

From: [Levine, Rachel \(HHS/OASH\)](#)
To: [Iademarco, Michael \(HHS/OASH\)](#); [Oh, Kathy \(OS/OASH\)](#)
Cc: [States, Leith \(HHS/OASH\)](#); [Boateng, Sarah \(HHS/OASH\)](#); [Calsyn, Maura \(HHS/OASH\)](#); [Mitra, Jenny \(ASPR/BARDA/OD\)](#); [Mataka, Arsenio \(HHS/OASH\)](#)
Subject: RE: Fluoride Discussion
Date: Sunday, August 21, 2022 2:06:50 PM
Attachments: [image003.png](#)
[image005.png](#)

RADM Iademarco, Good afternoon. Thank you for your email and the information, RLL

Rachel L. Levine, M.D.

ADM, United States Public Health Service

Assistant Secretary for Health

Office of the Assistant Secretary for Health

Email: rachel.levine@hhs.gov
hhs.gov/ash



From: Iademarco, Michael (HHS/OASH) <Michael.Iademarco@hhs.gov>
Sent: Thursday, August 18, 2022 4:46 PM
To: Levine, Rachel (HHS/OASH) <Rachel.Levine@hhs.gov>; Oh, Kathy (OS/OASH) <Kathy.Oh@hhs.gov>
Cc: States, Leith (HHS/OASH) <Leith.States@hhs.gov>; Boateng, Sarah (HHS/OASH) <Sarah.Boateng@hhs.gov>; Calsyn, Maura (HHS/OASH) <Maura.Calsyn@hhs.gov>; Mitra, Jenny (HHS/OASH) <Jenny.Mitra@hhs.gov>; Mataka, Arsenio (HHS/OASH) <Arsenio.Mataka@hhs.gov>
Subject: Fluoride Discussion

ADM Levine, The process details are outlined in this email chain and being led by Dr. Rick Woychick, director, NIEHS. Following a call for nominations, he is working with the NTP Board of Scientific Counselors to form a workgroup (not a sub-committee), which should be in place with five carefully vetted expert members by the end of August. He expects they will first meet in early September. The charge is outlined in the attachment. As a workgroup, the meetings will not be open to the public. I think we are on track. Best, Michael

From: Woychik, Rick (NIH/NIEHS) [E] <(b)(6)>
Sent: Thursday, August 18, 2022 10:16 AM
To: Schwetz, Tara (NIH/OD) [E] <(b)(6)>; Iademarco, Michael (HHS/OASH) <Michael.Iademarco@hhs.gov>
Cc: Simon, Dina (NIH/OD) [C] <(b)(6)>; Calsyn, Maura (HHS/OASH) <Maura.Calsyn@hhs.gov>; Oh, Kathy (OS/OASH) <Kathy.Oh@hhs.gov>; Lee, Kinbo (HHS/OASH) <Kinbo.Lee@hhs.gov>; Boateng, Sarah (HHS/OASH) <Sarah.Boateng@hhs.gov>; States, Leith (HHS/OASH) <Leith.States@hhs.gov>; D'Souza, Rena (NIH/NIDCR) [E] <(b)(6)>; Mitra, Jenny (HHS/OASH) <Jenny.Mitra@hhs.gov>

Subject: RE: Fluoride Discussion

Just a couple additional comments.

The National Toxicology Program is a virtual collaboration with just NCTR (FDA), NIOSH (CDC) and the DNTP (NIEHS). The two manuscripts that are under consideration are products of this virtual collaboration. The NTP has its own Board of Scientific Counselors (BSC), which is a FACA committee charged specifically with overseeing the work and the products of this virtual collaboration.

Let us know if you have other questions.

I apologize for the delay in getting this moving. This is my first time through having to engage the BSC in this type of activity, and it's the first time that the Director of the NTP has ever engaged the BSC in this way. It's also complicated by the fact that Dr. Berridge has announced that he will be stepping down as Scientific Director of our DNTP, which is responsible for generating most of the data for the two publications.

