ORAL ARGUMENT NOT YET SCHEDULED

Case No. 24-1188

IN THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN WATER WORKS ASSOCIATION, et al.,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,

Respondents.

On Petition for Review

AMICUS CURIAE BRIEF OF CENTER FOR ENVIRONMENTAL HEALTH, CAPE FEAR RIVER WATCH, TOXIC FREE NC, NORTH CAROLINA STOP GENX IN OUR WATER, HARPER PETERSON, MICHAEL WATTERS, DEBRA STEWART, JANE JACOBS AND LOVELL PIERCE, JR.

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RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, amici Center for Environmental Health, Cape Fear River Watch, Toxic Free NC and North Carolina Stop GenX in Our Water state that they are non-governmental, non-profit advocacy organizations dedicated to the protection of public health and the environment. They have no parent corporations and no publicly held corporation owns a 10 percent or greater ownership interest in these organizations.

Dated: January 17, 2025

/*s/Robert M. Sussman*
Robert M. Sussman

CERTIFICATION OF CONSENT TO AMICUS BRIEF BY ALL PARTIES

Pursuant to DC Circuit Rule 29(b), I certify that I reached out to counsel for the parties and was informed that all petitioners and intervenors and respondent consent to filing of this amicus brief.

I further certify under FRAP 29(a)(4)(E) that no party's counsel authored the brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting the brief; and no person—other than the amici curiae and their counsel—contributed money that was intended to fund preparing or submitting the brief.

Dated: January 17, 2025

/*s/Robert M. Sussman*
Robert M. Sussman
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INTERESTS OF THE AMICI

The amici filing this brief are four non-profit organizations representing communities in North Carolina's Cape Fear River Basin,[1] three individual area residents,[2] and two Native Americans with leadership positions in Cape Fear tribes.[3] Several of the amici have been personally affected by contamination of drinking water containing per- and polyfluoroalkyl substances (PFAS). Others speak for community and tribal members who have been directly harmed by this contamination. The amici are deeply concerned about the long-term health consequences of consuming PFAS-contaminated drinking water and committed

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[1] Center for Environmental Health is a national non-profit organization that partners closely with locally-based organizations to address PFAS concerns in the lower Cape Fear River Basin; Cape Fear River Watch is a grassroots membership organization based in Wilmington, North Carolina whose mission is to protect and improve the water quality of the Cape Fear River Basin; Toxic Free NC advances environmental health and justice in North Carolina by advocating for safe alternatives to harmful chemicals; and North Carolina Stop GenX in Our Water is a non-profit environmental advocacy group working to raise awareness about PFAS contamination in the Cape Fear region.

[2] Harper Peterson is a former Mayor and resident of Wilmington, North Carolina who has consumed PFAS-contaminated drinking water; Debra Stewart lives in the Grays Creek Community approximately three and one-quarter miles from the Chemours Fayetteville plant and relies on a private drinking water well contaminated with PFAS; Michael Watters is also a resident of the Grays Creek Community who relies on PFAS-contaminated private well water.

[3] Jane Jacobs is a member of the Tuscarora Nation and serves as Water Protector for the Tuscarora Cape Fear Tribe; Lovell Pierce, Jr. is Principal Chief of the Cape Fear Band of the Skarure Woccon Indians, whose indigenous rights are threatened by the dangers of PFAS contamination in the Cape Fear Region.

assuring that the drinking water supply in their communities is safe in the future. They also seek to hold The Chemours Company (Chemours) accountable for its decades-long PFAS pollution of the Cape Fear River and surrounding environment, which is responsible for the pervasive presence of PFAS in drinking water throughout the region.

The amici strongly support the 2024 national drinking water standards for six PFAS promulgated by respondent Environmental Protection Agency (EPA) under the Safe Drinking Water Act (SDWA). All six PFAS have been found in municipal drinking water and private wells in the Cape Fear basin. One of these PFAS -- Hexafluoropropylene oxide dimer acid (HFPO–DA) – has been and continues to be produced by Chemours at its Fayetteville, North Carolina manufacturing plant; studies confirming its detection as a drinking water contaminant in 2016 prompted a wave of concern and anxiety across the region. If upheld, the EPA drinking water limit for HFPO-DA of 10 parts per trillion (ppt) will provide long-term health protection for Cape Fear residents. Indeed, had this limit been in place decades ago, long-term exposure to HFPO-DA and the threat to health it poses would have been prevented.

In this brief, amici trace the history of PFAS contamination in the Cape Fear basin and refute Chemours' baseless attacks on the extensive scientific findings supporting EPA's drinking water standards for HFPO-DA. Amici also underscore the public health benefits of EPA's Hazard Index (HI) methodology for addressing the risks of mixtures of PFAS that co-occur in drinking water and have additive health effects.

