DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Hearing on "Examining the Federal response to the risks associated with per- and polyfluoroalkyl substances (PFAS)"

Testimony before the
Senate Committee on Environment and Public Works

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Reviewers: This testimony is based on prior cleared testimony. The highlighted passages are new to this version.

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Chairman Barrasso, Ranking Member Carper, Distinguished Members of the Senate Committee on Environment and Public Works, thank you for inviting me to testify at this hearing on a topic of increasing interest to the scientific community and to the greater public. I am Linda Birnbaum, the Director of the National Institute of Environmental Health Sciences (NIEHS) within the National Institutes of Health (NIH). I am also the Director of the National Toxicology Program (NTP), which serves to develop and coordinate toxicological testing across the Department of Health and Human Services, to conduct hazard assessments of toxic substances, and to manage the Interagency Coordinating Committee on the Validation of Alternative Methods. For the past 40 years I have conducted primary research in toxicology, and I am here today in my role as Director of NIEHS to provide a scientific perspective about the large, complex, and ever-expanding class of chemicals known as per and polyfluoroalkyl substances (PFAS).

The National Institute of Environmental Health Sciences (NIEHS)

The NIEHS is one of several Federal agencies actively working to address various aspects related to PFAS. The NIEHS mission, as set forth under the Public Health Service Act, is to conduct and support research, training, and health information dissemination with respect to environmental factors that may affect human health, directly or indirectly.[2] With this mandate, NIEHS researchers use state-of-the-art science and technology to investigate the interplay between environmental exposures, human biology, genetics, and human disease to help prevent illness, morbidity, and mortality, and improve human health. No age group or disease is beyond the NIEHS mission. Considering this fact, NIEHS researchers collaborate with their peers at the other NIH Institutes and Centers focused on specific life stages, organ systems, or diseases.

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[2] Sections 126(g) and 209(b) of the Superfund Amendments and Reauthorization Act of 1986. [HYPERLINK "https://www.govinfo.gov/content/pkg/STATUTE-100/pdf/STATUTE-100-Pg1613.pdf"]. October 17, 1986. ([HYPERLINK "http://uscode.house.gov/view.xhtml?req=(title:42%20section:9660a%20edition:prelim)%20OR%20(granuleid:USC-prelim-title42-section9660a)&f=treesort&edition=prelim&num=0&jumpTo=true"] and [HYPERLINK "http://uscode.house.gov/view.xhtml?req=(title:42%20section:9660%20edition:prelim)%20OR%20(granuleid:USC-prelim-title42-section9660)&f=treesort&edition=prelim&num=0&jumpTo=true"], respectively).

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hazardous substances in the environment; advanced techniques for the detection, assessment, and evaluation of the effects on human health of hazardous substances; methods to assess the risks to human health presented by hazardous substances; and basic biological, chemical, and physical methods to reduce the amount and toxicity of hazardous substances.

For nearly three decades,[3] NIEHS has been the leading Federal agency sponsoring basic research investigating health effects associated with human exposures to PFAS. NIEHS-supported research uses human observational studies, animal models, *in vitro* tissue and cell culture systems, *in silico* approaches, and high throughput screening to study the effects of environmental exposure.

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The research conducted to date reveals associations between PFAS exposures and a variety of specific adverse human health outcomes. These include the potential for effects on children's cognitive and neurobehavioral development, immune system dysfunction, endocrine disruption, obesity, diabetes, lipid metabolism, and cancer. While knowledge about these epidemiologic associations has steadily expanded in recent years, many questions remain unanswered. The NIEHS and NTP, in coordination with other Federal agencies and State and local governments, continue to conduct research to enhance our understanding of the potential mechanisms and biological processes through which PFAS may be affecting human health.

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Per and Polyfluoroalkyl Substances (PFAS)

Before detailing the health effects associated with PFAS exposures, it is necessary to describe this class of chemicals. First created in the 1930s and 1940s, PFAS include some 4,700 man-made chemicals that contain fluorine atoms bonded to a carbon chain.[4] The carbon-fluorine bond is one of the strongest ever created by man and is rarely seen in nature. The unique chemical composition of PFAS imparts desirable physical and chemical properties for consumer and industrial products, such as oil and water repellency, high and low temperature stability, and friction reduction. These properties have led to PFAS incorporation in a wide range of consumer products, including textiles, paper products, semiconductors, automotive and aerospace components, cookware, food packaging, and stain repellant clothing. Deliberative Process / Ex. 5

[3] Harris MW, Birnbaum LS. Developmental Toxicity of Perfluorodecanoic Acid in C57BL/6N Mice. *Fundam. Appl. Toxicol.* 1989; 12(3):442-448. DOI: [HYPERLINK "https://doi.org/10.1093/toxsci/12.3.442"].
[4] While approximately 4,700 fluorine-containing, man-made compounds have been created, not all of these compounds have entered into commerce or been actively used.

