Codes Excluded from the Study Area

Summary Activities for Recruitment of Controls

Mode	Number	Number	Number of	Total	Bounced/	Started	Finished	Completion	Response
	of	of	calls/reminders	calls/messages	spam/			Rate	Rate
	control mothers	invitations sent/calls	sent	sent	duplicate				
	and	to control							
	fathers	mothers and							
		fathers							
US Mail	8355	8355					357		4.3%
Email	7062	16198	32096	48294	15235	179	167	93.0%	2.4%
SMS Text	4832	8991	2612	11603	0	394	84	21.0%	1.7%
Phone follow- up	1091	831	280	1111			32		2.9%
Totals	8355	34375	34988	61008	15235	573	640	89.8%	7.7%

The Population Survey Facility (PSF) at the University of Pittsburgh assisted the research team in recruiting matched controls. Following the initial mailing to 8,355 potential controls, the PSF employed a multimode approach for recruiting controls which entailed a combination of email, text message, and follow-up phone calls. Before data cleaning and across all modes the response rate was 7.7%. Contact information was obtained from Lexis-Nexus and consisted of up to 6 emails for each control (i.e., up to 3 emails for both mothers and fathers) and 4 cell phone numbers (i.e., up to 2 for both mothers and fathers). Approximately 61,000 total calls or electronic messages were sent to recruit matched controls, resulting in 640 completed surveys prior to data cleaning.

The IRB Approval Letter



EXEMPT DETERMINATION

Date:	March 16, 2021
IRB;	STUDY21020141
PI:	Evelyn Talbott
Title:	Heath Effects of Hydraulic Fracturing
Funding:	Name: Pennsylvania Department of Health, Funding Source ID: Contract number: 4400018535
Grant Title:	None

The Institutional Review Board reviewed and determined the above referenced study meets the regulatory requirements for exempt research under 45 CFR 46.104.

Determination Documentation

Determination Date:	3/16/2021
Exempt Category:	(2)(iii) Tests, surveys, interviews, or observation (identifiable); and for which limited IRB review was conducted via expedited review
Determinations:	None
Approved Documents:	 Questionnaire, Category: Data Collection; Attachment 1 Agency Request for Project 09-04-20_Version_0.01.doc, Category: Sponsor Attachment; Case Brochure, Category: Recruitment Materials; CASE PRENOTIFICATION LETTER.docx, Category: Recruitment Materials; CONTROL PRENOTIFICATION LETTER.docx, Category: Recruitment Materials; Exempt Application Form, Category: IRB Protocol; Phone Call Script - Scheduling Interview, Category: Recruitment Materials; Verbal Consent Phone Script, Category: Recruitment Materials

If you have any questions, please contact the University of Pittsburgh IRB Coordinator, Dana DiVirgilio.

Please take a moment to complete our Satisfaction Survey as we appreciate your feedback.

Human Research Protection Office 3500 Fifth Avenue, Suite 106 Pittsburgh, PA 15213 www.hrpo.pitt.edu

Steps for Selection of County-Matched and Non-County-Matched Controls by PADOH Bureau of Health Statistics and Registries

Step 1) Import birth data for all Pennsylvania Cancer Registry (PCR) patients eligible for this study.

Step 2) To prepare for control selection, two fields were created for every patient – "Patient_Bin_1" for resident county-matched controls and "Patient_Bin_2" for those controls <u>not</u> matched to resident county. "Patient_Bin_1" was created by concatenating the mother's Race, the patient's sex per the birth record, and the mother's resident County at time of the patient's birth. "Patient_Bin_2" was created by concatenating the mother's race as reported on the birth record was recoded as the field "Moth_Race_Bin". The following logic was used to recode the mother's race:

Mother's Reported Race ("Moth_Race" via Birth data)	Recoded Field ("Moth_Race_Bin")
White	Whi
Black/African-American	Bla
All other entries	Oth

Step 3) To create the pool of potential controls, birth records from 1990-2019 (inclusive) were imported. Due to differences in the layout of these data, three separate data sets were created based on the following years of birth: 1990-2002, 2003-2012, and 2013-2019. Births that did not occur in one of the eight counties of interest for this study were removed from the pool of potential controls. Additionally, certain birth records were removed if, based on the mother's residence zip code, the mother resided in the City of Pittsburgh at the time of the birth. Two bins were created for each potential control: "Control_Bin_1" and "Control_Bin_2". "Control_Bin_1" leveraged the same methodology as described in Step 2 to create the "Patient_Bin_1" field, and "Control_Bin_2" leveraged the same methodology as described in Step 2 to create the "Patient_Bin_2" field.

Step 4) Prior to selecting the controls, all years of birth data were combined into one data set containing the respective bins used as part of the matching criteria, a unique ID for the birth record, and the potential control's date of birth. A random number was also associated with each respective birth record for use later in the selection process. A comprehensive data set was also created for the eligible patients that only included the respective bins used as part of the matching criteria, a unique ID for the birth record, and the patient's date of birth.

Step 5) County-matched controls were identified for all patients in a single Procedure in SAS SQL (Structure Query Language) step. This initial group of record pairings, "Control Group 1", contain patient-control record pairings that were matched on sex, race, and mother's residence county (contained in the "Control_Bin_1" field). Additionally, the matching criteria also included logic to only retain record pairings where the patient's date of birth was within 45 days of the control's date of birth. Controls that matched to multiple patients were isolated, and a single patient-control pairing was selected using simple random sampling (without replacement) via the SAS procedure Proc SurveySelect. Controls identified for "Control Group 1" were sorted by the random number assigned to the respective record during Step 4. A maximum of 40 controls were selected for each patient. Final checks were made

to ensure all eligible patients matched to a set of controls, verify there were no duplicate controls represented in the final data set, and determine the final frequency of patient-control pairings.

Step 6) The selection process for "Control Group 2" followed the same logic as described in Step 5 for "Control Group 1", however, controls identified in Step 5 were removed from the pool of eligible birth records prior to the selection process, and the residence county parity requirement was removed from the matching criteria. Sex, race, and date of birth proximity (i.e., controls born within 45 days of the respective patient) were leveraged during the record matching process. The sex and race fields were contained in the "Control_Bin_2" field.

Step 7) The final release files were created for the study group using the controls selected for "Control Group 1" and "Control Group 2".

Modification	Summary	Date Approved
Pitt IRB Modification #1	Revision of consent methodology from verbal to written	September 20, 2021
	Addition of osteosarcoma and EFOT cases aged 20-29	
	(previously restricted to 0-19)	
Pitt IRB Modification #2	Addition of QR code for ease of obtaining (electronic)	February 2, 2022
	written consent	
	Revision of LexisNexis contract to allow for phone number	
	and email address tracing	
	Approval of text and email-based recruitment strategies	
	Revision of phone call script for non-response follow-up	
Pitt IRB Modification #3	Revision of survey mode from 45-60 minutes by phone to	February 23, 2022
	20-25 minutes by phone or online	
	Revision of recruitment flyer to be included in	
	recruitment emails	
	Inclusion of Qualtrics-based online survey link in	
	recruitment emails	
Pitt IRB Modification #4	Addition of Dr. Jean Tersak as study co-investigator	May 5, 2022
	Survey staff personnel updates	
Pitt IRB Modification #5	Addition of paper-based residential history for eligible	May 16, 2022
	case families	
	Addition of Qualtrics-based text message and email	
	recruitment methodology	
	Revision of postcard to indicate survey mode preference	
Pitt IRB Modification #6	Approval of Dr. Jean Tersak's letter of support for case	June 6, 2022
	recruitment materials	
	Approval to host in-person informational sessions for	
	eligible case families at State Health Centers	
Pitt IRB Modification #7	Revision of Control Incentive to \$15; Updated verbiage to	July 22, 2022
	reflect shortened survey length (20-25 min)	
DOH IRB Modification #1	Verbal consent approved for cases and controls (double	August 21, 2022
	check)	

Dated Summary of Protocol Modifications.

Timeline of Study Activities

Action	Date
DOH Contract Effective Date	September 1, 2020
Study activities commenced by Pitt Study Team (kick-off meeting)	November 20, 2020
Study funding received by Pitt Public Health	December 8, 2020
Initial Pitt IRB Submission	February 23, 2021
Pitt IRB Approval	March 16, 2021
DOH Protected Use Agreement submission	April 19, 2021
Initial DOH IRB submission	June 14, 2021
DOH IRB Approval	June 17, 2021
DOH Protected Use Agreement Approval	July 7, 2021
External Advisory Board Inaugural Meeting	August 5, 2021
Initial case dataset received from DOH (survivors only)	September 2, 2021
Pitt IRB Modification #1 Approval	September 20, 2021
LexisNexis Contract Finalized	September 21, 2021
Case recruitment period commenced	September 28, 2021
Conclusion of 1 st quarter of recruitment efforts: n= 71 case interviews	December 31, 2021
Revised case dataset received from DOH includes corrected classification of cancer cases)	January 15, 2022
Pitt IRB Modification #2 Approval	February 2, 2022
Pitt IRB Modification #3 Approval	February 23, 2022
Revised case dataset received from DOH (includes decedents)	February 25, 2022
Conclusion of 2 nd quarter recruitment efforts: n= 107 case interviews	March 31, 2022
Complete control dataset received from DOH	April 21, 2022
Pitt IRB Modification #4 Approval	May 5, 2022
Pitt IRB Modification #5 Approval	May 16, 2022
Control recruitment period commenced	May 18, 2022
Pitt IRB Modification #6 Approval	June 6, 2022
Conclusion of 3 rd quarter of recruitment: n= 140 case interviews, n=126 control interviews	June 30, 2022
Pitt IRB Modification #7 Approval	July 22, 2022
SMS text message recruitment of control families commenced	September 8, 2022
Email recruitment of control families commenced	September 14, 2022
Electronic recruitment of control families (Emails and Texts) done	September 22, 2022
Conclusion of 4 th quarter of recruitment efforts: n= 234 case interviews, n= 640 Controls in	September 27 th , 2022
Case/control recruitment period closure	September 27th, 2022
Data cleaning phase commencement	August 2022
Data cleaning phase closure: n= 234 case interviews, n= 373 Control interviews	October 2022
Data analysis phase commencement	September 2022
Data analysis phase closure	October 2022
Report writing phase commencement	October 2022
Report writing phase complete	November 2022
Report 1A submitted to DOH, Report 1B submitted to DOH	11/16 &11/23 2022
Final report submitted to DOH	March 1, 2023

Geocoding Addresses

Addresses of cases and controls were geocoded in ArcMap 10.6, using ArcGIS World Geocoding Service (WCS). All addresses were matched to a set of geocoordinates. WCS included a percentage of accuracy for each match that it found. A decrease in percentage could be due to a typo in the address such as "Street" versus "Avenue" or a misspelling of street name. Sometimes WCS returned a match for a street, but the number provided by the participant was not a currently recognized address along with that street. WCS then identified the centroid of the street. Lastly, it was possible that WCS was not able to find a street with the same name that matched the city and zip code. In that case, WCS defaulted to selecting the centroid of the zip code. In some scenarios, WCS finds multiple potential matches with varying levels in the percentage of accuracy. The analyst can review these other potential matches and evaluate if another one could fit better to the information provided by a participant. If an alternative match was better, the analyst can manually match that set of geocoordinates instead of what was originally selected by WCS. If the other options are less well fitting, the analyst keeps the match the same.

A total of 892, or 78%, of addresses were matched with 100% accuracy, and 257 of the remaining addresses had certainty scores below 100%. However, upon review of these 257, 163 addresses were correctly matched to point addresses. In these instances, typos or inclusions of unit numbers, etc. caused a decrease in the accuracy percentage, but the correct point was identified. Of the remaining addresses with accuracy below 100%, 74 were matched to the centroid of the street and 19 used a zip code centroid where no street could be identified. Only 6 of the centroid addresses were manually rematched with a potential match not originally selected by WCS. In all other cases, the analyst agreed with the choice of geocoordinate selected by WCS. Once the review was done, the geocoding results were exported into a csv file to be uploaded to GCP to the data programmer for exposure metrics calculation. ArcMap was not used to calculate the IDW exposure metrics due to the computing power required to measure distances between all houses and wells.

Aggregating Exposure Metrics Across Residential History

To have a dataset representing individual participants as opposed to houses, exposure metrics were then aggregated across residences for each case and control. Metrics were first calculated by house and by time period as described above. Inverse distance weighted metrics were then summed across houses for all time periods.

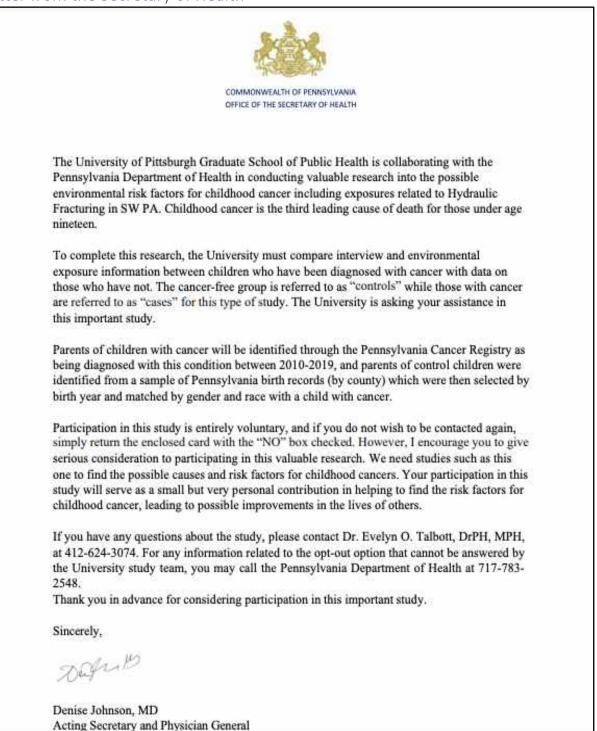
Since IDW Well counts cannot appropriately be summed across residences, as this would artificially inflate the counts of individuals who moved often, a different method was used for aggregation. Proportions were calculated for time spent in each individual house as part of the total time period of all residences listed per person. IDW well counts were multiplied by the proportion and then summed to get a time-weighted sum of wells for each person and time period. This potential inflation only occurs with this IDW well count variable but would not occur with the other metrics as they include a duration element. This is how the additional metrics calculated in this study improve upon metrics in the existing literature. For the other environmental exposure variables, the same procedure was used.

Addressing Issues with Incomplete Data

The study team anticipated incomplete data in exposure metrics and well data for the entire exposure period. To address these issues, the following protocol was used:

- For gaps in residency: If residency or well data were missing for some of the exposure period, the metric was based on available data. For each metric computed, a companion variable was calculated indicating the proportion of the time period with available data (variable name: data completeness). For example, the value ranges from 0 to 1 (depending on the proportion of residential history provided), a value of 1 indicates data was provided for the 100% of the participant's time period, while a value of 0.94 indicates data residential history was provided for 94% of the participant's time period. In the complete analysis, only 7 of 213 cases and 7 of 213 controls had less than 100% completion. A sensitivity analysis found that excluding these pairs did not change the results.
- For study participants who relocated to residences outside the eight-county study area: A buffering zone of 5 miles from all borders of the eight-county study area extending into the surrounding counties has been considered when downloading exposure data. Data within the buffering zone or of the adjacent counties that the buffering zone was in were downloaded.
- For study participants who relocated outside of the study area and its buffering area to another hydraulic fracturing county within Pennsylvania: DEP data was used to determine if the participant lived within ten miles of an area with hydraulic fracturing. If the participant lived within an area where hydraulic fracturing occurred, their exposure was considered unknown for that residence, which is accounted for in the data completeness variable described above. Residential histories for study participants who relocated outside of the study area and its buffering area to other states with hydraulic fracturing (West Virginia, Ohio, Texas, etc.) were flagged based on whether a hydraulic fracturing timeline and estimated exposure was able to be shown. If unable to be shown we their exposure was considered to be unknown for that residence, which is accounted for in the data completeness variable described above.
- Residential histories for study participants who relocated outside of the study area and its buffering area to other states without hydraulic fracturing were considered to have no exposure to hydraulic fracturing.
- For missing date information:
 - o If the day of the month was missing: the 15th of the month was used
 - o If the month was missing: the 7th month and 1st day was used
 - If the end date (move-out date) for a residence was missing: the date 1 day prior to the next listed residence was used
- For missing GIS information which could not be resolved to house number and street name:
 - If data had only street name, GIS coordinates corresponding to the centroid of the street were used
 - o If data had only town/city, GIS coordinates corresponding to centroid of town/city used
 - If data had only zip code, GIS coordinates corresponding to centroid of zip code used

Appendix C. Outreach and Subject Recruitment Materials Letter from the Secretary of Health



Pennsylvania Department of Health

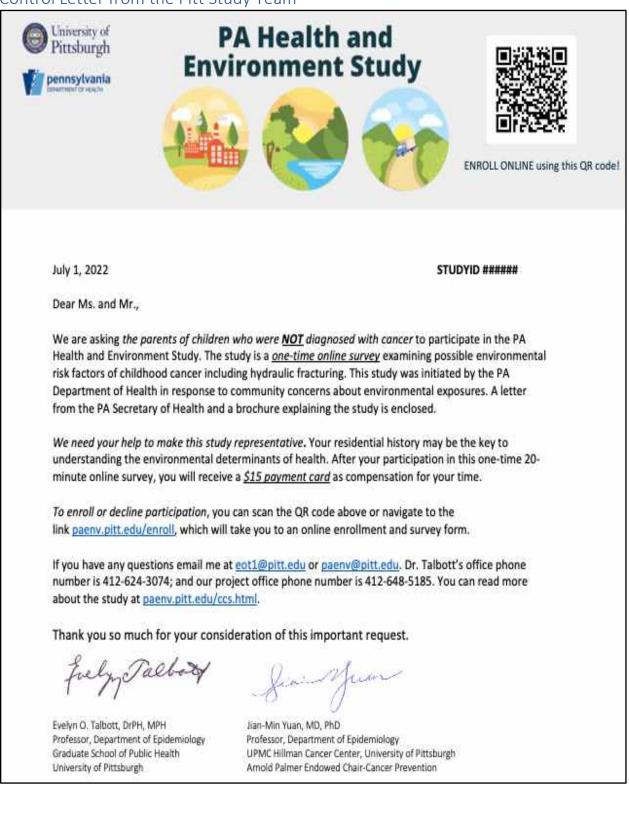
Case Letter from the Pitt Study Team

University of Pittsburgh



Arnold Palmer Endowed Chair-Cancer Prevention

Control Letter from the Pitt Study Team



Opt-In/Opt-Out Postcard

I DO wish to be contacted regarding this stud	
If yes, please fill out the contact information	n below:
Signature:	Date://20
Name:	
Email:	
Phone Number:	
Survey preference (check one): Text	_ Online Phone
Current Address:	
I DO NOT wish to be contacted regarding thi	
Signature:	Date://2
Name:	

Case Brochure



Why is this research being done?

Childhood cancer is the third leading cause of death in US children, yet there are very few known risk factors.

Pitt Public Health is conducting this study to consider some of the risks that may play a role. These include lifestyle behaviors, residential history, family medical history, workplace and environmental exposures, and other exposures during childhood and early life.



University of Pittsburgh Graduate School of Public Health Department of Epidemiology 130 DeSoto Street Pittsburgh, PA 15261

paenv.pitt.edu

Case Control Study: Childhood Cancer in Southwestern Pennsylvania



Recruiting Parents for an Important Study

Please see why inside!



How did we get your name?

 Information was obtained through the Pennsylvania Cancer Registry as well as from PA birth records (by county) from the Department of Health.

Participation is voluntary!

- If you do choose to participate:
 - O This will not impact your access to healthcare or treatment
 - Vou can withdraw from the study at any time





Who will be asked to participate in this research study?

Parents who have a child:

- Who was diagnosed with Ewing's/ bone cancers at age 0-29 years during 2010 through 2019, or
- Who was diagnosed with Childhood Leukemia, Lymphoma and Central Nervous System tumors at age 0-19 years during 2010 through 2019
- Resided in one of the following Pennsylvania counties:
 - Allegheny County
 - Armstrong County
 - Ø Beaver County
 - 0 Butler County
 - Fayette County
 - o Greene County
 - Washington County
 - Westmoreland County

What will parents be asked to do?

- Complete a one-time, 45-60 minute telephone interview
 - Includes guestions about individual, occupational, and environmental exposures
- · Your time will be compensated

Other Information

- We will only be speaking with parents
- Any information provided for this research study will be confidential

Contact Information

Evelyn O. Talbott, DrPH, MPH Principal Investigator

- Phone: (412) 648-5185
- Email: paenv@pitt.edu
- · Website: paenv.pitt.edu
- Project Office Location: University of Pittsburgh Graduate School of Public Health A545 Public Health Building, 130 De Soto St Pittsburgh, PA 15261

Control Brochure



Why is this research study being done?

Childhood cancer is the third leading cause of death in US children, yet there are very few known risk factors.

Pitt Public Health is conducting this study to consider some of the risks that may play a role. These include lifestyle behaviors, residential history, family medical history, workplace and environmental exposures, and other exposures during childhood and early life.



University of Pittsburgh Graduate School of Public Health Department of Epidemiology 130 DeSoto Street Pittsburgh, PA 15261

paenv.pitt.edu

Case Control Study: Childhood Cancer in Southwestern Pennsylvania



Recruiting Parents of Children Without Cancer as Controls for an Important Study

Please see why inside!





How did we get your name?

- Information was obtained from the PA birth records (by county) from the Department of Health.
- The participants in both groups must be matched in the following categories: Age, Sex, Race, and County.

What will parents be asked to do?

- Complete a one-time, 45-60 minute telephone interview
 - Includes questions about individual, occupational, and environmental exposures
- Your time will be compensated

Why are we asking you to participate in this study?

- We are recruiting a control group families of children without cancer to compare to families of children with this condition.
- Participation in this study will serve as an important and personal contribution in helping identify risk factors for childhood cancer.



- Participation in this study is limited to the following counties:
 - Allegheny County
 - Armstrong County
 - Beaver County
 - Butler County
 - Fayette County
 - Greene County
 Washington County
 - V Westmoreland County

Other Information

- We will only be speaking with parents
- Any information provided for this research study will be kept strictly confidential

Participation is voluntary!

 If you do choose to participate, you can withdraw from the study at any time

Contact Information

Evelyn O. Talbott, DrPH, MPH Principal Investigator

- Phone: (412) 648-5185
- Email: paenv@pitt.edu
- · Website: paenv.pitt.edu
- Project Office Location:
- University of Pittsburgh Graduate School of Public Health A545 Public Health Building, 130 De Soto St Pittsburgh, PA 15261

Recruitment Text Message Scripts

Text Message Enrollment Scripts

Script 1 (briefest, requires no interaction with study team): Header: Pitt Public Health Needs Your Help. Important study on childhood cancer and hydraulic fracturing in SW PA! Brief online survey, click here to consent and enroll: paeny.pitt.edu/enroll \$25 dollars for your time. Reply NO to decline.

Script 2 (brief, requires no interaction with study team):

Header: Pitt Public Health Needs Your Help.

Hi (participant) This is (staff) at Pitt Public Health. We're trying to reach you regarding a childhood cancer case-control survey. If you haven't already, will you consider participating in our brief, online survey? You will receive \$25 for your time.

Here is the link to consent and enroll: paeny.pitt.edu/enroll Reply NO to decline enrollment.

Script 3 (extended, requires interaction with study team):

Header: Pitt Public Health Needs Your Help.

Hi, this is Dr. Talbott's study team at the University of Pittsburgh School of Public Health. We are trying to contact Mr./Ms. _____ regarding a childhood health study. Do we have the right person? Reply YES or NO to decline.

No - Thank you, have a nice day.

Yes – We had sent a letter to him and wanted to confirm that he received it. The first letter was sent on <u>date</u> and the second letter was sent on <u>date</u>. Can you confirm that you received these letters? Reply YES or NO.

No, I did not receive the letters.

If you would like information about this study or would like to enroll, you can do so at paeny.pitt.edu/enroll

Yes, I received the letters.

That's great. As you know, we are studying the risk factors for childhood cancer, which we know very little about. Your participation would allow us to make accurate conclusions and help prevent childhood cancer in the future. You would receive \$25 for the one-time online survey. Would you be interested in participating? Reply YES or NO to decline.

No, I would not like to participate.

Thanks for your response. Have a nice day.

Yes, I would like to participate.

Thank you! You can enroll online at paeny.pitt.edu/enroll

Recruitment Letter from Dr. Tersak

UPMC CHILDREN'S Hematology/Oncology Sarvivotship Children's Hospital Drive 4401 Penn Avenue Pittsburgh, PA 15224 1 412-692-8570 F 412-692-3412 SurvivorConnectsichp.edu www.thp.udu/turvfeurship Dear Mr. and Mrs.: I am writing to you regarding an important study at the University of Pittsburgh, the "PA Health and Environment Study." I was asked to be involved due to my work as a pediatric oncologist. This study has the potential to help answer critical questions concerning environmental exposures within Southwestern Pennsylvania. A large number of participants from our region will increase the likelihood that we are able to answer the important questions of this study. As the enclosed brochure describes, Pitt Public Health, in partnership with the Pennsylvania Department of Health, is conducting a case-control study of environmental risk factors and childhood cancer. Studies like this are necessary to evaluate the impact of industrial activities, including hydraulic fracturing ("fracking") on human health, especially on children's overall health and cancer risk. I am writing to you in support of this state funded study and to encourage you to please consider participating when you are contacted by the Pitt study team. Participation in this study would require you to complete a short survey regarding your residential history, done over the phone or online, and should take approximately 20 minutes. When your answers are aggregated together with more than 1,000 participants like you, we can conduct detailed analysis and learn if the industrial activities are related to childhood cancer. Such knowledge is crucial for the development of strategies to mitigate or even eliminate such environmental risk factors in our community and beyond. Your participation will be a critical contribution to advancing our understanding of pediatric cancer's environmental origins. I thank you in advance for your consideration to participate. Please reach out to the study team or directly to me if you have any questions about the study. Sincerest thank you, Jean M.Tersak, MD

Eventbrite Email Invitation



Hello!

The University of Pittsburgh study team is hosting two informational sessions for parents who are eligible to participate in a paid survey for the PA Health and Environment Study. You can read more about the study at paenv.pitt.edu/ccs.html.

These informational sessions will be held on:

Wednesday, August 10th from 9-11 AM Westmoreland County's State Health Center, 233 W. Otterman St Greensburg, PA 15601

and

Friday, August 12th from 1-3 PM Washington County's State Health Center, 167 N. Main St., Suite 100 Washington, PA 15301

> If you would like to attend, we kindly ask that you RSVP online by <u>Sunday, August 7th</u> with a free ticket using password **PAENV** You can RSVP for the Westmoreland session here: <u>https://www.eventbrite.com/e/393175698097</u> or the Washington session here: <u>https://www.eventbrite.com/e/393191595647</u>

If you have any questions email the study team at paenv@pitt.edu or call (412) 648-5185.

Thank you so much for your time and we hope to see you at the informational session.

