IN THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 17-2473

KRISTEN GIOVANNI, et al., Appellants,

v.

UNITED STATES DEPARTMENT OF THE NAVY, *Appellee*.

On Appeal from the Order of the District Court of the Eastern District of Pennsylvania, Civil Action No. 16-04873 (Honorable J. Pappert)

BRIEF OF AMICI CURIAE IN SUPPORT OF APPELLANTS

Suzanne Novak NY Bar No. 292574 Earthjustice 48 Wall Street, 19th Fl. New York, NY 10005 (212) 845-7376 snovak@earthjustice.org

Counsel for Amici Curiae

DATED: October 5, 2017

TABLE OF CONTENTS

TABLE OF AUTHORITIES iii						
PREL	IMIN	ARY STATEMENT 1				
IDEN	TITY	AND INTEREST OF AMICI				
ARGUMENT						
I.	MEDICAL MONITORING IS A CRITICAL TOOL TO REDUCE AND TREAT CATASTROPHIC MEDICAL HARMS CAUSED BY EXPOSURE TO TOXIC SUBSTANCES					
	A.	It is Well-Documented that PFC Exposure Is Linked to Many of the Medical Conditions Amici and Their Families Have Suffered				
	B.	Medical Monitoring Can Prevent and Minimize Adverse Health Effects Caused by Exposure to Toxic Chemicals Such as PFCs 14				
II.		CLA DOES NOT BAR PLAINTIFFS' CLAIM UNDER THE HSCA HEALTH ASSESSMENTS AND MEDICAL MONITORING 18				
	A.	EPA and ATSDR's Roles under CERCLA in Devising and Implementing Responses to Hazardous Waste Contamination 18				
	B.	Plaintiffs' HSCA Claim Does Not Constitute a "Challenge to Removal or Remedial Action Selected."				
CONCLUSION						
LOCA	AL RU	LE 28.3 STATEMENT				
LOCAL RULE 31.1 STATEMENT						
CERTIFICATE OF COMPLIANCE						

CERTIFICATE OF SERVICE

TABLE OF AUTHORITIES

CASES	PAGE(S)
Boarhead Corp. v. Erickson, 923 F.2d 1011 (3rd Cir. 1991)	
Burlington Northern and Santa Fe Railway Co. v. U.S., 556 U.S. 599 (2009)	
Donovan v. Philip Morris USA, Inc., 455 Mass. 215 (Mass. 2009)	
Durfey v. E.I. DuPont De Nemours & Co., 59 F.3d 121 (9th Cir. 1995)	
<i>Fiorentino v. Cabot Oil & Gas Corp.</i> , 750 F. Supp. 2d 506 (M.D. Pa. 2010)	15
Hanford Downwinders Coal., Inc. v. Dowdle, 71 F.3d 1469 (9th Cir. 1995)	
Key Tronic Corp. v. United States, 511 U.S. 809 (1994)	
Pritikin v. Department of Energy, 254 F.2d 791 (9th Cir. 2001).	
Redland Soccer Club, Inc. v. Department of the Army and Department of Defense, 696 A.2d 137 (Pa. 1997)	
<i>Sutton v. St. Jude Medical S.C., Inc.,</i> 419 F.3d 568 (6th Cir. 2005)	
U.S. v. E.I. Dupont De Nemours & Co. Inc., 432 F.3d 161 (3d Cir. 2005)	

FEDERAL STATUTES

42 U.S.C. § 9604(a)(1)

42 U.S.C. § 9604(i)(1)(E)	19
42 U.S.C. § 9604(i)(6)	19
42 U.S.C. § 9604(i)(9)	19
42 U.S.C. § 9605(a)(8)(B)	19
42 U.S.C. § 9606(a)	18
42 U.S.C. § 9613(h)	19
42 U.S.C. § 9622(a)	18
42 U.S.C. § 9622(f)(3)	18
42 U.S.C. § 9622(f)(5)	18

STATE STATUTES

35 Pa. Cons. St. § 6020.702(a)(5)
----------------------------------	---

REGULATIONS

40 C.F.R. § 300.400(h)	
------------------------	--

LEGISLATIVE HISTORY

H.R. Rep. No. 99-253(I) (1985), reprinted in 1986 U.S.C.C.A.N. 2835 23	3
H.R. Rep. No. 99-253 (III) (1985), reprinted in 1986 U.S.C.C.A.N. 3038 23	3

OTHER AUTHORITIES

Maj.	Staff	of the	Subco	omm. (On Inv	restiga	tions a	and Ov	versight	of the	Comm.	
01	n Sci.	and Te	ech., 1	l 1 1 th (Cong.,	Rep. o	on AT	SDR (Comm.	Print 2		23

GLOSSARY OF ACRONYMS AND ABBREVIATIONS

ATSDR	Agency for Toxic Substances and Disease Registry
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
HSCA	Hazardous Sites Cleanup Act
MS	Multiple Sclerosis
NIEHS	National Institute of Environmental Health Sciences
NPL	National Priorities List
PFC	Perfluorinated compounds
PFOS	Perfluorooctane sulfonate
PFOA	Perfluorooctanoic acid
PLCs	Probable Link Conditions
WHO	World Health Organization

