UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

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

Plaintiffs,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,

Defendants.

Case No. 17-cv-02162-EMC

ORDER DENYING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Docket Nos. 116, 117

I. INTRODUCTION

Section 6(a) of the Toxic Substances Control Act ("TSCA") requires Defendant United States Environmental Protection Agency ("EPA") to regulate the use of certain chemical substances that it determines pose an unreasonable risk to health or the environment. 15 U.S.C. § 2605(a). Section 6(b) requires the EPA to perform its own *sua sponte* evaluation of the risks posed by certain chemical substances "under the conditions of use." *Id.* § 2605(b)(4)(A). Section 21 of the TSCA permits any person to petition the EPA to initiate rule-making under Section 6(a) if the petitioner demonstrates a chemical substance poses an unreasonable risk of harm. *Id.* § 2620(a). Furthermore, should the EPA Administrator deny a petition filed under § 21, "the petitioner may commence a civil action in a district court of the United States to compel the Administrator to initiate a rulemaking proceeding as requested in the petition." *Id.* § 2620(a)(4).

Plaintiffs petitioned the EPA under Section 21 to regulate the fluoridation of drinking water supplies under Section 6(a) because, they maintain, the ingestion of fluoride poses an unreasonable risk of neurotoxic harm to humans. After the EPA denied Plaintiffs' petition, Plaintiffs filed this suit seeking judicial review of the EPA's determination.

II. FACTUAL & PROCEDURAL BACKGROUND

Plaintiffs are a group of non-profit organizations and associations and individual parents who sue on behalf of themselves and their children.[1] They allege that fluoridation chemicals (specifically, hydrofluorosilicic acid, sodium silicofluoride, and sodium fluoride) are added to public water supplies across the United States to reduce dental caries (tooth decay). Complaint ¶ 3, Docket No. 1. Plaintiffs allege that the risks of fluoridation include a higher risk of dental fluorosis, a "hypominelarization of tooth enamel that produces noticeable discoloration of the teeth" and deleterious effects on the brain, including cognitive impairments and neurotoxicity. Complaint ¶¶ 8-16.

On November 22, 2016, Plaintiffs petitioned the EPA to issue a rule under Section 6(a) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2605, prohibiting the addition of "fluoridation chemicals" to drinking water supplies. Complaint ¶¶ 24, 105; *see also* 15 U.S.C. § 2620(a) (permitting "[a]ny person" to petition for such a rule). In the first paragraph of the cover letter, the petition states that the signatories "hereby petition the U.S. Environmental Protection Agency to protect the public and susceptible subpopulations from the neurotoxic risks of fluoride by banning the addition of fluoridation chemicals to water." Citizen Petition ("Petition") at 1, Exh. 1, Docket No. 117-1. The petition is approximately 30 pages long and summarizes scientific studies Plaintiffs maintain demonstrate the neurotoxic effects of ingesting fluoride, as well as the allegedly heightened risks to vulnerable subpopulations.

The EPA denied the petition on February 17, 2017. Complaint ¶¶ 25, 106. That denial was also published in the Federal Register. *See* Declaration of Norman Rave, Exh. 2, Docket No. 28-1; *see also* 82 Fed. Reg. 11,878 (Feb. 27, 2017) ("EPA Denial"). The denial contains a summary of the EPA's interpretation of the applicable statutory and regulatory framework and a response to the merits of Plaintiffs' petition. The EPA stated that "[a]fter careful consideration, EPA denied the TSCA section 21 petition primarily because EPA concluded that the petition has

[1] Plaintiff organizations are Food & Water Watch, Inc.; Fluoride Action Network; and Moms Against Fluoridation. The Individual Plaintiffs are Audrey Adams on behalf of herself and Kyle Adams; Kristin Lavelle on behalf of herself and Neal Lavelle; Brenda Staudenmaier on behalf of herself and Ko and Hayden Staudenmaier. *See* Complaint ¶ 1, 29-44.

not set forth a scientifically defensible basis to conclude that any persons have suffered neurotoxic harm as a result of exposure to fluoride in the U.S. through the purposeful addition of fluoridation chemicals to drinking water or otherwise from fluoride exposure in the U.S." 82 Fed. Reg. at 11,881, col. 3; *see also id.* at 11,882 (noting that "the evidence did not adequately account for the possibility that the confounding factors themselves, rather than concurrent fluoride exposure, were partly or wholly responsible for the health effects observed.'"); *id.* (criticizing petitioners' reliance on a study whose authors, the EPA states, "conclu[ded their data] . . . are unsuitable for evaluating levels of fluoride associated with neurotoxic effects and for deriving dose-response relationships necessary for risk assessment"); *id.* (noting that "[t]he petition suggested that a dose-response relationship between urinary fluoride and IQ is seen in several studies," but arguing that "it is not possible to determine whether effects on IQ were due to fluoride or to malnutrition (*i.e.*, nutritional status may be an uncontrolled confounding factor)"); *id.* (citing a study to conclude that "the petitioner's use of fluorosis levels as a surrogate for evidence of neurotoxic harm to the U.S. population is inappropriate evidence to support an assertion of unreasonable risk to humans from fluoridation of drinking water"); *id.* (criticizing use of another study because "[i]mportant issues such as the timing and methods of sample collection were also often not reported in the studies").

Plaintiffs filed this case in April 2017. *See* Docket 1. In September 2017, EPA filed a Motion to Dismiss. *See* Docket No. 28. The EPA argued that Plaintiffs' lawsuit should be dismissed because their administrative petition (1) failed to address conditions of use other than the fluoridation of drinking water, (2) failed to specifically identify the chemicals at issue, and (3) failed to justify treatment of those chemicals on a categorical basis. In ruling on the Motion to Dismiss, the Court found that "a citizen petition need not evaluate all conditions of use; that Plaintiffs sufficiently identified the chemicals they sought to regulate; and that Plaintiffs presented an adequate basis, in their administrative petition, for requesting categorical treatment of the chemicals they identified." Order Denying Defendant's Motion to Dismiss at 1–2, Docket No. 42. Since that order, the parties have engaged in extensive discovery. They now bring Cross-Motions for Summary Judgment. *See* Docket Nos. 116, 117. These motions are the only ones pending before the Court.

