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

FOOD & WATER WATCH, et al., Plaintiffs, vs. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al. Defendants.	Civ. No. 17-CV-02162-EMC **PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION TO LIFT THE STAY AND TAKE THE CASE OUT OF ABEYANCE** Judge: Hon. Edward M. Chen Date: October 20, 2022 Time: 1:30 p.m. Courtroom: Via Zoom Webinar

Table of Contents

Table of Authorities

Cases

Statutes & Rules

Legislative History

Secondary Sources

I. INTRODUCTION

In its response to Plaintiffs' motion, EPA agrees that "none of the considerations that moved the Court to put the case in abeyance persists today," including the Court's concerns about Plaintiffs' standing. Opp. Br. at 5:24-26, 6:14-16, 7:27-28. The parties are thus in agreement that the Court should lift the stay. The parties are also in agreement that the trial record provides a sufficient basis for the Court to make its determination. As EPA correctly notes, Plaintiffs believe the trial record presented "sufficient evidence to demonstrate a risk under" the Toxic Substances Control Act (TSCA). Opp Br. at 5:17-20. Plaintiffs maintain this position and would *not* object to the Court issuing its determination without taking further evidence (other than the supplemental facts on standing). However, Plaintiffs are also mindful of the Court's previously stated interest in considering post-trial scientific developments in a "phase two trial," including the pooled benchmark dose analysis, the Spanish study, and the NTP's monograph. ECF No. 311 at 7:24-8:2, 15:2-3. Plaintiffs are also mindful that, in a case with national policy implications, having more information is presumably better than having less. Plaintiffs have thus proposed a course of action that would allow the Court's determination to be informed by the NTP's assessment, the peer reviews of NTP's assessment, the pooled benchmark dose analysis, and the Spanish study, all of which are now available. What Plaintiffs object to is continuing to wait for a "final" NTP report, particularly since Dr. Woychik's declaration confirms that a "final" report *may never be released*, and, *if* it is released, there is no clear or definite timeframe on when that will be.

In considering what course to chart for the remainder of this litigation, the Court should look to the central policy concern that underlies TSCA, i.e., the urgent need to prevent irreversible chemical hazards before they occur. As discussed herein, Congress has made clear that "factual certainty" of harm is not needed to initiate rulemaking under the Act. Given this, the Plaintiffs respectfully request that the Court take this case out of abeyance and (A) render a determination based on the current trial record (as EPA proposes), or (B) schedule a phase two trial where the parties' experts can address the current state of the science, including the NTP's May 2022 monograph that, as detailed herein, *is the most extensively peer-reviewed monograph in NTP's history*.

II. ARGUMENT

A. The Future Course of This Litigation Should Be Guided, First and Foremost, By the Policy Interests that TSCA Was Enacted to Protect

In navigating the course forward for this litigation, the north star should be the public policy interests that Congress sought to protect when it enacted TSCA.

TSCA was enacted based on Congress's determination that environmental chemicals can cause "irreversible" harm and that "prevention of such harm is . . . urgently needed." H. Rept. 94-1341, 94th Cong., 2d Sess. (1976), attached hereto as **Exhibit O**, at 4.[1] The "overriding purpose" of TSCA, therefore, was "to provide protection of health and the environment through authorities which are designed to *prevent* harm." *Id.* at 7 (emphasis added). Since the statute was designed to prevent harm *before* it occurs, Congress recognized that "factual certainty respecting the existence of an unreasonable risk of a particular harm may not be possible and the bill does not require it."[2] *Id.* at 32. As the House Report noted, regulatory action to prevent harm is justified "even though there are uncertainties as to the threshold levels of causation." *Id.*

"Where a statute is precautionary in nature," like TSCA, it defeats the purpose of the act to require "rigorous step-by-step proof of cause and effect." *Ethyl Corp. v. E.P.A.*, 541 F.2d 1, 28 (D.C. Cir. 1976). This is because "[c]ertainty in the complexities of environmental medicine may be achievable only after the fact, when scientists have the opportunity for leisurely and isolated scrutiny of an entire mechanism." *Id.* at 25. In *Ethyl Corp*, the court upheld EPA's historic decision to phase out the addition of lead to gasoline despite EPA not having "factual proof of actual harm." *Id.* at 8 & 12. The court found that the "inconclusive but suggestive results of numerous studies" was sufficient grounds for EPA to infer a risk, *id.* at 28, and rejected any notion that factual certainty was required, or even possible, in the field of environmental health. *Id.* at 25.

