

No. 25-0384

United States Court of Appeals for the Ninth Circuit

FOOD & WATER WATCH; FLUORIDE ACTION NETWORK; MOMS
AGAINST FLUORIDATION; AUDREY ADAMS, individually and on behalf of
KYLE ADAMS; KRISTIN LAVELLE, individually and on behalf of NEAL
LAVELLE; BRENDA STAUDENMAIER, individually and on behalf of KO
STAUDENMAIER and HAYDEN STAUDENMAIER;

Plaintiffs-Appellees,

– v. –

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, an agency
of the United States; and LEE ZELDIN, in his official capacity as Administrator
of the U.S. Environmental Protection Agency;

Defendants-Appellants.

ON APPEAL FROM A DECISION OF THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA IN NO. 3:17-CV-02162-EMC,
HONORABLE EDWARD M. CHEN, DISTRICT JUDGE

BRIEF FOR PLAINTIFFS-APPELLEES

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**DISCLOSURE STATEMENT UNDER FRAP 26.1
AND CIRCUIT RULE 26.1-1**

Under FRAP 26.1 and Circuit Rule 26.1-1, Appellees Food & Water Watch and Moms Against Fluoridation are 501(c)(3) corporations who have no parent corporations and have no stock owned by a publicly held corporation or other publicly held entity. Appellee Fluoride Action Network is a project of the American Environmental Health Studies Project (AEHSP), which is a 501(c)(3) corporation. AEHSP does not have a parent corporation and has no stock owned by a publicly held corporation or other publicly held entity.

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GLOSSARY OF ACRONYMS

AOB	Appellants' Opening Brief
APA	Administrative Procedure Act
CDC	Centers for Disease Control and Prevention
ELEMENT	Early Life Exposures in Mexico to Environmental Toxicants
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
MG/L	Milligrams per Liter
MIREC	Maternal-Infant Research on Environmental Chemicals
NASEM	National Academies of Sciences, Engineering, & Medicine
NIH	National Institutes of Health
NTP	National Toxicology Program

INTRODUCTION

EPA does not appeal the merits of the district court’s finding that water fluoridation poses an unreasonable risk of neurodevelopmental harm to children. Instead, EPA sets its sights on the robust citizen petition process that Congress established to empower “any person” to force agency action when bureaucratic inertia threatens public health, as happened here.

Through its appeal, EPA asks this Court to rewrite Congress’s directive. If EPA had its way, many threatened citizens would be unable to sue; experts would be unable to rely on groundbreaking new studies, even when EPA concedes they are “indisputably central” to the case; and chastened judges would be hesitant to ensure that highly consequential decisions take account of what both parties consider to be the strongest science.

First, after conceding standing below, EPA seeks to limit which citizens can bring suit by expanding Article III’s causation/redressability requirements far beyond what the Constitution requires. EPA’s argument is based on “facts” it never presented below (despite ample opportunity), a demonstrably incorrect application of the district court’s findings, and inferences that contradict the actual record. The argument fails on multiple grounds.

Second, EPA insists that the “de novo proceeding” under Section 21 of TSCA is APA-style record review, despite the statute’s text, structure, and history all plainly

showing that this is not so. Alternatively, EPA argues that Section 21 allows some new evidence, but just not as much as the district court allowed. This too is devoid of statutory support. It is also undefined and unworkable, with EPA offering no intelligible yardstick to determine which post-petition studies can be considered, and which cannot.

Lastly, EPA seeks to undo years of diligent judicial management on the grounds of “party presentation.” EPA never raised this issue below, and thereby waived its right to do so here. But, even if preserved, the argument fails for a multitude of reasons, not least of which is that the district court never raised any new *legal* issues. Instead, it exercised its inherent authority to manage the proceedings, including development of the *factual* record, to resolve issues that the *parties* presented. Assuming *arguendo* that party presentation is even implicated, the district court did not violate it—let alone to the “drastic” degree necessary to justify reversal.

This Court should affirm the district court’s judgment.

STATEMENT OF THE ISSUES

1. Whether EPA can reframe the standing question on appeal with purported “facts” (and inferences therefrom) that EPA could have, but did not, present below, and *if* so, whether these new facts have any bearing on Plaintiffs’ standing in light of *Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100, 114 (2025), the district court’s factual findings, EPA’s incorrect application of these

findings, and the totality of record evidence, including the declarations of Jessica Trader, Julie Simms, Brenda Staudenmaier, and Kristin Lavelle.

2. Whether a district court in a TSCA Section 21 case is limited to reviewing the “administrative record” despite the statute’s requirement to hold a “de novo proceeding” and legislative history showing Congress intended the district court to “develop” a record and “gather[] evidence.”

3. Whether EPA waived/forfeited a “party presentation” challenge by failing to raise this issue below and, *if* not, whether the district court, having not raised any new *legal* issues, violated the principle by staying the case to further develop the *factual* record.

STATEMENT OF THE CASE

I. Legal Background: The Toxic Substances Control Act (“TSCA”)

The “overarching purpose of the TSCA is to protect the public from chemicals that pose an unreasonable risk to health and the environment.” *Food & Water Watch, Inc. v. United States EPA*, 302 F. Supp. 3d 1058, 1066 (N.D. Cal. 2018). One of the mechanisms TSCA provides for accomplishing this goal is a citizen petition process that permits citizens to file civil actions to compel rulemaking on chemicals that EPA has failed to adequately regulate. *See id.*; 15 U.S.C. § 2620.

Congress included the citizen petition provision to “ensure that bureaucratic lethargy does not prevent the appropriate administration of this vital authority.”

Env'tl. Def. Fund v. Reilly, 909 F.2d 1497, 1499 (D.C. Cir. 1990) (quoting 122 Cong. Rec. 32,857 (1976) (statement of Sen. Tunney)). As stated in the Senate Report, “[t]he responsiveness of government is a critical concern and the citizens’ petition provision will help to protect against lax administration of the bill.”¹ S. Rep. 94–698, 1976 U.S.C.C.A.N. 4491, 4503. In short, Congress viewed the citizen petition provision as a means to “assure that the [EPA] is *forced* to focus on the provisions of the bill directed at protecting health and the environment from the dangers of toxic chemicals.” *Id.* at 4502 (emphasis added).

Consistent with Congress’s intent, courts have described TSCA as having “unusually powerful procedures for citizens to force EPA’s hand.” *Trumpeter Swan Soc’y v. EPA*, 774 F.3d 1037, 1039 (D.C. Cir. 2014). These procedures, set forth in Section 21 (codified at 15 U.S.C. § 2620)), permit “any person”² to petition EPA to enact rules to ban or restrict the “particular use” of chemicals that pose unreasonable

¹ Similar language can be found in the individual Senators’ statements during the hearing in which the TSCA legislation was passed. *See* 122 Cong. Rec. 32,856 (1976) (“Citizens’ petitions are authorized which will force the Administrator to be more responsive to the needs of citizens in the establishment of rules under the act.” (statement of Sen. Hartke)); *id.* at 32,857 (“All of us have an interest in ensuring that agencies of the Federal Government are more responsive to the needs of citizens.” (statement of Sen. Tunney)); *id.* at 32,858 (stating that citizen petitions “ensure adequate and viable public input with respect to the effective administration of the bill” (statement of Sen. Pearson)).

² By giving any person the right to petition, Congress granted standing to the “outer limits” of Article III. *See Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*, 204 F.3d 149, 155 (4th Cir. 2000).

risk. *See* 15 U.S.C. § 2620(a) (citing § 2605)). If EPA denies the petition, TSCA requires that “the petitioner *shall* be provided an opportunity to have such petition considered by the court in a *de novo proceeding*.” § 2620(b)(4)(B) (emphases added).

Congress did not leave it a mystery as to why it required *de novo* proceedings. As the Senate Report explains, “[i]n a judicial review of the Administrator’s denial of a citizen’s petition or failure to act, there would be no record upon which the review could be based, and therefore *a de novo procedure is essential to provide the opportunity to develop such a record*.” S. Rep. 94–698, 1976 U.S.C.C.A.N. at 4502-03 (emphasis added). *De novo* proceedings were thus *expressly* intended as evidence gathering processes. *See also id.* at 4499 (“*After gathering evidence in a de novo procedure*, the courts would be authorized to require the initiation of the action requested if the petitioner has shown that the action requested is justified.” (emphasis added)).

II. Factual Background

A. Fluoride and Water Fluoridation

Fluoride is used in a variety of commercial and industrial products, from toothpaste to pesticides. 1-SER-69, 2 SER 403. When applied *topically* to the teeth, fluoride is effective at preventing cavities. 1-SER-52-54. When *ingested*, fluoride can present risks to health, as discussed herein. Unlike in Europe, where most

countries do not add fluoride to water (2-ER-206), the practice of water fluoridation is widespread in the United States, particularly in large metropolitan areas. 4-SER-794-95. In total, over 200 million Americans have their tap water treated with fluoridation chemicals (to a target concentration of 0.7 mg/L).³ 1-SER-69. Most other Americans are exposed to fluoridated water through the processed beverages and foods made with it. 1-SER-259, 4-SER-793-94.

B. EPA’s “Safe” Drinking Water Standard for Fluoride

In 1985, pursuant to its authorities under the Safe Drinking Water Act (“SDWA”), EPA established a “safe” drinking water standard for fluoride, known as the “Maximum Contaminant Level Goal” (“MCLG”). 1-SER-72. Although SDWA requires that an MCLG protect against all known or anticipated health effects, 42 U.S.C. § 300g-1(b)(4)(A), EPA decided to only protect against fluoride’s “most severe” effect: a condition called “crippling skeletal fluorosis.” *Id.* Given its decision to only protect against fluoride’s *crippling* effects, EPA set the MCLG at a high concentration (4 mg/L). *Id.*

In 2003, EPA asked the prestigious National Research Council (NRC) of NASEM to advise the Agency about new toxicological findings on fluoride. 2-SER-321-22. NRC’s report, issued in 2006, concluded that the fluoride MCLG poses risks

³ Like arsenic and lead, fluoride occurs naturally in the environment. 2-ER-233; 1-SER-159-¶124. The fluoride added to drinking water, however, is an industrial byproduct of phosphate fertilizer manufacturing. 2-ER-232 2-SER-272.

of bone disease and severe dental fluorosis and “should be lowered.” 2-ER-303. It is now nineteen years later, and EPA has *still* not lowered the fluoride MCLG. The agency’s failure to act, despite evidence of harm, is the kind of “bureaucratic lethargy” that led Congress to enact the citizen petition provision of TSCA. 4-SER-934.

C. The Evolving Science on Fluoride and the Brain

1. Pre-Petition Evidence

NRC’s 2006 review was a landmark report, not only for its conclusion that the MCLG is unsafe, but also for its conclusion that fluoride is an “endocrine disrupter” that can “interfere with the functions of the brain.” 2-SER-279-91; 2-SER-281, 290. Based on its findings, the NRC called for a sweeping array of studies to be performed in human populations, including studies of IQ, behavioral problems, dementia, and thyroid disease. 2-SER-281-82, 290-91.

