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

FOOD & WATER WATCH; AMERICAN
ACADEMY OF ENVIRONMENTAL
MEDICINE; FLUORIDE ACTION NETWORK;
INTERNATIONAL ACADEMY OF ORAL
MEDICINE & TOXICOLOGY; MOMS
AGAINST FLUORIDATION; AUDREY
ADAMS, individually and on behalf of KYLE
ADAMS; KRISTIN LAVELLE, individually and
on behalf of NEAL LAVELLE; and BRENDA
STAUDENMAIER, individually and on behalf
of KO STAUDENMAIER and HAYDEN
STAUDENMAIER,

Plaintiffs,

vs.

Civ. No.

COMPLAINT

U.S. ENVIRONMENTAL PROTECTION
AGENCY, an agency of the United States;
SCOTT PRUIT, Administrator, U.S.
Environmental Protection Agency, in his official
capacity,

Defendants.

1. Plaintiffs FOOD & WATER WATCH; AMERICAN ACADEMY OF ENVIRONMENTAL
MEDICINE; FLUORIDE ACTION NETWORK; INTERNATIONAL ACADEMY OF ORAL
MEDICINE & TOXICOLOGY; MOMS AGAINST FLUORIDATION; AUDREY ADAMS,
individually and on behalf of KYLE ADAMS; KRISTIN LAVELLE, individually and on behalf of
NEAL LAVELLE; and BRENDA STAUDENMAIER, individually and on behalf of KO
STAUDENMAIER and HAYDEN STAUDENMAIER (collectively "Plaintiffs") bring this suit against

1 Defendants, the U.S. ENVIRONMENTAL PROTECTION AGENCY and SCOTT PRUITT, in his
2 official capacity as Administrator of that Agency (collectively “EPA”), to compel the initiation of
3 rulemaking pursuant to the Toxic Substances Control Act (“TSCA”), 15 U.S.C. § 2605(a), to prohibit the
4 addition of fluoridation chemicals to drinking water supplies.

5 I. BACKGROUND

6 2. Industrial-grade fluoride chemicals (i.e., hydrofluorosilicic acid, sodium silicofluoride, and
7 sodium fluoride), derived primarily from the phosphate fertilizer industry, are added to many public
8 water supplies in the United States in an attempt to reduce tooth decay.

9 3. Approximately 200 million Americans live in communities with artificially fluoridated water.
10 Even people who don’t live in fluoridated areas now regularly consume fluoridated water since many
11 processed foods and beverages are made in fluoridated areas.

12 4. Water fluoridation began in the 1940s based on the mistaken premise that fluoride’s primary
13 benefit to teeth comes from *ingestion*.

14 5. It is now universally recognized by dental researchers, including the Centers for Disease
15 Control’s (CDC) Oral Health Division, that fluoride’s primary benefit comes from *topical* application.
16 Fluoride does not need to be *swallowed*, therefore, to prevent tooth decay.

17 6. The National Academy of Sciences (NAS) has repeatedly stated that fluoride is not an essential
18 nutrient. Fluoride does not need to be swallowed, therefore, to prevent *any disease* or promote *any health*
19 *benefit*.

20 7. Water fluoridation has been rejected or discontinued by the vast majority of European countries
21 without any demonstrated adverse effect on cavity rates.

22 8. Whereas fluoride’s benefits to teeth come from topical contact, fluoride’s health risks come
23 from ingestion. One of the risks of fluoride ingestion is dental fluorosis, a hypomineralization of tooth
24 enamel that produces noticeable discoloration of the teeth.

1 9. According to a 2011-2012 national survey by the CDC, a staggering 58% of American
2 adolescents now have dental fluorosis, with 23% of adolescents suffering advanced forms of the
3 condition. When present on the front teeth, dental fluorosis (even in its “mild” forms) is an aesthetically
4 objectionable condition that can cause children significant social anxiety and embarrassment.

5 10. The rate of dental fluorosis among U.S. children is far higher today than was the case when
6 fluoridation first began in the 1940s, and is several times higher than the rate documented in the 1980s.
7 The continued increase in fluorosis over the past 60 years highlights the fact that American children are
8 being exposed to unprecedentedly high doses of fluoride, primarily but not exclusively through water
9 fluoridation.
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11 11. The prevalence and severity of dental fluorosis is significantly greater in areas with fluoridated
12 water than in areas without. This is because children in fluoridated areas receive larger cumulative doses
13 of fluoride than children in non-fluoridated areas.

14 12. A primary concern with fluoride’s impact on human health today is its deleterious effect on the
15 brain.
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17 13. In 2006, the National Research Council (NRC) concluded that “it is apparent that fluorides have
18 the ability to interfere with the functions of the brain.”

19 14. Over 300 published, peer-reviewed studies have reported that fluoride interferes with the brain.
20 This includes over 50 studies linking fluoride exposure to cognitive impairments in human populations.
21 The majority of these studies have been published within the past 10 years.

22 15. In 2014, fluoride was added to the list of chemicals “*known* to cause developmental neurotoxicity
23 in *human* beings” in a review published by *Lancet Neurology*. Fluoride is one of only 12 chemicals that
24 are on this list, alongside lead, mercury, and PCBs.

25 16. Many of the studies investigating fluoride’s impact on the brain have found adverse neurotoxic
26 effects at doses ingested by a large number of Americans living in fluoridated communities.
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1 17. EPA's safety standards for fluoride dosing remain focused on preventing severe dental fluorosis
2 and/or crippling skeletal fluorosis, and do not account for fluoride's effects on the brain. Yet, studies in
3 humans and animals show that fluoride causes adverse neurotoxic effects at doses that are *lower* than
4 those which produce severe dental and skeletal fluorosis. Safety standards solely designed to protect
5 against severe dental and skeletal fluorosis will thus not protect against fluoride's neurological effects.

