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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.

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

) **PLAINTIFFS' REPLY IN SUPPORT OF**
) **THEIR MOTION FOR LEAVE TO**
) **AMEND THEIR COMPLAINT WITH**
) **SUPPLEMENTAL PLEADINGS**

) Date: April 22, 2021

) Time: 1:30 pm

) Courtroom: Zoom Webinar

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1 **A. Introduction**

2 In its opposition to Plaintiffs' motion to amend, EPA does not dispute that the newly arising facts
3 set forth in Plaintiffs' Supplemental Complaint are sufficient to establish standing. EPA's silence on this
4 issue speaks volumes, and highlights that the allegations in Plaintiffs' Supplemental Complaint are not
5 "futile," which was the principal issue that the Court asked to be addressed. ECF No. 277 at 4:13-18. Rather
6 than address the merits of the supplemental allegations, EPA spends much of its opposition arguing about—
7 and mischaracterizing—issues that are not yet before the Court (i.e., whether to re-open the record for
8 additional expert testimony).

9 When stripped of its irrelevance and errors, EPA's argument boils down to the contention that any
10 supplemental allegations are foreclosed by the parties' stipulation on standing. EPA claims this position is
11 supported by a comment from the Court that the "door is closed" on standing-related evidence, but fails to
12 acknowledge that the Court clarified that it was referring to standing evidence that was already in existence,
13 not "intervening developments" that may arise. ECF No. 264 at 26:9-13. The Court's distinction between
14 evidence that was already in existence and "intervening developments" is in harmony with the case law on
15 supplementing pleadings and setting aside stipulations. Indeed, courts have repeatedly exercised their
16 "broad discretion" to set stipulations aside where, as here, intervening factual developments have arisen
17 that facilitate a decision on the merits and the opposing party would not be unduly prejudiced by these facts
18 being considered. The Court should thus exercise its "broad discretion" to grant Plaintiffs' motion and set
19 aside, in part, the stipulation for the limited purpose of allowing consideration of the evidence on Jessica
20 Trader's pregnancy. Doing so will permit this case to be decided on the merits, rather than a technicality,
21 and will conserve the resources of the parties and the Court.

22 **B. EPA Has Conflated the Issues and Misstated the Facts**

23 EPA's opposition repeatedly conflates Plaintiffs' motion to amend their complaint (i.e., the matter
24 that is actually before the Court) with issues that the Court may or may not address later in the litigation,
25 and repeatedly mischaracterizes the post-trial course of this litigation. Because these mischaracterizations
26 are woven into every aspect of EPA's opposition, Plaintiffs begin by correcting and clarifying the record:

27 First, EPA incorrectly asserts that the Supplemental Complaint contains allegations that would

1 require re-opening expert discovery on “draft scientific papers that post-date trial.”¹ EPA Opp. at 6:18-19;
2 *see also* EPA Opp. at 2:13-15. The only reference to draft scientific papers (i.e., the NTP systematic review
3 and the pooled BMD analysis) in the Supplemental Complaint are two procedural paragraphs that
4 summarize the new scientific evidence that the Plaintiffs provided to EPA *at the Court’s request*. *See* Suppl.
5 Compl. ¶¶ 30, 32. To be clear, the Supplemental Complaint does not include allegations about the *findings*
6 of the NTP review or other post-trial studies. The only new research findings added to the Complaint are
7 the published, peer-reviewed findings of the NIH-funded birth cohort studies that were presented in depth
8 *at trial*, and which EPA agreed are “the most methodologically reliable human studies to date on the impact
9 of fluoride on neurodevelopment.” *Id.* ¶¶ 89, 90, 97a; ECF No. 197 at 3:18-19.

10 Second, EPA states that Plaintiffs “seek to reopen discovery” and “intend to present testimony by
11 multiple experts” on the post-trial scientific evidence. EPA Opp. at 6:20-25. *It was the EPA, however, that*
12 *first requested expert testimony* if the Court were to consider post-trial studies, not the Plaintiffs, and the
13 Court agreed that such testimony would be needed should it consider post-trial research.² ECF No. 264 at
14 32:2-18. Plaintiffs agree that expert testimony (whether by declaration or live testimony) on post-trial
15 scientific developments will be necessary if and when the Court were to consider such developments as
16 part of the record. The filing of a motion for leave to supplement a complaint, however, is not a request to
17 reopen expert discovery.