All the best,
Rick

From: Schwetz, Tara (NIH/OD) [E] <(b)(6)>
Sent: Thursday, August 18, 2022 9:48 AM
To: Iademarco, Michael (HHS/OASH) <Michael.Iademarco@hhs.gov>; Woychik, Rick (NIH/NIEHS) [E] <(b)(6)>
Cc: Simon, Dina (NIH/OD) [C] <(b)(6)>; Calsyn, Maura (HHS/OASH) <Maura.Calsyn@hhs.gov>; Oh, Kathy (OS/OASH) <Kathy.Oh@hhs.gov>; Lee, Kinbo (HHS/OASH) <Kinbo.Lee@hhs.gov>; Boateng, Sarah (HHS/OASH) <Sarah.Boateng@hhs.gov>; States, Leith (HHS/OASH) <Leith.States@hhs.gov>; D'Souza, Rena (NIH/NIDCR) [E] <(b)(6)>; Mitra, Jenny (HHS/OASH) <Jenny.Mitra@hhs.gov>
Subject: Re: Fluoride Discussion

Michael,

Please see below (in **purple**) for responses to your questions. Let us know if you have further questions.

Best,

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

Acting Principal Deputy Director, NIH

A: Building 1, Room 109

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

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

Date: Thursday, August 18, 2022 at 9:16 AM

To: "Woychik, Rick (NIH/NIEHS) [E]" <(b)(6)>, Tara Schwetz
<(b)(6)>, "Woychik, Rick (NIH/NIEHS) [E]" <(b)(6)>
Cc: "Simon, Dina (NIH/OD) [C]" <(b)(6)>, "Calsyn, Maura (HHS/OASH)"
<Maura.Calsyn@hhs.gov>, "Oh, Kathy (OS/OASH)" <Kathy.Oh@hhs.gov>, "Lee, Kinbo
(HHS/OASH)" <Kinbo.Lee@hhs.gov>, "Boateng, Sarah (HHS/OASH)"
<Sarah.Boateng@hhs.gov>, "States, Leith (HHS/OASH)" <Leith.States@hhs.gov>, "D'Souza,
Rena (NIH/NIDCR) [E]" <(b)(6)>, "Mitra, Jenny (HHS/OASH)"
<Jenny.Mitra@hhs.gov>
Subject: RE: Fluoride Discussion

Thanks everyone. Progress. Two questions...

1. If I recall the [NTP](#) is a federal advisory committee. **The NTP itself is an interagency program. The NTP BSC is a FACA committee.**
2. Is this subgroup of experts being formed a workgroup or a subcommittee? **It will be a working group of the NTP BSC, particularly since it will be time-limited. That is, it's not a standing subcommittee.**
3. Will their meetings be open to the public? **The WG meetings will not be public; however, they will report out on their recommendations at a public meeting of the NTP BSC.**

Best, Michael

From: Woychik, Rick (NIH/NIEHS) [E] <(b)(6)>
Sent: Wednesday, August 17, 2022 3:14 PM
To: Schwetz, Tara (NIH/OD) [E] <(b)(6)>; Iademarco, Michael (HHS/OASH)
<Michael.Iademarco@hhs.gov>; Woychik, Rick (NIH/NIEHS) [E] <(b)(6)>
Cc: Simon, Dina (NIH/OD) [C] <(b)(6)>; Calsyn, Maura (HHS/OASH)
<Maura.Calsyn@hhs.gov>; Oh, Kathy (OS/OASH) <Kathy.Oh@hhs.gov>; Lee, Kinbo (HHS/OASH)
<Kinbo.Lee@hhs.gov>; Gray, Oneika (HHS/OASH) <Oneika.Gray@hhs.gov>; Boateng, Sarah
(HHS/OASH) <Sarah.Boateng@hhs.gov>; Fisher, Megan (HHS/OASH) <Megan.Fisher@hhs.gov>;
States, Leith (HHS/OASH) <Leith.States@hhs.gov>; D'Souza, Rena (NIH/NIDCR) [E]
<(b)(6)>; Mitra, Jenny (HHS/OASH) <Jenny.Mitra@hhs.gov>
Subject: RE: Fluoride Discussion

Dear RADM Iademarco,

In response to the email you sent to Dr. Schwetz last Tuesday (see below), I am sending you a summary of where we stand relative to the WG to evaluate the two fluoride documents. I am also attaching a copy of the memo that I sent to you and the other key stakeholders across HHS last June which highlighted the "charge" to the WG.

