

No. 25-384

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UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT

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FOOD AND WATER WATCH, *et al.*  
*Plaintiffs-Appellees,*

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,  
*Defendants-Appellants.*

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Appeal from the United States District Court for the Northern District of California  
No. 3:17-cv-02162 (Hon. Edward M. Chen)

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REPLY BRIEF FOR DEFENDANTS-APPELLANTS

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## INTRODUCTION

Plaintiffs argue EPA’s appeal is an attack on Section 21’s “citizen petition process” that Congress designed to overcome “bureaucratic inertia.” FWW Br.1. But EPA simply asks this Court to enforce the balance that Congress struck. Section 21 lets citizens file a petition *with EPA* setting forth the facts establishing that regulation is necessary. If EPA denies the petition, Section 21 authorizes the petitioner to bring a lawsuit “respecting [the] petition” in which they “have such petition considered by the court in a de novo proceeding.” 15 U.S.C. §2620(b)(4)(B). The scope of the de novo proceeding is defined by consideration of “such petition,” including the facts set forth in that petition. That interpretation flows from the text, gives fair and coherent meaning to all of Section 21, and fulfills Congress’s purpose in creating a citizen petition process requiring administrative exhaustion before going to court.

Section 21 does not authorize what happened here: a judicial free-for-all that perfectly illustrates why Plaintiffs’ no-limits interpretation of Section 21 cannot be correct. Plaintiffs and the court overwhelmingly relied on evidence that did not exist at the time of the original petition. Even the district court, who engineered this outcome, expressed skepticism Congress could have intended such a result: “I don’t know if it contemplated a situation where the record before the Court under a Section 21 petition is very, very different and has evolved substantially differently than what

was presented.” 1-ER-31. Indeed. The court’s approach effectively rewrote Section 21 and nullified Congress’s requirement that these difficult scientific questions first be submitted to and considered by EPA. Nor could EPA have been suffering “bureaucratic inertia” by not beginning a rulemaking when the scientific evidence allegedly supporting that action *did not exist* when EPA denied the petition or even at the *conclusion of trial*.

Plaintiffs also fail to rebut EPA’s demonstration that the district court exceeded its powers under Article III both in finding standing (and thus exercising jurisdiction) and by commandeering the case in violation of party-presentation principles. On standing, even with the district court’s overt advocacy, Plaintiffs’ declarations still do not establish their standing by a preponderance of the evidence. On party presentation, the district court abused its discretion by commandeering the case after the close of the first trial. The court *directed* Plaintiffs to collect and submit key pieces of new evidence to cure gaping holes on both standing and substance—despite Plaintiffs insisting they had met their burden on both issues, and despite Plaintiffs’ stipulation that they would not introduce the very evidence the district court was now advocating for. The court improperly stepped into the role of inquisitor rather than neutral arbiter by disregarding Plaintiffs’ strategic judgments, instructing them on how to re-argue their case, and pervasively shaping the factual record.

This Court should reverse.

## ARGUMENT

### I. Plaintiffs lack Article III standing.

Despite substantial direction and assistance from the district court, Plaintiffs still fail to prove standing. After the first trial, Plaintiffs had not shown that community water fluoridation caused their alleged injuries. Opening Br.35-36. As the district court found: “Plaintiffs have not shown any relationship between the evidence presented” at trial “and the harms alleged.” 1-ER-25; 4-ER-757. The court was thus required to “dismiss the complaint in its entirety.” *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 514 (2006). Instead, the court abdicated its duty, “stayed the case over concerns about FWW’s standing,” 3-ER-838, and “directed [them] to address standing issues,” despite their *stipulation* that they would not submit additional evidence. 5-ER-813; 5-ER-933. Plaintiffs dutifully responded with the second Trader declaration, but it too is insufficient. Opening Br.37-42.

#### A. EPA did not concede standing, and this Court must independently examine Plaintiffs’ standing.

Plaintiffs contend EPA “*agreed* ... that pregnant women, and mothers of young children, living in fluoridated areas have standing.” FWW Br.21 (citing 4-ER-795). Not so. At the summary judgment hearing, EPA explained that, given the types of neurotoxic harms during critical developmental periods Plaintiffs alleged, the kind of person “who *could* satisfy standing is someone who is an expectant parent

... consuming fluoridated water.” 4-ER-795 (emphasis added). Plaintiffs had identified no such person. In explaining the clearest flaw with Plaintiffs’ proof, EPA’s response clarified that a person must *at least* be the kind of person who could potentially suffer the kind of harm at issue to have standing; it does not follow that the entire group of such people necessarily does. When EPA later opposed the court’s setting aside the stipulation binding Plaintiffs on the standing evidence, “EPA preserve[d] the argument that even if Plaintiffs were able to prove their new allegations about Ms. Trader, they would still lack standing.” 5-ER-904 n.3. Nonetheless, the district court reinterpreted EPA’s original statement as a concession by changing the “could” into a “would.” 5-ER-839 (citing 4-ER-795). But that does not mean the concession was made.