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Our scientific understanding of PFAS compounds stems almost entirely from studies on a select few. Deliberative Process / Ex. 5

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PFOA and PFOS are considered "long-chain" PFAS due to the length of their carbon chain backbones and have been studied for several decades. A wide range of "short-chain" PFAS have been introduced recently as alternatives to the linear, "long-chain" compounds. All PFAS have garnered increased attention by both the scientific community and the public. Current efforts within the NIEHS and NTP to greatly enhance our understanding of additional long-chain as well as short-chain PFAS are detailed later in this testimony.

The chemical composition of PFAS impart high stability for product design, and this characteristic makes PFAS extremely stable in the environment. In fact, PFAS and complex PFAS degradation products remain in the environment for so long that scientists are unable to accurately estimate an environmental half-life. As PFAS are incorporated into more diverse processes and products, they have greater potential for release into the environment.

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Deliberative Process / Ex. 5 As part of our portfolios, NIEHS and NTP contribute substantively to the field of alternatives assessment to ensure harmful chemicals are not replaced by similarly harmful but less well-studied related compounds.

Human Exposures

Humans are exposed to PFAS through myriad pathways, practices, and products. Ingestion, particularly through drinking water, is the predominant human exposure pathway for many individuals or communities,[6] but recent studies suggest that other exposure pathways, including

[5] Hu XC, Andrews DQ, Lindstrom AB, Bruton TA, Schaider LA, Grandjean P, Lohmann R, Carignan CC, Blum A, Balan SA, Higgins CP, Sunderland EM. Detection of Poly- and Perfluoroalkyl Substances (PFASs) in U.S. Drinking Water Linked to Industrial Sites, Military Fire Training Areas, and Wastewater Treatment Plants. *Environ. Sci. Technol. Lett.* 2016; 3(10):344-350. DOI: [HYPERLINK "https://doi.org/10.1021/acs.estlett.6b00260"].
[6] Agency for Toxic Substances and Disease Registry (ATSDR). Routes of Exposure and Health Effects. An Overview of Perfluoroalkyl and Polyfluoroalkyl Substances and Interim Guidance for Clinicians Responding to Patient Exposure Concerns. Interim Guidance. Revised on May 7, 2018. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service. Internet: [HYPERLINK

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inhalation and dermal absorption, are significant for human exposure.[7,8,9,10] Deliberative Process / Ex. 5

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Human exposures to PFAS are extremely widespread. The Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics' 2011–2012 U.S. National Health and Nutrition Examination Survey (NHANES) reported detectable PFAS blood serum concentrations in virtually all individuals (97 percent).[14] Deliberative Process / Ex. 5

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Health Effects Research

Our understanding of the health effects associated with PFAS and our ability to draw conclusions regarding the contribution of any specific PFAS to human disease is based on combined data from multiple studies investigating epidemiologic associations in human cohort studies, biological plausibility and pathways in animal studies, mechanistic effects in human tissue and cell culture systems, and rapid high-throughput screening. Deliberative Process / Ex. 5

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"https://www.atsdr.cdc.gov/pfas/docs/pfas_clinician_fact_sheet_508.pdf"].

[7] D'eon JC, Mabury SA. Is Indirect Exposure a Significant Contributor to the Burden of Perfluorinated Acids Observed in Humans? *Environ. Sci. Technol.* 2011; 45(19):7974–84. DOI: [HYPERLINK "https://pubs.acs.org/doi/abs/10.1021/es200171y"].

[8] Schaider, LA, Balan, SA, Blum, A, Andrews, DQ, Strynar, M, Dickinson, ME, Lunderberg, DM, Lang, JR, Peaslee, GF. Fluorinated Compounds in U.S. Fast Food Packaging. *Environ. Sci. Technol. Lett.* 2017; 4(3):105-111. DOI: [HYPERLINK "https://pubs.acs.org/doi/10.1021/acs.estlett.6b00435"].

[9] Franko J, Meade BJ, Frasch HF, Barbero AM, Anderson SE. Dermal Penetration Potential of Perfluorooctanoic Acid (PFOA) in Human and Mouse Skin. *J. Toxicol. Environ. Health A.* 2012; 75(1):50-62. DOI: [HYPERLINK "https://doi.org/10.1080/15287394.2011.615108"].

[10] Winkens K, Vestergren R, Berger U, Cousins IT. Early Life Exposure to Per- and Polyfluoroalkyl Substances (PFASs): a Critical Review. *Emerging Contaminants*. June 2017; (3)2:55-68. DOI: [HYPERLINK "https://doi.org/10.1016/j.emcon.2017.05.001"].

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[13] Scher DP, Kell JE, Huset CA, Barry KM, Hoffbeck RW, Yingling VL, Messing RB. Occurrence of Perfluoroalkyl Substances (PFAS) in Garden Produce at Homes with a History of PFAS-Contaminated Drinking Water. *Chemosphere*. 2018; 196:548-555. DOI: [HYPERLINK "https://doi.org/10.1016/j.chemosphere.2017.12.179"].