18 Third, EPA repeatedly asserts that Plaintiffs are somehow “cherry picking” a “biased selection” of
19 post-trial studies by focusing on the NTP’s systematic review and pooled BMD analysis in their

20
21 ¹ EPA’s brief repeatedly faults Plaintiffs for seeking to rely on “draft” scientific documents, using
22 the word “draft” no less than 16 times in its 10-page brief. It takes a certain degree of hubris for EPA to
23 take issue with draft scientific documents given that, at trial, EPA sought to rely upon an unpublished, non-
24 peer reviewed study from Spain that was only available in abstract form with threadbare details as to its
25 methodology. *See* ECF No. 243 at 818:10-23, 827:5-829:3, 832:15-836:16. Notwithstanding EPA’s double
26 standard, the Court has specifically stated that the NTP’s systematic review would likely provide probative
27 information even if it was only available in draft form. ECF No. 264 at 22:7-9 (“I am particularly interested,
28 I will tell you, in what the NTP says about this. Even if it’s not conclusory – you know, even if it’s – it
hasn’t reached a final conclusion”); *see also id.* at 21:11-13. Moreover, Plaintiffs anticipate that the
peer review of the pooled BMD analysis will be published in a peer-reviewed journal in the near future.

² As the Court explained, “I don’t want to hear ten experts, but I’d like to hear from a couple of
experts on -- one on each side, perhaps, about what this means I’m not going to just take this NTP
[report] and go into a closet and read it, and then come out with a conclusion. I want to know more about
it.” ECF No. 264 at 32:13-18.

1 supplemental petition. EPA Opp. at 6:23-25, 7:13-14, 7:18-20, 9:13-14. However, as EPA and this Court
2 are aware, Plaintiffs included these materials *at the direction of the Court*. It was the Court that rightfully
3 recognized that both the NTP systematic review and pooled BMD analysis are significant scientific
4 developments that warrant due consideration by the EPA and may well warrant re-opening the record in
5 this case. *See* ECF No. 264 at 9:3-14, 18:22-19:3, 21:11-13, 22:7-11, 26:16-10, 32:22-25.

6 Fourth, EPA states that “Plaintiffs would have this Court selectively disregard the NASEM peer
7 review and rely only on the draft NTP monograph.” EPA Opp. 8:5-6. At no point have Plaintiffs ever
8 articulated this position – in fact, to the contrary, Plaintiffs have *repeatedly* expressed their view to EPA’s
9 counsel that the peer review by NASEM (sometimes referred to colloquially as “NAS”) should be
10 considered in concert with the NTP’s report. An example of these communications from Plaintiffs to EPA’s
11 counsel is attached herein as **Exhibit 1**. It is at odds with the ethical duty of candor to the tribunal for EPA’s
12 counsel to blatantly misrepresent Plaintiffs’ position to the Court. *See, e.g.*, ABA Rule 3.3.

13 Fifth, after declining to accept this Court’s invitation to revisit Plaintiffs’ petition so it could apply
14 the correct legal rule applicable to TSCA risk determinations, EPA again misstates the evidentiary
15 foundation that must be established to support a risk determination under TSCA. EPA’s counsel declares—
16 *without benefit of the expert testimony EPA now seeks to avoid*—that “the most significant development
17 since trial has been that following NASEM’s peer review, NTP decided to forgo concluding that fluoride
18 is a hazard at any level.” EPA Opp. at 8:7-10. EPA’s counsel further proclaims that “any evidence that
19 Plaintiffs seek to present on the dose of fluoride that may produce a neurodevelopmental response has no
20 bearing on risk until they can establish that neurotoxicity is a hazard of fluoride exposure.” *Id.* at 8:16-18.
21 Not only did EPA’s own trial experts concede that neurotoxicity is a hazard of fluoride exposure,³ but there
22 is no requirement (nor a single solitary precedent) under TSCA that a risk determination can only be made
23 after the NTP reaches a hazard conclusion that has undergone peer review by NASEM. Were this the rule,
24 Sections 6 and 21 of TSCA would become effectively dead letters.