Regardless, standing is jurisdictional, and “federal courts are under an independent obligation to examine their own jurisdiction.” *United States v. Hays*, 515 U.S. 737, 742 (1995) (cleaned up). Here, EPA requests judicial notice of geographic facts disclosed in documents posted by the public water utility that serves Trader. ECF-23.1, Mot. Judicial Notice 2. The concentration of fluoride in the utility’s source water (the Kansas and Missouri Rivers) is 0.24 to 0.4 mg/L fluoride *before* the addition of any fluoride by that utility. *Id.*; ECF-44.1, Reply 3-4. Neither Plaintiffs’ response to the motion nor Answering Brief dispute that factual statement. This Court has taken judicial notice to resolve factual issues about standing on

appeal. *E.g.*, *Montana Green Party v. Jacobsen*, 17 F.4th 919, 927 (9th Cir. 2021). And a court must consider judicially noticeable facts when they establish, as here, a *lack* of jurisdiction.

Plaintiffs intentionally chose to forgo testimony about standing and rely solely on declarations. This Court can read them as well as the district court and should dismiss. *See, e.g.*, *Washington Env't Council v. Bellon*, 732 F.3d 1131, 1138-39 (9th Cir. 2013) (dismissing for lack of standing based on deficient declarations even though defendants did not object below). The district court's factual analysis below was limited to finding that "Trader's pregnancy satisfies Article III standing," and that Trader had incurred costs to avoid fluoride. 5-ER-839; 2-ER-82-83. EPA does not dispute her pregnancy nor that she has incurred costs.

**B. Plaintiffs failed to establish standing by a preponderance of the evidence.**

Plaintiffs bear the burden to establish standing "by a preponderance of the evidence." *DZ Rsrv. v. Meta Platforms*, 96 F.4th 1223, 1240 (9th Cir. 2024); *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992).

Trader's two short declarations do not provide sufficient facts to prove Trader suffers an actual and imminent injury caused by EPA's denial of Plaintiffs' petition that would be redressed by the suit. 3-ER-343-45, 3-ER-593-95. The declarations suggest the opposite. Opening Br.40-41. Trader's community water will contain 0.24 to 0.4 mg/L fluoride even if it stops adding fluoride. Opening Br.38-40. Trader

herself states “I try to do whatever I reasonably can to limit my ingestion of fluoride,” 3-ER-594, and I “do[] everything within my power to protect [my child] from fluoridation chemicals,” 3-ER-344. The straightforward reading of these declared facts is that she will not use the community water regardless of the outcome of this suit given the continuing presence of fluoride.

Under the district court’s findings (which EPA accepts solely for purposes of standing), the level of fluoride in Trader’s water utility’s sources (0.24 to 0.4 mg/L) would present an unreasonable risk. Opening Br.39. For example, the district court stated that accounting for risk factors (as urged by Plaintiffs, *e.g.*, 1-SER-249), “0.04 mg/L[] reflect[s] the tolerable concentration” of fluoride in *drinking* water, 2-ER-144, a much lower level than 0.24 to 0.4 mg/L. Plaintiffs’ own positions below view 0.24 to 0.4 mg/L as presenting unreasonable risk. “Plaintiffs argued for a point of departure of 0.179 mg/L in drinking water,” Opening Br.39 n.9 (citing 2-ER-186)—below the levels of fluoride in the source water for Trader’s utility. While Plaintiffs now dispute (FWW Br.27-28) EPA’s interpretation of some of the district court’s findings, they never address EPA’s second point that they *themselves* argued levels above 0.179 mg/L in drinking water are hazardous. *See* 2-ER-186; 2-ER-166. Similarly, one of Plaintiffs’ experts (Grandjean) identified a hazard level “below the background fluoride exposures represented in maternal urine samples from non-

fluoridated areas.” FER-6. And Plaintiffs do *not* now concede that the utility’s source levels of fluoride are safe.

Nonetheless, the calculation appearing in a footnote of our opening brief misinterpreted the district court’s findings, Opening Br.39 n.9, though EPA’s overall argument stands. Below EPA had argued one of “several gaps” in Plaintiffs’ case was the “lack of a [Physiologically-based Pharmacokinetic (PBPK)] model or other methodology to convert maternal urinary fluoride values to an intake value.” FER-15; FER-10. As a result, “Plaintiffs have not presented any defensible way to convert maternal urinary fluoride values to a fluoride intake value,” FER-7, and thus failed to establish the relationship between Plaintiffs’ proposed maternal urinary hazard levels and the exposure level from fluoride in drinking water. The district court rejected EPA’s argument, and EPA mistakenly interpreted the court’s language as attempting to close that gap. Upon closer examination, the court’s opinion is better read as saying that in its view, half of maternal urinary fluoride value comes from community water fluoridation, and there is no need to make any conversion. 2-ER-135, 2-ER-143.<sup>1</sup> The upshot remains that the district court’s findings indicate Trader’s source water would present a risk regardless of fluoridation: the half of the fluoride exposure attributable to “other sources” than fluoridation for the median

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<sup>1</sup> Plaintiffs’ responsive calculation (FWW Br.28) is thus similarly mistaken; the court did not establish a method of conversion.

woman (0.4 mg/L of 0.8 mg/L) would still “exceed the safe level ... of 0.28 mg/L.” 2-ER-143; *see also* 2-ER-129.

