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

13 FOOD & WATER WATCH, et al.,

14 Plaintiffs,

15 vs.

16 U.S. ENVIRONMENTAL PROTECTION  
17 AGENCY, et al.

18 Defendants.

19 ) Civ. No. 17-CV-02162-EMC

20 ) **PLAINTIFFS' MOTION TO LIFT THE**  
21 ) **STAY AND TAKE THE CASE OUT OF**  
22 ) **ABEYANCE**

23 ) Judge: Hon. Edward M. Chen

24 ) Date: October 20, 2022

25 ) Time: 1:30 p.m.

26 ) Courtroom: Via Zoom Webinar

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## I. INTRODUCTION

1  
2 Plaintiffs Food & Water Watch *et al.* respectfully request that the Court lift the stay that was entered  
3 on August 10, 2020 and take this case out of abeyance. “Courts within the Ninth Circuit have recognized  
4 that ‘the court may abandon its imposed stay of litigation if the circumstances that persuaded the court to  
5 impose the stay in the first place have changed significantly.’” *Tribe v. U.S. Bureau of Reclamation*, No.  
6 19-CV-04405-WHO, 2021 WL 4482117, at \*3 (N.D. Cal. Sept. 30, 2021) (citation omitted). Here, the four  
7 circumstances that persuaded the Court to stay the case over two years ago have changed *significantly*.

8  
9 First, the Court’s concerns with Plaintiffs’ standing have been addressed by the supplementation of  
10 the pleadings which, as the Court observed, “do appear to cure the complaint’s standing deficiencies.” ECF  
11 No. 262 at 1-3; ECF No. 290 at 7 fn 2. Second, two of the then unpublished studies that the Court placed  
12 the case in abeyance in order to consider (i.e., the pooled analysis and the Spanish study) have now been  
13 published. ECF No. 262 at 4:23-26; ECF No. 291; ECF No. 299 at 2:8-9. Third, the Court’s interest in  
14 giving EPA an opportunity to reconsider its denial of Plaintiffs’ petition in light of new science (e.g., the  
15 ELEMENT/MIREC studies) published after the denial, has been satisfied by Plaintiffs’ submission of a  
16 supplemental petition, which EPA considered and denied. ECF No. 262 at 5; ECF 270-1; ECF No. 278-1.  
17 Fourth, the Court’s interest in considering the expert assessment of the National Toxicology Program  
18 (NTP) has been satisfied by the NTP’s release of a thorough systematic review of fluoride’s  
19 neurodevelopmental effects. ECF No. 262 at 4:19-22; ECF 270-4. Although the NTP has not yet publicly  
20 released a “final” version of this report, the report that NTP released in September 2020 *is the expert*  
21 *assessment of NTP’s scientists*. Not all stakeholders have agreed with NTP’s expert assessment, but the  
22 Court has recognized that the NTP is an authoritative source of information, and has suggested that even  
23 its “proposed findings” are “likely to add substantially to the body of scientific analysis relevant to the  
24 precise questions before this court.” ECF No. 262 at 4:19-22; ECF No. 264 at 18:22-25.  
25  
26

27 Finally, the Court should no longer wait for a “final” version of the NTP report because—based on  
28

1 recent developments that are described herein—it is now unclear when, if *ever*, a “final” version will be  
2 released. Waiting for a “final” NTP report will thus keep this case in an *indefinite and potentially permanent*  
3 stay, which runs afoul of the Ninth Circuit’s guidance that “stays should not be indefinite in nature.”  
4 *Dependable Highway Exp., Inc. v. Navigators Ins. Co.*, 498 F.3d 1059, 1066 (9th Cir. 2007).

5 For these reasons, and as explained more fully herein, Plaintiffs request that the Court take this case  
6 out of abeyance and set a schedule for supplemental expert discovery and an abbreviated second trial where  
7 experts from both sides can summarize for the Court the scientific research that has been published since  
8 the June 2020 trial, including the pooled benchmark dose analysis of the ELEMENT/MIREC studies, the  
9 Spanish study, the NTP’s systematic review (and peer reviews thereof), and 10 additional studies that have  
10 found significant associations between fluoride exposure and reduced IQ in human populations. Through  
11 this abbreviated second trial, the Court’s ultimate determination will be informed by the expert judgment  
12 of NTP’s scientists, the peer reviews of NTP’s assessment, and other relevant research that has been  
13 published subsequent to the trial, all as explained through qualified expert testimony and the crucible of  
14 cross examination.  
15

