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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
AT SAN FRANCISCO

FOOD & WATER WATCH, et al., Plaintiffs, vs. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al. Defendants.	Civ. No. 17-CV-02162-EMC **PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AND PARTIAL SUMMARY JUDGMENT** Date: November 7, 2019 Time: 1:30 p.m. Judge: Hon. Edward Chen Courtroom: 5, 17th Floor

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I. INTRODUCTION

Plaintiffs agree with EPA that "this case is about dose." Opp. Br. at 1:4. It is a case about a chemical (fluoride) that is added to U.S. public water supplies at a concentration that produces doses repeatedly associated (in high-quality prospective studies) with neurotoxic effects that rival the impact of lead. It is a case about a chemical shown to cause neurotoxic effects in animals at doses *much* closer to the doses that humans receive than the margins that EPA has found to be unreasonably dangerous for *other* chemicals. Most importantly, it is a case about a chemical that that poses an unreasonable *risk* of neurotoxicity when added to water if judged according to EPA's own *risk assessment* procedures.

In its Opposition, EPA concedes that conclusive proof of harm is not a pre-requisite to a finding of *risk*, which vitiates EPA's experts' opinions on causation. Further, EPA's reliance on the *Framework for Metals Risk Assessment* to support consideration of health benefits is fundamentally flawed because the *Framework* is clear that only "essentiality" can be considered in risk assessment, and EPA has admitted that fluoride is *not* essential. Finally, EPA has failed to proffer *any* evidence on the relative risk of the chemicals it is handling under TSCA, thus confirming that the Agency will not be able to carry its burden for relief under Section 21(b)(4)(B)(ii).

II. SUMMARY OF UNDISPUTED MATERIAL FACTS

EPA concedes that fluoride causes adverse neurotoxic effects. Opp. Br. at 1:4-5. The only question, therefore, is whether the doses of fluoride produced by fluoridation chemicals pose a *risk* of neurotoxicity and whether this risk is unreasonable. The undisputed evidence shows the following:

A. Fluoride Has Repeatedly Been Linked to Neurotoxic Effects at, and Very Close to, the Doses Ingested in Fluoridated Communities

Highest Quality Studies Have Found Neurotoxic Harm at 0.7 mg/L: There is no dispute that the NIH-funded prospective cohort studies are the most reliable studies on fluoride neurotoxicity to date, and that each of these studies (Bashash 2017, Bashash 2018, Green 2019, Till in press), has found significant associations between fluoride and adverse neurotoxic effects. There is also no dispute that the MIREC cohort studies from Canada (Green 2019; Till in press) have found significant adverse effects from both prenatal *and* infant exposures to fluoride in artificially fluoridated communities (~0.7 mg/L). Further, there

is no dispute that the maternal urinary fluoride levels in the ELEMENT cohort studies are essentially the same as the maternal urinary fluoride levels in the artificially fluoridated areas in the MIREC studies. **Ex. 20** at 31:4-32:11, 165:2-15, 181:5-12; **Ex. 21** at 209:3-12. According to Dr. Howard Hu, therefore, the ELEMENT results "are consistent with and support the conclusion that fluoride is a developmental neurotoxicant at levels of exposure seen in the general population in artificially fluoridated communities." **Ex. 20** at 180:18-181:4.

Studies Have Consistently Found Neurotoxic Effects at >1.5 mg/L: Many studies have investigated the effects of naturally occurring fluoride at levels (>1.5 mg/l) and, despite their methodological limitations, have consistently found significant associations between fluoride and adverse neurotoxic effects. **Ex. 15** at 3.

Animal Studies Have Consistently Found Neurotoxic Effects at 1.2 to 4.0 mg/L: There is no dispute that EPA can make unreasonable risk determinations for humans based solely on findings in animals, and that "animal evidence is relevant to humans unless data counterindicate." **Ex. 32** at 305:10-13, 306:5-16. There is also no dispute that animal studies have "consistently" found neurotoxic effects when the human equivalent concentration exceeds 1.2 mg/L, and that the animal studies are "virtually unanimous" in finding neurotoxic effects at the human equivalent concentration of 4.0 mg/L. **Ex. 9** at 240:20-241:8, 241:10-19, 291:6-13, 362:1-363:2, 367:16-368:11.

B. EPA Often Makes Risk Determinations by Extrapolating from High Dose Studies

EPA often has to extrapolate from high dose studies in order to assess risks to humans in the general population. **Ex 39** at 2; **Ex. 40** at 2. This is evident by the fact that EPA uses the "Margin of Exposure" method to assess non-cancer risk. **Ex. 32** at 288:5-10. The "basic construct" of the MOE method is that an "unacceptable risk" exists if the Calculated MOE[1] is less than the Benchmark MOE[2]. **Ex. 32** at 288:11-289:8. An example of an MOE analysis can be found in EPA's assessment of the risks posed by sodium fluoride pesticies. **Ex. 45**. There, EPA set the Benchmark (i.e., "Target") MOE at *300* for any Point of Departure based on a LOAEL ("Lowest Observed Adverse Effect Level") in animals. *Id.* at 10-11.

