United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

FOOD & WATER WATCH, INC., et al., Plaintiffs, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al., Defendants.	Case No. 17-cv-02162-EMC **FINAL PRETRIAL CONFERENCE ORDER (PHASE TWO)**

I. TRIAL DATES & LENGTH

A bench trial shall be held beginning on January 31, 2024. Trial days are: January 31, February 1, 2, 5, 6, 7, 9, 12, 13 (nine days total) with one extra day available in case of logistical issues: February 14. Trial days shall begin at 8:30 a.m. and end at 1:30 p.m. Counsel are expected to be present at 8:00 a.m. at least, unless the Court orders otherwise.

Each side shall have 18 hours to present their case. This includes opening statements, direct and cross-examinations, and closing arguments.

II. TRIAL PROCEDURES

A. Evidence and Objections

A party must give the opposing party at least forty-eight (48) hours' notice of witnesses it intends to call, exhibits it intends to use, and/or demonstratives it intends to use. Saturdays and Sundays do not count. Thus, *e.g.*, for a Monday trial day that starts at 8:30 a.m., a party must give the opposing party notice by 8:30 a.m. on Thursday.

If the opposing party has an objection, then it must notify the party by 6:00 p.m. the same day of notice, and the parties shall meet and confer to see if they can resolve their differences. If

they cannot, then they shall file with the Court a joint statement twenty-four (24) hours in advance of the relevant trial day. In short, the Court requires a full day to resolve any objections.

The Court emphasizes that, because this will be a bench trial, it expects objections to be kept to a minimum.

B. Broadcast of Trial

The emergency CARE act has sunsetted and the Judicial Conference of the United States has enacted an advisory policy that limits broadcasting in civil cases to audio-only nonevidentiary hearings. However, the Ninth Circuit has yet to rescind its broadcast policy which allows for broadcasting civil proceedings by e.g. Zoom. In light of the benefits (including educational benefits and public interest) of broadcasting, the Court will broadcast the trial live via Zoom Videoconference.

C. Trial and Evidentiary Format

The trial is to take place in-person. Witnesses will be testifying in person with the exception of one witness that will be testifying via deposition video. Exhibits will be displayed electronically at trial to allow for a more efficiently display of evidence.

D. Proposed Findings of Fact

The parties are to submit a merged document with proposed findings of fact and conclusions of law by one week prior to the start of trial, i.e., by January 24, 2024. The Court shall require the parties to file on a rolling basis iterative proposed findings of fact based on the specific evidence that was presented on a given trial day. Citations to the relevant witness testimony and/or exhibit number will be helpful but are not necessary; the document need not include reference to specific pin-cites during the trial. The parties will work together to merge the documents under a single framework for organizing the proposed findings of fact and shall file the proposed findings one week before trial.[1]

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[1] Most likely, the Court will also order post-trial briefing as well.

III. UNDISPUTED FACTS

The parties do not dispute the following facts:

A. Undisputed Facts from First Trial

1. According to the United States Centers for Disease Control and Prevention (CDC), as of 2014, approximately 200,000,000 people in the United States live in communities that add fluoridation chemicals to the drinking water.
2. Plaintiffs' Citizen Petition sought to prohibit the addition of fluoridation chemicals to water on the grounds that this condition of use presents an unreasonable risk of neurologic harm.
3. Fluoridation chemicals are added to drinking water to prevent tooth decay (i.e., dental caries). In addition to being added to water, fluoride is added to dental products and certain pesticides.
4. In epidemiology, a cross-sectional study is a comparison of the prevalence of a specific health outcome across levels of a specific exposure in study subjects (or vice versa), with the exposure and outcome both measured at a given time, providing a "snapshot" of the association between the exposure and the health outcome at one time.
5. In epidemiology, a cohort study is a comparison of incidence rates of a specific health outcome between study subjects with various levels of a specific exposure who are observed over time.
6. A person's individual response to fluoride exposure depends on factors such as age, kidney function, body weight, activity level, nutrition, and other factors.
7. Human urine fluoride concentrations (biomonitoring) measure an internal dose.
8. Various factors can affect the concentration of fluoride in a urine sample, such as an individual's metabolism, when a urine sample is collected, and the time since the last void of the individual who provided the sample.
9. Historically, most studies to investigate the impact of fluoride on IQ in humans have used cross-sectional study designs. Most of these cross-sectional studies have been conducted in China, and other countries with elevated levels (>1.5 mg/L) of naturally occurring fluoride

in water. By contrast, fluoride is added to water in the United States to reach a concentration of 0.7 mg/L.

10. Prospective cohort studies have been conducted in Mexico City (ELEMENT cohort), where fluoride is added to salt, and Canada (MIREC cohort), where fluoride is added to water. These studies are the most methodologically reliable human studies to date on the impact of fluoride on neurodevelopment.[2]
11. Risk assessment is the process by which scientific judgments are made concerning the potential for toxicity in humans.
12. The National Research Council (NRC, 1983) has defined risk assessment as including the following components: hazard identification, dose-response assessment, exposure assessment, and risk characterization.
13. The term "risk evaluation" is a specialized term under TSCA.
14. Together, the components of EPA's risk assessment process, coupled with the ultimate risk determination, constitute a "risk evaluation" under TSCA.
15. The final step of a risk evaluation is to weigh a variety of factors to determine whether the chemical substance, under the conditions of use, presents an unreasonable risk of injury to health or the environment, referred to as the "risk determination" step in the TSCA risk-evaluation process.
16. EPA does not require that human exposure levels exceed a known adverse effect level to make an unreasonable risk determination under TSCA.[3]
17. In the ideal world, all risk assessments would be based on a very strong knowledge base (i.e., reliable and complete data on the nature and extent of contamination, fate and transport processes, the magnitude and frequency of human and ecological exposure, and the inherent toxicity of all of the chemicals). However, in real life, information is usually

[2] EPA's position is that this fact, as drafted, is no longer undisputed given the publication of the Spanish (INMA) and Danish cohort studies.

