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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' OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND PARTIAL SUMMARY JUDGMENT

Date: November 7, 2019
Time: 1:30 p.m.
Place: Courtroom 5, 17th floor

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INTRODUCTION

"The dose makes the poison" is a five-hundred-year-old adage in toxicology meaning that any substance—even water and oxygen—can be toxic if too much is ingested or absorbed into the body. This case is about dose. Fluoride, like many substances, can cause adverse neurotoxic effects, but at higher concentrations than the recommended concentration for reducing the risk of tooth decay of 0.7 milligrams per liter (mg/L) used in community water fluoridation programs in the United States. Adverse effects from exposure to fluoride at high doses does not alone demonstrate unreasonable risk under the Toxic Substances Control Act ("TSCA"). Instead, Plaintiffs must demonstrate, consistent with TSCA's risk-evaluation and scientific-standards requirements, an actual presence of neurotoxic harm at 0.7 mg/L before the Court can determine whether adding fluoridation chemicals to reach a concentration of 0.7 mg/L presents an unreasonable risk. As explained in EPA's Motion for Summary Judgment, ECF No. 116 ("EPA Br."), Plaintiffs cannot make such a showing.

Throughout their brief, Plaintiffs unsuccessfully attempt to demonstrate unreasonable risk by cherry-picking general precautionary principles from EPA documents in lieu of explaining the necessary scientific considerations for conforming to TSCA's standards. In doing so, they misstate TSCA's risk standard and try to bypass TSCA's statutory requirements for determining unreasonable risk in substance and process. Plaintiffs and their experts provide a superficial and overly simplistic risk-assessment outline without offering or explaining how their experts' opinions conform to TSCA's requirements for risk evaluation. Moreover, Plaintiffs attempt to shift their burden by arguing that EPA must demonstrate the absence of any risk altogether by staging an improper collateral attack on standards set under the Safe Drinking Water Act.

But even if the Court disagrees that Plaintiffs must demonstrate risk under the substantive requirements of TSCA, there are issues of material fact that must be resolved at trial. Additionally, Plaintiffs have not shown as a matter of law that health benefits are a nonrisk factor barred from consideration in TSCA risk evaluations. Finally, Plaintiffs' argument that EPA has not offered evidence to support a request to delay the rulemaking process is without support and, not ripe for resolution. For the reasons set forth herein, and those set forth in EPA's Motion for Summary

Judgment, Plaintiffs' Motion for Summary Judgment must be denied and judgment entered in favor of EPA.

BACKGROUND

EPA set out the factual and statutory background in this matter in its Motion for Summary Judgment. *See* EPA Br. 2–6. EPA will not reiterate that background here and adds the following.

EPA's *Guidelines for Neurotoxicity Risk Assessment*[1] were designed in 1998 to guide EPA's evaluation of substances that are suspected to cause neurotoxicity, in line with substantive standards established in the statutes administered by the Agency. 1998 Guidelines iv. "In particular, the Guidelines emphasize that risk assessments will be conducted on a case-by-case basis, giving full consideration to all relevant scientific information. This approach means that Agency experts study scientific information on each chemical under review and use the most scientifically appropriate interpretation to assess risk." *Id.* These general guidelines on neurotoxicity risk assessment preceded the 2016 TSCA amendments, which included revisions to the process used for assessing risk. The 1998 Guidelines set forth methodologies for conducting and evaluating neurotoxic risk assessments based on the scientific thinking in 1998. 1998 Guidelines 1. But risk-assessment principles have evolved. Since 1998, the National Academy of Sciences ("NAS") and the National Research Council ("NRC") expanded scientifically accepted risk-assessment principles, placing equal emphasis on fully characterizing the scope, uncertainties, limitations, and strengths of risk assessments.

In addition to the "risk characterization" step described in the 1998 Guidelines, TSCA, as amended, now requires an additional step that entails weighing a variety of factors to determine whether the chemical substance, under the conditions of use, presents an unreasonable risk of injury—this is referred to as the "risk determination" step in the TSCA risk-evaluation process. *E.g.*, Henry Decl. ¶ 21 (Oct. 8, 2019), ECF No. 116-2; Henry Dep. 269:16–17 (Aug. 20, 2019),

[1] Plaintiffs attached as Exhibit 33 to their opening brief excerpts of the guidelines, which are cited herein as "1998 Guidelines."

Exhibit 2.[2] Those factors include, but are not limited to: the effects of the chemical substance on health and human exposure to such substance under the conditions of use; the population exposed (including any potentially exposed or susceptible subpopulations); the severity of hazard (the nature of the hazard, the irreversibility of hazard); and uncertainties. *See* 82 Fed. Reg. 33,734–35; Henry Decl. ¶ 23. After overwhelming public comment supporting this approach, EPA's Risk Evaluation Rule did not define "unreasonable risk." *See* 82 Fed. Reg. 33,276, 33,734–35 (July 20, 2017); EPA Br. 5; Henry Decl. ¶ 22. This is because defining specific risk measures for use in all risk evaluations would be inappropriate to capture the broad set of health and environmental risk measures and information that might be relevant to chemical substances. 82 Fed. Reg. 33,734–35; Henry Decl. ¶ 22. In addition, a single definition would not account for the number of different risk-characterization approaches or for changes in the scientific understandings of chemical hazards, exposures, and risk. *Id.*

While the 1998 Guidelines continue to provide a framework for science policy decision making in risk assessment, "fit-for-purpose risk evaluations" under TSCA must use modern methodologies to systematically weigh the scientific evidence, taking into account exposures under the conditions of use. The concept of "fit-for-purpose risk evaluations" provides the flexibility to refine, as necessary, the process for evaluating risk using assumptions, uncertainty factors, and models or screening methodologies given the nature of the evidence, for the conditions of use. 82 Fed. Reg. 33,726, 33,739–40 (July 20, 2017). Important to Congress was ensuring that risk evaluations use an open and transparent *process* "to justify fair and objective decision making." 162 Cong. Rec. S3522 (daily ed. June 7, 2016).

STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 56(a), Plaintiffs' motion must be denied unless they "show[] 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); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). In considering the motion, "[t]he [C]ourt does not resolve disputed questions of fact or

[2] Unless otherwise indicated, all exhibits are attached to the accompanying Adkins Declaration.

credibility" and must "draw all inferences and view all evidence in the light most favorable to the nonmoving party." *Welenco, Inc. v. Corbell*, 126 F. Supp. 3d 1154, 1161 (E.D. Cal. 2015).

ARGUMENT

I. PLAINTIFFS HAVE NOT PROFFERED ANY EVIDENCE TO MEET THEIR BURDEN OF SHOWING THAT ADDING FLUORIDATION CHEMICALS TO DRINKING WATER POSES AN UNREASONABLE RISK OF NEUROTOXIC INJURY.