[1] The Calculated MOE is the "Point of Departure" (i.e., BMDL, NOAEL, or LOAEL) divided by the human dose. **Ex. 3A** at 64-65.
[2] The Benchmark MOE is the sum of applicable uncertainty factors. **Ex. 3A** at 65.

Translated, this means that EPA considered there to be a risk of concern in humans handling sodium fluoride pesticides even if they had exposures 299 times *lower* than the levels that caused harm in animals. In the case of fluoridation chemicals in drinking water, human exposures are *much* closer to—and almost the same as—the levels causing harm in animals, as discussed above.

C. Susceptibility of the Fetus to Fluoride Neurotoxicity

Fluoride passes through the placenta and gets into the brain of the fetus. **Ex. 9** at 180:17-181:5. Every human study to date that has examined the neurological impact of prenatal fluoride exposure has found adverse effects, including in pregnant women drinking ~0.7 mg/L of fluoride in their water. **Ex. 27** at 213:18-214:6. These studies have used prospective cohort designs, which are considered the "ideal study design" for investigating the impact of environmental chemicals on human health. **Ex. 19** at 162:25-163:7. Based on the results of the cohort studies, Dr. Bruce Lanphear, the senior investigator of the MIREC studies, recommends that pregnant women "begin taking steps to reduce their fluoride intake, including but not limited to reducing their consumption of fluoridated water." **Ex. 21** at 215:20-216:5. The CDC, as well as EPA's experts in this case, agree that prenatal fluoride exposure provides *no known benefit to the teeth*. **Ex. 11** at 213:19-23, 217:3-19; **Ex. 29** at 284:11-286:18.

D. Susceptibility of Infants to Fluoride Neurotoxicity

Fluoridation "dramatically" increases fluoride exposure for bottle-fed infants, a period of heightened sensitivity to neurotoxicants. **Ex. 2** at 286:18-287:1; **Ex. 9** at 233:7-15. The neonatal period is "a critical window of development" for the brain, because it is "a period of rapid development of the nervous system" without the protection of a fully developed blood brain barrier. **Ex. 34** at 42; **Ex. 36** at 5-4. By contrast, the CDC admits that fluoride exposure during the first 6 months of life provide *no known benefit to teeth*. **Ex. 11** at 224:7-11. Dr. Lanphear's team found that infants drinking formula made with fluoridated water have significantly reduced non-verbal IQ. **Ex. 21** at 223:20-224:7. The EPA's toxicologist in this case agrees that it is now reasonable to recommend that fluoridation chemicals not be added to infant

formula. **Ex. 9** at 403:16-404:5.

E. TSCA Risk Evaluations Require a Risk Assessment, But EPA's Experts Did Not Do One

A risk evaluation under TSCA requires a *risk assessment*. **Ex. 32** at 433:3-16; Henry Decl. ¶¶ 13. A risk assessment has four steps: hazard assessment, dose response assessment, exposure assessment, and risk characterization, and each of these four steps is required for an assessment of risk under TSCA. Henry Decl. ¶¶ 13, 15, 17, 19, 21. Despite this, EPA's risk assessment expert in this case did *not* conduct a risk assessment, but Plaintiffs' risk assessment scientist *did*. **Ex. 3** ¶ 3; **Ex. 9** at 41:12-16.

F. Under the TSCA Method for *Risk Characterization*, Fluoridation Chemicals Pose an "Unacceptable Risk" of Neurotoxicity

The EPA uses the Margin of Exposure ("MOE") method for risk characterization under TSCA. Opp. Br. at 5:2-3; **Ex. 32** at 267:20-268:9. EPA's experts in this case did *not* conduct a Margin of Exposure analysis, but Plaintiffs' expert *did*. **Ex. 3** ¶ 9. Application of the MOE method to the animal data on fluoride neurotoxicity shows that an "unacceptable risk" exists, including when using the Point of Departure that EPA's expert agreed would be reasonable to use. **Ex. 3** ¶ 9; **Ex. 9** at 259:14-21; **Ex. 32** at 288:13-289:11, 290:3-16. An unacceptable risk also exists if the MOE method is applied to the highest quality human data because the doses produced by fluoridation chemicals in water *exceed* the Points of Departure for IQ loss; a risk is demonstrated *without the application of a single uncertainty factor*. **Ex. 16** ¶¶ 7-8.

