

1 C. ANDREW WATERS, ESQ., CA Bar No. 147259  
2 MICHAEL CONNETT, ESQ., CA Bar No. 300314  
3 WATERS, KRAUS & PAUL  
4 222 N. Pacific Coast Hwy, Suite 1900  
5 El Segundo, CA 90245  
6 310-414-8146 Telephone  
7 310-414-8156 Facsimile

8 *Attorneys for Plaintiffs*

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

12 FOOD & WATER WATCH, et al.,

13 Plaintiffs,

14 vs.

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

17 Defendants.

Civ. No. 17-CV-02162-EMC

**PLAINTIFFS' OPPOSITION TO  
DEFENDANTS' MOTION FOR  
SUMMARY JUDGMENT**

Date: November 7, 2019

Time: 1:30 p.m.

Judge: Hon. Edward Chen

Courtroom: 5, 17th Floor

**TABLE OF CONTENTS**

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

I. INTRODUCTION ..... 1

II. FACTUAL BACKGROUND ..... 1

    A. Statutory Background ..... 1

    B. How EPA Assesses the Neurotoxic Risk of Environmental Toxicants ..... 2

    C. How EPA Determines Risk Under TSCA ..... 3

    D. Plaintiffs’ Evidence on Fluoride Neurotoxicity ..... 4

    E. Susceptible Subsets of the Population ..... 9

    F. Plaintiffs’ Expert Testimony on Risk: A Brief Summary ..... 10

III. ARGUMENT ..... 11

    A. Plaintiffs Have Sufficient Evidence to Demonstrate an Unreasonable Risk ..... 11

    B. There Is a Clear and Logical Basis to Extrapolate the Findings from Mexico and Canada to the United States ..... 15

    C. Plaintiffs’ Experts Assessed Risk Using EPA’s Own Methodologies ..... 16

    D. Section 21 Does Not Require a Formal Systematic Review, But, Irregardless, the Systematic Reviews by EPA’s Experts Confirm that the Best Available Science Has Been Considered ..... 17

    E. Plaintiffs Have Standing ..... 19

        i. The Factual Basis of Plaintiffs’ Standing ..... 19

        ii. Plaintiffs’ Injuries Come Within the Zone of Interests ..... 22

        iii. Plaintiffs Have Article III Standing ..... 23

IV. CONCLUSION ..... 25

**TABLE OF AUTHORITIES**

**Cases**

*Baur v. Veneman*,  
352 F.3d 625, 633 (2nd Cir. 2003) ..... 24, 25

*Catron County Bd. Of Com’rs, New Mexico v. United States Fish & Wildlife Service*, 75  
F.3d 1429, 1433 (10th Cir. 1996) ..... 25

*Central Delta Water Agency v. United States*,  
306 F.3d 938, 949 (9th Cir. 2002) ..... 24

*Covington v. Jefferson County*,  
358 F.3d 626, 641 (9th Cir. 2004) ..... 23

*Ethyl Corp. v. U.S. E.P.A.*,  
541 F.2d 1, 8, 12, & 25 (D.C. 1976)..... 12

*Food & Water Watch, Inc. v. United States Envtl. Prot. Agency*,  
291 F. Supp. 3d 1033, 1048 (N.D. Cal. 2017)..... 1, 2, 18

*Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*,  
528 U.S. 167 ..... 23, 24

*Hall v. Norton*,  
266 F.3d 969, 976 (9th Cir. 2001) ..... 24

*In re Zappos.com, Inc.*,  
888 F.3d 1020, 1027-29 (9th Cir. 2018)..... 24

*Lexmark Int’l Inc. v. State Control Components, Inc.*,  
572 U.S. 118, 1, 27 (2014) ..... 22

*Monsanto Co. v. Geertson Seed Farms*,  
561 U.S. 139, 153-154 (2010) ..... 24

*Natural Resources Defense Council v. U.S. E.P.A.*,  
735 F.3d 873, 881-84 (9th Cir. 2013)..... 3, 12

*Natural Resources Defense Council v. S.W. Marine, Inc.*,  
985 F.3d 985, 994, (9th Cir. 2000) ..... 23

*Natural Resources Defense Council v. United States Envtl. Prot. Agency*,  
735 F.3d 873, 878 (9th Cir. 2013) ..... 23

*Trumpeter Swan Soc. v. E.P.A.*,  
774 F.3d 1037, 1039 (D.C. Cir. 2014)..... 1

*United States v. Students Challenging Regulatory Agency Procedures (SCRAP)*,  
412 U.S. 669, ..... 23

*Village of Elk Grove v. Evans*,  
997 F.2d 328, 329 (7th Cir. 1993) ..... 24

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

*Washington Envtl. Council v. Bellon*,  
732 F.3d 1131, 1140 (9th Cir. 2013) ..... 23

**Statutes**

15 United States Code, section 2602(12) ..... 9

15 United States Code, section 2605 ..... 12

15 United States Code, section 2605(a)..... 1, 18, 25

15 United States Code, section 2605(b) ..... 1, 2, 17, 18

15 United States Code, section 2620 ..... 1, 2, 18, 19

15 United States Code, section 2620(b)(4)(B) ..... 1, 9, 18

15 United States Code, section 2625(h) ..... 17

15 United States Code, section 2625(i) ..... 17

40 Code of Federal Regulations, section 702.33 ..... 17

**Rules**

82 Fed. Reg. 33,726 (July 20, 2017) ..... 2

**Secondary Sources**

John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261, 271–73 (1991)..... 12

## I. INTRODUCTION

Plaintiff citizens hereby oppose the Environmental Protection Agency's (EPA) motion for summary judgment. The EPA contends in its motion that Plaintiffs have not proffered any evidence demonstrating an unreasonable risk. To the contrary, Plaintiffs' experts have demonstrated the existence of an unacceptably high risk using the actual methodology (i.e., Margin of Exposure, or "MOE") that EPA uses to characterize risk under the Toxic Substances Control Act (TSCA). Inexplicably, the EPA's motion fails to even mention the MOE method, and does not acknowledge—or make any attempt to address—Plaintiffs' application of it. The EPA's arguments about "systematic review" are similarly unavailing. The TSCA statute does not require systematic reviews for Section 21 *de novo* proceedings, but, even if it did, EPA's own experts conducted systematic reviews and conceded that Plaintiffs' experts did not omit any material studies. The Court will thus have all of the best available science at its disposal in this case. Finally, contrary to EPA's claims, Plaintiffs have standing, as demonstrated herein. EPA's motion should thus be denied.

## II. FACTUAL BACKGROUND

### A. Statutory Background

Citizen petitions under Section 21 of the Toxic Substances Control Act (TSCA) are an "unusually powerful procedure[] for citizens to force EPA's hand," to "ensure the EPA does not overlook unreasonable risks to health or the environment." *Food & Water Watch, Inc. v. United States Env'tl. Prot. Agency*, 291 F. Supp. 3d 1033, 1048 (N.D. Cal. 2017) (quoting *Trumpeter Swan Soc. v. E.P.A.*, 774 F.3d 1037, 1039 (D.C. Cir. 2014)).

Section 21 invests federal courts with the authority to order EPA to initiate rulemaking proceedings under Section 6(a) of TSCA "[i]f the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that" the chemical use at issue "presents an unreasonable risk of injury to health," including to a "susceptible subpopulation." 15 U.S.C. 2620(b)(4)(B).

In 2016, Congress amended TSCA to require that EPA conduct "risk evaluations" for certain chemical substances under Section 6(b) of the Act. 15 U.S.C. § 2605(b). On July 20, 2017, EPA published a Final Rule describing how the Agency will conduct these risk evaluations. 82 Fed. Reg. 33,726 (July 20,

1 2017) (hereafter, “Final Rule”). By its own terms, the Final Rule applies to the following three categories  
2 of chemical substances: “(1) The ten chemical substances the Agency was required to identify from the  
3 2014 update to the TSCA Work Plan within the first 180 calendar days after the signing of TSCA); (2) the  
4 chemical substances determined to be High-Priority Substances through the prioritization process  
5 published elsewhere in this Federal Register; and (3) chemicals selected in response to a manufacturer  
6 request that meets the criteria established by this rule.” *Id.* at 33,727; **Ex. 1** at 160:12-163:9.<sup>1</sup>

7  
8 The Final Rule does not discuss or address the process for evaluating risk in response to Section 21  
9 citizen petitions.<sup>2</sup> **Ex. 1** at 163:10-14. As it currently stands, “[t]he EPA has not proposed or adopted any  
10 rule specifically addressing Section 21.” *Food & Water Watch*, 291 F. Supp. 3d at 1049-50.

### 11 **B. How EPA Assesses the Neurotoxic Risk of Environmental Toxicants**

12 In 1998, EPA finalized its *Guidelines for Neurotoxicity Risk Assessment* (hereafter *Guidelines*)<sup>3</sup>  
13 that EPA has stated it “will use” to “evaluate data on potential neurotoxicity associated with exposure to  
14 environmental toxicants,” including in risk evaluations under TSCA. **Ex. 3** at 1; *see also Ex. 1* at 250:10-  
15 251:9; 251:21-252:15. The *Guidelines* describe four steps to the risk assessment: (1) Hazard  
16 Characterization, (2) Quantitative Dose Response, (3) Exposure Assessment, and (4) Risk Characterization.  
17 **Ex. 3** at 2-3; *see also Ex. 4* at 1-2.

