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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

CENTER FOR ENVIRONMENTAL HEALTH, CAPE FEAR RIVER WATCH, CLEAN CAPE FEAR, DEMOCRACY GREEN, THE NC BLACK ALLIANCE, and TOXIC FREE NC

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Plaintiffs,

vs.

MICHAEL REGAN, as Administrator of the United States Environmental Protection Agency, and the UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

.

Defendants.

Case No. 4:21-cv-01535-PJH

AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs, Center for Environmental Health, Cape Fear River Watch, Clean Cape Fear, Democracy Green, The NC Black Alliance, and Toxic Free NC ("Plaintiffs"), as and for their Amended Complaint, allege as follows against Defendants Michael Regan, as Acting Administrator of the Environmental Protection Agency ("EPA"), and the EPA:

INTRODUCTORY STATEMENT

1. Plaintiffs are nonprofit public health and environmental justice organizations, based in Oakland, California and Eastern North Carolina, concerned about the extensive environmental contamination caused by Per- and Polyfluoroalkyl Substances ("PFAS") and the absence of scientific data on the impacts of this contamination on the health of at risk communities in the Cape Fear River basin.

2. On October 14, 2020, plaintiffs petitioned defendant Environmental Protection Agency ("EPA") under Section 21 of the Toxic Substances Control Act ("TSCA") to require comprehensive health and environmental effects testing on 54 PFAS manufactured by The Chemours Company ("Chemours") at its chemical production facility in Fayetteville, North Carolina, adjacent to and upstream of the communities that plaintiffs represent.

3. The petition sought issuance of a rule or order under section 4 of TSCA compelling Chemours to fund and carry out the studies proposed in the petition under the direction of a panel of independent scientists. Although the petition demonstrated that the 54 PFAS meet the criteria for testing in section 4(a) of TSCA and the requested studies are necessary to determine the health impacts of PFAS exposure on affected communities, defendant EPA denied the petition on January 7, 2021 and published the grounds for the denial in the Federal Register on January 22, 2021 (86 Fed. Reg. 6602).

4. Plaintiffs filed their Complaint challenging the petition denial on March 3, 2021.

5. After the Biden Administration took office, on March 4, 2021, plaintiffs asked defendants to reconsider the petition denial and grant the petition. Defendants notified plaintiffs' counsel of the

outcome of the reconsideration process on December 28, 2021. While claiming to be "granting" the petition, defendants in fact failed to require testing on nearly all of the 54 PFAS and to require virtually all of the studies requested in the petition. Thus, EPA denied the petition for a second time.

6. This Amended Complaint describes events following filing of the initial Complaint and updates plaintiffs' claims to take these new circumstances into account.

7. PFAS have raised significant concern in the US and globally because of their persistence and potential to bio-accumulate, widespread presence in living organisms, products, and the environment, and demonstrated adverse health effects at low doses. In the last few years, several PFAS have been identified in drinking water sources serving over 300,000 people in the Cape Fear basin, in human blood and in environmental media, including air emissions, surface water, sediment, stormwater, groundwater and locally grown produce. This contamination has been linked to the Chemours facility in Fayetteville, which has discharged PFAS into the Cape Fear River and released them into the environment for the last four decades.

8. The North Carolina residents represented by the plaintiffs face serious health risks from long-term PFAS exposure but there is no or inadequate data on the health effects of the 54 PFAS included in the petition. These residents are concerned about the links between PFAS exposure and diseases that now afflict them and their families or may develop in the future. However, the lack of information on the health effects of the PFAS is depriving them and their medical professionals of important knowledge that would inform diagnosis and treatment. Plaintiffs filed their petition so that EPA would compel Chemours under TSCA to assume responsibility for the studies necessary to understand how PFAS pollution has harmed and will harm Cape Fear communities.

9. This action seeks judicial review of the January 7, 2021 and December 28, 2022 petition denials, as authorized in section 21(b)(4)(A) of TSCA. Plaintiffs ask the Court to compel defendants to initiate a

proceeding under section 4(a) of TSCA to issue a rule or order requiring Chemours to fund the studies identified in the petition. This relief is required by law because, as plaintiffs demonstrated in their petition and other submissions and will demonstrate to the Court by a preponderance of the evidence, the 54 PFAS meet the standard for testing requirements in section 21(b)(4)(B)(i) of TSCA because (1) available information is "insufficient to permit a reasoned evaluation of the[ir] health and environmental effects" and (2) the 54 PFAS "may present an unreasonable risk to health or the environment."

JURISDICTION AND VENUE

10. This action is brought under section 21(b)(4)(A) of TSCA, 15 U.S.C. § 2620, which provides that, upon the denial of a petition under section 21(a), the petitioner "may commence a civil action in a district court of the United States to compel the Administrator to initiate a rulemaking proceeding as requested in the petition."

11. Such an action must be filed within 60 days of the denial of the petition.

12. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 and 15 U.S.C. § 2620(b)(4).

13. The Court has the authority to grant the requested declaratory and injunctive relief under 28 U.S.C. §§ 2201-2202 and 15 U.S.C. § 2620(b)(4).

14. Venue is proper in the Northern District of California pursuant to 28 U. S.C. § 1391(e)(1)(C) and 15 U.S.C. § 2620(b)(4) because plaintiff Center for Environmental Health resides in the District.

PARTIES

15. Plaintiff Center for Environmental Health ("CEH") is a non-profit organization working to protect children and families from harmful chemicals in air, food, water and in everyday products. Its vision and mission are a world where everyone lives, works, learns and plays in a healthy environment. CEH protects people from toxic chemicals by working with communities, businesses, and the government to demand and support business practices that are safe for human health and the

environment. CEH is headquartered in Oakland, California, but members of its staff work in North Carolina and partner closely with locally-based organizations to address concerns relating to PFAS and other chemicals that threaten the health of North Carolinians.

16. Plaintiff Cape Fear River Watch ("CFRW") is a grassroots environmental nonprofit based in Wilmington, North Carolina whose mission is to protect and improve the water quality of the Cape Fear River Basin for all people through education, advocacy and action. Since its founding, over 25 years ago, it has worked on a wide variety of water quality issues – educating and organizing the community to take action, partnering with researchers, influencing decision makers, and holding polluters accountable. Since learning of the nearly four decades of PFAS contamination of the Cape Fear River, the drinking water supply for nearly 300,000 people, and a vital ecological and economical resource to the region, Cape Fear River Watch, in partnership with academia and the Southern Environmental Law Center, has worked to stop the source of pollution, understand and explain the impacts to human health and the ecosystem, and ensure that those responsible are held accountable.

