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8
9 **UNITED STATES DISTRICT COURT**
10 **NORTHERN DISTRICT OF CALIFORNIA**
11 **SAN FRANCISCO DIVISION**

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

13 Plaintiffs,

14 v.

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

16 Defendant.

Case No. 17-CV-02162 EMC

**DEFENDANTS' NOTICE OF
MOTION AND MOTION FOR
SUMMARY JUDGMENT**

Date: November 7, 2019

Time: 1:30 p.m.

Place: 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

MEMORANDUM OF POINTS AND AUTHORITIES..... 1

STATEMENT OF ISSUES 2

BACKGROUND 2

 A. Factual Background 2

 B. Statutory Background 4

STANDARD OF REVIEW 6

ARGUMENT..... 7

I. Plaintiffs Have Not Proffered Any Evidence Demonstrating an Unreasonable Risk of Injury From Exposure to Fluoridation Chemicals Used to Increase Water Fluoride Concentrations Up to 0.7 mg/L..... 7

 A. TSCA Section 6 Requirements for Risk Evaluation and Section 26 Standards for Science-Based Decisions Govern the Court’s Risk Determination. 7

 B. The Evidence Fails to Demonstrate an Unreasonable Risk Posed by the Use of Fluoridation Chemicals in the United States. 9

 1. Plaintiffs cannot demonstrate that fluoride exposure at or below 0.7 mg/L causes neurotoxic effects. 9

 2. Plaintiffs assume, without support, that studies conducted in Mexico and Canada are generalizable to the United States. 12

 C. Plaintiffs’ Evidence Does Not Conform to Well-Accepted Scientific Methodologies and TSCA’s Scientific Standards..... 14

 1. Plaintiffs failed to systematically review the available literature, which is necessary for identifying the best available science. 14

 2. Plaintiffs cannot demonstrate a valid scientific connection between their risk assessment and risk determination. 18

II. This Court Lacks Jurisdiction Because Plaintiffs Lack Standing..... 21

 A. Plaintiffs Fall Outside the Zone-of-Interests..... 21

 B. Plaintiffs Lack Article III Standing..... 23

CONCLUSION 24

TABLE OF AUTHORITIES

Cases

Adickes v. S.H. Kress & Co.,
398 U.S. 144 (1970) 6

Air Wis. Airlines Corp. v. Hoeper,
571 U.S. 237 (2014) 8

Anderson v. Liberty Lobby, Inc.,
477 U.S. 242 (1986) 6, 7

Barnes v. Arden Mayfair, Inc.,
759 F.2d 676 (9th Cir. 1985)..... 9

Carrico v. San Francisco,
656 F.3d 1002 (9th Cir. 2011)..... 23

Clapper v. Amnesty Int’l USA,
568 U.S. 398 (2013) 23

Flast v. Cohen,
392 U.S. 83 (1968) 24

Florida Audubon Soc’y v. Bentsen,
94 F.3d 658 (D.C. Cir. 1996) 24

Food & Water Watch, Inc. v. EPA,
291 F. Supp. 3d 1033 (N.D. Cal. 2017) 7

Fortyune v. Am. Multi-Cinema, Inc.,
364 F.3d 1075 (9th Cir. 2004)..... 6

Hardage v. CBS Broad., Inc.,
427 F.3d 1177 (9th Cir. 2005)..... 6

Henricksen v. ConocoPhillips Co.,
605 F. Supp. 2d 1142 (E.D. Wash. 2009) 10

Hunt v. Wash. State Apple Advert. Comm’n.,
432 U.S. 333 (1977) 21

In re Cybernetic Servs., Inc.,
252 F.3d 1039 (9th Cir. 2001)..... 8

1 *Jones v. Otis Elevator Co.*,
 2 861 F.2d 655 (11th Cir.1988)..... 10

3 *Krottner v. Starbucks Corp.*,
 4 628 F.3d 1139 (9th Cir. 2010)..... 23

5 *Lexmark Int’l Inc. v. Static Control Components, Inc.*,
 6 572 U.S. 118 (2014) 21

7 *Lujan v. Defender of Wildlife*,
 8 504 U.S. 555 (1992) 21, 23

9 *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*,
 10 475 U.S. 574 (1986) 6

11 *Nat. Res. Def. Council v. EPA*,
 12 735 F.3d 873 (9th Cir. 2013)..... 6

13 *Nissan Fire & Marine Ins. Co. v. Fritz Cos.*,
 14 210 F.3d 1099 (9th Cir. 2000)..... 6

15 *Pennsylvania v. New Jersey*,
 16 426 U.S. 660 (1976) 23

17 *Riva v. Pepsico, Inc.*,
 18 82 F. Supp. 3d 1045 (N.D. Cal. 2015) 22, 24

19 *Sanders v. City of Fresno*,
 20 551 F. Supp. 2d 1149 (E.D. Cal. 2008), *aff’d*, 340 F. App’x 377 (9th Cir. 2003)..... 6, 9

21 *Stegall v. Citadel Broad. Co.*,
 22 350 F.3d 1061 (9th Cir. 2003)..... 6

23 *Taylor v. List*,
 24 880 F.2d 1040 (9th Cir. 1989)..... 24

25 *Town of Westport v. Monsanto Co.*,
 26 877 F.3d 58 (1st Cir. 2017) 20

27 *United States v. \$133,420.00 in U.S. Currency*,
 28 672 F.3d 629 (9th Cir. 2012)..... 23

U.S. Dep’t of Energy v. Ohio,
 503 U.S. 607 (1992) 22

1 *United States v. Smith,*
 2 683 F.2d 1236 (9th Cir. 1982)..... 8

3 **Statutes**

4 15 U.S.C. § 2604(a) 19

5 15 U.S.C. § 2605(a) 6

6 15 U.S.C. § 2605(b)(4)(A)..... 4

7

8 15 U.S.C. § 2605(b)(4)(B) 4, 8

9 15 U.S.C. § 2605(b)(4)(F)..... 5, 8

10 15 U.S.C. § 2605(c)(2)..... 6

11 15 U.S.C. § 2620(a) 22

12

13 15 U.S.C. § 2620(b)(1) 22, 23

14 15 U.S.C. § 2620(b)(4)(A)..... 22

15 15 U.S.C. § 2620(b)(4)(B) 2, 23

16 15 U.S.C. § 2620(b)(4)(B)(ii) 7, 8

17

18 15 U.S.C. § 2625(h) 5, 20

19 15 U.S.C. § 2625(h)(1) 11

20 15 U.S.C. § 2625(i)..... 5, 14

21 15 U.S.C. § 2625(l)(5) 5, 8

22

23 15 U.S.C. §§ 2601–2692..... 4

24 42 U.S.C. § 300j-7(a)(1) 3

25

26 **Rules**

27 Fed. R. Civ. P. 56(a) 6

28

1 Fed. R. of Civ. P. 56..... iv

2 N.D. Cal. Civ. Local R. 56-1 iv

3

4 **Code of Federal Regulations**

5 40 C.F.R. § 702.33 5, 15, 17, 18

6 40 C.F.R. § 720.45 19

7 40 C.F.R. § 720.50 19

8

9 **Federal Register**

10 80 Fed. Reg. 24,936 (May 1, 2015) 3

11 82 Fed. Reg. 11,878 (Feb. 27, 2017) 4, 15

12 82 Fed. Reg. 33,726 (July 20, 2017)..... 5

13 82 Fed. Reg. 33,765 (July 20, 2017)..... 5

14

15 **Legislative Materials**

16 162 Cong. Rec. S3511 (daily ed. June 7, 2016)..... 4

17 162 Cong. Rec. S3517 (daily ed. June 7, 2016)..... 8

18 162 Cong. Rec. S3518 (daily ed. June 7, 2016)..... 15

19 162 Cong. Rec. S3522 (daily ed. June 7, 2016) 4, 5, 12

20 H.R. Rep. No. 114-176 (2015), at 28 4, 5

21

22 **Treatise**

23 29 Wright & Gold,

24 *Fed. Prac. & Proc. Civ.* § 6265 (1997) 14

25

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27

28

GLOSSARY

1
2
3
4
5
6
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- Frank R. Lautenberg Chemical Safety for the 21st Century Act (“Lautenberg Act”)
- Toxic Substances Control Act (“TSCA”)
- Maximum contaminant level goal (“MCLG”)
- Milligram/kilogram/day (“mg/kg/day”)
- Milligram/liter (“mg/L”)
- National Research Council (“NRC”)
- Point of departure (“POD”)
- Pre-manufacture notice (“PMN”)
- Reference dose (“RfD”)
- Safe Drinking Water Act (“SDWA”)
- Significant new use notice (“SNUN”)
- U.S. Public Health Service (“PHS”)

NOTICE OF MOTION FOR SUMMARY JUDGMENT

PLEASE TAKE NOTICE that on November 7, 2019, at 1:30 p.m., before the Honorable Edward M. Chen, United States District Judge, in Courtroom 5, 17th Floor, 450 Golden Gate Avenue, San Francisco, California 94102, Defendants will and hereby do move for summary judgment in their favor pursuant to Federal Rule of Civil Procedure 56 and Civil Local Rule 56-1. This motion is based on the points and authorities below, the attached declarations and exhibits, the record of this action, and argument that may be presented at any hearing on this motion.