EPA does not bear the burden to show the absence of risk regarding the practice of adding fluoridation chemicals to water. Plaintiffs brought this case pursuant to TSCA section 21(b)(4) to seek judicial review of EPA's denial of an administrative petition under TSCA section 21(a) to initiate a proceeding for a rulemaking to prohibit the addition of fluoridation chemicals to water "on the grounds that this use of fluoride presents an unreasonable risk of neurologic harm." Pls.' Br. 1, ECF No. 117. Under TSCA section 21, a petitioner must establish, by a preponderance of the evidence, that the chemical substance that was the subject of the underlying petition presents an unreasonable risk of injury to health, without consideration of costs or other nonrisk factors, under the conditions of use. *See* 15 U.S.C. § 2620(b)(4)(B)(ii). Thus, the burden is on Plaintiffs to show the requisite nexus between the practice of adding fluoridation chemicals to drinking water to reach a recommended optimal concentration for reducing the risk of tooth decay of 0.7 mg/L and neurotoxic injury.

Here, Plaintiffs cannot meet their burden. The evidence that Plaintiffs proffered does not meet the minimum scientific and statutory standards that TSCA requires for evaluating risk, and judgment must be entered in favor of EPA. *See* EPA Br. Part I(B)–(C).

A. The Applicable Standard Under TSCA is "Unreasonable Risk Under the Conditions of Use."

The risk standard to be applied under TSCA is "unreasonable risk . . . under the conditions of use," 15 U.S.C. § 2620(b)(4)(B)(ii); 162 Cong. Rec. S3522 (daily ed. June 7, 2016), not as Plaintiffs assert, "unacceptable risk." The goal of "risk characterization" is to compare toxicity levels with exposure doses to determine if risk may occur under a specific scenario. A Margin of

Exposure ("MOE")—a quantitative calculation for comparing toxicity to exposure—is just one of several approaches to risk characterization. While EPA will generally employ the MOE approach to characterize risk under TSCA, there is no statutory or regulatory *requirement* for doing so. 82 Fed. Reg. 33,735. More importantly, however, under the amended TSCA, risk characterization is not the end of the inquiry. Meaning, an MOE, should that approach be fit-for-purpose in any given risk characterization, must then be weighed against other factors in the risk-determination step of TSCA's risk-evaluation process. *See supra* p. 2–3. Without any explanation or support, Plaintiffs incorrectly state throughout their brief that the standard established for assessing risk under TSCA is "unacceptable" risk, presumably, as measured under an MOE approach. Plaintiffs again ignore TSCA's process requirements for evaluating "unreasonable risk"—the applicable statutory standard. But even so, Plaintiffs also fail to offer a factual predicate from which the Court can draw a reasonable inference of "unacceptable risk" using the MOE approach.

1. The applicable legal standard is unreasonable risk on the basis of the risk-evaluation process and scientific standards of TSCA.

Congress identified the minimum criteria to be considered as part of a risk evaluation, 15 U.S.C. § 2605(b)(4)(F), while also requiring that decisions based on science be consistent with the best available science using a weight of the scientific evidence approach, *id.* § 2625(h), (i). *See* 162 Cong. Rec. S3522 (daily ed. June 7, 2016). As directed by Congress, EPA codified a risk-evaluation process that includes the specific criteria and scientific standards required by law. *See* Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act ("Risk Evaluation Rule"), 82 Fed. Reg. 33,726; *see* 15 U.S.C. § 2605(b)(4). Also, as directed by Congress, EPA developed guidance in June 2017 setting forth, at a minimum, the "quality of the information submitted and the process to be followed in developing draft risk evaluations." 15 U.S.C. § 2625(*l*)(5).[3] Missing from Plaintiffs' Motion for Summary Judgment (and generally from their expert reports) is reference to either the Risk Evaluation Rule or the Risk Evaluation

[3] A copy of the guidance was attached as Exhibit 3 to EPA's Motion for Summary Judgement and is referred to herein as "Risk Evaluation Guidance."

Guidance. Instead, Plaintiffs argue that application of the 1998 Guidelines demonstrates an "unacceptable risk."

Even if Plaintiffs could demonstrate "unacceptable risk" under the 1998 Guidelines—they cannot—the substantive legal standard under TSCA, as amended, is a determination of unreasonable risk on the basis of the risk-evaluation process and the scientific standards required by the statute. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); EPA Br. 7–9.

While Congress did not define "unreasonable risk," it provided that the risk-evaluation *process* established by EPA "shall" provide the basis "to determine whether a chemical substance presents an unreasonable risk of injury to health . . . without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." 15 U.S.C. § 2605(b)(4)(A)–(B). This language tracks nearly verbatim Plaintiffs' burden here. *See* 15 U.S.C. § 2620(b)(4)(B)(ii). "[I]t 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." *Air Wis. Airlines Corp. v. Hoeper*, 571 U.S. 237, 248 (2014) (internal quotation marks omitted). Thus, the risk-evaluation *process* established by EPA "shall" provide the basis for determining risk, be it by EPA under section 6 or by this Court under section 21.

2. The case law does not change TSCA's legal standard to "unacceptable risk."

Plaintiffs assert that courts have defined "unacceptable risk" using an MOE approach under *other* health-protective statutes. Pls.' Br. 17. While both the Ninth Circuit and the Second Circuit describe the MOE method in the context of different regulatory and statutory provisions *requiring* its use, Plaintiffs offer no context for how these cases may be relevant to a risk evaluation conducted under TSCA, especially given that there is no such requirement for characterizing risk under TSCA.

In *Natural Resources Defense Council v. U.S. Environmental Protection Agency*, 735 F.3d 873 (9th Cir. 2013), the Ninth Circuit found that EPA's determination of "no risk" was arbitrary and capricious because it was inconsistent with EPA's stated assumptions in a rule for assessing risk from certain treated textiles under the Federal Insecticide, Fungicide, and Rodenticide Act. 735 F.3d at 884. In *Natural Resources Defense Council v. U.S. Environmental Protection Agency*, 658 F.3d 200 (2d Cir. 2011), the Second Circuit held that EPA's failure to provide an explanation for its decision not to use a tenfold children's safety factor in its margin of exposure calculation was arbitrary and capricious because such an explanation was required under the Food Quality Protection Act of 1996. 658 F.3d at 201. Because there is no statutory or regulatory requirement for employing the MOE approach under TSCA, these cases are inapposite.

B. Plaintiffs Cannot Demonstrate a Dose-Response Relationship for Characterizing Risk.

EPA agrees that Plaintiffs do not have to offer "conclusive proof" of actual harm, as they assert. Pls.' Br. 1. Rather, because fluoridation chemicals are only used to increase fluoride concentrations up to 0.7 mg/L, Plaintiffs must demonstrate the presence of harm, within a reasonable degree of scientific certainty, at an identifiable dose before the Court can consider whether *use* of fluoridation chemicals for that purpose presents an unreasonable risk. Plaintiffs cannot make such a showing because the opinions offered by their experts are not supported under TSCA in either process or substance.