III. DISCUSSION

A. Legal Standard

Federal Rule of Civil Procedure 56 provides that a "court shall grant summary judgment [to a moving party] if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). An issue of fact is genuine only if there is sufficient evidence for a reasonable jury to find for the nonmoving party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986). "The mere existence of a scintilla of evidence . . . will be insufficient; there must be evidence on which the jury could reasonably find for the [nonmoving party]." *Id.* at 252. At the summary judgment stage, evidence must be viewed in the light most favorable to the nonmoving party and all justifiable inferences are to be drawn in the nonmovant's favor. *See id.* at 255.[2]

Where a plaintiff moves for summary judgment on claims that it has brought (*i.e.*, for which it has the burden of proof), it "must prove each element essential of the claims . . . by undisputed facts." *Cabo Distrib. Co. v. Brady*, 821 F. Supp. 601, 607 (N.D. Cal. 1992). Where a defendant moves for summary judgment based on a claim for which the plaintiff bears the burden of proof, the defendant need only by pointing to the plaintiff's failure "to make a showing sufficient to establish the existence of an element essential to [the plaintiff's] case." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *see also Fontenot v. Upjohn Co.*, 780 F.2d 1190, 1194 (5th Cir. 1986) (stating that, "if the movant bears the burden of proof on an issue, either because he is the plaintiff or as a defendant he is asserting an affirmative defense, he must establish beyond peradventure all of the essential elements of the claim or defense to warrant judgment in his favor") (emphasis omitted).

[2] Evidence may be presented in a form that is not admissible at trial so long as it could ultimately be capable of being put in admissible form. *See* Fed. R. Civ. P. 56(c)(2) (providing that "[a] party may object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence"). *See, e.g., Fonseca v. Sysco Food Servs. of Ariz., Inc.*, 374 F.3d 840, 846 (9th Cir. 2004) (stating that "[e]ven the declarations that do contain hearsay are admissible for summary judgment purposes because they 'could be presented in an admissible form at trial'").

B. Analysis

1. Standing

Defendants contend that Plaintiffs lack standing because they cannot claim "neurotoxic injury or credible threat of neurotoxic injury as a result of their exposure to fluoridation chemicals." Defendants' Motion for Summary Judgment ("DMSJ") at 2, Docket No. 116. EPA alleges both that Plaintiffs fall outside the "zone-of-interests" (*i.e.* lack prudential standing) and that they lack Article III standing. *Id.* at 21. Although prudential standing "does not implicate subject-matter jurisdiction," *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 128 n.4 (2014), because the "lack of Article III standing requires dismissal for lack of subject matter jurisdiction," *Maya v. Centex Corp.*, 658 F.3d 1060, 1067 (9th Cir. 2011) (emphasis removed), Defendant's standing arguments are addressed first.

a. Statutory Standing

"Whether a plaintiff comes within 'the 'zone of interests' is an issue that requires [the court] to determine, using traditional tools of statutory interpretation, whether a legislatively conferred cause of action encompasses a particular plaintiff's claim." *Lexmark*, 572 U.S. at 127. Here, the relevant statute (Section 21 of the TSCA) states that "*[a]ny person* may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule," 15 U.S.C. § 2620(a) (emphasis added), and that if the Administrator denies a petition, "*the petitioner* may commence a civil action in a district court of the United States to compel the Administrator to initiate a rulemaking proceeding as requested in the petition," *id.* at § 2620(4)(A) (emphasis added). Thus, the statutory language permits *any person* to petition the Administrator and *any petitioner* to commence a civil action if the Administrator denies his or her petition. There is no language in the statute suggesting a limitation on who may proceed with such a lawsuit.[3] Thus, to the extent that EPA argues that "if petitioners do not suffer the unreasonable risk presented to EPA, then they do not have a cause of action to challenge EPA's denial of their petition in court,"

[3] *But see Corrosion Proof Fittings v. E.P.A.*, 947 F.2d 1201, 1209 (5th Cir. 1991), *opinion clarified* (Nov. 15, 1991) (finding that foreign petitioners lacked standing under the TSCA to contest EPA actions).

DMSJ at 22, the broad language of the statute suggests otherwise.

Relatedly, EPA argues that Plaintiffs lack standing because the facts and injuries alleged in the complaint do not track the facts and injuries alleged in the initial petition. TSCA petitioners are required to "set forth the facts [in their petition] which it is claimed establish that it is necessary to issue, amend, or repeal a rule," 15 U.S.C. § 2620(b), and are subsequently entitled to "have *such petition* considered by the court in a de novo proceeding," *id.* at § 2620(b)(4)(B). Here, EPA argues that Plaintiffs complain about "other harms" (such as physical pain, headaches/migraines, thyroid disease, cancer, dementia, and "unspecified impacts on the bones") in this lawsuit, rather than about the neurotoxicity concerns raised in the petition. *Id.* However, notwithstanding the declarations of the individual plaintiffs and the portion of the complaint that describes each party (which do address the wide range of "other harms" noted above), the complaint does track the original petition. For example, the petition asks the EPA "to protect the public and susceptible subpopulations from the neurotoxic risks of fluoride by banning the addition of fluoridation chemicals to water." Petition at 1. Similarly, the complaint focuses on the allegedly "neurotoxic effects" of fluoride, *see* Complaint ¶ 15–22, and fairly describes the original petition as one "to prohibit the addition of 'fluoridation chemicals' to drinking water supplies based on the voluminous peer-reviewed research linking fluoride exposure to neurotoxicity," *id.* ¶ 24. Thus, to the extent that EPA argues that Plaintiffs lack standing because the facts alleged in the complaint do not track the facts alleged in the petition, the argument is without merit.

