DEBRA J. CARFORA
JOHN THOMAS H. DO
BRANDON N. ADKINS
U.S. Department of Justice
Environmental Defense Section
P.O. Box 7611
Washington, D.C. 20044
Tel: (202) 514-2640
Fax: (202) 514-8865
Email: debra.carfora@usdoj.gov

Attorneys for Defendants

Additional Attorneys Noted Below

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

FOOD & WATER WATCH, INC, et al., Plaintiffs, v. U.S. Environmental Protection Agency, et al., Defendants.	Case No.: 17-cv-02162-EMC **JOINT PRETRIAL CONFERENCE STATEMENT** Date: January 7, 2020 Time: 2:30 p.m. Place: Courtroom 5, 17th floor

In accordance with the Court's June 13, 2019 Amended Case Management and Pretrial Order for Trial (ECF No. 107), the undersigned counsel of record respectfully submit the following Joint Pretrial Conference Statement:

1. The Action.

a. Substance of the Action: Plaintiffs have brought this case under Section 21 of the Toxic Substances Control Act (15 U.S.C. § 2620), on the grounds that the addition of fluoridation chemicals to drinking water presents an unreasonable risk of neurologic harm. Plaintiffs contend that the recent NIH-funded prospective cohort studies, taken

together with the many other studies of fluoride neurotoxicity in animals and humans, demonstrate that fluoridation chemicals pose an unreasonable risk when assessed according to well-established risk assessment methods. EPA contends that Plaintiffs cannot set forth a scientifically defensible basis to conclude that any persons suffer an unreasonable risk of neurotoxic harm as a result of exposure to fluoride in the U.S. through the addition of fluoridation chemicals to drinking water.

b. Relief Prayed: Pursuant to 15 U.S.C. § 2620(b)(4)(B), Plaintiffs seek injunctive relief in the form of an Order requiring EPA to initiate the rulemaking proceeding requested by Plaintiffs in their Petition to EPA. The remedy provided for in Section 21(b)(4)(B)(ii) is an order that EPA "initiate a proceeding for the issuance of a rule," 15 U.S.C. § 2620(a), which order may not proscribe the content of a rule or the outcome of such a proceeding. Further, pursuant to 15 U.S.C. § 2620(b)(4)(C), Plaintiffs seek recovery of their costs of suit and reasonable fees for attorneys and expert witnesses. Finally, Plaintiffs seek such further relief as the Court may deem just and proper. Defendants deny that Plaintiffs are entitled to relief.

2. Factual Basis of the Action.

a. **Undisputed Facts**:

1. According to the United States Centers for Disease Control and Prevention (CDC), as of 2014, approximately 200,000,000 people in the United States live in communities that add fluoridation chemicals to the drinking water.

2. Plaintiffs' Citizen Petition sought to prohibit the addition of fluoridation chemicals to water on the grounds that this condition of use presents an unreasonable risk of neurologic harm.

3. Fluoridation chemicals are added to drinking water to prevent tooth decay (i.e., dental caries). In addition to being added to water, fluoride is added to dental products and certain pesticides.

4. In epidemiology, a cross-sectional study is a comparison of the prevalence of a specific health outcome across levels of a specific exposure in study

subjects (or vice versa), with the exposure and outcome both measured at a given time, providing a "snapshot" of the association between the exposure and the health outcome at one time.

5. In epidemiology, a cohort study is a comparison of incidence rates of a specific health outcome between study subjects with various levels of a specific exposure who are observed over time.

6. A person's individual response to fluoride exposure depends on factors such as age, kidney function, body weight, activity level, nutrition, and other factors.

7. Human urine fluoride concentrations (biomonitoring) measures an internal dose.

8. Various factors can affect the concentration of fluoride in a urine sample, such as an individual's metabolism, when a urine sample is collected, and the time since the last void of the individual who provided the sample.

9. Historically, most studies to investigate the impact of fluoride on IQ in humans have used cross-sectional study designs. Most of these cross-sectional studies have been conducted in China, and other countries with elevated levels (>1.5 mg/L) of naturally occurring fluoride in water. By contrast, fluoride is added to water in the United States to reach a concentration of 0.7 mg/L.