Plaintiffs assert that EPA asks the Court to “infer how Trader would have answered questions,” FWW Br.22, but her own declarations state that she will take “whatever” reasonable steps to avoid fluoride and that she considers purchasing bottled water and water filters as reasonable steps. 3-ER-594. No inference required. In contrast, Plaintiffs (FWW Br.25) ask the Court to draw inferences from a clause about how she will continue to incur these costs while fluoride is added to her water supply. This clause does *not* state she will stop doing so given that fluoride will remain in her water supply. Plaintiffs ask the Court to infer answers to a simple question they chose not to ask: if the utility stopped adding fluoride, would you stop filtering the water or buying bottled water? For Plaintiffs to establish by a preponderance of the evidence that removing artificial fluoride from the public water supply would allow Trader to drink the water, they should have had her declare it— if it were true. But it would have been a risky question to ask. It is well known to anyone with an interest in fluoride that it occurs naturally in virtually all drinking water, and Trader’s public utility has long posted the levels in their source water. FWW Br.22 n.16. Given Trader’s concerns about fluoride, and the publicly available information establishing that her utility’s water sources contain 0.24 to 0.4 mg/L fluoride without any addition, the declaration’s silence is telling. *See*

*TransUnion LLC v. Ramirez*, 594 U.S. 413, 439 (2021) (“The production of weak evidence when strong is available can lead only to the conclusion that the strong would have been adverse.”) (citation omitted).

At trial, a plaintiff must submit evidence establishing standing, not evidence merely raising inferences that she could do so. *See, e.g., id.* (holding inferences “are insufficient to support standing”); *DZ Rsrv.*, 96 F.4th at 1240-41 (testimony about past purchase decisions insufficient absent testimony about future purchase decisions). A declaration lacking crucial facts connecting the basic links in the causal chain might well fail at even earlier stages of the proceedings. *E.g., In re Coca-Cola Prods.*, 2021 WL 3878654, at \*2 (9th Cir. 2021); *Yazzie v. Hobbs*, 977 F.3d 964, 967 (9th Cir. 2020).

Given Trader’s statements, the court’s findings, and Plaintiffs’ positions, even a favorable decision will leave Trader in the same position as before this suit. Trader’s tap water will contain fluoride, and she will continue to incur the expense of provisioning her family with bottled or filtered water to avoid fluoride exposure. There will be no incremental risk of injury from fluoride exposure because Trader will continue to purchase filtered water. *Contra* FWW Br.30-31. While Plaintiffs speculate (FWW Br.30-32) that EPA action on their petition might incrementally reduce Trader’s and her family’s indirect exposure to fluoride from fluoridation through processed beverages and foods, they provide no evidence that these

concerns are relevant to Trader. Instead, Plaintiffs cite a different declarant's declaration about her speculative concerns about consuming processed beverages. FWW Br.32 (citing 3-ER-580); FWW Br.26 (attempting to characterize Trader's silence on processed beverages as evidence of consumption). The limited record material about such indirect exposure is insufficient to provide a non-speculative basis for assessing whether any indirect effect causes an injury to Trader or could provide any redress if eliminated.

While plaintiffs may establish standing even with *partial* redress, plaintiffs still must present sufficient evidence to establish that partial redress is "likely." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 380 (2024). Plaintiffs' declarations fail to establish that the utility's addition of fluoride injures Trader or that ending that addition would likely redress any injury, given the levels of fluoride present in the source water either way.

### **C. Plaintiffs' remaining declarants lack standing.**

Plaintiffs' remaining declarants fail to establish they have standing. First, as a matter of constitutional, prudential, and statutory standing, Plaintiffs lack standing due to the misalignment between these declarants' alleged injuries (headaches, ADHD in adolescents, and thyroid risks) and the harms raised in the petition and lawsuit (neurodevelopmental injuries for babies). Opening Br.35-36; *see also, e.g., Hippocratic Med.*, 602 U.S. at 392-93. Plaintiffs cannot litigate one set of harms,

suffered by *other* people, on the theory that they suffer a distinct and different set of harms that do not align with the claimed legal right. *Lewis v. Casey*, 518 U.S. 343, 351 (1996).

Section 21's grant of jurisdiction is limited, as is the available remedy. Section 21 provides: "If [EPA] denies a petition ... the *petitioner* may commence a civil action ... to compel [EPA] to initiate a rulemaking proceeding as requested in the *petition*." 15 U.S.C. §2620(b)(4)(A) (emphases added). For a party to have standing to bring a Section 21 lawsuit, their actual injuries must be caused by the risks identified in the petition that will be the subject of the lawsuit. *Cf., e.g., Chapman v. Pier 1 Imports*, 631 F.3d 939, 953 (9th Cir. 2011) (holding Americans with Disabilities Act plaintiffs lack standing to challenge barriers that do not affect people with their particular disability). And because the remedy is limited to EPA initiating a proceeding as requested in the petition, even a successful petition on neurodevelopmental injuries for babies may "do nothing to ameliorate the [different] harms allegedly experienced by the standing Plaintiffs." 1-ER-25; *see Mayfield v. United States*, 599 F.3d 964, 971 (9th Cir. 2010) (finding no redressability given limited available remedy).

