From:	Fisher, Megan (HHS/OASH)
To:	Levine, Rachel (HHS/OASH)
Cc:	Boateng, Sarah (HHS/OASH); Handley, Elisabeth (OS/OASH); Iademarco, Michael (CDC/DDPHSS/CSELS/OD); Mataka, Arsenio (HHS/OASH); Calsyn, Maura (HHS/OASH); Lee, Kinbo (HHS/OASH); Oh, Kathy (OS/OASH)
Subject:	Background Material _ Meeting with ADA_01182022
Date:	Tuesday, January 18, 2022 11:08:21 AM
Attachments:	Background _ Meeting with American Dental Association _ 01.18.2022 v2.docx image001.png image002.png

---

Good morning ADM Levine,

We mentioned materials this morning for the ADA and you had acknowledge that you have the content. However, just in case – here is a compiled document with recent information from the discussions on Fluoride and the Amalgam issues.

Best,

Megan

Megan Fisher (she/her)

Special Assistant to ADM Rachel Levine

Assistant Secretary for Health

Office of the Assistant Secretary for Health

Email: megan.fisher@hhs.gov

Mobile: (b)(6)

hhs.gov/ash

Deliberative and pre-decisional communication

BRIEFING MEMO FOR ASSISTANT SECRETARY ADMIRAL LEVINE

Event: Meeting with American Dental Association

Event Date: January 18, 2022

Event Time: 12:00 PM ET

Location: Zoom

Staffing: RADM Iademarco, Arsenio Mataka, and Sarah Boateng

Version: 2

MEETING REQUEST INFO:

1) **Topic:** NTP Fluoride State-of-the-Science Report and FDA Dental Amalgam Recommendations

2) **Desired outcome of the meeting:** To ensure ADM Levine is fully briefed ahead of her scheduled meetings with (1) NTP/NIEHS staff about the neurotoxicity of fluoride and (2) CMS and HRSA staff about their promotion of FDA's dental amalgam recommendations.

3) **ADM Levine's role:** ADM Levine's main role would be to listen. We'd like to share the full history of how these projects/topics have unfolded, and to express our concerns about (and praise for) how the agencies have handled those projects/topics, both of which pre-date her term as Assistant Secretary for Health. (This meeting would essentially be contextual prep for her already-scheduled meetings with agency staff.)

BACKGROUND:

Letter from Oral Health Pandemic Response Workgroup:

Oral Health Pandemic Response Workgroup, which includes the ADA, sent a letter to Adm. Rachel L. Levine…asking that oral health be included in the revision of the HHS Strategic Plan and other policy, legislative, regulatory and administrative activities as integral to overall health. *We've since provided them with the paperwork to request a meeting and will be in the process of scheduling.*

A separate letter was sent to Micky Tripathi, Ph.D. National Coordinator at the Office of the National Coordinator for Health Information Technology (ONC). The letter asked for help improving the integration of medical and oral health care data and stated "Sharing patient data between medical and dental providers could significantly improve patients' dental and medical outcomes."

Additional requests in the letter include:

1. Ensuring that oral health experts, including practitioners, are included on all health policy commissions, task forces, and health-related meetings hosted by the Administration;
2. Ensuring that oral health is taken into account in all health policy decision-making; and
3. Convening an oral health summit or creating other opportunities to seek input from oral health stakeholders about opportunities for HHS to advance oral health and oral/medical integration.

Fluoride – Recent NTP/NIH Briefing:

At the last NTP meeting, two groups at NIH briefed ADM Levine on the possible neurocognitive effects of fluoride and its benefits.

Globally, we are seeing debate over this issue as several countries in Europe have stopped water Fluoridation(see Peckham, 2014).

At the NTP, the NIH science on the toxicology was presented. A consideration is how we present the information. If the emerging US data (there is a new neurocognitive problem with fluoride) are presented in isolation, based on Europe's experience, we may have unnecessary confusion and debate. It may be beneficial to frame the results in terms of the bigger picture. In order to frame the issue in from holistic approach, the associated data related to burden, impact, and cost (not just dental carries but the secondary effects) needs to be culled and analyzed for comparison.

The "comparison" is quite complicated due to the intertwined effects of education, myriad fluoride exposure (water, toothpaste, dental

treatments), dental hygiene and care (visits, quality of care, sealants [which can have fluoride], for example.