10. Prospective cohort studies have been conducted in Mexico City (ELEMENT cohort), where fluoride is added to salt, and Canada (MIREC cohort), where fluoride is added to water. These studies are the most methodologically reliable human studies to date on the impact of fluoride on neurodevelopment.

11. Risk assessment is the process by which scientific judgments are made concerning the potential for toxicity in humans.

12. The National Research Council (NRC, 1983) has defined risk assessment as including the following components: hazard identification, dose-response assessment, exposure assessment, and risk characterization.

13. The term "risk evaluation" is a specialized term under TSCA.

14. Together, the components of EPA's risk assessment process, coupled with the ultimate risk determination, constitute a "risk evaluation" under TSCA.

15. The final step of a risk evaluation is to weigh a variety of factors to determine whether the chemical substance, under the conditions of use, presents an unreasonable risk of injury to health or the environment, referred to as the "risk determination" step in the TSCA risk-evaluation process.

16. EPA does not require that human exposure levels exceed a known adverse effect level to make an unreasonable risk determination under TSCA. For example, if human exposure levels exceed a known no-adverse effect level divided by combined uncertainty factors, EPA may make an unreasonable risk determination under TSCA.

17. In the ideal world, all risk assessments would be based on a very strong knowledge base (i.e., reliable and complete data on the nature and extent of contamination, fate and transport processes, the magnitude and frequency of human and ecological exposure, and the inherent toxicity of all of the chemicals). However, in real life, information is usually limited on one or more of these key data needed for risk assessment calculations. This means that risk assessors often have to make estimates and use judgment when performing risk calculations, and consequently all risk estimates are uncertain to some degree. For this reason, a key part of all good risk assessments is a fair and open presentation of the uncertainties in the calculations and a characterization of how reliable (or how unreliable) the resulting risk estimates really are.

18. EPA's *Guidelines for Neurotoxicity Risk Assessment* were designed in 1998 to guide EPA's evaluation of substances that are suspected to cause neurotoxicity, in line with substantive standards established in the statutes administered by the Agency.

19. EPA's *Guidelines for Neurotoxicity Risk Assessment* preceded the 2016 TSCA amendments.

20. The current non-enforceable health goal for fluoride under the Safe Drinking Water Act ("SDWA"), or Maximum Contaminant Level Goal (MCLG), of 4.0 mg/L was promulgated in 1985 to protect against a condition known as crippling skeletal fluorosis (i.e., "stage III skeletal fluorosis"). Crippling fluorosis is the final, and most severe, stage of skeletal fluorosis.

21. Based on its 2006 review, the National Research Council (NRC) of the National Academies of Science (NAS) recommended that the MCLG of 4 mg/L be lowered to prevent children from developing severe dental fluorosis and reduce the lifetime accumulation of fluoride into bone that the majority of the committee concluded is likely to put individuals at increased risk of bone fracture and possibly skeletal fluorosis.

22. Based on the NRC's recommendation, in 2010, EPA's Office of Water completed a dose-response analysis using available data between 2000 and 2010 to calculate a reference dose ("RfD")—an estimate of the fluoride dose protective against severe dental fluorosis, stage II skeletal fluorosis, and increased risk of bone fractures—of 0.08 milligrams per kilograms per day (mg/kg/day), a measure of daily intake by body weight.

23. In addition to the tooth and bone effects, the NRC also evaluated neurotoxicity as an effect of fluoride exposure, among other health effects. The NRC concluded that the available data were inadequate to demonstrate a risk for neurotoxicity at 4.0 mg/L and made recommendations for additional research. Since that time, additional research has been conducted and the scientific database for studies that have examined neurotoxicity as an effect of fluoride exposure has grown.

24. In determining whether adding fluoridation chemicals to drinking water presents an unreasonable risk of neurotoxic effects under TSCA, EPA's Office of Pollution Prevention and Toxics would not rely on the 2010 RfD, but would instead apply a weight of the scientific evidence approach for identifying and characterizing the best available science from the most up-to-date scientific database of studies that have

examined neurotoxicity as an effect of fluoride exposure.

25. In conducting TSCA risk evaluations, EPA generally uses the Margin-of Exposure (MOE) approach to characterize the risk as a step in the risk assessment process. Using this approach, an MOE is calculated by comparing (dividing) the point-of departure directly to the expected exposure level. The MOE is then compared to a benchmark MOE, which is the product of all relevant uncertainty factors.

