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

FOOD & WATER WATCH, et al.,

Plaintiffs,

vs.

U.S. ENVIRONMENTAL PROTECTION  
AGENCY, et al.

Defendants.

Civ. No. 17-CV-02162-EMC

**PLAINTIFFS' OPPOSITION TO  
DEFENDANTS' ADMINISTRATIVE  
MOTION TO GOVERN FUTURE  
PROCEEDINGS**

## INTRODUCTION

EPA once again asks this Court to delay resolution of this case to give more time for the official release of a report that, at best, has no clear or reliable timeframe for release, and, at worst, will *never* be officially released. The Court has previously recognized the problem with “awaiting the final publication of the NTP review” where there is no assurance it will actually be published, let alone in a timely manner. ECF No. 319 at 4:9-11. EPA’s motion does nothing to address this concern. Instead, EPA’s motion, and Dr. Woychik’s new declaration, demonstrate the unlikelihood of HHS leadership ever authorizing release of an NTP report that conflicts with HHS’s policy interests on fluoride. EPA’s motion should be denied.

## SUMMARY OF THE FACTS

### A. The NTP’s May 2022 Monograph Was the Final Assessment of NTP’s Scientists

This case was put on hold for over two years to consider the expert assessment of the National Toxicology Program’s (NTP) scientists. As documented below, this assessment was completed by May 2022. Although agencies with strong partisan interests on fluoridation disagreed with NTP’s conclusions, this case was not put on hold to wait for all organizations that advocate for fluoridation to agree with the NTP’s independent assessment.

The evidence is clear that *NTP’s scientists* (the federal government’s subject matter experts on toxicology) considered the May 2022 monograph to be their final assessment. In January 2022, the NTP provided the following description of the remaining process for finalizing the NTP’s monograph:

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.***

Exhibit 1 (emphasis added); *accord* ECF No. 299 at 1:22-2:2. NTP never stated that the monograph would need approval by “agency subject matter experts,” let alone unidentified persons from agencies with strong

strong partisan interests on fluoridation. Instead, so long as the five independent external reviewers were in general agreement with the monograph, the monograph would be published.<sup>1</sup>

Dr. Woychik’s second declaration confirms that the five external reviewers “*concurred*” with the NTP’s conclusions. Woychik 2d Decl. ¶ 15 (emphasis added). The external reviewers offered some comments for additional revisions but the NIH has admitted that “[t]he NTP incorporated these comments, and by May 2022, had completed a finalized copy of the report.” Exhibit 2a (*Lavelle v NIH*, Complaint ¶ 19), Exhibit 2b (*Lavelle v NIH*, Answer ¶ 19).

Contemporaneous email communications from April and May 2022 confirm that NTP scientists considered the May 2022 monograph to be their final assessment. On April 28, 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 3. On May 11, Dr. Wolfe emailed CDC to let it know “We have set May 18 for publication of the monograph.” Exhibit 4. Later that same day, 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 5 (emphasis added). In short, Dr. Wolfe’s emails confirm that the May 2022 monograph was the report that this case was placed on hold for two years to consider. Then politics intervened.

#### **B. EPA’s Motion Confirms that NTP May Never Officially Release the Final Report**

EPA’s motion, and Dr. Woychik’s new declaration, confirm that the NTP’s assessment may never be published. Defs’ Mot. at 3:1-2; Woychik 2d Decl. ¶¶ 25 & 28. As EPA notes, Dr. Woychik “will make a final decision whether to publish the State of the Science Monograph” after receiving the recommendation of the Board of Scientific Counselors (BSC). Defs’ Mot. at 3:1-2. Even this may be overly optimistic, however, as it assumes Dr. Woychik has the power to release a report that clashes with HHS’s

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<sup>1</sup> This process (i.e., peer review by a *single* panel of external scientists) is what NTP has used for each of its previous monographs. See ECF No. 312 at 5:20-7:8. The brevity of the previous peer reviews of NTP monographs reflects NTP’s position as a uniquely authoritative, and neutral, body on toxicology issues.

1 policy interests. While Dr. Woychik claims responsibility for making the decision to quash the report in  
 2 May (as opposed to the unenviable task of publicly blaming his superiors), contemporaneous email  
 3 communications show that the decision was made by his boss, HHS Assistant Secretary of Health Rachel  
 4 Levine. Woychik 2d Decl. ¶ 19. According to a June 3, 2022 email from CDC, “**ASH Levine has put the**  
 5 **report on hold until further notice.**” Exhibit 6 (emphasis added). Since the Assistant Secretary made the  
 6 decision to put the monograph on hold, she presumably has the power to do so again in the future.