PRELIMINARY STATEMENT

Plaintiffs allege that the Defendant, the U.S. Department of the Navy, disposed hazardous chemicals, including perfluorinated chemicals ("PFCs") such as perfluorooctanoic acid ("PFOA") and perfluorooctane sulfonate ("PFOS"), that in turn contaminated public and private water sources of area residents, including their own. Joint Appendix ("J.A.") at 21, 25, 106. Exposure to PFCs is associated with risk of severe adverse medical effects. Because those risks, such as the risk of developing various cancers, can be ameliorated if caught early by medical monitoring programs, the State of Pennsylvania, through the Pennsylvania Hazardous Sites Cleanup Act ("HSCA"), instituted a private process by which a party could seek response costs for medical monitoring. See 35 Pa. Cons. St. § 6020.702(a)(5). The United States District Court for the Eastern District of Pennsylvania (the "District Court"), however, dismissed Plaintiffs' claim under the HSCA (the "District Court Order"), concluding that a state medical monitoring claim cannot be maintained against a potentially responsible party under the federal Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA") while a clean-up at the alleged source of the contamination is ongoing pursuant to CERCLA. J.A. at 119.

As discussed below, the District Court's conclusion is not mandated by this Court's prior decisions. Moreover, as explained by two Ninth Circuit cases, the District Court's conclusion is contrary to the language and intent of CERCLA. And, for the reasons discussed herein, a medical monitoring program would be of great benefit to *Amici*, who represent current and former members of Plaintiffs' community who have witnessed family and community members suffer from deadly cancers and other medical effects linked to PFC exposure.

IDENTITY AND INTEREST OF AMICI

Brendan Boyle, Lori Cervera, Renee Frugoli, Hope Grosse, Yvonne Love, Minde Ruch, Joanne Stanton, and Jacquelyn Rose Wiest (collectively, "*Amici*") are persons who currently or formerly lived close to the Naval Air Station Joint Reserve Base Willow Grove ("Willow Grove Base") in Willow Grove, Pennsylvania, and/or the Naval Air Warfare Center Warminster ("Warminster Base") in Warminster, Pennsylvania (collectively, the "Naval Bases"), and are, or have been, exposed to contaminants and hazardous substances released from the Naval Bases. Like Plaintiffs, *Amici* are all concerned about the health effects they and their families have suffered or will suffer as a result of that exposure. By filing this brief, *Amici* seek to illuminate the importance of medical monitoring for such exposed persons. They further seek to show how an affirmance of the District Court's order dismissing Plaintiffs' complaint will ensure that those persons in Pennsylvania and New Jersey subject to some of the nation's most

contaminated land will be deprived of meaningful monitoring, contrary to the intentions of the U.S. and their state governments.¹

Brendan Boyle is 49 years old and grew up in Warminster, Pennsylvania, down the street from the Warminster Base. He currently lives in Churchville, Pennsylvania approximately twelve minutes from the Warminster Base.

When Brendan's mother was only 45 years old, she died from breast cancer. His father was diagnosed with kidney cancer and passed away from it. His brother was diagnosed with lung cancer in his late 30s and passed away at age 41. Two of Brendan's aunts moved to Warminster from Ireland and after years of living near the Warminster Base, they passed away at age 60 and 45 from lung cancer and breast cancer, respectively.

Brendan's only child was diagnosed with a rare form of brain cancer at 11 years old. Doctors told Brendan that the cancer was a germ cell cancer that is related to both testicular and ovarian cancer. His son was treated with chemotherapy and radiation and eventually recovered.

After losing so many of his family members to cancer and enduring the trauma of having a critically ill child, Brendan wants to do everything possible to protect himself,

¹ Pursuant to Federal Rule of Appellate Procedure 29(a), *Amici* do not require leave of court to file this brief because all parties have consented to its filing. Pursuant to Federal Rule of Appellate Procedure 29(c)(5)(A)-(B), *Amici* affirm that counsel for the Appellees provided comments on a draft of this brief, but the Appellees made no financial contribution to the preparation or submission of this brief.

his family, and the community from risks associated with exposure to PFCs and other contaminants from the Warminster Base. Brendan would like medical testing and monitoring for him and his family to ensure their health and safety.

Lori Cervera lives approximately one quarter mile from the Willow Grove Base in Willow Grove, Pennsylvania. She moved there with her husband and four children in 2000 from Philadelphia because she believed life would be cleaner and safer in the suburbs.

Lori has no family history of multiple sclerosis ("MS") or cancer. In 2007, Lori was diagnosed with MS. In 2014, Lori was diagnosed with stage 2 cancer in her kidney, which resulted in the removal of almost half of her right kidney. After years of being cancer free, doctors recently discovered an abnormal cyst on her right ovary and a small mass on her left kidney. Additionally, Lori also suffered an ectopic pregnancy. She worries that toxic exposure to chemicals may also affect the reproductive systems of her four daughters.

These afflictions have not only damaged Lori's body, but have taken a toll on her entire family. Lori sees a therapist to deal with the emotional toll of the devastating health effects she has suffered. She would like medical testing to be provided for her own well-being and to protect the future health of her daughters and other children in her community.