The scientific community heeded NRC’s call. Research into fluoride’s neurological effects skyrocketed after the release of NRC’s report, including studies of fluoride’s potential impact on IQ. 2-ER-209; 4-SER-840-41. In 2012, a Harvard scientist, Dr. Philippe Grandjean, published a meta-analysis of the first 27 studies on fluoride and IQ (“Choi 2012”).⁴ 2-SER-358. Twenty-six of these 27 studies found

⁴ Throughout this litigation, the parties referred to studies by the name of the first listed author and year of publication. Here, “Choi” refers to Dr. Grandjean’s Harvard colleague, Dr. Anna Choi.

lower IQs in the higher fluoride areas. 1-SER-142-¶78.

NRC's report also catalyzed dozens of animal studies on fluoride's impact on learning and memory. 1-SER-193-196. In 2016, the National Toxicology Program (NTP), headquartered at NIH, published a systematic review of this animal research, finding "moderate" evidence that fluoride has a detrimental effect on learning/memory in adult animals. 1-SER-136. (Moderate is a descriptor NTP uses when there is "some hazard there." 2-SER-388.) NTP had less confidence in the studies looking at developmental exposures, due in part to there being fewer studies available. 2-SER-392.

2. Plaintiffs' Petition to EPA

In November 2016, Plaintiffs filed their citizen petition with EPA, challenging EPA's outdated safety standards and presenting the burgeoning research on brain effects from fluoride exposure. 2-ER-207-09. The petition attached 313 scientific papers, which the district court described as "voluminous." 2-ER-235-59; 1-ER-54. Plaintiffs stressed the importance of considering this data under the framework of EPA's *Guidelines for Neurotoxicity Risk Assessment*. 2-ER-208. Using this framework, Plaintiffs argued that fluoridation poses an unreasonable risk and called on EPA to ban the practice. *Id.*

In February 2017, EPA denied Plaintiffs' petition. 2-ER-188-201.

3. Post-Petition Evidence

About seven months after EPA denied the petition, the first fluoride/IQ study funded and vetted by the NIH was published (“Bashash 2017”). 1-SER-7-8; 2-SER-346-51. Using state-of-the-art methodology, the study examined the impact of so-called “optimal” levels of fluoride in a cohort of pregnant mothers living in Mexico City (the ELEMENT cohort). 1-SER-70-¶10; 1-SER-87-93. Notably, the study found that optimal levels of fluoride, when ingested during pregnancy, are associated with IQ decrements in the child. 1-SER-100-¶42.

In 2019, a second NIH-funded fluoride/IQ study was published (“Green 2019”). 1-SER-111; 2-SER-375. Green used the same state-of-the-art methodology but focused on a birth cohort from Canada (the MIREC cohort). 1-SER-70-¶10; 1-SER-111-13. MIREC’s results were consistent with ELEMENT: “optimal” fluoride exposure, during pregnancy, was again associated with IQ decrements in the child, although more consistently in boys than girls. 1-SER-114-16.

Back at the NIH, scientists at NTP conducted an animal study on fluoride, which they published in 2018 (“McPherson 2018”). 5-ER-1034-36. The study, which used relatively low levels of exposure for an animal experiment (5-ER-1035), failed to detect significant effects on learning and memory, although it did find a significant increase in pain sensitivity in the fluoride-treated animals. 2-SER-199.

In 2019, NTP scientists released the first draft of a comprehensive systematic review (a.k.a. “monograph”) of the research on fluoride and the brain. 1-SER-27. Though slated for completion in 2020, the extensive peer review process took longer than anticipated, including two rounds of peer review by NASEM, and a third round of peer review by a panel of independent experts. 4-SER-768-77. By May 2022, the monograph was approved for publication by NTP’s scientific director. 4-SER-776-77. It was not until August 2024, however, that NTP published the monograph.⁵ 4-SER-941.

The NTP identified a total of 72 studies that investigated the relationship between fluoride and IQ in human populations, including 19 classified as “high quality.” 2-ER-312. According to NTP, these “high-quality studies (i.e., studies with low potential for bias) consistently demonstrate lower IQ scores with higher fluoride exposure.” 4-SER-861. The NTP thus concluded, “with moderate confidence,” that higher fluoride exposure (i.e., 1.5 mg/L) “is consistently associated with lower IQ in children.” 2-ER-313.

⁵ While the final version is not identical to the May 2022 version, the parties agree “there are no material differences.” 4-SER-941. The Appellees focus here on the findings of the May 2022 monograph because that is the version that was entered into evidence in this case.

III. Procedural History

A. Initial Judicial Proceedings (2017-2018)

After an unsuccessful motion to dismiss,⁶ EPA moved to limit the scope of review to Plaintiffs’ petition, and EPA’s denial thereof. As with EPA’s motion to dismiss, the district court found the Agency’s argument to be at odds with TSCA’s “statutory text, structure, purpose, and legislative history.” 1-ER-69.

B. First Phase of Discovery (2018-2019)

The parties conducted ordinary fact and expert discovery consistent with the Federal Rules of Civil Procedure, with both parties relying upon studies published before and *after* the petition. 2-SER-267-¶46; 2-SER-453-54. For its part, EPA filed a motion to *extend* discovery to allow *additional* information to be introduced at trial. 6-ER-1161-67. Specifically, EPA wanted to (1) supplement its expert roster with one of the co-authors of the NIH birth cohort studies, and (2) rely upon the soon-to-be-released draft of the NTP monograph. *Id.* EPA argued that “the content and conclusions of the NTP Monograph are *indisputably central* to the expert opinions in this matter.” *Id.* at 1164 (emphasis added). EPA also noted that NTP’s systematic review is “conducted in the manner consistent with requirements of

⁶ EPA’s motion was based on a statutory interpretation of Section 21 that the district court found incompatible with the statute’s plain meaning, structure, purpose, legislative history, and *EPA’s own published interpretations*. *Food & Water Watch, Inc. v. EPA*, 291 F. Supp. 3d 1033, 1044-52 (N.D. Cal. 2017).

TSCA” and that “*this litigation would benefit substantially* if the parties’ were afforded additional expert discovery” to consider it. *Id.* (emphasis added).

Plaintiffs opposed EPA’s motion due, in part, to the disruptive effect it would have on the trial schedule. 6-ER-1153-60. The district court agreed, finding that EPA’s last-minute attempt to add a new expert was procedurally improper, and that the draft nature of the NTP monograph did not justify undoing the jointly agreed-upon trial setting. 6-ER-1150-52.

C. First Phase of Trial⁷ (June 2020)

1. Plaintiffs’ Trial Evidence

Relying on both pre-petition and post-petition evidence, Plaintiffs argued that the data on fluoride neurotoxicity is sufficient to demonstrate an unreasonable risk from fluoridation when analyzed under EPA’s *risk assessment* framework. 2-SER-332-33, 399-400, 505-07, 515; 3-SER-540.

Plaintiffs’ *pre*-petition evidence included testimony⁸ on NRC’s 2006 report (1-SER-135-36, 193, 203, 228, 241; 2-SER-271, 311-15, 321-24, 334-35, 401-02); Dr. Grandjean’s meta-analysis (1-SER-140-43, 2-SER-358-61); the post-NRC animal studies (1-SER-193-96, 213-26, 246-55); and the inadequacy of existing

⁷ On appeal, EPA characterizes this case as having two separate trials. However, the district court, *and the parties*, treated it as one trial split into two phases with a singular evidentiary record. 4-ER-730; 3-SER-663-65, 4-SER-830.

⁸ Most of the direct expert testimony during the first phase of trial was introduced in the form of expert declarations. *See* 5-ER-1095; 2-SER-459-60.

government standards (2-SER-301, 308, 316-18).

Plaintiffs' *post*-petition evidence included testimony about the NIH-funded birth cohort studies, including from the principal investigators of these studies. 1-SER-78-101, 146-47, 159-65, 2-SER-346-55, 371-77; 3-SER-525-30. Plaintiffs also introduced testimony regarding recent studies linking fluoridation to ADHD. 1-SER-91-94, 144-45, 3-SER- 559.

2. EPA's Trial Evidence

Like Plaintiffs, EPA introduced testimony on both pre- and post-petition research. For animal studies, EPA focused almost exclusively on NTP's 2016 systematic review and NTP's 2018 animal study ("McPherson 2018"). 5-ER-1031-40, 1-SER-65-66, 2-SER-453-58. For human studies, EPA spent considerable trial time eliciting testimony on an unpublished abstract of a Spanish birth cohort study that was first released in 2019 after the experts had finished their reports. 2-SER-364-68, 378-85, 466-98. Although the abstract provided threadbare details about its methodology, it found no adverse association between fluoride and IQ. 2-SER-477-98. EPA used this abstract to cast doubt on the findings of the ELEMENT and MIREC studies,⁹ which fed into EPA's main takeaway message: the science on fluoride was too new for judicial intervention. EPA told the court: "Today is not the

⁹ After 'ringing the bell,' EPA stipulated to strike all of the substantive testimony it elicited from its expert on the Spanish abstract before Plaintiffs began their cross-examination. 2-SER-500-01.

day for the Court to intervene. We’re asking the Court for prudence to allow the evolving science to play out.” 2-SER-343. EPA reiterated this in closing, stating “EPA asks the Court to let the science advance.” 3-SER-519. In a similar vein, EPA reminded the court that “simultaneous with this trial,” the NTP was continuing forward with its systematic review,¹⁰ and that this review would be “reach[ing] hazard conclusions in a manner that is consistent with the state of the science for reaching such conclusions.” 3-SER-518.

3. The Court’s Concluding Remarks

After the close of the first phase of trial, the district court stated that Plaintiffs had presented “serious evidence” raising “serious questions” about the safety of fluoridation, with much of this evidence unavailable to EPA when it denied the petition in 2017. 1-ER-29-32. Agreeing with one of Plaintiffs’ central theories of the case (*see, e.g.*, 1-SER-21-24), the court also noted that EPA had used the wrong standard to assess the evidence: a “standard of causation” which is “*not the proper standard.*” 1-ER-30 (emphasis added). The court indicated its intention to stay the case so that Plaintiffs could resubmit their petition to EPA (together with the new evidence) so that “the agency would take a serious look, *apply the proper standard,*

¹⁰ EPA argued that Section 21 requires a “systematic review” and that Plaintiffs had failed to perform one. 1-SER-63-67. EPA showcased NTP’s systematic review methods, therefore, as an example of what Plaintiffs should have done. 2-SER-412-51, 503-04, 518.

and look at this new evidence.” 1-ER-36 (emphasis added). Both parties expressed concerns about a potential delay in the resolution of the case, but neither party objected. 1-ER-33-47.

