November 4, 2020

Andrew Wheeler, Administrator
Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460
Email: wheeler.andrew@epa.gov

Re: Docket: EPA-HQ-OPPT-2016-0763-0001; FRL-9959-74

Dear Administrator Wheeler:

On November 22, 2016, the undersigned Petitioners submitted a Citizen Petition under Section 21 of the Toxic Substances Control Act ("TSCA"), requesting that the EPA prohibit the addition of fluoridation chemicals to drinking water in order to protect the public, including susceptible subpopulations, from fluoride's neurotoxic risks. After the EPA denied this petition, the Petitioners brought suit in the Northern District of California to challenge EPA's denial. Following a bench trial in June of 2020, the Court stated that EPA had used an incorrect standard in assessing the evidence that the Petitioners had presented. (6/17 Trial Tr. 1131:5-9, 1132:20-21, 1137:20-23.) The Court also noted that much of the evidence that the Petitioners relied upon at trial—including recent studies funded by the National Institutes of Health (NIH)—was not yet available at the time EPA denied the Petition. (Appendix A at 4.) In light of these facts, the Court asked Petitioners to re-submit evidence to the EPA in order to give the Agency an opportunity to give the evidence a "second look" using the "proper standard" at the administrative level, which the Court "urged" the EPA to do. (6/17 Trial Tr. 1131:17-19; Appendix A at 5.)

Pursuant to the Court's request, the Petitioners are hereby submitting this Supplement to their Petition and requesting that EPA reconsider its denial of the Petition based on the information presented herein.

EPA HAS THE AUTHORITY TO RECONSIDER ITS DENIAL OF A SECTION 21 PETITION

EPA has the inherent authority to reconsider its denials of Section 21 petitions, as the EPA itself has repeatedly acknowledged. The EPA has explained that: "Although TSCA does not expressly provide for requests to reconsider EPA denials of Section 21 petitions, 'the courts have uniformly concluded that administrative agencies possess inherent authority to reconsider their decisions, subject to certain limitations, regardless of whether they possess explicit statutory authority to do so.'" EPA Brief in *Trumpeter Swan Society v. Jackson*, 2014 WL 408986, at 23-24 (quoting *Tokyo Kikai Seisakusho, Ltd. v. United States*, 529 F.3d 1352, 1360 (Fed. Cir. 2008)). As the EPA has explained, "the power to reconsider is inherent in the power to decide." *Id.* at 24 (quoting *Albertson v. FCC*, 182 F.2d 397, 399 (D.C. Cir. 1950)).

Consistent with its inherent power to reconsider where, as here, the petitioners seek the same relief as in prior denied petitions, the EPA has repeatedly treated such "new" citizen

petitions as "motions for reconsideration." *See, e.g.*, *Walker v. U.S. E.P.A*., 802 F. Supp. 1568, 1572–73 (S.D. Tex. 1992) (describing how EPA treated a new Section 21 petition which "requested exactly the same rule change" as a previous petition as a "motion to reconsider"); Brief for EPA in *Trumpeter Swan Society v. Jackson* (No. 12-929, D.D.C. 2012), 2012 WL 4844872 ("EPA's treatment of the Second Submission as a motion for reconsideration rather than as a TSCA section 21 petition was entirely consistent with the language of the Act.").

As EPA's own words and actions over the past four decades make clear: the Agency has the authority to reconsider its prior denials of Section 21 petitions. For the reasons stated herein, therefore, Petitioners request that EPA reconsider its denial of their Petition.

GROUNDS FOR PETITIONERS' REQUEST FOR RECONSIDERATION

1. EPA Used an Incorrect and Impermissibly Stringent Standard of Proof

At the close of trial in June 2020, the Court observed that EPA has subjected Petitioners' evidence to an incorrect standard of proof. As the Court noted, "EPA appears to have applied a standard of causation which, from my read of TSCA, is not accurate. . . . It's not the proper standard." (6/17 Trial Tr. 1131:5-9.)

TSCA commands that EPA protect against "unreasonable *risk*," which exists when human exposure to a toxicant is *unacceptably close* to the estimated hazard level. (6/10 Trial Tr. 471:11-472:9.) At trial, EPA confirmed that "EPA does not require that human exposure levels exceed a known adverse effect level to make an unreasonable risk determination under TSCA." (Appendix H at 4.) Thus, EPA does not require proof that human exposures under a given condition of use *cause* the hazard. In fact, Dr. Tala Henry agreed at trial that EPA has "*never once in any of its risk evaluations to date under Section 6 used a causation standard*." (6/16 Trial Tr. 987:6-8.) Despite this, Dr. Henry admitted that EPA held Petitioners to a burden of proof where Petitioners needed to prove that human exposure to fluoride in water at 0.7 mg/L *causes* neurotoxicity. (6/16 Trial Tr. 985-15-987:2.) Dr. Henry thus made the extraordinary admission that EPA "held the plaintiffs to a burden of proof that EPA has not held a single chemical under Section 6 before." (6/16 Trial Tr. 987:16-19.)

