NO. 23-1476

In The

United States Court Of Appeals For The Fourth Circuit

CENTER FOR ENVIRONMENTAL HEALTH; CAPE FEAR RIVER WATCH; CLEAN CAPE FEAR; TOXIC FREE NC,

Plaintiffs – Appellants,

v.

MICHAEL S. REGAN, Administrator of the U.S. Environmental Protection Agency; UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Defendants – Appellees,

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NORTH CAROLINA AT WILMINGTON

BRIEF OF APPELLANTS

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
- Counsel has a continuing duty to update the disclosure statement.

No. 23-1476 Caption: CEH v. Regan

Pursuant to FRAP 26.1 and Local Rule 26.1,

Center for Enviornmental Health, Clean Cape Fear, Cape Fear River Watch, Toxic Free North Carolina
(name of party/amicus)

who is appellants, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐ YES ☑ NO

2. Does party/amicus have any parent corporations? ☐ YES ☑ NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐ YES ☑ NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐YES ☑NO
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding? ☐YES ☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim? ☐YES ☑NO
If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: //Robert M. Sussman Date: May 15, 2023

Counsel for: Appellants

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INTRODUCTION

The four plaintiff organizations in this case represent communities in Eastern North Carolina suffering from decades-long chemical pollution of the Cape Fear River by The Chemours Company ("Chemours"). For 40 years, Chemours' plant in Fayetteville has discharged into the River numerous toxic chemicals belonging to the class known as Per- and Polyfluoroalkyl Substances ("PFAS"). Chemicals in this class have prompted deep alarm around the world because of their persistence, accumulation in people and wildlife and harmful effects on human health. In Eastern North Carolina, the PFAS produced by Chemours have contaminated the drinking water and blood of hundreds of thousands of people. They have also been widely detected in air, soil, groundwater and locally grown food.

Yet residents living near to or downstream of the Chemours facility do not know -- and cannot determine -- how years of PFAS exposure have affected their health. This is because there are virtually no scientific data on the harmful effects of the specific PFAS produced by Chemours to which they have been chronically exposed.

To address this alarming data gap, plaintiffs petitioned the federal Environmental Protection Agency ("EPA") to require Chemours to undertake testing on 54 specific PFAS to which Cape Fear residents have been exposed. The petition was based on EPA's long-standing authority under section 4 of the Toxic

Substances Control Act ("TSCA") to compel manufacturers to assume responsibility for developing data on the health and environmental effects of substances that they place in commerce and release into the environment. Based on the advice of leading experts, the petition proposed an extensive testing program carefully designed to provide the most important information for understanding the health and environmental impacts of the 54 PFAS on exposed communities.

In December 2021, EPA rejected 97 percent of the studies requested by the petitioners but claimed it was "granting" the petition because of an existing testing initiative for the broad PFAS category that was not intended to address the impacts of the 54 PFAS on Cape Fear residents. Contending that EPA's petition response was in reality a "denial," plaintiffs filed suit to challenge EPA's decision. Although Section 21 of TSCA provides a uniquely powerful judicial remedy for petition "denials," EPA argued below that plaintiffs could not access this remedy because it had labeled its decision a "grant" of the petition and the District Court therefore lacked jurisdiction. The Court agreed and entered an order of dismissal.

As plaintiffs show in this brief, the lower court's decision must be reversed because its elevation of form over substance was contrary to the text, structure, intent and legislative history of sections 4 and 21 of TSCA and to EPA's historical implementation of the section 21 petition process.

JURISDICTIONAL STATEMENT

This Court has jurisdiction over appeals from the U.S. District Court for the Eastern District of North Carolina under 28 U.S.C. § 1292. Plaintiffs' Complaint in the District Court based jurisdiction on 15 U.S.C. § 2620. The District Court held that it lacked jurisdiction and dismissed the Complaint in its March 30, 2023 Order (JA664-692) and entered a Final Judgment (JA693). Plaintiffs filed a timely notice of appeal of the Judgment on April 25, 2023. JA694. Venue is proper under 28 U.S.C. § 1391(e) because three of the appellants reside in North Carolina.

STATEMENT OF ISSUES PRESENTED FOR DECISION

1. Did the District Court wrongly conclude EPA "granted" plaintiffs' petition for testing under section 21 of TSCA when plaintiffs' Amended Complaint showed that (a) EPA refused to require testing on 47 of the 54 substances specified in the petition and (b) rejected nearly all of the scientific studies requested?

2. Did the District Court misinterpret TSCA by concluding that EPA could grant the petition on the basis of its preexisting testing strategy for the large PFAS "category" even though the strategy and the petition had very different objectives and experts maintained that the strategy would not produce meaningful data on the impact of the 54 substances on the health of the exposed population?

3. Did the District Court misread TSCA by concluding that neither petitioners nor the Court could compel EPA to propose test rules or orders

requiring specific studies on particular chemicals even though plaintiffs' petition met the TSCA criteria for testing and the statute directs that in such cases the court shall order EPA "to initiate the action requested by the petitioner"?

STATEMENT OF THE CASE

I. Chemours' Pollution of the Cape Fear River Basin

Chemours' PFAS manufacturing 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. Over 300,000 residents of Wilmington and other population centers downstream from or adjacent to the facility use the River as a source of drinking water. JA24-25, JA164.

The Fayetteville facility was built and operated by DuPont and started producing PFAS 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. The plant is one of the largest US producers of PFAS. JA24-25.

Extensive PFAS pollution of the Cape Fear River by the Fayetteville plant began four decades ago but was not publicly known until the late 2010s. JA46, JA165. Starting in 2018, monitoring identified 10 PFAS in the River and drinking water downstream of the Fayetteville plant. In further sampling of the river

downstream of the plant, other scientists found 37 unique PFAS. Researchers at North Carolina State University also detected several of these compounds in the blood of residents of the Cape Fear region. Sampling in the Cape Fear River indicated that total PFAS concentrations (all substances combined) were 130,000 parts per trillion (ppt). JA47, JA165.

Water utilities serving Cape Fear communities subsequently identified numerous PFAS linked to the Chemours plant in municipal drinking water supplied to residents and businesses. JA47. As concern increased about surface water and drinking water contamination, monitoring of other environmental media for PFAS produced at the plant demonstrated the presence of numerous PFAS in private wells, wastewater, stormwater, sediment, groundwater, soil and local produce as a result of air emissions from Chemours plant. JA166. Despite reductions in water discharges and air emissions, recent sampling of drinking water systems and private wells documents continuing PFAS pollution by the plant. JA48, JA158,

II. The Dangers of PFAS

PFAS are often called “forever” chemicals because they do not break down or degrade over time and therefore are highly persistent. JA45. Thus, they build up in the natural environment and in biological systems, accumulating up the food chain from lower to higher organisms. 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. JA44-45, JA162-63. Several PFAS have been detected in the blood of the general population, with 99 percent of those sampled showing detectable levels of these compounds. JA45. Populations near PFAS-polluting facilities such as the Chemours plant have been shown to have significantly higher levels of PFAS than the general population.

In its National PFAS Testing Strategy, EPA identifies over 6500 substances that it classifies as PFAS. JA261. Testing to date on a small number of these PFAS demonstrates concern for 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. JA171-172, JA258-259. However, "significant gaps remain related to the impacts of other PFAS on human health and in the environment" (JA127, JA238) and "[m]ost PFAS have limited or no toxicity data." JA241.

III. TSCA Testing Requirements

TSCA was enacted in 1976 to create a national program for assessing and managing the risks of chemicals to human health and the environment. Central to the law is imposing accountability on chemical manufacturers for conducting testing to determine the health and environmental effects of their chemicals.

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

This policy is implemented in section 4 of TSCA, which provides EPA with broad authority to issue rules or orders directing manufacturers to undertake health and environmental effects studies upon EPA's determination that the testing criteria in section 4(a)(1)(a) are met.[1] These rules or orders 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 or mixture "does or does not present an unreasonable risk to health and the environment." 15 U.S.C. § 2603(a)(1).

Under section 4(b)(2)(A), test rules or orders may require studies to determine a chemical's effects on human health, such as cancer, birth defects, harm to unborn fetuses, and behavioral and neurological disorders.

[1] The 2016 TSCA Amendments strengthened EPA's Section 4 authority by authorizing EPA to issue administrative orders to compel manufacturers to conduct testing. Frank R. Lautenberg Chemical Safety for the 21st Century Act, P.L. 114-182 (06/22/2016).

15 U.S.C. § 2603(b)(2)(A). EPA may require "epidemiologic studies" – i.e., research on human populations exposed to a chemical to ascertain whether a causal connection exists between that exposure and an increased incidence of death and disease. It may also require studies on "mixtures" – i.e., combinations of substances that may have additive effects where people are exposed to them concurrently. Id.; § 2603(a)(1)(B).