D. The Stay (August 2020-October 2022)

On August 6, 2020, the court held a hearing to further discuss the stay. EPA formally objected to the idea; Plaintiffs did not. 4-ER-738-77. At no point in the hearing was the issue of party presentation raised. After receiving the parties’ input, the court stayed the case. 1-ER-23-27. Plaintiffs thereupon filed a supplemental petition with EPA in November 2020, which the agency denied in January 2021. 5-ER-936-78.

Simultaneous to the Plaintiffs’ filing of the supplemental petition, and in the months and years that followed, the parties litigated every aspect of the course forward that the court had identified in its August 2020 order, including the permissibility of the stay (1-ER-19-22; 5-ER-943-87); the length of the stay (4-ER-685-715; 4-ER-685; 5-ER-898; 3-SER-609-35); the mechanism of Plaintiffs amending their complaint (1-ER-22; 5-ER-976; 5-ER-980); the ability of Plaintiffs to supplement their allegations on standing (1-ER-4-18; 5-ER-716-935; 3-SER-581-97); and the power of the court to set aside the parties’ prior stipulation on standing¹¹

¹¹ EPA brazenly states that the district court acted “in violation” of the stipulation. AOB at 37. Not so. The district court applied governing law and held that the

(1-ER-10-14; 5-ER-933-34, 902-05; 3-SER-593-96). In its appeal, EPA does not allege legal error with *any* of the district court’s decisions on these discrete, litigated issues.

As to standing, the district court specifically noted that “EPA does not dispute that Plaintiffs ‘may cure standing deficiencies through supplemental pleadings.’” 1-ER-10 (citing *Northstar Fin. Advisors, Inc. v. Schwab Invs.*, 779 F.3d 1036, 1044 (9th Cir. 2015), *as amended on denial of reh’g en banc* (Apr. 28, 2015)); 1-ER-17 (citing *Scahill v. D.C.*, 909 F.3d 1177, 1184 (D.C. Cir. 2018) (“[W]e hold that a plaintiff may cure a standing defect under Article III through an amended pleading alleging facts that arose after filing the original complaint.”)).

E. Second Phase of Discovery (2022-2023)

On October 26, 2022, the district court lifted the stay and the parties engaged in further discovery. 5-ER-837-42. On standing, the parties agreed that Plaintiffs could introduce new facts concerning Jessica Trader’s pregnancy through a supplemental declaration, if EPA could then depose her. 3-SER-606. EPA ultimately declined, however, to depose Trader. 3-SER-659. EPA also declined to file either a motion to dismiss or a motion for summary judgment on Trader’s standing. 1-ER-10 n.2, 18; 3-SER-603, 659.

circumstances justified setting the stipulation aside. 1-ER-10-14; *see also* 3-SER-593-96. EPA does not allege error in this decision.

F. Second Phase of Trial (2024)

The parties resumed trial on January 31, 2024. 4-SER-707. In contrast to the first phase of trial, EPA did *not* dispute Plaintiffs’ standing. *Compare* 3-SER-680-81 (identifying disputed legal issues in second phase) *with* 1-SER-74-75 (identifying disputed legal issues in first phase). With standing out of the way, the parties focused on whether the scientific developments since the first phase of trial supported, or detracted from, a finding of unreasonable risk. Plaintiffs focused on the NTP monograph (3-SER-692-95; 4-SER-766-78, 788-90, 824-26), new NIH-funded studies of the ELEMENT and MIREC birth cohorts (3-SER-695-96; 4-SER-721-23, 737-45), and EPA’s methods and procedures for finding unreasonable risk under TSCA (3-SER-689-90, 4-SER-711-12, 756-60, 778-83, 796-800, 831-33). For its part, EPA focused on recent studies that failed to find associations between low-dose fluoride and neurotoxic effects. 3-SER-665-71.

During the second phase of trial, the parties agreed the court could, and should, consider the new studies. The parties thus *jointly* moved to admit dozens of new studies into evidence, including the NTP’s 2022 Monograph. 4-SER-730-32, 764-65, 816-17. EPA also moved to admit a Health Canada document, published a “couple of weeks” before trial, that it deemed helpful to its case. 4-SER-804-06; *see also* 4-SER-932.

SUMMARY OF ARGUMENT

EPA’s appeal fails on all three issues it raises.

First, there are no rare or exceptional circumstances that justify the EPA reframing the standing issue on appeal with facts it *could have raised below, but did not*. Even if the new “facts” are considered, Jessica Trader’s injury is still traceable/redressable: the district court found (and EPA does not dispute) that fluoridation poses a credible threat of neurodevelopmental harm to her children, and regulatory action would, at a minimum, reduce that threat, including the costs of avoiding it. It is not necessary for regulatory action to eliminate Trader’s fluoride exposure because partial redress is enough under *Diamond Alternative*, 606 U.S. at 114. Other Plaintiffs also have standing based on credible threats of harm from fluoridation, as supported by NRC, NIH, and NTP findings.

Second, TSCA Section 21 mandates de novo proceedings—not record review. The statutory text, structure, and legislative history are all consistent in showing that Congress intended full, evidence-gathering trials. The district court thus did not abuse its discretion by considering studies published after EPA’s denial of the petition. EPA’s argument to the contrary cannot be reconciled with the statute’s plain meaning, legislative history, and purpose.

Third, EPA waived its party presentation challenge by never raising the argument below. Even if preserved, its challenge is meritless because the principle

restricts courts from raising new *legal* issues; it does not bar a *district court* from requiring further development of the *factual* record to resolve *raised* issues, or from exercising its inherent authority to select the procedural mechanisms most appropriate for resolving a case.

ARGUMENT

I. Plaintiffs Have Article III Standing

“To demonstrate standing, plaintiffs must answer a basic question—‘What’s it to you?’” *Diamond Alternative*, 606 U.S. at 110 (citation omitted). “In other words, plaintiffs must show that they possess a ‘personal stake’ in the dispute and are not mere bystanders.” *Id.* (citation omitted) (quotation mark omitted). Jessica Trader’s declarations establish that she has such a personal stake, and that the answer to “what’s it to you?” is ‘the health of her children,’ born and unborn.¹² The district court agreed and found, “*at a minimum*,” that Plaintiffs have standing based on the facts set forth in Trader’s declarations. 2-ER-82-84 (emphasis added).

Trader is a member of Plaintiff Food & Water Watch (“FWW”). 3-ER-595. The district court found, and EPA does not dispute, that FWW satisfies the second

¹² The fact that many people have the same personal stake as Trader does not change the result. *See United States v. Students Challenging Regulatory Agency Procedures*, 412 U.S. 669, 687-88 (1973) (making clear that “standing is not to be denied simply because many people suffer the same injury” because doing so “would mean that the most injurious and widespread Government actions could be questioned by nobody”).

(i.e., germane interests) and third (i.e., nature of claim/relief) requirements of associational standing. *See Am. Unites for Kids v. Rousseau*, 985 F.3d 1075, 1096 (9th Cir. 2021). The dispute about FWW’s standing is thus limited to the standing of its individual members,¹³ including Trader and Julie Simms, discussed *infra*.

In 2018, at the time of her initial declaration, Trader was a 32-year-old woman with a fluoride-induced injury (dental fluorosis) living in San Francisco, where fluoride is added to drinking water. 3-ER-593-94. Due to concerns about fluoride’s potential toxic effects, including on the bones,¹⁴ thyroid gland,¹⁵ and brain, Trader was taking “reasonabl[e]” steps to limit her ingestion of fluoride, including

¹³ In light of *Mi Familia Vota v. Fontes*, 129 F.4th 691, 708-9 (9th Cir. 2025), there is arguably no need for FWW to identify specific members who are pregnant and exposed to fluoridated water given FWW’s large nationwide membership and the ubiquity of fluoridation. *See* 4-ER-678 (“FWW has over 70,000 members nationwide.”); *Nat’l Council of La Raza v. Cegavske*, 800 F.3d 1032, 1041 (9th Cir. 2015), *overruled on other grounds by Ariz. All. for Retired Americans v. Mayes*, 117 F.4th 1165 (9th Cir. 2024); *FGE v. Trump*, 782 F.Supp.3d 793, 810 (N.D. Cal. 2025) (applying *Fontes*).

¹⁴ The parties’ experts agreed, and the court so found, that ingested fluoride accumulates in bone, and that the fluoride which accumulates in a woman’s bones *prior* to pregnancy becomes a source of exposure to the baby in the womb (due to the breakdown of maternal skeletal tissue during pregnancy). 2-ER-100; 4-SER-724-26, 820, 834-¶331.

¹⁵ Plaintiffs introduced evidence, including an NIH-funded study, linking fluoridated water to higher rates of thyroid disease (hypothyroidism) in adult women (4-SER-737-45, 919-930), which provides a plausible mechanism by which a woman’s *pre*-pregnancy fluoride exposure can adversely impact the child. 1-SER-135-¶55, 202-04, 232-34; 4-SER-735-41, 744-45, 926; 1-ER-110.

purchasing a filter and spring water to avoid the fluoridation chemicals added to her tap water. *Id.* at 594.

In 2019, Trader became engaged to her partner, with whom she conceived a child in 2020. 3-ER-343. Now married and living in Leawood, Kansas, Trader birthed her first child, Olive, in August 2021, and is planning on having more children in the years ahead. *Id.* Since Leawood, like San Francisco, adds fluoridation chemicals to its water, Trader continues to spend money filtering her tap water and purchasing bottled water. *Id.* at 343-44. According to Trader, “[a]s long as fluoridation chemicals are added to my city’s water supply, I will continue incurring these costs to protect Olive” and future children. *Id.* at 344. Based on these facts, the district court had little trouble finding that Trader has standing. 2-ER-82-84. EPA did not argue otherwise. In fact, EPA *agreed* that pregnant women and infants are “susceptible populations” to the risks of fluoridation, 4-SER-835-36, and that pregnant women, and mothers of young children, living in fluoridated areas have standing. 4-ER-795.

But now, changing its tune on appeal, EPA asks this Court to reverse the district court’s fact-based holding based on newly proffered “facts” about the background fluoride levels in Leawood water that EPA never presented below. This highly prejudicial, eleventh hour gambit fails for a multitude of reasons.

A. The Court Should Disregard EPA’s Newly Proffered, Unvetted Facts

As discussed above, EPA had numerous opportunities to challenge the factual and legal basis of Trader’s standing during the second phase of the litigation. *See supra* p. 16. EPA also had the opportunity to introduce any evidence it deemed relevant on standing during the second phase of trial. But, again, EPA opted not to do so. *See Diamond Alternative*, 606 U.S. at 108 (“EPA’s silence on standing was telling—the proverbial dog that did not bark—because EPA routinely challenges a party’s standing when the agency believes that injury in fact, causation, or redressability is questionable.”).