July Taltor

Evelyn O. Talbott, DrPH, MPH Professor, Department of Epidemiology Graduate School of Public Health University of Pittsburgh

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Jian-Min Yuan, MD, PhD Professor, Department of Epidemiology UPMC Hillman Cancer Center, University of Pittsburgh Arnold Palmer Endowed Chair-Cancer Prevention

2-Page Residential Questionnaire

	2	ID.	Number			
I consent to pa	rticipate		10000	th and Environment Study	y 1	
Name:	2002/14/1	1995254949494104	Signatu	re:	#34	Date
Re(child's nam	e)	, please li	mm51986.55	Subjects where they are obtained	our child was conceived	through (date DX)
Email:	1.00		17 4 33345755			THE SAME AND A DATA SAME
ddress of Residence:	Zip	Nova-in	Move-	Was home within 1	Was there any oil/ gas	Was this home within 1 mile of a
Street Address and City/Town	Code	Date (Month & Year)	out Date (Month & Year)	mile of at least one major industrial facility? (check one)	activity or facility nearby? (check one)	farm/agricultural facility? (check one)
				YesNo Unknown If yes, describe:	Yes No Unknown If Yes, approx. date you noticed activity	YesNo Unknown If yes: please describe type (es: dairy
					or Don't Know	fann, apple orchard, etc.)
÷				YesNo Unimown if yes, describe	Yes No_Uninown_ If Yes, approx. date you noticed activity	Yes No
1.	2 2	-	-	YesNo	noticed activity or Dan't Know YesNoUnknown	Fyes: pleme describe type YesNo
				Unknown If yes, describe	noticed activity	Unknown If yes: piesse describe type
				Yes_No_	or Don't Know YesNoUnknown	Yas No
				Unknown If yes, describe:	If Yes, approx. date you noticed activity	Unknown If yes: please describe type
			-		or Don't Know	1
i.				YesNo Urknown If yes, describe:	YesNoUnknown If Yes, approx. date you noticed activity	YesNo
				1.22	or Don't Know	If yes: please describe type
Regarding (chi	d's name)		please list yo			ed theorem (detail)
Address of Residence: Street Address and City/Town	Zip Code	Move-in Date (Month & Year)	Move- out Date (Month & Year)	Was home within 1 mile of at least one major industrial	ear before your child was conceive Was there any oll/ gas activity or facility nearby? (check one)	Was this home within 1 mile of a farm/agricultural facility? (check one)
Street Address and City/Town		Date	out Date	Was home within 1 mile of at least one major industrial facility? (check one) Yes No	Was there any oill gas activity or facility nearby? (check one) Yes_No_Unknown_	Was this home within 1 mile of a farmiagricultural facility? (check one)
Street Address and City/Town		Date (Month &	out Date (Month &	Was home within 1 mile of at least one major industrial facility? (check one)	Was there any oll/ gas activity or facility nearby? (check one)	Was this home within 1 mile of a farm/agricultural facility? (check one) YesNo Unknown
Street Address and City/Town		Date (Month &	out Date (Month &	Was home within 1 mile of at least one major industrial facility? (check one) Yes_No Unknown	Was there any oil? gas activity or facility nearby? (check one) Yes_ No_Unknown_ #Yes, approx. date you noticed activity or Don't Know	Was this home within 1 mile of a farm/agricultural facility? (check one) YesNo Unknow If yes: please describe type (ex: dairy farm, apple orchard, etc.)
Street Address and City/Town		Date (Month &	out Date (Month &	Was home within 1 mile of at least one major industrial facility? (check one) Yes	Was there any oil/ gas activity or facility nearby? (check one) YesNoUnknown if Yes, approx, date you noticad activity	Was this home within 1 mile of a farm/agricultural facility? (check one) YesNo If yes: please describe type (ex: dairy farm, apple orchard, etc.) YesNo Unknown
Street Address and City/Town		Date (Month &	out Date (Month &	Was home within 1 mile of at least one major industrial facility? (check one) YesNo Unknown If yes_ describe: YesNo	Was there any oil? gas .activity or facility nearby? (check one) Yes NoUnknown if Yes Rounknown or Don't Know Yes NoUnknown if Yes Roprox, date you noticed activity	Was this home within 1 mile of a farm/agricultural facility? (check one) YesNo Unknown If yes: please describe type (ex: dairy farm, apple orchard, etc.) YesNo
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Street Address and City/Town 6. 7.		Date (Month &	out Date (Month &	Was home within 1 mile of at least one major industrial facility? (check one) VesNo	Was there any oil? gas activity of facility nearby? (check one) YesNoUnknown	Was this home within 1 mile of a farmingricultural facility? (check con; Yes
Street Address and		Date (Month &	out Date (Month &	Was home within 1 mile of at least one major industrial facility? (check one) YesNo_ Urknown	Was there any oil? gas activity or facility nearby? (check one) YesNoUnknown	Was this home within 1 mile of a farmingricultural facility? (check con; Yes

If yes: please describe type

Yes_____No____ Unknown_____ If yes: please describe type

Yes___No__ Unknown____ If yes, describe:

Appendix D. Medium-Length Qualtrics Survey (20-25 min)

SWPA Child Cancer - Shortened

Thank you, for participating in our study.

Childhood Cancer is the third leading cause of death among children in the US and yet there are very few known risk factors. This study will examine some risks that may play a role. These include environmental exposures, residential history, and lifestyle behaviors during childhood and early life. You will receive \$25 for your time completing the survey. If there are any questions that you are uncomfortable about, you may decline to answer at any time.

Please do not hesitate to contact our project office at 412-648-5185 or email paenv@pitt.edu, if you have any questions.

1. What is your full name?

First Name _______

2. What is your child's name? This is your child that was diagnosed with cancer between the ages of 0-29, in the years of 2010-2019.

First Name ______ Last Name ______

- 3. If you remember your four digit study ID number included in our enrollment materials please enter it here.
- 4. What is your relationship to the child?
- a) Biological Mother
- b) Biological Father
- c) Step Mother
- d) Step Father
- e) Other _____

5. What is the child's date of birth?

- 6. Confirm your child's gender.
- a) Male
- b) Female
- c) Child is Non-binary/third gender
- d) Prefer not to say
- 7. Would you describe the child as being of Hispanic origin?
- a) Yes

- b) No
- c) Unknown
- **8.** Which of the following terms best describes the child's racial background? Check all that apply.
- a) White
- b) Black or African American
- c) Native American/American Indian or Alaska Native
- d) Asian or Pacific Islander
- e) Other _____
- f) Unknown
- **9.** Now we would like to ask what daycares and schools the child has attended, beginning with their first daycare or school and continuing in order:

Please include ANY address outside the home where the child spent long periods of time during the day.

	Name of School or Daycate	Year Atlanded - From YEAR to YEAR		Schoel or Daycare Address				
	Name of Daycare or School	Year Start	Vear End	Street	CRy	State	2ip	
eycete / School L								
ayoare / School 2								
aycare / School 3						Ĩ.		
aycare / School 4						11		
eycare / School S			T I	1	1	11		
leycare / School ö				1				
aycare / School 7						Ìľ		
aycare / School B		ī — — — — — — — — — — — — — — — — — — —				11		

MOTHER'S BACKGROUND

- **10.** What was the highest grade or year of school you / the mother had completed at the time that the child was born?
- a) No formal schooling
- b) Less than high school
- c) 12 years, completed high school or equivalent
- d) 1-3 years of college
- e) Completed technical college
- f) Associates degree
- g) 4 years of college or Bachelors degree
- h) Advanced degree
- i) Don't know

11. What was your / the mother's marital status at the time the child was born?

- a) Married or living with partner
- b) Separated
- c) Divorced
- d) Widowed
- e) Never married and not living with partner
- f) Other _____

FATHER'S BACKGROUND

- **12.** What was the highest grade or year of school you / the father had completed at the time that the child was born?
- a) No formal schooling
- b) Less than high school
- c) 12 years, completed high school or equivalent
- d) 1-3 years of college
- e) Completed technical college
- f) Associates degree
- g) 4 years of college or Bachelors degree
- h) Advanced degree
- i) Don't know

13. What was your / the father's marital status at the time the child was born?

- a) Married or living with partner
- b) Separated
- c) Divorced
- d) Widowed
- e) Never married and not living with partner
- f) Other _____

RESIDENTIAL HISTORY

How many residences did you live in starting from one year before the conception of the child and ending with the date of the child's first cancer diagnosis?

14. How many residences did the biological mother live in starting from one year before the conception of the child and ending with the date of the child's first cancer diagnosis?

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15. How many residences did you live in starting from one year before the conception of the child and ending with the date of the child's first cancer diagnosis?

			Residences			Approximates	dave-Bii Date	Approximite Move-DUT Date	
	Etreet Address	City/Town	Torte	ZIF	County	Move-Ni Month	MOOD-IN VEAR	Nove-DUT More	Move-OUT YEAR
1. Address 1 Intacting 1 Year EEFORE CONCEPTION)	[][][11			[
L_ Andress 3							· · · · · ·		
mooress 2		ľ							
Address 4		i i						1	
Address 9		1							
Address 6		- I			i i i		i de la companya de		
Address 7		1	11			Ī			
. Address #		1]		i i i i i i i i i i i i i i i i i i i		
. Address 9									
"Addross. U		- î	11	1		1			

Now we are going to ask question about your house at Address 1.

- 16. What year was this residence built?
- **17. Which PRIMARY FORM of heating fuel do/did you use at this residence**? (choose all that apply)
 - a) Natural Gas
 - b) Electricity
 - c) Propane
 - d) Kerosene
 - e) Wood
 - f) Coal
 - g) Solar
 - h) Don't know

18. What type of air conditioning did you use at this residence?

- a) Central air conditioning
- b) Window/wall air conditioning units
- c) No air conditioning
- d) Other Please describe _____
- e) Don't know
- **19.** Did you or a family member/other resident operate a business out of this home, such as an auto mechanic shop or hair salon?
- a) Yes (Please describe business)
- b) No

c) Don't know

I am now going to ask you some questions about pesticide, herbicide, and insecticide use for your residence at Address 1.

- **20.** Was this residence ever exterminated for insects and pests so that you had to leave the house for a few hours?
- a) Yes
- b) No
- c) Don't know

Display This Question:

If: Was this residence ever exterminated for insects and pests so that you had to leave the house for... = Yes

21. How often was this residence treated for pests?

- a) Once a week
- b) Once a month
- c) Once every 2-3 months
- d) Once a year
- e) Don't know
- f) Other, please specify _____

- **22.** Was the yard or garden around this residence ever treated with insecticides or herbicides to control insects or weeds?
- a) Yes
- b) No
- c) Don't know

Display This Question:

If: Was the yard or garden around this residence ever treated with insecticides or herbicides to cont... = Yes

- 23. How often was this yard or garden treated for pests?
- a) Once a week
- b) Once a month
- c) Once every 2-3 months
- d) Once a year
- e) Don't know
- f) Other, please specify _____

24. What was the primary source of water for drinking and cooking at this residence? Please check all that apply:

- a) City or township water supply
- b) Well
- c) Bottled water (for cooking and drinking only, not for showering)
- d) Don't know

25. Did you ever have your water tested at this residence?

- a) Yes
- b) No
- c) Don't know

26. Did you ever have this residence tested for radon?

- a) Yes
- b) No
- c) Don't know

27. Did this residence ever require radon remediation?

- a) Yes
- b) No
- c) Don't know

Display This Question:

If: Did you ever have this residence tested for radon? = Yes

28. If you can recall, what were the approximate levels of radon detected?

29. Did this residence have an attached garage?

- a) Yes
- b) No
- c) Don't know

I am now going to ask you some questions about the proximity of Address 1 to some facility types.

30. Was this residence located within 1 mile of a MAJOR INDUSTRIAL FACILITY? Examples of these are: a factory, agricultural site or farm, power plant, steel mill, cement factory, chemical plant, etc.

- a) Yes
- b) No
- c) Don't know

Display This Question:

If was this residence located within 1 mile of a MAJOR INDUSTRIAL FACILITY? = Yes

31. Were there more than one MAJOR INDUSTRIAL facility within 1 mile of this residence?

- a) Yes. If yes, how many? _____
- b) No
- c) Don't know

Display This Question:

If was this residence located within 1 mile of a MAJOR INDUSTRIAL FACILITY? = Yes

32. If YES, can you describe all of these facilities?

33. Was this residence located within 1 mile of any OIL & GAS ACTIVITY or FACILITY

- a) Yes
- b) No
- c) Don't know

Display This Question:

If Loop current: Was this residence located within 1 mile of any OIL & GAS ACTIVITY or FACILITY... = Yes

34. Was there considerable noise at this residence due to OIL & GAS ACTIVITIES?

- a) Yes
- b) No
- c) Don't know

Display This Question:

If Loop current: Was this residence located within 1 mile of any OIL & GAS ACTIVITY or FACILITY... = Yes

- **35.** Did you or any of your household members notice excessive dust generated from the OIL & GAS ACTIVITIES?
- a) Yes
- b) No
- c) Don't know
- 36. Was this residence located within 1 mile of a FARM or AGRICULTURAL facility?
- a) Yes
- b) No
- c) Don't know

Display This Question:

If Loop current: Was this residence located within 1 mile of a FARM or AGRICULTURAL facility? = Yes

37. Did you or any of your household members notice excessive dust, noise, odors, or other irritants generated from the agricultural activities that impacted your daily quality of life?

MOTHER'S OCCUPATIONAL HISTORY

How many jobs did you/the mother have in the period starting one year before the conception of the child and ending 2 years after the child's birth.

- **38.** During the year before you were/the mother was pregnant with the child, did you work outside of the home?
- a) Yes
- b) No
- c) Other _____

39. How many jobs did you / the Mother have in the period starting one year before the conception of the child and ending 2 years after the child's birth.

Please tell me all of the different jobs you/the mother had outside of the home during this period - from 1 year before conception to 2 years post the birth of the child.

Please give the job title and month and year when you started and stopped working at that job.

40. How many jobs did you/the mother have in the period starting one year before the conception of the child and ending 2 years after the child's birth.

	Job Title	Date S	tarted	Date Stopped		
	Job Title	Month	Year	Month	Year	
L, Job 1						
🦕 Job 2					47. 1	
L, Job 3						
La Job 4		1				
🦕 Job 5						
🐫 Job 6						
La Job 7						
😋 Job 8						
e dol 😜						
dol ڬ 10						

- **41.** For the first job you listed as first job title, which of these categories are most similar to your occupational category?
- 11 = Agriculture, Forestry, Fishing and Hunting ... Refused
 - **42.** For the first job you listed as first job title, which of these occupations are most similar to your occupation?
- 1 = Accountant, auditor, or bookkeeper... Refused

Display This Question:

If For the first job you listed -- as first job title, which of these occupations a... = 27 = Other (specify):

43. You	said	"Other"	for	job	title.	Please	specify:

For the first job you listed - - as first job title, - please answer the questions below.

44. Did/do you/the mother work at this job part time or full time?

- a) Part time
- b) Full Time
- c) Don't Know

45. Did you/the mother continue to work at this job while pregnant?

- a) Yes
- b) No
- c) Don't Know
- **46.** If you were / the mother was at this job at the time you gave birth, did you / the mother take maternity leave?
- d) Yes
- e) No
- f) Don't Know

Now I would like to ask you more about the chemicals or substances that you/the mother may have used at work. Some of the names may not sound familiar to you, but please answer as best you can.

47. Did you/the mother work with any of the following materials?

	Did you work with these?		(IF VES) Were you them during prec pregner	onception or	
	Ves	No	Don't Knew	Pre-conception	Pregnancy
1. Adhesives or glues, like rubber cement	0	0	0		
Z. Alcohols, such as methanol or ethanol, formaldehyde	0	0	0		
3. Anesthetic gases	0	0	0		
 Automotive fluids, such as antifreeze, brake fluid, degreasers, freon, gasoline 	0	C	0		
5: Benzene	0	0	0	0	
 Voletile organics, such as: carbon disutfide, carbon tetrachloride, diesel tumes, ethylene oxide, glycol ethers, styrene, toluene, trichlorbethylene (TCE) or trichlorethane (TCA), xylene 	0	0	0		
7. Metals, such as: chromium, lead, manganese, nickel, metal dust or fules	0	0	0	D	
 Paint products, such as: oil-based paints, paint strippers, paint thinners, acquers 	0	0	0		
9. Pesticides, herbicides, fungicides, or insecticides	0	Ő	0		
LD. Pharmaceuticals or drugs	0	0	O		
11. Phihalates	0	0	0		
12. Vinyl chloride	0	0	0		
13. X-ray or radioactive materials	0	0	0	Ο	
14. Hair dyes	0	0	0		
15. Any other?	0	Q	o	D	

FATHER'S OCCUPATIONAL HISTORY

How many jobs did you / the father have in the period starting one year before the conception of the child and ending 2 years after the child's birth.

Please tell me all of the different jobs you/the father had outside of the home during this period - from 1 year before conception with the child to 2 years after the birth of the child.

48. Please give the job title and month and year when you/ the father started and stopped working at that job.

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	Job Title	Date S	tarted	Date Stopped		
	Job Title	Month	Year	Month	Year	
L. Job 1						
🦕 Job 2						
L, Job 3						
La Job 4						
L, Job 5						
L. Job 6						
La Job 7						
L. Job 8						
G dot 9						
dot 斗						

49. For the first job you listed – as first job title, which of these categories are most similar to your occupational category?

11 = Agriculture, Forestry, Fishing and Hunting ... Refused

50. For the first job you listed - as first job title, which of these occupations are most similar to your occupation?

1 = Accountant, auditor, or bookkeeper... Refused

Display This Question:

If For the first job you listed -- as first job title, which of these occupations a... = 27 = Other (specify):

51. You	said	"Other"	for	job	title.	Please	specify:

For the first job you listed - - as first job title, - please answer the questions below.

52. Did/do you/the father work at this job part time or full time?

- a) Part time
- b) Full Time
- c) Don't Know

Now I would like to ask you more about the chemicals or substances that you/the father may have used at work. Some of the names may not sound familiar to you, but please answer as best you can.

53. Did you/the father work with any of the following materials?

	Did you work with these?		(IF VES) Were you them during prec pregnan	onception or	
	Ves	No	Don't Knew	Pre-conception	Pregnancy
1. Adhesives or glues, like rubber sement	0	0	0		
Z. Alcohols, such as methanol or ethanol, formaldehyde	0	0	0		
3. Anesthetic gases	0	0	0		
 Automotive fluids, such as antifreeze, brake fluid, degreasers, freon, gasoline 	0	C	0		
5. Benzene	0	0	0	D	
 Volatile organics, such as: carbon disutfide, carbon tetrachloride, diesel tumes, ethylene oxide, glycol ethers, styrene, toluene, trichloroethylene (TCE) or trichlorethane (TCA), xylene 	0	0	0	D	
7. Metals, such as: chromium, lead, manganese, nickel, metal dust or fules	0	0	0	٥	
 Paint products, such as: oil-based paints, paint strippers, paint thinners, lacquers 	0	0	o	0	
9, Pesticides, herbicides, fungicides, or insecticides	0	O	0		
10. Pharmaceuticals or drugs	0	0	0		
11. Phihalates	0	0	0		
12. Vinyl chloride	0	0	0		
13. X-ray or radioactive materials	0	0	0	0	
14: Hair dyes	0	0	0		
15. Any other?	0	O	ō		

MOTHER'S SMOKING HISTORY

54. Have you/ has the mother smoked more than 100 cigarettes in your lifetime?

- a) Yes
- b) No
- c) Don't know

Display this Question:

If Have you/ has the mother smoked more than 100 cigarettes in your lifetime? = Yes

55. How many cigarettes a day did you / the mother usually smoke during the following time periods?

One pack is usually 20 cigarettes.

56. What about e-cigarettes (like vaping) or other tobacco products like a cigar or hookah?

57. During what time periods did you / the mother smoke, vape or use other tobacco products?

	How many cigarettes did you smoke in the [read time period]?	How many of times a day did you vape/use e-Cigs or other types of Tobacco?
	Number of Cigarettes/Day	Number of E-Cigs or Vape or Tobacco/Day
12 months prior to pregnancy		
1st trimester of pregnancy		
2nd trimester of pregnancy		
3rd trimester of pregnancy		
0-24 months after \${q://QID987/ChoiceTextEntryValue/1}'s birth		
After 24 months of \${q://QID987/ChoiceTextEntryValue/1}'s birth until the reference date		

Family Cancer History

Now I would like to ask you some questions about your family's medical history. Please take your time and focus on the blood relatives of the child. Please try to recall whether any of the relatives were ever diagnosed with cancer. Leukemia, brain tumors, lymphomas, and Hodgkin's disease are all types of cancer and should be included.

58. Please record any relatives that have had cancer, and what kinds of cancer they had?

	*Any information about the cancer type, site, etc. should be entered here			If answer yes to cancer
	Yes	No	Don't know	Cancer Type
Mother	0	0	0	
Father	0	0	0	
Maternal Grandmother	0	0	0	
Maternal Grandfather	0	0	0	
Paternal Grandmother	0	0	0	
Paternal Grandfather	0	0	0	
Siblings of CHILD (1)	0	0	0	
Siblings of CHILD (2)	0	0	0	
Siblings of CHILD (3)	0	0	0	

59. During pregnancy, did you/ the mother ever have any of the following medical procedures?

During pregnancy, did you/ the mother ever have any of the following medical procedures?

	C	olum	n 🐨		Colu	nn Options 🚽	e		Column Options +
	Options Receive this procedure?				During v	Frequency			
	Yes	No	Don't know	1 yr prior to conception	Pregnancy 1st Trimestor	Pregnancy Znd Trimester	Pregnancy 3rd Trimestor	Don't know	How many times did this happen?
Diagnostic X-rays	0	0	0		Ω				
Radiation therapy	0	0	0						
Dental X-rays - Traditional	O	O	O						
Dental X-rays - Panoramic	0	Ō	0		D				

60. Did the child ever have any of the following procedures, prior to their first cancer diagnosis?

	Did your child ever receive this procedure?			If yes, what was the reason?	Frequency of Procedure	Age
	Y	N	Don't know	Age	Frequency of Procedure	Age
Diagnostic X-rays	0	0	0			
Radiation therapy	0	0	0			
Dental X-rays - Traditional	0	0	0			
Dentol X-rays - Panovamic	0	0	0	1		

The following questions focus on your child's medical history before their first cancer diagnosis.

61. Did the child ever have any of the following infections?

	\${q://QID987/ChoiceTextEntryValue/1}'s Infections			Age at diagnosis
	Y	Ν	Don't know	Age at diagnosis
Measles	0	0	0	
Chickenpox	0	0	0	
Shingles	0	0	0	
Cytomegalovirus	0	0	0	
Hepatitis	0	0	0	
Monocleosis	0	0	0	
Herpes virus	0	0	0	[

62. At the time the child was born, what was your estimated total household income before taxes?

Please include income such as Medicaid, Social Security, and Unemployment payments.

- a) Less than 10 Thousand Dollars per year
- b) 10 to 30 Thousand Dollars
- c) 30 to 50 Thousand Dollars
- d) 50 to 70 Thousand Dollars
- e) 70 to 90 Thousand Dollars
- f) 90 to 110 Thousand Dollars
- g) More than 110 Thousand Dollars
- h) Don't know

63. Is there anything else you would like to share with the research team regarding your residence, occupation, exposures, or anything else addressed in this questionnaire that you feel is relevant to this study?

Please describe here:

Thank you for completing this questionnaire. Now that you have completed the survey, the research team will be mailing your \$25 payment card to the address you provided on your postcard.

We send out the payment cards every Thursday, so you can likely expect to receive it within two weeks of this date. If you don't receive it within 2 weeks, please call the project office at 412-648-5185, and we can investigate.

Upon receipt, you will need to call a project staff member to activate your card. These instructions will be included with the card mailing.

Thank you again for your participation in this research study. Your information could be used to further other studies in this area.