17. Plaintiff Clean Cape Fear ("CCF") is an all-volunteer, grassroots community group based in the Wilmington, NC area. Its members include educators, environmentalists, doctors, faith leaders, scientists, veterans, and concerned residents all working together to hold Chemours/DuPont accountable for decades of pollution. CFF was formed shortly after learning that toxic chemicals linked to cancer and other serious health problems were detected in finished tap water as a result of Chemours' discharges to the Case Fear River. These discharges and other environmental releases from the facility impact five counties with over 300,000 residents drinking contaminated tap water downstream from the facility and over 3,500+ well owners with contaminated groundwater near the Fayetteville, NC area.

18. Plaintiff Democracy Green ("DG") is an organization created and run by native North Carolinians-of-color to address the systemic impacts burdening disenfranchised communities across

North Carolina. DG works in partnership with communities, groups and organizations across the historic U.S. South, in addition to areas housing the descendants of U.S. chattel slavery and Indigenous sovereign nations. Communities represented by DG have seen the horrific damage caused by PFAS to North Carolinians and DG cannot stand idly by while the corporations responsible are not held accountable. Democracy Green stands against corporate polluters and the harmful impact of their pollutants and chemicals on frontline communities and low-wealth populations.

19. Plaintiff The NC Black Alliance ("NCBA") is working toward state-level systemic change by strengthening the network of elected officials representing communities of color throughout the state and collaborating with progressive, grassroots networks on intersecting issues. NCBA believes that the communities impacted by climate disasters also face the direct impact of health disparities created by exposure to dangerous chemicals, such PFAS. It is NCBA's conviction that all people have the right to clean air, clean water, access to health care, and a thriving economy.

20. Plaintiff Toxic Free NC ("TFNC") advances environmental health and justice in North Carolina by advocating for safe alternatives to harmful pesticides and chemicals. Founded in 1986, the organization has played a leading role in state-wide pesticide reform and has contributed to national efforts strengthening regulatory protections to protect vulnerable communities and the environment from petrochemical pollution. TFNC believes that PFAS contamination is at the nexus of clean water concerns in North Carolina and that, while high levels of PFAS have been detected in drinking water across the state, the full health impact on the exposed residents of North Carolina is still unknown. Together with other organizations in North Carolina, TFNC advocates for regulatory solutions to prevent further PFAS discharges into our environment and cleanup the PFAS already present. TFNC represents thousands of North Carolina residents whose drinking water has been contaminated and are deeply concerned about the consequences for their health.

21. Defendant Michael Regan, named in his official capacity as Administrator of EPA, has authority for the implementation of TSCA and is responsible for assuring that the Agency exercises its responsibilities under TSCA in compliance with the law.

22. Defendant EPA is an agency of the United States Executive Branch and, under the direction of Administrator Regan, is charged with implementing the provisions of TSCA, including by responding to citizens' petitions under section 21.

STATUTORY BACKGROUND

23. TSCA was enacted in 1976 to create a national program for assessing and managing the risks of chemicals to human health and the environment. The need for this comprehensive framework for managing chemical risks was described as follows in the Senate Report on the original law:

> As the industry has grown, we have become literally surrounded by a man-made chemical environment. We utilize chemicals in a majority of our daily activities. We continually wear, wash with, inhale, and ingest a multitude of chemical substances. Many of these chemicals are essential to protect, prolong, and enhance our lives. Yet, too frequently, we have discovered that certain of these chemicals present lethal health and environmental dangers.

Senate Rept. No. 94-698, 94th Cong. 2d Sess. (1976) at 3.

24. Among the goals stated in TSCA section 2(b), 15 U.S.C. § 2601(b), is that "adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of this information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures."

25. This policy is embodied in section 4 of TSCA, which provides EPA with broad authority to require industry to test its chemicals to determine their risks to human health and the environment. Recognizing the need for more testing to support chemical risk determinations, the 2016 TSCA amendments streamline and enhance section 4 by authorizing EPA to issue orders in addition to rules requiring development of data.

26. Section 4(a)(1)(A)(i) authorizes EPA to require testing where it determines that –

> the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, *may present an unreasonable risk of injury to health or the environment* (emphasis added).

27. In *Chemical Manufacturers Association v. U.S. Environmental Protection Agency,* 859 F.2d 977 (1988), the D.C. Circuit concluded that "[b]oth the wording and structure of TSCA reveal that Congress did not expect that EPA would have to document to a certainty the existence of an 'unreasonable risk' before it could require testing." It added that TSCA's legislative history demonstrates that "the word 'may' in section 4 was intended to focus the Agency's attention on chemical substances 'about which there is a basis for concern, but about which there is inadequate information to reasonably predict or determine the effects of the substance or mixture on health or the environment.'"

28. The D.C. Circuit acknowledged that "Congress did not intend to authorize EPA to issue test rules on the basis of mere hunches" but stressed that EPA need not demonstrate that exposure or toxicity is "probable." Instead, EPA may "rely on inferences in issuing a section 4 test rule, so long as all the evidence . . . indicates a more-than-theoretical probability of exposure." Inferences can also support findings of potential toxicity; this can include toxicity data on chemical analogs since "Congress explicitly contemplated that EPA would base test rules on comparisons among structurally similar chemicals."

29. In addition to a "may present" finding, section 4(a)(1)(A)(i) directs EPA to make two further determinations before requiring testing: (1) there is "insufficient information and experience" with which the chemical's effects on health and the environment "can reasonably be determined or predicted"; and (2) testing is "necessary to develop such information." The first determination will be justified whenever data either do not exist or are inadequate to support scientifically supportable conclusions about the chemical's adverse effects on health and the environment. The second determination will be warranted

where the testing to be required is necessary to obtain sufficient and reliable information about how the chemical may harm exposed populations or the environment.

30. Once EPA makes these findings, it must require that testing be conducted "to develop information with respect to the health and environmental effects for which there is an insufficiency of information and experience" and which are "relevant to a determination" whether the substance "does or does not present an unreasonable risk to health and the environment."

31. Under section 4(b)(2)(A), a broad range of studies may be required under test rules or orders. These may include studies to determine "carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment." Studies to be conducted may include "epidemiologic studies, serial or tiered testing, in vitro tests, and whole animal tests." The rule or order can also require development of information "for the assessment of exposure or exposure potential to humans or the environment."

32. Section 4(a)(1)(A) authorizes EPA to require testing on both "mixtures" and individual "chemical substances." Pursuant to section 4(a)(1)(B), testing on mixtures may be required for health and environmental effects that "may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture."

