

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ada.org%2Fabout%2Fpress-releases%2Famerican-dental-association-reaffirms-support-for-community-water-fluoridation%23%3A~%3Atext%3DThe%2520findings%2520in%2520the%2520NTP%2Cintervention%2520>. The American Academy of Pediatrics also reaffirmed their position:
<https://publications.aap.org/aapnews/news/29918/AAP-stands-by-recommendations-for-low-fluoride>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpublications.aap.org%2Faapnews%2Fstands-by-recommendations-for-low-fluoride&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C81d9822c3ddd4f6149c208dd2ba9d2ab%7C11d0e>

Cavities, tooth loss and swollen gums affect people of all ages. For children, uncomfortable tooth decay can influence school attendance, behavior, nutrition, speech patterns, self-esteem and a child's ability to thrive. Among working adults, rotting and missing teeth can impact employment opportunities, overall health, self-esteem, nutrition and how others perceive you. And for older adults, maintaining good oral health is more important than ever with a greater number of senior citizens retaining their original teeth than prior generations thanks in large part to water fluoridation and other dental care advances.

Treating cavities also can be expensive and intensify health and societal inequities. The lifetime cost of just one cavity is \$6,160. And not everyone is able to see a dentist regularly, meaning lower-income families, older adults on fixed incomes and young adults just starting out too often forgo care. Providing the right balance of fluoride in our tap water ensures everyone has a fair chance at added protection for their teeth against cavities.

On behalf of the Washington State Oral Health Coalition Board

Executive Committee Members:

Marcy Bowers, Chair

Russell Maier, MD, Vice Chair

Stacy Torrance, Treasurer

Sarah Vander Beek, DMD, Secretary

Correspondence can be directed to this email and will be responded to by a member of the Board.

From: Itle, Amber (AGR)
Sent: 1/3/2025 12:32:17 PM
To: lisa@informedchoicewa.org,DOH WSBOH
Subject: RE: for BOH packet for its January 8 meeting?prevent both fear and infection



attachments\535DF1AE9C5C4EAE_image004.png



attachments\EAA147086143417A_image003.png

Thanks for your email and information.

Because Avian Influenza is a foreign animal disease, we use the USDA HPAI RedBook <<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.aphis.usda.gov%2Fanimal-emergencies%2Fhpa&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cadd9c278ca8c4a54bd0c08dd2c>> for response that includes a section on proper cleaning and disinfection that includes hydrogen peroxide along with many other viable disinfectant options (FAD PReP/NAHEMS Guidelines: Cleaning & Disinfection <<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.aphis.usda.gov%2Fsites%2F> 5.4.7 Oxidizing Agents).

Options include physical (heat/ radiation) and many chemical disinfection methods. The hardest part is getting the environment clean enough to allow disinfection to occur properly. Cleaning and disinfection options are up to the producer. Many factors such as efficacy, product availability, housing type/ size/ scale, application ability, public safety/ health and environmental impacts all play a role and we tailor each C/D plan based on the best customized, science based options to meet the needs of each unique operation.

Thanks again for the information.

Have a great day.

Amber

Amber Itle VMD MS | Washington State Veterinarian

Washington State Department of Agriculture

Office: 360-902-1878 | Cell: 360-961-4129 | agr.wa.gov
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fagr.wa.gov%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cadd9c278ca8c4a54bd0c08dd2c>>

From: lisa@informedchoicewa.org <lisa@informedchoicewa.org>

Sent: Friday, January 3, 2025 10:54 AM
To: DOH WSBOH <WSBOH@SBOH.WA.GOV>
Cc: 'aitle@agr.wa.gov'; 'annette.cleveland@leg.wa.gov'; 'Marcus.Riccelli@leg.wa.gov';
Morgan, Melanie <Melanie.Morgan@leg.wa.gov>; Reeves, Kristine (LEG)
<kristine.reeves@leg.wa.gov>; Salomon, Jesse <Jesse.salomon@leg.wa.gov>
Subject: for BOH packet for its January 8 meeting?prevent both fear and infection

External Email

Dear Board of Health members,

I have cc'ed our state veterinarian, Dr. Amber Itle, as well as the chairs of our Senate and House health and agriculture committees. The following is a message similar to one I sent in August. I have not received a reply from the parties I copied at that time.

Now that California has declared an emergency regarding avian flu (<https://www.gov.ca.gov/2024/12/18/governor-newsom-takes-proactive-action-to-strengthen-robust-state-response-to-bird-flu/>)--<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.ca.gov%2F2024%2F12%2Fnewsom-takes-proactive-action-to-strengthen-robust-state-response-to-bird-flu%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cadd9c278ca8c4a54bd0c08dd2c35b4a6%7C11>> in the absence of a single case of human-to-human transmission worldwide (<https://www.cdc.gov/bird-flu/situation-summary/inhumans.html>)<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.cdc.gov%2Fbird-flu%2Fsituation-summary%2Finhumans.html&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cadd9c278ca8c4a54bd0c08dd2c35b4a6%7C11>>)--it is critical for our state to use available tools to empower citizens and farmers to protect themselves and their animals—all without creating an atmosphere of fear.

Hydrogen peroxide (H₂O₂) has been well-studied for use with animals, as well as humans, and has been shown to deactivate bird flu viruses. Solutions of hydrogen peroxide can be safely misted in coops and barns, directly on animals and eggs. Likewise, people of all ages can utilize this and other inexpensive antiviral substances via nasal rinse and gargling to prevent and stop upper respiratory infection. Please see the 21 studies linked below.

I can't stress enough how important it is that Washington State agencies embrace and educate the public on the benefits of oral and throat hygiene. Iodine solutions can inactivate any virus in 15 seconds, H₂O₂ in less than 30 seconds, and essential oils in under a minute. These substances can kill bacteria, too. These are not controversial prevention strategies; they are well-established to be safe and effective. Adding these tools to the public health toolbox could drastically prevent infection, reduce transmission, and lower incidence of severe infection.

Wouldn't it be exemplary if Washington took the lead on promoting this practice, and we ended up with the lowest respiratory infection rates in the nation? Public health policies

take time to disseminate, of course, but the DOH has a vast network and the ability to communicate with healthcare providers and the public with a simple push of the "send" button for emails, social media, press releases, even texts. Information about nasal spray/rinse and gargling could be including in the DOH's existing workflow.

The messaging could be included wherever handwashing is mentioned in regards to helping prevent the spread of respiratory infection. The supporting science spans decades, and the studies during COVID provide even more evidence. This education outreach doesn't need to recommend any specific OTC products. Just as DOH doesn't tell people what specific type or brand of soap to use, neither would they have to say what specific type or brand of nasal or gargling product to use. They could simply explain the basics, the ingredients studied (saline, iodine, H₂O₂, essential oils, grapefruit seed extract, etc.), and use standard language of "see your healthcare provider" and "use as directed."

I do believe we can easily do this!

Questions for Dr. Itle:

* Are you already aware of the many H₂O₂ studies and animal applications for preventing the spread of infection? Examples:

* Hydrogen Peroxide in Agriculture: A Proactive Approach to Farm Sanitation and Disease Prevention

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fnutrihydro.com%2Fhydrogen-peroxide-in-agriculture-a-proactive-approach-to-farm-sanitation-and-disease-prevention%2F%3Fv%3Da25496ebf095&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cadd9c278ca8>, <https://nutrihydro.com/hydrogen-peroxide-in-agriculture-a-proactive-approach-to-farm-sanitation-and-disease-prevention/?v=a25496ebf095>

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fnutrihydro.com%2Fhydrogen-peroxide-in-agriculture-a-proactive-approach-to-farm-sanitation-and-disease-prevention%2F%3Fv%3Da25496ebf095&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cadd9c278ca8>

* This is not a hydrogen peroxide study, but electrolyzed water is another effective approach: Reduction of microbial contamination on the surfaces of layer [chicken] houses using slightly acidic electrolyzed water

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F26371328/>, <https://pubmed.ncbi.nlm.nih.gov/26371328/>

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F26371328/>

* Would your office be willing to explore this approach further and disseminate the information to farmers and ranchers?

It's very important that we all help to prevent the spread of fear as well as the spread of infection. These simple and readily-available solutions can go a long way in fulfilling these objectives. I appreciate your time and efforts on this consequential matter.