### 7 **C. The New “Process” that Dr. Woychik Describes Has No End in Sight**

8 Even if HHS leadership were to eventually give NTP the authority to release its fluoride  
 9 monograph, Dr. Woychik’s new declaration shows that this day may be far in the future. First, a BSC  
 10 working group is currently working on the *fourth* external peer review of the NTP monograph, a review it  
 11 did not start until October 2022. Woychik 2d Decl. ¶¶ 20-22. Dr. Woychik does not provide a date for  
 12 when the working group’s report will be issued, but “currently expect[s]” it will be in “early 2023.” *Id.* ¶  
 13 22. Second, the BSC will consider the working group’s report and then provide its own recommendations  
 14 at some unknown point in time. *Id.* Third, “[i]f the BSC makes suggestions to revise the documents before  
 15 they can be published, this will take time, so the final publication will be determined by how quickly the  
 16 NTP authors can make the modifications.” *Id.* ¶ 24. Not only will it take an unknown amount of time for  
 17 NTP to incorporate the BSC’s recommended modifications, “**if the modifications are substantial, the**  
 18 **two documents will have be reviewed again** before they can move forward for publication, which will  
 19 also take time.” *Id.* (emphasis added). Dr. Woychik’s declaration thus contemplates the possibility of a  
 20 *fifth* external peer review of the NTP report before a publication decision is made. And even then,  
 21 publication is not guaranteed.  
 22  
 23  
 24

### 25 **D. The Transparency of the Current BSC Working Group Review Is Sorely Lacking**

26 In contrast to the previous peer reviews of NTP’s fluoride monograph, there has been a notable lack  
 27 of transparency regarding the BSC working group review. Neither the NTP nor NIH has made any public  
 28

announcement of the working group’s existence, let alone its written charge, or the identity of the reviewers.<sup>2,3,4</sup> Further, although the BSC working group will issue its report at a “public” meeting (Woychik 2d Decl. ¶ 22), and although NTP *always* provides the public with copies of draft NTP reports in advance of public meetings,<sup>5</sup> the government insists the May 2022 monograph “should not be released to the public.” Woychik 2d Decl. ¶¶ 4 & 30. Moreover, while Dr. Woychik claims the purpose of the BSC peer review is to “adjudicate” the comments made by “agency subject matter experts,” the NIH and EPA have refused to produce these comments.<sup>6</sup> Woychik 2d Decl. ¶¶ 17 & 20. To be clear, if the BSC peer review is to be a “public” process, as Dr. Woychik claims, the materials being “adjudicated” cannot be kept secret.

Finally, although the HHS argues that the public should not be permitted to see the NTP’s May 2022 monograph (a monograph that took six years of staff time to complete), someone at HHS saw fit to provide a copy to the nation’s largest lobbying group on fluoride issues, the American Dental Association (ADA). A September 10, 2022 email from the ADA states: “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.” Exhibit 7. The ADA, which is one of CDC’s “external partners” in promoting fluoridation (Exhibit 8), has been kept in the loop by CDC on the latest developments with the NTP review (*e.g.*, Exhibit 9), which is likely how the ADA knew about BSC’s review long before it was publicly announced. The

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<sup>2</sup> The NTP website has a section that identifies all existing BSC expert panels, but this section makes no mention of any working group on fluoride. See <https://ntp.niehs.nih.gov/events/panels/index.cfm> (last accessed on Jan. 5, 2023).

<sup>3</sup> The NIH’s “Peer Review Agenda” webpage makes no reference to the BSC review. See <https://infoquality.osp.od.nih.gov> (last accessed on Jan. 5, 2023).

<sup>4</sup> Federal agencies are supposed to abide by the peer review guidelines established by the Office of Management and Budget, which state that “an agency conducting a peer review of a highly influential scientific assessment must ensure that the peer review process is transparent by making available to the public the written charge to the peer reviewers, the peer reviewers’ names, the peer reviewers’ report(s), and the agency’s response to the peer reviewers’ report(s).” 70 Fed. Reg. 2665.

<sup>5</sup> See, *e.g.*, 86 Fed. Reg. 42869, 84 Fed. Reg. 368, 84 Fed. Reg. 25552, 84 Fed. Reg. 54908; 83 Fed. Reg. 4063; 82 Fed. Reg. 28672; 82 Fed. Reg. 52066; 81 Fed. Reg. 9867; 80 Fed. Reg. 27178.

<sup>6</sup> On December 22, 2022, within hours of receiving EPA’s motion, Plaintiffs’ counsel asked counsel for NIH and EPA if they would “voluntarily produce” the agency “comments” referenced in Dr. Woychik’s new declaration, and NTP’s responses thereto. Counsel for NIH and EPA declined this request.

HHS's selective sharing of the NTP report with the ADA suggests that HHS's insistence on keeping the report hidden from everyone else may be based on less-than-principled considerations.

## ARGUMENT

### **A. The Court Should Deny EPA's Motion for the Same Reasons It Lifted the Stay**

The Court should deny EPA's motion for the same reasons that it recently lifted the stay: i.e., "the final publication [of the NTP review] is no longer imminent because the NTP may never publish the final version." ECF No. 319 at 4:9-11. While EPA attaches a new declaration to its motion, this new declaration only creates further uncertainty about the report's future. Thus, staying the case to wait for HHS to authorize the report's release runs afoul of the Ninth Circuit's admonition that "stays should not be indefinite in nature." *Dependable Highway Exp., Inc. v. Navigators Ins. Co.*, 498 F.3d 1059, 1066 (9th Cir. 2007). It matters not if the stay is sequenced in 6-month allotments if there is no concrete basis to expect the report to be released in 6 months. The better course is to set the trial schedule now, and in the *unlikely* event that HHS authorizes the report's release prior to trial, to adjust the schedule if, and as, appropriate.