1. Plaintiffs failed to proffer a dose-response or risk characterization based on the best available science.

Beyond identifying hazard, establishing a dose-response relationship is critical for characterizing and then determining risk because it demonstrates how the health effect (the response) is related to the amount of exposure to a chemical substance (the dose provided). Henry Decl. ¶ 16. The exposure assessment, in turn, measures or estimates the intensity, frequency, and duration of human exposure. *Id.* ¶ 17. Next, the risk characterization combines the exposure and dose-response assessments to characterize the risk of a health effect under the conditions of use. *Id.* ¶ 19. As required by TSCA, a weight of the scientific evidence approach forces transparency

in choosing the information or studies that are "fit-for-purpose" in each assessment. 15 U.S.C. § 2625(i); *see also* 15 U.S.C. § 2605(F) (requiring integration of the available information on hazards and exposures). For example, while Choi et al. 2012, a study on which Plaintiffs' experts rely, *see* EPA Br. 15, may be useful in identifying a hazard at a certain level of exposure, the authors caution that the "review cannot be used to derive an exposure limit, because the actual exposures of the individual children are not known."[4] Choi et al. 2012, at 1366, Exhibit 4. More broadly, weight of the scientific evidence is a relatively new and complex area of science, the purpose of which is to integrate all of the available science after doing a careful analysis of the strengths and weaknesses in the data. *See* Thayer Dep. 94:23–95:19 (May 17, 2019), Exhibit 1.

Plaintiffs ignore this substantive requirement and instead argue that their MOE approach, based on studies they simply deem as relevant, demonstrate an "unacceptable" risk, entitling them to summary judgment. Pls.' Br. 18–21. Plaintiffs' approach is contrary to TSCA's substantive requirements and also fails to satisfy modern methodologies for assessing risk. As EPA Director of the Integrated Risk Information System ("IRIS") Division Dr. Kristina Thayer[5] explained:

> There are very sophisticated statistical methods to try to integrate across human studies . . . that were probably not deployed within the agency even ten years ago. . . . So I would say that again, thinking about something like fluoride, I would think that there would be that kind of thought process that if you have all these human studies available, you are probably not—you really wouldn't want to pick one. You would want to explore your ability to quantitatively integrate across the available studies after doing a careful analysis of their strengths and weaknesses.

Thayer Dep. 94:13–95:19.

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[4] When Dr. Philippe Grandjean was asked, "[Y]ou say in the Choi study that you can't extract a dose response because of the measurement of fluoride exposure . . . right?," Dr. Grandjean answered, "Yeah. I know. And I agree. Some people would say you could probably do that anyway, but my opinion is we would have to make too many assumptions. So that, let's say, a dose response relationship or benchmark dose, it would be too uncertain to be useful . . . ." Grandjean Dep. 211:11–20 (Sept. 13, 2019), Exhibit 3.

[5] EPA's IRIS Program identifies and characterizes health hazards of chemicals found in the environment independent of EPA's program and regional offices. Previously, Dr. Thayer was co-project lead on the National Toxicity Program's 2016 Systematic Literature Review on the Effects of Fluoride on Learning and Memory in Animal Studies.

None of Plaintiffs' experts attempted to weigh the evidence by conducting a systematic review of the scientific literature concerning potential neurotoxic effects from exposure to water fluoridation chemicals.[6] This fundamental omission is even more glaring after Plaintiffs moved to compel Dr. Thayer's testimony explicitly on the grounds that it was necessary for determining "how EPA establishes the safe dose for neurotoxicants like fluoride [a matter of] obvious relevance to the case, [that] will assist the experts, as well as the Court, in determining whether the doses of fluoride currently added to public water supplies are safe according to EPA's own risk assessment procedures." *See* Third Discovery Letter Brief 2–3, ECF No. 81.

Nor do Plaintiffs present a risk-determination analysis, a required step in risk evaluation under TSCA. Only one of Plaintiffs' experts—Dr. Kathleen Thiessen—even attempted to address the risk-determination step in her analysis.[7] However, it is undisputed that she proceeded under the wrong section of TSCA. EPA Br. 18–20. Dr. Thiessen used EPA's risk-assessment approach and regulatory framework for screening new chemicals under TSCA section 5, not the more robust risk-evaluation criteria for existing chemicals under TSCA section 6. *Id.* Thus, Plaintiffs' conclusion that the addition of fluoridation chemicals to water poses an unreasonable risk of neurotoxic injury is not supported. *Id.* at 20.

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[6] Weight of the scientific evidence" means "a systematic review method that uses a pre-established 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." *See* 40 C.F.R. § 702.33; 162 Cong. Rec. S3518 (daily ed. June 7, 2016); EPA Br. 14–15.

[7] Dr. Grandjean included in his report a section entitled, "Economic and societal value of preventing IQ losses." To the extent this section was meant to satisfy the risk-determination step, it fails to do so. Dr. Grandjean described several assumptions, including that "the U.S. population in fluoridated areas have similar urine-fluoride concentrations as Canadians." Grandjean Report 42, EPA Br. Ex. 5. The risk determination step of the risk-evaluation process is past the point of "exposure assumptions" and requires a weighing of the evidence-based conclusions reached in the earlier risk-assessment steps.

2. Plaintiffs' experts failed to employ substantive legal requirements for assessing risk under TSCA.

Plaintiffs argue that their experts "assessed the neurologic risk of fluoridation chemicals in three separate and distinct ways," Pls.' Br. 23, but made no attempt to explain why the opinions of Drs. Bruce Lanphear, Grandjean, or Thiessen demonstrate, as a matter of law, that fluoride presents an unreasonable risk. Rather, they demonstrate why EPA is entitled to judgment. EPA addresses each in turn.[8]

a. Bruce Lanphear

Dr. Lanphear was the co-principal author of a prospective birth cohort study using information from the Maternal-Infant Research on Environmental Chemicals ("MIREC") cohort in Canada.[9] Green 2019 studied whether maternal fluoride exposure during pregnancy was associated with IQ scores in the offspring in the MIREC cohort. The authors found in that Canadian birth cohort that fluoride exposure during pregnancy was associated with lower IQ scores in children aged 3 to 4 years. But Green 2019 does not, on its own, demonstrate unreasonable risk.