6 18. EPA has promulgated *Guidelines for Neurotoxicity Risk Assessment* (hereafter, *Guidelines*),
7 which set forth the principles, concepts, and procedures that EPA has stated it "will follow" when
8 "evaluating data on potential neurotoxicity associated with exposure to environmental toxicants."
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10 19. Despite the voluminous peer-reviewed scientific literature on fluoride neurotoxicity in humans,
11 animals, and cell cultures, EPA has never applied its own *Guidelines* to fluoride.

12 20. Application of EPA's *Guidelines* to the human, animal, and in vitro research on fluoride
13 neurotoxicity would show that (1) neurotoxicity is a hazard of fluoride exposure, and (2) the risk of this
14 hazard exists at doses that are now ingested by millions of Americans living in fluoridated communities.

15 21. Neurodevelopmental disabilities, including learning disabilities and attention deficit hyperactivity
16 disorder, are now widespread in the United States. Data from the CDC shows that 1 in 6 U.S. children
17 now suffer from a neurodevelopmental disability.
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19 22. In a nation besieged by neurological disorders of poorly understood etiology, both in young
20 children and the elderly, minimizing exposures to known neurotoxic substances must be a public health
21 priority.
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II. JURISDICTION AND VENUE

24. On November 22, 2016, a group of organizations and individuals, including Plaintiffs, petitioned EPA to exercise its authority under Section 6 of TSCA, 15 U.S.C. § 2605, to prohibit the addition of “fluoridation chemicals” to drinking water supplies based on the voluminous peer-reviewed research linking fluoride exposure to neurotoxicity. (The one and only chemical use of “*fluoridation* chemicals” is to fluoridate drinking water.)

25. By letter dated February 17, 2017, EPA denied the Petition.

26. Plaintiffs have a right to bring this action pursuant to TSCA, 15 U.S.C. § 2620(b)(4), which authorizes petitioners to commence a civil action in a district court of the United States to compel the EPA Administrator to initiate a rulemaking proceeding as requested in the petition.

27. This Court has jurisdiction pursuant to 15 U.S.C. § 2620(b)(4)(A) and 28 U.S.C. § 1331.

28. Venue is properly vested in this Court under 28 U.S.C. § 1391(e) as Plaintiff KRISTIN LAVELLE resides in Berkeley California, and Plaintiff FOOD & WATER WATCH has a regional office in Oakland, California.

III. PARTIES

29. Plaintiff FOOD & WATER WATCH (“FWW”) is a national, non-profit, public interest consumer advocacy organization with its headquarters in Washington, D.C. and a regional office in Oakland, California.

30. FWW’s mission includes educating consumers about the health and safety of our food and water systems and as such FWW advocates on behalf of the public for policies promoting environmental protection and the long-term well-being of individuals and communities.

31. FWW’s members live in fluoridated communities across the United States, and as with virtually all Americans, regularly purchase processed foods and beverages that are contaminated with fluoridated water. Since the labels on processed foods and beverages do not identify whether the products are made

1 with fluoridated water, it is often not possible for consumers to know which particular food or beverage
2 is contaminated. There is therefore a credible threat that FWW's members will be exposed to fluoridated
3 water and the health risks associated therewith, even if they purchase home water filtration systems to
4 remove the fluoride out of the tap water entering their homes.

5 32. Jessica Trader is an FWW member and a San Francisco business owner. San Francisco adds
6 industrial fluoride chemicals to its water. Jessica has moderate-to-severe dental fluorosis from over-
7 exposure to fluoride as a child. As a result of her fluorosis, Jessica's teeth have noticeable white and
8 brown stains, which have caused her social anxiety and embarrassment. Jessica is concerned about the
9 impact that her prior and ongoing exposures to fluoridation chemicals could have on her health and has
10 spent significant money in order to limit her exposure to this toxicant, including through the purchase and
11 installation of a professional water filtration system that removes fluoride.
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13 33. Dayna Stephens is a FWW member and professional saxophonist. Dayna currently resides in
14 Patterson, New Jersey. Although Patterson does not fluoridate its water, Dayna's musical career requires
15 him to spend a large percentage of his time travelling throughout the United States. Dayna suffers from
16 Focal Segment Glumereal Sclerosis (FSGS), a cause of kidney disease in children and adolescents as
17 well as a leading cause of kidney failure in adults. Dayna underwent dialysis for his kidney failure and
18 underwent kidney transplant surgery. It is well established in the scientific literature that kidney disease
19 greatly increases an individual's susceptibility to fluoride's toxicity. Dayna is aware of this research, and
20 is very concerned about the impact fluoride ingestion could have on his health. While at home, and while
21 travelling, Dayna spends a significant amount of time and money to avoid exposure to fluoridation
22 chemicals from tap water, processed foods, and processed beverages.
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25 34. Rosemary Fletcher is an FWW member and resident of Greenville, South Carolina, which adds
26 industrial fluoride chemicals to its water. Rosemary is an African American woman on a fixed income
27 who used to be dependent on a wheel chair due to a painful arthritic condition. After learning that her
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1 condition could be exacerbated by fluoride exposure, Rosemary stopped drinking fluoridated water and
2 experienced a major improvement in her symptoms. After several months of diligently eliminating
3 fluoridated water, Rosemary was able to abandon her wheel chair, and has not needed it since. Rosemary
4 continues to take every measure possible to avoid exposure to fluoridated water, including by purchasing
5 bottled water for her home drinking water needs. Rosemary's reliance on bottled water has created a
6 financial hardship for her, as she has very limited financial resources.