## 16 **II. FACTUAL AND PROCEDURAL BACKGROUND**

### 17 **A. Procedural History Up Through the Stay**

18 On November 22, 2016, Plaintiffs submitted a citizen petition under Section 21 of the Toxic  
19 Substances Control Act (“TSCA”; 15 U.S.C.A. §2620), requesting that the Environmental Protection  
20 Agency (“EPA”) prohibit the addition of fluoridation chemicals to drinking water in order to protect the  
21 public, including susceptible subpopulations, from neurotoxic risks. ECF No. 28-1. In February 2017, EPA  
22 denied this request and Plaintiffs thereupon commenced this action. *Food & Water Watch, Inc. v. United*  
23 *States Env’t Prot. Agency*, 291 F. Supp. 3d 1033, 1037–38 (N.D. Cal. 2017)  
24

25 On February 7, 2018, the Court denied EPA’s motion to limit the evidence in this “de novo  
26 proceeding” to the administrative record. *Food & Water Watch, Inc. v. United States Env’t Prot. Agency*,

1 302 F. Supp. 3d 1058 (N.D. Cal. 2018). Thereupon, the parties engaged in fact and expert discovery, and  
2 on June 8, 2020, the Court held a 7-day bench trial in which expert testimony was offered regarding the  
3 state of science on fluoride’s neurotoxicity.<sup>1</sup> Much of the expert testimony at trial focused on the results of  
4 the recent “ELEMENT” and “MIREC” studies funded by the National Institutes of Health (“NIH”) that  
5 found significant associations between early-life fluoride exposures and adverse neurodevelopmental  
6 effects in North American populations. ECF No. 262 at 1:15-2:3 & 4:4-18.

7 On June 17, 2020, after the conclusion of the trial, the Court noted that the Plaintiffs had presented  
8 “serious evidence” which raises “serious questions” about the safety of fluoridation chemicals in drinking  
9 water. ECF No. 245 at 1133:5-23. The Court further observed, in a subsequent written order, that “even  
10 EPA acknowledges that [the ELEMENT and MIREC] studies are the highest quality, most reliable studies  
11 to date on the subject.” ECF No. 262 at 4:6-18.

12 Although recognizing the quality and significance of the scientific evidence that Plaintiffs’ experts  
13 presented at trial, the Court exercised its discretion to place the case in abeyance. ECF No. 262. The Court  
14 entered stay for the following reasons:  
15

16 First, the trial evidence raised questions for the Court about whether Plaintiffs had standing, given  
17 that the evidence focused on harm from prenatal/infant exposures, whereas Plaintiffs’ personal injuries had  
18 been articulated as arising from adolescent/adult exposures. ECF No. 262 at 1-3. The Court invited further  
19 development of the record if “intervening developments” confirmed Plaintiffs had standing. ECF No. 264  
20 at 26:9-13; ECF No. 290 at 9:13-15.  
21

22 Second, the Court noted that the ELEMENT and MIREC studies were not published until after the  
23 EPA had denied Plaintiffs’ administrative petition. ECF No. 262 at 4:1-6. In light of the significance of this  
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25  
26  
27 <sup>1</sup> The transcripts of the trial are available at ECF No. 239 (June 8, 2020), ECF No. 240 (June 9, 2020),  
ECF No. 241 (June 10, 2020), ECF No. 242 (June 12, 2020), ECF No. 243 (June 15, 2020), ECF No. 244  
(June 16, 2020), and ECF No. 245 (June 17, 2020).

1 new evidence, the Court reasoned it would be prudent to permit the Agency to reconsider its denial,  
2 particularly since the Agency had previously used the wrong standard of review to assess the risk. ECF No.  
3 262 at 4:27-5:3; ECF No. 245 at 1131:5-9, 1132:18-21, 1133:5-23, 1137:1-22. The Court thus instructed  
4 Plaintiffs to submit another petition to EPA that presented the Agency with the studies published after  
5 February 2017. ECF No. 262 at 4:27-28.<sup>2</sup>

6 Third, the Court noted that the anticipated “imminent” publication of the National Toxicology  
7 Program’s (“NTP”) systematic review on fluoride neurotoxicity is “likely to add substantially to the body  
8 of scientific analysis relevant to the precise questions before this court.” *Id.* at 4:19-22. The Court was  
9 aware that the revised NTP report would undergo another round of peer review, but suggested that even  
10 NTP’s “proposed findings” would be probative to the Court’s assessment. *Id.*; *see also* ECF No. 264 at  
11 18:22-25 (noting that an analysis by NTP would be “at least presumptively, a credible thorough source or  
12 assessment”).  
13

14 Fourth, the Court noted that “there may be other developments that are also impending and which  
15 would shed important light on the issues contested in this case (e.g., pooling of the MIREC/ELEMENT  
16 data, publication of the Spanish birth cohort studies study, etc.).” ECF No. 262 at 4:23-26.  
17

18 Although the Court did not set a date for when the stay would be lifted, the Court’s expectation was  
19 that the stay would last for “months, not years.” ECF No. 245 at 1145:5-12; *see also id.* at 1137:22-23.

