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

Attorneys for Plaintiffs

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

FOOD & WATER WATCH, et al., Plaintiffs, vs. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al. Defendants.	Civ. No. 17-CV-02162-EMC **PLAINTIFFS' TRIAL BRIEF** Judge: Hon. Edward M. Chen Date: Jan 7, 2017 (Pretrial Conference) Time: 2:30 p.m. Courtroom: 5 - 17th Floor

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I. PLAINTIFFS' THEORY OF THE CASE

Plaintiffs' overall theory of this case is that fluoridation chemicals in drinking water present an unreasonable risk of neurotoxic harm, and that this is convincingly demonstrated when the evidence is analyzed according to EPA's longstanding methods and principles of risk assessment.

Under TSCA, regulatory action is required when there is an unreasonable risk to a "susceptible" subset of the population. Plaintiffs will thus focus much of their case on the risks that fluoridation chemicals pose to pregnant women (due to effects on the fetus), infants, and the elderly.

Much of Plaintiffs' burden is established through what is already undisputed, particularly with respect to the fetus and infant. First, even if the Court permits evidence on benefits, the Centers for Disease Control and Prevention (CDC) has conceded in this litigation that fluoridation chemicals present *no known benefit* during the *in utero* and *neonatal* period. Second, the fetal and neonatal brain do not have an effective blood-brain barrier and are thereby more vulnerable to the harmful effects of neurotoxicants. Third, fluoride crosses the placenta and gets into the fetal brain; thus fluoride has access to the brain at a point of heightened susceptility. Fourth, the National Research Council has concluded that fluoride causes neurotoxic effects in animals, and EPA agrees that "effects observed in animals are relevant to humans unless human data counterindicate." Fifth, *every* study that has examined the neurological effects of prenatal and infant fluoride exposure—including high-quality studies funded by the National Institutes of Health (NIH)—has found significant associations with reduced IQ and/or symptoms of ADHD.

A finding that fluoridation chemicals present a neurotoxic risk does *not* require the Court to find that any of the existing safety standards for fluoride were inadequate for the purposes established. As EPA has conceded, if it were to do a risk assessment of fluoride neurotoxicity (which it has not yet done), it would not rely upon existing safety standards. This is because the standards were established to protect against different endpoints (i.e., bone and tooth effects), and cannot be relied upon to protect against neurotoxicity. A finding of risk by this Court will *not* contradict the policies of old, but *will* help shine a

light for the necessary path forward.

To highlight the significance of the current moment, just two months ago, the U.S. National Toxicology Program (NTP) declared its assessment that fluoride is a presumed neurotoxicant that reduces IQ in humans. Yet, the peer-reviewed science upon which NTP based this conclusion does not currently inform any U.S. policy on fluoride, including the level of fluoride added to drinking water for caries prevention.

II. KEY EVIDENCE

A. Expert Testimony

At trial Plaintiffs will offer expert testimony from scientists who have been intimately involved with investigating the impacts of fluoride on human health, including the two principal investigators of the NIH-funded prospective studies on fluoride and neurodevelopment. EPA's experts, on the other hand, have never been involved with fluoride research prior to this case (i.e., Dr. Ellen Chang and Dr. Joyce Tsuji). Nor are EPA's experts actual EPA scientists; instead they are scientists from the industrial consulting firm Exponent.

The following is a brief summary of the expert testimony on risk that Plaintiffs intend to offer.

Dr. Howard Hu: Dr. Hu is a preeminent environmental epidemiologist and principal investigator of an EPA- and NIH-funded birth cohort study in Mexico City (i.e., the "ELEMENT cohort"). Dr. Hu and his team have found that prenatal fluoride exposure in the ELEMENT cohort is significantly correlated with adverse neurodevelopmental effects in the offspring, including reduced IQ and symptoms of ADHD. Plaintiffs will call Dr. Hu as a non-retained expert to explain the methods and findings of these studies, including their generalizability to communities drinking artificially fluoridated water in the United States. As Dr. Hu explained at his deposition, the results of his studies "are consistent with and support the conclusion that fluoride is a developmental neurotoxicant at levels of exposure seen in the general population in artificially fluoridated communities."

