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4	UNITED STATES DISTRICT COURT	
5	NORTHERN DISTRICT OF CALIFORNIA	
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7	FOOD & WATER WATCH, INC., et al.,	Case No. <u>17-cv-02162-EMC</u>
8	Plaintiffs,	
9	V.	ORDER GRANTING PLAINTIFFS' MOTION FOR LEAVE TO SUPPLEMENT COMPLAINT
0	UNITED STATES ENVIRONMENTAL	Docket No. 279
1	PROTECTION AGENCY, et al., Defendants.	Docket No. 279
2	Derendants.	
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Section 6(a) of The Toxic Substances Control Act (TSCA) requires Defendant United States Environmental Protection Agency (EPA) to regulate the use of certain chemical substances that it determines pose an unreasonable risk to health or the environment. 15 U.S.C. § 2605(a). Section 6(b), in turn, requires the EPA to perform its own *sua sponte* evaluation of the risks posed by certain chemical substances "under the conditions of use." Id. § 2605(b)(4)(A). The statute defines the "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." Id. § 2602(4). Section 21 of the TSCA permits any person to petition the EPA to initiate rulemaking under Section 6(a) if the petitioner demonstrates a chemical substance poses an unreasonable risk of harm. Id. § 2620(a).

Plaintiffs petitioned the EPA under Section 21 to regulate the fluoridation of drinking
water supplies under Section 6(a) because, they maintain, the ingestion of fluoride poses an
unreasonable risk of neurotoxic harm to humans. After the EPA denied Plaintiffs' petition,
Plaintiffs filed this suit seeking judicial review of the EPA's determination.

Pending before the Court is Plaintiffs' motion for leave to supplement their complaint with standing and scientific allegations pursuant to Federal Rule of Civil Procedure 15(d). *See* Docket No. 279 ("Mot."). For the following reasons, the Court **GRANTS** Plaintiffs' motion for leave to amend.

I. <u>BACKGROUND</u>

This order assumes familiarity with the lengthy factual and procedural background of this case and therefore only recites the facts and background necessary to resolve the pending motion.

On November 22, 2016, Plaintiffs filed their original petition asking the EPA to conduct rulemaking to prohibit the addition of fluoridation chemicals to drinking water supplies, which the EPA denied on February 17, 2017. *See* Mot. at 2. Plaintiffs promptly filed suit in this Court shortly thereafter on April 18, 2017. *See* Docket No. 1. ("Compl.").

More than two years into the case and about a year before trial, on May 22, 2019, the parties stipulated to the introduction of evidence in support of Plaintiffs' standing claims. *See* Docket No. 102 ("Standing Stipulation"). In that stipulation, the parties agreed that Plaintiffs would "rely exclusively" on the declarations attached to the stipulation "to establish the factual basis in support of [their] claims of standing." *Id.* \mathbb{P} 1. The stipulation also stated that the parties agreed to submit the declarations "in lieu of live direct testimony, as evidence in support of Plaintiffs' claims of standing at trial." *Id.* \mathbb{P} 5.

From June 8 to 19, 2020, the Court held a bench trial in this case. *See* Docket No. 219. On August 10, 2020, before issuing its findings of facts and conclusions of law, the Court issued an order holding all proceedings in abeyance in order to "afford the EPA an opportunity to consider the significant scientific developments that have occurred since the original petition was filed." Docket No. 262 ("Abeyance Order") at 5. The Court instructed Plaintiffs to file "a *new* petition with the EPA" including "as much underlying data and as many calculations as possible," and the EPA to "give such petition due consideration on the merits in light of the substantial scientific evidence proffered at trial." *Id.* at 5 (emphasis added).