### **B. The Court Now Has the Full Spectrum of Scientific Debate at Its Disposal**

The existence of "comments" from personnel at HHS agencies that advocate for fluoridation will give the Court the benefit of seeing the full spectrum of criticism regarding alleged deficiencies in the NTP monograph. Plaintiffs welcome that opportunity and seek to obtain, through discovery, the "comments" that Dr. Woychik references in his declaration (as well as the identities and credentials of the personnel), and the NTP's responses thereto. These comments, coupled with NTP's May 2022 monograph, will provide the Court and the parties' experts with a comprehensive body of information with which to vet the latest science. The availability of this information further reduces the justification for delay, as this Court recognized when denying EPA's previous attempt to delay trial. ECF No. 115 at 3:11-13 ("[B]oth parties are currently free to utilize the information and studies that will be the basis of the forthcoming Monograph; the current availability of these resources counsels against delaying the existing schedule.").

January 5, 2023

Respectfully submitted,

/s/ Michael Connett  
MICHAEL CONNETT  
Attorney for Plaintiffs

# **Exhibit 1**



**From:** Carfora, Debra (ENRD) <[Debra.Carfora@usdoj.gov](mailto:Debra.Carfora@usdoj.gov)>  
**Sent:** Tuesday, January 4, 2022 10:59 AM  
**To:** Michael Connett <[mconnett@waterskraus.com](mailto:mconnett@waterskraus.com)>  
**Cc:** Adkins, Brandon (ENRD) <[Brandon.Adkins@usdoj.gov](mailto: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,

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## **Exhibit 2a**

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

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

**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.

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

## **FACTUAL BACKGROUND**

### **A. The National Toxicology Program (NTP)**

6. The National Toxicology Program (“NTP”) is a federal government entity, headquartered within the Defendant NIH at the National Institutes of Environmental Health Sciences (“NIEHS”).

7. The mission of the NTP is “to build knowledge and advance toxicological sciences to protect and promote human health.” Towards this end, the NTP focuses exclusively on science, not policy.

8. According to scientists at NTP, “For more than 35 years, the National Toxicology Program (NTP) has conducted research, testing, and analysis activities and has disseminated information about potential health hazards in our environment. As the largest government program in toxicology, NTP has studied more than 2,800 substances for a variety of health effects, developed numerous new methods and tools, and published over 600 reports and monographs.”<sup>1</sup>

9. The NTP studies and evaluates the toxicity of chemicals; it does not enact regulations, rules, or policies to regulate how chemicals are used in society.

### **B. Fluoride & Neurodevelopment**

10. One of the chemicals that NTP has been studying in recent years is fluoride.

11. Fluoride is added to the drinking water of approximately 200 million Americans. The health consequences (beneficial and/or detrimental) of this chemical are of substantial public interest given its widespread use and concomitant exposures.

12. One of the hazards of fluoride that the NTP has been focusing on is fluoride’s potential to adversely affect the developing brain, particularly when the exposure occurs *in utero* or during early infancy. Concerns about this hazard have been fueled, in part, by studies funded by the NIEHS<sup>2</sup> which have found significant associations between early-life fluoride exposure and IQ loss in children.

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<sup>1</sup> Xie Y, Holmgren S, Andrews DM, Wolfe MS. Evaluating the Impact of the U.S. National Toxicology Program: A Case Study on Hexavalent Chromium. *Environ Health Perspect.* 2017 Feb;125(2):181-188. doi: 10.1289/EHP21. PMID: 27483499.

<sup>2</sup> Till C, et al. Fluoride exposure from infant formula and child IQ in a Canadian birth cohort. *Environ Int.* 2020, 134:4–11; Green R, et al. Association between maternal fluoride exposure during pregnancy and IQ scores in offspring in Canada. *JAMA Pediatr.* 2019, 173:940–948; Bashash M, et al: Prenatal fluoride

Continued on the next page

**C. NTP's First Report on Fluoride - Neurodevelopmental Effects in Animals**

13. 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 the mission and function of the NTP, the report was focused solely on the science, and did not make any policy determinations.

14. In 2018, drafts of the NTP's 2016 report were produced in discovery by the U.S. Environmental Protection Agency (EPA) in the case of *Food & Water Watch v. EPA*, No. 17-cv-02162-EMC, which is a case that is still pending before the Hon. Judge Edward Chen in the Northern District of California.<sup>3</sup>

15. In *Food & Water Watch*, the EPA voluntarily produced drafts of the NTP's 2016 report in response to Plaintiffs' discovery requests, but refused to produce any drafts that contained EPA's comments, claiming such drafts were protected under the deliberative process privilege. The court rejected EPA's assertion of privilege, and ordered that the Agency produce the draft NTP reports with EPA's comments. 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.*"<sup>4</sup>

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

16. In September 2019, the NTP publicly released a draft of its second report on fluoride, titled "Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects." Whereas the NTP's first report from 2016 had focused only on animal studies, this second report looked at both animal and *human* studies, with a focus on the latter. Consistent with the mission and function of the NTP, the report was focused solely on the science, and did not make any policy determinations.

17. The 2019 draft of the NTP's second fluoride report underwent peer review by the National Academy of Sciences, Medicine & Engineering (NASEM). NASEM issued its peer review comments in

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exposure and attention deficit hyperactivity disorder (ADHD) symptoms in children at 6-12 years of age in Mexico City. *Environ Int* 2018, 121(Pt 1):658-666; 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, 125(9):097017.

<sup>3</sup> The Plaintiff, Kristin Lavelle, is a plaintiff in the *Food & Water Watch* case.

<sup>4</sup> The Court's decision is attached hereto as **Exhibit A**. The relevant discussion of the draft NTP reports is on pages 6 and 7.

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<sup>5</sup> that the NTP maintains for studies it has reviewed as part of its evaluation of fluoride.