18  
19 In the Hazard Characterization analysis, EPA seeks to determine if there is “sufficient evidence” to  
20 conclude that a chemical can cause neurotoxicity at some level of exposure. “Sufficient evidence” is  
21 established if, *inter alia*, epidemiological studies show that “some neurotoxic effect is *associated* with  
22 exposure.” **Ex. 3** at 53. The *Guidelines* distinguish association from *causation*, and note that “causality is  
23

24  
25 <sup>1</sup> Unless otherwise indicated, the exhibits cited herein are attached to the accompanying declaration.

26 <sup>2</sup> In addition to promulgating the Final Rule, EPA has released guidance to “interested persons” on how to  
develop and submit draft risk evaluations. Adkins Decl., **Ex. 3**. As with the Final Rule, this guidance  
discusses risk evaluations under Section 6(b), but does not reference or discuss Section 21. *Id.*

27 <sup>3</sup> Plaintiffs filed their citizen petition on the grounds that “application of the Agency’s *Guidelines for*  
*Neurotoxicity Risk Assessment* to the existing database on fluoride shows that (1) neurotoxicity is a hazard  
of fluoride exposure, and (2) the reference dose that would reasonably protect against this hazard is  
incompatible with the doses now ingested by millions of Americans in fluoridated areas.” **Ex. 2** at 1.

1 a more stringent criterion than association.” *Id.* The *Guidelines* further note that sufficient evidence can be  
2 established by single “well-conducted study.” *Id.* at 55.

3 In the second step of the risk assessment, the dose-response relationship between the chemical and  
4 the hazard is analyzed to determine the dose (i.e., “reference dose”) of the chemical that “is likely to be  
5 without an appreciable risk of deleterious effects during a lifetime.” *Id.* at 57. To do this, the collective data  
6 is reviewed to identify a “Point of Departure” (POD), which can be a “Benchmark Dose” (BMD), “No  
7 Observed Adverse Effect Level” (NOAEL), or “Lowest Observed Adverse Effect Level” (LOAEL). *Id.*

8 After the POD is identified, it is divided by “uncertainty factors” to “compensate for human  
9 variability in sensitivity, the need to extrapolate from animals to humans,” and potentially other sources of  
10 uncertainty. *Id.* at 59. The *Guidelines* state that uncertainty factors “are typically multiples of 10.” *Id.*

### 12 C. How EPA Determines Risk Under TSCA

13 In its risk evaluations under TSCA, EPA uses the “Margin of Exposure” (MOE) method to  
14 characterize risk. <sup>4</sup> **Ex. 1** at 267:20-268:9; **Ex. 6** at 17-18; **Ex. 7** at 43. In the summer of 2019, EPA released  
15 draft risk evaluations for 1-Bromopropane (1-BP) and 1,4-Dioxane (Dioxane) and both of these risk  
16 evaluations used the MOE method to characterize non-cancer risk. **Ex. 8** at 193; **Ex. 9** at 3.

17 In an MOE analysis, EPA compares the Point of Departure (“POD”) directly to human exposures.  
18 **Ex. 6** at 18. The resulting “Calculated MOE” (i.e.,  $POD \div \text{Human Exposure}$ ) is then compared to a  
19 “Benchmark MOE,” which is the sum of the uncertainty factors. *Id.* If the Calculated MOE is *less* than the  
20 Benchmark MOE, an “unacceptable risk” is presumed to exist. **Ex. 1** at 288:13-289:8; **Ex. 7** at 43.

21 If a TSCA risk evaluation finds an unacceptable risk using the MOE method, EPA “may consider  
22 other risk related factors” before making a *risk determination*, including “number of people exposed,” “the  
23  
24  
25

---

26 <sup>4</sup> The Margin of Exposure method is “one of the standard approaches” that EPA uses for non-cancer risk  
27 characterizations, including for pesticides such as sodium fluoride. **Ex. 1** at 287:2-4, 288:5-10; **Ex. 3** at 65-  
28 66; **Ex. 5** at 10-11. A description of the MOE method has been provided by the Ninth Circuit, and other  
federal courts. *See, e.g., Nat. Res. Def. Council v. U.S. E.P.A.*, 735 F.3d 873, 881-84 (9th Cir. 2013); *Nat.  
Res. Def. Council v. U.S. E.P.A.*, 658 F.3d 200, 207-09 (2d Cir. 2011).

1 population exposed (including any potentially exposed or susceptible subpopulations); the severity of the  
2 hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties.” **Ex. 1** at  
3 271:14-273:11; Henry Decl. (attached to EPA’s motion) ¶ 23.

#### 4 **D. Plaintiffs’ Evidence on Fluoride Neurotoxicity**

5 In 1985, EPA established a Maximum Contaminant Level Goal (MCLG) for fluoride in drinking  
6 water to protect against a severe form of fluoride poisoning—*crippling* skeletal fluorosis. **Ex. 10** at 81:6-  
7 82:20, 83:9-16; 84:5-20; **Ex. 11** at 69:24-71:17, 72:9-25, 73:2-10. EPA’s lead scientist on fluoride issues,  
8 Dr. Joyce Donohue, has admitted that the MCLG is “out of date.” **Ex. 12** at 88:7-10, 267:9-14.

9  
10 Neurotoxicity was not considered when EPA set the MCLG. **Ex. 10** at 150:9-19; 152:9-14; **Ex. 13A**  
11 at 5. In the three decades since the MCLG was established, many studies have been published which link  
12 fluoride exposure to neurotoxic effects, including IQ decrements and ADHD. **Ex. 13A** at 5-6, 10-11, 15-  
13 18. One of the first studies to raise red flags was co-authored by an EPA neurotoxicologist named Karl  
14 Jensen. **Ex. 11** at 100:22-101:17, 102:17-104:12; **Ex. 12** at 38:2-13, 95:9-97:6. Dr. Jensen’s study found  
15 that rats drinking 1 mg/L of fluoride in their water (the same concentration then used to fluoridate drinking  
16 water) developed neuronal deformations and other cellular damage in the brain. **Ex. 11** at 100:22-101:17.  
17 Dr. Jensen’s findings caused concern among EPA’s professional staff; in 1999, the union representing EPA  
18 professionals at EPA headquarters called for an end to fluoridation, based in part on Dr. Jensen’s findings.  
19 **Ex. 14** at 180 & 182-83. The EPA took no action at that time, but in 2003, the Agency asked the NRC to  
20 review the new toxicologic data on fluoride, including the neurotoxicity literature. **Ex. 12** at 89:23-90:14.  
21 The NRC did so and released its landmark report in 2006. *Id.* at 90:15-17.  
22  
23

24 The NRC’s 2006 report is widely recognized as an authoritative and extensive review of the  
25 toxicologic literature on fluoride; both the EPA and CDC have accepted NRC’s findings as an “accurate  
26 summary of [fluoride’s] hazard.” **Ex. 15** at i; **Ex. 16** at 19:18-21, 114:17-24, 115:5-23. In its “Findings”  
27 section on neurotoxicity, the NRC concluded that fluoride “interferes with the brain” in experimental  
28

1 animals, as evident by neurochemical and cellular alterations. **Ex. 12** at 100:14-23; **Ex. 16** at 120:14-121:9,  
2 121:23-125:3, **Ex. 17** at 221-22; **Ex. 18** at 297:5-299:18, 301:8-12, 301:17-25, 302:18-22, 304:4-12,  
3 317:17-318:17; **Ex. 19** at 319:5-16. It was unclear to the NRC, however, if the neurochemical changes and  
4 cellular damage seen in the brain would manifest into outwardly demonstrable deficits in  
5 cognition/behavior (i.e., “functional” effects). **Ex. 17** at 223. The NRC called, therefore, for more animal  
6 research to examine fluoride’s impact on cognitive skills. *Id.* at 223.

7  
8 The NRC also reviewed the then-existing human data on neurotoxicity, which included four  
9 epidemiological studies from China associating fluoride exposure with reduced IQ in children. **Ex. 13A** at  
10 6. Unlike the animal data, the NRC found that the human data—while suggestive of a problem—was not  
11 yet sufficient to draw conclusions. **Ex. 17** at 220-221. The NRC thus recommended that additional research  
12 be conducted in human populations to investigate fluoride’s effects on the human brain, including studies  
13 to examine fluoride’s relationship to IQ and dementia. **Ex. 10** at 172:20-173:20; **Ex. 17** at 223.

14  
15 Based on NRC’s findings and recommendations, it was clear that “there were some big potential  
16 problems from fluoride exposure that needed to be investigated.” **Ex. 12** at 107:18-24. In fact, EPA’s  
17 30(b)(6) representative admitted that the NRC’s findings justified the application of an uncertainty factor  
18 to EPA’s reference dose for severe dental fluorosis in order to account for the potential neurotoxicity risk.  
19 **Ex. 10** at 200:4-202:14, 206:9-19. Yet, although the EPA is prohibited by law from requiring fluoridation,  
20 EPA did not apply an uncertainty factor because it would have resulted in a safe dose below the so-called  
21 “optimal dose” for caries prevention.<sup>5</sup> *Id.* at 206:9-19, 329:3-17; **Ex. 11** at 89:2-19, 90:15-91:17; **Ex. 20**.