Renee Frugoli grew up just down the road from the Warminster Base and now lives approximately three miles from the base. Renee's family has suffered significant health issues. Renee's sister developed stage 3 breast cancer at 33 years old. Renee experienced fertility issues, but conceived twins with the help of in vitro fertilization. One of her twins, F.F. was diagnosed with a Wilms tumor—stage 5 kidney cancer—at three years of age. The cancer soon spread to F.F.'s kidneys, lungs, and liver. Doctors told Renee that her daughter would likely die. During her treatment, F.F. endured nine months of five different chemotherapy drugs, some of which she received for five consecutive days at a time; multiple blood transfusions; multiple platelet transfusions; 11 rounds of radiation from here neck to her pelvis; and the removal of her right kidney and one-third of her left kidney. During treatment F.F. also contracted vancomycin-resistant enterococci, a dangerous infection that required her to receive treatment in isolation. Miraculously, despite the dire expectations, F.F survived.

Renee's family will always be affected by F.F's experience. Renee, her husband, and F.F.'s twin were all diagnosed as suffering from post-traumatic stress disorder and anxiety from watching F.F. suffer through her near-death experience. Renee herself at times is very overwhelmed, knowing that contaminated water may still run through their pipelines. She buys bottled water for her whole family, which has become expensive. However, it is a cost that she is willing to pay considering the life and death consequences that further exposure could have on her family.

Renee now does fundraising and advocates for awareness around PFC exposure. She has engaged in peaceful protests for more transparency and action around the contamination in Warminster. She spoke out against the proposed building of an elementary school over the contaminated site. Renee never wants another child to endure what F.F. did.

Hope Grosse was born in Warminster, Pennsylvania in 1964, and for the first 25 years of her life (until 1989) she lived directly across the street from the Warminster Base. Runoff from the base formed a creek, which migrated from the base to her family's property. Hope's family had a private well in their yard, which was the source of their water for drinking, bathing, brushing their teeth, use in their swimming pool, and mixing baby formula for her and her siblings when they were babies. During and after college, Hope worked on the Warminster Base, during which time she drank the water from the well on the base.

It was later discovered that over 75 chemicals from the base had seeped into the groundwater, which contaminated Hope's family's well water. Firefighting foams containing PFCs were also used on the base's firefighting training area, and those PFCs were found to have contaminated the municipal water supply and private drinking-water wells. Hope's family had switched to using municipal water in 1996.

Hope recalls her family's pets having tumors during her childhood. Then, in 1990, Hope's father died from brain cancer at 50 years old. Other neighbors died at an early

age as well. Three months later, at age 25, Hope was diagnosed with stage 4 melanoma, the most serious form of skin cancer, that had spread into her lymph nodes and into her blood. After five years of treatment, Hope went into remission. During her treatment, doctors also removed rare tumors from her body. Hope still gets yearly chest x-rays, MRIs, CAT scans, and blood work because the cancer could possibly reappear in her lungs or liver. Hope's sister, Faith, has serious health and autoimmune issues, including ovarian cysts, Lupus, fibromyalgia, abdominal aortic aneurysm, and vertebral aneurysm. Hope has two adult children, one of whom has multiple health issues. Almost all members of her family have suffered the loss of many of their teeth.

Hope is now an activist engaged in raising awareness of the toxic water situation in Warminster and around the country. She works to change policies and laws so that our children and grandchildren will not be poisoned, particularly by their own government.

Yvonne Murphy Love grew up on Penrose Lane in Warminster, Pennsylvania, down the road from the Warminster Base. When Yvonne was 9 years old, her older sister Michelle was diagnosed with acute myelogenous leukemia, at age 11. Michelle's doctors explained that this form of leukemia typically forms only in adults over 60 years old. They remarked that it was very rare for a child to have it, and asked their mother about environmental exposures. Michelle died 10 months after her diagnosis. After reading about contamination from the Warminster Base, Yvonne believes her sister's fatal illness was caused by exposure to hazardous chemicals. Yvonne's mother was diagnosed with breast cancer this year.

Yvonne is now an artist and an assistant professor of art at Penn State Abington College. She lives in Chalfont, Pennsylvania, 8 miles from the Warminster Base. Much of her artwork is about the loss of her sister. Yvonne's most recent project is the "Weight of Water," an interactive program that incorporates the various components of the water crisis in Warminster. It features medical records, scientific literature, ethnographies, portraits of residents, and digital reproductions of the Warminster Base to tell the story of how chemical contamination has impacted her life and her hometown.

Minde Ruch and her family live in Ivyland, Pennsylvania, approximately one mile from the Warminster Base. Minde and her husband moved to Ivyland with their two young daughters in 2002. Minde's youngest daughter, Rachel, was diagnosed with myelogenous leukemia when she was 16 years old. Doctors told Minde that this form of cancer typically forms only in adults over 60 years old. Rachel's doctor told Minde that the cancer was not genetic and that he had never seen anything like Rachel's case. In a fight to save her life Rachel endured chemotherapy and a bone marrow transplant. However, at 19 years old, Rachel succumbed to her illness and passed away. Minde has to purchase bottled water, and lives with great anxiety, not knowing if the land surrounding her is slowly poisoning her and her family. Joanne Stanton is 52 years old and grew up on Mueller Road in Warminster, Pennsylvania, near both the Warminster Base and the Willow Grove Base. In Joanne's adolescence, several of her friends' parents that lived on her street died prematurely of various cancers. Joanne recalls the Athletic Director at Archbishop Wood High School in Warminster, where Joanne attended and later worked, expressing concern since the 1970s that the municipally-provided water at the school, which was used to fill water jugs for the athletes, always had a yellow tinge and unpleasant odor.

