UNITED STATES DISTRICT COURT
ORTHERN 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 (KAW)

# ORDER REGARDING SECOND AND THIRD DISCOVERY LETTERS

Re: Dkt. Nos. 79, 81

Plaintiffs filed the instant lawsuit seeking judicial review of Defendant United States Environmental Protection Agency's ("EPA") denial of Plaintiffs' petition to regulate the fluoridation of drinking water supplies under the Toxic Substances Control Act ("TSCA"). (See Compl., Dkt. No. 1.) Pending before the Court are the parties' second and third discovery letters. (Second Discovery Letter, Dkt. No. 79; Third Discovery Letter, Dkt. No. 81.)

Having reviewed the parties' filings and the relevant legal authority, the Court GRANTS IN PART and DENIES IN PART Plaintiffs' request to produce documents in the second discovery letter, and GRANTS Plaintiffs' request to depose the identified witnesses in the third discovery letter.

# I. BACKGROUND

Plaintiffs are non-profit organizations, associations, and individual parents who assert that fluoridation chemicals in public water supplies cause a higher risk of dental fluorosis, cognitive impairments, and adverse neurotoxic effects. (Compl. ¶¶ 8-16.) On November 22, 2016, Plaintiffs petitioned the EPA to exercise its authority under the TSCA to prohibit the addition of fluoridation chemicals to drinking water supplies. (Compl. ¶ 24.) "The TSCA requires the EPA to regulate the use of certain chemical substances that pose an unreasonable risk of harm [to]

health or the environment." (Dismissal Ord. at 5, Dkt. No. 42.)

On February 17, 2017, the EPA denied Plaintiffs' petition. (Compl. ¶ 25.) The denial was based primarily on the EPA's conclusion that the petition "did not set forth a scientifically defensible basis to conclude that any persons have suffered neurotoxic harm as a result of exposure to fluoride in the U.S. through the purposeful addition of fluoridation chemicals to drinking water or otherwise from fluoride exposure in the U.S." 82 Fed. Reg. 11,878, col. 3 (Feb. 27, 2017) ("EPA Denial").

On April 18, 2017, Plaintiffs filed the instant action seeking de novo review of the EPA denial. Under the TSCA, if the petitioner is able to demonstrate by a preponderance of the evidence that "the chemical substance or mixture to be subject to the proposed rule presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors," then the reviewing "court shall order the Administrator to initiate the action requested by the petitioner." 15 U.S.C. § 2620(4)(B).

The parties subsequently filed the joint discovery letters at issue. On March 12, 2019, the Court requested supplemental briefing as to the second discovery letter, as well as the production of a representative sample of the documents at issue. (Dkt. No. 90 at 2.) On March 19, 2019, Defendants filed their supplemental brief. (Defs.' Supp., Dkt. No. 91.) On March 21, 2019, Plaintiffs filed their supplemental brief. (Plfs.' Supp., Dkt. No. 92.) On March 22, 2019, Defendants filed objections to exhibits attached to Plaintiffs' supplemental brief. (Defs.' Obj., Dkt. No. 93.) On March 25, 2019, Plaintiffs filed objections as well. (Plfs.' Obj., Dkt. No. 94.) On April 3, 2019, the Court requested further documents for in camera review. (Dkt. No. 95.)

# II. LEGAL STANDARD

The Federal Rules of Civil Procedure broadly interpret relevancy, such that each party has the right to the discovery of "any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case[.]" Fed. R. Civ. P. 26(b)(1). Discovery need not be admissible to be discoverable. Id. The court, however, "must limit the frequency or extent of discovery otherwise allowed" if "(i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome,

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or less expensive; (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or (iii) the proposed discovery is outside the scope permitted by Rule 26(b)(1)." Fed. R. Civ. P. 26(b)(2)(C). Furthermore, "[t]he court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense," including by precluding discovery, by conditioning disclosure or discovery on specified terms, by preventing inquiry into certain matters, or by limiting the scope of discovery to certain matters. Fed. R. Civ. P. 26(c)(1). "Rule 26(c) confers broad discretion on the trial court to decide when a protective order is appropriate and what degree of protection is required." Seattle Times Co. v. Rhinehart, 467 U.S. 20, 36 (1984).

### III. **DISCUSSION**

# Discovery Letter No. 2

Discovery Letter No. 2 concerns 61 documents that Defendants are withholding based on deliberative process privilege, divided into four categories of topics. (Second Discovery Letter at 1.) In support of the privilege, Defendants provide declarations by David P. Ross, the Assistant Administrator for the EPA's Office of Water. (See Second Discovery Letter, Exhs. C ("First Ross Decl."), E ("Second Ross Decl.").)