Second, as the district court also explained (while withholding a final ruling), Plaintiffs' "meager" evidence fails to establish, by a preponderance of the evidence, that these declarants face even a "credible threat" of these other harms. *See* 1-ER-

25. Standing requires that a plaintiff prove an injury that is “actual or imminent, not speculative.” *Hippocratic Med.*, 602 U.S. at 381. Plaintiffs’ fears that fluoride could cause various ailments (like headaches) do not establish standing. “It is the *reality* of the threat of repeated injury that is relevant to the standing inquiry, not the plaintiff’s subjective apprehensions.” *City of Los Angeles v. Lyons*, 461 U.S. 95, 107 n.8 (1983); *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 416 (2013) (holding parties cannot create standing through expenditures on “nonparanoid fears”). Plaintiffs are thus incorrect that a party establishes standing from exposure “irrespective of ... harm,” FWW Br.34, and their cited cases do not say that. Because alleged injuries based on increased risk of harm are inherently uncertain, they stretch standing’s imminence requirement to its outer bounds and warrant scrutiny. *See Lujan*, 504 U.S. at 564 n.2.

This Court has held that “an injury is ‘actual or imminent’ where there is a ‘credible threat’ that a probabilistic harm will materialize.” *NRDC v. EPA*, 735 F.3d 873, 878 (9th Cir. 2013); FWW Br.33. But a plaintiff still must show “‘a credible threat of harm’ due to that exposure.” *NRDC v. FDA*, 710 F.3d 71, 81 (2d Cir. 2013). In the cases which Plaintiffs cite, there was significant evidence that the substance at issue could cause a specific type of harm, and the government even acknowledged the risk. *See, e.g., Baur v. Veneman*, 352 F.3d 625, 638 (2d Cir. 2003) (relying on government confirmation of risks from “mad cow” disease); *FDA*, 710 F.3d at 82

(stating FDA “admit[ed]” triclosan “may be unsafe”); *NRDC*, 735 F.3d at 882 (finding standing to challenge registration of nanosilver pesticide which court found presented too high a risk as originally calculated by EPA). Here, Plaintiffs failed to prove by a preponderance of the evidence that fluoride presents a “credible threat” of the harms identified by these declarants.

Plaintiffs’ evidence is particularly insufficient because their feared ailments could have many potential independent or contributing causes, so Plaintiffs must provide evidence sufficient to “show that a causal connection exists” between these risks and fluoridation of water. *See Bellon*, 732 F.3d at 1142. They have not. None of these declarants presented any medical testing or diagnosis supporting their apprehensions. Perhaps most importantly, Plaintiffs provide only two actual studies arguably speaking to *any* of these harms—Adkins (2022) and Hall (2023). Each one speaks to different potential symptoms, and standing alone, these studies do not establish a credible threat. Moreover, the studies speak to effects on populations *different from* the declarant to whom they are allegedly relevant. *Compare* 4-SER-903 (suggesting an association with effects *at* age 12), 4-SER-920 (suggesting association with increased risk in pregnant women), *with* 3-ER-578 (relevant child is now 15), and 3-ER-599-604 (no mention of any interest in becoming pregnant).

While Plaintiffs’ brief includes many pin-cites (FWW Br.35-39), the cites do not support the strong assertions made. For example, Plaintiffs vastly exaggerate

the alleged evidence that fluoride presents a “credible threat” of causing headaches for Simms (or others). The district court noted “there are millions of causes of headaches,” 4-ER-786, and Simms admits having at least twenty different headache triggers. FER-27-32. The court summarized how little *scientific* evidence supports this concern. 1-ER-25. For example, Plaintiffs suggest (FWW Br.36) the 2006 NRC Report supports this allegation, but as the court explained, that Report contains “one appearance of the word ‘headaches’ ... referring to one of several symptoms reported in a study” of gastrointestinal effects. 1-ER-25 (citations omitted); FER-18. While one of Plaintiffs’ experts did testify the 2006 NRC Report had found fluoride hypersensitivity to be “credible,” FWW Br.36, the Report does not say that; it states that these patients “might be sensitive to the effects of silicofluorides and not the fluoride ion itself,” FER-19.

Lacking scientific support, Plaintiffs have not presented sufficient evidence to establish standing based on their apprehensions that their risk of these common ailments might increase with exposure to fluoride. *See Bellon*, 732 F.3d at 1142-46 (finding no standing “without any plausible scientific or other evidentiary basis that the” potentially regulated “emissions are the source of their injuries”).

Plaintiffs lack standing; this Court should dismiss the case.

**II. The district court violated Section 21 by allowing (and encouraging) petitioners to submit evidence overwhelmingly different from the facts set forth in the petition.**

The district court decided this case based on an evidentiary record overwhelmingly different from the one in the petition presented to and reviewed by EPA. In doing so, the court violated Section 21's text and Congress's carefully crafted administrative exhaustion requirement.

Plaintiffs do not (and cannot) meaningfully contest that the court's findings went far beyond the facts and evidence presented by their 2016 petition (and largely beyond the evidence cited in the later "supplement"). Opening Br.18-19, 46. In 2020, the court found "what was presented to the EPA was a very, very different record than what I have now." 1-ER-31; *see also* 1-ER-26-34. Plaintiffs attempt (FWW Br.49) to downplay this concern by suggesting EPA merely "references some post-2020 studies that the court cites." But the vast majority of the studies the court discussed in detail for both hazard and hazard level post-date 2016 and many post-date 2020 (2-ER-86-105, 2-ER-113-122), and the court relied more heavily on the later studies, *e.g.*, 2-ER-113 (citing 2022, 2023 analyses). Nor do Plaintiffs contend the court's approach complied with Section 21's administrative exhaustion requirement; Plaintiffs' Answering Brief never even refers to "exhaustion."