33. Under section 4(b)(3), testing rules or orders must place responsibility for developing the required data on the entities who manufacture and/or process the chemical to be tested. Section 4(b)(1) provides that the rule or order must prescribe the "protocols and methodologies" for conducting testing and procedures and deadlines for submitting interim and final test results.

34. These requirements are enforceable under TSCA and non-compliance may give rise to civil and criminal penalties under section 16 and specific enforcement under section 17.

35. Testing under TSCA section 4 can be required on chemicals produced for intentional use or as byproducts during a commercial chemical manufacturing operation. EPA defines "byproduct" under TSCA as "any chemical substance or mixture produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture." 40 C.F.R. § 712.3(a).

36. Since TSCA's inception, section 21 of the law has contained a petition process by which citizens can seek to compel action by EPA under different provisions of the law. 15 U.S.C. § 2620. The D.C. Circuit has recognized "TSCA's unusually powerful citizen-petition procedures." *Trumpeter Swan Society v EPA*, 774 F.3d 1037, 1939 (D.C. Cir. 2014). EPA is required to respond to the petition within 90 days. If EPA denies the petition or fails to act within 90 days, Section 21 empowers the petitioner to file a civil action in federal district court to "compel the [EPA] Administrator to initiate a rulemaking proceeding as requested in the petition." 15 U.S.C. § 2620(b)(4)(A).

37. As amended in 2016, section 21(a) authorizes citizens to petition for*, inter alia*, issuance of a rule or order under Section 4 requiring manufacturers and processors to conduct testing on chemical substances and mixtures. *Id.* § 2620(a). Under Section 21(b)(4)(B), where the petition sought issuance of a rule or order under section 4, "the petitioner shall be provided an opportunity to have such petition considered by the court in a *de novo* proceeding." 15 U.S.C. § 2620(b)(4)(B).

38. For petitions seeking issuance of rules or orders under section 4, Section 21(b)(4)(B)(i) directs the district court to "order the Administrator to initiate the action requested by the petitioner" if it "demonstrates to the satisfaction of the court by a preponderance of the evidence" that "(I) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance to be subject to such rule or order; and (II) in the absence of such information, the substance may present an unreasonable risk to health or the environment . . . ."

15 U.S.C. § 2620(b)(4)(B)(i)(I)-(II).

RISKS OF PFAS TO HUMAN HEALTH AND THE ENVIRONMENT

39. Plaintiffs' October 14, 2020 petition provides considerable background information on PFAS. Highlights are summarized in the paragraphs below.

40. PFAS have a unique set of properties with an unusual ability to cause serious and widespread harm to public health and the environment. A defining feature of PFAS is their carbon-fluorine bonds, which impart high thermal stability and resistance to degradation. Because of their pronounced ability to repel oil and water, PFAS have been used in a variety of industries in the US and around the globe.

41. The EPA Action Plan for PFAS identifies numerous human exposure pathways for these chemicals, including:[1]

- Drinking water from public water and private water systems, typically localized and associated with a release from a specific facility (e.g., manufacturer, processor, landfill, wastewater treatment, or facilities using PFAS-containing firefighting foams);
- Consumption of plants and meat from animals, including fish that have accumulated PFAS;
- Consumption of food that came into contact with PFAS-containing products (e.g., some microwaveable popcorn bags and grease-resistant papers);
- Use of, living with, or otherwise being exposed to commercial household products and indoor dust containing PFAS, including stain- and water-repellent textiles (including carpet, clothing and footwear), nonstick products (e.g., cookware), polishes, waxes, paints, and cleaning products;
- Employment in a workplace that produces or uses PFAS, including chemical production facilities or utilizing industries (e.g., chromium electroplating, electronics manufacturing, or oil recovery); and
- In utero fetal exposure and early childhood exposure via breastmilk from mothers exposed to PFAS.

42. PFAS are often called "forever" chemicals because they do not break down or degrade over time and therefore are highly persistent. Thus, they build up in the natural environment and in biological

[1] EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan, February 2019.

systems if they are bioaccumulative. These characteristics, combined with the high mobility of many PFAS, have resulted in their widespread distribution and pervasive presence both in environmental media and in people and wildlife around the globe, including many remote locations. Thus, PFAS have been detected in the blood of workers and the general population, with 99 percent of those sampled showing detectable levels of these compounds.

43. This PFAS body burden is a function of multiple exposure pathways, including drinking water, air emissions, food consumption, consumer products like carpet or clothing and house dust. Because of their resistance to degradation, there is no known safe method of disposal of PFAS that would prevent build-up in the environment at the end of their useful lives.

44. In addition to their persistence, PFAS have high mobility, especially in water. Their high water solubility and environmental persistence together make PFAS a ubiquitous pollutant of surface and groundwater. As a result, PFAS-contaminated drinking water is a significant concern: PFAS has been found in multiple locations in source water or tap water, raising concerns about drinking water safety and resulting in use of costly treatment systems in affected communities.

45. Animal studies demonstrate that, where tested, PFAS are often linked to many serious health effects, including cancer, hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immunotoxicity, often at low doses. Human studies of populations with elevated blood levels of PFAS have shown associations with a variety of health conditions, including kidney and testicular cancer, elevated cholesterol, liver disease, decreased fertility, thyroid problems and changes in hormone levels and immune systems. Moreover, concurrent exposure to multiple PFAS may have additive or synergistic effects.

46. To date, EPA has failed to use its testing authorities under TSCA section 4 to fill the extensive data-gaps on PFAS.

CONTAMINATION OF THE CAPE FEAR RIVER BASIN BY THE CHEMOURS FACILITY

47. Plaintiffs' petition described in detail the operation of the Chemours' facility in Fayetteville, North Carolina and the PFAS contamination it has created in the Cape Fear River basin. Key highlights are summarized in the following paragraphs.

48. The Chemours plant is located on a 2,150-acre site in a rural area south of Fayetteville, adjacent to the west bank of the Cape Fear River. The river continues for over 110 km to the City of Wilmington and then broadens into an estuary that ultimately flows into the Atlantic Ocean. Residents of Wilmington and other population centers downstream from or adjacent to the facility use the river as a source of drinking water.

49. The facility was built and operated by DuPont and started producing fluoropolymers in 1971. In 2015, DuPont spun off its performance chemicals business to Chemours, a newly created company which then acquired the Fayetteville plant and other former DuPont facilities.

50. The plant is a major producer and user of PFAS. Its PFAS-based product lines are Fluoromonomers, Fluorinated Vinyl Ethers and Nafion® Polymers, which are used as membranes in fuel cells and chlorine production. The mix of precursors, byproducts, degradation products, metabolites, impurities and commercial substances associated with these product lines is complex and not well-understood but likely involves hundreds if not thousands of individual PFAS, many of which have chemical structures that are as yet unidentified.