22  
23 ***Human Studies from “High” Fluoride Areas:*** Subsequent to the NRC’s review, a large number  
24 of human studies on fluoride and IQ have been published, the vast bulk of which have reported significant  
25 associations between fluoride and IQ loss.<sup>6</sup> Most of these studies have been conducted in China, and have

26  
27 <sup>5</sup> The Center for Disease Control’s 30(b)(6) representative in this case admitted that there is now  
28 “overwhelming evidence” that fluoride’s predominant benefit for caries-prevention comes from “*topical*”  
contact, *not ingestion*. **Ex. 16** at 198:21-199:3; *see also* **Ex. 13A** at 61.

<sup>6</sup> Sixty-seven human studies have associated fluoride with cognitive deficits. **Ex. 13A** at 15, n. 102.

1 examined the effect of waterborne fluoride levels (>1.5 mg/L) that generally exceed the levels added to  
2 water in the U.S. (0.7 mg/L). According to the National Toxicology Program (NTP), these studies provide  
3 “a strong suggestion” that fluoride reduces IQ at water fluoride levels exceeding 1.5 mg/L. **Ex. 21** at 3; *see*  
4 *also* **Ex. 18** at 388:1-15 (stating that the difference between 2 mg/L and 0.7 mg/L is “very small” for  
5 purposes of risk assessment); **Ex. 22** at 2 (stating that the EPA often has to extrapolate from high dose  
6 studies to assess general population risk). While these studies have a number of methodological limitations,  
7 they have been remarkably consistent in finding associations between fluoride and reduced IQ. In 2012,  
8 Dr. Philippe Grandjean, an environmental epidemiologist at the Harvard School of Public Health, published  
9 a meta-analysis which found that fluoride was associated with reduced IQ in 26 of the 27 studies that met  
10 the inclusion criteria of the analysis. **Ex. 19** at 315:18-316:6; **Ex. 23** ¶ 4. According to Dr. Grandjean, it is  
11 “very unlikely” that the consistent association between fluoride and IQ can be explained away by chance  
12 or some other factor. **Ex. 19** at 315:18-316:6; **Ex. 23B** at 6. Thus, in 2014, Dr. Grandjean and his colleague  
13 Dr. Phil Landrigan included fluoride as 1 of just 11 industrial chemicals<sup>7</sup> known to be developmental  
14 neurotoxicants in humans. **Ex. 24** at 1.

15  
16  
17 ***NIH-Funded Prospective Birth Cohort Studies:*** Since 1997, the EPA has partnered with the  
18 National Institutes of Health (NIH) to “investigate new frontiers in the field of children’s environmental  
19 health research.” **Ex. 25** at 8. As part of this effort, the EPA and NIH have funded prospective birth cohort  
20 studies to study the effect of environmental chemicals, including fluoride, on children’s health. *Id.* at 70-  
21 71. Short of intentionally dosing humans in controlled experiments (which are prohibited for ethical  
22 reasons), prospective cohort studies are the “ideal study design” for understanding the impact of  
23 environmental chemicals on human health. **Ex. 26** at 162:25-163:7; **Ex. 27** at 182:23-183:11.

24  
25 Two of the prospective cohort studies—the “ELEMENT” cohort in Mexico City and the “MIREC”  
26 cohort in Canada—have investigated the relationship between prenatal fluoride exposure and

27  
28 <sup>7</sup> In addition to its use as a water treatment chemical, fluoride is the active ingredient in several pesticides. *See, e.g.,* **Ex. 5** at 1. Like arsenic and lead, fluoride also occurs naturally. **Ex. 19** at 307:21-308:21.

1 neurodevelopmental outcomes. **Ex. 27** at 15:5-14. In 2017, the first NIH-funded study on prenatal fluoride  
2 and IQ (“Bashash 2017”) was published. *Id.* at 97:21-98:22. The study examined 299 mother-child pairs in  
3 the ELEMENT cohort, found a linear dose-response relationship between prenatal fluoride exposure (as  
4 measured in the urine of the mother) and reduced childhood IQ. *Id.* at 33:2-34:15; 108:20-24, 203:18-  
5 204:19. Notably, the concentrations of fluoride found in the urine of the mothers were roughly the same as  
6 the maternal urinary fluoride concentrations measured in pregnant women living in areas with artificially  
7 fluoridated drinking water. *Id.* at 31:4-32:11, 165:2-15, 181:5-12; **Ex. 28** at 209:3-12; **Ex. 23B** at 15; **Ex.**  
8 **29** at 4 & Tbl. 2. Each 0.5 mg/L increase of fluoride in the mother’s urine was associated with 3.15 less IQ  
9 points at 4 years of age—an effect size that rivals the effects of lead. **Ex. 27** at 205:2-206:8.

11 In 2018, the second NIH-funded prospective study on fluoride was published (“Bashash 2018”),  
12 again from the ELEMENT cohort, but this time focusing on ADHD symptoms instead of IQ. **Ex. 27** at  
13 125:15-126:13. This second study found that prenatal fluoride exposure (as measured in the urine of the  
14 mother) was significantly associated with increased symptoms (i.e., inattention) of ADHD in the offspring.  
15 *Id.* at 34:16-35:6. According to Dr. Howard Hu, the results from the ELEMENT studies “are consistent  
16 with and support the conclusion that fluoride is a developmental neurotoxicant at levels of exposure seen  
17 in the general population in artificially fluoridated communities.” *Id.* at 180:18-181:4. Dr. Donohue, from  
18 EPA’s Office of Water, testified that the ELEMENT studies are “well-conducted,” and further justify a  
19 reassessment of fluoride policies to ensure that children are not being overexposed. **Ex. 12** at 243:12-22,  
20 254:18-255:4; 257:24-258:16, 271:2-272:19.

22 In August of 2019, the results of the NIH-funded prospective study of the MIREC cohort (“Green  
23 2019”) were published in *JAMA Pediatrics*. **Ex. 28** at 120:20-121:7. The study examined 512 mother-child  
24 pairs living in communities with water fluoride levels at, or below, **0.7 mg/L** and found that prenatal  
25 fluoride exposure was significantly associated with reduced IQ in boys. *Id.* at 124:19-23, 209:15-210:13.  
26 Each 1 mg/L increase of fluoride in the mothers’ urine was associated with 4 to 5 less IQ points among the  
27  
28

1 boys, an effect size on par with lead. *Id.* at 211:10-213:8. The study also found significant associations  
2 between IQ (in both boys and girls) and maternal fluoride intake from water and other beverages. *Id.* at  
3 157:14-19. According to Dr. Bruce Lanphear, the senior investigator on the study, the findings from the  
4 MIREC study are “convergent” with the findings from the ELEMENT cohort and suggest that the *in utero*  
5 period is a “susceptible period of life vis-à-vis fluoride toxicity.” *Id.* at 62:11-64:9, 215:20-216:5. Based  
6 on these results, Dr. Lanphear recommends that pregnant women “begin taking steps to reduce their  
7 fluoride intake, including but not limited to reducing their consumption of fluoridated water.” *Id.* The editor  
8 of *JAMA Pediatrics* made a similar recommendation in a *JAMA* podcast accompanying the release of the  
9 study. Connett Decl. ¶ 49; **Ex. 28** at 216:6-218:25.

11 In addition to the *JAMA Pediatrics* study, Dr. Lanphear’s team has just finished a second study of  
12 the MIREC cohort (“Till, in press”) which examines the association between IQ and fluoride intake during  
13 *infancy*. **Ex. 28** at 165:18-166:1, 166:16-18. While not yet published, the new study of 398 children found  
14 a significant association between fluoride ingestion during infancy and reduced non-verbal IQ. *Id.* at 193:6-  
15 194:12. According to Dr. Lanphear, “this association remained significant after controlling for fetal fluoride  
16 exposure and other relevant covariates, suggesting that the susceptibility to fluoride’s adverse neurological  
17 effects may extend into infancy.” *Id.* at 223:20-224:7.

19 **Animal Studies:** Subsequent to the NRC’s 2006 review, over 100 animal studies investigating  
20 fluoride’s neurotoxicity have been indexed in the National Library of Medicine’s online database  
21 (“PubMed”). **Ex. 13A** at 10. Most of these animal studies have continued to focus on fluoride’s  
22 neurochemical and cellular effects, with the overwhelming majority confirming and expanding upon  
23 NRC’s conclusion that fluoride damages animal brain on the neurochemical and cellular level. *Id.* at 11. A  
24 subset of these studies have also examined fluoride’s “functional” effects on learning and memory, with  
25 most finding impaired performance in the fluoride-treated animals, thus confirming the *a priori* suspicion  
26 that neurochemical damage will ultimately manifest in outwardly demonstrable deficits. **Ex. 18** at 380:21-  
27

1 381:12. EPA scientist, Dr. Kristina Thayer, who studied the animal literature on fluoride neurotoxicity  
2 during her time at the National Toxicology Program (NTP), agrees that the animal data “supports the  
3 biological plausibility” of fluoride being a neurotoxicant in humans. **Ex. 26** at 11:15-12:3, 77:5-14, 164:17-  
4 165:4, 167:11-18; 248:21-249:5.