The fact that EPA used the wrong standard of proof to assess Petitioners' evidence is a reason for EPA to reconsider its denial of the Petition. As the Court noted at the end of trial: "But my main point is that, really, I would hope that the agency would take a serious look, *apply the proper standard*, and look at this new evidence." (6/17 Trial Tr. 1137:20-22)

2. Each of the Limitations that EPA Identified with the Fluoride/IQ Studies in the Petition Have Now Been Addressed by High Quality Studies Funded by the NIH

In its denial of the Petition, the EPA criticized the human studies that Petitioners cited on three primary grounds: (1) the studies were cross-sectional and thus "affected by antecedent-consequent bias";[1] (2) the studies failed to adjust for potential confounding factors; and (3) the studies failed to adequately establish a dose-response relationship between fluoride and

[1] According to EPA, "the antecedent-consequent bias means it cannot be determined whether the exposure came before or after the health effects, since both are evaluated at the same time." (Fed Reg, Vol. 82, No. 37, p. 11882.)

neurotoxicity.[2] (Fed Reg, Vol. 82, No. 37, p. 11882-83). In light of these limitations, EPA agreed with Choi et al. (2012) that "*further research should formally evaluate dose-response relationships based on individual-level measures of exposure over time, including more precise prenatal exposure assessment and more extensive standardized measures of neurobehavioral performance, in addition to improving assessment and control of potential confounders*."

The very type of research that EPA stated was necessary to address the limitations of the Petition has now been conducted and confirms a significant dose-response relationship between fluoride exposure and neurocognitive harm. (Appendix B at pp. 16-18.) EPA's criticisms of the human studies in the Petition are thus no longer applicable to the current evidence base.

Following EPA's denial of the Petition in February 2017, a series of prospective cohort studies funded by the National Institutes of Health (NIH) were published which evaluate the impact of individualized measurements of prenatal and early-infant fluoride exposure on standardized measures of neurobehavioral performance between ages 4 and 12 (Bashash 2017, Bashash 2018, Green 2019, Till 2020).

These NIH-funded studies address each of EPA's three criticisms of the studies in the Petition. First, the studies measured exposure prior to the onset of dysfunction and are therefore not affected by "antecedent-consequent" uncertainty. (Appendix B at pp. 90-91 ¶¶ 475-476.) Second, the studies address EPA's concern that the relationship between fluoride and neurodevelopment may be an artifact of confounding by extensive controlling for potential confounders (e.g., socioeconomic status, maternal education, and exposure to other neurotoxicants, including lead and mercury). (*Id.* at pp. 31-32 ¶¶ 165-68). Third, the studies scrutinized the dose-response relationship and found it to be linear across the range of doses relevant to water fluoridation. (*Id.* at p. 91 ¶ 479.)

There is no dispute that the NIH-funded studies are well designed and well conducted. Indeed, EPA agreed at trial that these studies "are the most methodologically reliable human studies to date on the impact of fluoride on neurodevelopment." (Appendix H at 3.) EPA's retained epidemiologist, Dr. Ellen Chang, concurred in this assessment. (6/15 Trial Tr. 806:19-20, 886:6-887:3.)

Given the high quality and rigorous nature of the NIH-funded studies, it is highly significant that the NIH-funded studies have *consistently* found large and robust associations between adverse neurocognitive effects and so-called "optimal" fluoride exposure. As explained by the principal investigators of the studies (Dr. Howard Hu and Dr. Bruce Lanphear), the magnitude of fluoride's effect on IQ in these studies is on par with the effect size of lead. (Appendix B at pp. 78-79 ¶¶ 408-416 & p. 88 ¶ 465.) Dr. Joyce Donohue, the senior scientist at EPA who specializes in fluoride issues, agreed that these studies warrant a reassessment of existing fluoride safety standards. (Appendix B at p. 11 ¶ 61.)

In its August 10, 2020 order, the Court stated that the NIH-funded studies "clearly . . . warrant serious consideration by EPA." (Appendix B at 5.) The Court cited these studies, and "the significant scientific developments that have occurred since the original petition was filed," as reasons supporting a reassessment by EPA. (*Id*.) The Court "urge[d]" EPA to give "due

[2] According to EPA, the "lack of a dose-dependent increase in effect with increasing exposure is a critical limitation of these data." (Fed Reg, Vol. 82, No. 37, p. 11883.)

consideration" to these scientific developments, and the "substantial scientific evidence proffered at trial." (*Id*.) Plaintiffs have attached the Court's order as **Appendix A**.

Consistent with the Court's request, Petitioners urge EPA to reconsider its denial of the Petition based on the evidence presented at trial, including, but not limited to, the NIH-funded studies showing significant adverse associations between "optimal" fluoride exposure and reduced IQ. To facilitate EPA's review of the trial record, Petitioners have attached their detailed summary of the trial evidence as **Appendix B**.[3] Petitioners have also attached a copy of the NIH-funded studies as **Appendix C**.