Sincerely,

Lisa Templeton

Informed Choice Washington Director

InformedChoiceWA.org

1. UConn Health Researchers Find a Simple Oral Rinse Can Inactivate the COVID-19 Virus

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https%3A%2F%2Fhealth-researchers-find-simple-oral-rinse-can-inactivate-covid-19-virus%2F*_%3BIw!!PRtDf9A!pcNxthqswetCvhQIUMNc9WTY6h7bbtE2P7YNEr3r4UrrZr3QaC3Q29szyUhWyL>
, <https://today.uconn.edu/2020/06/uconn-health-researchers-find-simple-oral-rinse-can-inactivate-covid-19-virus/#>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftoday.uconn.edu%2F2020%2F06%2Fhealth-researchers-find-simple-oral-rinse-can-inactivate-covid-19-virus%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cadd9c278ca8c4a54bd0c08dd2c35b4a6%7C>>

2. Can povidone iodine gargle/mouthrinse decrease the risk of transmission?

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov/33747261/>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F33747261/>>

3. Comparison of In Vitro Inactivation of SARS CoV-2 with Hydrogen Peroxide and Povidone-Iodine Oral Antiseptic Rinses

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https%3A%2F%2Fwww.ncbi.nlm.nih.gov/pmc/articles/PMC7361576/>
, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7361576/>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2Farticles%2FPMC7361576/>>

4. How to Make the Povidone Iodine Solution from the I-CARE FLCCC Protocol - Video Tutorial, <https://covid19criticalcare.com/tools-and-guides/how-to-make-the-povidone-iodine-solution-from-the-i-care-protocol/>

<<file:///C:/Users/glena/OneDrive/ICWA/Public%20Health/How%20to%20Make%20the%20Povidone%20Iodine%20Solution%20from%20the%20I-CARE%20FLCCC%20Protocol%20-%20Video%20Tutorial,%20https://covid19criticalcare.com/tools-and-guides/how-to-make-the-povidone-iodine-solution-from-the-i-care-protocol/>>

5. Known effective since 1977 at the latest Virus inactivation by hydrogen peroxide

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov/203115/>
, <https://pubmed.ncbi.nlm.nih.gov/203115/>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F203115/>>

6. Comparison of In Vitro Inactivation of SARS CoV-2 with Hydrogen Peroxide and Povidone-Iodine Oral Antiseptic Rinses

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https%3A%2F%2Fwww.ncbi.nlm.nih.gov/pmc/articles/PMC7361576/>
, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7361576/>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2Farticles%2FPMC7361576/>>

7. Expert Panel Discussion: Hydrogen peroxide in the prevention of Covid-19

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https%3A%2F%2Fwww.ncbi.nlm.nih.gov/pmc/articles/PMC7361576/>
, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7361576/>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2Farticles%2FPMC7361576/>>

, <https://www.brighteon.com/76f0c65b-69e9-4023-a2a8-0c31e72af047>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.brighteon.com%2F76f0c65b-69e9-4023-a2a8-0c31e72af047&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cadd9c278ca8c4a54bd0c08dd2c35b4a6>>

8. Hospital Study Shows that Covid-19 Can be Prevented with Hydrogen Peroxide
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__http
, <https://www.orthomolecular.org/resources/omns/v18n18.shtml>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.orthomolecular.org%2Fresources/omns/v18n18.shtml>>

9. Hydrogen Peroxide Nebulization and COVID Resolution
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.orthomolecular.org%2Fresources/omns/v17n13.shtml>
, <https://www.orthomolecular.org/resources/omns/v17n13.shtml>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.orthomolecular.org%2Fresources/omns/v17n13.shtml>>

10. Virucidal Efficacy of Different Oral Rinses Against Severe Acute Respiratory Syndrome Coronavirus 2
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__http
, <https://academic.oup.com/jid/article/222/8/1289/5878067?login=true>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Facademic.oup.com%2Fjid%2Farticle/222/8/1289/5878067?login=true>>

11. Curing Viruses with [Nebulized] Hydrogen Peroxide: Can a simple therapy stop the pandemic?
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Forthomolecular.org%2Fresources/omns/v16n43.shtml>
<https://orthomolecular.org/resources/omns/v16n43.shtml>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Forthomolecular.org%2Fresources/omns/v16n43.shtml>>

12. Protocol for Hydrogen Peroxide Mouth Wash and Nasal Cleanse
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Flatitudes.org%2Fprotocol-for-hydrogen-peroxide-mouthwash-and-nasal-cleanse%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cadd9c278ca8c4a54bd0c08dd2c35b4a6%7C1>
, <https://latitudes.org/protocol-for-hydrogen-peroxide-mouthwash-and-nasal-cleanse/>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Flatitudes.org%2Fprotocol-for-hydrogen-peroxide-mouthwash-and-nasal-cleanse%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cadd9c278ca8c4a54bd0c08dd2c35b4a6%7C1>>

13. In Vitro Analysis of the Anti-viral Potential of nasal spray constituents against SARS-CoV-2
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https
, <https://www.biorxiv.org/content/10.1101/2020.12.02.408575v3.full>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.biorxiv.org%2Fcontent%2F10.1101/2020.12.02.408575v3.full>>

14. Inhibitory effect of grapefruit seed extract (GSE) on avian pathogen
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https
[unc%24&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7Cadd9c278ca8c4a54bd0c08dd2c35b4a6%7C1](https://pubmed.ncbi.nlm.nih.gov/30713281/)
, <https://pubmed.ncbi.nlm.nih.gov/30713281/>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F30713281/>>

15. Grapefruit Seed Extract as a Natural Derived Antibacterial Substance against Multidrug-Resistant Bacteria
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https
, <https://pubmed.ncbi.nlm.nih.gov/33477436/>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F33477436/>>

16. An updated and comprehensive review of the antiviral potential of essential oils and their chemical constituents with special focus on their mechanism of action against various influenza and coronaviruses
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https>

, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9159739/>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2Farticles%2FPMC9159739/>>

17. Virucidal Activity of Different Mouthwashes Using a Novel Biochemical Assay
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8775226/>
, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8775226/>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2Farticles%2FPMC8775226/>>

18. Virucidal Efficacy of Different Oral Rinses Against Severe Acute Respiratory Syndrome Coronavirus 2
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7454736/>
, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7454736/>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2Farticles%2FPMC7454736/>>

19. A pilot, open labelled, randomised controlled trial of hypertonic saline nasal irrigation and gargling for the common cold
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6355924/>
, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6355924/>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2Farticles%2FPMC6355924/>>

20. Do saline water gargling and nasal irrigation confer protection against COVID-19?
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7528968/>
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7528968/>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2Farticles%2FPMC7528968/>>

21. Saline nasal irrigation and gargling in COVID-19: a multidisciplinary review of effects on viral load, mucosal dynamics, and patient outcomes
<[https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://urldefense.com/v3/](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://urldefense.com/v3/__https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10312243/__;!!PRtDf9A!pcNxt)
, [https://urldefense.com/v3/](https://urldefense.com/v3/__https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10312243/__;!!PRtDf9A!pcNxt)
, [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10312243/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10312243/__;!!PRtDf9A!pcNxt)
, [https://urldefense.com/v3/](https://urldefense.com/v3/__;!!PRtDf9A!pcNxt)
, [https://urldefense.com/v3/](https://urldefense.com/v3/__;!!PRtDf9A!pcNxt)
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://urldefense.com/v3/>

From: Kamali, Andrew R (SBOH)
Sent: 11/20/2024 1:10:44 PM
To: DOH WSBOH
Cc:
Subject: FW: WSSDA Response to School Health and Safety Environmental Rulemaking



attachments\953212AA713C48C8_image001.png

attachments\24CCCEAE988B4938_image002.png

Andrew Kamali (he/him)

School Rules Project Manager

Washington State Board of Health

andrew.kamali@sboh.wa.gov <mailto:andrew.kamali@sboh.wa.gov>

360-584-6737

Website

<<https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fsboh.wa.gov%2F&data=05%7C02>>

|Facebook

<[https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.facebook.com%2FWASBOH%](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.facebook.com%2FWASBOH%2F)>

|Twitter

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftwitter.com%2FWASBOH&data=0>>

From: Rathbone, Marissa (WSSDA) <M.Rathbone@wssda.org>
Sent: Wednesday, November 20, 2024 12:38 PM
To: DOH WSBOH School Environmental Health & Safety Project
<schoolehs@sboh.wa.gov>
Cc: Lubach, Tricia (WSSDA) <T.Lubach@wssda.org>; Sandy Hayes (sbdistrict4@nsd.org)
<sbdistrict4@nsd.org>; Derek Sarley <dsarley@wwps.org>; Geary, Christine (WSSDA)
<c.geary@wssda.org>; Lindsay Lofstrom <lindsay.lofstrom@dpsdmail.org>;
melissa.beard@tumwater.k12.wa.us; Kamali, Andrew R (SBOH)
<Andrew.Kamali@sboh.wa.gov>
Subject: WSSDA Response to School Health and Safety Environmental Rulemaking

Dear Members of the Washington State Board of Health,

My name is Marissa Rathbone, and I am the Director of Advocacy for the Washington

State School Directors' Association, representing the 1,477 locally elected school directors from across the state. Thank you for inviting us to share remarks at the Technical Advisory Committee meeting in Spokane this morning. We appreciated having the opportunity (and invitation) to share ways to make learning environments safer, healthier, and more effective for learning and teaching.

