

From: [Iademarco, Michael \(HHS/OASH\)](#)
To: [Boateng, Sarah \(HHS/OASH\)](#)
Cc: [Calsyn, Maura \(HHS/OASH\)](#); [Levine, Rachel \(HHS/OASH\)](#)
Subject: ASH Briefing on Fluoride - National Toxicology Program (NTP) Report
Date: Thursday, June 2, 2022 3:11:20 PM

Sara, keeping you in the loop. There's a point to discuss. Further in a quick scan of the two draft products, independent of any possible scientific limitations, I remain concerned that the messaging on potential fluoride toxicity is not balanced about the well-demonstrated benefits of fluoride on oral health and in turn overall wellbeing. Indeed, the monograph states, "Benefits of fluoride with respect to oral health are not addressed in this monograph." Best, Michael

From: Iademarco, Michael (HHS/OASH)
Sent: Thursday, June 2, 2022 3:00 PM
To: Schwetz, Tara (NIH/OD) [E] <(b)(6)>
Cc: Calsyn, Maura (HHS/OASH) <Maura.Calsyn@hhs.gov>
Subject: RE: ASH Briefing on Fluoride - National Toxicology Program (NTP) Report

Tara,

Thanks for the draft and the overall collaboration to move this forward. I will take a look at both. You are right, Mary did email me on May 16 the monograph draft. After I read it, I might want to see the comment matrix, that is what you are proposing to send to the BSC workgroup.

Thanks for the thoughts on moving forward. I think we need further discussion about the pro/con of using an external BSC workgroup review. Yesterday I heard that the workgroup would review the NIEHS adjudication of internal comments in clearance as part of moving forward, yet below it sounds like they will actually conduct external peer review of the products. I agree with your second bullet point about developing unified messaging for both products and related ones that balances oral health and potential fluoride toxicity. OASH IO Megan and Kelly are setting up the next meeting, a small one, with you and at your discretion with just Rick and Rena.

Best, Michael

From: Schwetz, Tara (NIH/OD) [E] <(b)(6)>
Sent: Thursday, June 2, 2022 1:17 PM
To: Iademarco, Michael (HHS/OASH) <Michael.Iademarco@hhs.gov>
Cc: Calsyn, Maura (HHS/OASH) <Maura.Calsyn@hhs.gov>
Subject: Re: ASH Briefing on Fluoride - National Toxicology Program (NTP) Report

Michael,

Please find attached the following:

- prepublication SoS monograph (draft that was shared previously)
- meta-analysis and supplemental materials

Do let us know if you have any questions.

Best,

Tara A. Schwetz, PhD

Acting Principal Deputy Director, NIH

A: Building 1, Room 138

P: 301-402-3965 | **M:** (b)(6)

From: Tara Schwetz <(b)(6)>

Date: Wednesday, June 1, 2022 at 7:17 PM

To: "Iademarco, Michael (HHS/OASH)" <Michael.Iademarco@hhs.gov>

Cc: "Calsyn, Maura (HHS/OASH)" <Maura.Calsyn@hhs.gov>

Subject: Re: ASH Briefing on Fluoride - National Toxicology Program (NTP) Report

Michael,

I was drafting an email to you when yours came in (even though I didn't get to finish for a while), so good timing! Agree that it went fairly well, and I'm glad to hear that you agree. I'll get you the latest versions of the meta-analysis and the monograph shortly. I definitely do not think they are final—they will still need to undergo the review by the BSC, etc.—so please keep that in mind.

In terms of next steps, we recognize the ASH's concerns and will not publish anything before circling back to brief the ASH. Our tentative plan is outlined below:

- Have a WG of the Board of Scientific Counselors, whose job it is to review the program, assess both the monograph and the meta-analysis, which will then be a decision point.
- If moving forward, we would share the revised version of the monograph with the other relevant OPDIVs and STAFFDIVs and develop a robust communications plan before bringing it back to brief the ASH (unless she would like an update before).
- In parallel, we would submit the meta-analysis to a scientific journal (tent. (b)(5))

Happy to keep you all in the loop throughout, if useful. How does this sound to you?

Best,

Tara A. Schwetz, PhD (*she/her*)

Acting Principal Deputy Director, NIH

A: Building 1, Room 109

Executive Assistant: Caroline Dzokoto-Pomenya (b)(6)

Scheduler: Dina Simon (b)(6)



From: "Iademarco, Michael (HHS/OASH)" <Michael.Iademarco@hhs.gov>

Date: Wednesday, June 1, 2022 at 4:30 PM

To: Tara Schwetz <(b)(6)>

Cc: "Calsyn, Maura (HHS/OASH)" <Maura.Calsyn@hhs.gov>

Subject: RE: ASH Briefing on Fluoride - National Toxicology Program (NTP) Report

Tara, I think that went well, better, more transparency, surfacing the debate, had almost all the players at the table, well organized with solid discussion time—so I think it worthwhile. Thanks to you and your NIH colleagues. The issue still remains unresolved, and I will advise OASH immediate office to proceed with next smaller meeting: you and the two institute directors (but am open to other configurations, such as just you). Can you send Maura and I the latest two drafts and the comments matrix that was mentioned, presumably the list of comments made and NIEHS's adjudication matrix? I want to review the two documents and the document matrices before the meeting. Best, Michael

-----Original Appointment-----

From: Levine, Rachel (HHS/OASH) <Rachel.Levine@hhs.gov>

Sent: Friday, May 13, 2022 12:45 PM

To: Levine, Rachel (HHS/OASH); Schwetz, Tara (NIH/OD) [E]; Woychik, Rick (NIH/NIEHS) [E];

lademarco, Michael (HHS/OASH); Boateng, Sarah (HHS/OASH); Calsyn, Maura (HHS/OASH); D'Souza, Rena (NIH/NIDCR) [E]; Howard, John (CDC/NIOSH/OD); Berridge, Brian (NIH/NIEHS) [E]; O'Shaughnessy, Jacqueline A (FDA/OC); Joskow, Renee (NIH/NIDCR) [E]

Cc: Fisher, Megan (HHS/OASH); Lee, Kinbo (HHS/OASH); Cure, Kelly (OS/OASH) (CTR); Gray, Oneika (HHS/OASH); Wolfe, Mary (NIH/NIEHS) [E]

Subject: ASH Briefing on Fluoride - National Toxicology Program (NTP) Report

When: Wednesday, June 1, 2022 3:00 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://hhs.gov.zoomgov.com> (b)(6)

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