G. EPA May Consider Other Risk Factors for a TSCA *Risk Determination*, But None of These Factors Provide a Basis for Finding the Unacceptable Risk to Be "Reasonable"

In addition to the Margin of Exposure, EPA "may" consider other risk-related factors prior to making its risk determination. **Ex. 32** at 271:14-18. These other factors include: the "number of people exposed," "the population exposed (including any potentially exposed or susceptible subpopulations); the severity of the hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties." *Id.* at 271:14-273:11; Henry Decl. (attached to EPA's motion) ¶ 23. In EPA's Opposition, the Agency makes no claim—nor presents *any* evidence to demonstrate—that these factors provide a basis

for finding the "unacceptable" risks identified by the MOE method to be "reasonable." In fact, the undisputed evidence shows that these other factors provide *further* justification for an unreasonable risk determination.

Number of People Exposed (including susceptible groups): This factor supports an unreasonable risk determination, because human exposure to fluoridation chemicals is "nothing short of massive," and EPA makes no claim to the contrary. **Ex. 3A** at 64.[3] Over 200 million Americans have fluoridation chemicals directly added to their home drinking water, *which is more than the rest of the world combined*. **Ex. 3** ¶ 10; **Ex. 28** at 156:9-157:1. Because of the widespread use of fluoridation chemicals in the U.S., millions of *susceptible* individuals are being exposed, including 2.9 million *pregnant women* and 1.2 million *exclusively bottle-fed infants*. *Id*. To put these numbers in perspective, EPA found unreasonable risks for conditions of use of 1-BP which involved *thousands* of workers, with *no* general population or susceptible subpopulation exposures. **Ex. 3** ¶ 10.

Severity of the Hazard: This factor further supports an unreasonable finding for fluoridation chemicals, and, again, EPA makes no claim to the contrary. Dr. Thiessen based her MOE analysis on learning impairment in animals which has been recognized by EPA as an appropriate endpoint to use for human risk assessment. **Ex. 3A** at 9, 56, 66-67. Further, Dr. Grandjean based his BMD analysis on IQ loss and estimated that fluoridation chemicals are causing a loss of 4.5 to 23 million IQ points among 0-to-5 year-olds, which rivals the effects of lead and mercury. **Ex. 16A** at 38-41. The EPA has recognized that the loss of a single IQ point results in a loss of lifetime earnings, and Dr. Henry agrees that "chemicals added

[3] EPA's hearsay objection to Plaintiffs' expert reports is meritless. EPA cites two cases for the "well-established precedent" that expert reports are inadmissible hearsay, but fails to recognize that these two cases were dealing with admissibility at *trial*. Opp. Br. at 10:20-26 (citing *Paddock v. Dave Christensen, Inc*., 745 F.2d 1254 (9th Cir. 1984); *Arizona v. Azarco*, LLC, 844 F. Supp. 2d 957 (D. Ariz. 2011)). At the summary judgment stage, it is firmly established in the Ninth Circuit, and other circuits, that *sworn* expert reports are admissible, whereas *unsworn* reports are not. *Liebling v. Novartis Pharm. Corp*., No. CV1110263MMMMRWX, 2014 WL 12576619, at *1–2 (C.D. Cal. Mar. 24, 2014) (citing numerous cases). Here, each of Plaintiffs' expert reports are accompanied by *sworn* declarations from each expert, and are thus admissible for purposes of summary judgment.

to drinking water should not cause reductions in IQ." **Ex. 18** at 3 (stating that the loss of 1 IQ point results in a loss of $11,500-$15,600 in lifetime earnings); **Ex. 32** at 409:4-11. Finally, EPA's litigation experts have previously published a study where they used a loss of 1 IQ point as the adverse effect to protect against and cited EPA as their basis for doing so. **Ex. 9** at 377:14-378:2; 416:15-19, 417:2-5.

Reversibility of the Hazard: Dr. Grandjean has explained that "[i]f a developmental process in the brain is halted or inhibited, there is little potential for later repair . . . and the consequences may therefore be permanent." **Ex. 16A** at 8. Further, with respect to the elderly brain, the EPA has acknowledged that the elderly brain is "at particular risk because of the limited ability of the nervous system to regenerate or compensate to neurotoxic insult." **Ex. 33** at 65.