- 1. Would you be willing to participate in follow-up studies or to give us additional information after the survey has concluded? (not including studies with specimen collections like blood, saliva, etc.)
- a) Yes
- b) No
- c) Don't know
- 2. Would you be willing to participate in follow-up studies to give us biosamples after the survey has concluded? Some examples of these may include blood sample, buccal swabs, other specimens.
- a) Yes
- b) No
- c) Don't know

Supplementary Tables

Supplementary Table S1. Distribution of Cases by Fine Categories of Childhood Malignancies in Southwestern PA 2010-2019)

Class (most detailed)	Frequency	Percent
(a.1) Precursor cell leukemias	112	22.1
(a.2) Mature B-cell leukemias	2	.4
(b) Acute myeloid leukemias	30	5.9
(c) Chronic myeloproliferative diseases	14	2.8
(d) Myelodysplastic syndrome and other myeloproliferative diseases	5	1.0
(e) Unspecified and other specified leukemias	2	.4
(a) Hodgkin lymphomas	52	10.3
(b.1) Precursor cell lymphomas	5	1.0
(b.2) Mature B-cell lymphomas (except Burkitt lymphoma)	12	2.4
(b.3) Mature T-cell and NK-cell lymphomas	5	1.0
(c) Burkitt lymphoma	5	1.0
(d) Miscellaneous lymphoreticular neoplasms	25	4.9
(e) Unspecified lymphomas	1	.2
(a.1) Ependymomas	9	1.8
(a.2) Choroid plexus tumor	5	1.0
(b) Astrocytomas	87	17.2
(c.1) Medulloblastomas	13	2.6
(c.2) PNET	1	.2
(d.1) Oligodendrogliomas	3	.6
(d.2) Mixed and unspecified gliomas	31	6.1
(e.1) Pituitary adenomas and carcinomas	12	2.4
(e.2) Tumors of the sellar region (craniopharyngiomas)	7	1.4
(e.3) Pineal parenchymal tumors	1	.2
(e.4) Neuronal and mixed neuronal-glial tumors	20	3.9
(e.5) Meningiomas	3	.6
(f) Unspecified intracranial and intraspinal neoplasms	2	.4
(a) Osteosarcomas	18	3.6
(b) Chondrosarcomas	2	.4
(c.1) Ewing tumor and Askin tumor of bone	20	3.9
(d.2) Malignant chordomas	2	.4
(d.4) Miscellaneous malignant bone tumors	1	.2

Supplementary Table S2. Distributions of UNGD Activities Metric Within 5 Miles of Buffer Zone among Children with Any of the Four Malignancies and their County-Matched Controls by Different Time Periods of Exposure in the Birth Record-Based Analysis (n=498)

Exposure Metrics within 5 miles*	Group	Time period†	Exposed N‡	Mean	Std Dev	Minimum	Maximum	10th Pctl	25th Pctl	Median	75th Pctl	90th Pctl
	Cases		94	3.50E-5	5.8E-5	6.06E-7	4.22E-4	4.71E-6	6.31E-6	12.0E-6	3.30E-5	10.9E-5
Overall		Postnatal (T2)	311	30.2E-5	74.3E-5	7.21E-7		8.91E-6	24.0E-6	82.0E-6	21.7E-5	65.0E-5
UNGD	County-	Pregnancy (T1)	99	3.70E-5	8.40E-5	1.43E-7	7.60E-4	2.73E-6	5.42E-6	10.0E-6	4.5E-5	7.80E-5
activities	Matched Controls	Postnatal (T2)	297	24.3E-5	67.1E-5	8.99E-7	71.6E-4	10.0E-6	28.0E-6	61.0E-6	20.2E-5	54.5E-5
Well pad	Cases	Pregnancy (T1)	48	4.54E-6	5.90E-6	4.32E-7	2.40E-5	6.04E-7	7.91E-7	2.03E-6	5.74E-6	1.60E-5
constructio		Postnatal (T2)	287	39.0E-6	105.0E-6	4.70E-7	125.0E-5	7.71E-7	23.1E-7	7.54E-6	28.0E-6	9.30E-5
n	County-	Pregnancy (T1)	50	9.06E-6	22.0E-6	1.28E-7	12.8E-5	5.59E-7	7.50E-7	1.87E-6	6.57E-6	1.8E-5
(counts/m²)	Matched Controls	Postnatal (T2)	272	26.0E-6	55.0E-6	0.61E-7	43.6E-5	6.41E-7	16.4E-7	6.18E-6	22.0E-6	6.2E-5
	Cases	Pregnancy (T1)	60	3.20E-5	5.00E-5	3.36E-8	2.88E-4	8.96E-7	2.81E-6	8.86E-6	4.50E-5	10.0E-5
Drilling		Postnatal (T2)	295	22.7E-5	64.1E-5	10.21E-8	74.8E-4	23.3E-7	9.49E-6	49.0E-6	16.2E-5	47.6E-5
(counts/m ²)	County-	Pregnancy (T1)	62	3.40E-5	7.00E-5	7.69E-8	5.02E-4	3.61E-7	1.58E-6	13.0E-6	3.90E-5	7.00E-5
	Matched Controls	Postnatal (T2)	280	18.1E-5	58.7E-5	12.98E-8	65.0E-4	18.5E-7	9.37E-6	37.0E-6	12.5E-5	43.3E-5
L harden and he	Cases	Pregnancy (T1)	60	0.019	0.060	3.60E-5	0.445	1.83E-4	7.59E-4	3.82E-3	0.012	0.031
Hydraulic fracturing		Postnatal (T2)	283	0.084	0.202	4.90E-5	1.331	9.51E-4	30.9E-4	16.1E-3	0.059	0.197
(depth in	County-	Pregnancy (T1)	60	0.016	0.042	6.40E-5	0.309	1.31E-4	9.28E-4	3.57E-3	0.018	0.033
(depth in m/m ²)	Matched Controls	Postnatal (T2)	268	0.077	0.249	7.00E-5	3.150	9.46E-4	42.2E-4	15.3E-3	0.052	0.201
	Cases	Pregnancy (T1)	88	0.787	4.64	20.0E-5	43.12	2.35E-3	0.013	0.075	0.316	0.813
Production		Postnatal (T2)	279	2.741	14.85	6.70E-5	190.9	6.93E-3	0.048	0.348	1.347	3.540
(volume in	County-	Pregnancy (T1)	88	0.302	0.857	5.58E-6	7.40	1.46E-3	0.011	0.046	0.321	0.725
m³/m²)	Matched Controls	Postnatal (T2)	269	2.145	12.30	1.43E-6	154.8	9.59E-3	0.072	0.445	1.225	2.621
	Cases	Pregnancy (T1)	94	2.251	4.518	-0.476	33.49	-0.075	0.082	0.681	2.249	6.944
C		Postnatal (T2)	311	0.817	3.806	-1.001	25.90	-0.942	-0.819	-0.481	0.656	3.091
Summed Z score§	County-	Pregnancy (T1)	99	2.569	7.219	-0.565	64.86	-0.270	0.004	0.366	2.920	5.274
scoreg	Matched Controls	Postnatal (T2)	297	0.463	3.368	-0.999	29.02	-0.923	-0.807	-0.560	0.238	2.178
	Cases	Pregnancy (T1)	97	27.48	35.82	1.00	154.00	1.00	4.00	9.00	34.00	85.00
Well		Postnatal (T2)	306	39.26	46.82	1.00	296.00	2.00	7.00	21.50	59.00	103.00
counts	County-	Pregnancy (T1)	99	22.31	29.05	1.00	117.00	1.00	2.00	10.00	28.00	67.00
counts	Matched Controls	Postnatal (T2)	293	37.97	47.26	1.00	333.00	2.00	6.00	18.00	58.00	101.00
	Cases	Pregnancy (T1)	97	1.44E-6	2.44E-6	1.68E-8	1.40E-5	4.49E-8	1.08E-7	3.26E-7	1.86E-6	3.98E-6
IDW well		Postnatal (T2)	306	3.09E-6	5.74E-6	1.56E-8	4.30E-5	6.40E-8	2.02E-7	8.94E-7	3.38E-6	7.84E-6
counts (counts/m²)	County-	Pregnancy (T1)	99	1.31E-6	2.37E-6	1.56E-8	1.40E-5	2.44E-8	6.76E-8	3.55E-7	1.23E-6	4.29E-6
(counts/m²)	Matched Controls	Postnatal (T2)	293	2.47E-6	4.70E-6	1.65E-8	4.40E-5	5.04E-8	18.45E-8	6.48E-7	2.81E-6	6.68E-6

* See the formulas for calculation of all metrics in Table 14a.

⁺ The pregnancy period was defined from the conception to birth using the gestation age on the birth records whereas the postnatal period from birth to the index date, which was the date of cancer diagnosis for cases and the corresponding date for the matched controls.
[‡] The difference between total N and Exposed N was the number of subjects with non-exposure (not shown).

§ calculated as
$$\sum_{ij}^{k} \frac{x_{ij} - \mu_{.j}}{\sigma_{.j}}$$
; where *i* is for subject; *j*, specific phases of UNGD activities (=k); *x*, individual measurement of UNGD activity; μ ,

mean; and σ , standard deviation.

Sociodemographic	Cases (N=2	13)	County-Matched C	ontrols (N=213)
Characteristic	Frequency	Percent	Frequency	Percent
Sex at Birth				
Female	99	46.5	99	46.5
Male	114	53.5	114	53.5
Maternal Age (years)				
<20	7	3.3	7	3.3
20-24	25	11.7	24	11.3
25-29	54	25.4	60	28.2
30-34	74	34.7	81	38.0
≥35	53	24.9	41	19.2
Maternal Race				
White	209	98.1	209	98.1
Black	2	0.9	2	0.9
Other	2	0.9	2	0.9
Maternal Education				
≤ 8 th Grade	0	0.0	1	0.5
Some High School	10	4.7	10	4.7
High School Diploma	50	23.5	30	14.1
Some College	43	20.2	45	21.1
College Degree or Higher	108	50.7	127	59.6
Unknown	2	0.9	0	0.0
Number of Prenatal Visits				
0-7	13	6.1	16	7.5
8-12	106	49.8	111	52.1
13-16	77	36.1	77	36.1
≥17	10	4.7	5	2.4
Unknown	7	3.3	4	1.9
Birth weight				
≤2500 g	12	5.6	10	4.7
2501- 4000 g	173	81.2	180	84.5
>4000 g	28	13.2	22	10.3
Unknown	0	0.0	1	0.5
Smoking during pregnancy				
Never	184	86.4	192	90.1
Ever	25	11.7	20	9.4
Unknown	4	1.9	1	0.5
Gestation in weeks				
Mean (S.D.)	38.9(1.66)		38.7(2.02)	

Supplementary Table S3. Distributions of Sociodemographic Characteristics of Childhood Cancer Cases Using Birth Record Information: 213 County-Matched Case-Control pairs Supplementary Table S4. Descriptives of Residential History Characteristics for Cases and County-Matched Controls

Variable	Cases (N=	213) *	County Matched Control	s (N=213) **
	Frequency	Percent	Frequency	Percent
Pre-1970s Housing				
Ever	71	58.2	102	62.6
Never	51	41.8	61	37.4
Missing/dk	27		8	
Item not presented	64		42	
Residence Exterminated				
Ever	19	15.2	26	17.8
Never	106	84.8	120	82.2
Missing/dk	24		25	
Item not presented	64		42	
Pesticide/Herbicide Used in	Yard			
Ever	54	45.0	82	55.4
Never	66	55.0	66	44.6
Missing/dk	29		23	
Item not presented	64		42	
Water Tested				
Ever	26	23.4	29	27.6
Never	85	76.6	76	72.4
Missing/dk	38		46	
Item not presented	64		42	
Radon Tested				
Ever	66	58.4	75	63.0
Never	47	41.6	44	37.0
Missing/dk	36		52	
Item not presented	64		42	
Radon Remediation				
Ever	26	22.2	25	19.5
Never	91	77.8	103	80.5
Missing/dk	32		43	
Item not presented	64		42	

*Out of 213 cases, a total of 149 cases had the opportunity to respond to surveys with a complete survey/residential history, 64 additional participants answered the short residential questionnaire without these items

**Out of 213 county-matched controls, a total of 171 county-matched controls had the opportunity to respond to surveys with a complete residential history, 42 filled out the short residential questionnaire without these items

Supplementary Table S4 Continued. Residential History Characteristics for Cases and County-Matched Controls

Variable	Cases (N=	213) *	County-matched ((N=213) *	
'	Frequency	Percent	Frequency	Percent
Attached Garage				
Ever	80	62.5	85	49.7
Never	48	37.5	86	50.3
Missing/dk	21		0	
Item not presented	64		42	
Well Water at Home				
Ever	20	14.8	18	10.4
Never	109	85.2	155	89.6
Missing/dk	20			
Item not presented	64		42	
¹ Perception – Residence within	1 mile of Industria	l Facility		
Ever	36	25.0	46	30.1
Never	108	75.0	107	69.9
Missing/dk	5		18	
¹ Perception – Residence within	1 mile of Farm			
Ever	40	27.6	37	25.9
Never	105	72.4	106	74.1
Missing/dk	4		28	
¹ Perception – Residence within	1 mile of Oil and G	as Industry		
Ever	23	17.4	23	18.1
Never	109	82.6	104	81.9
Missing/dk	15		44	

*Out of 213 cases, a total of 149 cases had the opportunity to respond to surveys with a complete survey/residential history, 64 additional participants answered the short residential questionnaire only

**Out of 213 county-matched controls, a total of 171 county-matched controls had the opportunity to respond to surveys with a complete residential history, 42 filled out the short residential questionnaire only

1 item presented to all 213 cases and control survey respondents

Supplementary Table S5. Total overall unconventional natural gas drilling (UNGD) activities and risk of four childhood/adolescent 4 malignances combined during two exposure periods in Southwestern Pennsylvania 2010-2019

Overall UNGD activities by exposure period	Count	y-match	l Study with ned Controls ntrol pairs)	Birth Record-based Study with County-matched Controls (498 case-control pairs)			
.,	Controls	Cases	OR (95% CI)†	Controls	Cases	OR (95% CI)†	
T1: During Mother's Pregn	ancy						
Non-exposed	172	174	1.00	399	404	1.00	
Exposed*	41	39	0.76 (0.30-1.89)	99	94	0.82 (0.47-1.41)	
By buffer zone							
Non-exposed	172	174	1.00	399	404	1.00	
(2-5] miles	26	30	0.80 (0.32-2.03)	64	63	0.84 (0.48-1.46)	
(1-2] miles	6	6	0.46 (0.08-2.47)	24	22	0.72 (0.31-1.67)	
(0.5-1] miles	- 9	2	0.10 (0.02.1.08)	9	7	0.65 (0.19-2.26)	
[0-0.5] miles	9	3	0.16 (0.02-1.08)	2	2	0.81 (0.05-14.62)	
P trend‡			0.0643			0.3817	
By overall UNGD activities	within 5 miles	5					
Non-exposed	172	174	1.00	399	404	1.00	
Lowest (1 st) quartile	10	14	1.17 (0.37-3.68)	24	17	0.63 (0.29-1.34)	
Low-middle (2 nd) quartile	10	8	0.51 (0.11-2.36)	25	22	0.77 (0.37-1.64)	
High-middle (3 rd) quartile	10	12	0.72 (0.20-2.58)	25	36	1.40 (0.63-3.14)	
Highest (4 th) quartile	11	5	0.26 (0.05-1.29)	25	19	0.75 (0.31-1.83)	
P trend‡			0.1443			0.7587	

* Exposed were individuals who lived within 5 miles of any UNGD activity during mother's pregnancy (T1) or from birth to the index date (i.e., date of cancer diagnosis for cases or the same date for matched controls); non-exposed otherwise.

⁺ All odds ratios (ORs) and their 95% confidence intervals (CIs) for different buffer zones or levels of exposures against non-exposed group were derived from unconditional logistic regression models with adjustment for matching factors (age, sex, race, and county of residence) and following variables including maternal age at childbirth (years), maternal education level, maternal smoking status at childbirth (no, yes), gestation age (weeks), birthweight (g), toxics release inventory (TRI) (no, yes), uranium mill tailings remedial action sites {UMTRA} (no, yes), and superfund site (no, yes).

[‡] The same unconditional logistic models were used for linear trend test for the exposure variable in ordinal values (1, 2 for high or low) that also included non-exposed individuals (coded as 0) to maintain the case-control matched pairs.

§ The index date was the date of malignancy diagnosis for cases and the same corresponding date for matched controls.

Supplementary Table S5 Continued. Total overall unconventional natural gas drilling (UNGD) activities and risk of four childhood/adolescent 4 malignances combined during two exposure periods in Southwestern Pennsylvania 2010-2019

Overall UNGD activities by exposure period	Count	y-match	Study with ed Controls ntrol pairs)	Cou	nty-mat	ased Study with ched Controls control pairs)
a) expected period	Controls	Cases	OR (95% CI)†	Controls	Cases	OR (95% CI)†
T2: From Birth to Index Date §						
Non-exposed	84	74	1.00	201	187	1.00
Exposed*	129	139	1.48 (0.88-2.5)	297	311	1.24 (0.87-1.78)
By buffer zone						
Non-exposed	84	74	1.00	201	187	1.00
(2-5] miles	72	75	1.43 (0.83-2.46)	178	170	1.18 (0.82-1.71)
(1-2] miles	24	38	2.09 (0.97-4.49)	72	77	1.49 (0.89-2.51)
(0.5-1] miles	21	14	0.82 (0.32-2.11)	37	38	1.61 (0.85-3.03)
[0-0.5] miles	12	12	1.47 (0.56-3.86)	10	26	3.94 (1.66-9.39)
P trend‡			0.6289			0.0041
By overall UNGD activities with	nin 5 miles					
Non-exposed	84	74	1.00	201	187	1.00
Lowest (1 st) quartile	32	48	2.24 (1.14-4.41)	74	86	1.40 (0.91-2.14)
Low-middle (2 nd) quartile	32	16	0.70 (0.33-1.49)	74	50	0.76 (0.46-1.25)
High-middle (3 rd) quartile	32	39	1.55 (0.79-3.04)	74	88	1.69 (1.01-2.82)
Highest (4 th) quartile	33	36	1.40 (0.61-3.21)	75	87	1.79 (1.00-3.19)
P trend‡			0.4496			0.0975
By overall UNGD activities with	By overall UNGD activities within 2 miles**					
Non-exposed	84	74	1.00	201	187	1.00
Lowest (1 st) quartile	14	17	1.84 (0.74-4.61)	29	37	1.74 (0.93-3.27)
Low-middle (2 nd) quartile	14	23	2.07 (0.84-5.08)	30	32	1.48 (0.77-2.84)
High-middle (3 rd) quartile	14	9	0.72 (0.25-2.11)	30	30	1.41 (0.72-2.77)
Highest (4 th) quartile	15	15	1.87 (0.66-5.3)	30	42	2.16 (1.10-4.25)
P trend‡			0.4837			0.0321

* Exposed were individuals who lived within 5 miles of any UNGD activity during mother's pregnancy (T1) or from birth to the index date (i.e., date of cancer diagnosis for cases or the same date for matched controls); non-exposed otherwise.

⁺ All odds ratios (ORs) and their 95% confidence intervals (CIs) for different buffer zones or levels of exposures against non-exposed group were derived from unconditional logistic regression models with adjustment for matching factors (age, sex, race, and county of residence) and following variables including maternal age at childbirth (years), maternal education level, maternal smoking status at childbirth (no, yes), gestation age (weeks), birthweight (g), toxics release inventory (TRI) (no, yes), uranium mill tailings remedial action sites {UMTRA} (no, yes), and superfund site (no, yes).

[‡] The same unconditional logistic models were used for linear trend test for the exposure variable in ordinal values (1, 2 for high or low) that also included non-exposed individuals (coded as 0) to maintain the case-control matched pairs.

§ The index date was the date of malignancy diagnosis for cases and the same corresponding date for matched controls.

** The same data for those with UNGD exposure within 2-5 mile of buffer zone were included in this modelling but not presented repeatedly.

WG Ex. 73-A

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Critical Review

Per- and Polyfluoroalkyl Substance Toxicity and Human Health Review: Current State of Knowledge and Strategies for Informing Future Research

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Abstract: Reports of environmental and human health impacts of per- and polyfluoroalkyl substances (PFAS) have greatly increased in the peer-reviewed literature. The goals of the present review are to assess the state of the science regarding toxicological effects of PFAS and to develop strategies for advancing knowledge on the health effects of this large family of chemicals. Currently, much of the toxicity data available for PFAS are for a handful of chemicals, primarily legacy PFAS such as perfluorooctanoic acid and perfluorooctane sulfonate. Epidemiological studies have revealed associations between exposure to specific PFAS and a variety of health effects, including altered immune and thyroid function, liver disease, lipid and insulin dysregulation, kidney disease, adverse reproductive and developmental outcomes, and cancer. Concordance with experimental animal data exists for many of these effects. However, information on modes of action and adverse outcome pathways must be expanded, and profound differences in PFAS toxicokinetic properties must be considered in understanding differences in responses between the sexes and among species and life stages. With many health effects noted for a relatively few example compounds and hundreds of other PFAS in commerce lacking toxicity data, more contemporary and high-throughput approaches such as read-across, molecular dynamics, and protein modeling are proposed to accelerate the development of toxicity information on emerging and legacy PFAS, individually and as mixtures. In addition, an appropriate degree of precaution, given what is already known from the PFAS examples noted, may be needed to protect human health. *Environ Toxicol Chem* 2021;40:606–630. © 2020 SETAC

Keywords: Per- and polyfluoroalkyl substances; Perfluorooctane sulfonate; Perfluorooctanoic acid; Persistent compounds; Contaminants of emerging concern

INTRODUCTION

Per- and polyfluoroalkyl substances (PFAS) are ubiquitous in environmental media because of their prolific use in a variety of industrial and consumer products and processes (Jian et al. 2018; Sunderland et al. 2019). Widespread human

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exposure to PFAS in water, food, and air coupled with the lengthy environmental persistence and biological half-lives of some PFAS have led to measurable PFAS in the blood of nearly the entire population in developed countries, with health effects reported globally (Kato et al. 2011; Khalil et al. 2016; Stubleski et al. 2016; Jian et al. 2018). Information needed to evaluate the potential risk of harm from PFAS includes the types of adverse health effects that might occur at environmentally relevant exposures, especially in sensitive life stages. Information is also needed regarding the mode(s) of action for

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PFAS toxicity, PFAS toxicokinetics in both humans and laboratory animal models, and dose-response relationships. Risk estimates can be used to inform public health exposure limits that will determine the need for exposure mitigation and environmental cleanup.

There are several challenges in obtaining the information needed to assess human health risk from the large number of PFAS with a wide range of structures and chemical properties (Buck et al. 2011; Wang Z et al. 2017; Organisation for Economic Co-operation Development 2018). Data on the identity, composition, and quantity of PFAS used in products and processes are often treated as confidential business information, hampering efforts to estimate exposure sources and routes. The Organisation for Economic Co-operation and Development's (OECD's) chemical inventory reports over 4000 substances that contain at least one perfluoroalkyl (-CnF2n-) moiety (Organisation for Economic Co-operation Development 2018), and the US Environmental Protection Agency (USEPA) has a curated list of over 8000 PFAS included, based on structure (US Environmental Protection Agency 2018) from the CompTox Chemicals Dashboard (Williams et al. 2017). The USEPA estimates that more than 600 PFAS are currently in commercial use (US Environmental Protection Agency 2019). Experimental studies of PFAS have been limited by funding and the availability of analytical standards, confounded by the prevalence of background contamination in laboratory materials, and challenged by physicochemical properties such as high surface activity that can interfere with and complicate measurements. Consequently, sufficient information to conduct quantitative risk assessment is currently available for only a relative few PFAS (Post 2020). Further, although typical human exposures involve various combinations of PFAS (Centers for Disease Control and Prevention 2017), only a few efforts address interactions of PFAS mixtures; and a well-founded, scientific basis on which to evaluate their combined toxic potential does not yet exist (Carr et al. 2013; Wolf et al. 2014; Zhou et al. 2017; Hoover et al. 2019; US Environmental Protection Agency 2020).

The Society of Environmental Toxicology and Chemistry (SETAC) North America held the focused topic meeting and workshop "Environmental Risk Assessment of PFAS" on 12 to 15 August 2019, covering a wide range of topics related to the characterization of health risks posed by PFAS. The overarching purpose of the meeting was to begin a scientific discussion on how best to approach studying, grouping, and regulating the large number of PFAS to which people and other species are potentially exposed (for charge questions and other details, see Johnson et al. 2020). We refer to these PFAS as "legacy" (those perfluoroalkyl acids for which there are accumulating health data but that may be phased out or decreased in use) and "emerging" (those which are being used as replacements, often with minimal health effects data). The objectives of the Human Health Toxicity section were to provide an assessment of the state of the science in understanding toxicological effects of PFAS and to explore and discuss strategies for advancing knowledge on the toxicity of individual and groups of PFAS.

CURRENT KNOWLEDGE OF PFAS TOXICITY IN HUMANS

Like other chemicals, PFAS are potentially capable of producing a wide range of adverse health effects depending on the circumstances of exposure (magnitude, duration, and route of exposures, etc.) and factors associated with the individuals exposed (e.g., age, sex, ethnicity, health status, and genetic predisposition). Aspects to consider when establishing the health effects of greatest concern are 1) effects for which evidence is the strongest (strength of evidence can come from consistency of effect across studies, strength of effect associations in epidemiological studies, and species concordance, as examples), and 2) effects for which potential impact is greatest (factors contributing to impact can include severity of effect, functional impairment, persistence, and specific age groups that are susceptible, as examples). Brief summaries of candidate PFAS health effects from human and experimental reports are provided in this section (Figure 1).

Immune function

Epidemiological studies have explored relationships between PFAS exposure and laboratory biomarkers of immunomodulation, such as vaccine responses. A doubling of perfluorooctane sulfonate (PFOS) in maternal serum was associated with a 39% (p < 0.001) reduction in diphtheria antibody concentration in children (age 5 yr), with increased odds of falling below clinically protective values against diphtheria and tetanus at age 7 yr. The authors noted that a "2-fold greater concentration of major PFCs [perfluorinated compounds] in child serum was associated with a difference of -49% (95% CI, -67% to -23%) in the overall antibody concentration" (Grandjean et al. 2012). Decreased immunological response persisted at age 13 yr (Grandjean et al. 2017). Adverse associations were also noted for responses to rubella, mumps, and Hemophilus influenza vaccinations in children and to vaccinations in adults (Granum et al. 2013; Looker et al. 2014; Stein et al. 2016; Abraham et al. 2020). In a single study, modest down-regulation of C-reactive protein response, a marker of human systemic inflammation, was also reported to be associated with perfluorooctanoic acid (PFOA) blood levels (Genser et al. 2015).

Disease outcomes linked with immunosuppression such as clinician-recorded diagnoses of childhood infections have also been associated with prenatal exposures to PFOS and perfluorohexane sulfonate (PFHxS) (Goudarzi et al. 2017). A pregnancy cohort study prospectively detected increased risk of airway and throat infections and diarrhea in children through age 10 yr, correlated with cord-blood PFAS measurements (Impinen et al. 2018, 2019). A recent review concluded that exposure to PFAS in infancy and childhood resulted in an immunosuppressive effect characterized by an increased incidence of atopic dermatitis and lower respiratory tract infections (Kvalem et al. 2020). Some of the immunological effects were sex-specific, but the authors cautioned that there were inconsistencies across studies (Kvalem et al. 2020).

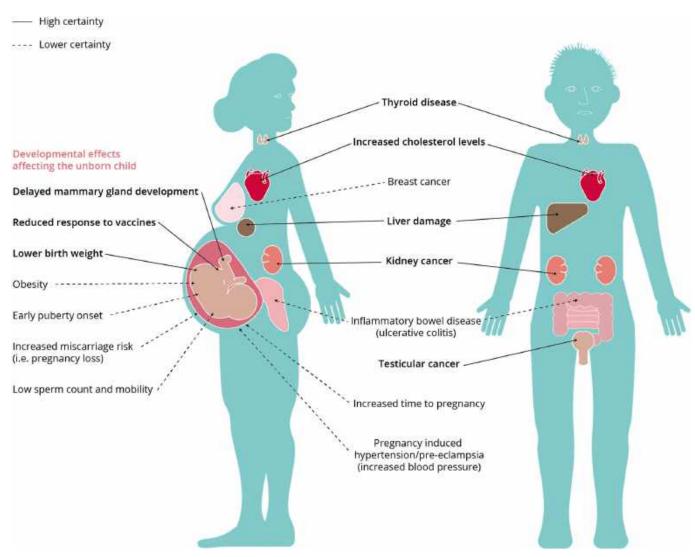


FIGURE 1: Effects of per- and polyfluoroalkyl substances on human health. Used with permission from European Environment Agency (2019). Original sources for this figure: National Toxicology Program (2016), C8 Science Panel (2012), IARC Working Group on the Evaluation of Carcinogenic Risks to Humans (2017), Barry et al. (2013), Fenton et al. (2009), and White et al. (2011b).

Overall, available data provide strong evidence that PFAS exposure can suppress the human immune response.

Population studies of immune hyperreactive diseases have resulted in mixed findings. Studies on childhood allergy and asthma outcomes have shown no association with PFAS (Impinen et al. 2018, 2019), whereas others have found substantial effects, including provocative evidence that subgroups of individuals not adequately immunized may be at an increased risk for disease a priori (Qin et al. 2017; Timmermann et al. 2017a). For example, a case–control study of Taiwanese children compared the first and fourth quartiles of serum measurements for 11 PFAS with asthma and other immune markers and reported confidence intervals well above 1.0 for PFOA and others (Qin et al. 2017). However, review articles concerning PFAS and childhood allergy and asthma offer nuanced, age- and sex-specific interpretations and advise against firm conclusions (Kvalem et al. 2020).

Chronic autoimmune outcomes, including thyroid disease (see section *Thyroid function*) and inflammatory bowel disease

(IBD), have also been considered. A study in contaminated communities (n=32254) detected an association between both prevalence and incidence of ulcerative colitis (UC) and PFOA exposure (linear trend p=0.0001 [Steenland et al. 2013]). A worker study (n=3713) found a higher prevalence (p=0.01) and incidence (p<0.05) of UC with increasing log PFOA serum concentrations (Steenland et al. 2015). A case-control study of children and young adults from a background exposure community in Atlanta, Georgia, USA, also found higher serum PFOA levels in patients with UC (Steenland et al. 2018b). In contrast to PFOA-related associations in US populations, a study of a contaminated community in Sweden (n=63074) did not show a consistent association of IBD with any PFAS exposure (Xu et al. 2020b).