The deliberative process privilege permits the government to withhold documents that "reflect[] advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated." NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 150 (1975). In order to qualify for the privilege, documents must be both "predecisional" and "deliberative." Carter v. U.S. Dep't of Commerce, 307 F.3d 1084, 1089 (9th Cir. 2002). The burden is on the party asserting the privilege to show that the documents are predecisional and deliberative. See Maricopa Audubon Soc'y v. U.S. Forest Serv., 108 F.3d 1089, 1092 (9th Cir. 1996).

A document is "predecisional if it was prepared in order to assist an agency decisionmaker

<sup>&</sup>lt;sup>1</sup> The Second Ross Declaration describes five categories of documents. Prior to filing the letter, Plaintiffs removed from the dispute all of the documents related to the U.S. Public Health Service's guidance and recommendation regarding the optimal fluoride concentrations in drinking water for community water systems. (Second Discovery Letter at 3 n.4.)

in arriving at his decision," and may include recommendations, draft documents, proposals, suggestions, and other subjective documents which reflect the personal opinions of the writer rather than the policy of the agency." Assembly of Cal. v. U.S. Dep't of Commerce, 968 F.2d 916, 920 (9th Cir. 1992) (internal quotations omitted). "Material which predates a decision chronologically, but does not contribute to that decision, is not predecisional in any meaningful sense." Id. at 921. Further, an "agency must identify a specific decision to which the decision is predecisional." Maricopa Audubon Soc'y, 108 F.3d at 1094. An agency, however, may not point to the potential use of information for "a decision that possibly may be made at some undisclosed time in the future." Assembly of Cal., 968 F.2d at 921.

A document is "deliberative" if "disclosure of the materials would expose an agency's decisionmaking process in such a way as to discourage candid discussion within the agency and thereby undermine the agency's ability to perform its functions." Assembly of Cal., 968 F.2d at 920 (internal quotation omitted). "Documents need not themselves be 'deliberative,' in the sense that they make nonbinding recommendations on law or policy, in order to qualify for the deliberative process privilege." Nat'l Wildlife Fed'n v. U.S. Forest Serv., 861 F.2d 1114, 1119 (9th Cir. 1988). Rather, even materials that are factual would "be exempt from disclosure to the extent that they reveal the mental processes of decisionmakers." Id. Thus, draft documents may be deliberative if such "[m]aterials . . . allow the public to reconstruct the predecisional judgments of the administrator . . . . " Id. at 1122.

## i. EPA's Six-year Review 3

The first category of documents concerns the EPA's Six-year Review 3. (Second Ross Decl. ¶ 7.) Under the Safe Drinking Water Act ("SDWA"), the EPA sets standards for drinking water quality. (Second Ross Decl. ¶ 8a.) The SDWA requires the EPA to review the existing standards not less than every six years, after which the EPA determines if revisions to the standards are necessary. (Second Ross Decl. ¶ 8a.)

Four documents are drafts of a 2014 report, "Weight of Evidence Document for Reproduction and Developmental Health Effects, Intelligence Quotient (IQ) Health Effects in Children and Effects on the Endocrine System due to Exposure to Fluoride in Drinking Water"

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("Weight of Evidence Document"). (Second Ross Decl. ¶ 8c.) Defendants explain that the Weight of Evidence Document "was prepared to assist principal EPA decisionmakers in considering whether revisions to regulations for fluoride were needed in Six-year Review 3." (Second Ross Decl. ¶ 8c.) Further, the drafts contained annotations and edits reflecting staff opinions, evaluations, and recommendations as to the technical analysis and evaluation of the literature being reviewed. (Second Ross Decl. ¶ 8c.)

The Court concludes that these four documents are protected under deliberative process privilege. The documents are predecisional because they were prepared to assist the EPA decisionmakers in deciding whether revisions to fluoride regulations were required under the SWA as part of the Six-year Review 3. Moreover, having reviewed the representative document considered by Mr. Ross (EPA 00206505) the Court finds that the documents are deliberative, as they include numerous comments that give opinions about the conclusions made and studies reviewed and emphasize the importance of certain information, as well as edits that affect the concreteness of findings and studies being reviewed.