INTRODUCTION: PFAS CONTAMINATION OF THE CAPE FEAR RIVER BASIN

PFAS are an unusually persistent, accumulative and toxic class of chemicals that have prompted widespread concern in the U.S. and globally. The Cape Fear River in Eastern North Carolina has been uniquely contaminated by decades of PFAS pollution linked to the operations of Chemours, one of the largest global producers of PFAS and a petitioner in this case. Because the River is a source of drinking water for approximately 500,000 people, numerous PFAS discharged by Chemours have been detected in the public drinking water supply and private wells downstream of the Chemours facility, endangering the health of drinking water consumers.

HFPO–DA (often called GenX) is among the PFAS that Chemours has discharged into the River. Based on a comprehensive assessment of its health effects, the Environmental Protection Agency (EPA) has found that HFPO-DA harms the liver, kidneys, immune system, and reproductive system, at extremely low levels of exposure.[4] HFPO-DA is one of six PFAS subject to EPA's 2024 National Primary Drinking Water Regulation (NPDWR) and health-based Maximum Contaminant Level Goals (MCLGs). The Agency's drinking water rule sets an MCLG and maximum contaminant level (MCL) for HFPO-DA of 10 ppt. At issue in this case is the validity of the MCLGs and MCLs for HFPO-DA and the other five PFAS to which the EPA rule applies.

HFPO-DA and several other PFAS are produced by Chemours at a 2,177-acre site in a rural area south of Fayetteville, adjacent to the west bank of the Cape Fear River.[5] The River continues downstream from Fayetteville through the City of Wilmington and then broadens into an estuary that flows into the Atlantic Ocean. The distance from the Fayetteville plant to the mouth of the Cape Fear River is 202 miles (325 kilometers) and PFAS pollution extends throughout this stretch of the River. Built and operated by DuPont, the Fayetteville facility started producing PFAS in the 1970s. In 2015, DuPont spun off its performance chemicals business to Chemours, a new company which became the owner of the Fayetteville plant and other former DuPont facilities.

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[4] EPA, *Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid*, 2024 (Final Toxicity Assessment).

[5] https://www.chemours.com/en/-/media/files/corporate/fayetteville-works/18-ncdeq-cfrw-20191031.pdf?rev=d2ba94c749644ba086dc43dac5a1ab4b.

For several decades, HPFO-DA was produced as a byproduct during the manufacture of other PFAS.[6] However, in 2015, Chemours also began producing HFPO-DA for intentional use as a processing aid in the manufacture of fluoropolymers. HFPO-DA replaced perfluorooctanoic acid (PFOA),[7] which had been phased out at the urging of EPA following widespread drinking water contamination at a DuPont (now Chemours) facility in Parkersburg, West Virginia.[8] After its manufacture in Fayetteville, HFPO-DA is transported to the Parkersburg plant and other Chemours sites that produce fluoropolymers, which are then widely used and distributed in consumer and industrial products. Final Toxicity Assessment, at 2-3. While most extensive in Eastern North Carolina, HFPO-DA contamination of drinking water has been documented in several other states, reflecting not just discharges from industrial facilities, but the substance's "continued and possibly increasing presence in consumer products and use."[9]

PFAS discharges to the Cape Fear River likely began shortly after the

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[6] EPA, *Maximum Contaminant Level Goals (MCLGs) for Three Individual Per- and Polyfluoroalkyl Substances (PFAS) and a Mixture of Four PFAS*, 2024, A-1 (Hazard Index MCLG).

[7] PFOA is also subject to EPA's drinking water rule and is still found in surface water and drinking water in Eastern North Carolina

[8] The Hollywood film *Dark Waters* recounts the history of this contamination and the related litigation.

[9] 89 Fed. Reg. 32532, 32557 (April 26, 2024).

Fayetteville plant started operations in the 1970s. However, this PFAS pollution was not publicly-known until, starting in 2015, reports of monitoring conducted by EPA researchers identified HFPO-DA and other PFAS in the River and drinking water intakes downstream of the plant.[10] Further monitoring documented a large universe of additional PFAS in drinking water attributable to Chemours' manufacturing activities as well as numerous legacy PFAS.[11]

For the next several years, drinking water concentrations of both total PFAS and individual substances were well-above levels of health concern. For example, at the Sweeney Water Treatment Plant in Wilmington, total PFAS levels in finished drinking water were as high as 672 ppt in 2018, 330 ppt in 2020 and 306 ppt in 2022.[12] At the same plant, HFPO-DA levels in raw drinking water were as high as 76 ppt in 2019 and 56 ppt in 2021. Similarly, in 2016, EPA researchers reported median HFPO-DA levels of 304 ng/L (304 ppt) with a

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[10] *Legacy and Emerging Perfluoroalkyl Substances Are Important Drinking Water Contaminants in the Cape Fear River Watershed of North Carolina,* Environ. Sci. Technol. Lett. 2016, 3, 12, 415–419.

[11] In addition to PFOA, these PFAS include perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS), all of which are subject to EPA's drinking water rule. The presence of these PFAS is not necessarily related to Chemours' operations although it is significant that levels of PFOA and PFOS in the blood of Eastern North Carolina residents are higher than median levels of these PFAS in the U.S. population. https://genxstudy.ncsu.edu/our-findings/.