After moving away from Warminster for a brief time to attend college, Joanne returned to her childhood home on Mueller Road while pregnant with her son Patrick. She lived there for the first six months of her pregnancy and regularly drank the tap water.

At six years old, Patrick was diagnosed with a cancerous brain tumor. His doctors immediately informed Joanne that a brain tumor in such a young child is very rare. They asked Joanne many questions about her and her son's environmental exposures and where she lived during her pregnancy, explaining that a fetus' brain develops during the first six weeks of pregnancy. Soon after the diagnosis, doctors informed Joanne that embryotic tissue was found inside of Patrick's tumor, which indicated that the tumor may have started to develop during pregnancy.

Three years after Patrick's diagnosis, the son of Joanne's childhood friend from Mueller Road was diagnosed with the same type of brain tumor as Patrick. Within the

last few years, Joanne further learned that the son of another childhood friend, who also grew up on Mueller Road and across the street from Joanne, was also diagnosed with a brain tumor. All of the tumors were cancerous.

Seeking answers and understanding after her son's diagnosis, Joanne returned to college to complete a B.S. in Public Health from Temple University, where she graduated first in her class. Joanne continues to learn of many alarming and rare health problems among people from her childhood community and their children. Based on her studies, Joanne believes the contaminated drinking water may have caused the medical devastation among her friends and family, contamination that shows no signs of abating. In 2014, two PFCs, PFOA and PFOS, were detected in private drinking-water wells and municipal drinking-water wells in her childhood hometown and surrounding towns. The Naval Bases used those toxic chemicals in routine firefighting exercises since the 1970s and took responsibility for the contamination.

The medical diseases linked to environmental exposure and suffered by people who grew up in Warminster and their children led Joanne to dedicate her life to the betterment of public health. She recently published a medically reviewed book entitled *Behind Closed Doors: Uncovering the Practices Harming Our Children's Health and What We Can Do About It*, an expose about the declining health of an entire generation of American children caused by poor industry practices, and steps that can be taken to reverse that trend. Jacquelyn Rose Wiest is 25 years old and has lived in Warminster, Pennsylvania, her whole life, approximately one mile from the Willow Grove Base and two miles from the Warminster Base. She lives with her parents and her two younger brothers. Jacquelyn knows many people in the community who suffer from serious health conditions that are linked to contaminants detected in the local water supply. She is concerned for her health and the health of her family. Additionally, she is concerned about the increased risk of diseases for any potential future children she may bear that could result from the accumulation of toxins in her body.

Jacquelyn will not drink water from the local water supplier because she does not trust that it is safe for her to drink. But that is not enough to allay her concerns. She wants a health risk assessment and medical monitoring done for her, her family, and her community so they can prevent diseases from developing, and can make informed decisions about whether to have children. She cannot, however, afford to pay for such testing and screening, nor does she think she should have to. She did not voluntarily choose to expose herself to the harmful toxins that the Naval Bases have released and dispersed into her community.

ARGUMENT

I. MEDICAL MONITORING IS A CRITICAL TOOL TO REDUCE AND TREAT CATASTROPHIC MEDICAL HARMS CAUSED BY EXPOSURE TO TOXIC SUBSTANCES.

A. It is Well-Documented that PFC Exposure Is Linked to Many of the Medical Conditions Amici and Their Families Have Suffered.

PFCs are found ubiquitously in blood samples across the U.S. population.² PFOA

and PFOS are among the most common and most extensively studied PFCs. Elevated

levels of PFOA and PFOS have been observed in occupational workers and individuals

living near sites contaminated with PFCs that have leached into ground water.³

PFCs have relatively long half-lives and it may take 2-9 years for certain PFCs to be fully

excreted from the human body.⁴ Prolonged presence of these toxicants in the body

results in an increased likelihood of adverse outcomes, long after the source of exposure

is removed.

² See Agency for Toxic Substances and Disease Registry ("ATSDR"), *Draft Toxicological Profile for Perfluoroalkyls* (Aug. 2015) (*hereinafter* "ATSDR 2015"), https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf; *see also* EPA, Proposed Rule, Perfluoroalkyl Sulfonates; Proposed Significant New Use Rule, 71 Fed. Reg. 12,311 (Mar. 10, 2006). Citations to scientific authorities have been placed in footnotes for readability purposes.

³ See Calafat A.M., et al. Polyfluoroalkyl chemicals in the U.S. population: data from the National Health and Nutrition Examination Survey (NHANES) 2003-2004 and comparisons with NHANES 1999-2000, 115(11) Envtl. Health Persp. 1596, 1596-1602 (2007); see also EPA, Long-Chain Perfluorinated Chemicals (PFCs) Action Plan, (Dec. 30, 2009), https://www.epa.gov/sites/production/files/2016-

^{01/}documents/pfcs_action_plan1230_09.pdf.