Uncertainties: In assessing uncertainties, EPA considers the confidence in the hazard assessment. Pls' Opp Br. at 15:2-3. Here, Dr. Thiessen concluded to "a high degree of confidence" that neurotoxicity is a hazard of fluoride exposure and EPA concedes in its opposition brief that "fluoride can cause adverse neurotoxic effects."[4] Opp. Br. at 1:4-5; **Ex. 3** ¶ 4. In addition to considering the confidence in the hazard assessment, the EPA also considers the confidence in the exposure assessment. Pls' Opp Br. at 15:2-3. Here, there can be no reasonable dispute that fluoridation chemicals added to *drinking water* cause people to be exposed to fluoride, and EPA's own 30(b)(6) representative admitted that fluoridation chemicals "dramatically" increase exposure to infants—a population that EPA considers to be especially susceptible to neurotoxicants. **Ex. 2 a**t 286:18-287:1; **Ex. 3** ¶ 4; **Ex. 9** at 233:7-15; **Ex. 34** at 42. Lastly, in assessing uncertainties, EPA has stated that "[a] lower benchmark MOE (e.g. 30) indicates greater certainty in the data (because fewer of the default uncertainty factors are relevant to a given point of departure . . . .)." Pls' Opp Br. at 15:7-10. This factor again weighs in favor of an unreasonable risk determination because Dr. Thiessen's MOE analyses show a Calculated MOE as low as 1.4 for infants, and application of Dr.

[4] EPA's risk assessment scientist did not conduct a hazard assessment, despite it being a "key component" of a risk evaluation under TSCA. **Ex. 9** at 321:12-13; Henry Decl. ¶ 15.

Grandjean's BMD results would show an unacceptable risk *even if the benchmark MOE is set at 1*. **Ex. 3** ¶ 9; **Ex. 16** ¶ 8.

Lastly, although EPA's experts have pointed out various uncertainties in the existing studies, EPA has not produced any evidence that these uncertainties are severe enough to negate a finding of risk. *See* Opp. Br. at 17:1-8; *see also Ethyl Corp. v. U.S. E.P.A.*, 541 F.2d 1, 25 (D.C. 1976) ("Certainty in the complexities of environmental medicine may be achievable only after the fact, when scientists have the opportunity for leisurely and isolated scrutiny of an entire mechanism. Awaiting uncertainty will often allow for only reactive, not preventive, regulation."); **Ex. 38** at 2 ("[A]ll risk estimates are uncertain to some degree."); **Ex. 41** at 32 ("[F]actual certainty respecting the existence of an unreasonable risk of a particular harm may not be possible and the bill does not require it.").

H. Plaintiffs' Expert, Dr. Thiessen, Conducted the "Effective" Equivalent of a Systematic Review

EPA's experts on the purported benefits of fluoridation chemicals did *not* conduct systematic reviews. **Ex. 28** at 23:25-29:24; **Ex. 29** at 45:9-47:16. Similarly, Plaintiffs' experts on risks did not do formal systematic reviews either. However, Dr. Thiessen conducted a risk assessment pursuant to the EPA's *Guidelines for Neurotoxicity Risk Assessment*, which Dr. Henry has stated is "effectively" the equivalent of a systematic review.[5] **Ex. 3** ¶ 4; **Ex. 32** at 254:4-8.

I. EPA's Systematic Reviews Confirm that Plaintiffs' Experts Did Not Omit Any Material Studies

In its opposition brief, the EPA states that its experts identified "numerous studies" that Plaintiffs expert did not address. Opp. Br. at 15:6-7. Notably, however, EPA does not claim that any of these studies challenge the conclusions drawn by Plaintiffs' experts. Nor could it, because EPA's own experts have admitted that their systematic reviews did not identify *any* studies that Plaintiffs omitted which materially

[5] As discussed in Plaintiffs' Opposition to EPA's Motion for Summary Judgment, systematic reviews are not required in *de novo* proceedings under Section 21. *See* Pls' Opp Br. at 17:17-19:9. To the extent that EPA is suggesting otherwise in footnote 14 of its Opposition, EPA is mistaken.

affect the results. First, EPA's retained epidemiologist, Dr. Chang, admitted that her systematic review did not identify any studies that were omitted by Plaintiffs' epidemiologist, Dr. Grandjean, that would materially challenge his opinion. **Ex. 27** at 242:14-243:10, 246:8-247:25, 249:16-23, 268:9-19, 269:5-270:19, 270:22-272:17; *see also* **Ex. 16** ¶ 11, **Ex. 16B** at 3-5. Second, EPA's retained toxicologist, Dr. Tsuji, admitted that her systematic review did not identify any animal study that was omitted by Dr. Thiessen. **Ex. 9** at 150:4-151:4. Finally, Dr. Chang agrees with Dr. Grandjean that the NIH-funded prospective cohort studies are the most reliable studies on fluoride and neurotoxicity to date, and that each of these studies reported significant associations between prenatal fluoride exposure and neurodevelopmental harm. Pls' Opp. Br. at 18:21-25; **Ex. 27** at 213:18-214:6. It is thus undisputed that *the most reliable studies ever conducted on fluoride and neurotoxic outcomes have each found significant adverse associations.*