25 In fact, if EPA were correct about the standard of proof (it is not), each of EPA’s ten recent risk

26 _____
27 ³ *See* ECF No. 256 ¶ 220 (citing testimony from Dr. Thayer, Dr. Tsuji, Dr. Chang, as well as
statements from EPA counsel during closing).

1 evaluations would be invalidated because, as the NASEM concluded in a withering critique issued on
2 February 16, 2021, the systematic review method that EPA’s OPPT program uses is (A) “not
3 comprehensive,” (B) “unworkable,” (C) “lacking objectivity,” (D) “compromised” in its transparency, and
4 (E) “d[oes] not meet the standards of systematic review methodology.”⁴ In light of these deficiencies, the
5 NASEM recommended that EPA “step back from the approach that it has taken” and consider incorporating
6 elements of the NTP’s systematic review methods because, unlike the OPPT’s methods, the NTP’s methods
7 “have a trajectory of use and community acceptance and reflect the state of the practice.” (p. 54). Perhaps
8 not surprisingly, *EPA’s opposition makes no mention of this NASEM peer review in its papers*. Instead, the
9 EPA focuses solely on NASEM’s (much less critical) peer review of the NTP monograph on fluoride.

10 Plaintiffs now turn to EPA’s legal arguments.

11

12 **C. The Stipulation Does Not Make the Supplemental Allegations Futile**

13 As this Court has recognized, “a proposed amendment is futile only if no set of facts can be proved
14 under the amendment to the pleadings that would constitute a valid and sufficient claim or defense.” *Lyon*
15 *v. U.S. Immigration & Customs Enf’t*, 308 F.R.D. 203, 216 (N.D. Cal. 2015) (quoting *Miller v. Rykoff-*
16 *Sexton, Inc.*, 845 F.2d 209, 214 (9th Cir. 1988)). Notably, EPA makes no attempt to contest the sufficiency
17 of the supplemental facts on standing that Plaintiffs have alleged. Instead, EPA contends that
18 “supplementation will be futile because Plaintiffs are precluded by stipulation from introducing evidence
19 to prove that they have standing.” EPA Opp. at 2:24-25. While Plaintiffs recognize that the stipulation may
20 be relevant to the separate and distinct issue of prejudice (discussed below), it is not responsive to the issue
21 of futility because the futility inquiry is focused, much like a Rule 12(b)(6) motion, on the allegations
22 contained within the four corners of the Complaint, and whether these allegations, if true, are sufficient to
23 set forth a viable claim. EPA makes no attempt to address this standard, and thus its futility argument fails.

24 EPA’s argument on futility also makes little sense when considering the context in which Plaintiffs’
25 motion was filed. Specifically, the Court *invited* Plaintiffs to supplement their standing allegations “to

26 ⁴ See NASEM. *The Use of Systematic Review in EPA’s Toxic Substances Control Act Risk*
27 *Evaluations* (2021). pp. 5-7. Available online at: [https://www.nap.edu/catalog/25952/the-use-of-](https://www.nap.edu/catalog/25952/the-use-of-systematic-review-in-epas-toxic-substances-control-act-risk-evaluations)
[systematic-review-in-epas-toxic-substances-control-act-risk-evaluations](https://www.nap.edu/catalog/25952/the-use-of-systematic-review-in-epas-toxic-substances-control-act-risk-evaluations)

1 remove the complicated standing issues with respect to the current named plaintiffs.” *See* ECF No. 264 at
 2 20:13-22; *see also id.* at 21:1-4, 33:6-10, 35:12-19. Consistent with this, the Court stated that it was “willing
 3 to *reopen the evidence* for things that arise, *intervening developments* . . . [a]nd if necessary, to resolve
 4 any *standing or jurisdictional issues*, if there’s some pleading questions or evidentiary questions that need
 5 to be looked at.” *Id.* at 35:12-19. The Court was obviously well aware of the parties’ stipulation when it
 6 made these statements and thus it cannot be, as EPA argues, that the stipulation renders any new allegations
 7 on standing futile. Were this the case, there would have been no point or purpose for the Court to invite
 8 Plaintiffs to supplement their standing allegations.