51. A major source of concern has been Chemours' production of "GenX" compounds. These chemicals have been produced as byproducts at the Fayetteville since the early 1980s and discharged into the Cape Fear River. They were recently commercialized as a replacement for perfluorooctanoic acid (PFOA), a surfactant in the polymerization of fluoropolymers that was phased out in 2015 in response to serious health and environmental concerns.

52. During monitoring by Strynar et al. and Sun et al., GenX and nine other PFAS were identified in the Cape Fear River and drinking water downstream of the Fayetteville plant.[2] In further sampling of the river downstream of the plant, McCord et al. (2019) found 37 unique PFAS molecules.[3] Several of these compounds were also detected in the blood of residents of the Cape Fear region, confirming human exposure.[4] Sampling in the Cape fear River indicated that total PFAS concentrations (all substances combined) were 130,000 parts per trillion (ppt).[5] Sampling by water utilities subsequently identified numerous PFAS linked to Chemours' operations in drinking water intakes.

53. As concern increased about surface water and drinking water contamination, monitoring of other environmental media for the presence of PFAS produced at the Fayetteville plant was initiated. As determined in Chemours' compliance testing under a North Carolina consent order, several additional PFAS associated with the Fayetteville Works facility have been detected in private wells, wastewater, stormwater, sediment, groundwater, soil, air emissions, and local produce, including a large number of compounds of uncertain chemical composition.

54. The 2019 consent order between Chemours and the North Carolina Department of Environmental Quality (DEQ) requires controls on wastewater discharges and air emissions of PFAS, directs Chemours to identify constituents of wastewater and process streams and to conduct environmental monitoring,

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[2] Hopkins, Z. R., Sun, M., DeWitt, J. C. & Knappe, D. R. U. Recently Detected Drinking Water Contaminants: GenX and Other Per- and Polyfluoroalkyl Ether Acids. *Journal AWWA* **110**, 13-28, doi:10.1002/awwa.1073 (2018).

[3] McCord, J. & Strynar, M. Identification of Per- and Polyfluoroalkyl Substances in the Cape Fear River by High Resolution Mass Spectrometry and Nontargeted Screening. *Environmental Science & Technology* **53**, 4717-4727, doi:10.1021/acs.est.8b06017 (2019).

[4] Kotlarz, N. *et al.* Measurement of Novel, Drinking Water-Associated PFAS in Blood from Adults and Children in Wilmington, North Carolina. *Environmental Health Perspectives* **128**, 077005, doi:doi:10.1289/EHP6837 (2020).

[5] Zhang, C., Hopkins, Z. R., McCord, J., Strynar, M. J. & Knappe, D. R. U. Fate of Per- and Polyfluoroalkyl Ether Acids in the Total Oxidizable Precursor Assay and Implications for the Analysis of Impacted Water. *Environ Sci Technol Lett* **6**, 662-668, i:10.1021/acs.estlett.9b00525 (2019).

provides for groundwater remediation, and requires limited health and environmental effects testing of five PFAS. Sampling of drinking water systems and private wells since the order was issued documents the continuing presence of several PFAS and therefore ongoing human exposure.

PLAINTIFFS' PETITION FOR A TEST RULE OR ORDER UNDER TSCA SECTION 21

55. Plaintiffs' petition identified 54 PFAS linked to the Chemours facility that warrant health and environmental effects testing. Petitioners selected these 54 PFAS based on evidence of known or anticipated human exposure as demonstrated by available data on their presence in human sera, drinking water, surface water, air emissions, rainwater, private wells, groundwater and produce. The petition maintained that the 54 PFAS meet TSCA criteria for testing because (1) data on their effects are insufficient or unavailable and (2) they may present unreasonable risks by virtue of the combination of potential toxicity and exposure.

56. The 54 PFAS were divided into Tier 1 substances (for which there is substantial known human exposure as evidenced by their detection in blood, food or drinking water) and Tier 2 substances (for which human exposure is probable based on detection in environmental media). The detailed justification for assigning substances to these Tiers is provided in Attachment 2 to the petition, the Chemours PFAS Master Testing List.

57. The petition explained that, since it is recognized that all PFAS have the potential for causing the adverse health and environmental effects linked to well-characterized substances in the class, there is a strong basis to conclude that the 54 PFAS "may present an unreasonable risk of injury" under TSCA section 4(a)(1)(A). According to the petition, this potential risk is magnified by the co-occurrence of multiple PFAS in drinking and surface water, other environmental media and the blood of humans and wildlife in the Cape Fear watershed. Where exposure is to multiple PFAS simultaneously, the petition

emphasized, their toxic effects may be additive or synergistic, resulting in greater overall risk than exposure to any individual PFAS alone.

58. The petition also maintained that the "sufficiency" of available information on the 54 PFAS should be determined by comparing available data with the known adverse effects of other PFAS. According to the petition, if a scientifically sound assessment of each of the 54 chemicals for these critical toxic endpoints cannot be conducted because of the lack of data, available information on these substances must be deemed "insufficient" under TSCA section 4(a).

59. The petition then showed that the 54 substances either lack any health and ecological effects data or the available studies are limited and incomplete and do not provide an adequate basis for hazard and risk assessment. Key data gaps include measurement of physical-chemical properties, methods of analysis, assessment of partitioning, bioaccumulation, and degradation, pharmacokinetics, and toxicity, especially for the endpoints commonly observed for the better studied PFAS, such as liver toxicity, and effects on the immune system, lipid metabolism, kidney, thyroid, development, reproduction, and cancer. In addition, despite their widespread detection in environmental media, ecotoxicity data are generally lacking.

60. Based on its showings of potential unreasonable risk and insufficiency of data, the petition proposed the following testing program:

Experimental Animal Studies

- Compounds in both Tiers would undergo 28-day repeated dose rodent toxicology studies coupled with reproductive and developmental toxicity screening assays, examining critical PFAS endpoints including hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immune system toxicity.

- These studies would also be conducted on three mixtures of PFAS representative of the groups of substances to which residents have been exposed through drinking water, human sera and other pathways.

- Multigeneration or extended one-generation and 2-year rodent carcinogenicity studies would be conducted on the 14 Tier 1 substances in recognition of the evidence of direct and substantial human exposure and the concerns for these endpoints demonstrated by other PFAS.

- Most studies would be carried out in two species (mice and rats) and by oral routes of administration, except inhalation would be used for volatile chemicals.

