From: Clifton Hill
Sent: 3/26/2024 6:17:11 AM
To: DOH WSBOH
Cc:
Subject: Fluoride is unnecessary and toxic

External Email

Dear Board Members,

I understand there was a recent hearing on fluoride in our water systems. I can tell you that my wife and I, and our three kids have been off fluoride for 17 years. We have no cavities. My kids have never had fluoride in their regular drinking water source, other than minimal when we go to a restaurant, and we rarely do that. And they have great teeth.

Sodium Fluoride is toxic and unnecessary. There are cities that do not add any fluoride. Such as Portland, Oregon.

--
Regards,
Clifton Hill

From: bill teachingsmiles.com
Sent: 4/1/2024 7:01:14 PM
To: DOH WSBOH
Subject: Public Comment for April 2024

External Email

Washington State Board of Health

Public Comment, April, 2024

Dear Board Members,

We have repeatedly asked the Board of Health to hold a "forum" as required by the Legislature. At the March 2024 Board meeting, the Board cherry picked members of the fluoridation lobby to provide endorsements of benefit (efficacy) and uncertainty about harm, such as damage to teeth, brains, kidneys, intestines, bones, thyroid, enzymes and the power house of every cell of the body, harm to the mitochondria.

By cherry picking participants who cherry pick evidence, the conclusion was determined prior to the presentations. In effect, the Board held a "rally" to support policy rather than a "forum" to protect the public health.

I didn't hear the fluoridation lobby mention to the Board that the U.S. Surgeon General no longer publicly endorses fluoridation?
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fchildrenshealthdefense.org%2Fde
fluoridation-us-surgeon-general-stop-support-lower-
iq%2F%3Futm_source%3Dluminate%26utm_medium%3Demail%26utm_campaign%3Ddefender%26utm_
Or that most developed countries do not support fluoridation.

The Board of Health failed to follow the law and failed to protect the public health with a rally.

"RCW 43.20.050 Powers and duties of state board of health . . . The state board of health shall provide a forum for the development of public health. . ."

(2) In order to protect public health, the state board of health shall:(a) Adopt rules . . . to assure safe and reliable public drinking water and to protect the public health." (emphasis supplied)

The Legislature does not include in the duty of the Board of Health the requirement to assure "benefit" or "efficacy?" NO. The Board is to assure safety, not to determine benefit, which is the duty of the FDA.

In research we can ethically perform high quality studies (randomized controlled trials RCTs) to determine benefit, good, efficacy. However, we cannot study "harm" or "risk" by intentionally causing harm with RCTs. Thus, the research of harm will always have "uncertainty" especially for those with vested interests.

The fluoridation lobby exaggerated and speculated to the Board on the benefits of fluoridation with endorsements and created uncertainty of harm. Board members are too young to remember how many decades it took to become confident tobacco smoking

(tobacco lobby) and lead (oil and paint lobbies) caused harm. Proponents constantly raised "uncertainty" regarding the evidence of harm. The fossil fuel industry and others are doing the same for global warming, "uncertainty." And the fluoridation lobby is doing the same for fluoride.

□□□□□We have more than 70 human studies reporting harm to the developing brain. The National Toxicology Program reported 18 of 19 high quality studies report harm. In court, Judge Chan asked the fluoridation lobby expert, "how many more studies would you need to be confident fluoride ingestion causes harm?" (paraphrased) The expert responded, "one or two more good studies." And those have and are being done and the fluoridation lobby, like the tobacco, lead, DDT and global warming lobbies, respond "we need more study." The NTP took 8 years of study on just one risk of excess fluoride exposure.

A big difference between fluoride and other toxins, fluoride is intentionally given with a misguided belief in significant benefit and is controlled by authorities without dosage informed consent or authorized FDA oversight.

Congress gave the job of determining efficacy, dosage, safety, label and good manufacturing practices of all substances with "INTENT" to prevent disease in humans to the U.S. Food and Drug Administration. Should the Board choose to follow the Washington State Legislature, the Board will rely on the Food and Drug Administration rather than endorsements from the fluoridation lobby.

The FDCA (Food Drug and Cosmetic Act and RCW) explicitly makes articles "drugs when the "intent" for use is in the treatment, mitigation and/or prevention of disease. Intent to prevent dental disease determines the regulatory agency, which is the FDA CDER.