[3] The parties have omitted the second sentence from this undisputed fact because they have agreed that it was vague, and redundant to undisputed facts 26 & 27.

limited on one or more of these key data needed for risk assessment calculations. This means that risk assessors often have to make estimates and use judgment when performing risk calculations, and consequently all risk estimates are uncertain to some degree. For this reason, a key part of all good risk assessments is a fair and open presentation of the uncertainties in the calculations and a characterization of how reliable (or how unreliable) the resulting risk estimates really are.

18. EPA's *Guidelines for Neurotoxicity Risk Assessment* were designed in 1998 to guide EPA's evaluation of substances that are suspected to cause neurotoxicity, in line with substantive standards established in the statutes administered by the Agency.

19. EPA's *Guidelines for Neurotoxicity Risk Assessment* preceded the 2016 TSCA amendments.

20. The current non-enforceable health goal for fluoride under the Safe Drinking Water Act ("SDWA"), or Maximum Contaminant Level Goal (MCLG), of 4.0 mg/L was promulgated in 1985 to protect against a condition known as crippling skeletal fluorosis (i.e., "stage III skeletal fluorosis"). Crippling fluorosis is the final, and most severe, stage of skeletal fluorosis.

21. Based on its 2006 review, the National Research Council (NRC) of the National Academies of Science (NAS) recommended that the MCLG of 4 mg/L be lowered to prevent children from developing severe dental fluorosis and reduce the lifetime accumulation of fluoride into bone that the majority of the committee concluded is likely to put individuals at increased risk of bone fracture and possibly skeletal fluorosis.

22. Based on the NRC's recommendation, in 2010, EPA's Office of Water completed a dose-response analysis using available data between 2000 and 2010 to calculate a reference dose ("RfD")—an estimate of the fluoride dose protective against severe dental fluorosis, stage II skeletal fluorosis, and increased risk of bone fractures— of 0.08 milligrams per kilograms per day (mg/kg/day), a measure of daily intake by body weight.

23. In addition to the tooth and bone effects, the NRC also evaluated neurotoxicity as an effect of fluoride exposure, among other health effects. The NRC concluded that the available

data were inadequate to demonstrate a risk for neurotoxicity at 4.0 mg/L and made recommendations for additional research. Since that time, additional research has been conducted and the scientific database for studies that have examined neurotoxicity as an effect of fluoride exposure has grown.

24. In determining whether adding fluoridation chemicals to drinking water presents an unreasonable risk of neurotoxic effects under TSCA, EPA's Office of Pollution Prevention and Toxics would not rely on the 2010 RfD, but would instead apply a weight of the scientific evidence approach for identifying and characterizing the best available science from the most up-to-date scientific database of studies that have examined neurotoxicity as an effect of fluoride exposure.

25. In conducting TSCA risk evaluations, EPA generally uses the Margin-of Exposure (MOE) approach to characterize the risk as a step in the risk assessment process. Using this approach, an MOE is calculated by comparing (dividing) the point-of departure directly to the expected exposure level. The MOE is then compared to a benchmark MOE, which is the product of all relevant uncertainty factors.

26. EPA considers the MOE, relative to the benchmark MOE, in addition to other factors, in determining whether risks are unreasonable under TSCA.

27. The National Research Council has stated that "the inference that results from animal experiments are applicable to humans is fundamental to toxicologic research."

28. EPA agrees that effects observed in animals are relevant to humans unless human data counterindicate.

29. The developing brain is distinguished by the absence of a bloodbrain barrier. The development of this barrier is a gradual process, beginning in utero and complete at approximately 6 months of age.

30. Fluoride passes through the placenta and gets into the fetal brain.

31. Whether harm would actually occur depends on the dose and nature of exposure.

Docket No. 378 (Joint Pretrial Statement) at 2-6.

B. Additional Undisputed Facts for the Second Phase of Trial

32. In addition to the ELEMENT and MIREC studies, prospective cohort studies on fluoride and IQ have now been conducted in Denmark (OCC cohort), Mexico (PROGRESS cohort), and Spain (INMA cohort).

33. Subsequent to the first phase of the trial, two pooled benchmark dose analyses have been published on the relationship between maternal urinary fluoride levels and childhood IQ. Plaintiffs' expert Dr. Philippe Grandjean is the lead author of both studies. One of the analyses, published in 2022, pooled the data from the ELEMENT and MIREC studies. The other analysis, published in 2023, pooled the data from the ELEMENT, MIREC and OCC cohorts.

34. The National Toxicology Program (NTP) has released two updated drafts of its State of the Science Monograph of fluoride neurotoxicity: one dated May 2022, and the other dated September 2022.

35. NTP has released an updated draft of its meta-analysis manuscript of fluoride and IQ, dated July 2022.

36. The NTP has released its Board of Scientific Counselors Working Group Report on the Draft State of the Science Monograph and the Draft Meta-Analysis Manuscript on Fluoride, May 16, 2023. The report includes interagency review comments, the NTP authors' responses to those comments, and the BSC Working Group's assessment of the NTP authors' responses.

37. Subsequent to the first trial, EPA published its first ten risk evaluations of existing chemicals under the Amended TSCA.

38. Under the Amended TSCA, EPA has made Unreasonable Risk determinations where it did not have high confidence in the hazard data.

39. In its first 10 risk evaluations under the Amended TSCA, EPA made Unreasonable Risk determinations where it had medium confidence in the hazard data.