III. ARGUMENT

A. EPA Has Vitiated Its Experts' Opinions on Causation by Conceding that Conclusive Proof of Harm at 0.7 mg/L Is Not Necessary for an Unreasonable Risk Determination

In its Opposition, EPA concedes that an unreasonable risk determination does not require "conclusive proof" of harm at 0.7 mg/L. Opp. Br. at 7:13-14. This concession conforms to the command of Congress, *see* **Ex. 41** at 32, as well as to the interpretation of "significant risk" set forth by the D.C. Circuit Court of Appeals in *Ethyl Corp. v. U.S. E.P.A.*, 541 F.2d 1, 8 &12 (D.C. 1976), neither of which EPA challenges. Unfortunately for EPA, however, its experts in this case did *not* analyze the science for the purpose of assessing *risk* – as evident by the fact that its experts did not conduct *risk assessments*. **Ex. 9** at 41:12-16, 94:17-95:5. Instead, EPA's experts analyzed the science to determine if a "*definitive conclusion*" can be drawn as to whether fluoride at 0.7 mg/L causes neurotoxic harm. *E.g.*, **Ex. 27** at 125:19-126:2 (defining "insufficient evidence" of causation—the standard Dr. Chang used in this case—as "not enough compelling evidence to reach a definitive conclusion"). This is fatal to EPA's case, because even

if its experts are correct that there is not yet definitive proof of neurotoxic harm at 0.7 mg/L, this does not negate or contradict Plaintiffs' experts' opinions that there is a serious and unreasonable *risk* of harm. Indeed, this is precisely the lesson of *Ethyl Corp.*: that absence of definitive proof does not contradict the existence of a significant risk. Plaintiffs' motion for summary judgment should thus be granted because EPA has no expert evidence to materially contradict Plaintiffs' conclusions on *risk*.

B. The Term "Unacceptable Risk" Is Fit for Purpose for Risk Characterizations Under TSCA

In its motion, EPA incorrectly implies that Plaintiffs imported the term "unacceptable risk" from cases interpreting the MOE method under other health protective statutes. Opp. Br. at 6:21-22. To the contrary, the term "unacceptable risk" comes directly from the writings and deposition testimony of Dr. Tala Henry, the Deputy Director of the EPA office that conducts risk evaluations under TSCA. **Ex. 32** at 270:14-19, 288:13-289:11, 290:3-16. Dr. Henry testified that an "unacceptable risk" is the "starting generalization" if the MOE analysis finds that the Calculated MOE is less than the Benchmark MOE. *Id.* at 270:14-19, 288:13-289:11, 290:3-16. Dr. Henry then explained that EPA "may" consider other risk-related factors prior to making its *risk determination.*[6] *Id.* at 270:14-271:6-272:4. Dr. Henry's testimony makes clear that the term "unacceptable risk" is "fit for purpose" for TSCA risk characterization. Contrary to EPA's contention, therefore, there is no need to import this standard from case law interpreting other health-protective statutes.[7] *See* Opp. Br at 6:19-7:10.

C. Plaintiffs' Risk Characterization Is Based on the Best Available Science, as EPA's Own Experts Have Admitted

EPA spuriously argues that Plaintiffs "failed to proffer a dose-response or risk characterization based on the best available science." Opp. Br. at 7:20-21. EPA's argument runs counter to the admissions

[6] As discussed earlier, these factors further support an unreasonable risk finding, rather than refute it, and EPA has attempted to argue otherwise. See *supra* Section II.G.

[7] Plaintiffs cited two FIFRA cases for the simple purpose of providing "a description of the MOE method," as the method is the same regardless of which statute it is applied under. Pls' Mot. at 17:14-15 (citing *Natural Resources Defense Council v. U.S. Envt'l Prot. Agency*, 735 F.3d 873 (9th Cir. 2013); *Natural Resources Defense Council v. U.S. Envt'l Prot. Agency*, 658 F.3d 200 (2d Cir. 2011)).

of its own experts. First, EPA characterizes Plaintiffs' MOE approach as being "based on studies they simply deem as relevant." Opp. Br. at 8:10-11. However, Dr. Thiessen based one of her MOE analyses on the NTP animal study ("McPherson 2018") that EPA's own expert, Dr. Tsuji, contends is the most reliable animal study on fluoride neurotoxicity, and which Dr. Tsuji agrees would provide a suitable Point of Departure (as a 20 mg/L NOAEL) for a risk assessment on neurotoxicity. **Ex. 9** at 257:6-10, 259:1-21. EPA makes no mention of this in its Opposition. Nor does EPA acknowledge that the MOE analysis using Dr. Tsuji's preferred study confirms the existence of an unacceptable risk. **Ex. 3** ¶ 9.