## 20 **B. Developments Since the Court Placed the Case in Abeyance**

### 21 1. Standing

22 On February 19, 2021, Plaintiffs filed a motion to amend their complaint with supplemental  
23  
24

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25 <sup>2</sup> The Court recognized that TSCA does not require Plaintiffs to provide EPA with an administrative  
26 opportunity to consider new evidence before the Court can make a ruling under Section 21. ECF No. 245,  
27 at 1132:8-10. However, the Court expressed a concern that Congress may not have “contemplated a  
28 situation where the record before the Court under a Section 21 petition is very, very different and has  
evolved substantially differently than what was presented [in the petition].” *Id.* at 1132:8-14.

1 pleadings on standing. ECF No. 279. The supplemental pleadings set forth, *inter alia*, that one of the  
2 original standing declarants, Jessica Trader, was of child-bearing age, had recently become pregnant with  
3 her first child, and planned to have several more children. ECF No. 279-1, ¶¶ 40-45. Ms. Trader was thus  
4 in the class of persons that EPA had previously conceded would have standing to litigate the instant action.  
5 ECF No. 133 at 14:9-17. On May 11, 2021, the Court granted Plaintiffs' motion to supplement the  
6 complaint with these pleadings. In its order, the Court noted that the supplemental pleadings "do appear to  
7 cure the complaint's standing deficiencies," but invited EPA to file a motion to dismiss if the Agency  
8 contested the pleadings' sufficiency. ECF No. 290 at 7 fn 2 & 15:3-4. The EPA did not file a motion. As  
9 noted in the parties' Joint Status Report on September 7, 2021, "EPA did not file a motion to dismiss the  
10 supplemental allegations for lack of standing and respectfully reserves the right to seek discovery." ECF  
11 No. 295 at 2:7.

## 12 13 2. Pooled Analysis and Spanish Study

14 Two of the studies that the Court had flagged as relevant to the Court's determination of the issues  
15 in this case have now been published. The pooled benchmark dose analysis of the ELEMENT and MIREC  
16 birth cohort data was published on June 8, 2021 in the journal *Risk Analysis*. ECF No. 291.<sup>3</sup> The Spanish  
17 birth cohort study was published in October 2021 in the journal *Environmental Research*. ECF No. 299 at  
18 2:8-9.

## 19 20 3. The NTP's Revised Systematic Review (Sept. 2020)

21 In September 2020, shortly after the Court entered the stay, the National Toxicology Program (NTP)  
22 released a revised version of its systematic review on fluoride's neurodevelopmental toxicity.<sup>4</sup> The revised  
23 draft, which was written by NTP scientists and approved by NTP leadership, incorporated the peer review  
24 input that NTP had received from the National Academy of Sciences, Engineering & Medicine (NASEM)  
25

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26  
27 <sup>3</sup> Plaintiffs have filed a copy of this pooled analysis with the Court. ECF No. 291-1.

<sup>4</sup> Plaintiffs have filed a copy of the NTP's 2020 report with the Court. ECF 270-4.



1 earlier that year. **Exhibit A.**<sup>5</sup> As with the first version of the report, the NTP concluded that fluoride is a  
2 presumptive neurotoxic hazard to humans (i.e., “fluoride is presumed to be a cognitive neurodevelopmental  
3 hazard to humans”). **Exhibit B**, at 1. NTP based this conclusion on the fact that “the human body of  
4 evidence provides a consistent and robust pattern of findings that higher fluoride exposure (e.g., >1.5 mg/L  
5 in drinking water) is associated with adverse effects on neurocognitive development, including lower  
6 intelligence quotient (IQ) in children.” *Id.* at 2. Given the “consistent and robust pattern of findings,” NTP  
7 had a “low expectation that new studies would decrease the hazard conclusion.” *Id.* at 68.

#### 8 4. Supplemental Petition to EPA

9  
10 On November 4, 2020, Plaintiffs filed a supplemental petition to the EPA that asked the Agency to  
11 reconsider its previous denial.<sup>6</sup> Plaintiffs based their request for reconsideration on two primary grounds:  
12 (1) EPA’s expert (Tala Henry) had conceded at trial that EPA had used the wrong standard to assess  
13 Plaintiffs’ evidence of risk; and (2) the ELEMENT/MIREC studies and NTP’s revised systematic review  
14 provide compelling new evidence that neurotoxicity is a hazard of fluoride, and that this hazard is a risk at  
15 the exposure levels associated with water fluoridation. ECF 270-1.

16  
17 On January 19, 2021, EPA responded to Plaintiffs’ supplemental petition. After acknowledging it  
18 had discretion to reopen the administrative record and consider the new evidence, EPA declined to do so,  
19 citing the agency’s many other priorities, including three risk evaluations requested by manufacturers. ECF  
20 No. 278-1 at 2. Although declining to formally consider the petition, EPA noted that its “position  
21 concerning the evidence presented at trial has not changed.” ECF No. 278-1 at 4.