Plaintiffs contend that "scientific assessments are not deliberative unless they involve the exercise of discretionary policy-making judgment." (Plfs.' Supp. at 1.) The Court disagrees. As the Ninth Circuit has recognized:

> Opinions on facts and the consequences of those facts form the grist for the policymaker's mill. Each opinion as to which of the great constellation of facts are relevant and important and each assessment of the implications of those facts suggests a different course of action by the agency. . . . Tentative policies may undergo massive revisions based on a reassessment of these variables, during which the agency may decide that certain initial projections are not reasonable or that the likely consequences of a given course of action have been over- or underestimated. Subjecting a policymaker to public criticism on the basis of such tentative assessments is precisely what the deliberative process privilege is intended to prevent.

Nat'l Wildlife Fed'n, 861 F.2d at 1120; see also id. at 1119 ("Where either the disclosure of the manner of selecting or presenting facts would expose the deliberative process . . . the material is exempt [from disclosure]."). In other words, opinions about the scientific assessments may go directly to how a decisionmaker ultimately decides an issue, as it affects how such information is

weighed in making a decision.

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To the extent Plaintiffs rely on Greenpeace v. National Marine Fisheries Service, 198 F.R.D. 540 (W.D. Wash. 2000) for the proposition that scientific evaluation is not deliberative unless it involves the exercise of policy-oriented judgment, Plaintiffs misread Greenpeace. In Greenpeace, the district court found that the determination of jeopardy or adverse modification under the Endangered Species Act was itself not a process that implicated the government's policy-oriented judgment. 198 F.R.D. at 544. Thus, the deliberative process privilege did not apply because there was no policy decision being made; without a policy decision, the documents could not be predecisional. Id. at 545 ("the process itself is unrelated to any discretionary policymaking."). Because there was no policy decision at issue, the Greenpeace court never had to determine whether the documents themselves were deliberative.

Here, sixteen documents are staff notes and communications analyzing studies related to fluoride and its associated health effects. (Second Ross Decl. ¶ 8d.) These "documents were prepared for the purpose of making a recommendation to agency Six-year Review 3 decisionmakers in determining whether revisions to regulations for fluoride were appropriate," and "reflect opinions, evaluations, and recommendations as to the technical analysis and evaluation of the literature being reviewed." (Second Ross Decl. ¶ 8d.)

Again, the Court concludes that these documents are subject to the deliberative process privilege. Like the draft Weight of Evidence Documents, these notes and communications were prepared to assist EPA decisionmakers in deciding whether to revise fluoride regulations as part of the Six-year Review 3. Further, having reviewed the representative document considered by Mr. Ross (EPA0235568) the Court finds these documents are deliberative because they contain opinions about the quality of particular studies, and thus, how much weight should be given to those studies.

### ii. National Toxicology Program's ("NTP") 2016 Systematic Review

The second category of documents concerns the NTP's systematic review of literature regarding neurotoxic effects of fluoride in animals. (Second Ross Decl. ¶ 10a.) The NTP selected fluoride for evaluation, and sought from EPA comments and recommendations on its preliminary

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drafts before finalizing its 2016 report. (Second Ross Decl. ¶ 10a.)

In its request for supplemental briefing, the Court requested that Defendants identify the specific decision to which these documents were predecisional. (Dkt. No. 90 at 1; see also Maricopa Audubon Soc'y, 108 F.3d at 1094.) In its supplemental brief, Defendants stated that the documents were "predecisional to the government's policy concerning what association, if any, exists between fluoride and impairments in learning and memory, as published in the final report titled Systematic Literature Review on the Effects of Fluoride on Learning and Memory in Animal Studies ('Animal Literature Review')." (Defs.' Supp. at 1.) This, however, is not a decision. Whether an association exists is a question of scientific fact, not a policy-oriented judgment entitled to protection under the deliberative process privilege. See Nat'l Wildlife Fed'n, 861 F.2d at 1117 ("To qualify... under the 'deliberative process' privilege, a document must be... 'predecisional' or antecedent to the adoption of agency policy") (internal quotation omitted).

Perhaps recognizing the lack of a policy decision, Defendants suggest that "[e]ven if the Court were to find that the Animal Literature Review does not set forth a 'policy,' that finding would not preclude shielding from disclosure the materials prepared to assist the NTP in reaching science-based policy decisions during the process of review." (Defs.' Supp. at 2.) Defendants point to the exercise of judgment in comparing scientific methods and inferences. These, however, are not policy decisions related to the adoption of agency policy. Assessment of the quality of scientific studies is not in and of itself a policy decision; even if decisions are required in assessing such studies, those decisions do not create any identifiable policy. See Greenpeace, 198 F.R.D. at 544 ("In order to be protected, expressions of expert opinion and professional judgment must relate to the exercise of policy-oriented judgment."). Accordingly, the Court concludes that Defendants have not satisfied their burden of identifying a specific decision to which the documents are predecisional. See Maricopa Audubon Soc'y, 108 F.3d at 1094.