In its abeyance order, the Court also reiterated its concern, stated at the conclusion of trial,
"that there are serious questions regarding whether the named Plaintiffs in this case have standing"

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1 because "[t]he evidence presented by Plaintiffs at trial focused overwhelming, if not exclusively, on the contention that fluoride poses a risk of neurodevelopmental harm." Id. at 1. The standing 2 3 problem, as the Court saw it, was that "[n]one of the standing Plaintiffs in this case claim to be subject to [] risk of [neurodevelopmental] harm; there are no allegations that the named Plaintiffs 4 are pregnant, planning to become pregnant, or caring for infants." Id. at 2. In other words, 5 "Plaintiffs have failed to demonstrate any link between the evidence presented at trial—which, 6 7 again, pertained to neurotoxic harm to fetuses and infants-and the harms of which they 8 personally complain." Id. Importantly, the abeyance order stated that "should the EPA deny the 9 new petition, the Court will permit amendment of the complaint herein." Id. at 5. On November 4, 2020, Plaintiffs filed a supplemental petition¹ with the EPA, see Docket 10 No. 271-1 ("Supp. Pet."), requesting that the EPA reconsider its earlier denial in light of new 11 12 information, including: 13 1) the trial record together with Plaintiffs' admitted exhibits and summary of the record; 2) the MIREC and ELEMENT studies; 3) 14 the pooled BMD analysis of the MIREC and ELEMENT data; 4) the National Toxicology Program's [NTP's] revised draft monograph 15 containing a systematic review of the fluoride literature; 5) a published statement from former NTP director Dr. Linda Birnbaum, 16 about the 'consequential' findings of the NTP's revised monograph; 6) the facts to which the parties stipulated at trial; and 7) several 17 orders of this Court which reject legal positions that EPA relied upon in its denial of the initial petition. 18 19 See Docket No. 272 ("Opp'n to Relief Mot.") at 2. The supplemental petition also explained that 20Plaintiffs had members who lived in fluoridated areas who were pregnant and/or actively seeking to become pregnant. Supp. Pet. at 11. According to Plaintiffs, it is the EPA's practice to consider 21 supplemental petitions seeking identical relief as "motions for reconsideration," id. at n.1 (citing 22 23 cases), such that the supplemental petition allowed the EPA to fully reconsider its denial of

- 24 Plaintiffs original petition, which is why this Court issued the abeyance order in the first place.
 - On October 28, 2020, the EPA filed a "motion for relief" from the abeyance order pursuant
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¹ Plaintiffs explain that they filed a supplemental petition rather than a new petition "based on their apprehension that a new petition under 15 U.S.C. § 2620 would require a *de novo* proceeding, and thereby an entirely new, lengthy and costly litigation." Mot. at 5 n.2.

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to Federal Rule of Civil Procedure 60(b)(6). *See* Docket No. 265 ("Relief Mot."). The gravamen of the relief motion was that the Court erred because it "should have dismissed this case for lack of jurisdiction, but instead has permitted Plaintiffs an opportunity to create standing where none exists." *Id.* at 1. The EPA asked this Court to vacate its abeyance order and dismiss this case with prejudice. *Id.*

While the supplemental petition and relief motion were pending, Jessica Trader, a Food & Water Watch (FWW) member, conceived her first child on December 2020. *See* Docket No. 279-1 ("Proposed Supp. Compl.") **P** 39. She is now five-months pregnant.

On January 13, 2021, the Court denied the relief motion in part as to the EPA's request to vacate the abeyance order and dismiss the complaint, but granted it in part as to the EPA's request to amend the abeyance order to require Plaintiffs to seek leave to amend the complaint should the EPA deny their supplemental petition. *See* Docket No. 277.

On January 19, 2021, the EPA denied Plaintiffs' supplemental petition after acknowledging that it had discretion to reopen the administrative record, consider the new scientific evidence, and reconsider its denial of the original petition. *See* Docket No. 278-1 ("2021 EPA Denial") at 7 ("EPA declines to exercise its discretionary authority to reopen the administrative record and reconsider the February 17, 2017 petition denial."). In denying the supplemental petition, the EPA addressed the merits of the supplemental petition, concluding that "the scientific evidence submitted for evaluating the risk of neurotoxic effects from exposure to fluoride is insufficient for EPA to reach an informed risk determination." *Id.* at 3–6. Importantly, the EPA underscored that "new information regarding the exposure and health effects of exposure to fluoride continues to develop," such that "without the final NTP monograph, reconsidering the petition denial at this time would not be prudent use of EPA's resources." *Id.* at 7. The final NTP monograph is thus essential for the EPA to properly assess the merits of Plaintiffs' supplemental petition and any similar petition Plaintiffs might file in the future.