40. Under the Amended TSCA, EPA has made Unreasonable Risk determinations where it did not have high confidence in the exposure data.

41. In its first 10 finalized risk evaluations under the Amended TSCA, EPA made Unreasonable Risk determinations where it had medium confidence in the exposure data.

42. EPA has made Unreasonable Risk determinations for conditions of use where average exposures did not present a risk, but highly exposed individuals (e.g., 95th percentile) had exposures of concern.

43. EPA has made Unreasonable Risk determinations for conditions of use that involve fewer than 500 people.

Id. at 6-8.

IV. DISPUTED FACTUAL ISSUES

1. Plaintiffs contend that fluoridation chemicals pose an unreasonable risk of neurotoxicity when added to drinking water because:
    a. neurotoxicity is a *hazard o*f fluoride exposure when the scientific literature is assessed according to the framework that EPA uses for hazard identification under the Amended TSCA;
    b. neurotoxicity is a *risk* at the exposure levels produced by fluoridation chemicals when assessed according to the framework for risk characterization that EPA uses under the Amended TSCA; and
    c. the risk of neurotoxicity posed by fluoridation chemicals is *unreasonable* when assessed according to the framework that EPA uses for risk determinations under the Amended TSCA.
2. EPA contends that the following disputed facts for the second phase of trial are material to Plaintiffs claim:
    a. The scientific evidence for evaluating the risk of neurotoxic effects from low-dose exposure to fluoride, especially considering the more recent scientific studies published after the first trial, is insufficient to reach an informed risk determination under TSCA.
    b. The existing scientific studies do not provide sufficient evidence to support a hazard assessment in a TSCA risk evaluation for low-dose fluoride exposure

associated with community water fluoridation in the United States.

c. Plaintiffs have not provided any way to convert a urinary-fluoride-based dose response to total intake levels, which is critical to making a risk calculation and subsequent determination. Assuming a one-to-one linear relationship of biomarkers based on dose-response data with intake levels is not supported by limited existing low-exposure data.

d. Plaintiffs did not conduct an exposure assessment.

e. Uncertainty in the hazard assessment and variability in response between the most reliable and robust studies at this time makes a risk estimation highly uncertain.

f. Plaintiffs have not set forth a scientifically defensible basis to conclude that there is an unreasonable risk of neurotoxic harm as a result of exposure to fluoride in the United States through the addition of fluoridation chemicals to drinking water.

Id. at 8-9.

V. WITNESSES

The parties have submitted a joint witness list. The parties are limited to these witnesses for their cases-in-chief. The witnesses are as follows:

Plaintiffs' Witnesses

(1) **Dr. Stanley Barone Jr., MS, Ph.D.,** is a scientist at the UPA who the EPA designated as its 30(b)(6) representative.[4]

(2) **Dr. Brian Berridge, D.V.M. Ph.D., D.A.C.V.P.,** (subject of Def's MIL No. 1), was the Scientific Director of the NTP from 2018 to 2023.

(3) **Dr. Philippe Grandjean, MD, DMSc,** is a physician and environmental epidemiologist who serves as Chair of Environmental Medicine at the University of Southern Denmark.

(4) **Dr. Howard Hu, MD, MPH, ScD**, is the Chair of the Department of Preventive Medicine, Keck School of Medicine, at the University of Southern California.

[4] As stated during the pretrial conference, Plaintiffs' request to call Dr. Barone as an expert witness is denied; Plaintiffs did not notice Dr. Barone as an expert witness.

(5) **Dr. Bruce Lanphear, MD, MPH**, is a Professor of Health Sciences at Simon Fraser University in Vancouver, British Columbia.

(6) **Dr. Kathleen Thiessen, PhD**, is a risk assessment scientist and President of Oak Ridge Center for Risk Analysis.

Defendants' Witnesses

(7) **Dr. David Savitz, MS, Ph.D.**, is a Professor of Epidemiology at Brown University School of Public Health, a Professor of Pediatrics, Obstetrics and Gynecology at Brown University Medical School, and is an Adjunct Professor of Epidemiology at both the Dartmouth School of Medicine and the Boston University School of Public Health.

(8) **Dr. Stanley Barone Jr., MS, Ph.D.,** is the Senior Science Policy Advisor and Deputy Science Integrity Official for the United States Environmental Protection Agency's ("EPA") Office of Chemical Safety and Pollution Prevention ("OCSPP").

(9) **Dr. Jesús Ibarluzea, Ph.D.**, is an epidemiologist and Professor at the University of the Basque Country in Spain. Dr. Ibarluzea studies the association between maternal fluoride exposure during pregnancy and neurodevelopmental outcomes in offspring in the INMA Gipuzkoa cohort.[5]

Absent further instruction, witnesses are permitted to watch testimony from other witnesses throughout the trial.

VI. MOTIONS IN LIMINE

A. Defendants' MIL No. 1 to Exclude the Testimony of Brian Berridge (Docket No. 374)

Defendants seek to exclude the testimony of former National Toxicology Program ("NTP") Scientific Director, Dr. Brian Berridge. *See* Docket No. 374 ("Def's MIL No. 1") at 1. Dr. Berridge served as the NTP Scientific Director from 2018 to 2023, where he oversaw development of NTP's May 2022 *Monograph on the State of the Science Concerning Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects: A Systematic Review* (the "NTP

[5] Dr. Jesús Ibarluzea is no longer available to testify and will not be testifying live. However, Plaintiffs reserve the right to introduce designations of the videotaped deposition of Dr. Ibarluzea should the EPA decide not to introduce this deposition.