#### 22 **C. Current Status of the NTP’s Systematic Review**

23  
24 As noted above, the NTP released a revised version of its systematic review in September 2020.

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25  
26 <sup>5</sup> All exhibits cited herein are attached to the declaration by Michael Connett, which is being filed  
concurrently herewith (hereafter, “Connett Decl.”)

27 <sup>6</sup> Plaintiffs filed a copy of their Supplemental Petition with the Court on November 4, 2020. ECF 270-  
1, 270-2, 270-3, 270-4, 270-5, 270-6, 270-7, 270-8, and 270-9.

1 The NTP then submitted this revised draft back to NASEM for another peer review, which NASEM  
2 completed in February 2021.

3 NASEM's second round of peer review comments were incorporated by NTP in a revised  
4 systematic review that the NTP completed by November 2021. In November 2021, the NTP sent the revised  
5 "State of the Science" report for one final round of peer review. **Exhibit C.** The peer reviewers for this  
6 third, and final, round of peer review were five scientists from outside the government. *Id.*

7 In January of 2022, the NTP informed the Department of Justice that "pending general reviewer  
8 agreement with our document, we anticipate public availability of a revised final state of the science report  
9 by the end of March [2022]." *Id.* The parties relayed this status update to the Court in a Joint Status Report  
10 that they filed on January 10, 2022. ECF No. 299 at 2:1-2.

11 On February 22, 2022, Plaintiffs' counsel was informed by an individual with knowledge of NTP's  
12 proceedings that the NTP had received the 5 external peer reviewers' comments, and that "the target for  
13 posting the final monograph is the first week in April." Connett Decl. ¶ 2. On April 11, 2022, Plaintiffs'  
14 counsel was informed by this same individual that the NTP was now in the "phase" of compiling  
15 communications materials, with the implication that the report itself was completed. *Id.* ¶ 3. On May 11,  
16 2018, Plaintiffs' counsel was informed by this individual that the final report was going to be publicly  
17 released in 7 days, i.e., on May 18, 2022. *Id.* ¶ 4.

18 The NTP did not release its (triple-peer reviewed) report on May 18, 2022. *Id.* ¶ 5.

19 On May 27, 2022, the parties filed a Joint Status Report with the Court which stated that "the parties  
20 understand that the National Toxicology Program (NTP) will be releasing its systematic review on fluoride  
21 neurotoxicity soon, but possibly not prior to June 7, 2022." ECF No. 302 at 1:23-25. In a follow-up status  
22 report on June 7, 2022, the parties informed the Court that "The National Toxicology Program's (NTP)  
23 Monograph has not yet been published, but the parties understand that it will be released soon." ECF No.  
24 304 at 1:14-15.

1 In July 2022, Plaintiffs' counsel learned from an individual with knowledge of NTP's proceedings,  
 2 that the NTP had submitted its report for yet another round of review. Connett Decl. ¶ 6. This time the  
 3 review is being conducted by federal agencies which Plaintiffs' counsel understands to include the Centers  
 4 for Disease Control (CDC) and National Institute for Dental & Craniofacial Research (NIDCR). *Id.*  
 5 Plaintiffs' counsel has been informed that this new round of "inter agency review" has no identified due  
 6 date for completion, and the date of publication for NTP's report is now unknown. *Id.*

#### 7 **D. Concern About Political Pressures**

8 Plaintiffs are concerned about the potential for the inter agency review to introduce political  
 9 pressures into what should be a strictly scientific endeavor. It is a matter of public record that the CDC and  
 10 NIDCR are partisans on the fluoridation issue, as both organizations have a long history of promoting  
 11 fluoridation as a measure to reduce tooth decay.<sup>7, 8</sup>

12 Documents obtained under the Freedom of Information Act ("FOIA") confirm that these agencies,  
 13 and their partners outside of government, are concerned about the impact the NTP's report could have on  
 14 water fluoridation, and have been working to mitigate that impact. For example:  
 15

16 An October 20, 2020 email from NIDCR's Chief of Programs Analysis and Program Branch,  
 17 Timothy Iafolla, to NIDCR's Director, Rena D'Souza, expresses concern about "the potential impact of  
 18

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19  
 20 <sup>7</sup> The CDC's 30(b)(6) representative in this litigation agreed that CDC "has taken an active role in  
 21 promoting water fluoridation." **Exhibit D**, at 19:5-7. CDC's website, for example, contains a page titled  
 22 "Water Fluoridation Promotional Resources" which provides infographics, animated graphics, and  
 23 "messages for social media" to help in the promotional effort for fluoridation. See  
<https://www.cdc.gov/fluoridation/resources/index.html>. In addition to promoting fluoridation, the CDC  
 works to develop technologies that will increase the number of U.S. water systems that add fluoride  
 chemicals. See <https://www.cdc.gov/media/releases/2021/p0318-Fluoridation.html> (discussing CDC's  
 initiative to create dissolvable fluoride tablets to permit small water systems to fluoridate their water).

