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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

FOOD & WATER WATCH, INC., et al.,

Plaintiffs,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,

Defendant.

Case No. 17-CV-02162 EMC

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

Date: November 7, 2019
Time: 12:00 p.m.
Place: Courtroom 5, 17th floor

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INTRODUCTION

In moving for summary judgment, EPA explained that Plaintiffs failed to employ the science standards and data-quality considerations required by TSCA to support a finding that the addition of fluoridation chemicals to drinking water up to the recommended concentration of 0.7 mg/L poses an unreasonable risk of neurotoxic effects. Plaintiffs implicitly acknowledge this failure in their response, arguing that because TSCA's risk-evaluation process and scientific standards provisions are not set forth in section 21, the Court may make a finding of "unreasonable risk" under section 21 completely unconstrained by the text and structure of the statute and congressional intent. Plaintiffs are wrong. In addition to failing to satisfy the statutorily required *process*, *criteria*, and *standards* for determining risk, there have been no published epidemiological studies measuring fluoride's potential neurotoxic effects in the United States. Plaintiffs instead ask the Court to assume, without support, that prenatal maternal urinary-fluoride concentrations in the United States must be similar to those observed in samples studied in Canada and Mexico City. Finally, Plaintiffs are not within the zone-of-interests of TSCA and lack Article III standing. The Court should grant EPA's Motion for Summary Judgment.

ARGUMENT

I. TSCA RISK DETERMINATIONS REQUIRE SYSTEMATIC REVIEW.

In deciding a motion for summary judgment, the substantive law identifies which facts are material to the dispute. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Here, the substantive legal *process*, *criteria*, and *standards* for determining whether a chemical substance "presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use," 15 U.S.C. § 21(b)(4)(B)(ii), are set forth in TSCA section 6(b)(4)(B) and (F) and section 26(h) and (i). Section 6(b)(4)(B) requires a risk evaluation *process*, section 6(b)(4)(F) sets forth *criteria* that must be used in conducting a risk evaluation, section 26(h) requires that in carrying out section 6, decisions based on science be employed in a manner consistent with the best available science, and section 26(i) requires that *all* section 6 decisions be based on the weight of the scientific evidence. 15 U.S.C. § 2605(b)(4)(A),

(F), § 2620(h), (i). Congress made clear that under modern risk assessment principles, "[t]he term 'weight of the evidence' refers to a systematic review method." *See* 162 Cong. Rec. S3518 (daily ed. June 7, 2016); H.R. Rep. No. 114-176, at 33 (2015). Thus, despite Plaintiffs' insistence to the contrary, TSCA *does* require the application of a systematic review method for determining risk, as a matter of law.

First, Plaintiffs' burden to show "unreasonable risk" under section 21(b)(4)(B)(ii) tracks nearly verbatim the standard for risk-evaluation in section 6(b), signifying that those concepts should be consistently construed. *See* EPA Opp'n 6, ECF No. 119; *Air Wis. Airlines Corp. v. Hoeper*, 571 U.S. 237, 248 (2014) ("It is a cardinal rule of statutory construction that, when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it is taken." (internal quotation marks omitted)). And because section 21 is one of three "pathways" to a section 6(a) rule, *see Food & Water Watch, Inc. v. EPA ("F&WW I")*, 291 F. Supp. 3d 1033, 1046 (N.D. Cal. 2017), the substantive requirements for demonstrating an unreasonable risk are "the 'facts' that would establish the existence of 'an unreasonable risk' under Section 6(a)."[1] *Id.* at 1045. Thus, the Court's consideration of risk must be based on the *process*, *criteria*, and *standards* that Congress made integral to determining whether regulation is warranted under section 6(a). *See also* EPA Br. 4–6; EPA Opp'n 5.

Further supporting this statutory construction is that Congress intended for EPA to rely on "the conclusions regarding . . . effects and exposures of the chemical in the risk evaluation itself" in determining how to regulate unreasonable risks. 162 Cong. Rec. S3517 (daily ed. June 7, 2016).

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[1] If a determination of unreasonable risk to health is made pursuant to subsection (b)(4)(A), "then a regulation to address that risk is warranted under section 6(a), and the Administrator must proceed to section 6(a) rulemaking." H.R. Rep. No. 114-176, at 23. In other words, "section 6(b) generally prohibits EPA from restricting a chemical substance before making this determination based on the findings of the risk evaluation." *Id.* at 24. "[W]hile the phrase 'unreasonable risk of injury' [was] not amended [in the Frank R. Lautenberg Chemical Safety for the 21st Century Act], it must be read in the context of the changes to section 6, including the functions and purposes delineated in subsections (a), (b), and (c)." *Id.* at 28. "Unreasonable risk" must be construed under section 21 in light of the overall statutory scheme and congressional intent.