Earlier in my career, I studied to be a Health Education Teacher and I come from a line of public educators. This background motivates me to uplift the importance of healthy school environments as the foundation for learning. Our school directors across the state also understand that the health and safety of students and staff is paramount to secure successful academic outcomes.

At the local level, boards approve district budgets that align with state laws while working to fulfill a moral and ethical responsibility to keep students and staff safe and well. In fact, school districts have determined on their own and without state funding to make many of the proactive or responsive environmental changes without new rules or laws. Additionally, school board governance requires that state and federal laws be followed. Often, however, the resources to implement those requirements are not allocated by policymakers. Therefore, difficult decisions must be made that impact students, families, staff, and communities. When there are not enough dollars allocated to implement requirements, the board is put in the most difficult position to make cuts, such as closing schools. And no one wants to be in that position.

In local elections this year, voters rejected most of the bonds and many of the levies on their local ballots. When bonds consistently fail in a district, new buildings cannot replace those in disrepair, and an effort to simply replace heating/cooling systems, failing roofs, and windows are prioritized through levies. This puts the financial responsibility on the districts to ensure the literal foundation for learning is in place before learning can occur. Although the state courts recently decided that school facilities are not part of basic education, we should all consider roofs and windows pretty basic.

As you continue to hear about the important health and safety considerations for the K-12 environment, we ask that the cost implications be considered, and their funding ensured, before codifying. We simply cannot support any good idea that isn't sufficiently funded - because any more unfunded requirements could ultimately shutter our schools.

As the legislature considers your recommendations, please emphasize the importance of local flexibility, proactive funding, simple majority for school bonds, and a flexible timeline. If any policy is important, the right timeline and resources to implement them should be too. A locally developed plan with state funding and flexibility to implement is our overall recommendation.

Please let us know as you have questions and opportunities to partner, learn, and advocate together.

From: Bob Runnells
Sent: 1/3/2025 10:53:46 AM
To: DOH WSBOH
Cc:
Subject: Public Comments for Jan 8 2025 WSBOH meeting



attachments\5F7C2BE051764CA4_rhodes-parry-2024-pharmaceutical-
_PRDTOOL_NAMETOOLONG.pdf

External Email

Dear Washington State Board of Health members,

In the International Journal of Risk & Safety in Medicine, a recent article was published titled "Pharmaceutical product recall and educated hesitancy towards new drugs and novel vaccines" that I think the Board should be aware of. Please read attached where it compares the number of death reports for historical drugs or vaccines that were subsequently withdrawn from the market.

The authors summarize their results as "Parallels with past drug withdrawals and gene-based vaccines include distortion of clinical trial data, with critical adverse event data absent from high-impact journal publications. Delayed regulatory action on pharmacovigilance data to trigger market withdrawal occurred with Vioxx (rofecoxib) and is apparent with the gene-based COVID-19 vaccines."

Therefore, the Washington State Board of Health would be justified in withdrawing their recommendations for the COVID-19 shots as the benefits continue to be outweighed by the risks.

Thank you,

Bob Runnells

Informed Choice Washington

From: Garry Blankenship
Sent: 11/19/2024 10:00:57 AM
To: ombuds@oc.fda.gov, hcinfo.infosc@canada.ca, DOH
WSBOH, OADS@cdc.gov, sheriff@co.clallam.wa.us, Berry, Allison 2
(DOHi), shahidafatin@gmail.com, ncarr@cityofpa.us, gbsjrm@sisna.com, Mark.Ozias@ClallamCountyWA.gov
Herald,
(DOHi), chutton@heraldnet.com, customerservice@theolympian.com, news@spokesman.com, voice@spokesman.com
City Herald (DOHi), Chapman, Mike (LEG), Tharinger, Steve, Van De Wege, Kevin
Cc:
Subject: Fwd: BREAKING NEWS - Twice-Censored Landmark COVID-19 Vaccine Autopsy
Study Fully Peer-Reviewed and Published

External Email

Good Day,

Below is yet more data among the inevitable landslide of information escaping main stream media, captured medical institutions and Federal censorship. The promotion of the COVID "vaccines" and associated penalties was and remains a catastrophic mistake. In the interest of starting small I implore all influencers to at a minimum halt the injection of our children with these experimental, unsafe and ineffective toxins. Adults are legally capable of informed consent; children are not. Lisa Domski was recently awarded \$ 12.6 million from Blue Cross / Blue Shield for wrongful termination because she did not COVID "vaccinate". I reveal that not as a threat, but as a plea to not only reconsider our vaccination policy, but to also publicly show contrition for all the harms which include death associated with "vaccine" restrictions, harms and mandates.

Sincerely,

Garry Blankenship
Concerned Sequim Citizen

<<https://eotrx.substackcdn.com/open?token=eyJtIjoiPDlwMjQxMTE4MjE1NzU4LjMuM2JhYjc2Zjg5MTI1YTlm>>

This paper has now passed TWO rounds of peer review in TWO different journals.

Conclusion: They looked at 240 deaths happening after vaccination. 74% were due to or significantly contributed to by COVID-19 vaccination.

If the vaccines is safe and effective, this is impossible to explain. The medical community should be castigated for missing such an obvious safety signal that should have been picked up early had the CDC seriously looked at any autopsy reports. With the re-publication, this should be impossible for the medical community to explain.

Ask your doctor to explain how a safe vaccine can cause 73% of the deaths that were investigated post-vaccine.

BREAKING NEWS - Twice-Censored Landmark COVID-19 Vaccine Autopsy Study Fully Peer-Reviewed and Published

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After enduring relentless censorship, our systematic review linking COVID-19 vaccines to death is now available for the entire world to read.

Nicolas Hulscher, MPH

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Nov 18

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<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fapp-link%2Fpost%3Fpublication_id%3D1119676%26post_id%3D151281405%26utm_source%3Dsubstack%26reaction%26r%3D15ift6&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C65bbedb499914492b3ec08dd08>

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by Nicolas Hulscher, MPH

The largest COVID-19 vaccine autopsy study to-date, providing robust evidence that COVID-19 vaccines can cause death, has been officially republished following successful peer-review in the journal *Science, Public Health Policy, and the Law: A Systematic Review Of Autopsy Findings In Deaths After COVID-19 Vaccination*

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. This comes after unethical censorship on two occasions: first, removal from

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Preprints with the *Lancet*

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and later, withdrawal by Elsevier

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after publication in *Forensic Science International*.

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30e466d5a164%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0

Hulscher N, Alexander P E., Amerling R, Gessling H, Hodkinson R, Makis W et al. A Systematic Review Of Autopsy Findings In Deaths After COVID-19 Vaccination. Science, Public Health Policy and the Law. 2024 Nov 17; v5.2019-2024

Here's what we found:

Background: The rapid development of COVID-19 vaccines, combined with a high number of adverse event reports, have led to concerns over possible mechanisms of injury including systemic lipid nanoparticle (LNP) and mRNA distribution, Spike protein-associated tissue damage, thrombogenicity, immune system dysfunction, and carcinogenicity. The aim of this systematic review is to investigate possible causal links between COVID-19 vaccine administration and death using autopsies and post-mortem analysis.