⁴ See Olsen G.W., et al. *Half-life of serum elimination of perfluorooctanesulfonate, perfluorohexanesulfonate, and perfluorooctanoate in retired fluorochemical production workers*, 115 Envtl. Health Persp. 1298, 1298-1305 (2007).

Studies of acute and chronic toxicological effects have found that exposure to PFCs may "reduce immune function; cause adverse effects on multiple organs, including the liver and pancreas; and cause developmental problems in...offspring exposed in the womb."⁵ Epidemiological studies of PFOA exposure in the general population have found adverse reproductive effects, including effects on sperm morphology, motility, and reproductive hormone levels.⁶ Women exposed to higher levels of PFOS and PFOA experienced longer time-to-pregnancy (>12 months) when compared to women with lower levels of the same PFCs (6 months or less).⁷

Of particular concern are the myriad of carcinogenic outcomes associated with PFC exposure, including cases of increased deaths from prostate, kidney, and testicular cancer.⁸ Indeed, an evaluation of data conducted by the U.S. Environmental Protection Agency ("EPA") found elevated incidences of cancer—including brain, testicular, kidney, and bladder cancers as well as myeloid leukemia—in persons exposed to PFOA. Many *Amici* or their family members have suffered with these conditions.⁹ The National

https://www.atsdr.cdc.gov/sites/pease/documents/perflourinated_chemicals_508.pdf. ⁶ See Vested, A., et al. *Persistent organic pollutants and male reproductive health*, 16(1) Asian J. Androl. 71, 71–80 (2014).

⁵ See NIEHS, Perfluorinated Chemicals (PFCs) (Sept. 2012),

⁷ ATSDR 2015 at 184.

⁸ *Id.* at 15.

⁹ See EPA, Health Effects Document for Perfluorooctanoic Acid (PFOA) (Feb. 2014) (hereinafter "EPA 2014") at 4-28,

https://nepis.epa.gov/Exe/ZyPDF.cgi/P100IRZ1.PDF?Dockey=P100IRZ1.PDF.

Toxicology Program is currently completing a long-term carcinogenicity review for PFOA.¹⁰ Additional studies of the adverse effects of PFC exposure are ongoing.¹¹

B. Medical Monitoring Can Prevent and Minimize Adverse Health Effects Caused by Exposure to Toxic Chemicals Such as PFCs.

The purpose of medical monitoring is to conduct screening to anticipate diseases before they occur. Screening tests are designed to "detect and treat abnormal changes that could later develop into a disease."¹² The detection of a disease before it becomes symptomatic is beneficial if there are available treatments known to be effective when started early.¹³

There are benefits to early detection of adverse health effects that may result from PFC exposure, particularly for diseases with a long latency period, like cancer and developmental toxicity. Indeed, early detection of certain cancers has been found to

https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0072602/.

¹⁰ See National Toxicology Program ("NTP"), *Testing Status of Perfluorooctanoic Acid M910070* (last updated Sept. 22, 2017), https://ntp.niehs.nih.gov/testing/status/agents/ts-m910070.html.

¹¹ See EPA 2014.

¹² See Institute for Quality and Efficiency in Health Care, *Benefits and risks of screening tests* (last updated Dec. 27, 2016),

¹³ See World Health Organization ("WHO"), *Screening* (last visited Oct. 4, 2017), <u>http://www.who.int/cancer/prevention/diagnosis-screening/screening/en/</u>.

improve survival rates and reduce morbidity and costs.¹⁴ For example, a recent article stated "if colorectal cancer is detected early, 95% of sufferers survive. Only 6% survive if the cancer reaches stage four. For many cancers, early detection is 'our greatest opportunity to improve survival.'"¹⁵ In 2017, ATSDR published a fact sheet describing the many ways that PFCs can affect public health and discussing the availability of diagnostic testing, including information specific to pregnant women, that can detect potential health effects resulting from PFC exposure.¹⁶

Courts have routinely acknowledged the importance and benefits of medical monitoring for persons exposed to toxic chemicals. *See, e.g., Redland Soccer Club, Inc. v. Dep't of the Army and Dep't of Defense of the U.S.,* 696 A.2d 137, 145 (Pa. 1997) (noting "important public health interest in fostering access to medical testing for individuals whose exposure to toxic chemicals creates an enhanced risk of disease") (citation and quotation marks omitted); Fiorentino v. Cabot Oil & Gas Corp., 750 F.

 ¹⁴ See Pepe, M.S., et al. Phases of Biomarker Development for Early Detection of Cancer,
 93 J. of the Nat'l Cancer Inst. 1054, 1054–1061 (July 2001),
 <u>https://academic.oup.com/jnci/article/93/14/1054/2906203/Phases-of-Biomarker-Development-for-Early</u>; see also WHO, Screening,

http://www.who.int/cancer/prevention/diagnosis-screening/screening/en/ ("[w]hen planned effectively, appropriately financed and implement[ed], screening can reduce deaths from cancer and, in some cancer type[s]...can also reduce the risk of developing cancer.").

¹⁵ See Technology Quarterly Targeting Tumours, *The Economist* (Sept. 16 2017), http://www.economist.com/technology-quarterly/2017-09-16/treating-cancer.

