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

KRISTIN LAVELLE, Plaintiff, vs. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	Civil Action No. 23-cv-1040 **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

INTRODUCTION

1. This is an action filed under the U.S. Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Plaintiff Kristin Lavelle seeks an order for declaratory and injunctive relief regarding a series of FOIA violations by the U.S. Department of Health and Human Services.

JURISDICTION AND VENUE

2. This case is brought under 5 U.S.C. § 552(a)(4)(B) and presents federal questions conferring jurisdiction on this Court. 28 U.S.C. § 1331.

3. Venue is proper under 5 U.S.C. § 552(a)(4)(B).

THE PARTIES

4. The Plaintiff, Kristin Lavelle, resides in Berkeley, California. Ms. Lavelle made the FOIA requests at issue in this case.

5. Mrs. Lavelle is a plaintiff in a pending case in this District (*Food & Water Watch v. EPA*, 17-cv-02162-EMC). In the case, the plaintiffs allege that fluoridation chemicals, when consumed by

pregnant women and bottle-fed infants, present an "unreasonable risk" under the Toxic Substances Control Act (15 U.S.C. § 2620).

6. Defendant U.S. Department of Health and Human Services ("HHS") is a federal agency that is subject to the Freedom of Information Act.

7. The Public Health Service ("PHS") carries out the health services missions of the HHS (as opposed to the human services missions).

8. The Office of the Assistant Secretary of Health ("OASH") is an office at HHS that oversees the PHS.

9. The PHS has different organizational entities contained within it, including, as relevant here, the Centers for Disease Control and Prevention ("CDC"), the Food & Drug Administration ("FDA"), the Indian Health Service ("HIS"), and the National Institutes of Health ("NIH").

10. The NIH is made up of 27 institutes and centers including, as relevant here, the National Institute for Environmental Health Sciences ("NIEHS") and National Institute for Dental & Craniofacial Research ("NIDCR").

11. The NIEHS's mission is "to reduce the burden of human illness and disability by understanding how the environment influences the development and progression of human disease."

12. The National Toxicology Program ("NTP") is a federal research program headquartered at NIEHS. The NTP evaluates chemicals of public health concern by developing and applying tools of modern toxicology, molecular biology, and systematic review.

FACTUAL BACKGROUND

A. The NTP Is Not a Regulatory or Policy-Making Organization

13. The NIEHS and NTP "are not regulatory agencies, and rules or regulations related to the environment are not formulated there."[1] NTP focuses instead on strengthening the science base in toxicology and providing the best available information about potentially toxic chemicals to all

[1] Linda Birnbaum, Paul Jung, Sheila A Newton, *Environmental Health Science for Regulatory Decision Making*, 21 DUKE ENVIRON. LAW POLICY FORUM 259, 265 (2011).

stakeholders, including federal and state regulatory agencies, the scientific and medical communities, and the public.

14. The research that NTP conducts and disseminates is instrumental in creating the science that serves as the basis for regulatory decisions made by agencies such as the EPA, the FDA, the Consumer Product Safety Commission, and the Occupational Safety and Health Administration.[2]

15. Given NTP's function as an objective source of scientific information for *all* stakeholders, including the public, it is crucial that its work remain strictly independent from partisan or political interests.

B. The Importance of Transparency to NTP's Mission

16. Transparency is essential to ensuring the credibility of scientific evaluations, including the health hazard evaluations that NTP performs. As the National Research Council has explained, "It is both a scientific and a policy-making objective that the process of conducting a risk assessment and the risk-assessment products themselves be transparent. Transparency is a requirement that is always present."[3]

17. The NTP recognizes the importance of ensuring transparency in its evaluations. This recognition is one of the key reasons why NTP's Office of Health Assessment and Translation (OHAT) pioneered the development of "systematic review" methodologies for the evaluation of environmental toxicants. As NTP has explained, "The objective of embedding systematic methods in the OHAT evaluation processes is to enhance transparency, promote participation by the public and stakeholders in the evaluation process, ensure consistency across evaluations, facilitate updates, and support more general acceptance of evaluations to other agencies."[4]

18. One of the ways that NTP ensures the transparency of its evaluations is by making drafts of its evaluations available to the public.

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[2] Birnbaum, *supra* note 1, at 265.

[3] National Research Council (2009). *Science and Decisions: Advancing Risk Assessment*. Washington (DC): National Academies Press, p. 91.

[4] National Toxicology Program (2019). Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration (updated March 4, 2019).

19. In addition to publicly releasing drafts of its evaluations, NTP invites the public to comment on these drafts so that NTP may consider the public's input prior to finalizing the evaluation.

20. As NTP has explained, permitting the public to see drafts at multiple stages of the evaluation improves the quality of the final product. But, perhaps just as importantly, allowing the public to read and comment on drafts of NTP's evaluations enhances the public's trust and confidence in the scientific integrity of NTP's work.

21. Dr. Linda Birnbaum was the director of NIEHS and NTP from 2009 to 2019. During Dr. Birnbaum's tenure, the NTP published 21 monographs.

22. According to Dr. Birnbaum, "Based on my experience at NTP, the release of draft monographs does not discourage candid discussion at the agency, or in any way impair the quality of the NTP's scientific analysis or process. NTP is devoted to providing the best available science to inform public health decisions, and as such, NTP's focus is on getting the science right. Transparency is an accepted, and indeed integral, part of accomplishing this important, if imperfect, endeavor."

C. The NTP's Research on Fluoride

23. According to Dr. Birnbaum, "In the United States, there is widespread exposure to fluoride chemicals, in part because of the addition of fluoridation chemicals to drinking water. Given the widespread exposure to fluoride, and the growing body of scientific research linking fluoride exposure to IQ deficits and other neurodevelopmental outcomes, the NTP determined that it would be appropriate to begin evaluating the science on this issue."

24. The NTP began its review of fluoride's neurodevelopmental effects in or about 2015.

25. Initially, NTP conducted a systematic review of animal studies to assess how fluoride impacts learning and/or memory in animal models. Next, NTP conducted its own animal study to evaluate neurotoxicity from fluoride exposure. Then, in 2016, NTP commenced working on a monograph that systematically evaluates all streams of evidence, including the relatively large number of epidemiological studies that have investigated fluoride exposure and IQ in human populations.

26. NTP released a first draft of its fluoride monograph to the National Academy of Science, Medicine, and Engineering (NASEM) in September 2019.

27. NASEM's peer review of the 2019 monograph was published in 2020. NTP incorporated NASEM's recommendations, and NASEM conducted a second peer review, which it completed in 2021.

28. Both the 2019 and 2020 drafts of the NTP monograph were made available to the public, as were the NASEM peer reviews of these drafts.

29. By November of 2021, the NTP had incorporated NASEM's recommendations in a revised monograph, which NTP termed a "State of the Science" (SoS) monograph. NTP submitted the SoS monograph for a third, and final, external peer review by five experts in the field.

D. The NTP's May 2022 Monograph

30. Under NTP's normal procedures, if external peer reviewers concur with the conclusions of a draft monograph, the NTP will publish it. Consistent with this, an attorney for NTP stated in January 2022 that if the five external reviewers were in general agreement with NTP's conclusions on fluoride, the NTP would publish the fluoride monograph. Exhibit 1.

31. Dr. Richard Woychik is the current Director of NIEHS. According to Dr. Woychik, the five external peer reviewers "concurred" with NTP's conclusions. Exhibit 2, ¶ 15.

32. By May 2022, the NTP had incorporated the external peer reviewers' input and had "a finalized copy of the report." Exhibit 3 (Complaint ¶ 19; Answer ¶ 19).

33. According to Dr. Birnbaum, the former director of NIEHS/NTP, "I am not familiar with any prior instances where an NTP monograph, which had cleared external peer review, was not published. Nor am I familiar with prior instances where an NTP monograph, which had cleared external peer review, was subjected to additional inter-agency review."

34. On April 28, 2022, Dr. Mary Wolfe, NTP's Director of Office of Policy, Review and Outreach, emailed a copy of the monograph to the CDC and stated "the analysis and conclusions are set." Exhibit 4.

35. On May 11, Dr. Wolfe emailed CDC to let it know "We have set May 18 for publication of the monograph." Exhibit 5.

36. In a follow-up email on May 11, Dr. Wolfe explained: "[W]e believe the current findings, as stated in the monograph, reflect the scope of our evaluation and the available scientific literature and *no revision is needed*." Exhibit 6 (emphasis added).

E. The Intervention by CDC and HHS Political Leadership to Quash the Monograph

37. The CDC's Division of Oral Health actively promotes the addition of fluoride to drinking water for the prevention of tooth decay.

38. One of CDC's policy objectives is to increase the number of communities in the United States that add fluoride chemicals to their water. To help accomplish this objective, the CDC works with advocacy organizations and public relations professionals in the private sector, including the American Dental Association (ADA), American Fluoridation Society, the Association for State and Territorial Dental Directors (ASTDD), and Jacobs Strategies LLC.

39. The CDC provides about $500,000 to the ASTDD each year, with the express expectation that the ASTDD will work to effectuate certain policy goals, including increasing the number of communities in the U.S. that add fluoridation chemicals to their water.

40. The CDC and its private partners, including ASTDD, are concerned about the impact that the NTP monograph could have on the policy of water fluoridation. *E.g.*, Exhibit 7.

41. On May 4, 2022, CDC's "Fluoridation Engineer" (Tracy Boehmer) at the Division of Oral Health privately told members of the ASTDD that "CDC was in the process of proactively and preemptively taking steps to intervene" with the NTP monograph. Exhibit 8.

42. On May 12, 2022, one day after NTP told CDC that the monograph would be released the following week (May 18), CDC met with officials from NIEHS, the NIH's Office of the Director ("NIH OD"), and HHS's Office of the Assistant Secretary of Health ("OASH") to discuss the monograph. According to the director of CDC's Division of Oral Health, Casey Hannan, one of the "takeaways" from this meeting is that "the May 18th release date for SoS report is almost certainly not going to happen" and "OASH and NIH OD are pretty clearly going to get more involved." Exhibit 9.

43. Later on May 12, a CDC official (Greg Holder) provided an "off the record" summary of the CDC/OASH/NTP meeting to CDC's private partners at the ASTDD. Holder told the ASTDD: "They (CDC) had met with NTP and NIEHS reps that morning, and reached an agreement that the NTP would hold off publishing the monograph for some length of time (not clear) until a response is prepared." Exhibits 8 & 10.

44. The CDC did not have authority to order NTP to quash the fluoride monograph, which the CDC recognized in internal emails. Exhibit 11. The OASH, however, does have this authority.

45. On June 3, 2022, CDC leadership told its private partner ASTDD that OASH was the office that instructed NTP to place the monograph "on hold." Exhibit 12.

E. The NIDCR Has Also Been Working to Influence the NTP Report

46. The CDC is not the only HHS entity that has intervened to influence the NTP report. For the past several years, the National Institute of Dental & Craniofacial Research ("NIDCR") has endeavored to make the monograph, and the messaging surrounding it, as compatible with water fluoridation as possible. *E.g.*, Exhibit 13.

47. The NIDCR is an ardent proponent of water fluoridation, which it describes "as a scientific revolution that shot dentistry into the forefront of preventive medicine."

48. The NIDCR boasts on its website that "NIDCR funding helped establish community water fluoridation as a safe, effective, and economical intervention for the control of dental caries."

49. As with the CDC, the NIDCR works with private "advocacy groups" to promote and protect water fluoridation, and has shared information with these groups about the NTP monograph. *E.g.*, Exhibit 14.

50. In February 2021, NIDCR officials gleefully celebrated the news that NTP would be removing formal hazard determinations from the monograph. On February 8, 2021, NIDCR's Acting Deputy Director, Jonathan Horsford, wrote: "Great news – NTP has decided to revise the monograph and remove the statement that 'F is a presumed hazard.'" Timothy Iafolla, an NIDCR official who heads the Program Analysis and Reports Branch, responded: "Wow – this is huge. I wish I'd been a fly on the wall for this discussion, but it's a game changer for the response to the report." Exhibit 15.

51. After the NTP announced in April 2022 that it would be publishing the monograph, the NIDCR worked with CDC, the NIH Office of Director's (OD) office, and OASH to stop the report's release. Exhibit 2, ¶ 18.

52. According to former NTP director, Dr. Birnbaum:

> As someone who believes deeply in NTP's science-based mission, I am concerned by the recent course of events with the fluoride monograph. The decision to set aside the results of an external peer review process based on concerns expressed by agencies with strong policy

> interests on fluoride suggests the presence of political interference in what should be a strictly scientific endeavor. Political interference in NTP's scientific evaluations, real or reasonably perceived, will erode and undermine the trust and confidence in NTP's work that is essential to NTP effectively carrying out its mission.

53. To address concerns about political interference in the NTP's review, Dr. Birnbaum believes there should be greater transparency with the public about what has transpired.

F. Concern about the NTP Monograph's Impact on the *Food & Water Watch* Case

54. *Food & Water Watch v. EPA* (No. 17-cv-02162-EMC) is a case addressing fluoride under the statutory framework of the Toxic Substances Control Act, 15 U.S.C. § 2620(b). The plaintiff environmental groups allege that fluoridation chemicals present an "unreasonable risk" of neurodevelopmental harm if consumed by pregnant mothers and bottle-fed infants.

55. Under the Toxic Substances Control Act ("TSCA"), if plaintiffs prove by a preponderance of the evidence that fluoridation chemicals present an unreasonable risk, the EPA will be statutorily mandated to eliminate this risk. 15 U.S.C. § 2620(b).

56. Emails obtained from previous FOIA requests show that officials at HHS, and HHS's private partners in the advocacy/lobbying community, have been closely following the *Food & Water Watch* case. *E.g.*, Exhibits 16, 17 & 18.

57. In June 2020, a 7-day bench trial took place in the *Food & Water Watch* case where the parties presented substantial expert testimony about the current science regarding fluoride's neurodevelopmental toxicity.

58. At the conclusion of the trial, Judge Chen noted that plaintiffs had presented "serious evidence" which raises "serious questions" about the safety of fluoride chemicals in water. However, Judge Chen stated he did not want to make a final determination until after reviewing the NTP monograph, which at the time, was expected to be finalized within a matter of months. Judge Chen stayed the case to, *inter alia*, consider the NTP's final findings.

59. Upon information and belief, the HHS and its private partners are concerned that the NTP monographs, as previously and currently written, could support a judicial determination of unreasonable risk in the *Food & Water Watch* case. This is one of the reasons that CDC, NIDCR, and HHS leadership intervened to quash the monograph from being published in May 2022.

G. The First Public Indications that the NTP Monograph Had Been Quashed

60. In the summer of 2022, the undersigned counsel, who also serves as counsel for Mrs. Lavelle in the *Food & Water Watch* case, learned from a source with knowledge that the long-awaited NTP monograph had actually been completed, but that it was unclear if it would ever be released.

61. After learning that the NTP had completed the monograph, Mrs. Lavelle and other concerned members of the public, filed FOIA requests to obtain a copy of the May 2022 monograph, as well as communications related thereto.

H. The HHS's Discredited Assertions of Privilege

62. The HHS denied the FOIA requests for the May 2022 monograph based on the agency's assertion that the monograph was protected by the deliberative process privilege. *E.g.*, Exhibit 19. Attorneys for the government in the *Food & Water Watch* case asserted the same privilege.

63. The government's assertion of privilege ultimately fell apart when Mrs. Lavelle discovered, through various state and federal FOIA requests, that officials at the HHS had given a copy of the May 2022 monograph to the American Dental Association ("ADA"), the nation's largest lobbying organization on fluoride issues. *E.g.*, Exhibit 20.

64. The ADA, which is one of CDC's private partners, is an organization that aggressively lobbies to, *inter alia*, restrict the public's access to dental therapists and promote water fluoridation. According to an article in the *Washington Post*,

> Among the general public, dentists tend to have a Norman Rockwell appeal — solo practitioners who clean your teeth, tell your kids to cut down on the candy, and put their seal of approval on a range of minty toothpastes and mouthwashes. But lawmakers from Maine to Alaska see a different side of dentists and their lobby, the American Dental Association, describing a political force so unified, so relentless and so thoroughly woven into American communities that its clout rivals that of the gun lobby.[5]

65. In 2021, the ADA heralded its work criticizing an earlier draft of the NTP monograph as one of its "federal legislative and regulatory accomplishments" of the year.

66. The HHS's assertion of privilege over a document that HHS had selectively given to a private trade organization was violative of the public trust, and offensive to the principles of transparency and openness that FOIA was enacted to protect. *See State of N. D. ex rel. Olson v. Andrus*, 581 F.2d 177, 181–82 (8th Cir. 1978) ("The selective disclosure exhibited by the government in this action is offensive

[5] Mary Jordan, *The Unexpected Political Power of Dentists*, WASH. POST, July 1, 2017.

to the purposes underlying the FOIA and intolerable as a matter of policy. Preferential treatment of persons or interest groups fosters precisely the distrust of government that the FOIA was intended to obviate.").

67. In February 2022, the HHS agreed to a course of action wherein it would rescind its assertion of privilege over the May 2022 monograph and related materials. In a stipulation which the court entered as an order in the *Food & Water Watch* case, the HHS agreed to post the May 2022 monograph on the NTP website by no later than March 15, 2023. The HHS further agreed to post the comments that NTP had received from CDC, NIDCR, and FDA about the monograph, as well as NTP's responses thereto. Exhibit 22.

J. The CDC's Production of Communications Related to the NTP

68. On September 13, 2022, Mrs. Lavelle submitted a FOIA request to the CDC requesting all emails to/from certain CDC employees (i.e., Casey Hannan, Lorena Espinoza, and Nicole Johnson) from March 1, 2022 to the present that discussed, or in any way referenced, the NTP report.

69. On September 15, 2022, the CDC FOIA Office responded by noting that the request was "complex" and that CDC "expect[ed] to receive and review voluminous records in response" to the request. Nevertheless, CDC estimated that they would be able to produce the responsive records by November 3, 2022.

70. On October 31, 2022, the CDC FOIA Office produced 1,860 pages of documents to Mrs. Lavelle in response to her request. This production of records from the CDC included the emails that are attached as Exhibits 4, 5, 6, 9, 11, 16, 47, & 50.

71. In addition to these 1,860 pages of records, the CDC's FOIA Office located "1,871 pages belonging to the National Institute of Health" which the CDC submitted to the NIH for processing. Exhibit 23.

72. On October 31, 2022, the NIH sent an email to Mrs. Lavelle stating it had received the documents from CDC and was treating it as a new FOIA request with a case number of 59213.

73. Mrs. Lavelle has not received any further communications from NIH on this request since its acknowledgment of receipt on October 31, 2023.

K. Plaintiffs' FOIA Requests at Issue in This Complaint

74. At issue in this Complaint are ten FOIA requests that Mrs. Lavelle submitted to HHS entities (to which she has not yet received determinations or responsive records) and Mrs. Lavelle's appeal of a small number of redactions that CDC made to the documents it produced on October 31, 2022.

75. As set forth herein, the HHS has violated its obligations to make timely determinations in response to Mrs. Lavelle's 10 FOIA requests and 1 FOIA appeal, and is unlawfully withholding non-exempt material.

76. The HHS's policies and procedures for replying to FOIA requests are inadequate for meeting HHS's statutory obligations under the Freedom of Information Act. Additionally, upon information and belief, the HHS made a determination in or about December 2022 to delay responding to Mrs. Lavelle's FOIA requests after it became aware of the undersigned counsel's utilization of documents from CDC's October 31, 2022 production in the *Food & Water Watch* case.

77. Upon information and belief, the HHS is concerned that the non-exempt material that is responsive to Mrs. Lavelle's FOIA requests will be adverse to the government's litigation position in the *Food & Water Watch* case, as well as to HHS's broader policy interests with respect to water fluoridation.

LEGAL FRAMEWORK

A. The Statutory Deadline for Agencies to Make a "Determination" Under the FOIA

78. The Freedom of Information Act (FOIA) commands that federal agencies make a "determination" regarding a FOIA request within 20 working days (excluding weekends and holidays) of receiving the request. 5 U.S.C. § 552(a)(6)(A)(i). The FOIA does not provide federal agencies with the option to respond to FOIA requests at some indefinite point in the future, or when it is merely convenient or preferable for the agency to do so.

79. The statutory requirement that agencies make a "determination" within 20 working days is not satisfied by an agency simply acknowledging receipt of the request; nor is it satisfied by telling the requester that the agency will address the request when time permits. *Citizens for Resp. & Ethics in Washington v. Fed. Election Comm'n*, 711 F.3d 180, 186 (D.C. Cir. 2013) ("It is not enough that, within the relevant time period, the agency simply decide[s] to later decide. Therefore, within the relevant time

period, the agency must at least inform the requester of the scope of the documents that the agency will produce, as well as the scope of the documents that the agency plans to withhold under any FOIA exemptions."); *Our Children's Earth Found. v. Nat'l Marine Fisheries Serv.*, 85 F. Supp. 3d 1074, 1089 (N.D. Cal. 2015) ("A 'determination' need not be the full production of documents, but at a minimum the agency must inform the requester what documents it will produce and the exceptions it will claim in withholding documents.").

80. The only exception that the FOIA provides to the 20-day determination deadline is if the federal agency provides written notice of certain *statutorily defined* "unusual circumstances." *See* 5 U.S.C. § 552(a)(6)(B)(i); 5 U.S.C. § 552(a)(6)(B)(iii).

81. When an agency provides written notice of "unusual circumstances," the agency is permitted an additional 10 working days to make its determination. 5 U.S.C. § 552(a)(4)(A)(viii)(II)(aa). Where unusual circumstances exist, an agency must thus make its determination no later than 30 working days from the date of receiving the request. *Citizens for Resp. & Ethics*, 711 F.3d at 184.

82. If a federal agency does not provide a determination within 20 working days of receiving a FOIA request (or within 30 working days if "unusual circumstances" exist), the requester has the right to seek immediate redress in federal court. *Citizens for Resp. & Ethics in Washington v. Fed. Election Comm'n*, 711 F.3d 180, 186-190 (D.C. Cir. 2013); *Brown v. U.S. Customs & Border Prot.*, 132 F. Supp. 3d 1170, 1172 (N.D. Cal. 2015); *Our Children's Earth Found. v. Nat'l Marine Fisheries Serv.*, 85 F. Supp. 3d 1074, 1089 (N.D. Cal. 2015).

83. Under the FOIA, the timeframe for processing an appeal is the same as the timeframe for processing the initial request (i.e., 20 working days, or 30 working days if unusual circumstances exist). 5 U.S.C. § 552(a)(6)(B)(ii) & 5 U.S.C. § 552(a)(4)(A)(viii)(II)(aa).

B. The Deliberative Process Privilege

84. The FOIA does not permit federal agencies to forego making a determination, or withhold producing responsive documents, on the grounds that the records may be embarrassing to the agency, or may be useful in a current or future lawsuit against the government.

85. In order to withhold a document from disclosure, the document must come within certain statutorily defined exemptions. 5 U.S.C. § 552(b). As relevant here, "Exemption 5" permits federal agencies to withhold information that is protected by the "deliberative process privilege." *Id.* § 552(b)(5).

86. "The Ninth Circuit has 'defined the ambit of the deliberative process privilege . . . narrowly.'" *Scalia v. Int'l Longshore & Warehouse Union*, 336 F.R.D. 603, 610 (N.D. Cal. 2020) (quoting *Sierra Club, Inc. v. United States Fish & Wildlife Serv.*, 925 F.3d 1000, 1011 (9th Cir. 2019)).

87. "The purpose of the deliberative process privilege 'is to prevent injury to the quality of agency decisions' by ensuring that the 'frank discussion of legal or policy matters' . . . is not inhibited by public disclosure." *Maricopa Audubon Soc. v. U.S. Forest Serv.*, 108 F.3d 1089, 1092–93 (9th Cir. 1997).

88. While the privilege is designed to encourage candid discussions among policymakers, courts have recognized the limits of this rationale, and that a "useful purpose" is conversely served by reminding policymakers that they too "are subject to scrutiny." *N. Pacifica, LLC v. City of Pacifica*, 274 F. Supp. 2d 1118, 1125 (N.D. Cal. 2003).

89. Courts have held that *scientific assessments* are not deliberative unless they are part of a *policy* making procedure. As one court explained, "a factual scientific report, produced 'independently from any' regulatory or policy decisions, does not qualify as deliberative." *Sierra Club v. United States Fish & Wildlife Serv.*, 523 F. Supp. 3d 24, 33–34 (D.D.C. 2021).

90. A scientific evaluation that "is meant 'to aid decision makers who must use the best available scientific information to make policy decisions'" (e.g., an NTP monograph), does not come within the purview of the deliberative process privilege. *Sierra Club*, 523 F. Supp. 3d at 33–34. Indeed, public disclosure of scientific evaluations "may be more likely to enhance the quality and thoroughness of the investigations." *Sterling Drug Inc. v. Harris*, 488 F. Supp. 1019, 1028–29 (S.D.N.Y. 1980).

91. If there is no policy being deliberated, a scientific assessment is not subject to the deliberative process privilege. *E.g.*, *Ctr. for Biological Diversity v. U.S. Envtl. Prot. Agency*, 279 F. Supp. 3d 121, 151 (D.D.C. 2017) ("[T]o fall under the deliberative process privilege, expert opinion must relate to an exercise of discretionary policy-making judgment."); *Greenpeace v. Nat'l Marine Fisheries Serv.*, 198 F.R.D. 540, 544 (W.D. Wash. 2000) ("In order to be protected, expressions of expert opinion and professional judgment must relate to the exercise of policy-oriented judgment.").

C. The Deliberative Process Privilege as Applied to Inter- and Intra-Agency Communications About Draft NTP Reports

92. In 2016, the NTP published a report titled "Systematic Literature Review on the Effects of Fluoride on Learning and Memory in Animal Studies." Consistent with NTP's mission and function, the report was focused solely on the science, and did not make any policy determinations.

93. In the *Food & Water Watch* case, the plaintiffs requested drafts and inter/intra-agency communications related to the NTP's 2016 report. EPA refused to produce these materials, claiming they were protected by the deliberative process privilege.

94. The *Food & Water Watch* court rejected EPA's assertion of privilege because NTP's draft evaluations of the scientific literature, and agency comments regarding same, are *not predecisional to any policy.* Exhibit 24 at 6-7.

95. As Magistrate Judge Kandis Westmore explained, "*whether an association exists [between fluoride and neurodevelopmental effects] is a question of scientific fact, not a policy-oriented judgment entitled to protection under the deliberative process privilege.*" Exhibit 24 at 7.

96. Pursuant to Judge Westmore's order, the EPA produced two separate drafts of the NTP report, as well as inter- and intra-agency communications wherein EPA and CDC employees (A) offered their assessment of the NTP draft reports, and (B) circulated and edited proposed talking points for how to communicate the report's findings to the public. *E.g.*, Exhibits 25-30.

FIRST CLAIM FOR RELIEF

FOIA Violation by HHS/NIDCR *(Request #58947)*

97. Plaintiff incorporates every allegation set forth above.

98. On September 8, 2022, Plaintiff submitted a FOIA request to the National Institute for Dental & Craniofacial Research ("NIDCR").

99. The request asked for all emails to/from certain NIDCR employees (i.e., Jeff Ventura, Jonathan Horsford, and Timothy Iafolla) that (A) address or relate to fluoride and (B) include at least one non-governmental person as sender or recipient. Exhibit 31.

100. The term "non-governmental person" was defined as "the following persons who are not employed by the US Government: (a) Matt Jacob, (b) Juliet Guichon, (c) Jennifer Meyer, (d) Christopher

Fox, (e) Johnny Johnson, (f) Jayanth Kumar, (g) Howard Pollick, (h) Robert Burns, (i) any individual who works at the American Dental Association and/or has an email address ending with @ada.org, and (j) advocacy groups."

101. The term "advocacy groups" was defined as "any other individual (beyond those identified above) that Jeff Ventura understands to be part of the "advocacy groups" that he referenced in his email from February 5, 2021." (Said email from Jeff Ventura is attached to this Complaint as Exhibit 14.)

102. The request limited the timeframe of relevance to the period of August 1, 2020 to the present.

103. NIDCR acknowledged receipt of Mrs. Lavelle's request, and assigned it a case number of 58947. Exhibit 31.

104. On November 8, 2022, the FOIA officer (Luke Wymer) handling Mrs. Lavelle's request stated that "the estimated completion date" for the production of records was November 30, 2022. Exhibit 32 at 5.

105. On December 6, 2022, Mrs. Lavelle asked for a status update on her request as she had not yet received the records. Mr. Wymer responded that the records "may require an additional review with the NIH FOIA Office," but that he expected the records to be produced by December 30, 2022. Exhibit 32 at 4.

106. On December 28, 2022, Mr. Wymer emailed Mrs. Lavelle, stating "My office has completed our review and will need to send the records to the NIH FOIA Office for their final determination." Exhibit 32 at 3.

107. On January 2, 2023, Mrs. Lavelle emailed Mr. Wymer with the following questions:

> Could you explain to me why the NIH FOIA office also has to review these records? Given that all of the communications I have requested here are to/from non-governmental persons, it is hard for me to understand how there could be any kind of privilege at issue. It would seem that once the government chooses to share information with some members of the public (eg lobbyist groups), it loses its right to prevent other members of the public from seeing those communications. Am I missing something?

Exhibit 32 at 3.

108. On January 3, 2023, Mr. Wymer answered Mrs. Lavelle's questions with the following explanation: "The responsive records have to go to the NIH FOIA for final determination as the subject is

related to multiple ongoing requests and ***lawsuits***." Exhibit 32 at 2. (emphasis added). Later, on January 11, 2023, Mr. Wymer sent a follow-up email stating: "I informed the NIH FOIA Office of your request for an estimated completion date, although you might find it helpful to contact them directly at nihfoia@od.nih.gov." Exhibit 32 at 1.

109. Mrs. Lavelle has not received any subsequent emails from Mr. Wymer.

110. On January 25, 2023, Mrs. Lavelle emailed the NIH FOIA Office stating:

> Based on my communications with NIDCR's FOIA team, I understand that your office (the NIH FOIA Office) is now reviewing the responsive records that NIDCR retrieved. Given that all the emails I have requested are emails to/from non-governmental advocacy groups/individuals, it would seem that the review of these records should be pretty and [sic] straightforward, as the deliberative process privilege will not apply. Do you have an estimate as to when I can expect to receive these records?

Exhibit 33.

111. The NIH FOIA Office did not respond to this email.

112. On February 7, 2023, Mrs. Lavelle once again emailed the NIH FOIA Office again, stating:

> I am writing to follow up on my email from January 25 (posted below) to which I received no response. Can someone please let me know when I can expect to receive these records? Additionally, can someone please explain what "lawsuit" my records relate to, and why this has any bearing on NIDCR producing the records?

Exhibit 33.

113. The NIH FOIA Office did not respond to this email.

114. On February 25, 2023, Mrs. Lavelle sent another follow-up email, once again asking for an estimated production date, and an explanation for the delay. The NIH FOIA Office did not respond. Exhibit 33.

115. Defendant has not yet provided a determination or any responsive records.

116. Defendant's failure to provide a determination within 20 working days is a violation of the FOIA. 5 U.S.C. § 552(a)(6)(A)(i).

117. Defendant has not asserted the presence of any "unusual circumstances" for this request.

118. Even if there were "unusual circumstances," Defendant's response would still be untimely and a violation of the FOIA. 5 U.S.C. § 552(a)(6)(B) & 5 U.S.C. § 552(a)(4)(A)(viii)(II)(aa).

119. Defendant has withheld responsive, non-exempt material in violation of the FOIA.

SECOND CLAIM FOR RELIEF

FOIA Violation by HHS/IHS *(Request #22-132)*

120. Plaintiff incorporates every allegation set forth above.

121. Rear Admiral Timothy Ricks works in the Surgeon General's office where he serves as the PHS's Chief Dental Officer.

122. Dr. Ricks has closely followed the developments with the NTP monograph, and has provided briefings about the report to his colleagues at the HHS, including officials at the Surgeon General's Office and NIDCR. Exhibit 34 at 3.

123. On September 13, 2022, Plaintiff submitted a FOIA request to the Public Health Service.

124. The request asked for all emails to/from Dr. Ricks discussing, or in any way, referencing the NTP report or fluoride neurotoxicity. The relevant timeframe of production was identified as September 13, 2019 to the present. Exhibit 35 at 6.

125. The Public Health Service transferred Plaintiffs' FOIA request for Dr. Ricks' emails to the Indian Health Service ("IHS").

126. On September 19, 2022 the IHS acknowledged receipt of Mrs. Lavelle's request. Exhibit 35 at 5.

127. On October 29, 2022, Mrs. Lavelle emailed the IHS asking for an update on when the records would be produced. Exhibit 35 at 4.

128. On November 2, 2022, IHS's FOIA Office (Jim Souther) responded that Mrs. Lavelle's request "is currently number 110 in our queue to process," and that "at this time we estimate making an disclosure on approximately February 14, 2023." Exhibit 35 at 3.

129. On December 15, 2022, Mrs. Lavelle emailed Mr. Souther to inquire whether he still believed the documents would be produced by February 14. Exhibit 35 at 3.

130. On December 22, 2022, Mr. Souther responded that Mrs. Lavelle's request was now "number 102 in our queue to process" and that he estimated "making a disclosure on approximately February 28, 2023." Exhibit 35 at 2.

131. On February 25, 2023, Mrs. Lavelle emailed Mr. Souther for another status update. Mr. Souther responded that the request was number 88 in the queue and that IHS would "not be able to make

the estimated production date." Mr. Souther added that "the updated estimated release date is March 31, 2023." Exhibit 35 at 1-2.

132. Given that Mrs. Lavelle's request only moved 22 notches in the queue (from 110 to 88) in 4 months, Mrs. Lavelle has no confidence that it will move another 88 notices in one month. Indeed, at IHS's current processing rate (i.e., ~5 notches in the queue each month), it will take another 18 months before her request is processed.

133. Defendant has not yet provided a determination or any responsive records.

134. Defendant's failure to provide a determination within 20 working days is a violation of the FOIA. 5 U.S.C. § 552(a)(6)(A)(i).