Methods: We searched PubMed and ScienceDirect for all published autopsy and organ-restricted autopsy reports relating to COVID-19 vaccination up until May 18th, 2023. All autopsy and organ-restricted autopsy studies that included COVID-19 vaccination as an antecedent exposure were included. Because the state of knowledge has advanced since the time of the original publications, three physicians independently reviewed each case and adjudicated whether or not COVID-19 vaccination was the direct cause or contributed significantly to death.

Results: We initially identified 678 studies and, after screening for our inclusion criteria, included 44 papers that contained 325 autopsy cases and one organ-restricted autopsy case (heart). The mean age of death was 70.4 years. The most implicated organ system among cases was the cardiovascular (49%), followed by hematological (17%), respiratory (11%), and multiple organ systems (7%). Three or more organ systems were affected in 21 cases. The mean time from vaccination to death was 14.3 days. Most deaths occurred within a week from last vaccine administration. A total of 240 deaths (73.9%) were independently adjudicated as directly due to or significantly contributed to by COVID-19 vaccination, of which the primary causes of death include sudden cardiac death (35%), pulmonary embolism (12.5%), myocardial infarction (12%), VITT (7.9%), myocarditis (7.1%), multisystem inflammatory syndrome (4.6%), and cerebral hemorrhage (3.8%).

Conclusions: The consistency seen among cases in this review with known COVID-19 vaccine mechanisms of injury and death, coupled with autopsy confirmation by physician adjudication, suggests there is a high likelihood of a causal link between COVID-19 vaccines and death. Further urgent investigation is required for the purpose of clarifying our findings.

Our study indicates that the COVID-19 injectable products must undergo an immediate Class I recall by the FDA to protect public safety. The U.S. Food and Drug Administration defines a

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Class I recall

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as: "A situation in which there is a reasonable probability that the use of or exposure to a

violative product will cause serious adverse health consequences or death.”

The censorship and retraction of studies that show COVID-19 mRNA injection harms is deeply concerning. First, this study was inappropriately removed from Preprints with the Lancet (SSRN)

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1abc7c0dd0a6%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0
. The paper was posted on the server on July 5th, 2023 and censored in less than 24 hours after receiving massive numbers of downloads and reads, "because the study's conclusions are not supported by the study methodology." However, the study initially satisfied SSRN screening criteria, which raises grave suspicions of censorship.

<[https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2Fdcc4182-4289-a469-](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2Fdcc4182-4289-a469-54333650e42a%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0)

54333650e42a%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0

Then began the long process of submitting critical COVID-19 vaccine autopsy data to nearly 20 publications, facing repeated rejections without peer-review:

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07c9e26ccb76%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0

Approximately a year after our study was wiped from Preprints with the Lancet, on June 21st, 2024, the paper was published after successful peer-review in

<[https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2Fa27a2ca-4a3a-9e60-](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2Fa27a2ca-4a3a-9e60-42e88111b61f%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0)

42e88111b61f%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0
Forensic Science International

<[https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2Fa27a2ca-4a3a-9e60-](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2Fa27a2ca-4a3a-9e60-42e88111b61f%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0)

42e88111b61f%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0

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<[https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F1b2f5f7-46b9-9b0d-](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F1b2f5f7-46b9-9b0d-3bbb211e53ca%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0)

3bbb211e53ca%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0

On July 3rd, 2024, our study was the #1 trending research paper worldwide across all subject areas within the last 2 weeks according to the Observatory of International Research

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Thus, we can assume that scientists, physicians, and the public were eager to learn about critical post-mortem safety data regarding COVID-19 injections. Unfortunately, in a striking act of censorship, Elsevier and Forensic Science International withdrew the article on August 2nd, 2024 in flagrant violation of their own withdrawal policy

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and COPE guidelines

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. They left no traces behind, completely wiping our paper from the webpage.

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Anonymous 'members of the scientific community' declared that our study should not be published. A comprehensive rebuttal against the unfounded concerns was provided to the journal, which was concerningly rejected in accordance with two anonymous post-publication reviewers. Elsevier and Forensic Science International failed to follow the proper scientific discourse method of allowing debate in Letters to the Editor. This type of academic censorship poses a serious threat to the progress of scientific discovery. The republication of our autopsy study marks a significant setback for the Biopharmaceutical Complex and their Academic Publishing Cartel

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, signaling a pivotal victory for transparency and accountability in science.

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Nicolas Hulscher, MPH

Epidemiologist and Foundation Administrator, McCullough Foundation

www.mcculloughfnd.org

Please consider following the McCullough Foundation

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and Nicolas Hulscher

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F4b60657-45b4-a071-65b16b6ee979%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0>>

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Comment

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fapp-link%2Fpost%3Fpublication_id%3D1119676%26post_id%3D151281405%26utm_source%3Dsubstack%26bTgs%26r%3D15ift6%26utm_campaign%3Demail-half-magic-comments%26action%3Dpost-comment%26utm_source%3Dsubstack%26utm_medium%3Demail&data=05%7C02%7Cwsboh%40sboh.w

Restack

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F2%2F494b4ac-4185-8063-f8ed5fe988ca%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=05%7C02%7Cwsboh%40sboh.w>

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Peter A. McCullough, MD, MPH

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Advancement of clinical science, protection of personal autonomy, liberty, and constitutional rights.

<<https://eotrx.substackcdn.com/open?token=eyJtIjoiPDlwMjQxMTE4MjE1NzU4LjMuM2JhYjc2Zjg5MTI1YTlm>

<https://email.mg1.substack.com/o/eJxMkEuu8yAMRldzGUYxj5IMWEtkjEnRLVDxqJTd_8rfyZ2eIx9ZH-Hgs7bLvWsfIrrjVSrJesAOrYH9YCSA4Y3odJxduODgcOP5YZXbxdGb3FtAEKw1HFRVQJCAC3pgoRi2Sk6vUALBJM6sAZEhdixx9uVy38xSk4MLBpte3mS8b1Ztf4_7l4T39QzXmWnk6DC_oXBzfa5Fu9EuFItdwVozdltGjumfqJrXDv8G9qnZ5ifEebndudeexWamO0-Dj5LwAA__9AxHG1

From: 2
Sent: 11/14/2024 11:19:19 AM
To: DOH WSBOH
Cc:
Subject: Why can't Washington do this



attachments\3FBDDBE628FF4EA1_GcUDmHXXkAA6ld_.jpg

External Email

Please see the attached letter of support for revision and update of Environmental Health and Safety Standards for Primary and Secondary Schools.

Thank you,

Jessica

Jessica Gehle, MPH (she/her)

Division Director

Environmental Health

(253) 649-1845 o • (253) 370-6163 c

jgehle@tpchd.org <<mailto:jgehle@tpchd.org>>

tpchd.org

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| X

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.twitter.com%2FTPCHD%2F8>

| YouTube

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.youtube.com%2Fchannel%2>

Nov. 13, 2024

Dear Washington State Board of Health:

Please support the revision and update of Environmental Health and Safety Standards for Primary and Secondary Schools.

Local Health Jurisdictions (LHJs) and schools currently rely on outdated rules to protect the health and safety of our students. By the time a student graduates from high school, they will spend on average more than 14,000 hours in school. It's imperative we ensure learning environments are safe, healthy, and improve health equity.

Current rules fall short on tackling important environmental factors like:

- Indoor air quality.
- Temperature control.
- Playground safety.
- Safety in career and technical education classrooms.

As wildfires and extreme heat become more frequent, schools must be adequately equipped to protect student health. [Environmental Protection Agency](#)'s research shows exposure to climate stressors can have lifelong consequences to children's health and development. It can disproportionately harm children who are Black, Indigenous, Hispanic or Latino, or reside in low-income families, or are underinsured.

LHJs and schools need modern guidelines to assess, inspect, and address environmental health and safety risks. Rule revision and updates will enable local inspectors and schools to promote environments where students can thrive.

I appreciate your support of environmental health and safety in Washington schools. Please support the revision and funding for rule implementation.