The court failed to keep the case within the scope of the petition or to require actual exhaustion before EPA. The result was plainly inconsistent with the text, structure, and purposes of Section 21, and this Court should reverse.

**A. Section 21’s text and structure allow citizens to petition EPA, and if denied, to seek district court consideration of “such petition.”**

As with all statutes, Section 21’s text must be read in its context in the overall statutory scheme. *Sturgeon v. Frost*, 577 U.S. 424, 438 (2016). Section 21 is entitled “Citizens’ petitions” and authorizes people to petition *EPA* for action. 15 U.S.C. §2620(a). Subsection 21(b) sets forth the procedures for filing “such petition” with EPA and for EPA’s consideration of them. *Id.* §2620(b). Within that provision, paragraph 21(b)(4) then provides a judicial backstop. *Id.* §2620(b)(4)(B). Subparagraph 21(b)(4)(B) provides: “[i]n an action ... respecting a petition [for EPA] to initiate a proceeding ..., the petitioner shall be provided an opportunity to have such petition considered by the court in a de novo proceeding.” *Id.* That language does not authorize an open-ended, years-long judicial inquiry into a chemical’s risks with a rolling evidentiary record reflecting emerging science beyond the petition, as occurred here.

Plaintiffs adopt (FWW Br.40-43) a strained reading of “de novo proceeding” that effectively rewrites Section 21. Plaintiffs would transform the “petition” at Section 21’s center into a mere notice requirement and give several terms meanings

inconsistent with their use elsewhere in Section 21. Plaintiffs' interpretation is wrong.

No one disputes that “de novo” means a “fresh” proceeding in which the court does not defer to EPA’s administrative findings. But Plaintiffs contend that “proceeding” is “a maximally *expansive* term,” based on their reading of one definition in Black’s Dictionary. FWW Br.40; *see* PROCEEDING, BLACK’S LAW DICTIONARY (12th ed. 2024) (“The regular and orderly progression of a lawsuit...”). From there, Plaintiffs insist (Br.40-41, 45-46) that definition of “proceeding” must mean a “trial,” and Plaintiffs then presuppose that it requires an open record limited only by the Federal Rules of Evidence and Civil Procedure. Plaintiffs overread “proceeding,” conflicting with its use in this context.<sup>2</sup>

Congress’s use of “proceeding” throughout Section 21 makes it clear Congress was *not* using Plaintiffs’ preferred meaning. Black’s Dictionary also defines “proceeding” as “[a]ny procedural means for seeking redress from a tribunal or agency.” PROCEEDING, BLACK’S LAW DICTIONARY (12th ed. 2024). Section

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<sup>2</sup> Plaintiffs try to bolster this argument with (FWW Br.40-41) inapposite precedent interpreting statutes with texts and structures considerably different from TSCA Section 21. *E.g.*, *Kim v. United States*, 121 F.3d 1269, 1272 (9th Cir. 1997) (interpreting 7 U.S.C. §2023(15)); *Callejo v. Resol. Tr. Corp.*, 17 F.3d 1497, 1498 (D.C. Cir. 1994) (interpreting 12 U.S.C. §1821(f)(1) (Supp. IV 1992)). These cases highlight that Congress would have chosen different language had it intended Plaintiffs’ desired result. *See, e.g.*, 7 U.S.C. §2023 (providing that suit “shall be a trial de novo by the court”).

21 must use “proceeding” in that sense because it refers to EPA engaging in various “proceedings” seven times—once in the very sentence at issue. *See* 15 U.S.C. §2620(b)(4)(B). For example, Section 21 authorizes EPA to conduct such “proceeding as [EPA] deems appropriate in order to determine whether” to grant the petition, and *that* proceeding would have to be completed within ninety days. *Id.* §2620(b)(2), (b)(3). Thus, the word “proceeding” does not mean “trial” and cannot imply everything Plaintiffs wish, even when combined with the phrase “de novo.” Giving it a consistent meaning, the district court’s de novo proceeding considering the petition will be comparable to administrative proceedings performed by EPA.

Plaintiffs’ interpretation renders meaningless Congress’s decisions to describe a Section 21 lawsuit as an “action ... *respecting a petition*” and to direct that such a suit provides the petitioner with “an opportunity to have *such petition* considered by the court.” 15 U.S.C. §2620(b)(4)(B) (emphases added). It also ignores Congress’s structural decision to embed this right within a Section focusing on the ability to petition EPA, not the court.

Plaintiffs contend (FWW Br.44) that the direction that the court consider “such petition” means little based on their theory that “such petition” merely refers to the “the ask.” Not so. As EPA explained in its Opening Brief at 43-44, Section 21 specifies that “[s]uch petition” “shall set forth the facts which it is claimed establish that it is necessary to issue” the relevant rule. 15 U.S.C. §2620(b)(1).

While not a formal definition of “petition,” this language makes clear that a petition “shall set forth the facts” that “establish” a rule is “necessary.” *Id.* Plaintiffs’ narrow reading of “petition” cannot be reconciled with this description of “[s]uch petition.” Moreover, Section 21 repeatedly refers to “the action requested by petitioner” when it refers to “the ask,” *e.g., id.* §2620(b)(4)(A), (B), so Congress is not using “petition” in that sense.