135. Defendant has not asserted the presence of any "unusual circumstances" for this request.

136. Even if there were "unusual circumstances," Defendant's response would still be untimely and a violation of the FOIA. 5 U.S.C. § 552(a)(6)(B) & 5 U.S.C. § 552(a)(4)(A)(viii)(II)(aa).

137. Defendant has withheld responsive, non-exempt material in violation of the FOIA.

THIRD CLAIM FOR RELIEF

FOIA Violation by HHS/CDC *(Request # 23-00162)*

138. Plaintiff incorporates every allegation set forth above.

139. Greg Holder is a public health analyst at CDC's Division of Oral Health.

140. Mr. Holder has been involved in formulating CDC's responses to the NTP monograph, and in drafting talking points about the monograph for the public. *E.g.*, Exhibits 5, 9, & 10.

141. Mr. Holder has also been monitoring the *Food & Water Watch* case, as evident by an email that CDC produced as part of its October 31, 2022 production. *E.g.*, Exhibit 16.

142. On November 1, 2022, Mrs. Lavelle submitted a FOIA request seeking all emails to/from Mr. Holder that discuss or reference the *Food & Water Watch* case. Exhibit 36 at 4.

143. To ensure that all responsive records were identified, Mrs. Lavelle included a separate document request that asked for all emails to/from Mr. Holder that included any of the following terms: "Trial Status Update," "Court," "Lawsuit," "Trial," "Hearing," "Testimony," "Status Conference," "EPA," "Plaintiffs," "Fluoride Action Network," "Food & Water Watch," "FWW," "Judge," "Chen," and "PACER." Exhibit 36 at 4.

144. In November 3, 2022, and again on November 21, 2022, a CDC FOIA Officer (Yvonne Jones) asked Mrs. Lavelle if she would narrow the scope of her search to minimize the number of documents unrelated to the *Food & Water Watch* lawsuit that would be retrieved. Mrs. Lavelle agreed to narrow the scope in response to both requests. Exhibits 36-39.

145. Mrs. Lavelle's limitations on the scope of the request satisfied the CDC FOIA Officer's concern. On November 29, 2022 Ms. Jones stated: "We reasonably anticipate that you should receive documents by December 29, 2022." Exhibit 40.

146. Contrary to this November 29, 2022 letter, Ms. Jones wrote to Mrs. Lavelle on December 15, 2022 stating: "you have not submitted a proper FOIA request because your request lacks the specificity needed to assist the agency to retrieve the information with a reasonable amount of effort." Exhibit 41.

147. In her December 15, 2022 letter, Ms. Jones asked Mrs. Lavelle to further limit the scope of her request, which Mrs. Lavelle again agreed to do. On December 19, 2022, Mrs. Lavelle agreed to eliminate all search terms from her second record request except for the term "Trial Status Update." Exhibits 41 & 42.

148. On January 10, 2023, CDC's FOIA Officer informed Mrs. Lavelle that "Program staff have completed their search for the records you requested, and your case is currently in this office awaiting final review." Exhibit 43.

149. In contrast to CDC's prior willingness to provide Mrs. Lavelle with estimated production dates, CDC refused, in its January 10 letter, to provide Mrs. Lavelle with an estimate of when she would receive the records. Exhibit 43.

150. On February 7, 2023, the CDC asked Mrs. Lavelle whether she would agree to omit all emails that "merely reference the lawsuit during public inquiry." Mrs. Lavelle declined. Exhibits 44 & 45.

151. Mrs. Lavelle has received no further communications from the CDC regarding this request.

152. The CDC asserted that "unusual circumstances" exist for this request on the grounds that "We reasonably expect to receive and review voluminous records in response to your request." Exhibit 40.

153. Defendant has not yet provided a determination or any responsive records.

154. Defendant's failure to provide a determination within 30 working days is a violation of the FOIA. 5 U.S.C. § 552(a)(6)(B) & 5 U.S.C. § 552(a)(4)(A)(viii)(II)(aa).

155. Defendant has withheld responsive, non-exempt material in violation of the FOIA.

FOURTH CLAIM FOR RELIEF

FOIA Violation by HHS/NIH *(Request # 59213)*

156. Plaintiff incorporates every allegation set forth above.

157. As discussed in paragraphs 67-69 above, Mrs. Lavelle submitted a FOIA request to the CDC on September 13, 2022 wherein she asked for emails to/from certain CDC employees that discuss or in any way reference the NTP monograph. Exhibit 23.

158. In response to Mrs. Lavelle's request, the CDC identified 1,871 pages of records that belonged to the NIH, which CDC forwarded to the NIH for its own review. Exhibit 23.

159. The NIH acknowledged receipt of the 1,871 pages of records in an October 31, 2022 email to Mrs. Lavelle. The NIH opened a new FOIA request case number (#59213) for its review of these records. Exhibit 46.

160. Mrs. Lavelle has received no further communications from NIH regarding this request. A determination has not yet been provided, nor have any of the 1,871 responsive records been produced.

161. Defendant has not yet provided a determination or any responsive records.

162. Defendant's failure to provide a determination within 20 working days is a violation of the FOIA. 5 U.S.C. § 552(a)(6)(A)(i).

163. Defendant has not asserted the presence of any "unusual circumstances" for this request.

164. Even if there were "unusual circumstances," Defendant's response would still be untimely and a violation of the FOIA. 5 U.S.C. § 552(a)(6)(B) & 5 U.S.C. § 552(a)(4)(A)(viii)(II)(aa).

165. Defendant has withheld responsive, non-exempt material in violation of the FOIA.

FIFTH CLAIM FOR RELIEF

FOIA Violation by HHS/OASH *(Request # 2023-00107-FOIA-PHS)*

166. Plaintiff incorporates every allegation set forth above.

167. Michael Iademarco serves as Rear Admiral (RADM) and Assistant Surgeon General for the PHS, and as Deputy Assistant Secretary for Science and Medicine for the OASH.

168. RADM Iademarco is the PHS officer who is "leading th[e] work for OASH" related to the NTP monograph. Exhibit 47.

169. On November 1, 2022, Mrs. Lavelle submitted a FOIA request to the HHS requesting all emails to, or from, RADM Michael Iademarco from January 1, 2022 to the Present that (A) discuss or reference fluoride and/or fluoridation; and/or (B) discuss or reference the NTP. Exhibit 48.

170. On November 3, 2022, the HHS acknowledged receipt of the request. In its acknowledgment letter, the HHS asserted the presence of "unusual circumstances" because the request seeks "records which require a search in another office." Exhibit 48.

171. Mrs. Lavelle has received no further communications from HHS regarding this request.

172. Defendant has not yet provided a determination or any responsive records.

173. Defendant's failure to provide a determination within 30 working days is a violation of the FOIA. 5 U.S.C. § 552(a)(6)(B) & 5 U.S.C. § 552(a)(4)(A)(viii)(II)(aa).

174. Defendant has withheld responsive, non-exempt material in violation of the FOIA.

SIXTH CLAIM FOR RELIEF

FOIA Violation by HHS/NIH OD *(Request #59250)*

175. Plaintiff incorporates every allegation set forth above.

176. Lawrence Tabak, DDS, PhD, is the Acting Director of the NIH, and heads the NIH's Office of Director ("NIH OD").

177. Dr. Tabak is a dentist by training and previously served as Director of the NIDCR.

178. Dr. Tabak has communicated regularly with officials at NIDCR about the NTP monograph, including NIDCR's Acting Deputy Director, Jonathan Horsford.

179. According to a source with knowledge of the NTP review, Dr. Tabak has been hostile to NTP publishing a report that could be detrimental to the policy of water fluoridation.

180. On November 6, 2022, Mrs. Lavelle submitted a FOIA request to NIH OD asking for all emails to, and/or from, Dr. Tabak between April 26, 2022 and July 26, 2022 that include one or more of the following terms: NTP, National Toxicology Program, or fluoride. Exhibit 49.

181. The NIH OD acknowledged receipt of the request on November 6, 2022, and assigned it case number 59250. Exhibit 49.

182. Mrs. Lavelle has received no further communications from NIH OD regarding this request.

183. Defendant has not yet provided a determination or any responsive records.

184. Defendant's failure to provide a determination within 20 working days is a violation of the FOIA. 5 U.S.C. § 552(a)(6)(A)(i).

185. Defendant has not asserted the presence of any "unusual circumstances" for this request.

186. Even if there were "unusual circumstances," Defendant's response would still be untimely and a violation of the FOIA. 5 U.S.C. § 552(a)(6)(B) & 5 U.S.C. § 552(a)(4)(A)(viii)(II)(aa).

187. Defendant has withheld responsive, non-exempt material in violation of the FOIA.

SEVENTH CLAIM FOR RELIEF

FOIA Violation by HHS/OASH *(Request #2023-00121-FOIA-OS)*

188. Plaintiff incorporates every allegation set forth above.

189. Rachel Levine is the Assistant Secretary of Health ("ASH") for HHS.

190. According to emails produced by the CDC, Dr. Levine is the HHS official who ordered the NTP to hold off on publishing the NTP monograph. *E.g.*, Exhibit 50.

191. On November 7, 2022, Mrs. Lavelle submitted a FOIA request to the HHS requesting all emails to, or from, Dr. Levine from April 26, 2022 to the Present that include the terms National Toxicology Program or NTP. Exhibit 51.

192. On November 9, 2022, the HHS acknowledged receipt of the request. In its letter, the HHS asserted the presence of "unusual circumstances" because the request seeks "records which require a search in another office." Exhibit 51.

193. Mrs. Lavelle has received no further communications from HHS regarding this request.

194. Defendant has not yet provided a determination or any responsive records.

195. Defendant's failure to provide a determination within 30 working days is a violation of the FOIA. 5 U.S.C. § 552(a)(6)(B) & 5 U.S.C. § 552(a)(4)(A)(viii)(II)(aa).

196. Defendant has withheld responsive, non-exempt material in violation of the FOIA.

EIGTH CLAIM FOR RELIEF

FOIA Violation by HHS/NIDCR *(Request #59249)*

197. Plaintiff incorporates every allegation set forth above.

198. On November 6, 2022, Mrs. Lavelle submitted a FOIA request to NIDCR wherein she requested all emails to/from certain NIDCR employees (i.e., Jonathan Horsford, Timothy Iafolla, Rena D'Souza, and Renee Joskow) written or received from April 26, 2022 to the present that include one or more of the following search terms: NTP, National Toxicology Program, "state of the science," OASH, Woychik, Wolfe, Levine, Iademarco, Tabak, or Hacker. Exhibit 52.

199. On November 7, 2022, the NIDCR sent an "interim letter" acknowledging receipt of the request. Exhibit 52.

200. On November 8, 2022, Mrs. Lavelle emailed NIDCR's FOIA Officer (Kathryn Gonzalez) asking if the response time for producing responsive records would be significantly reduced if the search terms were limited to just "NTP" and "National Toxicology Program." Exhibit 53 at 3.

201. On November 16, 2022, Ms. Gonzalez responded stating: "Yes, if you limit the search terms from the current set of 10 to just "National Toxicology Program" and "NTP", it will significantly speed up the processing time for the request." Exhibit 53 at 2-3.

202. On December 7, 2022, Mrs. Lavelle agreed to narrow the scope of the request to the terms NTP and National Toxicology Program. Exhibit 53 at 1.

203. Despite the significantly narrowed scope of the request, NIDCR's FOIA Officer emailed Mrs. Lavelle on December 13, 2022 stating it would take about "six months" for NIDCR to process the request, noting "the actual date of completion might be before or after the estimate based on the complexity of the records and other requests in the queue before it." Exhibit 53 at 1.

204. Mrs. Lavelle has received no further communications from Defendant regarding this request.

205. Defendant has not yet made a determination, nor produced any responsive records.

206. Defendant's failure to provide a determination within 20 working days is a violation of the FOIA. 5 U.S.C. § 552(a)(6)(A)(i).

207. Defendant has not asserted the presence of any "unusual circumstances" for this request.

208. Even if there were "unusual circumstances" for this request, Defendant's response would still be untimely and a violation of the FOIA. 5 U.S.C. § 552(a)(6)(B) & 5 U.S.C. § 552(a)(4)(A)(viii)(II)(aa).

209. Defendant has withheld responsive, non-exempt material in violation of the FOIA.

NINTH CLAIM FOR RELIEF

FOIA Violation by HHS/NIEHS *(Request #59447)*

210. Plaintiff incorporates every allegation set forth above.

211. On December 22, 2022, the EPA filed a declaration from NIEHS's Director, Dr. Woychik, as part of a motion that EPA filed in the *Food & Water Watch* case. Exhibit 2. In the declaration, Dr. Woychik stated that NTP received comments from "agency subject matter experts" at CDC, FDA, and NIDCR regarding the May 2022 monograph and associated meta-analysis. *Id.* ¶ 18. Dr. Woychik stated he had asked NTP's Board of Scientific Counselors ("BSC") to review these comments and NTP's responses thereto, and upon receiving the BSC's assessment would make a determination of whether to publish the NTP monograph. *Id.* ¶¶ 20 & 25.

212. On December 23, 2022, Mrs. Lavelle filed a FOIA request to NIEHS wherein she requested 5 sets of records identified in Dr. Woychik's declaration, including the agency subject matter expert comments on the NTP monograph and NTP's responses thereto.

213. On December 23, 2022, the NIEHS sent Mrs. Lavelle an email acknowledging receipt of her request. Exhibit 54.

214. On January 10, 2023, the NIEHS sent an "interim letter" wherein it asserted the presence of "unusual circumstances," specifically: "(1) the request requires us to search for and collect records from multiple components and/or field offices; (2) the request involves a voluminous number of records that must be located, compiled, transferred to this office, and reviewed." Exhibit 54.

215. On January 25, 2023, the NIEHS sent a "1st partial response" in which it produced a document responsive to one of the five sets of record requests (i.e., a June 10, 2022 email regarding the scope of the BSC review). The NIEHS redacted the vast bulk of the three-page email, and stated it was continuing to look for the other records that Mrs. Lavelle requested. Exhibit 55 at 2-5.

216. Mrs. Lavelle has received no further communications from Defendant regarding this request.

217. Defendant has not yet made a determination, nor produced any responsive records, in response to four of Mrs. Lavelle's five records requests, including the agency subject matter expert comments, NTP's responses thereto, and Dr. Woychik's written announcement to his staff that he was not going to publish the monograph.

218. As discussed in paragraph 66 above, the NIEHS has agreed to post the agency subject matter comments on the NTP website by no later than March 15, 2023. These comments, however, will not be in their original form, but will be published in a curated format where the dates of the comments, names of the commenters, and affiliation of the commenters will be omitted.

219. Defendant's failure to provide a determination to four of the five record requests within 30 working days is a violation of the FOIA. 5 U.S.C. § 552(a)(6)(B) & 5 U.S.C. § 552(a)(4)(A)(viii)(II)(aa).

220. Defendant has withheld responsive, non-exempt material in violation of the FOIA.

TENTH CLAIM FOR RELIEF

FOIA Violation by HHS/FDA *(Request #2023-21)*

221. Plaintiff incorporates every allegation set forth above.

222. Frederick Hyman is an FDA Dental Officer and one of FDA's subject matter experts on fluoride.

223. On December 27, 2022, Mrs. Lavelle submitted a FOIA request to FDA wherein she requested all emails to or from Frederick Hyman from August 1, 2019 to the Present that contain one or both of the following two terms: National Toxicology Program and NTP. Exhibit 56.

224. On January 3, 2023, the FDA acknowledged receipt of Mrs. Lavelle's FOIA request. Exhibit 56.

225. Mrs. Lavelle has received no further communications from Defendant regarding this request.

226. Defendant has not yet made a determination or produced any responsive records.

227. Defendant's failure to provide a determination within 20 working days is a violation of the FOIA. 5 U.S.C. § 552(a)(6)(A)(i).

228. Defendant has not asserted the presence of any "unusual circumstances" for this request.

229. Even if there were "unusual circumstances" for this request, Defendant's response would still be untimely and a violation of the FOIA. 5 U.S.C. § 552(a)(6)(B) & 5 U.S.C. § 552(a)(4)(A)(viii)(II)(aa).

230. Defendant has withheld responsive, non-exempt material in violation of the FOIA.

ELEVENTH CLAIM FOR RELIEF

FOIA Violation by HHS/FOI Privacy Acts Division *(Case No. 2023-00065-A-PHS)*

231. Plaintiff incorporates every allegation set forth above.

232. On October 31, 2022, the CDC produced 1,860 pages of records in response to Mrs. Lavelle's request for communications related to the NTP report, including 1,301 pages that were withheld in full, and hundreds of other pages that were withheld in part. In the "Final Response" letter that accompanied the records, the CDC informed Mrs. Lavelle of her right to appeal the redactions. To do so, CDC informed Mrs. Lavelle that she must submit the appeal by January 16, 2023.

233. On January 15, 2023, Mrs. Lavelle filed an appeal. In her appeal, Mrs. Lavelle explained: "Although I believe CDC has improperly redacted many pages in its response, I am limiting my challenge to a very small number of redactions . . . . I am doing so in the hope that this will facilitate a quick and timely resolution." Exhibit 57 at 1.

234. To help facilitate a quicker review, Mrs. Lavelle limited her appeal to only 5 documents.

235. Mrs. Lavelle contended that 4 of the 5 documents are neither (A) inter- or intra-agency communications (because they were sent to, or from, non-governmental persons and do not come within the "consultant corollary exception,") or (B) deliberative and predecisional. These 4 documents are as follows:

A. Document 1: A June 14, 2022 email from ADA's Fluoridation Spokesperson, Howard Pollick, regarding the *Food & Water Watch* lawsuit, in which many other non-governmental persons were cc'ed.

B. Document 2: A March 29, 2022 email from a Vermont health official to CDC wherein the official requests information regarding studies on fluoride and IQ.

C. Document 3: A June 15, 2022 email from an aide to a U.S. congresswoman to HHS asking for information related to the NTP monograph.

D. Document 4: An October 19, 2021 email from CDC Division of Oral Health director Casey Hannan to a team of research scientists concerning a paper that they recently published in the peer reviewed literature.

Exhibit 57 at 1-3.

236. Mrs. Lavelle contended that the 5th document, an August 9, 2022 email from a CDC scientist (Lorena Espinoza) concerning the *Food & Water Watch* case "does not appear to be subject to the deliberative process privilege as it is an email regarding a public court case which CDC is not a party to, and is written by a non-attorney. It is hard to conceive how passing remarks about a public lawsuit could be predecisional to a CDC legal or policy decision." Exhibit 57 at 3-4.

237. On January 17, 2023, the HHS acknowledged receiving Mrs. Lavelle's appeal on January 16, 2023 and assigned it as Case No. 2023-00065-A-PHS.

238. In HHS's January 17 acknowledgment letter, it asserted the existence of "unusual circumstances" because "our office will need to consult with another office or agency that has substantial interest in the determination of the appeal." The letter did not identify which "office or agency" has the substantial interest.

239. Mrs. Lavelle has received no further communications from Defendant regarding this request.

240. Defendant has not yet made a determination, nor produced any responsive records.

241. Defendant's failure to provide a determination within 30 working days is a violation of the FOIA. 5 U.S.C. § 552(a)(6)(B)(ii) & 5 U.S.C. § 552(a)(4)(A)(viii)(II)(aa).

242. Defendant has withheld responsive, non-exempt material in violation of the FOIA.

REQUESTED RELIEF

WHEREFORE, Plaintiff prays that this Court:

A. Issue an order finding that Defendant HHS has violated the FOIA;

B. Order the Defendant HHS to immediately produce the records requested by Plaintiff, as authorized by 5 U.S.C. § 552(a)(4)(B);

C. Award Plaintiff's attorneys' fees and costs as authorized by 5 U.S.C. § 552(a)(4)(E); and

D. Grant such other relief as justice may require or that the Court may deem appropriate.

March 8, 2023

Respectfully submitted,

/s/ Michael Connett
MICHAEL CONNETT
WATERS, KRAUS & PAUL
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El Segundo, CA 90245
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Email: mconnett@waterskraus.com
Attorney for Plaintiff

Exhibit 1

From: Carfora, Debra (ENRD) <Debra.Carfora@usdoj.gov>
Sent: Tuesday, January 4, 2022 10:59 AM
To: Michael Connett <mconnett@waterskraus.com>
Cc: Adkins, Brandon (ENRD) <Brandon.Adkins@usdoj.gov>
Subject: Fluoride Status Report - NTP Update

[CAUTION]: External Email

Hi Michael,

As a follow up to our conversation yesterday, we've heard from the lawyer for the NTP. Below is the status she's provided.

- **Status regarding publication of the NTP Monograph –** The NTP Monograph will be published as a state of the science document that does not reach hazard conclusions. A draft document was completed and sent to 5 external peer-reviewers in early November of 2021. We expect the peer review comments early in 2022 and will consider these comments in the final publication of the monograph. We have received one review and expect the other 4 in the coming weeks. Pending general reviewer agreement with our document, we anticipate public availability of a revised final state of the science report by the end of March.
- **Meta-analysis –** The meta-analysis is now a separate, standalone document under consideration as a journal publication. We anticipate resubmission by the middle of February. After that, we have no way to predict how long the journal peer review step will take.

Could you draft for our review a joint status report? EPA will probably want to include confirmation that the Spanish cohort study has been published, we can add that during our review.

Thanks,

DEBRA J. CARFORA, Senior Trial Counsel
Environmental Defense Section | Environment and Natural Resources Division | U.S. Department of Justice
Phone | office 202.514.2640 | cell 202.598.3835 | fax 202.514.8865
4 Constitution Square, 150 M Street NE, Room 4.1128, Washington DC 20002

Exhibit 2

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

FOOD & WATER WATCH, INC., et al.,

Plaintiffs,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,

Defendants.

Case No. 3:17-cv-02162 EMC

SECOND DECLARATION OF RICHARD P. WOYCHIK, Ph.D.

I, Richard P. Woychik, Ph.D., declare that the following statements are true and correct to the best of my knowledge and belief, and are based on my personal knowledge and information contained in the records of the National Institute of Environmental Health Sciences ("NIEHS"). NIEHS is one of the Institutes and Centers of the National Institutes of Health ("NIH"), which is a component of the U.S. Department of Health and Human Services ("HHS").

1. I am the Director of the NIEHS and have been in this position since June 2020. Before that I was the Deputy Director of NIEHS, a position I held since January 2011.

2. As Director of the NIEHS, I have a dual responsibility of also serving as the Director of the National Toxicology Program ("NTP") and have been with NTP since I was appointed Acting Director of NIEHS in October 2019. The NTP is an interagency partnership of NIH's NIEHS, the CDC's National Institute for Occupational Safety and Health, and the U.S.

Food and Drug Administration.

3. NTP monographs are typically published soon after external peer review and federal agency subject-matter expert review, when the reviewers concur with the monograph's findings and conclusions.

4. The NTP State of the Science Monograph on fluoride and the Meta-Analysis Manuscript (as defined below and in the first declaration I submitted in this action) have not yet been published because the scientific review is not complete. Therefore, it is my opinion that the drafts of these documents should not be released to the public, or referenced, at this time.

5. In this second declaration, I provide an update on the process that NTP is undertaking with respect to those documents.

6. In 2016, NTP initiated a systematic review to evaluate neurobehavioral health effects from exposure to fluoride during development through examination of human studies, experimental animal studies, and mechanistic data.

7. NTP prepared a first draft of its fluoride monograph, and it was ready for peer review in September 2019 ("draft monograph").

8. Because NTP was aware that its fluoride monograph could be an influential scientific document, and to ensure the scientific integrity of the monograph, NTP arranged for the National Academies of Sciences, Engineering, and Medicine ("NASEM") to conduct an independent peer review. NASEM is a prestigious scientific society, and it is the acknowledged gold standard for providing independent and objective advice on complex scientific issues.

9. The monograph was evaluated by NASEM using scientific criteria such as: appropriate use of statistical methods, documentation and application of the systematic review process, accurate data analysis and risk-of-bias assessments, validity of individual studies and use of independent data sources, and appropriate application of human, animal and/or mechanistic data.

10. In March 2020, NASEM released its peer-review report stating that the conclusions in the draft NTP monograph were not adequately supported. Therefore, NTP did not

publish the monograph.

11. Then, based on the NASEM peer-review comments, the NTP revised the draft monograph and submitted a second draft in September 2020 to NASEM for peer-review. In February 2021, NASEM released its peer-review report of the revised draft monograph, and again, the reviewers stated that the revised draft monograph's assessment was not adequately supported. Therefore, NTP did not publish the revised monograph.

12. However, the NASEM reviewers also stated, "The committee urges NTP to improve the clarity of the document. The monograph has great importance in the discussion about effects of fluoride on neurodevelopmental and cognitive health effects and will likely influence exposure guidelines or regulations."

13. Therefore, based on the NASEM report, NTP made additional revisions and removed the classification of fluoride as a cognitive neurodevelopmental hazard to humans. The NTP authors also decided to split the revised draft monograph into two distinct documents: a "State of the Science Monograph" with the *qualitative* review of studies on the association between fluoride and cognition and neurodevelopment, and a "Meta-Analysis Manuscript" with the *quantitative* statistical analysis of the epidemiologic studies specifically related to children's I.Q., so that each document could be published separately.

14. Per standard NTP procedure, the drafts of the State of the Science Monograph and the Meta-Analysis Manuscript were reviewed internally by subject-matter experts in various HHS agencies.

15. In November 2021, the draft State of the Science Monograph was also circulated for external peer review with five reviewers that the NTP identified based on their scientific expertise, which is the usual process for peer review of NTP reports. These peer reviewers concurred with the draft State of the Science Monograph conclusions but provided comments for additional revisions to the document. The NTP authors began addressing the reviewers' comments and prepared the State of the Science Monograph for publication.

16. Although the Meta-Analysis Manuscript was being prepared by NTP for

submission to a peer-reviewed scientific journal, agency subject-matter experts from the Centers for Disease Control and Prevention ("CDC"), the Food and Drug Administration ("FDA"), and the National Institute of Dental and Craniofacial Research at NIH ("NIDCR") raised concerns that the comments they had submitted during the development of the Meta-Analysis Manuscript had not been adequately addressed, and in many instances the NTP authors had disagreed with the comments and criticisms from the agency subject-matter experts. Therefore, the agency subject-matter experts objected to publication until their comments and the responses from the NTP authors could be adjudicated with scientific rigor.

17. Given the concerns expressed by the agency subject-matter experts, and the disagreements between those subject-matter experts and the NTP authors, in February 2022, I asked the chair of the NTP Board of Scientific Counselors ("BSC") to have the BSC adjudicate concerns raised by agency reviewers on the Meta-Analysis Manuscript. Since there was not sufficient subject-matter expertise on the NTP BSC, the Chair of the BSC made the decision to develop an independent working group of subject-matter experts, external to HHS, to adjudicate the comments and concerns that were raised by the agency subject-matter experts and the responses by the NTP authors.

18. Meanwhile, the NTP continued preparing the State of the Science Monograph for publication, and in April 2022, NTP shared its plan to publish the monograph with the CDC, the FDA, and the NIDCR. The target date for publication was May 18, 2022. Experts within these agencies expressed concerns about the conclusions in the monograph and objected to the planned May 18 publication.

19. By May 12, 2022, based on concerns raised by the agency subject matter experts and echoed by the NIH and HHS leadership, I made the decision that the State of the Science Monograph also needed additional review prior to publication. I communicated this to the NIH leadership and the HHS Assistant Secretary for Health. Days later, I informed the NTP staff that the State of the Science Monograph would not be published on May 18, 2022.

20. On June 10, 2022, I expanded the scope of the charge to the BSC to include an

adjudication of NTP's responses to peer-review comments and agency reviewers' comments on the State of the Science Monograph.

21. Individuals identified for the working group were screened to prevent conflicts of interest, and the group began its evaluation in October 2022.

22. I currently expect that the working group will present its report at a BSC meeting in early 2023. This meeting will be open to the public. Following the standard process, the BSC could accept the working group report and convey it to me as written, revise the report and convey the revised report to me, and/or offer other recommendations, which could include expanding the monograph and meta-analysis to add more studies published over the past year.

23. It is important to note that the State of the Science Monograph only includes research published through May 2020, and the Meta-Analysis Manuscript only includes research published through November 2021. Therefore, the current drafts of these documents do not include recently published research papers that may contain highly relevant information regarding the health effects of fluoride, or lack thereof, especially at the lower doses used to supplement public water supplies.[1]

24. If the BSC makes suggestions to revise the documents before they can be published, this will take time, so the final publication will be determined by how quickly the NTP authors can make the modifications. If the modifications are substantial, the two documents will have to be reviewed again before they can move forward for publication, which will also take time.

25. Following the BSC's action, the BSC chair will provide me the report. As the director of the NTP, I will decide whether NTP will publish the State of the Science Monograph

---

[1] Those papers are as follows:

Do, L.G., et al., *Early Childhood Exposures to Fluorides and Child Behavioral Development and Executive Function: A Population-Based Longitudinal Study*, Journal of Dental Research (2022) https://pubmed.ncbi.nlm.nih.gov/36214232/.

Ibarluzea, J., et al., *Prenatal Exposure to Fluoride and Neuropsychological Development in Early Childhood: 1-to 4 Years Old Children*, Environmental Research (2022) https://pubmed.ncbi.nlm.nih.gov/34627799/.

or to hold the report for additional work, and I will decide whether NTP authors should submit the Meta-Analysis Manuscript for peer-review and publication in a scientific journal. My decision will be based on the scientific criteria and the recommendations made to me by the BSC, not on any particular regulatory criteria.

26. The timing of my decision will depend on the progress made by the BSC working group and the outcome of adjudicating those comments and concerns.

27. I will do my best to make my decision as quickly as possible, but my obligation as director of NTP is to uphold the most rigorous scientific principles when providing scientific background that may inform the public health policies of the nation.

28. To my knowledge, there are two instances in which NTP monographs were not published as originally intended after undergoing external peer review and review by agency subject-matter experts. These monographs were studies of substances being considered for listing in the Report on Carcinogens, which is a congressionally mandated report of substances that pose cancer hazards.

a. NTP prepared a monograph on talc for the 10th Report on Carcinogens; however, peer-reviewers did not support the listing because of confusion in the scientific literature over the mineral nature of talc. Therefore, the talc monograph was not published.

b. NTP prepared a monograph on "light at night" and "shift work at night" for the 15th Report on Carcinogens; however, due to concern that "light at night" and "night shift work" might not meet the definition of a "substance," the monograph was not published. The monograph on "light at night" and "shift work at night" was later reformatted and posted on the NTP website as a cancer hazard assessment report.

29. When they are finalized, NTP's State of the Science Monograph and Meta-Analysis Manuscript have the potential to be highly influential scientific documents that may inform a wide array of public health and regulatory decisions. Therefore, it is imperative that the science is strong. I could not, in good conscience, authorize publication of the monograph in May 2022 when so many concerns about the science and conclusions were still being raised by

agency subject matter experts, as I explained above.

30. I believe that use of the draft State of the Science Monograph and Meta-Analysis Manuscript before the BSC working group's evaluation is completed and final decisions are made could cause confusion for the public. Furthermore, release of these draft documents to the public now could undermine the current BSC working group review.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on December 22, 2022, in West Palm Beach, Florida.

Richard P. Woychik -S

Digitally signed by Richard P. Woychik -S
Date: 2022.12.22 15:29:30 -05'00'

Richard P. Woychik, Ph.D.
Director, National Institute of Environmental Health Sciences
Director, National Toxicology Program

Exhibit 3

MICHAEL CONNETT, ESQ., CA Bar No. 300314
WATERS, KRAUS & PAUL
222 N. Pacific Coast Hwy, Suite 1900
El Segundo, CA 90245
310-414-8146 Telephone
310-414-8156 Facsimile

Attorneys for Plaintiffs

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

KRISTIN LAVELLE, Plaintiff, vs. NATIONAL INSTITUTE OF HEALTH, Defendants.	)	Civil Action No. 22-cv-05118 **COMPLAINT**

INTRODUCTION

1. This is an action filed under the U.S. Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, *et. seq*. Plaintiff Kristin Lavelle seeks an order compelling the immediate release of agency records improperly withheld by the National Institutes of Health.

THE PARTIES

2. Kristin Lavelle ("Plaintiff") resides in Berkeley, California. Ms. Lavelle made the FOIA request at issue in this case.

3. Defendant NATIONAL INSTITUTES OF HEALTH ("NIH") is a component entity of the Department of the Health and Human Services, a federal agency. The NIH is subject to the Freedom of Information Act, 5 U.S.C. § 552.

JURISDICTION AND VENUE

4. This case is brought under 5 U.S.C. § 552(a)(4)(B) and presents a federal question conferring jurisdiction on this Court. 28 U.S.C. § 1331.

early 2020, and NTP thereupon released a revised report in September 2020 which incorporated NASEM's suggestions. This revised draft was again submitted to NASEM for peer review. In February 2021, NASEM publicly released its second round of peer review comments.

18. By November of 2021, the NTP had completed a revised draft which incorporated NASEM's second round of peer review comments. In November 2021, the NTP submitted this revised draft for a third round of peer review. The NTP submitted the report to a group of 5 "external" (i.e., non-government) scientists. In January of 2022, NTP stated: "Pending general reviewer agreement with our document, we anticipate public availability of a revised final state of the science report by the end of March."

19. By February 2022, the NTP had received comments from all 5 external peer reviewers. The NTP incorporated these comments, and, by May 2022, had completed a finalized copy of the report. After internal discussions about how to communicate the report's findings to the public (e.g., through press releases, etc), the NTP decided to publicly release the report on May 18, 2022.

20. The NTP did not publicly release the report on May 18, 2022.

21. The NTP has still not released the report. Instead, the NTP agreed to a request from unknown persons or parties to submit the finalized report (which had already gone through three rounds of extensive peer review) to an "inter agency review" with no set timeline for the review's completion.

E. Plaintiff's FOIA Request

22. On August 9, 2022, Plaintiff submitted a FOIA request to the Defendant NIH through its online FOIA website: https://foiaportal.nih.gov.

23. In her FOIA request, Plaintiff asked for the following three documents:

(a) A copy of the report that NTP was going to publicly release on May 18, 2022;

(b) A copy of the report that the NTP recently circulated for inter-agency review;

(c) A copy of a December 30, 2021 email (and any attachments thereto) from a non-governmental scientist (Ibarluzea) to NTP regarding the findings of a study on fluoride and IQ in Spain. The email is cited and relied upon by NTP on a public database[5] that the NTP maintains for studies it has reviewed as part of its evaluation of fluoride.