Therefore, the twenty-six documents identified in the Second Ross Declaration ¶¶ 10b, 10c, and 10d must be produced.

### iii. NTP's Pending Systematic Review of Human Literature

The third category of documents are related to the NTP's Office of Health Assessment and

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Translation receiving "a nomination to carry out an integrated analysis of human, animal, and mechanistic evidence to develop hazard identification conclusions about whether fluoride is a developmental neurotoxicant." (Second Ross Decl. ¶ 11a.) In general, issues nominated to the NTP are usually announced in the Federal Register with a request for public comment, in conjunction with an interagency comment period. The "NTP then uses this information to decide whether to move a project forward." (Second Ross Decl. ¶ 11a.)

Six documents are drafts of NTP's "concept document," which proposed specific questions to be addressed by the study. (Second Ross Decl. ¶ 11b.) The Court finds that the documents at issue are predecisional. Specifically, Defendants explain that the documents "are predecisional to NTP's decision concerning the initiation of a new government program studying potential adverse health effects in humans exposed to fluoride." (Defs.' Supp. at 1.)

After reviewing the documents, however, the Court finds that these documents are not deliberative. Specifically, each document is a prior draft of the "Proposed NTP Evaluation on Fluoride Exposure and Potential for Developmental Neurobehavioral Effects." While the drafts have some changes from the final version, the changes generally do not concern any opinions, evaluations, or substantive recommendations, but are wording changes or other technical edits. The changes do not reveal the priorities, opinions, or other mental processes of the authors or decisionmakers. The primary exception is the summary of the project on page 3 of each draft document, which does contain changes that would expose the deliberative process. Therefore, the Court orders the production of EPA0112927 (except for page EPA0112929); EPA0112979 (except for page EPA0112981); EPA0120789 (except for page EPA0120791); EPA0120841 (except for page EPA0120843); EPA0221181 (except for page EPA0221183); and EPA0276416 (except for page EPA0276418).

Five documents are internal communications regarding how to present epidemiology data to the NTP Board of Scientific Counselors for additional analysis on whether the fluoride nomination should move forward. (Second Ross Decl. ¶ 11c.) Again, the Court finds that the documents are predecisional because they were prepared to assist NTP decisionmakers on whether to move the fluoride nomination forward, a policy decision. Having reviewed EPA0112798, the

Court also finds that the documents are deliberative. The communications are "related to the process by which policies are formulated" because they contain proposals and suggestions for how data should be presented and what information should be sought, thus "reflect[ing] the personal opinions of the writer rather than the policy of the agency . . . ." Nat'l Wildlife Fed'n, 861 F.2d at 1118-19 (internal quotation omitted). Thus, the deliberative process privilege applies.<sup>2</sup>

# iv. Nominations for the NTP's 2016 Report on Carcinogens

The last category of documents concern the NTP's request for recommendations from the EPA to determine whether fluoride should be considered for review in the 2016 Report on Carcinogens and for evaluation of non-cancer health outcomes by the Office of Health Assessment and Translation. (Second Ross Decl. ¶ 12a.) The four documents at issue are communications regarding whether the EPA should offer support for devoting governmental resources to a fluoride review. (Second Ross Decl. ¶ 12b.) The Court finds that these documents are predecisional because they go to the policy decision of whether the EPA would recommend that fluoride should be considered in the Report on Carcinogens. The Court also finds, after review of the representative document considered by Mr. Ross (EPA0151822), that the documents are deliberative because they contain the personal opinions of the authors on whether there was sufficient information or data to warrant adding fluoride to the NTP's health evaluation. Accordingly, the deliberative process privilege applies.

# v. Protective Order

privilege, for the reasons stated in this order.

As explained above, the Court orders Defendants to produce the twenty-six documents identified in the Second Ross Decl. ¶¶ 10b, 10c, and 10d, as well as the six documents identified in the Second Ross Decl. ¶ 11b, with the exception of the summary on page 3 of each of the documents. Defendants request that in the event of production, the Court issue a protective order prohibiting Plaintiffs from publicly releasing or using the documents for purposes other than

<sup>&</sup>lt;sup>2</sup> In their supplemental brief, Plaintiffs for the first time argue that EPA's arguments are inconsistent with other disclosures made in the case. (Plfs.' Supp. at 4-5.) Plaintiffs' arguments are improper, as the supplemental briefing was limited to what specific policy decision were the documents identified in the Second Ross Declaration ¶¶ 10-11 related. (See Dkt. No. 90 at 1-2.) In any case, the specific documents discussed by Plaintiffs are not covered by deliberative process

litigation. (Defs.' Supp. at 5.)