Recent, thorough reviews (National Toxicology Program 2016; DeWitt et al. 2019; Pachkowski et al. 2019) emphasize some key concepts: 1) there is concordance between animal studies and human epidemiological observations that PFAS modify the immune response, and 2) there are noted

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complexities in assuming dose-response continuums, including possible differences in life-stage vulnerability. Authors of these reviews note uncertainty about which outcome will be of most importance but agree that immunotoxicity should be included among sensitive human PFAS toxicity endpoints.

Thyroid function

The C8 Science Panelists concluded that there is a "probable link" of PFOA exposure to thyroid disease, with sexspecific outcomes in women (for hyperthyroid disease) versus men (hypothyroid disease) (C8 Science Panel 2012). Subsequent reviews drew attention to hypothyroid outcomes in women and children and to the possibility that populations with a priori circulating antithyroid peroxidase antibodies may be at additional risk (Coperchini et al. 2017). A broad childhood disease review noted "some evidence" that PFAS cause childhood hypothyroidism and characterized the number of studies as "limited" for childhood disease conclusions (Rappazzo et al. 2017). A meta-analysis of 12 child and adult studies that excluded populations with higher exposures noted that PFAS exposure is negatively associated with serum total thyroxine levels and that "PFAS could induce thyroid dysfunction and disease" (Lee and Choi 2017).

Human thyroid disease is mostly the result of an autoimmune response and is 5 to 10 times more prevalent in women than men (Tadic et al. 2018). Concerning PFAS and clinically diagnosed outcomes, women in the highest quartile of PFOA exposure (>5.7 ng/mL) reported clinical hypothyroid disease (odds ratio 2.2, 95% confidence interval [CI] 1.4-3.7) over 3 cycles of National Health and Nutrition Examination Survey (NHANES) data (1999–2006, n = 3974 adults), with similar findings in men (Melzer et al. 2010). The C8 Science Panel studies (median serum PFOA 26.1 ng/mL) found thyroid disease hazard ratios of 1.00, 1.24, 1.27, 1.36, and 1.37 across cumulative exposure quintiles in women (log-linear trend p = 0.03 [Winquist and Steenland 2014b]), with parallel hypothyroid findings in children aged 1 to 17 yr (Lopez-Espinosa et al. 2012). The Ronneby, Sweden, population experienced excess risk of thyroid disease in a discrete time period (1984-2005) among women (hazard ratio 1.29, 95% Cl 1.05-1.57) that did not persist over time despite higher cumulative PFAS exposure (Andersson et al. 2019). The authors did not link exposure to hypothyroid outcome, noting a nonmonotonic dose-response relationship (Andersson et al. 2019).

Human population studies augment experimental data that PFAS interact with thyroid hormone binding proteins (Berg et al. 2015; Ren et al. 2016; Zhang J et al. 2016), one of several mechanisms by which PFAS can perturb feedback relationships between free thyroid hormone and the hypothalamic– pituitary–thyroid axis. Exposures to PFAS also interfere with thyroid peroxidase (TPO) enzyme activity in vitro (Song et al. 2012). Several PFAS studies have pursued this putative mechanism, finding that maternal and neonatal thyroid hormone outcomes were more readily detected in those with a priori abnormally high circulating anti-TPO antibodies (Webster et al. 2014, 2016). One case–control study investigated congenital hypothyroidism, a rare condition. Serum concentrations of PFOA (5.40 vs 2.12 ng/mL; p < 0.01), perfluorononanoic acid (PFNA; 1.93 vs 0.63 ng/mL; p < 0.001), perfluorodecanoic acid (PFDA; 0.52 vs 0.30 ng/mL; p < 0.005), and perfluoroundecanoic acid (0.98 vs 0.44 ng/mL; p < 0.005) were higher in the diagnosed newborns; and levels of several PFAS, including PFOA and PFHxS, were correlated with thyroid autoantibodies (Kim et al. 2016).

Thyroid disease is not the only concern. Clinicians are concerned about subclinically elevated thyroid-stimulating hormone (TSH) in early pregnancy because it may be associated with several possible adverse maternal and fetal outcomes (Forhead and Fowden 2014). This general concern has prompted numerous PFAS-exposure evaluations of corresponding TSH in maternal serum, cord blood, and newborns. A review of maternal and child biomarkers with PFAS exposure noted that higher TSH has been reported in 4 second-trimester studies (Ballesteros et al. 2017), but there are also conflicting findings. Studies measuring PFAS in the first trimester have also found associations between PFAS exposure and altered TSH levels in newborns, including nonmonotonic patterns of dose response that mirror the marked alterations of thyroid hormone levels during pregnancy (Inoue et al. 2019).

From the available studies, PFAS definitively alter human thyroid hormones and potentially contribute to thyroid autoimmunity but do not so far appear to be a cause of thyroid cancer (Barry et al. 2013; Vieira et al. 2013). Also, thyroid cancer is usually survived; thus, morbidity rather than mortality studies are useful.

Liver disease and cancer

The liver is a primary target organ for long-chain PFAS storage, and accompanying experimental evidence of toxicity includes hepatocyte fat infiltration, specific P450 (CYP) pathway induction, apoptosis, hepatocellular adenomas and carcinomas, and disrupted fatty acid trafficking that can be peroxisome proliferator–activated receptor alpha (PPAR α)–dependent or –independent and present across species (Maestri et al. 2006; Cui et al. 2009; Wan et al. 2012; Huang et al. 2013; Perez et al. 2013; Filgo et al. 2015; Xu et al. 2016, 2020a; Yao et al. 2016; Zhang L et al. 2016b; Hui et al. 2017; Li et al. 2017a; Guillette et al. 2020; National Toxicology Program 2020a).

Population studies demonstrate significant associations of long-chain PFAS (>6 fluorinated carbons) exposure to higher liver enzymes, such as alanine aminotransferase in adults and adolescents (Sakr et al. 2007a; Gallo et al. 2012; Yamaguchi et al. 2013; Gleason et al. 2015; Attanasio 2019; Nian et al. 2019), including in longitudinal studies (Sakr et al. 2007b; Darrow et al. 2016). Following low-dose exposures, these associations may be more evident in obese participants (Lin et al. 2010; Gallo et al. 2012; Jain and Ducatman 2019e).

Based on experimental data (Martin et al. 2007; Wan et al. 2012; Wang et al. 2013; Das et al. 2017), nonalcoholic

fatty liver disease (NAFLD) has been investigated as a clinical outcome of PFAS exposure mediating consistent population PFAS-altered liver enzyme findings. Studies with NAFLD cytokeratin C18 biomarkers have provided supportive evidence for PFAS inducing steatosis (Bassler et al. 2019). Metabolomic studies have been directed at potentially explanatory human glycerophosphocholine and fatty acid profiles (Kingsley et al. 2019; Salihovic et al. 2019; Wahlang et al. 2019). Processes which favor steatosis promote advanced liver disease including liver cancer in humans (Massoud and Charlton 2018; National Toxicology Program 2020a). Associations of PFAS with advanced human liver disease and liver cancer are technically hard to study for reasons including (and not limited to) lethality, selection of comparison populations, and alterations of excretion mechanics associated with disease states. In a clinic-based study, mostly obese (85%) children aged 7 to 19 yr with biopsy-proven NAFLD had more advanced disease associated with PFOS and PFHxS exposure as well as associations with lipid and amino acid pathways linked to NAFLD pathogenesis (Jin et al. 2020). However, an adult study reported that serum PFHxS was inversely associated with hepatic lobular inflammation in morbidly obese bariatric surgery patients (Rantakokko et al. 2015). A study of heavily exposed workers (n = 462, geometric mean serum PFOA of 4048 ng/mL) detected significantly increased incident mortality for cirrhosis (relative risk = 3.87, 95% CI 1.18-12.7) and liver cancer (relative risk = 6.69, 95% CI 1.71-26.2) compared to a regional population (Girardi and Merler 2019), whereas no PFAS association to cancer or advanced liver disease was reported in a 3M worker cohort or in the C8 Health study population (Lundin et al. 2009; Barry et al. 2013; Vieira et al. 2013).

Emerging animal toxicology and histology and human population data provide mechanistic clues that PFAS disrupt hepatic metabolism, leading to increased bile acid reuptake and lipid accumulation in liver (Salihovic et al. 2020; Schlezinger et al. 2020). A review of NAFLD and toxicant exposure concluded that PFAS are associated with early steatosis ("fatty liver"), the preclinical stage of NAFLD (Armstrong and Guo 2019).

Lipid and insulin dysregulation

Cross-sectional and longitudinal investigations indicate that PFAS increase serum total and low-density lipoprotein cholesterol in adults and children (Steenland et al. 2009; Frisbee et al. 2010; Nelson et al. 2010; Eriksen et al. 2013; Fisher et al. 2013; Fitz-Simon et al. 2013; Geiger et al. 2013; Fu et al. 2014; Starling et al. 2014; Winquist and Steenland 2014a; Skuladottir et al. 2015; Zeng et al. 2015; Koshy et al. 2017; Convertino et al. 2018; He et al. 2018; Seo et al. 2018; Dong et al. 2019; Lin et al. 2019; Li et al. 2020; Liu G et al. 2020), including clinically defined high cholesterol (Steenland et al. 2009; Winquist and Steenland 2014a; Lin et al. 2019). Studies of large populations, featuring wide exposure ranges, demonstrate that serum lipids rapidly increase beginning at background (1–10 ng/mL) serum concentration and then are followed by attenuating ("plateaued") cholesterol measurements as (log-transformed) exposures to long-chain PFAS increase (Steenland et al. 2009; Frisbee et al. 2010; Li et al. 2020). These findings suggest partially saturable mechanisms; thus, the cholesterol dose response at pharmacologic or acutely toxic doses should be viewed with caution; associations can be missed or may be misleading when an environmental range of exposure is absent. At background exposure levels, residual associations may be more detectable in obese participants (Timmermann et al. 2014; Jain and Ducatman 2019d), a finding congruent with experimental PFAS outcomes in rodents fed "Western" or high-fat diets (Tan et al. 2013; Quist et al. 2015; Rebholz et al. 2016). Human gene expression pathways provide support for an interaction of obesity and PFAS exposures and suggest possible sex differences (Fletcher et al. 2013). A pharmacokinetic model predicts that approximately half of the PFOSexposed population would experience a >20% rise in serum cholesterol (Chou and Lin 2020). Risk-assessment implications for low-PFAS dose increases in cholesterol have been noted (New Jersey Drinking Water Quality Institute Health Effects Subcommittee 2017; Li et al. 2020), and a review of population and toxicity data concluded that dyslipidemia is the strongest metabolic outcome of PFAS exposure (Sunderland et al. 2019).

Human PFAS lipid findings may be related to experimental findings of induced adipogenesis, impaired bile acid metabolism/ synthesis, strongly decreased CYP7A1 enzyme activity, altered fatty acid transport, and intracellular lipid accumulation with steatosis, including in PPAR- α -null or PPAR- α -humanized animals (Guruge et al. 2006; Lau et al. 2007; Bijland et al. 2011; Bjork et al. 2011; Wang et al. 2014; Filgo et al. 2015; Das et al. 2017; Salihovic et al. 2019; Zhang et al. 2020). Independent of PFAS exposure, similar alterations in metabolic pathways have been related to disrupted fatty acid beta-oxidation and increased free cholesterol in toxicology studies (Perla et al. 2017).

Cross-sectional studies of diabetes outcomes can be misleading for reasons discussed in the renal section (see section Kidney disease, uric acid, and kidney cancer). Emerging longitudinal and diabetes clinical trial data indicate that PFAS may increase human insulin resistance, associated with dysregulated lipogenesis activity (Alderete et al. 2019; Lin et al. 2019). Longitudinal studies of clinically diagnosed diabetes patients have sometimes associated PFAS exposures with diabetes (Sun et al. 2018) or with small changes in glycemic markers (Cardenas et al. 2017); however, diabetes associations to date are not consistent (Karnes et al. 2014; Cardenas et al. 2017; Donat-Vargas et al. 2019). Future studies should consider whether PFAS may instigate autoimmune diabetic outcomes in humans, as shown in experimental studies (Bodin et al. 2016). Experimental data reveal that PFAS activate G protein-coupled receptor 40, a free fatty acid-regulated membrane receptor on islet ß cells, stimulating insulin secretion (Qin et al. 2020; Zhang L et al. 2020).

Kidney disease, uric acid, and kidney cancer

Extended human half-lives of long-chain PFAS are attributed to active renal tubular reabsorption. Of concern, legacy PFAS

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such as PFOA and PFOS are concentrated in renal tissues, and histopathologic, molecular, oxidative stress, and epigenetic studies provide evidence of potential nephrotoxicity (Wen et al. 2016; Stanifer et al. 2018; Sakuma et al. 2019; Rashid et al. 2020). In addition, the strong influence of kidney reabsorption on the extended half-lives of long-chain PFAS is consistent with both human protein binding and experimental PFAS excretion data.

Human studies have associated legacy PFAS exposure to diminished glomerular filtration and/or defined chronic kidney disease in adults and children (Shankar et al. 2011; Watkins et al. 2013; Kataria et al. 2015; Blake et al. 2018). However, this outcome may be due to reverse causation (Watkins et al. 2013; Dhingra et al. 2017). Some reviews of the available epidemiologic and toxicologic evidence suggest causative links between PFAS and diminished kidney function and chronic kidney disease (Stanifer et al. 2018; Ferrari et al. 2019); these authors also note several knowledge gaps and uncertainty about which proposed mechanisms of action are most important. A propensity score approach to NHANES data (Jain and Ducatman 2019c; Zhao et al. 2020) and a study with repeated PFAS and health measures over an 18-yr period (Blake et al. 2018) recently concluded that PFAS exposure likely causes diminished renal glomerular filtration.

Uric acid, a biomarker of increased risk for renal disease (Obermayr et al. 2008), is also consistently associated with PFAS exposure in adults and children (Steenland et al. 2010; Geiger et al. 2013; Gleason et al. 2015; Kataria et al. 2015; Qin et al. 2016; Zeng et al. 2019), including a visible dose-response curve that begins at or near historic background levels in human populations (Steenland et al. 2010; Zeng et al. 2019). Serum PFAS concentrations exhibit an inverted U-shaped pattern related to glomerular filtration, initially exhibiting a modest accumulation as glomerular filtration begins to decrease and then decreasing in advancing renal disease, likely due to failure of normal strong reabsorption mechanisms in moderate to severe kidney disease (Jain and Ducatman 2019c). This finding is more dramatic across stages of glomerular filtration when there is also albuminuria (Jain and Ducatman 2019b). Studies suggest that the association of PFAS to uric acid is not due to reverse causation and is underestimated because the failing kidney excretes long-chain PFAS but retains uric acid. An implication is that population outcomes that occur in the presence of either albuminuria or moderate to severe renal disease such as hypertension (Jain 2020) increasing presence of and uric acid (a biomarker of renal disease; Jain and Ducatman 2019a; Zeng et al. 2019) can be underestimated in crosssectional studies; in other words, the link between these health outcomes and PFAS exposure is obscured in these studies because of enhanced PFAS excretion patterns in the presence of either albuminuria or moderate to severe kidney disease. Furthermore, the strong influence of renal reabsorption on the long half-lives of long chain PFAS is consistent with both human protein binding of PFAS and experimental PFAS excretion rates in high-dose rodent studies (Cheng and Ng 2017).

Kidney cancer diagnoses have been increasing since 1975, a finding that is partially independent of improved detection, with

5-yr cancer-specific survival of approximately 80% (Gandaglia et al. 2014). The C8 Health studies noted longitudinal (n = 32254) increases of kidney cancer (hazard ratio = 1.10, 95% CI 0.98–1.24) and kidney cancer mortality (Steenland and Woskie 2012; Barry et al. 2013; Vieira et al. 2013). A review of 6 published studies found long-chain PFAS exposure associated with kidney cancer or kidney cancer mortality, with risks ranging from 1.07 to 12.8 (Stanifer et al. 2018). Subsequent preliminary data from the heavily exposed Veneto, Italy, population also suggest a significant increase in kidney cancer mortality with PFAS exposure (Mastrantonio et al. 2018). Evidence is accumulating for PFAS as a cause of chronic disease and kidney cancer. Study designs must consider the peculiar PFAS excretion mechanics involved in and associated with kidney disease.

Reproductive and developmental outcomes

Exposure to PFOA impairs human sperm motility and sperm penetration into viscous media (Sabovic et al. 2020; Yuan et al. 2020) and is longitudinally associated with lower sperm concentration and count and higher adjusted levels of luteinizing and follicle-stimulating hormones in young men (Joensen et al. 2009; Vested et al. 2013; Song et al. 2018). Serum concentrations of PFAS are also cross-sectionally associated with deleterious markers of semen quality (Louis et al. 2015; Pan et al. 2019).

Legacy and emerging PFAS have been found in follicular fluid (Kang et al. 2020). They appear to alter endometrial regulation such as progesterone activity in young women (Di Nisio et al. 2020b) and possibly menstrual cycle length (Lum et al. 2017). Associations with menarche and menopause may be substantially due to reverse causation because menstruation is a route by which women eliminate PFAS (Dhingra et al. 2017), partially explaining why men have higher PFAS levels than women in the same communities. Women on birth control and who do not menstruate or with poor cyclicity because of age, activity level, or disease may have elevated PFAS levels in comparison with menstruating women. Exposure to PFAS has been associated with endometriosis in the United States and in China (Louis et al. 2012; Campbell et al. 2016; Wang B et al. 2017a), but the specific PFAS associated with this effect vary among studies.

Time-to-pregnancy (fecundity) studies provide indirect evidence of changes in fertility. Methodologic considerations include maternal and paternal age, parity (which in turn affects serum PFAS), and health status. Among 1240 women in the Danish National Birth Cohort, PFOS exposure was associated with decreased fecundity (median serum PFOS 35.5 ng/mL; Fei et al. 2009). Reverse causation may explain this finding because it is duplicated in parous, but not among nonparous, women (Whitworth et al. 2012; Bach et al. 2015). Prospective odds of actual infertility in the Maternal–Infant Research on Environmental Chemicals cohort (n = 1743) at low-dose exposures were associated with PFOA (geometric mean 1.66 ng/mL; odds ratio = 1.31, 95% CI 1.11–1.53) and PFHxS

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(odds ratio = 1.27, 95% CI 1.09–1.48; Velez et al. 2015). The reported fertility rate improved following water filtration in a PFAS-contaminated community (incidence rate ratio 0.73, 95% CI 0.69–0.77 prior to filtration) along with measures of birth weight (Waterfield et al. 2020).

Per- and polyfluoroalkyl substances reliably move across the placenta and enter breast milk (Gyllenhammar et al. 2018; VanNoy et al. 2018); serum PFAS levels in young children generally exceed maternal serum concentrations (Fromme et al. 2010; Papadopoulou et al. 2016; Eryasa et al. 2019). Population studies provide evidence that breastfeeding duration and milk quantity are adversely affected by PFAS exposure (Romano et al. 2016; Timmermann et al. 2017b; Rosen et al. 2018).

A systematic review reported that PFOA exposure was associated with a small decrease in infant birth weight; the meta-analysis estimated that a 1-ng/mL increase in PFOA was associated with an approximately 19-g reduction (95% CI -29.8 to -7.9 g) in birth weight (Lam et al. 2014). The authors noted similarities in experimental studies (Johnson et al. 2014; Koustas et al. 2014) and concluded that there was "sufficient" human and corroborative toxicology evidence of a detrimental effect of PFOA on birth weight (Johnson et al. 2014; Koustas et al. 2014; Lam et al. 2014). However, another metasubpopulation analysis, focused on early pregnancy or the time shortly before conception, detected only a small and nonsignificant association, which was less subject to bias (Steenland et al. 2018a). Different approaches to the possible confounding role of shifting glomerular filtration rates in pregnancy can affect interpretations; evidence suggests this consideration can, at most, only partially explain associations of PFAS exposure to decreased birth weight (Interstate Technology and Regulatory Council 2020; Wikstrom et al. 2020). A recent review of mostly prospective cohort studies (n = 24 studies) noted PFAS associated with altered fetal and postnatal growth measures, such as lower birth weight. Many (n = 22) of the relevant studies suggest developmental and childhood immunomodulatory effects, whereas 21 studies concerning neurodevelopment were inconclusive (Liew et al. 2018). The authors of the review noted methodologic challenges of developmental and newborn epidemiology, including consideration of critical exposure windows for developmental effects, the effects of breastfeeding and parity on maternal PFAS levels, and the variety of possible mechanistic explanations for growth outcomes, such as disruption of glucocorticoid and thyroid hormone metabolism in utero (Liew et al. 2018). Recent Faroe Island studies report that prenatal PFAS effects on thyroid hormone status do not support a causal relationship (Xiao et al. 2020).

Review articles suggest that prenatal exposure to PFOA may increase risk of subsequent childhood adiposity, noting that steroid hormones, retinoid X receptor, and other pathways may be contributing to this effect (Halldorsson et al. 2012; Hall and Greco 2019). Prospective evidence supports this relationship in adults with a high risk of diabetes (Cardenas et al. 2017). However, some well-performed community studies do not support this outcome in adults or children (Barry et al. 2014; Martinsson et al. 2020). Based on several preliminary findings, supported by longitudinal follow-up studies (Stein et al. 2009; Savitz et al. 2012; Darrow et al. 2013; Avanasi et al. 2016a, 2016b), the C8 Science Panel concluded that PFOA is probably linked to pregnancy-induced hypertension or preeclampsia. Populationlevel evidence implicating additional PFAS having this effect has included studies with longitudinal designs (Huang et al. 2019; Wikstrom et al. 2019; Borghese et al. 2020). Experimental support includes PFAS effects on human trophoblast migration in vitro (Szilagyi et al. 2020) and recent evidence of PFOA and GenX (or hexafluoropropylene oxide dimer acid) effects on mouse placenta, as well as excessive gestational weight gain (Blake et al. 2020). However, a recent longitudinal study did not find an association of PFAS with pregnancy-associated hypertension (Huo et al. 2020).

The possibility that circulating PFAS may reduce bone mineral density has been investigated. Cross-sectional and practical trial associations have been found in adults (Lin et al. 2014; Hu et al. 2019; Di Nisio et al. 2020a), and there is emerging longitudinal evidence from a mother and child pair study indicating that children may also be affected (Cluett et al. 2019).

Testicular cancer diagnoses are increasing steadily, a trend unrelated to improved detection (Cheng et al. 2018; Park et al. 2018). Most patients diagnosed (>90%) will be cured and die of other causes; mortality studies therefore provide little help in understanding disease risk factors. The C8 Science Panel detected longitudinal evidence for increased testicular cancer risk (1.35, 95% CI 1.00–1.79) for cumulative PFOA exposure (Barry et al. 2013). There are ample supportive data of testicular damage following PFAS exposure, including strong evidence of endocrine disruption; but the cell-specific associations are different in humans (germ cell) than the outcomes in rodents (stromal).

Per- and polyfluoroalkyl substances have deleterious effects on conception, pregnancy, and infant development. The underlying birth weight data are mostly supportive, although the subsequent growth and adiposity literature is mixed. The most sensitive reproductive and developmental outcomes are a topic of ongoing discussion.

Outcomes replicated across populations, such as perfluorocarboxylate (PFCA) and perfluorosulfonate (PFSA) exposures associated with down-regulation of immune response; increases in cholesterol, liver enzymes, and uric acid; alterations in thyroid hormone binding proteins; growth deficits; and effects on breast milk and lactation, indicate priority areas for understanding mechanisms and health implications.

CURRENT KNOWLEDGE OF PFAS TOXICITY IN EXPERIMENTAL MODELS

Animal studies have focused most intensely on PFOA and PFOS, using laboratory rodents and, more recently, zebrafish as models. Perfluoroalkyl acids of varied carbon-chain lengths as well as a few replacement chemicals with ether linkages in the carbon backbone (such as GenX and 3H-perfluoro-3-[(3-methoxy-propoxy)propanoic acid], or ADONA) have also

20 h	ñ	18 h								q	34–0		9-0	26	σ	22	6 d	÷				ے	~1.6	,	1.2 h
Ч	8h 3h	8 h			7	-0.6h 1.0-1.7h 1.2h 2.4h 2-4h 4-6 d 1.4-6.4d 31-55d 59-75d 40-80d	7	-75 0	59-	5 d	31–5	σ	-6.4	1.4	b d	4-6	4 h	2-	2.4 h	Ч	1.2	7 h	0-1.	1.	-0.6 h
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	GenX		F-53B	53	- 1	PFDA (C10)	9) A	PFD			C9)	PFNA (C9)	PFI		8)	PFOA (C8)	FO	а.	PFHpA (C7)	Aq	ЪРЕ		(9)	9) 9)	PFHxA (C6)
1																					ns	nma	q þ	, an	onkey, and humans
Illy con-	sponses	or half-	hemical	PFHxS,	ats and	. These species	s PFOA	rate of	females	k differ- naller in	se also	n differ-	ation to	ions.	PFOA	wledge	orted in devel-	duction,	e often	n more	n orders	account	pheno-	inves-	es. Our S other

TABLE 1: Per- and polyfluoroalkyl substances serum half-life estimates in rat, mouse, monkey,

been examined, with outcome profiles thus far general sistent with legacy chemicals. The varying extent of res is likely related to toxicokinetic disposition (excretion life) and relative potency and affinity of the individual ch for binding to receptor proteins. Some PFAS (i.e., PFOA, and PFNA) have longer half-lives in mice than ra typically much longer half-lives in humans (Table 1). differences in elimination kinetics complicate the crossevaluation of toxicity. In addition, some PFAS (such as and PFNA) exhibit a profound sex difference in the chemical elimination and bioaccumulation in the rat: eliminate them much faster than males (Table 1). Sex ences in half-lives, although important, are much sm humans and have a different explanation. The mous typically has more limited sex-based PFAS elimination ences, making this species more amenable for extrapola humans, especially for mechanistic and toxicity evaluati

In general, human health effects associated with and PFOS exposure (described in section Current Know of PFAS Toxicity in Humans) have also been repo animal models: hepatic/lipid metabolic toxicity, opmental toxicity, immune suppression, tumor ind endocrine disruption, and obesity. These findings are derived from well-controlled laboratory experiments in than one species using wide dose ranges that are often of magnitude higher than typical human exposure, to a for differences in half-life across species. Some of the typic findings are supported by in vitro mechanistic tigation and/or molecular queries on target tissues. Our understanding of the toxicologic properties of PFAS other than PFOA and PFOS is notably less advanced and, in the case of emerging replacements and by-products, completely unexplored.