[5] *See, e.g.*, https://hawcproject.org/epi/result/9277/ and https://hawcproject.org/epi/result/9278/

STEPHANIE M. HINDS (CABN 154284)
United States Attorney
MICHELLE LO (NYBN 4325163)
Chief, Civil Division
EMMET P. ONG (NYBN 4581369)
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1301 Clay Street, Suite 340S
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E-mail: emmet.ong@usdoj.gov

Attorneys for Defendant NATIONAL INSTITUTES OF HEALTH

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

KRISTIN LAVELLE, Plaintiff, v. NATIONAL INSTITUTE OF HEALTH, Defendant.	Civil Action No. 4:22-cv-05118-YGR **DEFENDANT'S ANSWER TO COMPLAINT**

15. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in the first sentence of this paragraph and, therefore, denies them. The allegations in the second and third sentences in this paragraph characterize a judicial opinion in another action, a document that speaks for itself and is the best evidence of its content; any allegation contrary to the plain meaning and content of that document is denied. To the extent a response is required, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in the second and third sentences of this paragraph and, therefore, denies them.

D. NTP's Second Report on Fluoride - Neurodevelopmental Effects in Humans

16. Defendant admits the allegations in the first and second sentences of this paragraph. Regarding the allegations in the third sentence of this paragraph, Defendant admits that NTP does not make policy determinations. Defendant denies the remaining allegations in in the third sentence of this paragraph and avers that NTP's data and reports are used by federal agencies and state agencies to make policy determinations, support regulations, create guidelines, or ban hazardous substances.

17. Admit.

18. Deny.

19. Defendant admits the allegations in the first and second sentences of this paragraph. Defendant denies the allegations in the third sentence of this paragraph.

20. Admit.

21. Defendant admits the allegations in the first sentence of this paragraph. Defendant denies the allegations in the second sentence of this paragraph.

E. Plaintiff's FOIA Request

22. Admit.

23. Admit.

24. Admit.

25. Defendant admits that it had not made a determination on Plaintiff's FOIA request by the time the complaint was filed. Defendant denies the remaining allegations in this paragraph.

26. Deny.

Exhibit 4

From: Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>
Sent: Thursday, April 28, 2022 12:31 PM
To: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Cc: Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <pju3@cdc.gov>; Berridge, Brian (NIH/NIEHS) [E] <brian.berridge@nih.gov>; Woychik, Rick (NIH/NIEHS) [E] <rick.woychik@nih.gov>
Subject: Prepublication SoS Monograph -- Internal Deliberative Communication

Casey,
Attached is the prepublication draft of the NTP Monograph on the State of the Science on Fluoride. We are sharing this document for your awareness. At this time the analysis and the conclusions are set. We are not requesting comment; however, please let us know if you identify any error in the text. Please note that this document is not public and should be kept confidential.

In October 2021 we sent you the draft state of the science monograph and CDC provided comments. We appreciated CDC's review, and I have attached a document with our response to those comments. For your awareness, in addition to interagency input, the NTP state of the science monograph has received external peer review by letter from five experts. All comments have been carefully considered in finalizing the monograph.

Currently, we are preparing our communications plan for when the monograph is released. We are working toward its release in mid/late May and will share the date when it's set. In the meantime, to assist with preparation of our communications plan, please send me the name and contact information to whom we should refer any media inquiries, if received, that would be best addressed by CDC.

Do not hesitate to contact us if questions.
Best regards,
Mary

Exhibit 5

From: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH)
Sent: Wed, 11 May 2022 15:59:55 +0000
To: Holder, Gregory (CDC/DDNID/NCCDPHP/DOH); Espinoza, Lorena (CDC/DDNID/NCCDPHP/DOH); Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH)
Subject: RE: Communications plan for NTP SoS monograph -- internal deliberative communication

Glad the meetings with Donni and Sean were already on the calendar today!

From: Holder, Gregory (CDC/DDNID/NCCDPHP/DOH) <LHN5@cdc.gov>
Sent: Wednesday, May 11, 2022 11:34 AM
To: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>; Espinoza, Lorena (CDC/DDNID/NCCDPHP/DOH) <lee6@cdc.gov>; Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH) <nbg5@cdc.gov>
Subject: RE: Communications plan for NTP SoS monograph -- internal deliberative communication

(b)(5)

We have a call with Donni at 1:30 today, and I think Nicole does with Sean at 330.

From: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Sent: Wednesday, May 11, 2022 11:25 AM
To: Espinoza, Lorena (CDC/DDNID/NCCDPHP/DOH) <lee6@cdc.gov>; Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH) <nbg5@cdc.gov>; Holder, Gregory (CDC/DDNID/NCCDPHP/DOH) <LHN5@cdc.gov>
Subject: FW: Communications plan for NTP SoS monograph -- internal deliberative communication

FYI, here's their comms plan, which is a close hold.

From: Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>
Sent: Wednesday, May 11, 2022 11:12 AM
To: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Cc: Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <pju3@cdc.gov>; Berridge, Brian (NIH/NIEHS) [E] <brian.berridge@nih.gov>; Woychik, Rick (NIH/NIEHS) [E] <rick.woychik@nih.gov>; Mackar, Robin (NIH/NIEHS) [E] <robin.mackar@nih.gov>; Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>
Subject: Communications plan for NTP SoS monograph -- internal deliberative communication

Good morning,
On April 28, I shared the prepublication draft of the NTP Monograph on the State of the Science on Fluoride. We have set May 18, 2022, for publication of the monograph. The monograph will be posted to the NTP website, and we will email a notice of the posting to NTP listserv subscribers.

(b)(5)

(b)(5)

Please let us know if you have any questions,
Mary

Mary S. Wolfe, Ph.D.

Acting Deputy Division Director for Policy and Communication

Director, Office of Policy, Review, and Outreach

Division of the National Toxicology Program

National Institute of Environmental Health Sciences

111 T.W. Alexander Drive

Research Triangle Park, NC 27709

Phone: 984-287-3209

Email: wolfe@niehs.nih.gov

Exhibit 6

From: Hacker, Karen (CDC/DDNID/NCCDPHP/OD)
Sent: Thu, 12 May 2022 13:00:22 +0000
To: Wolfe, Mary (NIH/NIEHS) [E]; Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH)
Cc: Mackar, Robin (NIH/NIEHS) [E]; Flowers, Christine B (NIH/NIEHS) [E]; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD); Promoff, Gabbi (CDC/DDNID/NCCDPHP/OD); Woychik, Rick (NIH/NIEHS) [E]; Berridge, Brian (NIH/NIEHS) [E]
Subject: RE: Communications plan for NTP SoS monograph -- internal deliberative communication

Thank you for the clarification. Has this gone through NIH clearance? We understand another NIH institute had similar concerns to ours and I would like to make sure that NIH leadership is aware of this monograph.

Best,
Karen

From: Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>
Sent: Thursday, May 12, 2022 8:14 AM
To: Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <pju3@cdc.gov>; Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Cc: Mackar, Robin (NIH/NIEHS) [E] <robin.mackar@nih.gov>; Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <axz7@cdc.gov>; Promoff, Gabbi (CDC/DDNID/NCCDPHP/OD) <era6@cdc.gov>; Woychik, Rick (NIH/NIEHS) [E] <rick.woychik@nih.gov>; Berridge, Brian (NIH/NIEHS) [E] <brian.berridge@nih.gov>
Subject: Re: Communications plan for NTP SoS monograph -- internal deliberative communication

Dear Karen,
Thank you for your email. We have sent you the latest version of the prepublication monograph which considers the breadth of input that we've received from all stakeholders.

I responded on May 9 to the May 4 email from Casey Hannan regarding CDC's suggested revision to text in the abstract and summary of the prepublication monograph. My reply noted that we believe the current findings, as stated in the monograph, reflect the scope of our evaluation and the available scientific literature and no revision is needed.

Regards
Mary

Mary S. Wolfe, Ph.D.

Acting Deputy Division Director for Policy and Communication

Director, Office of Policy, Review, and Outreach

Division of the National Toxicology Program

National Institute of Environmental Health Sciences

111 T.W. Alexander Drive

Research Triangle Park, NC 27709

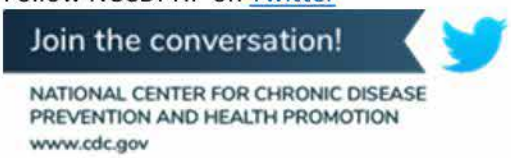
Phone: 984-287-3209

Email: wolfe@niehs.nih.gov

From: Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <pju3@cdc.gov>
Sent: Wednesday, May 11, 2022 4:57 PM
To: Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>; Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Cc: Mackar, Robin (NIH/NIEHS) [E] <robin.mackar@nih.gov>; Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <axz7@cdc.gov>; Promoff, Gabbi (CDC/DDNID/NCCDPHP/OD) <era6@cdc.gov>; Woychik, Rick (NIH/NIEHS) [E] <rick.woychik@nih.gov>
Subject: RE: Communications plan for NTP SoS monograph -- internal deliberative communication

Mary,
I don't believe we have seen the latest version that addressed our comments. Has this gone through NIH clearance yet and will it also be going through HHS interagency review?

Karen Hacker, MD MPH
Director, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)
Centers for Disease Control and Prevention
Phone: 770.488.5401
E-Mail: khacker@cdc.gov
Executive Assistant: Shantelle Graham
E-Mail: sln3@cdc.gov
On the web @ www.cdc.gov/chronicdisease/index.htm
Follow NCCDPHP on Twitter



From: Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>
Sent: Wednesday, May 11, 2022 11:34 AM
To: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>; Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <pju3@cdc.gov>
Cc: Mackar, Robin (NIH/NIEHS) [E] <robin.mackar@nih.gov>; Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <axz7@cdc.gov>; Promoff, Gabbi (CDC/DDNID/NCCDPHP/OD) <era6@cdc.gov>
Subject: Re: Communications plan for NTP SoS monograph -- internal deliberative communication

here is our availability:

- Thurs, May 12, 11-noon and 3:30-4:30
- Fri, May 13, 9-noon

please let us know would work and we'll send zoom info.
Mary

Mary S. Wolfe, Ph.D.

Acting Deputy Division Director for Policy and Communication

Director, Office of Policy, Review, and Outreach

Division of the National Toxicology Program

National Institute of Environmental Health Sciences

111 T.W. Alexander Drive

Research Triangle Park, NC 27709

Phone: 984-287-3209

Email: wolfe@niehs.nih.gov

From: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Sent: Wednesday, May 11, 2022 11:27 AM
To: Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <pju3@cdc.gov>; Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>
Cc: Mackar, Robin (NIH/NIEHS) [E] <robin.mackar@nih.gov>; Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <axz7@cdc.gov>; Promoff, Gabbi (CDC/DDNID/NCCDPHP/OD) <era6@cdc.gov>
Subject: RE: Communications plan for NTP SoS monograph -- internal deliberative communication

Having an additional day or two to better prepare ourselves for a meeting with NTP Comms staff would be preferred.

Mary, would it be possible to check with your Comms staff re: availability on Thursday and Friday?

Thanks for considering,

Casey

From: Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <pju3@cdc.gov>
Sent: Wednesday, May 11, 2022 11:24 AM
To: Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>; Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Cc: Mackar, Robin (NIH/NIEHS) [E] <robin.mackar@nih.gov>; Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <axz7@cdc.gov>; Promoff, Gabbi (CDC/DDNID/NCCDPHP/OD) <era6@cdc.gov>
Subject: RE: Communications plan for NTP SoS monograph -- internal deliberative communication

Unfortunately, those don't work for me and we need to see if others are available. Casey, can you weigh in? I think we need perhaps another few days

---

From: Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>
Sent: Wednesday, May 11, 2022 11:23 AM
To: Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <pju3@cdc.gov>; Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Cc: Mackar, Robin (NIH/NIEHS) [E] <robin.mackar@nih.gov>; Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <axz7@cdc.gov>; Promoff, Gabbi (CDC/DDNID/NCCDPHP/OD) <era6@cdc.gov>
Subject: Re: Communications plan for NTP SoS monograph -- internal deliberative communication

Karen,
Our Comms staff are available today
1-2 pm and 3:30-4 pm

please let me know if either time would work and i'll send a zoom link.
Mary

Mary S. Wolfe, Ph.D.

Acting Deputy Division Director for Policy and Communication

Director, Office of Policy, Review, and Outreach

Division of the National Toxicology Program

National Institute of Environmental Health Sciences

111 T.W. Alexander Drive

Research Triangle Park, NC 27709

Phone: 984-287-3209

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From: Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <pju3@cdc.gov>
Sent: Wednesday, May 11, 2022 11:16 AM
To: Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>; Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Cc: Berridge, Brian (NIH/NIEHS) [E] <brian.berridge@nih.gov>; Woychik, Rick (NIH/NIEHS) [E] <rick.woychik@nih.gov>; Mackar, Robin (NIH/NIEHS) [E] <robin.mackar@nih.gov>; Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <axz7@cdc.gov>; Promoff, Gabbi (CDC/DDNID/NCCDPHP/OD) <era6@cdc.gov>
Subject: RE: Communications plan for NTP SoS monograph -- internal deliberative communication

Thank you

From: Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>
Sent: Wednesday, May 11, 2022 11:16 AM
To: Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <pju3@cdc.gov>; Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Cc: Berridge, Brian (NIH/NIEHS) [E] <brian.berridge@nih.gov>; Woychik, Rick (NIH/NIEHS) [E] <rick.woychik@nih.gov>; Mackar, Robin (NIH/NIEHS) [E] <robin.mackar@nih.gov>; Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <axz7@cdc.gov>; Promoff, Gabbi (CDC/DDNID/NCCDPHP/OD) <era6@cdc.gov>
Subject: Re: Communications plan for NTP SoS monograph -- internal deliberative communication

yes. i will find when our comms staff are available.

Mary S. Wolfe, Ph.D.

Acting Deputy Division Director for Policy and Communication

Director, Office of Policy, Review, and Outreach

Division of the National Toxicology Program

National Institute of Environmental Health Sciences

111 T.W. Alexander Drive

Research Triangle Park, NC 27709

Phone: 984-287-3209

Email: wolfe@niehs.nih.gov

From: Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <pju3@cdc.gov>
Sent: Wednesday, May 11, 2022 11:14 AM
To: Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>; Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Cc: Berridge, Brian (NIH/NIEHS) [E] <brian.berridge@nih.gov>; Woychik, Rick (NIH/NIEHS) [E] <rick.woychik@nih.gov>; Mackar, Robin (NIH/NIEHS) [E] <robin.mackar@nih.gov>; Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <axz7@cdc.gov>; Promoff, Gabbi (CDC/DDNID/NCCDPHP/OD) <era6@cdc.gov>
Subject: RE: Communications plan for NTP SoS monograph -- internal deliberative communication

Hi Mary,
As we discussed we need to meet with you to discuss the rollout and messaging. Can we set that up as soon as possible?

From: Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>
Sent: Wednesday, May 11, 2022 11:12 AM
To: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Cc: Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <pju3@cdc.gov>; Berridge, Brian (NIH/NIEHS) [E] <brian.berridge@nih.gov>; Woychik, Rick (NIH/NIEHS) [E] <rick.woychik@nih.gov>; Mackar, Robin (NIH/NIEHS) [E] <robin.mackar@nih.gov>; Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>
Subject: Communications plan for NTP SoS monograph -- internal deliberative communication

Good morning,
On April 28, I shared the prepublication draft of the NTP Monograph on the State of the Science on Fluoride. We have set May 18, 2022, for publication of the monograph. The monograph will be posted to the NTP website, and we will email a notice of the posting to NTP listserv subscribers.

(b)(5)

Please let us know if you have any questions,
Mary

Mary S. Wolfe, Ph.D.

Acting Deputy Division Director for Policy and Communication

Director, Office of Policy, Review, and Outreach

Division of the National Toxicology Program

National Institute of Environmental Health Sciences

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Phone: 984-287-3209

Email: wolfe@niehs.nih.gov

Exhibit 7

All -

This news shared by Johnny Johnson today is very troubling. I plan to share this with the CWF Task Force later this week and I wanted to make sure you all got a chance to see it first. Thank goodness we have Dr. Denise Johnson as physician general at this point in time to defend CWF if the NTP Monograph causes a stir in PA as it has in at least one other state and in Israel.

Merrilynn

Begin forwarded message:

From: "Dr. Johnny Johnson" <drjohnny@americanfluoridationsociety.org>
Date: April 26, 2022 at 3:39:54 PM EDT
To: "Dr. Johnny Johnson" <drjohnny@americanfluoridationsociety.org>
Subject: An Open Letter to Oral Health Advocates & Public Health Leaders - Re: impending NTP Monograph release

April 26, 2022

Dear Friends,

I am taking this moment to share with you "An Open Letter to Oral Health Advocates & Public Health Leaders" from the American Fluoridation Society (AFS).

It has come to my direct attention that folks that were involved with the NTP DRAFT Monograph and its revision are having an impact on community water fluoridation (CWF) here in the U.S. as well as in the country of Israel.

In at least one U.S. state the NTP's DRAFT Monograph has led to that state's Toxicologist not being willing to support CWF as safe, when in the past that same Toxicologist *was* supportive. This is directly due to the NTP's report.

Dr. Linda Birnbaum spoke to Israel's Ministry of Health (MOH) a few weeks ago by Zoom. As a direct result of that meeting, the MOH Toxicologist has put the skids on Israel restarting CWF. As you may recall, CWF was stopped in Israel in 2014 by then Health Minister Yael German. This decision had nothing to do with the science about CWF. Cessations never do.

With their new Health Minister's (Yaakov Litzman) support, CWF was approved by the Knesset in 2016 to return to the entire country. The process for restarting takes time as we all understand. COVID impacted this process

as well. However, "testimony" about the NTP's findings by Birnbaum has had a shattering effect on the progression of this effective and safe public health intervention.

As such, the AFS has released this Open Letter as an appeal for all of you to reflect upon and take action to protect our families, both here and abroad, from being frightened by a report that was twice rejected by NASEM's peer review Committee and will not undergo a third peer review by NASEM.

Thank you for your time in reading this email and the Open Letter. Since some of you may not be able or allowed to open attachments, I have pasted the Open Letter below my signature. Please feel free to share this with your colleagues.

Warmest personal regards,

Johnny Johnson, Jr., DMD, MS
President
American Fluoridation Society
Pediatric Dentist
Diplomate, American Board of Pediatric Dentistry
Life Fellow, American Academy of Pediatric Dentistry
[redacted]
Email: DrJohnny@AmericanFluoridationSociety.org
Web: AmericanFluoridationSociety.org

April 26, 2022

An Open Letter to Oral Health Advocates & Public Health Leaders:

In the coming months, a committee of the National Toxicology Program (NTP) is expected to release a "state of the science" (SoS) report about fluoride. This report is likely to be misinterpreted by the public, policymakers and many health journalists as a *new* document. In fact, the NTP report will draw largely from an earlier document that failed twice to survive the peer review process.

I am a retired pediatric dentist and the President of the American Fluoridation Society (AFS), a federally recognized 501(c)4 non-profit organization. I

want you to be aware of the history of this NTP report, so you can lessen the likelihood that this SoS document confuses policymakers and leads some of them to make decisions that could harm public health.

In 2019, the NTP committee drafted a monograph that referred to fluoride as a *presumed* developmental neurotoxin. NTP asked the National Academy of Sciences, Engineering and Medicine (NASEM) to form a committee that would act as the peer reviewer.

In 2020, NASEM concluded its peer review and identified numerous deficiencies in the NTP monograph. It requested that NTP address these deficiencies and then resubmit its mono-graph. Later that year, the NTP committee resubmitted the monograph. In February 2021, NASEM issued its second round of peer review, writing that NTP had not provided "clear and convincing evidence" for its conclusion about fluoride. NASEM also issued another critical recommendation to NTP. In its peer review document, NASEM instructed the NTP committee to "make it clear that the monograph cannot be used to draw any conclusions" about low fluoride exposures, "including those typically associated with drinking-water fluoridation."

What happened then was very disturbing. Instead of responding to this second round of review by making appropriate revisions, the NTP committee abandoned this peer review process. The committee informed us that it would release its analysis of fluoride research in a SoS document.

Important Questions for NTP to Answer

Peer review is a hallmark of scientific inquiry. For the NTP committee to abandon this process and decide to push forward and publish its findings anyway is disturbing. Several questions arise:

- Will NTP publish without submitting its document to peer review?
- If the NTP truly values the peer review process, why did it allow the committee to abandon its peer review relationship with NASEM?
- Each page of the NTP monograph explicitly stated that the text "does not represent and should not be construed to represent any NTP determination or policy." Will NTP ensure that this disclaimer also appears on each page of the forthcoming report?

As AFS President, I was prepared to respect the outcome of the NTP-NASEM process — whatever that might have been. Initially, it was encouraging that NTP was willing to submit its monograph to peer review by NASEM. But now it appears that the NTP committee is operating on auto-pilot, disregarding the reviews they have received from NASEM. This strongly suggests that the NTP committee is guilty of confirmation bias.

Fluoridation: What the Science Shows

Community water fluoridation (CWF) is an effective and inexpensive way to prevent tooth decay. During the past several decades, studies in Australia, Brazil, England, Israel and other nations have confirmed CWF's ability to reduce the rate or severity of tooth decay. This is an important finding because tooth decay (dental caries) is globally one of the most common chronic diseases, and 530 million children have experienced tooth decay in their primary teeth.

Recent studies in the U.S. and Canada have shown that children's tooth decay rises significantly when CWF is ended. In the state of Alaska, a new study compared changes in the costs of cavity-related dental procedures in two cities. The average cost soared in Juneau (47%) after the city ended CWF, while the cost in Anchorage rose by only 5%. In Canada, researchers examined two cities in the same province. Children in Calgary had a lower rate of decay prevalence than Edmonton when the study period began. But, after Calgary ceased CWF, its childhood decay rate rose steadily until it reached 65%, which is much higher than the rate (55%) in continuously fluoridated Edmonton. Another Canadian city, Windsor, the city council voted to cease CWF in 2013 based on personal opinions. Cessations of CWF are *never* for scientific reasons. It always involves personal opinion and/or political reasons. Five years later, the health department reported back to the city council on any impact of this cessation on decay prevalence per the city council's request when they ceased it. The health department's findings were that ceasing CWF resulted in a 51% increase in decay or requiring urgent dental care. Based on this data, the city council overwhelmingly voted to restart CWF. It was recently restarted. Likewise, the city council of Calgary voted to return CWF based on strong scientific evidence of the harms of ceasing it.

We have no reason to believe that toothbrushing habits in Alaska or Canada changed significantly during the span of the studies cited previously. Indeed, this demonstrates that brushing with fluoride toothpaste is not an alternative to CWF.

Although most CWF studies have examined the benefits for children, research also reveals the positive *lifetime* impact that fluoridation has. The authors of a 2010 study on tooth loss shared their analysis, which showed that "for every 4 individuals currently living in a county that fluoridated at their times of birth, 1 individual had 1 more tooth than if that individual had not lived in a county that fluoridated." This means that in a fluoridated county with 40,000 people, residents would have retained 10,000 teeth that would otherwise have been lost without the protection of CWF. This analysis led the authors to conclude that CWF has "a "lasting effect" on good dental health and fluoridation's benefits "may be even larger than previously believed" by health officials. Tooth loss can make it harder for older adults to eat a healthy diet and compromise their quality of life, so this finding is very important.

Safety: What the Evidence Shows

For decades, opponents of CWF have pointed to a long list of health concerns that they have sought to link to fluoridation — ranging from acne to cancer. No valid scientific evidence supports such concerns. In recent years, critics have focused on the possibility of links between fluoride exposure and cognitive deficits (lower IQ scores). The IQ study that opponents cite most frequently is a 2019 research paper from Canada, and this study was one of many that were part of the NTP monograph, which failed to complete the peer review process.

Although opponents claim that the IQ-related evidence is stacked against fluoride, they tend to ignore three studies (published within the past eight years) that show no association between fluoride and lower cognitive performance. These studies were conducted in New Zealand (2015), Spain (2021) and Sweden (2021). In addition, the Spain study found that fluoride exposure was associated with *better* cognitive performance among boys.

Viewed collectively, there is no consistent pattern that emerges from the relevant research that has been conducted about fluoride and cognitive outcomes. This reality reinforces the conclusion reached by NASEM.

Independent Reviews of Fluoride Research

NASEM isn't the only scientific institution or panel that has reviewed the IQ-related research on fluoride. Others have conducted independent reviews and reached conclusions very similar to NASEM's.

- **Canadian Agency for Drugs and Technologies in Health** (CADTH): This is the premier agency in Canada for reviewing and evaluating the quality of research. CADTH conducted a 2020 research review of the evidence surrounding fluoride and its impact on cognitive performance. In its review, CADTH concluded that "there is insufficient evidence" to support the conclusion that fluoride exposure from CWF affects neurological development. In a prior review of the 2019 Canadian study, CADTH's evaluators wrote that the authors' claim of a fluoride link to lower IQ scores "was not supported by the data."

- **The Archives of Toxicology:** In 2020, this peer-reviewed journal published a review evaluating 23 recent epidemiological studies about fluoride and cognitive effects. These experts (31 toxicologists and food safety scientists) concluded that the evidence "does not support the presumption that fluoride should be assessed as a human developmental neurotoxicant at current exposure levels in Europe" which are similar to those in the U.S. and Canada. Last year, these 31 experts conducted a new review, considering additional analyses, and

> they concluded that " the available epidemiological evidence does not provide sufficient arguments to raise concerns with regard to CWF in the range of 0.7–1.0 mg/L, nor does it justify that fluoride should be categorized as a human developmental neurotoxicant …"

Perhaps most troubling of all is that three researchers who have voiced concern about fluoride's safety showed little regard for the peer review process. In an online commentary, these researchers acknowledged that NASEM "will review [the monograph] this fall" but chose not to disclose that NASEM had *already* conducted one round of peer review and found the NTP monograph did not offer adequate support for its conclusion. This was a crucial detail for these researchers to omit. Knowing that NASEM had given the draft monograph an unfavorable review would have led responsible researchers to exercise reasonable caution by awaiting the next round of NASEM review before publicly urging a major change in the medical guidance that women receive during pregnancy. Instead, these researchers were unwilling to delay their commentary until NASEM had completed its second round of peer review. In other words, these researchers recommended a change in medical guidelines based on a monograph that was still in peer review. Nowhere in their commentary article is the monograph referred to as a "draft" document, even though the NTP itself had emphasized this fact by capitalizing the word "DRAFT" on each page.

Respecting science means allowing each stage of the research process to be completed. Peer review and other evaluative reviews are a bedrock of scientific inquiry. Unfortunately, the NTP committee appears poised to disseminate this "state of the science" report at some point within the coming months. Having received two unfavorable peer reviews, the NTP committee is arrogantly pushing forward — and we suspect their report will characterize fluoride in a scientifically indefensible manner.

Thank you for your ongoing work to improve oral health. And thanks as well for your commitment to the highest standards of science. Let me know if you have any questions or if AFS can be of assistance in other ways.

Sincerely,

Johnny Johnson, Jr., DMD, MS
President
American Fluoridation Society
Pediatric Dentist
Diplomate, American Board of Pediatric Dentistry
Life Fellow, American Academy of Pediatric Dentistry
[redacted]
Email: DrJohnny@AmericanFluoridationSociety.org
Web: AmericanFluoridationSociety.org

Exhibit 8

astdd
Where oral health lives

ASTDD Fluorides Committee
May 4, 2022
Minutes

Participating: Bruce Austin, Tracy Boehmer, Emily Horney, Dixianne Parker, Howard Pollick, Gwen Sullentrup, Sandy Sutton, Matt Zaborowski; Chris Wood, Judy Feinstein

Guest: Kelli Broyles (Idaho)

Not available: Darwin Hayes, Julie Janssen, Johnny Johnson, Dustin Jurgensen, Sahira Khalid, Jay Kumar, Jenni Lansing, Gina Sharps

Agenda Item	Lead	Discussion/Topic	Outcome/Action/Update
1. Call to order	Bruce	Roll call Kelli Broyles, the new program director in Idaho sat in on the meeting, picking up from Matt Zaborowski [now with ADA].	Judy will check with Kelli about her interest in serving on this committee.
2. Minutes3/2/22	Bruce	Reviewed and approved	Moved: Dixianne Parker Seconded: Sandy Sutton
3. Agenda review	Judy	Informational	
4. Updates & brief reports as available/needed		Updates	
	Chris	ASTDD: Chris commented that she (and AAPHD) were very pleased with attendance.	
	Judy	• Fluoride documents revision remains in process. Judy did not have an expected timeline. • Annual awards as presented at the NOHC are ready to be added to the database (on the Members only page of ASTDD's website).	UPDATE: the database is up to date, as noted in ASTDD's Weekly Update on May 9.
	Tracy	CDC – Discrepancy reports are due soon and then she can start working on the next set of Quality Reports (for 2021).	
	Tracy, all	• FDA announcement of bottled water fluoride standard and implications: Tracy noted this is a final rule, for which CDC provided comments about 3 years ago (by Kip Duchon). She will review and let us know what she finds. Note that this only affects manufacturers that add fluoride back into the water, and she has not heard about anything else. Howard reiterated this point, commenting that regardless there could still be negative interpretations, but at the same time, the ruling might also protect companies that add fluoride. Also, some companies may be using	UPDATE: For the CWF CoP meeting on May 12, Johnny Johnson prepared a memo-style update with relevant talking points (to be provided separately).

		water in which the fluoride content exceeds the MCL. He called this an "interesting" ruling. • Howard asked Tracy if/when the interim range for CWF levels would be finalized. She said that this is still in process, with updates to the paper and supporting data, but the results appear to be the same as in 2018. She thought that if anything, they might tighten the range, but would want to be very careful about how this would be expressed, i.e., in terms of "allowable" and FDA language.	
	Howard	California's Fluoridation Manual has been circulated but the authors are changing some content and will finalize soon to formally launch the document. The authors decided that rather than repeating already available information, the content would focus on what a party who knows little or nothing about fluoride and CWF is in the role of initiating a start-up (or a campaign). It should also be useful to those countering challenges. Some 250 copies will be printed and sent to state dental directors; it is also available electronically.	A recorded webinar is available via the COHTAC website (scroll down).
	All	NTP report and "State of the Science"; at the time of the meeting, the release was expected sooner rather than much later, but Tracy noted that CDC was in the process of proactively and preemptively taking steps to intervene.	UPDATE: CDC provided more information albeit off the record in the May 12 CWF CoP call. The release of the NTP's report and a response have been delayed for some time (TBD) but are expected to be released on the same day. CDC, ASTDD, and AFS will provide talking points.
	Chris	ASTDD has requested (again) that a correction be printed in the journal *Environmental Health,* as drafted by Jay Kumar, about the methodology used in an article printed last year. Chris noted that the publisher, Elsevier, has told her they will run it.	
5. Encouraging use of and reporting in WFRS	Judy, all	Judy referred to previous discussions about the WFRS Questionnaire; responses to Question #20 pointed to where ASTDD can be most effective, e.g., by promoting and or assisting with training and education, and looking at how to enhance relationships between and among oral health programs and state drinking water programs or other agencies that have authority over water systems.	How ASTDD might develop resources in response will be pursued.

6. Supply line challenges	Judy, all	Judy and Tracy reported on a conversation with an EPA staffer and a webinar on supply chain issues. Fluoride additives have not been included, apparently because they are not seen as necessary for drinking water safety; however, national and at least New England regional staff have become more aware of the issues. In the short term, there are no apparent responses; EPA programs are more directed at infrastructure and equipment, and new funding initiatives carry a "Made in American" requirement. They plan to stay in touch with EPA contacts and Tracy is also reaching out to AWWA. Longer term approaches include strategies such as contract purchase agreements and regional compacts.	
7. Missouri proposal for a CWF meeting	Gwen	Gwen described the Missouri OH Program's interest in hosting a national (or regional) meeting specifically for state fluoridation contacts, to include not only updates on science and training but also a tour of their first pilot site of the New Wave tablet system. They received approval from the state DNR the previous week and expect the system to go online on July 1st. Gwen has broadly distributed a Survey Monkey to assess interest by potential attendees to attend the meeting, which could be scheduled for later in September.	
8. Planning for CWF CoP on May 12	Judy, all	Judy described the proposed agenda for the session, including discussion of developing a template for public notice of temporary cessation or suspension of CWF.	UPDATE: The session was well attended; the summary was emailed to this Committee.
9. News/ Sharing	All	N/A	
10. Next Meetings		June 1, July 6, August 10, September 7, October 5	NOTE: Judy requested changing the August meeting date to the 10th (from the 3rd).

Exhibit 9

From: Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH)
Sent: Thu, 12 May 2022 15:57:42 +0000
To: Promoff, Gabbi (CDC/DDNID/NCCDPHP/OD); London, Joel (CDC/DDNID/NCCDPHP/OD); Smalls, Donnica (CDC/DDNID/NCCDPHP/OD)
Subject: FW: update from NTP BSC 10am meeting

Plz see update below. Greg sent me a first draft of talking points/Q&A just a bit ago, I am about to start reviewing them now

---

From: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Sent: Thursday, May 12, 2022 11:55 AM
To: Espinoza, Lorena (CDC/DDNID/NCCDPHP/DOH) <lee6@cdc.gov>; Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH) <nbg5@cdc.gov>; Holder, Gregory (CDC/DDNID/NCCDPHP/DOH) <LHN5@cdc.gov>
Subject: update from NTP BSC 10am meeting

Here are my takeaways:

The May 18th release date for SoS report is almost certainly not going to happen
OASH and NIH OD are pretty clearly going to get more involved

Found out from Renee after this call there's a meeting on Monday morning with ADM Levine, leadership from NIEHS, NIDCR, NIH OD, and OASH senior staff

Not yet confirmed for 9am call tomorrow with NTP comms staff. Will keep you posted.

Even though the 5/18 release is not likely, we still need to provide a first draft of talking points today for NCCDPHP OD, policy & comms.