<sup>5</sup> See, e.g., <https://hawcproject.org/epi/result/9277/> and <https://hawcproject.org/epi/result/9278/>

24. On August 9, 2022, a FOIA Officer at NIH emailed Plaintiff to acknowledge NIH's receipt of her request, and to incorporate a clarification that Plaintiff had requested.<sup>6</sup> That day, Plaintiff's FOIA request was assigned the number 58806.

25. As of the time of this Complaint, the NIH has not made a determination, or provided any response, regarding Plaintiff's request.

26. The NIH has not yet even begun processing Plaintiff's request. On NIH's website, the NIH lists the "status" of Plaintiff's FOIA request as "Assigned for Processing."<sup>7</sup> This status means the "request has been assigned to a FOIA Specialist for processing." The status category that a FOIA request is assigned when an officer begins working on the request is "In Process." A request that is "In Process" is one which is "actively being processed by the FOIA Office." Plaintiff's request has never been listed as "In Process."

27. The NIH has not identified any "unusual circumstances" that it will face in responding to Plaintiff's request. *See* 5 U.S.C. § 552(a)(6)(B)(i).

### **LEGAL FRAMEWORK**

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

28. 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).

29. 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

<sup>6</sup> A copy of the FOIA Officer's email communications with Plaintiff are attached hereto as **Exhibit B**. The highlighted portion of the exhibit contains the specific language of Plaintiff's FOIA request.

<sup>7</sup> A print-out of the NIH website (taken on September 8, 2022 at 5:10 pm EST) showing the status of Plaintiff's request is attached as **Exhibit C**.

(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.”).

30. If a federal agency does not provide a determination within 20 working days of receiving a FOIA request, 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).

### **B. The Deliberative Process Privilege**

31. “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) (emphasis added) (citation omitted)). Accordingly, to come within the scope of the privilege the document must “‘make[] recommendations or express opinions *on legal or policy matters*.’” *First Resort, Inc. v. Herrera*, 2014 WL 988773, at \*5 (N.D. Cal. Mar. 10, 2014) (citation omitted).

32. Courts have held that *scientific assessments* are not deliberative unless they are part of a *policy* making procedure. Accordingly, 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. Env'tl. 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.”).

33. As Magistrate Judge Kandis Westmore recently explained in *Food & Water Watch v. EPA*, 17-cv-02162-EMC, draft NTP evaluations of the scientific literature are not subject to the deliberative process privilege because they are not “predecisional” to any policy or decision.<sup>8</sup>

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<sup>8</sup> Exhibit A, p. 7.



**CLAIM FOR RELIEF**

(Violation of the Freedom of Information Act  
5 U.S.C. § 552)

34. Plaintiff incorporates every allegation set forth above.

35. The Freedom of Information Act 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 to the agency to do so.

36. When, as in this case, an agency fails to respond within the statutory time frame, the requester will be deemed to have exhausted her administrative remedies and may seek relief in federal court. 5 U.S.C. § 552(a)(6)(A)(i); *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).

37. It has been over 20 working days since Plaintiff submitted her FOIA request.

38. NIH has not yet provided a determination, let alone any response, to Plaintiff's request.

39. Plaintiff's FOIA request is very limited in its scope. The request only asks for three documents, each of which are readily available to the NIH.

40. The draft NTP report(s) at issue in this request are not protected by the deliberative process privilege, for the same reasons that the draft NTP reports were not subject to the deliberative process privilege in *Food & Water Watch v. EPA*, 17-cv-02162-EMC.

41. The December 30, 2021 email from a *non-governmental* person to NTP, which NTP publicly cites and relies upon on its website, is not subject to any privilege under the FOIA.

42. NIH's failure to make a determination on Plaintiff's request is a violation of the statutory deadlines set forth in the FOIA.

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///

///

**REQUESTED RELIEF**

WHEREFORE, Plaintiff prays that this Court:

- A. Issue an order finding that the NIH has violated the FOIA;
- B. Order the NIH to immediately produce the three documents 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.

September 9, 2022

Respectfully submitted,

/s/ Michael Connett  
MICHAEL CONNETT  
WATERS, KRAUS & PAUL  
222 N. Pacific Coast Hwy  
El Segundo, CA 90245  
Tel: 310-414-8146  
Email: [mconnett@waterskraus.com](mailto:mconnett@waterskraus.com)  
*Attorney for Plaintiff*

## **Exhibit 2b**

STEPHANIE M. HINDS (CABN 154284)  
United States Attorney

MICHELLE LO (NYBN 4325163)

Chief, Civil Division

EMMET P. ONG (NYBN 4581369)

Assistant United States Attorney

1301 Clay Street, Suite 340S  
Oakland, California 94612-5217  
Telephone: (510) 637-3929  
Facsimile: (510) 637-3724  
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**

Defendant National Institutes of Health (“NIH”) hereby responds to the complaint (Dkt. No. 1) filed by Plaintiff Kristin Lavelle as follows:

### **INTRODUCTION**<sup>1</sup>

1. Defendant admits that Plaintiff has brought an action against Defendant under the Freedom of Information Act (“FOIA”). The remaining allegations in this paragraph characterize Plaintiff’s complaint, 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 remaining allegations in this paragraph and, therefore, denies them.

### **THE PARTIES**

2. Defendant admits that it received the FOIA request at issue in this action. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and, therefore, denies them.