IV. TSCA Citizens' Petitions for Test Rules and Orders

Section 21 of TSCA (15 U.S.C. § 2620) creates a petition process under which citizens can seek to compel EPA to exercise its authority to address chemical threats under different provisions of the law. As emphasized in the Senate report on the 1976 law, "[t]his section will assure that the Environmental Protection Agency is forced to focus on the provisions of the bill directed at protecting health and the environment from the dangers of toxic chemicals." JA293. Under section 21(a), petitions may seek initiation of a rule or order under Section 4 requiring manufacturers to undertake testing. *Id.* § 2620(a). Section 21(b)(3) requires EPA to respond to petitions within 90 days. Where petitions are denied, EPA must publish a notice in the Federal Register explaining the basis for the denial. Id. § 2620(b)(3). If EPA denies the petition or fails to act within 90 days, the petitioner may 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). The court must consider the merits of the petition "in a *de novo* proceeding" and "order the Administrator to initiate the action requested by the petitioner" if "a preponderance of the evidence" shows that the test chemicals meet the TSCA criteria for requiring testing. 15 U.S.C. § 2620(b)(4)(B)

V. Plaintiffs' Testing Petition

The communities in the Cape Fear River basin represented by the four plaintiff organizations face serious health risks from long-term exposure to PFAS produced and released into the environment by Chemours. 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, little or no scientific data are available on the health impacts of the PFAS in residents' drinking water, the air they breathe, the food they eat and their blood. This lack of information is depriving them and their medical professionals of important knowledge that would inform diagnosis and treatment. JA36.

On October 14, 2020, plaintiffs petitioned EPA under section 21 of TSCA to compel Chemours to undertake comprehensive health and environmental effects testing on 54 specific PFAS manufactured at its Fayetteville facility. JA152-200. Petitioners selected these 54 PFAS based on evidence of known or anticipated exposure by Cape Fear communities, as demonstrated by available data on the

presence of the PFAS in human blood, drinking water, surface water, air emissions, rainwater, private wells, groundwater and locally grown produce. JA168-170, JA196-200. The petition showed that the 54 PFAS meet the TSCA section 4(a)(1) criteria for testing because (1) "they may present unreasonable risks" to Cape Fear communities as a result of their potential for harmful health effects and known or probable human exposure, (2) "there is insufficient information and experience" to determine their effects on the health of Cape Fear residents and the basin's ecosystem, and (3) "testing is necessary to develop such information." JA170-176.

The petition requested that EPA require Chemours to conduct experimental animal studies, human studies and testing for ecological effects, fate and transport and physical-chemical properties. JA177-183. These specific studies were selected by petitioners' science advisors as the minimum necessary to determine the health outcomes of long-term exposure to the 54 PFAS by Cape Fear communities. IA176. Drawing on established EPA test guidelines, the petition recommended specific test methodologies for conducting the requested studies. JA184-187.

EPA received letters of support for the petition from dozens of non-profit organizations and numerous scientists. A672-673. Letters favoring the petition were submitted by 120 non-profit groups, nearly 50 scientists, and the City of Wilmington, County of Hanover and Cape Fear Public Utility Authority in North

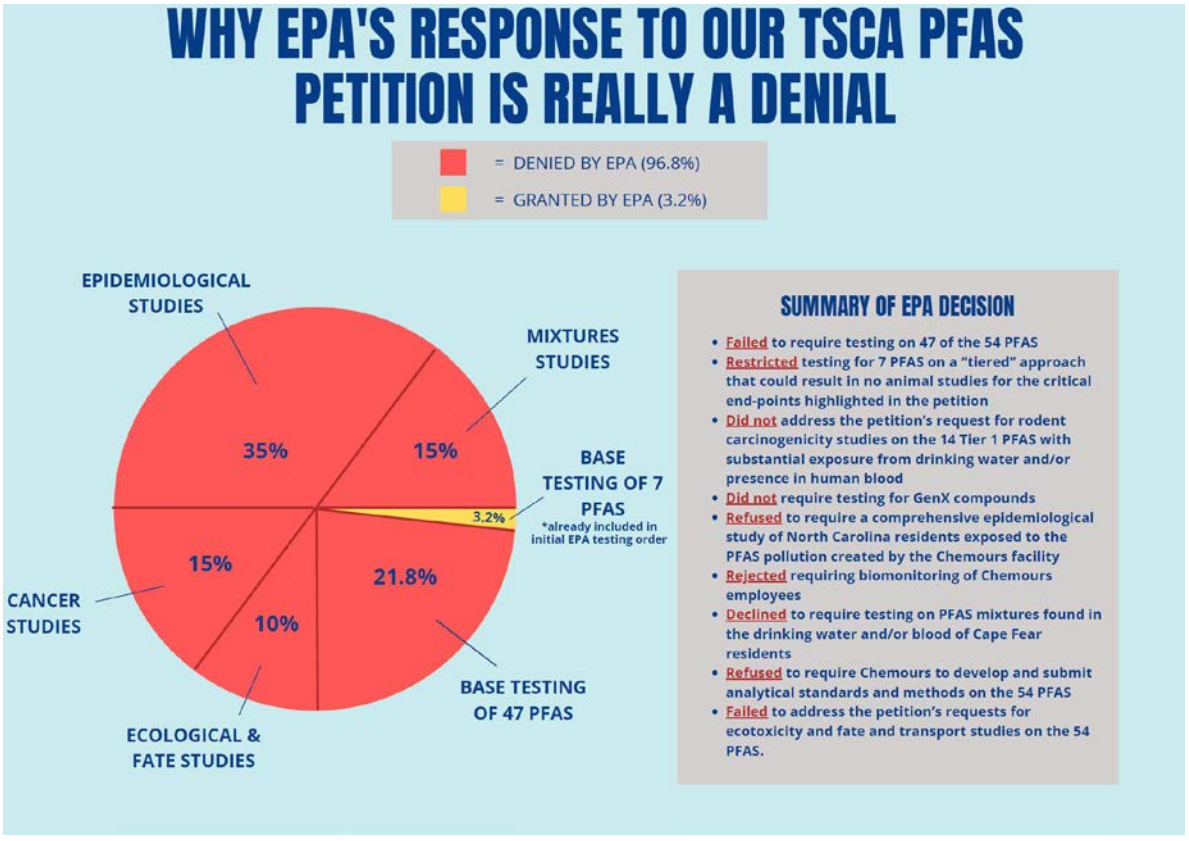
Carolina. On June 16, 2021, 7 members of the North Carolina Congressional delegation wrote to defendant Regan urging him to "require Chemours to fund studies necessary for North Carolina communities to understand the impacts of long-term PFAS exposure on the health of their residents." JA53-54.

VI. EPA's Responses to the Petition

The petition was denied by the Trump EPA on January 7, 2021. 86 Fed. Reg. 6602. On March 3, 2021, plaintiffs filed suit against EPA under section 21 of TSCA in the Northern District of California. JA14-33. The next day, they submitted a request for reconsideration to the Agency. JA133-141. Because the petition denial had faulted plaintiffs for failing to demonstrate the absence of data on the 54 PFAS, this request included a comprehensive literature search showing that the 54 PFAS lack virtually all of the studies proposed in the petition. JA139-142.

The Biden EPA granted reconsideration of the petition on September 16, 2021 (ECF24-1) and plaintiffs agreed to stay their suit during the reconsideration process (ECF24). On December 22, 2021, EPA issued a new decision purporting to "grant" the petition. JA201-229. EPA "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." JA208. As a result, it committed "to initiate a rulemaking proceeding or issue an order under TSCA section 4(a)(1)(A)(i) compelling health and environmental effects testing regarding PFAS." JA208.

However, the Agency only agreed to require testing on a small group of "representative" PFAS previously selected under its October 2022 National PFAS Testing Strategy, a research initiative to better understand variations in toxicity and chemical structure within the broad PFAS category. JA202-203. EPA declined to issue test rules or orders for 47 of the 54 Chemours PFAS identified in the petition (JA213-217) and rejected the principal studies that petitioners requested (JA217-223). As plaintiffs demonstrated in the District Court, EPA *declined to require 97 percent of the individual studies requested in the petition:*



JA117.

VII. Proceedings Below

Because plaintiffs considered EPA's decision a *denial* of their petition, they reactivated their suit and filed an Amended Complaint on December 1, 2022. JA34-66. After their case was transferred to the Eastern District of North Carolina on May 9, 2022 (ECF38). EPA moved to dismiss for lack of jurisdiction on June 23, 2022 (ECF47). Following a hearing on February 14, 2023, the District Court issued an order of dismissal on March 30, 2023 because "it lacks jurisdiction to review EPA's decision to grant a petition." JA664-692.