7 35. Franzi and Randy Talley are FWW members, restaurant owners, and residents of Asheville,
8 North Carolina, which adds industrial fluoride chemicals to its water. Approximately nine years ago,
9 Franzi was diagnosed with breast cancer, which she treated with chemotherapy. Subsequent to
10 chemotherapy, tests revealed that Franzi had an underactive thyroid gland, as evident by low circulating
11 thyroid hormone levels in her blood. The low thyroid function persisted for years, and was accompanied
12 by substantial fatigue. Last year, after learning of credible medical science linking fluoride exposure to
13 decreased thyroid function, Franzi stopped drinking the fluoridated city water. Franzi's thyroid hormone
14 levels began to increase within months of making this switch, and are now almost back to normal.
15 Franzi's energy level has also notably improved during this time as well. Avoiding fluoridated water is
16 therefore a critical health priority for Franzi as she seeks to continue her recovery. Both her and her
17 husband Randy continue to diligently do what they can to avoid fluoridated water, both for themselves
18 and the customers they serve. They would like to install a water filtration system at their restaurants
19 which can remove the fluoride, but they have run into technical difficulties implementing a filtration
20 system that is capable of removing fluoride that is also compatible with their operations.
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22 36. Karen Spencer is an FWW member and resident of Gloucester, Massachusetts which adds
23 industrial fluoride chemicals to its water. Karen long suffered from various health problems beginning
24 the month her city began fluoridation in 1981. Her symptoms include rashes, hives, gastrointestinal
25 problems, arthritis, general fatigue, pain, chronic dizziness and intermittent short periods of profound,
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1 debilitating and overwhelming fatigue. In 2014, Karen began to strictly eliminate her exposure to
2 fluoridated water to see if it would improve her health. In 9 days, she noted a dramatic improvement in
3 all her symptoms, including cessation her neurological symptoms. Karen has continued to strictly avoid
4 fluoridated water and food and has made a recovery from the illnesses that caused her decades of misery.

5 37. Plaintiff FLUORIDE ACTION NETWORK (“FAN”) is a project of the American Environmental
6 Health Studies Project, Inc. FAN is an organization of scientists, doctors, dentists, environmental health
7 researchers, and concerned citizens working to raise awareness about the impact of current fluoride
8 exposures on human health. FAN’s members live in fluoridated communities across the United States,
9 and many have expended significant sums of money to avoid the fluoride added to tap water and
10 processed foods and beverages. Many of FAN members have suffered dental fluorosis and other harm as
11 a result of their fluoride exposures, and have credible concerns about the impact that ongoing exposures
12 to fluoridated water will have on their health.
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14 38. Julie Simms is a FAN member, FWW member, and resident of Seattle, Washington, which adds
15 industrial fluoride chemicals to its water. For more than a decade, Julie experienced constant, daily
16 headaches. She experimented with numerous therapies to cure her of the condition, but nothing worked.
17 Then, in 2013, a friend suggested that Julie stop drinking fluoridated water. Julie was very skeptical of
18 this suggestion as she had long been a supporter of water fluoridation, believed in its safety and efficacy.
19 Nevertheless, at the insistence of her friend, Julie stopped drinking fluoridated water and to her great
20 surprise, the headaches became substantially less painful within just 3 days, and were completely gone
21 within weeks. Julie has continued to spend the necessary resources to avoid fluoridated water and
22 consequently her daily headaches have not returned. Based on her experience, Julie’s doctor has advised
23 that she continue to refrain from fluoridated water, not just for drinking and cooking, but bathing as well.
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1 39. Plaintiff AUDREY ADAMS, individually and on behalf of her son KYLE ADAMS, resides in
2 Renton Washington. The Adams are served by Soos Creek Water and Sewer District, a wholesale water
3 purveyor receiving pre-treated water from Seattle Public Utilities (“SPU”). SPU adds industrial fluoride
4 chemicals to its water supply. Kyle has autism and has specific metabolic weaknesses that heighten his
5 sensitivity to many chemicals, including fluoride. Kyle’s doctor concurs that Kyle must refrain from
6 exposure to fluoridated water for drinking, cooking and bathing, as he has a consistent history of
7 suffering severe reactions when exposed to fluoridated water. These reactions include (but are not
8 limited to) intense pain and headaches, with resulting extreme hyperactivity, accelerated heart rate and
9 intensification of autistic symptoms. Audrey Adams continues to expend substantial time and money
10 ensuring that Kyle is not exposed to fluoridated water, including the ongoing purchase of spring water
11 and reverse osmosis filtered water for all drinking and cooking and special water filtration for showering.
12 Kyle’s continued ability to work, recreate, communicate, participate in community outings and even to
13 sleep are reliant on strict avoidance of all sources of fluoridated water.

15 40. Plaintiff KRISTIN LAVELLE, individually and on behalf of her 12-year-old son NEAL
16 LAVELLE, is a resident of Berkeley, California. Kristin is an occupational health therapist, and is
17 concerned about the adverse effects that fluoride exposures could have on her and her family’s health,
18 including her son Neal. Since Berkeley adds industrial fluoride chemicals to its water, Kristin purchased
19 a \$2,000 whole house water filtration system in May of 2015. Although the filter was advertized to
20 reduce over 80% of the fluoride, and although Kristin has dutifully followed all of the maintenance
21 requirements, recent test results show that the filter is not removing any of the fluoride. Kristin has thus
22 purchased a new countertop water filter, which will require ongoing replacements of the filter cartridge,
23 and is considering purchasing a replacement filtration system. In addition to the expenses that Kristin
24 has incurred in trying to remove the fluoride chemicals from her tap water, Kristin also spends significant
25 time and money to minimize her and Neal’s exposure to fluoridated water when away from home.
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1 41. Plaintiff BRENDA STAUDENMAIER, individually and on behalf of her children KO
2 STAUDENMAIER and HAYDEN STAUDENMAIER, is a resident of Green Bay, Wisconsin, which
3 adds industrial fluoride chemicals to its water. Due to her concerns about the impact of fluoride on her
4 and her children's health, Brenda has purchased a water filtration system to filter the fluoride out of the
5 water. The filtration system requires that the filter cartridges be replaced approximately every six
6 months. Each cartridge costs approximately \$137.50, so Brenda has to pay approximately \$275 a year to
7 ensure access to fluoride-free water at home. Brenda is a single mother living on a low income, and \$275
8 a year represents a substantial expense for her.
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10 42. Plaintiff AMERICAN ACADEMY OF ENVIRONMENTAL MEDICINE was founded in 1965,
11 and is an international association of physicians and other professionals that provides research and
12 education in the recognition, treatment and prevention of illnesses induced by exposures to biological and
13 chemical agents encountered in air, food and water.