[12] PFAS Testing Results | Cape Fear Public Utility Authority Official Site (CFPUA Data).

maximum of 4,560 ng/L (4,560 ppt) in the source water of a water treatment facility downstream of the Chemours plant.[13] These levels, orders of magnitude above EPA's MCLG of 10 ppt, underscore the long-term unsafe exposure to HFPO-DA which Cape Fear communities have experienced.

Recently, HFPO-DA concentrations have declined in response to the installation of treatment technology by some water utilities and court-ordered decreases[14] in discharges by Chemours into the Cape Fear River. CFPUA Data. However, numerous PFAS continue to be detected in treated and untreated drinking water and total PFAS levels remain significant. In addition, monitoring of other environmental media has demonstrated the presence of numerous PFAS in private wells, air, wastewater, stormwater, sediment, groundwater, soil, and local produce, resulting in PFAS exposure from multiple sources.[15]

Cape Fear residents are concerned about the long-term health consequences of this historical and ongoing PFAS exposure from drinking water and other sources. This concern is centered not only on the known health effects of HPFO-

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[13] Hazard Index MCLGs, at A-2.
[14] These reductions were required by a judicially enforceable consent order between North Carolina, amicus Cape Fear River Watch and Chemours. https://www.deq.nc.gov/news/key-issues/genx-investigation/chemours-consent-order.
[15] Hazard Index MCLGs at A-11 to A-15.

DA and other individual PFAS but on the overall risks of co-exposure to multiple PFAS, including many that lack toxicity data.[16]

ARGUMENT

I. EPA's Scientific Findings on HPFO-DA Should Receive Deference as a Reasoned Application of its Technical Expertise

This case is Chemours' fourth attempt to block drinking water protections for HPFO-DA by seeking to overturn the findings of EPA's 2021 toxicity assessment for HPFO-DA. Chemours initially raised its concerns in detailed comments on the draft assessment in 2018 and 2019. Following issuance of the final assessment and EPA's rejection of its concerns in October 2021, Chemours submitted a Request for Correction (RFC) on March 18, 2022 under the Information Quality Act (IQA) seeking withdrawal and modification of the assessment.[17] Responding at length to Chemours' objections, EPA denied the request on June 14, 2022.[18] The next day, EPA issued a health advisory for HFPO-DA incorporating the findings of the assessment.[19] Chemours sought judicial

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[16] Only a small number of PFAS have undergone health effects testing. Of the Chemours-produced PFAS that have been found in drinking water, substantial health data are only available for HFPO-DA.
[17] https://www.epa.gov/system/files/documents/2022-03/3.18.22-request-for-correction-letter-and-exhibits_0.pdf,
[18] https://www.epa.gov/system/files/documents/2022-06/RFC_22001_Response_June2022.pdf.
[19] EPA, *Drinking Water Health Advisory: Hexafluoropropylene Oxide (HFPO) Dimer Acid (CASRN 13252-13-6)*, EPA/822/R-22/005 1 (June 2022).

review of the advisory in the Third Circuit, repeating its earlier scientific arguments. However, the Court dismissed the company's petition, holding that the advisory had no legal consequences and was unreviewable. *Chemours v. USEPA,* 109 F.4th 179 (3rd Cir. 2024). Now, in its challenge to EPA's final NPDWR and MCLG for HFPO-DA, Chemours is again asserting that the toxicity assessment was scientifically flawed and deviated from standard EPA toxicity assessment methodology. The Court should reject these claims.

A. EPA's HFPO-DA Toxicity Assessment Was the Outgrowth of an Exhaustive Peer Review and Public Comment Process

The HFPO-DA toxicity assessment was the result of a rigorous, painstaking and transparent multiyear scientific process. EPA released its draft toxicity assessment for HFPO-DA for public comment in November 2018.[20] Chemours and its scientific consultants were among many stakeholders and experts who submitted feedback to EPA. Five independent external peer reviewers reviewed the draft assessment in depth.[21] EPA convened a supplemental seven-member peer-review panel in the spring of 2021 to address new information received since the

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[20] EPA, *Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO),* Public Comment Draft, November 2018.

[21] EPA, *Response to Peer Review Comments on the Draft Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid*, November 2018 ("Peer Review I").

initial comment period.[22] This information included the report of a National Toxicology Program (NTP) Pathology Working Group (PWG) review of the slides[23] from key studies and recent reproductive/developmental toxicity data raising additional concerns about the effects of HFPO-DA on pregnancy.[24] As before, the supplemental review panel was supportive of EPA's approach and did not raise major concerns about the draft final assessment.

Upon finalizing the assessment in November 2021, EPA released a 69-page document responding to the public comments, including those from Chemours and its consultants.[25] In their comments, numerous independent scientists, states, and other organizations called for *strengthening* EPA's draft assessment, a path that EPA ultimately followed. In addition to addressing public comments, EPA issued reports responding to the recommendations and feedback of the initial and supplemental peer-review panels. (See FNs 21-22).