9 Finally, EPA repeatedly characterizes a singular, passing comment from the Court to suggest that
 10 the Court foreclosed any new evidence on standing. EPA Opp. at 1:7-10, 3:22-23 (quoting ECF No. 264 at
 11 26:9-10). EPA omits, however, the clarifying comments that the Court immediately provided after this
 12 statement. Specifically, after stating that the “door is closed” on standing-related evidence, the Court
 13 clarified that “I said *I would leave the record open*, to take into account things – *intervening developments*.
 14 Not a redo: Oh, I forget this study, or I forget to mention this. That’s over.” ECF No. 264 at 26:10-13. In
 15 other words, the Court foreclosed evidence on standing that was *already in existence* which Plaintiffs failed
 16 to identify, but did not foreclose evidence on standing that was based on “intervening developments.” *Id.*
 17 This is precisely the type of evidence that Plaintiffs rely upon in their Supplemental Complaint, yet EPA’s
 18 opposition never once acknowledges or grapples with this distinction.

19
 20 **D. The EPA Has Failed to Meet Its Burden of Showing that Supplementation Would Unduly
 Prejudice the Agency**

21 **1. EPA Has Applied the Wrong Burden and Standard of Proof**

22 In its opposition, EPA incorrectly assigns the burden of proving the prejudice of supplementation
 23 to the Plaintiffs, arguing that “Plaintiffs must show that EPA would not be prejudiced and that the Court
 24 will not be inconvenienced.” EPA Opp. at 6:6-7. This is not the law. As discussed in Plaintiffs’ motion, it
 25 is the party opposing supplementation that bears the burden of proving prejudice.⁵ *Agua Caliente Band of*

26
 27 ⁵ Plaintiffs recognize that, for purposes of setting aside a stipulation, the burden is on them to
 Continued on the next page

1 *Cahuilla Indians v. Coachella Valley Water District*, Case No. 13-cv-883-JGB, 2020 WL 5775174 at *2
2 (C.D. Cal. July 8, 2020) (“The party opposing amendment bears the burden of showing prejudice, unfair
3 delay, bad faith, or futility of amendment.”); *Cabell v. Zorro Prods. Inc.*, No. 5:15-CV-00771-EJD, 2016
4 WL 9180435, at *3 (N.D. Cal. Sept. 23, 2016) (“The party opposing a motion to supplement bears the
5 burden of showing prejudice.”); *Aristocrat Techs. v. Int’l Game Tech.*, No. C-06-03717 RMW, 2010 WL
6 2486194, at *1 (N.D. Cal. June 15, 2010) (“The party opposing the amendment bears the burden of showing
7 why leave to amend should not be granted.”).

8 EPA also errs with respect to the standard of proof for demonstrating prejudice. EPA suggests that
9 any level of prejudice, no matter how de minimis, will suffice to thwart supplementation. See EPA Opp. at
10 6:11-12 (“[T]he applicable standard is whether there would be a ‘lack of prejudice’ to EPA, not whether
11 there would be ‘undue prejudice.’”). The one case on supplementation that EPA cites to support this
12 proposition—*Nunes v. Ashcroft*, 375 F.3d 805, 808 (9th Cir. 2004)—does not do so. The *Nunes* decision
13 simply states that “lack of prejudice” is one of the factors to be considered; it says nothing about the
14 quantum of prejudice that must be present. EPA also cites the case of *Seymour v. Summa Vista Cinema,*
15 *Inc.*, 809 F.2d 1385, 1388 (9th Cir. 1987), but that case did not involve a motion to amend and, in any
16 event, is silent on what “lack of prejudice” means, and whether de minimis prejudice qualifies. Other cases,
17 including an opinion written by this Court, have explained that prejudice in both the motion to amend and
18 stipulation contexts means “undue,” “unfair,” and/or “substantial and real harm.” See *Foman v. Davis*, 371
19 U.S. 178, 182 (1962) (“undue prejudice”); *Chao v. Hotel Oasis, Inc.*, 493 F.3d 26, 32 (1st Cir. 2007)
20 (“unfairly prejudice the opposing party”); *Waldorf v. Shuta*, 142 F.3d 601, 617-18 (3d Cir. 1998)
21 (“substantial and real harm to the adversary”); *Logan Lumber Co. v. Comm’r*, 365 F.2d 846, 855 (5th Cir.
22 1966) (“substantial and real harm to the adversary”); *Dep’t of Fair Emp. & Hous. v. L. Sch. Admission*
23 *Council, Inc.*, No. C-12-1830 EMC, 2013 WL 485830, at *3 (N.D. Cal. Feb. 6, 2013) (“undue prejudice”);
24 *Sam Galloway Ford, Inc. v. Universal Underwriters Ins. Co.*, 793 F. Supp. 1079, 1082 (M.D. Fla. 1992)
25 (“unfairly prejudice the opposing side”).