Congress had the same understanding of risk when it enacted TSCA. According to the House Report, "[w]hen, as here, regulatory action is intended to be taken to *prevent* the occurrence of harm in the

[1] All exhibits cited herein are attached to the accompanying Second Declaration of Michael Connett.

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

future as well as protect against presently visible harm, such action often must be based on not only consideration of facts but also consideration of scientific theories, projections of trends from currently available data, modeling using reasonable assumptions, and extrapolations from limited data." Exhibit O, at 32. Congress thus understood that the goal of preventing harm *before* it occurs is incompatible with postponing action until there is final and perfected proof of harm, i.e., until "scientists have the opportunity for leisurely and isolated scrutiny of an entire mechanism." *See Ethyl Corp*., 541 F.2d at 25.

To help effectuate TSCA's health protective goals, Congress established an "unusually powerful procedure[ ] for citizens to force EPA's hand" through citizen petitions. *Food & Water Watch, Inc. v. E.P.A*, 291 F. Supp. 3d 1033, 1048 (N.D. Cal. 2017) (quoting *Trumpeter Swan Society v. E.P.A.*, 774 F.3d 1037, 1039 (D.C. Cir. 2014)). As the D.C. Circuit Court of Appeals has explained, "[c]itizen participation is broadly permitted [under the TSCA] to ensure that bureaucratic lethargy does not prevent the appropriate administration of this vital authority." *Env't Def. Fund v. Reilly*, 909 F.2d 1497, 1499 (D.C. Cir. 1990). The citizen petition provision is thus a check mechanism to ensure that "bureaucratic lethargy" does not impede the effective enforcement of the Act. *Food & Water Watch*, 291 F. Supp. 3d at 1048.

As scholars of environmental law well know, Congress's initial aspirations for TSCA as a vital authority to protect against chemical hazards did not come to pass, at least with the initial legislation.[3] The "final blow" came when the Fifth Circuit struck down EPA's ban on asbestos, which EPA had spent 10 years working on, including reviewing hundreds of studies, and holding numerous public hearings. Charles Franklin, *TSCA Reform Versus Replacement: Moving Forward in the Chemical Control Debate*, ABA Trends, May/June 2013, at 9, 10–11 (citing *Corrosion Proof Fittings v. E.P.A.*, 947 F.2d 1201 (5th Cir. 1991)). As one observer noted,

> While [*Corrosion Proof Fittings*'] legal significance was debatable, the lesson for EPA was that if ten years and thousands of pages of documentation were inadequate to ban asbestos, TSCA's section 6 risk management provision was a dead letter. EPA essentially put regulation pursuant to section 6 on a shelf and spent most of the next two decades seeking voluntary action from industry.

[3] Michael Freedhof, the Assistant Administrator of Chemical Safety and Pollution Prevention, concurred with this assessment in her congressional testimony that is attached to EPA's opposition. *See* Adkins Decl, Ex. A at 1-2 ("For nearly 40 years, TSCA had largely failed to serve its purpose – to protect people and the environment against the risks of dangerous chemicals.").

Id.

To address the "paralysis" of EPA enforcement under TSCA, *id.*, Congress amended the Act in 2016. Through the 2016 amendments, Congress invested EPA "with strong authority to oversee chemicals," including authority to "evaluate chemicals against a purely risk-based standard" (i.e., without consideration of costs). Adkins Decl, Ex. A at 2-3. Importantly, Congress incorporated this purely risk-based standard into the citizen petition provision of the statute. 15 U.S.C. § 2620(b)(4)(B)(ii).