[14] Hu XC, Andrews DQ, Lindstrom AB, Bruton TA, Schaider LA, Grandjean P, Lohmann R, Carignan CC, Blum A, Balan SA, Higgins CP, Sunderland EM. Detection of Poly- and Perfluoroalkyl Substances (PFASs) in U.S. Drinking Water Linked to Industrial Sites, Military Fire Training Areas, and Wastewater Treatment Plants. *Environ. Sci. Technol. Lett.* 2016; 3(10):344-350. DOI: [HYPERLINK "https://doi.org/10.1021/acs.estlett.6b00260"].

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Cancer

The epidemiological data on associations between PFAS and cancer risk are limited. Those published studies were recently summarized by the Agency for Toxic Substances and Disease Registry (ATSDR) in their Draft Toxicological Profile for Perfluoroalkyls.[18] According to the Toxicological Profile, "Occupational and community exposure studies have found increases in

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[15] Goldenthal EI, Jessup DC, Geil RG, Mehring JS. Final report, ninety day subacute rhesus monkey toxicity study, International Research and Development Corporation, study no. 137–090, November 10, 1978, U.S. EPA Administrative Record, AR226–0447.

[16] National Toxicology Program. Monograph on Immunotoxicity Associated with Exposures to PFOA and PFOS. Sept. 2016. Research Triangle Park, NC: U.S. Internet: [HYPERLINK "https://ntp.niehs.nih.gov/pubhealth/hat/noms/pfoa/index.html"].

[17] Kielsen K, Shamim Z, Ryder LP, Nielsen F, Grandjean P, Budtz-Jørgensen E, Heilmann C. Antibody Response to Booster Vaccination with Tetanus and Diphtheria in Adults Exposed to Perfluorinated Alkylates. *J. Immunotoxicol.* 2016; 13(2):270-3. DOI[HYPERLINK "https://www.ncbi.nlm.nih.gov/pubmed/?term=Antibody%2Bresponse%2Bto%2Bbooster%2Bvaccination%2Bwith%2Btetanus%2Band%2Bdiphtheria%2Bin%2Badults%2Bexposed%2Bto%2Bperfluorinated%2Balkylates" \h][HYPERLINK "https://doi.org/10.3109/1547691X.2015.1067259" \t "_blank"].

[18] Agency for Toxic Substances and Disease Registry (ATSDR). Toxicological profile for Perfluoroalkyls. (Draft for Public Comment). 2018. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service. Internet: [HYPERLINK "https://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=1117&tid=237"].

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the risk of testicular and kidney cancer associated with PFOA. No consistent epidemiologic evidence for other cancer types were found for PFOA.[19,20] For PFOS, one occupational exposure study reported an increase in bladder cancer,[21] but this was not supported by subsequent occupational studies. General population studies have not consistently reported increases in malignant tumors for PFOS. Epidemiologic studies examining other perfluoroalkyl compounds consisted of two case-control studies. No increases in breast cancer risk were observed for PFHxS or PFNA; an increased breast cancer risk was observed for PFOSA.[22] Another case- control study did not find increases in prostate cancer for PFOA, PFOS, PFHxS, PFNA, PFDeA, or PFUA.[23] However, among men with a first-degree relative with prostate cancer, associations were found for PFOA, PFOS, PFHxS, PFDeA, and PFUA, but not for PFNA."[24]

Child Development

PFOA and PFOS cause developmental toxicity in animals.[25,26,27] Human epidemiology studies also show associations between some PFAS and developmental effects.[28] One human study found that PFAS exposure during pregnancy was associated with decreased birth weight and head circumference only in males.[29] Similar decreases in birth weight have been reported in rodents for over a decade.[30] Recent findings from NIEHS-supported epidemiological studies of

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[19] Barry V, Winquist A, Steenland K. Perfluorooctanoic Acid (PFOA) Exposures and Incident Cancers Among Adults Living Near a Chemical Plant. *Environ. Health. Perspect.* 2013; 121(11-12):1313-1318. DOI: [HYPERLINK "https://doi.org/10.1289/ehp.1306615"].

[20] Steenland K, Woskie S. Cohort Mortality Study of Workers Exposed to Perfluorooctanoic Acid. *Am. J. Epidemiol.* 2012; 176(10):909-917. DOI: [HYPERLINK "https://doi.org/10.1093/aje/kws171"].

[21] Alexander BH, Olsen GW, Burris JM, Mandel JH, Mandel JS. Mortality of Employees of a Perfluorooctanesulphonyl Fluoride Manufacturing Facility. *Occup. Environ. Med.* 2003; 60:722-729. DOI: [HYPERLINK "https://doi.org/10.1136/oem.60.10.722"].

[22] Bonefeld-Jorgensen EC, Long M, Fredslund SO, Bossi R, Olsen J. Breast Cancer Risk After Exposure to Perfluorinated Compounds in Danish Women: A Case-Control Study Nested in The Danish National Birth Cohort. *Cancer Causes Control.* 2014; 25(11):1439-1448. DOI: [HYPERLINK "https://doi.org/10.1007/s10552-014-0446-7"].

[23] Hardell E, Karrman A, van Bavel B, Bao J, Carlberg M, Hardell L. Case-Control Study on Perfluorinated Alkyl Acids (PFAAs) and the Risk of Prostate Cancer. *Environ. Int.* 2014; 63:35-39. DOI: 10.1016/j.envint.2013.10.005.