26 _____
27 demonstrate lack of undue prejudice. For the reasons set forth in Plaintiffs’ motion, as well as herein,
28 Plaintiffs have met this burden.

1 Nov. 14, 2019) and *Mullen v. Surtshin*, 590 F. Supp. 2d 1233, 1238 (N.D. Cal. 2008)).

2 In *Mullen*, the “new” facts that the *pro se* plaintiff sought to add to the complaint “had been known
3 to plaintiff for years, as he concedes,” and, yet, these supplemental facts had never been included in any of
4 the numerous amended complaints that the court had permitted him to file. *Mullen*, 590 F. Supp. 2d at
5 1237. Here, by contrast, Plaintiffs are amending their complaint for the first time with facts that first arose
6 after trial was completed.

7 The facts of *Caruso* are similarly inapposite. There, the plaintiff sought to add entirely new causes
8 of action against entirely new parties, which would, in turn, require substantial new discovery and
9 significantly delay the resolution of the case against the existing defendants. *Caruso*, 2019 WL 6009465,
10 at *3-4. Here, Plaintiffs’ supplemental pleadings do not create a new cause of action, do not require adding
11 a new party, and do not require any new discovery, other than potentially one limited deposition of Jessica
12 Trader. The *Mullen* and *Caruso* cases thus provide precious little support for EPA’s position.

13 **4. EPA Fails to Articulate Any Undue Prejudice from Setting Aside the Stipulation**

14 In its opposition, EPA fails to articulate, let alone demonstrate, how it would be unduly prejudiced
15 from setting aside the stipulation. The most that EPA seems to offer is the conclusory assertion that “EPA
16 made countless decisions in light of this Stipulation regarding the scope of subsequent expert testimony,
17 the extent of evidentiary challenges, the amount of resources invested in the case, among other things.”
18 EPA Opp. at 3:18-21. What EPA fails to mention, however, is that EPA *benefited* from the stipulation, and
19 these benefits are *not undone* by partially setting it aside. Specifically, the stipulation allowed EPA to
20 forego the time and expense of deposing 9 standing witnesses, by locking these witnesses into a set of facts
21 that, if EPA is correct, fail to establish standing as *a matter of law*. If EPA’s legal contention is correct—
22 which Plaintiffs of course dispute—then deposing these witnesses would have been an unnecessary effort
23 both *then* and (with the exception of Jessica Trader) *now*. EPA also got the added benefit of removing
24 organizational-injury standing from the litigation, and this remains the case.⁶ Contrary to EPA’s contention,

25 ⁶ Plaintiffs refer here to standing that arises from injury to the organization itself, as opposed to
26 “associational” standing (i.e., the organization sues on behalf of its *members’* injuries), the latter of which
27 remains at issue. *See Doe #1 v. Trump*, 984 F.3d 848, 860 (9th Cir. 2020) (“Organizations can assert Article
28 III standing in their own right, or they may rely upon the Article III standing of their members under the
doctrine of associational standing.” (citations omitted)).

1 therefore, it is not just the Plaintiffs who benefited from the efficiencies that the stipulation afforded; EPA
2 benefited as well.

3 While EPA does not say it, the only potential prejudice that EPA has suffered is the potential loss
4 of a windfall. In other words, if the EPA can use the stipulation to defeat standing despite Plaintiffs factually
5 having standing, then EPA gets a get-out-of-jail-free card. Losing a potential windfall, however, is not the
6 kind of “prejudice” that the law has in mind, particularly where the stipulation “aided the effective
7 functioning of the court” by promoting judicial efficiency. *Park v. Transamerica Ins. Co.*, 917 F. Supp.
8 731, 736 (D. Haw. 1996). While it is understandable that certain defendants (e.g., chemical corporations
9 seeking to avoid government regulations) may jump at the opportunity for a get-out-of-jail-free card, the
10 equities are different when it is a government agency seeking to avoid its obligations to protect the public.
11 There is a reason EPA’s counsel is called the “Department of Justice” and not the “Department of
12 Winning.”