Second, EPA criticizes Dr. Thiessen for deriving Points of Departure from animal data, instead of the human data. Opp. Br. at 13:10-16. However, the key reason that Dr. Thiessen did this (which EPA fails to mention) is that Dr. Grandjean had done a BMD analysis of the human data and Dr. Thiessen didn't want to duplicate efforts. **Ex. 3** ¶ 4 ("I focused on the animal data as I understood that Dr. Grandjean had already calculated a BMDL from the human data.). As discussed below, Dr. Grandjean's BMD analysis of the human data found a clear risk of IQ loss in fluoridated areas. **Ex. 16** ¶ 8. It is meritless, therefore, for EPA to argue that Dr. Thiessen's decision to use the animal data was a form of "cherry picking," Opp. Br. at 13:6-10, particularly since Dr. Thiessen used Dr. Tsuji's preferred study (McPherson) as one of her points of departure.[8]

Third, EPA faults Dr. Grandjean for using the Green 2019 study as the basis for his dose-response analysis. Opp. Br. at 11:15-21. EPA omits the fact that Dr. Grandjean also did a dose-response analysis of the Bashash 2017 study, and that the results were largely the same between the two. **Ex. 16** ¶¶ 5-7. Moreover, EPA omits the fact that its own epidemiologist, Dr. Chang, agrees that the Green and Bashash

[8] EPA also criticizes Dr. Thiessen's risk characterization for considering factors that EPA uses for considering new chemicals under Section 5. Opp. Br. at 9:11-14. This, however, is a red herring, because—as discussed above—Dr. Thiessen also conducted an MOE analysis, which is the method that EPA uses to characterize risk for existing chemicals under Section 6. **Ex. 13** ¶ 9; **Ex. 32** at 267:20-268:9. Moreover, one of the factors that EPA considers under Section 5 (number of people exposed) is a key consideration under Section 6 as well.

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studies are the most reliable studies to date on fluoride and IQ. Pls' Opp Br. at 18:21-25. It is thus undisputed that the Bashash and Green studies are the best available science, and EPA fails to provide any reasons to the contrary.[9] Moreover, Dr. Tsuji agreed that the Green study is just as suitable to deriving a benchmark dose as a prospective birth cohort studies she previously used for this same purpose. **Ex. 9** at 383:20-384:4.

Lastly, EPA criticizes Dr. Grandjean for "dividing his BMD by an uncertainty factor of 10 without providing a rationale for assignment of this uncertainty factor." Opp. Br. at 12:10-11. As an initial matter, this is incorrect because Dr. Grandjean did not actually select an uncertainty factor. **Ex. 16** ¶ 8. Instead, Dr. Grandjean noted that EPA generally will apply an uncertainty factor to the benchmark dose, and that "*if* EPA's default uncertainty factor of 10 is applied," the exposure limits would be "on the order of 0.02 milligrams of fluoride per day." *Id*. Much more importantly, Dr. Grandjean's BMD analysis shows that—*without applying a single uncertainty factor*—the fluoride doses ingested in fluoridated communities *exceed* the doses that are linked to IQ loss in the ELEMENT and MIREC studies. *Id.* EPA's argument, therefore, about the uncertainty factor of 10 is a red herring, therefore, because Dr. Grandjean's finding of a risk *does not depend upon any uncertainty factors.*[10]

D. Fluoride Is Neither a Metal Nor an "Essential" Nutrient and Thus EPA's *Framework for Metals Risk Assessment* Provides No Support for Considering Fluoridation Chemicals' Purported Health Benefits in a TSCA Risk Assessment

In its Opposition, EPA cites the *Framework for Metals Risk Assessment* (hereafter, "*Metals Framework*") as support for its position that the EPA can consider health benefits in TSCA risk assessments. Opp. Br. at 21:1-10. The *Metals Framework*, however, provides no support for this position.

[9] There is also no merit to EPA's criticism that Dr. Grandjean "failed to explain why Green 2019 is consistent or relevant for the purpose of extrapolating a dose-response." Opp. Br. at 11:19-20. There should be little need to explain this, however, since it is plainly *obvious*. The Green study was funded by the NIH to for the specific purpose of investigating the neurological effects of fluoride exposures in communities with artificially fluoridated water. It is thus clearly relevant to the risk determination in this case, as EPA's own experts admit.

[10] In its Opposition, EPA reasserts its argument that Dr. Grandjean is not qualified to opine on BMD analyses because of a passing moment of levity in his deposition where he stated that "I wouldn't trust myself" to do the calculations. Opp. Br. at 12:3-9. Plaintiffs' addressed this point in their Opposition. *See* Pls' Opp. Br. at 13:8-25.