3. Defendant admits the allegations in the first sentence of this paragraph. Defendant denies the allegations set forth in the second sentence of this paragraph, and avers that the Department of Health and Human Services (“HHS”) is the only proper defendant in this action.

### **JURISDICTION AND VENUE**

4. Admit.

5. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

### **FACTUAL BACKGROUND**

#### **A. The National Toxicology Program (NTP)**

6. Defendant denies the allegations in this paragraph, and avers that NTP is an interagency program composed of, and supported by, three government agencies within HHS: 1) The National Center for Toxicological Research of the Food and Drug Administration; 2) The National Institute of

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<sup>1</sup> Defendant has included the headings listed in the complaint to assist in reading the pleadings and do not admit the accuracy of those headings.

Environmental Health Sciences of NIH; and 3) The National Institute of Occupational Safety and Health of the Centers for Disease Control and Prevention.

7. Defendant admits the allegations in the first sentence of this paragraph. Defendant denies the allegations in the second sentence of this paragraph. Defendant avers that, in carrying out its mission, the federal NTP partners develop and apply new methods, technologies, and research methods, necessary to achieve the vision of innovative and trusted toxicological science that protects human health. Defendant further avers that NTP partners work together to identify potentially hazardous substances and evaluate their effects for human health. Final peer reviewed data, reports, and monographs from NTP projects are freely available on the NTP website, and are used broadly by medical and scientific communities, health research and regulatory agencies, journalists and media professionals, and the public. These data and reports are also used by federal and state agencies to support regulations, create guidelines, or ban hazardous substances.

8. Admit.

9. Admit.

#### **B. Fluoride & Neurodevelopment**

10. Admit.

11. Admit.

12. Deny.

#### **C. NTP's First Report on Fluoride - Neurodevelopmental Effects in Animals**

13. Defendant admits the allegation in the first sentence of this paragraph. Regarding the allegations in the second sentence of this paragraph, Defendant admits that NTP does not make policy determinations. Defendant denies the remaining allegations in in the second 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.

14. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and, therefore, denies them.

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.

27. Admit.

## **LEGAL FRAMEWORK**

### **A. The Statutory Deadline for Agencies to Make a “Determination” Under the FOIA**

28. The allegations in this paragraph characterize the FOIA, a federal statute 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 this paragraph and, therefore, denies them.

29. The allegations in this paragraph characterize judicial opinions in other actions, documents that speaks for themselves and are the best evidence of their content; any allegation contrary to the plain meaning and content of those documents 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 this paragraph and, therefore, denies them.

30. The allegations in this paragraph characterize judicial opinions in other actions, documents that speaks for themselves and are the best evidence of their content; any allegation contrary to the plain meaning and content of those documents 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 this paragraph and, therefore, denies them.

### **B. The Deliberative Process Privilege**

31. The allegations in this paragraph characterize judicial opinions in other actions, documents that speaks for themselves and are the best evidence of their content; any allegation contrary to the plain meaning and content of those documents 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 this paragraph and, therefore, denies them.

32. The allegations in this paragraph characterize judicial opinions in other actions, documents that speaks for themselves and are the best evidence of their content; any allegation contrary to the plain meaning and content of those documents 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 this paragraph and, therefore, denies them.

33. The allegations 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 this paragraph and, therefore, denies them.

### **CLAIM FOR RELIEF**

(Violation of the Freedom of Information Act  
5 U.S.C. § 552)

34. Defendant hereby incorporates by reference its responses to each of the allegations set forth in the preceding paragraphs of Plaintiff's complaint.

35. The allegations in this paragraph characterize the FOIA, a federal statute 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 this paragraph and, therefore, denies them.

36. The allegations in this paragraph characterize judicial opinions in other actions, documents that speak for themselves and are the best evidence of their content; any allegation contrary to the plain meaning and content of those documents 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 this paragraph and, therefore, denies them.

37. Admit.

38. Defendant admits that it has not communicated a determination to Plaintiff regarding the FOIA request at issue. Defendant denies the remaining allegations in this paragraph.

39. Defendant admits that the FOIA request at issue seeks three records. Defendant denies the remaining allegations in this paragraph.

40. Deny.

41. Defendant admits that the e-mail referenced in this paragraph was sent by a person who is not employed by the federal government. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and, therefore, denies them.

42. Deny.

### **REQUESTED RELIEF**

The remainder of the complaint consists of Plaintiff's Requested Relief, to which no response is required. To the extent a response is required, Defendant denies the allegations in the Requested Relief section of the complaint, and denies that Plaintiff is entitled to any of the relief requested in subparts A through D, or to any relief whatsoever from Defendant.

\* \* \*

### **AFFIRMATIVE DEFENSES**

In further answer to the complaint and as separate and distinct defenses to Plaintiff's claims set forth in the complaint, Defendant alleges the following affirmative defenses:

#### **FIRST AFFIRMATIVE DEFENSE**

(Failure to State a Claim)

1. The complaint fails to state a claim upon which relief can be granted.

#### **SECOND AFFIRMATIVE DEFENSE**

(Exhaustion of Administrative Remedies)

2. To the extent that Plaintiff alleges or asserts matters not contained in a legally sufficient and timely administrative claim, this action is barred by a failure to exhaust administrative remedies.

#### **THIRD AFFIRMATIVE DEFENSE**

(Mootness)

3. The complaint raises claims that are moot.

**FOURTH AFFIRMATIVE DEFENSE**

(Statutory FOIA Exemptions)

4. The FOIA request at issues implicates certain information that is protected from disclosure by one of more statutory exemptions. Disclosure of such information is not required or permitted.