Casey J. Hannan, MPH
***Director**, Division of Oral Health*
Centers for Disease Control and Prevention
channan@cdc.gov
770.488.6054 (office) (b)(6) *(mobile)*
http://www.cdc.gov/oralhealth/

Exhibit 10

From: Judith Feinstein [redacted]>
Sent: Sunday, May 15, 2022 3:15 PM
To: Kumar, Jayanth@CDPH <Jayanth.Kumar@cdph.ca.gov>
Cc: Chris Wood <cwood@astdd.org>
Subject: Prep for the call with ASTTHO on Tues 5/17

EXTERNAL EMAIL. Links/attachments may not be safe. To report suspicious emails, click "Report Phish" button.

Hi Jay –
You likely received but may not have read my follow-up email to the CWF Community of

Practice meeting on Thursday. The first part of the meeting was not recorded so that it would be "off the record" at the request of the CDC staff who talked with us (it was Greg Holder). Chris and I have had some communication back and forth and we'd like to be sure that you see our brief summary (below) prior to the call with ASTHO on Tuesday, and we would also like to set up a short call with you, tomorrow, Monday May 16th, at any time that works for you starting at 12:30 pm ET/9:30 am PT through the rest of your day.

The following is what was sent to the various ASTDD lists.

> The first part of the meeting was a discussion of the potential upcoming release of the fluoridation report by the National Toxicology Program. This conversation was not recorded. We do not have a date but expect it to show up relatively soon, perhaps within a few weeks. Please note the following:
>
> - CDC has useful information on many related topics and will on this one as well. Email the CDC oralhealth@cdc.gov with specific questions, or, to receive updates on this and other issues, go to the website https://www.cdc.gov/oralhealth/about/index.htm , find "Stay Connected" on the navigation bar, or go directly here to sign up for email updates: https://www.cdc.gov/oralhealth/about/stay-connected.html).
> - CWF at the level recommended for water fluoridation – that is, the guideline of 0.7 mg/L [ppm] established in 2015 by the US Public Health Service– was determined then to be and remains now the level for drinking water that maximizes benefits for preventing tooth decay (dental caries) while minimizing risks to human health. CDC continues to recommend the PHS guideline for water fluoridation as a cornerstone of caries prevention in the United States.
> - As the National Academies of Science, Engineering, and Medicine noted in their last review, the NTP monograph cannot be used to draw conclusions about exposure to fluoride at the levels maintained in optimally fluoridated drinking water. It is expected that this will not change whenever the report is finally released.
> - CDC regularly consults with agency experts, including behavioral science experts who work with IQ development, environmental scientists, experts in systematic reviews and statistics, reviews relevant peer reviewed studies as they are released, and hosts listening sessions to hear directly from authors on their recent, relevant research.
>
> In anticipation of the report's publication, ASTDD is developing talking points for reference by State Dental Directors and State Health Officers. CDC will provide information to partners as appropriate and available. AFS (American Fluoridation Society) is drafting a response for distribution when the report is released.

Chris and I had a follow-up call with Greg on Friday. What he told us is essentially this: CDC officials, Assistant Secretary for Health Rachel Levine and others have looked at the monograph and are "pushing back hard" at NTP on the methodological issues. They (CDC) met with NTP and NIEHS reps that morning, and reached an agreement that the NTP would hold off publishing the monograph for some length of time (not clear) until a response is prepared, and that both should be released at the same time. He really emphasized that. He also told us that as HHS has paid more attention to this, and recognized how "aligned" the NTP is with FAN, to the degree of using their talking points, NTP is really digging in and standing by their report – and it's been [finally] a priority. In the call on Thursday, which we reiterated to Greg on Friday, it was really clear how very concerned the state folks are about responding and being able to work with their state health officers.

If I've missed anything, I hope Chris will jump in and add or correct what I've got here. Let us know a time that works for you.

Judy

Exhibit 11

Johnalyn (HHS/OASH) <Johnalyn.Lyles@hhs.gov>; Bradsher, Kris (HHS/ASL) <Kris.Bradsher@hhs.gov>
Subject: RE: REQUEST: NTP Draft Report

Thanks Jen. Adding a few ASL and OASH colleagues.

Would there be a time next week that CDC, NIH and OASH would be available for an internal call with ASL to discuss?

I can get back to staff as suggested below. Thanks, Garrick

From: Greaser, Jennifer (CDC/OD/CDCWO) <cbx5@cdc.gov>
Sent: Friday, June 24, 2022 11:52 AM
To: Groves, Garrick (HHS/ASL) <Garrick.Groves@hhs.gov>
Cc: Tourk, Nancy R. (CDC/OD/CDCWO) <wxk8@cdc.gov>; Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>; Mullman, Lauren (HHS/ASL) <Lauren.Mullman@hhs.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>; Zelenko, Leslie (HHS/ASL) <Leslie.Zelenko@hhs.gov>
Subject: FW: REQUEST: NTP Draft Report

Garrick,

There's important context on this request that would be good to discuss by phone. CDC's Oral Health division has been invited by Dr. Levine to a meeting next Friday (7/1) to discuss CDC's thoughts on the draft report. We recommend that ASL respond to Rep. Kelly's office initially to let them know that the draft report is being discussed internally at HHS and we will be back in touch with them. We recommend that CDC, NIH, ASL and the ASH coordinate on how to respond to this request and any similar future requests (i.e. who will respond on behalf of the department) once CDC has connected with the ASH.

It's important for ASL to know that **if CDC had been given the option to clear this draft report, we would have non-concurred**. Our SMEs plan to share additional details with Dr. Levine next Friday.

Let me know if you'd like to connect by phone today or early next week to discuss.

Thanks,
Jen

From: Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>
Sent: Wednesday, June 22, 2022 11:18 AM
To: Tourk, Nancy R. (CDC/OD/CDCWO) <wxk8@cdc.gov>; Groves, Garrick (HHS/ASL) <Garrick.Groves@hhs.gov>; Wortman, Eric (CDC/OD/CDCWO) <ltr3@cdc.gov>; Workman, Sara R. (CDC/OD/CDCWO) <hvh0@cdc.gov>; Greaser, Jennifer (CDC/OD/CDCWO) <cbx5@cdc.gov>
Cc: Zelenko, Leslie (HHS/ASL) <Leslie.Zelenko@hhs.gov>; Bradsher, Kris (HHS/ASL) <Kris.Bradsher@hhs.gov>; Mullman, Lauren (HHS/ASL) <Lauren.Mullman@hhs.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>
Subject: RE: REQUEST: NTP Draft Report

Hi all, adding Adrienne Hallett for awareness.

Exhibit 12

From: Chris Wood <cwood@astdd.org>
Sent: Friday, June 3, 2022 12:13 PM
To: Jayanth Kumar <jayanth.kumar@cdph.ca.gov>; Judy Feinstein <jafme52@gmail.com>
Subject: FYI re NTP report

On a call with CDC leadership this morning they told me that at the request of the Assistant Secretary for Health, the NTP State of the Science report is "on hold."

ASTDD Associate Membership is open to anyone interested in dental public health.

Christine Wood
Executive Director
Association of State and Territorial Dental Directors
3858 Cashill Blvd.
Reno, NV 89509
[redacted]
cwood@astdd.org
www.astdd.org

Proud member of OPEN (Oral Health Progress and Equity Network)

Exhibit 13

From: Flowers, Christine B (NIH/NIEHS) [E]
Sent: Wednesday, February 3, 2021 9:51 AM
To: Wolfe, Mary (NIH/NIEHS) [E]; Berridge, Brian (NIH/NIEHS) [E]
Cc: Bucher, John (NIH/NIEHS) [E]; Taylor, Kyla (NIH/NIEHS) [E]; Rooney, Andrew (NIH/NIEHS) [E]
Subject: RE: Response to NASEM review of NTP Fluoride Monograph – working document - DRAFT

Then go with "may be…"

Christine Bruske Flowers
Director, Office of Communications and Public Liaison
National Institute of Environmental Health Sciences
National Institutes of Health
U.S. Department of Health and Human Services
919-260-9651

From: Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>
Sent: Wednesday, February 3, 2021 9:42 AM
To: Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>; Berridge, Brian (NIH/NIEHS) [E] <brian.berridge@nih.gov>
Cc: Bucher, John (NIH/NIEHS) [E] <bucher@niehs.nih.gov>; Taylor, Kyla (NIH/NIEHS) [E] <kyla.taylor@nih.gov>; Rooney, Andrew (NIH/NIEHS) [E] <andrew.rooney@nih.gov>
Subject: Re: Response to NASEM review of NTP Fluoride Monograph – working document - DRAFT

Redacted by agreement

From: Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>
Sent: Wednesday, February 3, 2021 9:21 AM
To: Berridge, Brian (NIH/NIEHS) [E] <brian.berridge@nih.gov>
Cc: Bucher, John (NIH/NIEHS) [E] <bucher@niehs.nih.gov>; Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>; Taylor, Kyla (NIH/NIEHS) [E] <kyla.taylor@nih.gov>; Rooney, Andrew (NIH/NIEHS) [E] <andrew.rooney@nih.gov>
Subject: RE: Response to NASEM review of NTP Fluoride Monograph – working document - DRAFT

I'm sorry for my delayed response, but I was tied up yesterday with the Vaccine Confidence Campaign.

Brian – to a public and non-NTP audience, Redacted by agreement
Redacted by agreement
Redacted by agreement
Further, in all of our back-and-forth with NIH, NIDCR, and HHS, this is the language they went back to over and over

again as what needed to be included in a public statement regarding this report. Redacted by agreement
Redacted by agreement
Redacted by agreement

For this sentence…

Redacted by agreement

Perhaps an alternative could be…

Redacted by agreement

Christine Bruske Flowers
Director, Office of Communications and Public Liaison
National Institute of Environmental Health Sciences
National Institutes of Health
U.S. Department of Health and Human Services
919-260-9651

From: Berridge, Brian (NIH/NIEHS) [E] <brian.berridge@nih.gov>
Sent: Monday, February 1, 2021 5:18 PM
To: Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>
Cc: Bucher, John (NIH/NIEHS) [E] <bucher@niehs.nih.gov>; Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>; Taylor, Kyla (NIH/NIEHS) [E] <kyla.taylor@nih.gov>; Rooney, Andrew (NIH/NIEHS) [E] <andrew.rooney@nih.gov>
Subject: Re: Response to NASEM review of NTP Fluoride Monograph – working document - DRAFT

I hear you and I expect that Redacted by agreement
Redacted by agreement
Redacted by agreement For this statement, we should aim for a simple recitation of our original Redacted by agreement
Redacted by agreement followed by the final outcome of the peer review- can't support our assessment. It doesn't matter how the original conclusion was qualified since it wasn't supported. We're perpetuating a confusing argument if we do that.

As written, they are all true statements.

Brian R. Berridge, DVM, PhD, DACVP
Scientific Director, Division of NTP
Associate Director, National Toxicology Program
NIEHS
Office- 984-287-3111
Mobile- Personal Info
brian.berridge@nih.gov

For immediate assistance or scheduling, contact Lisa Wolf (lisa.wolf@nih.gov) or Beth Perry (beth.perry2@nih.gov).

From: "Flowers, Christine B (NIH/NIEHS) [E]" <bruskec@niehs.nih.gov>
Date: Monday, February 1, 2021 at 5:01 PM

Exhibit 14

Christine Bruske Flowers
Director, Office of Communications and Public Liaison
National Institute of Environmental Health Sciences
National Institutes of Health
U.S. Department of Health and Human Services
919-260-9651

From: Ventura, Jeff (NIH/NIDCR) [E] <jeff.ventura@nih.gov>
Sent: Friday, February 5, 2021 10:00 AM
To: Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>
Cc: Saffron, Jesse (NIH/NIEHS) [E] <jesse.saffron@nih.gov>
Subject: RE: Just checking in

Have you shared this with CDC also? And could we give our advocacy groups a heads up on Monday that it is coming?

From: Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>
Sent: Friday, February 5, 2021 9:39 AM
To: Ventura, Jeff (NIH/NIDCR) [E] <jeff.ventura@nih.gov>
Cc: Saffron, Jesse (NIH/NIEHS) [E] <jesse.saffron@nih.gov>
Subject: RE: Just checking in

Hi J.D. –
Attached is the NIEHS/NTP statement that our team has prepared to issue in response to press and public inquiries about the NASEM peer-review of the Draft NTP Monograph on Fluoride. NICDR comments are welcome, and I ask that you also send us any statement that NIDCR intends to provide to the press or public regarding this matter. Also, if you will be doing press interviews with NIDCR SMEs, we'd appreciate knowing who the NIDCR spokesperson will be and if they will be speaking from the NIDCR statement that you share with us.
Many thanks,
Christine

Christine Bruske Flowers
Director, Office of Communications and Public Liaison
National Institute of Environmental Health Sciences
National Institutes of Health
U.S. Department of Health and Human Services
919-260-9651

From: Ventura, Jeff (NIH/NIDCR) [E] <jeff.ventura@nih.gov>
Sent: Friday, February 5, 2021 8:35 AM
To: Flowers, Christine B (NIH/NIEHS) [E] <bruskec@niehs.nih.gov>
Subject: Just checking in

Do you think you'll have a holding statement today for review? Thanks in advance for letting me know.

Best,

J.D. Ventura, M.S., M.S.
Director, Office of Communications and Health Education
National Institute of Dental and Craniofacial Research
National Institutes of Health
(b)(6)

Exhibit 15

From: Iafolla, Timothy (NIH/NIDCR) [E]
Sent: Mon, 8 Feb 2021 19:02:40 +0000
To: Horsford, Jonathan (NIH/NIDCR) [E]
Subject: RE: NTP F update

Wow—this is huge. I wish I'd been a fly on the wall for this discussion, but it's a game changer for the response to the report.

Tim

From: Horsford, Jonathan (NIH/NIDCR) [E] <horsforj@nidcr.nih.gov>
Sent: Monday, February 8, 2021 1:47 PM
To: D'Souza, Rena (NIH/NIDCR) [E] <rena.d'souza@nih.gov>
Cc: Ventura, Jeff (NIH/NIDCR) [E] <jeff.ventura@nih.gov>; Stredrick, Denise (NIH/NIDCR) [E] <stredrid@mail.nih.gov>; Shum, Lillian (NIH/NIDCR) [E] <shuml@nidcr.nih.gov>; Iafolla, Timothy (NIH/NIDCR) [E] <iafollat@nidcr.nih.gov>; Meister, Alissa (NIH/NIDCR) [E] <alissa.meister@nih.gov>
Subject: NTP F update

Rena,

I talked to Gwen Collman (NIEHS Dep Dir) this morning about the NTP F report and next steps.

Great news – NTP has decided to revise the monograph and remove the statement that 'F is a presumed hazard'. This is a **very close hold**, but I wanted to share the update.

Thanks,

J

D. Jonathan Horsford, Ph.D.
Acting Deputy Director
National Institute of Dental and Craniofacial Research
National Institutes of Health
Cell: (b)(6)

Exhibit 16

From: Holder, Gregory (CDC/DDNID/NCCDPHP/DOH)
Sent: Tue, 7 Jun 2022 15:45:15 +0000
To: Turner, Victoria (CDC/DDNID/NCCDPHP/OD)
Cc: Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH); Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH); Espinoza, Lorena (CDC/DDNID/NCCDPHP/DOH); Boehmer, Tracy (CDC/DDNID/NCCDPHP/DOH); Stettner, Joanna L. (CDC/OCOO/OGC)
Subject: Trial Status Update - Minor

Hi Victoria – as I mentioned in yesterday's call, I imagined that the status conference scheduled for today 6/7 would be continued since the NTP report had not been released. I don't have the final order (grumble grumble PACER), but this proposed stipulation from last week shows that the status conference is continued until 6/14. Based on what I can gather, I do not think it will happen that day either. As soon as I see another stipulation and proposed order pop up, I'll let everyone know.

ENV_DEFENSE-#992660-v1-2022_05_27_Stipulation[22] (courtlistener.com)

V/r
Gregory Holder, MPH
Public Health Analyst
Division of Oral Health
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
(404) 498-5501 (office)

Exhibit 17

From: Iafolla, Timothy (NIH/NIDCR) [E]
Sent: Fri, 13 Nov 2020 16:34:56 +0000
To: Horsford, Jonathan (NIH/NIDCR) [E];D'Souza, Rena (NIH/NIDCR) [E];Shum, Lillian (NIH/NIDCR) [E];Meister, Alissa (NIH/NIDCR) [E]
Subject: Re: Pre-meeting for the discussion on the national toxicology program's draft fluoride report mtg

Hello all,
I spoke to Casey Hannan's deputy, who gave me the following status report of the lawsuit:
The last hearing was November 10th, with a petition by EPA to dismiss because of FAN's lack of standing to sue. FAN is now looking for pregnant women to bring into the suit (really).
Also, judge is waiting for final NASEM report to be released, so he has stated there will be no ruling until then.
Lastly, both sides have said they will appeal this ruling when it happens, so the final result is months away.
Thanks,
Tim

From: "Iafolla, Timothy (NIH/NIDCR) [E]" <iafollat@nidcr.nih.gov>
Date: Thursday, November 12, 2020 at 10:57:21 PM
To: "Horsford, Jonathan (NIH/NIDCR) [E]" <horsforj@nidcr.nih.gov>, "D'Souza, Rena (NIH/NIDCR) [E]" <rena.d'souza@nih.gov>, "Shum, Lillian (NIH/NIDCR) [E]" <shuml@nidcr.nih.gov>, "Meister, Alissa (NIH/NIDCR) [E]" <alissa.meister@nih.gov>
Subject: RE: Pre-meeting for the discussion on the national toxicology program's draft fluoride report mtg

Dr. D'Souza et al,

I have attached a summary of my quick literature search regarding the benefits of community water fluoridation (CWF). Limiting my search to the past ten years, I found 8 articles, including five systematic reviews (one of these was a Cochrane Review). Measured benefits included caries averted (prevalence and/or severity), reduction in caries-related dental spending, increase in caries-free children, and caries inequities based on insurance status. Results were consistent, showing that CWF programs are associated with these benefits (or conversely, that cessation of CWF is associated with a reduction in these benefits). Abstracts and links to these articles are provided in the attached document, with relevant sections highlighted.

Regarding my other action items: I sent an email to Casey Hannan (Director of CDC DOH) requesting a status update on the EPA lawsuit. The lawsuit was initiated in California by the Fluoride Action Network, Food and Water Watch, and Moms Against Fluoridation, seeking to compel EPA under Section 21 of the Toxic Substances Control Act to require local water utilities to stop adding fluoride to tap water due to putative neurotoxic effects.

Lastly, I searched for published studies regarding an association between dental fluorosis and neurotoxicity or IQ deficit, but was unable to locate any. However please note that three of the Chinese studies in the NTP report used dental fluorosis as a proxy for fluoride exposure at an early age.

Thanks,
Tim
.
-----Original Appointment----
From: Horsford, Jonathan (NIH/NIDCR) [E] <horsforj@nidcr.nih.gov>
Sent: Wednesday, October 28, 2020 5:28 PM
To: Horsford, Jonathan (NIH/NIDCR) [E]; D'Souza, Rena (NIH/NIDCR) [E]; Iafolla, Timothy (NIH/NIDCR) [E]; Shum, Lillian (NIH/NIDCR) [E]; Meister, Alissa (NIH/NIDCR) [E]
Subject: Pre-meeting for the discussion on the national toxicology program's draft fluoride report mtg
When: Thursday, November 12, 2020 4:00 PM-4:45 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Zoom meeting details below

Due to scheduling conflicts, we are moving this meeting to Thursday, November 12.

If you have any additional materials to share for the meeting, please send them to Suzanne so she can add them to the meeting notice to be reviewed before the meeting.

Join ZoomGov Meeting

(b)(6)

Exhibit 18

From: Fluorides on behalf of Dr. Johnny Johnson via Fluorides
To: Kumar, Jayanth@CDPH; [redacted]n
Cc: FLUORIDES COMMITTEE ASTDD
Subject: Re: ASTDD Fluorides Committee | Minutes, October 6
Date: Monday, October 25, 2021 1:55:05 PM
Attachments: image001.png
image001.png
ATT00001.txt

Outstanding summary, Jay. The judge will be pleased.

NTP has said that they will publish the "state of the science" in their final Monograph. No conclusions is what I understood them to have said. I did write and received a letter from the NTP on their 2nd NASEM review. It'll be interesting to see if they attempt to add conclusions and if they have someone do a final peer review of their final.

Warmly,

Johnny

From: Fluorides <fluorides@committees.astdd.org> on behalf of Kumar, Jayanth@CDPH via Fluorides <fluorides@committees.astdd.org>
Sent: Monday, October 25, 2021 2:55:16 PM
To: Judith Feinstein [redacted]>
Cc: FLUORIDES COMMITTEE ASTDD <fluorides@committees.astdd.org>
Subject: Re: ASTDD Fluorides Committee | Minutes, October 6

I could not attend the October meeting. I notice that the EPA lawsuit has been postponed to January. The judge is waiting for the NTP report and the Spanish study.

If you have not seen it, the much-awaited study from Spain has been published. Their results are diametrically opposite to what Green and colleagues reported in the JAMA Pediatrics paper. IQ scores increased with increasing exposure to fluoride in boys!

"Results: No association was found between MUFcr levels and Bayley Mental Development Index score. Nevertheless, regarding the McCarthy scales, it was found that per unit (mg/g) of MUFcr across the whole pregnancy, scores in boys were greater for the verbal, performance, numeric and memory domains (ß = 13.86, CI 95%: 3.91, 23.82), (ß = 5.86, CI 95%: 0.32, 11.39), (ß = 6.22, CI 95%: 0.65, 11.79) and (ß = 11.63, CI 95%: 2.62, 20.63) respectively and for General Cognitive Index (ß = 15.4, CI 95%: 6.32, 24.48). For girls there was not any cognitive score significantly associated with MUFcr, being the sex-F interactions significant (P interaction <0.05). Including other toxicants levels, quality of family context or deprivation index did not substantially change the results."

My explanation is that spot maternal urinary fluoride is a poor proxy for fetal fluoride exposure. When the fluoride exposure measurement is not valid, then it is not surprising to see these inconsistent results.

From: Fluorides <fluorides@committees.astdd.org>
Sent: Friday, October 15, 2021 6:55 PM
To: 'ASTDD Fluorides Committee' <fluorides@committees.astdd.org>
Subject: ASTDD Fluorides Committee | Minutes, October 6

The email sent earlier did not include the full version of the October 6th minutes. This one does.

Happy Friday... This time I'm not waiting for the whole month to pass by.

Please let me know if you have any questions, comments, corrections, etc., and have a good weekend.

Judy

Judith A. Feinstein, MSPH
Coordinator, ASTDD Dental Public Health Policy Committee
Coordinator, ASTDD Fluorides Committee
[redacted]

astdd
where oral health lives

Exhibit 19

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via E-mail: regina.imburgia@gmail.com

October 28, 2022

Regina Imburgia
5423 Goodwin Ave
Dallas, Texas 75206

Re: NIH FOIA Case No. 59110

Dear Ms. Imburgia:

This is the final response to your Freedom of Information Act (FOIA) request addressed to the National Institute of Environmental Health Sciences (NIEHS) FOIA Office, dated October 6, 2022 and received on the same day. Your request was referred to this office. You requested a copy of the May 2022 version of the National Toxicology Program's (NTP) monograph on fluoride's neurodevelopmental/cognitive health effects.

NIEHS conducted a search for records and located 288 pages responsive to your request, of which 2 pages are enclosed. Upon review of the records, we have determined to withhold 287 pages in their entirety, and a portion of the released page pursuant to exemption 5 of the FOIA, 5 U.S.C. § 552 (b)(5); and section 5.31 (e) of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 5 permits the withholding of internal government records which are pre-decisional and contain staff advice, opinion, and recommendations. This exemption is intended to preserve free and candid internal dialogue leading to decision-making.

Please note the additional page included in this production corresponds to the slip-sheet marking where pages were withheld in full. Therefore, of the original 288 pages, 287 pages were withheld in full, and the slip-sheet was added to clearly mark these withholdings.

You have the right to appeal this determination to deny you access to information in the Agency's possession. Should you wish to do so, your appeal must be sent within ninety (90) days of the date of this letter, following the procedures outlined in Subpart F of the HHS FOIA Regulations (https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations) to Assistant Secretary for Public Affairs at https://requests.publiclink.hhs.gov/App/Index.aspx.
Clearly mark the communication "Freedom of Information Act Appeal."

If you are not satisfied with the processing and handling of this request, you may contact the NIH FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison
Denean Standing-Ojo
Office of Communications and
Public Liaison
Building 31, Room 5B52S
31 Center Drive
Bethesda, MD 20892
301-496-5077 (phone)
nihfoia@mail.nih.gov (email)

OGIS
National Archives and Records Admin.
8601 Adelphi Rd – OGIS
College Park, MD 20740-6001
202-741-5770 (phone)
1-877-684-6448 (toll-free)
202-741-5769 (fax)
ogis@nara.gov (email)

In certain circumstances provisions of the FOIA and Department of Health and Human Services FOIA Regulations allow us to recover part of the cost of responding to your request. Because the cost is below the $25 minimum, there are no charges associated with our response.

If you have any questions about this response, please call 301-496-5633.

Sincerely,

Gorka Garcia-Malene
Freedom of Information Officer, NIH

Enclosed: 2 pages (PDF), including a slip-sheet

(b)(5)

Page 002 of 288 to Page 288 of 288

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information and Privacy Act

Exhibit 20

Thanks for reaching out, Bob. We are always ready to help in every conceivable manner in which we can.

Warm regards,

Johnny Johnson, Jr., DMD, MS
Pediatric Dentist
Diplomate, American Board of Pediatric Dentistry
Life Fellow, American Academy of Pediatric Dentistry
President, American Fluoridation Society
Web: AmericanFluoridationSociety.org
[redacted]
Email: DrJohnny@AmericanFluoridationSociety.org

AMERICAN FLUORIDATION SOCIETY

From: Burns, Robert J. <burnsr@ada.org>
Sent: Saturday, September 10, 2022 2:59 PM
To: Dr. Johnny Johnson <drjohnny@americanfluoridationsociety.org>
Cc: Fluorides <fluorides@committees.astdd.org>; Christine Wood <cwood@astdd.org>
Subject: Health Canada on Green-Till study 2019

Hi, Dr. Johnson. Your email regarding the Health Canada internal memo made its way to my desk. Are you at liberty to share a copy of the full document, or perhaps the citation? I'd like to include it in comments we're submitting to the NIEHS Board of Scientific Counselors.

The BSC is has been charged to review whether NTP appropriately responded to outside criticisms of its report on potential causality between fluoride exposure and low IQ, and recommend whether and how the report should move forward.

We have serious issues with the third (and purportedly final) draft. We're asking the BSC to make sure they are resolved before the report is finalized.

Thanks in advance for considering my request.

-Bob

Exhibit 21

2021 Federal Legislative and Regulatory Accomplishments

Congressional Bills

- McCarran Ferguson anti-trust reform bill was signed into law in January of 2021.
- Successfully advocated against an expansion of Medicare to include a dental benefit under Part B in House of Representatives passed Build Back Better legislation. At the same time raising awareness of the ADA alternative proposal to serve seniors with the greatest need under a new Medicare section.
- Received the support of over 300 bipartisan cosponsors (a supermajority) and 40 bipartisan Senate cosponsors for the Ensuring Lasting Smiles Act (ELSA). ELSA would require all private group and individual health plans to cover medically necessary services resulting from a congenital anomaly or birth defect. These services would include inpatient and outpatient care and reconstructive services and procedures, as well as adjunctive dental, orthodontic, or prosthodontic support.
- Worked to introduce the Dental and Optometric Care (DOC) Access Act in both the House and the Senate, which would prevent dental insurers from dictating fees a participating dentist may charge for non-covered services. This bipartisan legislation will provide greater access to high-quality care by helping to curb anti-patient and anti-competitive practices of dental insurance plans.
- Supported House passage of the PREVENT HPV Cancers Act, which encourages the use of the human papillomavirus vaccine in order to reduce the risk for HPV-related cancers. The ADA continues to urge the Senate to prioritize the bill and bring it to the floor for a vote.
- Supported the introduction of the Medicaid Dental Benefit Act of 2021, which would make comprehensive dental care a mandatory component of Medicaid coverage for adults in every state. Currently, less than half of the states provide "extensive" dental coverage for adults in their Medicaid programs. Without a federal requirement the optional adult dental benefit is sometimes not provided by states.
- Advocated for the successful introduction of the POST GRAD Act, which would allow dental students to take advantage of subsidized federal student loans.
- Worked with House staff to reintroduce the Health Enterprise Zones Act of 2021, which would designate areas as Health Enterprise Zones to reduce health disparities and improve health through tax incentives, grants, loan repayment opportunities and other benefits.
- Supported the reintroduction of the Indian Health Service Health Professions Tax Fairness Act, which would exclude from gross income payments under the Indian Health Service Loan Repayment Program and amounts received under the Indian Health Service Scholarships Program.
- Worked with Senate staff to introduce the Strengthening America's Health Care Readiness Act, which would provide a one-time, supplemental appropriation of $5 billion for scholarship and loan forgiveness awards through the National Health Service Corps (NHSC).The bill would also establish a demonstration project to harness members of the NHSC workforce to serve in emergency capacities.
- Helped secure $800 million for NHSC in the American Rescue Plan Act of 2021.
- Advocated for funding in the American Rescue Plan to strengthen community-based efforts in the Health Resources and Services Administration (HRSA), which led to the allocation of $46 million for the expansion of community-based

primary care medical and dental residency programs in rural and underserved communities. The new funding supports current residents in Teaching Health Centers (THCs), new community-based primary care residency programs, and expands the number of full-time equivalent (FTE) resident positions at existing and new THCs.

- Supported the introduction of the Doctors of Community Act in the House and Senate. The bill would permanently authorize the Teaching Health Center Graduate Medical Education program to support the training of primary care medical and dental residents with a focus on supporting residents in high-need communities.
- Supported the House passage of the Oral Health Literacy and Awareness Act, which would authorize a public education campaign across all relevant programs of the HRSA to increase oral health literacy and awareness. The ADA also supported appropriations funding for oral health literacy at HRSA.
- Supported the appointment of the Chief Dental Officer for the Centers for Medicaid and Medicare Services (CMS) through the federal appropriations process. In 2021, Dr. Natalia Chalmers was named CMS' first ever Chief Dental Officer.
- Advocated for provisions in the American Rescue Plan to address recovery efforts in Indian Country, which led to the appropriation of $2 billion for tribal health systems due to lost reimbursements for care during the pandemic. These funds will help make up for the financial loss across the entire Indian health system due to reduced patient visits and will strengthen long-term health care in Indian Country by helping the Indian Health Service (IHS) tribal and urban Indian health programs invest in higher quality provider salaries and services particularly impacted by the pandemic like dental health care.

Provider Relief Funding

- Secured dental eligibility in additional phases of the Provider Relief Funds (PRF).
- Ensured that HRSA distributed funding to new dentists, including reimbursing smaller providers for their changes in operating revenues and expenses at a higher rate compared to larger providers, and bonus payments based on the amount of services providers furnish to Medicaid/CHIP and Medicare beneficiaries.

Veterans

- Signed a memorandum of agreement with the Department of Veterans Affairs to advise the Center for Care and Payment Innovation on scaling and communications for its oral health pilot program, VETSmile.
- Advised and supported VETSmile as it launched in NYC and northern NJ. VETSmile has already served more than 475 unique veteran patients at NYU.

State Government Affairs (SGA)

- SGA supported 18 state societies in enacting 28 new laws to positively reform dental insurance.

Community Water Fluoridation

- Sent letters to 12 communities facing fluoridation challenges; 80% of communities facing challenges were able to reaffirm water fluoridation.
- Secured favorable recommendations from the U.S. Preventive Services Task Force for primary care clinicians to apply fluoride varnish and prescribe fluoride supplements in non-dental settings.
- ADA consulted in the reformation of the bill to focus on oral disease prevention rather than a limited scope of fluoridation only. USVI passed Bill No. 34-0051 to adjust the amount of fluoride in water and support dental in school-based health.

- H.R. 3684: Infrastructure Investment and Jobs Act. ADA sent a letter to include fluoridation in the scope of this bill. Section 50112 includes the advancement of drinking water technologies. Fluoridation can be included in proposals related to technology updates to drinking water systems.
- The ADA sent a letter to the National Academies of Science, Engineering, and Medicine (NASEM) regarding concerns related to the Draft National Toxicology Program (NTP) Monograph on fluoride and neurodevelopment. On February 9th, 2021, NASEM released their reviewing saying there are worrisome inconsistencies in the monograph and advised the NTP to revise their monograph. The NTP never released a final monograph in 2021.

Tobacco/Vaping

- Secured a commitment from the Food and Drug Administration (FDA) to ban menthol as an added flavor in cigarettes.

COVID-19

- Secured a CDC recommendation for dentists, their teams, and dental students to be offered immediate access to the COVID-19 vaccines.
- Secured nationwide approval for dentists and dental students to administer the COVID-19 vaccines under the PREP Act.
- Secured an exemption for dentistry in the Occupational Safety and Health Administration (OSHA's) emergency temporary standard for health care settings.

Emergency Department (ED) Referral Initiative

- 14 states prioritized for technical assistance to begin ED Referral programs.

Health Literacy

- The CA Oral Health Literacy Toolkit, a collaborative effort of the California Dental Association, the California Office of Oral Health and members of the National Advisory Committee for Health Literacy in Dentistry (NACHLD) launched in September.

Member Engagement and Fundraising: American Dental Political Action Committee (ADPAC)

- Sent 73,000 grassroots communications to House and Senate offices via Action Alert network.
- Scheduled over 200 meetings with Members of Congress during the 2021 ADA Dentist and Student Lobby Day.
- Reviewed and revised ADPAC's governance documents and processes.
- Held candidate workshops for 9 dentists interested in running for office.
- Raised $1.4 million in 2021.

Follow all of the ADA's advocacy efforts at **ADA.org/advocacy**.