1 **MEMORANDUM OF POINTS AND AUTHORITIES**

2 **INTRODUCTION**

3 Fluoride is a substance that occurs naturally in the environment. A common source of
4 human exposure to fluoride is drinking water, in which the fluoride ion may be present naturally
5 or added in controlled amounts for the prevention of dental caries. While some communities in the
6 United States have elevated levels of naturally occurring (or “background”) fluoride in their
7 drinking water, other communities add fluoridation chemicals to drinking water to reach a
8 recommended optimal concentration for reducing tooth decay of 0.7 milligrams per liter (mg/L).
9 This practice has been widely hailed as a successful public health breakthrough for dental caries
10 prevention.

11 A number of experimental animal and human epidemiology studies support a potential
12 association between high levels of naturally occurring fluoride in water and neurotoxic effects,
13 such as lower IQ in children. However, the existing studies suggesting a potential association use
14 data collected from fluoride-endemic regions in other parts of the world with higher background
15 levels of fluoride as compared to the recommended concentration used in community water
16 fluoridation programs in the United States. No study has examined potential associations in the
17 United States, and few studies have tested this association at exposure levels near 0.7 mg/L. The
18 few studies that do test for associations near community water fluoridation exposure levels have
19 undisputed limitations and data gaps, including generalizability to the United States population,
20 before an unreasonable risk determination can be made under the Toxic Substances Control Act
21 (“TSCA”). Nevertheless, Plaintiffs argue that the breadth of exposure to fluoridation chemicals in
22 the United States outweighs the uncertainties regarding fluoride toxicity at the level of exposure
23 associated with community water fluoridation programs and, thus, demonstrates unreasonable risk
24 of injury to health or the environment under TSCA. It does not. TSCA requires more.

25 TSCA’s statutory scheme establishes the substantive legal requirements for reaching a
26 determination that a chemical substance poses an unreasonable risk under each of the conditions
27 of use. Consistent with well-established scientific methodologies for assessing risks, TSCA
28 requires a transparent and objective risk-evaluation process, while also setting forth requirements

1 regarding scientific standards. Where, as here, decisions are based on science, the statute requires
2 application of a “weight of the scientific evidence” approach for identifying and characterizing the
3 “best available science” for the intended purpose. Rather than employ TSCA’s framework for
4 determining risk as required by law, Plaintiffs rely solely on the credentials of their proposed
5 experts to make unsupported inferences concerning fluoride exposures in the United States.
6 Because Plaintiffs fail to employ the science standards and data-quality considerations required by
7 TSCA to support a finding that the use of fluoridation chemicals for the purpose of increasing
8 fluoride concentrations in water up to 0.7 mg/L poses an unreasonable risk, EPA is entitled to
9 judgment as a matter of law. Further, Plaintiffs lack standing because they cannot show neurotoxic
10 harm from exposure to fluoridation chemicals.¹

11 STATEMENT OF ISSUES

12 1. Is EPA entitled to judgment as a matter of law where Plaintiffs cannot demonstrate
13 that adding fluoridation chemicals to drinking water up to the recommended concentration of 0.7
14 mg/L creates an unreasonable risk of neurotoxic effects based on the best available science and
15 using a weight of the evidence approach?

16 2. Do Plaintiffs lack standing to sue where they claim no neurotoxic injury or credible
17 threat of neurotoxic injury as a result of their exposure to fluoridation chemicals?

18 BACKGROUND

19 A. Factual Background

20 In 2006, EPA requested that the National Research Council (“NRC”) independently
21 evaluate the scientific basis of EPA’s maximum contaminant level goal (“MCLG”) for fluoride
22 concentrations in drinking water under the Safe Drinking Water Act (“SDWA”).²

24 ¹ By filing this motion for summary judgment, EPA does not waive its right to appeal any
25 prior decisions of this Court, including on the scope of review permitted by TSCA
26 section 21(b)(4)(B).

27 ² The maximum contaminant level or “MCL” is an enforceable standard setting the highest
28 level of a contaminant that is allowed in drinking water. MCLs are set as close to the MCLG as
feasible using the best available treatment technology and taking cost into consideration. The
current MCL for fluoride concentrations in drinking water is 4 mg/L. The MCLG, by contrast, is

1 NRC convened the Committee on Fluoride in Drinking Water, which was charged with
2 reviewing the scientific literature on fluoride to evaluate the adequacy of the guidelines, identify
3 data gaps, and make recommendations for future research in a report outlining its findings.³
4 Because the SDWA standards are guidelines for restricting the total amount of fluoride in drinking
5 water, “[a]ddressing questions of artificial fluoridation . . . was not part of the committee’s
6 charge.” NRC 2006, at 2.

7 Upon completion of its review, the committee recommended that EPA reassess the dose-
8 response relationships between hazard and the likelihood of specific adverse health effects related
9 to the amount and condition of exposure to fluoride (referred to as the dose-response assessment
10 step in the risk assessment). In 2010, EPA’s Office of Water completed the dose-response analysis
11 using available data between 2000 and 2010 to calculate a reference dose (“RfD”)—an estimate
12 of the fluoride dose protective against severe dental fluorosis, skeletal fluorosis, and increased risk
13 of bone fractures—of 0.08 milligrams per kilograms per day (mg/kg/day), a measure of daily
14 intake by body weight.⁴

15 For community water systems that add fluoridation chemicals to their water, the
16 U.S. Public Health Service (“PHS”) recommends an optimal fluoride concentration of 0.7 mg/L
17 for the prevention of dental caries. 80 Fed. Reg. 24,936 (May 1, 2015). While PHS recommends
18

19 _____
20 a non-enforceable health-based goal. The current MCLG for fluoride concentrations in drinking
21 water is also 4 mg/L.

22 Under 42 U.S.C. § 300j-7(a)(1), jurisdiction over petitions for review of “actions pertaining
23 to the establishment of national primary drinking water regulations” is vested exclusively “in the
24 United States Court of Appeals for the District of Columbia circuit.” For that reason, among others,
25 EPA’s action under the SDWA cannot be challenged here. Further, EPA expressly reserves its
26 right to challenge the relevance of its regulation under the SDWA to this litigation. The discussion
27 of this standard is included here only as background information necessary to demonstrate a
28 significant flaw in the scientific methodology utilized by Plaintiffs’ proposed experts.

³ Nat’l Research Council, *Fluoride in Drinking Water: A Scientific Review of EPA’s Standards* (2006), available at <http://www.nap.edu/catalog/11571.html> [hereinafter “NRC 2006”], Ex. 1 to Adkins Decl., Exhibit A.

⁴ EPA, Office of Water, *Fluoride: Dose-Response Analysis For Non-Cancer Effects i–ii*, 105 (December 2010) [hereinafter “Dose-Response Analysis 2010”]. Ex. 2 to Adkins Decl., Ex. A.

1 an optimal concentration, state and local governments decide whether to increase natural fluoride
2 concentrations to the recommended level by adding fluoridation chemicals to drinking water.