On February 19, 2021, Plaintiffs filed the instant motion for leave to supplement their
complaint. *See* Mot. The proposed supplemental complaint adds three types of allegations. First,
it describes the Court's post-trial orders. *See* Proposed Supp. Compl. PP 29–35. Second, it alleges

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that Jessica Trader, a Food & Water Watch (FWW) member who lives in a city that adds fluoridation chemicals to the water and who suffered from dental fluorosis as a result of overexposure to fluoride, began attempting to conceive her first child in the fall of 2020, conceived her first child on December 2020, is currently three months pregnant, and intends to have two more children. Id. PP 39-43. In order to limit her unborn child's in utero exposure to fluoridated tap water, Jessica has and will continue to "purchas[e] bottled water and purchas[e] replacement cartridges for her home water filtration system. These safety measures to protect her child represent an ongoing economic burden to Jessica." Id. P 42–43. According to the supplemental complaint, "[e]ven if fluoridated water posed no risk to Jessica personally, she would still incur the expense of purchasing non-fluoridated water in order to protect her unborn child and future children." Id. PP 44. Moreover, "it is 'impossible' for Jessica to eliminate her children's exposure to fluoridation chemicals so long as the EPA permits them to be added to drinking water," and "due to their ubiquitous presence in processed foods and beverages made in the United States and lack of labeling for fluoride content." Id. P 45 (quoting Nat. Res. Def. Council v. EPA, 735 F.3d 873, 875–76 (9th Cir. 2013)). This order will refer to these allegations as the "Supplemental Standing Allegations."

Third, and finally, the supplemental complaint adds allegations conforming to the evidence 17 18 introduced at trial regarding the findings of the National Institute of Health's (NIH's) recent 19 prospective studies on the impact of early life fluoride exposure on neurodevelopment, and the vulnerability of the fetal brain to fluoride exposure. *Id.* **P** 89–113. Importantly, the supplemental 20 complaint also adds a summary of the NTP's draft monograph and the Benchmark Dose (BMD) 21 22 pooled analysis of the data used in the ELEMENT and MIREC studies, which was made available 23 on November 4, 2020. Id. PP 30, 32. This memorandum will refer to these allegations as the "Supplemental Scientific Allegations." 24

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II. MOTION FOR LEAVE TO SUPPLEMENT

26 A. <u>Legal Standard</u>

Supplemental pleadings are governed by Rule 15(d), which provides that, "[u]pon motion
of a party the court may, upon reasonable notice and upon such terms as are just, permit the party

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to serve a supplemental pleading setting forth transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented." Fed. R. Civ. P. 15(d).

3 New claims, new parties, and allegations regarding events that occurred after the original complaint was filed are all properly permitted under Rule 15(d). See Griffin v. Cnty. School Bd. of 4 5 Prince Edward Cnty., 377 U.S. 218, 226 (1964); see also Eid v. Alaska Airlines, Inc., 621 F.3d 858, 874 (9th Cir. 2010) ("Rule 15(d) provides a mechanism for parties to file additional causes of 6 7 action based on facts that didn't exist when the original complaint was filed."); Keith v. Volpe, 858 8 F.2d 467, 473 (9th Cir. 1988) ("Rule 15(d) is intended to give district courts broad discretion in 9 allowing supplemental pleadings."). Importantly, Rule 15(d) "is a tool of judicial economy and convenience" and "is intended to give district courts broad discretion in allowing supplemental 10 pleadings." *Keith*, 858 F.2d at 473. The rule "enabl[es] a court to award complete relief, or more 12 nearly complete relief, in one action, and to avoid the cost, delay and waste of separate actions which must be separately tried and prosecuted." Id. (emphasis added) (quoting New Amsterdam 14 Casualty Co. v. Waller, 323 F.2d 20, 28–29 (4th Cir. 1963)). Therefore, because the goal 15 of Rule 15(d) is to promote judicial efficiency, supplementation is generally favored. See Planned Parenthood of S. Ariz. v. Neely, 130 F.3d 400, 402 (9th Cir. 1997) (citing Keith, 858 F.2d at 473). 16 "The legal standard for granting or denying a motion to supplement under Rule 15(d) is the 17 18 same as for amending one under 15(a)." Lyon v. U.S. Immigr. & Customs Enf't, 308 F.R.D. 203, 214 (N.D. Cal. 2015) (quoting Paralyzed Veterans of Am. v. McPherson, No. C 06–4670 SBA, 20 2008 WL 4183981, at *26 (N.D. Cal. Sept. 9, 2008)). In determining whether leave should be granted to supplement (or amend) the pleadings pursuant to a district court's discretion, the 22 Supreme Court has stated that: [i]n the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.-the leave sought should, as the rules require, be "freely given." Foman v. Davis, 371 U.S. 178, 182 (1962). In the Ninth Circuit, the above listed factors-referred