If the Court were to make a finding of unreasonable risk independent of the statutory standards for doing so, EPA could be put in the untenable position of making scientific judgments in the section 6(a) risk-management rule that are not supported by the best available science or weight of the scientific evidence as required by section 26(h) and (i). *See* EPA Br. 8. As evidence that Congress intended to avoid such a result, Congress required EPA to develop guidance setting forth, at a minimum, the "quality of the information submitted and the process to be followed in developing draft risk evaluations" to "assist interested persons in developing and submitting draft risk evaluations." 15 U.S.C. § 2625(*l*)(5); s*ee* EPA Br. 7–9. To wholly set aside the guidance would render section 26(*l*)(5) superfluous. "[T]he more natural reading of the statute's text, which would give effect to all of its provisions, always prevails over a mere suggestion to disregard or ignore duly enacted law as legislative oversight." *United Food & Commercial Workers Union Local 751 v. Brown Group, Inc.*, 517 U.S. 544, 550 (1996); *United States v. Mohrbacker*, 182 F.3d 1041, 1050 (9th Cir. 1999) (same).

Plaintiffs' out-of-context quotations from this Court's prior order do not support their argument that the substantive requirements of the statute do not apply to the Court's determination of risk under section 21. Pls.' Opp'n 17–18, ECF No. 120. In denying EPA's motion to dismiss, the Court declined to find that the full extent of conditions of use included in a risk evaluation under section 6(b) must also be included in a section 21 petition. *F&WW I*, 291 F. Supp. 3d at 1052. The Court compared the petition provision with the judicial-review provision of section 21, which "specifically identifies Section 6(a), suggesting that Section 6(a) (and not Section 6(b) discussing risk evaluations) is the only provision of Section 6 which pertains to citizen petitions." *Id.* Here, the construction of the statute put forward by EPA in its opening brief harmonizes section 21's judicial-review provision with TSCA's statutory scheme. *See Hernandez v. Williams, Zinman & Parham PC*, 829 F.3d 1068, 1073 (9th Cir. 2016).

Second, even if the Court were to set aside the section 6(b) *process* and *criteria* requirements that must inform section 6(a) rulemaking, TSCA section 26 sets forth the scientific standards for "making decisions" and "carrying out" section 6. 15 U.S.C. § 2625; *Hernandez*, 829 F.3d at 1073; EPA Br. 7. Section 26 requires that in carrying out section 6, decisions based on

science *shall* be consistent with the best available science and that *all* decisions *shall* be based on the weight of the scientific evidence. EPA Br. 7–9. Here, the Court's unreasonable-risk determination will be a science-based decision. *Food & Water Watch, Inc. v. EPA ("F&WW II")*, 302 F. Supp. 3d 1058, 1070 (N.D. Cal. 2018) ("Given the elements of the claim . . . , [the evidence] should be focused on scientific evidence and expert discovery regarding the risk of injury to health or the environment posed by the chemical substances at issue in Plaintiffs' petition."). Therefore, Plaintiffs must demonstrate that their evidence meets the statutory standards for section 6 decision making, including best available science and weight of the scientific evidence under section 26(h) and (i).[2] 15 U.S.C. §§ 2625(h), (i); *see* EPA Br. 5, 8.

"Weight of scientific evidence means a systematic review method . . . ." 82 Fed. Reg. 33,748 (July 20, 2017); 162 Cong. Rec. S3518 (daily ed. June 7, 2016). Plaintiffs' suggestion that, because EPA defined "weight of the scientific evidence" by regulation, Congress did not require "systematic review" under TSCA, is misleading. Pls.' Opp'n 17. In fact, EPA adopted verbatim Congress' definition of weight of the scientific evidence.[3] *See* 162 Cong. Rec. S3518 (daily ed. June 7, 2016); H.R. Rep. No. 114–176, at 33; EPA Br. 13–14. Thus, because Plaintiffs' experts cannot support their opinions with a systematic review, Plaintiffs' claim fails as a matter of law.