Sincerely,



Chantell Harmon Reed, MS-HCM, Doula
Director of Public Health

KC

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2F%40ladycasey&

Dec 14

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<https://substackcdn.com/image/fetch/w_36,c_scale,f_png,q_auto:good,fl_progressive:steep/https%3A%

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fapp-link%2Fpost%3Fpublication_id%3D1216460%26post_id%3D153121484%26utm_source%3Dsubstack%26share%26action%3Dshare%26triggerShare%3Dtrue%26isFreemail%3Dfalse%26r%3D15ift6%26token%3D

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<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F1be485b-40b1-932a-

99ff4ed36cb7%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F2d3f4f8-4d3c-8ccf-bff4eae45d7d%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2Fd9bf4f8-4ba2-a632-8c1f09e63bf4%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F4c61f2d-49b6-a2fc-5382e7836ad7%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F9714db4-4ba8-8d32-c0e0c47c8518%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F87111e9-4d93-a95c-aedf8e109433%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0

And a couple more graphics to drive home the point:

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F9851b8e-4285-8d92-5e07caaf0387%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0>

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2Fba80-42d5-9abb-ea20e64b2ece%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0>

I will post more images as I come across them. Please feel free to share widely, especially on social media to combat the “vaccines save lives” rhetoric (which rarely includes any evidence, science, or valid graphs whatsoever).

Share

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Comment

From: lisa@informedchoicewa.org
Sent: 1/3/2025 10:59:57 AM
To: DOH WSBOH
Subject: for BOH packet for its January 8 meeting?prevent both fear and infection

External Email

Dear Board of Health members,

I have cc'ed our state veterinarian, Dr. Amber Itle, as well as the chairs of our Senate and House health and agriculture committees. The following is a message similar to one I sent in August. I have not received a reply from the parties I copied at that time.

Now that California has declared an emergency regarding avian flu (<https://www.gov.ca.gov/2024/12/18/governor-newsom-takes-proactive-action-to-strengthen-robust-state-response-to-bird-flu/>)--<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.ca.gov%2F2024%2F12%2Fnewsom-takes-proactive-action-to-strengthen-robust-state-response-to-bird-flu%2F&data=05%7C02%7Cwsboh%40sboh.wa.gov%7Cd55350238b624310e17508dd2c2814a8%7C11d0>> in the absence of a single case of human-to-human transmission worldwide (<https://www.cdc.gov/bird-flu/situation-summary/inhumans.html>)<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.cdc.gov%2Fbird-flu%2Fsituation-summary%2Finhumans.html&data=05%7C02%7Cwsboh%40sboh.wa.gov%7Cd55350238b624310e17508>>)--it is critical for our state to use available tools to empower citizens and farmers to protect themselves and their animals—all without creating an atmosphere of fear.

Hydrogen peroxide (H₂O₂) has been well-studied for use with animals, as well as humans, and has been shown to deactivate bird flu viruses. Solutions of hydrogen peroxide can be safely misted in coops and barns, directly on animals and eggs. Likewise, people of all ages can utilize this and other inexpensive antiviral substances via nasal rinse and gargling to prevent and stop upper respiratory infection. Please see the 21 studies linked below.

I can't stress enough how important it is that Washington State agencies embrace and educate the public on the benefits of oral and throat hygiene. Iodine solutions can inactivate any virus in 15 seconds, H₂O₂ in less than 30 seconds, and essential oils in under a minute. These substances can kill bacteria, too. These are not controversial prevention strategies; they are well-established to be safe and effective. Adding these tools to the public health toolbox could drastically prevent infection, reduce transmission, and lower incidence of severe infection.

Wouldn't it be exemplary if Washington took the lead on promoting this practice, and we ended up with the lowest respiratory infection rates in the nation? Public health policies take time to disseminate, of course, but the DOH has a vast network and the ability to communicate with healthcare providers and the public with a simple push of the "send"

button for emails, social media, press releases, even texts. Information about nasal spray/rinse and gargling could be including in the DOH's existing workflow.

The messaging could be included wherever handwashing is mentioned in regards to helping prevent the spread of respiratory infection. The supporting science spans decades, and the studies during COVID provide even more evidence. This education outreach doesn't need to recommend any specific OTC products. Just as DOH doesn't tell people what specific type or brand of soap to use, neither would they have to say what specific type or brand of nasal or gargling product to use. They could simply explain the basics, the ingredients studied (saline, iodine, H₂O₂, essential oils, grapefruit seed extract, etc.), and use standard language of "see your healthcare provider" and "use as directed."

I do believe we can easily do this!

Questions for Dr. Itle:

* Are you already aware of the many H₂O₂ studies and animal applications for preventing the spread of infection? Examples:

* Hydrogen Peroxide in Agriculture: A Proactive Approach to Farm Sanitation and Disease Prevention

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fnutrihydro.com%2Fhydrogen-peroxide-in-agriculture-a-proactive-approach-to-farm-sanitation-and-disease-prevention%2F%3Fv%3Da25496ebf095&data=05%7C02%7Cwsboh%40sboh.wa.gov%7Cd55350238b624>, <https://nutrihydro.com/hydrogen-peroxide-in-agriculture-a-proactive-approach-to-farm-sanitation-and-disease-prevention/?v=a25496ebf095>

* This is not a hydrogen peroxide study, but electrolyzed water is another effective approach: Reduction of microbial contamination on the surfaces of layer [chicken] houses using slightly acidic electrolyzed water

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F26371328/>, <https://pubmed.ncbi.nlm.nih.gov/26371328/>

* Would your office be willing to explore this approach further and disseminate the information to farmers and ranchers?

It's very important that we all help to prevent the spread of fear as well as the spread of infection. These simple and readily-available solutions can go a long way in fulfilling these objectives. I appreciate your time and efforts on this consequential matter.

Sincerely,

Lisa Templeton

Informed Choice Washington Director

InformedChoiceWA.org

1. UConn Health Researchers Find a Simple Oral Rinse Can Inactivate the COVID-19 Virus

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://health-researchers-find-simple-oral-rinse-can-inactivate-covid-19-virus%2F*__%3BIw!!PRtDf9A!pcNxthqswetCvhQIUMNc9WTY6h7bbtE2P7YNEr3r4UrrZr3QaC3Q29szyUhWyL>
, <https://today.uconn.edu/2020/06/uconn-health-researchers-find-simple-oral-rinse-can-inactivate-covid-19-virus/#>

2. Can povidone iodine gargle/mouthrinse decrease the risk of transmission?

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://pubmed.ncbi.nlm.nih.gov/33747261/>

3. Comparison of In Vitro Inactivation of SARS CoV□2with Hydrogen Peroxide and Povidone□Iodine□Oral Antiseptic Rinses

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7361576/>

4. How to Make the Povidone Iodine Solution from the I-CARE FLCCC Protocol - Video Tutorial, <https://covid19criticalcare.com/tools-and-guides/how-to-make-the-povidone-iodine-solution-from-the-i-care-protocol/>

<<file:///C:/Users/glena/OneDrive/ICWA/Public%20Health/How%20to%20Make%20the%20Povidone%20Iodine%20Solution%20from%20the%20I-CARE%20FLCCC%20Protocol%20-Video%20Tutorial,%20https://covid19criticalcare.com/tools-and-guides/how-to-make-the-povidone-iodine-solution-from-the-i-care-protocol/>>

5. Known effective since 1977 at the latest Virus inactivation by hydrogen peroxide

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://pubmed.ncbi.nlm.nih.gov/203115/>

6. Comparison of In Vitro Inactivation of SARS CoV□2with Hydrogen Peroxide and Povidone□Iodine□Oral Antiseptic Rinses

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7361576/>

7. Expert Panel Discussion: Hydrogen peroxide in the prevention of Covid-19

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://www.brighteon.com/76f0c65b-69e9-4023-a2a8-0c31e72af047>

, <https://www.brighteon.com/76f0c65b-69e9-4023-a2a8-0c31e72af047>

8. Hospital Study Shows that Covid-19 Can be Prevented with Hydrogen Peroxide

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://www.orthomolecular.org/resources/omns/v18n18.shtml>

, <https://www.orthomolecular.org/resources/omns/v18n18.shtml>

9. Hydrogen Peroxide Nebulization and COVID Resolution

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.orthomolecular.org%2Fresources/omns/v17n13.shtml>>

, <https://www.orthomolecular.org/resources/omns/v17n13.shtml>

10. Virucidal Efficacy of Different Oral Rinses Against Severe Acute Respiratory Syndrome Coronavirus 2

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://academic.oup.com/jid/article/222/8/1289/5878067?login=true>