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 - 28 to as the Foman factors—are not weighted equally. Eminence Cap., LLC v. Aspeon, Inc., 316

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F.3d 1048, 1051–52 (9th Cir. 2003) ("Not all of the factors merit equal weight. As this circuit and 2 others have held, it is the consideration of prejudice to the opposing party that carries the greatest 3 weight." (citing DCD Programs, Ltd. v. Leighton, 833 F.2d 183, 185 (9th Cir. 1987)). Rather, courts have held that "the crucial factor is the resulting prejudice to the opposing party." Howey v. 4 United States, 481 F.2d 1187, 1190 (9th Cir. 1973). A motion may be denied, however, on 5 grounds of futility of the proposed amendments irrespective of prejudice. See generally Hoang v. 6 7 Bank of Am., N.A., 910 F.3d 1096, 1103 (9th Cir. 2018); see also Ecological Rights Found. v. Pac. 8 Gas & Elec. Co., 713 F.3d 502, 520 (9th Cir. 2013).

9 Courts also consider whether allowing leave to supplement would align with the goal of Rule 15(d), which is to promote judicial efficiency by resolving the parties' disputes in one action. 10 See Planned Parenthood of S. Ariz., 130 F.3d at 402; Keith, 858 F.2d at 473.

Β. Analysis

The EPA does not dispute that Plaintiffs "may cure standing deficiencies through supplemental pleadings." Northstar Fin. Advisors Inc. v. Schwab Invs., 779 F.3d 1036, 1044 (9th Cir. 2015), as amended on denial of reh'g and reh'g en banc (Apr. 28, 2015) (quoting Northstar Fin. Advisors, Inc. v. Schwab Invs., 781 F. Supp. 2d 926, 932-33 (N.D. Cal. 2011)). Nor does it dispute, for purposes of its opposition, that Plaintiffs' Supplemental Standing Allegations in fact cure the complaint's standing deficiencies. See Docket No. 285 ("Opp'n") at 5, n.2.² Instead, the EPA urges the Court to deny Plaintiffs leave to supplement their complaint for two reasons: (1) it would be futile because Plaintiffs stipulated not to introduce new evidence to prove that they have standing; and (2) it would prejudice the EPA. Neither of these arguments has any merit. Moreover, granting leave to supplement the complaint would promote judicial efficiency.

- 23 24
- 1. Supplementation Would Not be Futile

The EPA's only futility argument is that the parties' May 2019 standing stipulation

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² The EPA "preserves the argument that even if Plaintiffs were able to prove their new allegations 26 about Ms. Trader, they would still lack standing." Opp'n at 5, n.2. As stated on the record during the hearing on the instant motion, the EPA may file a motion challenging the merits of the 27 Supplemental Standing Allegations later. It is worth mentioning that, in the Court's preliminary

view, the Supplemental Standing Allegations do appear to cure the complaint's standing 28 deficiencies.