3. The National Toxicology Program Has Concluded that Fluoride Is a Presumed Human Neurotoxicant that Lowers IQ in Children

Petitioners' contention that fluoride is a neurotoxicant has gained powerful new support from the National Toxicology Program's (NTP) recently revised systematic review and meta-analysis. Based on the NTP's findings and the state of current science, the recently retired director of the NTP, Dr. Linda Birnbaum, has stated that "it is time to protect those who are most vulnerable," including pregnant women and bottle-fed infants.[4]

A. NTP Agrees that Fluoride Is a Likely Neurodevelopmental Hazard to Humans

On September 16, 2020, the NTP released its *Draft Monograph on the Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects*. The Monograph is a revised version of a draft issued in October 2019, and incorporates the recommendations made by a committee of the National Academy of Sciences (NAS). After making the changes recommended by the NAS, the NTP reconfirmed its conclusion that "fluoride is *presumed to be a cognitive neurodevelopmental hazard to humans.*" (p. 2)

The NTP's hazard conclusion is based on the fact that "the human body of evidence provides a consistent and robust pattern of findings that higher fluoride exposure (e.g., >1.5 mg/L in drinking water) is associated with adverse effects on neurocognitive development, including lower intelligence quotient (IQ) in children." (p. 2) In light of this "consistent and robust pattern of findings," the NTP has a "low expectation that new studies would decrease the hazard conclusion." (p. 68)

The NTP's findings are based not only on a thorough systematic review, but also the most comprehensive meta-analysis of fluoride neurotoxicity ever conducted. The NTP's meta-analysis, which included 46 studies, is consistent with the findings of the meta-analysis that Petitioners relied upon in their Petition (Choi 2012) and shows an average difference in IQ between high- and low-fluoride communities of approximately 7 IQ points (SMD = -0.50). (p. 49) As the NTP notes, "The random-effects pooled SMD estimate from the 46 studies included in the group-level meta-analysis was consistent with two previous meta-analyses reporting statistically significant associations between higher fluoride exposure and lower IQ in children."

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[3] Petitioners will be submitting the trial record to the EPA under separate cover, including Trial Transcripts, Petitioners' expert declarations, Petitioners' exhibits, and the written discovery materials that Petitioners entered into evidence.

[4] Dr. Birnbaum's statement, which was co-authored by Dr. Bruce Lanphear and Dr. Christine Till, was published as an Op-Ed in *Environmental Health News* on October 7, 2020. It can be accessed online at: https://www.ehn.org/fluoride-and-childrens-health-2648120286.html Petitioners have also attached a copy as Appendix E.

(p. 71) This consistent adverse association remained after extensive refinement, including a subgroup analysis where the NTP limited the analysis to the 9 higher quality studies at lowest risk of bias. (p. 71).

B. The Relationship Between Fluoride and Neurotoxic Effects Is Unlikely to Be Explained by Confounding or Other Issues of Methodology and Bias

The NTP reached its hazard conclusion for fluoride after carefully considering issues of study quality and bias, including potential confounding, publication bias, translation bias, and the validity of exposure and outcome assessments. Each of these methodological issues were raised at trial by EPA to question the confidence in the numerous studies reporting neurotoxicity from fluoride exposure. Importantly, the NTP's report makes clear that none of the issues identified by EPA at trial warrant a downgrade in the confidence that fluoride is a human neurotoxicant. In other words, the issues identified by EPA at trial do not explain the overwhelmingly consistent association between fluoride and neurotoxic harm.

Potential Confounding: The NTP concluded that "the consistency of the results among the lower risk-of-bias studies indicates that confounding is not a major concern in this body of evidence." (p. 40) In support of this, the NTP noted that "Seven of the lower risk-of-bias studies confirmed the robustness of the results by conducting sensitivity analyses." (p. 40) Further, the NTP observed that "None of the sensitivity analyses adjusting for additional confounders found meaningful shifts in the association between fluoride exposure and IQ or other measures of cognitive function." (p. 40).