As an initial matter, fluoride is a halogen, not a metal. More importantly, the *Metals Framework* is very clear that only "essentiality" can be considered in risk assessment, not mere benefit. *See* **Ex. 11** to Adkins Decl. at 1-10 ("*Essentiality* thus should be viewed as part of the overall dose-response relationship for those metals shown to be *essential* . . . ." (emphases added)). This is fatal to EPA's reliance on the *Metals Framework* because EPA has admitted that fluoride is *not* an essential nutrient. **Ex. 2** at 330:1-4.

Essential nutrients *need* to be *systemically absorbed* into the body at sufficient levels, otherwise a disease will result. **Ex. 28 a**t 267:3-268:1. With fluoride, the "overwhelming evidence" shows that its predominant benefit comes from *topical* contact with the outside surface of the teeth, *not from ingestion*. **Ex. 11** at 198:21-199:3; **Ex. 31** at 142:3-21. In addition, essential nutrients are necessary for the proper functioning of at least one metabolic pathway in the body, yet EPA's expert on benefits admitted that there are no metabolic pathways which require fluoride. **Ex. 28** at 260:5-8, 261:24-262:3. Even *if* ingesting fluoride can provide some marginal benefit, ingestion is not *necessary* for the prevention of caries, or any other disease. **Ex. 30** ¶ 3 ("It is not necessary . . . to ingest fluoride for caries control."). Finally, unlike essential metals like iron, fluoride tablets are defined as *medication*, not nutritional supplements, and unlike essential metals, fluoride tablets cannot be purchased over the counter as they require a *prescription*. **Ex. 28** at 271:23-273:7; **Ex. 22** ¶¶ 7 & 9. The *Metals Framework* is thus completely inapposite to fluoride.

E. Dr. Henry's Testimony *and* EPA's Risk Evaluation Rule *Both* Support the Interpretation that Health Benefits Are a "Non-Risk Factor"

EPA is correct that Section 6(c)(2) includes both risk and non-risk factors, a point that Dr. Henry appears to have acknowledged at her deposition when she stated that Section 6(c)(2) is "not *just* nonrisk factors." **Ex. 32** at 386:4-8. Importantly, however, Dr. Henry agreed with the characterization that "benefits of the chemical substance" *is* a cost/non-risk factor. *Id.* at 386:3-6. Further, when asked if fluoride's effects on caries prevention can be considered during the risk evaluation, Dr. Henry stated that "if there was an endpoint such as the severe dental fluorosis, that is an *adverse* effect that can be considered in the risk evaluation." *Id.* at 390:8-15. The implication of Dr. Henry's answer is that *adverse* effects can be considered, not beneficial ones. This is consistent with Dr. Henry's testimony that "caries prevention" would be considered as part of the "rulemaking proceeding," and that she does not know how it "would

even be possible" for EPA to consider health benefits as part of a risk evaluation. *Id.* at 391:2-5, 476:6-14.

Dr. Henry's interpretation of the statute is consistent with, and supported by, EPA's interpretation of the "risk" factors that can be considered during a risk evaluation. In its Final Rule on Section 6(b) risk evaluations, the EPA listed various factors that EPA can consider to make a risk determination. 82 Fed. Reg. at 33,735; *see also* Opp. Br. at 3:1-4. Notably, EPA included some, *but not all*, of the factors identified in Section 6(c)(2). Specifically, EPA included "the effects of the chemical substance on human health," and the "effects of the chemical substance on the environment," which are almost verbatim to the first two Section 6(c)(2) factors. EPA did *not* include Section 6(c)(2)'s last two factors, which are "the benefits of the chemical substance"[11] and "the reasonably ascertainable economic consequences of the rule." 82 Fed. Reg. at 33,735. EPA's risk evaluation rule thus implicitly recognizes that health benefits are the domain of risk management.

F. EPA Has Failed to Address the Policy Reasons for Excluding Dental Benefits

In its Opposition, EPA attempts to refute Plaintiffs' additional reasons for excluding dental benefits by resorting to a clear misrepresentation of the record. Specifically, EPA denies that it stated that EPA may elect to exempt water fluoridation from a Court-ordered rule if the Agency finds, during the rulemaking proceeding, that fluoridation provides a substantial benefit to health. Opp. Br. at 22:18-22. EPA claims that its Expert Disclosure "was not describing a process with respect to whether EPA was acting under a judicial mandate to initiate rulemaking pursuant to Section 21." *Id.* at 22:26-23:1. This contention is refuted by the plain language of the disclosure. After explaining that EPA "may find a need for exemption of regulation of water fluoridation because of its substantial benefit to health," EPA stated that "*[i]f the court were to find that fluoride presents an unreasonable risk to health* or the environment, EPA should be able to regulate the risk found based on these considerations." **Ex. 50** at 5:9-10. Contrary to what EPA professes in its Opposition, therefore, the Expert Disclosure was specifically addressing what EPA believes it can do while acting under a judicial mandate to initiate rulemaking.