Exhibit 22

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

FOOD & WATER WATCH, INC. *et al.*, Plaintiffs, v. U.S. ENVIRONMENTAL PROTECTION AGENCY *et al.*, Defendants.	Civil Action No. 3:17-cv-02162-EMC **STIPULATION AND ~~[PROPOSED]~~ ORDER REGARDING DECEMBER 2, 2022 PROTECTIVE ORDER**

At the January 12, 2023 status conference, "the Court directed the parties to schedule adjudication of EPA's assertion of privilege over the May 2022 draft of the NTP report and FWW's entitlement to discovery into critiques of that draft." *See* Dkt. No. 340, Order at 3. On January 17, 2023, Plaintiffs served non-party National Institute for Environmental Health Sciences ("NIEHS") with a subpoena requesting the production of agency comments, NTP's responses thereto, and other documents related to NTP's decision whether to publish the May 2022 prepublication fluoride monograph and the related meta-analysis. (NTP is an interagency program that is administratively headquartered at NIEHS.)

On February 3, 2023, counsel for Plaintiffs and NIEHS met and conferred regarding the subpoena. NIEHS notified Plaintiffs that NTP will be publicly posting to NTP's website the materials provided to the NTP Board of Scientific Counselors ("BSC") working group that is evaluating the comments on the monograph and the related meta-analysis, as well as NTP's responses thereto. The materials posted will include the May 2022 prepublication monograph and the related meta-analysis, both of which are presently subject to the Court's December 2, 2022 protective order (Dkt. No. 324). The posting will also include, without attribution or complete date information, the agency comments sought by the subpoena as well as NTP's responses thereto.[1] NIEHS intends to post these materials on or by March 15, 2023.

In light of these developments, NIEHS has notified Plaintiffs that it does not object to the lifting of the December 2, 2022 protective order upon the earlier of March 15, 2023 or the posting of these materials to NTP's website. Further, NIEHS has agreed to produce to Plaintiffs a copy of the materials provided to the BSC working group as soon as practicable on the condition that they are made subject to the protective order until the protective order is lifted.

To that end, Plaintiffs, Defendants, and NIEHS stipulate to and jointly request an order providing the following:

- NIEHS's document production in response to Plaintiffs' January 17, 2023 subpoena shall be subject to the December 2, 2022 protective order.

[1] Plaintiffs and NIEHS continue to meet and confer regarding production of the name and date information associated with the agency comments and NTP's responses.

- The December 2, 2022 protective order shall be lifted at the earlier of March 15, 2023 at 5:00 p.m. Eastern Daylight Time or the posting of the materials provided to the BSC working group on NTP's website.

IT IS SO STIPULATED.

DATED: February 8, 2023

Respectfully submitted,

WATERS, KRAUS & PAUL

/s/ Michael Connett
MICHAEL CONNETT
C. ANDREW WATERS
KAY GUNDERSON REEVES *(pro hac vice)*

Attorneys for Plaintiffs

DATED: February 8, 2023

Respectfully submitted,

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United States Attorney

*/s/ Emmet P. Ong**
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Attorneys for Defendants U.S. Environmental Protection Agency and Michael S. Regan, in his official capacity as Administrator of U.S. Environmental Protection Agency, and Non-Party National Institute of Environmental Health Sciences

*In compliance with Civil Local Rule 5-1(h)(3), the filer of this document attests under penalty of perjury that concurrence in the filing of the document has been obtained from the other Signatory.

~~[PROPOSED]~~ ORDER

Pursuant to stipulation of the parties, IT IS SO ORDERED.

DATED: February 14, 2023

HON. EDWARD M. CHEN
United States Senior District Judge

Exhibit 23

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

October 31, 2022

Kristin Lavelle
[redacted]
Berkeley, 94707
Via email: kristieclendenning@yahoo.com

Dear Ms. Lavelle:

This letter is regarding your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of September 13, 2022, assigned #22-02194-FOIA, seeking:

> "March 1, 2022 to the Present day.
>
> DOCUMENTS REQUESTED:
>
> 1) All emails to or from Casey Hannan (including emails in which Mr. Hannan is a cc or bcc recipient) that discuss, or in any way reference, the NTP FLUORIDE REVIEW.
>
> 2) All emails to or from Casey Hannan (including emails in which Mr. Hannan is a cc or bcc recipient) that contain the words "National Toxicology Program," NTP, neurotoxic!, and/or neurodevelop!.
>
> 3) All emails to or from Lorena Espinoza (including emails in which Dr. Espinoza is a cc or bcc recipient) that discuss, or in any way reference, the NTP FLUORIDE REVIEW.
>
> 4) All emails to or from Lorena Espinoza (including emails in which Dr. Espinoza is a cc or bcc recipient) that contain the words "National Toxicology Program," NTP, neurotoxic!, and/or neurodevelop!.
>
> 5) All emails to or from Nicole Johnson (including emails in which Ms. Johnson is a cc or bcc recipient) that discuss, or in any way reference, the NTP FLUORIDE REVIEW.
>
> 6) All emails to or from Nicole Johnson (including emails in which Ms. Johnson is a cc or bcc recipient) that contain the words "National Toxicology Program," NTP, neurotoxic!, and/or neurodevelop!"

We located 1860 pages of responsive records (559 pages released in full or part; 1301 pages withheld in full). After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemption(s) 4, 5, and 6. The foreseeable harm standard was considered when applying these redactions.

EXEMPTION 4

Exemption 4 protects trade secrets and commercial or financial information obtained from a person that is privileged or confidential. We have determined that the information withheld is customarily and actually kept private and confidential by the submitter of the information.

EXEMPTION 5

Exemption 5 protects inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency. Exemption 5 therefore incorporates the privileges that protect materials from discovery in litigation, including the deliberative process, attorney work-product, and attorney-client privileges. Information withheld under this exemption was protected under the deliberative process privilege. The deliberative process privilege protects the decision-making process of government agencies. The deliberative process privilege protects materials that are both pre-decisional and deliberative. The materials that have been withheld under the deliberative process privilege of Exemption 5 are both pre-decisional and deliberative, and do not contain or represent formal or informal agency policies or decisions. Examples of information withheld include deliberative discussions, and draft/pre-decisional documents.

EXEMPTION 6

Exemption 6 protects information in personnel and medical files and similar files when disclosure would constitute a clearly unwarranted invasion of personal privacy. The information that has been withheld under Exemption 6 consists of personal information, such as personal emails, cell and direct phone numbers, and login credentials. We have determined that the individual(s) to whom this information pertains has a substantial privacy interest in withholding it.

In addition to the pages listed above we located 1,876 pages of records that originated with other agencies. We located 1,871 pages belonging to the National Institute of Health, 5 pages belonging to the Department of Health and Human Services. These pages have been referred to the perspective agencies for direct response. To obtain additional information regarding these pages you may contact the agencies at the following:

Department of Health and Human Services (HHS) Office of the Secretary (OS)
Freedom of Information Act Office
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C. 20201
E-mail: FOIARequest@hhs.gov
Phone: 202-690-7453
Fax: 202-690-8320

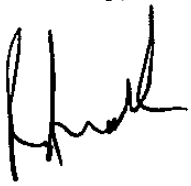
National Institute of Health
FOIA Office
Building 31, Room 5B35
31 Center Drive, MSC 2107
Bethesda, MD 20892-2107
Phone: 301-496-5633
Fax: 301-402-4541
E-mail: nihfoia@mail.nih.gov

You may contact our FOIA Public Liaison at 770-488-6246 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services

(OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by January 16, 2022.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

Enclosures

22-02194-FOIA

Exhibit 24

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 (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,

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

A. 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.[1] (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

[1] 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"

("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.

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 policy-making."). 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

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

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.[2]

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

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

[2] 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 privilege, for the reasons stated in this order.

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

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.

B. 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.)

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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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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

United States District Court
Northern District of California

Exhibit 25

From: Blair, Nicole (CDC/ONDIEH/NCCDPHP) <nbg5@cdc.gov>
To: thayer@niehs.nih.gov; Harrouk, Wafa (FDA/CDER); Mendez, Elizabeth; Donohue, Joyce; Lowit, Anna; wolfe@niehs.nih.gov; Harry, Jean (NIH/NIEHS) [E]; Strong, Jamie; Swartz, Christina; Doherty, Michael; Gooch, Barbara (CDC/ONDIEH/NCCDPHP); Iafolla, Timothy (NIH/NIDCR) [E]; Behl, Mamta (NIH/NIEHS) [E]; Tucker, Nicole; DAgostino, Jaime; Rodgers-Jenkins, Crystal; Wang, Lili; Runner, Susan (FDA/CDRH); bucher@niehs.nih.gov; Weno, Katherine (CDC/ONDIEH/NCCDPHP)
Sent: 6/22/2016 2:22:24 PM
Subject: RE: NTP fluoride and animal neurobehavior report

Comments from CDC:

Hi Kris – I'm sorry I was not able to get our comments to you sooner. On the whole, this is a very well done and reported systematic review, and provides a lot of needed detail that can be used to objectively discuss the quality of these studies. I have a few more specific suggestions below, but the main piece of feedback is the reminder that this report will be highly scrutinized by interested parties who may not have a strong scientific background. Thus, there is potential that some pieces of the report may be misinterpreted or taken out of context. For that reason, we encourage providing greater clarity or repetition of certain points, including what "moderate level of evidence" really means, where it actually applied, and that the vast majority of fluoride exposures reflected in the studies are well beyond what would ever be relevant for human exposure.

Specific comments:

- Low to moderate evidence findings should also specify relevant doses (almost all of the data reviewed are at very high doses) and I count only 2 statistically significant results at doses below 5ppm
- This literature (where many of the studies short term are conducted in small numbers of rodents) probably has a high likelihood of publication bias which would have the effect of overestimating effects.
- Included studies: given the significant overlaps in many of the authorship lists and study characteristics, many of the included studies should probably be re-characterized as multiple reports on the same study. (the current treatment of multiple publications on what appears to be multiple reports on the same study overstates the depth of the current literature.)
- A measure of central tendency of the dose ranges included is essential, almost all of the doses are very high
- The results limited to < 5 or < 4 ppm need more emphasis. Again, I count only 2 statistically significant results at doses below 5
- The indirectness of the dose ranges (generally very high), species (rodents), and outcome measures (of uncertain relevance to humans) needs more emphasis
- Consider doing more with dose response. There seem to be very few significant results at levels below 5, more at levels 5-50, and even more at levels above 50. At least levels above 50 and probably levels above 4 are essentially irrelevant to current PH applications in people in the US.
- Clarify for the reader with more detail that you carefully reviewed all provided studies and why different studies were retained or dropped. Critics on both sides will be wondering either why some studies stayed in or why others were not included.

From: Blair, Nicole (CDC/ONDIEH/NCCDPHP)
Sent: Wednesday, June 22, 2016 2:06 PM
To: Thayer, Kristina (NIH/NIEHS) [E] <thayer@niehs.nih.gov>; Harrouk, Wafa (FDA/CDER)

<Wafa.Harrouk@fda.hhs.gov>; 'Mendez, Elizabeth' <Mendez.Elizabeth@epa.gov>; Joyce Donohue <Donohue.Joyce@epa.gov>; Lowit.Anna@epa.gov; Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>; Harry, Jean (NIH/NIEHS) [E] <harry@niehs.nih.gov>; Jamie Strong <Strong.Jamie@epa.gov>; 'Swartz, Christina' <Swartz.Christina@epa.gov>; 'Doherty, Michael' <Doherty.Michael@epa.gov>; Gooch, Barbara (CDC/ONDIEH/NCCDPHP) <bfg1@CDC.GOV>; Iafolla, Timothy (NIH/NIDCR) [E] <iafollat@nidcr.nih.gov>; Behl, Mamta (NIH/NIEHS) [E] <mamta.behl@nih.gov>; 'Tucker, Nicole' <Tucker.Nicole@epa.gov>; DAgostino.Jaime@epa.gov; 'Rodgers-Jenkins, Crystal' <Rodgers-Jenkins.Crystal@epa.gov>; Lili Wang <Wang.Lili@epa.gov>; Runner, Susan (FDA/CDRH) <Susan.Runner@fda.hhs.gov>; Bucher, John (NIH/NIEHS) [E] <bucher@niehs.nih.gov>; Weno, Katherine (CDC/ONDIEH/NCCDPHP) <fon2@cdc.gov>
Subject: RE: NTP fluoride and animal neurobehavior report

<< File: NTP fluorideJune2016 V2 msgs_NBJ_CH.docx >>

-----Original Appointment-----
From: Thayer, Kristina (NIH/NIEHS) [E]
Sent: Thursday, June 02, 2016 4:43 AM
To: Thayer, Kristina (NIH/NIEHS) [E]; Harrouk, Wafa (FDA/CDER); 'Mendez, Elizabeth'; Joyce Donohue; Lowit.Anna@epa.gov; Wolfe, Mary (NIH/NIEHS) [E]; Harry, Jean (NIH/NIEHS) [E]; Jamie Strong; Blair, Nicole (CDC/ONDIEH/NCCDPHP); 'Swartz, Christina'; 'Doherty, Michael'; Gooch, Barbara (CDC/ONDIEH/NCCDPHP); Iafolla, Timothy (NIH/NIDCR) [E]; Behl, Mamta (NIH/NIEHS) [E]; 'Tucker, Nicole'; DAgostino.Jaime@epa.gov; 'Rodgers-Jenkins, Crystal'; Lili Wang; Runner, Susan (FDA/CDRH); Bucher, John (NIH/NIEHS) [E]; Weno, Katherine (CDC/ONDIEH/NCCDPHP)
Subject: NTP fluoride and animal neurobehavior report
When: Wednesday, June 22, 2016 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: 866-692-4541; passcode: 9415373

From: Thayer, Kristina (NIH/NIEHS) [E]
Sent: Thursday, May 26, 2016 5:20 AM
To: Harrouk, Wafa (FDA/CDER); 'Mendez, Elizabeth'; Joyce Donohue; Lowit.Anna@epa.gov; Wolfe, Mary (NIH/NIEHS) [E]; Harry, Jean (NIH/NIEHS) [E]; Jamie Strong; Blair, Nicole (CDC/ONDIEH/NCCDPHP); 'Swartz, Christina'; 'Doherty, Michael'; Gooch, Barbara (CDC/ONDIEH/NCCDPHP); Iafolla, Timothy (NIH/NIDCR) [E]; Behl, Mamta (NIH/NIEHS) [E]; 'Tucker, Nicole'; DAgostino.Jaime@epa.gov; 'Rodgers-Jenkins, Crystal'; Lili Wang; Runner, Susan (FDA/CDRH); Bucher, John (NIH/NIEHS) [E]; Weno, Katherine (CDC/ONDIEH/NCCDPHP)
Subject: NTP fluoride and animal neurobehavior report

Good morning,

Please find attached our report "Systematic Literature Review on the Neurobehavioral Effects of Fluoride in Animal." Since you've last seen this report in Fall 2015 we've updated the literature to January 2016 and had the report externally peer-reviewed. In addition, we asked animal toxicologists at EPA to do another round of review. We are planning on releasing this report towards the end of June and wanted to share with you in advance. The document will undergo technical editing in parallel to your review.

Robin Mackar and Mary Wolfe will be contacting staff from our agencies to work on a communication strategy. As you recall, names of points of contact for communication were identified last fall.

Please respond to the doodle poll below if you'd like to participate in a conference call to discuss the report and be updated on our other fluoride-related activities (systematic review of human literature, animal toxicology studies), which were discussed at the December 1-2, 2015 NTP Board of Scientific Counselors meeting (http://ntp.niehs.nih.gov/go/9741).

http://doodle.com/poll/avk7eztcxsyydriv

Sincerely,

Kris

Kristina Thayer, Ph.D.
Deputy Director for Analysis, Division of the NTP
Director, NTP Office of Health Assessment and Translation (OHAT)
NIEHS/NTP
530 Davis Drive
Room 2150/Mail Drop K2-04
Morrisville, NC 27560
Ph: 919-541-5021
Fax: 301.480.3286
thayer@niehs.nih.gov

Exhibit 26

From: Strong, Jamie
To: Donohue, Joyce
Subject: RE: Fluoride Sys Rev report
Date: Wednesday, October 14, 2015 10:49:00 AM

How about this?

Kris,
Thank you for the opportunity to review the Systematic Review of the Neurobehavioral Toxicity of Fluoride in Animal Studies report. The report is very thorough, particularly related to the description of the method. The presentation of scientific details from the studies that lead to the conclusions was not as transparent (perhaps that was outside the scope of the project). Specifically, the document could benefit from presentation of a discussion related to the biochemistry of fluoride and its interaction with the nervous system as support for the effects observed. For example, fluoride salts are, in some cases, pretty insoluble (e.g. Al, Ba, Ca, Fe, Pb, Mg). Questions that are relevant and important include, does the formation of ion pairs or insoluble salts in some way impact signaling or neurotransmission? This point may be something to keep in mind as NTP considers a more in depth systematic review of the neurotoxicity literature.

Presentation of dose rather than concentration may be a more accurate measure of exposure given that these were animals studies. NTP concluded that the strongest evidence available was for the high dose studies (> 25ppm). EPA's current MCLG/MCL for fluoride is 4 mg/L. The document does not include any sort of discussion about the potential risk to humans at low doses (i.e., concentrations of 4 mg/L and lower).

From: Thayer, Kristina (NIH/NIEHS) [E] [mailto:thayer@niehs.nih.gov]
Sent: Thursday, September 10, 2015 8:25 PM
To: Strong, Jamie
Subject: RE: Fluoride Sys Rev report

Thanks Jamie,

Would you be able to update Joyce (Donohue.Joyce@epa.gov) and Lila (Wang.Lili@epa.gov) on what was discussed today? – they were identified from an August 2015 interagency outreach via NTP Executive Committee points of contact (so, separate outreach than via Peter). Alternatively, I can get in touch with them but I am up to eyeballs busy until last week in September….

Thanks for thinking of us on the ORD connection – we are in regular contact with Vince and Glinda!! We are actually planning to meet with Glinda (or someone from her team) on evaluation of animal studies….we had several meetings on evaluation of human studies earlier this year…very productive and resulted in a manuscript….still waiting to see if it's accepted, but it basically says that while we use different tools to assess quality of human studies they are getting at similar content.

From: Strong, Jamie [mailto:Strong.Jamie@epa.gov]
Sent: Thursday, September 10, 2015 1:26 PM
To: Thayer, Kristina (NIH/NIEHS) [E]
Subject: Fluoride Sys Rev report

Kris,
Thank you again for the briefing on fluoride. I will coordinate the OW review of the draft systematic review report for neurobehavioral effects of fluoride. We will send comments by 10/12, if not before. The IRIS Program in ORD is doing a lot of work on systematic review. They are also undertaking the development of hazard descriptors for noncancer effects and I am sure they would be interested to hear about the assessment of confidence laid out in the report. Vince Cogliano or Glinda Cooper are potential points of contact in IRIS on this topic.

Thanks,
Jamie

Jamie Strong, Chief Human Health Risk Assessment Branch
Health and Ecological Criteria Division, 4304-T
Office of Science and Technology, Office of Water
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC 20460

phone: 202.566.0056
fax: 202.566.1140

Exhibit 27

From: Strong, Jamie
To: Thayer, Kristina (NIH/NIEHS) [E]
Cc: Donohue, Joyce; Wang, Lili; Rodgers-Jenkins, Crystal
Subject: EPA OW comments on NTP fluoride sys rev report
Date: Wednesday, October 14, 2015 1:50:00 PM

Kris,
Thank you for the opportunity to review the Systematic Review of the Neurobehavioral Toxicity of Fluoride in Animal Studies report. The report is very thorough, particularly related to the description of the method. The presentation of scientific details from the studies that lead to the conclusions was not as transparent (perhaps that was outside the scope of the project). Specifically, the document could benefit from presentation of a discussion related to the biochemistry of fluoride and its interaction with the nervous system as support for the effects observed. For example, fluoride salts are, in some cases, are pretty insoluble (e.g. Al, Ba, Ca, Fe, Pb, Mg). Questions that are relevant to this property of fluoride include the issue of whether the formation of ion pairs or insoluble salts in some way impact signaling or neurotransmission? This point may be something to keep in mind as NTP considers a more in depth systematic review of the neurotoxicity literature and study designs.

One other comment relates to the presentation of dose rather than concentration, as dose may be a more accurate measure of exposure given that these were animals studies. NTP concluded that the strongest evidence available was for the high concentration studies (> 25ppm). EPA's current MCLG/MCL for fluoride is 4 mg/L. The document does not include any sort of discussion about the potential risk to humans at low doses (i.e., those delivered by a concentrations of 4 mg/L and lower). In the EPA exposure assessment of intakes of fluoride from food, beverages, toothpaste and soils (U.S. EPA, 2011) the intakes for children from 0.5 months to 14 years excluding drinking water ranged from 0.35 mg/day to 1.09 mg/day. The average drinking water concentration for Public Water Systems at a 90% intake contributed 0.84 to 1.23 mg/day. It will be important to add context to the report relative to representative human exposures in the US and other countries compared to the findings in the animals studies. We can only provide information related to exposures in the U.S.

Thank you again for the opportunity to provide input. We look forward to further discussion as NTP moves forward with their fluoride programs.

Jamie

Jamie Strong, Chief Human Health Risk Assessment Branch
Health and Ecological Criteria Division, 4304-T
Office of Science and Technology, Office of Water
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC 20460

phone: 202.566.0056
fax: 202.566.1140

From: Thayer, Kristina (NIH/NIEHS) [E] [mailto:thayer@niehs.nih.gov]
Sent: Thursday, September 10, 2015 8:25 PM
To: Strong, Jamie
Subject: RE: Fluoride Sys Rev report

Thanks Jamie,

Would you be able to update Joyce (Donohue.Joyce@epa.gov) and Lila (Wang.Lili@epa.gov) on what was discussed today? – they were identified from an August 2015 interagency outreach via NTP Executive Committee points of contact (so, separate outreach than via Peter). Alternatively, I can get in touch with them but I am up to eyeballs busy until last week in September….

Thanks for thinking of us on the ORD connection – we are in regular contact with Vince and Glinda!! We are actually planning to meet with Glinda (or someone from her team) on evaluation of animal studies….we had several meetings on evaluation of human studies earlier this year…very productive and resulted in a manuscript….still waiting to see if it's accepted, but it basically says that while we use different tools to assess quality of human studies they are getting at similar content.

From: Strong, Jamie [mailto:Strong.Jamie@epa.gov]
Sent: Thursday, September 10, 2015 1:26 PM
To: Thayer, Kristina (NIH/NIEHS) [E]
Subject: Fluoride Sys Rev report

Kris,
Thank you again for the briefing on fluoride. I will coordinate the OW review of the draft systematic review report for neurobehavioral effects of fluoride. We will send comments by 10/12, if not before. The IRIS Program in ORD is doing a lot of work on systematic review. They are also undertaking the development of hazard descriptors for noncancer effects and I am sure they would be interested to hear about the assessment of confidence laid out in the report. Vince Cogliano or Glinda Cooper are potential points of contact in IRIS on this topic.

Thanks,
Jamie

Jamie Strong, Chief Human Health Risk Assessment Branch
Health and Ecological Criteria Division, 4304-T
Office of Science and Technology, Office of Water
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC 20460

phone: 202.566.0056
fax: 202.566.1140

Exhibit 28

From: Donohue, Joyce </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BB5340EC745149EDBF80D2B8B2F9B919-JDONOHUE>
To: Strong, Jamie
Sent: 10/14/2015 10:09:42 AM
Subject: RE: fluoride and NIEHS - I am getting lost on where you want to go on this.

Ok

From: Strong, Jamie
Sent: Wednesday, October 14, 2015 10:01 AM
To: Donohue, Joyce
Subject: RE: fluoride and NIEHS - I am getting lost on where you want to go on this.

Sorry lets chat sometime today.

From: Donohue, Joyce
Sent: Wednesday, October 14, 2015 10:00 AM
To: Strong, Jamie
Subject: RE: fluoride and NIEHS - I am getting lost on where you want to go on this.

I am not a fast thinker.

From: Strong, Jamie
Sent: Wednesday, October 14, 2015 9:56 AM
To: Donohue, Joyce
Subject: RE: fluoride and NIEHS

So is this accurate…and what can we say about their conclusions regarding the high dose vs low dose data and evidence?

Presentation of dose rather than concentration may be a more accurate measure of exposure given that these were animals studies. NTP concluded that the strongest evidence available was for the high dose studies (> 25ppm)….

From: Donohue, Joyce
Sent: Wednesday, October 14, 2015 8:31 AM
To: Strong, Jamie
Subject: RE: fluoride and NIEHS

Dear Jamie

There were 30 studies that were used in the final assessment. 11 had concentrations <10 ppm, 12 used concentrations 11 to 25 ppm and 19 had concentrations > 25 ppm. The studies were placed in two groups, developmental and adult. There were obvious some studies that covered both ages. Since they were animal studies I think dose would have been a better metric than concentration.

Joyce

From: Strong, Jamie
Sent: Wednesday, October 14, 2015 7:44 AM
To: Donohue, Joyce

Subject: RE: fluoride and NIEHS
Importance: High

Can you elaborate on the last paragraph…not sure I understand…is there animal data below 25ppm?

From: Donohue, Joyce
Sent: Tuesday, October 13, 2015 3:30 PM
To: Strong, Jamie
Subject: RE: fluoride and NIEHS

Dear Jamie:

I cannot find whatever I remember writing so maybe I never sent it. I read the report. I found it to be very thorough about how they did the assessment but not very transparent about the scientific details from the studies that lead them to their conclusions. To me the biggest weakness was a lack of any discussion related to the biochemistry of fluoride in tis interaction with the nervous system in a manner that could explain the effects observed. For example fluoride salts are, in some cases, pretty insoluble (e.g. Al, Ba, Ca, Fe, Pb, Mg). Does the formation of ion pairs or insoluble salts in some way impact signaling or neurotransmission. I attended a meeting once on fluoride neurotoxicity research needs wherein most of the suggestions for research focused on the potential for the metal fluoride salts or complexes being a factor in studies where the fluoride levels are high.

Classifying the lowest exposure to <4 mg/L was also problematic for me relative to the levels of fluoride that are currently of the greatest concern to the OW. As I recall they found the evidence strongest for the > 25 ppm water concentration. They used concentration rather than dose.

This is what I remember

Joyce

From: Strong, Jamie
Sent: Tuesday, October 13, 2015 2:25 PM
To: Donohue, Joyce
Subject: FW: fluoride and NIEHS

This is all I have from you…

From: Donohue, Joyce
Sent: Friday, September 04, 2015 2:22 PM
To: Strong, Jamie
Subject: RE: fluoride and NIEHS

The attachment is their systematic review of the animal data, that I mentioned. I did not know that it was limited to animal studies. They apparently plan to have it published.

Conclusion: This review of neurobehavioral studies in experimental animals (rats and mice) exposed to fluoride in drinking water or diet during either the young adult/adult, or gestational and young adult life stages, found evidence of potential detrimental effects on learning and memory. The confidence in these findings is moderate primarily based on limitations in the studies that prevent precise estimates of effect sizes in many of the studies, and the potential confounding of the learning and memory assessments by deficits in motor function or fear responses.

They probably want to talk about it. I will read it and give you some input before I leave.

From: Strong, Jamie
Sent: Thursday, September 03, 2015 1:53 PM

To: Donohue, Joyce
Subject: fluoride and NIEHS

Joyce,
I just got invited to a meeting on fluoride with NIEHS while you are gone. No indication of what the meeting is about other than to discuss their research plan. Here is the attachments. I know you are swamped and leaving but any thoughts would be great.

Thanks,
Jamie

Jamie Strong, Chief Human Health Risk Assessment Branch
Health and Ecological Criteria Division, 4304-T
Office of Science and Technology, Office of Water
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC 20460

phone: 202.566.0056
fax: 202.566.1140

Exhibit 29

DRAFT COMMUNICATIONS STRATEGY AND MESSAGING
NTP PROGRAM OF STUDY ON FLUORIDE

Animal Literature Review Completed
DRAFT June 21, 2016

Key Messages

The National Toxicology Program (NTP) has completed its systematic review of the published animal literature looking at the neurobehavioral effects of exposure to fluoride.

NTP found low to moderate level of evidence in the animal literature suggesting there may be adverse effects on learning and memory in the rats and mice exposed to fluoride in drinking water or diet.

The evidence was strongest for adult exposure studies.

Additional studies are needed to better determine whether the effects were specifically related to learning and memory—versus a possible impact on motor or sensory function that could have impaired the ability of the animal to perform the learning and memory tests.

Additional research is needed to better understand potential effects on learning and memory following exposure during development.

The animals in the studies were exposed to fluoride during development and adulthood at levels above the US drinking water standard of 0.7 parts per million, which is the recommended level of community water fluoridation in the United States.

There is very little evidence available to directly assess learning and memory effects in humans at the current Public Health Service level of 0.7 ppm.

For this animal literature review, NTP looked at more than 4000 studies before narrowing it down and thoroughly evaluating findings from 32 studies that focused on learning and memory. This review of the animal literature is part of a larger programmatic undertaking by NTP to look at potential non-cancer health outcomes from fluoride.

- NTP is also conducting a systematic review of the human evidence, and mechanistic studies focused on neurological effects.
- NTP is also conducting rodent studies to fill data research gaps identified in the review of the animal literature.

These peer reviewed animal findings will be available on the NTP website at XXXX on July 1.

Background

The National Toxicology Program (NTP) received a nomination to review the literature associating exposures to fluoride during development with memory and behavior.

In response to this public nomination, the NTP proposed a concept for a new program of activities related to fluoride.

These activities were presented to NTP Board of Scientific Counselors at a public meeting in December, 2015. Public comments were also solicited. Information about the meeting and the concepts presented are available at http://ntp.niehs.nih.gov/go/165

NTP is conducting a review of the published research investigating neurobehavioral effects of developmental exposure to fluoride and is conducting additional studies in experimental animals, focused on learning and memory.

Fluoridation of water for the prevention of caries is considered one of the most significant public health achievements of the 20th century. This additional research and analysis by NTP will not re-evaluate the effectiveness of fluoridation to prevent dental cavities.

The NTP expects its analysis of the literature, and information from the new animal studies it will conduct, to be completed by 2018.

NTP will continue to work collaboratively with other government agencies to conduct, review, and report on research related to the potential health effects of fluoride.

Communications Approach

NIEHS/NTP is not planning on doing proactive outreach to the media about this completed animal review of the literature, but wants to be prepared if questions do come in.

Communications staff at relevant agencies will be briefed on the findings on June 22.

If questions do arise from the media, refer them to NIEHS/NTP communications (Robin Mackar, 919-541-0073, rmackar@niehs.nih.gov)

NIEHS/NTP communications will facilitate media requests and schedule individual interviews with NTP spokesperson.

NTP Spokesperson: Dr. Kristina Thayer, Director, NTP Office of Health Assessment and Translation (OHAT) 919-541-5021, Thayer@niehs.nih.gov

The projects are expected to be completed in 2018.

Exhibit 30

DRAFT COMMUNICATIONS STRATEGY AND MESSAGING
NTP PROGRAM OF STUDY ON FLUORIDE

Animal Literature Review Completed
DRAFT June 21, 2016

Key Messages

The National Toxicology Program (NTP) has completed its systematic review of the published animal literature looking at the neurobehavioral effects of exposure to fluoride.

This review looked at ~~of the~~ animal literature ~~a~~is part of a larger programmatic undertaking by NTP to look at potential non-cancer health outcomes from fluoride. The animals in these studies were exposed to fluoride during development and adulthood at levels far above the US drinking water standard of 0.7 parts per million, which is the recommended level of community water fluoridation in the United States. For example, many of the studies that observed effects found effects at levels at 50 or 100 ppm.

NTP found a low level of evidence for [X], indicating that [insert meaning of low].

NTP found a ~~to~~ moderate level of evidence for adult exposure studies, indicating [insert meaning of moderate].
~~in the animal literature suggesting there may be adverse effects on learning and memory in the rats and mice exposed to fluoride in drinking water or diet~~

There were relatively few available studies that considered fluoride levels less than 4 or 5 ppm and those generally showed no effect.

~~The evidence was strongest for adult exposure studies.~~

~~Additional studies are needed t~~To better determine whether the effects noted in these studies were specifically related to learning and memory—versus a possible impact on motor or sensory function that could have impaired the ability of the animal to perform the learning and memory tests~~---~~, additional studies would be needed.

Additional research is needed to better understand potential effects on learning and memory following exposure during development.

~~The animals in the studies were exposed to fluoride during development and adulthood at levels above the US drinking water standard of 0.7 parts per million, which is the recommended level of community water fluoridation in the United States.~~

~~There is very little evidence available to directly assess learning and memory effects in humans at the current Public Health Service level of 0.7 ppm.~~

Commented [BN(1]: In line with feedback on the paper about bringing the dose higher in the discussion and unbundling the low and moderate level findings, a rough new outline is proposed below

Commented [BN(2]: Flesh these out as needed

Commented [BN(3]: While the evidence was stronger for adult exposure than the other categories, it still wasn't "strong" – I'm afraid this could be misleading. I think the proposed reorg above conveys the point

Commented [BN(4]: From a purely scientific perspective we can always say more research is needed, but this implies you aren't happy with what you know so far and need more to make a particular point, which could fuel misinterpretation. Perhaps better to say more research is needed that reflects current relevant exposure levels?

For this animal literature review, NTP reviewed ~~looked at for~~ more than 4000 studies before narrowing it down and thoroughly evaluating findings from 32 studies that focused on learning and memory. ~~This review of the animal literature is part of a larger programmatic undertaking by NTP to look at potential non-cancer health outcomes from fluoride.~~

As part of this project:

- NTP is also conducting a systematic review of the human evidence, and mechanistic studies focused on neurological effects.
- NTP is also conducting rodent studies to fill data research gaps identified in the review of the animal literature.

Commented [CJH5]: Can we define this?

These peer reviewed animal findings will be available on the NTP website at XXXX on July 1.

Background

The National Toxicology Program (NTP) received a nomination to review the literature associating exposures to fluoride during development with memory and behavior.

In response to this public nomination, the NTP proposed a concept for a new program of activities related to fluoride.

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The NTP expects its analysis of the literature, and information from the new animal studies it will conduct, to be completed by 2018.

NTP will continue to work collaboratively with other government agencies to conduct, review, and report on research related to the potential health effects of fluoride.

Communications Approach

NIEHS/NTP is not planning on doing proactive outreach to the media about this completed animal review of the literature, but wants to be prepared if questions do come in.

Communications staff at relevant agencies will be briefed on the findings on June 22.