SUMMARY OF ARGUMENT

1. Where dismissal of a complaint is sought for lack of jurisdiction, the facts alleged in the complaint are taken as true, and the motion must be denied if the complaint alleges sufficient facts to invoke subject matter jurisdiction. Here, citing the many aspects of the petition that EPA rejected, plaintiffs' Amended Complaint disputed whether EPA's decision can properly be characterized as "granting" their petition. The Court should have construed the Amended Complaint in the light most favorable to plaintiffs, concluded that the facts alleged were sufficient to establish that the petition was denied, and determined that it had jurisdiction over the case.

2. Numerous cases recognize that, where courts face challenges to their jurisdiction to review agency action, they are not bound by the labels that agencies

attach to these actions but must independently determine their nature and effect. Plaintiffs' Amended Complaint demonstrates that EPA's response to their petition was in fact a "denial" in all but name. JA54-62. Because section 21(b)(4)(A) of TSCA authorizes suits challenging petition denials, the District Court had jurisdiction to hear this case and its order of dismissal must be reversed.

3. Plaintiffs' petition proposed a detailed testing program on 54 specific PFAS produced by Chemours and demonstrated that, as a result of Chemours' polluting activities, Cape Fear residents are exposed to these chemicals in drinking water, air, soil, groundwater and locally grown food. The petition showed that the 54 PFAS met the TSCA section 4 criteria for testing because they "may present an unreasonable risk" to North Carolina communities and "there is insufficient information" to determine their health effects on exposed populations. EPA's response to this evidence was to point to limited testing it had previously announced on the broad class of PFAS under its PFAS Testing Strategy but decline to require additional testing on 47 of the 54 PFAS to which Cape Fear communities are exposed or compel the studies necessary to understand the impact of long-term exposure on their health. Under the plain meaning of the statute, this was not a "grant" of the petition but a "denial."

4. EPA's petition response was also contrary to the TSCA petition process designed by Congress. Section 21(b)(1) calls for petitions to present the

"facts" demonstrating that testing is "necessary." EPA has consistently focused on whether petitioners have met their burden under TSCA of justifying the specific relief requested. As emphasized in TSCA's legislative history, where the evidence shows that the criteria for testing in section 4(a) are met, EPA must "promptly commence an appropriate proceeding to take the action requested." JA310. EPA subverted this scheme by ignoring the evidence presented by the petitioner, relying on largely unrelated testing that the petition did not seek, and rejecting nearly all the testing it proposed -- all while purporting to "grant" the petition.

5. Because Congress wanted citizens to have a strong voice in shaping EPA's TSCA regulatory agenda, it granted petitioners a *de novo* proceeding in district court to challenge petition denials. 15 U.S.C. § 2620(b)(4)(B). If the court finds that a preponderance of the evidence shows that the TSCA testing criteria are met, it "shall order the Administrator to initiate the action requested by the petitioner." Congress' decision not to provide a comparable judicial remedy where EPA *grants* a petition can only mean that it expected EPA would give the same relief to successful petitioners that they could obtain in a *de novo* proceeding challenging a petition denial. Given its strong desire to hold EPA accountable, it is inconceivable that Congress would have left petitioners without legal recourse where the Agency refuses nearly all the relief requested by their petition.

6. The District Court was wrong that "the Plaintiffs packaged their petition as a request for testing PFAS as a class." JA690. Plaintiffs did not petition for testing on the 6500+ chemicals in the broad "category of PFAS." The focus of their petition was on a single geographic area, a single PFAS production facility, a single set of chemicals to which a specific population was exposed, and a particular testing program to address the impacts of such exposure. To treat the petition as a request to test PFAS generally was contrary to the goals of the petition and the relief it requested.

7. EPA's "grant" of the petition was predicated on its previously adopted National PFAS Testing Strategy, which "grouped 6,504 PFAS by structural and physical-chemical properties into 70 total terminal categories" and selected 24 representatives of these categories for testing. While TSCA sections 4(h)(1)(B) and 26(c) allow EPA to issue test rules and orders for "categories" of chemicals, they must be "suitable for classification as such for purposes of this Act." Substituting the broad category of all PFAS for the narrowly defined universe of PFAS targeted by the petition was not "suitable" because it redefined the purpose of the petition and assumed without evidence that limited data on representative members of the large PFAS category can be extrapolated to a highly exposed population impacted by 54 discrete PFAS from one polluting facility.

8. The district court wrongly concluded that EPA could satisfy section 21 by agreeing to require testing in general, without committing to specific test chemicals, studies and methodologies. This reading of section 21 is incompatible with its express requirement that, upon concluding that a petition has satisfied the criteria for testing, "the court shall order the Administrator to initiate the action requested by the petitioner." If the court could only direct EPA to undertake an open-ended proceeding with little resemblance to the elements of the petition, Congress' goal of giving citizens' a powerful voice in setting EPA's priorities for testing would be meaningless. Moreover, while courts cannot dictate the final action EPA takes at the *conclusion* of a proceeding to issue a rule or order, they can and often do direct EPA to *propose* rules with specific provisions and set deadlines for initiating and completing rulemaking. Since test rules and orders must specifically contain "protocols and methodologies" under section 4(b) of TSCA, petitioners had every right to request them in their petition and the Court has authority to require them under section 21(b)(4)(A).

ARGUMENT

I. EPA's DECISION ON APPELLANTS' PETITION WAS A "DENIAL" IN SUBSTANCE AND EFFECT AND WAS THEREFORE SUBJECT TO JUDICIAL CHALLENGE UNDER SECTION 21(b)(4)

A. On a Motion to Dismiss, Plaintiffs' Allegations That EPA Denied Their Petition Must be Taken as True and Provide a Sufficient Basis for Subject Matter Jurisdiction

The District Court dismissed plaintiffs' Amended Complaint for lack of jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure. A complaint should not be so dismissed "unless it appears to a certainty that the plaintiff would be entitled to no relief under any state of facts which could be proved in support of his claim." *Johnson v. Mueller,* 415 F.2d 354, 355 (4th Cir. 1969). Where the claimed basis for dismissal is **"**that a complaint simply fails to allege facts upon which subject matter jurisdiction can be based," the "facts alleged in the complaint are taken as true, and the motion must be denied if the complaint alleges sufficient facts to invoke subject matter jurisdiction*." Kerns v. U.S.*, 585 F.3d 187, 192 (4th Cir. 2009). As this Court held in *Adams v. Bain,* 697 F.2d 1213, 1219 (4th Cir. 1982), "where the jurisdictional facts are intertwined with the facts central to the merits of the dispute," a presumption of truthfulness should attach to the plaintiff's allegations and a" trial court should then afford the plaintiff the procedural safeguards — such as discovery — that would apply" during normal litigation. *Kerns*, supra, at 193. Dismissal is warranted only when the jurisdictional

allegations are "clearly . . . immaterial, made solely for the purpose of obtaining jurisdiction or where such a claim is wholly unsubstantial and frivolous." *Bell v. Hood*, 327 U.S. 678, 682 (1946).

The District Court dismissed plaintiffs' Amended Complaint because EPA "granted" plaintiffs' petition and TSCA section 21 provides a judicial remedy only for petition "denials." [2] However, in their Amended Complaint, plaintiffs disputed whether EPA's decision can properly be characterized as a "grant" of their petition. Citing the many aspects of the petition that EPA rejected, the Amended Complaint maintained that EPA effectively "denied" the petition, thereby allowing them to bring "a civil action in district court of the United States to compel the" Agency to grant the relief sought. JA54-63. The Court should have construed the Amended Complaint in the light most favorable to plaintiffs, concluded that the facts alleged were sufficient to establish that the petition was denied, and determined that it had jurisdiction over the case.

B. The District Court Could Not Defer Uncritically to EPA's Claim that it "Granted" the Petition but Was Obligated to Independently Determine the Nature and Effect of its Petition Response

In determining its jurisdiction, the Court should not have accepted EPA's characterization of its petition response at face value but independently examined

[2] This Court's review of the District Court's subject matter jurisdiction is *de novo*. *In re Phar-Mor, Inc. Sec. Litig.*, 172 F.3d 270, 273 (3d Cir. 1999)

its substance and effect, taking into account not only the language and intent of TSCA but the Agency's disposition of the specific requests in the petition as described in the Amended Complaint.