13 **E. The Law on Setting Aside Stipulations Is Not as Rigid and Extreme as EPA Contends**

14 **1. Courts Have “Broad Discretion” to Set Aside Stipulations**

15 EPA seeks to advance an exceptionally rigid, and extreme, view on the law regarding stipulations.
16 EPA asserts that courts can only set aside stipulations in “exceptional cases,” but fails to note that the one
17 case it relies upon for this proposition is an unpublished and non-citable decision. EPA Opp. at 2:19-21
18 (citing *U.S. Dep’t of Labor v. Kerr-McGee Chem. Corp.*, 985 F.2d 577, 577 (9th Cir. 1993)). Based on its
19 rigidly narrow construction of the law, EPA goes so far as to suggest that the parties’ stipulation cannot be
20 set aside because “Plaintiffs will not be imprisoned based on an outdated law.” EPA Opp. at 4:17-18.

21 Curiously absent from EPA’s opposition is any acknowledgement that courts have “broad
22 discretion” to set aside a stipulation. *Common Cause S. Christian Leadership Conf. of Greater Los Angeles*
23 *v. Jones*, 213 F. Supp. 2d 1110, 1112 n.1 (C.D. Cal. 2002); *McMorgan & Co. v. First California Mortg.*
24 *Co.*, 931 F. Supp. 699, 703 (N.D. Cal. 1996).⁷ In exercising this “broad discretion,” courts, including the
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26 ⁷ *Accord Morrison Knudsen Corp. v. Ground Improvement Techniques, Inc.*, 532 F.3d 1063, 1075
27 (10th Cir. 2008); *Southworth v. Bd. of Regents of Univ. of Wisconsin Sys.*, 307 F.3d 566, 571 (7th Cir.
28 2002); *Waldorf v. Shuta*, 142 F.3d 601, 616 (3d Cir. 1998); *Morrison v. Genuine Parts Co.*, 828 F.2d 708,
709 (11th Cir. 1987); *Coastal States Mktg., Inc. v. Hunt*, 694 F.2d 1358, 1369 (5th Cir. 1983).

1 U.S. Supreme Court, have set aside stipulations “when it is reasonable to do so” and “upon cause shown.”
 2 *Muller v. Dows*, 94 U.S. 277, 278 (1876) (“upon cause shown”); *Cates v. Morgan Portable Bldg. Corp.*,
 3 780 F.2d 683, 690 (7th Cir. 1985) (“reasonable to do so”); *Sam Galloway Ford*, 793 F. Supp. at 1082
 4 (“reasonable to do so”); *Direct Lineal Descendants of Jack v. Sec’y of the Interior*, No. 3:13-CV-00657-
 5 RCJ, 2014 WL 5439781, at *1 (D. Nev. Oct. 24, 2014) (“good cause”).

6 **2. EPA Misconstrues the “Manifest Injustice” Standard**

7 EPA correctly notes that “manifest injustice” is one of the grounds for setting aside a stipulation,
 8 but it misconstrues the elements of this standard. EPA’s error is apparent by its confused assertion that
 9 Plaintiffs “did not apply the manifest injustice standard.” EPA Opp. at 4:27-28. EPA bases this assertion
 10 on the fact that Plaintiffs analyzed the elements set forth in *Waldorf*. See Pls’ Mot. at 19:11-20:4. What
 11 EPA fails to recognize is that the elements set forth in *Waldorf* are the elements of the manifest injustice
 12 standard. *United States v. Kanu*, 695 F.3d 74, 81 (D.C. Cir. 2012) (citing *Waldorf* for the elements of
 13 manifest injustice); *State Farm Fire & Cas. v. McDevitt*, No. C-00-2240 EDL, 2001 WL 637419, at *8
 14 (N.D. Cal. May 21, 2001) (same); see also *Tesoro Ref. & Mktg. Co. LLC v. Pac. Gas & Elec. Co.*, No. 14-
 15 CV-00930-JCS, 2015 WL 5675861, at *10 (N.D. Cal. Sept. 28, 2015) (citing *State Farm*, and by extension
 16 *Waldorf*, for the manifest injustice elements); *Morrison v. Zangpo*, No. C-08-1945 EMC, 2008 WL
 17 4449585, at *4 (N.D. Cal. Sept. 30, 2008) (same); *Schaum v. Honeywell Retiree Med. Plan No. 507*, No.
 18 CV-04-2290-PHX-MHM, 2005 WL 8160583, at *3 (D. Ariz. Sept. 15, 2005) (same).