Please let us know if you have any questions.

All the best,
Tara and Rick

Update on NTP Fluoride Study Activities

NIEHS Boord of Scientific Counselors (BSC) Working Group Development—Completed Steps

NIEHS worked with Dr. Eaton, NTP BSC Chair, to develop a process to create a working group of the outside experts to review the NTP fluoride documents.

- Initial screening of the 20 Nominees received from stakeholder agencies identified information about each person including affiliation, position, research topics, areas of expertise from websites, LinkedIn, etc.
- Each person was then evaluated for their participation/affiliation with fluoride activities (NASEM panel, fluoride-related publications, webinars/symposia, public comments to NASEM).
- Dr. Eaton identified 6 possible candidates and then conducted an in-depth COI screening via Lexis/Nexis (news articles and networks), SCOPUS (2019-2022, looked at topic, cross-checked collaborators with other potential WG members and persons involved with NTP fluoride project), Google (podcast topics, news articles, opinion pieces, etc.).
- From this group, 5 persons were best qualified without any COIs.

Thus far, Dr. Eaton and NIEHS has held these confidential interviews by zoom with all 5 individuals. WG candidates were told about the WG activity including charge, timeline, SoS and meta-analysis documents, honorarium, expertise areas needed, WG's product, BSC meeting, etc. All 5 are willing to continue with the process.

NIEHS BSC Working Group Development—Ongoing Steps

Dr. Eaton and NIEHS leadership will review all of the details relating to the qualifications and COIs for the nominated candidates during the last week of August in preparation for an HHS stakeholder meeting. NIEHS is scheduling this meeting for early September when the HHS stakeholders are all available.

Following the meeting with the HHS stakeholder group, a COI screening package will be sent to persons who are interested and qualified in participating on the WG. The package will identify the chemical and topic of the systematic review/meta-analysis and will ask for standard information (e.g., CV, COI form, anti-lobbying form) and ask about relationships with listed staff who have been involved in development/review of the two documents.

NIEHS BSC Working Group Development—Next Steps

Materials [e.g., CV, COI form, search results (i.e., Lexis/Nexis, SCOPUS, Google)] will be shared with Dr. Eaton and NIEHS leadership for their approval of the WG membership.

The goal is to have the COI screening and have the proposed BSC WG identified by Aug 31. In early September, at a time when the HHS stakeholders are available, the stakeholder group will be convened to provide detailed reasoning for the choice of the WG members and to confirm the next steps. Then, Dr. Eaton will officially charge the working group (see attached document that Dr. Woychik shared with the stakeholder group last June, which includes the language describing the charge). Of note, this is not meant to be a thorough peer review of both manuscripts, but rather will be a focused effort of the working group dedicated to be: a)

primarily an adjudication of the written comments from key stakeholders (e.g., NIDCR, NIH-OD, FDA, CDC, and OASH), b) secondarily to provide any additional insights into the quality of the work, including whether strength of the underlying data was appropriately and thoroughly assessed.

The WG will meet as necessary to consider the elements of the charge, and then will make recommendations to the NTP BSC, which will then conduct a public session to review the recommendations from the WG. The Chair of the NTP BSC will then make recommendations to Dr. Woychik, who will decide how to proceed with the two publications after meeting with the HHS stakeholder group, including the ASH.

From: Schwetz, Tara (NIH/OD) [E] <(b)(6)>
Sent: Tuesday, August 9, 2022 11:51 PM
To: Iademarco, Michael (HHS/OASH) <Michael.Iademarco@hhs.gov>
Cc: Simon, Dina (NIH/OD) [C] <(b)(6)>; Calsyn, Maura (HHS/OASH) <Maura.Calsyn@hhs.gov>; Oh, Kathy (OS/OASH) <Kathy.Oh@hhs.gov>; Lee, Kinbo (HHS/OASH) <Kinbo.Lee@hhs.gov>; Gray, Oneika (HHS/OASH) <Oneika.Gray@hhs.gov>; Boateng, Sarah (HHS/OASH) <Sarah.Boateng@hhs.gov>; Fisher, Megan (HHS/OASH) <Megan.Fisher@hhs.gov>; Woychik, Rick (NIH/NIEHS) [E] <(b)(6)>; States, Leith (HHS/OASH) <Leith.States@hhs.gov>; D'Souza, Rena (NIH/NIDCR) [E] <(b)(6)>; Mitra, Jenny (HHS/OASH) <Jenny.Mitra@hhs.gov>
Subject: Re: Fluoride Discussion