Now, having lost on the merits, EPA asks this Court to reverse the district court’s factual findings on standing based on “facts” it could have,¹⁶ but did not, present during the district court proceedings.¹⁷ Worse, EPA asks this Court to infer how Trader would have answered questions related to these facts if EPA had given her the opportunity to do so. *See, e.g.*, AOB at 40 (asking the Court to infer that

¹⁶ *See, e.g.*, Dkt. 42-2 at 18-19 ¶ 23, Ex. M (showing that the WaterOne webpage contained the same information about background fluoride levels well before EPA received Trader’s declaration). One does not need to review an archived website, however, to know that if the background fluoride levels in Leawood’s water are as undisputable as EPA claims, such information would be readily available long before this litigation, particularly to a sophisticated entity like EPA.

¹⁷ Appellees have separately filed their opposition to EPA’s request for judicial notice. *See* Dkt. 42-2 at 2.

Trader “will continue to incur the expense” of filtering her water); *Ethridge v. United States*, 258 F.2d 234, 236 (9th Cir. 1958) (refusing to make assumptions about “facts not in evidence”); *Scheiding v. Dinwiddie Construction Co.*, 69 Cal.App.4th 64, 81 (1999) (“[W]e can infer nothing at all with respect to questions which were neither asked nor answered.”).

In so doing, EPA has violated this Court’s admonition that “a party cannot treat the district court as a mere ill-placed bunker to be circumvented on his way to this court where he will actually engage his opponents.” *Allen v. Ornoski*, 435 F.3d 946, 960 (9th Cir. 2006) (citation omitted). “Absent exceptional circumstances,” the Ninth Circuit will “not consider arguments raised for the first time on appeal.” *Baccei v. United States*, 632 F.3d 1140, 1149 (9th Cir. 2011) (citations omitted). While there are three discretionary exceptions to this rule, none has applicability here, and EPA does not contend otherwise. *See id.* at 1149. In any event, the Ninth Circuit has made clear that “we will not reframe an appeal to review what would be in effect a different case than the one decided by the district court.” *Roley v. Google LLC*, 40 F.4th 903, 910-11 (9th Cir. 2022) (quoting *Baccei*).

It matters not that EPA seeks to introduce these purported facts through judicial notice, or that the information pertains to subject matter jurisdiction. First, the Ninth Circuit has stated “[i]t is rarely appropriate for an appellate court to take

judicial notice of facts that were not before the district court.”¹⁸ *Fleischer Studios, Inc. v. A.V.E.L.A., Inc.*, 654 F.3d 958, 966 (9th Cir. 2011) (citation omitted); *Reina-Rodriguez v. United States*, 655 F.3d 1182, 1193 (9th Cir. 2011) (same). Second, the fact that standing is never waived as a *legal* issue does not give an appellant license to recreate the *factual record* on appeal. This is apparent from the different standard that applies to an appellate court’s review of the *legal* determination of standing (*de novo*) versus its underlying *factual* basis (clear error). *See NEI Contracting and Engineering, Inc. v. Hanson Aggregates Pacific Southwest, Inc.*, 926 F.3d 528, 531 (9th Cir. 2019); *cf. Summers v. Earth Island Inst.*, 555 U.S. 488, 500 (2009) (“The dissent cites no instance in which ‘supplementation’ has been permitted to resurrect and alter the outcome in a case that has gone to judgment, and indeed after notice of appeal had been filed.”).

B. FWW Has Standing Even if the Court Considers the Newly Proffered “Facts”

Even if this Court considers EPA’s newly proffered facts, the result does not change: FWW has standing.

¹⁸ The one case that EPA cites where an appellate court took judicial notice of jurisdictional facts not considered below is inapposite because it involved a Rule 12(b)(1) motion to dismiss. *See* Dkt. 44.1 at 8 (citing *Kareem v. Haspel*, 986 F.3d 859, 866-67 n.5 (D.C. Cir. 2021)). Further, as the case that *Kareem* relies on explains, “*only the court*, not the plaintiff (or defendant), can *elicit* information outside the pleadings.” *Haase v. Sessions*, 835 F.2d 902, 908 (D.C. Cir. 1987) (emphases added). EPA failed to heed *Hasse*’s admonition here.

1. The Inferences EPA Draws About Trader’s Future Conduct Are at Odds with the Plain, Natural Meaning of Her Declarations

EPA asks this Court to serve as a factfinder. It asks this Court to find that, even if EPA were to end fluoridation,¹⁹ Trader will continue to spend the same amount of money avoiding fluoride from her tap water as she does now. AOB at 31, 40-42. The problem with this assertion is that it contradicts the natural and plain meaning of what Trader declared.

Trader declared that she will continue spending money on filtration and bottled water “[a]s long as *fluoridation chemicals* are added to my city’s water supply.” 3-ER-345 (emphases added). The plain and natural corollary to this is that, when fluoridation chemicals are no longer added, Trader will cease incurring these expenses.

Trader is also clear that the measures she takes to *reduce* her ingestion of fluoride are not exhaustive.²⁰ In her first declaration, for example, Trader states that

¹⁹ EPA’s obligation, under the district court’s order, is to initiate a rulemaking proceeding under Section 6(a) to ensure that fluoridation “no longer presents” an unreasonable risk, which could include a ban on fluoridation. *See* 2 ER 72, 82-83, 150; 15 U.S.C. § 2605(a). The possibility that EPA might opt for something short of a ban does not impact the redressability analysis. *See Citizens for Better Forestry v. U.S. Dep’t. of Agric.*, 341 F.3d 961, 975–76 (9th Cir. 2003); *Catron County Bd. of Comm’rs v. United States Fish & Wildlife Serv.*, 75 F.3d 1429, 1433 (10th Cir. 1996).

²⁰ As the evidence showed at trial, it is impossible to avoid all exposure to fluoride in our modern industrialized society. 4-SER-733-34.

she takes whatever measures she “reasonably” can to “limit” her exposure. 3-ER-594. She identifies these “reasonabl[e]” measures as being: (1) avoiding the fluoridation chemicals *added* to tap water, and (2) not buying fluoride-containing dental products. *Id.* Unlike other standing declarants,²¹ Trader makes no mention of taking steps to limit her consumption of processed beverages, such as sodas and fruit drinks, which are routinely made with fluoridated water. 4-SER-793-94. Nor does Trader make any mention of spending money to avoid background levels of fluoride in water or food. Her focus instead is on removing the “fluoridation chemicals”²² that are “added” to water, and the fluoride that is added to dental products. 3-ER-345, 594. Therefore, since background fluoride is not “added,” and since Trader has expressed no intention of paying to remove it, the Court should not credit EPA’s speculation that she will begin doing so for the first time in her life.

2. EPA Inflates the Risks of Background Fluoride Levels by Making Incorrect Statements About the Court’s Findings

Ignoring the plain meaning of Trader’s words, EPA argues that she will continue filtering her water, even if fluoridation ends, because the background levels

²¹ See 4-ER-679 (describing common steps FWW members take to reduce fluoride exposure); 3-ER-476 (Simms).

²² Per the record evidence, the industrial chemicals that are added to drinking water for fluoridation may present additional health risks (e.g., leaching of lead from pipes) that are not present with naturally occurring fluoride. 2-SER-274, 277-78, 280; *see also* 2-ER-232-33.

are “above what the district court found to present an unreasonable risk.” AOB at 39. But this premise is *incorrect*. The district court *never considered, nor made any findings*, about whether background fluoride levels in water present “unreasonable risk.” The Court made one, and only one, determination of unreasonable risk and that was for the condition of use of water fluoridation at a concentration of 0.7 mg/L. *See, e.g.*, 2-ER-73 (“*Specifically*, the Court finds that *fluoridation of water at 0.7 milligrams per liter (“mg/L”)* – the level presently considered ‘optimal’ in the United States – poses an unreasonable risk of reduced IQ in children.” (emphases added)); *id.* at 145-50 (analyzing whether water fluoridation at 0.7 mg/L presents an unreasonable risk and concluding that it does).

EPA’s false assertion that the Court found background fluoride levels pose an unreasonable risk is based on two equally erroneous predicates. First, EPA treats the district court’s identification of a “point of departure”²³ (i.e., 0.28 mg/L in maternal urine) as equivalent to an “unreasonable risk” determination. *See* AOB at 39 n.9. But a point of departure is *not* the same thing as a determination of unreasonable risk. The latter requires additional considerations (including an assessment of uncertainties) that are *not* factored into the point of departure. 4-SER-786-87. If any litigant in the world should know this, it is EPA.

²³ The point of departure is the exposure level at which a chemical may become hazardous. 2-ER-84-¶25a.

Second, in converting the district court’s *urine*-based point of departure into a hazard level for *water*, EPA erroneously applies the court’s finding that “approximately half of the maternal urinary fluoride . . . is attributed to *community water fluoridation*.” See AOB at 39 n.9 (quoting 2-ER-135 (emphasis added)). EPA’s brief construes this finding as meaning that there is a **1-to-2** ratio between fluoride in water (*regardless of its concentration*) and the fluoride in urine that is attributable to it.²⁴ This is *not* what the district court found. The court’s finding addressed the percent of urinary fluoride *in fluoridated areas* that is attributable to *community water fluoridation*.²⁵ 2-ER-134-35. In this context, the court found that the ratio of fluoride in *water* (0.7 mg/L) to the fluoride in *urine* attributable to it (0.4 mg/L) is approximately **1-to-0.6**, which goes in *the opposite direction* of what EPA has construed. See *id.*

EPA’s factual errors are fatal to its legal argument. Indeed, if one applies the court’s calculation to the 0.28 mg/L *urine*-based point of departure, it translates to a water fluoride level of approximately **0.5 mg/L**, which *exceeds* the alleged

²⁴ See AOB at 39 n.9 (“Pursuant to the court’s conclusions . . . , concentrations as low as 0.14 mg/L of fluoride in drinking water could result in maternal urinary levels of 0.28 mg/L.”).

²⁵ The district court did not address the urinary contribution from background levels of fluoride in water, such as the alleged levels (0.2 to 0.4 mg/L) in Leawood.

background levels (0.2 to 0.4 mg/L) in Leawood's water.²⁶ EPA's argument about the lack of traceability/redressability for Trader's injury thus rests on factual errors which undermine its position.²⁷

3. Trader's Injury Is Traceable/Redressable Even if the Background Fluoride Level in Leawood's Water Contributes to Her Risk

Even if the background levels in Leawood's water *contribute* to Trader's overall risk, regulating fluoridation will *reduce* this risk. This is all that Article III requires.

As the Supreme Court recently explained, redressability does not need to be complete; *partial* redressability is enough. *See Diamond Alternative*, 606 U.S. at 114. In *Diamond Alternative*, a group of gasoline fuel producers challenged EPA's decision to approve California's requirement that new vehicle fleets contain a certain percentage of electric or hybrid vehicles. EPA argued that redressability was lacking because, even if the regulation was invalidated, auto manufacturers would still make fewer gasoline-powered cars due to a decrease in market demand unrelated to the

²⁶ This is consistent with the evidence at trial, which showed that there is much more uncertainty about the effects of background fluoride than there is with the effects of water fluoridation. 4-SER-718-19, 733-34, 748-49.