B. The Facts in Richard Woychik's Declaration Strongly Counsel Against Waiting for a "Final" NTP Report

Of the three options that the parties have articulated for how this case should proceed, the one that is least compatible with TSCA's health protective goals is the option of continuing to wait for a potentially illusory "final" report from NTP. The declaration from Richard Woychik, the director of NTP, underscores the problems with waiting for the official release of a "final" report.

First, Dr. Woychik's declaration confirms that a final report may no longer be released. In the concluding paragraph of his declaration, Dr. Woychik states "I will decide about NTP's *potential* publication" at some undefined point in 2023. Woychik Decl. ¶ 8 (emphasis added).

Second, Dr. Woychik's declaration confirms that, *if* a "final" report is released, the timeframe for release is undefined and uncertain. According to Dr. Woychik, a working group of the Board of Scientific Counselors (BSC) will be reviewing the report, but this review has not yet begun. *Id.* ¶¶ 6-7. Dr. Woychik "*anticipates*" that the membership for the BSC working group will be finalized in October/November 2022, and "*hopes*" that the working group can provide its findings to BSC "in early 2023." *Id.* ¶ 7 (emphases added). The BSC will then make recommendations to Dr. Woychik, who will then make a decision about whether to publish the report. *Id.* ¶¶ 7-8. None of these steps has any definitive timeframe, including (A) when the working group will be assembled, (B) when the working group will begin its review, (C) when the working group will complete its review, (D) when the working group will provide its recommendations to the BSC, (E) when the BSC will provide its recommendations to Dr. Woychik, (F) when Dr. Woychik will decide whether to release the report, and, assuming Dr. Woychik decides to release the report, (G)

when the report will actually be released.

Third, Dr. Woychik's declaration confirms Plaintiffs' concerns that NTP's monograph is being reviewed, and thereby influenced, by parties that have longstanding partisan interests on the fluoridation issue. As Dr. Woychik notes, the report has undergone review "by various Department of Health and Human Services ('HHS') entities." *Id.* ¶ 5. As noted in Plaintiffs' motion, these HHS entities include the National Institute of Dental & Craniofacial Research (NIDCR) and the Centers for Disease Control (CDC),[4] both of which actively promote the addition of fluoridation chemicals to drinking water. Pls' Mot. at 8-10. Further, Dr. Woychik's declaration confirms that these HHS entities were reviewing the report as recently as July 2022, Decl. ¶ 5, which is several months *after* NTP finalized the report following the peer-review by "5 external peer reviewers" in the early months of 2022. *See* Pls' Mot. at 7 & Exhibit C. This external review process was described by NTP's attorney in January 2022 as the *final* review that the report would undergo before release. *See* Exhibit C to Pls' Mot.

Fourth, while Dr. Woychik's declaration omits reference to the external peer review that occurred earlier this year, he identifies four other review processes that have occurred. In total, therefore, the NTP monograph on fluoride will have undergone at least *five* separate review processes prior to being released, if it will ever be released at all. These reviews are as follows:

1. A peer review by NASEM from September 2019 to March 2020;
2. A peer review by NASEM from September 2020 to February 2021;
3. A peer review by 5 external peer reviewers from November 2021 to February 2022;
4. A review by various HHS entities between July 2021 and July 2022;
5. A future review by a working group of BSC.

While EPA characterizes these reviews as simply a "thorough scientific process," Opp Br. at 9, the process is thoroughly *unusual*. The unusual, and indeed unprecedented, nature of this review process can be appreciated when comparing it against the peer review process that NTP has used for each of its previous 21 monographs, as detailed in the following table.[5] (The relevant discussions of the peer review processes for these previous monographs are attached hereto as **Exhibit P**.)

[4] The CDC and NIDCR are both HHS entities, as set forth in the organizational chart on HHS's website. *See* https://www.hhs.gov/about/agencies/orgchart/index.html (last accessed Oct. 3, 2022).