Chemours seizes on critical scientific findings in the assessment and portrays them as "arbitrary and capricious assumptions" that ignored contrary

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[22] EPA, *Response to Additional Focused External Peer Review Of Draft Human Health Toxicity Values For Hexafluoropropylene Oxide (HFPO) Dimer Acid*, October 2021 ("Peer Review II").
[23] The slides preserve the tissue samples from exposed animals and document pathology caused by the test substance.
[24] 89 Fed. Reg. 32548-49.
[25] *EPA Response to Public Comments on Draft Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid*, October 21, 2021.

evidence. Ind. Pet. Br. at 53. But this is at best a highly selective and one-sided picture of the assessment process that omits the enormous lengths to which EPA went to review and respond to Chemours' scientific claims, justify its differing interpretation of the data, and ensure that this interpretation passed muster with respected independent experts.

Chemours claims that, because major aspects of the final 2021 assessment differed from the 2018 draft, EPA necessarily rejected "good" science in order to inflate the adverse health effects of HFPO-DA. Id. at 53-54. But the record fully explains EPA's rationale for modifying the assessment and shows that these changes were a logical outcome of EPA's iterative science process, in which it sifted through the input of peer reviewers and public commenters, reviewed new studies and further analyzed the data. That EPA developed heightened concerns about HFPO toxicity as its work progressed is not troubling or unusual: this is how a healthy scientific process should work.

"When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential." *Baltimore Gas & Electric Co. v. Natural Resources Defense Council, Inc.*, 462 U.S. 87, 103 (1983). "[W]e 'will give an extreme degree of deference to the agency when it 'is evaluating scientific data within its technical expertise.''" *City of Waukesha*, 320 F.3d 228, 247 (D.C. Cir. 2003) (per curiam).

"Deference to an agency's technical expertise and experience is particularly warranted with respect to questions involving ... scientific matters. " *United States v. Alpine Land & Reservoir Co*., 887 F.2d 207, 213 (9th Cir.1989). *See also Texas v. U.S. Envtl. Prot. Agency*, 690 F.3d 670, 677 (5th Cir. 2012).

B. EPA and Its Peer Reviewers Carefully Considered Chemours' Scientific Concerns and Explained Why They Lacked Merit

For each of the "flaws" in the EPA assessment claimed by Chemours, EPA exhaustively explained the evidence for its scientific determinations and rebutted Chemours' concerns.

1. Relevance of PPAR-alpha Liver Effects to Humans

Chemours claims that the HFPO-DA rodent liver effects involve a peroxisome proliferator-activated receptor alpha (PPAR-alpha) mechanism that is not relevant to humans. Ind. Pet. Br. at 57. However, the first peer-review panel generally agreed with EPA that "the MOA [Mechanism of Action] of [HFPO-DA] is largely unknown and that given the paucity of data, [it] could not conclude that PPARα was the sole cause of observed liver effects, such as liver weight and single-cell necrosis." RFC Denial at 7. The reviewers concurred that the weight of evidence for adverse liver effects was supported by the data, clearly described and scientifically justified. Peer Review I at 28-30. None advised EPA that liver effects were irrelevant to humans.

The final toxicity assessment "concluded there are not yet enough data to conclude that PPARα activation is the sole mechanism underlying the liver effects associated with exposure to GenX chemicals." Final Toxicity Assessment at 86. Moreover, EPA's IQA response cited a 2021 article emphasizing that "PPARs are a well-known pharmacological target for the treatment of multiple diseases in humans" and that "modulation of both PPARα and/or PPARγ by exogenous agents, such as PFAS, are relevant to human health." RFC Denial at 11.

Chemours claims that EPA ignored the 2020 Chappell, et al. study, which determined that the "liver changes observed in GenX-treated mice occur via [the PPAR-alpha] mode of action." However, EPA's response to Chemours RFC addressed the study in detail, explaining that its results "do not change EPA's conclusions in the toxicity assessment . . . that there is evidence that these GenX chemicals have multiple MOAs, including PPARα," and "the Chappell publication supports data already summarized in the toxicity assessment for GenX chemicals" Id. at 8.

2. Constellation of Liver Effects

EPA's final toxicity assessment concludes that "[t]he available data indicate that multiple [Mechanisms of Action] could be involved in the liver effects observed after GenX chemicals exposure" and support "a role for PPARα, cytotoxicity, mitochondrial dysfunction, and PPARγ." Final Toxicity Assessment at 82-86. As EPA explains, "the constellation of liver lesions observed in the rodent are relevant to human health and not a result of PPARα-induced cell proliferation unique to rodents." Id. at xii.