Where agencies argue that their decisions are not subject to judicial review because they lack legally binding consequences, courts do not defer to the label assigned by the agency but examine its action *de novo. Reno-Sparks Indian Colony v. EPA*, 336 F.3d 899, 909 n.11 (9th Cir. 2003). "Agencies have never been able to avoid notice and comment simply by mislabeling their substantive pronouncements. On the contrary, courts have long looked to the *contents* of the agency's action, not the agency's self-serving *label*, when deciding whether statutory notice-and-comment demands apply." *Azar v. Allina Health Services*, 139 S. Ct. 1804, 1812 (2019). Thus, the Tenth Circuit has held that "[t]he agency's own label for its action is not dispositive" of the Court's jurisdiction. *Sorenson Commc'ns, Inc*. v. F.C.C., 567 F.3d 1215, 1223 (10th Cir. 2009). Similarly, the D.C. Circuit has held that "agencies may not use shell games to elude review." *Tesoro Alaska Petroleum Co*. v. FERC, 234 F.3d 1286, 1293 (D.C. Cir. 2000). *See also Guardian Federal Savings Loan Ass'n v. FSLIC*, 589 F.2d 658, 666-67 (D.C. Cir. 1978) ("If it appears that a so-called policy statement is in purpose or likely effect one that narrowly limits administrative discretion, it will be taken for what it is — a binding rule of substantive law"); *Iowa League of Cities v. EPA*, 711 F.3d 844,

862 (8th Cir. 2013) ("to place any great weight on [EPA's own characterization of its action] could permit an agency to disguise its promulgations through superficial formality, regardless of the brute force of reality").

As in these cases, since the District Court would lack jurisdiction if EPA "granted" plaintiffs' petition, it had a responsibility to look beyond EPA's self-serving characterization of its decision and examine its nature and effect. As demonstrated below, the reality is that EPA rejected nearly all of petitioners' requests for testing and thus denied their petition in substance if not in name. The District Court should have taken a hard look at the nature and effect of EPA's petition response and affirmed its jurisdiction.

C. When Granting or Denying Testing Petitions under Section 21, EPA Must Address the Specific Substances and Studies Identified in the Petition and the Facts Presented to Justify Testing

Whether a petition is "granted" or "denied" is central to section 21. Denial of a petition triggers *de novo* consideration of the petition in an evidentiary proceeding in the District Court under section 21(b)(4)(A). By contrast, where EPA grants a petition, the Agency must initiate an "appropriate" proceeding under section 21(b)(3) to take the actions requested by petitioners and no judicial remedy is available.

The statute does not define the terms "grant" and "deny" but their meaning is well understood. In *Pontarelli v. U.S. Dept. of the Treasury*, 285 F.3d 216, 225

(3d Cir. 2002), the court cited Webster's 1993 Dictionary, which defines the term "denial" as a "refusal to grant, assent to, or sanction" or a "rejection of something requested, claimed, or felt to be due." By contrast, "[t]he applicable dictionary definition of 'grant' means to 'give, bestow, [or] confer.'" *Bare v. Barr*, 975 F.3d 952, 967 (9th Cir. 2020). Thus, in common parlance, if EPA refuses to take some or all of the actions requested in a petition, it would be "denying" the petition, whereas it would be "granting" the petition if it agrees to the petitioners' requests.

TSCA's detailed requirements for petitions to compel testing under section 4 shed further light on the terms "grant" and "deny" and reinforce their plain meaning. Section 21(a) authorizes petitions "to initiate a proceeding for the issuance of . . . rule [or] order" requiring manufacturers to conduct testing under section 4 of TSCA. Under section 21(b)(1), such petitions "shall set forth the facts which it is claimed establish that it is necessary to issue . . . a rule [or] order under [section 4]." To meet this burden, petitioners must specify the elements of the test rule or order they want EPA to issue. Under section 4(b)(1) of TSCA, test orders or rules must include both an "identification of the chemical substance or mixture for which testing is required" and "protocols and methodologies for the development of information for such substance or mixture." The petition must thus designate the specific chemicals proposed for testing, the particular studies requested and the precise methods for conducting these studies and present "facts" demonstrating

that the proposed testing is "necessary" under the criteria for issuing test rules and orders in TSCA section 4(a)(1)(A).

The obligation of the petitioner to justify its specific requests for testing is underscored in the House report on the original law: "[i]n the case of a petition for the issuance of a [testing] rule under section 4, the petitioner must show that the manufacture, distribution in commerce, processing, use or disposal *of the substance or mixture to be subject to the rule* may cause or significantly contribute to an unreasonable risk to health or the environment" (emphasis added). JA378. It follows that EPA's task in responding to testing petitions is to examine the specific testing program presented in the petition (i.e. the proposed test substances, studies and methodologies) and determine whether the petitioner has justified the testing requested under the section 4(a)(1) testing criteria. If EPA concludes that the "facts" presented show that testing is warranted under TSCA section 4(a)(1)(A), then the petition must be "granted" and, under section 21(b)(3), EPA must commence an "appropriate proceeding" to develop rules or orders requiring the requested testing. TSCA's legislative history is clear on this point. The 1976 Senate Report states that "[i]f a petition is granted, the Administrator must commence an appropriate proceeding *to comply with such petition*" (emphasis added). JA310. The House Report similarly indicates that "if a petition is granted, the Administrator must promptly commence an appropriate proceeding

to take the action requested" (emphasis added). JA378. That EPA could claim it "granted" a petition but fail "to take the action requested" is contrary to the plain meaning and structure of section 21.

Over the years, EPA's decisions on section 21 petitions have consistently mirrored the framework described above. In nearly all instances, EPA has undertaken a thorough analysis of the specific requests of the petitioner to determine whether they are justified under the TSCA criteria for initiating the rule or order sought. EPA's practice has been to "deny" petitions which it found lacked "facts" showing that the requested action was "necessary" under TSCA requirements.[3] It has then published Federal Register notices explaining the

[3] Since September 2007, EPA has denied 28 section 21 petitions and granted only 3 (not including the petition at issue here). https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-21#polyvinyl. Examples of denials include: 87 Fed. Reg. 57665 (Sept. 21, 2022) (petition to regulate global warming gases denied because it was insufficiently specific and failed to establish that a rule under TSCA section 6 is necessary); 86 Fed. Reg. 64129 (Nov. 17, 2021) (petition denied for failure to demonstrate facts supporting an EPA determination of unreasonable risk to the environment from cosmetic disposal); 86 Fed. Reg. 27546 (May 21, 2021) (petition failed to provide facts to demonstrate that there is insufficient information on the effects of phosphogypsum and process wastewater on health or the environment and did not show that the testing requested under section 4 is necessary to develop that information); 84 Fed. Reg. 60986 (Nov. 12, 2019) (petition does not provide sufficient facts establishing that it is necessary for the Agency to issue a rule under TSCA section 6(a) to prohibit oil refineries from using hydrofluoric acid in manufacturing processes); 79 Fed. Reg. 64722 (Oct. 31, 2014) (petition does not set forth sufficient facts for EPA to find that the toxicity information available to the Agency is insufficient to permit a reasoned evaluation of the health effects of PVC constituents, or to conclude that toxicity testing is necessary to develop any missing data under section 4).

rationale for the denial. In the few instances where EPA has "granted" petitions, it has agreed to initiate the proceeding requested in the petition.[4] EPA has never – before now – "granted" a petition while refusing to initiate specific actions requested by the petitioner. Indeed, when it initially denied plaintiffs' testing petition on January 7, 2021, the Trump EPA found (erroneously in plaintiffs' view) that the petition "does not set forth 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 effect* is necessary to develop such information." 86 Fed. Reg. 6602, 6610 (January 22, 2021) (emphasis added). Ironically, both the Biden EPA's "grant" of the petition on December 22, 2021 and the Trump EPA's "denial" ten months earlier had the same consequence – to reject testing on nearly all the 54 PFAS subject to the petition. Yet since it was labeled a "denial," the Trump decision could be challenged under section 21(b)(4) while the Biden decision would be insulated from review under the reasoning of the District Court.

[4] In the three instances where EPA has "granted" petitions since 2007, it agreed to all the relief requested by the petition. See JA624-625 (granting petition to amend provisions of TSCA Chemical Data Reporting rule for certain bio-based products and denying second petition as moot); https://www.epa.gov/sites/default/files/2015 10/documents/owens.cadmium.response.8.30.10.pdf (granting petition for TSCA section 8(d) reporting requirements on cadmium and cadmium products); https://www.epa.gov/sites/default/files/2015-10/documents/document.pdf. (granting petition for TSCA section 6 rule prohibiting lead wheel balancing weights).