26. EPA considers the MOE, relative to the benchmark MOE, in addition to other factors, in determining whether risks are unreasonable under TSCA.

27. The National Research Council has stated that "the inference that results from animal experiments are applicable to humans is fundamental to toxicologic research."

28. EPA agrees that effects observed in animals are relevant to humans unless human data counterindicate.

29. The developing brain is distinguished by the absence of a blood-brain barrier. The development of this barrier is a gradual process, beginning in utero and complete at approximately 6 months of age.

30. Fluoride passes through the placenta and gets into the fetal brain.

31. Whether harm would actually occur depends on the dose and nature of exposure.

b. **Disputed Factual Issues**:

1. Plaintiffs contend that fluoridation chemicals pose an unreasonable risk of neurotoxicity when added to drinking water because

(A) neurotoxicity is a *hazard o*f fluoride exposure when the scientific literature is assessed according to EPA's Guidelines on Neurotoxicity Risk Assessment;

(B) neurotoxicity is a *risk* at the exposure levels produced by fluoridation chemicals when assessed according to EPA's long-standing risk assessment methodologies, including Benchmark Dose and Margin of Exposure analysis, and

(C) the risk of neurotoxicity posed by fluoridation chemicals is

unreasonable when assessed according to the risk-related factors that EPA has identified as relevant to risk determinations under TSCA.

2. EPA contends that the following disputed facts are material to Plaintiffs claim:

i. Plaintiffs did not conduct an exposure assessment.

ii. Plaintiffs did not conduct a systematic review.

iii. The existing body of evidence for fluoride neurotoxicity does not support the identification of a hazard of neurotoxicity at the levels of exposure to fluoridation chemicals under the condition of use being assessed.

iv. The existing body of evidence for fluoride neurotoxicity does not support the identification of a dose response that is probative of water fluoride concentrations in the United States at or below 0.7 mg/L.

v. Fluoridation of public drinking water systems has been demonstrated as an effective public health intervention in reducing dental caries.

vi. Plaintiffs have not set forth a scientifically defensible basis to conclude that any persons suffer an unreasonable risk of neurotoxic harm as a result of exposure to fluoride in the U.S. through the addition of fluoridation chemicals to drinking water.

3. Disputed Legal Issues:

1. For the reasons set forth in Plaintiffs' Motion *in Limine* No. 1, Plaintiffs contend that the benefits (or lack thereof) of fluoridation chemicals are "nonrisk factors" that cannot be considered in the unreasonable risk determination.

2. For the reasons set forth in Plaintiffs' Motion *in Limine* No. 2, Plaintiffs contend that any evidence to support a deferral in the rulemaking under Section 21(b)(4)(B)(ii) should be excluded because EPA cannot demonstrate one of the requisite factors, and thus introduction of evidence would be futile and waste judicial resources.

3. EPA contends that the Court must apply the substantive requirements of TSCA's statutory scheme for determining whether the use of fluoridation chemicals to

increase water concentrations levels to 0.7 mg/l presents an unreasonable risk of injury to health or the environment, specifically the risk evaluation process and criteria set forth in section 6(b), 15 U.S.C. § 2605(b), and 40 CFR Part 702, as well as the scientific standards set forth is section 26(h) and (i), 15 U.S.C. § 2625(h), (i), and 40 CFR Part 702. This issue is currently before the Court on EPA's pending motion for summary judgment.

4. EPA contends that any unreasonable risk determination requires the consideration of health benefits.

5. EPA contends that Plaintiffs' alleged injuries fall outside the zone-of-interests of Section 21 because they are not within the scope of neurotoxic risks alleged in the Petition. This issue is currently before the Court on EPA's pending motion for summary judgment.

6. EPA contends that Plaintiffs lack Article III standing. This issue is currently before the Court on EPA's pending motion for summary judgment.

4. Estimated of Trial Time:

Plaintiffs estimate that, with an 8-day trial schedule, they will need 20 hours of testimony (including both direct examination of Plaintiffs' witnesses, and cross-examination of Defendants' witnesses), although Plaintiffs believe the issues in this case would benefit from additional trial time. Should the Court be willing to allow more time, Plaintiffs could efficiently use up to 25 hours of testimony (if benefits are excluded) and up to 30 hours (if benefits are included).