14 43. Plaintiff INTERNATIONAL ACADEMY OF ORAL MEDICINE & TOXICOLOGY
15 ("IAOMT") has been dedicated to its mission of protecting public health through the practice of
16 biological dentistry since it was founded in 1984. A worldwide organization of over 800 dentists,
17 physicians, and research professionals in more than 14 countries, IAOMT's mission is accomplished by
18 funding and promoting relevant research, accumulating and disseminating scientific information,
19 investigating and promoting non-invasive scientifically valid therapies, and educating medical
20 professionals, policy makers, and the general public.
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22 44. Plaintiff MOMS AGAINST FLUORIDATION ("MOMS") is a nonprofit organization
23 that educates mothers, pregnant women, families, medical professionals, and all citizens about the now
24 known health effects and ethical issues of ingesting artificial fluoridation chemicals to our water supply.
25 MOMS takes the position that using the public's drinking water to deliver a drug in indiscriminate doses
26 that vary widely from person to person without is a violation of the medical right to informed consent.
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IV. STATUTORY FRAMEWORK

45. Section 6 of the Toxic Substances Control Act (TSCA) invests EPA with the authority and duty to take certain prescribed actions if it determines that “the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance . . . presents an unreasonable risk of injury to health.” 15 U.S.C. § 2605(a). In making this determination, TSCA commands that EPA consider not only risks to the general public, but to “susceptible subpopulation[s]” as well. 15 U.S.C. § 2605(b)(4)(A).

46. TSCA commands that EPA conduct its risk evaluation “without consideration of costs or other nonrisk factors.” 15 U.S.C. § 2605(b)(4)(A).

47. If EPA determines that a chemical substance presents an unreasonable risk to the general public or susceptible subpopulation(s), the Agency “shall” take action “to the extent necessary to protect adequately against such risk using the least burdensome requirements.” 15 U.S.C. § 2605(a). The actions that EPA may take include: (1) prohibiting the manufacture and distribution of the substance for a “particular use,” and (2) prohibiting “any manner or method of commercial use” of the substance. 15 U.S.C. § 2605(a)(2) & (5).

48. EPA’s authority to prohibit and regulate the use of chemical substances under TSCA encompasses drinking water additives. EPA recognized this in its June 12, 1979 Memorandum of Understanding (MOU) with the FDA, in which the Agency stated unequivocally that it has authority “to regulate direct and indirect *additives to drinking water* as chemical substances and mixtures under TSCA.” As EPA explained in the MOU, “[a]lthough Section 3(2)(B) of TSCA excludes from the definition of ‘chemical substance’ food and additives as defined under FFDCA, the implicit repeal by the [Safe Drinking Water Act] of FDA’s authority over drinking water enables EPA to regulate direct and indirect additives to drinking water as chemical substances and mixtures under TSCA.”

49. In proposing and promulgating a rule under 15 U.S.C. § 2605(a), the EPA shall consider and

1 publish a statement addressing, inter alia, the (A) the effects of the chemical substance on human health
2 and the exposure of human beings to it; (B) the benefits of the chemical substance; and (C) the
3 reasonably ascertainable economic consequences of the rule. 15 U.S.C. § 2605(c)(2)(A).

4 5 **V. STATEMENT OF FACTS**

6 **A. The National Research Council's 2006 Review and Subsequent Peer-Reviewed Research** 7 **Demonstrates Fluoride's Ability to Harm the Brain**

8 50. In 2003, the EPA asked the National Research Council (NRC) to review the adequacy of EPA's
9 Maximum Contaminant Level Goal (MCLG) for fluoride, which then and now is set at 4 mg/L. In
10 response, the NRC reviewed the existing research on fluoride toxicity and concluded, in March 2006,
11 that the MCLG is not protective of public health and should be lowered.
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13 51. The NRC conclusion was based on fluoride's adverse effects on bone and teeth, but the NRC also
14 raised numerous concerns about the potential for fluoride to cause other systemic harm, particularly to
15 the endocrine and nervous systems.

16 52. With respect to the endocrine system, the NRC concluded that fluoride is an "endocrine
17 disrupter," that can alter the function of numerous endocrine glands in the body, including the thyroid
18 gland. The NRC reviewed numerous studies linking fluoride to altered thyroid function, noting that "[i]n
19 humans, effects on thyroid function were associated with fluoride exposures of 0.05-0.13 mg/kg/day
20 when iodine intake was adequate and 0.01-0.03 mg/kg/day when iodine intake was inadequate." These
21 doses are ingested by many people living in fluoridated areas. In light of the established link between
22 thyroid function and neurological health, the NRC called for more research into fluoride's role "in the
23 development of several diseases or mental states in the United States."
24

25 53. With respect to the nervous system, the NRC concluded: "On the basis of information largely
26 derived from histological, chemical, and molecular studies, it is apparent that fluorides have the ability to
27 interfere with the functions of the brain."
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1 54. The NRC's conclusion about fluoride's interference with the brain rested primarily on its review
2 of animal studies, because few human studies were available at the time of the NRC review. In the last
3 decade, however, many studies have reported links between fluoride exposure and cognitive deficits in
4 humans, providing additional foundation for concerns about fluoride's threats to the brain.