[24] Ibid.

[25] White SS, Calafat AM, Kuklenyik Z, Thibodeaux J, Wood C, Fenton, SE. Gestational PFOA Exposure of Mice Is Associated with Altered Mammary Gland Development in Dams and Female Offspring. *Toxicol. Sci.* 2007; 96(1):133-144. DOI: [HYPERLINK "http://doi.org/10.1093/toxsci/kfl177"].

[26] Butenhoff JL, Ehresman DJ, Chang SC, Parker GA, Stump DG. Gestational and Lactational Exposure to Potassium Perfluorooctanesulfonate (K+PFOS) in Rats: Developmental Neurotoxicity. *Reprod. Toxicol.* 2009 Jun; 27(3-4):319-30. DOI: [HYPERLINK "https://doi.org/10.1016/j.reprotox.2008.12.010"].

[27] Chen T, Zhang L, Yue JQ, Lv ZQ, Xia W, Wan YJ, Li YY, Xu SQ. Prenatal PFOS Exposure Induces Oxidative Stress and Apoptosis in the Lung of Rat Off-Spring. *Reprod. Toxicol.* 2012 Jul; 33(4):538-45. DOI: [HYPERLINK "https://doi.org/10.1016/j.reprotox.2011.03.003"].

[28] White SS, Fenton SE, Hines EP. Endocrine Disrupting Properties of Perfluorooctanoic Acid. *J. Steroid Biochem. Mol. Biol.* 2011 Oct; 127(1-2):16–26. DOI: [HYPERLINK "https://dx.doi.org/10.1016%2Fj.jsbmb.2011.03.011"].

[29] Valvi D, Oulhote Y, Weihe P, Dalgård C, Bjerve KS, Steuerwald U, Grandjean P. Gestational Diabetes and Offspring Birth Size at Elevated Environmental Pollutant Exposures. Environ. Int. 2017 Oct; 107:205-215. DOI: [HYPERLINK "https://doi.org/10.1016/j.envint.2017.07.016"].

[30] Hines, EP, White, SS, Stanko, JP, Gibbs-Flournoy JE, Lau C, Fenton SE. Phenotypic Dichotomy Following Developmental Exposure to Perfluorooctanoic Acid (PFOA) in Female CD-1 Mice: Low Doses Induce Elevated Serum Leptin and Insulin, and Overweight in Mid-Life. *Mol. Cell. Endocrinol.* 2009 May 25; 304(1-2):97-105.

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a cohort of mothers and babies showed that prenatal exposure to PFOS is associated with cognitive effects and decreased ability to regulate behavior in school-age children. However, no similar association was observed in this study for PFOA exposure.[31]

A review of the epidemiological literature by an NIEHS-funded scientist summarized findings from several prospective cohorts on the relationship between prenatal exposure to certain PFAS and neurodevelopmental and neurobehavioral outcomes – for example, cognitive abilities, psychomotor development, attention-deficit hyperactivity disorder, and cerebral palsy. So far, the available body of evidence is inconsistent with respect to these associations, both with respect to which compounds may have adverse effects and timing of potential windows of vulnerability. Additional studies are needed to resolve these questions. Deliberative Process / Ex. 5

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Endocrine Disruption

Studies suggest that some PFAS may interfere with healthy hormonal function in the body. Our endocrine system controls our basic physiology, including metabolism, growth, fertility, and development. Human studies suggest a concern that early-life exposures to some PFAS may contribute to altered insulin resistance.[33,34]obesity type 2 diabetes Although further confirmation is required, the findings from one study suggest that exposures to some PFAS during pregnancy may influence lipid metabolism and glucose tolerance.[35] A study of pregnant women in Cincinnati found that those with higher prenatal PFAS levels had children with higher body fat

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DOI: [HYPERLINK "https://doi.org/10.1016/j.mce.2009.02.021"].

[31] Vuong AM, Yolton K, Webster GM, Sjödin A, Calafat AM, Braun JM, Dietrich KN, Lanphear BP, Chen A. Prenatal Polybrominated Diphenyl Ether and Perfluoroalkyl Substance Exposures and Executive Function in School-Age Children. *Environ. Res.* 2016 May; 147:556–564. DOI: [HYPERLINK "file:///C:\\Users\\bullockjr\\AppData\\Local\\Microsoft\\Windows\\Temporary%20Internet%20Files\\Content.Outlook\\XN6I05Q9\\Function"].

[32] Braun J. Early-Life Exposure to EDCs: Role in Childhood Obesity and Neurodevelopment. *Nat. Rev. Endocrinol.* 2017 Mar; 13(3):161–173. DOI: [HYPERLINK "https://doi.org/10.1038/nrendo.2016.186"].

[33] Donat-Vargas C, Bergdahl IA, Tornevi A, Wennberg M, Sommar J, Kiviranta H, Koponen J, Rolandsson O, Åkesson A. Perfluoroalkyl Substances and Risk of Type II Diabetes: A Prospective Nested Case-Control Study. Environ. Int. 2019 Feb; 123:390-398. DOI: [HYPERLINK "http://doi.org/10.1016/j.envint.2018.12.026"].