b. Article III Standing

Plaintiffs also argue that Defendants lack Article III standing. The oft-cited language from *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992), sets out the rule: To have Article III standing, a plaintiff (1) "must have suffered an "injury in fact"—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) "actual or imminent, not 'conjectural' or 'hypothetical,'" (2) " there must be a causal connection between the injury and the conduct complained of—the injury has to be "fairly ... trace[able] to the challenged action of the defendant," and (3) "it must be "likely," as opposed to merely "speculative," that the injury will be "redressed by a favorable decision." *Lujan*, 504 U.S. at 560–61.

EPA contends that Plaintiffs cannot establish Article III standing because they cannot show that their injuries are caused by exposure to fluoride. DMSJ at 23. As *Lujan* counsels, "the injury has to be fairly traceable to the challenged action of the defendant." *Lujan*, 504 U.S. at 560 (internal brackets and quotation makes omitted). However, "at the summary judgment stage the plaintiffs need not establish that they in fact have standing, but only that there is a genuine question of material fact as to the standing elements." *Cent. Delta Water Agency v. United States*, 306 F.3d 938, 947 (9th Cir. 2002); *see also Native Vill. of Kivalina v. ExxonMobil Corp.*, 696 F.3d 849, 867 (9th Cir. 2012) (quoting *Lujan*, 504 U.S. at 561) ("A plaintiff must support each element of the standing inquiry 'in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation.'").

At the summary judgment hearing, the Court asked Plaintiffs' counsel for the "best examples" of individual plaintiffs that "have some neurologically-related injury." Transcript of Hearing from November 15, 2019 ("Transcript"), at 4 – 5, Docket No. 133. Plaintiffs' counsel first discussed Julie Simms, who suffered from daily headaches for more than a decade, until she stopped drinking fluoridated water, at which point "the headaches became substantially less painful . . . and were completely gone within weeks." Complaint ¶ 38. No medical tests confirmed fluoridated water as the cause of Ms. Simms' headaches, Transcript at 7, and no medical diagnoses concluded that her headaches were because of consumption of fluoridated water, Transcript at 13–14. However, Plaintiffs' counsel emphasized (1) the "temporal nexus" between the cessation of drinking fluoridated water and the end of Ms. Simms' headaches, *id.* at 6, as well as (2) the scientific literature purportedly linking fluoride exposure and headaches (as a neurological ailment), *id.*

With respect to the scientific literature, in their original petition Plaintiffs attached a study linking headaches and fluoride exposure. Transcript at 15–16 (referring to the Sharma (2009) study). That study took place in India and, in relevant part, interviewed 1,546 adults, who were classified based on reported fluoride exposure and asked about their neurologic ailments. *See* Prevalence of Neurological Manifestations in Human Population Exposed to Fluoride in Drinking

Water ("Sharma") at 127, Docket No. 120-1. The study found that "the most prevalent neurological manifestation was headache in both children and adults," *id.* at 129, but it qualified its conclusions by noting that fluoride "may cause various neurological manifestations among subjects residing in endemic areas," *id.* at 131. By way of reference, the group classified as "low" exposure in the Sharma study included people drinking water with fluoride levels at less than 1.0 mg/L, *id.* at 127 (the "high" exposure group had water with fluoride levels between 1.5–6.4 mg/L), while in the United States, drinking water can only be fluoridated up to concentrations of 0.7 mg/L. Thus, although Ms. Simms does not live in an endemic area, the Sharma study permits an inference that her headaches could have resulted from exposure to fluoride.

In addition to discussing Ms. Simms, Plaintiffs' counsel also discussed Kyle Adams, who alleges (through his mother) that he "has a consistent history of suffering severe reactions when exposed to fluoridated water. These reactions include (but are not limited to) intense pain and headaches, with resulting extreme hyperactivity, accelerated heart rate and intensification of autistic symptoms." *Id.* ¶ 39; *see also* Declaration of Audrey Adams ("Adams Decl.") ¶ 2, Docket No. 116-1, Exh. 13. A note from one of Mr. Adams' doctors states that Mr. Adams' has a "well documented sensitivity to certain chemical compounds, including Fluoride," but the note does not include headaches as one of the numerous physical symptoms that Mr. Adams experiences in response to fluoride exposure. *See* Note from Dr. Charles W. Butler, Docket No. 120-1 at 838. However, a note from Mr. Adams' naturopathic doctor does include headaches as one of the symptoms that Mr. Adams experiences upon exposure to fluoride. *See* Note from Nooshin K. Darvish, ND, Docket No. 120-1 at 840.

As explained in *Central Delta Water Agency*, at the summary judgment stage, "plaintiffs need not establish that they in fact have standing, but only that there is a genuine question of material fact as to the standing elements," 306 F.3d at 947, although where inferences about injury and/or causation are purely speculative, Article III standing is not established, *see e.g.*, *Riva v. Pepsico, Inc.*, 82 F. Supp. 3d 1045, 1053, 1064 (N.D. Cal. 2015) (finding Plaintiffs lacked standing where "the inferences of increased risk of harm . . . are speculative" because "[t]here is no plausible inference that [the accused substance] causes bronchioloalveolar cancer in humans");

cf. Food & Water Watch, Inc. v. Vilsack, 808 F.3d 905, 919 (D.C. Cir. 2015) ("Plaintiffs here cannot establish standing by incurring costs that are simply the product of their fear." (internal quotation marks omitted)). However, here it cannot be said that there is "no plausible inference" that fluoride caused Plaintiffs' headaches; their allegations—supported by a doctor's note, a related scientific study, and a temporal nexus—rise above the purely speculative, albeit perhaps barely, for standing purposes. As a result, the Court finds that Plaintiffs have adequately alleged neurotoxic harm, in the form of headaches, to have Article III standing.