[5] NTP's 21 current monographs are available on NTP's website at: https://ntp.niehs.nih.gov/publications/monographs/index.html (last accessed on Oct. 3, 2022).

Prior NTP Monographs		
Monograph	**Year**	**Peer Review Process**
NTP Monograph on Health Effects of Low-Level Lead	2012	"Peer review of the Draft NTP Monograph was conducted by an **ad hoc expert panel** at a **public meeting** held November 17-18, 2011"
Report on Carcinogens Monograph on 1-Bromopropane	2013	"Peer review of the Draft RoC Monograph on 1-Bromopropane was conducted by an **ad hoc expert panel** at a **public meeting** held March 21–22, 2013"
NTP Monograph on Developmental Effects and Pregnancy Outcomes Associated with Chemotherapy Use During Pregnancy	2013	"Peer review of the Draft NTP Monograph was conducted by a 9-member **ad hoc expert panel** at a **public meeting** held October 1-2, 2012"
Report on Carcinogens Monograph on Pentachlorophenol and By-products of Its Synthesis	2014	"Peer review of the Draft RoC Monograph on Pentachlorophenol and By-Products of its Synthesis was conducted by an **ad hoc expert panel** at a **public meeting** held December 12–13, 2013"
Report on Carcinogens Monograph on ortho-Toluidine	2014	"Peer review of the Draft RoC Monograph on ortho-toluidine was conducted by an **ad hoc expert panel** at a **public meeting** held December 12–13, 2013"
NTP Monograph: Identifying Research Needs for Assessing Safe Use of High Intakes of Folic Acid	2015	No peer review process identified in the Table of Contents (and no discussion of peer review process in body of report).
Report on Carcinogens Monograph on Trichloroethylene	2015	"Peer review of the Draft RoC Monograph on Trichloroethylene was conducted by **an ad hoc expert panel** at a **public meeting** held August 12, 2014"
Report on Carcinogens Monograph on Cobalt and Cobalt Compounds That Release Cobalt Ions In Vivo	2016	"Peer review of the Draft RoC Monograph on Cobalt and Certain Cobalt Compounds1 was conducted by an **ad hoc expert panel** at a **public meeting** held July 22, 2015"
Report on Carcinogens Monograph on Epstein-Barr Virus	2016	"Peer review of the Draft RoC Monograph on Epstein-Barr Virus (EBV) was conducted by an **ad hoc expert panel** at a **public meeting** held December 17, 2015"
Report on Carcinogens Monograph on Human Immunodeficiency Virus Type 1	2016	"Peer review of the Draft RoC Monograph on Human Immunodeficiency Virus Type 1 (HIV-1) was conducted by an **ad hoc expert panel** at a **public meeting** held December 17, 2015"
Report on Carcinogens Monograph on Human T-Cell Lymphotropic Virus Type 1	2016	"Peer review of the Draft RoC Monograph on Human T-cell Lymphotropic Virus Type 1 (HTLV-1) was conducted by an **ad hoc expert panel** at a **public meeting** held December 17,