Defendants estimate that they will need 20 hours of testimony (including both direct examination of Plaintiffs' witnesses, and cross-examination of Defendants' witnesses) and request no less than half the total time allotted for all parties by the Court. Defendants oppose any additional trial time. For the reasons set forth in Defendants' motions in limine, Defendants believe that the trial time should be limited to 4 days.

The parties agree that the time for each witness should be allocated to the parties based on the time of each party's respective examinations – i.e., in Plaintiffs case-in-chief, the time of Defendants' cross examinations would be allocated against the

Defendants, while in Defendants' case, the time of Plaintiffs' cross-examinations would be allocated against the Plaintiffs.

5. Trial Alternatives and Options.

a. Settlement Discussion: The parties agree that there are no possible grounds for settlement in this matter.

b. Consent to Trial Before a Magistrate Judge: The parties do not consent to having this case conducted by a Magistrate Judge.

c. Amendments or Dismissals: There are no amendments or dismissals.

d. Bifurcation of Separate Trial of Issues: EPA requests a bifurcation procedure, which Plaintiffs oppose.

EPA's position is as follows:

Upon a finding of unreasonable risk, the Court may permit EPA to defer rulemaking if the Court finds (1) that "the extent of the risk to health or the environment alleged by [Plaintiffs] is less than the extent of risks to health or the environment with respect to which [EPA] is taking action" and (2) that "there are insufficient resources available to [EPA] to take the action requested by [Plaintiffs]." 15 U.S.C. § 2620(b)(4)(B)(ii). When Congress amended TSCA in 2016, Pub. L. No. 114-182, 130 Stat. 448, it imposed new mandatory requirements and deadlines for EPA to systematically evaluate chemicals currently in U.S. commerce. The 2016 amendments also mandated that EPA begin initial risk evaluations for ten chemicals drawn from the existing 2014 update to EPA's TSCA Work Plan for Chemical Assessments (the "Work Plan"). 15 U.S.C. § 2605(b)(2)(A). In December 2016, EPA published a list of ten chemicals drawn from the Work Plan for initial risk evaluations and began the process of evaluating their risks. 81 Fed. Reg. 91,927 (Dec. 19, 2016). Risk evaluations must be completed within three-and-a-half years. *See* 15 U.S.C. § 2605(b)(4)(G). The first risk evaluations under the amended TSCA are expected to be complete next year.

The outcome of these ongoing risk evaluations will inform EPA's determination of whether to seek a deferral under section 21(b), because EPA must

understand the full extent of the risk posed by adding fluoridation chemicals to drinking water, if at all, as determined by the Court and the full extent of the risks to which it must take action pursuant to the ongoing risk evaluations under TSCA section 6. If the issue of deferral under section 21(b) were not bifurcated from the issue of unreasonable risk, EPA would be prejudiced by requiring it to demonstrate the full extent of the risks to which it is taking action before the time allowed by statute to complete the first ten risk evaluations under the amended TSCA and before the Court has make any unreasonable risk determination on fluoride.

Plaintiffs oppose EPA's bifurcation request for the reasons set forth in Plaintiffs' Motion *in Limine* No. 2.

6. Witnesses.

a. See attached Appendix A.

7. Exhibits:

a. See attached Appendix B.

8. Use of Discovery Responses.

a. See attached Appendix C.

Dated: December 19, 2019

Respectfully submitted,

/s/ *Debra J. Carfora*
DEBRA J. CARFORA
JOHN THOMAS DO
BRANDON N. ADKINS
Environmental Defense Section
4 Constitution Square,
150 M Street NE, Room 4.1114
Washington, DC 20001
Tel: (202) 514-2640
Email: debra.carfora@usdoj.gov

Attorneys for Defendants

/s/ Michael Connett (by permission)
MICHAEL CONNETT
C. ANDREW WATERS
Waters Kraus & Paul
222 N. Pacific Coast Hwy

El Segundo, CA 90245
Tel: (310) 414-8146

Attorneys 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 19th day of December, 2019, upon all ECF registered counsel of record using the Court's CM/ECF system.

/s/ *Debra J. Carfora*

Debra J. Carfora, Trial Attorney