Defendant reserves the right to assert additional affirmative defenses as warranted.

**DEFENDANT'S PRAYER FOR RELIEF**

WHEREFORE, Defendant prays that:

1. Plaintiff takes nothing by the complaint;
2. The complaint be dismissed with prejudice;
3. Judgment be entered in favor of Defendant;
4. Defendant be awarded its costs of suit;
5. The Court award such other and further relief, as it may deem proper.

DATED: November 10, 2022

Respectfully submitted,

STEPHANIE M. HINDS  
United States Attorney

/s/ Emmet P. Ong  
EMMET P. ONG  
Assistant United States Attorney

*Attorneys for Defendant National Institutes of Health*

## **Exhibit 3**

---

**From:** Wolfe, Mary (NIH/NIEHS) [E] <[wolfe@niehs.nih.gov](mailto:wolfe@niehs.nih.gov)>

**Sent:** Thursday, April 28, 2022 12:31 PM

**To:** Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <[clh8@cdc.gov](mailto:clh8@cdc.gov)>

**Cc:** Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <[pju3@cdc.gov](mailto:pju3@cdc.gov)>; Berridge, Brian (NIH/NIEHS) [E] <[brian.berridge@nih.gov](mailto:brian.berridge@nih.gov)>; Woychik, Rick (NIH/NIEHS) [E] <[rick.woychik@nih.gov](mailto: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 4**

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**From:** Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <[clh8@cdc.gov](mailto:clh8@cdc.gov)>

**Sent:** Wednesday, May 11, 2022 11:25 AM

**To:** Espinoza, Lorena (CDC/DDNID/NCCDPHP/DOH) <[lee6@cdc.gov](mailto:lee6@cdc.gov)>; Johnson, Nicole (CDC/DDNID/NCCDPHP/DOH) <[nbg5@cdc.gov](mailto:nbg5@cdc.gov)>; Holder, Gregory (CDC/DDNID/NCCDPHP/DOH) <[LHN5@cdc.gov](mailto: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](mailto:wolfe@niehs.nih.gov)>

**Sent:** Wednesday, May 11, 2022 11:12 AM

**To:** Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <[clh8@cdc.gov](mailto:clh8@cdc.gov)>

**Cc:** Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <[pju3@cdc.gov](mailto:pju3@cdc.gov)>; Berridge, Brian (NIH/NIEHS) [E] <[brian.berridge@nih.gov](mailto:brian.berridge@nih.gov)>; Woychik, Rick (NIH/NIEHS) [E] <[rick.woychik@nih.gov](mailto:rick.woychik@nih.gov)>; Mackar, Robin (NIH/NIEHS) [E] <[robin.mackar@nih.gov](mailto:robin.mackar@nih.gov)>; Flowers, Christine B (NIH/NIEHS) [E] <[bruskec@niehs.nih.gov](mailto: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](mailto:wolfe@niehs.nih.gov)



## **Exhibit 5**

**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](mailto:wolfe@niehs.nih.gov)

---

**From:** Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <[pju3@cdc.gov](mailto:pju3@cdc.gov)>

**Sent:** Wednesday, May 11, 2022 4:57 PM

**To:** Wolfe, Mary (NIH/NIEHS) [E] <[wolfe@niehs.nih.gov](mailto:wolfe@niehs.nih.gov)>; Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <[clh8@cdc.gov](mailto:clh8@cdc.gov)>

**Cc:** Mackar, Robin (NIH/NIEHS) [E] <[robin.mackar@nih.gov](mailto:robin.mackar@nih.gov)>; Flowers, Christine B (NIH/NIEHS) [E] <[bruskec@niehs.nih.gov](mailto:bruskec@niehs.nih.gov)>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <[axz7@cdc.gov](mailto:axz7@cdc.gov)>; Promoff, Gabbi (CDC/DDNID/NCCDPHP/OD) <[era6@cdc.gov](mailto:era6@cdc.gov)>; Woychik, Rick (NIH/NIEHS) [E] <[rick.woychik@nih.gov](mailto: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](mailto:khacker@cdc.gov)

Executive Assistant: Shantelle Graham

E-Mail: [sln3@cdc.gov](mailto:sln3@cdc.gov)

On the web @ [www.cdc.gov/chronicdisease/index.htm](http://www.cdc.gov/chronicdisease/index.htm)

Follow NCCDPHP on [Twitter](#)

Join the conversation!



NATIONAL CENTER FOR CHRONIC DISEASE  
PREVENTION AND HEALTH PROMOTION  
[www.cdc.gov](http://www.cdc.gov)

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**From:** Wolfe, Mary (NIH/NIEHS) [E] <[wolfe@niehs.nih.gov](mailto:wolfe@niehs.nih.gov)>

**Sent:** Wednesday, May 11, 2022 11:34 AM

**To:** Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <[clh8@cdc.gov](mailto:clh8@cdc.gov)>; Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <[pju3@cdc.gov](mailto:pju3@cdc.gov)>

**Cc:** Mackar, Robin (NIH/NIEHS) [E] <[robin.mackar@nih.gov](mailto:robin.mackar@nih.gov)>; Flowers, Christine B (NIH/NIEHS) [E] <[bruskec@niehs.nih.gov](mailto:bruskec@niehs.nih.gov)>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <[axz7@cdc.gov](mailto:axz7@cdc.gov)>; Promoff, Gabbi (CDC/DDNID/NCCDPHP/OD) <[era6@cdc.gov](mailto: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](mailto:wolfe@niehs.nih.gov)