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1 "precludes [Plaintiffs] from submitting any further standing evidence." Opp'n at 3. Not so. 2 "[R]elief from a pretrial order [or stipulation] is committed to the district court's discretion." 3 Seymour v. Summa Vista Cinema, Inc., 909 F.2d 1385, 1388 (9th Cir. 1987) (citing Angle v. Sky Chef, Inc., 535 F.2d 492, 495 (9th Cir. 1976)). District courts have "broad discretion in deciding 4 5 whether to hold the parties to a stipulation." Common Cause S. Christian Leadership Conf. of Greater L.A. v. Jones, 213 F. Supp. 2d 1110, 1112 (C.D. Cal. 2002) (quoting McMorgan & Co. v. 6 7 First Cal. Mortg. Co., 931 F. Supp. 699, 703 (N.D. Cal. 1996)); see also United States v. Kanu, 8 695 F.3d 74, 78 (D.C. Cir. 2012) ("Stipulations entered into by the parties 'in the course of legal 9 proceedings are not as irrevocable as other contracts,' and the '[t]rial court[] may, in the exercise of sound judicial discretion and in furtherance of justice, relieve parties from stipulations into 10 which they have entered." (quoting Nat'l Audubon Soc'y, Inc. v. Watt, 678 F.2d 299, 307 (D.C. 11 12 Cir. 1982)); Wheeler v. John Deere Co., 935 F.2d 1090, 1098 (10th Cir. 1991) ("District courts 13 are vested with broad discretion in determining whether to hold a party to a stipulation."); Am. Honda Motor Co. v. Richard Lundgren, Inc., 314 F.3d 17, 21 (1st Cir. 2002) ("Stipulations 14 15 between parties are not 'absolute,' and a party may be relieved of a stipulation for good causewhich means, in a nutshell, that good reason must exist and that relief must not unfairly prejudice 16 the opposing party or the interests of justice." (quoting TI Fed. Credit Union v. DelBonis, 72 F.3d 17 18 921, 928 (1st Cir.1995)). Courts can relieve parties of pre-trial stipulations and orders if they 19 demonstrate (1) "manifest injustice," (2) "lack of prejudice to [the opposing party]," and (3) "minimal inconvenience to the court." Seymour, 909 F.2d at 1388. All three of these factors 20 support setting aside the standing stipulation here. 21

First, Plaintiffs will suffer manifest injustice if they are prevented from supplementing their pleadings because that would likely require this Court to dismiss their case. Contrast *Seymour*, 909 F.2d at 1388 ("liability was unaffected by the excluded evidence"). District courts often set aside stipulations when the facts underlying those stipulations change in a material way *after* the stipulation is entered. *See, e.g., Peschel v. City of Missoula through Missoula Police Dep 't*, No. CV 08-79-M-RFC-JCL, 2008 WL 11417151, at *1 (D. Mont. Dec. 30, 2008) (setting aside stipulation that in-car arrest video was "gone" because the police identified a computer from

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which the video might be retrievable); McMorgan, 931 F. Supp. at 703 (setting aside stipulation recognizing joint client relationship because subsequently discovered facts showed that no such relationship existed); Sam Galloway Ford, Inc. v. Universal Underwriters Ins. Co., 793 F. Supp. 1079, 1082 (M.D. Fla. 1992) (setting aside pre-trial factual stipulation because newly discovered evidence indicated that the facts stipulated to were incorrect); Morrison v. Genuine Parts Co., 828 F.2d 708, 709 (11th Cir. 1987) (setting aside pre-trial damages stipulation because evidence at trial revealed the actual damages where much lower than the stipulated damages). In these cases, as here, the facts that compel setting aside the stipulations were not known or readily ascertainable at the time the parties entered the stipulations; new facts were material to the outcome of the case and that ignoring them would result in manifest injustice. Sam Galloway Ford, 793 F. Supp. at 1082 ("Justice cannot be done unless the *actual facts* of the case go to trial, and this Court is not interested in erroneous facts going to trial due to a pretrial stipulation that was made before the true facts were completely discovered and brought to light."). Here, Ms. Trader's pregnancy is the kind of intervening factual development that justifies setting aside the standing stipulation because it occurred *after* the parties entered the stipulation; it is material to standing.