C. Plaintiffs' Motion for Summary Judgment

In their Motion for Summary Judgment, Plaintiffs devote substantial discussion to the degree of proof required at this stage. Section 21 of TSCA provides that when a citizen petition is denied and the petitioner commences a civil action, "the petitioner shall be provided an opportunity to have such petition considered by the court in a *de novo* proceeding," in which the petitioner must demonstrate their case "to the satisfaction of the court by a preponderance of the evidence." 15 U.S.C. 2620(a)(4)(B). Plaintiffs also discuss what factors may permissibly be considered by the Court, and what types of analysis their experts may or may not have been required to conduct. For example, Plaintiffs argue that "conclusive proof of harm" is not required, Plaintiffs' Motion for Summary Judgment ("PMSJ") at 1, 14, Docket No. 117, and that the "consideration of 'costs and non-risk factors'" is prohibited at this stage, *id.* at 2. They further contend that—for various reasons—their experts were not required to conduct formal "systematic reviews" in order to comply with the requirements of TSCA's citizen petition provisions. *Id.* at 21. However, even assuming all of these considerations are resolved in Plaintiffs' favor (*i.e.* determining—for the sake of argument—that conclusive proof is not required, that costs and non-risk factors will not be considered at this stage, and that systematic reviews were not required), it is impossible to say that no reasonable juror could find that EPA is entitled to a verdict in its favor. Plaintiffs present several different categories of evidence to support their position; each is discussed below and none (either separately or together) indicate that Plaintiffs are entitled to summary judgment.

1. Pre-NRC Report Research

Plaintiffs first focus on the "landmark report" published by the National Research Council (a research body of the National Academy of Sciences) in 2006. PMSJ at 4. They contend that "the NRC concluded that fluoride causes neurochemical and anatomical changes in animal brain[s]" and that "fluoride 'interferes with the brain' in animals." *Id.* at 4–5. However, Plaintiffs admit that the NRC report conceded that the animal-study data was insufficient to determine whether such effects would "manifest into outwardly demonstrable deficits in cognition/behavior"; consequently, the NRC called for "more animal research to examine fluoride's impact on cognitive skills." *Id.* at 5. In addition, "the NRC found that the human data . . . was not yet sufficient to draw conclusions." *Id.* Plaintiffs also assert that the NRC report "unanimously concluded that the MCLG [Maximum Contaminant Level Goal] is unsafe and called on EPA to lower the level." *Id.* at 4. However, the recommendation about lowering the MCLG was based on a risk of children developing severe enamel fluorosis, together with the conclusion that the MCLG was unlikely to protect against bone fractures – it was not responsive to concerns about neurotoxicity. *See* DMSJ at 10. With respect to fluoride's potentially neurotoxic effects, the NRC concluded that additional researched was warranted. *Id.* at 11. The NRC also noted that its "conclusions regarding the potential for adverse effects from fluoride at 2 to 4 mg/L in drinking water do not address the lower exposures commonly experienced by most U.S. citizens." *Id.* at 10. Thus, because (1) the NRC's recommendation regarding the MCLG for fluoride was responsive to dental concerns, rather than potential neurotoxicity, (2) the report explicitly stated that further research on neurotoxicity was warranted, and (3) it did not address the levels of exposure commonly experienced in the United States, it affords only moderate support to Plaintiffs' position.

2. Human Studies from Endemic Areas

Plaintiffs also allege that, since the 2006 NRC Report, "a large number of human studies on fluoride and IQ have been published" and that the "vast bulk . . . have reported significant associations between fluoride and IQ loss." PMSJ at 5. They further contend that "[s]ixty-seven human studies have associated fluoride with cognitive deficits," *id.* at 5 n.4, and that "[a]ccording

to the National Toxicology Program (NTP), these studies provide 'a strong suggestion' that fluoride reduces IQ at water fluoride levels exceeding 1.5 mg/L," *id.* at 5. However, the very next sentence in the NTP report quoted by Plaintiffs states: "Overall, these studies were considered low quality, as they did not fully account for known confounding factors with regard to IQ (e.g., nutritional status, socioeconomic status), nor other potential influencing factors." *See* Docket No. 117-1, Exh. 15.

Plaintiffs also assert that one of their experts published a meta-analysis in which "fluoride was associated with reduced IQ in 26 of the 27 studies that met the inclusion criteria" for the analysis. *Id.*at 6. However, this meta-analysis has two drawbacks. First, meta-analyses cannot "be used to identify, confirm, or refute causal relationships." D. Opp. at 8. In order to do that, "the underlying studies in a meta-analysis must be systematically evaluated based on their settings, methodological qualities, and results." *Id.* (internal citations omitted). Second, even the authors of the meta-analysis cautioned that it could not "be used to derive an exposure limit, because the actual exposures of the individual children are not known." *Id.* Thus, although these studies from high-fluoride areas indicate an association between fluoride and reduced IQ at high levels of exposure, they do not necessary suggest an unreasonable risk at more relevant levels of exposure. Thus, like the 2006 NRC report, these studies afford only moderate support to Plaintiffs' position.