Dr. Lanphear did not systematically review the available literature assessing fluoride exposure and potential neurotoxic effects, he did not identify a dose-response for fluoride, and he did not characterize the risk—all necessary steps for evaluating risk under TSCA. Thus, the opinion offered by Dr. Lanphear based on his individual research does not establish, without more, that fluoride presents an unreasonable risk under the conditions of use. As Dr. Thayer noted: In

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[8] Plaintiffs rely upon several of their experts' reports. Pls.' Br. Ex. 3 (Thiessen report); Pls. Ex. 16 (Grandjean reports); Ex. 30 (Fejerskov report); Pls. Ex. 46 (Wells report). EPA objects to these expert reports as inadmissible hearsay under well-established precedent. *See Paddack v. Dave Christensen, Inc.*, 745 F.2d 1254 (9th Cir. 1984); *Arizona v. Asarco, LLC*, 844 F. Supp. 2d 957 (D. Ariz. 2011) (party's own expert reports are "classic" examples of hearsay). As such, the Court cannot consider the reports on summary judgment. EPA's reliance on Plaintiffs' expert's reports in its Motion for Summary Judgement is permissible because Plaintiffs have adopted the reports, and, therefore, the reports constitute admissions of a party opponent. Defendants further object to Plaintiffs' reliance on a podcast, Connett Decl. ¶ 52, another form of inadmissible hearsay. *James Stewart Ent'mt, LLC v. L&M Racing*, LCC, No. EDCV 12-0049-JGB, 2014 WL 12742612 (C.D. Cal. Mar. 27, 2014). Much of Plaintiffs' remaining evidence is irrelevant, and EPA reserves all evidentiary objections to be raised at a later date.

[9] Association Between Maternal Fluoride Exposure During Pregnancy and IQ Scores in Offspring in Canada, JAMA Pediatrics (2019) [hereinafter, "Green 2019"], EPA Br. Ex. 10.

epidemiology a prospective cohort study is an "ideal study design, but that study design on its own does not mean that every prospective cohort study is going to automatically be high quality" for its intended purpose. Thayer Dep. 163:19–23.

Using a weight of the scientific evidence approach is not just a matter of measuring the design and rigor of the methodologies employed in the individual studies, but also allows for the identification of consistencies and inconsistencies in the findings of those studies based upon the metrics being tested. In other words, individual studies can create or close gaps within the literature for understanding the hazard and identifying a dose-response. For example, Green 2019 observed heterogeneous results between boys and girls, whereas Bashash, et al. 2017, EPA Br. Ex. 7, studying a similar metric in a different population, did not. Chang Dep. 283:16–23 (Aug. 29, 2019), Exhibit 5. Because Dr. Lanphear made no attempt to integrate the information from Green 2019 across the existing body of scientific evidence, any opinion on risk is inconsistent with the substantive requirements for assessing risk under TSCA.

b. Philippe Grandjean

By failing to conduct a systematic review, Dr. Grandjean ignored TSCA's requirement, and EPA's guidance, for transparently identifying the best available science. 15 U.S.C. §§ 2625(h), (i), 2605(b)(4). Nevertheless, Dr. Grandjean selected Green 2019 for calculating a benchmark dose ("BMD") for fluoride. Pls.' Br. 18. Dr. Grandjean's benchmark dose calculation is fundamentally flawed on three grounds. First, Dr. Grandjean failed to explain why Green 2019 is consistent with or relevant for the purpose of extrapolating a dose-response, *see* 15 U.S.C. § 2625(h)(1)–(2) (describing the scientific standards to be employed in carrying out section 6). In fact, Dr. Grandjean conceded that his benchmark-dose levels are estimates based on assumptions in the linearity and [Gaussian] distribution. Grandjean Dep. 310:12–13; *id.* at 310:14–15 ("So when the real data are used, maybe the numbers will be slightly different.").

Second, Dr. Grandjean asserted that his BMD modeling is based on urinary fluoride concentrations, not the concentration of fluoride in drinking water. *See* Grandjean Dep. 314:11–22. A benchmark dose *can* be based on an "internal dose" or biomarker such as urine concentration, however, a relationship between water ingestion and urinary concentration would need to translate

the urinary concentration (which is correlated to the IQ response) back to a water concentration. *E.g.*, Henry Dep. 354:13–355:5. Dr. Grandjean did not present this translation in his analysis. When asked about the merits of his calculation, Dr. Grandjean 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." Grandjean Dep. 94:19–95:6. "Even where a witness has special knowledge or experience, qualification to testify as an expert also requires that the area of the witness's competence matches the subject matter of the witness's testimony." 29 Wright & Gold, Federal Practice & Procedure: Evidence § 6265 (1997).

Third, Dr. Grandjean divided his BMD by an uncertainty factor of ten without providing a rationale for assignment of this uncertainty factor. Instead, Dr. Grandjean asserted that an uncertainty factor of ten is the default assumption provided for in the 1998 Guidelines. However, the 1998 Guidelines cautioned that "[d]efault assumptions should not be applied indiscriminately." 1998 Guidelines 6. Further, "[t]he size of the final uncertainty factor used will vary from agent to agent and will require the exercise of scientific judgment, taking into account interspecies differences, the shape of the dose-response curve, and the neurotoxicity endpoints observed." *Id.* at 59. Moreover, Dr. Thayer cautioned that "[t]ypically, the preference would be *not* to go to default but to see if there is other information that can help you go from a default to something that's more evidence-based." Thayer Dep. 44:17-21 (emphasis added). In fact, Dr. Grandjean advocates that Green 2019 is evidence-based because it measured responses in children, the most sensitive subpopulation alleged, during what Plaintiffs argue is the critical window of vulnerability, therein contradicting the need for applying any uncertainty factor.

In sum, because Dr. Grandjean failed to integrate across all relevant lines of the scientific evidence, any subsequent attempt to calculate a benchmark dose, assuming Dr. Grandjean could offer competent testimony for such a calculation, is unsupported. Further, without properly calculating a benchmark dose, Dr. Grandjean cannot estimate risk from exposure to fluoridation chemicals under the condition of use. Accordingly, Dr. Grandjean failed to proffer any factual predicate from which the Court can draw an inference of unreasonable risk. *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) ("[I]nferences 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.").

c. Kathleen Thiessen

Like Dr. Grandjean, Dr. Thiessen's dose-response assessment and risk characterization are fundamentally flawed and unsupported by the best available science. Dr. Thiessen hides behind general precautionary principles cherry-picked from EPA's 1998 Guidelines without explaining "the most scientifically appropriate interpretation" for assessing risk under TSCA. *See* 1998 Guidelines 1.