---

**From:** Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <[clh8@cdc.gov](mailto:clh8@cdc.gov)>

**Sent:** Wednesday, May 11, 2022 11:27 AM

**To:** Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <[pju3@cdc.gov](mailto:pju3@cdc.gov)>; Wolfe, Mary (NIH/NIEHS) [E] <[wolfe@niehs.nih.gov](mailto:wolfe@niehs.nih.gov)>

**Cc:** Mackar, Robin (NIH/NIEHS) [E] <[robin.mackar@nih.gov](mailto:robin.mackar@nih.gov)>; Flowers, Christine B (NIH/NIEHS) [E] <[bruskec@niehs.nih.gov](mailto:bruskec@niehs.nih.gov)>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <[axz7@cdc.gov](mailto:axz7@cdc.gov)>; Promoff, Gabbi (CDC/DDNID/NCCDPHP/OD) <[era6@cdc.gov](mailto: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](mailto:pju3@cdc.gov)>  
**Sent:** Wednesday, May 11, 2022 11:24 AM  
**To:** Wolfe, Mary (NIH/NIEHS) [E] <[wolfe@niehs.nih.gov](mailto:wolfe@niehs.nih.gov)>; Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <[clh8@cdc.gov](mailto:clh8@cdc.gov)>  
**Cc:** Mackar, Robin (NIH/NIEHS) [E] <[robin.mackar@nih.gov](mailto:robin.mackar@nih.gov)>; Flowers, Christine B (NIH/NIEHS) [E] <[bruskec@niehs.nih.gov](mailto:bruskec@niehs.nih.gov)>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <[axz7@cdc.gov](mailto:axz7@cdc.gov)>; Promoff, Gabbi (CDC/DDNID/NCCDPHP/OD) <[era6@cdc.gov](mailto: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](mailto:wolfe@niehs.nih.gov)>  
**Sent:** Wednesday, May 11, 2022 11:23 AM  
**To:** Hacker, Karen (CDC/DDNID/NCCDPHP/OD) <[pju3@cdc.gov](mailto:pju3@cdc.gov)>; Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <[clh8@cdc.gov](mailto:clh8@cdc.gov)>  
**Cc:** Mackar, Robin (NIH/NIEHS) [E] <[robin.mackar@nih.gov](mailto:robin.mackar@nih.gov)>; Flowers, Christine B (NIH/NIEHS) [E] <[bruskec@niehs.nih.gov](mailto:bruskec@niehs.nih.gov)>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <[axz7@cdc.gov](mailto:axz7@cdc.gov)>; Promoff, Gabbi (CDC/DDNID/NCCDPHP/OD) <[era6@cdc.gov](mailto: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

Email: [wolfe@niehs.nih.gov](mailto:wolfe@niehs.nih.gov)

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

Thank you

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

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

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

111 T.W. Alexander Drive

Research Triangle Park, NC 27709

Phone: 984-287-3209

Email: [wolfe@niehs.nih.gov](mailto:wolfe@niehs.nih.gov)



## **Exhibit 6**

**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](http://www.cdc.gov/washington)  
202-245-0600

## **Exhibit 7**

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](http://AmericanFluoridationSociety.org)  
[REDACTED]  
Email: [DrJohnny@AmericanFluoridationSociety.org](mailto:DrJohnny@AmericanFluoridationSociety.org)



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**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 8**

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

FOOD & WATER WATCH, et al.,

Plaintiffs,

vs.

U.S. ENVIRONMENTAL PROTECTION  
AGENCY, et al.,

Defendants.

CIVIL ACTION

FILE NO.

17-cv-2162-EMC

**ORIGINAL**

VIDEOTAPE RULE 30(b)(6) DEPOSITION OF  
CENTERS FOR DISEASE CONTROL & PREVENTION  
THROUGH  
CASEY HANNAN

Tuesday, November 6, 2018

10:15 a.m.

1600 Clifton Road  
Building 21, Suite 10000  
Atlanta, Georgia

Linda C. Ruggeri, CCR-A-261

1 basically. It's oversight of all the units within the  
2 division, you know, the branches, if you will.  
3 There's a program branch. There's a surveillance,  
4 investigations, and research branch. There's a  
5 science and evaluation team. There's a policy and  
6 communications team. And our mission is to through  
7 population-based approaches prevent the burden of oral  
8 disease to improve people's quality of life and  
9 physical health.

10 **Q. And so what are some of the tasks that go**  
11 **along with fulfilling your responsibilities as acting**  
12 **director?**

13 A. Tasks. Well, a big part of what I do is  
14 in reviewing and clearing documents. So if it's a  
15 scientific document, I'm part of a clearance chain  
16 that ensures that the document has been prepared in a  
17 way consistent with high scientific standards of the  
18 agency, programmatic documents that reflect guidance  
19 to funded and unfunded constituencies, reviewing  
20 policy and communications materials that might be  
21 prepared for places like one-page information sheets,  
22 for our web content. So that's a big portion.

23 Another task is representing the division  
24 with external partners. That could be other federal  
25 partners such as HRSA or NIH. It could be with

1 national partners such as the Association of State and  
2 Territorial Dental Directors. It could be National  
3 Association of Chronic Disease Directors. So  
4 interfacing with partners to coordinate and synergize  
5 efforts basically to hopefully leverage our resources  
6 and theirs in ways that have more beneficial outcomes  
7 on oral disease burden.