24 <sup>8</sup> See, e.g., [https://www.nidcr.nih.gov/sites/default/files/2022-01/NIDCR-Strategic-Plan-2021-](https://www.nidcr.nih.gov/sites/default/files/2022-01/NIDCR-Strategic-Plan-2021-2026.pdf)  
 25 [2026.pdf](https://www.nidcr.nih.gov/sites/default/files/2022-01/NIDCR-Strategic-Plan-2021-2026.pdf) ("Almost 75 years [after its formation], NIDCR can point to significant advances and  
 26 accomplishments to improve the oral health of the nation. NIDCR funding helped establish community  
 27 water fluoridation as a safe, effective, and economical intervention for the control of dental caries.");  
<https://www.nidcr.nih.gov/health-info/fluoride/the-story-of-fluoridation> ("It started as an observation, that  
 soon took the shape of an idea. It ended, five decades later, as a scientific revolution that shot dentistry into  
 the forefront of preventive medicine. This is the story of how dental science discovered-and ultimately  
 proved to the world-that fluoride, a mineral found in rocks and soil, prevents tooth decay.").

1 [the NTP’s] conclusions on the messaging around community water fluoridation.” **Exhibit E.**

2 A February 3, 2021 email from Christine Flowers, the Director of Communications for the National  
3 Institute of Environmental Health Sciences (NIEHS),<sup>9</sup> states: “in all our back-and-forth with NIH, NIDCR,  
4 and HHS, this is the language that they went back to over and over again as what needed to be included in  
5 a public statement regarding this report [redacted].” **Exhibit F.**

6 On February 8, 2021, officials at the NIDCR gleefully celebrated news that the NTP would not be  
7 making hazard conclusions in its final report. NIDCR’s Acting Deputy Director, Jonathan Horsford, wrote:  
8 “Great news – NTP has decided to revise the monograph and remove the statement that ‘F is a presumed  
9 hazard.’” NIDCR’s Timothy Iafolla responded: “Wow – this is huge. I wish I’d been a fly on the wall for  
10 this discussion, but it’s a game changer for the response to the report.” **Exhibit G.**

11 On February 5, 2021, NIEHS’s Christine Flowers writes to other colleagues at NIEHS: “[Y]ou  
12 shouldn’t be surprised if someone at NIDCR gets out a message something like ‘fluoride in water is still  
13 great and there’s no reason to change this successful public health initiative based on a report twice rejected  
14 by NASEM.’ That’s what I expect will be the CDC response too—worded more softly perhaps.” **Exhibit**  
15  
16  
17 **H.**

18 On February 22, 2021, several weeks after an NIDCR official mentioned sharing the NASEM peer  
19 review with “our advocacy groups,” **Exhibit I**,<sup>10</sup> a pro-fluoride advocacy group sends a letter to NIEHS  
20 lambasting the institute for its fluoride report. **Exhibit J.** The letter states: “We write to ask that you require  
21 the NTP 2019 and 2020 fluoride monographs, or publications based on them, not to be published on any  
22 NIH-related website” due to the detrimental impact the NTP reports could have on fluoridation promotion  
23 efforts. **Exhibit J.** Alternatively, the letter requests that if NTP “insists” on publishing a report, that “each  
24

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25 <sup>9</sup> The NIEHS is the institute in which the National Toxicology Program (NTP) is headquartered.

26 <sup>10</sup> As with the NIDCR, the CDC also works with private advocacy groups to promote fluoridation.  
27 **Exhibit D** at 17-19 (discussing CDC’s work with “external partners” such as the American Dental  
28 Association to promote fluoridation).

1 page bear a watermark that reads: Rejected.” *Id.* NIDCR’s Director, Rena D’Souza, who is cc’ed on the  
2 letter, forwards it to other NIDCR officials, and states “This letter says it all.” *Id.*

3 A few weeks later, a second outside advocacy group emails the NTP, copying NIDCR’s D’Souza,  
4 who then forwards the email to a third outside advocacy group, who responds: “Perfect.” **Exhibit K.**

5 On February 7, 2022, the American Dental Association (ADA) writes a letter to NTP, expressing  
6 its concern that statements by NTP of fluoride being a neurotoxin could “undermine national, state, and  
7 local efforts to expand the practice [of fluoridation].” **Exhibit L.**<sup>11</sup>

#### 8 **E. FOIA Request**

9  
10 On August 9, 2022, after learning that the NTP’s triple-peer reviewed report is undergoing a *fourth*  
11 round of review by agencies that actively promote fluoridation, one of the Plaintiffs in this action (Kristin  
12 Lavelle) submitted a FOIA request to the NIH asking for a copy of the NTP report that was approved for  
13 release on May 18, 2022. **Exhibit M**, ¶¶ 22-23. NIH did not provide a response to this request within the  
14 statutory deadline of 20 working days. *Id.* ¶¶ 24-25. Ms. Lavelle has thus filed a complaint in federal court  
15 (filed in this District as a related case) to compel the disclosure of the report. *Id.* ¶ 1.