- Toxicokinetic studies would be conducted to characterize relationships between serum concentrations and dermal, oral and inhalation exposures in the test species, and to evaluate biological half-life and potential for bioaccumulation.

- Testing requirements would be based on EPA and Organisation for Economic Co-operation and Development (OECD) guidelines, with appropriate adjustments to reflect sensitive endpoints that have been reported for PFOA, PFOS, and GenX.

Human Studies

- A human health study for the Cape Fear watershed would be conducted using a similar study design to that used for the Parkersburg, WV PFOA (C8) study. The goal of the study would be to determine the relationship between exposure to the mixtures of PFAS that characterize current and historical exposure in the Cape Fear watershed and health outcomes among exposed populations.

- Testing would also be performed to determine human half-lives of the listed chemicals through longitudinal biomonitoring and exposure estimation in workers.

Ecological Effects/Fate and Transport and Physical-Chemical Properties Studies

- Testing would include ecological effects studies, similar to studies conducted on GenX.

- EPA would require development of analytical standards where not currently available, physical-chemical properties tests, and fate and transport studies in order to identify and predict exposures.

61. The petition requested that, to maximize the credibility and objectivity of the data and key findings, EPA contract with the National Academy of Sciences (NAS) to form an independent expert science panel with responsibility for overseeing all aspects of the testing program. The public and Chemours would have the opportunity to submit nominations for membership on the panel.

EPA'S FIRST DENIAL OF PLAINTIFFS' PETITION

62. The January 7, 2021 petition denial affirmed EPA's "high concern" about PFAS and did not dispute that all PFAS are of concern for serious health effects based on the overall properties of the class.

Nor did EPA deny that most of the 54 PFAS have been detected in the environment, resulting in exposure by North Carolina residents and putting them at risk of harm.

63. The bulk of the petition denial consists of a lengthy summary of the EPA PFAS Action Plan and a detailed list of the various PFAS-related measures EPA has taken under the Plan and other programs. This list of EPA accomplishments is irrelevant to the petition. These EPA actions do not speak to whether the 54 PFAS in the petition meet the criteria for testing in section 4 of TSCA and provide no basis for denying the petition.

64. The petition denial also asserts that "the petitioners have not provided the facts necessary for the Agency to determine for each of the 54 PFAS that existing information and experience are insufficient and testing of such substance or mixture with respect to such effects is necessary to develop such information."

65. However, before filing the petition, plaintiffs reviewed the available data for the 54 PFAS. As the petition explains, some testing has been conducted or is underway on a small number of compounds but it fails to provide necessary data for all-endpoints and most of the 54 PFAS have no health effects data at all.

66. In addition, EPA and many other expert bodies agree that there are fundamental data gaps for nearly all PFAS. As underscored in EPA's PFAS Action Plan, "[t]here are many PFAS of potential concern to the public that may be found in the environment. Most of these PFAS lack sufficient toxicity data to inform our understanding of the potential for adverse human or ecological effects."

67. The petition denial also "finds that the petitioners failed to address ongoing testing and data collection for some of the 54 PFAS, thereby failing to set forth facts that are necessary to establish there is a need for the testing sought in the petition. This research may provide information that overlaps with testing the petitioners requested, which would render the information unnecessary under TSCA section

4(a)(1)(A)(i)(III)."

68. However, nearly all the ongoing research cited by EPA consists of *in vitro* assays, including high-throughput testing conducted by the EPA Office of Research and Development (ORD) to determine various markers of bioactivity that might signal the potential for *in vivo* effects. The health effects testing proposed in the petition consists of *in vivo* animal studies, epidemiological research and limited monitoring of workers. No *in vitro* assays are included. Non-animal test methods (New Approach Methods or NAMs) cannot at this time provide a scientifically sufficient understanding of the health and environmental effects of PFAS.

PETITIONERS' REQUEST FOR RECONSIDERATION

69. On March 4, 2021, plaintiffs submitted to defendant EPA a request to reconsider and grant their October 14, 2020 petition. The request provided a point-by-point rebuttal to the grounds for Agency's January 7, 2021 petition denial.

70. To eliminate any possible doubt about the insufficiency of available data for the 54 PFAS, the reconsideration request provided the results of a systematic and comprehensive literature search conducted by petitioners' scientific consultants on these substances. This search encompassed EPA's ChemView and CompTox data-bases as well as Pub-Med and ECHA files. The search showed that the 54 PFAS lack most or all of the studies proposed in plaintiffs' petition.

71. Not surprisingly, most of the reported toxicology data were for a small number of commercially significant compounds, such as Gen-X, tetrafluoroethylene and hexafluoropropylene. Even for these substances, however, there were still significant gaps in health effects and ecotoxicity information that would necessitate further testing. Moreover, 41 of the 54 PFAS did not have any reported data for health and environmental effects.

72. The literature search also found that, with one exception, no human epidemiological data were

available for the 54 PFAS. Similarly, only one substance (GenX) had data for immunological effects, an endpoint of high concern for PFAS as a class. Finally, no testing on mixtures for the endpoints identified in the petition was reported.

73. The reconsideration request also responded to the assertion in EPA's petition denial that a "multi-site health study is being implemented through the Centers for Disease Control and Prevention and ATSDR cooperative agreements" but petitioners "provide no analysis of overlap or what testing might be duplicative with what is proposed and thus might not be necessary."

74. To demonstrate that the new North Carolina study proposed in the petition would not be duplicative, the reconsideration request emphasized that "Cape Fear communities have distinct demographics and health conditions, are exposed to a mix of PFAS uniquely associated with the Chemours facility and its operations, experience exposure by a specific set of drinking water and other pathways, and have had high long-term levels of exposure that likely differed in magnitude and duration from those in other communities."

75. Both before and after submitting the request for reconsideration, plaintiffs sent letters and other submissions to EPA amplifying their position on several issues raised by the petition. These communications were dated March 16, April 12, June 4, July 28, and November 1 and 18, 2021

76. EPA received letters of support for the petition from dozens of non-profit organizations on November 18, 2020 and numerous recognized scientists on March 15, 2021. After submission of the reconsideration request, additional support letters were received from 120 non-profit groups on December 2, 2021, nearly 50 leading scientists on December 20, 2021, and the City of Wilmington, County of Hanover and Cape Fear Public Utility Authority in North Carolina on December 14, 2021. On June 16, 2021, 7 members of the North Carolina Congressional delegation wrote to defendant Regan urging him to "require Chemours to fund studies necessary for North Carolina communities to understand the impacts

of long-term PFAS exposure on the health of their residents."