²⁷ Plaintiffs do not assert that counsel for EPA made these errors knowingly or intentionally. However, now that the errors have been identified, EPA's counsel has an ethical obligation to correct the record. *See* ABA Model Rule of Prof'l Conduct 4-3.3; Cal. Rules of Prof. Conduct 3.3.

regulation. The Court rejected this argument and held that “invalidating the California regulations would likely redress *at least some* of the fuel producers’ monetary injuries.” *Id.* (emphasis added). As the Court explained, “[e]ven ‘one dollar’ of additional revenue for the fuel producers *would satisfy the redressability component* of Article III standing.” *Id.* at 114 (citing *Uzuegbunam v. Preczewski*, 592 U.S. 279, 292 (2021) (emphasis added)).

Here, the evidence at trial showed that the risk from fluoride exposure is *additive*: the more a person ingests, the greater the risk of harm.²⁸ 4-SER-792. The addition of fluoridation chemicals thus *adds to*, and *compounds*, whatever risks are posed by background exposures. *Id.* (explaining that “if you have some background fluoride exposure,” fluoridation “makes it more likely that there will be an effect” and “makes any effect potentially more severe”). Further, this is not a situation where fluoridation adds a *de minimus* amount of exposure when compared to other sources; the district court specifically found that fluoridation’s contribution to overall exposure is “highly consequential,” and credited expert testimony showing it to be “the primary driver.”²⁹ *See* 2-ER-133-34. Thus, if EPA were to regulate fluoridation,

²⁸ The NTP, for example, found that the “best fit” for the existing dose-response data on urinary fluoride and IQ is “linear”: meaning, as the fluoride level in urine increases, IQs decrease. 4-SER-890; *see also id.* at 900-01.

²⁹ This case is thus far different from those that EPA cites where independent contributions drowned out the contribution, if any, from the challenged conduct. *See*

it would *reduce* the risk that Trader faces from her drinking water. This is sufficient for Article III, even if there is some residual risk remaining from the background level in water. *See Barnum Timber Co. v. United States EPA*, 633 F.3d 894, 901 (9th Cir. 2011) (“We do not think Barnum must allege that EPA is the sole source of the devaluation of its property.”).

Even if redressability is narrowly analyzed in terms of the *money* that Trader needs to spend to protect her children, the result remains the same.³⁰ As *Diamond Alternative* makes clear, redressability is satisfied if the reduction in risk from EPA regulating fluoridation leads Trader to purchase just *one less bottle of water*. *See* 606 U.S. at 114 (stating that a savings of “one dollar” is sufficient for redressability). As discussed above, Trader’s declarations show that she would stop filtering her water if fluoridation ends. At a *minimum*, Trader would have no need to purchase bottled water when visiting towns and cities that do not have elevated levels of background fluoride. *See Diamond Alternative*, 606 U.S. at 120 n.5 (analyzing redressability based on “[t]he totality of record evidence, along with commonsense inferences about market realities”); *Barnum*, 633 F.3d at 900-01 (relying on “commonsense

Murthy v. Missouri, 603 U.S. 43 (2024); *California v. Texas*, 593 U.S. 659 (2021); *Wash. Envtl. Council v. Bellon*, 732 F.3d 1131 (9th Cir. 2013).

³⁰ While EPA asks that the redressability analysis be framed in this narrow fashion, the more appropriate framing is whether regulation of fluoridation would lessen the threat that fluoride in water poses to Trader’s children.

assessment” in declarations).

4. Trader’s Injury Is Redressable Even if She Does Not Spend One Less Dollar Avoiding Fluoride

Assuming *arguendo* that EPA regulation of fluoridation will have *no* impact on the amount of money Trader spends to avoid fluoride in public water supplies, her injury is *still* redressable. This is because restricting or banning fluoridation would reduce Trader’s, and her children’s, exposure to fluoride through processed beverages and foods. As the district court found (2-ER-135), and as the evidence at trial indisputably showed, the widespread addition of fluoridation chemicals to drinking water in the United States causes processed beverages and foods made in fluoridated areas to have elevated levels of fluoride. 1-SER-259; 4-SER-793-94. Since these products are consumed in non-fluoridated areas, people living in areas with no fluoride added to water are still exposed to elevated levels of fluoride. 1-SER-170-¶156; 4-SER-733-34; 3-ER-580-¶13. Because there are no labels to indicate the fluoride content, it is “nearly impossible” for consumers, like Trader, to avoid fluoridation chemicals in everyday products like juice, soda, cereal, etc. *See* 4-603-¶13; *NRDC v. United States EPA* (“*NRDC I*”), 735 F.3d 873, 878 (9th Cir. 2013). Restricting or banning fluoridation would reduce the fluoride content of these processed beverages and foods and thereby partially redress Trader’s injury.

C. Plaintiffs' Standing Is Not Limited to Jessica Trader

Finally, even if EPA were correct (it is not) that Trader's injury is not traceable/redressable, Plaintiffs have standing based on the declarations of the other standing declarants, and the record evidence that supports the credibility of the declarants' concerns.³¹ When judged against controlling Ninth Circuit precedent, Plaintiffs' evidence is sufficient for Article III.

1. The Credible Threat Standard

A "credible threat" of future harm is sufficient to establish an injury-in-fact for purposes of Article III standing. *San Luis & Delta-Mendota Water Authority v. Jewell*, 747 F.3d 581, 645 n.49 (9th Cir. 2014). A credible threat exists if the defendant's conduct exposes the plaintiff to potentially dangerous chemicals. *NRDC I*, 735 F.3d at 878 (finding standing where it would be "nearly impossible" for plaintiffs to avoid the pesticide); *NRDC v. FDA* ("*NRDC IP*"), 710 F.3d 71, 74-75 & 83 (2d Cir. 2013) ("[S]tanding may be based on exposure to a potentially dangerous product"); *cf. Council of Ins. Agents & Brokers v. Molasky-Arman*, 522 F.3d

³¹ While the district court expressed concerns about Plaintiffs' standing, the court expressly rejected EPA's contention that it had made a determination on the issue. *See* 1-ER-21 ("**In fact, the Court has not yet ruled on whether Plaintiffs have standing or not**" (emphasis added)). Moreover, the concerns the court expressed at the close of the first phase of trial were formed without consideration of the scientific evidence that Plaintiffs introduced during the second phase. *See Baur v. Veneman*, 352 F.3d 625, 637 n.11 (2d Cir. 2003) ("Although a plaintiff's standing is 'assessed as of the time the lawsuit is brought,' post-filing events may confirm that a plaintiff's fear of future harm is reasonable." (citation omitted)).

925, 932 (9th Cir. 2008) (“The basic idea that comes out in numerous cases is that an identifiable trifle is enough to fight out a question of principle.”).

The evidentiary burden for proving a credible threat for Article III purposes is less than the burden for proving the merits of the underlying claim. *See Friends of the Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 181 (2000); *Ecological Rights Found. v. Pacific Lumber Co.*, 230 F.3d 1141, 1152 (9th Cir. 2000). An injury-in-fact has thus been found to exist where the challenged law may expose the plaintiff against her will to the chemical of concern, irrespective of whether the plaintiffs’ anticipated exposure has been associated with harm. *NRDC I*, 735 F.3d at 878; *NRDC II*, 710 F.3d at 83; *N.Y. Pub. Interest Research Grp. v. Whitman*, 321 F.3d 316, 325-26 (2d Cir. 2003); *LaFleur v. Whitman*, 300 F.3d 256, 270-71 (2d Cir. 2002); *Ctr. for Food Safety v. Price*, 2018 WL 4356730, 2018 U.S. Dist. LEXIS 155794, at *18-19 (S.D.N.Y. Sep. 12, 2018). This remains the rule at the trial stage as well. *Am. Unites for Kids v. Rousseau*, 985 F.3d 1075, 1097 (9th Cir. 2021) (finding standing based on a single declaration asserting that teachers at a school with “illegal levels of PCBs” had “concerns” their health “might” be affected, without requiring evidence that the teachers’ actual exposures placed them at personal risk).

Finally, where a credible threat exists, a plaintiff does not lose standing because she spends money to avoid the threat. Indeed, the Supreme Court has

explained that spending money to avoid an Article III injury is an injury in and of itself. *See Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 153-155 (2010); *cf. United States v. Texas*, 599 U.S. 670, 676 (2023) (“Monetary costs are of course an injury.”).

2. Simms, Staudenmaier, and Lavelle Satisfy the Credible Threat Standard

Plaintiffs’ standing evidence, *even without Trader*, satisfies the credible threat standard. The following is a discussion of some, but not all, of Plaintiffs’ evidence.

Julie Simms is a member of FWW and resident of Seattle, where fluoridation chemicals are added to water. 3-ER-473-74. Simms suffered daily migraine headaches for over 12 years. *Id.* at 474-75. She tried “every remedy” she could think of, including medications, but nothing worked. *Id.* at 475. Then, in 2013, at the advice of a friend, Simms (a prior advocate of water fluoridation) stopped drinking fluoridated water. *Id.* Within three days, the pain had decreased, and within three weeks, the daily headaches were *gone*. *Id.* This gave Simms ample reason to continue avoiding fluoridated water, and she has done so ever since. Her daily headaches have never returned. *Id.* at 476. In short, Simms has a “personal stake” in this case. *See Diamond Alternative*, 606 U.S. at 110. But Simms’s standing is based on more than her direct personal experience, compelling though it is.

Dr. Kathleen Thiessen, a co-author of NRC’s 2006 report, testified that some people are “hypersensitive”³² to fluoride and can experience neurological symptoms, including headaches,³³ at exposures that are well tolerated by most people.³⁴ 1-SER-192-93-¶61; 2-SER-404-07; 3-SER-511-12. Dr. Thiessen, who co-authored a second NRC review on fluoride, testified that NRC deemed the evidence of fluoride hypersensitivity to be “credible.” 2-SER-396-98; 3-SER-511-12; *see also* 2-SER-276-77.

Taken together, the existence of credible science linking fluoride to hypersensitive reactions, including headaches, and Simms’ own compelling personal experience, is sufficient for Article III. *See Denney v. Deutsche Bank AG*, 443 F.3d 253, 264-65 (2d Cir. 2006) (“[E]xposure to toxic or harmful substances has been held sufficient to satisfy the Article III injury-in-fact requirement . . . even though exposure alone may not provide sufficient ground for a claim under state tort law.”); *Ecological Rights Found.*, 230 F.3d at 1151 (counseling against conflating the “jurisdictional inquiry . . . with the merits inquiry”).