Exposure Assessment: The NTP concluded that "In general, there were few or no risk-of-bias concerns regarding exposure assessment in the lower risk-of-bias studies." (p. 44) The NTP explained that "Many of the lower risk-of-bias studies used individual urine or water measures with appropriate analyses." (p. 44). While the EPA questioned the use of urine fluoride as an exposure metric for fluoride at trial, the NTP found that "many studies provide evidence to suggest that urinary fluoride is a reasonable measure of exposure." (p. 44)

Outcome Assessment: The NTP found that "The lower risk-of-bias studies have few concerns regarding outcome assessment." (p. 45) With the exception of a small handful of the low risk-of-bias studies, "the remainder of the studies used appropriate measures of IQ or other cognitive effects for the study population." (p. 45) Moreover, "Seventeen of the studies reported blinding of the outcome assessors or correspondence with the study authors indicated that it was not likely an issue." (p. 45)

Publication Bias: The NTP's meta-analysis assessed the presence and impact of publication bias. Importantly, the NTP found "no publication bias among the lower risk-of-bias studies." (p. 66) Although the NTP did find potential publication bias among higher risk-of-bias studies, "a trim-and-fill analysis estimated that, in the absence of publication bias, the negative direction of effect and statistical significance remained." (p. 66) In light of these findings, the NTP concluded that publication bias is not an issue that warrants downgrading the confidence in the fluoride database. (p. 66)

Translation Bias: The NTP also addressed a concern that EPA raised at trial that the translations of Chinese studies that the Fluoride Action Network (FAN) has conducted may represent a biased cross section of Chinese research by omitting no-effect studies. (p. 22) To assess this, the NTP conducted its own systematic search of Chinese research databases. In total it found 16 studies that had not been translated by FAN, but noted that 15 of these studies

"contained results that would likely add to the body of evidence showing a negative association between fluoride exposure and primary neurological outcomes." (p. 22) In other words, the non-translated studies further *support* the hazard conclusion, rather than detract from it. If anything, therefore, FAN's translations *understate* the current extent of Chinese research showing neurologic harm from fluoride exposure. Moreover, the only "no-effect" study that the NTP identified (Kang 2011) is a study that FAN has identified on its website (p. 22), and which the Petitioners actually included in their Petition as study number 123. There is thus no basis for the assertion that there has been a selection bias in the Chinese studies which have been translated.

C. The NTP Identified a Large Number of Low Risk-of-Bias Studies Linking Fluoride to Neurotoxicity

The NTP's systematic review identifies a very large number of studies that have associated fluoride with neurotoxic effects. In total, the NTP identified 92 human studies that have investigated the impact of fluoride on neurodevelopment, which the NTP describes as a "relatively robust" evidence base. (p. 25) Even after excluding studies that have a higher potential for bias, the number of available human studies was still notably large. In total, the NTP identified 31 human studies on fluoride and neurodevelopment that it found to have a relatively low potential for bias (p. 25) and the vast majority of these studies found significant associations between fluoride and adverse effects. This highlights that the association between fluoride and neurotoxicity is not the artifact of poor study design or bias, as EPA argued at trial.

D. The NTP Has Judged the New Zealand Studies that EPA Has Relied Upon to Be at High Risk of Bias

At trial, the EPA placed great emphasis on the null findings from a series of studies from New Zealand (Shannon 1986, Spittle 1998, Broadbent 2015). EPA's retained epidemiologist, Dr. Ellen Chang, identified the New Zealand studies as three of the ten studies that she gave greatest weight to in her causal analysis. (Chang Trial Decl. at p. 40 ¶ 182.)

In sharp contrast to EPA's assessment and in agreement with Petitioners' experts, the NTP identified the Shannon and Broadbent studies as suffering from a high risk of bias and gave them little weight in its analysis.[5] In addition, the NTP excluded the Spittle study altogether because it was a mere abstract. (p. 10)

The NTP's assessment of the New Zealand studies shows that the EPA has given too much weight to these studies. In reconsidering the Petition, therefore, the EPA should give the New Zealand studies the minimal weight they warrant.

E. The Animal Data Supports the Conclusion that Fluoride Produces Neurodevelopmental Effects

Based on its review of the animal literature, the NTP has determined that "The animal data do provide evidence for effects of fluoride on neurodevelopment." (p. 70) Although the NTP found that the subset of studies on learning/memory fail to distinguish between a direct effect on cognition and a secondary effect of fluoride's impacts on the motor/sensory systems, the NTP agrees that "There are sufficient mechanistic data [from the animal studies] to determine that

[5] The NTP's risk-of-bias review for the Broadbent and Shannon studies can be accessed online at: https://hawcproject.org/rob/study/264439/ and https://hawcproject.org/rob/study/267334/

fluoride exposure at lower concentrations has effects on the nervous system." (p. 71) The animal data thus support the NTP's presumed hazard conclusion, but do not yet warrant an upgrade in the hazard identification conclusion:

> "[T]he evidence of neurological effects at exposure levels more relevant to humans that is demonstrated in the mechanistic data supports the NTP conclusion that fluoride is presumed to be a cognitive neurodevelopmental hazard to humans; however, it does not provide enough evidence to increase confidence in the human body of evidence or support a higher hazard identification conclusion." (p. 71)

A copy of the NTP's revised Monograph is attached as **Appendix D**.

F. The NTP's Recently Retired Director Has Called for Measures to Protect Pregnant Women and Bottle-Fed Babies from the Neurotoxic Effects of Fluoride

The relevance of the NTP's findings to water fluoridation has recently been highlighted by none other than the recently retired director of the NTP, Dr. Linda Birnbaum.