Hepatic and metabolic toxicity

In rodent studies, dose-dependent increases in liver weight, in hepatocellular hypertrophy associated with vacuole formation, and with or without increased peroxisome proliferation have been observed with a significant body burden of PFAS, especially for the most persistent and potent longchain homologs. Hepatocyte proliferation, necrosis, and apoptosis are outcomes occurring at relatively low doses. This is also true for a new replacement chemical, GenX, which altered liver histopathology and function and increased apoptosis in mice and fish (Blake et al. 2020; Guillette et al. 2020). Correspondingly, transcriptional activation of mouse and, to a lesser extent, human PPAR α -related genes in liver was detected in adult-exposed models; activation of other nuclear receptors such as PPARy, constitutive androstane receptor (CAR), and pregnane X-receptor (PXR) has also been reported. These nuclear receptors, metabolic sensors that regulate lipid and glucose metabolism and transport and inflammation, tend to be more responsive in tissues of rodents than in humans (Wolf et al. 2012; Rosen et al. 2017). Recent work using developmental models reports that

	15.3 yr	-
	2.5–4.3 yr	-
30d 21d	2.1–3.8 yr	
	1.2–2.5 yr 2.1–3.8 yr	
2.4h 5.3h	32 d	
1.7 d	3 d	-
3.5d 4.0d 87d 141d 110d 132d	3.4–5.0 yr	
87 d 141 d	5.3–8.5 yr	
d 4.0 d	28 d	
Synomolgus 3.5 c Monkey	luman	
0	Т	(

0.4–0.6 h ~1.2 h

4 6--9 l2h

1.0–1.8 h Зh

38-41 d 36-4 d

62–71 d 31–3 d

28–3 d 6.8 d

25--2 d 1.8 d

2.1–4.5h 5.8 h

0.6-4.0 h 4.5 h

Mouse

Rat

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(C4) PFBA (

(C8)

PFOS (

PFH_xS (C6)

PFBS (C4)

GenX = hexafluoropropylene oxide dimer acid; PFBA = perfluorobutanoic acid; PFBS = perfluorobutanesulfonic acid; PFDA = perfluorodecanoic acid; PFHPA = perfluorohexanoic acid; PFHPA = perflu PFHXS = perfluorohexane sulfonate; PFNA = perfluorononanoic acid; PFOA = perfluorooctanoic acid; PFOS = perfluorooctane sulfonate

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mitochondrial dysfunction is associated with hepatocellular hypertrophy in young adult mice (Quist et al., 2015) and that other fatty acid metabolism pathways are activated (Jones et al. 2003; Shabalina et al. 2016). Steatosis is also a common feature of PFAS chronic exposure in rodents. Exposure in rodent models typically decreases serum cholesterol, whereas elevations of circulating cholesterol levels have been reported in humans. The mode of action concerning serum cholesterol is debatable. For example, PFOA exposure increased liver weight, increased liver enzymes, and led to persistent histopathological changes (particularly damage to the bile duct) in livers of wild-type and PPARa-null rodent strains (reviewed in Division of Science and Research, New Jersey Department of Environmental Protection 2019). Many of these effects are reversible on cessation of PFAS exposure, and this observation has been interpreted by some as evidence of "adaptive" responses to exposure. However, this reversibility is irrelevant to ongoing environmental PFAS exposure (for instance, from drinking water) because exposure will persist until contamination is remediated. In summary, there is a strong confluence of animal toxicology and histology and human population data that PFAS disrupt hepatic metabolism and lead to lipid accumulation in liver, although the mechanism(s) is unclear. Effects on bile acid metabolism, mitochondrial perturbation, and cholestatic mechanisms deserve further investigation at human-relevant exposures.

Reproductive and developmental toxicity

Only a few reproductive toxicity studies of males and females are available, primarily focusing on long-chain PFAS. Profound developmental toxicity has been described following gestational and lactational exposure to PFOS, PFOA, and PFNA in mice (Thibodeaux et al. 2003; Lau et al. 2006; Das et al. 2015) and in mice and rats gestationally exposed to GenX (Conley et al. 2019; Blake et al. 2020). Neonatal morbidity and mortality were seen with exposure to high doses of legacy PFAS; growth deficits and developmental delays were noted in offspring exposed to lower doses. Evidence of lactation impairment was seen in mice at doses of 5 mg PFOA/kg body weight (White et al. 2007), leading to increased offspring mortality (Lau et al. 2006); recent studies have indicated a role of placental dysfunction in these adverse developmental outcomes (Blake et al. 2020). Deficits of mammary gland development were also observed in mice exposed to PFOA (doses of 1 mg/kg body wt and lower) during gestation, which persisted into adulthood, although these exposure levels did not alter body weight, lactational function, or neonatal growth of offspring (F1 or F2 mice; Macon et al. 2011; White et al. 2011b; Tucker et al. 2015). Systematic reviews support a relationship between in utero exposure to PFOA and PFOS and reduced fetal growth in animals and humans, and the relationship between PFOA and reduced fetal growth in mice was recently validated (Koustas et al. 2014; Blake et al. 2020). Also, PFAS are reported to have reproductive effects such as ovulation failure in mice (Zhang Y et al. 2020).

Immunotoxicity

A few long-chain PFAS (PFOS, PFOA, PFNA, and PFDA) have been shown to alter immune status in rodents and nonhuman primates. Effects are predominantly immunosuppressive and include reductions in thymus and spleen weights and associated immune cell populations, in numbers of circulating immune cells, in certain aspects of innate immunity (i.e., natural killer cell cytotoxicity), in infectious disease resistance, and in antibodies produced in response to an antigen (i.e., analogous to the vaccine response in humans). In their 2018 draft Toxicological Profile for Perfluoroalkyls, the US Agency for Toxic Substances and Disease Registry (ATSDR) noted changes to the aforementioned immune parameters observed in experimental rodents exposed to PFOA, PFOS, PFNA, PFHxS, PFDA, perfluorobutanesulfonic acid (PFBS), or perfluorobutanoic acid (PFBA; Agency for Toxic Substances and Disease Registry 2018). The US National Toxicology Program conducted a systematic review of the immunotoxicological literature for PFOA and PFOS and concluded that PFOA and PFOS were presumed to be immune hazards to humans based on a high level of evidence for suppression of antibody responses in experimental animals and a moderate level of evidence for suppression of antibody responses in humans (National Toxicology Program 2016). The ATSDR (Agency for Toxic Substances and Disease Registry 2018) also included a decreased antibody response to vaccines (PFOA, PFOS, PFHxS, and PFDA) and increased risk of asthma diagnosis (PFOA) among the list of adverse health effects in PFAS-exposed humans. Reduction in the antibody response to a vaccine, an adaptive immune function, is a well-accepted measure of immunotoxicity, is consistent with the mode of action for the effects of fatty acids on immune system function (Fritsche 2006), and is compelling evidence that the immune system is a sensitive target of PFAS.

Tumor induction

Per- and polyfluoroalkyl substances are not known to be directly mutagenic; PFOA, PFOS, and other tested PFAS show little or no evidence for induction of gene mutation, clastogenicity, or aneuploidy in vitro or in vivo by a direct mode of action (see EFSA Panel on Contaminants in the Food Chain [2020] for details). There is evidence that PFAS can induce DNA damage, such as strand breaks, and other genotoxic effects, secondary to oxidative stress (EFSA Panel on Contaminants in the Food Chain 2020). This occurs at concentrations or doses that are high relative to human environmental exposures to PFAS, and the mechanism is such that their dose–response will be sublinear. Hence, PFAS are unlikely to be of mutagenic concern in exposed populations.

In adult-exposed rodents and fish, PFOA and PFOS have been shown to induce tumors. Liver adenomas, pancreatic acinar cell tumors, and testicular Leydig cell adenomas have been detected in rats treated chronically with PFOA (IARC Working Group on the Evaluation of Carcinogenic Risks to Humans 2017) as well as its replacement, GenX (Caverly Rae et al. 2015). Following

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gestational and chronic exposure to PFOA, 58% of male rats demonstrated pancreatic tumors at the lowest dose administered (National Toxicology Program 2020b). This finding has spurred Minnesota and California policymakers to consider cancer as an endpoint in risk assessment, whereas the European Food Safety Authority (EFSA Panel on Contaminants in the Food Chain 2020) has the opinion that there is not adequate evidence for a link between exposure to PFAS and cancer risk in humans. This "tumor triad" profile has been associated with the PPARamediated molecular signaling pathway in rats exposed to high doses of PFAS. Consequently, liver tumors involving this mode of action are not considered relevant to humans at equivalent PFAS exposures (Post et al. 2017). The human relevance of PPAR α -mediated pancreatic tumors in rodents remains to be determined. Liver lesions evident in PPARa-null mice exposed to PFOA during pregnancy and lactation (Filgo et al. 2015) suggest a non-PPARα-mediated liver response. Induction of liver tumors mediated by estrogen receptor (ER) activation has also been reported in fish (Tilton et al. 2008), and several non-PPARamediated hypotheses, including increased reactive oxygen species formation, oxidative stress, and mitochondrial dysfunction; decreased tumor cell surveillance by the immune system; and diminished gap junction cellular communication, are documented (IARC Working Group on the Evaluation of Carcinogenic Risks to Humans 2017; New Jersey Drinking Water Quality Institute Health Effects Subcommittee 2017).

Endocrine disruption

The primary evidence for the endocrine-disrupting potential of PFAS involves induction of hypothyroxinemia and reduction of serum testosterone in rats. An early review of PFAS endocrine-disrupting properties in humans concluded that the "thyroid may be one axis significantly affected by PFOA exposure while the animal toxicology literature is less certain due to technical issues" (White et al. 2011a).

The effects of PFAS on thyroid hormone status detected in animal studies differ from classical hypothyroidism, in that reduction of circulating total thyroxine is not accompanied by a compensatory increase of TSH. A possible mechanism for these effects may be related to the propensity of protein binding of legacy PFAS, which could lead to displaced total thyroxine binding to its carrier proteins (transthyretin and thyroxinebinding globulin). Human population studies augment animal data showing that PFAS interact with thyroid hormone binding proteins (Berg et al. 2015; Ren et al. 2016; Zhang J et al. 2016a), one of several mechanisms by which PFAS can perturb feedback relationships between free thyroid hormone available to cells (free total thyroxine) and the hypothalamic-pituitary axis. Some estrogenic effects of PFAS have also been illustrated by in vitro studies, although there is no evidence of direct transactivation of estrogen, androgen, or glucocorticoid receptors (Behr et al. 2018, 2020b).

The evidence for PFAS affecting ER signaling in humans and animals is mixed. Although studies have identified some PFAS as being without estrogenic activity (Behr et al. 2018; Borghoff et al. 2018; Gogola et al. 2019), others suggest an ability of PFAS to modulate or even activate ER-mediated effects (Benninghoff et al. 2010; Kjeldsen and Bonefeld-Jørgensen 2013; Wang et al. 2018; Bjerregaard-Olesen et al. 2019; Qiu et al. 2020), with some effects only observed in aquatic organisms (Wei et al. 2009; Chen et al. 2016, 2018). Microarray analyses of human primary hepatocytes confirmed that PFOA activated the ER pathway (Buhrke et al. 2015).

Neurotoxicity

Potential adverse effects of PFAS on the nervous system and functions have not been widely investigated. A few studies reported neurotoxicity of PFOS, PFHxS, and PFOA in cell culture systems (Slotkin et al. 2008), as well as altered behavioral responses (Goulding et al. 2017) and deficits in learning and memory ability in rodents (Viberg et al. 2013). In contrast, no significant developmental neurotoxic effects were seen from prenatal exposure to PFOS in USEPA guideline–based studies with rats (Butenhoff et al. 2009).

Obesity

Numerous cell-based assays in human and mouse preadipocytes and animal studies with and without high-fat diets have consistently shown that some PFAS have the potential to increase lipid production by adipocytes and fat pads (van Esterik et al. 2016). Exposure of pregnant mice to low doses of PFOA produced obesity in young adult female offspring (Hines et al. 2009; van Esterik et al. 2016), a finding that was recapitulated in Danish women exposed in utero to PFOA (Halldorsson et al. 2012). Both PFOA and GenX increased weight gain of pregnant mice (Blake et al. 2020), an effect also seen in women during pregnancy (Ashley-Martin et al. 2016), although discordant results have been reported in other studies (Barry et al. 2014; Ngo et al. 2014). These apparently disparate findings in experimental models may be associated with differences among mouse strains examined, exposure periods, statistical methodology, and/or the rodent diets used.

There are specific differences in human and rodent health outcomes that deserve further investigation: 1) cholesterol metabolism, 2) thyroid effects, 3) mode of action for liver effects (different or same), and 4) kidney transporter or other mode of action leading to large differences in half-life. However, species concordance in the 6 human health effects discussed in the present review supports a weight of evidence for these effect for the handful of extensively studied PFAS.

Human health advisory and guidance values for a few PFAS have been issued to date by the USEPA, the ATSDR, several individual state environmental agencies or health departments, as well as regulatory agencies in Canada and Europe that are largely (but not exclusively) based on toxicological findings in animal models. However, risk-assessment scientists have not reached consensus in selecting a singular apical endpoint as the basis for a point of departure for assessments. Three

toxicological features of PFAS that have been commonly highlighted, based on their sensitivity (low dose effect), strength of evidence (robust corroborating studies with mechanistic support for human relevance), and corresponding findings noted in epidemiological investigation, are hepatotoxicity (and alterations in lipid metabolism), developmental toxicity, and immunotoxicity. It should be noted that apical endpoints that drive risk assessments often differ among individual PFAS, perhaps highlighting the complexity of these chemicals and the family of PFAS, in general.

IMPORTANCE OF TOXICOKINETICS IN UNDERSTANDING PFAS TOXICITY

Species and sex differences

Few of the substantial number of structurally diverse PFAS have been tested for toxicological effects. Some available toxicological information has come from studies in animals, where marked species and (in rat) sex differences in half-life for some PFAS (Table 1) have been observed and the relevance to humans is uncertain. These differences are due to toxicokinetic and toxicodynamic factors. There are also differences in mean PFAS serum levels between men and women in the same communities. Children may have elevated serum levels compared to parents, even with the same exposures (Emmett et al. 2006; Daly et al. 2018; Graber et al. 2019), for reasons relating to transplacental transfer, breastfeeding, and body mass (Emmett et al. 2006; Daly et al. 2018; Graber et al. 2019; Blake et al. 2020). Transplacental transfer of PFAS confers a substantial burden to the newborn infant. Because the infant has a smaller overall mass and blood volume. PFAS are concentrated, increasing PFAS per volume (Koponen et al. 2018). In addition, transfer of PFAS is common through lactation, and the longer a child breastfeeds, the higher the body burden (Gyllenhammar et al. 2018; VanNoy et al. 2018).

Effects of comorbidity on PFAS toxicokinetics

Factors affecting renal function can influence PFAS toxicokinetics. As discussed, opposing types of causation should be considered. Human toxicokinetics appear to vary bidirectionally with changing renal function, leading to nonmonotonic dose–response relationships and, depending on the study goal, possibly to errors in estimating disease associations. As progress is made in the field of PFAS toxicokinetics, new chemistries may have different clearance factors and nuances that vary by PFAS group or structures, and that will need to be investigated to accurately model half-lives in different exposure subgroups.

Sources of information on toxicokinetics in humans: strengths and limitations of studies

Some PFAS half-life data in humans were obtained from retired industry workers, particularly those who worked with PFOS, PFOA, and PFHxS (Olsen et al. 2007). Since then, these estimates have been modified slightly or confirmed with longitudinal data and modeling from contaminated communities once uncontaminated water options were provided (Bartell et al. 2010; Li et al. 2018). Other contemporary PFAS estimates are derived from biomonitoring studies of production workers, blood donors, study participants, and/or occupationally exposed cohorts (Olsen et al. 2009, 2017; Russell et al. 2013; Zhang et al. 2013). Some caution must be taken in using these data because variables affecting PFAS clearance may not be taken into consideration (age, sex, menstruation, disease, and medication status) and may contribute to confounding.

The challenge in determining a reliable human half-life in these types of studies is that exposure does not end with a clean water source, retirement, or a change of job and that continued exposures vary over potential depuration periods. Model components may also vary in subclasses. Children (small blood volumes and a large fraction of exposures comes from drinking), pregnant women (large increase in blood volume and water intake), parous women (transfer to fetus and breast milk), and athletes (water intake elevated) are examples of subpopulations with expected variation in half-life compared to adult men (Post et al. 2017). There will be more human estimates of PFAS forthcoming that involve variations in half-life (Post et al. 2017). Realistic computational modeling can help, so long as it clearly characterizes exposures and applicable populations. The continued goal should be to provide predictive values for those PFAS lacking actual measurements, based on chemical structures and trusted physiological parameters.

Physiologically based pharmacokinetic/ toxicokinetic modeling in different-aged populations

In the blood and other tissues, PFAS toxicokinetics are influenced by their interactions with proteins (Andersen et al. 2006; Katakura et al. 2007; Nakagawa et al. 2008; Weaver et al. 2009; Figure 2). Certain toxicokinetic features are saturable, and thus dosing in toxicokinetic studies is of profound importance. Studies of renal reabsorption mechanisms in mammals show that reduced activity of transporters such as organic anion transporting polypeptide 1a1, through inactivation (e.g., genetic manipulation, castration, treatment with estrogen) or by saturation at increasing doses, leads to substantial reductions in half-lives of PFOA and PFOS (Andersen et al. 2006; Nakagawa et al. 2008; Weaver et al. 2009; Yang et al. 2009).

These protein-associated toxicokinetic processes were recently incorporated into a model for PFOA in the male Sprague-Dawley rat (Cheng and Ng 2017), which provides a useful platform to explore how changes in protein interactions might affect estimates of PFAS half-life (Figure 3). At high doses, it is typical to see clear biphasic behavior with rapid initial clearance, during which the serum half-life appears to be shorter especially at high enough doses that processes such as renal reabsorption are saturated, followed by a much longer tail

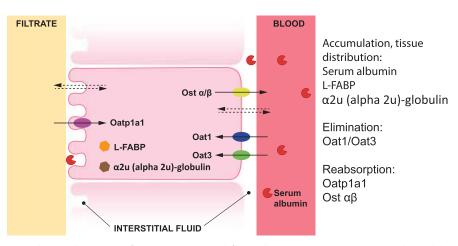


FIGURE 2: Example of proteins that are known to influence per- and polyfluoroalkyl substance toxicokinetics through binding (which affects tissue distribution and accumulation) and facilitation of membrane transport (which affects clearance and reabsorption). Illustrated for kidney and blood. L-FABP = liver fatty acid binding protein; Oat1 = organic anion transporting 1; Oatp1a1 = organic anion transporting polypeptide 1a1; Ost = organic solute transporter.

(Figure 3A). In a similar fashion, the magnitude of internal dose and rate of serum clearance can be profoundly influenced by proteins known to bind PFAS, such as serum albumin (Figure 3B). Increasing and decreasing the extent of reabsorption in the kidney increases and decreases the serum half-life, respectively (Figure 3C). Finally, the effect of saturating reabsorption is magnified when the half-life is longer because of increased serum binding (Figure 3D). In this case, taking an initial slope to calculate the serum half-life at high doses would lead to a profound underestimation.

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Differences in protein expression, circulating levels, and even protein type across populations, sex, and species could lead to important species and sex differences in PFAS biological half-lives (Han et al. 2012); such differences should be

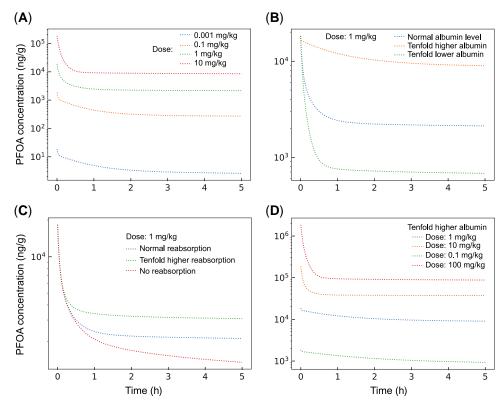


FIGURE 3: Simulations based on Cheng and Ng (2017), perfluorooctanoic acid (PFOA) toxicokinetic model for Sprague-Dawley rats. (**A**) Effect of dose on initial half-life. (**B**) Effect of higher and lower levels of serum albumin, which binds to PFOA, on serum clearance dynamics. (**C**) Effect of extent of reabsorption in kidney on serum half-life, based on organic anion transporting polypeptide 1a1 activity. (**D**) Effect of dose on elimination kinetics when half-life is longer because of higher albumin binding. Oat1 = organic anion transporting 1; Oat3 = organic anion transporting 3; Ost = organic solute transporter.

investigated and taken into account in the extrapolation to human equivalent doses. Because expression of proteins may change at different life stages, clearance factors and toxicokinetics may also change.

Given the large number of species-, sex-, and age-specific differences that have been observed, coupled with the lack of data for many PFAS, the parameterization of complex physiologically based toxicokinetic models remains a persistent challenge. Therefore, lower-resolution models (e.g., onecompartment or few-compartment models) may be more appropriate for species and settings where insufficient data are available for reasonably accurate parameterization. Alternatively, in silico and in vitro methods are under development that could aid in parameterization in the absence of in vivo data, as discussed in the section *New approaches for developing PFAS toxicity information*.

SO MANY PFAS, SO LITTLE TIME: ACCELERATING THE PACE OF DISCOVERY

Importance of determining mode of action and adverse outcome pathways

Information on modes of action and/or adverse outcome pathways (AOPs) is invaluable in 1) establishing human relevance of experimental evidence, 2) assessing causality in epidemiological studies, 3) applying "read-across" to PFAS for which there is little toxicological information, 4) assessing risks from mixtures, 5) guiding development and interpretation of new approach methodologies, 6) informing the development of biomarkers in epidemiologic investigation, and 7) identifying potentially vulnerable subpopulations and life stage–specific effects (Meek et al. 2014; LaLone et al. 2017). Verified modes of action and AOPs can inform risk assessment based on intermediate effects and enable development of new methodology-based approaches to assess PFAS safety (Meek et al. 2014).

Postulated modes of action/AOPs for PFAS

Mechanistic studies have been performed on only a few PFAS. These have been shown to activate a range of putative molecular initiating targets, among which are the nuclear receptors PPARα, PPARγ, PPARβ/δ, CAR, PXR, liver X receptor α, and ERα (Bijland et al. 2011; Bjork et al. 2011; Rosen et al. 2017; Li et al. 2019). However, modes of action verified by agreed procedures (World Health Organization 2020) have been established for few reported effects of PFAS, and those that have been interrogated involve activation of PPARa and, at higher doses, CAR as molecular initiating events (Klaunig et al. 2012; Rosen et al. 2017). Several AOPs involving these molecular targets are in various stages of development (Organisation for Economic Co-operation Development 2020), but few have been endorsed by the OECD following its agreed procedures (Organisation for Economic Co-operation Development 2017). Demonstration of receptor activation alone is insufficient to establish involvement of a mode of action or AOP in an

observed effect, for which an overall weight-of-evidence approach is necessary (World Health Organization 2020).

Andersen et al. (2007) provide a useful, albeit dated, review of possible PFAS modes of action. Established modes of action are restricted largely to the liver and include species-specific hepatic hyperplasia and liver tumors (Butenhoff et al. 2012; Elcombe et al. 2012; Corton et al. 2018). Available studies on PFBS, PFHxS, perfluorohexanoic acid, PFNA and PFDA suggest that they share molecular targets with similar consequences, albeit with differences in potency, in part due to differences in their excretion and protein-interaction kinetics (Zeilmaker et al. 2018). However, studies in vitro have established intrinsic differences in potency among PFAS analogues. Potency in activating PPARa showed some relationship with PFAS chain length (Wolf et al. 2008). A mode of action or AOP provides a causal chain of key events between chemical exposure and outcome. The established modes of action for PFOS and PFOA provide a causal explanation for development of liver tumors observed in rodents on exposure to these compounds, through activation of PPAR α , and the possible relevance to humans. However, this does not mean that other effects of PFAS are due to activation of PPAR α or that other pathways might not lead to liver tumors in humans, such as secondary to the primary effect of steatosis.

Until recently, there has been little study of modes of action/ AOPs for effects of PFAS other than hepatic outcomes in rodents, particularly for critical effects, such as immunosuppression and developmental toxicity, and from PFAS other than PFOS and PFOA (EFSA Panel on Contaminants in the Food Chain 2020; Temkin et al. 2020). The ability of various PFAS to interact with and modify lipid metabolism is, however, an intriguing hypothesis (Xu et al. 1999; Jones et al. 2003; Andersen et al. 2007; Tan et al. 2013; Pouwer et al. 2019). Other putative molecular initiating/key events for PFAS, in addition to nuclear receptor activation, include gap junctional inhibition to disrupt cell-cell communication, mitochondrial dysfunction, interference of protein binding, partitioning into lipid bilayers, oxidative stress, altered calcium homeostasis, and inappropriate activation of molecular signals controlling cell functions. Many of these effects are consistent with a nonspecific action of PFAS on the cellular lipid membrane (Spector and Yorek 1985; Bourre et al. 1989; Dodes Traian et al. 2012; Casares et al. 2019). However, these alternative events lack robust evidence to support a specific pathophysiological role in the multifaceted effects of PFAS. A better characterization of the modes of action/AOPs for PFAS toxicities remains an important area of future investigation, necessary to improve our understanding of PFAS impacts on human health.

At present, there is insufficient evidence to determine which of, and to what extent, these molecular interactions play a pathophysiological role in observed adverse outcomes of PFAS (Michigan PFAS Science Advisory Panel 2018). Hence, there is a need to integrate such mechanistic information into a weightof-evidence framework, first by establishing the mode of action or AOP linking a proposed chain of key events to an adverse outcome and then by demonstrating that at human exposure levels of PFAS the established AOP or mode of action is causal in the adverse outcome observed. The substantial advantage offered by such an approach is the ability to read across from representative members of appropriate PFAS groupings, based on quantitative information from new approach methodologies and exposure estimates. Hence, better characterization of the modes of action/AOPs for PFAS toxicities remains a critical area of future investigation and will allow us to understand which adversely PFAS-modified pathways must be interrogated prior to new chemicals joining this class. Predicting PFAS activity in the body should be the goal prior to approving novel PFAS for use.

New approaches for developing PFAS toxicity information

When it comes to determining which PFAS should be prioritized for further testing, there are too many chemicals, even in one subclass, for traditional approaches. Numerous creative and high-throughput methodologies are being developed and tested to provide valuable data on PFAS with no toxicity data.

Collaborative approaches. Problem formulation and approach must be guided by available equipment, funds, and technical staff, and important principles: 1) What biological activity and toxicology information can be generated in a *responsive time frame*? 2) Can this information be used to make public health decisions? 3) What are appropriate tools to bring to this problem (platforms, species/sex of cells used, metabolic competency of the model system, and data analysis)? 4) How do we organize, and what are the best mechanisms to report useful biological activity/toxicological information?

Developing "how" to evaluate potential health effects of new PFAS requires some thought to PFAS heterogeneity. Although subclass names have been suggested by several investigators (Buck et al. 2011; Wang Z et al. 2017; Sha et al. 2019), there is still disagreement on those groupings. In addition, half-lives and biological persistence are not predictable based on structure, and exposure routes may be complex. Given that traditional approaches to generate toxicity information are resource-intensive, new approach methodologies, which may include in vitro high-throughput toxicity screening and toxicokinetic testing, will be needed to inform further (in vivo) testing of PFAS.