3 On November 23, 2016, EPA received a petition submitted by Plaintiffs pursuant to TSCA
4 section 21 requesting that EPA ban the addition of fluoridation chemicals to water pursuant to
5 EPA's authority under section 6 of TSCA. Pet., ECF No. 28-1. EPA denied the petition on
6 February 17, 2017. 82 Fed. Reg. 11,878 (Feb. 27, 2017). EPA determined that the petition, on its
7 face, did not set forth facts that provided a basis to initiate the requested rulemaking. Specifically,
8 EPA concluded that "[t]he petition has not set forth a scientifically defensible basis to conclude
9 that any persons have suffered neurotoxic harm as a result of exposure to fluoride in the U.S.
10 through the purposeful addition of fluoridation chemicals to drinking water or otherwise from
11 fluoride exposure in the U.S." *Id.* at 11,887.

12 On April 18, 2017, Plaintiffs commenced this action by filing a Complaint seeking to
13 compel EPA to initiate a proceeding for the issuance of a rule prohibiting the addition of
14 fluoridation chemicals to water under TSCA section 6.

15 **B. Statutory Background**

16 On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act
17 ("Lautenberg Act") was signed into law, amending TSCA. 15 U.S.C. §§ 2601–2692. The
18 Lautenberg Act sets in motion a process under which EPA will for the first time systematically
19 review the safety of chemicals in active commerce. "While this will take many years, the goal of
20 the legislation is to ensure that all chemicals on the market get such a review." 162 Cong. Rec.
21 S3511 (daily ed. June 7, 2016). TSCA, as amended, establishes "unreasonable risk under the
22 conditions of use" as the "safety standard" to be applied. *Id.* at S3522. "Unreasonable risk under
23 the conditions of use" does not mean "no risk"; rather, it means there must be a determination as
24 to whether the risk posed by a chemical is "reasonable in the circumstances of exposure and use."
25 *Id.*

26 "Risk evaluation" is the scientific process specified under section 6(b)(4)(A) for
27 determining whether a chemical substance presents an unreasonable risk of injury to health or the
28 environment, without consideration of costs or other nonrisk factors, under the conditions of use.

1 15 U.S.C. § 2605(b)(4)(A). Although Congress delegated to EPA the authority “to establish by
2 rule, a process to conduct risk evaluations,” *Id.* § 2605(b)(4)(B), Congress also identified the
3 minimum criteria to be considered as part of a risk evaluation, 15 U.S.C. § 2605(b)(4)(F). The
4 criteria include certain components that are consistent with risk-assessment standards prescribed
5 by the National Academy of Sciences and National Research Council for public policy and
6 regulation. Henry Decl. ¶ 10, Exhibit B. Moreover, Congress intended that risk determinations rest
7 on the best available science using a weight of the scientific evidence approach. 15 U.S.C.
8 § 2625(h), (i); *see also* 162 Cong. Rec. S3522 (daily ed. June 7, 2016).

9 As required under section 6(b)(4), EPA issued a rule establishing a process for conducting
10 risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury
11 under the conditions of use, which incorporates the scientific-standards requirements of the statute,
12 including best available science and weight of the scientific evidence. Procedures for Chemical
13 Risk Evaluation Under the Amended Toxic Substances Control Act (“Risk Evaluation Rule”), 82
14 Fed. Reg. 33,726 (July 20, 2017). While the Risk Evaluation Rule includes a non-exhaustive list
15 of policy considerations for addressing the reasonableness of risk, such as effects of exposure to a
16 substance under the conditions of use, the population exposed, the severity of the hazard, and
17 uncertainties in the data, the rule also sets forth the procedural steps necessary to ensure scientific
18 integrity, transparency, and objectivity in the risk-evaluation process.

19 TSCA section 26(h) sets forth the required considerations for determining whether the
20 existing science is reliable and unbiased. 15 U.S.C. § 2625(h); *see also* 40 C.F.R. § 702.33
21 (defining “best available science” as “reliable and unbiased” and identifying the factors
22 enumerated in the statute for consideration as applicable).

23 To ensure that draft risk evaluations conducted by “interested persons” meet the same high-
24 quality standards as those developed at EPA, Congress required that EPA develop guidance setting
25 forth, at a minimum, the “quality of the information submitted and the process to be followed in
26 developing draft risk evaluations.” 15 U.S.C. § 2625(l)(5); Guidance to Assist Interested Persons
27 in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act;
28

ARGUMENT**I. PLAINTIFFS HAVE NOT PROFFERED ANY EVIDENCE DEMONSTRATING AN UNREASONABLE RISK OF INJURY FROM EXPOSURE TO FLUORIDATION CHEMICALS USED TO INCREASE WATER FLUORIDE CONCENTRATIONS UP TO 0.7 mg/L.**

TSCA section 21(b)(4)(B)(ii) requires Plaintiffs to demonstrate by a preponderance of the evidence that “the chemical substance” that was the subject of their petition “presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use.” 15 U.S.C. § 2620(b)(4)(B)(ii). Plaintiffs’ petition “sought to regulate only one condition of use, fluoridation of drinking water.” *Food & Water Watch, Inc. v. EPA*, 291 F. Supp. 3d 1033, 1053–54 (N.D. Cal. 2017). Plaintiffs refer to three chemical substances containing the fluoride ion that are added to community water systems, which are silicofluoride, fluorosilicic acid, and sodium fluoride. *Id.* at 1052–53. Because these fluoridation chemicals are only used to increase water fluoride concentrations up to 0.7 mg/L, Plaintiffs must demonstrate that use of fluoridation chemicals results in adverse neurotoxic effects at that concentration. As set forth below, Plaintiffs cannot show that their scientific assertions are based on the minimum scientific and statutory standards necessary to demonstrate an unreasonable risk. Because there is no evidence to satisfy the substantive requirements of the statute, there is no genuine issue of material fact, and the Court must grant judgment in favor of EPA.

A. TSCA Section 6 Requirements for Risk Evaluation and Section 26 Standards for Science-Based Decisions Govern the Court’s Risk Determination.

In determining whether genuine issues of material fact exist, the Court applies the relevant substantive law. *See Anderson*, 477 U.S. at 248. Here, TSCA’s statutory scheme sets forth substantive requirements applicable to determining whether a chemical substance presents an unreasonable risk under the conditions of use. Section 26 requires that section 6 decisions based on science be consistent with the best available science using a weight of the scientific evidence approach. Section 6(b) establishes the standards for making a risk determination for existing chemicals. “[I]t is a cardinal rule of statutory construction that, when Congress employs a term of

1 art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word
2 in the body of learning from which it is taken.” *Air Wis. Airlines Corp. v. Hoeper*, 571 U.S. 237,
3 248 (2014) (internal quotation marks omitted). Thus, sections 6(b) and 26 contain the substantive
4 legal requirements for making a risk determination concerning the use of fluoridation chemicals
5 under section 21(b)(4)(B)(ii). That the Court apply these same standards is consistent with
6 congressional intent that the phrase unreasonable risk “be read in the context of the changes to
7 section 6,” including the new risk-evaluation process delineated in subsection (b). H.R. Rep. No.
8 114-176, at 28 (2015).

9 Further supporting this statutory construction is that Congress intended for EPA to rely on
10 “the conclusions regarding . . . effects and exposures of the chemical in the risk evaluation itself”
11 in determining how to regulate unreasonable risks. 162 Cong. Rec. S3517 (daily ed. June 7, 2016).
12 Otherwise, EPA could be put in the untenable position of making scientific judgments in the
13 section 6(a) risk-management rule, were the Court to make the finding of unreasonable risk that
14 would require such a rulemaking, that are not supported by the best available science or weight of
15 the scientific evidence as required by section 26(h) and (i). “It is proper, and indeed essential, to
16 interpret the words of a statute in the light of the purposes Congress was seeking to serve.” *United*
17 *States v. Smith*, 683 F.2d 1236, 1240 (9th Cir. 1982); see *In re Cybernetic Servs., Inc.*, 252 F.3d
18 1039, 1055 (9th Cir. 2001).