#### 5 **E. Susceptible Subsets of the Population**

6 Under the 2016 amendments to TSCA, a citizen petition must be granted if the preponderance of  
7 the evidence demonstrates an unreasonable risk to a “susceptible subpopulation.” 15 U.S.C. 2620(b)(4)(B).  
8 The statute defines susceptible subpopulations as people who “due to either greater susceptibility or greater  
9 exposure, may be at greater risk than the general population of adverse health effects from exposure to a  
10 chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.” 15  
11 U.S.C. § 2602(12). In the context of *neurotoxicity* risk assessments, the EPA states that *life stage* is a critical  
12 criterion for identifying susceptible populations, noting that “a population subgroup is susceptible if  
13 exposure occurs during a period of sensitivity.” **Ex. 3** at 64-65; **Ex. 26** at 109:4-15; **Ex. 30** at 42.  
14

15 **Fetus:** According to the EPA, “[t]he developing brain is distinguished by the absence of a blood-  
16 brain barrier. The development of this barrier is a gradual process, beginning *in utero* and complete at  
17 approximately 6 months of age. Because the blood-brain barrier limits the passage of substances from blood  
18 to brain, in its absence, toxic agents can freely enter the developing brain.” **Ex. 31** at 58; *see also* **Ex. 32** at  
19 177:18-179:11; **Ex. 19** at 70:16-71:11, **Ex. 26** at 104:4-12; **Ex. 27** at 185:4-186:8. EPA’s retained  
20 toxicologist, Dr. Joyce Tsuji, agreed that the absence of a blood brain barrier renders the brain more  
21 vulnerable to the harm posed by neurotoxicants. **Ex. 32** at 180:3-16. Dr. Tsuji also agreed that fluoride  
22 passes through the placenta, and gets into the fetal brain. *Id.* at 180:17-181:5. Further, based on the recent  
23 prospective studies, Dr. Tsuji agreed that the *in utero* period is a critical period of concern for fluoride  
24 neurotoxicity. *Id.* at 182:12-183:5.  
25

26 **Infants:** The 30(b)(6) representative for EPA agreed that the addition of fluoridated water to infant  
27  
28

1 formula “dramatically” increases an infant’s exposure to fluoride. **Ex. 10** at 286:18-287: 1. Based on data  
2 identified by the EPA, infants receiving formula made with fluoridated water ingest roughly 100 times  
3 more fluoride than an exclusively breastfed baby. *Id.* at 257:20-258:1, 258:21-259:6, 259:12-260:18. As a  
4 result, EPA’s expert Dr. Tsuji admitted that infants drinking formula made with fluoridated water can  
5 exceed EPA’s reference dose (0.08 mg/kg/day) for severe dental fluorosis, and that this is a cause for  
6 concern. **Ex. 32** at 233:7-15; 403:16-404:5. In short, there is no dispute that fluoridation exposes infants to  
7 fluoride. Nor is there a dispute that infancy is a “period of sensitivity” for neurotoxicity—the EPA has  
8 termed the neonatal period “a critical window of development” for the brain, because it is “a period of rapid  
9 development of the nervous system” without the protection of a fully developed blood brain barrier. **Ex.**  
10 **30** at 42; **Ex. 33** at 5-4.

12 ***Elderly:*** In addition to the developing brain, the EPA has recognized that the elderly brain is also  
13 “at particular risk because of the limited ability of the nervous system to regenerate or compensate to  
14 neurotoxic insult.” **Ex. 3** at 65. Plaintiff’s risk assessment expert, Dr. Kathleen Thiessen, has identified a  
15 number of factors that will render the elderly more vulnerable to the neurotoxic effects of fluoride,  
16 including: (1) fluoride accumulates in the skeletal system throughout life, and this accumulated fluoride  
17 begins to be released back into the blood as the skeleton begins to break down in the post-  
18 menopausal/elderly years; (2) the kidney becomes less efficient at excreting fluoride with older age, thus  
19 more of the fluoride circulating in the blood stays in the body; and (3) the blood brain barrier is more  
20 permeable in the elderly, thus the increased fluoride circulating in the blood will have greater access to the  
21 elderly brain. **Ex. 13A** at 44-45. Consistent with Dr. Thiessen’s assessment, a study published earlier this  
22 year in the *British Journal of Psychiatry* reported a significant association between low levels of fluoride  
23 in drinking water and dementia. **Ex. 34** at 1.

#### 26 **F. Plaintiffs’ Expert Testimony on Risk: A Brief Summary**

27 ***Dr. Kathleen Thiessen:*** Dr. Thiessen is a risk assessment scientist who has co-authored both of the  
28

1 NRC’s reviews on fluoride toxicity since 2000, including the landmark 2006 report; she has also written  
2 health assessment reports for EPA, including on fluoride. **Ex. 13** ¶ 3; **Ex. 32** at 420:21-422:14. In this case,  
3 Dr. Thiessen conducted a risk assessment pursuant to EPA’s *Guidelines*. **Ex. 13** ¶ 4; **Ex. 18** at 318:5-16.  
4 Based on her assessment, Dr. Thiessen concluded *inter alia* that (1) neurotoxicity is a hazard of fluoride  
5 exposure, and (2) EPA’s Margin of Exposure (MOE) method demonstrates that fluoridation chemicals pose  
6 an unacceptable risk of neurotoxicity. **Ex. 13** ¶¶ 4, 7, 9-10.

7 **Dr. Philippe Grandjean:** Dr. Grandjean is an NIH-funded epidemiologist and specialist in the field  
8 of developmental neurotoxicity at the Harvard School of Public Health. **Ex. 23** ¶ 4. As part of his expert  
9 reports in this case, Dr. Grandjean conducted Benchmark Dose (BMD) analyses of the prospective birth  
10 cohort studies<sup>8</sup> to determine the level of maternal urinary fluoride that is associated with a 1-point drop in  
11 IQ. *Id.* ¶¶ 5-8. Dr. Grandjean’s BMD analysis demonstrates a substantial neurologic risk from fluoridation  
12 chemicals in water that rivals the effects of lead (i.e., up to 23 million lost IQ points for children aged 0 to  
13 5). **Ex. 19** at 75:13-78:9, 96:3-14; **Ex. 23** ¶¶ 6-8; **Ex. 23A** at 40-43.

### 14 **III. ARGUMENT**

#### 15 **A. Plaintiffs Have Sufficient Evidence to Demonstrate an Unreasonable Risk**

16 In its motion, EPA argues that Plaintiffs cannot prove that an unreasonable risk exists because  
17 “Plaintiffs cannot demonstrate that fluoride at or below 0.7 mg/L causes neurotoxic effects.” Mot at 9:18-  
18 19. As an initial matter, this argument fails because it incorrectly assumes that an unreasonable risk  
19 determination for a given condition of use requires proof of harm at the level of exposure associated with  
20 the use. *See id.* at 7:15-16 (“Plaintiffs must demonstrate that use of fluoridation chemicals results in adverse  
21 neurotoxic effects at [0.7 mg/L].”) While this is the standard that EPA’s retained experts used for their  
22 analyses in this litigation,<sup>9</sup> it is *not* the way that EPA assesses risk under TSCA, nor is it the standard that  
23  
24  
25  
26

27 <sup>8</sup> The senior investigators of the ELEMENT and MIREC studies, Dr. Howard Hu and Dr. Bruce Lanphear,  
28 have agreed to testify in this case as non-retained experts for Plaintiffs. Connett Decl. ¶ 51.

<sup>9</sup> EPA’s retained epidemiologist, Dr. Ellen Chang, contends that there is “insufficient evidence” to prove  
Continued on the next page

1 Congress envisioned for TSCA, nor is it the standard that courts have used for judging “significant risk”  
 2 under health-protective statutes. *See* **Ex. 1** at 303:4-7; **Ex. 6** at 17-18; **Ex. 35** at 7 & 32; *Ethyl Corp. v. U.S.*  
 3 *E.P.A.*, 541 F.2d 1, 8, 12, & 25 (D.C. 1976).<sup>10</sup> In the real world, EPA judges risk by using the Margin of  
 4 Exposure method to determine if human exposure is unacceptably close to the known toxicity level. *See*  
 5 *supra* Section II.C; *see also* *NRDC*, 735 F.3d at 881-84. Despite this, EPA’s motion never once even  
 6 mentions Margin of Exposure or its acronym “MOE.”