In the most prominent example, Dr. Thiessen noted, "In light of the human data now available, animal data would no longer be the preferred source of the POD [or point of departure] for fluoride neurotoxicity. However, several considerations *could* justify use of animal data to establish an RfD [or reference dose] for fluoride."[10] Thiessen Report 54, Exhibit 6 (emphasis added). Her concession alone demonstrates that her dose-response analysis fails to conform to TSCA's legal requirements for using the best available science. Dr. Thiessen's argument for justifying the use of animal data is simply that EPA has done it before in other contexts. *See id*.; Thayer Dep. 93:22–94:5 (explaining that "it would be a priority to understand what's happening with the human evidence, and if that's where the action is in terms of having the richness of the evidence base to work with, then you could update on the animal evidence, but it's not clear whether it's really going to be as meaningful as the human analysis"). Dr. Thiessen then compounds this error by asserting that, "[a]ccording to the [1998] Guidelines, if data are considered sufficient for risk assessment, and if neurotoxicity is the effect occurring at the lowest dose level (i.e., the critical effect), an oral or dermal RfD, or an inhalation RfC, based on neurotoxic

[10] In toxicology, the POD is the point on a toxicological dose-response curve established from experimental data or observational data generally corresponding to an estimated low effect level or no effect level. The POD marks the beginning of extrapolation to an RfD. The most common POD used to derive an RfD is no-observed-adverse-effect level (or, NOAEL), lowest-observed-adverse-effect level (or, LOAEL"), or statistical benchmark dose. *E.g.*, Thiessen Dep. 222:4–224:6 (Aug. 27, 2019), Exhibit 9.

effects, is then derived." Thiessen Report 28. An RfD calculation measures the likelihood "to be without an appreciable risk of deleterious effects during a lifetime." However, a dose-response assessment fit-for-purpose under TSCA requires a measurement of the likelihood and severity of health effects related to the amount and condition of exposure. Risk Evaluation Guidance 18–19.

Similarly, rather than integrating across all relevant lines of the existing available evidence to conduct an exposure assessment, Dr. Thiessen relied on the NRC's 2006 review ("NRC 2006") fluoride intake estimates. EPA Br. Ex. 1. As EPA's expert Dr. Tala Henry testified, while the NRC is a reliable scientific organization, whether the data should be relied upon for an exposure assessment "would depend very much on what the time period was that they searched for and reviewed." Henry Dep. 326:17–327:1; *see also id.* at 327:2–7 (explaining that there is no reason to believe that the NRC assessment was anything but reliable "at the time it was performed"). In other words, it is inappropriate to rely on NRC 2006 without first doing a careful analysis of the weight of the scientific evidence to determine whether NRC 2006 includes the best available information for measuring exposure today. In any event, because Dr. Thiessen relied on animal data, despite conceding that the human data is the best available science, both her reference-dose assessment and her subsequent risk characterization calculation fail to conform to TSCA's legal requirements for risk evaluation.

Because Plaintiffs cannot proffer any evidence that satisfies TSCA's legal requirements necessary for characterizing and then determining whether adding fluoridation chemicals to water up to 0.7 mg/L presents an unreasonable risk, their claim fails as a matter of law.

C. If the Court Determines that Plaintiffs Can Survive EPA's Motion for Summary Judgment, there are Issues of Material Fact that Prevent Summary Judgment in Favor of Plaintiffs.

If the Court disagrees that Plaintiffs must demonstrate risk under the substantive requirements of TSCA, there are significant issues of material fact that must be resolved at trial.

First, EPA's experts conducted a systematic review of human epidemiological and experimental animal toxicological studies concerning whether there is an association between fluoride exposure and human developmental neurotoxicity. Their reviews were not limited to

"narrow causal analyses" as Plaintiffs argue. Pls.' Br. 23. Rather, EPA's experts conducted broad searches of the scientific literature using predefined and documented criteria and critically evaluated the results of those searches using predefined criteria, as TSCA requires. *E.g.*, Second Chang Decl. ¶¶ 5–18 (Oct. 18, 2019), Exhibit 7; Tsuji Decl. ¶ 8–18 (Oct. 18, 2019), Exhibit 8; EPA Br. Part I(A). EPA's experts' opinions are in contrast to Plaintiffs' experts, none of whom conducted a systematic review, EPA Br. Part I(C)(1), and none of whom addressed numerous studies that EPA's experts identified and considered. *E.g.*, Chang Decl. ¶¶ 9, 13 (Oct. 9, 2019), EPA Br. Ex. C; Thiessen Dep. 320:5–23 (testifying that Dr. Chang "may have" identified studies that she did not).

Second, EPA's experts did not require "conclusive proof" that fluoride causes neurotoxic effects under the condition of use. Pls.' Br. 23. Plaintiffs' citation, without explanation, to various pages of deposition testimony by Dr. Joyce Tsuji support their contention. Rather, the testimony shows at most that Dr. Tsuji and Dr. Chang did not rely on EPA's 1998 Guidelines in their analyses. Tsuji Dep. 41:3–16; 95:1–5 (Sept. 11, 2019), Exhibit 10. EPA does not dispute that fact. But TSCA does not require the application of the 1998 Guidelines. The only explanation Plaintiffs provide for their position that the 1998 Guidelines are controlling here is their misstatement that EPA will use them to evaluate potential neurotoxicity associated with environmental toxicant exposures, "including in risk evaluations under TSCA," Pls.' Br. 16, as if every assessment of a chemical with neurotoxic potential is forevermore bound to follow the 1998 Guidelines. But the 1998 Guidelines say no such thing. Moreover, they were published eighteen years before the 2016 TSCA amendments, which identify, *inter alia*, certain minimum criteria to be considered as part of a risk evaluation. 15 U.S.C. § 2605(b)(4)(F); *see also* EPA Br. 4–6.

In fact, as Dr. Henry testified, EPA explained in its Risk Evaluation Rule, 82 Fed. Reg. 33,726, that prior agency guidance, which would include the 1998 Guidelines, may be considered when performing a risk assessment. Henry Dep. 250:13–21. Dr. Henry also testified, however, that one evaluating the potential neurotoxicity of fluoride should use the guidelines only "to the extent they're applicable." *Id.* at 252:20. And Dr. Henry further testified that one must also consider the "vintage of the guidelines, what newer science has become available since then, what potentially

[superseding] guidance that EPA has, as well as the context, in this case specifically TSCA, context you're conducting a risk assessment." *Id.* at 257:6–12; *see* 1998 Guidelines 1 ("The Guidelines set forth *current* scientific thinking and approaches for conducting and evaluating neurotoxic risk assessments." (emphasis added)).

In any event, even if the 1998 Guidelines were controlling here—they are not—Plaintiffs do not explain in any meaningful way how the opinions of EPA's experts are deficient.[11] Thus, Plaintiffs' strawman argument—that Dr. Tsuji's and Dr. Chang's opinions are somehow inconsistent with EPA's risk-assessment guidance—fails.

Further, Dr. Tsuji testified that rather than performing a "hazard assessment," she "tr[ied] to assess what is the weight of [the scientific] evidence for having dose-response and what is the dose-response at higher versus lower doses." Tsuji Dep. 321:11–17. Although it is not clear why Plaintiffs cite pages of Dr. Chang's deposition testimony comparing different meanings of causation in epidemiology and how the National Toxicology Program ("NTP") uses the term, Pls.' Br. 23 (citing Chang Dep. 123:17–124:17; 125:9–126:17), Dr. Chang's testimony certainly does not support the proposition that her analysis focused on whether there was "conclusive proof" that community water fluoridation causes neurotoxic effects. Even the pages Plaintiffs cited from Dr. Chang's and Dr. Tsuji's expert reports, which summarize their systematic reviews of the epidemiological and toxicological studies regarding fluoride's potential neurotoxic effects in light of the quality and reliability of the scientific literature, do not support Plaintiffs' argument. Evaluating scientific studies based on their methodologies and potential uncertainties (rather than stubbornly ignoring those limitations to reach a preconceived opinion) is required by TSCA's weight of the scientific evidence standards. EPA Br. Part I(A). Thus, Plaintiffs' statement that "EPA's experts abandoned essentially every basic tenet of EPA risk assessment" rings hollow. Pls.' Br. 23.