19 Risk evaluations are the central element of section 6. But more importantly, Congress
20 sought to ensure all risk evaluations be conducted in a transparent and objective evaluation process,
21 based on the best available science and using a weight of the scientific evidence approach. For
22 example, Congress required that EPA establish by rule, subject to notice and comment, a process
23 to conduct risk evaluations, 15 U.S.C. § 2605(b)(4)(B), while also setting forth the minimum
24 requirements for risk evaluations, including weight of the scientific evidence, *id.* § 2605(b)(4)(F).
25 In addition, Congress required that EPA develop guidance for “interested persons” setting forth
26 the “quality of the information submitted and the process to be followed in developing draft risk
27 evaluations,” *id.* § 2625(l)(5).
28

1 Thus, TSCA’s risk evaluation and scientific standards provisions set forth the applicable
2 substantive law that this Court should apply. But even if the Court’s risk determination were not
3 bound by those statutory requirements, however, they are instructive because they reflect the most
4 up-to-date generally accepted scientific practices for assessing risk in the TSCA context.

5 **B. The Evidence Fails to Demonstrate an Unreasonable Risk Posed by the Use of**
6 **Fluoridation Chemicals in the United States.**

7 Plaintiffs put forward two experts who offer opinions that the available scientific evidence
8 demonstrates an unreasonable risk of neurotoxic effects from exposure to fluoride—Drs. Kathleen
9 Thiessen and Philippe Grandjean. The studies that Drs. Thiessen and Grandjean identified and
10 relied upon as supporting a dose response are not probative of water fluoride concentrations at or
11 below 0.7 mg/L. Because Plaintiffs cannot demonstrate a valid scientific connection between
12 neurotoxic risk and exposure to fluoridation chemicals under the condition of use, their claim fails
13 as a matter of law. *See Barnes v. Arden Mayfair, Inc.*, 759 F.2d 676, 680 (9th Cir. 1985) (“A party
14 opposing summary judgment is entitled to the benefit of only *reasonable* inferences that may be
15 drawn from the evidence put forth.” (emphasis added)); *Sanders*, 551 F. Supp. 2d at 1163
16 (“[I]nferences are not drawn out of the air, and it is the opposing party’s obligation to produce a
17 factual predicate from which the inference may be drawn.”).

18 **1. Plaintiffs cannot demonstrate that fluoride exposure at or below 0.7**
19 **mg/L causes neurotoxic effects.**

20 First, Dr. Thiessen and Dr. Grandjean argue that the EPA Office of Water’s oral RfD for
21 fluoride of 0.08 mg/kg/day is not protective for neurotoxicity. Thiessen Report 4 (June 27, 2019);
22 Grandjean Report 42 (June 21, 2019).⁶ As an initial matter, any dispute as to the sufficiency of the
23 RfD is not material here because the RfD is based on a body of evidence studying severe dental
24 fluorosis, a different health end point. Dose-Response Analysis 2010, at 105. In establishing an
25 estimated oral RfD for fluoride, EPA assessed data on nutritional benefit in combination with the
26 data on severe dental fluorosis to define a level that provides anti-caries protection without causing

27 ⁶ Excerpts of Dr. Thiessen’s and Dr. Grandjean’s reports are attached as Exhibits 4 and 5 to
28 Adkins Declaration.

1 severe dental fluorosis when consumed daily for a lifetime. *Id.* Therefore, Drs. Thiessen’s and
2 Grandjean’s critique of the 2010 EPA dose-response assessment is immaterial to neurotoxic end
3 points.

4 More fatal to Plaintiffs’ case is that, although Drs. Thiessen and Grandjean assert that
5 neurotoxicity is a more sensitive effect associated with exposure to fluoride, they fail to identify
6 or demonstrate an actual observable effect at or below 0.7 mg/L (the relevant point of exposure to
7 fluoridation chemicals in the United States). Instead, they advocate that uncertainties in the toxicity
8 of dose should be resolved in favor of caution. While absolute certainty is not what the law
9 requires, expert opinions “must be based on facts which enable [them] to express a reasonably
10 accurate conclusion as opposed to conjecture or speculation.” *Henricksen v. ConocoPhillips Co.*,
11 605 F. Supp. 2d 1142, 1169–70 (E.D. Wash. 2009) (citing *Jones v. Otis Elevator Co.*, 861 F.2d
12 655, 662 (11th Cir. 1988)).

13 Dr. Thiessen’s and Dr. Grandjean’s main critique of EPA’s RfD is that an uncertainty
14 factor⁷ of ten should have been used because of the *potential* for adverse effects of other health
15 end points identified in the NRC 2006 review of fluoride in drinking water—specifically, potential
16 effects on neurological and endocrine functions. This critique is fundamentally flawed and
17 inconsistent with TSCA’s scientific standards for two reasons. First, the NRC committee noted
18 that its conclusions “regarding the *potential* for adverse effects from *fluoride at 2 to 4 mg/L* in
19 drinking water do not address the lower exposures commonly experienced by most U.S. citizens.”
20 NRC 2006, at 11 (emphasis added). Second, the NRC committee identified gaps in the available
21 information on neurotoxic and endocrine affects from exposure to fluoride that prevented it from
22 making “judgments about the safety or the risks of fluoride at concentrations of 2 to 4 mg/L.” *Id.*
23 The NRC committee recommended that EPA “develop an MCLG that is protective against severe
24 enamel fluorosis, clinical stage II skeletal fluorosis, and bone fractures,” *id.* at 10, the only “three
25 toxicity end points for which there were sufficient relevant data for assessing” risk, *id.* at 345–46.

26 ⁷ Because the availability of dose-response data can have limitations, extrapolation of an
27 RfD from a point of departure can include the application of uncertainty factors. The size of the
28 final uncertainty factor requires the exercise of scientific judgment, taking into account
uncertainties in the body of science for each particular substance of concern. *See infra* note 8.

1 Because the NRC committee could not make judgments about neurotoxic and endocrine
2 risks at water fluoride concentrations of 2 to 4 mg/L, the committee’s 2006 report does not support
3 a reasonable inference of risk at water fluoride concentrations at or below 0.7 mg/L. Moreover,
4 since the release of the NRC 2006 report, a number of additional animal and epidemiological
5 studies of fluoride’s potential effects on neurological and endocrine functions have been published.
6 Thus, the NRC 2006 report is neither the best available science for answering the relevant question
7 here (adverse effects from exposure to concentrations of 0.7 mg/L) nor the most current science
8 for assessing risk. *See* Henry Dep. 67:3–69:4 (Aug. 20, 2019), Ex. 21 to Adkins Decl.

9 Although Dr. Thiessen attempted to calculate an alternative RfD, she conceded that, in
10 light of the observational human data now available for fluoride, experimental animal data are not
11 the best available science for identifying a point of departure (“POD”) for neurotoxic effects from
12 exposure to fluoride.⁸ Thiessen Report 54. Nevertheless, Dr. Thiessen relied on animal studies to
13 identify a range of study candidates from which EPA *could* derive a POD and extrapolate an RfD.
14 Thiessen Dep. 230:14–231:19. Although Plaintiffs offered Dr. Thiessen as an expert in risk
15 assessment, she refused to identify specific data that *should* be used to calculate an RfD. Thiessen
16 Dep. 228:20–230:12.

17 When pressed, however, Dr. Thiessen identified one study because the results identified
18 the most sensitive effects. Thiessen Dep. 274:11–22 (citing Bartos et al.). Dr. Thiessen did not
19 critically analyze the study using any pre-established criteria. Nor did Dr. Thiessen offer an
20 explanation that would allow the Court to determine to what extent the study is otherwise
21 “reasonable for and consistent with the intended use of the information.” 15 U.S.C. § 2625(h)(1)
22 (defining criteria for evaluating the best available science). Certain limitations by themselves may
23 not wholly prevent an individual study from being used for this purpose, but because Dr. Thiessen
24

25 ⁸ In toxicology, the POD is the point on a toxicological dose-response curve established from
26 experimental data or observational data generally corresponding to an estimated low effect level
27 or no effect level. The POD marks the beginning of extrapolation to an RfD. The most common
28 POD used to derive an RfD is no-observed-adverse-effect level (or, NOAEL), lowest-observed-
adverse-effect level (or, LOAEL”), or statistical benchmark dose. *E.g.*, Thiessen Dep. 222:4–224:6
(Aug. 27, 2019), Ex. 6 to Adkins Decl.