Plaintiffs' two policy arguments thus stand unrefuted: (1) if the Court considers benefits in reaching its unreasonable risk determination, the Court's ruling may be effectively rendered into an advisory opinion

[11] EPA does not mention health "benefits" once in the Final Rule.

if EPA ultimately determines that the benefits warrant exempting fluoridation from a rule; and (2) hearing testimony from the parties' *four* experts on benefits at trial will be a waste of judicial resources as EPA has expressed its intent to relitigate benefits during the rulemaking proceeding.

G. EPA Has Failed to Produce *Any* Evidence that Could Support a *Relative Risk* Finding Under Section 21(b)(4)(B)(ii); Partial Summary Judgment Is Thus Justified on this Purely Legal Matter

In its Opposition, EPA states that "Plaintiffs mistakenly claim that the only evidence EPA put forward to support a deferral determination is testimony by Dr. Henry." Opp. Br. at 23:15-16. EPA then proceeds to spend over a page discussing all of the requirements that EPA currently has under TSCA. Opp. Section 6(a) Br. at 23:16-25:3. Notably absent from this discussion, however, is *any* evidence on the *risks* posed by the chemicals that EPA is currently acting on, let alone any evidence on how these risks compare to those presented by fluoridation chemicals. EPA's brief thus *confirms* Plaintiffs' contention that EPA has *no* evidence that could support the pre-requisite relative risk finding under Section 21(b)(4)(ii). The Court should thus grant Plaintiffs' motion for partial summary judgment on this issue. *See Porter v. Cal. Dep't of Corr*., 419 F.3d 885, 891 (9th Cir. 2005) (stating that nonmoving party "must set forth specific facts showing that there is a genuine issue for trial" and may not rely on mere denials).

EPA's argument that Section 21(b) requires the Court to balance the risks, and that it is "impossible" to do so at this juncture, misses the point. As its Opposition makes clear, EPA has no expert testimony or evidence to establish the relative risk of the chemicals it is working on, and thus there will be nothing for the Court to weigh the risks of fluoridation chemicals against. This issue is thus a "purely legal" matter whose adjudication is properly asserted and adjudicated at the summary judgment stage. *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Engineers*, 440 F.3d 459, 463–64 (D.C. Cir. 2006) (stating that ripeness inquiry considers "whether the issue is 'purely legal,' whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final"); *see also id.* at 465 ("[W]here, as is the case here, there are no significant agency or judicial interests militating in favor of delay, [lack of] hardship cannot tip the balance against judicial review.").

H. EPA Misapprehends the Reasons Why Plaintiffs Discussed the MCLG

EPA misapprehends the reasons why Plaintiffs addressed the crudeness of EPA's 4 mg/L MCLG for fluoride. Plaintiffs did not address the MCLG for the purpose of asking the Court to set it aside. Rather, Plaintiffs addressed the standard to provide the Court with important context for assessing the risks of fluoridation chemicals in drinking water. An impartial observer might be forgiven for believing that a federally permitted "safe" level of a contaminant in drinking water is actually safe. This, however, is not the case with fluoride, as EPA's own scientists (readily concede. **Ex. 4** at 88:2-10; **Ex. 6** at 70:10-71:17. Further, since this is a case about neurotoxicity, Plaintiffs wanted to make clear that EPA's current drinking water standard for fluoride did not consider this endpoint, and thus the MCLG provides no assurance of neurological safety of fluoride levels below 4 mg/L. **Ex. 2** at 150:9-19; 152:9-14. Finally, EPA's persistent failure to listen to the concerns of its own scientists and responsibly regulate[12] fluoride in drinking water highlights why relief under Section 21 of TSCA is necessary. *See Environmental Defense Fund v. Reilly*, 909 F.2d 1497, 1499 (D.C. Cir. 1990) (stating that Congress enacted Section 21 to "ensure that bureaucratic lethargy does not prevent the appropriate administration of [TSCA's] vital authority").

IV. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court grant their Motion for Summary Judgment and/or Motions for Partial Summary Judgment.

Dated: October 24, 2019

Respectfully submitted,

/s/ Michael Connett
MICHAEL CONNETT

[12] EPA's Opposition highlights EPA's continued refusal to acknowledge the serious problems with the MCLG, as EPA implies that the NRC "reaffirmed" the safety of the MCLG, which is emphatically incorrect. Opp. Br. at 19:14-20.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served by Notice of Electronic Filing this 24th day of October, 2019, upon all ECF registered counsel of record using the Court's CM/ECF system.

/s/ Michael Connett
MICHAEL CONNETT