Plaintiffs (*e.g.*, FWW Br.43-44) argue that because “[s]uch petition” “shall set forth the facts,” 15 U.S.C. §2620(b)(1), but does not use the word “evidence,” it places *no* limits on the factual evidence that a plaintiff can later present in court. But the word “facts” sweeps broadly to encompass “[s]omething that actually exists; an aspect of reality.” FACT, BLACK’S LAW DICTIONARY (12th ed. 2024). The “facts” establishing that a Section 6 rule “is necessary” must demonstrate that a chemical presents an unreasonable risk under TSCA’s rigorous scientific standards. Those facts must include facts that studies and scientific findings “actually exist” that establish the chemical presents such an unreasonable risk. *Cf.* 2-ER-84-150 (district court’s 68-page “findings of fact” that studies exist and factual findings court thought those studies supported). That the studies are *also* “evidence” does not mean that their existence, and their contents, are not facts that needed to be set forth in the petition. As the government has acknowledged, a court has limited leeway to allow plaintiffs to provide additional evidence—such as expert testimony—to understand

or clarify the facts set forth in the petition. But the district court’s decision to allow (and eventually, effectively require) an open-ended, continually updated collection of new studies over seven years eviscerated the limit that the court must “consider” the petition originally submitted.

Plaintiffs suggest (FWW Br.46) a distinction between “forward” versus “backward” inquiries that does not appear in the statute’s text and which renders some text meaningless. In contrast, EPA’s interpretation gives weight to each part of the whole: the court “consider[s]” “such petition,” and in doing so, the court considers whether the “petitioner” demonstrated “by a preponderance of the evidence” whether the chemical “presents an unreasonable risk.” 15 U.S.C. §2620(b)(4)(B).

**B. Plaintiffs’ reliance on legislative history from an earlier, different version of TSCA only highlights that Congress did not adopt their approach.**

Plaintiffs and amici contend the legislative history supports their interpretation of de novo proceeding, citing a Senate Report’s discussion of “gathering evidence.” FWW Br.42-43; CEH Br.10-11; NRDC Br.22. But Congress did *not* pass the version of Section 21 discussed in that Senate report; it modified Section 21 and added crucial language focusing the lawsuit on consideration of “such petition.”

The Senate version of the relevant provision being discussed in that earlier report provided that: “If the petitioner can demonstrate to the satisfaction of the court, by a preponderance of the evidence in a de novo proceeding before such court, that the action requested in the petition conforms to the applicable requirements of this Act, the court shall order [EPA] to initiate the action requested by the petitioner.” S. Rep. No. 94-698 at 68 (March 16, 1976). That version of the text arguably *would* have the result Plaintiffs desire: there the only part of the petition relevant to the lawsuit appears to be whether “the action requested in the petition” meets TSCA’s requirements.

Congress did not keep that language and instead adopted the very different language discussed in Part II.A. In sum, “Congress had before it ... language that would have accomplished the result” Plaintiffs claim “that it intended, yet it chose not to use that language.” *Hall v. USDA*, 984 F.3d 825, 841 (9th Cir. 2020). Thus, Congress did not intend that result. *See id.*

The Conference Report does not clarify precisely what Congress sought to achieve by rejecting the earlier version and adding the language focusing the court’s consideration on the petition. H. Rep. No. 94-1679 at 97-99 (Sept. 23, 1976); *see also* ACC Br.19-23 (discussing reports). But members of the House had criticized the earlier version for “forc[ing] the Federal courts to hear complex, scientific testimony and make technical decisions more appropriately left to an expert

regulatory agency.” H.R. Rep. No. 94-1341 at 140 (July 14, 1976). One member of the House, John McCollister, who generally supported TSCA, expressed concerns Section 21’s de novo petition process would have negative impacts “not only on the workload of the agencies, but also on the caseload of the Federal courts.” 122 Cong. Rec. 27,139, 27,160 (1976). Given these criticisms, Congress rationally modified it to ensure that Section 21 lawsuits would not be so open-ended and would instead focus on consideration of the petition initially submitted to and considered by the expert agency, EPA.

The legislative history does not clarify the exact scope of the district court consideration, but it forecloses Plaintiffs’ preferred interpretation and generally supports EPA’s.

**C. The district court’s failure to follow Section 21 is not subject to abuse-of-discretion review.**

Plaintiffs attempt (FWW Br.46-50) to reframe the district court’s failure to follow Section 21’s statutory requirements as typical evidentiary rulings reviewed for an abuse of discretion. Not so. Section 21 limits the district court’s consideration to “such petition” and forecloses Plaintiffs (and the court) from producing a rolling evidentiary record based on newly emerging studies never set forth in the petition. This Court reviews that legal question of statutory interpretation de novo, not for abuse of discretion. And given that the court relied overwhelmingly on materials

post-dating the petition and even the later supplement for its findings, its erroneous ruling on this legal issue undoubtedly changed the substantive outcome below.