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[35] Matilla-Santander N, Valvi D, Lopez-Espinosa MJ, Manzano-Salgado CB, Ballester F, Ibarluzea J, Santa-Marina L, Schettgen T, Guxens M, Sunyer J, Vrijheid M. Exposure to Perfluoroalkyl Substances and Metabolic Outcomes in Pregnant Women: Evidence from the Spanish INMA Birth Cohorts. *Environ. Health. Perspect.* 2017 Nov 13; 125(11):117004. DOI: [HYPERLINK "https://doi.org/10.1289/EHP1062"].

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levels at age eight[36]—a finding reinforced by other epidemiological studies[37,38] and similar effects on excessive body weight gain reported for experimental animals.[39] It appears that some PFAS may also affect body weight later in life. Scientists at the Harvard School of Public Health have found that adults with higher blood levels of some PFAS have lower resting metabolic rates, meaning they burn fewer calories while resting, which makes it difficult for them to maintain weight loss.[40] Effects on weight gain have been seen in numerous animal studies,[41,42,43] supporting this association in humans. It is particularly concerning that some PFAS alter thyroid hormone homeostasis that regulates metabolism and growth.[44,45,46]

Deliberative Process / Ex. 5

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[36] Braun JM, Chen A, Romano ME, Calafat AM, Webster GM, Yolton K, Lanphear BP. Prenatal Perfluoroalkyl Substance Exposure and Child Adiposity at 8 Years of Age: The HOME Study. *Obesity*. 2016 Jan; 24(1):231-7. DOI: [HYPERLINK "https://doi.org/10.1002/oby.21258"].

[37] Mora AM, Oken E, Rifas-Shiman SL, Webster TF, Gillman MW, Calafat AM, Ye X, Sagiv SK. Prenatal Exposure to Perfluoroalkyl Substances and Adiposity in Early and Mid-Childhood. *Environ. Health. Perspect.* 2017 Mar; 125(3):467-473. DOI: [HYPERLINK "https://doi.org/10.1289/EHP246"].

[38] Karlsen M, Grandjean P, Weihe P, Steuerwald U, Oulhote Y, Valvi D. Early-Life Exposures to Persistent Organic Pollutants in Relation to Overweight in Preschool Children. *Reprod. Toxicol.* 2017 Mar; 68:145-153. DOI: [HYPERLINK "https://doi.org/10.1016/j.reprotox.2016.08.002"].

[39] Hines EP, White SS, Stanko JP, Gibbs-Flournoy EA, Lau C, Fenton SE. Phenotypic Dichotomy Following Developmental Exposure to Perfluorooctanoic Acid (PFOA) in Female CD-1 Mice: Low Doses Induce Elevated Serum Leptin and Insulin, and Overweight in Mid-Life. *Mol. Cell. Endocrinol.* 2009 May 25; 304(1-2):97-105. DOI: [HYPERLINK "https://doi.org/10.1016/j.mce.2009.02.021"].

[40] Liu G, Dhana K, Furtado JD, Rood J, Zong G, Liang L, Qi L, Bray GA, DeJonge L, Coull B, Grandjean P, Sun Q. Perfluoroalkyl Substances and Changes in Body Weight and Resting Metabolic Rate in Response to Weight-Loss Diets: A Prospective Study. *PLoS Med.* 2018; 15(2):e1002502. DOI: [HYPERLINK "https://dx.doi.org/10.1371%2Fjournal.pmed.1002502"].

[41] Grün F, Blumberg B. Endocrine Disrupters as Obesogens. *Mol. Cell. Endocrinol.* 2009 May 25; 304(1-2):19-29. DOI: [HYPERLINK "https://doi.org/10.1016/j.mce.2009.02.018"].

[42] Shi Z, Zhang H, Ding L, Feng Y, Xu M, Dai J. The Effect of Perfluorododecanonic Acid on Endocrine Status, Sex Hormones and Expression of Steroidogenic Genes in Pubertal Female Rats. *Reprod. Toxicol.* 2009 Jun; 27(3-4):352-9. DOI: [HYPERLINK "https://doi.org/10.1016/j.reprotox.2009.02.008"].

[43] Holtcamp W. Obesogens: An Environmental Link to Obesity. *Environ. Health. Perspect.* 2012; 120:a62–8. DOI: [HYPERLINK "https://doi.org/10.1289/ehp.120-a62"].

[44] Byrne SC, Miller P, Seguinot-Medina S, Waghiyi V, Buck CL, von Hippel FA, Carpenter DO. Exposure to Perfluoroalkyl Substances and Associations with Serum Thyroid Hormones in a Remote Population of Alaska Natives. *Environ. Res.* 2018 Oct; 166:537-543. DOI: [HYPERLINK "https://doi.org/10.1016/j.envres.2018.06.014"].