		2015"
Report on Carcinogens Monograph on Kaposi Sarcoma-Associated Herpesvirus	2016	"Peer review of the Draft RoC Monograph on Kaposi Sarcoma-Associated Herpesvirus (KSHV) was conducted by an **ad hoc expert panel** at a **public meeting** held December 17, 2015"
Report on Carcinogens Monograph on Merkel Cell Polyomavirus	2016	"Peer review of the Draft RoC Monograph on Merkel Cell Polyomavirus (MCV) was conducted by an **ad hoc expert panel** at a **public meeting** held December 17, 2015"
NTP Monograph on Immunotoxicity Associated with Exposure to Perfluoroctanoic Acid (PFOA) or Perfluoroctane Sulfonate (PFOS)	2016	"Peer review of the draft NTP Monograph was conducted by an **ad hoc expert panel** in a **public meeting** held July 19, 2016"
Report on Carcinogens Monograph on Haloacetic Acids Found as Water Disinfection By-Products	2018	"Peer review of the draft RoC Monograph on Haloacetic Acids Found as Drinking Water Disinfection By-products was conducted by an **ad hoc expert panel** at a **public meeting** held July 24, 2017"
Report on Carcinogens Monograph on Antimony Trioxide	2018	"Peer review of the Draft RoC Monograph on Antimony Trioxide was conducted by an **ad hoc expert panel** at a **public meeting** held on January 24, 2018"
Report on Carcinogens Monograph on Helicobacter pylori (Chronic Infection)	2018	"The Draft Report on Carcinogens Monograph on Helicobacter pylori (chronic infection) was peer reviewed **by letter by [three] individuals with expertise in H. pylori and cancer**."
NTP Monograph on the Systematic Review of Occupational Exposure to Cancer Chemotherapy Agents and Adverse Health Outcomes	2019	"The National Toxicology Program (NTP) conducted a peer review of the draft NTP Systematic Review . . . **by letter** in **March 2018** by the experts listed below." [The report then identifies 5 non-governmental scientists.]
NTP Monograph on the Systematic Review of Long-term Neurological Effects Following Acute Exposure to Sarin	2019	"The National Toxicology Program (NTP) convened a virtual **external ad hoc panel** to peer review the Draft NTP Monograph . . . on February 4, 2019. . . . **The public could view the proceedings online** and opportunities were provided for submission of written and oral public comments."
NTP Monograph on the Systematic Review of Traffic-related Air Pollution and Hypertensive Disorders of Pregnancy	2019	"The National Toxicology Program (NTP) conducted a peer review of the draft NTP Monograph . . . **by letter** in **August 2019** by the [five] experts listed below."

None of NTP's previous 21 monographs was subjected to a peer review by NASEM, let alone *two* peer reviews by NASEM, let alone a *private non-transparent review* by "various [HHS] entities." Exhibit P. As can be seen in the above table, the peer review process for 17 of NTP's 21 previous monographs was conducted *in public* by an ad hoc expert panel at a meeting lasting only *one to two days.* For 3 of the prior monographs, the peer review was conducted by an ad hoc panel "by letter" over the course of a *month*, and for 1 of the monographs (folic acid), no peer review process is indicated. The brevity of the peer reviews for NTP's previous monographs is reflective of NTP's position as a uniquely authoritative, and neutral, body on matters of toxicology.

The unusual, and *non-transparent*, nature of the review process for NTP's *fluoride* monograph increases Plaintiffs' concerns about a devolving integrity in the process. NTP's handbook on systematic reviews repeatedly emphasizes the importance of "transparency" and "consistency," and EPA's experts at trial stressed the inviolable importance of these two principles as well. *See* **Exhibit Q** (NTP Handbook), **Exhibit R** (Trial Testimony of Dr. Kristina Thayer) & **Exhibit S** (Trial Testimony of Dr. Tala Henry). And, yet, in what may prove to be the single most consequential report to the outcome of this litigation, these principles, while once present, are now lacking. Given these deficiencies, it is questionable whether a "final" report will be as credible, let alone more credible, than the September 2020 or May 2022 reports.

For the foregoing reasons, the facts set forth in Dr. Woychik's declaration strongly counsel against keeping this case in abeyance until a "final" NTP report is released. Instead, the Court should rule on the record as it stands (as proposed by EPA),[6] or permit a phase two trial where the Court can receive expert testimony on post-trial scientific developments, including the NTP's May 2022 report.

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[6] Plaintiffs have met and conferred with EPA about how the supplemental standing facts would be entered into the trial record if the Court were to rule on the record as it currently stands. The parties have agreed on an approach whereby Plaintiffs would enter the facts into the record through a sworn declaration by Jessica Trader, and EPA would have the right to depose Ms. Trader following receipt of this declaration.