DEFENDANTS' SECOND DENIAL OF PLAINTIFFS' PETITION

77. EPA informed plaintiffs' counsel on September 16, 2021 that it was granting plaintiffs' request for reconsideration and would "review the petition denial and will endeavor to provide a response as expeditiously as possible."

78. Subsequently, EPA agreed to make a decision granting or denying the petition by December 28, 2021.

79. On that date, Michal Friedhoff, Assistant Administrator of the Office of Chemical Safety and Pollution Prevention, wrote to plaintiffs' counsel to convey the Agency's response to the petition.

80. While not "making any final determination . . . whether the TSCA section 4 criteria have been met," the response did not dispute that the 54 PFAS lacked sufficient information "to permit a reasoned evaluation of their health and environmental effects" and "in the absence of such information. . . may present an unreasonable risk to health or the environment. . .," as required to grant petitions seeking testing under TSCA section 21(b)(4)(B)(i). Indeed, EPA acknowledged that "the vast majority of PFAS are 'data-poor', that is, lacking data that inform behavior in the environment or in exposed ecological or human populations."

81. Emphasizing that the Agency "understands, and shares, petitioners' concerns about the historic and ongoing exposures to PFAS in the Cape Fear River watershed of North Carolina," EPA asserted that it "is granting the petition under TSCA section 21 to . . . issue an order under TSCA section 4(a)(1)(A)(i) compelling health and environmental effects testing regarding PFAS." It added that:

> "EPA has determined that the petition sets forth facts demonstrating that it is appropriate to issue a section 4 order to address the health and environmental effects of PFAS. As such, EPA is granting the petition and will exercise its TSCA authorities to compel development of information on PFAS."

82. Despite claiming to be "granting" the petition and issuing test orders under TSCA section 4,

EPA refused to require testing for 47 of the 54 substances proposed for testing in the petition and rejected nearly all of the studies that petitioners requested. Thus, in reality, the Agency denied the petition.

83. In summary, the petition response:

- Failed to require testing on 47 of the 54 PFAS;
- Conditioned testing for 7 PFAS on a "tiered" approach that could result in no animal studies for the critical end-points highlighted in the petition;
- Did not address the petition's request for multigeneration or extended one-generation and 2-year rodent carcinogenicity studies on the 14 Tier 1 PFAS with substantial exposure from drinking water and/or presence in human blood;
- Did not require testing for GenX compounds despite EPA's recognition in its own toxicity assessment of the need for more studies on this ubiquitous and harmful PFAS;
- Refused to require a comprehensive epidemiological study of North Carolina residents exposed to the PFAS pollution created by the Chemours facility;
- Rejected requiring biomonitoring of Chemours employees;
- Declined to require testing on PFAS mixtures found in the drinking water and/or blood of Cape Fear residents;
- Refused to require Chemours to develop and submit analytical standards and methods on the 54 PFAS; and
- Failed to address the petition's requests for ecotoxicity and fate and transport studies on the 54 PFAS.

These elements of EPA's petition denial are described more fully in the following paragraphs.

Lack of Testing on 47 of the 54 PFAS

84. EPA's petition response only agreed to require testing on 7 of the 54 Chemours PFAS. Moreover, these PFAS were not selected for testing in response to the petition. Instead, they had previously been included in Phase 1 of the general PFAS Testing Strategy which the Agency announced on October 18, 2021.[6]

[6] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/national-pfas-testing-strategy.

85. This Strategy is not focused on the needs of communities exposed to PFAS but seeks to obtain data on substances "representative" of 70 broad categories of PFAS. The 7 Chemours PFAS were among a group of 24 substances included in the initial phase of testing to represent 24 categories containing a total of 2,950 PFAS.

86. EPA declined to require testing for 47 of the 54 PFAS in the petition on the following basis:

- 23 of the PFAS will be "covered" by data for other substances in the group of 24 "representative" PFAS that will undergo testing under the first phase of the Testing Strategy.
- 9 of the PFAS "may be covered" by future testing on "representative" substances for other PFAS subcategories under the Strategy.
- 15 of the PFAS "do not fit the definition of PFAS used in developing the Testing Strategy" and may later be tested after EPA conducts "more in-depth analyses of the existing data."

87. By asserting that many of these 47 PFAS would be "covered" by the Strategy, EPA apparently believed that it could make judgments about their health impacts on Cape Fear communities by "extrapolating" from data on other substances. This highly theoretical and unproven approach, based on complex computational models that have not been peer reviewed, was rejected in the December 20, 2021 letter of leading scientists to defendant Regan:

> "[T]he testing strategy will have limited value in informing exposed communities about the health impacts of PFAS pollution because the 24 test substances were selected without regard to whether they are widespread in the environment and human blood and contribute significantly to exposure and risk. Thus, the strategy is unlikely to provide information on those PFAS with the greatest potential to harm exposed populations."

Limited Tiered Testing

88. Even for the 7 PFAS to be tested under the Strategy, there was no assurance that all the studies proposed by petitioners for Tier 2 substances will be conducted. This is because the Strategy uses a "tiered testing" approach under which the need to conduct the important animal studies proposed in the petition would depend on the results of a set of non-animal screening assays.

89. Since these screening assays are not reliable predictors of the health effects of concern for PFAS, the health effects of the PFAS undergoing PFAS could easily be overlooked if no animal testing is required. As stated in the scientists letter:

> "We are also concerned that the strategy is unduly reliant on *in vitro* tests, including New Approach Methods (NAMs) that have not been adequately validated, while failing to adequately emphasize the studies that will be most informative to communities, health researchers, and regulators."

Lack of Comprehensive Testing for Tier 1 High-Exposure PFAS

90. EPA's December 28, 2021 response also rejected plaintiffs' request in their petition to conduct comprehensive health effects testing for the 14 PFAS assigned to Tier 1 because of their documented presence in drinking water and/or human blood. In light of this evidence of direct and substantial human exposure to the 14 PFAS, the petition asked EPA to require multigeneration or extended one-generation and 2-year rodent carcinogenicity studies on each substance.

91. EPA's response did not address the evidence of substantial exposure to the Tier 1 compounds or the benefits of the proposed testing except to say that "[s]ubsequent tiers of testing . . . . may include additional endpoints (e.g., cancer), depending on the results of the initial tiers of tests and consistent with the TSCA statutory requirement regarding tiered testing." Thus, EPA effectively denied this portion of plaintiffs' petition.

Failure to Require Testing on GenX that EPA Itself Recognized Was Necessary

92. EPA also failed to require any testing for GenX, one of the 14 Tier 1 PFAS, even though the Agency recently recognized several critical data-gaps that impeded a full evaluation of the health risks of this widespread drinking water contaminant produced by Chemours.