"The term "drug" means

(A) articles recognized in the official United States Pharmacopoeia . . .; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food) intended to affect the structure of any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C). . . ." [2]

1. Sodium Fluoride is a drug because it is listed in the US Pharmacopeia. [3]
2. Fluoride is a drug because the FDA told Congress fluoride is a drug. [Supplement A]
3. The FDA confirmed fluoride is an unapproved drug. [Supplement B]
4. The Washington State Board of Pharmacy determined fluoride is a legend drug (requires the patient's doctor to write a prescription).
5. The Idaho State Board of Pharmacy confirmed fluoride is a drug.
6. The approved fluoridated toothpaste label states "Drug Facts," with dosage: "use a pea size" which refers to 0.25 mg of fluoride, the same as a large glass of CWF, and warnings such as, "do not swallow." The Board has no authority or experts to disagree with the FDA's warning, "Do Not Swallow."
7. The EPA (The USA Environmental Protection Agency) water law office confirmed the "EPA does not have responsibility for substances added to water solely for preventative health care purposes, such as fluoride. . . the FDA remains responsible for

regulating the addition of drugs to water supplies for health care purposes." [Supplement C]

8. The FDA has notified fluoride supplement manufacturers their product is unapproved, in part because: "There is no substantial evidence of drug effectiveness as prescribed, recommended, or suggested in labeling."[4] Whether fluoride is in a pill or dissolved in tap water make no alleged therapeutic difference; although, pills provide for patient informed consent and a doctor's prescription.

9. The FDA has responded that application for CWF NDA (New Drug Application), "effectively would ban public water fluoridation. . . ." [5] The evidence for efficacy, dosage, safety, label, informed patient consent and chemical purity is incomplete. Yet the Board of Health would not even agree to basic public notifications of potential harm.

10. The FDA was "notified" of a health claim for fluoridated bottled water, which circumvented the scientific regulatory drug approval process. The FDA has warned fluoridated bottled water manufacturers, "the health claim is not intended for use on bottled water products specifically marketed for use by infants." nor "for infants or toddlers less than two years of age. . . . ." [Supplement D] CWF is without label and without individual informed consent; however, bottled water is an option for those choosing to ingest fluoride.

11. Fluoride is not a nutrient because the absence of fluoride does not cause dental caries or any disease and is not used by the body in any physiologic function. Due to fluoride's toxicity, fluoride fits into legal definitions [6] of "poison" and "highly toxic substances," and fluoride is exempt from poison laws only when regulated under drug or pesticide laws. Fluoride is not exempt as a food or nutrient, regardless of endorsements from non-regulatory agencies and industry such as the CDC, HHS, NIH, IOM, HEW, AAP, NJ, USSG, PHS, and ADA.[7]

12. The fluoride compounds added to public water are not pharmaceutical grade, the contaminated, adulterated waste products of manufacturing, without accompanying assay, [8] and often imported from countries which have banned CWF, such as China. [9]

13. The FDA determines the "quality" of evidence from all streams for approval. Efficacy requires RCTs. Safety studies cannot ethically have RCTs because we cannot intentionally harm cohorts. However, when efficacy studies are done, safety evaluation can and must be incorporated in the RCT. Observational studies and non-randomized controlled trials are lower quality and more open to controversy (as they should be), such as the study at hand.

The FDA has several rolls to play when manufacturers make application for approval of a drug including, but not limited to:

1. Efficacy: The FDA requires Randomized Controlled Trials (RCT). The only RCT published study on fluoride's potential caries prevention [10] reported no significant benefit in reducing dental caries. Observational studies are replete with confounders. The FDA is correct, evidence of efficacy is incomplete.

2. Dosage: CWF is a concentration of fluoride, not a dosage. Not everyone drinks the same amount of water. There are many sources of fluoride and total individual fluoride exposure is an individual's dosage.[11] RCTs are needed to determine dosage.