¹⁶ See ATSDR, *Talking to Your Doctor about Exposure to PFAS* (Aug. 18, 2017), <u>https://www.atsdr.cdc.gov/pfc/docs/Talking_to_Doctor.pdf</u>.

Supp. 2d 506, 511 (M.D. Pa. 2010) (explaining that surveillance to monitor effects of exposure to toxic chemicals is "reasonable and necessary" when early diagnosis of toxic contaminant valuable for serious disease and exposure has been extensive); *Sutton v. St. Jude Medical S.C., Inc.*, 419 F.3d 568, 575 (6th Cir. 2005) ("[T]here is something to be said for disease *prevention*, as opposed to disease *treatment*. Waiting for a plaintiff to suffer physical injury before allowing any redress whatsoever is both overly harsh and economically inefficient.") (emphasis in original). As the Massachusetts Supreme Court explained:

Modern living has exposed people to a variety of toxic substances. Illness and disease from exposure to these substances are often latent, not manifesting themselves for years or even decades after the exposure. . . [P]hysiological changes may occur which . . . are warning signs to a trained physician that the patient has developed a condition that indicates a substantial increase in risk of contracting a serious illness or disease and thus the patient will require periodic monitoring.

Donovan v. Philip Morris USA, Inc., 455 Mass. 215, 225 (Mass. 2009).

Successful medical monitoring programs for persons exposed to toxic chemicals, such as PFCs, have been implemented in the United States. For example, in 2005, a class action lawsuit against DuPont regarding its facility in Woodbridge, West Virginia, led to a medical monitoring program for PFOA.¹⁷ The class members were part of communities

¹⁷ See C-8 Medical Panel 2013, Information on the C-8 (PFOA) Medical Monitoring Program Screening Tests Prepared by the Medical Panel for the C-8 Class Members (Nov. 18, 2013), <u>http://www.c-</u> 8medicalmonitoringprogram.com/docs/med_panel_education_doc.pdf. affected by the release of, and subsequent chronic exposure to, PFOA.¹⁸ The medical monitoring program led to the formation of a science panel and a medical panel to identify and administer recommendations regarding the potential adverse health effects resulting from exposure to PFOA. Based on extensive research, the science panel identified six "Probable Link Conditions" ("PLCs") found to be linked to exposure to PFOA, including: high cholesterol; thyroid disease; ulcerative colitis; testicular cancer; kidney cancer; and high blood pressure during pregnancy.¹⁹

Subsequently, the medical panel established a set of recommendations regarding the myriad of medical screening tests that members could have performed based on the PLCs. It also issued recommendations as to when individuals should seek screening tests that were stratified by age, gender and pregnancy status. Moreover, the medical panel set forth the benefits and risks resulting from early detection of each PLC. By and large, the medical panel found that the benefits of screening for persons exposed to PFOA greatly outweighed any harms.

A similar medical monitoring program would be of great benefit to *Amici*, who have been exposed to PFCs and other chemicals from the Naval Bases; whose families have suffered severe adverse medical effects linked to PFC exposure; who are concerned for their own well-being and that of their families and communities; and who are

¹⁸ *Id.* at 1.

¹⁹ Id.

concerned about having children after watching the children of so many exposed people develop and suffer unusual and deadly cancers.

II. CERCLA DOES NOT BAR PLAINTIFFS' CLAIM UNDER THE HSCA FOR HEALTH ASSESSMENTS AND MEDICAL MONITORING.

A. EPA and ATSDR's Roles under CERCLA in Devising and Implementing Responses to Hazardous Waste Contamination.

CERCLA is a "comprehensive statute that grants the President broad power to command government agencies and private parties to clean up hazardous waste sites." Key Tronic Corp. v. United States, 511 U.S. 809, 814 (1994). It is "designed to promote the cleanup of hazardous waste sites and to ensure that cleanup costs are borne by those responsible for the contamination." Burlington Northern and Santa Fe. Ry. Co. v. U.S., 556 U.S. 599, 601 (2009). EPA plays a broad role in implementing CERCLA, both in developing and overseeing the clean-up plan. See, e.g., U.S. v. E.I. Dupont De Nemours & Co. Inc., 432 F.3d 161, 164-65, 173-74 (3d Cir. 2005); 42 U.S.C. §§ 9622(a), (f)(3), (f)(5); 40 C.F.R. § 300.400(h). A CERCLA clean-up may be accomplished either through (1) an EPA-supervised private-party cleanup, or, (2) a government conducted cleanup, after either of which the government can recover its cost from responsible parties, which may include private parties or other government agencies. 42 U.S.C. § 9604(a)(1), § 9606(a); Burlington Northern, 556 U.S. at 609; Dupont, 432 F.3d at 164-65.

Although focused on cleaning up hazardous waste sites, CERCLA includes provisions that could, in theory, lead to federally-devised medical monitoring of persons exposed to the contamination from those Superfund sites. When a site meets the necessary hazardous waste criteria under CERCLA, it is placed on the National Priorities List ("NPL") in order to effectuate the cleanup of that site. 42 U.S.C. § 9605(a)(8)(B). ATSDR must then perform a health assessment within one year of a facility being proposed for the NPL. *Id.* § 9604(i)(6). If ATSDR concludes that a significant increased risk of adverse health effects from hazardous substance exposure is associated with the site, then it shall develop and initiate a medical monitoring program, and it has discretion to initiate such a program in other circumstances as well. *See id.* § 9604(i)(1)(E), (i)(9).