C. The Currently Available NTP Reports Have Been More Thoroughly Peer Reviewed Than Any of NTP's Previous Monographs and Provide the Court with a Well-Developed Assessment of the Science

The currently available drafts of the NTP report (from 2019 and 2020), as well as the May 2022 report that the NTP was days away from releasing, provide this Court with NTP's expert assessment of the current literature on fluoride neurotoxicity. Even if the Court only considered NTP's 2020 evaluation, this report is a more thoroughly peer-reviewed NTP monograph than any monograph that NTP has ever previously released. *See* Exhibit P. The May 2022 report, which reflects the additional input from NASEM's *second* peer review as well as the input from "5 external peer reviewers,"[7] is even *more* thoroughly reviewed.[8] Given the advanced, thoroughly reviewed, status of the existing NTP reports, there is little compelling need to continue waiting for the official release of a "final" report, particularly given the deficiencies with transparency and consistency discussed above and the fact that a "final" report may never be released.

D. The Existence of the NASEM Peer Reviews Provides Further Justification for the Court Considering the Currently Available NTP Reports

The fact that NASEM has provided some critical comments about the 2019 and 2020 NTP reports does not provide a basis to forego considering them, or the May 2022 report. To the contrary, the NASEM peer reviews provide additional justification for the Court to consider these reports, as the peer reviews will enable the Court to fully assess the NTP monograph's strengths and weaknesses. Plaintiffs welcome the Court's consideration of NASEM's evaluation, as many of NASEM's criticisms highlight areas where NTP's analysis *understated* the evidence of fluoride neurotoxicity, particularly at *low levels of exposure*.[9]

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[7] *See* Exhibit C to Pls' Motion.

[8] The Plaintiffs do not yet have a copy of the May 2022 report, but intend to seek leave of this Court to obtain it through discovery. Separately, one of the Plaintiffs to this action (Kristin Lavelle) is seeking to obtain the report through a FOIA complaint that the undersigned counsel recently filed in this District. *See* Exhibit M to Pls' Mot.

[9] For example, NASEM criticized NTP's 2019 report for stating that fluoride's neurotoxic effects are mostly associated with higher fluoride levels than are used for water fluoridation. As NASEM explained, the downplaying of neurotoxicity hazards at low levels "seems to contradict the earlier assertion [by NTP] that nearly all studies are positive including ones that evaluated groups exposed to lower concentrations." **Exhibit T**, at 44. NASEM made a similar criticism of NTP's 2020 analysis, explaining that NTP did not do the kind of "full dose-response assessment" that would permit NTP to make any conclusions about the hazard at low levels. **Exhibit U**, at 14. Plaintiffs agree with NASEM on both of these critical points, and intend to introduce expert testimony to further elaborate on them.

Moreover, the fact that NASEM identified some weaknesses with NTP's monograph does not negate the substantial probative information that NTP's comprehensive assessment will provide for the Court's determination. Indeed, if criticisms from NASEM were fatal to a hazard assessment, all of EPA's risk evaluations under the amended TSCA would need to be stricken, given NASEM's withering criticism of the systematic review method that EPA used for these assessments. According to NASEM, EPA's systematic review methodology is "not comprehensive," "lack[s] objectivity at each step," is "compromised" in its transparency, and "d[oes] not meet the standards of systematic review methodology." **Exhibit V** (NASEM's Peer Review), at 5-8. Despite these criticisms from NASEM, EPA is moving forward (and rightly so) with rulemaking proceedings to protect the public from the risks identified in these evaluations. To not move forward with rulemaking proceedings to protect the public from these risks would be letting the perfect be the enemy of the good. The same principle holds for NTP's currently available monographs on fluoride and this Court's determination of the risk.

E. EPA Fails to Identify Any Persuasive Reason for Not Having a Phase Two Trial on the Current State of the Science

EPA advances a number of arguments for why this Court should not hold a phase two trial on the current state of the science, including the NTP monograph from May 2022 that was 7 days away from being released. None of EPA's arguments are persuasive.