National Dental Data:

- As a nation, at least 4 out of 5 Americans aged 6 years and older have experienced tooth decay, irrespective of poverty or race/ethnicity status
- In particular, we see higher levels of caries experience in the primary (baby) teeth of young Hispanic and Black children
- National Health Survey data have shown that among children and adolescents aged 2 to 19 years, the prevalence of total dental caries experience and of untreated caries were significantly higher in non-Hispanic Black youth compared with non-Hispanic White youth"
- Caries prevalence is higher for those living in poverty compared to those living in more affluent households (65% vs. 49%)
- 64 million people live in dental health professional shortage areas), and access/ transportation are significant, especially in rural areas
- The increase in youth with dental insurance has also paralleled a considerable reduction in out-of-pocket dental expenditures for children (from mean of $155 to $100) and for adolescents (from mean of $444 to $418) between 1999-2004 and 2011-2014.
- For older adults, mean out of pocket expenses have continued to climb even after adjusting for inflation (2015 dollars) from $539 to $568.
- More than half of working-age adults living in poverty have untreated caries (52%), whereas only 1 out of 5 adults with incomes of twice the FPG or higher have untreated caries (20%) (Figure 18). Twenty years ago, a typical working-age adult living in poverty had about four tooth surfaces affected by untreated caries, whereas a more affluent adult had only one tooth surface affected by untreated caries

Dr. Judy Steinberg's Talking Points – Strengthen Primary Care Initiative:

- OASH launched an initiative to Strengthen Primary Heath Care in Sept 2021
- The Initiative's first task is to develop an HHS Plan for strengthening primary health care to move us from the current state to a goal state of primary care

- The goal state of primary care includes integration of services in primary care, including oral health
- The OASH Primary Care team is meeting with external stakeholders about the Initiative, including dental societies to hear their perspectives and innovations in oral health and primary care integration. The Primary Care team would welcome the opportunity to speak with the ADA.

Amalgam – State of Play

Back in September 2021, FDA issued updated recommendations concerning dental amalgam and potential risks to certain high-risk individuals that may be associated with these mercury-containing fillings used to restore the missing structure and surfaces of a decayed tooth.

The FDA found that certain groups may be at greater risk for potential harmful health effects of mercury vapor released from the device. This finding resulted in FDA recommending certain high-risk groups avoid getting dental amalgam whenever possible and appropriate. Those groups include:

- Pregnant women and their developing fetuses;
- Women who are planning to become pregnant;
- Nursing women and their newborns and infants;
- Children, especially those younger than six years of age;
- People with pre-existing neurological disease such as multiple sclerosis, Alzheimer's disease or Parkinson's disease
- People with impaired kidney function; and
- People with known heightened sensitivity (allergy) to mercury or other components of dental amalgam.

In December 2021, staff at the White House Council on Environmental Quality reached out to our Office regarding the use of amalgam. CEQ took a meeting with health advocates who raised concerned about the use of dental amalgam in light of FDA's recent recommendation. Arsenio convened a group of HHS (FDA, CMS, IHS, NIH) subject matter experts working on this issue. On December 17, 2021, those meeting participants met with CEQ and health advocates to discuss the group's concerns. The

take-away or ask from the group was to the administration – at least stop using amalgam in federal facilities.

Generally speaking, the use of dental amalgam is declining. Dr. Chalmers (Chief Dental Officer CMS) and Arsenio Mataka worked with Fair Health to pull private insurance claim data that supports the declining trend of use. Data from IHS, Department of Defense, Bureau of Prisons generally support the declining trend as well. **We are still waiting for CMS to provide Medicaid data on amalgam use.**

Stephanie Psaki and Arsenio Mataka met with the Andrew Clark from the State Department to discuss the Minamata Convention on Mercury. The European Union and Africa Countries have proposed amendments to phase down amalgam use.

We are still trying to gather insights internally here at HHS on whether there is more that can be done to limit the use of amalgam. A path here would have to be carefully designed. One path, could be a narrow commitment at Minamata where the Federal Government commits to phase out for Federal Agencies.

REFERENCES

- Oral Health Pandemic Response Group (includes ADA)
- Oral Health Pandemic Response Workgroup Urges Federal Prioritization of Oral Health | CareQuest Institute for Oral Health
- Their letter to ASH
- ADA.org/Advocacy
- Fluoride: Potential Developmental Neurotoxicity (nih.gov)
- 2014 Beckham, Water Fluoridation: A Critical Review of the Physiological Effects of Ingested Fluoride as a Public Health Intervention
- Dental Amalgam Fillings | FDA
- FDA Recommendations on Dental Amalgam, September 2020 (mo.gov) (TPs)
- Oral Health | CDC (About 100 million Americans don't have fluoridated water, so they have higher IQs?)
- Dental Amalgam Fillings | FDA
- Oral Health | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov)

- cib-07-10-2014.pdf (medicaid.gov)
- Quality Oral Health Care through Health Information Technology | Digital Healthcare Research (ahrq.gov)