D. Deferring to EPA's Claim that it "Granted" Appellants' Petition Would Undermine Congress' Goal of Giving Citizens an Independent Judicial Determination of The Merits of Their Petitions

TSCA does not create a procedure for public or judicial oversight of grants of petitions. EPA has no obligation to publish a Federal Register notice explaining its decision to grant a petition, as it must do for petition denials under section 21(b)(3). Nor is there any mechanism by which petitioners can challenge the grant of a petition in court. By contrast, in section 21(b)(4), Congress provided an unprecedented judicial remedy for unjustified petition denials.

The 1976 House Report emphasized that "section 21 provides an important mechanism for public initiation of actions to protect the health and environment." JA377. The D.C. Circuit has described section 21 as an "unusually powerful procedure[] for citizens to force EPA's hand" in *Trumpeter Swan Society v EPA*, 774 F.3d 1037, 1939 (D.C, Cir. 2014). As the court explained in *Env. Def. Fund v. Reilly*, 909 F.2d 1497, 1499 (D.C. Cir. 1990), "[c]itizen participation is broadly permitted [under TSCA] to ensure that bureaucratic lethargy does not prevent the appropriate administration of this vital authority" (quotation and citation omitted)). In *Food & Water Watch, Inc. v. U.S. Envtl. Prot. Agency*, 302 F. Supp. 3d 1058, 1066 (N.D. Cal. 2018), the district court emphasized that "the overarching purpose of the TSCA is to protect the public from chemicals that pose an unreasonable risk

to health and the environment, and citizen petitions are considered a powerful tool in forcing the EPA's hand in that regard." As the court noted, TSCA's legislative history underscores that "[t]he responsiveness of government is a critical concern and the citizens' petition provision will help to protect against lax administration of the [TSCA]." JA294. The court emphasized that "the role of citizen oversight, including access to federal courts, weighs considerably" in applying section 21.

Because Congress wanted citizens to have a strong voice in shaping EPA's regulatory agenda, it directed the district court to consider the merits of a petition denied by EPA "in a *de novo* proceeding." 15 U.S.C. § 2620(b)(4)(B). A "de novo proceeding in district court modeled after traditional trial-like proceedings" requires a far more active judicial role than the traditional judicial task of "review[ing] the soundness of the EPA's findings" to determine whether they are "supported by substantial evidence." *Food & Water Watch, Inc.*, 302 F. Supp. 3d at 1066, 1068. Thus, in a *de novo* proceeding to consider a petition for testing, section 21(b)(4)(B) directs the district court to determine whether the petitioner has "demonstrate[d] to the satisfaction of the court by a preponderance of the evidence" that:

> "(i)(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 . . . "(emphasis added).

In short, the court must apply virtually the same criteria for determining the need for testing on which EPA must base its own testing decisions under section 4(a)(1)(A) [5] but independently assess the evidence presented by petitioners, without deference to prior EPA findings. Where this evidence demonstrates that the chemical substances "to be subject to such rule or order" meet the TSCA testing criteria, the obligation of the court is clear. As stated in the 1976 Senate Report, "[i]f the petitioner can satisfy the court . . . that the action requested in the petition conforms to the applicable requirements of this act, the court shall order the Administrator to initiate the action requested by the petitioner." JA310.

Congress' decision not to provide a comparable judicial remedy for petition grants makes sense only if it expected that EPA would give the same relief to successful petitioners that they could obtain after prevailing in a *de novo* proceeding challenging a petition denial.[6] Given the importance it attached to holding EPA accountable through judicial oversight, it is inconceivable that

[5] The two findings the court must make under section 21(b)(4)(B)(i) are similar to the findings EPA must make under section 4(a)(1)(A)(i)(I)-(II). However, EPA must make a third finding under clause III -- "testing of such substance or mixture with respect to such effects is necessary to develop such information" – that the Court is not required to make under section 21(b)(4)(B).

[6] That the criteria in section 21(b)(4)(B)(i) for prevailing in a *de novo* proceeding are strikingly similar to the criteria which section 21 petitions must meet under section 4(a)(1) further confirms the Congressional expectation that the relief provided when EPA "grants" a petition would be the same as the relief ordered by a court in a *de novo* proceeding challenging a petition denial.

Congress would have left petitioners without recourse where the Agency refuses nearly all the relief requested by the petitioner but claims it "granted" the petition. In this event, EPA could avoid any judicial accountability simply by declaring that it had "granted" a petition, even though (as here) it has taken virtually none of the actions requested in the petition and initiated a sham "proceeding" that purports to address the petition but in fact does not grant the relief sought. This would eviscerate the expansive role of the courts under section 21 by allowing EPA to wall off petition denials from challenge merely by calling them "grants."

E. However Labeled, EPA's Petition Response Was a Denial Because It Refused to Grant Nearly All the Requests for Testing in The Petition

A side-by-side comparison of plaintiffs' October 14, 2020 petition and EPA's December 22, 2021 response demonstrates that plaintiffs proposed a comprehensive set of studies on 54 PFAS and, with limited exceptions, EPA refused to require testing on these PFAS and rejected the requested studies.

1. The Petition Requested a Detailed and Extensive Testing Program on 54 PFAS and Showed that these PFAS and Proposed Studies Met the Section 4 Criteria for Testing

Plaintiffs' petition requested testing on 54 PFAS linked to the Chemours facility. The 54 PFAS were selected based on specific evidence of known or anticipated human exposure by residents of the Cape Fear River basin. For each PFAS, the petition identified available data on their presence in human blood,

drinking water, surface water, air emissions, rainwater, private wells, groundwater and produce. JA196-200. Based on a review of these data, the 54 PFAS were divided into 14 Tier 1 substances (for which there was substantial known human exposure as evidenced by their detection in blood, food or drinking water) and 40 Tier 2 substances (for which human exposure was probable based on detection in environmental media). JA166-170.

As required by section 21, the petition demonstrated that the 54 PFAS met the criteria for testing in section 4(a)(1)(A) of TSCA. As it showed, data on the health and environmental effects of the 54 PFAS are either non-existent or insufficient for determining their risks to people in Eastern North Carolina and the Cape Fear River ecosystem. JA174-176. The petition explained that these PFAS raised health concerns because they are analogous to other PFAS known to have adverse health effects but their unique impacts on human health could only be determined by testing them individually. JA170-172, JA176-177. According to the petition, the combination of well-grounded health concerns with actual or potential exposure demonstrated that each of the 54 PFAS "may present an unreasonable risk" to health, while the lack of data showed that there was "insufficient information and experience" to determine their effects on health or the environment. JA156. These showings satisfied two of the three prerequisites for requiring testing in section 4(a)(1)(A) of TSCA.

Plaintiffs' scientific consultants then developed a testing program that would determine whether or not the 54 PFAS do or not have the adverse health effects on exposed communities that petitioners suspected based on their similarity to other well-studied PFAS. JA177-183. Identifying these studies was essential to satisfy the third critical prong of the justification for testing under section 4(a)(1)(A) – that testing "is necessary" to determine the health and environmental endpoints for which sufficient information is lacking on the 54 PFAS. It was also necessary to identify the "protocols and methodologies" for testing, which are required in test rules and orders under section 4(b)(1)-(2). As defined in TSCA section 3(15), this broad term includes the health and environmental effects to be investigated, the information and analysis to be developed and the test procedures to be employed.

The specific studies included in the program were selected because of their ability to provide data not now available that would define whether and how each of the 54 PFAS may have harmed, and may continue to harm, residents of exposed communities and aquatic species in the Cape Fear River Basin who have been exposed to releases and discharges of these PFAS by the Chemours facility. According to the petition, "the studies proposed by petitioners are the minimum necessary for a full understanding of the health risks from past present and future exposure to the 54 PFAS by petitioners, their families and the communities they

represent and for health protective reductions in risk and exposure going forward." JA176. The proposed program had the following key elements (JA177-188):

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.

Human Studies

- A human health study for the Cape Fear watershed would be conducted using a similar study design to that used to examine the health effects of perfluorooctanoic acid ("PFOA"), a PFAS used at the Chemours (formerly DuPont) facility in Parkersburg, West Virginia. 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 Chemours workers.

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

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

- 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.

2. The Petition Response Refused to Require Testing on Nearly All 54 PFAS and Rejected Virtually All the Studies in Plaintiffs' Proposed Testing Program

EPA's December 22, 2021 petition response (JA201-229) accepted the need for testing PFAS generally, but refused to require any testing on 47 of the 54 specific PFAS and concluded that the great bulk of studies proposed in the petition were unwarranted. The response addressed several of the requested studies of most importance to the petitioners, including human epidemiology assessments for the Cape Fear basin population, bio-monitoring of Chemours workers to determine the half-lives of the PFAS in their blood and studies of the mixtures of PFAS present in drinking water and human blood. In each case, EPA asserted that the proposed studies were unnecessary and rejected requiring them in test rules or orders issued to Chemours. JA217-223.