On October 7, 2020, shortly after the NTP released its revised Monograph, Dr. Birnbaum issued a public statement calling for measures to protect pregnant women and bottle-fed babies from the neurotoxic effects of fluoride. Dr. Birnbaum noted that the NTP's conclusion is "consequential," given that "about 75 percent of Americans on community water systems have fluoride in their water."

According to Dr. Birnbaum, "Given the weight of evidence that fluoride is toxic to the developing brain, it is time for health organizations and regulatory bodies to review their recommendations and regulations to ensure they protect pregnant women and their children."

Dr. Birnbaum added that, "[w]e can act now by recommending that pregnant women and infants reduce their fluoride intake."

"Given that safe alternatives are available and that there is no benefit of fluoride to babies' teeth before they erupt or appear," Dr. Birnbaum stated that "it is time to protect those who are most vulnerable."

Dr. Birnbaum's statement, which was co-authored by the two principal investigators of the NIH-funded MIREC study in Canada, is attached as **Appendix E**.

G. Limitations and Weaknesses of NTP's Report

The NTP Monograph provides an exceptionally comprehensive review of the scientific literature on fluoride neurotoxicity, and provides ample support for its conclusion that fluoride is a neurotoxicant that reduces IQ. There are, however, some limitations and weaknesses with the NTP's analysis that Petitioners wish to bring to the EPA's attention.

First, despite the critical importance of "timing" to an evaluation of a chemical's neurotoxicity,[6] despite the heightened vulnerability of the fetal brain,[7] and despite fluoride's

[6] *See* Appendix B at p. 30 ¶¶ 154-55.
[7] *See* Appendix B at p. 36 ¶¶ 196-197.

known ability to pass through the placenta and get to the fetal brain,[8] the NTP failed to separately analyze the studies that have specifically evaluated the impact of prenatal fluoride exposure. This is a troubling omission from the NTP's analysis for two reasons: (1) The studies that have examined prenatal fluoride exposure are the most methodologically rigorous studies to date (e.g., Bashash 2017, Bashash 2018, Green 2019, Till 2020, Valdez-Jiminez 2017). (2) Had the NTP separately considered the prenatal studies, it could *not* maintain the conclusion that the evidence of harm is "inconsistent and unclear" below 1.5 mg/L. Indeed, as demonstrated at trial, the prenatal studies have consistently found adverse effects at levels of exposure seen in artificially fluoridated communities. (Appendix B at p. 89 ¶ 467.)

Second, the NTP's dose-response assessment is fundamentally flawed in several critical respects. The NTP failed to utilize benchmark dose (BMD) modeling, which is the standard method for dose-response analysis, as recognized by the EPA. Instead of using BMD modeling, the NTP used a meta-analysis method that relied upon group-level data from cross-sectional studies instead of individual-level data from the highest-quality (North American) prospective studies. The NTP's curious use of group-level data in its dose-response analysis instead of individual-level data runs directly counter to EPA's methods. In fact, in EPA's denial of the Petition, the EPA specifically stated that group level data from cross-sectional studies is "unsuitable for evaluating levels of fluoride associated with neurotoxic effects and for deriving dose-response relationships necessary for risk assessment." (Fed. Reg. Vol 82, No. 37 at 11882.)

Third, the NTP's justifications for not doing a dose-response analysis of the studies with individual data do not withstand scrutiny. The NTP provided the following justification for not doing an analysis of individual-based data:

> "A dose-response meta-analysis using the effect estimates reported in studies with individual-level exposure was considered. However, because of the small number of studies (n = 10), the various types of exposure metrics, and the different types of reported effect estimates that could not be combined, a dose-response meta-analysis of these studies could not be conducted." (p 253)

Each of these three asserted justifications lack merit as they apply equally to other subgroup-analyses that NTP performed as part of its dose-response meta-analysis. Specifically, the NTP did subgroup analyses that (1) pooled as few as four studies at a time, (2) pooled studies that used different exposure metrics, and (3) pooled studies with different effect estimates. (pp. 248-252.)

Fourth, against the specific recommendations of the NAS, the NTP engaged in an ad hoc and superficial analysis of the "generalizability to the U.S. population." (pp. 72-74) In its generalizability analysis:

- The NTP does not separately consider the prenatal studies, all of which have found effects at levels of exposure seen in fluoridated areas of the U.S.
- The NTP spends far more time discussing group-level data from China than individual-participant data from the North American prospective birth cohort studies.
- The NTP includes only one sentence that discusses the results of the North American prospective studies, and that one sentence misleadingly states that "Bashash et al. (2017) concluded that there was no clear association between IQ scores and maternal

[8] *See* Appendix B at pp. 35-36 ¶¶ 193-195; Appendix H at 6.

urinary fluoride below 0.8 mg/L." The NTP fails to mention that Bashash (2017) found *no threshold* in the GCI results for the 4-year-olds, which is a highly material finding.