Plaintiffs' reliance on EPA's experts' systematic reviews to identify the best available science does not save their claim. To begin with, Plaintiffs' argument that EPA's systematic reviews place before the Court the best available science misses the point entirely. Systematic review requires more than the collection of scientific studies; rather, it is necessary to document a

[2] Although this argument assumes, arguendo, that Plaintiffs are not required to satisfy the *process* and *criteria* requirements in section 6(b)(4), Plaintiffs appear to concede that at least some risk-assessment process must be used to meet their burden under section 21(b)(4)(B)(ii). *See* Pls.' Opp'n 2–4 (explaining the first two steps in risk assessments and EPA's general use of the 1998 Guidelines for Neurotoxicity Risk Assessment). Because section 26 governs the standards for decisions making under section 6, the scientific standards and weight of the scientific evidence requirements in sections 26(h) and (i) apply to each step of whatever risk-assessment process Plaintiffs may use to justify a finding of unreasonable risk under section 21.

[3] Although Congress defined the term "weight of the evidence" under modern day risk assessment principles, Congress did not include that definition in the statute to preserve EPA's ability to redefine that term as "necessary to reflect new scientific developments or understandings." *See* 15 U.S.C. §2625(*l*)(2).

comprehensive and transparent process for ensuring consistency in the results and objectivity in employing scientific judgment throughout the entire risk-assessment process. Even if Plaintiffs' experts found the same studies as EPA's experts,[4] Plaintiffs' experts failed to systematically integrate the "evidence as necessary and appropriate based upon strengths, limitations, and relevance." 162 Cong. Rec. S3518 (daily ed. June 7, 2016); *see* EPA Br. 14–18. This integration is required by law, but it is also essential for offering credible scientific opinions on risk.

The only opinion of record based on Dr. Ellen Chang's systematic review of epidemiological studies and Dr. Joyce Tsuji's systematic review of the toxicological studies is that of Dr. Tala Henry, EPA's risk-assessment expert. Dr. Henry opined that "based on Dr. Tsuji's and Dr. Chang's expert review and evaluation of the body of literature . . . sufficient information is not reasonably available at this time to integrate information on hazards and exposures into a risk characterization, a necessary step for reaching a determination of risk under *any* risk assessment process." Second Henry Decl. ¶ 8 (Oct. 23, 2019) (emphasis added), Exhibit A.

Third, Plaintiffs' argument that "EPA's own conduct" is evidence of the legal standard in this case is nonsensical. Pls.' Opp'n 18. To begin with, Plaintiffs, not EPA, must demonstrate by a preponderance of the evidence that adding fluoridation chemicals to drinking water poses an unreasonable risk. *See* EPA Opp'n 4–7. Moreover, Plaintiffs concede that EPA's epidemiology and toxicology experts *did* conduct systematic reviews, upon which Plaintiffs now seek to rely in light of their failure to put forward evidence that meets TSCA's minimum scientific requirements. Thus, because the opinions offered by Plaintiffs' experts Drs. Kathleen Thiessen and Philippe Grandjean are unsupported by section 26's substantive requirements for carrying out and making decisions under section 6, Plaintiffs' claim fails as a matter of law.

II. PLAINTIFFS HAVE NOT PROFFERED EVIDENCE TO DEMONSTRATE UNREASONABLE RISK.

Plaintiffs point to Dr. Thiessen's Margin-of-Exposure ("MOE") analysis and Dr. Grandjean's Benchmark Dose ("BMD") analysis as evidence of unreasonable risk. Pls.' Opp'n 12–13. While it is true that in conducting TSCA risk evaluations, EPA *generally* uses an

[4] Plaintiffs' assertion that their experts did not miss studies because of their failure to conduct a systematic search of the literature is plainly contradicted by the record. EPA Br. 16.

MOE approach to characterize risk, *any* approach for characterizing risk is only as good as the assumptions made and the data (or information) used in the calculation. Here, because Drs. Thiessen and Grandjean failed to (1) demonstrate that their analyses are based on information consistent with its intended use, as required by section 26(h) and (i) and (2) demonstrate a scientifically sound integrative analysis based on the preceding components of the risk assessment, as required by section 6(b) and risk-assessments generally, the Court lacks a factual predicate from which an inference of unreasonable risk can be drawn. *See Sanders v. City of Fresno*, 551 F. Supp. 2d 1149, 1163 (E.D. Cal. 2008), *aff'd*, 340 F. App'x 377 (9th Cir. 2009) (explaining that in ruling on a motion for summary judgment, inferences are not drawn out of the air, and it is the opposing party's obligation to produce a factual predicate from which the inference may be drawn); EPA Br. 9; EPA Opp'n 11–13.