³² Simms is highly sensitive to a number of other substances, which is consistent with her having a “hypersensitive” immune system. *See* 5-ER-1026-¶27.

³³ It has long been known that high levels of fluoride can cause headaches in non-sensitive persons. 1-SER-136-¶59, 2-SER-362.

³⁴ According to NRC, hypersensitive reactions to fluoride have been reported to occur at exposures as low as 0.02 mg/kg/day, which is a dose that some people can ingest just from drinking fluoridated water. 2-SER-464-65; 3-SER-512.

But Plaintiffs’ standing evidence goes further. Plaintiff **Brenda Staudenmaier**, a water treatment professional, lives in (fluoridated) Green Bay, Wisconsin. 3-ER-577-80. Like Trader, Staudenmaier spends money to protect her children from the risks posed by fluoridation. *Id.* Staudenmaier’s son, Ko, was ten years old during the first trial and is now fifteen. *Id.* at 578-¶4. While Ko is no longer in the highest risk (perinatal) stage of life, this does not mean there is *no* risk. For example, two studies of human populations in North America have found significant associations between *adolescent* fluoride exposure in *fluoridated* areas and neurological issues. One of these studies (Riddell 2019) was judged to be a “low risk-of-bias” (i.e., high-quality) study by the NTP. 4-SER-870, 874-79. It found children aged 6-to-17 living in fluoridated areas of Canada had a six-fold-higher-odds of having an ADHD diagnosis.³⁵ 1-SER-145; 4-SER-874-79. Another study (Adkins 2022) found a significant adverse association between adolescent fluoride exposure and neurological effects (internalizing symptoms) in a fluoridated area of the U.S. 4-SER-746-47, 902-18. The authors of the Adkins study³⁶ explain that the brain is still developing during adolescence and that this represents a continued period of vulnerability. 4-SER-908.

³⁵ While the evidence of fluoride causing non-IQ effects, like ADHD, is not as large as the evidence on IQ, Plaintiffs’ expert Dr. Grandjean explained that a chemical that reduces IQ would be expected to impact the brain in other ways as well. 4-SER-751.

³⁶ This study was introduced into evidence as Trial Exhibit 112. *See* 4-SER-902-18.

These studies need not be sufficient to prove causation in a personal injury case, or to demonstrate unreasonable risk in a Section 21 case. They need only be sufficient to justify a parent taking measures to protect her child from the risk. The Riddell, Adkins, and animal studies might not reach that bar if they were at odds with a large body of data supporting the neurological safety of fluoridation. But there is no such safety data for fluoridation. EPA admitted its safety standards cannot be relied upon to protect against neurological effects (1-SER-72-¶24), FDA does not have a position on fluoridation's neurological safety (2-SER-301), and CDC does not yet know fluoride's neurologically tolerable dose (2-SER-316-18). This absence of safety data, coupled with published findings of harm at the *actual exposure level*³⁷ produced by fluoridation, is sufficient to establish a credible threat for Article III. *See NRDC II*, 710 F.3d at 82 (listing FDA's lack of safety data as a factor supporting standing for plaintiffs exposed to a chemical in soap).

Plaintiff **Kristin Lavelle** has standing for similar reasons. Lavelle is a health care professional who lives in (fluoridated) Berkeley, California. 4-ER-599-604. Based on the health concerns identified by NRC and other credible sources, Lavelle has spent considerable sums of money avoiding the fluoride added to her water. *Id.* at 600-03. One of NRC's findings that causes Lavelle concern is its conclusion that

³⁷ By contrast, EPA has not had evidence of harm at the human exposure level for most of its *unreasonable risk* determinations under TSCA. 4-SER-779-83, 796-800.

fluoride is an “endocrine disrupter” that can depress thyroid function, particularly since subsequent studies have found associations between fluoridation and thyroid impairment. *Id.* at 601. As Lavelle explains, “I am aware that thyroid disease, including hypothyroidism, is a common cause of illness for women my age.” *Id.* Plaintiffs introduced *credible* scientific evidence across both phases of trial to substantiate Lavelle’s concern, including an *NIH-funded* study from Canada (Hall 2023)³⁸ that found a significant association between fluoridated water and hypothyroidism in women. 1-SER-203-04; 2-SER-284-91, 401-02; 4-SER-735-45, 919-30.

As with Staudenmaier, the standing analysis for Lavelle might be different if there were a large body of studies showing that fluoridation is safe for the thyroid. But that is not the case. EPA admitted it is not aware of “any” primary studies which “demonstrate or support the thyroid safety of fluoridated water,” and FDA “has no position on the topic.” 2-SER-301, 308. This absence of safety data coupled with the evidence of harm from credible scientific sources (NRC and NIH) is sufficient to demonstrate a credible threat for purposes of Article III.

³⁸ This study was introduced into evidence as Trial Exhibit 120. 4-SER-919-30.

II. Section 21 Permits, and Indeed Requires, District Courts to Conduct “De Novo Proceedings” in Which New Evidence Can Be Gathered

A. The Plain Language of the TSCA Statute Makes Clear that Section 21 Cases Are Not Limited to the Administrative Record

“As with any question of statutory interpretation, our analysis begins with the plain language of the statute.” *Newsom v. Trump*, 141 F.4th 1032, 1046 (9th Cir. 2025) (citation omitted)).

1. The Statutory Text

The text of Section 21 provides that petitioners “*shall* be provided an opportunity to have such petition considered by the court in a *de novo proceeding*.” 15 U.S.C. § 2620(b)(4)(B) (emphases added). The term “de novo” means “[a]new, afresh, or over again.” *Black’s Law Dictionary* (12th ed. 2024). De novo modifies the word that immediately follows: “proceeding,” a maximally *expansive* term which Black’s Law Dictionary defines as “[t]he regular and orderly progression of a lawsuit, including all acts and events between the time of commencement and the entry of judgment.” *Id.* A de novo proceeding is thus de novo for *all* events in the case, including *trial*. As the Ninth Circuit has stated, “a trial de novo is a trial which is not limited to the administrative record.” *Kim v. United States*, 121 F.3d 1269, 1272 (9th Cir. 1997).

Given its expansive breadth, courts have consistently interpreted the term de novo proceeding as including *both* the standard *and* scope of review. *See e.g., Hyatt v. Kappos*, 625 F.3d 1320, 1338 (Fed. Cir. 2010), *aff’d and remanded*, 566 U.S. 431

(2012) (“Since it is a de novo proceeding . . . the methodology of analysis of the evidence does not depend on whether the [agency] had also received the same evidence.”); *Callejo v. Resolution Trust Corp.*, 17 F.3d 1497, 1501 & n.3 (D.C. Cir. 1994) (characterizing “de novo proceedings” as “de novo trial[s]” and distinguishing them from “de novo review” under APA); 1-ER-58-59 (citing other cases). Consistent with this, the D.C. Circuit Court of Appeals distinguished Section 21’s de novo proceeding from ordinary review under the APA on the grounds that the latter “must be conducted on the administrative record.” *Reilly*, 909 F.2d at 1506. “The clear implication” of *Reilly* is that “Section 21 petitions are not limited to the administrative record.”³⁹ 1-ER-57-58.

Lastly, as the district court observed, the EPA below did not identify a single example of a court ever defining de novo proceeding as being confined to the administrative record. *See* 1-ER-59 n. 3. The EPA has had seven additional years to find such a case, but it cites none in its appeal.

2. The Statutory Structure

Section 21’s requirement that district courts provide de novo proceedings stands in stark contrast to what TSCA requires for *other* forms of judicial actions. In Section 19, the statute addresses judicial reviews of prior rules or orders that EPA

³⁹ Although dicta from *Trumpeter* (774 F.3d at 1042) appears to contradict this, the district court correctly explained that, unlike in *Reilly*, *Trumpeter*’s dicta was unrelated to its holding, and thus carries little weight. 1-ER-56-57.

has issued. 15 U.S.C. § 2618. Unlike Section 21, Section 19 specifically limits the *scope* of materials that can be considered by the court. § 2618(b) (authorizing courts to consider “additional oral and written presentations” but only if they are “material” and if “reasonable grounds” exist as to why they were not provided during the administrative proceeding). Section 19 also instructs that the standard of review is governed by the APA. *Id.* § 2618(c) (citing 5 U.S.C. §§ 701 et seq.).

Section 19 demonstrates that Congress understood it could provide limitations on the scope of information that a reviewing court can consider. The Court can thus presume that Congress’s omission of any limitation in Section 21 was intentional. *See Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 452 (2002).

In summary, the plain meaning of Section 21 demonstrates Congress’s intention to free citizen petitions from the encumbrances of APA record review. That ends the inquiry. *Logan v. U.S. Bank Nat’l Ass’n*, 722 F.3d 1163, 1171 (9th Cir. 2013) (stating that courts “look to legislative history only if the language is unclear”). To the extent, however, there is *any* ambiguity in the statutory text, such ambiguity is eliminated upon review of the legislative history.

B. The Legislative History Confirms that De Novo Proceedings Are Not Limited to the Administrative Record

Congress left no room for doubt about its intentions for Section 21 de novo proceedings. Given the minimal process that Section 21 requires at the

administrative level,⁴⁰ Congress recognized that the agency would create “no record upon which the [court’s] review could be based.” S. Rep. 94–698, 1976 U.S.C.C.A.N. at 4502-03. A *de novo* proceeding was thus considered “essential to provide the opportunity to develop such a record.” *Id.* Accordingly, the Senate Report describes the *de novo* proceeding as a process of “gathering evidence.” *Id.* at 4499.

As the district court correctly noted, “there is no way to square the language [in the legislative history] concerning ‘gathering evidence’ and ‘develop[ing] a record’ with Defendant’s interpretation.” 1-ER-64. Rather than acknowledge this, EPA acts as if the legislative history does not exist.

C. EPA’s Interpretation of the Words “Such Petition” and “Facts” Is Incompatible with Their Plain Meaning

EPA’s aversion to the legislative history is matched only by its aversion to the dictionary. EPA argues that “such petition” means “the administrative record” (i.e., the petition plus the denial). But there is nothing plain about that interpretation. As the district court noted, “[b]y expanding the term ‘such petition’ to ‘administrative record’ so that it encompasses the EPA’s denial, the EPA has implicitly conceded that the term cannot be construed literally to circumscribe the scope” of the district

⁴⁰ EPA has no obligation to even conduct an investigation. *See* 15 U.S.C. § 2620(b)(2) (“The Administrator *may* hold a hearing or *may* conduct such investigation or proceeding as the Administrator deems appropriate” (emphasis added)).

court's review. 1-ER-56.

A more viable interpretation of “such petition” is that it refers to the action that petitioners seek to initiate (i.e., “the ask”). This interpretation accords with the fact that “such petition” is repeatedly used in reference to EPA granting or denying. *E.g.*, 15 U.S.C. § 2620(b)(2), (b)(3), & (b)(4)(A). EPA does not grant or deny the “administrative record”; it grants or denies the action that petitioners request.