Second, setting aside the standing stipulation would not prejudice the EPA. The EPA broadly contends that it "made countless decisions in light of this Stipulation regarding the scope of subsequent expert discovery, the extent of evidentiary challenges, the amount of resources 19 invested in this case, among other things." Opp'n at 3. But the EPA has failed to demonstrate 20 how it would have presented different evidence at trial had it known Ms. Trader was pregnant. The scientific issues were clearly joined at trial. See Eminence Cap., 316 F.3d at 1052 (9th Cir. 2003) ("[The] party opposing amendment 'bears the burden of showing prejudice."" (quoting 22 23 DCD Programs, 833 F.2d at 185)).

24 The EPA also fails to respond to Plaintiffs' contention that supplementation would impose "little additional discovery," LaSalvia v. United Dairymen of Ariz., 804 F.2d 1113, 1119 (9th Cir. 25 1986), because the Supplemental Standing Allegations involve only one person who is already 26 involved in the case. Mot. at 18. As Plaintiffs point out, at most the EPA would need to conduct a 27 short deposition of Ms. Trader narrowly focused on her standing allegations. See, e.g., LaSalvia, 28

804 F.2d at 1119 ("We see no prejudice to defendants in allowing the amendment. Because most of the information on the added claim would be available in UDA's own files, little additional discovery would be needed."); *Lyon*, 308 F.R.D. at 215 ("While allowing the addition of the Bakersfield facility would require little additional discovery, requiring Plaintiffs to bring a second suit on behalf of detainees at the Bakersfield facility would force them to duplicate several depositions already taken for this suit."). And, as Plaintiffs correctly point out, allowing the Supplemental Standing Allegations about Ms. Trader would not undo all the benefits of the standing stipulation for the EPA. *See* Docket No. 287 ("Reply") at 8. The standing stipulation still holds for the other eight witnesses.

Additionally, the EPA's prejudice argument is wholly undermined by the fact that the EPA 10 repeatedly asks the Court to dismiss this case for lack of standing so that Plaintiffs could file a 11 12 third petition with the EPA and, if that petition is denied, an entirely new case challenging that 13 denial. See Opp'n at 1 ("The most logical way to address all new developments is through a new 14 petition to EPA, and, if necessary, a new, streamlined case." (emphasis added)); id. ("[I]f EPA 15 denies the petition, Plaintiffs could file a new case, for which their alleged harm will not long postdate the new complaint." (emphasis added)); Id. at 3 ("If EPA denies the petition, Plaintiffs can 16 bring a *new* case in which they can attempt to prove their standing unencumbered by stipulation, 17 18 and in which all of the expert testimony will be based on a single body of evidence, not one that 19 continues to evolve with every phase of the case." (emphasis added)); id. at 5 ("And should EPA 20 deny a new petition, Plaintiffs can file a *new* case, which can proceed efficiently, without multiple iterations of discovery." (emphasis added)). Starting from scratch with a third petition and a new 21 22 case cannot be more efficient or less prejudicial to the EPA; it would further delay the resolution 23 of this dispute and could require all parties—including the EPA—to re-do discovery, dispositive 24 motions, and even trial. To the contrary, the best way to preserve the resources the EPA has 25 already invested in this case and to expeditiously dispose of Plaintiffs' claims is to allow the Supplemental Standing Allegations and any limited discovery related thereto to be considered in 26 addition to the existing record so that this Court, which has already conducted an entire bench trial 27 28 on the merits, can adjudicate the merits as soon as possible.

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dispositive motions and in holding a bench trial. Asking this Court—or any other Court down the line—to start from scratch would impair judicial economy.

Court, which has already expended considerable time and resources in adjudicating the parties'

Third, and relatedly, setting aside the standing stipulation would greatly inconvenience the

Accordingly, the Court has ample and justifiable reason set aside the stipulation.

2. <u>Supplementation Would Not Prejudice the EPA</u>

For the reasons stated above,³ the EPA would not be prejudiced if the Court were to allow Plaintiffs to supplement their complaint with the allegations of Ms. Trader's standing to sue.

The EPA also argues, however, that it would be prejudiced if the Court allows Plaintiffs to supplement their complaint with the Supplemental Scientific Allegations because doing so would require the Court to reopen expert discovery. Opp'n at 6. In fact, the EPA avers in its opposition that it has tried to "mitigate some of the prejudice to EPA that would result from supplementing the complaint by negotiating the scope and terms of potential future discovery and evidence," to no avail. *Id.* at 6 n.4.