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Federal Rule of Civil Procedure 26(c) permits a court to, "for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense . . . . " "A party seeking good cause bears the burden, for each particular document it seeks to protect, of showing that specific prejudice or harm will result if no protective order is granted." Foltz v. State Farm Mut. Auto. Ins. Co., 331 F.3d 1122, 1130 (9th Cir. 2003) (internal quotation omitted); see also Beckman Inds. v. Int'l Ins. Co., 966 F.2d 470, 476 (9th Cir. 1992) ("Broad allegations of harm, unsubstantiated by specific examples or articulated reasoning, do not satisfy the Rule 26(c) test." (internal quotation omitted)).

Here, Defendants argue that Plaintiff Fluoride Action Network ("FAN") could release the information "to embarrass EPA staff and mislead the public regarding the health risks associated with fluoride in such a way as to discourage candid discussion within and among government agencies." (Defs.' Supp. at 5.) Such arguments are speculative, and Defendants provide no specific reasons why the staff opinion could create embarrassment or harm to the public. Accordingly, the Court finds that Defendants have not satisfied their burden of showing the specific prejudice or harm that will result, and denies the request for a protective order.

### В. **Third Discovery Letter**

Discovery Letter No. 3 concerns the depositions of three EPA employees: Kristina Thayer, Paul Price, and Joyce Donohue. (Third Discovery Letter at 2-3.) Defendants object that the depositions are duplicative and burdensome, irrelevant, and may involve testimony that is protected by the deliberative process privilege. (Id. at 1-2.) The Court disagrees.

First, Defendants argue that the depositions are duplicative and burdensome because Plaintiffs have already deposed EPA witnesses on the scientific bases for the EPA's regulation of fluoride under the SDWA. (Third Discovery Letter at 1.) Plaintiffs, however, explain that they do not intend to ask the witnesses about those issues. Specifically, Plaintiffs state they will ask Ms. Thayer about the NTP study she authored, and how the EPA establishes the safe dose for neurotoxicants like fluoride. (Id. at 2-3.) Plaintiffs further state that they will ask Mr. Price about the basis for his personal concerns about his disagreements with the EPA's standard. (Id. at 3.)

Finally, Plaintiffs state they will ask Ms. Donohue about the EPA's 2010 risk assessment on fluoride, as well as other recent EPA-funded studies regarding neurological effects from prenatal fluoride exposure. (Id.) These topics do not overlap with prior testimony regarding the EPA's regulation of fluoride under the SDWA.

Second, Defendants contend that the factual and legal validity of the EPA's regulation of fluoride under the SDWA is not at issue in this litigation because the instant case concerns the EPA's authority under the TSCA to regulate or ban fluoridation of water supplies. (Third Discovery Letter at 1-2.) Thus, the merits of the EPA's existing regulations under the SDWA is not relevant. (Id. at 2.) The Court disagrees. The SDWA concerns goals and standards for drinking water quality, which according to Defendants, requires an evaluation of the risks of contaminants including fluoride. (Id. at 1 nn.2, 3.) The instant suit, in comparison, requires that the presiding judge make findings on "whether the ingestion of fluoride in drinking water causes neurotoxic harm." (Dkt. No. 68 at 1.) Although the SDWA is a different statutory scheme from the TSCA, both concern the potential risks caused by fluoride in drinking water, and therefore can inform the ultimate inquiry of this case.

Finally, to the extent Defendants assert deliberative process privilege, such objections are premature. Moreover, it is not clear that asking these witnesses about their opinions years after the decisions at issue have been made would raise the deliberative process privilege, as they would not be predecisional. See Assembly of Cal., 968 F.2d at 920 ("documents deemed 'postdecisional' do not enjoy the protection of the deliberative process privilege.").

Accordingly, the Court ORDERS Defendants to produce Ms. Thayer, Mr. Price, and Ms. Donohue for deposition.

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# United States District Court Northern District of California

# IV. CONCLUSION

For the reasons stated above, the Court ORDERS Defendants to produce: (1) the twenty-six documents identified in the Second Ross Declaration ¶¶ 10b, 10c, and 10d; and (2) the six documents identified in the Second Ross Declaration ¶ 11b, except for the summary on page 3 of each of the documents. The Court also orders Defendants to produce Ms. Thayer, Mr. Price, and Ms. Donohue for deposition.

IT IS SO ORDERED.

Dated: April 12, 2019

KANDIS A. WESTMORE United States Magistrate Judge