7 ***Dr. Thiessen’s MOE Analysis:*** EPA’s motion fails to address or even acknowledge that Plaintiffs’  
 8 expert, Dr. Thiessen, conducted an MOE analysis. Using the MOE method, Dr. Thiessen found  
 9 unacceptable risks for *every* point of departure that can be justified from the animal literature, including  
 10 the point of departure that EPA’s own expert agreed was reasonable to use (i.e., a 20 mg/L NOAEL). **Ex.**  
 11 **13 ¶¶ 7 & 9; Ex. 13A** at 67; **Ex. 32** at 259:14-21. For each of the points of departure that Dr. Thiessen  
 12 used, the Calculated MOEs indicated risks for multiple subpopulations, including bottle-fed infants, adults  
 13 of child-bearing age, and/or the elderly. **Ex. 13A** at 67. The risks that Dr. Thiessen found using the MOE  
 14 method are, in the words of EPA’s own expert, “unacceptable.” **Ex. 1** at 288:16-289:11; **Ex. 7** at 43. Dr.  
 15 Thiessen’s MOE analyses are thus sufficient, *by themselves*, to create a triable issue on risk.<sup>11</sup>

16 ***Dr. Grandjean’s BMD Analysis:*** Dr. Thiessen’s MOE analysis is not the only evidence of risk that  
 17 Plaintiffs have proffered. For example, Dr. Grandjean conducted BMD analyses of the NIH-funded  
 18 prospective birth cohort studies to determine the levels of fluoride exposure that are associated with IQ  
 19  
 20  
 21

22 \_\_\_\_\_  
 23 that fluoridated water at 0.7 mg/L causes neurotoxicity. Dr. Chang explained, however, that her definition  
 24 of “insufficient evidence” is “not enough compelling evidence to reach a *definitive* conclusion.” **Ex. 36** at  
 25 125:19-126:2. Dr. Chang admitted that her conclusion of “insufficient evidence” is not inconsistent with  
 26 the chemical being a *presumed* cause. *Id.* at 123:17-124:17, 125:9-126:17.

27 <sup>10</sup> *See also* John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic*  
 28 *Substances Control*, 91 COLUM. L. REV. 261, 271–73 (1991) (describing the unreasonable risk standard as  
 “a regulation of risk instead of actual harm”).

<sup>11</sup> Elsewhere in EPA’s motion, EPA criticizes Dr. Thiessen’s risk characterization for considering factors  
 that EPA considers in *Section 5* risk evaluations for *new chemicals*. *Mot.* at 18:14-20:7. This, however, is  
 a red herring, because 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**. Moreover, one of the factors that  
 EPA considers under *Section 5* (number of people exposed) is also considered under *Section 6*.

1 loss. **Ex. 23** ¶ 5. EPA routinely uses BMD levels as the POD for risk characterization, including for MOE  
2 analyses under TSCA. Mot. at 11:26-28; **Ex. 23** ¶ 6; **Ex. 1** at 346:1-4; **Ex. 9** at 154. While Dr. Grandjean  
3 “did not attempt to calculate a specific exposure limit,” the BMDL values that he calculated (e.g., 0.13 to  
4 0.21 mg/L in maternal urine) “are well below the exposure levels that have been documented in fluoridated  
5 communities in North America. **Ex. 23** ¶ 8. By logical extension, therefore, “[e]xposure limits calculated  
6 from these BMDL values . . . will be substantially exceeded by the daily doses produced by artificial water  
7 fluoridation.” *Id.*

8  
9 EPA’s motion does not question or challenge the results of Dr. Grandjean’s BMD calculations.  
10 Instead, EPA seizes upon a fleeting moment of levity in Dr. Grandjean’s seven-hour deposition to argue  
11 that Dr. Grandjean is not qualified to testify about BMD analyses. Specifically, EPA cites Dr. Grandjean’s  
12 passing comment that “I wouldn’t trust myself” to calculate BMD levels. Mot. at 14:5-6. What EPA fails  
13 to mention is that Dr. Grandjean has extensive experience in BMD analysis, including (1) working with  
14 EPA and the National Academy of Sciences (NAS) to develop a reference dose for methylmercury based  
15 on Dr. Grandjean’s BMD data on mercury and neurodevelopmental harm, and (2) publishing a BMD  
16 analysis on blood lead and IQ. **Ex. 19** at 95:16-96:19; **Ex. 37** at 8-10. In this case, as with his previous  
17 BMD work, Dr. Grandjean collaborated with Dr. Esben Budtz-Jorgensen, a biostatistician who is “one of  
18 the key experts in the world” on BMD. **Ex. 19** at 89:22-95:1. While Dr. Budtz-Jorgensen is the one who  
19 actually calculates the BMDs, this does not deprive Dr. Grandjean of the foundation to discuss the results.  
20 Indeed, if this were the rule, no expert in this case could testify about any data that they themselves did not  
21 personally generate, which would eliminate both of EPA’s experts on risk because neither has conducted a  
22 study on fluoride neurotoxicity. **Ex. 32** at 5:15-6:8, 15:2-5; **Ex. 36** at 27:9-28:6. Dr. Grandjean’s moment  
23 of levity, therefore, does not provide a basis for excluding the results of his BMD analyses.  
24  
25

26 ***Other Risk Factors:*** The other factors that may be considered in making a risk determination under  
27 TSCA provide *further* support for an unreasonable risk finding for fluoridation chemicals.  
28

1            Number of People Exposed (including susceptible groups): This factor strongly supports an  
2 unreasonable risk determination, because human exposure to fluoridation chemicals is “nothing short of  
3 massive.” **Ex. 13A** at 64. Over 200 million Americans have fluoridation chemicals directly added to their  
4 home drinking water, including 2.9 million pregnant women each year. **Ex. 13** ¶ 10. An additional 1.2  
5 million infants are exposed each year to fluoridation chemicals in their infant formula *every day for their*  
6 *first six months of life*, and EPA’s 30(b)(6) representative agreed that this “dramatically” increases a  
7 newborn baby’s exposure to fluoride. *Id.*; **Ex. 10** at 286:18-287:1. To put these numbers in perspective,  
8 EPA found unreasonable risks for conditions of use of 1-BP which involved just *hundreds* of workers, with  
9 *no* general population or susceptible subpopulation exposures. **Ex. 13** ¶ 10.

11            Severity of the Hazard: This factor further supports an unreasonable finding for fluoridation  
12 chemicals. Dr. Thiessen based her MOE analysis on learning impairment in animals which has been  
13 recognized by EPA as an appropriate endpoint to use for human risk assessment. **Ex. 13A** at 56, 66-67; **Ex.**  
14 **18** at 383:19-25; *see also* **Ex. 32** at 130:2-10. Further, Dr. Grandjean based his BMD analysis on IQ loss  
15 and estimated that fluoridation chemicals are causing a loss of 4.5 to 23 million IQ points among 0-to-5  
16 year-olds, which rivals the effects of lead and mercury. **Ex. 23A** at 38-41. The EPA has recognized the  
17 need to protect against the loss of a single IQ point, and Dr. Henry testified at her deposition that “chemicals  
18 added to drinking water should not cause reductions in IQ.” **Ex. 32** at 416:15-19, 417:2-5; **Ex. 1** at 409:4-  
19 11; *see also* **Ex. 25** at 3 (stating that the loss of 1 IQ point results in a loss of \$11,500-\$15,600 in lifetime  
20 earnings). Consistent with this, EPA’s litigation experts have previously conducted an RfD analysis for  
21 arsenic where they used a loss of 1 IQ point as the adverse effect to protect against. **Ex. 32** at 377:14-378:2.

22            Reversibility of the Hazard: Dr. Grandjean has explained that “[i]f a developmental process in the  
23 brain is halted or inhibited, there is little potential for later repair . . . and the consequences may therefore  
24 be permanent.” **Ex. 23A** at 8. Further, with respect to the elderly brain, the EPA has acknowledged that the  
25 elderly brain is “at particular risk because of the limited ability of the nervous system to regenerate or  
26  
27  
28

compensate to neurotoxic insult.” **Ex. 3** at 65; *see also* **Ex. 18** at 357:15-19.

Uncertainties:. In assessing uncertainties, EPA considers the confidence in the hazard and exposure assessments. **Ex. 8** at 256; **Ex. 9** at 153. Here, Dr. Thiessen concluded to “a high degree of confidence” that neurotoxicity is a hazard of fluoride exposure, 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 the neurotoxic effects of chemicals. **Ex. 10** at 286:18-287:1; **Ex. 13** ¶ 4; **Ex. 30** at 42. Further, in assessing uncertainties, EPA has stated “[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 . . . .)” **Ex. 8** at 257; **Ex. 9** at 154. This factor again weighs in favor of an unreasonable risk determination because Dr. Thiessen found risks using a benchmark MOE of 30. **Ex. 13** ¶ 9.

**B. There Is a Clear and Logical Basis to Extrapolate the Findings from Mexico and Canada to the United States**

The EPA contends in its motion that there is “no basis to infer that studies conducted in Mexico and Canada are generalizable to the United States.” Mot. at 13:24-25. This is meritless. First, as Dr. Lanphear has explained, “there’s no reason to suspect biologically speaking that Canadians and Americans are different,” and it is “silly” to suggest otherwise. **Ex. 28** at 58:20-23. Second, both the Canadian and Mexico City cohorts were exposed to “optimal” fluoride levels through either their water (Canada) or salt (Mexico), and their urinary fluoride levels were effectively the same. **Ex. 27** at 196:12-197:18; **Ex. 28** at 209:3-12. There is no apparent reason—and *EPA’s motion does not identify one*—why Americans exposed to “optimal” fluoride levels in their water will have materially *less* fluoride exposure.<sup>12</sup> Third, Dr. Grandjean did not “merely assume[], without any support, that pregnant women living in fluoridated areas in the United States would have similar urine-fluoride concentrations.” Mot. at 13:7-8. In his initial report, Dr. Grandjean explained that “the higher rate of dental fluorosis and greater reach of water fluoridation in the

<sup>12</sup> If Americans have *more* fluoride exposure in fluoridated areas than their counterparts in Canada and Mexico, this will only make the problem worse.