As this Court has indicated, the evolving science warrants reopening of expert discovery and trial evidence. For example, on January 26, 2021, the National Academy of Science,

Engineering and Medicine (NASEM) peer-reviewed the draft NTP monograph—with which

Plaintiffs seek to supplement the complaint—and issued a letter report concluding as follows:

Even though the evidence provided appears to show consistent indications of an association between exposure to high fluoride concentrations and cognitive deficits in children, the monograph falls short of providing a clear and convincing argument that supports its assessment. It also needs to emphasize that much of the evidence presented comes from studies that involve relatively high fluoride concentrations and that the monograph cannot be used to draw conclusions regarding low fluoride exposure concentrations (less than 1.5 mg/mL), including those typically associated with drinking water fluoridation.

Docket No. 280-1 ("NASEM Letter Report").

In response to the NASEM's letter report, the NTP issued a statement on February 9, 2021,

³ The EPA acknowledges in its opposition that "the second reason for denying supplementation overlaps with the second and third factors for voiding a stipulation: additional piecemeal litigation will prejudice EPA and inconvenience the Court." Opp'n at 2–3.

stating that it "will carefully consider all of the committee's comments as [it] finalize[s] and publish[es] the NTP Fluoride Monograph as a 'state of the science' document later in 2021." Docket No. 280-2 ("NTP's Statement"). The EPA contends that this statement means that the "NTP decided to forgo concluding that fluoride is a hazard at any level." Opp'n at 8. Therefore, according to the EPA, allowing Plaintiffs to supplement their complaint with only the *draft* NTP monograph would allow them to present their evidence "but deny EPA the opportunity to present evidence of the *final* result of NTP's process," which might contradict the draft. *Id*.

Similarly, Plaintiffs' seek to supplement their complaint with the draft manuscript of the Mexican and Canadian cohorts' pooled analysis, but not the analyses of other cohorts that show conflicting results, including those of a Spanish cohort that has issued relevant abstracts since the trial. *Id.* at 8 n.5 (citing Ibarluzea, Jesus, et al., Are Low Fluoride Levels in Drinking Water Really Detrimental for Neurodevelopment in Childhood, International Society for Environmental Epidemiology, Aug. 24–27, 2020 ("Conclusions: Positive associations between fluoride levels during pregnancy and neuropsychological development at 4 years of age were found. Detrimental effects of fluoride in neurodevelopment were not supported by our data."). According to the EPA, allowing Plaintiffs to supplement now would "limit EPA's ability to gather more scientific evidence that could rebut the limited selection of new drafts they seek to present to the Court." *Id.* at 9.

The Court agrees. The EPA should be given a chance to weigh in, on, *e.g.*, the final NTP monograph, the NASEM Letter Report, and possibly the Canadian, Mexican, and Spanish cohorts studies after they are peer-reviewed.

Allowing Plaintiffs to add the Supplemental Scientific Allegations would not preclude the EPA to weigh in when more scientific evidence becomes available. The Court intends to continue to hold the case in abeyance at least until the final NTP monograph is released and possibly until the Canadian, Mexican, and Spanish cohorts are peer-reviewed. The Court may instruct Plaintiffs to file a new or second supplemental petition with the EPA and afford the EPA an opportunity to reconsider its administrative review and, if necessary, to further litigate the issues in this Court.

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3. <u>Supplementation Promotes Judicial Economy</u>

Finally, and most importantly, allowing Plaintiffs to supplement the allegations in their complaint would surely promote judicial economy. "In deciding whether to permit a supplemental pleading, a court's focus is on judicial efficiency." *Yates v. Auto City 76*, 299 F.R.D. 611, 613 (N.D. Cal. 2013); *see also Planned Parenthood of S. Ariz.*, 130 F.3d at 402 (9th Cir.1997) ("[P]romot[ing] judicial efficiency [is] the goal of Rule 15(d)." (citing *Keith*, 858 F.2d at 473)). Judicial efficiency is achieved where "the entire controversy between the parties could be settled *in one action.*" *Planned Parenthood of S. Ariz.*, 130 F.3d at 402 (emphasis added) (quoting 6A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Prac. And Proc.: Civil 2D* § 1506 (1990)).