[45] Kim MJ, Moon S, Oh BC, Jung D, Ji K, Choi K, Park YJ. Association Between Perfluoroalkyl Substances Exposure and Thyroid Function in Adults: A Meta-Analysis. *PLoS One*. 2018 May 10; 13(5):e0197244. DOI: [HYPERLINK "https://doi.org/10.1371/journal.pone.0197244"].

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NIEHS Superfund Research Program (SRP)

Recently, NIEHS competitively awarded a five-year grant to the University of Rhode Island to fund its "Sources, Transport, Exposure and Effects of PFASs (STEEP) Superfund Research Program Center" (Fiscal Years 2017-2022).[51] The Center is assessing the impact of PFAS exposures on immune dysfunction[52] and metabolic abnormalities by examining the health of nine-year-old children from birth cohorts in the Faroe Islands (Denmark).[53] Deliberative Process / Ex. 5

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[48] Timmermann CA, Budtz-Jørgensen E, Petersen MS, Weihe P, Steuerwald U, Nielsen F, Jensen TK, Grandjean P. Shorter Duration of Breastfeeding at Elevated Exposures to Perfluoroalkyl Substances. *Reprod. Toxicol.* 2017 Mar; 68:164-170. DOI: [HYPERLINK "https://doi.org/10.1016/j.reprotox.2016.07.010"].

[49] Romano ME, Xu Y, Calafat AM, Yolton K, Chen A, Webster GM, Eliot MN, Howard CR, Lanphear BP, Braun JM. Maternal Serum Perfluoroalkyl Substances During Pregnancy and Duration of Breastfeeding. *Environ. Res.* 2016 Aug; 149:239-246. DOI: [HYPERLINK "https://doi.org/10.1016/j.envres.2016.04.034"].

[50] White SS, Calafat AM, Kuklenyik Z, Villanueva L, Zehr RD, Helfant L, Strynar MJ, Lindstrom AB, Thibodeaux JR, Wood C, Fenton SE. Gestational PFOA Exposure of Mice is Associated with Altered Mammary Gland Development in Dams and Female Offspring. *Toxicol. Sci.* 2007 Mar; 96(1):133-44. DOI: [HYPERLINK "https://doi.org/10.1093/toxsci/kfl177"].

[51] NIH Grant No. P42ES027706. Sources, Transport, Exposure and Effects of PFASs (STEEP). McCann, Alyson. University of Rhode Island. Awarded August 30, 2017. [HYPERLINK "https://projectreporter.nih.gov/project_info_details.cfm?aid=9258541&icde=41091914&ddparam&ddvalue&ddsub&cr=13&csb=default&cs=ASC&pball"].

[52] Budtz-Jørgensen E, Grandjean P. Application of Benchmark Analysis for Mixed Contaminant Exposures: Mutual Adjustment of Perfluoroalkylate Substances Associated with Immunotoxicity. *PLoS One.* 2018; 13(10):e0205388. DOI: [HYPERLINK "https://doi.org/10.1371/journal.pone.0205388"].

[53] Dassuncao C, Pickard H, Pfohl M, Tokranov AK, Li M, Mikkelsen B, Slitt A, Sunderland EM. Phospholipid Levels Predict the Tissue Distribution of Poly- and Perfluoroalkyl Substances in a Marine Mammal. *Environ. Sci Technol. Lett.* 2019; 6(3):119-125. DOI: [HYPERLINK "https://doi.org/10.1021/acs.estlett.9b00031"].

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Deliberative Process / Ex. 5 Additionally, the Center is developing and validating novel passive sampling tools for PFAS to measure time weighted average concentrations for some PFAS and their volatile precursors. These tools can be deployed to aid site managers in their risk characterization.[54] Deliberative Process / Ex. 5

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Deliberative Process / Ex. 5 Other NIEHS Superfund Research Program Centers are providing technical assistance regarding PFAS to State and local governments, water authorities, and private well users. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5 Through Small Business Innovation Research (SBIR) grants, the Program provides support to scientists and engineers developing novel technologies for mitigation and remediation of PFAS in the environment. NIEHS SBIR grantee CycloPure, Inc., is developing

Deliberative Process / Ex. 5

novel, high-affinity cyclodextrin polymers for the cost-effective remediation of PFAS from water.[61] In another NIEHS SBIR project, EnChem Engineering, Inc. is developing and demonstrating an innovative combined *in-situ / ex-situ* technology to cost-effectively expedite treatment of PFAS at Superfund sites. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5 Also of note, the University of California, Berkeley Superfund Research Center is combining biological and chemical treatment options to degrade and destroy PFAS and AFFF.[67,68,69]

NIEHS Time-Sensitive Research Awards

In addition to its regular funding programs, NIEHS has used a mechanism to support time-sensitive research opportunities related to PFAS. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

and collects human health and exposure data.[70] Researchers at the Colorado School of Public

[61] NIH Grant No. R43ES029401. Remediation of Perfluorinated Chemicals in Water Using Novel High-Affinity Polymer Adsorbents. Barin, Gokhan. CycloPure, Inc. Awarded March 22, 2018. [HYPERLINK "https://projectreporter.nih.gov/project_info_description.cfm?aid=9555528&icde=39590241"].