First, EPA contends that Plaintiffs fail to justify their request for a second round of expert discovery and trial. Opp Br. at 14:27-28. However, it was the Court that first identified the need for further trial if EPA declined to reconsider its position based on the new evidence. At the hearing on Plaintiffs' motion to amend the complaint, the Court stated that if EPA declines to reconsider its position, "my intent would be to reopen the record, and we're going to have a sort of phase-two trial." ECF No. 311 at 15:2-6. Under ordinary rules of civil litigation, expert testimony requires expert discovery. *See* FRCP 26(a)(2). The Court recognized this in its order granting Plaintiffs' motion: "As this Court has indicated, the evolving science warrants reopening of *expert discovery* and trial evidence." ECF No. 290 at 11:15-16 (emphasis added).

Second, contrary to EPA's characterization, Plaintiffs do not seek "far-ranging post-trial discovery." Opp. Br. at 11:25-26. Plaintiffs are willing to forego any additional fact discovery, with the

limited exception of obtaining a copy of the May 2022 NTP report. Producing a single document can hardly be deemed "far ranging." With the exception of this single document, the discovery would be limited to the exchange of expert reports and expert depositions, a process that can be completed within a relatively short period of time (i.e., 1 to 2 months).

Third, EPA contends that "[t]he Court never suggested that the parties would be permitted to introduce all scientific research published since the June 2020 trial." Opp Br. at 12:17-19. The Court stated, however, that "whatever you would have wanted to present, you'll have a chance" at the phase two trial. ECF No. 8:1-2. That said, Plaintiffs have conferred with EPA and offered to limit the post-trial studies to only those that were previously identified by the Court. **Exhibit W** (Email Exchange with EPA's Counsel). Despite this, EPA stated it will still oppose Plaintiffs' proposed course of action. (*Id.*) While Plaintiffs remain amenable to limiting the scope of the post-trial research, Plaintiffs believe the question of which studies should be addressed is most appropriately left to the parties' respective experts.[10]

Fourth, EPA claims that Plaintiffs should be estopped from asking the Court to consider the currently available NTP reports based on Plaintiffs' opposition to EPA's motion to undo the trial schedule back in 2019. Opp. Br. at 11. Plaintiffs' opposition to that motion was based on unique considerations that are not present here, including whether a draft report that had not yet undergone peer review (as opposed to *three* rounds of peer review) justifies undoing the schedule for dispositive motions and trial (a schedule that was the subject of extensive negotiations and which EPA had agreed to just seven days prior to filing its motion). ECF No. 114 at 2:5-21. Further, while Plaintiffs did note the reduced trustworthiness of draft reports, Plaintiffs did *not* object to the Court considering the non-peer reviewed draft. *See id.* at 3:19-21 (stating that the draft monograph should be given "whatever due weight [the Court] deems appropriate").

Fifth, in its attempt to avoid additional discovery EPA resorts to arguments of statutory construction that the Court soundly rejected when denying EPA's motion to limit discovery to the administrative record.

[10] One of the studies that Plaintiffs believe will be probative to the issues before the Court is a new birth cohort study from the PROGRESS cohort in Mexico which has confirmed an association between maternal fluoride exposure and reduced IQ in the offspring. The relationship between maternal fluoride exposure and reduced IQ in offspring has thus now been demonstrated in three separate birth cohorts. *See* Cantoral A, et al. Dietary fluoride intake during pregnancy and neurodevelopment in toddlers: A prospective study in the progress cohort. *Neurotoxicology.* 2021 Dec;87:86-93.

Opp Br. at 12-13; *Food & Water Watch*, 302 F. Supp. 3d at 1062-71. In addition to the plain meaning of the statute, which EPA again ignores, the legislative history makes clear that Congress *wanted* the district court to "gather[] evidence" and that a "de novo procedure is essential to provide the opportunity to develop . . . a record." S. Rep. No. 94-698, at 9, 13 (1976), reprinted in 1976 U.S.C.C.A.N. 4491, at 4499, 4503.