1 fails to identify, much less integrate, the strengths and limitations of the study within the existing
2 body of evidence, the Court has no basis to determine whether the single study is the best available
3 science for calculating a protective dose. Thus, while Dr. Thiessen identified a study that she
4 asserts *could* be used to derive an RfD, she failed to provide a rationale for whether the Court
5 *should* rely on the study for assessing a dose-response relationship here. This is exactly the type
6 of cherry-picking that the amended TSCA seeks to prevent. *See* 162 Cong. Rec. S3522 (daily ed.
7 June 7, 2016).

8 **2. Plaintiffs assume, without support, that studies conducted in Mexico**
9 **and Canada are generalizable to the United States.**

10 Absent evidence to support such an assumption, the Court cannot assume that studies
11 conducted on sample populations in Mexico and Canada are generalizable to populations in the
12 United States. Yet Plaintiffs would have the Court do precisely that.

13 Dr. Grandjean relied on studies that purport to support his assertion that fluoride is a
14 developmental neurotoxin at levels consistent with exposure in the U.S. population. Grandjean
15 Report 38. Two of the studies considered the potential association of prenatal exposure to fluoride
16 with offspring neurocognitive development and symptoms of attention-deficit/hyperactivity
17 disorder in mother-children pairs of a birth cohort study in Mexico.⁹ A third study sought to
18 evaluate the potential association of prenatal fluoride exposure and cognitive effects in infants in
19 Mexico.¹⁰ And a fourth study examined whether there was an association between prenatal fluoride
20

23 ⁹ Bashash, M., et al., Prenatal Fluoride Exposure and Cognitive Outcomes in Children at 4
24 and 6–12 Years of Age in Mexico, *Environmental Health Perspectives* (2017) [hereinafter,
25 “Bashash 2017”]; Bashash, Morteza, et al., Prenatal fluoride exposure and attention deficit
26 hyperactivity disorder (ADHD) symptoms in children at 6–12 years of age in Mexico City, *121*
Environment International 658 (2018) [hereinafter, “Bashash 2018”]. Copies of Bashash 2017 and
Bashash 2018 are attached as Exhibits 7 and 8 to Adkins Declaration.

27 ¹⁰ Valdez Jimenez, L., et al., In Utero Exposure to Fluoride and Cognitive Development
28 Delay in Infants, *59 NeuroToxicology* 65 (2017) [hereinafter, “Valdez Jimenez 2017”]. A copy of
Valdez Jimenez 2017 is attached as Exhibit 9 to Adkins Declaration.

1 exposure and IQ scores in a birth cohort study in Canada.¹¹ Plaintiffs have put forward no studies
2 showing that fluoride exposure at the levels found in community water fluoridation (0.7 mg/L)
3 leads to cognitive deficits in fetuses *in utero* or children in the United States. While
4 Dr. Grandjean’s opinion is that the maternal urine-fluoride concentrations (a biomarker used to
5 estimate all prenatal exposure to fluoride) observed in the studies were “within ranges occurring
6 in fluoridated communities” (presumably referring to communities in the United States),
7 Grandjean Report 38, Dr. Grandjean merely assumed, without any support, that pregnant women
8 living in fluoridated areas in the United States would have similar urine-fluoride concentrations
9 and total exposure to fluoride as those observed in the Mexico and Canada studies and that the
10 observed biomarkers across the populations studied would be comparable to U.S. populations.
11 *E.g.*, Grandjean Report 42.

12 In fact, some of the studies that Dr. Grandjean relied on specifically acknowledge
13 limitations in the data that prevent extrapolating the results to other populations. *See* Bashash 2017,
14 at 11 (“[O]ur ability to extrapolate our results to how exposures may impact on the general
15 population is limited given the lack of data on fluoride pharmacokinetics during pregnancy. There
16 are no reference values for urinary fluoride in pregnant women in the United States.”);
17 Bashash 2018, at 664 (“While urinary fluoride is a valid biomarker to identify differences in
18 exposure levels in pregnant women, it is not possible, with the currently available data, to estimate
19 how concentration levels relate to intake.”); *see also* Hu Dep. 86:19–24 (Q: “[I]n the publication,
20 Thomas 2016, you did not compare the results of maternal urinary fluoride levels with those levels
21 found in the United States; is that correct?”; A: “Correct. And, again, because we could not find
22 such data.”); 121:3–5 (Q: “And Bashash 2017 did not attempt to generalize its findings to the
23 United States, correct?”; A: “Correct.”) (Sept. 24, 2019), Ex. 11 to Adkins Decl. Lacking the
24 necessary evidence to support such an assumption, the Court has no basis to infer that studies
25 conducted in Mexico and Canada are generalizable to the United States.

26 _____
27 ¹¹ Association Between Maternal Fluoride Exposure During Pregnancy and IQ Scores in
28 Offspring in Canada, *JAMA Pediatrics* (2019) [hereinafter, “Green 2019”]. A copy of Green 2019
is attached as Exhibit 10 to Adkins Declaration.

1 Nevertheless, Dr. Grandjean used the data from the Green 2019 Canadian study in an
2 attempt to calculate a benchmark dose for fluoride. When asked about the merits of his calculation,
3 Dr. Grandjean conceded that calculating a dose was outside the scope of his expertise. Grandjean
4 Dep. 94:19–95:6 (Sept. 13, 2019) (“I decided I would rather have the chairman of biostatistics be
5 responsible for [the calculations] because he is a world expert on benchmark dose. I wouldn’t trust
6 myself.”), Ex. 12 to Adkins Decl. “Even where a witness has special knowledge or experience,
7 qualification to testify as an expert also requires that the area of the witness’s competence matches
8 the subject matter of the witness’s testimony.” 29 Wright & Gold, Federal Practice & Procedure:
9 Evidence § 6265 (1997).

10 Because neither Dr. Thiessen nor Dr. Grandjean identified evidence to support a dose-
11 response relationship between neurotoxicity and exposure to water fluoridation concentrations at
12 or below 0.7 mg/L, Plaintiffs cannot meet their burden of demonstrating an unreasonable risk
13 under the condition of use being reviewed.

14 **C. Plaintiffs’ Evidence Does Not Conform to Well-Accepted Scientific
15 Methodologies and TSCA’s Scientific Standards.**

16 The opinions offered by Plaintiffs’ epidemiology (Dr. Grandjean) and toxicology
17 (Dr. Thiessen) experts are of no value for assessing the risk of adding fluoridation chemicals to
18 water because the methodologies employed do not conform to TSCA’s standards, including
19 reliable scientific principles and methods. Neither expert conducted a systematic review, which is
20 necessary to identify the best available science. Because Plaintiffs cannot proffer any evidence
21 from which a reasonable inference of neurotoxic injury may be drawn, there is no dispute of
22 material fact.

23 **1. Plaintiffs failed to systematically review the available literature, which
24 is necessary for identifying the best available science.**

25 Consistent with reliable risk-assessment principles and methods, EPA defined “weight of
26 the scientific evidence” to mean “a systematic review method that uses a pre-established protocol
27 to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream
28 of evidence, including strengths, limitations, and relevance of each study and to integrate evidence

1 as necessary and appropriate based upon strengths, limitations, and relevance.” *See* 40 C.F.R.
2 § 702.33; *see also* 162 Cong. Rec. S3518 (daily ed. June 7, 2016); Henry Decl. ¶¶ 33–39. Neither
3 Drs. Thiessen nor Grandjean systematically reviewed the available literature assessing fluoride
4 exposure and potential neurotoxic effects, a necessary step for demonstrating that their risk
5 determinations were based on the best available science.

6 There is no dispute that Dr. Thiessen did not conduct a systematic review of the scientific
7 literature concerning neurotoxic effects from fluoride exposure. *See* Thiessen Dep. 227:25–228:2.
8 In her expert report, Dr. Thiessen stated that she did not consider a “systematic review of the
9 human literature . . . necessary.” Thiessen Report 15. Dr. Thiessen later testified that it “takes a lot
10 of time and effort to do [a systematic review] in detail,” and that it “was not [her] place to do a
11 formal systematic review.” Thiessen Dep. 228:5–12.