Plaintiffs and amici also suggest (FWW Br.46-50; CEH Br.26) EPA invited the errors here because, after the district court ruled that the evidentiary record was wide open and not limited to the petition's identification of factual studies (or even their existence at the time of the petition), EPA also addressed and relied on emerging studies. But EPA argued below that Section 21 required the court to limit the scope of the record and evidence based on the petition, and the district court rejected that argument. 1-ER-53-69. Thus, EPA preserved the argument for appeal. EPA was then "entitled to treat this ruling as the 'law of the trial' and to negatively rebut or explain, ... the evidence admitted over [EPA's] protest." 1 McCormick On Evid. §55 (9th ed.); 1 McCormick On Evid. §57 (9th ed.).

The district court committed legal error by interpreting Section 21 to permit Plaintiffs to introduce voluminous materials that did not even exist at the time of the petition.

**III. The district court's takeover of the case to ensure the submission of facts allegedly meeting Plaintiffs' burdens on both standing and the merits shifted it from neutral arbiter to inquisitor.**

At the close of the first trial, the district court improperly stepped into the role of inquisitor rather than neutral arbiter. The court sought to correct the perceived strategic missteps of Plaintiffs' counsel and to ensure the parties submitted the

evidence the judge considered appropriate. In particular, the court abdicated its duty to dismiss the case for lack of jurisdiction after the first trial, and it refused to rule on the merits—notwithstanding the parties’ insistence that the case was ready for resolution. The court instead directed Plaintiffs to submit specific evidence it wanted on both standing and the merits. The court signaled that it would set aside the binding stipulation in which Plaintiffs had intentionally made a strategic decision to limit the evidence they could submit regarding standing. The court abused its discretion by thus commandeering the case.

**A. EPA did not forfeit any party-presentation argument.**

EPA did not forfeit its party-presentation arguments for two related reasons. First, EPA objected to the court’s numerous rulings that effected the takeover, including the court’s decisions to allow Plaintiffs to introduce new standing declarations and to stay the case to allow additional science to develop. 4-ER-768; 5-ER-875-78, 5-ER-899-909, 5-ER-984-85. At one point EPA identified for the court that **“the parties agree that the Court should lift the abeyance and decide the merits of this case based *only* on the trial record.”** 5-ER-844; 5-ER-854 (Plaintiffs’ agreement); Opening Br.27.

Second, higher courts review “party presentation” arguments for an abuse of discretion, but they do not subject these arguments to the typical rules of forfeiture (Plaintiffs cannot contend that EPA affirmatively waived its right to a neutral

arbiter). Plaintiffs identify no cases where the courts have done so. The Supreme Court found this Court violated party-presentation principles in *United States v. Sineneng-Smith*, 590 U.S. 371 (2020), even though the United States had not raised that issue below *or* in its petition for certiorari. Petition for Certiorari, 2021 WL 2650478, at \*I (June 23, 2021). Similarly, this Court has found a district court violated party-presentation principles even in cases where the issue was not raised below. *Trader Joe's Co. v. Trader Joe's United*, 150 F.4th 1040, 1054-55 (9th Cir. 2025).

**B. The district court commandeered the case by setting aside Plaintiffs' strategic choices and extensively directing the parties to present new facts and evidence after trial.**

Plaintiffs contend (FWW Br.50-53) a court can violate party-presentation principles only by raising and introducing new legal issues. No precedent supports that contention, and the general principles underlying party presentation apply equally to a court stepping into an inquisitorial role and shaping the *facts* before it to fill gaps in a party's case. A court abuses its discretion by doing so when, as here, it overrules a party's strategic decisions knowingly and intentionally adopted. *See Wood v. Milyard*, 566 U.S. 463, 472-73 (2012).

“What makes a system adversarial rather than inquisitorial is the presence of a judge who does not (as an inquisitor does) conduct the *factual* and legal *investigation* himself, but instead decides on the basis of *facts* and arguments pro

and con *adduced by the parties.*” *Sanchez-Llamas v. Oregon*, 548 U.S. 331, 357 (2006) (emphases added) (citation omitted). Even on factual issues, the Supreme Court has recognized that “party presentation” principles allow the court to decide cases “based on the historical record compiled by the parties.” *New York State Rifle & Pistol Ass’n v. Bruen*, 597 U.S. 1, 25 n.6 (2022); *see also United States v. Robertson*, No. 24-1475, 2025 WL 3687773, at \*22 (1st Cir. 2025) (explaining “the party presentation principle caution[s]” against rule requiring the court to do “the yeoman’s work” of assessing factual circumstances); *Bordeaux v. Lions Gate Ent.*, No. 23-4340, 2025 WL 655065, at \*1 (9th Cir. 2025) (citing party presentation in declining to reach undisputed issue). “To put it plainly, courts ‘call balls and strikes’; they don’t get a turn at bat.” *Clark v. Sweeney*, No. 25-52, 2025 WL 3260170, at \*1 (U.S. 2025) (citation omitted).

Plaintiffs cite several cases (FWW Br.51-53) for their theory that a court cannot abuse its discretion by taking over a case and actively shaping the factual and evidentiary record, but none of the cases say that. Rather, the decisions recognize that party-presentation principles apply, but the courts found they had not been violated, often explaining that a court need not resolve party-raised issues “in accordance with the position of one of the parties.” *See, e.g., United States v. Cortez-Nieto*, 43 F.4th 1034, 1052 (10th Cir. 2022) (giving example that “[i]f one party challenges the admissibility of evidence and the proffering party provides a

ground of admissibility, the court may admit the evidence but give a limiting instruction.”). Plaintiffs do not discuss the facts of these cases, which are a “far cry from *Sineneng-Smith*,” *Tekmen v. Reliance Standard Life Ins.*, 55 F.4th 951, 963 (4th Cir. 2022), and are similarly a far cry from what happened below.