19 **3. Under the Manifest Injustice Standard, Intervening Factual Developments Are Very**
 20 **Significant, Despite EPA’s Suggestion to the Contrary**

21 One of the elements of the manifest injustice standard is “the occurrence of intervening events since
 22 the parties agreed to the stipulation.” *State Farm*, 2001 WL 637419, at *8 (citing *Waldorf*). Despite this,
 23 EPA makes the bewildering suggestion that intervening “factual” developments do not matter, stating
 24 “[w]hile an ‘intervening change in law’ can result in manifest injustice, Plaintiffs cite no case in which a
 25 court held that a *factual* development rendered a stipulation unjust.” EPA Opp. at 5:6-7 (emphasis in
 26 original). Contrary to EPA’s suggestion, there is a long history of courts setting aside stipulations based on
 27 newly arising factual developments. *Carnegie Steel Co v. Cambria Iron Co*, 185 U.S. 403, 443–44 (1902)

1 (setting aside a stipulation about the amount of molten metal in a mixer “upon the facts being more fully
2 ascertained”); *Morrison*, 828 F.2d at 709-10 (setting aside stipulation on the amount of damages after
3 evidence at trial indicated a lower number than the parties had agreed upon); *Peschel v. City of Missoula*
4 *through Missoula Police Dep’t*, No. CV 08-79-M-RFC-JCL, 2008 WL 11417151, at *2 (D. Mont. Dec. 30,
5 2008) (setting aside a stipulation that no video of the arrest existed after the police identified a computer
6 from which the video might be retrievable); *McMorgan*, 931 F. Supp. at 703 (setting aside a stipulation
7 that two parties had a “joint client relationship” after subsequently discovered facts showed that no such
8 relationship existed); *Sam Galloway Ford*, 793 F. Supp. at 1081-82 (setting aside a stipulation on facts
9 relevant to an insurance policy’s coverage of a claim after evidence showed it was based on factual
10 inaccuracies); *cf. Waldorf*, 142 F.3d at 618 (refusing to set aside stipulation because the “new” evidence
11 was discoverable long before the stipulation was entered); *Mullen*, 590 F. Supp. 2d at 1237 (same).

12 The intervening development at issue in Plaintiffs’ motion (i.e., Jessica Trader’s pregnancy) is
13 precisely the kind of development that has justified setting aside stipulations in the aforementioned cases.
14 Specifically, the development did not pre-date the stipulation, and thus was not omitted from the stipulation
15 out of carelessness or lack of diligence. Instead, the development took place long *after* the stipulation was
16 signed. This Court has already recognized the significance of whether any supplemental standing evidence
17 pre-dates or post-dates the stipulation, stating that the “door is closed” on evidence that could have been
18 presented previously, but is potentially open to evidence that arises from “intervening developments.” ECF
19 No. 264 at 26:9-13; *see also id.* at 38:20-23. The law and this Court’s guidance are thus in harmony.

20 Finally, while EPA argues that “parties would never agree to stipulations if they could be undone
21 merely because circumstances change,” see EPA Opp. at 5:8-9, things are not that simple. As one court has
22 noted, the “willingness on the part of courts to set aside stipulations *encourages parties to stipulate* since
23 the parties feel more confident that courts will set aside the stipulations if there is a reasonable basis to do
24 so.” *Sam Galloway*, 793 F. Supp. at 1082 (emphasis added).