May 2022 State of the Science Monograph" or "State of the Science Monograph") (submitted as Pl's Exhibit No. 67). Docket No. 378 (Joint Pretrial Statement) at 2. Dr. Berridge also oversaw the development of NTP's July 2022 manuscript *Association between fluoride exposure and children's intelligence: A systematic review and meta-analysis* (the "NTP July 2022 meta-analysis" or "NTP Meta-Analysis") (submitted as Pl's Exhibit No. 68). *Id.* For the reasons discussed herein, the Court **GRANTS** in part and **DENIES** in part Defendants' first motion in limine. Dr. Berridge's testimony regarding political influence upon the State of the Science Monograph's draft status is to be excluded. However, Dr. Berridge may testify as to the first two issues identified in the parties' witness list. *See* Docket No. 378-1 at 2.[6]

In Plaintiffs' Initial Disclosures pursuant to Federal Rule 26, submitted on May 8, 2023, Plaintiff disclosed Dr. Berridge as a witness among other "[c]urrent and former NTP scientists who have knowledge of the [NTP] Monograph," and specifically knowledge of the "history of [the Monograph's] development, the peer review processes and scientific methodologies that it has employed, and *the political pressures that it has been subjected to by officials and agencies with strong policy interests on fluoride.*" Docket No. 374, Declaration of Brandon N. Adkins ("Adkins Decl."), Ex. D (Pl's Initial Disclosures) at 2. In the pretrial filings, Plaintiffs list Dr. Berridge as a witness testifying to:

> (1) NTP's purposes and procedures, including the hazard focused nature of NTP evaluations, as opposed to risk-focused; (2) the extensive review process that the NTP's fluoride monograph and meta-analysis on fluoride neurotoxicity have undergone, and (3) why Dr. Berridge made the decision to publish the May 2022 monograph, and how in the normal course of events this would have been the final and dispositive step for publishing the monograph, but was not.

Docket No. 378 (Joint Pretrial Statement) at 2.

The NTP May 2022 State of the Science Monograph has not yet been published by NTP, and the parties do not anticipate that it will be published before the second phase of trial. *See*

[6] This includes "(1) NTP's purposes and procedures, including the hazard focused nature of NTP evaluations, as opposed to risk-focused; (2) the extensive review process that the NTP's fluoride monograph and meta-analysis on fluoride neurotoxicity have undergone." Docket No. 378-1 at 2.

Docket No. 376 (Def's Trial Brief for Second Phase of Trial) at 5; Docket No. 379 (Pl's Trial Brief for Second Phase of Trial) at 4. Plaintiffs state that on May 11, 2022, NTP announced that the systemic review of the State of the Science Monograph was complete and intended to be released in seven days, but that political leadership of the Department of Health & Human Services (HHS) prevented the publishing of the document. Docket No. 379 at 4. The parties agree the State of the Science Monograph remains unpublished at present. *See* Docket No. 376 (Def's Trial Brief for Second Phase of Trial) at 5; Docket No. 379 (Pl's Trial Brief for Second Phase of Trial) at 4. Thereafter, an additional draft was published in September 2022. *See* Docket No. 378 (Joint Pretrial Statement) at 7.[7] Though not published as final, the May 2022 State of the Science Monograph, along with comments and criticisms and responses regarding the State of the Science Monograph have been made publicly available.

Defendants take issue with Dr. Berridge testifying as to the alleged impact of political influence upon declining to publish as final the State of the Science Monograph regarding fluoride exposure conducted by NTP in May 2022 when it was completed. Def's MIL at 1. Defendants argue that this testimony should be excluded pursuant to Federal Rules of Evidence 401, 402, and 403. *Id.* Namely, Defendants argue that the evidence is not relevant pursuant to Federal Rule 401 (test for relevancy) and thus should be excluded under Federal Rule 402 (providing that all relevant evidence not otherwise excluded should be admitted). *Id.* at 1, 3. Additionally, that the evidence should be excluded pursuant to Federal Rule 403 as its probative value is substantially outweighed by the danger of confusing issues, wasting time, or being needlessly cumulative, to the extent it is relevant. *Id.* at 4. Defendants also argue there is a procedural deficiency here. *Id.* at 3. Specifically, Defendants argue that the attempt to submit this evidence is unsound because the Court already ruled that political influence upon the publishing of the State of the Science Monograph is not relevant. *Id.* To revisit this ruling, Defendants argue, Plaintiffs should have sought leave to file a motion for reconsideration pursuant to Local Rule 7-9 which Plaintiffs failed to do. *Id.* at 3. Defendants also argue that because of the prior ruling by the Court as to relevant

[7] Plaintiffs assert that the September 2022 draft is nearly identical in substance from the May 2022 draft. Accordingly, that there are multiple drafts does not change the calculus.

of political influence, Defendants forewent taking discovery from Dr. Berridge as to political influence and would suffer prejudice now if his testimony were allowed. *Id.*

Plaintiffs' position is that the issue of political influence upon the decision not to publish the State of the Science Monograph is highly relevant because it impacts the weight afforded that the document, which remains in draft form and is now a central piece of evidence in this case. Pl's Opp. to MIL (available as attachment to Def's MIL, Docket No. 374) at 5. Plaintiffs also argue that the Court has yet to opine on the admission of witness testimony on political influence at trial, and the previous ruling was on a distinct issue and that there is no prejudice to Defendants based upon their decision not to take discovery of Dr. Berridge based on the Court's previous ruling. *Id.* at 5-7. Additionally, Plaintiffs argue that the issues that Dr. Berridge intends to testify about beyond political influence fall within his purview as a fact witness. *Id.* at 7.

As an initial matter, the Court takes note of its prior rulings relating to the relevancy or admissibility of evidence regarding political influence on the Monograph to assess the import of the Court's previous ruling here. The Court has yet to rule definitively on the admissibility at trial of such materials, and only considered the propriety of allowing discovery to be taken on the issue.