5 55. At the time, the NRC only had five human studies on fluoride's cognitive effects to consider in
6 drawing its conclusions; however, there are now over 50 studies linking fluoride to cognitive deficits in
7 humans, as reflected by reduced IQ scores, impaired performance on the Neurobehavioral Core Test
8 Battery (NCTB) test, and impaired performance on the Rey Osterrieth Complex Figure test. In addition,
9 at least three studies have found that the human fetal brain is damaged by elevated prenatal fluoride
10 exposures, which may be one of the mechanisms by which fluoride lowers IQ.

11 56. The evidence linking fluoride to neurotoxicity in humans is far more extensive today than it was
12 when NRC published its review in 2006, and is far more extensive than the evidence for most of the
13 other chemicals known or suspected to be neurotoxins. Despite this fluoride continues to be used as a
14 water additive.
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16 57. A recent systematic review of suspected developmental neurotoxins by EPA scientists found that
17 few chemicals have been linked to neurotoxicity in humans. The EPA scientists stated that chemicals
18 linked to neurotoxicity in humans are "gold standard" chemicals that warrant prioritization.
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20 58. In the case of fluoride, not only is there human data on neurotoxicity, there are so many human
21 studies linking fluoride to neurotoxic effects that fluoride has been classified by experts as one of only 12
22 chemicals "*known to cause developmental neurotoxicity in human beings.*"
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24 59. Fluoride's ability to impair cognition in humans is consistent with animal studies showing that
25 fluoride exposure impairs learning and/or memory capacity in rodents under carefully controlled
26 laboratory conditions. There are now at least 45 animal studies linking fluoride to cognitive deficits in
27 rodents.
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1 60. Fluoride's ability to harm the brain has been further confirmed by over 100 animal studies
2 published since the NRC review which show that fluoride exposure produces a range of adverse
3 neuroanatomical and neurochemical alterations in the brain, including at concentrations that humans
4 experience in fluoridated areas in the United States.

5 61. It has been 10 years since the NRC determined that the MCLG for fluoride be lowered based on
6 the available data, and the data has continued to mount exponentially, but the EPA has ignored NRC's
7 recommendations and failed to act to protect the public health.
8

9 **B. Fluoride Poses Neurotoxic Risks at Doses Comparable to the Doses Ingested in Fluoridated**
10 **Communities in the United States**
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12 62. A frequent claim made by those who continue to promote fluoridation is that the water fluoride
13 concentrations associated with neurotoxicity in humans are not relevant to the water fluoride
14 concentrations in the United States; that the drinking water concentrations linked to neurotoxicity exceed
15 the concentration used in domestic water fluoridation programs (0.7 mg/L).
16

17 63. In support of this claim, proponents of fluoridation often point to the *highest* water fluoride
18 concentrations that have been linked to neurotoxicity, while ignoring the *lowest* concentrations (and even
19 the *typical* concentrations) that have been associated with harm.

20 64. This focus on the *highest* concentrations that cause harm as the starting point for analysis, rather
21 than the lowest concentrations, clashes with standard tenets of risk assessment, including EPA's
22 *Guidelines*.
23

24 65. The focus on the water fluoride *concentrations* associated with neurotoxic harm also overlooks
25 the fact that it is the total daily *dose* of fluoride that causes toxicity (i.e., how much fluoride a person
26 actually ingests), not simply the concentration of fluoride in the water. For example, a person consuming
27 two liters of water containing 0.7 mg/L fluoride (the concentration used in fluoridation programs) will
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1 consume the same waterborne dose as a person consuming water with 1.4 mg/L (a concentration that has
2 repeatedly been linked to IQ loss). Some Americans, including athletes, manual laborers, and diabetics,
3 consume large quantities of water, far in excess of two liters a day. Further, many of the studies which
4 have investigated fluoride's impact on IQ have been conducted in rural China, where very few children
5 are exposed to fluoride toothpaste and other fluoridated dental products. Since the vast majority of
6 American children use fluoridated dental products, and since use of fluoridated dental products during
7 the early years of life can result in substantial fluoride ingestion, an American child can receive the same
8 daily dose of fluoride as a Chinese child despite having less fluoride in the water.
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10 66. Contrary to the oft-repeated claim that fluoride neurotoxicity is only found at irrelevantly high
11 water fluoride concentrations, the existing studies of fluoride-exposed human populations consistently
12 find neurotoxic impacts within water fluoride concentrations that the EPA currently considers safe (≤ 4
13 milligrams/liter), with many of these studies finding IQ loss at just 0.8 to 2 mg/L.

14 67. In total, there are 24 published studies reporting statistically significant reductions in IQ in areas
15 with water fluoride concentrations less than the EPA's MCLG.
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17 68. Many of the studies investigating fluoride's effect on IQ have provided individual-level data on
18 fluoride exposure, including: (a) daily fluoride dose from all sources, (b) urine fluoride level, (c) serum
19 fluoride level, and (d) dental fluorosis status. Each of these metrics have been found to correlate with
20 reduced IQ.

21 69. The *daily fluoride dose* associated with reduced IQ in endemic fluorosis areas is exceeded by
22 many Americans living in fluoridated areas.
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24 70. The *urine fluoride level* associated with reduced IQ in children in endemic fluorosis areas is
25 exceeded by many Americans living in fluoridated areas.