To begin with, neither the legislative history, case law, nor Dr. Henry's testimony support the application of the "significant risk" or "unacceptable risk" standard advanced by Plaintiffs. Notably, in support of the argument that Congress envisioned the standard for judging risk under TSCA to be "significant risk," Plaintiffs cite the discussion of *section 6 standards* in the July 14, 1976 House Report on the Toxic Substances Control Act. Pls.' Opp'n 11–12. Plaintiffs thus concede that the Court should apply *section 6 standards* for determining risk. *See supra* Part I. But by relying on the pre-amendment legislative history, Plaintiffs ask the Court to ignore that the 2016 TSCA amendments made "substantive, clarifying, and structural changes to TSCA section 6," including section 6(a). H.R. Rep. No. 114–176, at 23.

Next, in support of the argument that courts apply "significant risk" as the standard for judging risk under TSCA, Plaintiffs cite *Ethyl Corp. v. U.S. Environmental Protection Agency*, 541 F.2d 1 (D.C. Cir. 1976), which involved a challenge to an EPA rulemaking pursuant to a Clean Air Act ("CAA") provision that authorized regulation of gasoline additives whose emission products "will endanger" the public health or welfare. The "significant risk of harm" standard applied in that case was based on EPA's interpretation of the CAA, not the court's. 541 F.2d at 12.

Finally, Plaintiffs attempt to rely on Dr. Henry's testimony to suggest that EPA determines risk solely on an MOE calculation. Pls.' Br. 17, ECF No. 117. As Dr. Henry testified, however,

the MOE is a "starting point" for the risk-determination step required under the amended TSCA. Henry Dep. 270:20–271:13; 298:3–19; *see also* 82 Fed. Reg. 33,735 (listing factors EPA may weigh in making a risk determination as the final step of the risk-evaluation process). Thus, the MOE does not on its own constitute a finding of "unreasonable risk" under TSCA.

EPA explained why the deficiencies in the analyses of Drs. Thiessen and Grandjean require judgment in favor of EPA, EPA Opp'n 7–14, and will not reiterate those reasons here, except to note that Plaintiffs do not dispute *three* material facts that are fatal to their claim.

First, Plaintiffs do not dispute that "Dr. Thiessen found unacceptable risks for every point of departure that can be justified from the *animal literature* . . . ." Pls.' Opp'n 12 (emphasis added); Thiessen Decl. ¶¶ 6–7. Neither do Plaintiffs dispute—nor could they—that the best available science for conducting a dose-response assessment is the human epidemiological data. *See* Thayer Dep. 56:9–19 (May 17, 2019) ("[A]fter an assessment, at the end of the day if you felt like you had epidemiological data that had the right features to lend themselves for dose-response, you would explore that first; *id.* at 149:19–25 ("[I]f we have that information that shows humans suffer harm, then . . . that would be our first line of evidence . . . ."). Because Dr. Thiessen did not assess a dose response "consistent with the best available science," her MOE analysis cannot be used to support a finding of unreasonable risk under TSCA. 15 U.S.C. § 2625(h); EPA Opp'n 14.

Second, Plaintiffs do not dispute Dr. Grandjean's failure to "actually calculate[] the BMDs." Pls.' Opp'n 13. Plaintiffs' characterization of Dr. Grandjean's admission as a "fleeting moment of levity" is not credible in light of the importance of the BMD calculation nor does it make up for the lack of a factual predicate from which the Court could infer risk. *See* EPA Br. 14; EPA Opp'n 11–13. In other words, the Court cannot assume that the BMD offered by Dr. Grandjean identifies a threshold dose at which effects may be seen, especially where, as here, the calculation fails to include a material translation from fluoride urinary concentration (which is correlated to the IQ response) back to a fluoride water concentration. *E.g.*, Henry Dep. 354:13–355:5.

Third, Plaintiffs do not dispute that Dr. Grandjean failed to "calculate a specific exposure limit." Grandjean Decl. ¶ 8; Pls.' Opp'n 13. Thus, Dr. Grandjean omitted two steps in the risk-

assessment process required under TSCA. Whether under the 1998 Guidelines or the Risk Evaluation Rule, risk assessment requires that risk characterization (here, the MOE approach) be based on an actual dose-response assessment and exposure assessment. *See* Pls.' Opp'n 2–3 (discussing risk-assessment steps); *see also* Tala Decl. ¶¶ 17–20. Instead, Plaintiffs offer inadmissible double-hearsay to assert that "the BMDL [benchmark dose level] values that [Dr. Grandjean] calculated are well below the exposure levels that have been documented in fluoridated communities in North America." Grandjean Decl. ¶ 8.[5] In addition, because Dr. Grandjean did not conduct a systematic review, the Court cannot assume that the referenced studies, if at all, are "consistent with" or "relevant for" calculating exposure. *See* 15 U.S.C. § 2625(h), (i); EPA Opp'n 11–13.