If questions do arise from the media, refer them to NIEHS/NTP communications (Robin Mackar, 919-541-0073, rmackar@niehs.nih.gov)

NIEHS/NTP communications will facilitate media requests and schedule individual interviews with NTP spokesperson.

NTP Spokesperson: Dr. Kristina Thayer, Director, NTP Office of Health Assessment and Translation (OHAT) 919-541-5021, Thayer@niehs.nih.gov

The projects are expected to be completed in 2018.

Exhibit 31

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Institute of Dental and Craniofacial Research
FOIA/PA Office, RKL 1, 4th Floor
6705 Rockledge Drive
Bethesda, MD 20892

September 12, 2022

Kristin Lavelle
[redacted]
Berkeley, CA 94707

Re: FOIA Case Number: 58947

Dear Ms. Lavelle:

This acknowledges your Freedom of Information Act (FOIA) request addressed to National Institute of Dental and Craniofacial Research (NIDCR), National Institutes of Health (NIH), dated and received September 8, 2022. You requested copies of the following emails about fluoride between the specified NIDCR employees and non-governmental persons: 1) all fluoride emails in which Jeff Ventura is a sender or recipient, 2) all fluoride emails in which Jonathan Horsford is a sender or recipient, 3) all fluoride emails in which Timothy Iafolla is a sender or recipient. For purposes of this request, the following terms shall have the following meanings: Fluoride emails means emails that (a) address or relate to fluoride issues, and (b) have at least one non-governmental person sender or recipient. Non-governmental person means the following persons who are not employed by the US Government: (a) Matt Jacob, (b) Juliet Guichon, (c) Jennifer Meyer, (d) Christopher Fox, (e) Johnny Johnson, (f) Jayanth Kumar, (g) Howard Pollick, (h) Robert Burns, (i) any individual who works at the American Dental Association and/or has an email address ending with @ada.org, and (j) Advocacy groups. Advocacy groups means any other individual (beyond those identified above) that Jeff Ventura understands to be part of the "advocacy groups" that he referenced in his email from February 5, 2021. Recipient means someone who receives the email, including, but not limited to, direct recipients, cc recipients, and bcc recipients.

If any documents responsive to your request are located, they will be reviewed for releasability, and all releasable information will be sent to you. We will do everything possible to comply with your request in a timely manner. Please feel free to call me on 301-496-9737 for additional information or to inquire about the status of your request.

Provisions of the FOIA allow us to recover part of the cost of complying with your request. We shall charge you for records in accordance with the Department of Health and Human Services (DHHS) FOIA Regulations as they apply to “other” requesters. As an “other” category requester you will be charged for duplication at 10 cents per page although the first 100 pages are free; 2 hours of search time are free, and thereafter search time is charged at the hourly rate ($23.00, $46.00 and $83.00) of the searcher; there is no charge for review time. Please be advised that the DHHS FOIA Regulations allow us to charge for search time even if we do not locate any responsive records or if we determine that some or all of the responsive records are exempt under one of the FOIA’s nine exemptions. If there are any fees associated with processing this request, you will be sent an invoice with our final response.

At any time during the processing of your request, you may seek assistance from the NIDCR FOIA Public Liaison:

NIDCR FOIA Public Liaison
Marianne Manheim
Rockledge One, 4th Floor
6705 Rockledge Drive
Bethesda, MD 20892
301-496-9737 (phone)
301-402-3604 (fax)
marianne.manheim@nih.gov (email)

Sincerely,

/s/

Luke Wymer
Government Information Specialist, NIDCR

Exhibit 32

RE: [EXTERNAL] Re: NIDCR FOIA Case 58947 - Interim Letter & Question

From: Wymer, Luke (NIH/NHLBI) [E] (wymerr@mail.nih.gov)

To: kristieclendenning@yahoo.com

Date: Wednesday, January 11, 2023 at 12:47 PM PST

Hi Ms. Lavelle,
Thank you for your email. I'll inform the NIH FOIA Office about the exclusions.

There are 679 pages of responsive records, but there is some overlap/duplication in that total.
I informed the NIH FOIA Office of your request for an estimated completion date, although you might find it helpful to contact them directly at nihfoia@od.nih.gov.

Thank you again,

Luke

Robert "Luke" Wymer
Government Information Specialist
Freedom of Information and Privacy Act Branch
National Heart, Lung, and Blood Institute
National Institutes of Health
301-496-9737 FOIA line
301-827-6256 direct line
301-402-3604 fax

From: Kristie Lavelle <kristieclendenning@yahoo.com>
Sent: Tuesday, January 10, 2023 11:17 AM
To: Wymer, Luke (NIH/NHLBI) [E] <wymerr@mail.nih.gov>
Subject: Re: [EXTERNAL] Re: NIDCR FOIA Case 58947 - Interim Letter & Question

Mr. Wymer –

I am willing to exclude the following information from the responsive records: cell phone numbers, wet ink signatures, Zoom meeting links, meeting ids, and phone numbers. The one thing I am not comfortable excluding is personal email addresses, as excluding this information may obscure the identity of one or more of the advocates that the NIDCR is communicating with. For example, sometimes the only identifying information about an email sender/recipient is their email address in the sender/recipient sections. In such situations, if the person's email address is excluded, the public would be denied from knowing which lobbyist/advocate the NIDCR has been coordinating with, which I do not believe would be consistent with the disclosure requirements of the FOIA.

That said, as a compromise, I am willing to exclude all personal email addresses where the person's identity is otherwise disclosed in the email. For example, sometimes the recipient column of the email will provide both the person's name and email address. In these situations, I would be fine with the personal email address being redacted. Please let me know if this is an agreeable approach for you.

Exhibit 32

Also, I would appreciate if you could let me know how many documents are responsive my request, and an updated estimate as to when I will be receiving these documents. As previously noted, the emails I have requested here are to/from private persons, and as such, it is unclear to me how the NIH can prevent disclosure.

Thanks,

Kristin Lavelle

On Tuesday, January 3, 2023 at 06:39:15 AM PST, Wymer, Luke (NIH/NHLBI) [E] <wymerr@mail.nih.gov> wrote:

Hello Ms. Lavelle,

Thank you for your email. The responsive records have to go to the NIH FOIA for final determination as the subject is related to multiple ongoing requests and lawsuits.

Regarding the responsive records, would you be willing to exclude personal information (cell phone numbers, personal email addresses, and wet ink signatures) and Zoom meeting links, meeting ids, and phone numbers?

Thank you,

Luke

Robert “Luke” Wymer

Government Information Specialist

Freedom of Information and Privacy Act Branch

National Heart, Lung, and Blood Institute

National Institutes of Health

301-496-9737 FOIA line

301-402-3604 fax

From: Kristie Lavelle <kristieclendenning@yahoo.com>
Sent: Monday, January 2, 2023 1:55 PM
To: Wymer, Luke (NIH/NHLBI) [E] <wymerr@mail.nih.gov>
Subject: Re: [EXTERNAL] Re: NIDCR FOIA Case 58947 - Interim Letter & Question

Mr Wymer -

Could you explain to me why the NIH FOIA office also has to review these records? Given that all of the communications I have requested here are to/from non-governmental persons, it is hard for me to understand how there could be any kind of privilege at issue. It would seem that once the government chooses to share information with some members of the public (eg lobbyist groups), it loses its right to prevent other members of the public from seeing those communications. Am I missing something?

Also, per your email, I would appreciate if you could find out how long the NIH FOIA office will take reviewing these communications with non-governmental persons.

Thanks,

Kristin Lavelle

On Wednesday, December 28, 2022 at 01:04:11 PM PST, Wymer, Luke (NIH/NHLBI) [E] <wymerr@mail.nih.gov> wrote:

Hi Ms. Lavelle,

Thank you very much for your email. My office has completed our review and will need to send the records to the NIH FOIA Office for their final determination. I can ask the NIH FOIA Office for an estimated completion date for their review.

Regarding the responsive records, would you be willing to exclude personal information (cell phone numbers, personal email addresses, and wet ink signatures) and Zoom meeting links, meeting ids, and phone numbers?

Please let me know and I'll inform the NIH FOIA Office for purposes of their review.

Thank you,

Luke

From: Kristie Lavelle <kristieclendenning@yahoo.com>
Sent: Thursday, December 22, 2022 8:57 AM
To: Wymer, Luke (NIH/NHLBI) [E] <wymerr@mail.nih.gov>
Subject: Re: [EXTERNAL] Re: NIDCR FOIA Case 58947 - Interim Letter & Question

Dear Mr. Wymer –

I'm just checking in again on my FOIA request. Is everything still on track for a production on/by December 30?

Thank you,
Kristin Lavelle

Sent from Yahoo Mail for iPhone

On Monday, December 12, 2022, 6:19 PM, Wymer, Luke (NIH/NHLBI) [E] <wymerr@mail.nih.gov> wrote:

Good morning Ms. Lavelle,

Thank you for your email. My office is currently still processing your NIDCR FOIA Case 58947 and may require an additional review with the NIH FOIA Office.

The estimated completion date for our office is December 30, 2022.

Thank you for your patience,

Luke

From: Kristie Lavelle <kristieclendenning@yahoo.com>
Sent: Tuesday, December 6, 2022 6:56 PM
To: Wymer, Luke (NIH/NHLBI) [E] <wymerr@mail.nih.gov>
Subject: Re: [EXTERNAL] Re: NIDCR FOIA Case 58947 - Interim Letter & Question

Dear Mr. Wymer –

I am writing to follow-up regarding the status of my FOIA request. You had previously estimated that the records would be produced by November 30, but I have not yet received them. Can you please let me know when you expect to be producing these materials?

Thank you,

Kristin Lavelle

Sent from Yahoo Mail for iPhone

On Tuesday, November 8, 2022, 1:05 PM, Wymer, Luke (NIH/NHLBI) [E] <wymerr@mail.nih.gov> wrote:

Hello Ms. Lavelle,

My office is currently reviewing the records for Case 58947 and the estimated completion date is November 30, 2022.

Please let me know if you have any questions.

Thank you,

Luke

From: Wymer, Luke (NIH/NHLBI) [E]
Sent: Thursday, November 3, 2022 7:36 AM
To: Kristie Lavelle <kristieclendenning@yahoo.com>
Subject: RE: [EXTERNAL] Re: NIDCR FOIA Case 58947 - Interim Letter & Question

Hi Ms. Lavelle,

Thank you very much for the email and the information for your request. A search for responsive records is currently underway and I should have a better idea of an estimated completion date once my office receives the search results. I will be in touch as soon as I receive the responsive results and provide you with an estimated date.

Thank you again,

Luke

From: Kristie Lavelle <kristieclendenning@yahoo.com>
Sent: Saturday, October 29, 2022 7:35 PM
To: Wymer, Luke (NIH/NHLBI) [E] <wymerr@mail.nih.gov>
Subject: [EXTERNAL] Re: NIDCR FOIA Case 58947 - Interim Letter & Question

Dear Mr. Wymer,

I apologize for my delay in responding. I am aware of the following email addresses for the individuals that I identified in my FOIA request:

a. Matt Jacob - mattlivesindc@**gmail**.com and mjacob@cdhp.org

b. Juliet Guichon - guichon@ucalgary.ca

c. Jennifer Meyer - jameyer2@alaska.edu

d. Christopher Fox – cfox@iadr.org

e. Johnny Johnson - drjohnnyjohnson@gmail.com

f. Jayanth Kumar - Jayanth.Kumar@cdph.ca.gov

g. Howard Pollick - howard.pollick@ucsf.edu

h. Robert Burns – burnsr@ada.org

To the extent that you find other email addresses for these individuals in the responsive records, I would ask that these other email addresses also be queried in your searches.

Were you able to get the requested information from Mr. Ventura? Do you have a sense at this point as to how long it will take you to produce responsive records for this request?

Thank you,

Kristin Lavelle

On Monday, September 12, 2022 at 08:41:30 AM PDT, Wymer, Luke (NIH/NHLBI) [E] <wymerr@mail.nih.gov> wrote:

Hello Ms. Lavelle,

The interim letter for your NIDCR FOIA request submitted and received on 09/08/22 is attached. It has been assigned case # 58947.

Regarding your request, can you please provide my office with the email addresses for the non-governmental persons you listed:

a. Matt Jacob

b. Juliet Guichon

c. Jennifer Meyer

d. Christopher Fox

e. Johnny Johnson

f. Jayanth Kumar

g. Howard Pollick

h. Robert Burns

My office will ask NIDCR about the advocacy groups referenced in Jeff Ventura's email from February 5, 2021.

Thank you,

Luke

Robert "Luke" Wymer

Government Information Specialist

Freedom of Information and Privacy Act Branch

National Heart, Lung, and Blood Institute

National Institutes of Health

301-496-9737 FOIA line

301-827-6256 direct line

301-402-3604 fax

Exhibit 33

Subject: Re: NIDCR FOIA Request #58947
Date: Saturday, February 25, 2023 at 6:42:13 PM Eastern Standard Time
From: Kristie Lavelle
To: nihfoia@od.nih.gov

[CAUTION]: External Email

I am writing again to request a status update on my request. What is the reason for the delay in producing these records, and when I can expect to receive them?

Thanks,

Kristin Lavelle

Sent from Yahoo Mail for iPhone

On Tuesday, February 7, 2023, 2:31 PM, Kristie Lavelle <kristieclendenning@yahoo.com> wrote:

> I am writing to follow up on my email from January 25 (posted below) to which I received no response. Can someone please let me know when I can expect to receive these records? Additionally, can someone please explain what "lawsuit" my records relate to, and why this has any bearing on NIDCR producing the records?
>
> Thank you,
>
> Kristin Lavelle
>
> On Wednesday, January 25, 2023 at 09:10:24 AM PST, Kristie Lavelle <kristieclendenning@yahoo.com> wrote:
>
> To whom it may concern –
>
> I am writing regarding my FOIA request to the NIDCR (#58947). Based on my communications with NIDCR's FOIA team, I understand that your office (the NIH FOIA Office) is now reviewing the responsive records that NIDCR retrieved. Given that all the emails I have requested are emails to/from non-governmental advocacy groups/individuals, it would seem that the review of these records should be pretty and straightforward, as the deliberative process privilege will not apply. Do you have an estimate as to when I can expect to receive these records?

Also, I was informed that one of the reasons it is taking long to process my request is that it relates to ongoing “lawsuits.” Can you please let me know what “lawsuits” my request relates to, and why this is a factor under the FOIA statute that would justify delaying the release of these records?

Thank you,

Kristin Lavelle

Exhibit 34

From: Horsford, Jonathan (NIH/NIDCR) [E]
Sent: Fri, 21 Aug 2020 13:33:49 +0000
To: Ventura, Jeff (NIH/NIDCR) [E]
Subject: FW: Revised NTP fluoride monograph

Let's discuss.

D. Jonathan Horsford, Ph.D.
Acting Deputy Director
NIDCR, NIH
Cell: (b)(6)

From: Ricks, Tim DMD (IHS/HQ) <Tim.Ricks@ihs.gov>
Sent: Friday, August 21, 2020 9:29 AM
To: Horsford, Jonathan (NIH/NIDCR) [E] <horsforj@nidcr.nih.gov>; Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@CDC.GOV>
Subject: RE: Revised NTP fluoride monograph

(b)(5)

Timothy L. Ricks, DMD, MPH, FICD
Rear Admiral (RADM), Assistant Surgeon General
Chief Dental Officer, U.S. Public Health Service
IHS Headquarters Division of Oral Health

- Continuing Dental Education Coordinator
- Oral Health Promotion/Disease Prevention Coordinator
- Expanded Function Dental Assistant Program Coordinator
- Dental Lead, Government Performance and Results Act
- Oral Health Surveillance Coordinator

From: Horsford, Jonathan (NIH/NIDCR) [E] <horsforj@nidcr.nih.gov>
Sent: Friday, August 21, 2020 8:22 AM
To: Ricks, Tim DMD (IHS/HQ) <Tim.Ricks@ihs.gov>; Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH)

<clh8@cdc.gov>
Subject: RE: Revised NTP fluoride monograph

Tim,

(b)(5)

Jonathan

D. Jonathan Horsford, Ph.D.
Acting Deputy Director
NIDCR, NIH
Cell (b)(6)

From: Ricks, Tim DMD (IHS/HQ) <Tim.Ricks@ihs.gov>
Sent: Thursday, August 20, 2020 2:32 PM
To: Horsford, Jonathan (NIH/NIDCR) [E] <horsforj@nidcr.nih.gov>; Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@CDC.GOV>
Subject: RE: Revised NTP fluoride monograph

Thank you for sharing, Jonathan. I really think it is safe for the SG to issue that statement of support, don't you? I mean it is unclear that CWF is harmful <1.5 mg/L, and we can emphasize that. Here's what I wrote to Dr. Wright at OSG. (b)(5)

(b)(5)

PLEASE KEEP THIS E-MAIL CONFIDENTIAL.

Good afternoon Dr. Wright:

Earlier today, the National Toxicology Program (NTP) provided the National Institute of Dental and Craniofacial Research (NIDCR) with an advanced copy of their revised monograph, *Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects.* This document should be considered pre-decisional, and NTP and NIDCR have specifically requested that "distribution be limited

and restricted to those within your agencies with a need to know." Obviously, given that I have provided briefings to all of you on this subject multiple times, I am sending you the document.

It was my understanding from our telephone conversation back on July 2nd that the Surgeon General would or should not sign a statement of support for community water fluoridation (CWF) because this monograph had not been published, and I believe that someone – maybe Tara – said that it was going to be published in the *Journal of the American Medical Association (JAMA)* in September (likely an excerpt and not 314 pages!). The first page of this monograph is dated September 16, 2020 and says "this current draft….is being submitted to the same NASEM review panel for an additional round of peer review." I am not sure when this NASEM review will occur, but it doesn't look like it has occurred yet.

However, it is important to know that the conclusion DID change slightly in its language, and it's an important change (highlighted):

> When focusing on findings from studies with exposures in ranges typically found in the United States [e.g., approximately 0.03 to 1.5 mg/L in drinking water based on NHANES data (Jain 2017)] that can be evaluated for dose response, effects on cognitive neurodevelopment **are inconsistent, and therefore unclear.** However, when considering all the evidence, including studies with exposures to fluoride levels higher than 1.5 mg/L in water, NTP concludes that fluoride is ***presumed*** *to be a cognitive neurodevelopmental hazard to humans*.

With this new conclusion – that the effectives of fluoride on cognitive neurodevelopment are unclear in the range normally found in CWF in the U.S. – I believe it is safe for the Surgeon General to issue a statement of support. If interested, I can modify the previous statement to include some of this specific language. For your convenience only (so you don't have to go searching through countless e-mails), I am adding all of the relevant materials – the monograph (sorry about the 11 MB…it is 314 pages), the SG statement, the e-mail from Jennifer on 6/24 on the subject, and the previous SG statements from 2016, 2013, 2004, and 2001.

Please let me know if you would like feedback from the CDC and NIDCR on this topic. I am in touch with both Dr. Horsford (still acting deputy director at NIDCR) and Mr. Hannan (CDC Division of Oral Health Director) on this topic. I'll respect whatever the final decision is, but I wanted to make sure I provided you with the latest information.

V/r,
RADM Ricks

From: Horsford, Jonathan (NIH/NIDCR) [E] <horsforj@nidcr.nih.gov>
Sent: Thursday, August 20, 2020 12:39 PM
To: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>; Ricks, Tim DMD (IHS/HQ) <Tim.Ricks@ihs.gov>
Subject: RE: Revised NTP fluoride monograph

Their conclusion is much the same, but they did change the messaging slightly in the conclusion to start with the inconclusive data on CWF. We will see what NASEM says.

Conclusions: When focusing on findings from studies with exposures in ranges typically found in the United States [e.g., approximately 0.03 to 1.5 mg/L in drinking water based on NHANES data (Jain 2017)] that can be evaluated for dose response, effects on cognitive neurodevelopment are inconsistent, and therefore unclear. However, when considering all the evidence, including studies with exposures to fluoride levels higher than 1.5 mg/L in water, NTP concludes that fluoride is *presumed to be a cognitive neurodevelopmental hazard to humans*.

D. Jonathan Horsford, Ph.D.
Acting Deputy Director
NIDCR, NIH
Cell (b)(6)

From: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Sent: Thursday, August 20, 2020 12:53 PM
To: Horsford, Jonathan (NIH/NIDCR) [E] <horsforj@nidcr.nih.gov>; Ricks, Tim DMD (IHS/HQ) <Tim.Ricks@ihs.gov>
Subject: RE: Revised NTP fluoride monograph

Thanks Jonathan for sending to Tim.

We have a call with NTP tomorrow for an update on the revised monograph. After a quick glance, their conclusion appears to be the same as the last draft available for public review.

From: Horsford, Jonathan (NIH/NIDCR) [E] <horsforj@nidcr.nih.gov>
Sent: Thursday, August 20, 2020 12:43 PM
To: Ricks, Tim DMD (IHS/HQ) <Tim.Ricks@ihs.gov>
Cc: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Subject: FW: Revised NTP fluoride monograph

Tim,

See the email and attachment. They request *distribution be limited and restricted to those within your agencies with a need to know.*

Best,

Jonathan

D. Jonathan Horsford, Ph.D.
Acting Deputy Director
NIDCR, NIH
Cell: (b)(6)

From: Bucher, John (NIH/NIEHS) [E] <bucher@niehs.nih.gov>
Sent: Thursday, August 20, 2020 12:31 PM
To: Beltran, Eugenio D. (CDC/DDNID/NCCDPHP/DOH) (CTR) <edb4@cdc.gov>; Briss, Peter (CDC/DDNID/NCCDPHP/OD) <pxb5@CDC.GOV>; Dye, Bruce (NIH/NIDCR) [E] <bruce.dye@nih.gov>;

Espinoza, Lorena (CDC/DDNID/NCCDPHP/DOH) <lee6@CDC.GOV>; Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@CDC.GOV>; Iafolla, Timothy (NIH/NIDCR) [E] <iafollat@nidcr.nih.gov>; Horsford, Jonathan (NIH/NIDCR) [E] <horsforj@nidcr.nih.gov>; Macek, Mark (CDC/DDNID/NCCDPHP/DOH) (CTR) <wzm2@cdc.gov>; McBryde, Kevin (NIH/NIDCR) [E] <kevin.mcbryde@nih.gov>
Cc: Taylor, Kyla (NIH/NIEHS) [E] <kyla.taylor@nih.gov>; Rooney, Andrew (NIH/NIEHS) [E] <andrew.rooney@nih.gov>; Wolfe, Mary (NIH/NIEHS) [E] <wolfe@niehs.nih.gov>
Subject: Revised NTP fluoride monograph

Dear All,

Thank you again for contributing to the technical review of the Sept 6, 2019 draft of the NTP Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects. As you may know the draft was reviewed by a committee convened by the National Academy of Science, Engineering and Medicine (NASEM) in November of last year and a report containing the committee's recommendations can be found here http://nap.edu/25715. The committee had many quite helpful comments on all areas of the draft report and we've worked over the last 8 or so months to address these comments.

The majority of the revisions to the Sept 6, 2019 draft address comments on the human epidemiology sections of the report. These involved updating and expanding the literature search and including 2 Chinese databases that were not included in the earlier draft, expanding discussion of the risk of bias decisions for key studies, and carrying out a 3-part meta-analysis of the collection of studies addressing effects on children's IQ.

We've asked NASEM to reconvene a review committee and we're fortunate that all of the original committee members have agreed to serve once again to review a revised draft document. The committee is scheduled to meet in open session on October 19, 2020 from 1 to 2:30 pm to ask questions of our staff and hear public comments.

A "near final" draft of the document that will be posted for public viewing on the NASEM website in mid-September is attached for your awareness. While you are free to distribute this draft to others, we ask that distribution be limited and restricted to those within your agencies with a need to know.

Sincerely,

Kyla Taylor, Ph.D.
Andrew Rooney, Ph/D.
John Bucher Ph.D.

Division of the National Toxicology Program,
NIEHS

Exhibit 35

Subject: Fw: 22-132 FOIA Acknowledgement
Date: Monday, February 27, 2023 at 7:41:52 AM Pacific Standard Time
From: Kristie Lavelle
To: Michael Connett
Attachments: image002.jpg, image004.jpg

[CAUTION]: External Email

FYI

Kristie

----- Forwarded Message -----
From: Souther, James (IHS/HQ) <james.souther@ihs.gov>
To: 'Kristie Lavelle' <kristieclendenning@yahoo.com>; IHS FOIA Mailbox <ihsfoiamailbox@ihs.gov>
Sent: Monday, February 27, 2023 at 06:16:58 AM PST
Subject: RE: 22-132 FOIA Acknowledgement

Good morning Ms. Lavelle,

I apologize, we will not be able to make the estimated production date of Feb 28, 2023. The updated estimated release date is March 31, 2023. Presently , this request is #88 in our processing queue.

v/r

Jim Souther

Government Information Specialist

Indian Health Service

5600 Fishers Lane, Mail stop: 09E47

Rockville, MD 20857

Phone: (240)460-3711

IHSFOIAMailbox@ihs.gov

From: Kristie Lavelle <kristieclendenning@yahoo.com>
Sent: Saturday, February 25, 2023 6:43 PM
To: IHS FOIA Mailbox <IHSFOIAMailbox@ihs.gov>
Subject: Re: 22-132 FOIA Acknowledgement

Dear Mr. Souther –

You had previously estimated that the documents responsive to my FOIA request would be produced on February 28. Is that still the case? If not, can you let me know what number in the queue my request is, and when you expect to produce the documents?

Thank you,

Kristin Lavelle

Sent from Yahoo Mail for iPhone

On Thursday, December 22, 2022, 5:37 AM, IHS FOIA Mailbox <IHSFOIAMailbox@ihs.gov> wrote:

> Hello Ms. Lavelle,
>
> *Thank you for contacting the IHS FOIA Team regarding your FOIA request (22-132). Your request is currently number 102 in our queue to process.*
>
> *With our current work load, I estimate making a disclosure on approximately February 28, 2023.*
>
> v/r
>
> Jim Souther
>
> Government Information Specialist
>
> Indian Health Service
>
> 5600 Fishers Lane, Mail stop: 09E47
>
> Rockville, MD 20857
>
> Phone: (240)460-3711

James.Souther@ihs.gov

The Division of Regulatory and Policy Coordination (DRPC) strives to strengthen IHS program management and operations, and we accomplish this by remaining responsive to our customers.

Please provide feedback to my Supervisor if I helped you (green button) or if you'd like assistance (red button) by selecting the image below.

From: Kristie Lavelle <kristieclendenning@yahoo.com>
Sent: Thursday, December 15, 2022 2:01 PM
To: IHS FOIA Mailbox <IHSFOIAMailbox@ihs.gov>
Subject: Re: 22-132 FOIA Acknowledgement

Dear Mr. Souther –

I am writing to check in on the status of my FOIA request (22-132). Will the documents still be produced by February 14, 2023 as you had previously estimated?

Thank you,

Kristin Lavelle

On Wednesday, November 2, 2022 at 07:05:25 AM PDT, IHS FOIA Mailbox <ihsfoiamailbox@ihs.gov> wrote:

Good morning,

Thank you for contacting the IHS FOIA Team regarding your FOIA request (22-132). Your request is currently number 110 in our queue to process. Unfortunately, IHS is experiencing a significant backlog, at this time we estimate making an disclosure on approximately February 14, 2023.

Please know that while the FOIA Team is responding to requests in the order they were received, we work diligently to continue meeting the mission of the IHS while remaining responsive to the public. Should you wish to narrow or withdraw your request, please respond to this email with your FOIA number located on your Acknowledgement Letter. For additional information, please refer to the Acknowledgement Letter you received in response to your FOIA request. Thank you for your patience and continued interest in the Indian Health Service.

V/r

Jim Souther

Government Information Specialist

Indian Health Service

5600 Fishers Lane, Mail stop: 09E47

Rockville, MD 20857

IHSFOIAMailbox@ihs.gov

From: Kristie Lavelle <kristieclendenning@yahoo.com>
Sent: Saturday, October 29, 2022 7:39 PM
To: IHS FOIA Mailbox <IHSFOIAMailbox@ihs.gov>
Subject: Re: 22-132 FOIA Acknowledgement

Dear Mr. Souther –

Can you please update me on the status of my FOIA request (22-132), including when you anticipate making a determination and producing responsive records? If a determination is not forthcoming in the near future, please take note that I may be seeking relief in federal court.

Thank you,

Kristin Lavelle

On Monday, September 19, 2022 at 04:16:18 AM PDT, Souther, James (IHS/HQ) <james.souther@ihs.gov> wrote:

Good Morning Kristin Lavelle,

We received your FOIA request and attached is our acknowledgment letter which includes your FOIA case number 22-132.

I am the Government Information Specialist assigned to your FOIA case.

Please refer to your FOIA case number when checking on the status of your request. If you have any questions, please contact:

Jim Souther

Government Information Specialist

Indian Health Service

5600 Fishers Lane, Mail stop: 09E47

Rockville, MD 20857

IHSFOIAMailbox@ihs.gov

Request for Documents for Request # '2022-01188-FOIA-PHS'. Your response due date is: 9/30/2022 12:00:00 AM Message from SENDER: The attached FOIA Request is a referral for direct response to the requester.

We notified the requester of this referral and closed the request in our side.

If you have any questions, please call the HHS OS FOIA Office at 202-690-7453 or foiarequest@hhs.gov

Hello,

A new FOIA request was submitted to your agency component:

The following list contains the entire submission submitted September 14, 2022 08:45:02am ET, and is

---

Contact information

First name	Kristin

Last name	Lavelle
Mailing Address	[redacted]
City	Berkeley
State/Province	California
Postal Code	94707
Country	United States
Phone	[redacted]
Company/Organization	n/a
Email	kristieclendenning@yahoo.com

Request

Request ID	442276
Confirmation ID	441746
Request description	BACKGROUND: Documents previously obtained from the National Institute of Dental Craniofacial Research (NIDCR) under FOIA show that Rear Admiral Tim Ricks (the Chief Dental Officer for PHS) has been involved in communications related to the National Toxicology Program's (NTP) ongoing review of fluoride's neurodevelopmental effects. In September 2019, the NTP released a draft report titled "Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects." This report was reviewed by the National Academy of Sciences, Engineering & Medicine (NASEM), which provided its peer-review comments in early 2020. The NTP incorporated NASEM's peer review comments in a revised draft of the report which NTP released in September 2020. The NASEM then reviewed this revised draft and issued further peer review comments in February 2021. The NTP incorporated this second round of peer review comments in drafts that the NTP has since circulated to HHS and the Office of Surgeon General in 2021 and 2022. DEFINITION: The term NTP FLUORIDE REVIEW means the National Toxicology Program's ongoing review of fluoride's neurodevelopmental effects, including all iterations of the reports that NTP has written on this subject from 2019 to the present. DATE RANGE OF REQUESTED DOCUMENTS: September 13, 2019 to the Present day. DOCUMENTS REQUESTED: 1) All emails to or from Rear Admiral Tim Ricks (including emails in which Dr. Ricks is a cc or bcc recipient) that discuss, or in any way reference, the NTP FLUORIDE REVIEW. 2) All emails to or from Rear Admiral Tim Ricks (including emails in which Dr. Ricks is a cc or bcc recipient) that contain the words "National Toxicology Program," NTP, NASEM, neurotoxic!, and/or neurodevelopment!.

Supporting documentation

Fees

Request category ID	other
Fee waiver	no
Willing to pay	300.00

Expedited processing

Expedited Processing	no

The following table contains the entire submission, and is formatted for ease of copy/pasting into a sp

request_id confirmation_id address_city address_country address_line1 address_state_provin

Exhibit 36

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

November 3, 2022

Kristin Lavelle
[redacted]
Berkeley, CA 94707
Via email: kristieclendenning@yahoo.com

Dear Ms. Lavelle:

This letter is in response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of November 1, 2022, seeking:

"1) All emails to and/or from Gregory Holder, from May 1, 2020 to the Present, which reference or discuss the FLUORIDE/TSCA LAWSUIT.

2) All emails to and/or from Gregory Holder, from May 1, 2020 to the Present, which include any of the following terms:

- 'Trial Status Update'
- Court
- Lawsuit
- Trial
- Hearing
- Testimony
- 'Status Conference'
- EPA
- Plaintiff(s)
- 'Fluoride Action Network'
- 'Food & Water Watch'
- FWW
- Judge
- Chen
- PACER".

Please provide the information marked below to aid the agency in complying with your request:

X Please clarify if Item #2 of your request also refer to the court case described; and/or
X Are you amendable to the elimination of items like unsolicited solicitation for employment/assistance (resume's Cv's, etc.); Product solicitation; suggestions/advice from various sources; news reports or links to media reports; links to external sites; internal announcements (CDC, HHS, etc.); requests for leave or scheduling conflicts; scheduling teleconferences with outside entities; documents related to hiring employees or filling temporary positions; journal articles (drafts, published, etc.); invitations to speak; draft talking points; final talking points; grant or contract documents; etc.

At this time, your request has been placed on hold until we receive the information requested. If you have any questions regarding your request, please contact Yvonne Jones at 678-475-4933.

Sincerely,

Yvonne Jones
CDC/ATSDR FOIA Office
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

23-00162-FOIA

Exhibit 37

Subject: Re: Your CDC FOIA Request #23-00162-FOIA
Date: Thursday, November 3, 2022 at 10:17:16 AM Pacific Daylight Time
From: Kristie Lavelle
To: skx8@cdc.gov

[CAUTION]: External Email

Dear Ms. Jones –

Thank you for your letter, and for giving me an opportunity to provide input on your questions.

First, my second document request is not limited to communications that specifically refer to the Fluoride/TSCA court case. While I suspect that most of the communications that are responsive to my second request will refer to the Fluoride/TSCA case, some may not. For example, there may be emails that discuss "Fluoride Action Network," or "EPA" that would be relevant to the court case, but might not specifically reference the case. Another example might be an email that references "testimony" by a certain individual without specifically stating that the testimony came from the court case.