, <https://academic.oup.com/jid/article/222/8/1289/5878067?login=true>

11. Curing Viruses with [Nebulized] Hydrogen Peroxide: Can a simple therapy stop the pandemic?

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Forthomolecular.org%2Fresources/omns/v16n43.shtml>>

, <https://orthomolecular.org/resources/omns/v16n43.shtml>

12. Protocol for Hydrogen Peroxide Mouth Wash and Nasal Cleanse

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Flatitudes.org%2Fprotocol-for-hydrogen-peroxide-mouthwash-and-nasal-cleanse%2F&data=05%7C02%7Cwsboh%40sboh.wa.gov%7Cd55350238b624310e17508dd2c2814a8%7C>>

, <https://latitudes.org/protocol-for-hydrogen-peroxide-mouthwash-and-nasal-cleanse/>

13. In Vitro Analysis of the Anti-viral Potential of nasal spray constituents against SARS-CoV-2

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://www.biorxiv.org/content/10.1101/2020.12.02.408575v3.full

14. Inhibitory effect of grapefruit seed extract (GSE) on avian pathogen

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://pubmed.ncbi.nlm.nih.gov/30713281/

15. Grapefruit Seed Extract as a Natural Derived Antibacterial Substance against Multidrug-Resistant Bacteria

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://pubmed.ncbi.nlm.nih.gov/33477436/

16. An updated and comprehensive review of the antiviral potential of essential oils and their chemical constituents with special focus on their mechanism of action against various influenza and coronaviruses

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9159739/

17. Virucidal Activity of Different Mouthwashes Using a Novel Biochemical Assay

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8775226/

18. Virucidal Efficacy of Different Oral Rinses Against Severe Acute Respiratory Syndrome Coronavirus 2

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7454736/

19. A pilot, open labelled, randomised controlled trial of hypertonic saline nasal irrigation and gargling for the common cold

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6355924/

20. Do saline water gargling and nasal irrigation confer protection against COVID-19?

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7528968/

21. Saline nasal irrigation and gargling in COVID-19: a multidisciplinary review of effects on viral load, mucosal dynamics, and patient outcomes

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Furldefense.com%2Fv3%2F__https://urldefense.com/v3/__https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10312243/__;!!PRtDf9A!pcNxl

From: Garry Blankenship

Sent: 12/2/2024 8:24:52 AM

To: Van De Wege, Kevin, Chapman, Mike (LEG), DOH

WSBOH, sheriff@co.clallam.wa.us, mozias@co.clallam.wa.us, rjohnson@co.clallam.wa.us, shahidafatin@gmail

Allison 2 (DOHi)

Cc:

Subject: COVID Vaccines Accurately Summarized

External Email

<https://brownstone.org/articles/the-vaccine-paradox/>

From: Jim Sledge
Sent: 1/3/2025 12:13:27 PM
To: DOH WSBOH
Cc:
Subject: My Public Comments

External Email

The FDA doesn't have jurisdiction over drinking water so this change is designed to subvert the authority of the EPA which does have jurisdiction. Please refrain from approving this Trojan Horse attempt to remove fluoride from our drinking water!
James N Sledge,DDS, FACD

greater CFM/person, including (as California emphasizes

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.cdph.ca.gov%2FPrograms%2F19%2FCOVID-19-and-Improving-Indoor-Air-Quality-in-Schools.aspx&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C90f73141dcfa48bdc39808dd08d21d3b%7C11d0e1>

) adding portable air cleaning devices with clean, "mechanical"-only filtration (pleated filters, no electronic cleaning technologies). Slide 43 shows multiple "passing" scenarios for a ~9,000 cu ft classroom like my daughter's.

I speak from experience here because I spent over a year working with Member Buck trying to update the Lake Washington School District's policy on portable HEPA filters, which currently fall under a blanket "personal appliances" ban. I referenced guidance from EPA

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.epa.gov%2Fcoronavirus%2Findoor-environments-schools-during-covid-19-pandemic-and-beyond&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C90f73141dcfa48bdc39808dd08d21d3b%7C11d0e1>

, CDC

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2Fncov%2Fprevent-getting-sick%2Fimproving-ventilation-in-buildings.html&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C90f73141dcfa48bdc39808dd08d21d3b%7C11d0e1>

, WA DOH

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdoh.wa.gov%2Fsites%2Fdefault%2F07%2F333-256.pdf%3Fuid%3D62df0b3b8ceb2&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C90f73141dcfa48bdc39808dd08d21d3b%7C11d0e1>

, ASHRAE

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Frochesterashrae.org%2Fimages%2Fcountless>

, countless

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.sciencedirect.com%2Fscience%2Farticle%2Fpii%2FS0168133522000000&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C90f73141dcfa48bdc39808dd08d21d3b%7C11d0e1>

, and even a pilot bulk HEPA purchase program in nearby King County school districts

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdeohs.washington.edu%2Fhsm-blog%2Fhealthy-air-healthy-schools&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C90f73141dcfa48bdc39808dd08d21d3b%7C11d0e1>

, but Member Buck emphasized the district policy that portable units are "not recommended" where central HVAC is deemed sufficient. We eventually agreed on a policy exception permitting me to set up and maintain the filter in my child's classroom,

but only with a "documented medical need."

While I'm grateful for the accommodation for a HEPA filter that costs less than 3 cents/day to operate at ~45dB and adds 2.25 ACH (or roughly 13 CFM/person with an occupancy of 25 people), policies that are hostile to portable filters will keep thousands of classrooms from enjoying the health benefits (and reduced absenteeism) of cleaner indoor air—especially in the absence of WAC language requiring schools meet modern standards.

If not a higher minimum codified into WAC for new and existing schools, even a recommendation of higher CFM/person would offer school officials an appropriate standard to target with the goal of creating healthier communities. It would be even more effective to pair that with official language on keeping CO2 below 800ppm, as WA DOH has recommended

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(as a proxy for air quality and viral transmission risk), and clearly condoning the use of HEPA filters when central HVAC proves insufficient or thermal/energy concerns prevent the addition of more outside air.

I would be happy to speak to these concerns at tomorrow's meeting or in any other forum (although I do not see an agenda item

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for public comment). I also was not able to find more information on the "focus groups" cited on the project website

<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsboh.wa.gov%2Frulemaking%2Frules-and-activity%2F2024-2025-school-rule-review-project&data=05%7C02%7Cwsboh%40sboh.wa.gov%7C90f73141dcfa48bdc39808dd08d21d3b%7C11d0e2>

as being set up in December, but would be happy to join those as well. Thank you all for your time and for bringing your expertise to this project on behalf of kids, educators, and families across the state.

Greg Howard
Kirkland, WA

From: Bob Runnells
Sent: 11/24/2024 10:49:01 AM
To: bill teachingsmiles.com
Subject: Re: Petition for Rule Change #22

External Email

Thank you Bill.
And thank you for all your efforts.

Do you finally feel a tailwind?

<https://www.tampabay.com/news/florida-politics/2024/11/22/florida-ladapo-surgeon-general-rfk-trump-fluoride/>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.tampabay.com%2Fnews%2Fpolitics%2F2024%2F11%2F22%2Fflorida-ladapo-surgeon-general-rfk-trump-fluoride%2F&data=05%7C02%7CWSBOH%40sboh.wa.gov%7C2e04a8c419d64990380408dd0cb8a6ae%7C>>

And feel even more emboldened by the last article in Saturday's Coffee & COVID newsletter by Jeff Childers, Esq.

<https://www.coffeeandcovid.com/p/doge-opoly-saturday-november-23-2024>
<<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.coffeeandcovid.com%2Fp%2Fdoge-opoly-saturday-november-23-2024&data=05%7C02%7CWSBOH%40sboh.wa.gov%7C2e04a8c419d64990380408dd0cb8a6ae%7C11d0e>>

(Apologies, but I took the liberty to Reply All, since I know quite a few of those on your mailing list already).

Regards,
Bob Runnells

Fighting for more natural healthcare and informed consent.
CHD - WA Chapter co-lead; ICWA president,

On Sun, Nov 24, 2024 at 9:50 AM bill teachingsmiles.com
<<https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fteachingsmiles.com%2F&data=05%7C02%7CWSBOH%40sboh.wa.gov%7C2e04a8c419d64990380408dd0cb8a6ae%7C11d0e>>
<bill@teachingsmiles.com <<mailto:bill@teachingsmiles.com>> > wrote:

Dear Washington State Board of Health,

Public Health Malpractice

Protecting the public health rather than profits of industry.