One example of how agencies/institutes are collaborating to prioritize a list of PFAS needing further study is the REACT Program (Responsive Evaluation and Assessment of Chemical Toxicity). Scientists from the USEPA and the National Institute of Environmental Health Sciences (NIEHS) National Toxicology Program have joined forces to determine if read-across approaches would work. Essentially, they will use existing data for a data-rich substance (the source, e.g., PFOA or PFOS) as an anchor for a data-poor substance (the target, a novel PFAS), which is considered similar enough to the source substance to use the same data as a basis for the safety assessment. For example, the US National Toxicology Program 28-d PFAS or chronic PFOA data set (National Toxicology Program 2020c) could be used as an anchor. The goal is to group PFAS by biological activities and then use in vitro to in vivo extrapolation data and models to estimate oral equivalent exposures for PFAS. For example, multiple biological endpoints (Table 2) were chosen to generate data on 150 PFAS (Patlewicz et al. 2019), representing several structural subclasses for use in read-across.

Selecting assays shown in Table 2 based on PFOA and PFOS health effects covers a broad range of biology. However, because of the structural diversity of PFAS, biological activity of subclasses of PFAS may be missed; but this can be addressed in 2 ways. First, using transcriptomics as a screen, similar and unique pathways altered by different PFAS can be identified. Second, structure-activity relationships may predict potentially missing biological activities. As an example, Leadscope model predictions conducted at the NIEHS predicted biology that was covered in assays already chosen for evaluation, which increased confidence in the approaches chosen. Because model predictions are only as robust as data sets from which they are generated, these outputs should be used to identify assays for screening efforts and not as synonymous with toxicities induced by PFAS. Ultimately, the REACT program aims to prioritize PFAS for additional targeted testing and follow-up with in vivo studies as needed.

Molecular dynamics and protein interactions. Advances in computational tools, many developed for drug discovery, allow environmental and public health researchers to better anticipate some impacts of emerging contaminants even in the absence of substantial experimental data (Rabinowitz et al. 2008). For example, molecular docking and molecular dynamics to predict strengths of interactions between biomolecules and

TABLE 2: Fit-for purpose assays proposed in the REACT program

Endpoint of interest	Assay proposed
High-throughput transcriptomics	Metabolically competent human liver cells/MCF-7 (Tempo-Seq $^{ extsf{w}}$)
Hepatotoxicity	2D HepaRG [®] cells
Developmental toxicity	Zebrafish embryo assay
Developmental neurotoxicity	Multielectrode array in neonatal cortical cells and neurite outgrowth
Immunotoxicity	Cytokine alterations in human vascular endothelial cells (BioSeek®)
Hepatic clearance	Metabolic clearance in 50 donor-pooled hepatocyte suspensions
Plasma protein binding	Serum protein binding assay using human serum
Enterohepatic recirculation	Qualyst B-CLEAR [®] hepatocyte transporter assay
In vitro disposition	In vitro disposition in cell lines under study

REACT = Responsive Evaluation and Assessment of Chemical Toxicity.

contaminants can be an in vitro screening tool for assessing legacy and emerging PFAS for bioaccumulation potential, to identify potential sites of toxic action (Salvalaglio et al. 2010; Ng and Hungerbuehler 2015; Cheng and Ng 2018; Li et al. 2019) and to gain insights into toxic mechanisms (Sheng et al. 2018). Relatively strong binding with particular proteins (e.g., serum albumin, liver fatty acid binding protein) has already proven useful in correlating PFAS structure with potential for bioaccumulation (Ng and Hungerbühler 2014; Cheng and Ng 2017). Tools including molecular docking and molecular dynamics can correlate relative binding affinities of emerging PFAS with these target proteins and subsequently compare with affinities of legacy chemicals with known bioaccumulation potentials, thus providing a first-tier rapid screening mechanism (Luebker et al. 2002; Cheng and Ng 2018).

The use of fluorinated substances in pharmaceutical products has led to an unexpected data source for discovery of structural features in PFAS associated with various types of bioactivity. These data were recently used to train machine learning models to predict potential bioactivity for thousands of untested PFAS (Cheng and Ng 2019). Classification approaches such as these serve as preliminary screening tools for identifying PFAS as a first step in a tiered assessment when detailed mechanistic information is not available.

Addressing mixtures. Based on their potential for complex exposure patterns, PFAS are a mixtures issue. Communities with water-monitoring programs reporting PFAS concentrations demonstrated that they are exposed to mixtures of PFAS. This mixture may be from one or more point sources releasing multiple PFAS and/or PFAS by-products into the air and water, such as a Chemours plant in North Carolina, and suggest that exposures may be substantial (McCord and Strynar 2019). However, numerous other PFAS sources are known to impact community exposure to PFAS mixtures, such as landfill leachate, biosolids recycling, and aqueous film-forming foam contamination of drinking water sources, among others (Sunderland et al. 2019; Solo-Gabriele et al. 2020). Aqueous film-forming foam and other mixtures evident in drinking water, food packaging, health and beauty products, and food-based sources are often poorly characterized (Sunderland et al. 2019; Susmann et al. 2019).

Discussions on whether PFAS may be addressed using a relative potency framework or toxic equivalency factor approach are ongoing. Substances could be grouped by bioaccumulation and persistence (toxicokinetics), function (biology), molecular initiating events, with potency factors derived from several assays, or subclass (structural similarity).

SPECIAL CONSIDERATIONS IN FUTURE STUDY DESIGNS

Future epidemiological studies

Future human studies need to characterize immune outcomes including (and not limited to) immune effects from exposure in early pregnancy and possible roles of PFAS in initiating allergic and autoimmune processes, conditions for which a dose response is hard to predict. Interactions of immune pathways with liver and lipid toxicity deserve additional consideration.

Liver and lipid studies have reasonably characterized associations between PFAS and effects and should now address why and what to do about it. Characterization of possible a priori susceptibility, such as in the obese, is important. Human and animal lipid data suggest that future experimental studies should focus on mitochondrial toxicity, alterations in bile acid metabolism, cholestasis, and resultant steatosis. These outcomes are already known to be associated with altered serum lipids, liver enzymes, and uric acid in the human population regardless of PFAS (Cohen and Fisher 2013; Sattar et al. 2014; Arguello et al. 2015; Jensen et al. 2018).

Studies of human kidney markers related to PFAS exposures illustrate the importance of understanding physiology to inform study design choices and reasonable interpretations. These substances have complex excretion mechanics that vary with dose, state of the healthy or progressively diseased kidney, as well as a potentially additional causative effect on kidney disease outcome(s). Appropriate definition of biological and mechanistic targets and more precise investigation of PFAS subclasses will better inform study designs and research questions. For example, consistent reports of disrupted cholesterol metabolism should prompt mechanistic studies evaluating effects on steroid hormones that may influence cancer, fecundity, lactation, and developmental signals seen in human population data. More attention could be given to effects of PFAS on the hypothalamic-pituitary-gonadal axis and then reconsidered based on life stages.

The history of long-chain PFAS studies indicates that collaborative team approaches featuring clinical, epidemiologic, computational modeling, and laboratory toxicological expertise are needed. Future population designs and more sensitive analytical methodologies should address replacement chemicals, typically found as mixtures; study designs must account for shorter PFAS half-lives and unpredictable PFAS detection in exposed individuals/communities. Innovative use of biomarkers in specifically designated risk subpopulations (obesity, immune) will likely be important.

Sex differences, nonmonotonic dose responses, sensitive subpopulations

Although serum-level differences exist between men and women similarly exposed to individual PFAS, sex-dependent differences in half-life have not been reported in human populations for short-chain (PFBS, PFBA) or long-chain perfluoroalkyl acids thus far (Li et al. 2017b). Perhaps the half-life differences between the sexes is similar to interindividual variability and cannot be detected above background, or studies deriving data sets used to model half-lives were not designed to detect sex differences (convenience sampling or workers were mostly male, etc.). However, sex-specific elimination halflives are defined (Table 1) for some PFAS in rodent models. In addition, developmental exposure studies in experimental models have consistently shown effects at lower doses than adult-only exposures and should be given priority in testing replacement chemicals. In vitro and alternative models that capture developmental susceptibility are encouraged. In summary, care should be taken in testing replacement PFAS in rodent or alternative (cell-based or zebrafish, for example) models to consider 1) the possibilities of sex-based differences in elimination half-lives, 2) dose range used (to include human relevant exposures), 3) life stage represented in the model system, and 4) variability of the response to enable the use of data generated for risk assessment.

Future experimental model studies

Experimental rodent studies have been essential in confirming PFAS health effects (liver and thyroid disease, lipid homeostasis), even when effects were not identical to those in humans; in some cases, novel targets (mammary and immune changes) were identified in animals. Future animal, cellbased, and high-throughput toxicity screening should enhance transparency in reporting to include blinded dose allocation, reporting of all data, adherence to Animal Research Reporting In Vivo Experiments (ARRIVE) guidelines (Kilkenny et al. 2010), and dose ranges that approach human relevance (adjusted to reflect the differences in elimination between species and potentially chronic exposures) so that they suitably inform systematic reviews that may be used in chemical regulation.

Model selection for health effects evaluation is critical. An appropriate model should be sensitive, be susceptible to the outcome(s) of interest (obesity, immune), and produce outcomes that will inform human health effects. Alternative research models, such as transgenic mice, zebrafish, developmental models for most affected target tissues, and diet-challenged designs in susceptible rodent strains, will strengthen our knowledge of PFAS-related health effects. Validation of fish neurobehavior models to inform mammalian, including human, developmental responses is needed.

Finally, advanced human cell-based platforms—that have been validated for relevant outcomes in humans—will facilitate concurrent screening of larger numbers of PFAS, but bioavailability of PFAS in the culture system needs to be understood because binding to media proteins or labware, the instability of some PFAS in some vehicles, and altered metabolism may exist in some cases (Gaballah et al. 2020; Liberatore et al. 2020).

Future alternative approaches

One way to determine the toxicity of the large number of PFAS compounds currently used in commerce is to develop quantitative structure–activity relationships (QSAR). Such QSAR attempt to define relationships between a PFAS compound structure with a specific biological activity or response that identifies or is a biomarker for toxicity. Few data are available for receptor binding of PFAS, mainly limited to a few PFCAs and PFSAs; and even between carboxylates and sulfonates of similar chain length substantial differences have been observed (Cheng and Ng 2017, 2018). If there are substantial differences between perfluoroalkyl carboxylic and sulfonic acids, which differ only in their acid head group, construction of successful QSAR for the large and diverse class of all PFAS will be particularly challenging. Several QSAR may be developed, each predictive of toxicity of a distinct class or subclass of PFAS, based on a unique functional moiety or other feature. Although this brings additional challenges in finding sufficient data for QSAR training and validation, big data approaches, such as the recently developed machine learning models to predict PFAS bioactivity (Cheng and Ng 2019), show promise for advancing these computational approaches at the screening level.

For example, it may be determined by affinity for receptorspecific binding and nonspecific interactions with cellular membranes that the specific toxic effect exhibits a multiphasic dose response reflecting 2 potential modes of action. In addition, the critical effect may change with levels of PFAS exposure. Add to this that people are typically exposed to PFAS mixtures, each of which may have a different affinity for a binding site and ability to impact cellular membrane fluidity, and the potential to predict PFAS toxicity becomes extremely complicated. In the foreseeable future, we may be limited to assessing PFAS toxicity using high-throughput assays designed to inform regulators as to the relative toxicity of PFAS mixtures or compounds. Such approaches are suited to the use of artificial intelligence (i.e., machine learning approaches) that integrate data from multiple sources to identify bioaccumulation potential, relevant pathways triggered, protein binding affinities, and modes of action involved in the development of individual and mixture toxicity of PFAS.

The utility of any future approach to determining PFAS toxicity must consider tissue-specific modes of action. Such an approach may rely on molecular interactions with specific binding sites on enzymes/storage/transport proteins or the nonspecific ability to alter cell membrane fluidity by which membrane-bound protein activities are altered within a particular organ/system. Regardless of the mode of action, model, and/or simulation, the predictive result should be biologically plausible and represent dose–effect responses across species.

CONCLUSION

Future research on the health effects of replacement PFAS and mechanistic studies on legacy PFAS must apply "lessons learned" such as those highlighted in the present review. There are only a handful of PFAS with enough health effects data for use in decision-making, as evidenced by state-led standard setting. There are numerous health effects reported for those PFAS tested, which sets this family of chemicals apart from many others and elevates the need for precautionary action. With hundreds of PFAS lacking health effects data, translational research teams using innovative methodologies and carefully designed studies will be critical to our state of knowledge on 622

PFAS-related health effects and our enhanced strategies for informing risk assessment of this large family of chemicals.

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Separating People from Pollution

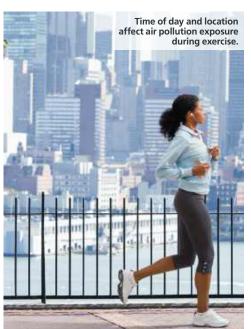
Individual and Community Interventions to Mitigate Health Effects of Air Pollutants

Efforts to minimize people's exposure to air pollution historically have focused on curbing emissions from tailpipes and smokestacks. But increases in vehicle-kilometers traveled—that is, more cars

spending more time on the road—have tempered that effect. Moreover, residential areas, hospitals, and schools often are built adjacent to main traffic arteries, where emissions are highest. An international group of public health researchers now says it's time to start separating people from sources of air pollution as a means of protecting public health [*EHP* 119(1):29– 36; Giles et al.].

Air pollution can cause myriad cardiovascular and respiratory problems including asthma, bronchitis, and heart disease. Outdoor air pollutants can easily migrate indoors, and most exposure to ambient air pollution occurs inside buildings. Recent research indicates that people living near congested highways face a greater risk of such diseases and that moving to a lesspolluted neighborhood lowers their risk.

The authors describe "promising and largely unexplored" approaches to reducing the health impact of air pollution through interventions targeted at communities and



at individuals. They base their recommendations on published studies and discussions from a 2009 workshop on this topic held in Vancouver, Canada.

The authors argue that cities can improve residents' health by considering air quality during land-use planning. For example, creating high-density, mixed-use areas would enable more people to walk or bicycle to work, school, and shops, thereby reducing emissions and encouraging more exercise; ideally, safe pedestrian and cycling greenways would be located away from traffic. For longerdistance travel, the authors suggest low-emission public transit.

And in areas where wood burning is an important heating method, woodstove exchange programs can help residents acquire cleaner-burning stoves affordably.

Risk factors for heart disease include a sedentary lifestyle, obesity, and a high-sodium diet. Therefore, the authors posit that another approach to reducing a person's risk of being affected by air pollution is to minimize one's overall risk of heart disease. This could involve interventions that encourage people to eat a diet rich in omega-3 fatty acids and antioxidants and to get regular exercise. However, because pollution levels vary even within cities, exercise should be planned to minimize exposure. Variations occur by season, with ozone being higher in the summer and particulates from woodstoves higher in the winter, for example. Traffic-related pollutants also spike during rush hour and are higher in heavily traveled areas.

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Estrogens from the Outside In Alkylphenols, BPA Disrupt ERK Signaling *in Vitro*

The body produces estrogens—including estrone (E_1), estradiol (E_2), and estriol (E_3)—that direct reproductive system processes and contribute to the normal function of tissues including the brain, bone, and cardiovascular system. Certain xenoestrogens (estrogenic compounds introduced from outside the body) are suspected of disrupting these activities. In a new study, xenoestrogenic alkylphenols and bisphenol A (BPA) interfered with normal estrogenic signaling *in vitro*, which suggests they could disrupt normal physiologic function at critical life stages [*EHP* 119(1):104–112; Jeng and Watson].

Different estrogen receptors control different functions: receptors in the cell nucleus direct gene transcription, whereas receptors in the cell membrane direct signaling pathways via extracellular signal– regulated kinases (ERKs). ERK-controlled pathways respond to many biochemical stimuli and integrate these signals to direct a cell toward division, differentiation, death, or malignant transformation. The structurally related alkylphenols and BPA interact weakly with nuclear estrogen receptors, but they can have pronounced effects on signaling pathways mediated by estrogen receptors in the cell membrane.

In the current study, a rat pituitary cancer cell line was used to study the effect of alkylphenols and BPA on ERK1 and ERK2 activation (measured as phosphorylation), both alone and in combination with each physiologic estrogen. After treatment with each physiologic and environmental estrogen, the researchers measured time-dependent surges in ERK activation. In most cases, E_1 and E_2 prompted early, intermediate, and late surges in ERK activation at 5, 10–30, and > 30 min, respectively; alkylphenols and E_3 typically triggered early and late surges. Interestingly, a very low concentration of BPA (10⁻¹⁴ M) yielded a similar two-peak response, but a higher concentration (1 nM) induced a three-peak response like that of E_1 and E_2 . Both BPA concentrations were typical of environmental exposures and, along with ineffective midrange doses, also illustrated the nonmonotonic dose–response relationship characteristic of many estrogenic compounds.

When physiologic estrogens and xenoestrogens were combined, the response pattern generally shifted to a single major peak at an intermediate time. Xenoestrogens that caused a strong response when administered alone at a particular point in time or concentration tended to inhibit ERK activation in response to a physiologic estrogen. But at other times or concentrations, the same xenoestrogen might cause a weak response on its own, in which case it would tend to enhance ERK phosphorylation in response to physiologic estrogens.

There were exceptions to these general patterns, however, which highlights the need to study effects of individual xenoestrogens at different points in time, at varying concentrations, and in different tissues. The effect of shifts in the patterns of ERK activation are only just beginning to be explored, although it is known that these patterns constitute an important component of information flow within a cell. The correct flow of information is likely to be especially critical during windows of vulnerability that are based in part on life stage.

Julia R. Barrett, MS, ELS, a Madison, WI–based science writer and editor, has written for EHP since 1996. She is a member of the National Association of Science Writers and the Board of Editors in the Life Sciences.

A Measure of Community **Exposure**

PFOA in Well Water Correlates with Serum Levels

The first detailed investigation into contamination of private wells with perfluorooctanoic acid (PFOA) and levels of the compound in human blood serum suggests that drinking water was the dominant source of exposure to PFOA in a community industrially exposed to the compound [EHP 119(1):92-97; Hoffman et al.]. The study, conducted in 2005 and 2006, included only people who obtained their drinking water from private wells. The results showed that each 1-µg/L increase of the compound in the participants' water supply was associated with a 141.5-µg/L increase in people's serum PFOA concentrations.

The participants lived around DuPont's Washington Works facility in Parkersburg, West Virginia, where PFOA (also known as C8) is used in the manufacture of Teflon' nonstick polymers. PFOA has been shown to increase risk of cancer, reproductive problems, and liver damage in laboratory animals, although human health effects are less clear. Many of the water monitoring data used in this study were collected as part of an agreement between DuPont and the U.S. Environmental Protection Agency (EPA) to conduct a human health risk assessment for PFOA.

The groundwater in the Parkersburg area had been contaminated by DuPont's releases of PFOA into the nearby Ohio River. A second source of contamination was PFOA that was released into the atmosphere and deposited onto soils, which then leached into the groundwater.

Lead Doesn't Spare the Rod Low-Level Exposure Supercharges Retinal Cell Production in Mice

Low-level gestational lead exposure has been shown to increase the electrical response of the rod signaling pathway in the retinas of children, monkeys, and rats, which could in turn contribute to retinal disease. Now researchers demonstrate the phenomenon underlying this effect:

increased proliferation of retinal progenitor cells, which give rise to functionally differentiated retinal cells that sense and transmit visual information [EHP 119(1):71-77; Giddabasappa et al.].

Using a previously described mouse model of low-level gestational lead exposure, the researchers set out to test the hypothesis that such exposure selectively increases rod photoreceptors and bipolar cells in the rod signaling pathway. (The rod signaling pathway detects gradations of light, as opposed to the cone signaling pathways, which detect colors.) Female mice were given water containing varying concentrations of lead: 0 ppm (control), 27 ppm ("low" dose), 55 ppm ("moderate" dose), or 109 ppm ("high" dose). The exposures were administered for 2 weeks before mating, during pregnancy, and through postnatal day 10-a model for the human gestation period. On postnatal day 10, unspiked water replaced the water-lead mixtures for all groups.

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Moderate Lead Control Rhodopsin & PKCa ONL INL PKCα Chx10 &

Chx10 = rod and cone bipolar cell nuclei; ONL = outer nuclear layer; INL = inner nuclear layer; IPL = inner plexiform layer; scale bar = $20 \,\mu m$

The retina comprises several layers; among them, the ONL is composed of rod and cone nuclei, while the INL is composed of bipolar cells that transmit signals from the rods and cones to retinal nerve cells as well as numerous other cell types. Gestational lead exposure selectively increased the number of rods and bipolar cells.

Previous research in this study area linked drinking water supplied by six local water districts and consumption of home-grown vegetables to PFOA levels in participants' serum [EHP 118(8):1100-1108; Steenland et al.]. The new study provides a quantitative estimate of the relationship between drinking water and serum PFOA levels based on exposure to a wider range of PFOA levels in drinking water from 62 wells. It also corroborates the earlier finding about consumption of home-grown vegetables.

Many of the wells in the study had PFOA concentrations that exceeded the EPA's 0.4-µg/L advisory level, although the median concentration in the well water samples was half that level. The concentrations of PFOA in participants' serum ranged from 0.9 to 4,751 µg/L, with a median of 75.7 µg/L, approximately 20 times the average level in the U.S. general population.

The association between PFOA in drinking water and serum was similar for both shorter- and longer-term residents of the area. The researchers found the associations held after excluding participants who reported drinking bottled water and those who worked at the DuPont facility. Compared with other factors (including age, sex, body weight, cigarette smoking, and alcohol consumption), drinking water was consistently the strongest predictor of serum PFOA levels.

The 141.5:1 ratio estimated for drinking water to serum PFOA concentrations is close to the 114:1 ratio predicted by a steady-state pharmacokinetic model employed by the authors. These findings may be useful in developing drinking water guidelines and studying other communities where PFOA is manufactured.

Kellyn S. Betts has written about environmental contaminants, hazards, and technology for solving environmental problems for publications including EHP and Environmental Science & Technology for more than a dozen years.

The adult mammalian retina consists of six types of neurons and a Müller glial cell. These cell types develop in one of two distinct phases: primarily in utero ("early-born") or primarily after birth ("late-born"). In examining controls and exposed mice at postnatal day 60, the researchers found that late-born rod photoreceptors and rod and cone bipolar cells increased by 16-30% in exposed offspring, whereas Müller glial cells (also classified as late-born retinal cells) did not increase. Low and moderate lead doses showed the greatest effects. Gestational lead exposure also increased and prolonged

retinal progenitor cell proliferation but did not alter developmental apoptosis (programmed cell death), indicating that the higher numbers of rods and bipolar cells were due to increased production, not decreased apoptosis.

These results demonstrate that gestational lead exposure resulting in blood lead levels of 10 µg/dL alters retinal development by selectively promoting the development of rod photoreceptor cells and bipolar cells. The authors speculate that the increased number of rods and bipolar cells in the lead-exposed animals could accelerate age-related retinal degeneration. These nonmonotonic dose-response results raise complex issues for neurotoxicology, risk assessment, public health, and children's health.

Angela Spivey writes from North Carolina about science, medicine, and higher education. She has written for EHP since 2001 and is a member of the National Association of Science Writers.



respondents into groups that align with the source categories identified in the rule.

Reporting facilities include, but are not limited to, those operating one or more units that exceed the CO₂e threshold for the industry sectors listed in Table A-4 of 40 CFR 98.2(a)(2) or those in the categories in which all must report, such as petroleum refining facilities and all other large emitters listed in Table A-3 of 40 CFR 98.2(a)(1). Additionally, the GHGRP requires reporting of GHGs from certain suppliers as listed in Table A-5 of 40 CFR 98.2(a)(4) and of certain emissions information associated with mobile sources (e.g., for permit applications or emissions control certification testing procedures).

Respondent's Obligation To Respond: Mandatory (Sections 114 and 208 of the Clean Air Act provide EPA authority to require the information mandated by the Greenhouse Gas Reporting Program because such data will inform and are relevant to future policy decisions).

Estimated Number of Respondents: 11,080 (total).

Frequency of Response: Annual.

Total Estimated Burden: 739,187 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total Estimated Cost: \$99,831,931 per year, which includes \$30,621,791 for capital investment and operation and maintenance costs for respondents, labor cost of \$57,210,010 for respondents, and \$12,000,130 for the EPA.

Changes in the Estimates: This change in burden reflects an update in the number of respondents, an adjustment of labor rates to 2014 Bureau of Labor and Statistics (BLS) labor rates, an adjustment of capital costs to reflect 2013 dollars, a re-evaluation of the costs to monitor and report combustion emissions across the entire program, a re-evaluation of the activities and costs associated with Petroleum and Natural Gas Systems (Subpart W) and Geologic Sequestration of Carbon Dioxide (Subpart RR), and the addition of new segments and new reporters under Subpart W.

Courtney Kerwin,

Acting Director, Collection Strategies Division.

[FR Doc. 2016-12310 Filed 5-24-16; 8:45 am] BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2014-0138; FRL-9946-91ōwi

Lifetime Health Advisories and Health **Effects Support Documents for** Perfluorooctanoic Acid and Perfluorooctane Sulfonate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: The Environmental Protection Agency (EPA) announces the release of lifetime health advisories (HAs) and health effects support documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS). EPA developed the HAs to assist federal, state, tribal and local officials, and managers of drinking water systems in protecting public health when these chemicals are present in drinking water. EPA's HAs, which identify the concentration of PFOA and PFOS in drinking water at or below which adverse health effects are not anticipated to occur over a lifetime of exposure, are: 0.07 parts per billion (70 parts per trillion) for PFOA and PFOS. HAs are non-regulatory and reflect EPA's assessment of the best available peer-reviewed science. These HAs supersede EPA's 2009 provisional HAs for PFOA and PFOS.

FOR FURTHER INFORMATION CONTACT:

Jamie Strong, Health and Ecological Criteria Division, Office of Water (Mail Code 4304T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 566–0056; email address: strong.jamie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. How can I get copies of this document and other related information?

1. Docket. EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-2014-0138. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426.

2. Electronic Access. You may access this Federal Register document electronically from the Government Printing Office under the "Federal Register" listings FDSys (http:// www.gpo.gov/fdsys/browse/ collection.action?collectionCode=FR).

II. What are perfluorooctanoic acid and perfluorooctane sulfonate and why is EPA concerned about them?

PFOA and PFOS are fluorinated organic chemicals that are part of a larger group of chemicals referred to as perfluoroalkyl substances. They were used to make carpets, clothing, fabrics for furniture, paper packaging for food and other materials (e.g., cookware) that are resistant to water, grease or stains. They are also used for firefighting at airfields and in a number of industrial processes. Both PFOA and PFOS are persistent in the environment and in the human body. Over time both chemicals have become widely distributed in the environment and have accumulated in the blood of humans, wildlife, and fish. Studies indicate that exposure to PFOA and PFOS over certain levels may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast-fed infants (e.g., low birth weight, accelerated puberty, skeletal variations), cancer (e.g., testicular, kidney), liver effects (e.g., tissue damage), immune effects (e.g., antibody production and immunity), and other effects (e.g., cholesterol changes).