3. Birth Cohort Studies

Plaintiffs' also present evidence from "Birth Cohort Studies," including the "ELEMENT" cohort in Mexico City and the "MIREC" cohort in Canada. PMSJ at 6. Plaintiffs contend that the two studies examining the ELEMENT cohort separately "found a linear dose-response relationship between prenatal fluoride exposure (as measured in the urine of the mother) and reduced IQ in the children at ages 4 and 6-12," *id.*, and "found that prenatal fluoride exposure (as measured in the urine of the mother) was significantly associated with increased symptoms (*i.e.*, inattention) of ADHD in the offspring," *id.* at 7. The study involving the MIREC cohort "found that prenatal fluoride exposure was significantly associated with reduced IQ in boys at age 3 to 4" and "found significant associations between IQ (in both boys and girls) and maternal fluoride

intake from beverages." *Id.*

However, EPA contests the applicability of these findings to the United States. Specifically, the Agency notes that "some of the studies that Dr. Grandjean relied on specifically acknowledge limitations in the data that prevent extrapolating the results to other population." DMSJ at 13. Those acknowledgments include:

- "[O]ur ability to extrapolate our results to how exposures may impact on the general population is limited given the lack of data on fluoride pharmacokinetics during pregnancy. There are no reference values for urinary fluoride in pregnant women in the United States." *Id.* (citing Bashash 2017, at 11).
- "While urinary fluoride is a valid biomarker to identify differences in exposure levels in pregnant women, it is not possible, with the currently available data, to estimate how concentration levels relate to intake." *Id.* (citing Bashash 2018, at 664).
- Hu Deposition (Q: "[I]n the publication, Thomas 2016, you did not compare the results of maternal urinary fluoride levels with those levels found in the United States; is that correct?"; A: "Correct. And, again, because we could not find such data."). *Id.* (citing Hu Deposition 86:19–24).
- Hu Deposition (Q: "And Bashash 2017 did not attempt to generalize its findings to the United States, correct?"; A: "Correct."). *Id.* (citing Hu Deposition 121:3–5).

In addition, EPA argues that "Dr. Grandjean merely assumed, without any support, that pregnant women living in fluoridated areas in the United States would have similar urine-fluoride concentrations and total exposure to fluoride as those observed in the Mexico and Canada studies and that the observed biomarkers across the populations studied would be comparable to U.S. populations." *Id.* As a result, the Agency argues: "Lacking the necessary evidence to support such an assumption, the Court has no basis to infer that studies conducted in Mexico and Canada are generalizable to the United States." *Id.*

Some observations from the studies themselves also prove helpful. In Bashash 2017, the authors stated: "Our findings must be confirmed in other study populations, and additional research is needed to determine how the urine fluoride concentrations measured in our study population are related to fluoride exposures resulting from both intentional supplementation and environmental contamination." Bashash 2017 at 11, Docket No. 116-1, Exh. 7; *see also id.* at 10–11 (discussing other limitations to the study). In Bashash 2018, the authors noted: (1) that "it is

not possible, with the currently available data, to estimate how concentration levels relate to intake," (2) that only parent reports were used to identify ADHD-associated behaviors, and "previous studies have shown that there can be considerable variation" between parental observations and clinical diagnoses, and (3) that "[r]eplication of these findings is warranted in other population-based studies." Bashash 2018 at 664–65, Docket No. 116-1, Exh. 8. In addition, EPA observes that it is unusual that "Green 2019 observed heterogeneous results between boys and girls, whereas Bashash, et al. 2017, studying a similar metric in a different population, did not." D. Opp. at 11. These considerations represent meaningful drawbacks to the relevancy and persuasive power of the birth cohort studies.

In his supplemental report, however, Dr. Grandjean highlights a recent, unpublished study from California that examined the urinary fluoride levels of 48 pregnant women and found "similar urine fluoride levels relative to community water fluoride concentrations for pregnant women, as those reported . . . in a much larger sample of 1,566 Canadian women living in 10 cities across Canada." *See* Fluoride Concentrations in Urine, Serum and Amniotic fluid in 2nd Trimester Pregnant Women in Northern California ("California Study"), Docket No. 120-1 at PDF p. 692. While this small study bolsters the strength of the inference that the results of the MIREC studies could be extrapolated to the United States, it is not sufficient to establish that no reasonable juror could find that EPA is entitled to a verdict in its favor. It still requires extrapolation and inference, and every reasonable juror might not be inclined to do such extrapolating or infer in Plaintiffs' favor.

4. Animal Studies

Plaintiffs also marshal animal studies in support of their position. PMSJ at 8. They state that "over 100 animal studies investigating fluoride's neurotoxicity have been indexed in the National Library of Medicine's online database" with "the overwhelming majority confirming and expanding upon NRC's conclusion that fluoride damages animal brain[s] on the neurochemical and cellular level." *Id.* Plaintiffs further state the "the National Toxicology Program (NTP) published a systematic review of the subset of animal studies that investigated fluoride's effects on learning and memory . . . [and] concluded that that the overall evidence 'suggests adverse effects

on learning and memory in animal[s] exposed to fluoride.'" *Id.* However, that 2016 NTP report contains the following remarks:

> Very few studies assessed learning and memory effects in experimental animals (rats and mice) at exposure levels near 0.7 parts per million, the recommended level for community water fluoridation in the United States. At concentrations higher than 0.7 parts per million, this systematic review found a low to moderate level-of-evidence that suggests adverse effects on learning and memory in animal exposed to fluoride. . . . Confidence in these findings was reduced primarily based on potential confounding of the learning and memory assessments by deficits in motor function or fear and risk of bias limitations. Additional research is needed, in particular to address potential effects on learning and memory following exposure during development to fluoride at levels nearer to 0.7 parts per million.

Docket No. 117-1, Exh. 15 at vii. Furthermore, EPA notes that "[s]ince the 2016 NTP review, there have been twelve developmental neurotoxicity studies published, including one animal study conducted by NTP researchers specifically to follow up on and fill the gap regarding the uncertainties and deficiencies noted in the NTP 2016 review, McPherson et al. 2018. McPherson et al. 2018 is the most comprehensive and well-conducted and reported developmental neurotoxicity study of learning and memory in animals among the studies published after the NTP 2016 review." D. Opp. at 17–18 (internal citations omitted). That study found "no significant decrements in learning/memory at the human equivalent concentration of 1.2 mg/L." PMSJ at 10. Thus, as with much of the other evidence presented by Plaintiffs, these studies afford only moderate support to their position. The inferences Plaintiffs seek to draw are disputed.