Second, I am amenable to eliminating the following items from the scope of my request:

- Unsolicited solicitation for employment/assistance (resumes/CVs, etc);
- Product solicitation;
- Requests for leave (but not discussions about "scheduling conflicts")

I am also amenable to eliminating any documents that include one of the referenced words where it is clear on the face of the document that the communication is NOT related to the fluoride controversy or the FLUORIDE/TSCA LAWSUIT. To give you a better sense of my thinking on this, here are some illustrative examples where I would not want the communications that contain the referenced words:

- An email that talks about a "court" case or "lawsuit" or "hearing" or "plaintiffs" or "judge" that has nothing to do with fluoride (e.g., a newspaper article that talks about a court hearing regarding Donald Trump, or a lawsuit against CDC for wrongful termination, etc).
- An email that uses the words "Court," "Trial," and "Hearing" in a completely non-legal context (e.g., using the word "court" in the phase "tennis court," or the word "hearing" as in "he's hard of hearing").

If I can provide any further clarification on this, or any other information that would help assist with your review, please let me know.

Thank you again,

Kristin Lavelle

On Thursday, November 3, 2022 at 06:19:49 AM PDT, <skx8@cdc.gov> wrote:

November 3, 2022

Request Number: 23-00162-FOIA

Dear Ms. Lavelle:

This is regarding your Freedom of Information Act (FOIA) request of November 1, 2022, for BACKGROUND: Employees at CDC's Division of Oral Health have expressed an interest in a lawsuit on fluoride that is currently being litigated in the Northern District of California before Judge Edward Chen. The lawsuit was filed pursuant to a federal law known as the Toxic Substances Control Act, aka "TSCA." The lawsuit seeks to ban the addition of fluoridation chemicals to drinking water on the grounds that these chemicals pose an unreasonable risk of neurotoxic effects. The plaintiffs in the case include Food & Water Watch (FWW) and Fluoride Action Network (FAN), while the defendant is the Environmental Protection Agency (EPA). The case number is 17-cv-02162-EMC. Over two years ago, in May and June of 2020, pre-trial hearings and a trial was held, in which arguments and testimony were made about the neurotoxicity of fluoridation. In August of 2020, the Judge in the case paused (aka "stayed") the case so that the Court could consider the results of the National Toxicology Program's (NTP) report on fluoride's neurodevelopmental effects, which--at the time of the Judge's ruling--was expected to be published within months. The NTP's report, however, has still not been published. This year, in September and October of 2022, the Plaintiffs filed a motion to lift the stay on the grounds that the NTP's report has been delayed for too long, and that the NTP report may no longer be released. The Court granted this motion to lift the stay at a hearing on October 26, 2022, which the Court memorialized in a written order on October 28, 2022. Gregory Holder is a Public Health Analyst at CDC's Division of Oral Health, and is one of the CDC employees who has been closely tracking the fluoride/TSCA lawsuit. Mr. Holder's email address is LHN5@cdc.gov. Mr. Holder sends emails about the lawsuit to other CDC employees, including Casey Hannan (clh8@cdc.gov), Lorena Espinoza (lee6@cdc.gov), Nicole Johnson (nbg5@cdc.gov), and Tracy Boehmer. DEFINITION: The term FLUORIDE/TSCA LAWSUIT shall refer to the court case described above. DOCUMENTS REQUESTED: 1) All emails to and/or from Gregory Holder, from May 1, 2020 to the Present, which reference or discuss the FLUORIDE/TSCA LAWSUIT. 2) All emails to and/or from Gregory Holder, from May 1, 2020 to the Present, which include any of the following terms: - "Trial Status Update" - Court - Lawsuit - Trial - Hearing - Testimony - "Status Conference" - EPA - Plaintiff(s) - "Fluoride Action Network" - "Food & Water Watch" - FWW - Judge - Chen - PACER.

Please see the attached letter.

Sincerely,
CDC/ATSDR FOIA Office
770-488-6399

Exhibit 38

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

November 21, 2022

Kristin Lavelle
[redacted]
Berkeley, CA 94707
Via email: kristieclendenning@yahoo.com

Dear Ms. Lavelle:

This letter is regarding to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of November 1, 2022, assigned #23-00162-FOIA, seeking:

"DOCUMENTS REQUESTED:

1) All emails to and/or from Gregory Holder, from May 1, 2020 to the Present, which reference or discuss the FLUORIDE/TSCA LAWSUIT.

2) All emails to and/or from Gregory Holder, from May 1, 2020 to the Present, which include any of the following terms:

- "Trial Status Update"
- Court
- Lawsuit
- Trial
- Hearing
- Testimony
- "Status Conference"
- EPA
- Plaintiff(s)
- "Fluoride Action Network"
- "Food & Water Watch"
- FWW
- Judge
- Chen
- PACER

This letter is to notify you that you have not submitted a proper FOIA request because your request lacks the specificity needed to assist the agency retrieve the information with a reasonable amount of effort. While we appreciate your clarification of the documents sought, and elimination of unsolicited solicitation, Requests for leave, etc., we continue to need your consideration to narrow the scope of the request. Upon preliminary electronic search, we returned a large data set that we estimate to be within tens of thousand pages. The largest data sets appear for the terms "EPA", "Hearing", "Court", "Lawsuit", and "Trial". To further narrow the data set to obtain the records sought, a manual search would be required. As an "All Others"

categorized requester, you are entitled to two hours of search free of charge. To avoid additional fees, and to assist the agency in electronically locating the records sought, we recommend the following:

- Use of Boolean search operators such as:
  - AND, OR, NOT or AND NOT
  - Term A within X # of words, etc.
- Narrow the date range.

At this time, your request has been placed on hold until we receive the information requested. Please send your response to me at Skx8@cdc.gov, or I can be reached by phone at 678-475-4933. If you fail to submit a proper FOIA request by December 21, 2022, we will close your request.

Sincerely,

Yvonne Jones

Yvonne Jones
CDC/ATSDR FOIA Office
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

23-00162-FOIA

Exhibit 39

Subject: Re: Your CDC FOIA Request #23-00162-FOIA
Date: Tuesday, November 22, 2022 at 6:20:38 AM Pacific Standard Time
From: Kristie Lavelle
To: skx8@cdc.gov

[CAUTION]: External Email

Ms. Jones –

Thank you bringing these issues to my attention. To address your concerns, I will agree to eliminate the following search terms:

- Court
- Lawsuit
- Trial
- Hearing
- Plaintiffs
- Judge

This would leave the following (more unique) search terms:

- "Trial Status Update"
- Testimony
- "Status Conference"
- "Fluoride Action Network"
- "Food & Water Watch"
- FWW
- Chen
- Pacer

Please let me know if this addresses your concerns, or if you need me to narrow it further.

Thank you,
Kristin Lavelle

Sent from Yahoo Mail for iPhone

On Monday, November 21, 2022, 6:59 PM, skx8@cdc.gov wrote:

> November 21, 2022
>
> Request Number: 23-00162-FOIA
>
> Dear Ms. Lavelle:

Exhibit 40

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

November 29, 2022

Kristin Lavelle
[redacted]
Berkeley, CA 94707
Via email: kristieclendenning@yahoo.com

Dear Ms. Lavelle:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your Freedom of Information Act (FOIA) request dated November 1, 2022. Your request assigned number is 23-00162-FOIA, and it has been placed in our complex processing queue.

Extension of Time

In unusual circumstances, an agency can extend the twenty-working-day limit to respond to a FOIA request.

We will require an additional ten-working-days to respond to your request because:

X We reasonably expect to receive and review voluminous records in response to your request.

To process your request promptly, please consider narrowing the scope of your request to limit the number of responsive records. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request Yvonne Jones at 678-475-4933 or our FOIA Public Liaison, Roger Andoh at 770-488-6277. Additionally, you may contact the Office of Government Services (OGIS) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services; National Archives and Records Administration; 8601 Adelphi Road-OGIS; College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

Fee Category

Because you are considered an "Other requester" you are entitled to two hours of free search time, and up to 100 pages of duplication (or the cost equivalent of other media) without charge, and you will not be charged for review time. We may charge for search time beyond the first two hours and for duplication beyond the first 100 pages. (10 cents/page).

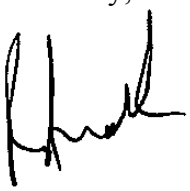
Cut-off-date

If you don't provide us with a date range for your request, the cut-off date for your request will be the date the search for responsive records starts.

You may check on the status of your case on our FOIA webpage https://foia.cdc.gov/app/Home.aspx and entering your assigned request number. If you have any questions regarding your request, please contact me at 770-488-6299 or via email at mhu9@cdc.gov.

We reasonably anticipate that you should receive documents by December 29, 2022. Please know that this date roughly estimates how long it will take the agency to close requests ahead of your request in the queue and complete work on your request. The actual date of completion might be before or after this estimated date.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

23-00162-FOIA

Exhibit 41

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

December 15, 2022

Kristin Lavelle
596 Spruce St
Berkeley, CA 94707
Via email: kristieclendenning@yahoo.com

Dear Ms. Lavelle:

This letter is regarding to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of November 1, 2022, assigned #23-00162-FOIA, seeking:

> "...Gregory Holder is a Public Health Analyst at CDC's Division of Oral Health, and is one of the CDC employees who has been closely tracking the fluoride/TSCA lawsuit. Mr. Holder's email address is LHN5@cdc.gov.
>
> Mr. Holder sends emails about the lawsuit to other CDC employees, including Casey Hannan (clh8@cdc.gov), Lorena Espinoza (lee6@cdc.gov), Nicole Johnson (nbg5@cdc.gov), and Tracy Boehmer...
>
> DOCUMENTS REQUESTED:
>
> 1) All emails to and/or from Gregory Holder, from May 1, 2020 to the Present, which reference or discuss the FLUORIDE/TSCA LAWSUIT.
>
> 2) All emails to and/or from Gregory Holder, from May 1, 2020 to the Present, which include any of the following terms:
>
> - "Trial Status Update"
> - Court
> - Lawsuit
> - Trial
> - Hearing
> - Testimony
> - "Status Conference"
> - EPA
> - Plaintiff(s)
> - "Fluoride Action Network"
> - "Food & Water Watch"
> - FWW
> - Judge
> - Chen
> - PACER."

Your request was later narrowed to include only the following terms:

- "Trial Status Update"
- Testimony
- "Status Conference"
- "Fluoride Action Network"
- "Food & Water Watch"
- FWW
- Chen
- Pacer

This letter is to notify you that you have not submitted a proper FOIA request because your request lacks the specificity needed to assist the agency retrieve the information with a reasonable amount of effort. After conducting a preliminary search of the narrowed terms, the data set returned thousands of pages of documents. To assist the agency in locating the records you are requesting, we need you to provide the following additional information:

- Reduce the time frame you would like records searched
- Reduce the number of record custodians
- Consider Boolean terms for "Testimony, and 'Status Conference'"

At this time, your request has been placed on hold until we receive the information requested. Please send your response to me at Skx8@cdc.gov, or I can be reached by phone at 678-475-4933. If you fail to submit a proper FOIA request by January 17, 2023, we will close your request.

Sincerely,

Yvonne Jones

Yvonne Jones
CDC/ATSDR FOIA Office
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

23-00162-FOIA

Exhibit 42

Subject: Re: Your CDC FOIA Request #23-00162-FOIA
Date: Monday, December 19, 2022 at 3:19:37 PM Pacific Standard Time
From: Kristie Lavelle
To: skx8@cdc.gov

[CAUTION]: External Email

Ms. Jones –

I will agree to limit my second document request to only those emails that contain the term "Trial Status Update." All other search terms in the second document request can be eliminated. (The first document request would remain the same.) Please let me know if this addresses your concern, and when I can expect to receive the responsive records.

Thanks,

Kristin Lavelle

Sent from Yahoo Mail for iPhone

On Monday, December 19, 2022, 8:17 AM, skx8@cdc.gov wrote:

> December 19, 2022
>
> Request Number: 23-00162-FOIA
>
> Dear Ms. Lavelle:
>
> This is regarding your Freedom of Information Act (FOIA) request of November 1, 2022, for BACKGROUND: Employees at CDC's Division of Oral Health have expressed an interest in a lawsuit on fluoride that is currently being litigated in the Northern District of California before Judge Edward Chen. The lawsuit was filed pursuant to a federal law known as the Toxic Substances Control Act, aka "TSCA." The lawsuit seeks to ban the addition of fluoridation chemicals to drinking water on the grounds that these chemicals pose an unreasonable risk of neurotoxic effects. The plaintiffs in the case include Food & Water Watch (FWW) and Fluoride Action Network (FAN), while the defendant is the Environmental Protection Agency (EPA). The case number is 17-cv-02162-EMC. Over two years ago, in May and June of 2020, pre-trial hearings and a trial was held, in which arguments and testimony were made about the neurotoxicity of fluoridation. In August of 2020, the Judge in the case paused (aka "stayed") the case so that the Court could consider the results of the National Toxicology Program's (NTP) report on

Exhibit 43

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 10, 2023

Kristin Lavelle
Health Professional
[redacted]
Berkeley, CA 94707

Dear Ms. Lavelle:

This is in response to an email dated today, from Mr. Michael Connett of Waters, Kraus, Paul, concerning your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request #23-00162-FOIA.

As we advised in our acknowledgement letter, CDC processes all FOIA requests on a first-in, first-out basis, which is the court-approved method for agencies operating under a backlog. Program staff have completed their search for the records you requested, and your case is currently in this office awaiting final review. Processing time is contingent upon the number of requests ahead of yours and their complexity and volume. Therefore, we are unable to give you an exact time frame for completion of your request. Please be assured, however, that a response will be sent to you as quickly as possible.

You may check on the status of your case by going to our FOIA webpage at https://foia.cdc.gov nd entering your request number. The fiscal year is the first two numbers and the request ID is the second set of numbers. If you have any questions regarding your request, please contact Yvonne Jones at 678-475-4933.

Sincerely,

Yvonne Jones

Yvonne Jones
CDC/ATSDR FOIA Office
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

Exhibit 44

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

February 7, 2023

Kristin Lavelle
[redacted]
Berkeley, CA 94707
Via email: kristieclendenning@yahoo.com

Dear Ms. Lavelle:

This letter is in response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of November 1, 2022, for

"...1) All emails to and/or from Gregory Holder, from May 1, 2020 to the Present, which reference or discuss the FLUORIDE/TSCA LAWSUIT.

2) All emails to and/or from Gregory Holder, from May 1, 2020 to the Present, which include any of the following terms: ...'Trial Status Update.'"

In an effort to provide a quicker response, please provide clarifying information regarding the below marked portion of your request:

> "1) All emails to and/or from Gregory Holder, from May 1, 2020 to the Present, which reference or discuss the FLUORIDE/TSCA LAWSUIT."

X We've begun review of records that were electronically retrieved in response to this request. Among the records are emails that do not pertain to the lawsuit, but merely reference the lawsuit during public inquiry. Please clarify if you are amendable to omitting such emails.

At this time, your request has been placed on hold until we receive the information requested. If you have any questions regarding your request, please contact Yvonne Jones at 678-475-4933.

If we do not receive a response from you by March 21, 2023, we will consider your request withdrawn and it will be closed.

Sincerely,

Yvonne Jones

Yvonne Jones
CDC/ATSDR FOIA Office
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

23-00162-FOIA

Exhibit 45

Subject: Re: Your CDC FOIA Request #23-00162-FOIA
Date: Tuesday, February 7, 2023 at 10:44:11 AM Pacific Standard Time
From: Kristie Lavelle
To: skx8@cdc.gov

[CAUTION]: External Email

Ms. Jones –

I have previously agreed, on multiple occasions, to limit my FOIA request in response to previous requests. I am not amenable to limiting it any further.

I'd appreciate if you could let me know when I can expect to receive the records.

Thank you,

Kristin Lavelle

On Tuesday, February 7, 2023 at 08:51:35 AM PST, skx8@cdc.gov <skx8@cdc.gov> wrote:

February 7, 2023

Request Number: 23-00162-FOIA

Dear Ms. Lavelle:

This is regarding your Freedom of Information Act (FOIA) request of November 1, 2022, for BACKGROUND: Employees at CDC's Division of Oral Health have expressed an interest in a lawsuit on fluoride that is currently being litigated in the Northern District of California before Judge Edward Chen. The lawsuit was filed pursuant to a federal law known as the Toxic Substances Control Act, aka "TSCA." The lawsuit seeks to ban the addition of fluoridation chemicals to drinking water on the grounds that these chemicals pose an unreasonable risk of neurotoxic effects. The plaintiffs in the case include Food & Water Watch (FWW) and Fluoride Action Network (FAN), while the defendant is the Environmental Protection Agency (EPA). The case number is 17-cv-02162-EMC. Over two years ago, in May and June of 2020, pre-trial hearings and a trial was held, in which arguments and

Exhibit 46

Status Update for Request #59213

From: foia_noreply@nih.gov

To: kristieclendenning@yahoo.com

Date: Monday, October 31, 2022 at 09:34 AM PDT

Dear Kristin Lavelle,

The status of your FOIA request #59213 has been updated to the following status 'Received'. To log into the NIH FOIA Public Portal click on the Application URL below.

https://foiaportal.nih.gov

Sincerely,

National Institutes of Health

Exhibit 46

Request - 59213 ← Back

Requester Details

To modify request details please update your requester profile or contact the our office for assistance.

Kristin Lavelle
N/A
[redacted]
Berkeley, CA 94707
[redacted]
kristieclendenning@yahoo.com

Requester Default Category: Others

Request Details

Date Requested	10/31/2022
Status	Assigned for Processing

General Information

Please select the NIH Institute or Center where your request should be directed. **If you are uncertain, select OD**.

Institute or Center	NIEHS
Institute or Center Name	NIEHS
Request Type	FOIA
Requester Category	Others

Request Information

Description	All emails to or from Casey Hannan (including emails in which Mr. Hannan is a cc or bcc recipient) that discuss, or in any way reference, the NTP
Date Range for Record Search: From(mm/dd/yyyy)	
To (mm/dd/yyyy)	
Description Document	Add Attachment

Fee Information

See our fee schedule, here.

Willing to Pay All Fees ☐

Willing Amount ($) 25.00

We generally assume that when you request records you are willing to pay the fees we charge for services associated with your request. You may specify a limit on the amount you are willing to spend. We will notify you if it appears that the fees will exceed $25.00 or your specified limit and ask whether you nevertheless want us to proceed with the search. We do not send an invoice to requesters if assessable processing fees are less than $25.00. 5 U.S.C. 552 (a) and (h).

Fee waiver required criteria.

Fee Waiver Requested ☐ Add Attachment

Fee Waiver Request Reason

Cost Details :

Total Cost	$0.00
Cost Incurred	$0.00
Amount Paid	$0.00
Balance Amount	$0.00
Payment Status	No Charges

Expedite Information

Criteria for Expedited Processing:

1) A detailed statement, certified to be true and correct, explaining how a failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

2) A detailed statement, certified to be true and correct, explaining how there is an urgent need to inform the public about an actual or alleged Federal Government activity (this criterion applies only to those requests made by a person primarily engaged in disseminating information to the public).

Please note that the above standards are intended to be narrowly applied, and requests that do not meet the criteria for expedited processing may extend processing times.

Expedite Requested ☐ Add Attachment

Expedite Reason

Exhibit 47

From: Lyles, Johnalyn (HHS/OASH) <Johnalyn.Lyles@hhs.gov>
Sent: Thursday, July 7, 2022 5:43 PM
To: Iademarco, Michael (HHS/OASH) <Michael.Iademarco@hhs.gov>; Groves, Garrick (HHS/ASL) <Garrick.Groves@hhs.gov>; Masand, Jasmine (HHS/ASL) <Jasmine.Masand1@hhs.gov>
Cc: Tourk, Nancy R. (CDC/OD/CDCWO) <wxk8@cdc.gov>; Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>; Mullman, Lauren (HHS/ASL) <Lauren.Mullman@hhs.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>; Zelenko, Leslie (HHS/ASL) <Leslie.Zelenko@hhs.gov>; Sullivan, Rose (HHS/ASL) <Rose.Sullivan@hhs.gov>; Bradsher, Kris (HHS/ASL) <Kris.Bradsher@hhs.gov>; Calsyn, Maura (HHS/OASH) <Maura.Calsyn@hhs.gov>; Greaser, Jennifer (CDC/OD/CDCWO) <cbx5@cdc.gov>
Subject: RE: REQUEST: NTP Draft Report

+ Jasmine while Garrick is out of the office.

Best,
Johnalyn

From: Iademarco, Michael (HHS/OASH) <Michael.Iademarco@hhs.gov>
Sent: Thursday, July 7, 2022 4:35 PM
To: Groves, Garrick (HHS/ASL) <Garrick.Groves@hhs.gov>
Cc: Tourk, Nancy R. (CDC/OD/CDCWO) <wxk8@cdc.gov>; Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>; Mullman, Lauren (HHS/ASL) <Lauren.Mullman@hhs.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>; Zelenko, Leslie (HHS/ASL) <Leslie.Zelenko@hhs.gov>; Sullivan, Rose (HHS/ASL) <Rose.Sullivan@hhs.gov>; Lyles, Johnalyn (HHS/OASH) <Johnalyn.Lyles@hhs.gov>; Bradsher, Kris (HHS/ASL) <Kris.Bradsher@hhs.gov>; Calsyn, Maura (HHS/OASH) <Maura.Calsyn@hhs.gov>; Greaser, Jennifer (CDC/OD/CDCWO) <cbx5@cdc.gov>
Subject: RE: REQUEST: NTP Draft Report

Any update on timing of a meeting? Apologies if I missed a queue. Michael

---

From: Calsyn, Maura (HHS/OASH) <Maura.Calsyn@hhs.gov>
Sent: Friday, June 24, 2022 12:10 PM
To: Groves, Garrick (HHS/ASL) <Garrick.Groves@hhs.gov>; Greaser, Jennifer (CDC/OD/CDCWO) <cbx5@cdc.gov>
Cc: Tourk, Nancy R. (CDC/OD/CDCWO) <wxk8@cdc.gov>; Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>; Mullman, Lauren (HHS/ASL) <Lauren.Mullman@hhs.gov>; Hallett, Adrienne (NIH/OD) [E] <adrienne.hallett@nih.gov>; Zelenko, Leslie (HHS/ASL) <Leslie.Zelenko@hhs.gov>; Sullivan, Rose (HHS/ASL) <Rose.Sullivan@hhs.gov>; Lyles, Johnalyn (HHS/OASH) <Johnalyn.Lyles@hhs.gov>; Bradsher, Kris (HHS/ASL) <Kris.Bradsher@hhs.gov>; Iademarco, Michael (HHS/OASH) <Michael.Iademarco@hhs.gov>
Subject: RE: REQUEST: NTP Draft Report

Thanks Garrick. Adding RADM Iademarco, who is leading this work for OASH.

Exhibit 48

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Assistant Secretary for Public Affairs
Washington, D.C. 20201

Refer to: Request Number **2023-00107-FOIA-PHS**

November 03, 2022

Sent via email:
Kristin Lavelle
kristieclendenning@yahoo.com

Dear Kristin Lavelle:

This acknowledges receipt of your November 01, 2022, Freedom of Information Act (FOIA) request, submitted to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division concerning **"... requesting the following emails to, or from, RADM Michael Iademarco:**

- **All emails from January 1, 2022 to the Present that discuss or reference fluoride and/or fluoridation;**
- **All emails from January 1, 2022 to the Present that discuss or reference the National Toxicology Program (aka "NTP").**

I understand that Mr. Iademarco works in the Office of the Assistant Secretary for Health (OASH), and that his email address is: Michael.Iademarco@hhs.gov".
We received your request on November 01, 2022.

Because you seek records which require a search in another office, "unusual circumstances" apply to your request, automatically extending the time limit to respond to your request for ten additional days. See 5 U.S.C. 552 § (a)(6)(B)(i)-(iii) (2012 & Supp. V. 2017). Further, we estimate needing more than 10 additional days to respond to your request and so, in the next paragraph of this letter we are offering you an opportunity to narrow your request, in case narrowing the request would enable us to respond to the request sooner. The actual time needed to process your request will depend on the complexity of our records search and on the volume and complexity of any material located. For your information, this Office assigns incoming requests to one of three tracks: simple, complex, or expedited. Each request is then handled on a first-in, first-out basis in relation to other requests in the same track. Our current workload is approximately 3000 cases.

Your request is assigned to the complex track. In an effort to speed up our records search, you may wish to narrow the scope of your request to limit the number of potentially responsive records or agree to an alternative time frame for processing, should records be located. You may also wish to await the completion of our records search to discuss either of these options.

I regret the necessity of this delay, but I assure you that your request will be processed as soon as possible. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request, Ray Noussoukpoe at FoiaRequest@PSC.hhs.gov.

If you are not satisfied with any aspect of the processing and handling of this request, you have the right to seek dispute resolution services from:

HHS FOIA/PA Public Liaison
FOI/Privacy Acts Division
Assistant Secretary for Public Affairs (ASPA)
Office of the Secretary (OS)
U.S. Department of Health and Human Services (HHS)

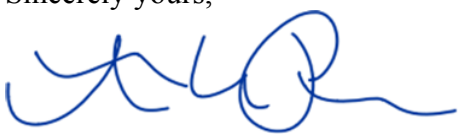
Telephone: (202) 690-7453
E-mail: HHS_FOIA_Public_Liaison@hhs.gov

and/or:

Office of Government Information Services
National Archives and Records Administration
Telephone: 202- 741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov

If you are not already submitting your requests through our Public Access Link (PAL), we recommend all future requests and appeals be submitted through PAL - https://requests.publiclink.hhs.gov/. Submitting requests through PAL automatically logs your requests into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your request, receive your documents directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

Sincerely yours,



Arianne Perkins
Director, Initial FOIA Requests
FOI/Privacy Acts Division

Exhibit 49

Status Update for Request #59250

From: FOIA_noreply@nih.gov (foia_noreply@nih.gov)

To: kristieclendenning@yahoo.com

Date: Sunday, November 6, 2022 at 08:39 AM PST

Dear Kristin Lavelle,

The status of your FOIA request #59250 has been updated to the following status 'Received'. To log into the NIH FOIA Public Portal click on the Application URL below.

https://foiaportal.nih.gov

Sincerely,

National Institutes of Health

Request - 59250 ← Back

Requester Details

To modify request details please update your requester profile or contact the our office for assistance.

Kristin Lavelle
N/A
[redacted]
Berkeley, CA 94707
[redacted]
kristieclendenning@yahoo.com

Requester Default Category: Others

Request Details

Date Requested	11/06/2022
Status	In Process

General Information

Please select the NIH Institute or Center where your request should be directed. **If you are uncertain, select OD**.

Institute or Center	OD
Institute or Center Name	OD
Request Type	FOIA
Requester Category	Others

Request Information

Description	All emails to, and/or from, Lawrence Tabak between April 26, 2022 and July 26, 2022 that include one or more of the following terms: - NTP
Date Range for Record Search: From(mm/dd/yyyy)	04/26/2022
To (mm/dd/yyyy)	07/26/2022
Description Document	Add Attachment

Fee Information

See our fee schedule, here.

Exhibit 49

Exhibit 50

From: Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH)
Sent: Fri, 3 Jun 2022 18:33:42 +0000
To: Greaser, Jennifer (CDC/OD/CDCWO); Cucchi, Sean (CDC/DDNID/NCCDPHP/OD)
Subject: RE: monograph

Hi – thanks so much for reaching out. The latest we heard (yesterday) is that ASH Levine has put the report on hold until further notice. Happy to chat and tell you more about it.

From: Greaser, Jennifer (CDC/OD/CDCWO) <cbx5@cdc.gov>
Sent: Friday, June 3, 2022 2:32 PM
To: Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <axz7@cdc.gov>; Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH) <nbg5@cdc.gov>
Subject: monograph

We got a heads up from NIH leg affairs about National Toxicology Program monograph coming out soon on fluoride and IQ. Assume you are aware. Do we need to chat?

Jennifer Greaser
CDC Washington Office
www.cdc.gov/washington
202-245-0600

Exhibit 51

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary
Assistant Secretary for Public Affairs
Washington, D.C. 20201

Refer to: Request Number **2023-00121-FOIA-OS**

November 09, 2022

Sent via email:
Kristin Lavelle
kristieclendenning@yahoo.com

Dear Kristin Lavelle:

This acknowledges receipt of your November 07, 2022, Freedom of Information Act (FOIA) request, submitted to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division concerning **"Emails to and/or from, the Assistant Secretary of Health Rachel Levine:**
•All emails from April 26, 2022 to July 26, 2022 that include one or more of the following terms: "National Toxicology Program," NTP, fluoride".
We received your request on November 07, 2022.

Because you seek records which require a search in another office, "unusual circumstances" apply to your request, automatically extending the time limit to respond to your request for ten additional days. See 5 U.S.C. 552 § (a)(6)(B)(i)-(iii) (2012 & Supp. V. 2017). Further, we estimate needing more than 10 additional days to respond to your request and so, in the next paragraph of this letter we are offering you an opportunity to narrow your request, in case narrowing the request would enable us to respond to the request sooner. The actual time needed to process your request will depend on the complexity of our records search and on the volume and complexity of any material located. For your information, this Office assigns incoming requests to one of three tracks: simple, complex, or expedited. Each request is then handled on a first-in, first-out basis in relation to other requests in the same track. Our current workload is approximately 3000 cases.

Your request is assigned to the complex track. In an effort to speed up our records search, you may wish to narrow the scope of your request to limit the number of potentially responsive records or agree to an alternative time frame for processing, should records be located. You may also wish to await the completion of our records search to discuss either of these options.

I regret the necessity of this delay, but I assure you that your request will be processed as soon as possible. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request, Ray Noussoukpoe at FoiaRequest@PSC.hhs.gov.

If you are not satisfied with any aspect of the processing and handling of this request, you have the right to seek dispute resolution services from:

HHS FOIA/PA Public Liaison
FOI/Privacy Acts Division
Assistant Secretary for Public Affairs (ASPA)
Office of the Secretary (OS)
U.S. Department of Health and Human Services (HHS)

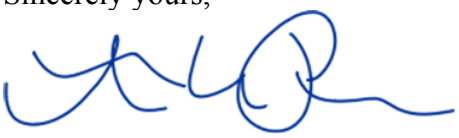
Telephone: (202) 690-7453
E-mail: HHS_FOIA_Public_Liaison@hhs.gov

and/or:

Office of Government Information Services
National Archives and Records Administration
Telephone: 202- 741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov

If you are not already submitting your requests through our Public Access Link (PAL), we recommend all future requests and appeals be submitted through PAL - https://requests.publiclink.hhs.gov/. Submitting requests through PAL automatically logs your requests into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your request, receive your documents directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

Sincerely yours,



Arianne Perkins
Director, Initial FOIA Requests
FOI/Privacy Acts Division

Exhibit 52

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Institute of Dental and Craniofacial Research
FOIA/PA Office, RKL 1, 4th Floor
6705 Rockledge Drive
Bethesda, MD 20892

November 7, 2022

Kristin Lavelle
[redacted]
Berkeley, CA 94707

Re: FOIA Case Number: 59249

Dear Ms. Lavelle:

This acknowledges your Freedom of Information Act (FOIA) request addressed to National Institute of Dental and Craniofacial Research (NIDCR), National Institutes of Health (NIH), dated November 6, 2022 and received November 7, 2022. You requested all emails to, and/or from, NIDCR employees Jonathan Horsford, Timothy Iafolla, Rena D'Souza, and Renee Joskow that include one, or more, of the following 10 words/phrases:

- NTP
- "National Toxicology Program"
- "state of the science"
- OASH
- Woychik
- Wolfe
- Levine
- Iademarco
- Tabak
- Hacker

(Date Range for Record Search: From 04/26/2022 To 11/06/2022)

If any documents responsive to your request are located, they will be reviewed for releasability, and all releasable information will be sent to you. We will do everything possible to comply with your request in a timely manner. Please feel free to call me on 301-496-9737 for additional information or to inquire about the status of your request.

Provisions of the FOIA allow us to recover part of the cost of complying with your request. We shall charge you for records in accordance with the Department of Health and Human Services (DHHS) FOIA Regulations as they apply to "other" requesters. As an "other" category requester you will be charged for duplication at 10 cents per page although the first 100 pages are free; 2 hours of search time are free, and thereafter search time is charged at the hourly rate ($23.00, $46.00 and $83.00) of the searcher; there is no charge for review time. Please be advised that the DHHS FOIA Regulations allow us to charge for search time even if we do not locate any responsive records or if we determine that some or all of the responsive records are exempt under one of the FOIA's nine exemptions. If there are any fees associated with processing this request, you will be sent an invoice with our final response.

At any time during the processing of your request, you may seek assistance from the NIDCR FOIA Public Liaison:

NIDCR FOIA Public Liaison
Marianne Manheim
Rockledge I, 4th Floor
6705 Rockledge Drive Bethesda, MD 20892
301-496-9737 (phone)
301-402-3604 (fax)
marianne.manheim@nih.gov (email)

Sincerely,
/s/
Kathryn Gonzalez
Government Information Specialist, NIDCR

Exhibit 53

RE: [EXTERNAL] Re: FOIA Case# 59249

From: Gonzalez, Kathryn (NIH/NHLBI) [E] (kathryn.gonzalez@nih.gov)

To: kristieclendenning@yahoo.com

Date: Tuesday, December 13, 2022 at 10:20 AM PST

Ms. Lavelle,

We are estimating six months for this request. This is just an estimate, the actual date of completion might be before or after the estimate based on the complexity of the records and other requests in the queue before it.

Thank you,
Kathryn

From: Kristie Lavelle <kristieclendenning@yahoo.com>
Sent: Wednesday, December 7, 2022 10:20 AM
To: Gonzalez, Kathryn (NIH/NHLBI) [E] <kathryn.gonzalez@nih.gov>
Subject: Re: [EXTERNAL] Re: FOIA Case# 59249

Ms. Gonzalez –

To the extent it was not already clear, I am writing to confirm that I have narrowed the scope of my request to emails containing the terms “NTP” and/or “National Toxicology Program.” I would appreciate if you could let me know when you expect the records to be produced.

Thank you,
Kristin Lavelle

On Thursday, November 17, 2022 at 09:55:38 AM PST, Kristie Lavelle <kristieclendenning@yahoo.com> wrote:

Ms Gonzalez,

Can you provide me with an estimate as to when I can expect to receive responsive records if we use the narrower scope?