1 U.S. suggests that urine-fluoride concentrations may be higher than in Canada.” **Ex. 23A** at 15. Further, in  
2 his supplemental report, Dr. Grandjean discussed a new study of pregnant women living in Northern  
3 California which found that the “urinary fluoride concentrations were similar to those reported from  
4 Canada.” **Ex. 23B** at 15; **Ex. 29** at 4. The pregnant women living in fluoridated areas of California were  
5 found to have 0.74 mg/L of fluoride in their urine, versus 0.69 mg/L among pregnant women living in  
6 fluoridated areas of Canada. *Compare Ex. 29 Tbl. 2 to Adkins Decl. Ex. 10 at 1.* EPA’s motion entirely  
7 ignores this study, as well as Dr. Grandjean’s reliance on it.

8  
9 Finally, it is not just Dr. Grandjean who believes the results of the ELEMENT and MIREC cohort  
10 studies are generalizable to the United States; the actual authors of the studies do as well. **Ex. 27** at 181:5-  
11 12; **Ex. 28** at 40:8-13. Moreover, the editor of *JAMA Pediatrics* stated that—in light of the MIREC  
12 findings—he would now recommend that pregnant women not drink fluoridated water. Connett Decl. ¶ 49;  
13 **Ex. 28** at 216:6-218:25. EPA fails to acknowledge or grapple with any of this evidence in its motion.

### 14 **C. Plaintiffs’ Experts Assessed Risk Using EPA’s Own Methodologies**

15  
16 EPA argues that the opinions offered by Plaintiffs’ experts “are of no value for assessing the risk of  
17 adding fluoridation chemicals water because the methodologies employed do not conform to TSCA’s  
18 standards, including reliable scientific principles and methods.” Mot. at 14:15-18. This argument does not  
19 withstand scrutiny.

20  
21 First, Dr. Thiessen conducted a neurotoxicity risk assessment pursuant to EPA’s own *Guidelines*,  
22 which is what EPA has stated it “will use” to assess the “potential neurotoxicity of environmental  
23 toxicants.” **Ex. 13** ¶ 4; **Ex. 1** at 251:21-252:15; **Ex. 3** at 1. Dr. Henry testified that a risk assessment  
24 conducted pursuant to the *Guidelines* would be “effectively” a systematic review, and provide “credible”  
25 results. **Ex. 1** at 254:4-8, 257:1-6. EPA’s motion makes no mention of Dr. Thiessen’s application of the  
26 *Guidelines*. Instead, EPA inexplicably resorts to the false claim that “Dr. Thiessen relied entirely on  
27 findings of three previously published meta-analyses” and “ignored” studies published after 2016. Mot. at  
28

1 15:12-21. In fact, Dr. Thiessen discussed many other human studies besides the meta-analyses, including  
2 the prospective cohort studies published since 2017, as even a cursory review will reveal. *See* **Ex. 13** ¶ 4;  
3 **Ex. 13A** at 16-24.

4 Second, Dr. Grandjean conducted a comprehensive “narrative review” of the scientific literature,  
5 wherein he relied on the “best available science” and did a “weight of the evidence” analysis. **Ex. 19** at  
6 232:16-233:9; 330:15-333:1. EPA’s own experts in this case have testified that narrative reviews are a  
7 reliable method for assessing the scientific literature, and Congress has specifically called on EPA to rely  
8 on the best available science and conduct weight of the evidence analyses. 15 U.S.C. § 2625(h)-(i); **Ex. 38**  
9 at 25:16-20; **Ex. 39** at 46:6-21. Further, Dr. Grandjean placed greatest weight on the prospective cohort  
10 studies, which EPA’s own scientist has called the “ideal study design,” and which EPA’s retained  
11 epidemiologist agreed are the most reliable studies ever conducted on fluoride and IQ. **Ex. 26** at 162:25-  
12 163:7; **Ex. 36** at 208:1-210:2. Finally, as discussed earlier, Dr. Grandjean quantitatively assessed the risk  
13 by conducting a BMD analysis, which is a well-established method that EPA routinely uses in risk  
14 assessment, including in TSCA risk evaluations. Mot. at 11:26-28; **Ex. 23** ¶ 6; **Ex. 1** at 346:1-4.

15  
16  
17 **D. Section 21 Does Not Require a Formal Systematic Review, But, Irregardless, the Systematic  
18 Reviews by EPA’s Experts Confirm that the Best Available Science Has Been Considered**

19 EPA contends that the opinions of Plaintiffs’ experts are fatally flawed because they did not conduct  
20 “systematic reviews.” Mot. at 14:18-21. This argument is wrong, both legally and factually.

21 First, as a matter of law, the TSCA statute does not require “systematic review”; in fact, the words  
22 “systematic review” do not appear anywhere in the statute. **Ex. 1** at 181:18-21. Congress only requires that,  
23 if the EPA is to make a decision based on science, the Agency do so based on the “best available science”  
24 and “weight of the scientific evidence.” 15 U.S.C. § 2625(h)-(i). Although EPA has defined the term  
25 “weight of the scientific evidence” to include a “systematic review method” for purposes of *Section 6(b)*  
26 risk evaluations, 40 C.F.R. § 702.33, this Court has recognized that Section 21 is “independent of the  
27 Section 6(b) risk evaluation process.” *Food & Water Watch*, 291 F. Supp. 3d at 1046. TSCA “did not  
28

1 mandate the EPA perform any risk evaluations” prior to the 2016 Amendments, and “[t]here is no reason  
2 to think that . . . Congress intended to incorporate all of the new provisions of Section 6(b) related to the  
3 EPA’s risk evaluations into the Section 21 process, particularly in light of the express limitation to Section  
4 6(a) in Section 21’s judicial review provisions.” *Id.* at 1046 n. 7. The only requirement that Congress  
5 imposed for *de novo* proceedings is that the petitioner “demonstrate[] to the satisfaction of the court by a  
6 preponderance of the evidence” that an unreasonable risk exists. 15 U.S.C. § 2620(b)(4)(B). Congress left  
7 it to the courts to determine what preponderance of the evidence means in any given case.

8  
9 Second, EPA’s own conduct in this case demonstrates that systematic reviews are not necessary in  
10 Section 21 proceedings. Specifically, EPA’s two experts on the purported benefits of fluoridation chemicals  
11 (Drs. Charlotte Lewis and Gary Slade) produced narrative reviews,<sup>13</sup> as both experts were already familiar  
12 with the literature. **Ex. 38** at 23:25-29:24; **Ex. 39** at 45:9-47:9. As with Drs. Lewis and Slade, Plaintiffs’  
13 experts on risks were already familiar with the literature and chose to write narrative reviews as well.

14 Third, the systematic reviews that EPA’s experts on risk conducted *confirm* that Drs. Grandjean  
15 and Thiessen considered the best available science. EPA’s retained epidemiologist, Dr. Chang, admitted  
16 that her systematic review did not identify any studies that were omitted by Dr. Grandjean that would  
17 materially challenge his opinion. **Ex. 36** at 242:14-243:10, 246:8-247:25, 249:16-23, 268:9-19, 269:5-  
18 270:19, 270:22-272:17; *see also* **Ex. 23** ¶ 11, **Ex. 23B** at 3-5. Similarly, EPA’s retained toxicologist, Dr.  
19 Tsuji, admitted that her systematic review did not identify any “no effect” animal study that was omitted  
20 by Dr. Thiessen. **Ex. 32** at 150:4-151:4; *see also* **Ex. 18** at 327:23-328:11. Moreover, Dr. Chang agrees  
21 with Dr. Grandjean that the NIH-funded prospective cohort studies are the most reliable studies on fluoride  
22 and neurotoxicity to date, and that each of these studies reported significant associations between prenatal  
23 fluoride exposure and neurodevelopmental harm. **Ex. 19** at 332:5-333:1; **Ex. 36** at 208:1-210:2, 213:18-  
24 214:6. There is thus no dispute in this case that *the best studies ever conducted on fluoride and neurotoxic*

25  
26  
27  
28  

---

<sup>13</sup> The vast majority of *EPA’s own risk assessments* have used narrative reviews. **Ex. 1** at 212:7-14; 213:11-17; 236:1-8, 240:18-241:1; *see also* **Ex. 26** at 289:6-12.