- The NTP never once discusses the very probative findings from Green (2019) and Till (2020), where the studies specifically examined, and found adverse effects from, fluoride exposure in fluoridated communities of Canada.
- The NTP performs a crude assessment of fluoride exposure in the US, as it focuses on the fluoride concentration in water without giving due consideration to the wide range of exposures among people exposed to the same waterborne concentration.[9] In fact, EPA's Exposure Factors Handbook shows that 95th percentile per capita water intake is more than three times larger than the average intake and, therefore, high-end water consumers drinking water at 0.7 mg/L receive a higher internal dose than the average water consumer drinking water at 1.5 mg/L. (Pls' Trial Ex. 25 at p. 3-4.)

The key flaws in the NTP's generalizability analysis were identified by the NAS in its peer review earlier this year. According to the NAS:

> "the discussion section of the monograph provides an informal assessment of the evidence with regard to exposure and concludes that adverse health effects are observed largely in association with exposures above those associated with water fluoridation. The basis of that conclusion is not apparent and *seems to contradict the earlier assertion that nearly all the studies are positive, including ones that evaluated groups exposed to lower concentrations*." (NAS 2020, p. 5.)

The contradiction that the NAS identified remains in the current Monograph. Indeed, rather than the evidence being "inconsistent and unclear" at water fluoride concentrations below 1.5 mg/L, the highest quality studies (i.e., the NIH-funded prospective studies) are consistent and clear in showing effects below 1.5 mg/L.

The Petitioners have attached a more detailed analysis of the limitations and weaknesses of the NTP report in **Appendix F**.

H. Even with Its Limitations, the NTP Monograph Demonstrates that Water Fluoridation Poses an Unreasonable Risk of Neurodevelopmental Harm

Even with its limitations, the NTP Monograph demonstrates that neurotoxicity is an unreasonable risk of water fluoridation.

As discussed earlier, the EPA does not condition an unreasonable risk finding on whether human exposure equals or exceeds a known adverse effect level. (Appendix H at 4.) Indeed, EPA has "*never once in any of its risk evaluations to date under Section 6 used a causation standard*" to determine risk for a condition of use. (6/16 Trial Tr. at 987:6-8.) This is obvious upon review of EPA's risk evaluations (both draft and final) as EPA has repeatedly made unreasonable risk findings where human exposures are well below the estimated hazard level (i.e., LOAEL or BMD), and EPA has also made unreasonable risk findings where the exposures are below the "No Observable Adverse Effect Level."[10] As but one example, EPA's

[9] The NTP does recognize that bottle-fed babies may consume "excessive amounts" of fluoride if they are fed formula reconstituted with fluoridated water, and that this needs to be taken into account as part of the generalizability analysis. (p. 74)

[10] As the EPA explained at trial: "if human exposure levels exceed a known *no-adverse* effect level *divided by combined uncertainty factors*, EPA may make an unreasonable risk

final risk evaluation for 1-Bromopropane (1-BP) made an unreasonable risk finding for developmental toxicity among humans exposed to *80 times less* of the chemical than the estimated hazard level in animals.[11]

In light of how EPA has defined unreasonable risk for other chemicals, it would be clearly erroneous for the EPA to conclude that fluoridated water does not pose an unreasonable risk of neurotoxicity simply because the level of fluoride added to water in fluoridation programs (0.7 mg/L) is less than NTP's estimated hazard level (1.5 mg/L). (6/10 Trial Tr. 478:18-479:19.) In fact, the margin between the so-called "optimal" level and the NTP's hazard level is precariously small and far lower than what EPA has found to be unacceptable in its other TSCA risk evaluations.

The danger of a mere two-fold margin between the hazard and exposure level is apparent when considering the wide range of susceptibility to toxic substances, including fluoride, that exists across the human population. EPA calls this range of susceptibility "intraspecies variability," and almost always applies a safety factor (i.e., uncertainty factor) to the estimated hazard level to ensure that susceptible members of the population are adequately protected. (Appendix B at pp. 55-56 ¶¶ 297-98.)

As discussed at trial, EPA uses a default safety factor of ten to protect susceptible humans. (Appendix B at p. 56 ¶ 298.) This default factor of 10 is "considered to be appropriate in the absence of *convincing data to the contrary*." (Pls' Trial Ex. 20 at p. 5-17.) EPA has used a safety factor of 10 for intraspecies variability in each of its risk evaluations under TSCA. (Appendix B at p. 56 ¶ 298.)