Dr. Bruce Lanphear: Dr. Lanphear is a clinician scientist and epidemiologist whose research on the impacts of low levels of lead on IQ have helped to shape public health policy in the United States. Dr. Lanphear has begun researching the impact of fluoride on IQ, and serves as co-principal investigator of an NIH-funded cohort in Canada (i.e., the "MIREC cohort"). As with the ELEMENT cohort studies, Dr. Lanphear's studies have found that early-life exposure to fluoride (both prenatal *and* early postnatal period) in artificially fluoridated areas of Canada is significantly associated with reduced childhood IQ. Based on the "convergent" findings of the ELEMENT and MIREC cohort studies, Dr. Lanphear recommends that pregnant women should not be consuming fluoridated water. Plaintiffs will call Dr. Lanphear as a non-retained expert to explain the methods and findings of his studies, and to explain the reasons for his recommendation that pregnant women should not consume fluoride-treated water.

***Dr. Philippe Grandjean*:** Dr. Grandjean is a physician and environmental epidemiologist at Harvard School of Public Health who has published extensively on fluoride issues over the past 30 years, including a meta-analysis of epidemiological studies on fluoride and IQ. In this case, Dr. Grandjean conducted a weight-of-the-evidence analysis of the epidemiological literature on fluoride neurotoxicity which has recently been accepted and published in a peer-reviewed scientific journal. As part of his evaluation, Dr. Grandjean conducted a "benchmark dose" (BMD) analysis of the ELEMENT and MIREC studies to determine the level of prenatal fluoride exposure that is associated with IQ loss. Dr. Grandjean's BMD analysis shows that pregnant women living in fluoridated areas (0.7 mg/L) have fluoride exposures that "greatly exceed the science-based limit needed to protect against developmental neurotoxicity." Dr. Grandjean will explain the results of his analysis at trial, and will discuss the societal-wide implications of fluoridation chemicals reducing IQ.

***Dr. Kathleen Thiessen*:** Dr. Thiessen is a risk assessment scientist who has performed health assessments for the EPA and co-authored the National Research Council's authoritative review on fluoride toxicity in 2006. In this case, Dr. Thiessen has conducted a risk assessment of fluoride neurotoxicity

pursuant to EPA's *Guidelines for Neurotoxicity Risk Assessment* (hereafter *Guidelines*). Dr. Thiessen's risk assessment shows, to a high degree of confidence, that neurotoxicity is a hazard of fluoride exposure. Dr. Thiessen's risk assessment also shows that EPA's "Margin of Exposure" method of risk characterization demonstrates an unacceptable risk when applied to the current animal toxicity data on fluoride.

B. EPA Publications

In addition to introducing the aforementioned expert testimony, Plaintiffs intend to introduce EPA's own publications to demonstrate: (1) the large doses of fluoride that substantial portions of the U.S. population receive from fluoridated drinking water, (2) that the evidence of fluoride neurotoxicity is far more substantial than what EPA has deemed to be sufficient for making hazard and risk determinations with other chemicals; and (3) even small reductions in IQ can have very large consequences on the societal level.

C. Analytical Framework

Plaintiffs will present evidence in this case consistent with the analytical framework set forth in EPA's *Guidelines*. As with other EPA risk assessments, the *Guidelines* set forth four distinct steps to the analysis: (1) Hazard Assessment, (2) Quantitative Dose Response, (3) Exposure Assessment, and (4) Risk Characterization.

Additionally, Plaintiffs will introduce evidence to address the risk-related factors that EPA considers in determining whether a risk is an "unreasonable risk" under TSCA. The risk-related factors that EPA considers include: number of people exposed; type of population exposed (e.g., susceptible subpopulations, etc); severity of the hazard; reversibility of the hazard, and uncertainties.