In *Planned Parenthood of Southern Arizona*, the district court issued a final order declaring Arizona's parental consent abortion statute unconstitutional and entered a permanent injunction in September 1992. *Id.* at 401. That final disposition was never appealed. *Id.* The Arizona legislature then amended the law several years later, and the district court allowed Plaintiffs to supplement their original complaint with allegations pertaining to the amended law, instead of requiring them to file a new lawsuit. *Id.* at 402. The Ninth Circuit held that the district court abused its discretion in allowing the plaintiffs to supplement their original complaint because "[t]he supplemental complaint filed by plaintiffs involved *a new and distinct action* that should have been the subject of a separate suit." *Id.* at 402. In other words, permitting the plaintiffs to supplement their original complaint could not promote judicial efficiency because the first case had "reached final disposition," *id.* at 403, such that "there would necessarily be two actions," *id.* at 402.

Here, by contrast, the instant case has not reached final disposition; the Court has not entered a final appealable order disposing of Plaintiffs' claims. Therefore, unlike in *Planned Parenthood of Southern Arizona*, allowing Plaintiffs' Supplemental Standing Allegations would lead this Court to adjudicate "the entire controversy between the parties . . . in one action," avoiding the need for Plaintiffs to file a second lawsuit, which is the entire *raison d'être* of Rule 15(d). *Id.*; *see also Northstar Fin. Advisors Inc. v. Schwab Invs.*, 779 F.3d at 1044 ("Rule 15(d)

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permits a supplemental pleading to correct a defective complaint and circumvents 'the *needless* formality and expense of instituting a new action when events occurring after the original filing indicated a right to relief." (emphasis added) (quoting Wright, Miller, & Kane, Federal Practice and Procedure: Civil 3d § 1505, pgs. 262-63.)); Keith, 858 F.2d at 473 ("Rule 15(d) . . . is a useful device, enabling a court to award complete relief, or more nearly complete relief, in one action, and to avoid the cost, delay and waste of separate actions which must be separately tried and 6 prosecuted." (emphases added) (quoting New Amsterdam Casualty Co., 323 F.2d at 28-29)); Scahill v. D.C., 909 F.3d 1177, 1184 (D.C. Cir. 2018) ("[W]e hold that a plaintiff may cure a standing defect under Article III through an amended pleading alleging facts that arose after filing the original complaint. The alternative approach forces a plaintiff to go through the *unnecessary* hassle and expense of filing a new lawsuit when events subsequent to filing the original complaint have fixed the jurisdictional problem." (emphasis added)).

The Court in the instant case can promote judicial efficiency by allowing supplementation of the original complaint because the instant action is still ongoing. If anything, the EPA's proposal to instead dismiss this action and instruct the Plaintiff to file a new petition contravenes judicial efficiency because it would likely result in re-litigating this case from scratch. This 16 needless duplication of efforts and waste of judicial resources is precisely what Rule 15(d) was designed to prevent. See San Luis & Delta-Mendota Water Auth. v. U.S. Dep't of Interior, 236 F.R.D. 491, 501 (E.D. Cal. 2006) ("[S]upplementation serves the interest of judicial economy, as consuming administrative and judicial resources of the court in not having to open a new case, randomly assigning it, going through the related-case low number analysis, and initiating Rule 16 scheduling as if this were a new case, do not serve judicial economy.").

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Northern District of California United States District Court

1	III. <u>CONCLUSION</u>	
2	For the foregoing reasons, the Court GRANTS Plaintiffs' motion for leave to supplement	
3	their complaint. Should the EPA seek to challenge Plaintiffs' standing, it shall file a motion to	
4	dismiss within thirty (30) days from the date of this order. The abeyance of this case otherwise	
5	remains in place until further ordered.	
6	This order disposes of Docket No. 279.	
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8	IT IS SO ORDERED.	
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10	Dated: May 11, 2021	
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13	EDWARD M. CHEN United States District Judge	
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