Because Dr. Thiessen did not assess a dose response using the human data, "consistent with the best available science," and, because Plaintiffs ask the Court to assume that Dr. Grandjean's BMD level is below the levels of exposure to fluoridated water programs in the United States, Plaintiffs fail to offer the factual predicate necessary to support a risk characterization and, thus, their claim fails as a matter of law.

EPA is also entitled to judgment as a matter of law because Plaintiffs did not complete all of the risk-assessment steps, which are required to provide the factual predicate for the Court to weigh evidence-based conclusions. *See* 82 Fed. Reg. 33,734–35; Henry Decl. ¶ 23; EPA Opp'n 2–3. For example, none of Plaintiffs' experts completed an exposure assessment. *See* EPA's Opp'n 14 (discussing Dr. Thiessen's assumptions); *id*. at 9 n.7 (discussing Dr. Grandjean's assumptions). Even if Plaintiffs were not required to demonstrate each of the substantive risk-evaluation steps under section 6(b)(4), their claim still fails as a matter of law because Plaintiffs concede that to meet their burden here, risk must be assessed using *some* risk-assessment process. *See supra* note 2.

[5] Dr. Grandjean relies upon his own reports to support his assertion. His expert reports constitute the first layer of inadmissible hearsay. *See* EPA Opp'n 10 n.8. The references within his expert reports are the second layer of inadmissible hearsay. *See* Fed. R. Evid. 805.

III. PLAINTIFFS FAILED TO SHOW THAT STUDIES CONDUCTED IN MEXICO AND CANADA ARE GENERALIZABLE TO THE UNITED STATES.

Plaintiffs' expert, Dr. Grandjean, relied on studies conducted in Mexico and Canada to support his assertion that fluoride is a developmental neurotoxin at levels consistent with exposure in the U.S. population. EPA Br. 12. However, Plaintiffs failed to point to evidence to support a series of assumptions they made to conclude that the results of those studies are generalizable to the United States. *See id.* at 12–14.

Dr. Howard Hu testified that the fluoride concentrations in prenatal maternal urine—a biomarker used to estimate total fluoride exposure—collected from mothers in Mexico City in one project were within the range of urinary fluoride concentrations of pregnant women in Canada for a different project. Hu Dep. 31:23–32:11. This comparison, however, has nothing to do with any population in the United States. Rather, Plaintiffs rely on a vague statement that Canadians and Americans are, "biologically speaking," similar, Pls.' Opp'n 15 (citing Lanphear Dep. 58:20–23), and assume that prenatal maternal urine concentrations in the United States must be similar to those observed in a sample studied in Canada. Pls.' Opp'n 15. But even statements from Plaintiffs' experts' publications explain that data are not available for such a comparison. *See* EPA Br. 13.

Plaintiffs then further assume without support that the overlapping range of maternal urinary fluoride concentrations observed in the Mexico City and Canada populations studied shows that those populations experience the same total fluoride exposure and, further still, that the U.S. population must also experience the same fluoride exposure. Yet Plaintiffs acknowledge that the source of fluoride exposure differs across Mexico and Canada. In Mexico, the main source of fluoride exposure is salt, and in Canada, water. *See* Pls.' Opp'n 15. Dr. Hu could not say whether or not the source of fluoride exposure influences observed fluoride concentrations in the urine of pregnant women. Hu Dep. 91:13–20; *id.* at 128:14–21. Nor was Dr. Hu aware of any studies measuring whether or not the source of exposure could influence fluoride concentrations in maternal urinary biomarkers. *Id.* at 92:6–7. Dr. Hu further testified that a comparison of fluoride biomarkers across populations with different sources of exposure could not support inferences

regarding external exposures. *Id.* at 97:5–9; *id.* 132:24–133:1 ("I think that our data just simply don't allow us to infer anything about fluoride intake for a variety of reasons.").[6]