[62] NIH Grant No. R43ES028649. Bench Scale Studies of Novel In-situ Aquifer Remediation of Recalcitrant Fluorinated Organic Compounds at Superfund Sites. Ball, Raymond. EnChem Engineering, Inc. Awarded August 28, 2017. [HYPERLINK "https://projectreporter.nih.gov/project_info_description.cfm?aid=9409532&icde=35973822"].

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[66] Tian H, Gao J, Li H, Boyd SA, Gu C. Complete Defluorination of Perfluorinated Compounds by Hydrated Electrons Generated from 3-Indole-acetic-acid in Organomodified Montmorillonite. *Sci. Rep.* 2016; 6:32949. DOI: [HYPERLINK "https://doi.org/10.1038/srep32949"].

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[69] Yi S, Harding-Marjanovic KC, Houtz EF, Gao Y, Lawrence JE, Nichiporuk RV, Iavarone A, Zhuang W, Field JA, Sedlak DL, Alvarez-Cohen L. Biotransformation of AFFF Component 6:2 Fluorotelomer Thioether Amido Sulfonate Generates 6:2 Fluorotelomer Thioether Carboxylate Under Sulfate-Reducing Conditions. *Environ. Sci. Technol. Lett.* 2018; 5:283-288. DOI: [HYPERLINK "https://pubs.acs.org/doi/10.1021/acs.estlett.8b00148"].

Deliberative Process / Ex. 5

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Health, the University of Colorado Anschutz Medical Campus, and the Colorado School of Mines are studying PFAS exposures in residents near Colorado Springs whose wells and public water systems were contaminated with a wide range of PFAS, including high levels of perfluorohexane sulfonate (PFHxS).[71,72] This time-sensitive study started near the peak of exposure after contamination was discovered and will explore ways to measure how exposure levels to PFAS in the residents change over time.

In 2016, elevated levels of GenX, a short-chain PFAS containing an ether link generated in the production of non-stick coatings, were detected in North Carolina's Cape Fear River. The Cape Fear River provides drinking water for approximately 300,000 people and a production facility had been releasing GenX upstream. NIEHS funded a study at North Carolina State University to address community questions about GenX exposure and health effects, including GenX's potential toxicity, how it is stored in the body, and how long it remains in the environment.[73,74] Initial results from nearly 200 homes show detectable levels of GenX in treated tap water from the Cape Fear River but none above 140 parts per trillion, the current North Carolina public health goal for GenX in drinking water. Many other PFAS were also measured in treated Cape Fear River tap water. GenX was not detected in the tap water of homes whose groundwater was treated with granular activated carbon filtration. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

NTP REACT Program

Deliberative Process / Ex. 5

[71] NIH Grant No. R21ES029394. Exposure and Health Effects from Poly- and Perfluoroalkyl Substances in Colorado Water. Adgate, John L. University of Colorado Denver. Awarded December 13, 2017. [HYPERLINK "https://projectreporter.nih.gov/project_info_details.cfm?aid=9552471&icde=41091919&ddparam&ddvalue&ddsub&cr=1&csb=default&cs=ASC&pball"].

[72] Gill N. Exposure Study to Assess People and Water Near Colorado Springs; Toxic Chemicals Have Contaminated Water Supplies for 65,000. *CU Anschutz Today*. December 21, 2017. Internet: [HYPERLINK "https://www.cuanschutztoday.org/exposure-study-assess-people-water-near-colorado-springs."]

[73] NIH Grant No. R21ES029353. Assessing Impact of Drinking Water Exposure to GenX (Hexafluoropropylene Oxide Dimer Acid) in the Cape Fear River Basin, North Carolina. Hoppin, Jane. North Carolina State University Raleigh. Awarded on October 31, 2017. [HYPERLINK "https://projectreporter.nih.gov/project_info_details.cfm?aid=9537950&icde=41091915&ddparam&ddvalue&ddsub&cr=4&csb=default&cs=ASC&pball"].

[74] Peake T. Researchers Receive Grant to Study GenX Exposure in New Hanover County Residents. *NC State News*. November 1, 2017. Internet: [HYPERLINK "https://news.ncsu.edu/2017/11/genx-study/"].

REACT uses a combination of approaches. One project analyzes the chemical structure of PFAS compounds to see what information is available in databases for that compound or others with similar structure. Chemical structure plays a major role in how chemicals interact and chemicals with similar structure often have similar toxicity. This computer-based step is known as *in silico* screening. Based on *in silico* results, chemicals can be selected for further targeted laboratory testing with cells, known as *in vitro* testing. Examples include testing whether PFAS cause cells to die or substantially alter the function of human liver, placenta, or mammary gland derived cells. Some of these tests are similar to, or a refinement of, those used in the automated Toxicology in the 21st Century (Tox21) Program, a Federal collaboration among the NIH, the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA).[75] The *in vitro* data are then examined to prioritize select chemicals for toxicity testing in animals, known as *in vivo* studies, so the data can be considered all together. REACT is a collaborative program with EPA. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Current Challenges

Real-world human exposures to PFAS involve complex mixtures, not individual chemicals. This fact complicates both the science of exposure and the assessment of health risks.[76] Currently, analytical techniques are limited for determining which specific PFAS are contained in a given complex mixture. Further, toxicological information on these combined PFAS mixtures remains incomplete. Additional research is needed to assess environmental exposures to mixtures and determine their combined effects.