In the case of fluoride, there is ample evidence demonstrating substantial variability in how humans respond, including differences in toxicokinetics (e.g., people with renal impairment have increased accumulation of fluoride) and differences in toxicodynamics (e.g., people with iodine deficiency may suffer harm at lower levels of exposure than those with adequate intake). (Appendix B at p. 56 ¶ 299.) While the magnitude of human variability to fluoride is difficult to precisely quantify, the data *support* the *need* for an intraspecies uncertainty factor as opposed to providing "convincing data" *against* one. (*Id*. ¶¶ 299-300) Indeed, EPA itself has used a safety factor of 10 for intraspecies variability to protect susceptible humans from the toxic effects of sodium fluoride when it is used as a pesticide.[12] (*Id*. ¶ 301) EPA has thus recognized the appropriateness of using an intraspecies uncertainty factor of 10 for fluoride toxicity. (*Id*.)

Applying a safety factor of 10 to the NTP's estimated hazard level for fluoride neurotoxicity results in a water fluoride level of 0.15 mg/L, which is well below the concentration used in fluoridation programs (0.7 mg/L). In fact, even if the EPA only used a safety factor of 3, the safe level would still be less than the concentration used in fluoridation. It is thus clear that water fluoridation presents a risk of neurotoxicity if EPA applies its TSCA methods for risk characterization to the NTP's hazard assessment.

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determination under TSCA." (Appendix H at 4.) Since the combined uncertainty factor in EPA's risk evaluations is almost always $\geq$30, this means that EPA may find an unreasonable risk where the human exposure is 30+ times *lower* than the *no-adverse* effect level.

[11] Petitioners refer here to EPA's unreasonable risk determinations for bystander exposure to refrigerant flush products (Final 1-BP Risk Evaluation at pp. 316 & 345).

[12] The sodium fluoride that is used as a pesticide is the "same exact chemical" as the sodium fluoride that is added to drinking water for fluoridation. (6/10 Trial Tr. 500:8-14.)

4. Pooled BMD Analysis of the NIH-Funded Birth Cohort Data Confirms that Pregnant Women in Fluoridated Areas Are Exceeding the Dose Associated with IQ Loss

A team of scientists, including the authors of the NIH-funded studies, have recently completed a *pooled* benchmark dose (BMD) analysis of the maternal urinary fluoride data from the ELEMENT and MIREC datasets (Grandjean, et al. 2020, in review). The pooled analysis, which is currently undergoing peer review, found that that the BMDL (i.e., BMCL) for the loss of 1 IQ point among 4-year-old children across the two cohorts is just **0.18 mg/L**. This is consistent with the preliminary findings presented by Dr. Philippe Grandjean at trial and is *far below the urinary fluoride levels found in pregnant women living in fluoridated areas of North America*. (Appendix B at pp. 45-47 & 68-69.) Sensitivity analyses of the pooled sample using non-linear models confirm that the *linear* model presents a reasonable approximation of the dose-response relationship.

Given that BMD analysis is EPA's preferred method for determining toxicity values and risk estimates, the new pooled analysis provides compelling grounds for EPA to reconsider its denial of the Petition. The analysis, which became publicly available on November 4, 2020, is attached as **Appendix G**.

Petitioners will also be submitting to the EPA under separate cover the regression coefficient data upon which the pooled BMD analyses are based. In addition, Petitioners will be submitting under separate cover the scatterplot data from Figures 2 and 3 of the Bashash 2017 study as extracted by WebPlotDigitizer. This data will permit the EPA to do its own BMD analyses of the data should the Agency wish to do so.

5. Millions of Americans Are at Risk of Harm as a Result of EPA's Failure to Regulate Fluoridation, Including Petitioners

One of the consequences of widely dispersing a toxicant through the environment is that susceptible members of the general public may be exposed. This is the case with fluoridation chemicals. Each year, there are approximately 2.5 million pregnancies in fluoridated areas; *in utero* exposures are thus widespread. (Appendix B at p. 78 ¶ 406.) Many of those exposed *in utero* will also be exposed during the sensitive neonatal period, with upwards of 1.9 million infants living in fluoridated areas being fed formula at least part of the time, including 400,000 infants who are exclusively formula-fed for their first six months. (*Id*.) Petitioner Organizations have members who fall within these zones of danger.

Petitioner Organizations have many members of childbearing age living in fluoridated areas who are subject to the risks identified by the NIH-funded prospective studies. The members of Petitioner Organizations include women who are currently pregnant, women who are actively seeking to become pregnant, and/or mothers of infants. This includes, but is not limited to, Food & Water Watch members **Jennifer Baugh**, **Jacqueline Devereaux**, **Brooke Errett**, **Leah Garland**, **Hanna Rodgers**, **Olivia Stancil, Whitney Stolman**, **Jessica Trader**, and **Chassity Woolums.** In light of the science linking early-life exposure to fluoridated water to adverse neurodevelopmental effects, each of these members is taking steps to limit their child's exposure to fluoride, including through purchasing filtered and bottled water.

EPA's failure to regulate the fluoridation chemicals in water is forcing millions of Americans, including Petitioners' members, to choose between subjecting their children to a risk of permanent neurological harm, or spending hard-earned money to avoid the water that is delivered into their homes. Petitioners implore the Agency to reconsider its denial of the Petition

so that its members, and millions of other Americans, are no longer forced to make this injurious choice.