1 *outcomes have each reported significant adverse associations.*

2 Finally, even *if* systematic reviews are required for Section 21 *de novo* proceedings, the systematic  
 3 reviews conducted by EPA’s experts satisfy this requirement. In its motion, EPA states that systematic  
 4 reviews are “a necessary step for demonstrating that . . . risk determinations are based on the best available  
 5 science.” Mot. at 15:2-5. As discussed above, the systematic reviews by Drs. Chang and Tsuji confirm that  
 6 Plaintiffs’ risk determinations *are* based on the best available science, and EPA does not attempt to explain  
 7 otherwise in its motion. The systematic reviews that EPA’s experts have conducted thus confirm that this  
 8 Court will have the best available science at its disposal in making its risk determination.  
 9

## 10 **E. Plaintiffs Have Standing**

### 11 i. The Factual Basis of Plaintiffs’ Standing

12 The Plaintiffs have produced declarations setting forth the factual basis for their standing, ECF Nos.  
 13 100 & 102, which Plaintiffs will briefly summarize here.<sup>14</sup>  
 14

15 Plaintiff **Food & Water Watch (FWW)** is a nonprofit membership organization that champions  
 16 healthy food and clean water for all. **Ex. 40** ¶ 4. A “core” part of FWW’s mission is “the belief that clean,  
 17 safe water for drinking and recreational uses is a fundamental right that should be afforded to all people.”  
 18 *Id.* FWW thus advocates for more government responsibility in protecting drinking water resources, and  
 19 engages in legal efforts to oppose regulatory action/inaction that threatens the safety of drinking water. *Id.*  
 20 ¶¶ 6-7. Some of FWW’s 70,000 members “expend substantial sums of money and endure substantial  
 21 inconvenience in order to protect themselves and their families from the credible risks of neurological harm  
 22 posed by fluoridation chemicals in food and water.” *Id.* ¶¶ 5 & 10. The concern about neurological risks  
 23 expressed by some FWW members is “based, in part, on neurological ailments they, or their children, have  
 24 suffered from drinking fluoridated water.” *Id.* ¶ 11.  
 25  
 26  
 27

28 <sup>14</sup> Some, but not all, of these declarations are attached to EPA’s motion, which Plaintiffs refer to herein as “Simms Decl.,” “Lavelle Decl.,” “Adams Decl.,” “Staudenmaier Decl.,” and “Trader Decl.”

1 **Julie Simms** is one of the FWW members that has suffered neurological ailments from fluoridation  
2 chemicals. *Id.* As described in her declaration, Ms. Simms had suffered from daily headaches and frequent  
3 debilitating migraines for over 20 years until, at a friend’s suggestion, she stopped drinking fluoridated  
4 water. Simms Decl. ¶¶ 6-13; **Ex. 41** at 103:9-104:25, 110:18-111:18; 114:9-116:4. As reflected in her  
5 medical records, Ms. Simms experienced an “amazing improvement in general health since she stopped  
6 having any exposure to fluoride.” **Ex. 42**; *see also* **Ex. 43** (stating that Ms. Simms “was having daily  
7 headaches until 3 weeks after she started avoiding all fluoride”). Ms. Simms stopped consuming fluoridated  
8 water in 2013, and her daily headaches have not returned since. **Ex. 41** at 115:23-116:4. Avoiding  
9 fluoridation chemicals has been a costly and emotionally taxing endeavor for Ms. Simms, as it has required  
10 her to spend “considerable sums of money” and “has also interfered with my ability to enjoy things that  
11 others may take for granted, like drinking water from my sink, taking a bath in my house, and travelling to  
12 other places without having to worry about whether the food or water will make me sick.” Simms Decl.  
13 Ex. 15 ¶¶ 20.

14  
15 Plaintiff **Audrey Adams** is another FWW member who has been impacted by the neurological  
16 effects of fluoridation chemicals. As detailed in her declaration, Ms. Adams’s autistic son, Plaintiff **Kyle**  
17 **Adams**, has experienced various adverse symptoms, including headaches, when exposed to fluoridated  
18 water. Adams Decl. ¶¶ 11-14. Due to Kyle’s apparent sensitivity to fluoride, Audrey has been advised by  
19 both of Kyle’s treating doctors to avoid exposing Kyle to fluoride, including in water. **Ex 44**; **Ex 45**. Ms.  
20 Adams has thus “incurred whatever financial expense is necessary” as well as “extraordinary  
21 inconvenience” in order “to protect Kyle from fluoridation chemicals contained in the tap water in our  
22 home, and most other communities” in her area. Adams Decl. ¶¶ 18 & 20.

23  
24 Plaintiff **Kristin Lavelle** is a health professional at San Francisco General Hospital/San Francisco  
25 Department of Public Health who first became concerned about the risks of fluoridation chemicals after  
26 reading a review by an EPA scientist explaining why EPA’s Headquarters union opposes fluoridation.  
27  
28

1 Lavelle Decl. ¶¶ 1-2. One of Ms. Lavelle’s primary health concerns with fluoride exposure is the potential  
2 risk of dementia, as she has “seen first hand the devastating effects of Alzheimer’s, as my grandfather  
3 suffered from it at the end of his life, and my aunt and father-in-law are both currently suffering from it as  
4 well.” *Id.* ¶¶ 5-6. Ms. Lavelle’s concern about the dementia risk was heightened upon reading the NRC’s  
5 2006 review, as it reported that the brain changes seen in fluoride-treated animals “parallel the changes  
6 seen in humans with dementia” and called for studies to investigate fluoride’s relationship to dementia in  
7 humans. *Id.* ¶ 7; **Ex. 17** at 222-23. Ms. Lavelle was also concerned to read in the NRC report that the half-  
8 life of fluoride in human bone is 20 years, and that the “fluoride stored in bone begins to be released back  
9 into our bloodstream at increasing rates after menopause.” Lavelle Decl. ¶ 9. According to Ms. Lavelle, the  
10 “increased circulation of fluoride in our blood later in life concerns me in light of the NRC’s concerns about  
11 fluoride’s potential link with dementia, and the studies linking fluoride to cognitive decline in late-life  
12 years.” *Id.* ¶ 9.

14 Based on these, and other health concerns, Ms. Lavelle has spent considerable sums of money to  
15 protect herself and her family from fluoridation chemicals, including purchasing water filters and bottled  
16 water. *Id.* ¶¶ 7-14. However, Ms. Lavelle recognizes that she cannot fully eliminate her exposure to  
17 fluoridated water because “many processed beverages and foods are made with” it, yet there are no labels  
18 to indicate the fluoride content on any given product. *Id.* ¶ 15.

20 Plaintiff **Brenda Staudenmaier** is a water treatment professional who has taken steps to minimize  
21 her family’s exposure to fluoridation chemicals due to the health concerns reported in the scientific  
22 literature. Staudenmaier Decl. ¶¶ 1-11. Due to limited financial resources, Ms. Staudenmaier is not able to  
23 fully eliminate her exposure, and continues to consume processed beverages and foods. *Id.* ¶¶ 11, 14. As a  
24 result, urinary fluoride tests show that Ms. Staudenmaier’s urinary fluoride levels are sometimes as high as  
25 1 mg/L, which is a concentration associated with significant neurological harm in the NIH-funded  
26 prospective studies. *Id.* ¶ 13; **Ex. 27** at 205:2-206:8; **Ex. 28** at 211:10-213:8. According to Ms.  
27  
28

1 Staudenmaier, “[u]ntil fluoridation chemicals are removed from water, I will continue suffering economic  
2 harm by spending my hard-earned and limited finances to limit my family’s exposure to fluoridation  
3 chemicals.” Staudenmaier Decl. ¶ 14.

4 ii. Plaintiffs’ Injuries Come Within the Zone of Interests

5 The EPA argues that “to fall within the zone-of-interests, Plaintiffs must demonstrate that  
6 community water fluoridation causes them the neurotoxic harm *they discussed in the petition.*” Mot. at  
7 22:7-8. As an initial matter, the EPA provides no legal authority for its unusual application of the zone-of-  
8 interests test to Plaintiffs’ *petition*. In its motion, the EPA recognizes that the zone-of-interests test is a  
9 question of “*statutory* interpretation,” i.e., “whether a legislatively conferred cause of action encompasses  
10 a particular plaintiff’s claim.” Mot. at 21:15-18 (quoting *Lexmark Int’l Inc. v. State Control Components,*  
11 *Inc.*, 572 U.S. 118, 1, 27 (2014)). The closest the EPA comes to statutory interpretation is its threadbare  
12 contention that the statute’s allowance of “petitioners” to file suit means the petitioners must “suffer the  
13 unreasonable risk presented to EPA.” Mot. at 22:2-5. The plain language of the statute does not command  
14 this result, and EPA provides no legal authority—whether legislative history or case law—to support it.  
15

16 But, assuming *arguendo* that EPA’s statutory construction is correct, it is of no avail because  
17 Plaintiffs’ petition discussed research linking fluoride to “neurological symptoms.” **Ex. 2** at 4. This research  
18 included a study (which Plaintiffs attached to their petition) that found a significant linear association  
19 between fluoride in water and *headaches*, in both children and *adults*. Connett Decl. ¶ 47; **Ex. 46.**<sup>15</sup>  
20 Consistent with this, Julie Simms suffered from chronic daily *headaches* prior to ending her consumption  
21 of fluoridated water, and she is now enduring ongoing economic injury, as well as loss of enjoyment of her  
22 home, to keep these headaches from returning by spending money to avoid the fluoridation chemicals that  
23 are added to her city and home water supply. Simms Decl. ¶¶ 13, 15-20. Similarly, Plaintiff Kyle Adams  
24 has a sensitivity to fluoridated water that results in *headaches* if he is exposed; his doctors have thus advised  
25  
26

27 \_\_\_\_\_  
28 <sup>15</sup> The relationship between fluoride and headaches is addressed by both Dr. Grandjean and Dr. Thiessen  
in their respective expert reports. **Ex. 13A** at 15; **Ex. 23A** at 17.