In the first instance, in March 2023, the Court adjudicated a discovery letter brief wherein Defendants moved to quash two subpoenas for fact depositions of Jayanth Kumar and Christine Wood. Docket No. 346 (Joint Discovery Brief Regarding Depositions of Jayanth Kumar and Christine Wood). The depositions fell within the presumptive limit of ten depositions to be taken by Plaintiffs. *See id.* Defendants argued that the then-current scope of discovery (pertaining to subject matter, and not number of depositions) identified by the Court did not allow the depositions. *Id.* at 1. Specifically, the Court determined at a prior status that limited discovery would be permitted only: (1) fact discovery only to "allow for the production of the May 2022 NTP draft review . . . [to] help the Court determine future scheduling," and (2) expert discovery insofar as to allow "commencement of expert review of the new scientific evidence." ECF No. 319 at 5. Defendants also argued that the depositions were unfairly prejudicial, irrelevant, and disproportionate because the depositions relate to Plaintiffs' narrative that "the NTP draft has been

subjected to improper 'partisan' interference" and further that this issue "is of little-to-no-relevance to the issues in this litigation, and it is not proportionate to the needs of this case." *Id.* at 2. The Court allowed taking of the depositions, in part because the State of the Science Monograph is "the centerpiece of this dispute." Docket No. 346 (Order Denying Request for Emergency Hearing and Clarifying Discovery Scope) at 2. The Court explained that because Dr. Kumar and Mr. Wood may have knowledge as to why the May 2022 monograph was not published, the testimony of these witnesses "may shed light on EPA's defenses regarding the draft status and industry criticisms of the NTP monograph." *Id.* As such, allowing the depositions, which fell within the scope of depositions allotted to Plaintiffs, was warranted. *See id.* Of course, relevance for discovery purposes is not the same as admissibility at trial.

Subsequently, in April 2023 the parties submitted their Seventh Joint Status Report identifying a dispute between the parties as to whether Plaintiffs should be granted leave to exceed the presumptive limit of ten depositions. Docket No. 350 (Seventh Joint Status Report) at 3. Specifically, the parties provided "the parties continue to meet and confer regarding fact depositions, and whether Plaintiffs will need to seek leave of the Court to exceed 10 depositions in this litigation (including the depositions taken prior to the first trial.)." *Id.* At the status conference, Plaintiffs explained they intended to seek leave to conduct fact depositions of federal officials at the Department of Health and Human Services ("HHS") regarding alleged political pressures imposed upon NTP leading up to its decision not to publish the State of the Science Monograph. *See* Docket No. 352 (Minute Entry, April 11, 2023, Status Conference).

At that time, Plaintiffs argued that the depositions were needed because the decision not to publish the State of the Science Monograph in the first instance speaks to the weight and scientific merit of the report as evidence. *Id.* at 1. Plaintiffs explained that the Court would eventually be confronted with "the question of how much weight do you give to the NTP's May 2022 assessment because . . . by the time we got to trial next January, there [may not] be a final NTP monograph for us all to rely upon." Docket No. 374, Adkins Decl., Ex. A (April 11, 2023, Status Conference Transcript) at 10:4-10. Plaintiffs further argued that they suspected that at trial, EPA would argue that the State of the Science Monograph is merely a draft report and should not be

given much weight. *See id.* at 10:11-15. Plaintiffs' position was that the Monograph was not published in May due to political pressure. *Id.* at 11:19-20.

Defendants argued in rebuttal that the comments and NTP's responses to comments regarding the State of the Science Monograph's draft have since been made public, thus, enlarging the number of depositions allotted to Plaintiffs to assess political impact upon the decision to delay publication of the State of the Science Monograph were not needed. *Id.* at 2. Additionally, because Plaintiffs would be able to put on expert testimony regarding the legitimacy of the State of the Science Monograph substantively at trial, depositions were not necessary. *Id.* Specifically, "Counsel can rebut [claims made by EPA with respect to the draft monograph] by putting on expert testimony, explaining what the comments were, and whether it was reasonable or not to stop publication." *Id.* at 12:32-7. In other words, Plaintiffs could put on evidence speaking to the merits of the State of the Science Monograph to rebut EPA's arguments the draft should be given less weight, instead of context regarding e.g., political reasons not to publish it. *See id.* Ultimately, Defendants' position was that the decision not to initially publish the May 2022 draft was a tangential issue not speaking to the heart of the matter which is whether fluoridation in the water supply presents a hazard. *Id.*

As explained in the minutes for the April 11, 2023, status conference hearing, the Court sided with Defendants and ordered—without prejudice—that allowing additional depositions beyond the presumptive limit to depose government officials related to NTP's decision not to publish the State of the Science Monograph would not be permitted. *See* Docket No. 352 (Minute Entry, April 11, 2023, Status Conference). The Court reasoned the relevancy of the issue was not obvious and/or was limited, as the report and criticisms of the draft have since been made public. *Id.* As the Court explained, "[a]bsent good cause, the Court . . . must proceed on the merits of the science which does not require the information Plaintiffs seek in the depositions." *Id.* To this end, the Court explained at the status conference:

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> [W]e ought to focus on the science to the extent [EPA] attempt[s] to criticize the monograph and to down-play the importance of the draft that will be the scientific debate that I am going to have to listen to. That's more important [than] whether politicians got involved and tried to squelch this thing. Whether they did or not, I have to look at the science at the end of the day. So the motive for delaying the publication now that it's all out is not really on point.