Chemours claims that this "constellation of liver lesions" was an "invented" and "unprecedented" toxicological concept with no scientific basis. Ind. Pet. Br. at 59. However, EPA's analysis was based on the findings of the independent, expert PWG formed by NTP to examine selected tissues from the two pivotal HFPO-DA studies after Chemours asserted that the original reading of the liver pathology slides by DuPont was erroneous. As EPA noted, all seven pathologists on the NTP PWG "unanimously agreed on the classifications of single cell necrosis, focal necrosis and apoptosis in the reanalysis of the slides (and later referred to as a constellation of lesions)." RFC Denial at 13. The PWG concluded "that the dose response and constellation of lesions (i.e., cytoplasmic alteration (including hepatocellular hypertrophy), single-cell necrosis, focal necrosis, and apoptosis), rather than each lesion individually, represent adversity in these studies." Id. EPA's second peer-review panel agreed with the PWG's determination of a "constellation of lesions" and several reviewers characterized EPA's assessment of the liver effects as thoroughly described and justified. Id. at 14.

3. Uncertainty Factors

Long-standing EPA practice in developing toxicity assessments is to apply Uncertainty Factors (UFs) to account for limitations and gaps in the available data and the possibility that further testing would identify additional end-points of concern or known adverse effects at lower doses. EPA issued detailed guidance for selecting UFs in 2002 and has followed this guidance in numerous assessments.[26] In the final HFPO-DA assessment, EPA relied on the guidance to calculate five separate UFs which, when combined, resulted in a total UF of 3000 for determining a "safe" level of exposure. Final Toxicity Assessment at 92-99. Chemours claims that EPA used "significantly inflated" UFs which "deviate from its own standard methods and ignored relevant evidence." Ind. Pet. Br. at 52.

As EPA explained, the ten-fold increase in the total UF (from 300 to 3000) between EPA's draft and final toxicity assessments resulted from increasing two UFs – for data limitations and lack of chronic toxicity data – from 3 to 10. Chemours says larger UFs are arbitrary and capricious because EPA "relied on new studies that actually *reduced* uncertainty regarding toxicity." Id. (emphasis in original). However, EPA explained that, even with the new data, "[t]he toxicity database for GenX chemicals is relatively small" and the available toxicity data is "limited as key studies are not available." It also emphasized that "[r]ecently

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[26] EPA, *A Review of the Reference Dose and Reference Concentration Processes*, 2002.

published toxicokinetic and toxicological findings . . . heighten concerns regarding the impact of Gen X chemicals exposure on reproduction, development, and neurotoxicity." RFC Denial at 14. The Agency's charge to the supplemental peer-review panel elaborates that the new information demonstrates "accumulation of GenX chemicals in the whole embryo and identified additional adverse effects that EPA had not considered in applying a database uncertainty factor of 3." Peer Review II, at 3-4. Increased UFs, EPA determined, were needed in light of the higher level of concern about developmental and reproductive harm, coupled with the lack of definitive data to define these potential adverse effects. All seven independent expert peer reviewers concurred with EPA's 10X uncertainty factor to account for limitations of the database. Id. at 15-19.

EPA's charge to the supplemental peer review panel also explained why a larger UF for lack of chronic toxicity data was needed:

> Because a 2-year chronic mouse study is unavailable, the impact of a longer dosing duration on both the incidence and severity of liver effects in mice is unknown. This is important because the new analysis by NTP indicates that the duration of exposure appears to play a larger role than previously understood in the progression and severity of liver effects resulting from GenX chemical exposure, as evidenced in female rats. . . .[A] 2-year chronic study in the mouse would provide information critical to understand the progression of these liver effects. Specifically, it is possible that a longer duration study would result in an increased frequency and/or magnitude of response and could also reveal additional adverse effects observed in the existing less-than-chronic mouse studies.

Id. at 4. The majority of the panel (5 of the 6 peer reviewers that responded to EPA's charge questions) agreed with EPA's 10X UF to account for the extrapolation from a subchronic to a chronic study. Id. at 20-23.

In another case under SDWA, the D.C. Circuit rejected similar industry challenges to EPA scientific findings:

> Happily, it is not for the judicial branch to undertake comparative evaluations of conflicting scientific evidence. Our review aims only to discern whether the agency's evaluation was rational. EPA provided ample explanation for its decision . . . It received and replied to extensive comments on the issue, and it detailed its reasons for giving greater weight to the positive studies than to the negative or inconclusive studies.

NRDC v. EPA, 824 F.2d 1211, 1216-17 (D.C. Cir. 1987).

II. The Relative Source Contribution Used to Determine the HFPO-DA MCLG Was Within EPA's SDWA Authority and Supported by the Record

A. EPA's Longstanding Practice of Considering Exposure from Non-Drinking Water Sources in Deriving MCLGs Was Authorized by SDWA

Chemours also claims that EPA "dramatically reduced" its MCLG for HFPO-DA by arbitrarily assuming that drinking water ingestion makes a 20% Relative Source Contribution (RSC) to total exposure, with other sources accounting for the remaining 80%. Ind. Pet. Br. at 54-57. However, EPA's RSC calculation was within its authority, consistent with long-standing EPA guidance and supported by the record.