Attached is our 22nd petition to protect the public health.

We cannot understand the persistent denial by the Board of Health to even have a forum to even discuss fluoridation's lack of benefit and serious harm to the public. The public is not served by hiding and ignoring science.

Putting the cities in liability for harm and claiming you do not add the fluoride to water and are not the final manufacturer of the illegal drug makes no moral or ethical

sense.

Your prompt response and action is required.

Sincerely,
Bill Osmunson DDS MPH
Washington Action for Safe Water

--

-Bob

From: Derek Kemppainen
Sent: 1/3/2025 12:01:53 PM
To: DOH WSBOH
Cc:
Subject: My Public Comments for January 8th BOH Meeting - Water Fluoridation



attachments\A179463269C94AE3_10 Facts about Fluoride with Detail.pdf



attachments\704B2C62AFF24C96_3 Reasons to End Water Fluoridation.pdf



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Recommen_PRDTOOL_NAMETOOLONG.docx*



attachments\09F36D94E2CD4E3A_50 Reasons to Oppose Fluoridation.pdf

External Email

Subject: Concerns Regarding WSDOH Recommendation on Water Fluoridation

Dear WSBOH,

I am writing to express my concerns regarding the current WSDOH recommendation to fluoridate drinking water.

It seems unthinkable for a physician to prescribe a lifelong dosage of a potentially toxic substance, with no proven clinical benefit, to someone they have never met, interviewed, or examined. Such an approach disregards individual medical histories and informed consent. Even more troubling, this recommendation effectively suggests that the public consume an unspecified amount of this substance indefinitely, not because of their individual needs, but because some children may suffer from tooth decay.

This one-size-fits-all approach is not only unscientific but also illegal, unethical and unacceptable.

On September 24, 2024, the U.S. District Court for the Northern District of California issued a landmark ruling, determining that water fluoridation at 0.7 mg/L poses an "unreasonable risk" to children's health by reducing IQ. This decision underscores the urgent need to reevaluate the continued recommendation of fluoride at these levels, as it is no longer justifiable in light of the demonstrated harm.

In addition to my concerns, I would like to share the attached Top 50, Top 10, and Top 3 Reasons to Discontinue Fluoridation for your consideration. These reasons encapsulate a range of ethical, scientific, and public health perspectives that I believe warrant serious reflection.

The recommendation to fluoridate drinking water is in violation of numerous state and federal laws.

The Department of Health is complicit in encouraging violations of RCW 69.41.030, which governs the distribution and administration of legend drugs. Fluoride, classified as a legend drug, is being recommended for unauthorized delivery to the public without prescriptions, medical oversight, or the involvement of licensed professionals. This circumvention of lawful distribution channels and medical oversight constitutes a breach of RCW 69.41.030.

Additionally, under RCW 69.38.010, sodium fluoride meets the state's definition of a

poison. The intentional addition of poison to the water supply contravenes RCW 69.40.030, which criminalizes the willful mingling of poisons in water supplies and carries penalties of imprisonment and substantial fines.

The Department also fails to ensure compliance with WAC 246-290-220, which mandates adherence to ANSI/NSF Standard 60 & 61. These standards limit the leaching of harmful contaminants into drinking water and ensure the additives are safe. Moreover, the recommendation violates RCW 70A.125.060 by failing to prioritize the safety of the public water system, thereby compromising water quality and endangering public health.

Further, the promotion of fluoridation by the Department infringes upon federal regulations under CFR Title 21. Specifically, it violates 21 CFR 202.1(e) by failing to disclose side effects and making false or misleading claims about fluoride. This also constitutes a breach of the Food, Drug, and Cosmetic Act by promoting and distributing an unapproved drug without proper oversight or informed consent.

Finally, by recommending the addition of fluoride to water supplies without informed consent or medical oversight, the Department of Health is in violation of ethical standards set by the Nuremberg Code and the Belmont Report. These actions infringe upon constitutional rights, including the right to bodily integrity and freedom of medical choice.

Under federal law, fluoridation qualifies as medical experimentation. Fluoride is an unapproved drug being administered to human subjects without their consent, in violation of 21 CFR § 312.3(b). The Department has not ensured "legally effective informed consent" as required by 21 CFR § 50.20 and 21 CFR § 50.25(a)(1). Furthermore, no Investigational New Drug (IND) application has been filed, as required under 21 CFR § 312, nor has Institutional Review Board (IRB) approval been sought, as mandated by 21 CFR Part 56.

Lastly, under the Food, Drug, and Cosmetic Act (FD&C Act), the recommendation to fluoridate constitutes the unlawful introduction of an unapproved drug into interstate commerce without the required New Drug Application (NDA) or IND, in violation of 21 U.S.C. § 355. These actions amount to illegal medical experimentation and a failure to protect public health.

I urge the Department of Health to reconsider this recommendation in light of these legal, ethical, and public health concerns. Thank you for your attention to this matter.

Sincerely,

Derek Kempainen

31404 NE 142nd Ave

Battle Ground, WA 98604

360-975-2011



WATER FLUORIDATION IS THE PRACTICE OF ADDING INDUSTRIAL-GRADE FLUORIDE CHEMICALS TO WATER FOR THE PURPOSE OF PREVENTING TOOTH DECAY. ONE OF THE LITTLE KNOWN FACTS ABOUT THIS PRACTICE IS THAT THE UNITED STATES, WHICH FLUORIDATES OVER 70% OF ITS WATER SUPPLIES, HAS MORE PEOPLE DRINKING FLUORIDATED WATER THAN THE REST OF THE WORLD COMBINED. MOST DEVELOPED NATIONS, INCLUDING ALL OF JAPAN AND 97% OF WESTERN EUROPE, DO NOT FLUORIDATE THEIR WATER.

In the United States, the Oral Health Division of the Centers Disease Control (CDC) hails fluoridation as one of the “top ten public health achievements of the 20th century.” However, comprehensive data from the World Health Organization reveals that there is no discernible difference in tooth decay between the minority of western nations that fluoridate water, and the majority that do not. In fact, the tooth decay rates in many non-fluoridated countries are now lower than the tooth decay rates in fluoridated ones.

As is becoming increasingly clear, fluoridating water supplies is an outdated, unnecessary, and dangerous relic from a 1950s public health culture that viewed mass distribution of chemicals much differently than scientists do today.

Communities Are Starting to Get the Message

In recent years, communities throughout the United States and Canada have started to reassess the conventional wisdom of fluoridating their water. Many of these communities, including over 50 since 2010, are reaching the obvious conclusion: when stripped of its endorsements, well-meaning intentions, and PR-praise, fluoridation simply makes no sense.

Europe reached this conclusion a long time ago. It is now time for the U.S. and other English-speaking nations to follow suit.



3 REASONS TO END WATER FLUORIDATION

1) FLUORIDATION IS AN OUTDATED FORM OF MASS MEDICATION

Unlike all other water treatment processes, fluoridation does not treat the water itself, but the person consuming it. The Food & Drug Administration accepts that fluoride is a drug, not a nutrient, when used to prevent disease. By definition, therefore, fluoridating water is a form of mass medication. This is why most western European nations have rejected the practice—because, in their view, the public water supply is not an appropriate place to be adding drugs, particularly when fluoride is readily available for individual use in the form of toothpaste.

2) FLUORIDATION IS UNNECESSARY AND INEFFECTIVE

The most obvious reason to end fluoridation is that it is now known that fluoride's main benefit comes from topical contact with the teeth, not from ingestion. Even the CDC's Oral Health Division now acknowledges this. There is simply no need, therefore, to swallow fluoride, whether in the water, toothpaste, or any other form. Further, despite early claims that fluoridated water would reduce cavities by 65%, modern large-scale studies show no consistent or meaningful difference in the cavity rates of fluoridated and non-fluoridated areas.

3) FLUORIDATION IS NOT A SAFE PRACTICE

First, there is no dispute that fluoridation is causing millions of children to develop dental fluorosis, a discoloration of the teeth that is caused by excessive fluoride intake. Scientists from the Centers for Disease Control have even acknowledged that fluoridation is causing “cosmetically objectionable” fluorosis on children's front teeth—an effect that can cause embarrassment and distress at a time of life when physical appearance is the single most important predictor of self-esteem.