Docket No. 374, Adkins Decl., Ex. A at12:16-13:12 (cleaned up). Accordingly, the Plaintiffs were not permitted to take additional depositions of witnesses beyond the presumptive limit. *See* Docket No. 352 (Minute Entry, April 11, 2023, Status Conference).

The Court maintains the focus at trial should be on the scientific merits as opposed to ancillary issues including, e.g., political influence upon the "draft" status of the State of the Science Monograph. Though there is a path to relevancy for the testimony regarding the decision not to publish as final the State of the Science Monograph, the probative value of that testimony is outweighed by the undue delay it will cause.

Federal Rule 401 provides that evidence is relevant if "(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401. "To be 'relevant' evidence need not be conclusive proof of a fact sought to be proved, or even strong evidence of the same. All that is required is a 'tendency' to establish the fact at issue." *United States v. Curtin*, 489 F.3d 935, 943 (9th Cir. 2007) (citing Fed. R. Evid. 401).

The issue of publishing the State of the Science Monograph is somewhat relevant, but its probative value is limited and attenuated. At bottom, the issue in this suit is whether and at what amount fluoridation chemicals added to public drinking water presents an unreasonable risk of injury to health under the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2620(b)(4)(B). *See* Docket No. 376 (Def's Trial Brief) at 1; Docket No. 379 (Pl's Trial Brief). To be sure, the State of the Science Monograph, i.e., NTP's latest study addressing the impact of fluoridation on health, is a key piece of evidence in answering that question. *See, e.g.*, Docket No. 346 (Order Denying Request for Emergency Hearing and Clarifying Discovery Scope) at 2 (monograph is "centerpiece" of dispute); Docket No. 262 (Order Holding Proceedings in Abeyance) at 4 (holding

case in abeyance in part because of "imminent" publishing of monograph among other forthcoming scientific research); Docket No. 290 (Ordering Granting Pl's Mot. for Leave to File Supp. Compl.) at 5 (citing Docket No. 279-1 ("Proposed Supp. Compl.") ¶¶ 30, 32)) (granting leave in light of supplemental evidence included in propose amended complaint including a summary of the draft monograph along with the Benchmark Dose (BMD) pooled analysis of the data used in previously considered ELEMENT and MIREC studies).

Plaintiffs explain that Dr. Berridge, the former Director of Science for NTP, decided to publish the State of the Science Monograph, which in his opinion, absent improper political influence would have been the final word on this issue of publication. *See* Pl's Opp. at 2 (citing Connett Decl., Ex. 1, Ex. 5). Insofar as Defendants intend to argue that the State of the Science Monograph, and its conclusions therein, should be afforded less weight as evidence in assessing health impacts of fluoridation, as Plaintiffs anticipate, the circumstances leaving the State of the Science Monograph in draft form are relevant. In other words, as explained previously in relation to the motion to quash, the political interference issue "may shed light on EPA's defenses regarding the draft status" of the Monograph. Docket No. 346 (Order Denying Request for Emergency Hearing and Clarifying Discovery Scope) at 2.

However, per Defendants' trial brief, it appears that Defendants are not focusing upon the draft status of the document in arguing that the State of the Science Monograph does not support finding an unreasonable risk presented by fluoridation in water but focuses instead upon the substance of the draft including its "methodolog[y] and the scientific quality of the presented information."[8] Def's Trial Brief at 2. As the Court understands it, Plaintiffs' primary contention is not that political influence impacted the scientific conclusions expressed in the State of the Science Monograph in the first instance, only its draft status.[9] *See* Pl's Opp. at 1-2, 5-6.

[8] Insofar as Defendants take a different approach at trial such that the draft status of the document becomes highly relevant the Court reserves the right to revisit this finding.

[9] There seems to be some suggestion that the decision to delay publication opened the State of the Science Monograph up to additional and unnecessary rounds of criticism and comment, thus, in a sense impacting the outcome of the monograph. *See* Pl's Exhibit No. 76 (email from Dr. Berridge stating that, in regard to the State of the Science Monograph "I have significant concerns that the level of engagement on the scientific product has crossed the line from rigorous peer review to

Accordingly, the draft status will not be highly pertinent in the suit in assessing the probative value of the State of the Science Monograph. The Court will afford the Monograph the weight that it deserves based on the merits; its status as an unpublished draft will have little bearing on that question.

Additionally, for the testimony at issue to be relevant, Plaintiffs would need to show that absent political influence the monograph would have been published, i.e., that neutral non-political factors were not a separate and legitimate basis to stall its publishing and ask for additional comment. This question itself could warrant an entire trial considering e.g., typical procedures by the agency, motives, and intent of particular actors, and would require assessing the hypothetical but-for world in which the alleged political influence did not exist. This would present the classic trial-within-a-trial on a collateral issue against which Fed. R. Evid. 403 is design to safeguard. Hence, testimony regarding political influence upon the draft status of the State of the Science Monograph will be excluded. *See* Fed. R. Evid. 403.[10] *See also Denker v. Ricchio*, 2022 WL 17885690, at *6 (C.D. Cal. Nov. 22, 2022) (excluding evidence that could "easily devolve into a time-wasting trial within a trial"); *Ohio House LLC v. City of Costa Mesa*, 2022 WL 2189541, at *6 (C.D. Cal. Mar. 28, 2022) (finding admission of evidence leading to a "trial within a trial," was not warranted as it would impose an "undue consumption of time"); *United States v. Sathre*, 2022 WL 889285, at *3 (D. Alaska Mar. 25, 2022) (excluding evidence that may result in a sub-trial where evidence presented minimal probative value).[11]

On the other hand, Plaintiffs set forth two topics that are both relevant and pose little risk

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ensure balance and accuracy to one that could be construed as attempting to influence the outcomes."). But the comments discussed have been made public and can be properly assessed based on their substance at trial.