5. Susceptible Subpopulations

Finally, Plaintiffs also address the issue of "susceptible subpopulations," asserting that fetuses and infants in particular may be at greater risk of adverse health effects from exposure to fluoride and that a "TSCA risk evaluation must consider susceptible subpopulations." *See* PMSJ at 13. With respect to fetal exposure, Plaintiffs rely primarily on (1) the birth cohort studies, (2) "[s]everal Chinese studies of human fetuses," and (3) Dr. Lanphear's recommendation that pregnant women limit their intake of fluoridated drinking water. The Court's assessment of the birth cohort studies is discussed above. With respect to the Chinese studies of human fetuses exposed to fluoride via maternal intake of contaminated food, Dr. Thiessen reports that

"[h]ousehold use of coal in parts of China results in fluoride contamination of air and food." Docket No. 117-1 at 36. This fact means that "the potential confounding of other chemicals in polluted air limits the conclusions that can be drawn from the human fetal brain studies," which reduces the persuasive power of this evidence. *Id.* Finally, Dr. Lanphear recommends that pregnant women limit the amount of fluoridated water that they drink. PMSJ at 8. This recommendation is based on the results on the birth cohort studies. Plaintiffs' Reply in Support of Motion for Summary Judgment ("P. Reply") at 3, Docket No. 126-1. While Dr. Lanphear's recommendation provides support to Plaintiffs' case, it does not—as is required at the summary judgment stage—constitute "undisputed facts" that entitle Plaintiffs to summary judgment. *Cabo Distrib. Co.*, 821 F. Supp. at 607.

Regarding postnatal infant exposure, Plaintiff's Motion asserts the following: (1) that "infants receiving formula made with fluoridated water ingest roughly 100 times more fluoride than an exclusively breastfed baby," PMSJ at 13–14; (2) "that infants drinking formula made with fluoridated water can exceed EPA's reference dose (0.08 mg/kg/day) for severe dental fluorosis," *id.* at 14; and (3) "that infancy is a 'period of sensitivity' for neurotoxicity . . . because it is 'a period of rapid development of the nervous system' without the protection of a fully developed blood brain barrier," *id.* at 14. With respect to the relative exposure for formula- and breastfed babies, "a breastfed baby receives virtually no fluoride," so this comparison does not afford much support to Plaintiffs' position. *See* Deposition of Edward Ohanian, Ph.D. at 257–58, Docket No. 117-1, Exh. 2. With respect to points (2) and (3), the evidence makes clear that infant brains are particularly vulnerable because of the absence of a blood-brain barrier and that infants who drink formula made with tap water from fluoridated areas may exceed the reference dose for dental fluorosis. While these facts, in conjunction with findings from several of the studies cited by Plaintiffs, could be sufficient to permit an inference that water fluoridation poses an unreasonable risk of neurotoxic harm to infants, they are insufficient to prove that point as a matter of law. For example, Dr. Thiessen acknowledges both that "studies have not yet specifically addressed the impact on IQ of feeding formula prepared with fluoridated water" and that preliminary evidence of potential associations "could, in principle, be due to [numerous other factors]." Report of Dr.

Kathleen Thiessen ("Thiessen Report") at 54–55, Docket No. 117-1, Exh. 6.

Because summary judgment is only appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law," Fed. R. Civ. P. 56(a), Plaintiffs here are not entitled to summary judgment. Although factual certainty is not required, Plaintiffs have failed to demonstrate that no reasonable jury could find that EPA is entitled to a verdict in its favor, particularly where—at this stage—the evidence must be viewed in the light most favorable to the nonmoving party and all justifiable inferences are to be drawn in the nonmovant's favor.

D. Defendant's Motion for Summary Judgment

In their Motion for Summary Judgment, EPA argues both that Plaintiffs have failed to comply with TSCA's procedural and methodological requirements for risk evaluation and science-based decisions and also that Plaintiffs' evidence fails to demonstrate unreasonable risk. DMSJ at 1–2. For several reasons—including (1) the fact that Sections 6(b) and 26 are not directly incorporated into Section 21 (although their provision may be looked to for guidance), (2) uncertainty pertaining to the amount of deference to be given to the Agency's interpretation of "weight of the scientific evidence," and (3) the fact that the definition of "systematic review" contained that interpretation is not so clear that the Court can presently determine whether Plaintiffs conducted the functional equivalent of such a review—the Court finds it inappropriate to resolve this matter on summary judgment. For these reasons, the Court **DENIES** the Agency's Motion for Summary Judgment.

1. Procedural and Methodological Requirements

Turning first to EPA's procedural and methodological challenges, the EPA contends that Section 26 and Section 6(b) govern the Court's risk determination in a case brought under Section 21. Section 6(b)(4)(B) and (F) and section 26(h) and (i) set out processes, standards, and guidelines for determining whether an "unreasonable risk" exists with respect to a particular substance. 15 U.S.C. § 2605(b)(4)(B) and (F); 15 U.S.C. § 2625(h) and (i). Section 6(b)(4)(B) directs the administrator to "establish, by rule, a process to conduct risk evaluations." 15 U.S.C. § 2605(b)(4)(B). In relevant part, Section 6(b)(4)(F) directs the Administrator (for the purpose of

conducting risk evaluations) to:

> (i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;
>
> (ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration;
>
> (iii) not consider costs or other nonrisk factors;
>
> (iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and
>
> (v) describe the weight of the scientific evidence for the identified hazard and exposure.