Michael,

You read my mind! I was actually in NC today, visiting the NIEHS campus, and Rick and I discussed providing an update soon. We'll get something together and get it to you next week.

Best,

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

Acting Principal Deputy Director, NIH

A: Building 1, Room 109

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

From: "Iademarco, Michael (HHS/OASH)" <Michael.Iademarco@hhs.gov>
Date: Tuesday, August 9, 2022 at 2:53 PM
To: Tara Schwetz <(b)(6)>
Cc: "Simon, Dina (NIH/OD) [C]" <(b)(6)>, "Calsyn, Maura (HHS/OASH)" <Maura.Calsyn@hhs.gov>, "Oh, Kathy (OS/OASH)" <Kathy.Oh@hhs.gov>, "Lee, Kinbo (HHS/OASH)" <Kinbo.Lee@hhs.gov>, "Gray, Oneika (HHS/OASH)" <Oneika.Gray@hhs.gov>, "Boateng, Sarah (HHS/OASH)" <Sarah.Boateng@hhs.gov>, "Fisher, Megan (HHS/OASH)"

<Megan.Fisher@hhs.gov>, "Woychik, Rick (NIH/NIEHS) [E]" <(b)(6)>, "States, Leith (HHS/OASH)" <Leith.States@hhs.gov>, "D'Souza, Rena (NIH/NIDCR) [E]" <(b)(6)>, "Mitra, Jenny (HHS/OASH)" <Jenny.Mitra@hhs.gov>
Subject: RE: Fluoride Discussion

Tara, I'd like to provide a brief update summary to ADM Levine in the next week or so. Could you help facilitate? Best, Michael

From: D'Souza, Rena (NIH/NIDCR) [E] <(b)(6)>
Sent: Wednesday, June 29, 2022 6:08 AM
To: Levine, Rachel (HHS/OASH) <Rachel.Levine@hhs.gov>; Iademarco, Michael (HHS/OASH) <Michael.Iademarco@hhs.gov>; Boateng, Sarah (HHS/OASH) <Sarah.Boateng@hhs.gov>
Cc: Simon, Dina (NIH/OD) [C] <(b)(6)>; Calsyn, Maura (HHS/OASH) <Maura.Calsyn@hhs.gov>; Handley, Elisabeth (OS/OASH) <Elisabeth.Handley@hhs.gov>; Oh, Kathy (OS/OASH) <Kathy.Oh@hhs.gov>; Lee, Kinbo (HHS/OASH) <Kinbo.Lee@hhs.gov>; Gray, Oneika (HHS/OASH) <Oneika.Gray@hhs.gov>; Fisher, Megan (HHS/OASH) <Megan.Fisher@hhs.gov>; Schwetz, Tara (NIH/OD) [E] <(b)(6)>; Woychik, Rick (NIH/NIEHS) [E] <(b)(6)>; States, Leith (HHS/OASH) <Leith.States@hhs.gov>
Subject: Re: Fluoride Discussion

Thank you for this summary VADM Iademarco.

Minor edits and 2 comments from me for you to consider.