The RSC has been a standard element of EPA's approach to drinking water protection for more than 30 years. *E.g.*, 54 Fed. Reg. 22062, 22069-70 (May 22, 1989); 56 Fed. Reg. 3526, 3526, 3536 (Jan. 30, 1991) (using RSC for national primary drinking water regulations for several noncarcinogenic contaminants). The "policy of considering multiple sources of exposure when deriving health-based criteria . . . is important for adequately protecting human health … [with] protective health criteria."[27]

A critical goal in identifying contaminants for action under the SDWA is whether they exceed "levels of public health concern." This concept encompasses not just the levels of a contaminant in drinking water but whether the combination of these levels with other exposures can cause harmful effects. 42 U.S.C. § 300g-1(b)(1)(A)(ii). Similarly, the Act's rulemaking provisions direct EPA to determine "the maximum level of contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety." 42 U.S.C. §300g-1(b)(4)(A). An MCLG which ignores non-drinking water contributors to exposure and risk would not protect against "known or anticipated adverse effect[s] on the health of persons" and therefore would not provide "an adequate margin of safety." In fact, EPA would be in

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[27] EPA, *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health,* EPA-822-B-00-004 4-4 (2000) (Methodology).

violation of SDWA if it had scientific evidence of the contribution of non-drinking water sources to total risk but failed to use this evidence in identifying levels of a contaminant that protect against "known or anticipated adverse effects" on drinking water users.

B. The HFPO-DA MCLG Followed the RSC Decision-Tree in EPA's Methodology

EPA's approach to determining RSCs was formalized in its comprehensive 2000 Methodology. That guidance sets out an Exposure Decision Tree to determine the RSC, which is "the percentage of total exposure typically accounted for by the exposure source"—here, drinking water—that is "applied to the [reference dose] to determine the maximum amount of the [reference dose] 'apportioned'" to drinking water. Methodology at 4-5. Under the decision tree, a "'ceiling' level of 80 percent of the [reference dose] and a 'floor level' of 20 percent of the [reference dose] are applied." Id. As EPA explains, "[w]hen adequate data are available, they are used to make protective exposure estimates for the population(s) of concern. When other sources or routes of exposure are anticipated but data are not adequate, there is an even greater need to make sure that public health protection is achieved." Id. at 4-6. In these cases, EPA's guidance recommends use of default assumptions "that allow for the inadequacies of the data while protecting human health." Id.

Thus, where there are "significant known or potential uses/sources other than the source of concern," but insufficient "information [is] available on each source to make a characterization of exposure," EPA uses the "default assumption that contaminant levels in drinking water represent 20% of the [reference dose]." *Id.* at 4-8, fig.4-1. However, when scientific data are available demonstrating that sources and routes of exposure other than drinking water are not anticipated for a specific pollutant, the RSC could be raised as high as 80%. Id. at 4-15.

For HFPO-DA, EPA adopted a default RSC of 20% after completing the steps in the Methodology's decision tree. To begin with, EPA undertook an exhaustive literature review and screening process for information on HFPO-DA exposure routes and sources. This review produced a body of data from U.S. and international sources. Hazard Index MCLG at 2-3, 2-4. Not surprisingly, evidence of the presence of HFPO-DA in food, air, soil and sediment was most pronounced in areas near fluoropolymer production plants where GenX is produced or used, such as the Chemours Fayetteville facility. Id. Appendix A.

The detailed evidence EPA assembled contradicts Chemours's surprising assertion that "the only relevant exposure pathway for HFPO is drinking water," Ind. Pet. Br. at 56. Among the non-drinking water sources of exposure documented by EPA were:

- **Food:** HFPO-DA was detected in produce (collard greens, cabbage) collected near a PFAS production plant in national studies of the potential exposure to the U.S. population to PFAS and in composite fish samples collected from a lake near a PFAS manufacturing facility in North Carolina at a concentration of 70 nanograms per kilogram.[28] Hazard Index MCLG, at A-11. EPA also noted that HFPO-DA was detected at low levels in 14% of vegetable garden crops (endive, beets, celery, lettuce, and tomatoes) grown near a PFAS manufacturing facility in the Netherlands. Id.
- **Soil:** GenX was detected in 5 out of 13 soil samples in Ohio and West Virginia that were upstream of and downwind from the Chemours facility in West Virginia, results that also indicate air emissions of GenX. Id. at A-13, A-14.
- **Air and rainwater:** A study estimated that the Chemours Fayetteville plant had annual HFPO-DA air emissions exceeding 2,700 pounds from 2017-2018. Id. "[R]ainwater samples collected within a seven-mile radius of this facility were reported to have detectable levels of [HFPO-DA] …

[28] Based on data showing even higher levels in fish, North Carolina's fish consumption advisory for PFAS is the most stringent issued by the state.

with the highest concentration of 810 ppt found in a rainwater sample collected five miles from the facility." Id. The three samples collected seven miles from the plant had HFPO-DA concentrations ranging from 45.3 to 60.3 ppt. Id. at A-13.

- **Other exposure sources:** Other potential routes of exposure identified by EPA include "dermal exposure (contact of exposed parts of the body with water containing GenX chemicals during bathing, showering, etc.) and inhalation exposure (during bathing or showering, using a humidifier or vaporizer, etc.)." Final Toxicity Assessment at 28.