B. Plaintiffs' HSCA Claim Does Not Constitute a "Challenge to Removal or Remedial Action Selected."

CERCLA contains a "Timing of Review" provision to ensure that CERCLA-

supervised clean-ups do not get delayed by litigation challenging the selected clean-up

plan. More specifically, CERCLA provides that:

No Federal court shall have jurisdiction under Federal law... or under State law which is applicable or relevant and appropriate under section 9621 of this title (relating to cleanup standards) **to review any challenges to removal or remedial action selected** under section 9604 of this title, or to review any order issued under section 9606(a) of this title.

42 U.S.C. § 9613(h) (emphasis added). The District Court held that this Court's decision in *Boarhead Corporation v. Erickson*, 923 F.2d 1011, 1018 (3rd Cir. 1991), compelled

dismissal of Plaintiffs' claims under Pennsylvania's HSCA for lack of jurisdiction under 42 U.S.C. § 9613(h). J.A. at 105. The District Court determined that the Ninth Circuit's holding in *Durfey v. E.I. DuPont De Nemours & Co.*, 59 F.3d 121(9th Cir. 1995), that state law medical monitoring claims were not barred by § 9613(h), was not well reasoned.

The District Court's conclusions are in error. Both this Court in *Boarhead*, and the Ninth Circuit in *Durfey* and *Hanford Downwinders Coalition, Inc. v. Dowdle*, 71 F.3d 1469 (9th Cir. 1995), correctly concluded that § 9613(h) removes court jurisdiction from considering, and therefore bars, claims that challenge the federal government's actions, only *in its role under CERCLA as selector of the removal or remedial actions* that would interfere with *clean-up* of a Superfund site. The Ninth Circuit cases explained that § 9613(h) does not deprive courts of jurisdiction to hear private claims for medical monitoring of health effects related to the *release* of hazardous releases by a contaminator, even if the contaminator may separately be a party responsible for *clean-up* of a Superfund site under CERCLA.

Boarhead involved a suit against EPA, in its oversight role for, and selector of, CERCLA clean-up activities, a fact critical to this Court's holding in the case. 923 F.2d at 1018-19. EPA had designated the property as a Superfund site on its NPL and informed Boarhead Corporation that it considered the company a potential responsible party for the contamination. *Id.* at 1014. Boarhead then sued EPA seeking, *inter alia*, a stay of any EPA activities affecting its farm. *Id.* at 1015. This Court held that dismissal under § 9613(h) for lack of jurisdiction was proper. *Id.* at 1023-24. It explained that Congress gave EPA authority to expeditiously respond to serious hazards and did not want that authority "stopped in its tracks by legal entanglement before or during the…clean-up." *Id.* at 1018-19 (noting that the plain language of the provision "shows Congress's intent to limit a private party's ability to challenge the EPA's activities under CERCLA" until clean-up was complete).

Two Ninth Circuit opinions relating to the same Superfund site, issued within months of each other, squarely held that § 9613(h) does not bar private claims for medical monitoring. *See Durfey*, 59 F.3d at 123; *Hanford*, 71 F.3d at 1471. In *Durfey*, the plaintiffs sued several contractors that had operated the Hanford Nuclear Reservation, a government owned plutonium production site, alleging state tort claim for medical monitoring. 59 F.3d at123. The Ninth Circuit held that the claims against the potentially responsible parties were not "selected removal or remedial action" barred by § 9613(h). *Id.* at 126. The *Durfey* Court further held that whether ATSDR may perform medical monitoring in the future had no bearing on whether the plaintiffs' private claims could proceed. *See id*.²⁰

Later that year, in *Hanford Downwinders Coalition, Inc. v. Dowdle*, 71 F.3d 1469, the Ninth Circuit held that a suit against ATSDR seeking to compel the agency to conduct medical monitoring related to the Hanford Nuclear Reservation *was* a challenge barred by § 9613(h). 71 F.3d 1469. The Court explained that § 9613(h) bars a medical monitoring claim during an ongoing CERCLA clean-up only when the defendant is a federal agency, usually EPA, charged with devising a remedial plan under CERCLA, not when the defendant is a potentially responsible party under CERCLA. *Id.* at 1471. It thus distinguished *Durfey*, explaining that ATSDR, created as part of CERCLA specifically tasked with health-related duties, was, like EPA, part of the *government's* core response in selecting and devising a clean-up plan. *Id.* at 1474, 1477-78.²¹

²⁰ The Court stated that if medical monitoring were a "removal" or "remedial" action under CERCLA, then medical monitoring claims would constitute an impermissible "challenge" to such actions while a clean-up was ongoing. *See Durfey*, 59 F.3d at123. It noted that CERCLA referenced "monitoring" and "health and welfare" in the definitions of "removal" and "remedial actions," but held that such language "is directed at containing and cleaning up hazardous substance releases," and that "[m]onitoring longterm health has nothing to do with preventing such contact." *Id.* at 125-26 (citation omitted). Thus, it held that the presence of those terms in the definitions did not command a different result. *Id.*