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 human exposure from drinking water and/or presence in human blood;
- Did not require any testing for GenX compounds – a set of PFAS receiving broad public attention in Eastern North Carolina – despite the identification by EPA risk assessors of serious data gaps 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.

JA54-55, JA674. As petitioners emphasized in the District Court, EPA effectively rejected *97 percent* of the studies requested in the petition. JA117. This dramatic disconnect between the petition and EPA's response cannot be brushed aside as the expression of minor disagreements over technical aspects of testing procedure.

Rather, EPA simply substituted its own framework for testing for the one petitioners proposed. Under any construction of the term, this was a "denial" of the petition.

3. EPA Did Not Meaningfully Open the Door to Future Consideration of Studies it Rejected

EPA's petition response indicated that it might "defer" some elements of appellants' proposed testing program "pending development of additional information that will inform future decision-making." JA202. The District Court similarly suggested that, as EPA's "appropriate proceeding" evolves, EPA could consider requiring additional studies identified in the petition. JA602. But these possibilities are presented in highly speculative terms and fall far short of a definite commitment to future testing. The clear message is that the proposed studies are not on the table now and will not be for the foreseeable future.

For example, the most important element of the petition's proposed testing program was an epidemiological study examining associations between different diseases and exposures to the 54 PFAS by Cape Fear residents. However, EPA's response to this request was that:

> "[c]onsidering the multiple ongoing nationwide efforts to address community PFAS exposures and the significant resources it would take for EPA to initiate such a study, the Agency currently believes it is both appropriate and consistent with EPA's statutory obligations to continue to engage and partner with existing ongoing research efforts related to PFAS health studies . . . 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."

JA219. Thus, EPA concluded that "it is not appropriate to compel such a study at this time."[7] JA221.

Similarly, EPA rejected petitioners' request to require Chemours to conduct studies on mixtures representative of combinations of PFAS detected in Cape Fear drinking water and the blood of residents:

> "EPA believes that a better understanding of individual PFAS that have been strategically selected to be representative of thousands of PFAS – a goal that would be furthered by the category approach contemplated in EPA's Testing Strategy – will provide the tools to assess many more PFAS mixtures than an immediate focus on a limited few discrete PFAS mixtures that have a finite applicability, i.e., limited to only that specific mixture. . . EPA believes it would be premature to require testing on discrete PFAS mixtures before better understanding the individual component chemicals."

JA217. Again, the message is clear: EPA will **not** require Chemours to conduct the requested mixture studies.

[7] Both in its March 4, 2021 request for reconsideration and in a July 28, 2021 letter to Assistant Administrator Freedhoff, plaintiffs explained that the ongoing human studies EPA relied on did not relate to the Cape Fear basin and "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." JA53, JA58-59. EPA did not address these points in its petition response.

EPA similarly rebuffed the petition's request for biological monitoring of Chemours' employees:

> "At this time, EPA believes 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 . . ."

JA222.

While EPA may have had its reasons for not requiring these studies, their rejection cannot be interpreted as anything other than a denial of key portions of the petition. Even if there were a legitimate rationale to conclude that the studies were unnecessary, the proper place to present it would be in a *de novo* proceeding under section 21(b)(4)(B). EPA's reservations about particular studies cannot convert a plain denial of the petition into a "grant" that precludes plaintiffs from seeking a judicial remedy.

II. THE LOWER COURT ERRED IN CONCLUDING THE PETITION SOUGHT TESTING ON THE PFAS CATEGORY AND EPA's PFAS TESTING STRATEGY WOULD THEREFORE ACHIEVE THE PETITION'S GOALS

In contrast to previous petition responses, EPA's December 22, 2021 petition response did not address whether petitioners had met their burden of demonstrating that their specific testing requests were warranted under the criteria in section 4(a)(1)(A) of TSCA. Instead, EPA disclaimed "making any final determination . . . whether the TSCA section 4 criteria have been met" for the 54 PFAS (JA208) and

thus took no position on whether petitioners had demonstrated a sufficient basis for testing these substances under TSCA. EPA then said that it had --

> "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."

JA208. This "grant" of the petition was carefully worded to cover PFAS in general, not the 54 PFAS identified in the petition. Thus, while EPA may have been agreeing to require testing on *some* PFAS, it had already made this commitment in its National PFAS Testing Strategy. Nowhere does the petition response go further and agree to issue test rules or orders for the 47 *specific* PFAS not subject to testing under the Strategy or to require the *specific* studies petitioners considered most relevant to how these PFAS were impacting exposed communities.

The District Court found that EPA did not need to address the specifics of appellants' petition because "the 54-plus unspecified requests in Plaintiffs' petition [were] a single petition requesting EPA fill information gaps with respect to PFAS" (JA686) and EPA had simply "granted Plaintiffs' petition as to the category of substances requested in the petition." JA682. On this basis, the Court found that EPA could adequately address the petition by pursuing testing on the broad PFAS category under its preexisting PFAS Testing Strategy. As shown below, this approach both grossly mischaracterized plaintiffs' petition and erroneously allowed

EPA to bypass the specific data needs identified in the petition by misapplying its authority under TSCA to regulate chemical "categories."

A. The Fact that Petitioners Combined Multiple Testing Requests in a Single Document Did Not Authorize EPA to Treat the Petition as Applying to the Broad PFAS Category

According to the District Court, "the Plaintiffs packaged their petition as a request for testing PFAS as a class") and "EPA permissibly construed the petition as a petition for testing a category of substances – PFAS." JA690. This is simply untrue.

Plaintiffs did not petition for testing on the 6500+ chemicals in the broad "category of PFAS." The focus of their petition was on a single geographic area – the lower Cape Fear River basin in southeastern North Carolina – and a single PFAS production facility -- the Chemours plant in Fayetteville. The petitioners underscored that they were "deeply concerned about the contamination of the Cape Fear River and resulting harm to human health from PFAS released into the environment by the Chemours Fayetteville chemical manufacturing facility." JA158. The 54 substances the petition targeted for testing were a subset of PFAS produced by Chemours that "have been identified in drinking water sources serving over a quarter of a million people in the Cape Fear watershed, in human blood and in environmental media, including air emissions, surface water, sediment, stormwater, groundwater and

locally grown produce." JA155. As the petitioners explained the goals of testing:

> "Under a consent order between EPA and Chemours, GenX compounds have undergone some toxicological testing but, as EPA has recognized, available studies are incomplete. There is also some testing underway on a small number of other PFAS under a North Carolina consent order, but these studies are limited in scope. *No health or environmental effects testing has been conducted on the remainder of the 54 PFAS. Thus, for all 54 substances, there is an absence of sufficient data to determine risks to the large exposed population within range of the Fayetteville facility and the surrounding ecosystem* and to set risk reduction targets and other protective measures. *For residents and their families, the inability to determine the health impacts of their historical, ongoing and future PFAS exposure is a deep source of anxiety and concern*" (emphasis added).

The studies proposed in the petition were selected for their potential to shed light on the impacts of PFAS exposure on local communities. For example, to justify the need for epidemiology studies, the petition explained that "[b]ecause of the extensive exposure to PFAS by communities in the larger Cape Fear watershed, it is important to better understand the levels and extent of PFAS exposure, the specific PFAS present in blood and urine and the medical histories of individuals in this population and to examine the association between these indicators of PFAS exposure and health outcomes." JA180.

While the petition reviewed the body of health effects data on the overall PFAS class, this review was intended to show that the 54 PFAS might be toxic for the same endpoints as better-studied PFAS. JA162-163, JA171-172. Thus, in the

section entitled Heath Effects of PFAS as a Class, the petition pointed to the toxicological similarities among PFAS as demonstrating "a strong basis to conclude that the 54 PFAS included in the petition 'may present an unreasonable risk'" to health, thereby satisfying one of the criteria for testing under section 4(a)(1)(A). JA172. However, the petition did *not* argue that the 54 PFAS were interchangeable with each other or with other PFAS not produced by Chemours or found in the Cape Fear basin. Nor did it suggest that the health effects of the 54 PFAS could be determined by extrapolating from testing on other PFAS to which Cape Fear residents were not exposed. Thus, the District Court was incorrect that plaintiffs viewed the 54 PFAS as simply part of the large PFAS "category" and believed that testing on the category as a whole could substitute for testing the 54 PFAS.