8 Q. And you mentioned some partners. Would  
9 the American Dental Association be a partner?

10 A. Yes.

11 Q. And would the Campaign for Dental Health  
12 be a partner?

13 A. I'm trying to remember. Campaign for  
14 Dental Health, I believe so. Is that the one under  
15 the American Association -- the AAP?

16 Q. I think so. I'm not sure.

17 A. I believe so, but I'm not certain.

18 Q. It's the website that's I Like Teeth,  
19 ilikemyteeth.org, I think.

20 A. The same answer. I'm not certain.

21 Q. Okay. So what about American Fluoridation  
22 Society, is that a partner of the CDC's Oral Health  
23 Division?

24 A. I'm not aware that it is.

25 Q. Okay. And in terms of your work's



1 interfacing with the American Dental Association, part  
2 of that would be about working together to promote  
3 community water fluoridation, correct?

4 A. Yes.

5 Q. Okay. And CDC has taken an active role in  
6 promoting water fluoridation, correct?

7 A. Yes.

8 Q. Okay. So you're still the acting  
9 director, correct?

10 A. Correct.

11 Q. What is there -- I mean, are you -- are  
12 you going to be the director or what's the process of  
13 going from acting director to director?

14 A. What's the process from going to acting --  
15 at this point I wouldn't be eligible to apply.

16 Q. Okay. We don't need to go into that. So  
17 now let's talk now about what you did to prepare for  
18 today's deposition. And, first, do you understand  
19 that you are appearing today as a representative of  
20 the CDC?

21 A. I do.

22 Q. And do you have an understanding as to  
23 what this case is about?

24 A. I do.

25 Q. What is your understanding?

## **Exhibit 9**

**Sent:** Mon, 11 Jul 2022 18:24:15 +0000  
**To:** Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH); Boehmer, Tracy (CDC/DDNID/NCCDPHP/DOH)  
**Cc:** Espinoza, Lorena (CDC/DDNID/NCCDPHP/DOH)  
**Subject:** RE: National Fluoridation Advisory Committee meeting July 25-26 Washington DC

Hi Casey,  
Were you planning on attending the meeting in person, going to call in, or not be able to attend? I thought we can begin developing the agenda on what we will share since I will be on level.

Division updates:  
NTP (OASH meeting?)  
New staff

Water Fluoridation updates:  
MITRE

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**From:** Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <clh8@cdc.gov>  
**Sent:** Tuesday, June 28, 2022 4:57 PM  
**To:** Boehmer, Tracy (CDC/DDNID/NCCDPHP/DOH) <opm9@cdc.gov>; Espinoza, Lorena (CDC/DDNID/NCCDPHP/DOH) <lee6@cdc.gov>  
**Subject:** FW: National Fluoridation Advisory Committee meeting July 25-26 Washington DC  
**Importance:** High

Have y'all responded about attending the NFAC meeting?

---

**From:** Grover, Jane <groverj@ada.org>  
**Sent:** Tuesday, June 28, 2022 4:40 PM  
**To:** [mollyeconlon@gmail.com](mailto:mollyeconlon@gmail.com); Jayanth Kumar (CDPH-CDIC) <[Jayanth.Kumar@cdph.ca.gov](mailto:Jayanth.Kumar@cdph.ca.gov)>; Levy, Steven M <[steven-levy@uiowa.edu](mailto:steven-levy@uiowa.edu)>; Pollick, Howard <[Howard.Pollick@ucsf.edu](mailto:Howard.Pollick@ucsf.edu)>; [dkduchon@gmail.com](mailto:dkduchon@gmail.com); [canno208@umn.edu](mailto:canno208@umn.edu); [arianamotavalli@ucla.edu](mailto:arianamotavalli@ucla.edu); [jwolfe@carequest.org](mailto:jwolfe@carequest.org); Hannan, Casey J. (CDC/DDNID/NCCDPHP/DOH) <[clh8@cdc.gov](mailto:clh8@cdc.gov)>; [opma@cdc.gov](mailto:opma@cdc.gov); [jafme52@gmail.com](mailto:jafme52@gmail.com); OConnor, Paul <[oconnorp@ada.org](mailto:oconnorp@ada.org)>  
**Cc:** Wils, Wendy J <[wilsw@ada.org](mailto:wilsw@ada.org)>; Sewell, Earl K. <[sewelle@ada.org](mailto:sewelle@ada.org)>; Clary, Kathy <[ClaryK@ada.org](mailto:ClaryK@ada.org)>  
**Subject:** National Fluoridation Advisory Committee meeting July 25-26 Washington DC  
**Importance:** High

Hello everyone

We're needing to reserve rooms at the hotel for NFAC and due to a busy DC summer, they would like to know today.

Please let me know if you'll be joining us in person or virtually.

Thanks!

Jane

**Jane Grover DDS MPH**

Senior Director

Council on Advocacy for Access and Prevention

(b)(6)

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**American Dental Association** 211 E. Chicago Ave. Chicago, IL 60611 [www.ada.org](http://www.ada.org)

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing was served by Notice of Electronic Filing this 5<sup>th</sup> day of January, 2023, upon all ECF registered counsel of record using the Court's CM/ECF system.

/s/ Michael Connett  
MICHAEL CONNETT  
Attorney for Plaintiffs