[11] In contrast, Dr. Henry testified that Plaintiffs' experts failed to conduct certain minimum components that should be included in a risk evaluation and that their opinions regarding unreasonable risk of neurotoxic effects of fluoride are not supported. Henry Decl. 39–64, Ex. B to EPA Br.

Third, Drs. Chang and Tsuji testified to significant limitations in the methodologies and conclusions of the studies on which Plaintiffs rely. With respect to the human studies, the vast majority of the available epidemiological studies of the association between fluoride exposure and human developmental neurotoxicity are of poor quality and insufficient to establish causal effects of fluoride exposure due to their methodological limitations, including their cross-sectional design, high potential for bias, ecological or otherwise non-specific assessment of fluoride exposure, and minimal control for confounding. Second Chang Decl. ¶ 20. Most of the available epidemiological studies were conducted in populations where average fluoride exposure levels were well above those attained through community water fluoridation in the United States, such that their findings cannot reliably be extrapolated to the potential health effects of consuming artificially fluoridated drinking water in the United States. *Id.* ¶ 22. Concerns about editorial and publication bias also undermine the reliability of conclusions based on many of the available published epidemiological studies of fluoride exposure and developmental neurotoxicity. *Id.* ¶ 21. In the past two years, however, the available epidemiological literature has been augmented by higher-quality studies in Western populations with lower levels of fluoride in drinking water. *Id.* ¶ 24. However, the number of such studies is relatively small; methodological uncertainties remain about the assessment of fluoride exposure and neurodevelopmental outcomes; and the reported findings are plausibly explained by confounding, bias, and chance. *Id.* ¶ 25.

Because Drs. Grandjean and Thiessen simply tally the positive findings of hazard in the available experimental animal studies, their analysis depends on overwhelmingly poor-quality studies. Moreover, they downgrade the most rigorously conducted experimental animal study published by the NTP that characterized the potential developmental neurotoxicity of fluoride at doses of relevance to the U.S. population. Tsuji Decl. ¶ 19. In 2016, NTP published a systematic review that identified key data gaps in the available data and the lack of comprehensive, well-conducted studies for assessing the dose-response at relevant human exposures, especially concerning the developmental neurotoxicity of fluoride. *Id.* ¶ 13. Since 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. *Id.* ¶ 16. 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. *Id.* ¶ 17. Plaintiffs' experts failed to fully consider the results of McPherson et al. 2018. *Id.* ¶¶ 20–24. Other studies published after the 2016 NTP review had significant issues of study quality, risk of bias, indirectness for testing learning and memory, and hence reliability for basing conclusions, including serious limitations for quantifying the dose-response of fluoride exposure and developmental neurotoxicity and the consistency of this evidence with the epidemiological studies of cognitive effects in children. *Id.* ¶ 18. Thus, if the Court were to deny EPA's Motion for Summary Judgment, there are issues of material fact that must be resolved at trial.

D. Plaintiffs May Not Base Their Case on an Improper Collateral Attack on EPA's Safe Drinking Water Act Regulations.

Plaintiffs raise an improper collateral attack on EPA's Safe Drinking Water Act ("SDWA") regulations. Pls.' Br. 3–4, 25. While the SDWA, 42 U.S.C. § 300f-300j-26, authorizes EPA to regulate the total amount of fluoride allowed in drinking water using a *safety* standard, TSCA, by contrast, authorizes EPA to regulate the *risk*, if at all, posed by the use of fluoridation chemicals to reach a recommended optimal concentration for reducing the risk of tooth decay of 0.7 mg/L. Plaintiffs incorrectly conflate these clearly distinct statutory schemes and, therein, seemingly attempt to shift their burden of demonstrating unreasonable risk to EPA to demonstrate that the use of fluoridation chemicals is "safe." This is not what TSCA requires.

The safety *goal* ("maximum contaminant level goal" or "MCLG") under the SDWA is set "at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." 42 U.S.C. § 300g-1(b)(4). The SDWA safety *standards* ("maximum contaminant level" or "MCL") must generally be "as close to the [MCLG] as is feasible," 42 U.S.C. § 300g-1(b)(4)(B), taking into account available technology, and cost. 42 U.S.C. § 300g-1(b)(3), (4). By contrast, the *risk* standard applied under TSCA is "unreasonable

risk under the conditions of use," 162 Cong. Rec. S3522 (daily ed. June 7, 2016), without consideration of costs or other nonrisk factors, 15 U.S.C. § 2605(b)(4)(A).

The existing MCLG for fluoride (4 mg/L) is based on a body of scientific literature assessing the health end point of severe skeletal fluorosis. Here, by contrast, Plaintiffs argue that the addition of fluoridation chemicals to water at or below 0.7 mg/L presents an unreasonable risk of "neurologic harm." Pls.' Br. 1. Plaintiffs allege that neurologic harm occurs at a lower dose than EPA's point of departure for severe skeletal fluorosis and, as such, the MCLG does not allow for an "adequate margin of safety." This argument amounts to an inappropriate collateral attack on the SDWA standards.

EPA's rule establishing the recommended maximum contaminant level for fluoride under the SDWA was reviewed and upheld by the United States Court of Appeals for the District of Columbia. *Nat. Res. Def. Council, Inc. v. E.P.A.*, 812 F.2d 721 (D.C. Cir. 1987). There, as here, the petitioners "assail[ed] as arbitrary EPA's failure to take into account numerous other health risks that may be connected with fluoride." *Id.* at 725. The D.C. Circuit disagreed, finding that EPA "gave reasoned explanations for finding that" the existing science "did not convincingly establish a cognizable connection between fluoride in drinking water" and a host of various other health end points. *Id.* Notably, nineteen years later, the 2006 NRC report reaffirmed this finding by indicating that severe enamel fluorosis, clinical stage II skeletal fluorosis, and bone fractures were the only "three toxicity end points for which there were *sufficient relevant data for assessing*" risk. NRC 2006, at 345–46, EPA Br. Ex. 1 (emphasis added).

By offering the same attack on the existing standards for fluoride under the SDWA here—failure to take into account other health risks—Plaintiffs' arguments amount to an unauthorized, and indeed naked, effort to bypass the D.C. Circuit's holding in *NRDC* and the SDWA's judicial review provisions. See 42 U.S.C. § 300j-7(a). The SDWA establishes a detailed statutory scheme that reflects a clear intention to channel proceedings for judicial review into the courts of appeals, rather than the district courts. The text of 42 U.S.C. § 300j-7(a)(1) demonstrates that Congress wished to ensure that challenges calling into question EPA's implementing regulations "pertaining to the establishment of national primary drinking water regulations" would be brought in the D.C.