EPA's disregard of TSCA's plain meaning is further apparent by its treatment of the word “facts.” Section 21 requires that the petitioner “set forth the facts” which justify the requested action. 15 U.S.C. § 2620(b)(1). EPA construes this to mean that the petitioner must present all “evidence,”⁴¹ but facts and evidence are not synonyms. In legal proceedings, evidence (e.g., documents and testimony) is submitted to prove a fact. *See, e.g.*, Fed. R. Evid. 401 (“*Evidence* is relevant if . . . it has any tendency to make a *fact* more or less probable than it would be without the evidence” (emphases added)). Consistent with the plain meaning of these terms, Section 21 first uses the word “evidence,” not in describing the requirements at the *administrative* level, but in describing the petitioner's burden at the *judicial* level. *See* 15 U.S.C. § 2620(b)(4)(B) (“If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence . . .”).

⁴¹ *See, e.g.*, AOB at 32 (“Section 21 requires petitioners to bring forth all their evidence in their petition, so that EPA may pass on it.”).

While petitioners at the administrative level clearly have an incentive to include documentation (“evidence”) which supports their asserted facts (hence why Plaintiffs attached 313 scientific papers to their petition), this is not a statutory *requirement*. Some petitioners with limited resources might elect to provide citations to the scientific literature without attaching the cited papers. In such a situation, the petitioners would be providing the “facts” (e.g., study X found this, study Y found that), but not the underlying evidence. The statute allows for this approach, even if it might not be the most strategically effective. In short, the statute’s use of the word “facts” when discussing the *administrative* process, and the word “evidence” when discussing the *judicial* process, further evinces Congress’s intention for de novo proceedings to be evidence-gathering procedures.⁴²

D. Section 21 Places No Limits on the Amount of New Evidence a District Court Can Consider

EPA fares little better with its alternative argument that Section 21 places a limit on the amount of new evidence a district court can consider. EPA identifies no statutory text or legislative history supporting this limitation. While muddled, EPA’s argument appears to be that “EPA could not have erred” in denying a petition if the

⁴² Even if petitioners have a “high bar” to persuade EPA (*see* AOB at 43), this does not change the result. However high or low the bar, the statute gives the petitioner the option of meeting it through facts alone. If these facts fail to persuade EPA, the statute gives petitioners the option of marshalling the evidence to prove their claim to a court.

evidence upon which a district court finds risk was published after the denial. *See* AOB at 45. The problem with this argument is that Section 21 does not ask the district court to determine if EPA erred (a *backward-looking* inquiry), but rather, whether the petitioners have proven by a preponderance of the evidence that an unreasonable risk exists (a *forward-looking* inquiry). Under this framework, it makes little sense to freeze the record in time to what EPA considered. This is especially so given that TSCA’s “overarching purpose” is “to protect the public,” not to protect EPA from the public. *See* 1-ER-62.

Lastly, to the extent that some future petitioner files a “bare-bones petition” and sandbags the agency with new evidence at trial (a prospect that seems counterintuitive and unlikely given the expense of potentially-avoidable litigation), this concern can be addressed without undermining the statutory scheme. As Justice Sotomayor explained in the patent context, the district court could exclude any information that the petitioner purposely withheld from the administrator. *Kappos v. Hyatt*, 566 U.S. 431, 447 (2012) (Sotomayor, J., concurring).

E. The District Court Did Not Abuse Its Discretion by Considering the Post-Petition Studies

Since TSCA does not impose any limitations on the evidence a district court can consider, EPA is left with having to demonstrate that the district court abused its discretion. This is a high bar, particularly for a *bench* trial, and EPA does not come close to meeting it. *See* Charles Alan Wright, Arthur R. Miller & Mary Kay

Kane, *Federal Practice and Procedure* § 2885 (2d ed. 2010) (citations omitted) (“In nonjury cases the district court can commit reversible error by excluding evidence, but it is almost impossible for it to do so by admitting evidence.”); *c.f.* *U.S. v. Preston*, 706 F.3d 1106, 1117–18 (9th Cir. 2013) (“Rule 403 is inapplicable to bench trials.”).

First, the reasons the district court gave for considering post-petition studies are eminently reasonable and mirror EPA’s own admonitions. EPA warned the court that its “decision about the risk that community water fluoridation poses” will be “significant and consequential” and thus “it is imperative that the science is strong.” 3-SER-613. The court agreed.⁴³ Accordingly, the court exercised its discretion to consider the latest, and most reliable, data. The NTP monograph was one such piece of evidence. In EPA’s own words, the NTP monograph “is indisputably central to the expert opinions,” 6-ER-1164, and “of unquestionable relevance and importance” to the case. 3-SER-612. The court agreed⁴⁴ and acted accordingly.

⁴³ *E.g.*, 1-ER-37 (noting the “seriousness and consequential impact of whatever we do”); 4-ER-702 (stating the court’s interest in getting the latest data “because it’s an important decision and important consequences either way and we want to try to get this correct”).

⁴⁴ *E.g.*, 3-SER-599 (stating that NTP report is “so critical, and so central” that it would be “irresponsible for the Court to make findings without seeing what the NTP ultimately does”); 3-SER-626 (“I think the government’s concern is a trial that is uninformed...which was my concern too -- that it was completely divorced from the NTP process.”).

Second, given the statute’s forward-looking focus it would have been an abuse of discretion for the district court *not* to consider the new data. *See City of Pomona v. SQM N. Am. Corp.*, 866 F.3d 1060, 1072 (9th Cir. 2017) (holding that district court abused its discretion by constraining expert to data in his initial report because, after the case went on appeal, the science “evolved significantly”). The district court’s consideration of the evolving research here accords with the Ninth Circuit’s decision in *Pomona*.⁴⁵

Third, although not required to do so, the district court gave EPA the opportunity to consider the post-petition research at the administrative level.⁴⁶ The court thus gave EPA what it wanted,⁴⁷ but in a manner that did not upend judicial economy.⁴⁸ This was not an abuse of discretion; it was the well-balanced exercise thereof.

⁴⁵ *See* 4-ER-701 (“I do not accept the Government’s position that we should just freeze the record as it existed in 2020. That would be putting our head in the sand for, frankly, no good reason because there’s been—things have developed.”).

⁴⁶ The district court considered the issue a discretionary matter of *comity*, rather than a statutory requirement. *E.g.*, 4-ER-729-30.

⁴⁷ At the outset of the litigation, the court asked EPA how it should handle new studies. EPA responded: “they should be submitted to the agency first.” 1-SER-8-9; *accord* 1-SER-16-17.

⁴⁸ *See, e.g.*, 1-ER-17 (rejecting EPA’s argument that Plaintiffs should file a new lawsuit to have new information considered as “contraven[ing] judicial efficiency because it would likely result in re-litigating this case from scratch”).

Fourth, EPA argues that the district court crossed some line between acceptable and unacceptable reliance on new studies. But it provides no intelligible yardstick against which an appellate court could draw the line. EPA references some post-2020 studies that the court cites in one particular section of its opinion but fails to meaningfully explain how the court abused its discretion in relying on these particular studies. *See* AOB at 46. Which of these studies should have been excluded and why? EPA makes no attempt to explain.

Finally, contrary to the repeated implication in EPA’s brief,⁴⁹ the district court’s willingness to consider new studies applied equally to *both* parties and EPA did not hesitate to take advantage of the opportunity.⁵⁰ It was *EPA*, for example, that sought to extend the expert discovery period to permit consideration of the NTP’s draft monograph. 6-ER-1161. It was *EPA* that sought to introduce a new, undisclosed abstract *during* trial. 2-SER-466-74. It was *EPA* that moved to admit a Health Canada document published just weeks before trial. 4-SER-804-06. And, contrary to its expressions of dismay on appeal (*see* AOB at 29, 46), EPA made *no*

⁴⁹ *See, e.g.*, AOB at 45 (“The court allowed *Plaintiffs* to present voluminous, extensive evidence” (emphasis added)); *id.* at 47 (“The district court allowed *Plaintiffs* to introduce a rolling evidentiary record based on newly emerging studies” (emphasis added)).

⁵⁰ EPA’s litigation position for the second phase of trial was that the new studies were particularly helpful in proving EPA right (i.e., that there is no risk from low doses of fluoride). 3-SER-667-71.

objection to the court considering the “Taher 2024” study that was published during the second trial. In fact, *EPA was the party that moved to admit it.* 4-SER-808-09. EPA’s argument, therefore, that the court erred in considering new research is in tension with the fact that much of this research was introduced by the EPA or introduced without EPA’s objection.⁵¹

III. EPA’s Party Presentation Challenge Is Both Waived and Meritless

A. EPA Waived/Forfeited Its Party Presentation Challenge

Because EPA did not assert its party presentation challenge below, it waived/forfeited the issue.⁵² EPA’s counsel, the Department of Justice (“DOJ”), was well aware that a party presentation objection can, and must, be raised directly to the district court if the court is deemed to have violated the principle. Indeed, several months before the district court entered the stay here, the DOJ had raised a party presentation objection to a decision by a district court in Virginia. *See United States v. Powell*, 467 F. Supp. 3d 360, 383 n.13 (E.D. Va. 2020). Despite this, the DOJ

⁵¹ Plaintiffs do not dispute that EPA preserved its primary argument that TSCA does not permit consideration of *any* evidence beyond the administrative record. EPA’s preservation of its alternative argument (i.e., that TSCA permits *some* new evidence, but not as much as the court allowed) is much murkier. Even if EPA can be deemed to have technically preserved the argument, the contradictory signals it provided to the district court should be considered when assessing the court’s decision to continue considering new studies.

⁵² Whether it was waiver or forfeiture, the practical consequences are the same. *See Alaska Dep’t of Fish & Game v. Fed. Subsistence Bd.*, 139 F.4th 773, 788 n.15 (9th Cir. 2025).

attorneys never saw fit to utter the words “party presentation” a single time during the course of this seven-year litigation. By depriving the district court (and Plaintiffs) of an opportunity to address this issue below, EPA waived its right to assert it here.