III. What are health advisories?

Under the Safe Drinking Water Act, EPA may publish HAs for contaminants that are not subject to any national primary drinking water regulation. SDWA section 1412(b)(1)(F). EPA develops HAs to provide information on the chemical and physical properties, occurrence and exposure, health effects, quantification of toxicological effects, other regulatory standards, analytical methods, and treatment technology for drinking water contaminants. HAs describe concentrations of drinking water contaminants at which adverse health effects are not anticipated to occur over specific exposure durations (e.g., one-day, ten-days, and a lifetime). HAs serve as informal technical guidance to assist federal, state and local officials, as well as managers of public or community water systems in protecting public health. They are not regulations and should not be construed as legally enforceable federal standards. HAs may change as new information becomes available.

IV. Information on the Drinking Water Health Advisories for PFOA and PFOS

EPA's HA levels, which identify the concentration of PFOA and PFOS in drinking water at or below which adverse health effects are not anticipated to occur over a lifetime of exposure, are: 0.07 parts per billion (70 parts per trillion) for PFOA and PFOS. Because these two chemicals cause similar types of adverse health effects, EPA recommends that when both PFOA and PFOS are found in drinking water the combined concentrations of PFOA and PFOS be compared with the 0.07 part per billion HA level.

EPA's lifetime HAs are based on peerreviewed toxicological studies of exposure of animals to PFOA and PFOS, applying scientifically appropriate uncertainty factors. The development of the HAs was also informed by epidemiological studies of human populations that have been exposed to PFOA and PFOS. The HAs are set at levels that EPA concluded will not result in adverse developmental effects to fetuses during pregnancy or to breastfed infants, who are the groups most sensitive to the potential harmful effects of PFOA and PFOS. EPA's analysis indicates that exposure to these same levels will not result in adverse health effects (including cancer and noncancer) to the general population over a lifetime (or any shorter period) of exposure to these chemicals.

EPA's HAs for PFOA and PFOS are supported by peer-reviewed health effects support documents that summarize and analyze available peerreviewed studies on toxicokinetics, human epidemiology, animal toxicity, and provide a cancer classification and a dose response assessment for noncancer effects. On February 28, 2014, EPA released draft versions of these health effects support documents for a 60-day public comment period and initiated a contractor-led, independent public panel peer review process (79 FR 11429). The peer review panel meeting occurred on August 21-22, 2014, and included seven experts in the following areas: Epidemiology, toxicology (liver, immune, neurological and reproductive and developmental effects), membrane transport, risk assessment, pharmacokinetic models, and mode-ofaction for cancer and noncancer effects (79 FR 39386). Comments submitted to EPA's public docket during the 60-day public comment period were provided to the peer reviewers ahead of the meeting for their consideration. A peer review summary report and other supporting documents may be found at:

http://www.regulations.gov under the docket EPA–HQ–OW–2014–0138.

Dated: May 19, 2016.

Joel Beauvais,

Deputy Assistant Administrator, Office of Water.

[FR Doc. 2016–12361 Filed 5–24–16; 8:45 am] BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2015-0021; FRL-9946-40]

Pesticide Product Registration; Receipt of Applications for New Active Ingredients

AGENCY: Environmental Protection Agency (EPA). **ACTION:** Notice.

SUMMARY: EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before June 24, 2016.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the File Symbol of interest as shown in the body of this document, by one of the following methods:

• Federal eRulemaking Portal: http:// www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/ DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http:// www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone

number: (703) 305–7090; email address: BPPDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

• Crop production (NAICS code 111).

• Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. Submitting CBI. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that vou claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Registration Applications

EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

1. File Symbol: 91197–E. Docket ID number: EPA–HQ–OPP–2016–0251. Applicant: AFS009 Plant Protection,



Regulations from the Michigan SIP, which is incorporated by reference in accordance with the requirements of 1 CFR 51.5.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

• Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993), 13563 (76 FR 3821, January 21, 2011), and 14094 (88 FR 21879, April 11, 2023);

• Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

• Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal agencies to identify and address "disproportionately high and adverse human health or environmental effects" of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. EPA defines environmental justice (EJ) as "the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies." EPA further defines the term fair treatment to mean that "no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies."

EGLE did not evaluate EJ considerations as part of its SIP submittal; the CAĀ and applicable implementing regulations neither prohibit nor require such an evaluation. EPA did not perform an EJ analysis and did not consider EJ in this action. Due to the nature of the action being taken here, this action is expected to have a neutral to positive impact on the air quality of the affected area. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving EJ for people of color, lowincome populations, and Indigenous peoples.

This action is subject to the Congressional Review Act, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 12, 2024. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it

extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of this Federal Register, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference.

Dated: June 3, 2024.

Debra Shore,

Regional Administrator, Region 5.

For the reasons stated in the preamble, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

§52.1170 [Amended]

■ 2. In § 52.1170, the table in paragraph (c) is amended by removing the section heading entitled, "Hazardous Waste Management" and the entry for "R 299.9109(p)".

[FR Doc. 2024–12519 Filed 6–10–24; 8:45 am] BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141

[EPA-HQ-OW-2022-0114; FRL 8543-04-OW]

RIN 2040-AG18

PFAS National Primary Drinking Water Regulation; Correction

AGENCY: Environmental Protection Agency (EPA). ACTION: Final rule; correction.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is correcting formatting and entry designations in a final rule that was published in the **Federal Register** on April 26, 2024. The rule finalized National Primary Drinking Water Regulations under the Safe Drinking Water Act for five individual per- and polyfluoroalkyl substances (PFAS): perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO–DA, commonly known as GenX Chemicals). The rule finalized a NPDWR for two or more mixtures of PFNA, PFHXs, HFPO-DA and perfluorobutane sulfonic acid (PFBS). This document corrects formatting and entry designations in the final regulation.

DATES: Effective on June 25, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-2022-0114. All documents in the docket are listed on the https://www.regulations.gov website. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through https:// www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Alexis Lan, Office of Ground Water and Drinking Water, Standards and Risk Management Division (Mail Code 4607M), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number 202–564–0841; email address: *PFASNPDWR@epa.gov.*

SUPPLEMENTARY INFORMATION: The EPA is making several corrections for inadvertent errors in the regulatory text for the final rule:

I. Does this action apply to me?

This action makes formatting changes for the incorporation of the April 26, 2024, final PFAS National Primary Drinking Water Regulation into the Code of Federal Regulations. The agency included in the April 26, 2024, final rule a list of those entities that may be potentially affected by the final PFAS National Primary Drinking Water Regulation.

II. What does this correction do?

The EPA issued a final rule in the Federal Register on April 26, 2024 (89 CFR 32532) (FRL 8543-02-OW), finalizing National Primary Drinking Water Regulations under the Safe Drinking Water Act for PFAS: PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and as well as two or more mixtures of PFNA, PFHXs, HFPO-DA and PFBS. The EPA inadvertently listed incorrect entry designations in §141.61. This document corrects the designation of entries in the tables in § 141.61(c)(1) and §141.61(c)(2). With the corrections to §141.61(c)(1) and §141.61(c)(2), the subsequent tables in § 141.61(c) are also renumbered; tables 5 and 6 are changed to tables 3 and 4. These corrections to § 141.61 are also now reflected appropriately in amendatory instructions 7 and 8. This document corrects the final regulation.

III. Why is this correction issued as final rule?

Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(3)(B)) provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a final rule without providing notice and an opportunity for public comment. The EPA has determined that there is a good cause for making this correction final without prior proposal and opportunity for comment, because the EPA inadvertently listed the designation of entries incorrectly in §141.61 in the document published in the Federal **Register**. The EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(3)(B).

Corrections

In FR Doc. 2024–07773 beginning on page 32532 in the **Federal Register** of April 26, 2024, the EPA is making the following corrections:

§141.60 [Corrected]

■ 1. On page 32744, in the third column, in § 141.60, in paragraph (a)(4), "The effective date for paragraphs (c)(34) through (40) of § 141.61 (listed in table 4 to paragraph (c)) is April 26, 2029." is corrected to read "The effective date for § 141.61(c)(2)(i) through (vii) is April 26, 2029." ■ 2. On page 32744, starting in the third column, amendatory instruction 8 for § 141.61 and the accompanying regulatory text are corrected to read as follows:

8. Amend §141.61 by:

a. In paragraph (a), revising the introductory text and adding a table heading;

b. In paragraph (b), revising the introductory text and the table heading;

c. Revising and republishing paragraph (c); and

d. Adding paragraphs (d) and (e). The revisions and additions read as follows:

§141.61 Maximum contaminant levels for organic contaminants.

(a) The following maximum contaminant levels for volatile organic contaminants apply to community and non-transient, non-community water systems.

Table 1 to Paragraph (a)—MaximumContaminant Levels for VolatileOrganic Contaminants

* * *

(b) The Administrator, pursuant to section 1412 of the Act, hereby identifies as indicated in table 2 to this paragraph (b) granular activated carbon (GAC), packed tower aeration (PTA), or oxidation (OX) as the best technology, treatment technique, or other means available for achieving compliance with the maximum contaminant level for organic contaminants identified in paragraphs (a) and (c) of this section, except for per- and polyfluoroalkyl substances (PFAS).

Table 2 to Paragraph (b)—BAT for Organic Contaminants in Paragraphs (a) and (c) of This Section, Except for PFAS

(c) The following maximum contaminant levels (MCLs) in paragraphs (c)(1) and (2) of this section for synthetic organic contaminants apply to community water systems and non-transient, non-community water systems; paragraph (c)(2) of this section also contains health-based water concentrations (HBWCs) for selected per- and poly-fluoroalkyl substances (PFAS) used in calculating the Hazard Index.

(1) MCLs for Synthetic Organic Contaminants, Except for PFAS.

CAS No.	Contaminant	MCL (mg/l)
(i) 15972–60–8	Alachlor	0.002
(ií) 116–06–3	Aldicarb	0.003
(iií) 1646–87–3	Aldicarb sulfoxide	0.004
(iv) 1646–87–4	Aldicarb sulfone	0.002
v 1912–24–9	Atrazine	0.003
(ví) 1563–66–2	Carbofuran	0.04
(vii) 57–74–9	Chlordane	0.002
(viií) 96–12–8	Dibromochloropropane	0.0002
(ix) 94–75–7	2,4-D	0.07
x) 106–93–4	Ethylene dibromide	0.00005
(xí) 76–44–8	Heptachlor	0.0004
xii) 1024–57–3	Heptachlor epoxide	0.0002
xiii) 58–89–9	Lindane	0.0002
(xiv) 72–43–5	Methoxychlor	0.04
(xv) 1336–36–3	Polychlorinated biphenyls	0.0005
xví) 87–86–5	Pentachlorophenol	0.001
xvii) 8001–35–2	Toxaphene	0.003
xviii) 93–72–1	2,4,5-TP	0.05
(xix) 50–32–8	Benzo[a]pyrene	0.0002
(xx) 75–99–0	Dalapon	0.2
(xxi) 103–23–1	Di(2-ethylhexyl) adipate	0.4
(xxii) 117–81–7	Di(2-ethylhexyl) phthalate	0.006
(xxiii) 88–85–7	Dinoseb	0.007
(xxiv) 85–00–7	Diguat	0.02
(xxv) 145–73–3	Endothall	0.1
(xxvi) 72–20–8	Endrin	0.002
(xvii) 1071–53–6	Glyphosate	0.7
(xxviii) 118–74–1	Hexacholorbenzene	0.001
(xxix) 77–47–4	Hexachlorocyclopentadiene	0.05
(xxx) 23135–22–0	Oxamyl (Vydate)	0.2
(xxxi) 1918–02–1	Picloram	0.5
(xxxii) 122–34–9	Simazine	0.004
(xxxiii) 1746–01–6	2,3,7,8-TCDD (Dioxin)	3×10^{-8}

(2) MCLs and HBWCs for PFAS.

CAS. No.	Contaminant	MCL (mg/l) (unless otherwise noted)	HBWC (mg/l) for Hazard Index calculation
(i) Not applicable	Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA).	1 (unitless) ¹	Not applicable.
(ii) 122499–17–6 (iii) 45187–15–3 (iv) 108427–53–8 (v) 72007–68–2 (vi) 45285–51–6 (vii) 45298–90–6	PFHxS PFNA PFOA	0.00001 No individual MCL 0.00001 0.00001 0.000040 0.0000040	0.00001. 0.002. 0.00001. 0.00001. Not applicable. Not applicable.

¹ The PFAS Mixture Hazard Index (HI) is the sum of component hazard quotients (HQs), which are calculated by dividing the measured component PFAS concentration in water by the relevant health-based water concentration when expressed in the same units (shown in ng/l for simplification). The HBWC for PFHxS is 10 ng/l; the HBWC for HFPO–DA is 10 ng/l; the HBWC for PFNA is 10 ng/l; and the HBWC for PFBS is 2000 ng/l.

Hazard Index = ([HFPO–DA _{water} ng/l]/	ng/l = nanograms per liter
$[10 \text{ ng/l}]) + ([PFBS_{water} \text{ ng/l}]/[2000])$	PFAS _{water} = the concentration of a
ng/l] + ([PFNA _{water} ng/l]/[10 ng/l])	specific PFAS in water
+ ([PFHxS _{water} ng/l]/[10 ng/l]) HBWC = health-based water	(d) The Administrator pursuant to
	(d) The Administrator, pursuant to section 1412 of the Act, hereby
concentration HQ = hazard quotient	identifies in table 3 to this paragraph (d)
ng – nazaru quonent	identifies in table 5 to this paragraph (d)

the best technology, treatment technique, or other means available for achieving compliance with the maximum contaminant levels for all regulated PFAS identified in paragraph (c) of this section:

TABLE 3 TO PARAGRAPH (d)-BEST AVAILABLE TECHNOLOGIES FOR PFAS LISTED IN PARAGRAPH (c) OF THIS SECTION

Contaminant	BAT
Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA)	Anion exchange, GAC, reverse osmosis, nanofiltration.
HFPO–DA	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFHxS	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFNA	Anion exchange, GAC, reverse osmosis, nanofiltration.

TABLE 3 TO PARAGRAPH (d)—BEST AVAILABLE TECHNOLOGIES FOR PFAS LISTED IN PARAGRAPH (c) OF THIS SECTION— Continued

Contaminant	BAT
PFOA	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFOS	Anion exchange, GAC, reverse osmosis, nanofiltration.

(e) The Administrator, pursuant to section 1412 of the Act, hereby identifies in table 4 to this paragraph (e) the affordable technology, treatment technique, or other means available to systems serving 10,000 persons or fewer for achieving compliance with the maximum contaminant levels for all regulated PFAS identified in paragraph (c) of this section:

TABLE 4 TO PARAGRAPH (e)—SMALLSYSTEMCOMPLIANCENOLOGIES (SSCTS) FOR PFAS

Small system compliance technology ¹	Affordable for listed small system categories ²
Granular Activated Carbon. Anion Exchange Reverse Osmosis, Nanofiltration ³ .	All size categories. All size categories. 3,301–10,000.

¹Section 1412(b)(4)(E)(ii) of SDWA specifies that SSCTs must be affordable and technically feasible for small systems.

²The Act (ibid.) specifies three categories of small systems: (i) those serving 25 or more, but fewer than 501, (ii) those serving more than 500, but fewer than 3,301, and (iii) those serving more than 3,300, but fewer than 10,001.

³ "Technologies reject a large volume of water and may not be appropriate for areas where water quantity may be an issue.

Bruno Pigott,

Assistant Administrator.

[FR Doc. 2024–12645 Filed 6–10–24; 8:45 am] BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 200124-0029; RTID 0648-XD967]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; 2024 Red Snapper Private Angling Component Accountability Measure in Federal Waters Off Alabama, Florida, and Mississippi

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule, accountability measure.

SUMMARY: Through this temporary rule, NMFS implements accountability measures for the red snapper recreational sector private angling component in the Gulf of Mexico (Gulf) off Alabama, Florida, and Mississippi for the 2024 fishing year. Based on information provided by the Alabama Department of Conservation and Natural Resources (ADCNR), the Florida Fish and Wildlife Conservation Commission (FWC), and the Mississippi Department of Marine Resources (MDMR), NMFS has determined that landings in each of these States exceeded the State's 2023 regional management area private angling component annual catch limits (ACL) for Gulf red snapper. Therefore, NMFS reduces the Alabama, Florida, and Mississippi 2024 private angling component ACLs. This reduction will remain in effect through the remainder of the current fishing year on December 31, 2024.

DATES: This temporary rule is effective from 12:01 a.m., local time, on June 13, 2024, until 12:01 a.m., local time, on January 1, 2025.

FOR FURTHER INFORMATION CONTACT: Frank Helies, NMFS Southeast Regional Office, 727–824–5305, *frank.helies@ noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS manages the Gulf reef fish fishery, which includes red snapper, under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP). The Gulf of Mexico Fishery Management Council prepared the FMP, which was approved by the Secretary of Commerce, and NMFS implements the FMP through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). All red snapper weights discussed in this temporary rule are in round weight.

In 2015, Amendment 40 to the FMP established two components within the recreational sector fishing for red snapper: the private angling component, and the Federal charter vessel and headboat (for-hire) component (80 FR 22422, April 22, 2015). In 2020, NMFS implemented Amendments 50 A–F to the FMP, which delegated authority to the Gulf States (Alabama, Florida, Louisiana, Mississippi, and Texas) to establish specific management measures for the harvest of red snapper in Federal waters of the Gulf by the private angling component of the recreational sector (85 FR 6819, February 6, 2020). These amendments allocated a portion of the private angling ACL to each State, and each State is required to constrain landings to its allocation as part of State management.

As described at 50 CFR 622.39(a)(2)(i), the Gulf red snapper recreational sector quota (ACL) is 7,991,900 pounds (lb) (3,625,065 kilograms(kg)) and the recreational private angling component quota (ACL) is 4,611,326 lb (2,091,662 kg). These catch limits are based, in part, on landings estimates generated by the Marine Recreational Information Program (MRIP) and, prior to the 2023 fishing year, the State-specific ACLs for Alabama, Florida, Louisiana, Mississippi were also MRIP-based. These MRIP-based State ACLs are not directly comparable to the landings estimates produced by each State's survey. Therefore, in 2023, NMFS implemented a framework action under the FMP to calibrate the red snapper ACLs for Alabama, Florida, Louisiana, and Mississippi so they could be directly compared to the landings estimates produced by each of those State's data collection program (Calibration Framework)(87 FR 74014, December 2, 2022). This framework action established State-specific calibration ratios that NMFS applied to the MRIP-based ACLs to establish Statesurvey based ACLs, which allow a direct comparison to the landings estimates produced by each State.

On May 14, 2024, NMFS published a final rule for a framework action to the FMP that modified the State-specific ratios for Alabama, Florida, and Mississippi and modified each of these State's private angling component ACL based on the new ratios (89 FR 41896). That final rule will be effective on June 13, 2024, and adjusts the State-survey based ACLs as follows: the Alabama regional management area private angling component ACL will be 664,552





Per- and Polyfluoroalkyl Substances (PFAS) and Your Health

Per- and Polyfluoroalkyl Substances (PFAS) and Your Health Home

PFAS in the U.S. Population



Most people in the United States have been exposed to PFAS and have PFAS in their blood.

The National Health and Nutrition Examination Survey (NHANES) has measured PFAS-levels in blood in the U.S. population since 1999. NHANES is a program of studies designed by the Centers for Disease Control and Prevention (CDC) to evaluate the health and nutrition of adults and children in the United States. NHANES data are publicly released in 2-year cycles.

Since 2002, the production and use of PFOS and PFOA in the United States has declined. As the use of some PFAS have declined, some blood PFAS levels have gone down as well.

- From 1999-2000 to 2017-2018, blood PFOS levels declined by more than 85%.
- From 1999-2000 to 2017-2018, blood PFOA levels declined by more than 70%.

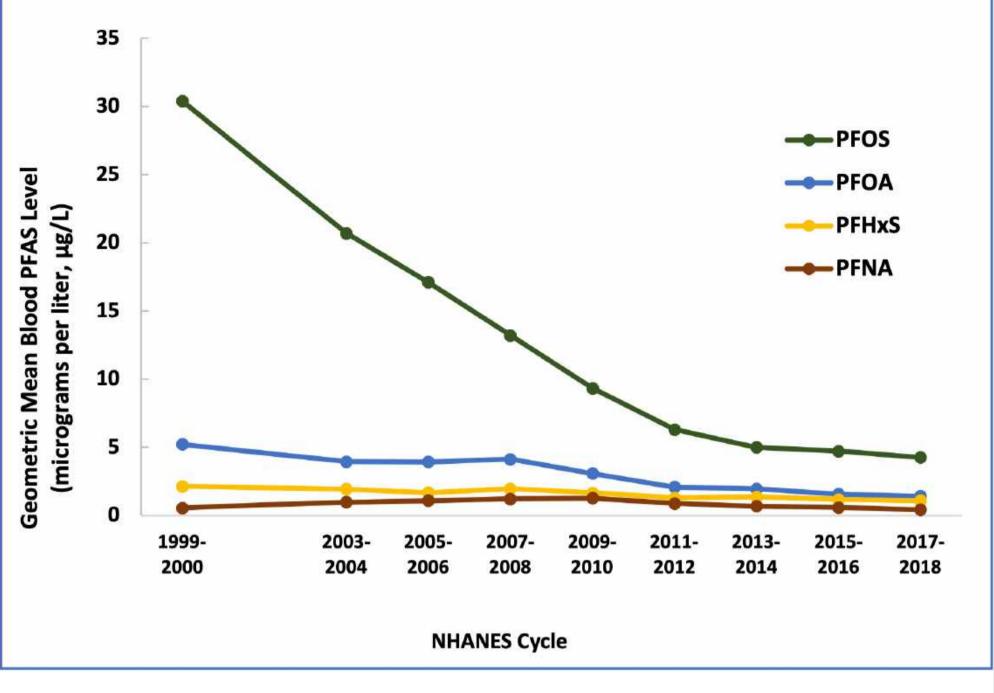
However, as PFOS and PFOA are phased out and replaced, people may be exposed to other PFAS.

Biomonitoring Studies

Biomonitoring studies have measured PFAS levels in other groups including:

- Workers in PFAS manufacturing facilities
- Communities with contaminated drinking water
- The general U.S. population

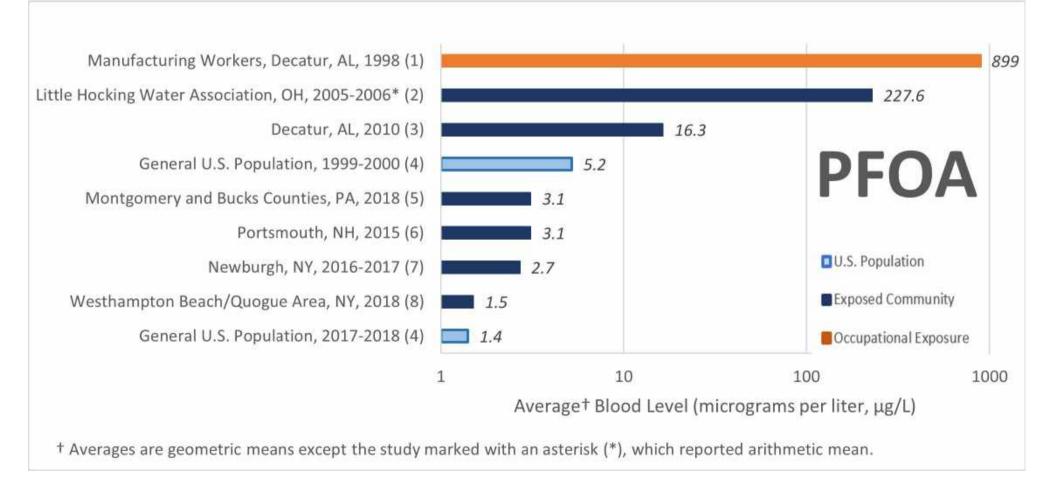
Blood Levels of the Most Common PFAS in People in the United States Over Time



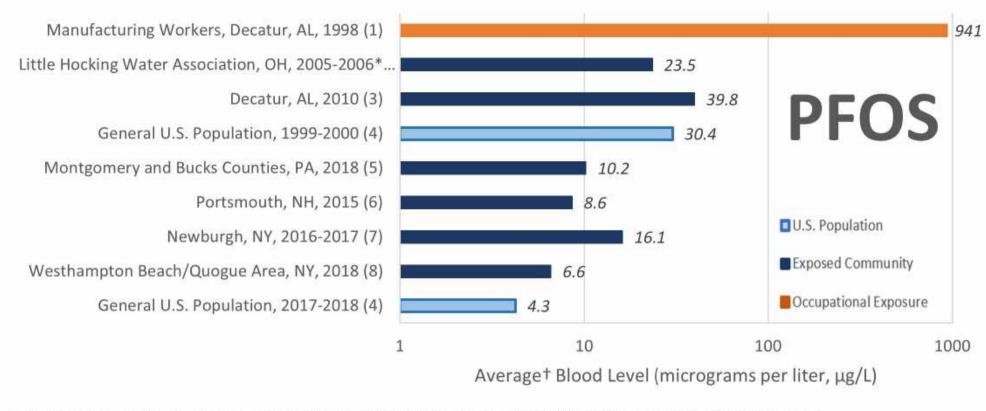
Data Source

Centers for Disease Control and Prevention. National Report on Human Exposure to Environmental Chemicals, Biomonitoring Data Tables for Environmental Chemicals. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.

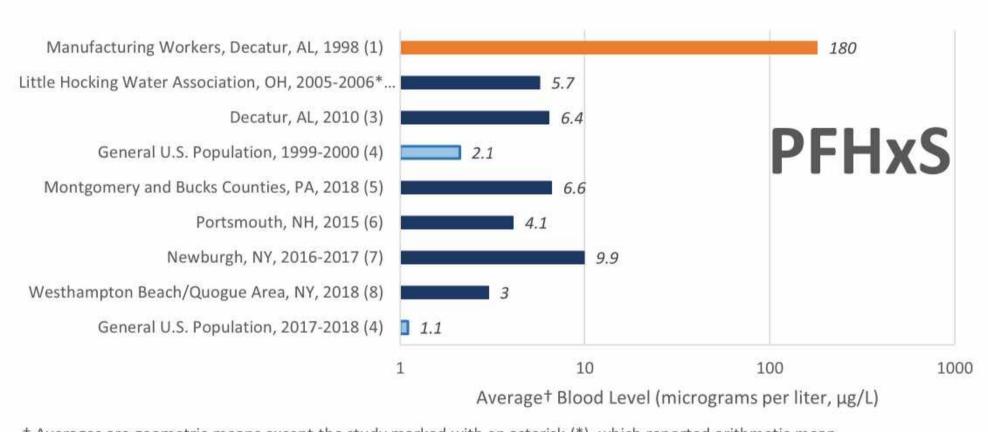
The figures below show PFOA, PFOS, and PFHxS blood levels measured in different exposed populations, compared to levels CDC measured in the general U.S. population in 1999-2000, 2015-2016, and 2017-2018. ATSDR biomonitoring information is also available through PFAS exposure assessments.