#### 16 **F. Meet & Confer with EPA**

17  
18 In August, Plaintiffs met and conferred with EPA about the instant motion and related issues. After  
19 giving it consideration, EPA’s counsel responded: “EPA’s position on your proposed motion is that the  
20 case should come out of abeyance only to be decided on the June 2020 trial record.” **Exhibit N.** The parties  
21 were thus unable to reach agreement because Plaintiffs believe the Court should consider the scientific  
22 developments that have occurred since the June 2020 trial, including the pooled analysis of the  
23 ELEMENT/MIREC data, the Spanish study, the NTP’s systematic review (and the peer reviews thereof),  
24 and other relevant research.  
25

26  
27 <sup>11</sup> This letter was obtained from the ADA’s website, not from a FOIA request. Connett Decl. ¶ 18.

### III. LEGAL STANDARD

1  
2 A district court has “broad discretion” to stay proceedings. *Clinton v. Jones*, 520 U.S. 681, 683  
3 (1997). “The corollary to this power is the ability to lift a stay previously imposed.” *Tribe v. U.S. Bureau*  
4 *of Reclamation*, No. 19-CV-04405-WHO, 2021 WL 4482117, at \*3 (N.D. Cal. Sept. 30, 2021) (citation  
5 omitted). Thus, “[t]he same court that imposes a stay of litigation has the inherent power and discretion to  
6 lift the stay.” *Akeena Solar Inc. v. Zep Solar Inc.*, No. C 09-05040-JSW, 2011 WL 2669453, at \*2 (N.D.  
7 Cal. July 7, 2011) (quoting *Canady v. Erbe Elektromedizin GmbH*, 271 F.Supp.2d 64, 74 (D.D.C.2002)).

8  
9 “Courts within the Ninth Circuit have recognized that ‘the court may abandon its imposed stay of  
10 litigation if the circumstances that persuaded the court to impose the stay in the first place have changed  
11 significantly.’” *Tribe*, 2021 WL 4vc482117, at \*3 (quoting *United States v. Fallbrook Pub. Util. Dist.*, No.  
12 51-cv-1247, 2017 WL 1281915, at \*2 (S.D. Cal. April 6, 2017)); *see also Canady*, 271 F.Supp.2d at 74  
13 (“When circumstances have changed such that the court’s reasons for imposing the stay no longer exist or  
14 are inappropriate, the court may lift the stay.”).

15  
16 One of the important factors that courts look to when assessing a stay is the length of time it will  
17 remain in effect. As the Ninth Circuit has explained, “[w]hen reviewing a stay order such as that issued in  
18 this case, we balance the length of the stay against the strength of the justification given for it. If a stay is  
19 especially long or its term is indefinite, we require a greater showing to justify it.” *Yong v. I.N.S.*, 208 F.3d  
20 1116, 1119 (9th Cir. 2000) (citing *Landis v. N. Am. Co.*, 299 U.S. 248, 257 (1936) & *Hines v. D’Artois*,  
21 531 F.2d 726, 733 (5th Cir. 1976)). When a stay cannot be assured to be completed within “reasonable  
22 limits,” the “fetters should fall off.” *Landis*, 299 U.S. at 257.

23  
24 According to the Ninth Circuit, “[g]enerally, stays should not be indefinite in nature.” *Dependable*  
25 *Highway Exp., Inc. v. Navigators Ins. Co.*, 498 F.3d 1059, 1066 (9th Cir. 2007). In *Dependable Highway*,  
26 the Ninth Circuit struck a stay that had been in effect for two years, because there was “no specific deadline  
27 for when the stay will terminate” and the related proceedings had an unknown completion date. *Id.* at 1067;

1 *see also S.E.C. v. Deloitte Touche Tohmatsu CPA Ltd.*, 940 F. Supp. 2d 10, 12 (D.D.C. 2013) (“[I]f the  
2 stay is of ‘indefinite duration,’ the party must establish a ‘pressing need’ for it.”).

3 In addition to the length of the stay, courts also look to whether the stay could harm the interests of  
4 one of the parties. As the Ninth Circuit has noted, “if there is even a fair possibility that the stay . . . will  
5 work damage to someone else,’ the stay may be inappropriate absent a showing by the moving party of  
6 ‘hardship or inequity.’” *Dependable Highway*, 498 F.3d at 1066 (quoting *Landis*, 299 U.S. at 257).