[10] Plaintiffs correctly note that Federal Rule of Evidence 403 is of lesser import in the context of a bench trial rather than a jury trial, particularly as it relates to potential for prejudice, but it is not to be ignored entirely. *See, e.g., E.E.O.C. v. Farmer Bros. Co.*, 31 F.3d 891, 898 (9th Cir. 1994) (recognizing reduced risk of prejudice in bench trial compared to jury trials); *United States v. Ziska*, 267 F. App'x 717, 719 (9th Cir. 2008) (explaining that risk of unfair prejudice is "lessen[ed]" in a bench trial). Here the issue is not so much prejudice as it is a waste of time.

[11] Because the Court finds exclusion of this testimony is proper, the Court need not address Defendants' arguments pertaining to the import of the Court's prior order on this issue, i.e., Defendants' arguments about procedure and prejudice. Def's MIL No. 1 at 3-5.

of prejudice or delay upon the case and should be admitted – though with a caveat. Specifically, Plaintiffs wish to have Dr. Berridge testify as a fact witness as to: (1) " NTP's purposes and procedures, including the *hazard* focused nature of NTP evaluations, as opposed to *risk*-focused;" and (2) "the extensive review process that the NTP's fluoride monograph and meta-analysis on fluoride neurotoxicity have undergone." Docket No. 378-1 at 2. Defendants rebut that this testimony will be duplicative as other witnesses are already slotted to testify about the peer review and scientific methodologies of NTP. Def's MIL at 3-4. And further, because these subjects should be opined upon by an *expert* witnesses as opposed to *fact witness*, Dr. Berridge. *Id.* at 3-4.

As a threshold matter, the parties seem to agree that this evidence regarding the scientific methodologies employed by the NTP is relevant, as this evidence impacts the probative value of the substance of the State of the Science Monograph. *See* Def's MIL at 3-4 (arguing evidence is already going to be addressed by other witnesses for which the Defendants do not object to testifying on relevancy grounds). The key question is whether the subjects that Dr. Berridge seek to testify about are impermissible lay testimony, i.e., properly the subject of expert testimony only.[12]

Federal Rules 701 and 702 govern the line between lay person testimony and testimony by an expert. Under Rule 701, if a witness is not testifying as an expert, the testimony in the form of an opinion must be limited to one: "(a) rationally based on the witness's perception;" (b) "helpful to clearly understanding the witness's testimony or to determining a fact in issue;" and (c) "not based on scientific, technical, or other specialized knowledge within the scope of Rule 702." The conceptual line between expert and lay testimony rests upon whether the witness is opining as to facts for which they have firsthand knowledge, e.g., observations (lay), or where the witness is using their background or expertise to assess information not observed firsthand, and to provide an

[12] The potential for duplicative testimony is of little concern. Methodologies of the State of the Science Monograph are quite relevant, and Dr. Berridge has unique insight to offer as to methodologies employed by NTP given his position as former Science Director of the NTP during its drafting. *See* FRE 403. Additionally, Plaintiffs proceed at their own peril in using limited time afforded to them in putting on their case in determining whether and how much time to allot to overlapping issues.

opinion on that information based more generally on that expertise (expert). *Compare United States v. Meling*, 47 F.3d 1546, 1156-57 (9th Cir. 1995) *cert. denied*, 516 U.S. 843 (1995) *with United States v. Jackson*, 2022 WL 331687, at *1 (9th Cir. Feb. 3, 2022).

To illustrate, in *United States v. Meling*, the Ninth Circuit found that the district court did not abuse its discretion in admitting lay testimony of a 911 operator and paramedic regarding whether the defendant was faking grief at the time of making the call, in a trial against a husband accused of poisoning his wife. 47 F.3d at 1156-57. The court explained that lay opinion testimony is admissible what it is "rationally based on the perception of the witness." *Id.* Though, the experience of the witness may properly impact the observation. The court reasoned that, as paramedics are "trained to respond quickly in emergency situations," and the responder had ample time to form an impression regarding the defendant's emotional state, the testimony was rationally formed and was admissible. *Id.* This can be compared with the evidence at issue in *United States v. Jackson*, 2022 WL 331687, at *1. There, the Ninth Circuit explained that where a treating physician was asked to testify regarding the rate at which alcohol dissipates from the body; this was properly categorized as expert testimony. *See id.*

Accordingly, insofar as Dr. Berridge plans to testify regarding events he has observed firsthand including the processes of the NTP in producing the State of the Science Monograph, i.e., the facts underlying the organization's methodology, this is properly admissible lay person testimony.[13] *See* Fed. R. Evid. 701, 702, 602. On the other hand, to the extent that Dr. Berridge intends to offer a general opinion as to the import of those methodologies upon the weight of the monograph or its scientific value, based on his expertise as a scientist and/or epidemiologist, such testimony would cross the line into impermissible expert testimony, and the Court will be inclined to sustain a properly raised objection on this basis at trial. For these reasons, the Court **GRANTS** in part and **DENIES** in part Defendants' First Motion in Limine as described herein.

[13] The Court notes that Defendants elicited this same type of testimony, i.e., regarding methodologies of NTP, from Dr. Kristina Thayer, a fact witness and former NTP scientist working on NTP's review of animal studies on fluoride neurotoxicity published in 2016 at the first trial. *See* Docket No. 2442 at 594:3-7; 596:14-21; 614:2-10.

VII. EXHIBITS

A. Scope of Exhibit List

The exhibit list incorporates exhibits previously admitted in the first phase of trial in this case. As the Court previously explained, those exhibits are subsumed into this phase of trial. Parties need not reintroduce these exhibits and can refer to previous exhibit numbers.