3. Safety: Only after efficacy at a specific dosage is determined with RCTs, can safety be judged. Informed consent for cohorts in RCTs must include monitoring subjects for side-effects and harm. For example, an RCT of fluoride ingestion must ethically monitor for dental fluorosis, both cosmetic and functional, [12] developmental neurotoxicity as measured with lower IQ, miscarriage, premature birth, infant mortality, and monitoring for thyroid, bone, pineal gland, enzymatic stress, ADHD, bone fractures, cancers, both in the short term and lifetime.[11]

4. Label: Intent of use, dosage and warnings for risks, side effects and harm must be included in dispensing fluoride for the education and informed consent of patients.

5. Safety Factor: The FDA must also include a margin of error, uncertainty factor, along with intraspecies variation.

6. The FDA monitors manufacturing to ensure pharmaceutical grade chemicals are

not misbranded or adulterated. The EPA regulates fluoride as a contaminant, not to the purity the FDA requires. The fluoridation chemicals may contain lead and arsenic and the Maximum Contaminant Level Goal for those is 0.0 mg/L.
7. The FDA determines whether fluoride is to be dispensed "over the counter" or as a legend (prescription) drug.
8. The FDA determines whether fluoride can be dispensed to everyone without their informed consent, individual autonomy, their doctor's oversight, knowing their total exposures, or allergic reactions, etc.

The FDA has the experts, policies and procedures to make judgment on safety. IQ is only one measurement of developmental neurotoxicity and only one adverse outcome of excess total fluoride exposure, now reported in two out of three of our young. [13]

Known harm such as both aesthetic and functional dental fluorosis have not been refuted and known for over 80 years. The harm has been marginalized, stubbornly rejected, as simply side effects, cosmetic. Dentists placing black fillings had little concern for cosmetics. Just like a scratch on a car is just cosmetic, it is indeed damage. Costs to treat harm are usually ignored and Journals often refuse to publish the real-world costs.[16] Authors and industry promoting CWF who refuse to even admit an obvious and known harm of dental fluorosis, both cosmetic and functional (chipped, pitted, broken, warn and fractured teeth) [12] frequently treated by dentists and costing far more than alleged benefit,[16] are ill equipped to evaluate and make rational judgment on other risks from fluoride ingestion.

CWF is controversial, in part because laws and the FDA have been ignored. Robust inclusion of all streams of evidence from both sides are essential in academic freedom, excellence and the protection of our patients and the public health. The FDCA <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fbooks%
[17] mandates drug manufacturers submit evidence of new drugs' safety and effectiveness before marketing and distribution to the general public.

The NTP draft monograph "concludes that fluoride is presumed to be a cognitive neurodevelopmental hazard to humans." National Library of Medicine, National Center for Biotechnology Information, Lancet Neurology 2014 Mar; 13(3): 330-338 <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2

Our petition to notify caregivers to not give infants formula made with fluoridated water is reasonable and science based until the FDA provides approval for CWF.

Bill Osmunson DDS MPH is the sole author of this letter and requests it to be published in open access. Bellevue, Washington USA Orcid 0000-0002-2716-7105 bill@teachingsmiles.com

Bill Osmunson DDS MPH has no conflict of interest. He is a retired dentist of 46 years clinical preventative, cosmetic and neuromuscular practice and teaching, with master's degree in public health.

[1] CDC (1999). Achievements in Public Health, 1900-1999: Fluoridation of Drinking Water to Prevent Dental Caries. MMWR, 48(41); 933-940, October 22

[2] 21 USC 321(g)(1)

[3] USP

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.usp.org%2Fsearch%3Fsearc

[4] Drug Therapy, June 1975.

[5] Email to the Washington State Board of Health from the FDA as reported in their June 9, 2010 letter to this author.

[6] RCW 69.38.010
<https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fapp.leg.wa.gov%2FRCW%2Fdefaul

[7] Smile Spokane
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Fspokane-city-council-information-on-fluoride-2020-09-08.pdf&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C8d09cdb1d38741d0a78f08dc52b7cf60%7C11d0e2
NIH National Institute of Health , IOM Institute of Medicine, HEW Health Education and Welfare, AAP American Academy of Pediatrics, NJ Nutrition Journal, ADA American Dental Association and HHS Health and Human Services, US Surgeon General, US Public Health Service. Note: All agencies in this letter are USA agencies.

