

EXHIBIT A

1 Food and Drug Administration.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

27 20. On June 10, 2022, I expanded the scope of the charge to the BSC to include an
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1 adjudication of NTP’s responses to peer-review comments and agency reviewers’ comments on
2 the State of the Science Monograph.

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

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

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

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

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

23 ¹ Those papers are as follows:

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

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

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

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

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

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

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

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

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

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

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

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

8 **Richard P.**
9 **Woychik -S**

Digitally signed by Richard
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