26 71. The *urine fluoride level* associated with cognitive impairment in adults in endemic fluorosis areas
27 is exceeded by many Americans living in fluoridated areas.
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1 72. The *serum fluoride level* associated with reduced IQ in endemic fluorosis areas is exceeded by
2 many Americans living in fluoridated areas.

3 73. Studies have found that children with mild, moderate, and moderate/severe fluorosis have lower
4 IQs than children with no fluorosis. Consistent with this, studies of rodents have repeatedly found
5 neurotoxic effects, including learning impairments, among rats with only mild forms of fluorosis. As
6 noted by Niu, et al, “these findings indicate that fluoride . . . can influence spontaneous behaviors and
7 lower the learning ability of rats *before the appearance of dental lesions*.”

8 74. The studies linking fluorosis to cognitive deficits become extremely significant to the question of
9 U.S. regulatory policy when considering the rate of dental fluorosis among the U.S. population.

10 75. CDC’s 2011-2012 National Health and Nutrition Examination Survey (NHANES) found dental
11 fluorosis in 58.3% of the surveyed adolescents, including an astonishing 21.2% with moderate fluorosis,
12 and 2% with severe. Since there are an estimated 42-million adolescents currently living in the U.S., the
13 NHANES data suggests that up to 24-million adolescents now have some form of dental fluorosis, with
14 over 8 million adolescents having moderate fluorosis, and 840,000 having severe fluorosis.

15 76. The NHANES survey does not provide data on the respective rates of fluorosis in fluoridated vs.
16 non-fluoridated communities, but research has repeatedly confirmed that both the prevalence and severity
17 of dental fluorosis are greater in U.S. communities with fluoridated water than in communities without.
18 Stopping the addition of fluoride to drinking water will thus reduce the number of children developing
19 dental fluorosis, and the accompanying neurotoxic risks associated with the doses that produce fluorosis.

20 77. Recent epidemiological studies in Canada, England, and the United States provide further reason
21 for concern about the neurotoxic dangers posed by fluoridation. In 2016, researchers from Canada found
22 that urinary fluoride levels were significantly correlated with learning problems. In 2015, Malin and Till
23 found a significant correlation between the prevalence of water fluoridation at the state level in the U.S.
24 and Attention-Deficit Hyperactivity Disorder (ADHD). Another 2015 study, by Peckham et al., found
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1 that fluoride levels greater than 0.7 mg/L significantly correlated with higher rates of hypothyroidism in
2 the United Kingdom, even after controlling for the covariates of age, gender, and index of deprivation.
3 The correlation between fluoridation and hypothyroidism, which is biologically plausible and consistent
4 with prior animal and human studies, provides further mechanistic support for the capacity of fluoridated
5 water to cause neurotoxic effects. Finally, recent epidemiological and laboratory studies strongly suggest
6 that fluoridating water with hydrofluorosilicic acid increases the corrosion of lead (a potent neurotoxin)
7 from brass pipes and fittings, resulting in elevated blood lead levels. This provides yet another
8 mechanism whereby fluoridation can produce adverse neurotoxic effects at relevant use and exposure
9 levels.
10

11 78. Studies of rodents further demonstrate the neurotoxic hazards of the fluoride doses ingested in
12 fluoridated areas. The National Toxicology Program has estimated that over 10% of children living in
13 fluoridated areas will receive a comparable waterborne fluoride dose as rats drinking water with 9 mg/L.
14 This is significant because studies have repeatedly found neurotoxic effects among rats drinking water
15 with just 1 to 9 mg/L; including oxidative stress, alterations in neurotransmitters, learning impairment,
16 behavioral changes, and pathological changes in the synaptic structure.
17

18 79. Studies of cells have found that fluoride can damage brain cells at concentrations as low as 9 parts
19 per *billion*. Most Americans living in fluoridated areas have more than 9 parts per billion fluoride in
20 their blood, with some individuals having 50 to 100+ parts per billion in their blood. Since fluoride
21 circulating in the blood has access to the brain, and since the blood brain barrier loses its efficacy with
22 aging, many Americans will have fluoride levels in their brain that are known to harm brain cells in
23 carefully controlled laboratory experiments.
24
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28

C. Susceptible Subpopulations Are at Heightened Risk of Fluoride Neurotoxicity

80. EPA's *Guidelines* recognize that individual susceptibility to the neurotoxicity of environmental toxicants can vary by a factor of ten or more, and is influenced by factors such as nutritional status, age, genetics, co-exposure to other toxicants, and disease.

81. Each of these factors—nutritional status, age, genetics, co-exposure to other toxicants, and disease—are known to influence an individual's susceptibility to chronic fluoride toxicity.

82. Recent research has specifically demonstrated that nutrient deficiencies and genetics amplify fluoride's neurotoxicity. Zhang et al. (2015), for example, reported that certain COMT gene polymorphisms greatly influence the extent of IQ loss resulting from fluoride exposure, which is consistent with research on other neurotoxins, including methyl mercury.