B. Bellwether Exhibit Objections

Parties jointly filed Bellwether Objections to certain of the opposing parties' proposed exhibits. Docket No. 382. Plaintiffs have withdrawn objections to EPA Exhibits 653 and 654 and have no objections to EPA's exhibits in the second phase of trial. *See id.* at 1. Defendants seek ruling on two exhibits serving as bellwethers in the action. *See id.* at 1-4.

1. Exhibit 76: Alleged Political Influence on NTP Draft Monograph

Defendants first seek a ruling as to the admissibility of Pl's Trial Exhibit 76, which serves as a bellwether as to how the Court may rule on EPA's objections to Pl's Trial Exhibits 72-80. *Id.* at 1. Pl's Trial Exhibit 76 is a May 2022 email exchange between Dr. Berridge, Tara Schwetz, Acting Principal Deputy Director of National Institutes of Health ("NIH") Rick Woychik, another NIH employee, and other NIH/NTP employees. Plaintiffs primarily seek to introduce the May 12, 2022, email authored by Dr. Berridge in this chain and do not oppose eliminating the other email included therein. Docket No. 382 at 4-5. That email involved Dr. Berridge questioning the decision to subject the State of the Science Monograph to additional peer review instead of allowing the document to be published. Exhibit 76 at 2. In a similar vein as discussed above, the purported relevance of this Exhibit is to exemplify the political influence upon the decision to delay publication of the State of the Science Monograph. *See* Docket No. 378-2 (Exhibit List) at 4 ("Goes to the weight the Court should give NTO's May 2022 Monograph"). Setting aside the issue of hearsay, which is also of concern here, this evidence and evidence that relates to the political influence imposed upon delaying the publication of the State of the Science Monograph is properly excluded for the reasons discussed previously in relation to Defendant's first motion in limine under, at a minimum FRE 403. Accordingly, Defendant's objection is sustained as to Pl's Trial Exhibit 76 and the Court is inclined to rule similarly regarding exhibits 72-80.

2. Exhibit 89: Incomplete Deposition Exhibits

Pl's Trial Exhibit 89 is a true/false questionnaire that was filled out by EPA's 30(b)(6) representative Dr. Stanley Barone, assessing EPA's risk evaluations. This document serves as a bellwether to Pl's Exhibits 89-93. Defendant argues that these exhibits should be excluded as incomplete deposition exhibits on the grounds that Dr. Barone attempted to clarify the binary responses provided during his deposition but was rebuffed on direct examinations during the deposition. *See, e.g.*, Barone Tr. 121:2–8 ("Q. Okay. So, let's go back to Exhibit 6 [Trial Exhibit 89] the true/false questions. A. May I add to that? Q. I think you've answered the question, sir. Counsel can ask you questions later if they want to. A. Okay."). However, ultimately, Dr. Barone filled in a few written notations and admitted that the statements including those that were modified, reflected in Exhibits 90, 91, and 92, were factually correct at his deposition. *See* EPA 30(b)(6) Dep Tr. at 162:8-12; EPA 30(b)(6) Dep Tr. at 171:16-172:11; EPA 30(b)(6) Dep Tr. at 162:8-12. As such, these questionnaires have been adopted by Dr. Barone and are thus admissible. To the extent that Dr. Barone wishes to clarify his responses or add nuances to his binary answers, Defendants' counsel is free to elicit this information during cross-examination of Dr. Barone. Additionally, several of these statements are to be properly admitted as non-hearsay under FRE 801(d)(2)(A) as a statement made by an opposing party. As stated above, the document is a series of statements made by Dr. Stanley Barone, who was designated as the EPA's 30(b)(6) representative regarding how EPA conducts risk evaluations under the Amended TSCA. The document pertains to precisely that issue. The Court expects that Plaintiffs, in laying the foundation for admission of this document, will clarify the purposes for which it will be used in Plaintiffs' case. The Court will impose a limiting instruction to ensure that portions of the exhibit not adopted by Dr. Barone or not relevant to Plaintiffs' case are not improperly admitted, and so that Defendants need not spend unnecessary time examining him on such matters. With this caveat, the Court is inclined to deny Defendants' objection as to Pl's Ex. No. 89 and to rule similarly upon Exhibit Nos. 90-93.

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VIII. MISCELLANY

A. Legal Dispute: Impeachment Evidence Dr. Ibarluzea

The parties have an additional dispute as to how to handle impeachment materials for EPA's expert, Dr. Jesús Ibarluzea. When Plaintiffs took the deposition of Dr. Ibarluzea, parties agree that there was an understanding by the parties that Dr. Ibarluzea would be testifying at trial via Zoom. Docket No. 378 (Joint Pretrial Statement) at 9. Because of this understanding Plaintiffs forewent a trial preservation examination and thus did not show or question Dr. Ibarluzea regarding impeachment materials probative to credibility. *Id.* Thereafter parties learned Dr. Ibarluzea will be unable to testify live at trial. *Id.* Given this development, the parties have a dispute about if and how Plaintiffs can introduce materials that impeach Dr. Ibarluzea's credibility. *Id*

At the pretrial conference Plaintiffs' counsel limited their request to introduction of a single document for impeachment purposes. The Court is inclined to admit this document but will provide Dr. Ibarluzea an opportunity to respond to the document in a sworn, written statement or via a short (i.e., fifteen minute) deposition. *See* Fed. R. Evid. 613(b). At the Defendants' request, parties are permitted to submit a one-page joint letter brief discussing whether the email should be excluded for failure to timely produce the document, notwithstanding obligation to disclose the document during discovery. The Court thus reserves ruling on admissibility of the subject document.

IT IS SO ORDERED.

Dated: January 18, 2024

EDWARD M. CHEN
United States District Judge