Finally, EPA contends that it will be "unfairly prejudiced" if it has to engage in additional expert discovery and trial. In support of this contention, EPA notes it has already spent $450,000 in expert fees; one of its litigation experts from Exponent (Ellen Chang) can apparently no longer be an expert in this case; and EPA may need to find another scientist to address the recent science. Opp. Br. at 14. These facts hardly amount to undue prejudice, particularly when judged against the policy interests that TSCA was enacted to advance. Indeed, EPA's articulation of prejudice, including its frustration at having to find a scientist who can address the recent science on fluoride, evokes the kind of "bureaucratic lethargy" that Section 21 was designed to protect against. *Food & Water Watch*, 291 F. Supp. 3d at 1048 (quoting *Reilly*, 909 F.2d at 1499). Further, EPA's concern that its work on this case may interfere with its work under Section 6, suggests an Agency which views its responsibilities under Section 21 as somehow of lesser importance or priority than its responsibilities under Section 6. But there is nothing in the statute that would justify this treatment. Additionally, although EPA suggests that lack of funding has been the major barrier to carrying out its responsibilities under TSCA, Adkins Decl., Ex. A, a recent survey of EPA employees who work in the office that enforces TSCA[11] as well as recent whistleblower complaints,[12, 13] suggest that lack of fiscal

[11] 60.4% of EPA's employees who work in the Office of Pollution Prevention and Toxics (OPPT) expressed a "negative" view when asked whether the "organization's senior leaders maintain high standards of honesty and integrity," according to a recent Federal Employee Viewpoint Survey conducted by the U.S. Office of Personnel Management. **Exhibit X.** The negative response in the OPPT office (the office that enforces TSCA) was substantially higher than in EPA as a whole (60.4% vs. 28.1%). *Id.* at 2.

[12] Four EPA scientists who work in the Office of Chemical Safety and Pollution Prevention (the office which houses the OPPT) have filed complaints alleging "fraud and corruption in OCSPP, involving deliberate tampering with chemical risk assessments conducted under the Toxic Substances Control Act (TSCA) . . . and the deletion of potential health effects without the knowledge or consent of the human health assessors." **Exhibit Y**, at 1. The four whistleblowers allege that the problems "are not due solely to the Trump Administration and its appointees," as similar issues existed "prior to Trump taking office" and the problems "continue under the current administration." *Id.* at 2.

[13] Dr. Tala Henry, one of EPA's testifying experts in this case, *see* Exhibit S, has been identified as one of the EPA officials who "played a significant role in pressuring scientists to dismiss the risks posed by products the EPA is assessing." **Exhibit Z.**

resources is not the only, or even central, barrier to EPA fulfilling its obligations under TSCA.

III. CONCLUSION

Plaintiffs appreciate the Court's reasonable desire to consider NTP's expert assessment of the science before rendering its decision. Plaintiffs have thus been prepared, these past 2+ years, to wait for NTP's "final" report to be released. The "final" report that the parties and the Court have been waiting for was completed in May of 2022 after *three* rounds of external peer review, but this completed report was, unfortunately, not released. Now, as evident by Dr. Woychik's declaration, there is no longer any meaningful guarantee that a report will ever be released, and *if* it is released, there is no clear or definite timeframe on when that will be. Given these circumstances, it would be contrary to the public policy interests that underlie TSCA to continue conditioning the resolution of this action on the official release of a "final" report from NTP.

For these reasons, Plaintiffs respectfully request that the Court either rule on the trial record as is (as supplemented by Plaintiffs' supplemental evidence on standing), or schedule a phase two trial where the parties' experts can address the scientific developments that have occurred since the June 2020 trial, including the NTP's May 2022 assessment, which is the most thoroughly peer reviewed NTP monograph in NTP's history. This latter course of action will provide the Court with a fully vetted assessment of the most up-to-date science, and will, in turn, provide an abundantly sufficient evidentiary basis to either affirm, or negate, a risk determination under Section 21.

October 3, 2022

Respectfully submitted,

/s/ Michael Connett
MICHAEL CONNETT
Attorney for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served by Notice of Electronic Filing this 3rd day of October, 2022, upon all ECF registered counsel of record using the Court's CM/ECF system.

/s/ Michael Connett
MICHAEL CONNETT