EPA thus concluded that its research "identified several relevant HFPO-DA exposures and pathways, including dietary consumption, incidental oral consumption via dust and soil or dermal exposure via soil and dust, and inhalation exposure via ambient air." Hazard Index MCLG, at A-15.

As amici can personally attest, the extensive PFAS contamination at the Chemours site and throughout the Cape Fear Basin has resulted in multiple sources of HFPO-DA exposure in addition to drinking water. According to amicus Michael Watters, "[t]he high levels of [HFPO-DA] in air, soil and locally-grown produce significantly increase the health risks of exposure by those of us who tend vegetable gardens." Watters Declaration. ¶ 8, filed in *Chemours v. USEPA* (3rd Cir. No. 22-2287) ECF No. 9-2. Dana Sargent, director of amicus Cape Fear River

Watch, reports that "[r]esidents continuously voice concerns … about showering or bathing their children in PFAS, or swimming in pools filled with it, or eating food grown with PFAS-contaminated water and eating food off of dishes washed in it." Suppl. Sargent Suppl Decl. ¶ 18, *Chemours v. USEPA,* ECF No. 35-2.

Chemours cites 22 "independent reports" purportedly showing the absence of exposure from non-drinking water pathways and claims that EPA disregarded this information. Ind. Pet. Br. at 55. However, EPA did in fact review and evaluate these reports.[29] In several cases, it assigned them no weight because they did not contain new information, were not peer reviewed or provided study summaries rather than actual data. In other cases, the cited reports presented data on the presence of HFPO-DA in areas in Europe, the United States, and China distant from facilities producing or using HFPO-DA. (The limited data from Eastern North Carolina reflected in these reports in fact show the presence of HFPA-DA in soil samples.) While EPA incorporated a number of these reports in its RSC analysis, they did not negate extensive other data (from areas where HPFO-DA was produced or used such as North Carolina) that in fact showed multiple pathways of human exposure apart from drinking water. Understandably,

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[29] EPA, *Responses to Public Comments on Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation Rulemaking,* EPA Document No: 815R24005, April 2024, at 4-587 to 592, 4-590 to 599 (presenting chart describing the 22 reports).

therefore, EPA concluded that populations consuming contaminated drinking water (like those in the Cape Fear Basin) were also exposed to HPFO-DA from other sources and this exposure needed to be accounted for in setting an MCLG that fully protected the health of drinking water users.

Despite finding substantial evidence of non-drinking water pathways of exposure, EPA also determined that "there was inadequate quantitative data to describe the central tendencies and high-end estimates for all of the potentially significant sources." Hazard Index MCLG, at A-15. For example, consistent with its obligation under SDWA to protect vulnerable groups, EPA identified "lactating women and women of childbearing age [as] . . . potential populations of concern" but found that "limited information was available regarding specific exposure of these populations to HFPO-DA in different environmental media." Id. Similarly, while noting the evidence of HFPO's presence in the food supply, the Agency said "it is not possible to determine whether . . .vegetables and soil should be considered major or minor contributors to total HFPO-DA exposure." Id. Accordingly, consistent with the Exposure Decision Tree," EPA "recommend[ed] an RSC of 20% (0.20) for HFPO-DA." Id

Chemours cites an "expectation" in the Methodology that the 20% default would be used "infrequently," Ind. Pet. Br. at 55, but the Methodology also states the default should be used unless available data "more accurately reflect[]

exposures." Here, despite evidence of non-drinking water pathways of exposure, the information available was insufficient to quantify the percent of total HFPO-DA exposure attributable to such sources, requiring use of the 20% default.

In sum, following long-standing EPA guidance, its RSC applied a default health-protective assumption to account for known, but inadequately characterized, HFPO-DA exposures from non-drinking water sources. Thus, EPA "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983).

III. The Rule's Regulation of PFAS Mixtures Using a Hazard Index Approach Was Legally Permissible, Scientifically Sound and Health-Protective

EPA's rule establishes an MCLG and MCL for the mixture of four PFAS (PFHxS, PFNA, HFPO-DA, and PFBS) when two or more of these substances co-occur in sources of drinking water. This approach is well within EPA's statutory authority and is a prudent, science-based response to the real-world health risks of co-exposure to multiple PFAS in the drinking water supply. Far from being unprecedented, EPA has used this approach in previous regulations. EPA Br. at 28-29.

As EPA explains, it is increasingly common to detect the "occurrence and co-occurrence of multiple PFAS in drinking water." Hazard Index MCLG at 1-2.

To determine the health effects of these mixtures, EPA and its science advisors adopted the principle of "dose additivity," under which "the risk of adverse health effects following exposure to the mixture is equal to the sum of the individual doses or concentrations scaled for potency." Id. PFAS are amenable to a dose additivity approach because many of them "elicit similar adverse health effects on several of the same biological systems and functions including thyroid hormone signaling, lipid synthesis and metabolism, development, and immune and liver function." Id. As a result, "exposure to these PFAS, at doses that individually would not likely result in adverse health effects," may be harmful "when combined in a mixture." Id. According to EPA, PFHxS, PFNA, HFPO-DA, and PFBS are "associated with many of the same or similar adverse health endpoints and outcomes" and therefore should be regulated as a mixture when they co-occur in drinking water. Id. at 1-7.