12 Instead, Dr. Thiessen relied entirely on findings of three previously published meta-
13 analyses: Tang et al. 2008, Choi et al. 2012, and Duan et al. 2018.¹² Thiessen Report 15 n.100.
14 Meta-analysis is a statistical procedure used to combine data from multiple studies. Chang Decl.
15 ¶ 11, Exhibit C. While meta-analyses can be helpful in detecting associations of chemical
16 exposures in certain circumstances, they cannot, on their own, be used to identify, confirm, or
17 refute causal relationships. Chang Decl. ¶ 18. To determine whether identified effects are caused
18 by exposures, the underlying studies in a meta-analysis must be systematically evaluated based on
19 their settings, methodological qualities, and results. Chang Decl. ¶¶ 19–21.

20 Moreover, Dr. Thiessen ignored numerous other relevant studies. For example, none of the
21 meta-analyses on which Dr. Thiessen relied included any studies published after 2016.¹³ Chang

22
23 ¹² EPA discussed two of the meta-analyses that Dr. Thiessen cited in her report—Tang et al.
24 2008 and Choi et al. 2012—in its response to Plaintiffs’ petition. 82 Fed. Reg. 11,878, 11,888
(Feb. 27, 2017).

25 ¹³ Other significant limitations in the meta-analyses and the underlying studies that formed
26 the meta-analyses exist, on which EPA’s experts are prepared to offer testimony should the Court
27 deny summary judgment. For example, a systematic evaluation reveals that nearly all of the
28 underlying studies in the three meta-analyses evaluated drinking water fluoride levels in regions
with drinking water fluoride levels greater than 1.0 mg/L. Chang Decl. ¶¶ 14–16. However, for
purposes of this motion, Dr. Thiessen’s failure to conduct a systematic review and instead rely on
three meta-analyses shows that Plaintiffs cannot meet even the minimum requirements under

1 Decl. ¶¶ 11–13. Indeed, Dr. Thiessen testified that EPA’s expert, Dr. Ellen Chang, conducted a
2 systematic review in this case and “may have” identified studies that Dr. Thiessen did not.
3 Thiessen Dep. 320:5–23. Dr. Thiessen explained that this was so because she “did not discuss the
4 entire set of epidemiologic papers.” Thiessen Dep. 320:22–23. Dr. Thiessen’s statement in her
5 report, “As those familiar with the literature know, there are many more studies reporting
6 associations of fluoride exposure with neurotoxic outcomes than the reverse,” is not a stand-in for
7 a systematic search and analysis of the literature. Thiessen Report 15. Thus, because Dr. Thiessen
8 did not identify pre-established criteria to search, select, and critically assess the studies described
9 in her expert report, which are essential tenets to systematic review, the conclusions she reached
10 do not rise to the level of objective, impartial assessment of the best available science, as required
11 under TSCA.

12 Dr. Grandjean’s opinion similarly does not satisfy TSCA’s weight of the scientific
13 evidence standards. Dr. Grandjean claims to have performed only a narrative review, and he has
14 not employed any stated principles or methods to support his purported weighing of the scientific
15 literature.

16 Dr. Grandjean stated in his report that he relied upon the NRC 2006 review of EPA’s
17 standards regarding fluoride in drinking water, as well as two of the three meta-analyses that
18 Dr. Thiessen relied upon (Choi et al. 2012 and Duan et al. 2018), instead of conducting a
19 systematic review. Grandjean Report 5. Like Dr. Thiessen, Dr. Grandjean did not systematically
20 evaluate the underlying studies in those reviews based on their settings, methodological qualities,
21 and results, especially in consideration of whether they are relevant to fluoride exposures from
22 community water fluoridation programs in the United States.

23 Rather, as Dr. Grandjean stated in his report, he “follow[s]” the fluoride literature through
24 weekly updates from the PubMed database and, specifically to prepare his expert report in his case,
25 conducted vague and undefined “supplementary literature searches” in the PubMed database.
26 Grandjean Report 15. Dr. Grandjean testified that he “scanned the literature” and that he has “been

27 _____
28 TSCA to show unreasonable risk under the conditions of use by best available science and weight
of the scientific evidence standards.

1 collecting that literature over the years.” Grandjean Dep. 232:20–22. Although Dr. Grandjean
2 admits that he did not “necessarily cite all reports that may be relevant,” he concluded that his
3 review “presents a reasonably comprehensive coverage of the relevant epidemiological evidence.”
4 Grandjean Report 6, 15. Further, Dr. Grandjean admitted, without explanation, that he considered
5 it “beyond the present report to evaluate” fourteen studies published on fluoride and intelligence
6 since publication of his 2012 meta-analysis, Choi et al. Grandjean Report 21. The apparent
7 inconsistencies in Dr. Grandjean’s methodology and execution of that methodology illustrate the
8 importance of using pre-established criteria consistent with well-accepted principles of systematic
9 review, especially when the opinion is being offered as scientific support for nationwide policy.

10 Even if the Court were to find that Dr. Grandjean’s undefined supplementary searches were
11 sufficient under TSCA’s weight of the scientific evidence requirement, Dr. Grandjean did not
12 employ any pre-established criteria for *selecting* which studies to review or for how to critically
13 *assess* those studies in light of the conditions of use relevant to this case. *See, e.g.*, 40 C.F.R.
14 § 702.33. Dr. Grandjean testified that he conducted a “narrative review” that “looked at the validity
15 of the methods used [in studies],” the “biostatistics methods,” and “covariates.” Grandjean Dep.
16 233:5–10. He further testified that he “look[ed] at the strength of the evidence” when evaluating
17 scientific studies regarding fluoride exposure, which he testified was summarized on page thirty
18 of his report. Grandjean Dep. 249:13–15; 250:17–21. Dr. Grandjean’s expert report, however, did
19 not refer to any criteria he used to evaluate studies he identified in his searches. Grandjean
20 Report 30. Instead, Dr. Grandjean’s report contains vague statements about the contribution of
21 human studies, the benefits of studies with a cross-sectional design, the desirability of prospective
22 information on exposed birth cohorts, a description of the concept “bias toward the null,” and
23 historical statements regarding critiques and challenges to studies that have found associations
24 between fluoride exposure and neurotoxicity. Grandjean Report 30–33. In any event,
25 Dr. Grandjean did not explain whether or how he applied these statements to critically assess the
26 studies on fluoride exposure that he did choose to consider.

27 Therefore, neither Dr. Thiessen nor Dr. Grandjean used—nor do they claim to use— “a
28 pre-established protocol to comprehensively, objectively, transparently, and consistently, identify

1 and evaluate each stream of evidence, including strengths, limitations, and relevance of each study
2 and to integrate evidence as necessary and appropriate based upon strengths, limitations, and
3 relevance.” 40 C.F.R. § 702.33. Dr. Tala Henry, a toxicologist with over twenty-five years of
4 technical and managerial experience at EPA, testified that due to these fundamental and significant
5 flaws in approach, Drs. Thiessen’s and Grandjean’s conclusions regarding unreasonable risk of
6 neurotoxic effects of fluoride cannot be relied upon in light of TSCA’s requirements.¹⁴ Henry Decl.
7 ¶¶ 2–7, 39–54. Application of the weight of the scientific evidence analysis required by TSCA is
8 an integrative and interpretive process—not the simple tallying of the number of positive and
9 negative studies, as Plaintiffs’ experts did here. Henry Decl. ¶ 33. For these reasons, Dr. Thiessen’s
10 and Dr. Grandjean’s “weight of evidence” assertions fail to meet the minimum standards required
11 to support a finding of unreasonable risk under TSCA.¹⁵ See Henry Decl. ¶¶ 49–50.

12 **2. Plaintiffs cannot demonstrate a valid scientific connection between**
13 **their risk assessment and risk determination.**

14 Even if Plaintiffs could identify a dose-response relationship, their risk-determination
15 analysis is fundamentally flawed. First, Dr. Thiessen proceeded under the wrong section of TSCA.
16 Dr. Thiessen used EPA’s risk-assessment approach and regulatory framework for screening new
17 chemicals under TSCA section 5, not the more robust risk evaluation criteria for existing chemicals
18 under TSCA section 6. Dr. Thiessen testified that interested parties should conduct risk
19 assessments that rely on guidance issued by EPA. Thiessen Dep. 263:20–25. Nevertheless, Dr.
20 Thiessen used the TSCA section 5’s screening analysis for new substances to conduct a “short
21

23 ¹⁴ Dr. Henry has provided toxicology and risk assessment expertise and guidance, oversight
24 and daily programmatic management to multiple chemical management programs, and leadership
25 of science policy development and implementation across EPA, with other federal agencies, and
in several international fora. Henry Decl. ¶ 3.