Plaintiffs' Proposed Findings of Fact summarize the facts that Plaintiffs expect to establish for each step of the risk assessment/determination framework. *See* ¶¶ 31-169 (facts for Hazard Assessment); ¶¶ 170-219 (Dose-Response Assessment); ¶¶ 220-253 (Exposure Assessment), ¶¶ 254 to 268 (Risk Characterization), and ¶¶ 269 to 356 (Risk Determination).

III. PLAINTIFFS' RESPONSE TO ANTICIPATED DEFENSES

Plaintiffs anticipate that EPA will raise the following defenses at trial.

A. Systematic Review

EPA contends that Plaintiffs' expert conclusions on risk are not "credible" because they are not the product of a formal systematic review. This contention is unpersuasive for the following reasons:

Up until the past 5 to 10 years, EPA did not use a systematic review protocol for its risk assessments. To find, therefore, that a risk assessment is not credible if it does not use a systematic review would call into question the credibility of most of EPA's own risk assessments, which are the scientific basis of numerous environmental regulations in this country.

EPA's experts on fluoridation's benefits in this case (Dr. Charlotte Lewis and Dr. Gary Slade) did not conduct systematic reviews, but instead performed narrative reviews of the scientific literature using a weight of the evidence analysis. Both of these experts testified that narrative reviews using a weight-of-the-evidence methodology remain a reliable way of evaluating the scientific literature.

EPA's experts, Dr. Chang and Dr. Tsuji, conducted systematic reviews of both the epidemiological and animal literature for this case, and did not identify any studies that were omitted by Plaintiffs' experts which would materially alter the conclusions.

Plaintiffs' epidemiologist, Dr. Grandjean, derived his BMD estimates from the ELEMENT and MIREC studies, which EPA and its experts both agree are the most methodologically reliable studies on fluoride neurotoxicity.

Plaintiffs' risk assessment expert, Dr. Thiessen, conducted a risk assessment pursuant to the *Guidelines*. Dr. Tala Henry, the Deputy Director of EPA's Office of Pollution Prevention and Toxics, testified that a risk assessment conducted pursuant to the *Guidelines* is "effectively" a systematic review. (At the time Dr. Henry provided this testimony, she was not aware that Dr. Thiessen had done a risk assessment under the *Guidelines*.)

B. Generalizability of the ELEMENT and MIREC Findings to the U.S.

EPA contends that the findings from the ELEMENT and MIREC cohort studies are not "generalizable" to the United States. This contention is also not persuasive.

EPA routinely relies upon data on chemical toxicity from other countries to estimate risks from those same chemicals in the United States. For example, the EPA relied on Dr. Grandjean's data on methylmercury and neurotoxicity from a cohort in Faroe Islands to establish a reference dose. EPA has used this reference dose as the basis for guidance and regulations regarding the health effects of methylmercury in the U.S.

In the specific context of fluoride neurotoxicity, EPA and other federal agencies have cited and relied upon a study of IQ in fluoridated areas of New Zealand as supporting the safety of fluoridated water in the US with no analysis to assess the "generalizability" of these findings.

The ELEMENT and MIREC studies were funded by the US-based National Institutes of Health, and the ELEMENT study was co-funded by EPA. If the studies are not generalizable to the U.S., why would EPA and NIH have invested millions of dollars funding them?

The authors of the studies, including Dr. Hu and Dr. Lanphear, have stated quite clearly that the findings of the studies are generalizable to the U.S.

In order to conclude that the ELEMENT and MIREC studies are not generalizable to fluoridated areas of the United States one or both of the following must be true: (1) people in the United States are biologically more resistant to the toxic effects of fluoride than Canadians or Mexicans, (2) the levels of fluoride associated with harm in the Canadian and Mexican are materially higher than the levels of exposure in fluoridated areas of the U.S. EPA has failed to identify any reason to believe that either of these premises are true.

As explained in Plaintiffs Proposed Findings, the available published data support the generalizability of the ELEMENT and MIREC findings to the United States. *See* ¶¶ 331-42

C. Proof of Causation at 0.7 mg/L

EPA's two retained experts on epidemiology and toxicology have focused their analysis on whether there is sufficient evidence to *prove* that fluoridated water at 0.7 mg/L causes neurotoxicity. This, however, is not the relevant standard for a risk determination under TSCA.