In a last-ditch effort, Plaintiffs point to Dr. Grandjean's tenuous statement that the relatively higher rate of dental fluorosis (a condition associated with fluoride consumption) and reach of water fluoridation in the United States "suggests" that urine fluoride concentrations in the United States "may be higher than in Canada." Pls.' Opp'n 15–16 (quoting Grandjean Report 15). This statement does not support the assumptions Plaintiffs make. Moreover, Plaintiffs' selective quote from Dr. Grandjean's report,[7] ignores his further statement that the "lack of large and representative studies on fluoride concentrations in urine . . . makes it hard to judge the overall fluoride exposure levels in U.S. populations." Grandjean Report 15, EPA Br. Ex. 5. In any event, Dr. Grandjean's assertion of what "might" be cannot satisfy Plaintiffs' burden to support their assertions with evidence. Finally, Dr. Grandjean's statement in his rebuttal report that he is "aware" of an unpublished manuscript that he claims is a fluoride exposure assessment in California, wherein the "maternal urinary fluoride concentrations were similar to those reported from Canada," does not satisfy Plaintiffs' burden here. Dr. Grandjean failed to explain in any meaningful way how the analyses and methodologies used to collect and analyze fluoride concentrations in urine samples in the unpublished manuscript are comparable to the Canadian cohort studies. And even if they were comparable, Dr. Grandjean's assertion still leaves Plaintiffs' assumptions regarding the source of exposure across the populations unsupported. Therefore, Plaintiffs failed to provide evidentiary support for each of the logical leaps they make to assert that

[6] Dr. Hu even acknowledged that the source of exposure could have "public health ramifications," because one "need[s] to know something about the absorption rates, etc. to understand how much fluoride is advisable in either salt or water"; "[u]ltimately, that will determine what your internalized exposure is to fluoride." Hu Dep. 92:23–93:5.

[7] For the reasons stated in EPA's Opposition, EPA objects to Plaintiffs' reliance on Dr. Grandjean's expert reports and a podcast, Pls.' Opp'n 16, as inadmissible hearsay. EPA Opp'n 10 n.8.

studies conducted in Mexico and Canada are generalizable to the United States.[8] *See Sanders*, 551 F. Supp. 2d at 1163.

IV. PLAINTIFFS CANNOT BRING THIS CASE ABOUT NEUROTOXIC HARM BECAUSE THEY FACE NO CREDIBLE THREAT OF NEUROTOXIC HARM.

Plaintiffs argue that fluoridation chemicals in drinking water result in neurotoxic harm, particularly in reducing IQ. It is not unreasonable to ask: who among Plaintiffs suffers from this claimed threat of neurotoxic harm? Plaintiffs' best response is that Julie Simms claims to have experienced headaches during the time she consumed fluoridated water. Pls.' Opp'n 22. Plaintiffs never before claimed that headaches are an unreasonable risk, and they have not shown that fluoridated drinking water causes headaches, much less that there is a genuine dispute of fact.

A. TSCA Section 21 Petition Denials May Be Challenged Only By Those Who Suffer the Purported Unreasonable Risk.

Plaintiffs and Defendants agree: to fall within the zone-of-interests of a statute, Congress must have intended the litigant be able to seek judicial review. TSCA limits the availability of judicial review to those who first petition EPA. 15 U.S.C. § 2620(b)(4)(A). Plaintiffs must explain the "facts" that establish the "unreasonable risk" to EPA in their petition, and these facts will "frame" any case Plaintiffs may bring. *See F&WW II*, 302 F. Supp. 3d at 1069–70. Plaintiffs identified neurotoxic harm as the only unreasonable risk in the petition and have focused on the neurotoxic impacts *in utero* and on infants. *See* Pls' Br. 13–14. But none of the Plaintiffs is pregnant, a potential parent, or an infant, nor can any otherwise claim to have suffered neurotoxic harm. EPA Br. Part II(A). Plaintiffs agree that they must show an unreasonable risk of neurotoxic harm, but seem to contend that they can seek judicial review regarding the purportedly unreasonable risk of neurotoxic harm without demonstrating any threat of risk themselves. This argument has no basis in TSCA. Only those at risk may sue the federal government for redress. *Summers v. Earth Island Inst.*, 555 U.S. 488, 495–96 (2009). Plaintiffs primarily argue that they

[8] Plaintiffs' attempt to flip the burden on EPA is without support. *See* Pls.' Opp'n 15 (explaining that EPA's brief did not identify a reason why Americans exposed to community water fluoridation will have less fluoride exposure).

presented headaches as an unreasonable risk to EPA, and that two of their declarants are at risk of this harm. This alternative argument is incorrect for several reasons.