26 ¹⁵ The insufficiencies identified in Dr. Thiessen’s and Dr. Grandjean’s opinions are why
27 Plaintiffs’ fail to put forth sufficient evidence to support their claim. Should the Court deny the
28 instant motion, EPA reserves the right to move to exclude Dr. Thiessen’s and Dr. Grandjean’s
proposed testimony under *Daubert* on the basis that they failed to reliably apply well-accepted
methodologies.

1 screening assessment” rather than the more robust TSCA section 6 guidance for assessing risk of
2 existing chemicals. Thiessen Dep. 264:4–12.

3 A “new” chemical substance is a substance that is not listed in the TSCA Inventory of
4 Chemical Substances. Section 5 requires anyone who plans to manufacture (including import) a
5 new chemical substance for a non-exempt commercial purpose or manufacture or process a
6 chemical substance for a significant new use obtain EPA’s approval by submitting a pre-
7 manufacture notice (“PMN”) or significant new use notice (“SNUN”) prior to the manufacture or
8 import. 15 U.S.C. § 2604(a). Under the statutory scheme in section 5, EPA has ninety days to
9 review a PMN or SNUN and make a specific determination. *Id.* The only information that must be
10 provided to EPA in the notifications are: chemical identity information, trade names, byproducts,
11 and impurities; production, import, and use information, including the amount for each use; worker
12 exposure and environmental release information; and any existing test data in the possession or
13 control of the notifier. 40 C.F.R. §§ 720.45, 720.50.

14 As a consequence, the empirical hazard and exposure data available to EPA for new
15 chemicals is often limited. The section 5 screening analysis that Dr. Thiessen used was designed
16 to support a rapid hazard assessment for the purpose of efficiently “binning” chemical assessments
17 into those which require additional and often more detailed or refined analysis (for high or
18 moderate hazard chemicals) and those which conservative screening indicate are of low hazard
19 and do not warrant detailed or refined analysis. Henry Decl. ¶ 59. Because human toxicity data are
20 rarely, if ever, available for new chemicals, the section 5 classification scheme is based on dose or
21 concentration values from standardized, guideline animal toxicity tests. Thus, this approach was
22 neither intended nor envisioned to be used with human studies. Henry Decl. ¶ 60.

23 Dr. Thiessen does not dispute that fluoridation chemicals are existing chemicals in the
24 TSCA Inventory of Chemical Substances. Thiessen Dep. 267:8–19 (conceding that fluoride is not
25 a new chemical). When presented with the error in her report, Dr. Thiessen admitted that she would
26 have included the appropriate analysis under section 6 and related guidance. Thiessen Dep. 271:8–
27 272:3. Dr. Thiessen further admitted that there is an abundance of animal and human literature
28 studying the neurotoxic effects of fluoride exposure at levels above 0.7 mg/L. Thiessen Dep.

1 267:20–25. Therefore, the statutorily required and scientifically appropriate methodology for
2 making risk determinations for water fluoridation chemicals is the more robust risk evaluation
3 process set forth in section 6, the Risk Evaluation Rule, and the related EPA Guidance. *See* Henry
4 Decl. ¶¶ 55–64. For these reasons, Dr. Thiessen’s conclusion that the addition of fluoridation
5 chemicals to water poses an unreasonable risk of neurotoxic injury is not supported because she
6 did not apply the statutory or scientific standards designed for determining unreasonable risk for
7 existing chemicals under TSCA. *See* Henry Decl. ¶ 63.

8 Second, Dr. Grandjean does not apply any criteria. Instead, he asks the Court to accept his
9 opinion based on his experience rather than the application of a scientific methodology.
10 Dr. Grandjean testified that he judges the quality and the reliability of studies based on his
11 experience. Grandjean Dep. 115:15–19; 116:3–5. No matter how imposing a witness’ credentials
12 may be, the Court “cannot allow conjecture to substitute for the evidence necessary to survive
13 summary judgment.” *Town of Westport v. Monsanto Co.*, 877 F.3d 58, 66 (1st Cir. 2017) (internal
14 quotations marks omitted). Dr. Grandjean further testified that while he agrees it is important to
15 explain what considerations were taken into account when judging the validity of a study, he
16 believes that he did so in his report. Grandjean Dep. 121:6–17. Yet nowhere in his report did
17 Dr. Grandjean explain how he judged the validity of any of the studies supporting or not supporting
18 the opinion that fluoride is a neurotoxin. TSCA requires more than blind acceptance of a scientist’s
19 opinion without sufficient explanation of the methods used to arrive at that opinion. *See* 15 U.S.C.
20 § 2625(h) (requiring the use of “scientific information, technical procedures, measures, methods,
21 protocols, methodologies, or models, employed in a manner consistent with the best available
22 science”).

23 Therefore, neither Dr. Thiessen nor Dr. Grandjean offer a scientifically acceptable source
24 of evidence to support their opinions that exposure to fluoridation chemicals used for community
25 water supplied in the United States poses an unreasonable risk of neurotoxic injury. Because
26 Plaintiffs failed to proffer evidence to satisfy their burden, judgment must be entered in favor
27 of EPA.
28

1 **II. THIS COURT LACKS JURISDICTION BECAUSE PLAINTIFFS LACK**
 2 **ARTICLE III STANDING.**

3 Plaintiffs petitioned EPA to ban community water fluoridation to protect certain
 4 subpopulations, including pregnant women, babies, and very young children, from neurotoxic
 5 effects. Pet. 1, 18. Yet Plaintiffs have not identified a single person who can credibly claim to be
 6 harmed by the alleged neurotoxicity of adding fluoridation chemicals to drinking water. Plaintiffs
 7 set forth declarations to support standing for five individuals. All are adults, two with school-age
 8 children, but none is pregnant and none has very young children.¹⁶ The standing declarants now
 9 claim that fluoridated drinking water causes them other harms, like cancer and physical pain. Those
 10 claims are equally unsubstantiated. Plaintiffs do not fall within TSCA’s zone-of-interests, *Lexmark*
 11 *Int’l Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 129 (2014), and their concerns are
 12 insufficient to demonstrate standing. *Lujan v. Defender of Wildlife*, 504 U.S. 555, 560–61 (1992).

13 **A. Plaintiffs Fall Outside the Zone-of-Interests.**

14 Because Plaintiffs claim to suffer from harms not presented in their administrative petition
 15 to EPA, Plaintiffs fall outside the zone-of-interests of TSCA. Sometimes called “prudential
 16 standing” *Lexmark*, 572 US. at 127, the Supreme Court has clarified that this is actually a question
 17 of statutory interpretation—“whether a legislatively conferred cause of action encompasses a
 18 particular plaintiff’s claim.” *Id.* TSCA does not encompass Plaintiffs’ claims.

19 As with other questions of statutory interpretation, we look to the text of the statute. And
 20 because this statute concerns the scope of potential lawsuits against the United States as sovereign,
 21 its text must be “construed strictly in favor of the sovereign.” *U.S. Dep’t of Energy v. Ohio*, 503
 22 U.S. 607, 615 (1992). TSCA requires the public to petition EPA for relief before resorting to the
 23 courts. 15 U.S.C. § 2620(a). The petition must “set forth the facts which it is claimed establish that
 24 it is necessary” to initiate the rulemaking. *Id.* § 2620(b)(1). If EPA denies the petition, “the

25 ¹⁶ Pursuant to stipulation, ECF No. 100, Plaintiffs offer no evidence of standing for Fluoride
 26 Action Network, Franzi and Randy Talley, Rosemary Fletcher, Dayna Stephens, and Karen
 27 Spencer. Further, the organizational standing witnesses Food & Water Watch and Moms Against
 28 Fluoridation base their standing exclusively on individual members. Because its members lack
 standing, so too do the organizations. *Hunt v. Wash. State Apple Advert. Comm’n*, 432 U.S. 333,
 342 (1977).