Contrary to the industry petitioners, Ind. Pet. Br. at 31-33, nothing in SDWA forecloses EPA from setting drinking water standards for mixtures of co-occurring PFAS as opposed to single substances. The law's standard-setting process applies to "contaminants," which are defined as "*any* physical, chemical, biological, or radiological substance *or matter* in water." 42 U.S.C. § 300f(6) (emphases added). While "substance" may denote an individual compound, "matter" is a broad term whose plain meaning extends to groupings (or mixtures) of substances. To reject this common-sense understanding of "matter" would defeat the law's health-protective goals.

EPA's MCLG and MCL for mixtures of four PFAS are based on a Hazard Index (HI) methodology that accounts for differences in toxicity among these PFAS and their relative concentrations in drinking water at a specific location. The first step in the methodology is calculating a chemical-specific "health-based water concentration" protective of health over a lifetime. Hazard Index MCLG at 1-20 to 1-21. The concentration in drinking water of each substance is then divided by this health-based level to calculate a Hazard Quotient (HQ) and the results are added for the mixture components. Both the MCLG and MCL in the rule are set at 1 – meaning that concentrations of the mixture in drinking water cannot exceed the adjusted health-based limits. Id.

There is no merit to industry's claim that this approach is unlawful because standards under SDWA can only be expressed as the maximum allowable *concentration* of a specific contaminant in drinking water. The definition of MCL does not refer to "concentrations" but instead requires EPA to set "the maximum permissible *level* of a contaminant in water." 42 U.S.C. § 300f(3) (emphasis added). Plainly, this "level" can be expressed as a hazard index formula as well as a specific concentration.

All four of the HI Index PFAS have been detected in drinking water in the Cape Fear Basin (CFPUA Data) and therefore EPA's rule provides tangible protections to Cape Fear communities. From a broader perspective, the drinking water consumed by these communities has contained scores of PFAS (including both Chemours-produced and legacy substances) and monitoring has consistently shown total PFAS levels dramatically higher than the concentrations of HFPO-DA and other individual substances alone. Moreover, Chemours' own data shows that there are 257 "unknown" PFAS being discharged and/or emitted from its facility.[30] However, the contribution of these PFAS to human exposure is undetermined because no standards exist by which to measure their concentrations in drinking water, fish and food supplies, groundwater or soil. In addition, the principal method for analyzing PFAS concentrations in water -- EPA method 1633 -- is currently able to measure only 40 compounds, which do *not* include the 20 PFAS most frequently detected by Chemours in groundwater.[31] Thus, the data now available to agencies and the public for assessing the extent of PFAS

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[30] Chemours, PFAS NON-TARGETED ANALYSIS AND METHODS INTERIM REPORT: Process and Non-Process Wastewater and Stormwater. June 30, 2020.
[31] https://docs.google.com/spreadsheets/d/14VFQmNGzk8gkMd4lCQXgryTBEwUDkhdG/edit?gid=1855166798#gid=1855166798.

contamination in the Cape Fear region does not account for nearly 300 unique PFAS compounds and greatly understates the full magnitude of exposure and risk.

In short, co-exposure to multiple PFAS has been (and remains) a significant risk driver for the exposed Cape Fear population. EPA's HI methodology is an initial step in addressing PFAS co-exposure but, because of its limited application under the rule, fails to protect against the hundreds of PFAS co-occurring in the drinking water of Cape Fear communities.

While regulating individual PFAS may indirectly lower drinking water concentrations of unregulated PFAS, this substance-by-substance approach has limited benefits. Noting the tens of thousands of chemical compounds in use, the House Committee responsible for SDWA emphasized it would be "impossible for EPA to regulate each of these contaminants which may be harmful to health on a contaminant-by-contaminant basis." H.R. Rep. No. 93-1185 (1974) at 10.

Developing drinking water standards for PFAS mixtures using a Hazard Index framework builds on the growing body of data showing common health effects within the PFAS class and achieves greater overall health protection more efficiently. Upholding EPA's standard-setting authority for mixtures and the use of dose-additivity to set regulatory limits would thus preserve EPA ability to use this important tool to address pervasive PFAS contamination of drinking water in many regions of the U.S.

CONCLUSION

EPA's PFAS drinking water rule should be upheld by the Court.

January 17, 2025

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CERTIFICATE OF SERVICE

I hereby certify that, on January 17, 2025, I filed the foregoing Amicus Brief using the Court's ECF system. Service on all counsel of record for all parties was accomplished electronically using the Court's CM/ECF system.

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CERTIFICATE OF COMPLIANCE

1. This Amicus Brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) because the Brief contains 6498 words, excluding the parts of the Brief exempted by Fed. R. App. P. 32(f) as counted by the automated function of Microsoft Word.

2. This Brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word Times Roman 14-point font.

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