EPA's retained epidemiologist, Dr. Chang, has concluded that the epidemiological evidence is not yet sufficient to establish fluoride at 0.7 mg/L as a "known" cause of neurotoxicity. Dr. Chang has reached similar conclusions regarding other chemical-related health concerns using similar methods as she has applied in this case. Dr. Chang is careful to point out, however, that her conclusion of "insufficient evidence" of being a "known" cause of an effect is not inconsistent with the chemical being a "presumed" cause under the standards used by the NTP.

EPA has conceded that it "does *not* require that human exposure levels exceed a *known* adverse effect level to make an unreasonable risk determination under TSCA." Instead, EPA bases its unreasonable risk determinations on whether human exposures are unacceptably close to the estimated adverse effect levels.

The material question for this risk determination, therefore, is not whether there is conclusive proof of causation at 0.7 mg/L, but whether 0.7 mg/L is unacceptably close to the danger level. Neither Dr. Chang, nor Dr. Tsuji, attempted to answer this question.

IV. CONTROLLING ISSUES OF LAW

A. AN UNREASONABLE RISK DOES NOT REQUIRE PROOF OF HARM AT THE EXPOSURE LEVELS PRODUCED BY THE CONDITION OF USE

The seminal environmental case of *Ethyl Corp. v. U.S. E.P.A.*, 541 F.2d 1 (D.C. 1976) provides a thorough examination of the quantum of evidence that is sufficient to demonstrate a "significant risk." Although *Ethyl Corp.* involved a regulation under the Clean Air Act, the D.C. Circuit *en banc* panel expressed a very similar conception of risk that Congress contemplated for TSCA, and is thus instructive to the definition of risk in this case.

At issue in *Ethyl Corp*., was EPA's proposed phase-out of lead from gasoline. The quandary before the Court was that the EPA did not yet have proof that the levels of exposure associated with leaded gasoline were causing harm because the available studies generally involved higher exposure levels, or had methodological limitations that prevented definitive conclusions. The lead industry argued that this was not enough, that EPA needed "factual proof of actual harm" in order to prove the requisite "significant risk." 41 F.2d at 12. The D.C. Circuit rejected this position, holding that proof of harm was not necessary to make a finding of *risk*. The court noted that "certainty in the complexities of environmental medicine may be achievable only after the fact," and that "[a]waiting certainty will often allow for only reactive, not preventive, regulation." *Id.* at 25. Thus, "[w]here a statute is *precautionary* in nature," the court reasoned that it would defeat the purpose of the act to require "rigorous step-by-step proof of cause and effect." *Id.* at 28. Accordingly, the court held that a significant risk can be proved despite "conflicting and inconclusive evidence", and "must be decided by assessment of risks as well as by proof of facts." *Id.* at 24 & 26.

The D.C. Circuit's conception of "significant risk" is relevant to and closely mirrors what Congress contemplated for risk determinations under TSCA. First, Congress described TSCA as "protective legislation" whose "overriding purpose is to provide protection of health and the environment through authorities which are designed to *prevent* harm." H.R. Rep No. 94-1431, at 7 (1976). Thus, the statute is *precautionary*. Second, as with the D.C. Circuit, Congress recognized that "factual certainty respecting the existence of an unreasonable risk of a particular harm may not be possible," and made clear that "the bill does not require it."[1] *Id.* at 32. Finally, in close unison with the D.C. Circuit, Congress explained that the demonstration of risk "must be based not only on consideration of facts but also on consideration of scientific theories, projections of trends from currently available data, modeling using reasonable assumptions, and extrapolations from limited data."[2] *Id.*

[1] *See also* John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261, 271–73 (1991) (describing the unreasonable risk standard as "a regulation of risk instead of actual harm").