1 *petitioner* may commence a civil action . . . to compel [EPA] to initiate a rulemaking proceeding
 2 *as requested in the petition.*” *Id.* § 2620(b)(4)(A) (emphasis added). The statute is clear that only
 3 “petitioner[s]”¹⁷ may bring suit and the only basis for their suit is the petition itself. It follows that
 4 if petitioners do not suffer the unreasonable risk presented to EPA, then they do not have a cause
 5 of action to challenge EPA’s denial of their petition in court.

6 Here, the entirety of the petition, and the thrust of this case, concerns the neurotoxicity of
 7 fluoride. Thus, to fall within the zone-of-interests, Plaintiffs must demonstrate that community
 8 water fluoridation causes them the neurotoxic harm they discussed in the petition. But instead,
 9 Plaintiffs largely complain about other harms such as: physical pain, Adams Dep. 53:1–55:25
 10 (Nov. 28, 2018), Ex. 14 to Adkins Decl.; Adams Decl. ¶¶ 11, 13, 17, Ex. 13 to Adkins Decl.;
 11 migraines, Simms Decl. ¶ 13, Ex. 15 to Adkins Decl.; thyroid disease, Lavelle Decl. ¶ 8, Ex. 16 to
 12 Adkins Decl.;¹⁸ cancer, Staudenmaier Decl. ¶ 10, Ex. 17 to Adkins Decl.; dementia, Lavelle Decl.
 13 ¶¶ 5–6;¹⁹ or unspecified impacts on the bones, Trader Decl. ¶ 6, Ex. 18 to Adkins Decl. Petitioners’
 14 obligation under TSCA was to present “facts” that “establish” the “necess[ity]” of rulemaking to
 15 EPA before seeking judicial review, and such facts would show harm. *Id.* § 2620(b)(1). Petitioners
 16 cannot claim one harm to EPA, then turn to the courts, claiming that harms never presented to EPA
 17 pose an unreasonable risk. Allowing any petitioners to do so would create an end-run around the

18 _____
 19 ¹⁷ Ms. Trader and Ms. Simms were not petitioners, and therefore, cannot be plaintiffs in their
 20 own right. *See* Pet. 2; 15 U.S.C. § 2620(b)(4)(A). We nonetheless address their claimed injuries
 21 because they are members of Food and Water Watch, which was a petitioner.

22 ¹⁸ Though the petition hypothesizes that because hypothyroidism has “been associated with
 23 reduced IQ in offspring,” if fluoridation causes hypothyroidism, there can also be an effect on IQ,
 24 the petition does not present any evidence to support this hypothesis, and the petition does not
 25 identify thyroid disease itself as an unreasonable risk. Even if it did, a study cited by Plaintiffs “did
 26 not find evidence that fluoride exposure, when considered by itself, contributes to thyroid
 27 dysfunction among the general population.” Malin et al. 2018, at 671, Ex. 20 to Adkins Decl.

28 ¹⁹ The petition expresses vague concern for the elderly, but does not identify dementia as an
 unreasonable risk of fluoridated drinking water. Plaintiffs now cite an animal study to support their
 claim that fluoride may cause dementia. This animal study cannot be reliably extrapolated to
 human effects. *See Riva v. Pepsico, Inc.*, 82 F. Supp. 3d 1045, 1061 (N.D. Cal. 2015). In fact, the
 only article cited in Ms. Lavelle’s standing declaration on cognitive impairment and the elderly
 concludes that “certain low dose of fluoride intake may play a potential protective rather than
 harmful role in cognitive functions.” Lavelle Decl. ¶¶ 5–6 (citing Li 2016, Ex. 19 to Adkins Decl.).

1 administrative procedure that Congress established. Further, the only relief Congress made
2 available on judicial review is for courts “to initiate a rulemaking as requested in the petition”—
3 based on the harm shown in the petition. *Id.* § 2620(b)(4)(B). There is no logical rationale for
4 allowing people who do not suffer the harm presented in the petition to demand that EPA conduct
5 a rulemaking to address that harm.

6 **B. Plaintiffs Lack Article III Standing.**

7 Plaintiffs also cannot show all three elements of constitutional standing—*injury-in-fact*,
8 causation, and redressability. *Lujan*, 504 U.S. at 560–61. At summary judgment, they must
9 demonstrate standing just like any other element of their case, through “specific facts” from sworn
10 affidavits and other admissible evidence. *Id.* at 561. Unsupported, conclusory, or self-serving
11 allegations are not enough. *United States v. \$133,420.00 in U.S. Currency*, 672 F.3d 629, 638 (9th
12 Cir. 2012); *Carrico v. San Francisco*, 656 F.3d 1002 (9th Cir. 2011). Yet Plaintiffs’ cannot
13 demonstrate that fluoridated drinking water is specifically causing them any “real” or “immediate”
14 injury. *Lujan*, 504 U.S. at 560. Although the injury cannot be “conjectural or hypothetical,”
15 *Krottner v. Starbucks Corp.*, 628 F.3d 1139 (9th Cir. 2010), conjecture and hypothesis are the
16 lynchpins of Plaintiffs’ standing declarations.²⁰ Plaintiffs fail to establish their personal exposure
17 level to fluoride and how such exposure causes the claimed harm. The record concerns studies
18 about the neurodevelopment of fetuses *in utero* and infants in other countries. *See supra* Argument
19 I.B.2. Absent are studies on how the low levels of fluoride in community drinking water supplies
20 cause harm to people of the ages of the standing declarants and their wards. Even if Plaintiffs could
21 show harm to certain populations, Plaintiffs do not represent those populations, and they are not
22 “proper part[ies]” to bring suit. *Flast v. Cohen*, 392 U.S. 83, 99–100 (1968).

23 Ms. Lavelle expresses vague concern for her fifteen-year-old son’s neurodevelopment.
24 Lavelle Decl. ¶¶ 3–4; *see Taylor v. List*, 880 F.2d 1040, 1045 (9th Cir. 1989) (“A summary
25 judgment motion cannot be defeated by relying solely on conclusory allegations unsupported by

26 ²⁰ And any self-inflicted economic harm the standing declarants may have incurred to avoid
27 fluoridated water was caused by their own unsubstantiated concerns, not any actions traceable to
28 EPA. *See Pennsylvania v. New Jersey*, 426 U.S. 660, 664 (1976); *see Clapper v. Amnesty Int’l*
USA, 568 U.S. 398, 418 (2013).

1 *factual data.*” (emphasis added)). But Plaintiffs have produced no evidence that the specific
2 consumption of low levels of fluoride in U.S. drinking water during *adolescence* has an adverse
3 neurotoxic effect. When the scientific evidence is limited to effects on certain ages, only those of
4 that age (or their guardians) have standing. *See Nat. Res. Def. Council v. EPA*, 735 F.3d 873, 879
5 (9th Cir. 2013) (holding that when scientific studies showed adverse effects on children, declarants
6 with children had standing). Plaintiffs, therefore, cannot show that Ms. Lavelle’s concern for her
7 teenage son’s neurodevelopment is credible.

8 Like Ms. Lavelle, Ms. Staudenmaier fears unspecified “adverse effects on brain and
9 cognition” of her children. Staudenmaier Decl. ¶ 10. But her children are ages eight and sixteen.
10 *Id.* ¶ 4. Like Ms. Lavelle’s child, these children are also too old, and their exposure level
11 unestablished. A court is not required to accept the causal relationships that a plaintiff asserts the
12 facts allegedly support, *see Florida Audubon Soc’y v. Bentsen*, 94 F.3d 658, 670 (D.C. Cir. 1996),
13 and this Court declines invitations to engage in an “academic exercise in the conceivable” to
14 establish Plaintiffs’ standing, *Riva*, 82 F. Supp. 3d at 1061.

15 Because Plaintiffs lack standing, the Court must dismiss their claim.

16 CONCLUSION

17 For the forgoing reasons, the Court should dismiss for lack of standing or, if Plaintiffs have
18 standing, grant Defendants’ motion for summary judgment and enter judgment in favor of EPA.
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1 Date: October 9, 2019
2 Washington, DC

3 Respectfully Submitted,

4 /s/ Brandon N. Adkins

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of October, 2019, a true and correct copy of the foregoing Defendant's Notice of Motion and Motion for Summary Judgment was filed electronically with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served on all counsel of record via transmission of Notices of Electronic Filing generated by CM/ECF.

/s/ Brandon N. Adkins
Brandon N. Adkins
United States Department of Justice