Best, Rena

Rena N. D'Souza, D.D.S., M.S., Ph.D.,

Director,

National Institute of Dental and Craniofacial Research/NIH

31 Center Drive, MSC 2290 Building 31C, Suite 2C39

Chief,

Section on Molecules & Therapies for Craniofacial & Dental Disorders

National Institute of Child Health and Human Development

National Institutes of Health

Bethesda, Maryland 20892

Email: <(b)(6)>

Phone: 301-496-3571

Cell: <(b)(6)>

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

Date: Tuesday, June 28, 2022 at 8:15 PM

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

Cc: Simon, Dina (NIH/OD) [C] <(b)(6)>, Calsyn, Maura (HHS/OASH) <Maura.Calsyn@hhs.gov>, Handley, Elisabeth (OS/OASH) <Elisabeth.Handley@hhs.gov>, Oh, Kathy (OS/OASH) <Kathy.Oh@hhs.gov>, Lee, Kinbo (HHS/OASH) <Kinbo.Lee@hhs.gov>, Gray, Oneika (HHS/OASH) <Oneika.Gray@hhs.gov>, Fisher, Megan (HHS/OASH) <Megan.Fisher@hhs.gov>, Schwetz, Tara (NIH/OD) [E] <(b)(6)>, D'Souza, Rena (NIH/NIDCR) [E] <(b)(6)>, Woychik, Rick (NIH/NIEHS) [E] <(b)(6)>, States, Leith (HHS/OASH) <Leith.States@hhs.gov>

Subject: RE: Fluoride Discussion

RADM Iademarco, Sounds good, Thanks, RLL

Rachel L. Levine, M.D.

ADM, United States Public Health Service

Assistant Secretary for Health

Office of the Assistant Secretary for Health

Email: rachel.levine@hhs.gov
hhs.gov/ash



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

Sent: Tuesday, June 28, 2022 3:26 PM

To: Levine, Rachel (HHS/OASH) <Rachel.Levine@hhs.gov>; Boateng, Sarah (HHS/OASH) <Sarah.Boateng@hhs.gov>

Cc: Simon, Dina (NIH/OD) [C] <(b)(6)>; Calsyn, Maura (HHS/OASH) <Maura.Calsyn@hhs.gov>; Handley, Elisabeth (OS/OASH) <Elisabeth.Handley@hhs.gov>; Oh, Kathy (OS/OASH) <Kathy.Oh@hhs.gov>; Lee, Kinbo (HHS/OASH) <Kinbo.Lee@hhs.gov>; Gray, Oneika (HHS/OASH) <Oneika.Gray@hhs.gov>; Fisher, Megan (HHS/OASH) <Megan.Fisher@hhs.gov>; Schwetz, Tara (NIH/OD) [E] <(b)(6)>; D'Souza, Rena (NIH/NIDCR) [E] <(b)(6)>; Woychik, Rick (NIH/NIEHS) [E] <(b)(6)>; States, Leith (HHS/OASH) <Leith.States@hhs.gov>

Subject: RE: Fluoride Discussion

ADM Levine, Attached is a meeting summary that Tara and I worked out, just to capture the approach. Anyone copied, should let me know if there are any concerns. Based on communications with the NIH, these steps are underway. V/r, Michael

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

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

Sent: Thursday, June 2, 2022 8:02 PM

To: Levine, Rachel (HHS/OASH); Levine, Rachel (HHS/OASH); Schwetz, Tara (NIH/OD) [E]; D'Souza, Rena (NIH/NIDCR) [E]; Woychik, Rick (NIH/NIEHS) [E]; Iademarco, Michael (HHS/OASH); Boateng, Sarah (HHS/OASH)

Cc: Simon, Dina (NIH/OD) [C]; Calsyn, Maura (HHS/OASH); Handley, Elisabeth (OS/OASH); Oh, Kathy (OS/OASH); Cure, Kelly (OS/OASH) (CTR); Lee, Kinbo (HHS/OASH); Gray, Oneika (HHS/OASH); Fisher, Megan (HHS/OASH)

Subject: Fluoride Discussion

When: Monday, June 6, 2022 5:30 PM-6:00 PM (UTC-05:00) Eastern Time (US & Canada).

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

(b)(6)

ADM Rachel Levine is inviting you to a scheduled ZoomGov meeting.

Join ZoomGov Meeting

<https://hhsgov.zoomgov.com> (b)(6)

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Meeting ID: (b)(6)

Find your local number: <https://hhsgov.zoomgov.com> (b)(6)

Join by SIP

(b)(6)@sip.zoomgov.com

Join by H.323

(b)(6)

Meeting ID: (b)(6)

Passcode: (b)(6)