Circuit within 45 days of the issuance of the regulations.[12] Thus, the SDWA provides the appropriate forum and statute of limitations for challenges to EPA's drinking water regulations of fluoride. Allowing Plaintiffs to "evade the statutory-review process" would be contrary to Congress's intent in establishing that process. *See Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994) (holding that Congress's intent to preclude district court review was fairly discernible from a detailed statutory scheme providing for internal administrative review, followed by judicial review of the final agency decision in the court of appeals). Thus, any attack on the SDWA standards amounts to an improper collateral attack, which is barred by 42 U.S.C. § 300j-7(a). In fact, Plaintiffs argue against EPA's drinking water standard under the SDWA, rather than under TSCA. *See* Pls.' Br. 25. Therefore, to the extent Plaintiffs seek to set aside the SDWA standard, their claim is barred.

II. THE COURT CAN CONSIDER DENTAL HEALTH BENEFITS WHEN DETERMINING WHETHER FLUORIDE PRESENTS AN UNREASONABLE RISK UNDER THE CONDITION OF USE.

TSCA risk evaluations must be conducted for a variety of chemicals, some of which may have health benefits, some of which may not. Although EPA has not yet had occasion to conduct a risk evaluation under the amended TSCA that considered a chemical substance with health benefits, health benefits can, as a matter of law, be part of the risk evaluation. Indeed, in some cases, the absence of a chemical could be characterized as a risk to human health itself, and the presence of a chemical can be characterized as a risk reduction. In other words, when a chemical has direct health benefits, that health benefit can be a risk factor—in effect, the reduction, or cancelling out, of a health risk—instead of a nonrisk factor that can only be considered in risk management.[13]

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[12] The SDWA requires EPA to review and revise, as appropriate, all existing drinking water standards every 6 years, 42 USC 300g-1(b)(9), including fluoride. The most recent review, completed in January 2017, includes a history of fluoride regulation under the SDWA and an analysis of whether revision of the fluoride standard is appropriate. 82 Fed. Reg. 3,518, 3,531–32 (Jan. 11, 2017).

[13] EPA did not address the issue of benefits in its Motion for Summary Judgment because the Court need not reach the issue to rule in favor of EPA and against Plaintiffs.

EPA may consider health benefits this way in the context of risk evaluations under TSCA and in risk assessments more generally. For example, because some metals are important for human health, EPA may consider those health benefits in the overall dose-response relationship when conducting a risk assessment. *See* Office of the Science Advisor, Framework for Metals Risk Assessment 1-10 (March 2007), Exhibit 11 ("Essentiality thus should be viewed as part of the overall dose-response relationship for those metals shown to be essential . . . ."). Congress mandated that EPA use the Framework for Metals Risk Assessment when conducting risk evaluations for metals and metal compounds under TSCA section 6, demonstrating congressional intent that health benefits can be considered during TSCA risk evaluations. *See* 15 U.S.C. § 2605(b)(2)(E). Plaintiffs' argument to the contrary is unsupported.

First, Plaintiffs incorrectly assert that TSCA defines "costs or other nonrisk factors" to include "the benefits of a chemical substance." Pls.' Br. 24 (citing 15 U.S.C. § 2605(c)(2)). In fact, TSCA section 6—upon which Plaintiffs rely—states that risk evaluations conducted by EPA must be made "without consideration of costs or other nonrisk factors."[14] 15 U.S.C. § 2605(b)(4)(A). TSCA, including section 6(c)(2), does not define "costs" or "nonrisk factors." *Id.* Rather, section 6(c)(2) lists certain topics, including "benefits of the chemical substance or mixture for various uses," on which EPA must publish a statement when proposing and promulgating a rule under section 6(a); that provision of TSCA does not define "costs" or "nonrisk factors" to include "benefits" as Plaintiffs' argued. 15 U.S.C. § 2605(c)(2)(A)(iii).

Second, Dr. Henry did not testify that fluoride's health benefits cannot be considered when EPA conducts a risk evaluation. *See* Pls.' Br. 24 (citing Henry Dep. 389:8–13; 390:8–391:5). In fact, Dr. Henry testified that when conducting a risk evaluation, EPA cannot consider the "*economic costs*" of the regulation of fluoride. Henry Dep. 389:8–13. And Dr. Henry, who was not testifying in the capacity of a representative of the EPA, testified that she did not know whether EPA can consider fluoride's *health* benefits. *Id.* at 390:1–7 ("I think benefits can be different things. There's different kinds of benefits and it's not clear to me that health—like if something

[14] Notably, Plaintiffs appear to agree that the Court's risk determination must be based on TSCA's risk-determination standards. Pls.' Br. 24 (citing section 6); *see* EPA Br. Part I(A).

prevents a disease. I'm not sure. I just don't know if that can be considered. It hasn't come up."); *see also id.* at 144:20–145:4 ("[C]ertain things have health benefits and I don't really have the understanding of whether or not that kind of consideration can come [into] play because it does speak to risk. It can.").

Nor did Dr. Henry testify that "costs" or "nonrisk" factors are defined to include "benefits of the chemical substance or mixture for various uses." Pls.' Br. 24 (citing Henry Dep. 383:11–387:3). Rather, Dr. Henry testified that the topics listed in section 6(c)(2)(A) are "for . . . a risk management rule" and that they are "what you can consider in the rulemaking." Henry Dep. 384:17–20. In response to counsel's question about what may be considered in a rulemaking, "And these costs and nonrisk factors include the benefits of the chemical substance or mixture?," Dr. Henry testified, "yes." Counsel's reference to "these costs and nonrisk factors" was to "costs and nonrisk factors that EPA can consider in the risk-management phase." *Id.* at 384:9–13. And in any event, Dr. Henry's testimony is clear that her view is that those nonrisk factors include *economic* benefits. *Id.* at 147:4–6 (Q: "And the nonrisk factors would include benefits, right?"; A: "Economic benefits, yes."). Thus, Dr. Henry did not testify that *health* benefits of a chemical substance cannot be considered in a TSCA risk evaluation.