B. The Party Presentation Principle Does Not Constrain a District Court’s Authority to Develop the *Factual* Record to Resolve Legal Issues Presented by the *Parties*

The party presentation principle “restricts courts from raising new issues.” *United States v. Cortez-Nieto*, 43 F.4th 1034, 1052 (10th Cir. 2022).⁵³ The principle “generally restricts the court from raising issues sua sponte, but it does not preclude a court from resolving a presented issue in a way not proposed by any party.” *United States v. Hunt*, 63 F.4th 1229, 1251 (10th Cir. 2023) (citation omitted). In other words, “the principle does not say that once an issue has been raised and responded to, a court must render its decision in accordance with the position of one of the parties.” *Cortez-Nieto*, 43 F.4th at 1052. Indeed, “[c]ourts have always had authority to resolve raised issues as fairness requires.” *Id.*

EPA insists that the party presentation doctrine is not limited to raising new legal issues, and that it applies with equal force to a court’s authority to “shape the

⁵³ See also Amanda Frost, *The Limits of Advocacy*, 59 Duke L.J. 447, 449 (2009) (describing party presentation as a doctrine focused on “issue creation—that is, raising legal claims and arguments that the parties have overlooked or ignored”); accord *John v. Quality Loan Serv. Corp. of Wash.*, 857 F. App’x 943, 943 (9th Cir. 2021) (finding no violation of party presentation where “district court decided only the issues Stafne raised and did not reach claims, issues, or theories that the parties themselves did not present”).

evidence and contours of a proceeding.” AOB at 51. However, the one legal authority EPA cites to support this proposition does precious little to do so. *Id.* at 51-52 (citing *Duncan et al. v. Bonta*, 133 F.4th 852, 889-90 (9th Cir. 2025) (Berzon, J., concurring)). EPA’s one authority is a *concurring* opinion involving facts developed *on appeal* in the form of *expert* testimony from a dissenting *judge*. This is not in the same orbit as the circumstances at issue here and does not establish the sweeping proposition that EPA claims.

Further, while EPA omits them, there are cases where courts have considered party presentation in situations, like here, where *district courts* have taken different approaches to *evidence* and *procedure* than the parties asked for or preferred. In these cases, appellate courts have invariably rejected claims that a departure from the parties’ preferred approach violates the party presentation principle.⁵⁴ These

⁵⁴ *E.g.*, *Phillips v. United States*, 2023 WL 5499543, 2023 U.S. App. LEXIS 13100, at *7 (6th Cir. May 25, 2023) (holding that district court did not violate party presentation by refusing to hold an evidentiary hearing even though “the parties repeatedly agreed that an evidentiary hearing was necessary”); *People v. Fisher*, 2023 WL 6889660, 2023 Cal. App. Unpub. LEXIS 6235, at *12-14 (Oct. 19, 2023) (holding that “the trial court’s solicitation of supplemental evidence” did not violate party presentation); *Elmen Holdings, L.L.C. v. Martin Marietta Materials, Inc.*, 86 F.4th 667, 673-74 (5th Cir. 2023) (finding no violation where magistrate judge interpreted the parties’ contract in a manner at odds with the parties’ longstanding agreed-upon understanding); *Tekmen v. Reliance Std. Life Ins. Co.*, 55 F.4th 951, 963 (4th Cir. 2022) (finding no violation where district court “did not reshape the legal question presented by the parties; it simply adjusted the procedural mechanism it would use to address” it); *see also New York v. UPS*, 942 F.3d 554, 596 (2d Cir. 2019); *Employers Ins. of Wausau v. Granite State Ins. Co.*, 330 F.3d

rulings are sound for two intersecting reasons. First, the party presentation principle restricts a court’s authority to raise new *legal* issues, not the manner in which a court resolves the issues that the *parties* have raised. *See Cortez-Nieto*, 43 F.4th at 1052. Second, a district court has broad and inherent power to manage and control the course of proceedings. *See Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936). When these two tenets of law are considered together, it becomes apparent that party presentation has little, if any applicability, to a district court’s management of evidentiary and procedural issues.

Finally, even when a court raises new legal issues, such conduct does not necessarily violate the party presentation principle. *See United States v. Sineneng-Smith*, 590 U.S. 371, 376 (2020). As the Supreme Court has explained, the party presentation principle “is supple, not ironclad.” *Id.* Thus, as the Court made clear, “[t]here are no doubt circumstances in which a modest initiating role for a court is appropriate.” *Id.* For example, the Court attached an addendum to *Sineneng-Smith* wherein it identified numerous examples in just the previous five years where the Court had sua sponte requested supplemental briefing on issues not raised by the parties. *Id.* at 380-82. The question, therefore, is not simply whether a court raises a new legal issue, but whether it has “*departed so drastically from the principle of*

1214, 1220 (9th Cir. 2003) (stating that this Court can consider unpublished state decisions).

party presentation as to constitute an abuse of discretion.” *Id.* at 375 (emphasis added).

C. The District Court Did Not Abuse Its Discretion

The district court did not violate the party presentation principle, let alone in the “drastic[]” way that would be required to justify reversal. *Sineneng-Smith*, 590 U.S. at 375.

First, the district court did not raise a new legal issue. Instead, the district court established a procedure for resolving the legal issues raised by the parties. Specifically, the court exercised its inherent and broad authority to enter a stay⁵⁵ to allow for consideration of additional evidence that would inform its determination of the standing and merits issues. Assuming party presentation is even implicated here, the court’s decision did not “depart[] so drastically” from it “to constitute an abuse of discretion.” *Id.*

Second, other than the court’s “modest initiating role” in *initiating* the stay, every aspect of the stay and the court’s proposed course forward was *litigated* through an *adversarial* process. For example, the parties litigated the permissibility

⁵⁵ *Clinton v. Jones*, 520 U.S. 681, 706 (1997) (“The District Court has broad discretion to stay proceedings as an incident to its power to control its own docket.”); *Microfinancial, Inc. v. Premier Holidays Int’l, Inc.*, 385 F.3d 72, 77 (1st Cir. 2004) (“It is apodictic that federal courts possess the inherent power to stay proceedings for prudential reasons.”); *Doyle v. OneWest Bank, N.A.*, No. CV 13-05951, 2015 U.S. Dist. LEXIS 100526, at *9 (C.D. Cal. May 21, 2015) (“The power to stay also includes the power to do so sua sponte.” (citing cases)).

of the stay, the length of the stay, the mechanism by which Plaintiffs could amend their complaint, the futility (or lack thereof) of Plaintiffs' amendment, and the authority of the court to set aside the parties' prior stipulation on standing. *See supra* pp. 15-16. Each and every one of these issues was briefed by the parties and decided by the court. Importantly, EPA does not allege legal error in any of these decisions.

Third, the reasons the court gave for entering the stay align with those that have been considered sufficient for justifying a stay. For example, the court's interest in awaiting the results of NTP's independent proceeding aligns with the Ninth Circuit's holding that "[a] trial court may, with propriety, find it is efficient for its own docket and the fairest course for the parties to enter a stay of an action before it, pending resolution of independent proceedings which bear upon the case." *Leyva v. Certified Grocers of Cal., Ltd.*, 593 F.2d 857, 863-64 (9th Cir. 1979). As the *Levy* court explained, "[t]his rule applies whether the separate proceedings are judicial, administrative, or arbitral in character, and does not require that the issues in such proceedings are necessarily controlling of the action before the court." *Id.* Additionally, the court's interest in promoting an amicable resolution of the case aligns with the "strong judicial policy that favors settlement." *Plikington v. Cardinal Health, Inc.*, 516 F.3d 1095, 1101 (9th Cir. 2008); *Pule v. Macomber*, 2021 WL 3686696, 2021 U.S. Dist. LEXIS 139492, at *1-3 (D. Haw. July 27, 2021) (entering stay sua sponte to encourage settlement discussions).

Fourth, while the parties did not propose the course of action that the court adopted, the court's reasons for charting this course followed logically from the parties' own theories of the case. For example, the court's desire that EPA give the evidence a "second look" flowed not only from the fact that new science had emerged, but also because the court agreed with Plaintiffs that EPA had been using the wrong standard.⁵⁶ 1-ER-29-32, 36. In addition, the court's interest in awaiting the results of NTP's systematic review flowed naturally from EPA's own argument that the review was "indisputably central" to the case (6-ER-1164), as well as EPA's trial evidence which stressed the state-of-the-art nature of NTP's work (2-SER-412-54), and the need for the court to "allow the evolving science to play out."⁵⁷ 2-SER-343. The court's reasoning for entering the stay was thus a product of the parties' own theories of the case. *See Colorado v. United States EPA*, 989 F.3d 874, 885-86 (10th Cir. 2021) (finding no violation of party presentation where, inter alia, "the district court did not cut [its] theory of harm out of whole cloth"); *Whyte Monkee Prods. LLC v. Netflix, Inc.*, 2025 WL 974940, 2025 U.S. Dist. LEXIS 62663, at *10-

⁵⁶ EPA cannot bring itself to acknowledge this embarrassing determination by the court. *See* 1-ER-30. Ignoring it, and the court's comments about the "serious evidence" Plaintiffs presented (1-ER-32), EPA depicts the court's concerns as being singularly focused on purported deficits in Plaintiffs' case. If EPA's characterization was correct (it is not), one wonders why a court so skeptical of Plaintiffs' evidence, and so convinced by EPA's, would waste so much time extending the case.

⁵⁷ 3-SER-642 ("I think the government's concern is a trial that is uninformed, which was my concern too that it was completely divorced from the NTP process.").

12 (N.D. Cal. Apr. 1, 2025) (similar). In fact, when the district court first broached the idea of staying the case to give EPA a second chance to review the evidence, EPA’s first response was that it had “anticipated” the question. 1-ER-33.

Lastly, any suggestion that Plaintiffs were somehow unified with EPA in ‘resisting’ the district court’s management of the case is incorrect. While Plaintiffs expressed some initial concerns about the stay, they never objected. Further, Plaintiffs were “mindful that, in a case with national policy implications, having more information is presumably better than having less,” and that in “navigating the course” of the litigation, “the north star should be the public policy interests that Congress sought to protect when it enacted TSCA.” 5-ER-854-55. Recognizing the “enormous task” of a de novo proceeding (1-ER-31), the district court was mindful of these same concerns, and responsibly exercised its discretion accordingly.

CONCLUSION

EPA’s appeal aims not to apply the law, but to change it, and in so doing, to eliminate the vitality of the citizen petition process that Congress deemed critical to TSCA’s success. The Court should affirm the district court’s judgment.

Dated: November 17, 2025

Respectfully submitted,

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STATEMENT OF RELATED CASES

9th Cir. Case Number 25-0384

The undersigned attorney for Plaintiffs-Appellees state the following:

I am unaware of one or more related cases currently pending in this court.

Dated: November 17, 2025

Respectfully submitted,

/s/ Michael Connett

Michael Connett

CERTIFICATE OF COMPLIANCE

I am the attorney on behalf of the Plaintiffs-Appellees.

This brief contains 13,979 words, excluding the items exempted by Fed R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 3d(a)(5) and (6).

I certify that this brief complies with the word limit of Cir. R. 32-1.

Dated: November 17, 2025

Respectfully submitted,

/s/ Michael Connett
Michael Connett

CERTIFICATE OF SERVICE

I hereby certify that on November 17, 2025 I electronically filed the foregoing APPELLEES' ANSWERING BRIEF with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the ACMS system. Participants in the case are registered ACMS users, and service will be accomplished by the ACMS system.

Dated: November 17, 2025

Respectfully submitted,

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