Apart from the challenge of characterizing PFAS in environmental samples is the challenge of studying PFAS in the human body. Our present understanding is that the time required for elimination of PFAS from the human body can vary. While some longer chain molecules may remain in the blood for years, shorter chain PFAS may be more quickly eliminated. Differences in elimination rates of longer and shorter chain PFAS complicates biomonitoring as well as toxicological studies. However, lack of biological persistence does NOT mean lack of toxicity, particularly for chemicals like PFAS that may have consistent daily exposures.

Traditional methods for measuring the body burden of PFAS—namely analyzing serum—are not as effective for shorter chain PFAS as for longer chain PFAS. Scientists are beginning to measure PFAS in urine,[77] in plasma, and in whole blood, as well as in serum.[78] These expanded

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[75] U.S. Environmental Protection Agency. Toxicology Testing in the 21st Century (Tox21). Internet: [HYPERLINK "https://www.epa.gov/chemical-research/toxicology-testing-21st-century-tox21"].

[76] Kotthoff M, Bücking M. Four Chemical Trends Will Shape the Next Decade's Directions in Perfluoroalkyl and Polyfluoroalkyl Substances Research. *Front. Chem.* 2018 Apr 5; 6:103. DOI: [HYPERLINK "https://doi.org/10.3389/fchem.2018.00103"].

[77] Hartmann C, Raffesberg W, Scharf S, Uhl M. Perfluoroalkylated Substances in Human Urine: Results of a Biomonitoring Pilot Study. *Biomonitoring* 2017; 4:1-10. DOI: [HYPERLINK "https://doi.org/10.1515/bimo-2017-0001"].

[78] Poothong S, Thomsen C, Padilla-Sanchez JA, Papadopoulou E, Haug LS. Distribution of Novel and Well-Known Poly- and Perfluoroalkyl Substances (PFASs) in Human Serum, Plasma, and Whole Blood. *Environ. Sci. Technol.* 2017 Nov 21; 51(22):13388-13396. DOI: [HYPERLINK

biomonitoring techniques for sampling and analyses will further inform our understanding of exposures and risks. Using these techniques, many scientists are rightly focusing on measuring the total exposure to all PFAS as opposed to the past focus on one substance in isolation. This is important as it allows for understanding cumulative effects of PFAS mixtures as a class. Examining the person in the context of the measure of all the exposures they have experienced in their lifetime and how they relate to their health is in step with the latest science.

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Manufacturers have begun recently to produce and market AFFF devoid of any PFAS. Such fluorine-free AFFF is now being used at Heathrow Airport in London, United Kingdom and at major airports in Sweden. It will be important to evaluate these alternatives for potential health effects as well.

Federal Collaboration

NIEHS and the NTP will continue to provide scientific leadership with respect to PFAS research. Communication and collaboration both within the Department of Health and Human Services, and across the Federal Government, about PFAS is intensifying. In February 2018, a Federal information exchange meeting about PFAS was held on the NIH campus in Bethesda, Maryland.[79] NIEHS was among other Federal agencies that participated at the PFAS National Leadership Summit hosted by EPA in May 2018.[80] Within the Department of Health and Human Services and primarily through NTP, NIEHS works closely with the FDA and the CDC on PFAS matters. Additionally, NIEHS is specifically being consulted by ATSDR on the design and conduct of the exposure assessments and health studies authorized by the National Defense Authorization Act for Fiscal Year 2018, as amended.[81]

Conclusion

Thank you again for allowing me to share a scientific perspective on this important topic. In closing, I note that NIEHS is well-positioned to continue contributing essential scientific knowledge about this complex and large class of chemicals. This knowledge can help regulators make sound, science-based decisions and informs the medical and public health communities about the potential health effects associated with exposure to PFAS. I welcome your questions.

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[79] Lenox K. Federal Agencies Exchange PFAS Updates. *NIEHS Environmental Factor*. 2018, Mar. Internet: [HYPERLINK "https://factor.niehs.nih.gov/2018/3/science-highlights/pfas/index.htm"].

[80] U.S. Environmental Protection Agency. EPA PFAS National Leadership Summit and Engagement. May 22-23, 2018. Internet: [HYPERLINK "https://www.epa.gov/pfas/pfas-national-leadership-summit-and-engagement"].

[81] Sec. 316 of the National Defense Authorization Act for Fiscal Year 2018. [HYPERLINK "https://www.congress.gov/115/plaws/publ91/PLAW-115publ91.pdf"]. December 12, 2017.

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Appendix to Testimony of Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S.
Director, National Institute of Environmental Health Sciences (NIEHS) and
National Toxicology Program (NTP), National Institutes of Health (NIH)
Senate Committee on Environment and Public Works Hearing – March 28, 2019

LIST OF CITATIONS TO PUBLICATIONS ABOUT
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