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26 ///

27 ///

F. Rule 16(e) Does Not Apply But, Even if It Did, It Would Not Command a Different Result

EPA claims that Rule 16(e) is applicable to Plaintiffs' motion "because the Stipulation was incorporated into the parties' pretrial statement." EPA Opp. at 4:2-3. This is *yet another* factually incorrect statement in EPA's brief. The only page from the pretrial statement that EPA cites is a portion of Plaintiffs' *exhibit list* which includes the declarations as exhibits, but not the stipulation. *See* ECF No. 153-1 at 8. Further, while the Court had previously approved the stipulation, *see* ECF No. 102, this was long before the pre-trial conference and thus does not come within the orbit of Rule 16(e). As such, the Court's prior approval of the stipulation would be subject to Local Rule 7-9, which permits courts to reconsider prior orders where there is "the emergence of new material facts . . . after the time of such order." Civ. Loc. 7-9(b)(1). Here, new material facts have arisen since the Court approved the stipulation, and thus relief under Local Rule 7-9 would clearly be appropriate.⁸

Even if Rule 16(e) applies to this motion (it does not), the result would not change because, as with the law on stipulations, the Rule permits modification when not doing so would create "manifest injustice." As the Ninth Circuit has explained, a pretrial order is not "an inexorable decree" or "legal straightjacket" and should be "adaptab[le] to meet changed or newly discovered conditions or to respond to the special demands of justice." *Jeffries v. United States*, 477 F.2d 52, 55 (9th Cir. 1973) (citation omitted); *Fresno Rock Taco, LLC v. Nat'l Sur. Corp.*, No. 1:11-CV-00845-SKO, 2013 WL 3803911, at *5-6 (E.D. Cal. July 19, 2013). Thus, even if Rule 16(e) were applicable, the change in circumstances would justify modifying the order.

April 2, 2021

Respectfully submitted,

/s/ Michael Connett
MICHAEL CONNETT
Attorney for Plaintiffs

⁸ To the extent the Court desires Plaintiffs to file a formal motion under Local Rule 7-9 to expressly request this relief, separate and apart from the instant motion, Plaintiffs will do so.

Exhibit 1

From: [Michael Connett](#)
To: [Carfora, Debra \(ENRD\)](#)
Subject: RE: 3:17-cv-02162-EMC Food & Water Watch, Inc. et al v. Environmental Protection Agency et al Motion to Amend/Correct
Date: Wednesday, February 24, 2021 5:12:00 PM

Hi Debbie,

I have now had a chance to speak with my clients in depth about the possible stipulation we discussed yesterday. Based on the terms we discussed yesterday, I think we may be pretty close to an agreement.

I have authority to propose the following:

Plaintiffs will agree to close the record in this case (thereby precluding any further live testimony, and precluding the admission of any additional studies/reports) on the following terms:

- A declaration from Jessica Trader is admitted into evidence which sets forth the newly arising facts identified in the Supplemental Complaint, and EPA agrees to waive its opposition to the Motion to Amend.
- The **NTP and NAS reports** are admitted into evidence.
- The parties will simultaneously submit short **expert declarations that address the NAS and NTP reports** at a date TBD. There will be defined limits on the number of declarations per side (either 2 or 3) and the number of pages for the declarations.
- After receiving the expert declarations, the parties will have the opportunity to simultaneously submit one short rebuttal declaration at a date TBD, with defined page limits.
- After the expert declarations are submitted, the record will be closed, and the parties will agree to submit the case for a ruling by the Court.

Please let me know your thoughts. I am around now if you still have time to discuss. I'll be in a deposition for much of the day tomorrow, so may be difficult to speak then, but my schedule will be pretty open again on Friday.

Michael

From: Carfora, Debra (ENRD) <Debra.Carfora@usdoj.gov>
Sent: Wednesday, February 24, 2021 6:08 AM
To: Michael Connett <mconnett@waterskraus.com>
Subject: RE: 3:17-cv-02162-EMC Food & Water Watch, Inc. et al v. Environmental Protection Agency et al Motion to Amend/Correct

[CAUTION]: External Email

Do you want to try and touch based today re: your vm? I just have some follow up questions. You can call me at your convenience, I'll be free until 3 eastern.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served by Notice of Electronic Filing this 2nd day of April, 2021, upon all ECF registered counsel of record using the Court's CM/ECF system.

/s/ Michael Connett .
MICHAEL CONNETT