[8] The National Sanitation Foundation, NSF.org,
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.nsf.org%2F&data=05%7C02
is an independent company, funded by manufacturers, providing annual manufacturing and transportation inspections, but does not provide batch testing or provide results to the consumer. NSF permits contaminants in the product up to 10% of EPA's MCL, which is 4 mg/L. When asked how fluoride is permitted at 1.0 mg/L when 10% of 4 is 0.4 mg/L, the NSF responded the 10% applies to the contaminants in the product not the product which is an EPA contaminant.

[9] WCVB 5 ABC
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fluoride-in-mass-water-raises-concern%2F8157985%23%3A~%3Atext%3Dtoys%2520from%2520China.%2522-%2CSince%25202007%252C%2520most%2520of%2520the%2520sodium%2520fluoride%2520has%252

[10] Leverett DH, Adair SM, Vaughan BW, Proskin HM, Moss ME. Randomized clinical trial of the effect of prenatal fluoride supplements in preventing dental caries. Caries Res. 1997;31(3):174-9. PubMed
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F916

[11] Fluoride in Drinking Water; A Scientific Review of EPA's Standards. 2006 NASEM
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fnap.nationalacademies.org%2Fcat
in-drinking-water-a-scientific-review-of-epas-standards&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C8d09cdb1d38741d0a78f08dc52b7cf60%7C11d

[12] Collins, E., V. Segreto, H. Martin, AND H. Dickson.
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fcfpub.epa.gov%2Fsi%2Fsi_public_
ANALYSIS OF COSTS FOR THE TREATMENT OF DENTAL FLUOROSIS. U.S. Environmental Protection Agency, Washington, D.C., EPA/600/5-87/001 (NTIS PB87170817), 1987. Revised 2005. [EPA Link
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fcfpub.epa.gov%2Fsi%2Fsi_public_
], However, Data Revised 08/02/2022 . EPA Science Inventory
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fcfpub.epa.gov%2Fsi%2Fsi_public_
Accessed Dec. 27, 2022

[13] Neurath C, Limeback H, Osmunson B, Connett M, Kanter V, Wells CR. Dental Fluorosis Trends in US Oral Health Surveys: 1986 to 2012. JDR Clin Trans Res. 2019 Oct;4(4):298-308. Pubmed <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F309

[14] Water fluoridation status in Western Europe <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fw

[15] Diesendorf M, HOW SCIENCE CAN ILLUMINATE ETHICAL DEBATES A CASE STUDY ON WATER FLUORIDATION Link <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.fluorideresearch.org%2F282 104.pdf&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C8d09cdb1d38741d0a78f08dc52b7cf60%7C11d0e and Spittle B, THE ETHICS OF WATER FLUORIDATION, Editorial, Fluoride 28 920 May 1995. Link <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.fluorideresearch.org%2F282 060.pdf&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C8d09cdb1d38741d0a78f08dc52b7cf60%7C11d0e

[16] Ko L, Thiessen KM. A critique of recent economic evaluations of community water fluoridation. Int J Occup Environ Health. 2015;21(2):91-120. doi: 10.1179/2049396714Y.0000000093. Epub 2014 Dec 3. PMID: 25471729; PMCID: PMC4457131. [PubMed <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F254]

[17] The FDCA <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fbooks% Lam C, Patel P. Food, Drug, and Cosmetic Act. [Updated 2023 Jul 31]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK585046/ <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fbooks% See also FDA.gov

1. Lead: Exposure to lead, often found in old paint, contaminated soil, and water, can impair brain development and cause cognitive deficits <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2 1 <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2 .
2. Methylmercury: Found in certain fish and seafood, methylmercury can harm the developing nervous system, especially during pregnancy <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2 1 <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2 .
3. Polychlorinated Biphenyls (PCBs): These industrial chemicals, although banned, persist in the environment and can affect brain development

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4. Arsenic: Arsenic exposure, often through contaminated water or food, has been linked to developmental neurotoxicity
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.
5. Toluene: Commonly found in paints, solvents, and glues, toluene exposure can harm the developing brain1
6. manganese,
7. fluoride, chlorpyrifos, dichlorodiphenyltrichloroethane (DDT), tetrachloroethylene, and polybrominated diphenyl ethers (PBDEs) have also been identified as developmental neurotoxicants1It's essential to recogn2
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4422%252813%252970278-
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neurotoxicology&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C8d09cdb1d38741d0a78f08dc52b7cf60%7
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P 44.m 2020.