83. While the full range of individual susceptibility to fluoride neurotoxicity in the U.S. cannot be precisely calculated, a number of identifiable subpopulations are clearly at elevated risk, including:

a. **Infants:** Although *breast fed* infants receive the lowest fluoride intake by bodyweight (<0.001 mg/kg/day) of all age-groups, this situation is flipped on its head when infants are fed *formula reconstituted with fluoridated water*, as infants consuming fluoridated formula receive the highest dosage of any age group in the population. In fact, the average daily dose received by an infant receiving fluoridated formula *exceeds* the dose that has been associated with reduced IQ in studies of Chinese children. Not only do formula-fed infants receive an unnaturally high dose, they have an impaired ability to excrete the fluoride they ingest, retaining up to 87% of the absorbed dose. As a result of this high body burden, infants exposed to fluoridated water suffer far higher rates of dental fluorosis, thus demonstrating their vulnerability to fluoride's systemic effects.

b. **Elderly:** As noted in EPA's *Guidelines*, "[T]he aged population is considered to be at particular risk [of neurotoxicity] because of the limited ability of the nervous system to

1 regenerate or compensate to neurotoxic insult.” This is of concern because the brain will
2 be more exposed to fluoride in older age due to the (1) increased level of fluoride
3 circulating in the serum as a result of age-related degenerations in kidney and bone health,
4 and (2) increased permeability of the blood-brain barrier. Consistent with this, studies
5 have found a very high prevalence of cognitive impairment (up to 82%) among elderly
6 individuals in endemic fluorosis areas.

- 7
8 c. ***Individuals with suboptimal nutrient intake:*** It has been known for over 70 years that
9 suboptimal nutrient intake (e.g., calcium, vitamin C, vitamin D, iodine, etc) render
10 individuals more susceptible to fluoride toxicity. This is of significant concern vis-à-vis
11 fluoride neurotoxicity in the U.S. as suboptimal nutrient intake remains a widespread
12 problem. For example, 86% percent of African Americans, for example, do not get
13 enough calcium; the median urine iodine concentrations for women of child-bearing age
14 “border on insufficiency”; and 6% of Americans have a vitamin C deficiency.
- 15
16 d. ***Individuals with COMT gene polymorphisms:*** The study by Zhang et al. (2015) suggests
17 that children with the COMT val/val genotype suffered a five-fold larger drop in IQ than
18 children with the COMT val/met and met/met genotypes.
- 19
20 e. ***Individuals with kidney disease:*** The kidneys are the principal way that the human
21 excretes fluoride. When the kidneys are damaged, the ability to excrete fluoride becomes
22 impaired, leading to an excess accumulation of fluoride in the body. It is well established,
23 therefore, that individuals with advanced kidney disease are at far higher risk of suffering
24 fluoride toxicity.
- 25
26 f. ***African Americans:*** The African American community suffers disproportionate risks
27 from fluoride exposure, as it has a heightened prevalence of multiple risk factors for
28 fluoride toxicity, including elevated use of infant formula, elevated exposure to lead,

1 depressed calcium and anti-oxidant intake, and significantly higher rates of dental
2 fluorosis, including in its moderate and severe forms.

3 84. These susceptible subpopulations will suffer neurotoxic effects at doses of fluoride exposure that
4 are lower than the general population.

5
6 **D. A Reference Dose Protective Against Fluoride Neurotoxicity Is Incompatible with Water**
7 **Fluoridation if Standard Risk Assessment Procedures Are Applied**

8 85. Because of the wide range of sensitivity in the human population to neurotoxicants, EPA's
9 Guidelines endorse the application of "uncertainty factors" (UF) when converting the "lowest observable
10 adverse effect level" (LOAEL), "no observable adverse effect level" (NOAEL) or Benchmark Dose
11 (BMD) level into a safe "reference dose" (RfD). Typically, the uncertainty factors are at least one order
12 of magnitude (i.e., a factor of 10).

13
14 86. Application of a *single* uncertainty factor of 10 to the dose of fluoride associated with harm
15 and/or the doses associated with no effect, produce RfD that is far below the levels that most Americans
16 now receive in fluoridated areas. The dose that would protect against fluoride neurotoxicity according to
17 EPA's Guidelines, and standard risk assessment procedures, is incompatible with the doses of fluoride
18 ingested in fluoridated areas.

19 87. Application of EPA's BMD methodology to available dose-response data (Xiang et al.) indicates
20 that ingestion of 0.7 mg fluoride per day is associated with an average loss of 2.5 IQ points when
21 compared to a child with no fluoride exposure. This is a dose of fluoride that tens of millions of
22 American children living in fluoridated communities now ingest.

23
24 88. A recent published quantitative risk analysis by a former Senior EPA risk assessment scientist
25 concludes that fluoride ingestion should be kept below 0.05 mg/day if neurotoxicity is to be avoided.
26 Virtually every person living in a fluoridated area consumes more than 0.05 mg/day from fluoridated tap
27 water and processed foods and beverages made with fluoridated water.
28

1 89. The reduction in IQ associated with fluoride exposure is severe enough in some children to
2 produce mental retardation, the impact of which is obvious and catastrophic. However, even the loss of a
3 single IQ point is associated with significant economic loss. As calculated by Spadaro et al., a loss of a
4 single IQ point causes an average drop in lifetime earnings of \$18,000 in 2005 U.S. dollars, which, when
5 adjusted for inflation, amounts to \$22,250 in current dollars.

6 90. Since 200 million Americans now live in areas where water is fluoridated, and since virtually all
7 Americans consume processed foods and beverages made with fluoridated water, even a small reduction
8 in IQ from fluoridated water stands to have immense economic consequences.
9

10 11 **E. Recent Studies Show that Fluoridation Presents Little Meaningful Benefit to Teeth**

12 91. Fluoridation chemicals are the only chemicals added to municipal water that don't treat the water
13 itself. The sole purpose of adding fluoridation chemicals to water for use as a drug to reduce tooth decay,
14 a non-waterborne disease. Current research, however, demonstrates that the purported dental benefits
15 from fluoridation are much smaller than previously believed, with many studies failing to find any
16 measurable, clinically significant difference in tooth decay between fluoridated and non-fluoridated
17 areas.
18

19 92. There are no randomized controlled trials on the effectiveness of fluoridation, and few of the
20 available studies adequately account for potential confounders like socioeconomic status, sealants, and
21 dietary habits. The evidence has thus been characterized by the Cochrane Collaboration as having "high
22 risk of bias" and limited applicability to modern lifestyles.
23

24 93. Notwithstanding these methodological limitations, modern studies of fluoridation and tooth decay
25 have found that the difference in cavity rates between fluoridated and non-fluoridated areas is small,
26 inconsistent, and often non-existent, particularly in the permanent teeth.
27
28

94. Because of the meager differences in cavities now seen between fluoridated and non-fluoridated areas, sensitive measurements of tooth decay must be utilized in order to detect *any* differences in decay. But, even when sensitive measurements are utilized, the differences remain small in absolute terms, inconsistent, and greatly overshadowed by the influence of other factors known to affect decay.