93. On October 25, 2021, EPA issued its final human health toxicity assessment for hexafluoropropylene oxide (HFPO) dimer acid and its ammonium salt (referred to as "GenX

chemicals").[7] This assessment concludes that GenX chemicals cause serious liver and other health effects at levels *below* those present in drinking water downstream of the Chemours plant and in private drinking water wells.

94. The assessment also finds that some of the available studies on GenX chemicals are inadequate and that no studies were available for several critical endpoints. As a result, EPA cautioned that its "safe level" may be unprotective and could fail to account for adverse health impacts that GenX exposure may be causing in North Carolina communities.

95. In their November 21 letter to defendant Regan, plaintiffs emphasized that their proposed testing program for Tier 1 PFAS would address several GenX data needs identified in the assessment, including immunotoxicity, developmental and reproductive toxicity, thyroid hormone levels, developmental neurotoxicity, developmental immunotoxicity, developmental reproduction (including mammary gland development) and carcinogenesis in the mouse.

96. However, EPA's petition response ignored the significant data gaps for GenX that it had itself recognized, thereby denying plaintiffs' request for additional testing of this pervasive and harmful contaminant.

Refusal to Conduct an Epidemiological Study on Cape Fear Populations

97. The petition response also denied plaintiffs' request for a comprehensive epidemiological study of PFAS-exposed populations in the Cape Fear basin, claiming that "multiple epidemiological studies are ongoing, both by EPA and other federal partners, and EPA intends to consult and cooperate with its federal partners, e.g., Centers for Disease Control (CDC) and the NIEHS, to continue to evaluate how ongoing research will directly inform this issue."

[7] https://www.epa.gov/chemical-research/human-health-toxicity-assessments-genx-chemicals.

98. Plaintiffs provided a detailed critique of these ongoing studies in their July 28, 2021 letter to Assistant Administrator Freedhoff. The letter explained the rationale for a human study specific to Cape Fear populations exposed to the particular PFAS discharged from the Chemours facility as follows:

> "For Cape Fear communities exposed to PFAS manufactured at the Chemours facility, human studies provide the ability to examine the association between indicators of PFAS exposure and health outcomes by collecting and analyzing detailed information about the levels and extent of PFAS exposure, as well as the specific PFAS present in blood and urine, and the health status and medical histories of exposed individuals. The findings of these studies can then point the way to diagnostic tools which enable physicians and other medical professionals to identify diseases and disorders in their patients that are likely linked to PFAS exposure and to implement medical monitoring preventative care, and treatment strategies."

The letter then demonstrated why none of the ongoing studies could meet this objective.

99. For example, the letter indicated that the CDC/ATSDR studies are "largely examining the health impacts of drinking water contamination associated with releases of firefighting foams (AFFF) from airports and military bases" located in other parts of the country." As such, they "will not provide data relevant to Cape Fear communities, which have distinct demographics and health conditions, have been chronically exposed to high concentrations of a mix of PFAS uniquely associated with the Chemours facility and its operations, and have experienced exposure by a specific set of drinking water and other pathways (e.g., inhalation and consumption of local produce, fish and game) unlikely to be found elsewhere." The letter also showed that the two North Carolina studies cited by EPA "are plainly inadequate to determine human health impacts of PFAS exposure by Cape Fear communities and are not adequate substitutes for the studies requested by the petition."

100. EPA's petition response fails to address the inadequacies in these studies or explain how they will meet the needs of Cape Fear communities.

101. Plaintiffs' petition described similar PFAS epidemiology studies that could serve as a model for a Cape Fear River study and proposed a detailed framework for designing the study:

> "This study should recruit at least 100,000 children and adults (equally of both sexes for both

> children and adults) from communities exposed to PFAS-contaminated drinking water. The study should obtain blood samples from participants to measure PFAS serum levels and several effect biomarkers such as lipids, and thyroid, kidney, immune and liver function. The study would also obtain urine samples from participants to measure PFAS levels and kidney function biomarkers. Based on this information, the study would examine associations between exposure to PFAS compounds and lipids, renal function and kidney disease, thyroid hormones and disease, liver function and disease, glycemic parameters and diabetes, as well as immune response and function and cancers in both children and adults. In addition, the study would investigate PFAS differences in sex hormones and sexual maturation, vaccine response, and neurobehavioral outcomes in children. In adults, additional outcomes of interest would include cardiovascular disease, osteoarthritis and osteoporosis, endometriosis, and autoimmune disease."

103. Despite this framework, the petition response claims that "it could take years to develop and a significant level of Agency resources to initiate such a study since a broadly accepted protocol and guideline for regulatory purposes does not exist at this point in time." This unsubstantiated claim is contradicted by the numerous qualified epidemiologists now working at EPA, the epidemiology research that EPA itself conducts or sponsors, the precedents for the study proposed by plaintiffs and the detailed framework for designing the study provided in plaintiffs' petition.

Half-Life Studies in Humans

104. The petitioners proposed that EPA compel Chemours to conduct "longitudinal studies" of its workers to measure "the rate of increase and rate of decay of serum or tissue levels as exposure begins or ceases in order to determine half lives in humans." This testing is necessary, according to the petition, because "half-lives in humans may not be predicted from animal studies," and the "variability [in half-life] appears to drive some of the apparent differences in toxicity" among PFAS.

105. Although human half-life data would be a critical element of evaluating the health risks of PFAS produced by Chemours to Cape Fear populations, EPA concluded that "it is appropriate to defer any actions to further characterize the half-lives of PFAS in humans because the results of the animal studies included in the initial test orders will inform the design of such human studies and, as described in further detail below, there are both existing studies and ongoing research efforts that will inform the Agency's

deliberations on whether and which additional tests are necessary."

Mixture Studies

106. The petitioners proposed that, to "capture the interactions between the multiple PFAS to which local populations have been exposed," testing should be conducted on three representative mixtures "reflecting distinct subgroups in the exposed population": "1) the mixture of PFAS detected in drinking water consumed by Cape Fear communities downstream of the Chemours plant; 2) the mixture of PFAS found in the blood of area residents during bio-monitoring; and 3) the mixture of compounds to which residents living near the Chemours facility have been exposed as a result of plant emissions and discharges (i.e., PFAS measured in ambient air, private wells, and local produce)."

107. Even though EPA's own guidance recognizes that "[d]ata associated with whole mixtures (i.e., a specific mixture of interest) are considered optimal," the petition response claims that "[s]uch mixture studies are unlikely to meaningfully capture the interactions between the hundreds of PFAS potentially present in the environment and the range of exposures of the Cape Fear River watershed communities."