Exhibit 53

Thank you,

Kristin Lavelle

Sent from Yahoo Mail for iPhone

On Thursday, November 17, 2022, 8:14 AM, Gonzalez, Kathryn (NIH/NHLBI) [E] <kathryn.gonzalez@nih.gov> wrote:

Thank you for your email. The broader search that includes people's names would be more likely to pick up loads of random junk to filter through and would require an actual subject matter to be identified in addition to those search terms. NTP/National toxicology program is more or less a subject matter and will help filter to the desired email content.

From: Kristie Lavelle <kristieclendenning@yahoo.com>
Sent: Thursday, November 17, 2022 9:33 AM
To: Gonzalez, Kathryn (NIH/NHLBI) [E] <kathryn.gonzalez@nih.gov>
Subject: Re: [EXTERNAL] Re: FOIA Case# 59249

Dear Ms. Gonzalez –

Thank you for your email. In making this determination, it would be helpful for me to understand when you would expect to produce the responsive materials if I amended my request, and when you would expect to produce the materials if the request remained in its current form. Also, do you have a sense at this point as to how many responsive records there are for the narrower request and for the originally worded request?

Thank you,

Kristin Lavelle

On Wednesday, November 16, 2022 at 09:06:58 AM PST, Gonzalez, Kathryn (NIH/NHLBI) [E] <kathryn.gonzalez@nih.gov> wrote:

Dear Ms. Lavelle,

Yes, if you limit the search terms from the current set of 10 to just “National Toxicology Program” and “NTP”, it will significantly speed up the processing time for the request. Please confirm you would like to amend your request to include search terms “National Toxicology Program” and “NTP” by responding to this email.

Thank you,

Kathryn

From: Kristie Lavelle <kristieclendenning@yahoo.com>
Sent: Tuesday, November 8, 2022 2:59 PM
To: Gonzalez, Kathryn (NIH/NHLBI) [E] <kathryn.gonzalez@nih.gov>
Subject: [EXTERNAL] Re: FOIA Case# 59249

Dear Ms. Gonzalez –

Thank you for your letter regarding my FOIA request. I have a time-sensitive interest in obtaining these records, and as such, have a question that I am hoping you could answer. If I were to limit the search terms from the current set of 10 to just “National Toxicology Program” and NTP, would that significantly speed up the processing time for my request? Any insights you could provide on that, including the difference in processing time for the 10 search terms versus the 2 search terms, would be greatly appreciated.

Thank you,

Kristin Lavelle

On Monday, November 7, 2022 at 09:12:20 AM PST, Gonzalez, Kathryn (NIH/NHLBI) [E] <kathryn.gonzalez@nih.gov> wrote:

Thank you,

Kathryn Gonzalez

Government Information Specialist

Freedom of Information and Privacy Act Branch OM/OD/NHLBI

Direct Line: 301-827-6264

FOIA Line: 301-496-9737

Fax: 301-402-3604

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Exhibit 54

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Institute of
Environmental Health Sciences
P.O. Box 12233, MD K3-16
Research Triangle Park, NC 27709-2233
Phone: 984-287-3354
Fax: 301-480-3371
E-mail: niehsfoia@niehs.nih.gov

SENT VIA ELECTRONIC MAIL

January 03, 2023

Ms. Kristin Lavelle
N/A
[redacted]
Berkeley, CA 94707
[redacted]
kristieclendenning@yahoo.com

Re: FOIA Request Case No. NIH #59447

Dear Ms. Lavelle:

This correspondence is regarding your request seeking certain public records at the National Institute of Environmental Health Sciences (NIEHS) under the Freedom of Information Act (FOIA). Your request, dated December 23, 2022, was submitted via the NIH FOIA Portal available at https://foiaportal.nih.gov/ and received by our office on the same day. It was subsequently assigned FOIA request case number NIH #59447. A copy of your submission is enclosed for reference.

In sum, your request seeks:

Seeking documents that are referenced in the attached December 22, 2022 declaration by Dr. Rick Woychik.

1) The "comments" about NTP's fluoride meta-analysis from "agency subject matter experts" at CDC, FDA, and NIDCR that Dr. Woychik mentions in paragraph 16 of his declaration.

2) The written comments that NTP received from CDC, FDA, and NIDCR where these agencies "expressed concern about the conclusions in the monograph and objected to the planned May 18 publication," as referenced in paragraph 18 of Dr. Woychik's declaration.

3) Dr. Woychik's May 12, 2022 communication(s) to NIH leadership and HHS Assistant Secretary of Health, as referenced in paragraph 19 of Dr. Woychik's declaration.

4) Dr. Woychik's communication(s) to NTP staff "days after" May 12, 2022 where Dr. Woychik informed them the State of the Science Monograph would not be published on May 18, 2022, as discussed in paragraph 19 of Dr. Woychik's declaration.

5) Dr. Woychik's June 10, 2022 communication where he "expanded the scope of the charge to the BSC to include an adjudication of NTP's responses to peer-review comments and agency reviewers' comments on the State of the Science Monograph," as discussed in paragraph 20 of Dr. Woychik's declaration.

NIEHS is currently working through a very high volume of FOIA requests. The following unusual circumstances, as defined by Federal FOIA Regulations, may impact our ability to fulfill a FOIA request within 20 business days. These include circumstances such as (1) the request requires us to search for and collect records from multiple components and/or field offices; (2) the request involves a voluminous number of records that must be located, compiled, transferred to this office, and reviewed. In addition, given our high volume of requests, and in accordance with federal regulations, our processing policy includes factors such as the date of the request as well as the complexity of the request. Due to current circumstances, we may not be able to process your request within 20 days.

In certain circumstances, provisions of the FOIA and the Department of Health and Human Services (HHS) FOIA Regulations allow us to recover part of the cost of responding to your request. It is too early to know whether there will be fees assessed for processing your request. Note: if fees are assessed, your request for a fee waiver will be reviewed at that time. However, the following information is provided if fees are assessed for processing your request.

The charges applied would be for "other" requesters (individuals and public interest groups) – i.e., if applicable, charges could include: duplication costs at 10-cents per page although the first 100 pages are free; 2 hours of search time are free and thereafter search time is charged at the hourly rate of the searcher ($23.00, $46.00 and $83.00); and, there is no charge for review time. Please be advised that the HHS FOIA Regulations allow us to charge for search time even if we do not locate any responsive records or if we determine that some or all of the responsive records are exempt under one of the FOIA's nine exemptions. If there are any fees associated with processing this request, you will be sent an invoice and you may be asked to submit payment in advance of receiving the records.

If you are not satisfied with the handling of this request so far, please contact me or our institute's FOIA Public Liaison:

NIEHS FOIA Public Liaison
Regina J. Stabile, J.D.
Office of Communications and Public Liaison
P.O. Box 12233
Mail Drop K3-16
Research Triangle Park, NC 27709
984-287-3354 (phone)
301-480-3371 (fax)
niehsfoia@niehs.nih.gov (email)

We will do everything possible to comply with processing your request in a timely manner. Please feel free to contact our office for additional information or to inquire about the status of your request.

Sincerely,

Tony Livingston
Government Information Specialist
NIEHS/OD/FOIA Office

Enclosure:
Request Form

Exhibit 55

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via E-mail: kristieclendenning@yahoo.com

January 25, 2023

Kristin Lavelle
[redacted]
Berkeley, CA 94707

Re: NIH FOIA Case No. 59447

Dear Ms. Lavelle:

This is the 1st partial response to your Freedom of Information Act (FOIA) request addressed to the National Institute of Environmental Health Sciences (NIEHS) FOIA Office, National Institutes of Health (NIH), dated December 23, 2022, and received on the same day. Your request was referred to this office. You requested the following documents that are referenced in the December 22, 2022 declaration by Dr. Rick Woychik:

1) The "comments" about NTP's fluoride meta-analysis from "agency subject matter experts" at CDC, FDA, and NIDCR that Dr. Woychik mentions in paragraph 16 of his declaration.

2) The written comments that NTP received from CDC, FDA, and NIDCR where these agencies "expressed concern about the conclusions in the monograph and objected to the planned May 18 publication," as referenced in paragraph 18 of Dr. Woychik's declaration.

3) Dr. Woychik's May 12, 2022 communication(s) to NIH leadership and HHS Assistant Secretary of Health, as referenced in paragraph 19 of Dr. Woychik's declaration.

4) Dr. Woychik's communication(s) to NTP staff "days after" May 12, 2022 where Dr. Woychik informed them the State of the Science Monograph would not be published on May 18, 2022, as discussed in paragraph 19 of Dr. Woychik's declaration.

5) Dr. Woychik's June 10, 2022 communication where he "expanded the scope of the charge to the BSC to include an adjudication of NTP's responses to peer-review comments and agency reviewers' comments on the State of the Science Monograph," as discussed in paragraph 20 of Dr. Woychik's declaration.

Kristin Lavelle (59447)

NIEHS searched the files of National Toxicology Program (NTP) for records and located 3 pages responsive to item #5 listed above, all of which are enclosed. I have determined to withhold portions of the released pages pursuant to exemption 5 of the FOIA, 5 U.S.C. § 552 (b)(5); and sections 5.31 (e) of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 5 permits the withholding of internal government records which are pre-decisional and contain staff advice, opinion, and recommendations. This exemption is intended to preserve free and candid internal dialogue leading to decision-making.

We continue to search for additional records responsive to the other items listed in your request.

If you have any questions about this response, please call 301-496-5633.

Sincerely,

Gorka Garcia-Malene
FOIA Officer, NIH

Enclosure: one pdf file (3 pages total)

From: Woychik, Rick (NIH/NIEHS) [E]
To: Berridge, Brian (NIH/NIEHS) [E]; Wolfe, Mary (NIH/NIEHS) [E]
Cc: Archer, Trevor (NIH/NIEHS) [E]; Baber, Nathan (NIH/NIEHS) [C]
Subject: SoS and Meta papers
Date: Friday, June 10, 2022 11:30:00 AM
Attachments: Fluoride SoS and Meta Analysis Review procedure final 6-10-2022.docx

Dear Brian and Mary,

See the attached document that outlines the process that I'll be using for reviewing the SoS and Meta analysis papers. (b)(5)

(b)(5)

(b)(5)

Let Trevor or me know if you have any questions.

Thanks,
Rick

6-10-2022

(b)(5)

(b)(5)

All the best,

Rick

Exhibit 56

U.S. FOOD & DRUG ADMINISTRATION

January 03, 2023

N/A
KRISTIN LAVELLE
[redacted]
Berkeley CA 94707 US

In Reply refer to
FOIA Control #:
2023-21

Requester reference:

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

All emails to and/or from FDA Dental Officer Frederick Hyman (aka Fred Hyman) that contain one or both of the following two terms:

- National Toxicology Program
- NTP

[The date range for this request is August 1, 2019 to the Present.]

In processing your FOIA request, FDA will apply, as appropriate, the FOIA exemptions in 5 USC 552(b) and the foreseeable harm standard in 5 USC 552(a)(8)(i). We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Rochelle A. Coleman, Information Technician, at (301) 796-8982 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA control number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

Office of Government Information Services
National Archives and Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001
Telephone:202-741-5770
Toll-Free: 1-877-684-6448
Email:ogis@nara.gov
Fax: 202-741-5769

and/or

FDA FOIA Public Liaison
Office of the Executive Secretariat
US Food and Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER
Director

Exhibit 57

Kristin Lavelle
[redacted]
Berkeley, CA 94707
kristieclendenning@yahoo.com

January 15, 2023

Subject: Appeal of Certain Redactions in CDC's Response to My FOIA Request (22-02194-FOIA)

To whom it may concern:

On October 31, 2022, the CDC provided its "Final Response" to my FOIA request 22-02194-FOIA that sought email communications to/from certain CDC employees regarding a report on fluoride from the National Toxicology Program (NTP). In its Final Response, CDC identified 1860 pages of documents, including 559 pages that were produced in full or in part, and 1301 pages that were withheld in full. CDC's response stated I have until January 16, 2023 to appeal its response.

Pursuant to CDC's Final Response, I hereby submit the following appeal. Although I believe CDC has improperly redacted many pages in its response, I am limiting my challenge to a very small number of redactions, as discussed herein. I am doing so in the hope that this will facilitate a quick and timely resolution.

REDACTIONS AT ISSUE

I am challenging the Exemption 5 redactions in the following 5 documents, which I have attached herein in for your convenience:

- **Document 1:** A June 14, 2022 email from Howard Pollick (a private person) to a large number of private persons and one CDC employee.
- **Document 2:** A March 29, 2022 email from Robin Miller (a private person) to CDC's Tracy Boehmer.
- **Document 3:** A June 15, 2022 email from Anita Burgos (a congressional staff member) to HHS employee Jonathan Lyles.
- **Document 4:** A October 19, 2021 email from CDC's Casey Hannan to various private persons, including Jan Hengstler.
- **Document 5**: A August 9, 2022 email from CDC's Lorena Espinoza to Gary Wright concerning a public lawsuit on fluoride.

BASIS FOR APPEAL

Documents 1 to 4 Are Not Inter- or Intra- Agency Communications

Both the FOIA statute and Supreme Court precedent make clear that Exemption 5 only applies to "inter-agency and intra-agency" communications. 5 U.S.C. § 552(b)(5); *Dep't of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 7–8 (2001). Accordingly, courts have held that

emails between government employees and *private persons* are **not** subject to Exemption 5 unless the narrow circumstances of the "consultant corollary" are present. *See, e.g.*, *Am. Oversight v. U.S. Dep't of Health & Hum. Servs.*, 380 F. Supp. 3d 45, 55 (D.D.C. 2019); *Ctr. for Biological Diversity v. Off. of U.S. Trade Representative*, 450 F. App'x 605, 608–09 (9th Cir. 2011). The "consultant corollary" exception to the inter/intra-agency requirement only applies where the private person is an agency "consultant," who is acting "just as a[ ] [government] employee would be expected to do," and the communication "played essentially the same part in an agency's process of deliberation as documents prepared by agency personnel." *See, e.g.*, *Am. Oversight*, 380 F. Supp. 3d at 55; *Ctr. for Biological Diversity*, 450 F. App'x at 608–09.

Documents 1 to 4 are not inter-agency or intra-agency communications and, as such, cannot be withheld under Exemption 5.

The redacted communication at issue in **Document 1** is an email from Dr. Howard Pollick, a professor at the University of California-San Francisco (USCF), and an active member of organizations (e.g., American Dental Association) that lobby governments on oral health- and fluoride-related issues. Dr. Pollick sent this email, which concerns a public lawsuit on fluoride, to a large group of private persons, including Dr. Pollick's dental colleagues at UCSF. The fact that *one* of the many recipients of the email is a CDC employee (Tracy Boehmer) does nothing to transform this email among *non-governmental* dental professionals into an "inter/intra-agency" memorandum. Exemption 5 clearly does not apply.

The redacted communication at issue in **Document 2** is an email from a private person, Robin Miller, to another private person, Dustin Jurgenson, as well as CDC's Tracy Boehmer. Ms. Miller is the Oral Health Director for the Vermont Department of Health,[1] while Dustin Jurgenson is a Program Coordinator for the State of Vermont with no professional training, or education, in health matters.[2] The unredacted portion of Ms. Miller's email concerns an article in a newsletter that she thought would be of interest to Ms. Boehmer, while the redacted portion of the email contains a "request regarding the Mexico studies."[3] The fact that Ms. Miller and Mr. Jurgenson are employees for a *state* government does not transform this email into an "inter-agency" memorandum, as the FOIA statute defines "agency" as the "authority of the Government of the United States." 5 U.S.C. § 552(f). Further, while there is no reason to believe that Ms. Miller and Mr. Jurgenson are "consultants" to the CDC, even *if* they were, they are not providing any advice here *to* the CDC, but instead are asking for advice *from* the CDC. This is important because, as the Department of Justice has recognized, the "advice from a consultant must be coming into the agency, not from the agency" for the "consultant corollary" to apply. *See* https://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/exemption5_0.pdf.

---

[1] *See, e.g.*, https://tinyurl.com/robinmiller01, https://tinyurl.com/robinmiller02 and https://tinyurl.com/robinmiller03

[2] *See, e.g.*, https://www.linkedin.com/in/dustin-jurgenson-313b1473/

[3] It is very likely that the "Mexico studies" being referenced are the NIH-funded studies of the ELEMENT birth cohort in Mexico City that have investigated the relationship between maternal fluoride exposure and childhood IQ/ADHD outcomes. *See* Bashash M, et al. Prenatal Fluoride Exposure and Cognitive Outcomes in Children at 4 and 6-12 Years of Age in Mexico. Environ Health Perspect. 2017 Sep 19;125(9):097017. doi: 10.1289/EHP655. PMID: 28937959; PMCID: PMC5915186; Bashash M, et al. Prenatal fluoride exposure and attention deficit hyperactivity disorder (ADHD) symptoms in children at 6-12 years of age in Mexico City. Environ Int. 2018 Dec;121(Pt 1):658-666. doi: 10.1016/j.envint.2018.09.017. PMID: 30316181.

The redacted communication at issue in **Document 3** is an email from a *congressional staff member*, Anita Burgos, to an HHS employee. Federal courts have repeatedly explained that Congress is *not* an "agency" for purposes of Exemption 5. *See, e.g.*, *Am. Oversight v. U.S. Dep't of Health & Hum. Servs.*, 380 F. Supp. 3d 45 (D.D.C. 2019). Further, the email at issue here is simply a request to HHS for information about the NTP's fluoride report, and, as such, it is hard to conceive how the "consultant corollary" exception could possibly apply to this email.

The redacted communication at issue in **Document 4** is an email from CDC's Casey Hannan to Jan Hengstler, a private scientist at a German research institute.[4] The email, which is titled "Request to discuss your fluoride study," is contained in a thread on which other private persons are copied, including Hengstler's colleague Angelika Roth.[5] The paper that CDC is asking about is likely a review on fluoride neurotoxicity that Hengstler and Roth published in the open peer-reviewed literature (a review that has been lauded by advocates of fluoridation, but strongly criticized by scientists as an unbalanced and biased assessment).[6] This unsolicited email *from* the CDC to partisan non-governmental scientists, who appear to have no pre-existing consulting relationship with CDC, does not qualify for the "consultant corollary" exception. But, even *if* these private persons were generously assumed to be "consultants" to CDC, the email does not reveal any advice that they provided *to* the CDC. *See* https://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/exemption5_0.pdf ("Advice from a consultant must be coming into the agency, not from the agency.").

None of the 5 Documents Appear to Be Both Predecisional and Deliberative

A separate and independent basis for my appeal of CDC's redactions is that none of these 5 documents appear to be protected by the deliberative process privilege. "The purpose of the deliberative process privilege 'is to prevent injury to the quality of agency decisions' by ensuring that the 'frank discussion of legal or policy matters' . . . is not inhibited by public disclosure." *Maricopa Audubon Soc. v. U.S. Forest Serv.*, 108 F.3d 1089, 1092–93 (9th Cir. 1997) (citing *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 150-51 (1975)). Courts have identified two separate elements that must be present for the deliberative process privilege to apply: the communication must be "predecisional" (i.e., it must relate to a legal or policy decision that has not yet been made) and it must be "deliberative" (i.e., it must reflect opinions or recommendations on legal or policy matters). *Assembly of State of Cal. v. U.S. Dep't of Commerce*, 968 F.2d 916, 920 (9th Cir. 1992).

The communications at issue in **Documents 1 to 4** do not appear to be subject to the deliberative process privilege because none of these documents appears to relate to a legal or policy decision and thus, even *if* they are deliberative, they are not predecisional.

The communication at issue in **Document 5** does not appear to be subject to the deliberative process privilege as it is an email regarding a *public* court case which CDC is not a party to, and

[4] *See, e.g.*, https://www.ifado.de/toxicology/staff-2/jan-hengstler/
[5] *See, e.g.*, https://www.ifado.de/toxicology/staff-2/
[6] *See* Guth S, et al. Toxicity of fluoride: critical evaluation of evidence for human developmental neurotoxicity in epidemiological studies, animal experiments and in vitro analyses. Arch Toxicol. 2020 May;94(5):1375-1415. doi: 10.1007/s00204-020-02725-2. PMID: 32382957; https://pubmed.ncbi.nlm.nih.gov/32382957/.

is written by a non-attorney (Lorena Espinoza). It is hard to conceive how passing remarks about a public lawsuit could be predecisional to a CDC legal or policy decision.

SUMMARY

Through this appeal, I am challenging CDC's Exemption 5 redactions in Documents 1 through 5. As discussed above, Documents 1 through 4 are not inter- or intra-agency communications, and, as such, cannot qualify for protection under Exemption 5. In addition, none of the five documents appear to be *both* predecisional *and* deliberative, and as such, do not appear to be privileged.

Given the limited scope of my appeal, I am hopeful this appeal can be decided promptly. To the extent I can provide any further information to assist in your evaluation, please do not hesitate to let me know.

Yours Sincerely,
Kristin Lavelle

Document 1

From: Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH)
Sent: Tue, 19 Jul 2022 17:58:53 +0000
To: Stettner, Joanna L. (CDC/OCOO/OGC)
Subject: FW: Postponement of EPA fluoridation lawsuit status report

Hey there – just wanted to let you know that we had our mtg with the ASH last week. I'll be happy to chat any time to let you know how it went

---

From: Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH)
Sent: Monday, July 11, 2022 10:49 AM
To: Turner, Victoria (CDC/DDNID/NCCDPHP/OD) <qnn4@cdc.gov>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <axz7@cdc.gov>; Stettner, Joanna L. (CDC/OCOO/OGC) <czl8@cdc.gov>
Cc: Holder, Gregory (CDC/DDNID/NCCDPHP/DOH) <LHN5@cdc.gov>
Subject: FW: Postponement of EPA fluoridation lawsuit status report

Hi all – I just found this lurking, still open on my desktop. We may have had this conversation, but just in case we haven't, (b)(5)

Also, mostly as a heads up for Joanna, we have been invited to meet with the OASH to share our reflections on the draft NTP report. That meeting is scheduled for tomorrow afternoon, we'll let you know how it goes.

Cheers,
Nicole

From: Pollick, Howard <(b)(6)
Sent: Tuesday, June 14, 2022 2:42 PM
To: Miyahara, Keiko <(b)(6)
(b)(6)
(b)(6) Ng, Danika
(b)(6) ; Parmar, Digvijaysinh
(b)(6) (b)(6) Obadan-Udoh, Enihomo <(b)(6) ; Chong, Gabriel (b)(6)
(b)(6) Megally, Hayam
(b)(6) ;
Aalboe, Joanna@CDPH (b)(6)
(b)(6)
(b)(6) Stocks, Marjorie <(b)(6)
(b)(6) ; Garcia, Samantha (b)(6)
(b)(6) Karande, Sharvari <(b)(6)
(b)(6) ; Silverstein, Steven <(b)(6)
(b)(6) Boehmer, Tracy (CDC/DDNID/NCCDPHP/DOH)

<opm9@cdc.gov> (b)(6)
Subject: Postponement of EPA fluoridation lawsuit status report

(b)(5)

Regards

Howard

Howard Pollick, BDS, MPH
Fluoridation Consultant, California Dept. of Public Health
https://oralhealthsupport.ucsf.edu/people/howard-pollick-bds-mph

Health Sciences Clinical Professor,

Preventive & Restorative Dental Sciences,

UCSF School of Dentistry

707 Parnassus Ave., D-1030, Box #0758 | San Francisco, CA 94143-0758

tel: (b)(5)

fax: 415-476-0858

(b)(6) | http://dentistry.ucsf.edu

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UCSF Dental Center on Facebook

Document 2

(b)(5)

From: Espinoza, Lorena (CDC/DDNID/NCCDPHP/DOH) <lee6@cdc.gov>
Sent: Tuesday, March 29, 2022 9:25 PM
To: Boehmer, Tracy (CDC/DDNID/NCCDPHP/DOH) <opm9@cdc.gov>; Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH) <nbg5@cdc.gov>
Subject: RE: Fluoridation

Thanks Tracy.
Nicole,
Do we have cleared material regarding Mexico or other studies?

From: Boehmer, Tracy (CDC/DDNID/NCCDPHP/DOH) <opm9@cdc.gov>
Sent: Tuesday, March 29, 2022 11:58 AM
To: Espinoza, Lorena (CDC/DDNID/NCCDPHP/DOH) <lee6@cdc.gov>
Cc: Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH) <nbg5@cdc.gov>
Subject: FW: Fluoridation

Hi Lorena and Nicole,

See note below from Robin Miller. This is mostly for awareness, but also see last item with request regarding the Mexico studies.

Tracy

Theresa "Tracy" J. Boehmer, P.E.
Fluoridation Engineer
Division of Oral Health
Centers for Disease Control and Prevention
(404) 498-0774 (office)

From: Miller, Robin N <(b)(6)
Sent: Tuesday, March 29, 2022 11:18 AM
To: Boehmer, Tracy (CDC/DDNID/NCCDPHP/DOH) <opm9@cdc.gov>
Cc: Jurgenson, Dustin <(b)(6)
Subject: FW: Fluoridation

Hi Tracy,
I thought this might be of interest to you (see below). This was from a water operator who was responding to our recent article about the CDC fluoridation awards in the VT Rural Water Association's NewsLeaks newsletter, I took out the identifying information. Rather than responding by email I asked

(b)(5)

Thanks Tracy,
Robin

Sent: Friday, March 25, 2022 12:28 PM
To: Miller, Robin N <(b)(6)

Subject: Fluoridation

EXTERNAL SENDER: Do not open attachments or click on links unless you recognize and trust the sender.
Robin,

My name is _____, I am the head water and wastewater operator for _____. Your article in the VRWA magazine peeked my interest. First, I did not know that there was a program helping municipalities to establish Fluoridation. Actually, the article didn't specifically say how much the awards were and what they are used for. Were these awards given out as grants, loans, or in the form of physical equipment? What did those 11 Municipalities get this year? Has this program been going on for years, or is this just the first year? Seems like you nailed most of the biggest municipalities in the State. Will smaller systems get an opportunity to participate some day?

The other question is how have these programs been received in the communities? Were the communities, or at least customers asked for feedback or about comfort level? I know I have seen a few messages come across social media over the years. Some asking if we use fluoride, some accusing the system of using it, and then some conspiracy theories. I tend to shut it down quickly with a "we never have and never will" kind of response.

As a head water operator, who has zero experience and little knowledge, I have always try to avoid the controversy surrounding fluoride. How do you overcome the misinformation that people have been hearing for 75 years and get buy in. This interest me because I'm always looking out for my customers, and want to make things better for them. If you can convince me that it's worth it, I can talk to the Board of Trustees and see how they react.

Document 3

Sent via the Samsung Galaxy S20 FE 5G, an AT&T 5G smartphone
Get Outlook for Android

From: Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <axz7@cdc.gov>
Sent: Wednesday, June 22, 2022 12:42:28 PM
To: Greaser, Jennifer (CDC/OD/CDCWO) <cbx5@cdc.gov>; Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH) <nbg5@cdc.gov>; Bishop, Ann (Lindsay) (CDC/DDNID/NCCDPHP/OD) <xii4@cdc.gov>
Subject: RE: REQUEST: NTP Draft Report

Sure. I am free for next 18 minutes and then am open at 5pm today.

From: Greaser, Jennifer (CDC/OD/CDCWO) <cbx5@cdc.gov>
Sent: Wednesday, June 22, 2022 12:31 PM
To: Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH) <nbg5@cdc.gov>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <axz7@cdc.gov>; Bishop, Ann (Lindsay) (CDC/DDNID/NCCDPHP/OD) <xii4@cdc.gov>
Subject: FW: REQUEST: NTP Draft Report

Can we jump on the phone to discuss today?

From: Groves, Garrick (HHS/ASL) <Garrick.Groves@hhs.gov>
Sent: Wednesday, June 22, 2022 10:33 AM
To: Tourk, Nancy R. (CDC/OD/CDCWO) <wxk8@cdc.gov>; Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>; Wortman, Eric (CDC/OD/CDCWO) <ltr3@cdc.gov>; Workman, Sara R. (CDC/OD/CDCWO) <hvh0@cdc.gov>
Cc: Zelenko, Leslie (HHS/ASL) <Leslie.Zelenko@hhs.gov>; Bradsher, Kris (HHS/ASL) <Kris.Bradsher@hhs.gov>; Mullman, Lauren (HHS/ASL) <Lauren.Mullman@hhs.gov>
Subject: FW: REQUEST: NTP Draft Report

Hi everyone, Looping in CDC colleagues on a Rep. Kelly's staff request (came to us through OASH for) CDC's perspectives/contribution on National Toxicology Program (NTP) draft report.

Please let me know if CDC has any feedback to share and whether CDC would prefer to have a call with staff. It would be helpful to please loop in ASL on the proposed response ahead of time given all the coordination involved on the report. If CDC would prefer, I am happy to pull together a precall/call or share any written feedback. Thanks, Garrick

---

Garrick Groves
Office of the Assistant Secretary for Legislation
U.S. Department of Health and Human Services
(202) 253-1083
garrick.groves@hhs.gov

From: Burgos, Anita <Anita.Burgos@mail.house.gov>
Sent: Wednesday, June 15, 2022 10:54 AM
To: Lyles, Johnalyn (HHS/OASH) <Johnalyn.Lyles@hhs.gov>
Subject: NTP Draft Report

Hi Johnalyn,

(b)(5)

Thanks so much for your work on this important issue.

P.S. - On a personal note, I really enjoyed our conversation and learning more about your career trajectory. Thanks for chatting!

Best,
Anita

Anita Burgos, PhD
Senior Health Policy Advisor
Congresswoman Robin L. Kelly (IL-02)
2416 Rayburn House Office Building
Washington, DC 20515

Document 4

From: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH)
Sent: Thu, 17 Mar 2022 13:52:22 +0000
To: Hengstler, Jan
Cc: Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH); Holder, Gregory (CDC/DDNID/NCCDPHP/DOH); Guth, Sabine; Roth, Angelika; Villar-Fernandez, Maria
Subject: RE: Request to discuss your fluoride study

Thank you, Jan. We are looking forward to it.

Casey

From: Hengstler, Jan (b)(6)
Sent: Thursday, March 17, 2022 9:44 AM
To: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Cc: Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH) <nbg5@cdc.gov>; Holder, Gregory (CDC/DDNID/NCCDPHP/DOH) <LHN5@cdc.gov>; Guth, Sabine (b)(6); Roth, Angelika (b)(6); Villar-Fernandez, Maria (b)(6)
Subject: AW: Request to discuss your fluoride study

Dear Casey, dear all,

only for confirmation; we will then enter the zoom link today at 15:00 that has been sent by Angela in February.

Best wishes

Jan

Von: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Gesendet: Montag, 29. November 2021 15:34
An: Hengstler, Jan (b)(6)
Cc: Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH) <nbg5@cdc.gov>; Holder, Gregory (CDC/DDNID/NCCDPHP/DOH) <LHN5@cdc.gov>; Guth, Sabine (b)(6); Roth, Angelika (b)(6); Villar-Fernandez, Maria (b)(6)
Betreff: RE: Request to discuss your fluoride study

Dear Jan and Sabine –

Thanks so much for staying in touch. I will work with CDC colleagues to see if we are available on the proposed dates below. I will be in touch as soon as I can.

Kind regards,

Casey

From: Hengstler, Jan (b)(6)
Sent: Sunday, November 28, 2021 2:44 PM
To: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov> (b)(6)
Cc: Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH) <nbg5@cdc.gov>; Holder, Gregory (CDC/DDNID/NCCDPHP/DOH) <LHN5@cdc.gov>; Guth, Sabine (b)(6); Roth, Angelika (b)(6) Villar-Fernandez, Maria (b)(6)
Subject: AW: Request to discuss your fluoride study

Dear Casey,

Again Thank you very much for your invitation. Would one of the following suggestions fit to your plans?

January 19 or26;
February 16;

any time between 9:00 and 13:00 (your time; which corresponds to 15 – 19:00 our time) would be fine.

Please send alternatives if these suggestions do not fit.

Are there any specific questions you are particularly interested in on which we should focus?

We could also give a general overview (20 min) including the challenges as described in the article.

We are looking forward to the discussion.

Best wishes

Jan and Sabine

Von: Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>
Gesendet: Dienstag, 19. Oktober 2021 15:18
An (b)(6) Hengstler, Jan (b)(6)
Cc: Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH) <nbg5@cdc.gov>; Holder, Gregory (CDC/DDNID/NCCDPHP/DOH) <LHN5@cdc.gov>
Betreff: Request to discuss your fluoride study

(b)(5)

(b)(5)

Kind regards,

Casey

Casey J. Hannan, MPH
***Director**, Division of Oral Health*
Centers for Disease Control and Prevention
channan@cdc.gov
770.488.6054 (office) | (b)(6) *(mobile)*
http://www.cdc.gov/oralhealth/

Document 5

From: Espinoza, Lorena (CDC/DDNID/NCCDPHP/DOH)
Sent: Tue, 9 Aug 2022 01:22:14 +0000
To: Wright, Gary
Subject: TSCA
Attachments: original tsca_fluoride_petition.pdf, EPA_Fluoride_TSCA_Response_FRN.docx

FYI:

(b)(5)

Exhibit 58

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2023-00065-A-PHS

January 17, 2023

Kristin Lavelle
[redacted]
Berkeley, California 94707
Sent via email: kristieclendenning@yahoo.com

Dear Mrs. Lavelle:

This letter acknowledges receipt of your Freedom of Information Act (FOIA) appeal, which was submitted to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division. We received your appeal on January 16, 2023. It challenges the Centers for Disease Control and Prevention (CDC) response to your initial request, 22-02194-FOIA. We assigned your appeal the tracking number above based on when it was received in this office. Please refer to this number on any future correspondence.

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 C.F.R. § 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal and consultation with other U.S. Department of Health and Human Services (HHS) components involved.

Each appeal is handled on a first-in, first-out basis in relation to the other open appeals in the processing queue. Currently, there are approximately 450 open appeals in the processing queue. For more information about how your appeal will be processed please refer to the HHS FOIA regulations (https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations).

As a final note, if you are not already submitting your appeals through our Public Access Link (PAL), we recommend all future appeals be submitted through PAL - https://requests.publiclink.hhs.gov/. Submitting appeals through PAL automatically logs your appeal into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your appeal, receive your response directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

If you have any questions, please email us at foiarequest@psc.hhs.gov.

Sincerely yours,

Alesia Y. Williams

Alesia Y. Williams
Director, FOIA Appeals and Litigations
FOI/Privacy Acts Division