The District Court determined that, because plaintiffs had combined proposals to test multiple chemicals using multiple methodologies into a single section 21 petition, EPA could grant or deny the petition as a whole, without considering the need for testing each of the 54 PFAS or the merits of each proposed study. JA691. But section 21 does not limit petitions to one request for relief; petitioners can and often do combine multiple related requests in a single petition, as plaintiffs did here. Where petitions have requested a range of studies on different chemicals, EPA's consistent practice has been to analyze each testing

request separately and explain why the request was being granted or denied.[8] On two occasions where EPA accepted some of a petition's requests but rejected others, it said that the petition was being "granted in part and denied in part." 78 Fed. Reg. 41768 (July 11, 2013) (regulation and testing of hydraulic fracturing chemicals); 50 Fed. Reg. 4426 (January 30, 1985) (regulation, testing and reporting on dioxins and furans) JA600-623.[9]

This approach flows logically from the statutory emphasis (discussed above) on examining the specific "facts" presented by a petition to determine whether the particular actions requested are "necessary" under the applicable TSCA criteria. Here, contrary to the District Court, plaintiffs never presented EPA with an all-or-nothing choice between an unqualified grant or denial of their petition. Nor did EPA perceive the petition as presenting this choice. Despite the District Court's claim that "[p]laintiffs' petition did not separately delineate each petition or request such that the agency (or this court) could determine how many

[8] See, e.g., 82 Fed. Reg. 1760 (April 12, 2017) (denial of petition seeking section 4 testing orders requiring several specific studies on chlorinated phosphate esters; denial analyzes each requested study and explains why it has not been adequately justified); 82 Fed. Reg. 14171 (March 17, 2017) (denying petition seeking testing order requiring several specific studies on tetrabromobisphenol A based on detailed analysis of each requested study).

[9] Indeed, a section 21 case relied on by the District Court in fact upheld EPA's position that a single petition can present multiple requests for relief and that acting on one request is not equivalent to responding to the entire petition. *Center for Biological Diversity v. Jackson*, 815 F. Supp. 2d 85 (D.D.C. 2011).

possible 'petitions' it had before it," JA690, EPA had no difficulty parsing the petition's component parts: as described above, it separately addressed and rejected petitioners' requests for an epidemiology study, mixture studies, biomonitoring of Chemours' employees and development of analytical standards and methods. Thus, while EPA may have chosen to treat the petition as seeking testing on PFAS broadly and "granted" the petition on this assumption, this was a voluntary choice by the Agency, not one compelled by how the petition was framed. Had the Agency treated the petition for what it was – a focused request to conduct testing on several substances using numerous studies – the only plausible response would have been a full or partial denial given that EPA rejected 97 percent of the testing requested.

B. EPA Could Not "Grant" the Petition by Substituting a Broad Category-Wide Approach to PFAS Testing for the Cape Fear-Focused Testing Program Proposed by Petitioners

EPA's "grant" of the petition was predicated on its National PFAS Testing Strategy, one element of EPA's comprehensive Roadmap for addressing PFAS-related concerns across its statutory authorities. JA241, JA256-271. Finalized in October 2021, the Strategy was under development well before EPA responded to plaintiffs' petition and was designed to address the "thousands of PFAS that have historically been made or used in the U.S." JA209. "[T]hrough implementation of the Testing Strategy, EPA expects to gather information on physical-chemical

properties, fate and transport, human health effects, and, in the future, environmental effects relevant" to the broad subsets of substances within the PFAS universe. JA209.

To that end, the Testing Strategy "grouped 6,504 PFAS by structural and physical-chemical properties into 70 total terminal categories." JA209. For 24 of these categories, EPA selected category members for initial testing. These PFAS were chosen as "representative" of the range of chemical structures within the category, not because of their production volume, presence in products or the environment or potential for significant exposure by the US population. JA264-266. Testing on the 24 PFAS will be conducted in "tiers," with the results of limited initial testing potentially triggering more advanced studies that may lead to testing for major end-points like cancer. JA267-269. So far, implementation of the strategy is proceeding slowly. Testing orders have been issued on only two of the initial 24 test substances and minimal testing has been conducted. JA491-545; https://www.epa.gov/system/files/documents/2022-06/9829-01_testorder-6_2_Fluorotelomer_sulfonamide_betaine.pdf.

The overlap between the Testing Strategy and the testing program proposed in plaintiffs' petition is limited. Seven of the 54 PFAS are among the 24 representative PFAS selected for initial testing. JA202. Another 23 of the 54 PFAS will not be tested but, according to EPA, fall within categories with other

representative PFAS that will undergo testing. Nine of the PFAS are not covered by the current test program but "may be covered" by future categories added to the program. An additional 15 of the 54 PFAS "do not fit the definition of PFAS used in developing the Testing Strategy." [10] These substances will not be addressed at all by the Strategy. JA215-216. The ultimate scope of testing under the Strategy is unclear but EPA has no plans to require epidemiological studies, testing on mixtures, biomonitoring of workers or other exposed populations, or long-term studies for cancer and other major health effects, which would be conducted on Tier 1 PFAS found in human blood or drinking water under plaintiffs' petition.

In its petition response, EPA maintained that it "is granting the petition under TSCA section 21" by issuing section 4 test orders under its Testing Strategy that will "compel[] health and environmental effects testing regarding PFAS." JA208. Thus, EPA believed it could satisfy the petition without requiring the specific studies it requested by treating all PFAS as a "category" under TSCA Sections 4(h)(1)(B) and 26(c), which allow EPA to issue category-based test rules and orders. JA211-212. The District Court endorsed this approach, holding that EPA could "grant" the petition for the PFAS category because "anywhere the

[10] However, plaintiffs and their scientific advisors believe that these 15 substances are properly defined as PFAS and in any case independently meet the criteria for testing in sections 4 and 21 of TSCA.

statute says 'a chemical substance or mixture,' the EPA may substitute that text with 'a category of chemical substances or mixtures.'" JA688.

However, TSCA does not give EPA *carte blanche* to apply the Act's requirements to "categories" in all circumstances. Section 4(h)(1)(B)(ii) encourages "the grouping of 2 or more chemical substances into" into categories but only where "testing of a chemical substance would provide scientifically valid and useful information on other chemical substances in the category." Section 26(c)(2) allows substances to be grouped together in categories but only where they are "suitable for classification as such for purposes of this Act." Perhaps all PFAS are "suitable" for inclusion in a single category under the Testing Strategy for the broad purpose of understanding how variations in chemical structure may affect toxicity. But plaintiffs' petition had a very different purpose -- to determine how 54 PFAS produced by a specific company in a particular location had affected a particular population exposed to long-term drinking water contamination as a result of the company's pollution of the Cape Fear basin.

Whether limited testing conducted on representative members of the 6500+ PFAS category can be extrapolated to a highly exposed population impacted by 54 discrete PFAS from a polluting facility is at best debatable. The District Court accepted this premise on faith but pointed to no supporting evidence. In its petition response, EPA likewise made no effort to explain how data developed

under the Testing Strategy could be used to inform determinations of risk to the Cape Fear population from exposure to the Chemours PFAS.

Plaintiffs' Amended Complaint maintained that using data on unrelated PFAS to make "judgments about [the 54 PFAS'] health impacts on Cape Fear communities" is a "highly theoretical and unproven approach, based on complex computational models that have not been peer reviewed." JA56. Similarly, as 50 leading scientists emphasized in a December 20, 2021 letter to EPA, "[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." JA126-132.

It was error for the District Court to uphold EPA's "grant" of the petition on the ground that petitioners' specific requests for testing were adequately addressed by its preexisting testing strategy for the broad PFAS "category." At most, whether testing on the category might replace the need for some or all of the testing proposed in the petition could be a relevant issue in a *de novo* proceeding under section 21(b)(4)(B). But this does not change the undisputed fact that petitioners' testing requests were rejected. Because this rejection comprised a

"denial" of the petition, the Court's dismissal of the Amended Complaint was unwarranted.

III. THE DISTRICT COURT WRONGLY CONCLUDED THAT EPA COULD SATISFY SECTION 21 BY AGREEING TO REQUIRE TESTING IN GENERAL, WITHOUT COMMITTING TO SPECIFIC TEST SUBSTANCES, STUDIES AND METHODOLOGIES

A. Section 21 Requires Specificity in the Substances, Studies and Methodologies Proposed for Testing

The District Court concluded that, even where petitioners prevail in a *de novo* proceeding, section 21 only allows it to "require EPA to initiate a proceeding to issue a rule or order, it does not empower the court to dictate to the agency the substance of a rule or order." JA683. According to the Court, the "Plaintiffs overread the statute in suggesting that the court can order EPA to issue a rule that encompasses specific proposals from Plaintiffs' petition. . . . [T]he statute does not require EPA to adopt the petitioners' preferred tests, rules, and orders." JA684, JA686. These findings are correct but they beg the question of what EPA must do when *initiating* a proceeding for a rule or order in response to a directive from the court under section 21(b)(4)(A) or when "granting" a petition under section 21(b)(3).