15 U.S.C. § 2605(b)(4)(F). Section 26, in relevant part, states that the Administrator shall (in carrying out sections 4, 5, and 6), "to the extent that the Administrator makes a decision based on science," use "scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable":

> (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
>
> (2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;
>
> (3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;
>
> (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
>
> (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

15 U.S.C. § 2625(h). Section 26 also states: "The Administrator shall make decisions under

sections 4, 5, and 6 based on the weight of the scientific evidence." *Id.* § 2625(i).

Defendants contend that "TSCA's statutory scheme sets forth substantive requirements applicable to determining whether a chemical substance presents an unreasonable risk under the conditions of use," and that Sections 6 and 26 should apply to determinations about risk made pursuant to Section 21. DMSJ at 7. While Plaintiffs do not specifically address the applicability of Section 26, they do dispute the applicability of Section 6 to citizen petitions. Plaintiffs argue that "Section 21 is independent of the Section 6(b) risk evaluation process." P. Opp. at 17 (internal quotation marks omitted). Plaintiffs further assert: "The only requirement that Congress imposed for *de novo* proceedings is that the petitioner 'demonstrate[] to the satisfaction of the court by a preponderance of the evidence' that an unreasonable risk exists. Congress left it to the courts to determine what preponderance of the evidence means in any given case." *Id.* at 18 (quoting 15 U.S.C. § 2620(b)(4)(B)).

Turning first to the applicability of Section 6(b), the Court addressed an aspect of this issue in its previous order. *See* Docket No. 42. At issue in the Court's prior order was whether Plaintiffs were required to identify *all* conditions of use for a chemical substance in their petition. The Court determined that Plaintiffs were *not* required to identify all conditions of use in their petition, and in so holding stated:

> The text of Section 21 imposes only a procedural requirement that a petition must be filed with the Administrator and a substantive requirement that the petition "set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under section 2603, 2605, or 2607 of this title or an order under section 2603 or 2604(e) or (f) of this title." *See* 15 U.S.C. §2620(b)(1). Section 21 does not explicitly impose any other substantive requirements for the administrative petition. *Cf. Trumpeter*, 774 F.3d at 1039 (holding that pre-amendment Section 21 imposes only same two statutory requirements on petitioners, and that satisfying those requirements entitles a petitioner to judicial review in case of denial). Additional substantive requirements, if any, could arise therefore only through Section 21's incorporation of Section 6.

Docket No. 42 at 14. The Court then went on to explain: "Section 21 refers only generally to Section 6; it does not specifically refer to Section 6(b). That general reference to Section 6 cannot reasonably be read to import the entire risk evaluation process into Section 21." *Id.* at 15–16; *see also id.* at 16 ("Indeed, Section 21's judicial review provision 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.* ("Section 21 governs the third pathway, one that appears to be independent of the Section 6(b) risk evaluation process.").

Thus, by the text of the statute, the only procedural requirement imposed by Section 21 is that petitions must be filed with the Administrator, while the only substantive requirement is that the petition "set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under section 2603, 2605, or 2607 of this title or an order under section 2603 or 2604(e) or (f) of this title." *See* Docket No. 42 (citing 15 U.S.C. §2620(b)(1)). Section 21 does not explicitly impose any other substantive requirements on the submission of a citizen petition. Thus, while there are several important policy reasons to borrow the requirements of Sections 6 and 26 in adjudicating the citizen petition process outline by Section 21 (see discussion below), the plain text of Section 21 does not explicitly incorporate those sections.

Because a petitioner is not required to comply with the processes and criteria outlined in Sections 6 and 26 when submitting a petition pursuant to Section 21, the Court declines to grant summary judgment for Defendant on the basis of Plaintiffs' failure to comply with all the requirements set forth in Sections 6 and 26 of TSCA. However, the Court does heed EPA's contention that "even if the Court's risk determination were not bound by those statutory requirements . . . they are instructive because they reflect the most up-to-date generally accepted scientific practices for assessing risk in the TSCA context." DMSJ at 9. The EPA's position is supported by the logic of the TSCA's structure and policy concerns.

First, in determining whether to apply the requirements of Section 6(b) to Section 21, the Court notes that the language explaining risk evaluation in Section 6 is nearly identical to the language in Section 21. *See Air Wisconsin 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."). Both Sections say that the purpose of a risk evaluation is:

> to determine 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. §2620(b)(4)(B)(ii); 15 U.S.C. 2605(b)(4)(A). However, Section 6 adds "identified as relevant to the risk evaluation by the Administrator" between "susceptible subpopulation" and "under the conditions of use." Since the two sections of the statute define the purpose of risk evaluation in the same way, it makes sense that Congress would have intended the relevant risk evaluation processes and criteria to be similar.

Second, EPA notes: "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)." *Id.* That is to say, EPA could end up in a situation where it is forced to make down-stream decisions about regulating fluoride despite the fact that the best available science and/or weight of the scientific evidence under its more rigorous analysis indicates that the substance does *not* actually pose an unreasonable risk.

Third, requiring citizen petitioners to comply with the standards set forth in Sections 6 and 26 coheres with Section 21. Because Section 21 requires the petitioner to "set forth the facts which it is claimed establish that it is necessary" for EPA to issue a rule, 15 U.S.C. § 2620(b)(1), and also requires the EPA to act on a petition within 90 days, *id.* at § 2620(b)(3) (as compared with the three-and-a-half years the Agency has to complete a *sua sponte* risk evaluation, *id.* at § (b)(2)(B)), it is reasonable to conclude that a petitioner is required to provide the EPA with all of the facts needed to review the petition and reach a decision that is consistent with the overall statutory scheme.[4] If Congress has required EPA to make decisions based on the weight of the scientific evidence (which EPA has defined as a systematic review method, *see* 40 C.F.R. § 702.33 ("Weight of scientific evidence means a systematic review method")) and consistent with

[4] That some aspects of Section 6(b) may be inapplicable to Section 21 – such as its requirement that the petitioner must address *all* conditions of use (Docket No. 42 at 18) – does not prevent the Court from looking to the standards of assessing the evidence under Rule 6(b) where to do so ensures a coherent relationship between Section 6(b) and 21.

the best available science, it is not unreasonable to believe that it should be evaluating citizen petitions using those same yardsticks. Thus, given the short timeline that the EPA has to respond to citizen petitions, *see* 15 U.S.C. § 2620(b)(3), it is not unreasonable to think that the petitioner could be tasked with producing substantial information consistent with or akin to the requirements of Sections 6(b) and 21.