First, Plaintiffs did not once mention "headaches" in their petition. Plaintiffs claim that they did petition EPA on the alleged unreasonable risk of headaches because they attached a single study to their petition that discussed headaches as one symptom participants reported from drinking fluoridated water. Attaching one study, among over three hundred others, that discusses self-reported headaches as a symptom without actually naming "headaches" as a risk in the petition is not sufficient to identify this risk in the petition. *See Dep't of Transp. v. Pub. Citizen*, 541 U.S. 752, 764–65, (2004) (A bedrock of administrative law is "alert[ing] the agency to the [parties'] position and contentions in order to allow the agency to give the issue meaningful consideration."); *Mossville Envtl. Action Now v. EPA*, 370 F.3d 1232, 1238 (D.C. Cir. 2004) (An attachment to a comment letter that "does not directly address" an issue does not alert an agency with "reasonable specificity."); *Northside Sanitary Landfill, Inc. v. Thomas*, 849 F.2d 1516, 1519 (D.C. Cir. 1988) (agency need not divine why a fact buried in eleven attachments is relevant to a rulemaking). EPA cannot be expected to scour every attachment to identify every risk not mentioned in a petition.

Second, "headaches" do not fall into the category of risk presented in the petition. The only risk presented in the petition was the risk of neurotoxic harm. *See F&WW II*, 302 F. Supp. 3d at 1069–70. The physiological pain of headaches are merely a *symptom* and are described as symptoms in the study Plaintiffs attached to the petition. Headaches are altogether different from the other neurotoxic risks discussed in the petition, for example, reduced neurodevelopment of the brain, which is a source of injury and can be objectively measured. Plaintiffs needed to separately identify headaches in the petition itself if headaches are the only risk they suffer.

Even if the Court determines that Plaintiffs identified headaches as an unreasonable risk in their petition and that Plaintiffs have established a sufficient evidentiary basis that Ms. Simms and Kyle Adams experience headaches, all other individual and organizational Plaintiffs should be dismissed from this case. Plaintiffs have not attempted to demonstrate that any other Plaintiffs or declarants have suffered an unreasonable risk identified in the petition. Summary judgment is a time to narrow issues and parties for trial.

B. Plaintiffs Lack Article III Standing

Setting aside Plaintiffs' inability to demonstrate that they are exposed to the risks that they presented to EPA in their petition, Plaintiffs are unable to demonstrate that they suffered any injury caused by fluoridation chemicals in drinking water or that their injuries are redressable. EPA Br. 23–24. Plaintiffs claim that they suffer three types of injuries: reduction in well-being from avoiding fluoridation chemicals in drinking water, costs of avoiding fluoridation chemicals in drinking water, and fear of neurological harm in adults. The first two types rely on the substance of the third. Avoiding fluoridation chemicals in drinking water is not a cognizable harm unless there is a substantiated concern that drives this behavior. *Pennsylvania v. New Jersey*, 426 U.S. 660, 664 (1976). Otherwise, Plaintiffs' avoidance is not traceable to EPA's action. Plaintiffs attempted to demonstrate neurological injury to adults based on "Plaintiffs' first-hand experiences with headaches." Pls.' Opp'n 25. But Plaintiffs' experiences do not establish a genuine issue that fluoridation chemicals in U.S. drinking water cause headaches.

Even if headaches are a neurotoxic harm, the only study Plaintiffs cite in support of the relationship between fluoride and headaches *does not conclude* that low levels of fluoride, such as in U.S. fluoridated drinking water, cause headaches. Rather, the lowest exposure group consumed fluoridated water at levels at or below 1 mg/L. Pls.' Opp'n Ex. 46, at 1. By comparison, U.S. drinking water can be fluoridated to concentrations of 0.7 mg/L. The study tenuously concluded that fluoride "may cause various neurological manifestations among subjects" in the *highest* or "endemic" areas. *Id*. at 1, 131. But the study did not conclude that exposure to fluoride in the lowest exposure group had any effect on self-reported headaches.

And even if fluoridation chemicals could potentially cause headaches in the general population, Plaintiffs have not established that their declarants are at risk of headaches if they consume fluoridated water in the United States. Plaintiffs rely on Ms. Simms' declaration in which she claims to have experienced headaches after drinking fluoridated water. But Ms. Simms also admits that she experiences headaches when drinking un-fluoridated water, and that alcohol, lack of sleep, and aged cheese may also trigger her headaches. Simms Decl. ¶ 15. Further, she made other health changes at the same time she stopped drinking fluoridated drinking water, which may

explain any decrease in headaches. Simms Decl. ¶¶ 15, 17, 19. Plaintiffs also suggest that Mr. Adams experiences headaches when drinking fluoridated water. His mother reports that Mr. Adams complained of headaches in the morning, which "would inevitably seem to set in prior to leaving for work or starting his day." Adams Decl. ¶ 11. She further claims that Mr. Adams would not experience these headaches while camping or after short, low-pressure showers of filtered, low-fluorine water. *Id*. ¶¶ 14–15. Because Plaintiffs have in no way isolated the effects of fluoridated drinking water on Mr. Adam's headaches, as opposed to other factors like environment or time or pressure, their allegations that fluoridated water is the cause of the headaches is based on speculation, not facts. There is no science or data to support their claim that low concentrations of fluoride cause Ms. Simms's or Mr. Adams's purported headaches. These conclusory, self-serving declarations are not enough to support Plaintiffs' burden.