6. EPA Erred in Considering the Purported Dental Benefits of Fluoridation in its Denial of the Petition

In its denial of the Petition, EPA cited the purported dental benefits of fluoridation as a basis for its denial. This was improper[13] because the Amended TSCA statute forbids risk evaluations from considering "costs and other nonrisk factors." 15 U.S.C. § 2620(b)(4)(B(ii). In a May 11, 2020 order, the Court ruled that the statute's prohibition on considering "costs and other nonrisk factors" extends to purported health benefits. As the Court noted, "the plain text of the statute, the structure of the statute, and its legislative history all indicate that consideration of benefits at the risk evaluation stage is inappropriate." (Appendix H at 12.) In considering whether fluoridation presents an unreasonable risk of neurotoxicity, therefore, the EPA must not consider purported benefits as that is the province of risk management, not risk evaluation.

The Petitioners have attached a copy of the Court's May 11, 2020 decision as **Appendix H**.

7. EPA Erred in Claiming that Petitioners Failed to Adequately Identify the Chemicals at Issue

Finally, in denying the Petition, the EPA asserted that Petitioners failed to justify treatment of fluoridation chemicals as a "category" of chemicals. (Fed Reg, Vol. 82, No. 37, p. 11888). EPA noted that Petitioners had failed to identify "the specific chemical substances that should comprise the category of fluoridation chemicals."[14] (*Id*.) Further, EPA argued that "if EPA were to grant the petitioner's [sic] request, the Agency would become obligated to address all conditions of use of the category." (*Id*.) During the litigation on this matter, the Court considered and rejected each of these arguments, and held that the Petitioners had adequately identified the chemicals at issue, and that there was no merit to EPA's contention that it "would become obligated to address all conditions of use of the category."

The Petitioners have attached the Court's order addressing these issues as **Appendix I**.

SUMMARY

Congress enacted Section 21 to "ensure that bureaucratic lethargy does not prevent the appropriate administration of [TSCA's] vital authority." *Environmental Defense Fund v. Reilly*, 909 F.2d 1497, 1499 (D.C. Cir. 1990). This is precisely why the Petitioners filed their Section 21 Citizen Petition, because EPA has failed to protect the public from the dangers posed by fluoride in drinking water.

The reasons that EPA proffered for denying Petitioners' Citizen Petition, which were questionable when written, are neither credible nor tenable in light of the aforementioned developments that have transpired since EPA's denial. In light of these developments,

[13] Petitioners recognize that they discussed the lack of benefits in the Petition, but that does not change the fact that the statute forbids such consideration, as Petitioners have since learned.

[14] As EPA well knows, there are three chemicals used to fluoridate drinking water: hydrofluorosilicic acid, sodium fluorosilicate, and sodium fluoride.

Petitioners request that EPA reconsider its denial of the Petition and exercise its authority under TSCA to prohibit the addition of fluoridation chemicals to drinking water.

Dated: November 4, 2020

Respectfully submitted,

/s/ Michael Connett
MICHAEL CONNETT
Attorney for Petitioners

CC (by email):

Brandon Adkins, DOJ
Debra Carfora, DOJ
Yvette Collazo, EPA
J.T. Do, DOJ
Alexandra Dunn, EPA
Tala Henry, EPA

THE PETITIONERS

ORGANIZATIONS:

Food & Water Watch (FWW) is a nonprofit membership organization that champions healthy food and clean water for all, and advocates for a democracy that improves people's lives and protects our environment. Core to FWW's mission is the belief that clean, safe water for drinking and recreational uses is a fundamental right that should be afforded to all people. FWW has over 70,000 members nationwide, including the following women of childbearing age who are concerned about the credible threat of neurological harm that fluoridation chemicals pose to their children and expected children: **Jennifer Baugh**, **Jacqueline Devereaux**, **Brooke Errett**, **Leah Garland**, **Hanna Rodgers**, **Olivia Stancil, Whitney Stolman**, **Jessica Trader**, and **Chassity Woolums.**

Fluoride Action Network (FAN), was founded in 2000 as a project of the American Environmental Health Studies Project, Inc. FAN is an organization of scientists, doctors, dentists, environmental health researchers, and concerned citizens working to raise awareness about the impact of current fluoride exposures on human health.

Moms Against Fluoridation is a national nonprofit with a mission to increase awareness of the unsafe and unethical practice of artificial water fluoridation in America today.

INDIVIDUALS:

Audrey Adams, a resident of Renton, Washington (individually and on behalf of her son Kyle Adams); **Kristin Lavelle**, a resident of Berkeley, California (individually and on behalf of her son Neal Lavelle); and **Brenda Staudenmaier** from Green Bay, Wisconsin (individually and on behalf of her children Ko Staudenmaier and Hayden Staudenmaier).