Related to the broader question whether these sections of the TSCA apply to Section 21 is the specific question whether Plaintiffs were required to conduct a "systematic review" of the existing studies and evidence and present that review as part of their petition. As noted above, Section 26 directs the Administrator to "make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence." *Id.* § 2625(i). Section 6(b) also directs the Administrator to "describe the weight of the scientific evidence" in conducting a risk evaluation. *Id.* § 2605(b)(4)(F). EPA has defined "'[w]eight of the scientific evidence' [to] mean[] 'a systematic review method that uses a preestablished protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.'" Defendants' Opposition to Plaintiffs' Motion for Summary Judgment ("D. Opp.") at 9 n.6 (citing 40 C.F.R. § 702.33; 162 Cong. Rec. S3518 (daily ed. June 7, 2016)), Docket No. 119; *see also* DMSJ at 14–15 (making same assertion and citing same sources). This is relevant because Plaintiffs appear not to have conducted a systematic review – although they allege (1) that their experts did not need to because of their familiarity with the landscape of existing studies, and (2) that they conducted the equivalent of a systematic review. P. Opp. at 18.

However, as noted above, Section 21 does not, by its text, expressly incorporate the requirements of Sections 6 and 26 (and the interpretation regulation, 40 C.F.R. § 702.33). Even if it did, it is not clear how much weight should be given to the Agency's definition of "weight of the scientific evidence" under the regulation. The Court was unable to find, and the parties have not provided, any case law equating the phrase "weight of the scientific evidence" with "systematic review," or otherwise addressing the regulation. Furthermore, although the regulation goes into

some detail in describing what "a systematic review method" means, *see* 40 C.F.R. § 702.33, the definition is not so clear that the Court can readily discern that Plaintiffs' expert did not, as a matter of law, conduct the functional equivalent of a systematic review.

Accordingly, summary judgment cannot be granted to the EPA on this basis.

2. Evidence of Harm

Defendants contend that Plaintiffs, through their experts, "fail to identify or demonstrate an actual observable effect at or below 0.7 mg/L (the relevant point of exposure to fluoridation chemicals in the United States)" and therefore that their "claim fails as a matter of law." DMSJ at 10–11. As an initial matter, Plaintiffs dispute that "an unreasonable risk determination for a given condition of use requires proof of harm at the level of exposure associated with the use." Plaintiffs' Opposition to Defendant's Motion for Summary Judgment ("P. Opp.") at 11, Docket No. 127-1. However, even assuming this dispute was resolved in Defendant's favor (*i.e.* determining—for the sake of argument—that Plaintiffs must demonstrate an actual observable effect at or below 0.7 mg/L), it is impossible to say that no reasonable juror could find that Plaintiffs are entitled to a verdict in their favor. While it is not the EPA's burden to "demonstrate the absence of any risk altogether," D. Opp. at 1, in order to prevail on their motion for summary judgment, the Agency must point to Plaintiffs' failure "to make a showing sufficient to establish the existence of an element essential to [the plaintiff's] case." *Celotex*, 477 U.S. at 322. EPA attempts to make this showing by challenging the expert opinions offered by Drs. Kathleen Thiessen and Philippe Grandjean. *See* DMSJ at 9.

With respect to Dr. Grandjean's conclusions, EPA argues (1) that he "failed to explain why Green 2019 is consistent with or relevant for the purpose of extrapolating a dose-response" and that he "conceded that his benchmark-dose levels are estimates based on assumptions in the linearity and [Gaussian] distribution," D. Opp at 11, (2) that he "conceded that calculating a benchmark dose was outside the scope of his expertise by testifying, 'I decided I would rather have the chairman of biostatistics be responsible for [the calculations] because he is a world expert on benchmark dose. I wouldn't trust myself,'" *id.* at 12, and (3) that he utilized "an uncertainty factor of ten without providing a rationale for assignment of this uncertainty factor," *id.* However,

there is evidence in the record that suggests that none of these objections are sufficient to find for Defendant as a matter of law. For example, the birth cohort studies, *see e.g.*, Bashash 2017, Bashash 2018, and Green 2019, in conjunction with the findings from the recent study of pregnant women in California, *see* California Study *supra* Section III.C.3, raise genuine issues of material fact that make summary judgment for the EPA inappropriate even under the rigorous scientific modes embraced by Rules 6(b) and 26. Because the Court finds that there are questions of fact that make summary judgment for the EPA inappropriate, it need not reach EPA's specific arguments pertaining to Dr. Thiessen's report or any other evidence of neurotoxic harm presented by Plaintiffs as failing to meet the rigorous standards of Rules 6(b) and 26.

Accordingly, the Court **DENIES** Defendants' Motion for Summary Judgment.

IV. CONCLUSION

For the foregoing reasons, the Court **DENIES** Plaintiffs' Motion for Summary Judgment and Defendant's Motion for Summary Judgment.

This order disposes of Docket Nos. 116 and 117.

IT IS SO ORDERED.

Dated: December 30, 2019

EDWARD M. CHEN
United States District Judge

United States District Court
Northern District of California