108. These assertions fail to recognize that, because of extensive monitoring of drinking water sources and human blood, the identities and concentrations of the PFAS to which Cape Fear communities are exposed are in fact defined and studies of these mixtures would provide a meaningful basis for determining the interactions between these mixture components under the conditions of actual exposure.

109. EPA also maintained that it "would be premature to require testing on discrete PFAS mixtures before better understanding the individual component chemicals." But the small fraction of substances out of the thousands of known PFAS to be tested under EPA's Strategy means that nearly all components of the mixtures found in drinking water and human blood in the Cape Fear basin will *not* undergo individual testing. Instead, the toxicity of these mixture components will be assessed through extrapolation from a small number of "representative" PFAS that may or may not have the same health

effects.

110. Because of this high degree of uncertainty, testing of the actual mixtures to which communities are exposed will in fact more "reasonably and efficiently" determine these mixtures' impacts on health and the environment than the extrapolation approach in the testing strategy.

Test Standards

111. The petition requested that, insofar as Chemours lacks test standards for measuring the 54 PFAS in environment media, EPA should require it to develop and submit valid analytical tools for detecting and measuring the presence of these PFAS in the environment.

112. EPA's petition response rejected this request on the ground that it lacks authority under TSCA to issue a rule or order "for the development and submission of analytical standards."

113. TSCA Section 4 provides EPA with the authority to issue a rule or order to Chemours to develop and submit analytical standards.

Eco-Toxicity and Fate and Transport Studies

114. Plaintiffs' petition emphasized that "[a]n understanding of the eco-toxicity of the 54 PFAS is critical because many of them have been detected in surface water and in aquatic species and, if persistent, bio-accumulative and mobile, will be widely found in fish, wildlife and other biota and may migrate up the food chain."

115. The petition proposed a battery of eco-toxicity studies for the 54 PFAS modeled on the testing EPA earlier required for GenX.

116. EPA did not address these requests in its petition response.

117. Under the Testing Strategy, eco-toxicity testing will not be required under the initial 24 testing orders EPA plans to issue but may be required, if at all, in a subsequent phase of testing.

118. Plaintiffs' petition also emphasized that, "[i]n addition to toxicity testing in animals and

humans, conducting risk evaluations for these 54 chemicals will require the ability to effectively identify and quantify concentrations of the chemicals in various media. Thus, additional testing is necessary to evaluate fate and transport for the 54 PFAS, including their propensity to bioaccumulate, bind to organic material, partition to air or water, and degrade under various conditions."

119. The petition proposed that EPA require a battery of fate and transport studies on the 54 PFAS based on earlier EPA requirements for GenX and EPA guidelines for these types of tests.

120. Although EPA's PFAS Action Plan recognizes that "[i]nformation for many PFAS sources, fate and transport, and human and ecological exposure is sparse, both spatially and temporally," no fate and transport studies are included in the initial testing orders under its Testing Strategy and its petition response fails to respond to plaintiffs' request to require such studies on the 54 PFAS.

CLAIM FOR RELIEF

121. Plaintiffs hereby incorporate by reference the allegations contained in paragraphs 1 through 119 as if fully set forth herein.

122. TSCA section 21(b)(4)(A) provides a right to judicial review in an appropriate district court within 60 days following denial of a petition to issue a rule or order requiring testing under TSCA section 4.

123. On October 14, 2020, plaintiffs petitioned defendant EPA under Section 21(a) of TSCA to require health and environmental effects testing on 54 PFAS manufactured by Chemours at its chemical production facility in Fayetteville, North Carolina, upstream of the communities that plaintiffs represent.

124. The petition sought issuance of a rule or order under section 4 of TSCA compelling Chemours to fund and carry out this testing under the direction of a panel of independent scientists.

125. EPA initially denied the petition on January 7, 2021.

126. Plaintiffs timely filed this case to challenge the initial petition denial on March 4, 2021.

127. After plaintiffs sought reconsideration, defendants denied the petition again on December 28, 2021.

128. Following the denial of a petition seeking the issuance of a testing rule or order under TSCA section 4, section 21 of the law provides that "the petitioner shall be provided an opportunity to have such petition considered by the court in a de novo proceeding." 15 U.S.C. § 2620(b)(4)(B).

129. Section 21(b)(4)(B)(i) provides that, where the petition seeks issuance of a rule or order under section 4, the district court shall "order the Administrator to initiate the action requested by the petitioner" if it "demonstrates to the satisfaction of the court by a preponderance of the evidence" that "(I) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance to be subject to such rule or order; and (II) in the absence of such information, the substance may present an unreasonable risk to health or the environment . . . ." 15U.S.C. § 2620(b)(4)(B)(i)(I)-(II).

130. The preponderance of the evidence to be presented by plaintiffs demonstrates that the 54 PFAS proposed for testing in their petition meet these criteria for ordering EPA to issue a test rule or order under section 4 of TSCA.

131. The Court must thus direct EPA to initiate a proceeding for the issuance of a rule or order requiring Chemours to carry out the studies on the 54 PFAS specified in plaintiffs' petition.

REQUEST FOR RELIEF

WHEREFORE, plaintiffs respectfully request judgment in their favor and against defendants upon their claims and, further, request that this Honorable Court enter judgment against defendants:

(1) Declaring that plaintiffs have demonstrated by a preponderance of the evidence that, with respect to the 54 PFAS proposed for testing in their petition, "(I) information available to the Administrator is insufficient to permit a reasoned evaluation of the

health and environmental effects of the chemical substance to be subject to such rule or order; and (II) in the absence of such information, the [PFAS] may present an unreasonable risk to health or the environment . . .," pursuant to 15 U.S.C. § 2620(b)(4)(B)(i);

(2) Ordering defendants to initiate a proceeding for the issuance of a rule or order under TSCA section 4 requiring Chemours to conduct the studies on the 54 PFAS requested in plaintiffs' petition, pursuant to 15 U.S.C. § 2620(b)(4)(B);

(3) Awarding plaintiffs their costs of suit and reasonable fees for attorneys and expert witnesses in this action pursuant to 15 U.S.C. § 2620(b)(4)(C); and

(4) Granting plaintiffs such further and additional relief as the Court may deem just and proper.

Respectfully submitted this 1st day of February 2022.

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CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of February, 2022, a true and correct copy of the foregoing Amended Complaint was filed electronically with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served on all counsel of record via transmission of Notices of Electronic Filing generated by CM/ECF.

/s/ Robert M. Sussman
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