1 that Kyle avoid exposure to fluoride, including fluoridated water, which results in an ongoing economic  
2 injury to his caretaker, Plaintiff Audrey Adams. **Ex. 44; Ex. 45**; Adams Decl. ¶ 8-9, 18-20. Accordingly,  
3 even *if* EPA’s application of the zone-of-interests test to the scope of a *citizen petition* is doctrinally  
4 justified, Plaintiffs pass the test.

5       iii.    Plaintiffs Have Article III Standing

6           A wide variety of injuries can qualify as an injury in fact for purposes of Article III standing. *See*  
7 *United States v. Students Challenging Regulatory Agency Procedures (SCRAP)*, 412 U.S. 669, 690 n.14  
8 (1973) (agreeing that “an identifiable trifle is enough for standing” (citation omitted)). For example,  
9 evidence showing that a challenged action impairs a plaintiffs’ “[a]esthetic and environmental well-being”  
10 is sufficient to establish an injury in fact. *Washington Envtl. Council v. Bellon*, 732 F.3d 1131, 1140 (9th  
11 Cir. 2013); *see Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181-84 (2000)  
12 (holding that injury in fact established by evidence that members of plaintiff organizations had refrained,  
13 and would continue to refrain, from activities in or near river, including fishing and swimming, because of  
14 concerns about pollution from discharges of mercury into river); *Covington v. Jefferson County*, 358 F.3d  
15 626, 641 (9th Cir. 2004) (holding that injury in fact established based on plaintiffs’ “fear” that liquids  
16 leaking from “white goods” in nearby landfill “will contaminate their property”; injury in fact shown  
17 because “[a] credible threat of risks to their home yields a loss of enjoyment of property”); *Natural*  
18 *Resources Defense Council v. S.W. Marine, Inc.*, 985 F.3d 985, 994, (9th Cir. 2000) (holding that injury  
19 in fact established by evidence that plaintiffs’ use and enjoyment of bay “has been curtailed because of  
20 their concerns about pollution, contaminated fish, and the like,” from discharge of pollutants into bay).

21           An injury in fact can also be established by showing a *credible possibility* that the plaintiff will  
22 suffer *future physical injury* from the challenged action, or will experience an *increased risk* of injury. *See*  
23 *Natural Resources Defense Council v. United States Envtl. Prot. Agency*, 735 F.3d 873, 878 (9th Cir. 2013)  
24 (*NRDC*) (“As with many Article III standing cases, the threatened harm is ‘by nature probabilistic.’ . . . We  
25  
26  
27  
28

1 have consistently held that an injury is ‘actual or imminent’ where there is a ‘credible threat’ that a  
2 probabilistic harm will materialize.”); *Baur v. Veneman*, 352 F.3d 625, 633 (2nd Cir. 2003) (holding that  
3 in “food and drug safety suits,” “enhanced risk” is an injury that is “cognizable for standing purposes,  
4 where the plaintiff alleges exposure to potentially harmful products”); *Central Delta Water Agency v.*  
5 *United States*, 306 F.3d 938, 949 (9th Cir. 2002) (“[E]ven a small probability of injury is sufficient to create  
6 a case or controversy . . . .” (quoting *Village of Elk Grove v. Evans*, 997 F.2d 328, 329 (7th Cir. 1993));  
7 *Hall v. Norton*, 266 F.3d 969, 976 (9th Cir. 2001) (“It follows that evidence of a credible threat to the  
8 plaintiff’s physical well-being from airborne pollutants falls well within the range of injuries to cognizable  
9 interests that may confer standing.”).

11 An injury in fact can also be demonstrated by showing that the challenged action is causing, or  
12 might cause, *economic injury* to the plaintiff. See *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139,  
13 153-154 (2010) (holding that economic costs incurred by alfalfa farmers for testing and alternate sourcing,  
14 stemming from possible contamination of their non-genetically-engineered alfalfa by agency’s decision to  
15 deregulate a variety of genetically engineered alfalfa, were “harms” that farmers “will suffer even if their  
16 crops are not actually infected with the Roundup Ready gene” and were “sufficiently concrete to satisfy  
17 the injury-in-fact prong of the constitutional standing analysis”); *In re Zappos.com, Inc.*, 888 F.3d 1020,  
18 1027-29 (9th Cir. 2018) (holding that increased risk of future identity theft, resulting from hackers’ theft  
19 of customers’ financial information, was sufficient to establish an injury in fact).

21 Here, the evidence shows that Plaintiffs are suffering from each of the aforementioned injuries in  
22 fact. First, like the plaintiffs in *Laidlaw* and *Covington*, the Plaintiffs are suffering a loss in environmental  
23 well-being and enjoyment of property by not being able to enjoy the water piped into their homes without  
24 worry or fear that it will cause them harm. *E.g.*, Adams Decl. ¶¶ 8, 18, 20-21; Lavelle Decl. ¶ 16; Simms  
25 Dec. ¶ 20. Second, as in *NRDC* and *Baur*, the addition of fluoridation chemicals to drinking water produces  
26 a credible possibility of neurological harm in adults, as evident by the proclamations of *EPA’s own*  
27  
28

1 *scientists*; the NRC’s concerns about fluoride being a possible cause of dementia; Plaintiffs’ first-hand  
 2 experiences with headaches; and the medical advice of two of Plaintiffs’ own treating doctors. Lavelle  
 3 Decl. ¶¶ 3-7; Simms Dec. ¶ 13; **Ex. 14**, **Ex. 17** at 222-23; **Ex. 41** at 85:12-87:15; **Ex. 42**; **Ex. 43**; **Ex. 44**;  
 4 **Ex. 45**. Moreover, as in *NRDC*, there is no way for Plaintiffs to avoid all exposure to fluoridation chemicals,  
 5 because fluoridated water is added to countless processed beverages and foods, yet there are no labels to  
 6 indicate the fluoride content on any given product. Lavelle Decl. ¶ 18; Simms Decl. ¶ 15; Staudenmaier  
 7 Decl. ¶¶ 11 & 13; *see NRDC*, 735 F.3d at 879 (“[T]he probability that NRDC’s members will be able to  
 8 avoid exposing their children to the risk of harm is quite low.”); *Baur*, 352 F.3d at 641 (“[O]nly the exposure  
 9 must be imminent, not the actual onset of disease.”). Finally, Plaintiffs are suffering ongoing economic  
 10 injury to avoid the credible threats posed by fluoridation chemicals by spending money to avoid fluoridated  
 11 water. Adams Decl. ¶¶ 9, 18-20; Lavelle Decl. ¶¶ 10-14; Simms Decl. ¶¶ 16, 19-20; Staudenmaier Decl.  
 12 ¶¶ 11 & 13; Trader Decl. ¶¶ 7-8. These facts, taken to be true, are sufficient to establish that Plaintiffs have  
 13 suffered an injury in fact under Article III.<sup>16</sup>  
 14

#### 15 **IV. CONCLUSION**

16 As Plaintiffs have described in their own motion for summary judgment, the evidence in this case  
 17 permits summary judgment in the Plaintiffs’ favor because EPA has not materially countered any of  
 18 Plaintiffs’ evidence of risk. For purposes of the instant motion, however, it suffices that there are *at the*  
 19 *very least* genuine questions of material fact on each and every one of the issues identified by the EPA. The  
 20 Plaintiffs respectfully request, therefore, that the Court deny EPA’s motion.  
 21  
 22  
 23

24 <sup>16</sup> EPA’s motion does not appear to challenge the causation or redressability prongs of Article III standing,  
 25 but to the extent it does, the evidence readily satisfies both. First, with respect to causation, TSCA gives  
 26 EPA the authority to prohibit the particular use of chemical substances, which encompasses drinking water  
 27 additives. 15 U.S.C. § 2605(a)(2); **Ex. 47** at 4. EPA’s failure to exercise this authority (i.e., EPA inaction)  
 28 is a cause of the Plaintiffs’ exposure to fluoridation chemicals. Second, with respect to redressability, courts  
 have recognized that an order granting a plaintiff’s request for an administrative rulemaking proceeding  
 satisfies the redressability prong, even if the rulemaking proceeding is not guaranteed to bring about the  
 relief the plaintiff seeks. *E.g.*, *Catron County Bd. Of Com’rs, New Mexico v. United States Fish & Wildlife*  
*Service*, 75 F.3d 1429, 1433 (10th Cir. 1996).

Dated: October 18, 2019

Respectfully submitted,

/s/ Michael Connett  
MICHAEL CONNETT

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing was served by Notice of Electronic Filing this 18th day of October, 2019, upon all ECF registered counsel of record using the Court's CM/ECF system.

/s/ Michael Connett  
MICHAEL CONNETT

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28