95. Studies from Canada, Cuba, Finland, Germany, and the United States did not detect *any* measurable increase in decay following the termination of water fluoridation programs.

F. Fluoridation Is Unnecessary as There Are Safer, More Effective Alternatives, Including Topical Fluoride Products

96. The addition of fluoridation chemicals to drinking water began in the U.S. prior to the advent of topical fluoride products in an era when public health authorities believed fluoride's predominant benefit to teeth comes from *ingestion*. Things have changed dramatically since that time.

97. Today, over 95% of toothpastes contain fluoride, as do many other dental products, and dental researchers now universally acknowledge that fluoride's predominant benefit is topical, not systemic. As explained in the *Journal of the American Dental Association*, "fluoride incorporated during tooth development is insufficient to play a significant role in cavity protection." (Featherstone 2000) The Centers for Disease Control has confirmed the primacy of fluoride's topical mechanisms, declaring that "fluoride's predominant effect is *posteruptive* and *topical*." (CDC 2001) The NRC has confirmed this as well, stating that "the major anticaries benefit of fluoride is *topical* and *not systemic*." (NRC 2006)

98. Since fluoride's primary benefit comes from topical contact with the teeth, there is little benefit from swallowing fluoride, in water or any other product. In fact, a recent NIH-funded prospective study of the relationship between tooth decay and total daily fluoride ingestion failed to find a detectable relationship between the two. (Levy et al. 2009). Other recent studies investigating the relationship

1 between tooth decay and individual biomarkers of fluoride intake (e.g., toenail fluoride content and
2 dental fluorosis) have reported similar results.

3 99. The widespread availability of topical fluoride products highlights the lack of necessity of adding
4 fluoridation chemicals to water, particularly since the quality of evidence for fluoride toothpastes has
5 been recognized as vastly superior to the quality of evidence for water fluoridation. Furthermore, it is
6 well established that western countries that do not fluoridate their water have tooth decay rates that are
7 just as low, and often lower, as western countries that do fluoridate their water.

8 100. While fluoride toothpastes and other fluoridated dental products carry their own potential hazards
9 *when ingested*, these products—unlike drinking water—are not *designed* to be ingested. Further, unlike
10 the addition of fluoridation chemicals to drinking water, the use of topical fluoride products does not
11 result in the contamination of processed foods and beverages, thus making it easier to regulate the
12 amount of fluoride ingested when topical fluoride products are the vehicle for delivering fluoride to those
13 who want it.
14

15 16 VI. CAUSE OF ACTION

17 101. TSCA provides that a party that petitions EPA under 15 U.S.C. § 2620 is entitled to a *de novo*
18 review by a federal district court if EPA denies the petition.

19 102. If the petitioner demonstrates to the court by a preponderance of evidence that “the chemical
20 substance or mixture to be subject to the proposed rule presents an unreasonable risk of injury to health
21 or the environment, without consideration of costs or other nonrisk factors, including an unreasonable
22 risk to a potentially exposed or susceptible subpopulation, under the conditions of use,” there is
23 reasonable, “the court shall order the Administrator to initiate the action requested by the petitioner.” 15
24 U.S.C. § 2620(4)(B).
25

26 105. On November 22, 2016, Plaintiffs submitted a Petition to EPA, supported by over 300 attached
27 studies, documenting each of the allegations contained in Paragraphs 2 to 23 and 50 to 100 above.
28

106. EPA denied Plaintiff's Petition on February 17, 2017 based on a legally erroneous, factually incorrect, and scientifically flawed assessment, wherein, *inter alia*, the EPA (A) erroneously interpreted the Frank R. Lautenberg Chemical Safety for the 21st Century Act as placing onerous new evidentiary burdens on citizen petitioners, (B) dismissed studies relied upon by Plaintiffs on demonstrably false grounds, and (C) failed to consider the research on fluoride neurotoxicity through the framework of its *Guidelines on Neurotoxicity Risk Assessment*.

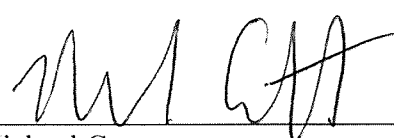
107. Plaintiffs are therefore entitled to a *de novo* judicial review of the Petition.

VII. PRAYER FOR RELIEF

108. WHEREFORE, Plaintiffs respectfully request that the Court grant the following relief;

- a. Declare that Plaintiffs have demonstrated by a preponderance of the evidence that artificial fluoridation of drinking water supplies 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, pursuant to 15 U.S.C. § 2620(b)(4)(B)(ii).
- b. Order EPA to initiate the action requested by Plaintiffs in their petition pursuant to 15 U.S.C. § 2620(b)(4)(B).
- c. Award Plaintiffs their costs of suit and reasonable fees for attorneys and expert witnesses in this action pursuant to 15 U.S.C. § 2620(b)(4)(C).
- d. Grant Plaintiffs such further and additional relief as the Court may deem just and proper.

Respectfully submitted this 18th day of April, 2017.

By: 

Michael Connett
Attorney for Plaintiffs