Here, the district court abused its discretion by taking over the case after the close of trial and *directing* Plaintiffs to collect and submit certain evidence to cure gaps in their case on both standing and substance—despite Plaintiffs asserting they had met their burden on both. *See* 4-ER-771; 1-ER-42. In issuing its abeyance order, the district court “direct[ed] Plaintiffs to file a new petition,” 1-ER-26-27; 5-ER-838, and Plaintiffs understood the court had “directed [them] to address standing issues,” 5-ER-813. Similarly, on the substantive questions, the court urged Plaintiffs to provide certain scientific materials. 5-ER-918; 1-ER-27. Later, Plaintiffs emphasized they included new scientific materials “*at the direction of the Court.*” 3-SER-588 (emphasis added). The court drove the collection of new evidence: “we’ve got other things that *I* want to hear about” and “*I* really wanted to get the latest and the most available evidence possible. And that’s still *my* goal.” 4-ER-701, 4-ER-702 (emphases added); *see also* 4-ER-705. Plaintiffs explained that they, in producing new materials, were “try[ing] to ... adhere closely to the studies that the Court expressed an interest in.” 4-ER-706.

Particularly with respect to standing, the court effectively overruled Plaintiffs' strategic decisions and stepped in, after trial, to attempt to fill gaps in Plaintiffs' case, even when Plaintiffs insisted it was unnecessary. Given the court's recognition that Plaintiffs lacked standing, the court had a duty to dismiss, *supra* p.3, but instead it commandeered the case by refusing to rule on standing, 1-ER-21. Plaintiffs had signed a stipulation that they would "rely exclusively" on the attached declarations for standing. 4-ER-682-683. Plaintiffs consciously and intentionally made that strategic choice. Plaintiffs and the court later relied on that stipulation to reject certain of EPA's evidentiary objections, 4-ER-790; 5-ER-1089-90, reaping benefits from their choice.

Even after the court expressed concerns about Plaintiffs' showing, Plaintiffs insisted that they had "met our burden." 4-ER-771. But the judge responded that he was "not going to be convinced that there's not serious questions," and "that's why—one reason why I'm going to put this case in abeyance," 5-ER-771, with the direction that Plaintiffs "remove the complicated standing issues," 5-ER-757. The court effectively reversed Plaintiffs' strategic choices and directed Plaintiffs to provide more facts. Later, when Plaintiffs argued they should be able to get out of the stipulation, they emphasized: "the Court *invited* Plaintiffs to supplement their standing allegations," 3-SER-589; 5-ER-933, and in doing so, the "Court was obviously well aware of the parties' stipulation," 3-SER-590. A court particularly

“depart[s] from the principle of party presentation” when it addresses issues that a party strategically and knowingly abandoned, and it is ““an abuse of discretion”” to overrule a party’s deliberate waiver or relinquishment of an issue. *See Wood*, 566 U.S. at 472-73.

Plaintiffs’ various counterarguments (FWW Br.54-57) are unpersuasive and fail to grapple with the court’s pervasive takeover of the case. Plaintiffs suggest (FWW Br.54-55) no takeover occurred because the parties continued to file and brief motions—but a favored party acceding to a court’s takeover and following its directions does not cure the Article III problem. Of course a prudent counsel will “r[i]de with [the] argument[s] suggested by the” court; “How could she do otherwise?” *Sineneng-Smith*, 590 U.S. at 379.

Plaintiffs insist (FWW Br.56) the court’s decision that it needed more scientific evidence was reasonable because it flowed from EPA’s arguments that Plaintiffs had not (and could not) carry their burden of proof on the *existing* science. Under that standard, a court could never affect a takeover as long as it is responding to a party’s identification of weaknesses in the opposing party’s case. That cannot be so.

The court’s abeyance enabled it to refuse to rule on the factual record presented by the parties and instead to shape the facts itself. And Plaintiffs are also incorrect to suggest (FWW Br.55) the stay finds support in the cited precedent. A

court may enter a stay “pending resolution of independent proceedings which bear upon the case,” whether they are “judicial, administrative, or arbitral.” *Leyva v. Certified Grocers of California*, 593 F.2d 857, 863-64 (9th Cir. 1979). But Plaintiffs cite no precedent supporting a court entering a stay *sua sponte* to allow new scientific evidence to develop to bolster a party’s case before it.

\* \* \* \* \*

Underlying much of Plaintiffs’ arguments is that the court’s open approach to accepting and even actively seeking “groundbreaking new studies” could never be erroneous under Section 21 or Article III because of the “highly consequential decisions” at stake. FWW Br.1. But it is when the stakes are highest that a court must be most diligent in recognizing the limits on its powers under the relevant statutes and in our adversarial system. A court should be particularly cautious when the core merits questions require resolving complex scientific issues in an area of ongoing and evolving research—neither judges nor legal advocates are best positioned to answer those questions. The court’s open-ended and extensive demand for the most up-to-date evidence exceeded the limits on its authority.

## CONCLUSION

The Court should reverse.

Respectfully submitted,

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