[2] *See also* Applegate, *supra*, at 273 ("Risk is an expression of uncertainty; it is easier to prove than actual

In short, Congress's conception of risk under TSCA harmonizes with the D.C. Circuit's analysis, and supports using the methods and principles of *risk assessment* to make an unreasonable risk determination under TSCA. This is what Plaintiffs' experts have done. By contrast, EPA's experts utilized a narrow "causal analysis" that is analogous to the lead industry's position in *Ethyl Corp.* which the D.C Circuit and Congress have rejected.

B. PLAINTIFFS HAVE ARTICLE III STANDING

1. The Zone of Interests Test for Prudential Standing Does Not Apply

The Fourth Circuit's *en banc* decision in *Friends of the Earth, Inc. v. Gaston Copper Recycling Corp*., 204 F.3d 149, 155 (4th Cir. 2000) demonstrates that the zone of interests test for prudential standing does not apply to citizen petitions under TSCA. In *Gaston*, the court addressed a citizen suit provision in the Clean Water Act which allows "a person or persons having an interest which is or may be adversely affected" to file a claim. 204 F.3d at 155. The Gaston court interpreted the statute's expansive definition of who can bring suit as a grant standing to "the outer limits of Article III." *Id.* The Court held, therefore, "if a Clean Water Act plaintiff meets the constitutional requirements for standing, then he *ipso facto* satisfies the statutory threshold as well." *Id.* The Fourth Circuit's holding applies with even greater force to citizen petitions under TSCA because the statute is even more expansive. Under Section 21 of TSCA, "any person" to file a petition, with no limitation placed on who can do so. 15 U.S.C. § 2620(a). As in *Gaston*, therefore, if the Plaintiffs meet the constitutional requirements for standing they *ipso facto* have standing.

2. Plaintiffs Have Standing Under *NRDC v. EPA*, 735 F.3d 873 (9th Cir. 2013)

Here, all of the individual standing declarants, including Ms. Lavelle and Ms. Staudenmaier, have an actual or imminent injury-in-fact under the precedent set forth in *Natural Resources Defense Council v. United States Envtl. Prot. Agency*, 735 F.3d 873, 878-79 (9th Cir. 2013) (hereafter, "*NRDC*"). In *NRDC*,

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harm. Regulation based on risk permits regulatory action based on *ex ante* collective danger rather than *ex post* individual injury, and also operates preventatively to avert injury to the public as a whole.").

the Ninth Circuit addressed a challenge to an EPA pesticide regulation. In its standing analysis, the court focused on the fact that, if the pesticide was introduced into the market, there was no effective way for the plaintiffs to avoid it because it would be in many products with no labels to warn of its presence. *NRDC*, 735 F.3d at 878-79. Notably, the only basis the court had for inferring that the pesticide posed a health risk were the results of an EPA "Margin of Exposure" analysis of animal data. *Id.* at 881-85.

As in *NRDC*, the Plaintiffs here are also unable to avoid exposure to fluoridation chemicals because, even if they filter them out of their tap water, fluoridated water is used to make countless processed foods and beverages and there are no labels to indicate their presence. Further, as in *NRDC*, application of the Margin of Exposure method indicates a risk (based on *both* animal *and* human data), and this risk extends to adult populations. Thus, under *NRDC*, the Plaintiffs face a "credible threat" of being exposed to chemicals at issue, and these chemicals have been identified as posing a risk under EPA's Margin of Exposure analysis.

3. Plaintiffs' Have Standing Under *Baur v. Veneman*, 352 F.3d 625 (2nd Cir. 2003)

An injury-in-fact for purposes of Article III "need not be capable of sustaining a valid cause of action under applicable tort law." *Denney v. Deutsche Bank AG*, 443 F.3d 253, 264–65 (2d Cir. 2006). This is especially so where, as here, the statute is designed to *prevent* harm *before* it occurs. *Baur v. Veneman*, 352 F.3d 625, 633 (2nd Cir. 2003) ("[W]here the very purpose of the regulatory statute is risk minimization, it should be presumed that plaintiffs 'should be allowed to bring suit to prevent the sorts of injuries that the regulatory scheme was designed to prevent ... to ensure that the agencies adhere to the will of Congress." (citation omitted)). An injury-in-fact in Section 21 suits, therefore, may be established by evidence of a reasonable concern that the challenged policy puts the plaintiff at increased *risk* of harm. *Central Delta Water Agency v. United States*, 306 F.3d 938, 949 (9th Cir. 2002). As evident by the Ninth Circuit's decision in *Hall v. Norton*, 266 F.3d 969, 976 (9th Cir. 2001), an injury-in-fact does not require expert testimony to corroborate the plaintiff's individual concerns.