The Court assumed that even at these stages, the Agency would have no obligation to adopt the test substances or studies proposed in the petition but could simply fill the "information gap" identified in the petition however it chose.

JA686. However, this is contrary to Congress' express requirement that, upon concluding that a petition has satisfied the criteria for testing, "the court shall order the Administrator to initiate the action requested by the petitioner." If the court could only direct EPA to undertake an open-ended proceeding with little resemblance to the elements of the petition, Congress' goal of giving citizens' a powerful voice in setting EPA's priorities for testing would be meaningless.[11]

Moreover, the petition process prescribed in section 21(a) does not merely allow petitioners to seek testing "to fill a data gap" but requires them to request issuance of a specific "rule" or "order" under section 4. As noted above, section 4(b)(1) requires such a rule or order to identify the "chemical substance or mixture for which testing is required" and prescribe "protocols and methodologies for the development of information for such substance or mixture." Thus, petitioners must identify these elements of a rule or order in their petition. Where, as here, EPA purports to grant a petition in general but does not commit to initiating rules or orders identifying the specific substances to be tested, the health effects to be investigated or the test methods to be used, its petition response would be

[11] The District Court assumed that a petition could only request "a proceeding to issue a rule or order" and that **any** rule or order addressing a data gap identified in the petition would suffice. JA689**.** But as discussed in the text, TSCA specifically defines the required elements of test rules and orders and, consistent with the statute, EPA has generally demanded that the petitioner present "facts" demonstrating that these elements are "necessary."

incomplete, allowing a suit against the Agency for "fail[ing] to grant or deny the petition" under section 21(a)(4)(A).

B. Courts May Order EPA To Initiate Rulemaking by Proposing Test Rules and Studies for Specific Substances

To support its reading of TSCA, the District Court relied on a statement in the 1976 TSCA Senate Report that "in reviewing a denial of the citizen's petition by [EPA], . . . [th]e court would not be allowed . . . to determine the content of a rule or outcome of such a proceeding." JA293. However, this limitation (based on the principle of separation-of-powers) only applies to the action EPA takes at the *conclusion* of a proceeding to issue a rule or order. It does not restrict what the court may require the Agency to do under section 21(b)(4)(A) when compelling it "to *initiate* a rulemaking proceeding as requested in the petition" (emphasis added).

Upon concluding that agencies have failed to properly respond to a petition or otherwise meet their legal obligations, courts commonly direct them to *propose* rules with specific provisions and set deadlines for initiating and completing rulemaking.[12] This would be the required course where a court requires EPA to

[12] *See, e.g., Cmty. Voice v. United States EPA*, 878 F.3d 779, 788 (9th Cir. 2017) (EPA ordered to propose regulations amending its standards for preventing harmful exposure to lead-based paint); *Public Citizen Health Research Group v. Auchter*, 702 F.2d 11t50, 1157-59 (D.C. Cir. 1983) (OSHA ordered to propose an emergency workplace standard for ethylene oxide); *Public Citizen Health Research Group v. Com'r, FDA*, 724 F. Supp. 1013,1023 (D.D.C. 1989) (FDA ordered to issue

"initiate the action requested by the petitioner" under section 21(b)(4)(B). The Administrative Procedure Act ("APA") defines a notice of proposed rulemaking as the first step in the rulemaking process and defines the elements this notice must contain. 5 U.S.C. § 553(b). In accordance with the APA, to "initiate the action requested by the petitioner," EPA would need to *propose* a test rule incorporating the test chemicals, studies and methodologies requested by the petition. However, the Agency would retain its discretion over the contents of the *final rule*.

Thus, in a case involving a section 21 petition to require testing, *Citizens for a Better Env't v. Thomas*, 704 F. Supp. 149, 152 (N.D. Ill. 1989), the court rejected a constitutional challenge to section 21 of TSCA on separation-of-powers grounds, holding that:

> "If a petitioner can satisfy the court by a preponderance of the evidence that the action requested in the petition conforms to the requirements of the Act, *the court shall order the petitioner to initiate the rulemaking procedures requested by the petitioner* (*id.*). . . *Permitting a court to require the executive to initiate rulemaking upon judicial findings has never been held to be a violation of the separation of power. Wisc. Electric Power Co. v. Costle*, 715 F.2d 323, 328 (7th Cir. 1983); *WWHT, Inc. v. FCC*, 656 F.2d 807, 1818 (D.C. Cir. 1981). *If the Act permitted the court to substitute its judgment and promulgate the final rule, a significant intrusion into executive power would exist but that is not the case here."* (Emphasis added).

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regulation requiring standardized tampon absorbency labeling); *Environmental Defense Fund v. E.P.A.*, 852 F.2d 1316, 1331 (D.C. Cir. 1988) (EPA required to propose rule determining which processing wastes remain within a statutory exclusion).

The proper remedy under section 21 is illustrated in a recent case directing EPA to grant a petition seeking a proposed rule under section 8(a) of TSCA to require industry to report on the importation and use of asbestos. *Asbestos Disease Awareness Org. v. Wheeler*, 508 F. Supp. 3d 707, 735 (N.D. Cal. 2020). After concluding that EPA's petition denial was unlawful, the court's order – consistent with section 21(b)(4)(B) – stated that "EPA is directed to initiate a rulemaking proceeding to require reporting on asbestos under . . . Section 8(a) of TSCA that addresses the information-gathering deficiencies identified herein." JA640. In contrast to the position EPA takes in this case, it then entered into a settlement agreement committing to propose a rule that included all the reporting elements required by the court and setting a schedule for publishing the proposed rule and taking final action.[13] JA647-663. This agreement "compel[led] EPA to initiate a rulemaking proceeding as requested in the petition" in accordance with section 21 but did not dictate the contents of final rule. The same remedy would be available if this case goes forward on remand and plaintiffs carry their burden of proof in a *de novo* proceeding under section 21(b)(4)(A): EPA would need to

[13] That a court would set deadlines for the initiation and completion of action by EPA is implicit in section 21(b)(4)(B), which states that "the court may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes" if resource limitations or higher priorities constrain EPA's ability to "initiate the action requested by the petitioner" on the schedule set by the court.

propose a rule containing the testing elements requested in plaintiffs' petition but would retain discretion over the contents of the final rule.

C. EPA Did Not Commence an "Appropriate Proceeding" In Accordance with Section 4 under Section 21(b)(3)

Under section 21(b)(3), if EPA "grants" a petition seeking to require testing, it "shall promptly commence an appropriate proceeding in accordance with section 4." The District Court found that EPA's actions EPA in response to the petition comprise such an "appropriate proceeding." JA681. However, the threshold issue in this case is whether EPA *granted* plaintiffs' petition. If its petition response was in fact a *denial*, the adequacy of the "proceeding" commenced by the Agency is simply not relevant to the District Court's jurisdiction.

In any case, EPA's limited actions do not rise to the level of an "appropriate proceeding." The only steps it has taken to date are issuance of two testing orders for PFAS, one of which is not within the scope of plaintiffs' petition.[14] It has not yet initiated testing orders or proposed rules for the 22 other "representative" substances and has no timetable for doing so. Moreover, as discussed above, EPA has effectively closed the door both to testing the remaining 47 PFAS and requiring the key studies requested in the petition.

[14] *See* EPA 6:2 fluorotelomer sulfonamide betaine testing order (available at https://www.regulations.gov/docket/EPA-HQ-OPPT-2021-0897).

Most importantly, where EPA properly grants a petition, its obligation under section 4(a)(3) "to promptly commence an appropriate proceeding under section 4" should parallel the relief a court would grant after a *de novo* judicial proceeding under section 4((b)(4)(A). This would necessarily mean proposing a section 4 test rule that takes "the action requested by the petitioner." However, the Testing Strategy and other actions that EPA claims discharge its obligations under section 21(b)(3) at best comprise a vague and open-ended plan for possible future testing. They are not a "proceeding in accordance with section 4" of TSCA because they do not initiate a rulemaking or an order requiring testing, the two formal actions by which EPA carries out its testing authority under section 4(a)(1)(A), and fail to take the actions requested by the petitioner.

CONCLUSION

The Court should vacate the District Court's Order of dismissal and remand this case with instructions to deny the motion to dismiss.

REQUEST FOR ORAL ARGUMENT

Appellants hereby request that their appeal be scheduled for oral argument.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. The foregoing brief complies with the type-volume limitations of Fed. R. App. P. 32(a)(7) because the brief contains 12,985 words.

2. The brief also 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 this brief has been prepared in a proportionally spaced typeface using Microsoft Office 365 in Times New Roman 14-point font.

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