#### 7 **IV. ARGUMENT**

##### 8 **A. The Circumstances that Prompted the Stay Have Changed Significantly and No Longer 9 Justify a Stay**

10 The stay of this litigation should be lifted because “the circumstances that persuaded the court to  
11 impose the stay in the first place have changed significantly.” *Tribe*, 2021 WL 4482117, at \*3. As discussed  
12 herein, each of the four concerns that prompted the Court to enter the stay have been addressed by  
13 subsequent developments.

14 First, Plaintiffs have supplemented the pleadings to add facts of Jessica Trader’s pregnancy, and  
15 expected additional pregnancies, that address the Court’s concern about Plaintiffs’ standing. ECF No. 279,  
16 ECF No. 279-1, ¶¶ 40-45, ECF No. 290 at 7 fn 2. As the Court noted in its order granting Plaintiffs’ motion  
17 to amend the complaint, the supplemental pleadings “do appear to cure the complaint’s standing  
18 deficiencies.” ECF No. 290 at 7 fn 2. Although the Court allowed the EPA to file a motion to dismiss the  
19 amended complaint on the merits, *id.*, the EPA did not do so. ECF No. 295 at 2:7.<sup>12</sup> The Court’s concerns  
20 about standing have thus been addressed.

21 Second, two of the studies which the Court expected “would shed important light on the issues  
22 contested in this case,” i.e., the “pooling of the MIREC/ELEMENT data” and “publication of the Spanish  
23

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25  
26 <sup>12</sup> EPA’s decision to not challenge the sufficiency of the pleadings is consistent with EPA’s prior  
27 concessions that a woman who is pregnant, or expecting to become pregnant, would have standing to bring  
28 this action. ECF No. 133 at 14:9-17, ECF No. 248 at 2:2-7.

1 birth cohort studies study,” have now been published. ECF No. 262 at 4:23-26; ECF No. 291, ECF No.  
2 299.

3 Third, the NTP released a revised systematic review of fluoride neurotoxicity in September 2020.  
4 ECF No. 270-4. This report provides the Court with the assessment of *NTP’s scientists*, which, as the Court  
5 noted when it entered the stay, is “likely to add substantially to the body of scientific analysis relevant to  
6 the precise questions before this court.” ECF No. 262 at 4:19-22. The Court’s interest in considering how  
7 *NTP’s scientists* view the science on fluoride neurotoxicity has thus been addressed as the NTP’s 2020  
8 report provides just that: the expert assessment of *the NTP*.

9  
10 Fourth, pursuant to the Court’s instruction, the Plaintiffs submitted a supplemental petition to the  
11 EPA to give the Agency the *opportunity* to reconsider its prior denial given the emergence of the NTP’s  
12 systematic review and the ELEMENT and MIREC studies. ECF 270-1. While EPA declined to seize this  
13 opportunity, ECF No. 278-1, the Court’s prudential interest in administrative exhaustion has been satisfied.  
14 ECF No. 245 at 1132:8-14.

15 Given these developments, “the court’s reasons for imposing the stay no longer exist.” *Canady*, 271  
16 F.Supp.2d at 74. Accordingly, the case should be taken out of abeyance.

17  
18 **B. Waiting for a “Final” NTP Report Will Cause Indefinite, and Injurious, Delay**

19 Waiting for a “final” report from NTP has proved somewhat akin to waiting for Godot. In January  
20 of this year, Plaintiffs were hopeful that the end was in sight when the NTP stated the report would undergo  
21 a third, and *final*, round of peer review, and that the report would likely be released “in March” if there was  
22 “general reviewer agreement.” Exhibit C. Plaintiffs remained hopeful in February, when they learned that  
23 “all” of the reviews were in that the “target posting for posting the monograph is the first week of April.”  
24 Connett Decl. ¶ 2. Plaintiffs also remained hopeful when they learned, in early April, that NTP was in the  
25 “phase” of preparing communications materials. *Id.* ¶ 3. Plaintiffs were even more hopeful when they  
26 learned on May 11, 2022, that the report was complete and would be released in 7 days. *Id.* ¶ 4. But May  
27



1 18 arrived, and the report was not released. *Id.* ¶ 5. So the Plaintiffs went back to waiting for the *triple peer*  
2 *reviewed* report to be released. Then, in July, Plaintiffs learned the report (a) was being submitted for yet  
3 another round of review, (b) the review included agencies that actively promote fluoridation,<sup>13</sup> and (c) and  
4 the review had an indefinite duration. *Id.* ¶ 6. At this point, Plaintiffs’ patience reached its end.

5 The point of waiting for the NTP’s assessment was to allow consideration of a purely scientific  
6 analysis of fluoride neurotoxicity by an authoritative and *neutral* source. The NTP’s 2020 report provided  
7 this analysis, and presumably, the NTP’s May 2022 report does as well. But that same assurance is lacking  
8 now that the content of the NTP report is subject to the review of agencies with strong advocacy interests  
9 on the fluoridation issue. See *supra* Section II.D. The inter-agency review also eliminates any assurance as  
10 to *when* the report will be released, *if ever*.