As in *Baur v. Veneman*, 352 F.3d 625, 637 (2nd Cir. 2003), there are "two critical factors that weigh in favor of concluding that standing exists in this case." The first critical factor that *Baur* identified is whether "government studies and statements confirm" at least some of plaintiffs' key allegations. *Id.* at 637-40. That requirement is met here. First, the National Research Council's report, which was conducted at the request of EPA, concluded that neurotoxicity is a hazard of fluoride in animals, and that the brain changes in fluoride-treated animals parallel the changes seen in humans with dementia. Second, EPA agrees that "effects observed in animals are relevant to humans unless human data counterindicate," thus highlighting the due concern that should be given to the NRC's findings. Third, the National Toxicology Program issued a draft systematic review in October 2019 wherein NTP announced its conclusion that fluoride is a presumed neurotoxicant in human beings. Fourth, the National Institutes of Health have been funding studies to examine the neurotoxic effects of low-level fluoride exposure in North American populations. This is not a case of lay citizens subjectively fearing alien abduction or some other paranoid notion; this is a case where the plaintiffs have reasonable health concerns that are supported by a rich body of scientific evidence that even federal health authorities recognize to be troubling.

The second critical factor under *Baur* is whether the plaintiffs' exposure is the direct result of a government policy. *Baur*, 352 F.3d at 640-41. This factor is again met here because fluoridation is a government policy, and it is undisputed that EPA has the authority under TSCA to prohibit it. Plaintiffs' risk arises directly out of EPA's failure to exercise its authority. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561–62 (1992) (stating that the challenged policy for purposes of standing can be either government "action" and "inaction").

4. Plaintiffs Have Standing Under *Friends of the Earth* and Its Progeny

Plaintiffs have suffered an injury-in-fact based on the loss of enjoyment of their environment and their property under the precedents of *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181-84 (2000), *Covington v. Jefferson County*, 358 F.3d 626, 641 (9th Cir. 2004), and *Gaston*,

204 F.3d 149, 155 (4th Cir. 2000). In these cases, the plaintiffs suffered an injury-in fact based on their concerns about the potential (yet unproven) effects of chemical contaminants in nearby waterways and adjacent properties which caused them, *inter alia*, to stop fishing or swimming. Here, the Plaintiffs express similar concerns, albeit here the chemicals are directly entering their homes via their tap water, and are causing Plaintiffs to avoid drinking, or bathing in, the water in their own homes. As explained by the Fourth Circuit in *Gaston*, no federal circuit has "required additional scientific proof where there was a direct nexus between the claimant and the area of environmental impairment." *Gaston*, 204 F.3d at 159.

Finally, it is no consequence that the injury-in-fact that Plaintiffs suffered is shared by many people in the population. The Supreme Court has "already made it clear that standing is not to be denied simply because many people suffer the same injury." U*nited States v. Students Challenging Regulatory Agency Procedures (SCRAP)*, 412 U.S. 669, 687 (1973). Indeed, "[t]o deny standing to persons who are in fact injured simply because many others are also injured, would mean that the most injurious and widespread Government actions could be questioned by nobody. *Id.* at 688.

December 20, 2019

Respectfully submitted,

/s/ Michael Connett .
MICHAEL CONNETT
Attorney for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served by Notice of Electronic Filing this 20th day of December, 2019, upon all ECF registered counsel of record using the Court's CM/ECF system.

/s/ Michael Connett .
MICHAEL CONNETT