Third, Plaintiffs' policy argument that there are "additional considerations that counsel in favor of excluding dental benefits from this case," Pls.' Br. 24, is wrong. To begin with, contrary to Plaintiffs' motion, EPA's Expert Disclosures and Designations (June 27, 2019) did not state that EPA "may elect to disregard the Court's command to implement a rule if it finds, during the rulemaking proceeding, that fluoridation chemicals present a 'substantial benefit to health.'" Pls.' Br. 24 (citing EPA Disclosures 5:3–6). Rather, that portion of EPA's disclosures, which was a summary of the facts and opinions to which Dr. Henry is expected to testify and not a statement about EPA's legal position as to this issue, was clearly describing the process that EPA follows when "proposing and promulgating a TSCA section 6(a) rule," under the typical administrative rulemaking process. EPA Disclosures 4:22–23, Pls.' Br. Ex. 50. The disclosure was not describing a process with respect to whether EPA was acting under a judicial mandate to initiate rulemaking

pursuant to section 21, as Plaintiffs assert.[15] Therefore, Plaintiffs have not shown as a matter of law that the health benefits of fluoride are irrelevant to the Court's risk determination in this case. Plaintiffs' request for partial summary judgment must be denied.[16]

III. AN ISSUE OF MATERIAL FACT EXISTS AS TO WHETHER THERE IS A BASIS FOR DEFERRING THE INITIATION OF RULEMAKING IF THE COURT FINDS THAT FLUORIDE PRESENTS AN UNREASONABLE RISK UNDER THE CONDITION OF USE.

Plaintiffs speculate that EPA will ask the Court to delay the rulemaking process if the Court finds that fluoridation chemicals present an unreasonable risk under the condition of use. Pls.' Br. 24–25. Upon a finding of unreasonable risk, the Court may permit EPA to defer rulemaking if the Court finds (1) that "the extent of the risk to health or the environment alleged by [Plaintiffs] is less than the extent of risks to health or the environment with respect to which [EPA] is taking action" and (2) that "there are insufficient resources available to [EPA] to take the action requested by [Plaintiffs]." 15 U.S.C. § 2620(b)(4)(B)(ii). Plaintiffs' argument that EPA has not offered evidence to support a request to delay the rulemaking process is without support, nor is it ripe.

First, Plaintiffs mistakenly claim that the only evidence EPA put forward to support a deferral determination is testimony by Dr. Henry. Pls.' Br. 25. When Congress amended TSCA in 2016, Pub. L. No. 114-182, 130 Stat. 448, it imposed new mandatory requirements and deadlines for EPA to evaluate chemicals. In particular, the 2016 amendments required EPA to establish a risk-based screening process whereby EPA must designate high-priority and low-priority

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[15] Nor does Dr. Henry's testimony support Plaintiffs' policy argument on this issue. To the extent Plaintiffs cite her deposition for what "EPA stated," *e.g.*, Pls.' Br. 24, those representations are unsupported and directly contradicted by Dr. Henry's testimony, *e.g.*, Henry Dep. 389:18–19 ("I can't speak on behalf of EPA."). Further, Dr. Henry's testimony indicated that she was not in a position to provide a legal opinion regarding whether a section 6(g)(1)(C) exemption could apply where EPA conducts risk management pursuant to a judicial determination of unreasonable risk under section 21. *See* Henry Dep. 387:19–388:9 ("It's really more an exemption from whatever regulatory remedy is being proposed in the rule. It's not issuing an exemption per se, *but get with the lawyers on that*." (emphasis added)).

[16] EPA reserves the right to contest assertions in the "Statement of Facts" section of Plaintiffs' brief regarding the extent of the health benefits of fluoridation chemicals.

substances. *Id.* § 2605(b)(1).[17] A high-priority substance is "a chemical substance that [EPA] concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by [EPA]." *Id.* § 2605(b)(1)(B)(i). A low-priority substance is one that does not meet the definition of a high-priority substance. *Id.* § 2605(b)(1)(B)(ii).

The 2016 amendments also mandated that EPA (1) begin initial risk evaluations for ten chemicals drawn from the existing 2014 update to EPA's TSCA Work Plan for Chemical Assessments (the "Work Plan")[18] and (2) begin additional risk evaluations on at least twenty high-priority substances, both by specific deadlines, among other requirements. 15 U.S.C. § 2605(b)(2)(A)–(B). Upon completion of one risk evaluation, EPA must designate another chemical as high-priority, such that there will always be at least twenty risk evaluations ongoing at any given time (after the initial ten risk evaluations), at least half of which are chemicals from the Work Plan, until the Work Plan chemicals are exhausted. *See id.* § 2605(b)(2)(B), (3)(C).

In December 2016, EPA published a list of ten chemicals drawn from the Work Plan for initial risk evaluations and began the process of evaluating their risks. 81 Fed. Reg. 91,927 (Dec. 19, 2016). Risk evaluations must be completed within three-and-a-half years, and EPA has released draft risk evaluations for four chemicals so far. *See id.* 15 U.S.C. § 2605(b)(4)(G). In March 2019, EPA initiated the prioritization process for forty additional chemical substance candidates—that is, twenty high-priority candidates, all from the Work Plan, and twenty low-priority candidates. 84 Fed. Reg. 10,491 (Mar. 21, 2019).

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[17] *See also* Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33,753 (July 20, 2017).

[18] The Work Plan is a list of ninety chemicals that EPA identified for further evaluation prior to the 2016 TSCA amendments using a systematic screening system that considered combined hazard, exposure and persistence, and bioaccumulation characteristics. The fluoride ion does not fall within the purview of TSCA, and none of the identified fluoridation chemicals are listed in the Work Plan. A copy is attached as Exhibit 12.

Allowing a dissatisfied petitioner to, in essence, "jump the line" at this early stage in EPA's implementation of the new law would disrupt the new risk evaluation and prioritization process that Congress mandated under the 2016 amendments. There is at least a dispute of fact whether the ten chemicals for which EPA is currently conducting initial risk evaluations and the twenty proposed high-priority substances present a higher risk than the fluoridation chemicals at issue here. Thus, Plaintiffs are wrong in their contention that EPA would be wholly "incapable" of supporting a request to defer rulemaking merely because Dr. Henry testified that she is not offering an opinion regarding the extent of the risk for the ten chemicals undergoing initial risk assessment or for chemicals on the Work Plan.

Second, because a deferral determination under section 21(b) requires the Court to balance the "extent of the risk" that Plaintiffs allege, it would be impossible for the Court to make a deferral determination without first knowing the full extent of the risk posed by adding fluoridation chemicals to drinking water. This is especially so where, as here, Plaintiffs have not demonstrated the presence of neurotoxic harm at 0.7 mg/L. Nor has EPA even requested deferral at this point in the case. Therefore, Plaintiffs request "partial summary judgment" as to an issue that is not ripe, and which may never come before the Court. Thus, the request should be denied. *See, e.g.*, *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967), *overruled on other grounds*, *Califano v. Sanders*, 430 U.S. 99, 105 (1977).

CONCLUSION

For the forgoing reasons, and the reasons stated in EPA's Motion for Summary Judgment, the Court should deny Plaintiffs' Motion for Summary Judgment and Partial Summary Judgment.

Date: October 18, 2019
Washington, DC

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of October, 2019, a true and correct copy of the foregoing Defendant's Opposition to Plaintiffs' Motion for Summary Judgment and Partial 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/ Brandon N. Adkins
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