⁺ Averages are geometric means except the study marked with an asterisk (*), which reported arithmetic mean.



[†] Averages are geometric means except the study marked with an asterisk (*), which reported arithmetic mean.

References and Data Sources

- 1. G.W. Olsen, et al., 2003. https://www.tandfonline.com/doi/pdf/10.1080/15428110308984859?needAccess=true 🗹
- 2. Frisbee, et al., 2005/2006. https://ehp.niehs.nih.gov/doi/pdf/10.1289/ehp.0800379
- 3. Agency for Toxic Substances and Disease Registry, 2010.

https://www.atsdr.cdc.gov/HAC/pha/Decatur/Perfluorochemical_Serum%20Sampling.pdf 🔼

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5. Pennsylvania Department of Health, 2019.

https://www.health.pa.gov/topics/Documents/Environmental%20Health/PEATT%20Pilot%20Project%20Final%20Report%20 April%2029%202019.pdf 📙 🏼 🖆

6. New Hampshire Department of Health and Human Services, 2015. https://www.dhhs.nh.gov/sites/g/files/ehbemt476/files/documents/2021-11/pease-pfc-blood-testing.pdf 🔼 🏼 🖸

7. New York Department of Health, 2016/2017.

https://www.health.ny.gov/environmental/investigations/newburgh/docs/infosheetgroupresults.pdf 🔼 🏼 🖆

8. New York Department of Health, 2018.

https://www.health.ny.gov/environmental/investigations/drinkingwaterresponse/docs/westhampton_quogue_group_level_

blood_testing \square

For more information about PFAS visit:

ATSDR: https://www.atsdr.cdc.gov/pfas/

EPA: https://www.epa.gov/chemical-research/research-and-polyfluoroalkyl-substances-pfas 🗹

Last Reviewed: January 18, 2024

https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html#print



► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/ oemed-2017-104651).

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ORIGINAL ARTICLE

Half-lives of PFOS, PFHxS and PFOA after end of exposure to contaminated drinking water

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ABSTRACT

Background Municipal drinking water contaminated with perfluorinated alkyl acids had been distributed to one-third of households in Ronneby, Sweden. The source was firefighting foam used in a nearby airfield since the mid-1980s. Clean water was provided from 16 December 2013.

Objective To determine the rates of decline in serum perfluorohexane sulfonate (PFHxS), perfluorooctane sulfonate (PFOS) and perfluorooctanoate (PFOA), and their corresponding half-lives.

Methods Up to seven blood samples were collected between June 2014 and September 2016 from 106 participants (age 4–84 years, 53% female). **Results** Median initial serum concentrations were PFHxS, 277 ng/mL (range 12–1660); PFOS, 345 ng/mL (range 24–1500); and PFOA, 18 ng/mL (range 2.4–92). The covariate-adjusted average rates of decrease in serum were PFHxS, 13% per year (95% CI 12% to 15%); PFOS, 20% per year (95% CI 19% to 22%); and PFOA, 26% per year (95% CI 24% to 28%). The observed data are consistent with a first-order elimination model. The mean estimated half-life was 5.3 years (95% CI 4.6 to 6.0) for PFHxS, 3.4 years (95% CI 3.1 to 3.7) for PFOS and 2.7 years (95% CI 2.5 to 2.9) for PFOA. The interindividual variation of half-life was around threefold when comparing the 5th and 95th percentiles. There was a marked sex difference with more rapid elimination in women for PFHxS and PFOS, but only marginally for PFOA.

Conclusions The estimated half-life for PFHxS was considerably longer than for PFOS and PFOA. For PFHxS and PFOS, the average half-life is shorter than the previously published estimates. For PFOA the half-life is in line with the range of published estimates.

INTRODUCTION

Perfluorinated and polyfluorinated substances (PFASs) comprise a group of many different synthetic substances that have been produced and widely used for approximately 50 years. They are found in industrial applications and household products mainly due to their properties of with-standing heat, oil, dirt and water. PFASs are also used as surfactants in firefighting foam of the aqueous film forming foam (AFFF) type.¹

In the general population, the dominating sources of exposure are through diet and consumer products.² However, during the past decade it has become apparent that localised PFAS contamination to surface and groundwater occurs around

What this paper adds

- Limited information on the elimination of perfluorinated alkyl acids in humans after end of exposure has suggested half-lives of several years.
- This study provides refined estimates of halflives of perfluorohexane sulfonate (PFHxS) and perfluorooctane sulfonate (PFOS) from a highly exposed general population after end of exposure. There is substantial interindividual variability and slower excretion for men than women, for PFHxS and PFOS.
- Future research to understand the determinants of elimination is needed in order to guide risk assessment and regulatory measures for perfluorinated chemicals.

military and civilian firefighting training facilities, where large quantities of AFFF foams have been used. These substances are further disseminated by means of groundwater flows, and may also reach drinking water wells.

PFASs are excreted via urine and faeces. In animals half-lives (T¹/₂) for PFASs vary markedly between species and are usually much shorter than in humans, with elimination half-life counted in hours or days.³ Reabsorption by organic anion transporters (OATs) in the kidneys and extensive uptake from enterohepatic circulation for PFASs are believed to be more active processes in humans, slowing down the excretion of these substances. In observational studies, based on observations in individuals followed over time, T¹/₂ between 2 and 3 years was reported for perfluorooctanoic acid (PFOA), while longer half-lives for perfluorooctane sulfonic acid (PFOS) and perfluorohexane sulfonic acid (PFHxS), 4 and 7 years, respectively, have been observed (table 1). Time-trend general population studies during periods of observed decay have reported half-lives in similar ranges.

However, it should be noted that the interindividual variation in elimination of PFASs can be substantial in both high and low exposure ranges, as observed in retired fluorochemical workers and after drinking water exposure.^{4 5} Observational data and pharmacokinetical modelling indicate that PFAS half-life is likely to be shorter in women, explained partly by menstrual blood losses, but there may also be other sex-specific elimination mechanisms.⁶ Except for perfluorobutane sulfonic



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Table 1	Table 1 Half-lives for PFOS, PFHxS and PFOA in longitudinally followed l	ngitudinally followed h	humans				
				Initial PFAS level (na/mL.	Half-life (years)		
Reference	Setting	Model	Subjects	serum)	PFOS	PFHxS	PFOA
Olsen <i>et al</i> ⁴	Retired fluorochemical workers, followed 5 years Repeated samplings with batch-wise analysis	First-order elimination First and last sample	22 men, 2 women Age 55–75	Median (range) PFOS: 626 (145–3490) PFHxS: 193 (16–1295) PFOA: 408 (72–5100)	Median 4.6, range 2.4–21.7 GM 4.8 95% Cl 4.0 to 5.8	Median 7.1, range 2.2–27.0 GM 7.3 95% Cl 5.8 to 9.2	Median 3.4, range 1.5–9.1 GM 3.5 95% Cl 3.0 to 4.1
Brede <i>et al</i> ⁵	Drinking water exposure to PFOA, follow- up 2 years after installation of charcoal filters	First-order elimination First and last sample	20 children 22 mothers 23 men	Median (range) PFOS: ≈9 (2.6–33.3) PFHxS: ≈2.0 (<0.1–2.7) PFOA: ≈24 (6.4–77.5)	(Relative reduction 2006–2008, 22% in women, 25% in men)	(Relative reduction 2006–2008, (Relative reduction 2006–2008, 22% in women, 25% in men) 30% in women, 14% in men)	GM 3.26 years (range 1.03–14.67) (relative reduction 2006– 2008, 39% in women, 25% in men)
Bartell <i>et al</i> ¹²	² Drinking water exposure to PFOA, follow- up after installation of charcoal filter Repeated sampling, follow-up after 1 year	First-order elimination Mixed models, five samples per person	100 men 100 women Age 53±15	Mean, SD PFOA 180±209	1	1	Average 2.3 95% Cl 2.1 to 2.4 No sex-dependence
Gomis <i>et al</i> ¹³	³ Ski waxers, followed after marked reduction of occupational exposure		4 men	Range 250–1050	1	1	Median 2.4, range 2.0–2.8
Worley <i>et al</i> ' ¹¹	¹ Drinking water exposure to PFAS, emanating from contaminated sewage sludge applied to agricultural fields; follow- up after 6 years	One-compartment pharmacokinetic model First and last sample	First sample: 63 men, 90 women Average 52 Last sample: 22 men, 23 women	GM PFHxS: 6.4 PFOS: 39.8 PFOA: 16.3	Average 3.3	Average 15.5	Average 3.9
PFHxS, perflu	PFHxS, perfluorohexane sulfonate; PFOA, perfluorooctanoate; PFOS, perfluorooctane sulfonate.	PFOS, perfluorooctane sulfor	nate.				

Table 2Perfluorinated and polyfluorinated substance levels (ng/L)in outgoing drinking water from the two waterworks in Ronneby,Sweden, on 10 December 2013

	Brantafors	Kärragården
Perfluoropentanoic acid	38	10
Perfluorohexanoic acid	320	3.6
Perfluoroheptanoic acid	32	1.4
Perfluorooctanoic acid	100	1.0
Perfluorononanoic acid	<1	<1
Perfluorodecanoic acid	<1	<1
Perfluoroundecanoic acid	<10	<10
Perfluorododecanoic acid	<10	<10
Perfluorobutane sulfonic acid	130	<2.6
Perfluorohexane sulfonic acid	1700	4.6
Perfluoroheptane sulfonic acid	60	<1
Perfluorooctane sulfonic acid	8000	27

acid, which has a much shorter half-life, around 1 month,⁷ there are no human data after end of exposure for other PFASs.

Ronneby: a case study from Sweden

In autumn 2013 a survey of groundwater quality in Blekinge county in southern Sweden showed alarmingly high levels of PFASs in groundwater from a glaciofluvial water reservoir, the Bredåkra delta, which has a military and civil airfield located in its centre. Extended water sampling revealed very high levels of PFASs in outgoing drinking water from Brantafors, one of the two municipal waterworks in Ronneby, a municipality with 28 000 inhabitants (table 2). This waterworks provided drinking water to one-third of the households in Ronneby. The contaminated waterworks was closed on 16 December 2013, and clean water was promptly provided by Kärragården, the second waterworks in the municipality. After a few days no elevated levels of PFASs could be detected in the distribution network. Brantafors waterworks was reopened in May 2014, supplied with new coal filters and using water only from wells with low PFASs levels, but the trial was ended in October 2014. During this trial the levels of PFASs (sum of 11) were closely monitored, reaching at most 40 ng/L (ie, well below 90 ng/L, the present Swedish recommended action level).

It was soon confirmed that the fire drill site at the nearby military airport localised within the aquifer area had leached PFASs to the environment. Despite considerable efforts from the Armed Forces, it has not been possible to reconstruct the detailed historical use of AFFF at the airfield, but the best estimate as to the start of the use of these foams is the mid-1980s. Very little information on past or current PFAS content in the foams used at the facility was available, only that PFOS-containing foams were not purchased since 2004. For a general overview of AFFFs, see refs 1 and 8.

Extensive biomonitoring in the municipality population started in June 2014, approximately 6 months after end of exposure through drinking water, by open invitations and free of cost. Subjects living and working in the contaminated as well as in the uncontaminated district were invited. During the period 2014–2016 a total of 3418 persons from Ronneby participated. Considerable efforts were made to recruit persons with little exposure to the contaminated water, in order to ensure a broad range of serum PFASs levels for further research on health effects. A reference group of 242 subjects from a nearby unexposed municipality (Karlshamn) was also examined in 2016.

METHODS Study group

From among the first participants in the screening programme, volunteers were invited to participate in the half-life study until the target of 100 subjects, evenly split by gender, was achieved. The panel study group (n=106) with a large age span, 4–83 years at baseline, was established in June 2014. The proportion of women was 53%. There were 20 men aged 15–50, and 30 women (menstruating ages). The participants have donated blood regularly, initially every third month, then with longer intervals. Analysis of PFASs in serum is performed after each sampling round and the individual results are immediately reported back to the participants.

We here report findings from the first seven sampling rounds (in June 2014, October 2014, January 2015, April 2015, September 2015, March 2016 and September 2016). The median number of samples per person was 6. Continued sampling twice a year is planned for several years to come.

Chemical analysis

Plasma concentrations of PFHxS, PFOS and PFOA were analysed at the Department of Occupational and Environmental Medicine in Lund, Sweden, using liquid chromatography-tandem mass spectrometry (LC/MS/MS). The samples were analysed according to a modified method⁹ and determined as the total, non-isomer-specific compounds. The aliquots of 25 µL serum were added with 75 µL of water. A solution containing labelled internal standards were added and the proteins were precipitated using acetonitrile followed by vigorous shaking for 30 min. The samples were then centrifuged and 1 µL of the supernatant was analysed using an LC (UFLCXR, Shimadzu Corporation, Kyoto, Japan) connected to the MS/MS (QTRAP 5500, AB Sciex, Foster City, California, USA). Limits of detection determined as the concentrations corresponding to three times the SD of the responses in chemical blanks were 0.5 ng/mL for PFHxS and PFOS, and 0.4 ng/mL for PFOA. Coefficients of variation of quality control (QC) samples at 100 ng/mL were 6% for PFHxS and PFOS, and 8% for PFOA. The analyses of PFOS and PFOA are part of a quality control programme between analytical laboratories coordinated by Professor Hans Drexler, Institute and Outpatient Clinic for Occupational, Social and Environmental Medicine, University of Erlangen-Nuremberg, Germany.

Modelling of half-life

A linear mixed-effect model was used to assess predictors of subject-specific serum PFAS concentrations over time, from which we derive excretion rate and serum elimination half-lives of each PFAS. The following mixed model was used to fit the panel data:

$$In C_{ij} = \alpha_i + t_{ij}k_i + X_i\beta + \varepsilon_{ij},$$

where C_{ij} is the serum PFAS concentrations for individual *i* and sampling round *j*, α_i is the subject-specific intercept, t_{ij} is the time elapsed between the clean water was provided and the blood sample collection, k_i is the subject-specific slope, X_i is a vector of fixed covariates for individual *i*, including age, gender and body mass index (BMI), β is the fixed effect coefficient and ε_{ij} is the random error term. The subject-specific intercept α_i , the subject-specific slope k_i and the random error term ε_{ij} were modelled as random with normal distribution; others were treated as fixed effects.

The slope (k_i) is the excretion rate constant, and the mean value of k_i derived from the model was converted to half-life $(ln2/mean(k_i))$. The values of k_i were predicted using the best

WG Ex. 77

PFAS	Group	Participants (n)	Mean±SD	(Min, median, max)
PFHxS	Panel study	106	353±260	(12.3, 277, 1660)
	Main Ronneby	3418	228±232	(<0.5*, 152, 1790)
	Karlshamn reference	242	1.91±5.27	(<0.5*, 0.84, 60.1)
PFOS	Panel study	106	387±259	(24.1, 345, 1500)
	Main Ronneby	3418	245±234	(0.58, 176, 1870)
	Karlshamn reference	242	5.68±6.19	(<0.5*, 4.21, 55.3)
PFOA	Panel study	106	21.1±14.7	(2.38, 17.5, 92)
	Main Ronneby	3418	13.7±12.0	(<0.4*, 10.4, 91.9)
	Karlshamn reference	242	1.77±0.81	(<0.4*, 1.59, 4.98)

*Limit of detection.

PFAS, perfluorinated and polyfluorinated substance; PFHxS, perfluorohexane sulfonate; PFOA, perfluorooctanoate; PFOS, perfluorooctane sulfonate.

linear unbiased prediction method.¹⁰ To examine the variability of the half-life, the predicted k_i values were converted to halflives. A small number of observations were however excluded, with negative values (apparently increasing serum levels) or extremely high half-life (with minimal k_i). Summary half-life values have been presented as either a mean half-life (calculated from the mean elimination rate constant k) or as median half-life (the median value of the individually modelled half-life values). The 95% CI for mean(k_i) from the regression was used to derive the CI for the half-life, by converting as for the mean.

The analyses were repeated for the age group 15-50 (at the start), stratified by gender. An interaction term for gender and excretion rate constant was used to test the significance of a sex difference in excretion rate.

The general background exposure was not subtracted when modelling the half-life, since the PFAS levels of the last sample for all the individuals were far above what is expected in the background.

RESULTS

Serum levels at baseline

The median serum level of PFHxS was 180 times higher in the investigated Ronneby population compared with the referents from a neighbouring municipality, 42 times higher for PFOS and 6 times higher for PFOA (table 3). In the main Ronneby study group 98% of the 3418 participants had PFHxS levels over the 90th centile (2.58 ng/mL) of PFHxS levels observed in the Karlshamn group. A similar pattern was seen for PFOS, where 90% of the main Ronneby group had levels in excess of the 90th centile (9.85 ng/mL) in the Karlshamn group, and PFOA, where 85% of the main Ronneby group had levels in excess of the 90th centile (2.91 ng/mL).

The participants in the panel study initially had serum levels of PFHxS, PFOS and PFOA that were somewhat higher than in the main Ronneby study population. This difference reflected the fact that the main population, but not the panel group, included persons living in the non-exposed area of Ronneby. The base-line serum levels in the panel study group ranged from 12.3 to 1660 ng/mL for PFHxS, 24.1 to 1500 ng/mL for PFOS, and 2.38 to 92 ng/mL for PFOA (table 3).

 Table 4
 Excretion rate and half-lives for serum PFAS concentrations in 106 participants in a panel study after end of exposure through contaminated drinking water

	All	All		Men aged 15–50		Women aged 15–50	
	Mean	95% CI	Mean	95% CI	Mean	95% CI	р*
Excretion rate	e constant (per yea	ır)†					
PFHxS	0.13	0.12 to 0.15	0.09	0.07 to 0.11	0.15	0.12 to 0.18	0.008
PFOS	0.20	0.19 to 0.22	0.15	0.11 to 0.18	0.22	0.19 to 0.26	0.004
PFOA	0.26	0.24 to 0.28	0.25	0.19 to 0.26	0.29	0.23 to 0.34	0.29
Half-life (yea	rs)‡						
PFHxS	5.3	4.6 to 6.0	7.4	6.0 to 9.7	4.7	3.9 to 5.9	0.008
PFOS	3.4	3.1 to 3.7	4.6	3.7 to 6.1	3.1	2.7 to 3.7	0.004
PFOA	2.7	2.5 to 2.9	2.8	2.4 to 3.4	2.4	2.0 to 3.0	0.29

The subgroup aged 15-50 includes 20 men and 30 women.

*p Values for the difference between genders in the model for excretion rate.

†The estimates in the table are adjusted for age, gender and body mass index in a mixed-effects model.

#Half-life values are all calculated from excretion rate constant.

PFAS, perfluorinated and polyfluorinated substance; PFHxS, perfluorohexane sulfonate; PFOA, perfluorooctanoate; PFOS, perfluorooctane sulfonate.

Age at baseline had a strong effect on serum PFHxS, PFOS and PFOA concentrations with average increases of 1.5%, 1.4% and 1.1% per year of age, respectively. Gender and BMI were not associated with any of the PFAS at baseline.

Decline of serum levels during follow-up

The average decreases in serum level were for PFHxS 25%, for PFOS 35% and for PFOA 38% from June 2014 to September 2016.

Table 4 shows the results for each excretion rate constant and the corresponding half-life in models for each PFAS. The mean excretion rate constant for PFHxS was 0.13, which is the annual change in log concentration, equivalent to the concentration of PFHxS in serum reducing by 13% per year since clear water was provided. This excretion rate constant is equivalent to a mean half-life of 5.3 (95% CI 4.6 to 6.0) years. For PFOS, the annual decrease was 20%, and the mean half-life was 3.4 years (95% CI 3.1 to 3.7 years). The average decrease in PFOA was 26% of its previous value each year, corresponding to a mean half-life of 2.7 years (95% CI 2.5 to 2.9 years).

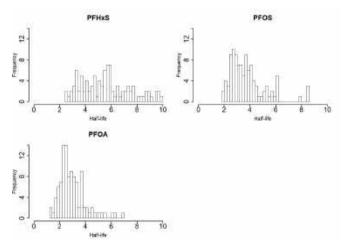


Figure 1 The interindividual variation of half-lives for perfluorinated and polyfluorinated substances in 106 participants in a panel study after end of exposure through contaminated drinking water, excluding outliers. PFHxS, perfluorohexane sulfonate; PFOA, perfluorooctanoate; PFOS, perfluorooctane sulfonate.

The distributions of half-lives are shown in figure 1, after exclusion of outliers for the fitted estimated half-life as follows: one with a negative half-life (n=1 for PFHxS) and nine over 10 years (n=8 for PFHxS, n=1 for PFOS). The median value of the remaining half-lives for PFHxS was 5.5 years (5%–95% range: 3.0-9.2 years). For PFOS, the median half-life was 3.5 years (5%–95% range: 2.2-6.2 years). For PFOA, the median half-life for PFOA was 2.7 years (5%–95% range: 1.8-5.1 years).

Women aged 15–50 had a considerably shorter mean halflife for PFHxS compared with men (table 3), with men 1.6-fold longer. For PFOS the pattern was similar, with men 1.5-fold longer. For PFOA the difference was small. The distributions of half-lives in women and men aged 15–50 are illustrated in online supplementary figure S1.

DISCUSSION

Among 106 persons observed between 6 and 33 months after end of exposure to PFAS-contaminated drinking water, the shortest half-life was observed for PFOA with a mean of 2.7 years. The half-life for PFHxS was twice as long, 5.3 years, and for PFOS the mean was 3.4 years. These results are somewhat shorter than the prior results for PFOS and PFHxS, based on observations in 24 retired fluorocarbon workers, to our knowledge the only other study that hitherto has reported apparent half-lives for PFOS and PFHxS after end of exposure that was substantially higher than the general population background.⁴ The retired workers, all but two men, were older than our population, had higher serum levels of PFOA and PFOS, and were followed for a longer period, 5 years. For PFHxS, the apparent half-life has been estimated to be 15.5 years in a recent study from a community with residential exposure to PFAS.¹¹ The PFHxS levels in serum in that study were much lower than in our study, that is, 6.4 ng/mL vs 152 ng/mL. Furthermore, their population still had ongoing exposure, and a pharmacokinetic modelling approach based only on water intake was used to account for ongoing exposure. In our study, the background exposure was not subtracted when modelling half-life since the exposure levels in the general population from all sources were negligible compared with earlier drinking water intake in the study population. Our estimate of apparent halflife, which was obtained after a documented abrupt end of the dominating source of exposure, is thus a reliable estimate of the actual half-life of PFHxS.

Our estimate of apparent half-life for PFOA is in the range of values reported from five studies with averages ranging from 2.3 to 3.94 years, observed in fluorocarbon workers⁴; studies in populations living in PFOA-polluted areas around production plants, followed for 1–2 years after provision of clean drinking water^{5 12}; occupationally exposed ski waxers¹³; and a study in a community exposed residentially to PFAS.¹¹ For PFOS, the population half-life has been estimated to be 4.3 years from studies in US blood donors reflecting general population reduction in exposure.¹⁴ After an abrupt end of a dominating source of exposure, as in Ronneby, the finding of a shorter apparent half-life is as expected.

The interindividual variation in half-life was substantial, with a threefold difference between the 5th and 95th percentiles in each of the three PFAS, plus a few extreme outliers with extremely long half-lives. Large interindividual differences were also observed in retired fluorocarbon workers⁴ and in the general population after end of drinking water exposure.^{5 12} The variability between individuals, and between men and women, has not yet been adequately explained.

Blood loss due to menstruation accounts partly for a shorter elimination half-life in women, and was estimated to account for 30% of the discrepancy in elimination of PFOS between men and women.⁶ In this respect, the marked gender difference in elimination of PFHxS, as observed in our study and by Brede *et al*⁵ but not for PFOA (our study and Bartell *et al*¹²), with PFOS in between, is intriguing. Elimination pathways that are sex-specific and substance-specific appear to exist.

Reabsorption by OATs in the kidneys and extensive uptake from enterohepatic circulation for PFOS and PFOA are active processes that may differ between individuals, but also between different PFASs. An increased renal PFAS elimination at high doses indicates a capacity-limited, saturable renal resorption process via high-efficiency OATs,^{15–16} which may have sex-different expression.¹⁷ Moreover, in a PFOA-exposed US population, the excretion rate was related to polymorphisms (single-nucleotide polymorphisms; SNPs) in tubular transporter proteins.¹⁸ Faecal elimination is little studied in humans, with the exception of some case reports that indicate that cholestyramine, a lipid-lowering pharmaceutical, may enhance elimination.¹⁹

In addition to differences between individuals as to excretion capacity, recent data using paired human serum and urine samples for estimation of T^{1/2} have indicated marked differences between excretion of PFASs with different chain-length and isomers.²⁰ It is likely that linear isomers are preferentially retained,²¹ but observational longitudinal human data on the excretion of linear versus branched chain isomers are absent. Thus, variation of T^{1/2} between populations and between individuals using total PFOS, PFOA and PFHxS determinations (as in this study) may in part reflect body burdens with different isomer composition.

Such differences are likely to be found in humans, given the varying production methods of PFAS over time. Synthesis of PFAS is by electrochemical fluorination or fluorotelomerisation. Electrochemical fluorination was used from the 1950s until the early 2000s and yielded branched and linear isomers. By contrast, fluorotelomerisation, which was later introduced, produces almost exclusively linear compounds.²² The fire-fighting foams used over time have differed in composition, but there may also be varying fate of different PFAS structural isomers during soil and groundwater transportation. Thus, it is of importance to include determination of both linear and branched isomers of PFOS, PFHxS and PFOA in order to understand differences in observed half-lives.

Refined estimates of the half-lives of PFAS compounds and the important denominators of variance are needed to reconstruct historical exposure for epidemiological studies as well as to project future exposures for risk assessment.

Out of the hundreds of PFAS compounds now available, only PFOS is internationally regulated according to the Stockholm Convention, and PFOA is on the candidate list. The human data on PFHxS uptake and elimination are hitherto very limited. The present observations confirm the long persistence of this compound after end of external exposure—a rough extrapolation based on the mean half-life indicates that 10-year-old children from the contaminated water district cannot expect to attain the same PFHxS levels as their peers in the neighbouring town of Karlshamn until the age of 60–70. Thus, even after prompt end of external exposure, AFFF contamination of drinking water can result in very high exposure levels in a life-course perspective in local general populations. Hence, the need for precautionary regulations for classes of PFASs is imperative.

Limitation

The main limitation of the present first analysis is that the serum samples were analysed during a 2-year period and each individual's samples were not analysed in the same batch. All samples were analysed at the same laboratory with the same methods and work-up procedure. However, there is a need to reanalyse all samples from each individual in the same batch to reduce laboratory variation, especially when determinants for variation in half-lives are investigated. This is planned as a next step in our studies.

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