²¹ Despite its authority to do so, ATSDR rarely initiates a medical monitoring program. ATSDR did not exercise its medical monitoring authority for fourteen years prior to the 1997 decision to implement medical monitoring at the Hanford site. *See Durfey*, 59 F.3d at 125; CDC Newsroom, *Announcement of ATSDR's Decision on Medical Monitoring for Hanford*, CDC (March 1997), <u>https://www.cdc.gov/media/pressrel/radiat1.htm</u>. And

This Court should adopt the reasoning of the Ninth Circuit and reverse the District Court's holding that Plaintiffs' state law claims constitute an impermissible challenge to a selected removal or remedial action under § 9613(h). Legislative history confirms that a challenge to the federal government's authoritative role for selecting and devising a clean-up plan under CERCLA—a challenge absent from Plaintiffs' claim—was the concern underlying the passage of § 9613(h). *See, e.g.*, H.R. Rep. No. 99-253(III), at 23 (1985), *reprinted in* 1986 U.S.C.C.A.N. 3038, 3046 ("This provision is not intended to allow review of the selection of a response action prior to completion of the action...."); H.R. Rep. 99-253(I), at 81 (1985), *reprinted in* U.S.C.C.A.N. 2835, 2863 ("[T]here is no right of judicial review of the Administrator's selection and implementation of response actions until after the response action have been completed to their completion."); *see also Hanford*, 71 F.3d at 1477.

even after determining that medical monitoring was necessary at Hanford, ATSDR never began the medical monitoring program—thus prompting the *Hanford Downwinders Coal., Inc. v. Dowdle* lawsuit—because of funding disputes between ATSDR and the responsible party, the Department of Energy. *See Pritikin v. Department of Energy*, 254 F.2d 791 (9th Cir. 2001). And neither the ATSDR nor the CDC's websites indicate any other subsequent instance where ATSDR exercised its authority to initiate a medical monitoring program, even when independent experts concluded such programs were necessary. *See, e.g.*, Maj. Staff of the Subcomm. on Investigations and Oversight of the Comm. on Sci. and Tech., 111th Cong., Rep. on ATSDR (Comm. Print 2009). The absence of ATSDR-initiated medical monitoring programs highlights the need to maintain state alternatives for implementing medical monitoring programs to protect those who have been exposed to hazardous chemicals.

Here, Plaintiffs did not sue EPA, ATSDR, or another federal agency charged with devising and implementing a CERCLA clean-up plan. Similarly, Plaintiffs claims are not premised upon allegations regarding the federal government's core response in selecting and devising a clean-up plan. And no medical monitoring is currently taking place for the affected communities. J.A. at 26. Rather, Plaintiffs seek relief from an alleged release of contaminants and hazardous chemicals because of alleged harms resulting from exposure to such releases-irrespective of any CERCLA clean-up. See J.A. 0025-27. Indeed, an affirmance of the District Court's Order would mean that all state law claims for medical monitoring would be barred if the defendant is a potential responsible party for an ongoing CERCLA clean-up. That would lead to the perverse result that claims pursuant to state medical monitoring laws promulgated to save lives, would be severely delayed, and thus rendered meaningless, *only* for those people for whom medical monitoring is most important—those people living near, and potentially exposed by, sites recognized by the federal government as among the most hazardous in the country. Such a result is neither required nor just.

CONCLUSION

For the foregoing reasons, *Amici* respectfully request that this Court reverse the District Court Order and remand the matter for further proceedings.

Dated: October 5, 2017

Respectfully submitted,

/s/Suzanne Novak

Suzanne Novak NY Bar No. 292574 Earthjustice 48 Wall Street, 19th Fl. New York, NY 10005 (212) 845-7376 snovak@earthjustice.org

Counsel for Amici Curiae

LOCAL RULE 28.3 STATEMENT

Counsel hereby certifies, in accordance with 3d Cir. L.A.R. 28.3(d), that the undersigned has applied for admission to the United States Court of Appeals for the Third Circuit.

DATED: October 5, 2017

LOCAL RULE 31.1 STATEMENT

Counsel hereby certifies, in accordance with 3d Cir. L.A.R. 31.1(c), that the text of the electronic **Brief of Amici Curiae** is identical to the text in the paper copies. Further, counsel certifies that a virus detection program has been run on this file and that no virus was detected. The virus detection program used was version 10.2.5.3201 of Kaspersky Endpoint Security.

DATED: October 5, 2017

CERTIFICATE OF COMPLIANCE

Counsel hereby certifies, in accordance with Federal Rules of Appellate Procedure 29(a)(5) and 32(g)(1), that the foregoing **Brief of Amici Curiae** contains 5,808 words, as counted by counsel's word processing system, and thus complies with the 6,500 word limit.

Further, this document complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5) & (a)(6) because this document has been prepared in a proportionally spaced typeface using **Microsoft Word 2010** using **size 14 Times New Roman** font.

DATED: October 5, 2017

CERTIFICATE OF SERVICE

I hereby certify that I have served the foregoing Brief of Amici Curiae on all

parties through the Court's electronic case filing (ECF) system.

DATED: October 5, 2017