Plaintiffs cite "the medical advice" in the form of notes of unverified authorship for Ms. Simms and Mr. Adams. Pls.' Opp'n 25. The notes are inadmissible hearsay. Fed. R. Evid. 801. In any event, the notes regarding Ms. Simms do not provide any advice on fluoride but instead merely parrot Ms. Simms' self-reported "history." Pls.' Opp'n Ex. 42 & 43. To the extent Mr. Adams' post-litigation notes provide advice, despite Plaintiffs' characterization of the notes as being from Mr. Adams' treating "doctors," Pls.' Opp'n 20, one note is clearly not written by a medical doctor. Pls.' Opp'n Ex. 45 (signed "ND"). Additionally, the notes do not reference any independent medical testing to confirm the declarants' complaints that fluoridated drinking water was the cause of their symptoms. Conclusory notes are no better than other conclusory statements, and a "summary judgment motion cannot be defeated by relying solely on conclusory allegations unsupported by factual data." *Taylor v. List*, 880 F.2d 1040, 1045 (9th Cir. 1989).

Finally, Plaintiffs cite the 2006 NRC study, Pls.' Opp'n 25, which does discuss an animal study that may be of interest to those studying cognitive effects in the elderly, Pls.' Opp'n Ex. 17, at 220, but the 2006 NRC study does not conclude that dementia is a risk of fluoride exposure.

Even if Plaintiffs could cite other evidence on dementia,[9] they have no evidence that the level of fluoride in drinking water poses a risk of dementia. Moreover, not a single declarant can claim that dementia is an "actual or imminent" injury. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 564–65 (1992). No declarant purported to be in the age group Plaintiffs claim is susceptible to dementia; no declarant claimed that they have an imminent fear of dementia; and no declarant provided evidence that exposure to fluoride at his or her age would lead to dementia. Their "some day" fears "do not support a finding of the 'actual or imminent' injury" required by case law. *Id*. at 565.

Plaintiffs have not shown that winning this case will redress their alleged injury. They also failed to establish that their individualized total intakes of fluoride would lead to injury. It is undisputed that declarants are exposed to fluoride from sources other than drinking water, and they have not accounted for the fluoride to which they are exposed from other sources. *See Wash. Envtl. Council v. Bellon*, 732 F.3d 1131, 1141–42 (9th Cir. 2013) (standing demonstration is weak when there are multiple potential causes of injury). Plaintiffs have not established that eliminating fluoridated water would reduce their declarants' exposure below the threshold of harm because their declarants will continue to be exposed to fluoride. And because Plaintiffs seek injunctive relief to remedy future harm, they must show "a very significant possibility of future harm; it is insufficient for them to demonstrate only a past injury." *San Diego Cty. Gun Rights Comm. v. Reno*, 98 F.3d 1121, 1126 (9th Cir. 1996).

Any other neurological injury to other subpopulations is not of "imminent" and personal concern to Plaintiffs' standing declarants. Plaintiffs have not shown that they have or will suffer injury from fluoridation chemicals, and, therefore, this case must be dismissed.

CONCLUSION

For each of the forgoing independent reasons, and the reasons stated in EPA's Motion for Summary Judgment, and EPA's Opposition to Plaintiffs' Motion for Summary Judgment, the Court should grant EPA's Motion for Summary Judgment.

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[9] Plaintiffs also cite an inadmissible 1999 union document that does not conclude that fluoride poses a risk of neurological harm in adults. Pls.'s Opp'n Ex. 14. Plaintiffs do not specify where in the document EPA scientists "proclaim[ed]" this risk to adults. Pls.'s Opp'n 24.

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Washington, DC

Respectfully Submitted,

/s/ Brandon N. Adkins

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CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of October, 2019, a true and correct copy of the foregoing Defendant's Reply in Support of their Motion for Summary Judgment was filed electronically with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served on all counsel of record via transmission of Notices of Electronic Filing generated by CM/ECF.

/s/ John Thomas H. Do
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United States Department of Justice