11  
12 The uncertain and indefinite nature of when the NTP report will be released weighs strongly against  
13 maintaining the stay. *Dependable Highway*, 498 F.3d at 1066 (“Generally, stays should not be indefinite  
14 in nature.”). When the Court placed the case in abeyance, the Court anticipated it would last “months, not  
15 years.” ECF No. 245 at 1145:5-12. But, as with the stay in *Dependable Highway*, the stay has now been in  
16 effect for *two years*, which is far longer than originally contemplated. And, as with the stay in *Dependable*  
17 *Highway*, the related “proceeding” (i.e., the “final” NTP review) still has an unknown completion date. The  
18 timeframe of the “final” report’s release is thus unacceptably indefinite to justify a stay, particularly given  
19 the current context of the 2+ year abeyance.  
20

21 Waiting for a “final” report that *may never be released* is also deeply prejudicial to the interests of  
22 the Plaintiffs. Each year that passes by waiting for a “final” NTP report is a year that Plaintiffs, and the  
23 citizens they represent, continue to incur the risks that this action was filed to address. Worse, if the NTP  
24 report is never released, then staying the case to wait for it would operate as a *de facto* dismissal. The adage  
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26

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27 <sup>13</sup> See *supra* notes 7 and 8.

1 “justice delayed is justice denied” is thus applicable here. At a minimum, there is as “a fair possibility that  
 2 the stay . . . will work damage to” Plaintiffs’ interests, which counsels in favor of lifting the stay.  
 3 *Dependable Highway*, 498 F.3d at 1066.

4 **C. Waiting for a “Final” NTP Report Is Not a Sufficient Basis to Continue the Stay**

5 Finally, the Court is not faced with a situation where lifting the stay will leave it in the dark as to  
 6 what NTP’s scientists think of the current science on fluoride neurotoxicity. Indeed, NTP’s thorough  
 7 assessment of the science from September 2020 will be available for the experts and the Court to consider,  
 8 and the NTP’s updated May 2022 report may also be available as well (subject to the outcome of the  
 9 pending FOIA complaint in this District).<sup>14</sup> Given the availability of these NTP assessments, and the peer  
 10 reviews thereof, there is no “pressing need” to wait for the “final” report. *Deloitte*, 940 F. Supp. 2d at 12  
 11 (“[I]f the stay is of ‘indefinite duration,’ the party must establish a ‘pressing need’ for it.”).

12 While some stakeholders have disagreed with NTP’s assessment,<sup>15</sup> and while some peer reviewers  
 13 have identified areas for improvement, there is no need for Section 21 plaintiffs to demonstrate complete  
 14 unanimity among stakeholders in the scientific community before obtaining relief. The burden for Section  
 15 21 plaintiffs is to prove their case by a “preponderance of the evidence”—nothing more, nothing less. 15  
 16 U.S.C. § 2620(b)(4)(B). Were unanimity required to obtain relief—including among stakeholders with  
 17 *interests adverse to the citizen petitioners*—Section 21 would be a dead letter.

18 **V. CONCLUSION & PROPOSED COURSE OF ACTION**

19 For the foregoing reasons, Plaintiffs respectfully request that the Court lift the stay and take this  
 20 case out of abeyance. In doing so, Plaintiffs propose that the Court set a schedule for supplemental expert  
 21  
 22  
 23  
 24

25 <sup>14</sup> The plaintiff in the FOIA litigation, who is represented by the undersigned counsel, has identified  
 26 the FOIA action as related to the instant matter due to the overlap of factual issues and the potential for  
 27 added efficiency that would result from consolidating (in whole or in part) the two cases. Connett Decl. ¶  
 19.

28 <sup>15</sup> See, e.g., Exhibits G, H, J, K, and L.

1 discovery followed by an abbreviated second trial where experts from both sides can summarize the  
2 scientific developments that have occurred since the first trial, including the pooled benchmark dose  
3 analysis of the ELEMENT/MIREC studies, the Spanish study, and the NTP's systematic review (and peer  
4 reviews thereof). Through an abbreviated second trial, the Court's final determination will be informed by  
5 the expert judgment of NTP's scientists, the peer reviews of NTP's assessment, and other relevant scientific  
6 developments that have occurred since the June 2020 trial, all as explained and vetted by the parties'  
7 qualified experts.  
8

9 September 12, 2022

Respectfully submitted,

10  
11 /s/ Michael Connett  
12 MICHAEL CONNETT  
13 Attorney for Plaintiffs  
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**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing was served by Notice of Electronic Filing this 12th day of September, 2022, upon all ECF registered counsel of record using the Court's CM/ECF system.

/s/ Michael Connett  
MICHAEL CONNETT