Second, it is known that fluoridated water caused severe bone disease in dialysis patients up until the late 1970s (prior to dialysis units filtering fluoride). While dialysis units now filter out the fluoride, research shows that current fluoride exposures are still resulting in dangerously high bone fluoride levels in dialysis patients and patients with other advanced forms of kidney disease. It is unethical to compromise the health of some members in a population to obtain a purported benefit for another — particularly in the absence of these vulnerable members' knowing consent.

And, finally, a growing body of evidence reasonably indicates that fluoridated water, in addition to other sources of daily fluoride exposure, can cause or contribute to a range of serious effects, including arthritis, damage to the developing brain, reduced thyroid function, and possibly osteosarcoma (bone cancer) in adolescent males.



FLUORIDEALERT.ORG
Fluoride Action Network

50 REASONS TO OPPOSE FLUORIDATION

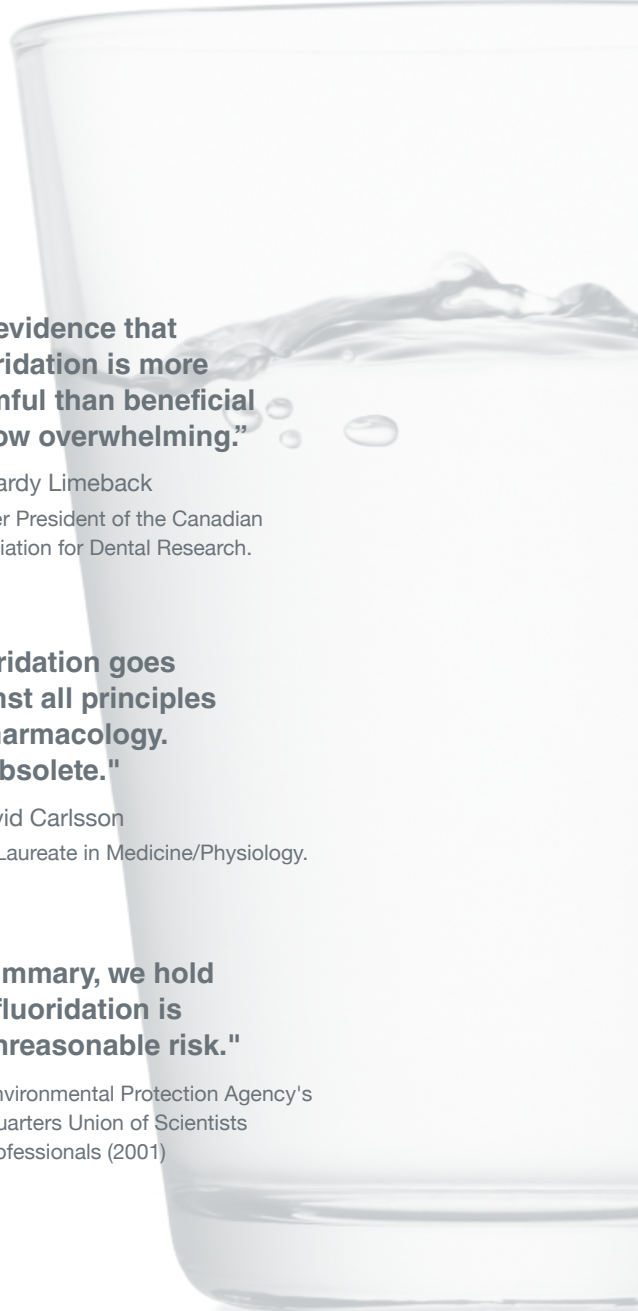
Written by

PAUL CONNETT, PHD.

Fluoride Action Network

OTHER CONTRIBUTORS:

James Beck, MD, PhD
Michael Connett, JD
Hardy Limeback, DDS, PhD
David McRae
Spedding Micklem, D.Phil



**"The evidence that
fluoridation is more
harmful than beneficial
is now overwhelming."**

Dr. Hardy Limeback
Former President of the Canadian
Association for Dental Research.

**"Fluoridation goes
against all principles
of pharmacology.
It's obsolete."**

Dr. Arvid Carlsson
Nobel Laureate in Medicine/Physiology.

**"In summary, we hold
that fluoridation is
an unreasonable risk."**

U.S. Environmental Protection Agency's
Headquarters Union of Scientists
and Professionals (2001)

UPDATED AUGUST, 2012

Fluoridation is the practice of adding a fluoride compound to the public drinking water supply ostensibly for the purpose of fighting tooth decay. The levels used range from 0.6 to 1.2 milligrams of fluoride ion per liter. The practice began in the United States in 1945 and was endorsed by most U.S. medical and dental associations shortly thereafter. Very few countries, however, have adopted the practice to any significant extent. Only eleven countries in the world have more than 50% of their populations drinking artificially fluoridated water (Australia, Brunei, Chile, Hong Kong, Ireland, Israel, Guyana, Malaysia, New Zealand, Singapore, and the United States).

In Europe, only Ireland (73%), Poland (1%), Serbia (3%), Spain (11%), and the U.K. (11%) fluoridate any of their water. Most developed countries, including Japan and 97% of the western European population, do not consume fluoridated water.

In the U.S., about 70% of public water supplies are fluoridated. This equates to approximately 185 million people, which is over half the number of people drinking artificially fluoridated water worldwide. Some countries have areas with high natural fluoride levels in the water. These include India, China and parts of Africa. In these countries measures are being taken to remove the fluoride because of the health problems that fluoride can cause.

“WE’VE GONE WITH THE STATUS QUO REGARDING FLUORIDE FOR MANY YEARS—FOR TOO LONG, REALLY—AND NOW WE NEED TO TAKE A FRESH LOOK. IN THE SCIENTIFIC COMMUNITY, PEOPLE TEND TO THINK THIS IS SETTLED. BUT WHEN WE LOOKED AT THE STUDIES THAT HAVE BEEN DONE, WE FOUND THAT MANY OF THESE QUESTIONS ARE UNSETTLED AND WE HAVE MUCH LESS INFORMATION THAN WE SHOULD, CONSIDERING HOW LONG THIS HAS BEEN GOING ON.”

Dr. John Doull

CHAIRMAN, NATIONAL RESEARCH COUNCIL'S REVIEW ON FLUORIDE IN DRINKING WATER.

FLUORIDATION IS A BAD MEDICAL PRACTICE

1) FLUORIDE IS THE ONLY CHEMICAL ADDED TO WATER FOR THE PURPOSE OF MEDICAL TREATMENT.

The U.S. Food and Drug Administration (FDA) classifies fluoride as a drug when used to prevent or mitigate disease (FDA 2000). As a matter of basic logic, adding fluoride to water for the sole purpose of preventing tooth decay (a non-waterborne disease) is a form of medical treatment. All other water treatment chemicals are added to improve the water's quality or safety, which fluoride does not do.

2) FLUORIDATION IS UNETHICAL.

Informed consent is standard practice for all medication, and one of the key reasons why most of Western Europe has ruled against fluoridation. With water fluoridation we are allowing governments to do to whole communities (forcing people to take a medicine irrespective of their consent) what individual doctors cannot do to individual patients.

Put another way: Does a voter have the right to require that their neighbor ingest a certain medication (even if it is against that neighbor's will)?

3) THE DOSE CANNOT BE CONTROLLED.

Once fluoride is put in the water it is impossible to control the dose each individual receives because people drink different amounts of water. Being able to control the dose a patient receives is critical. Some people (e.g., manual laborers, athletes, diabetics, and people with kidney disease) drink substantially more water than others.

4) THE FLUORIDE GOES TO EVERYONE REGARDLESS OF AGE, HEALTH OR VULNERABILITY.

According to Dr. Arvid Carlsson, the 2000 Nobel Laureate in Medicine and Physiology and one of the scientists who helped keep fluoridation out of Sweden:

“Water fluoridation goes against leading principles of pharmacotherapy, which is progressing from a stereotyped medication — of the type 1 tablet 3 times a day — to a much more individualized therapy as regards both dosage and selection of drugs.

The addition of drugs to the drinking water means exactly the opposite of an individualized therapy” (Carlsson 1978).

5) PEOPLE NOW RECEIVE FLUORIDE FROM MANY OTHER SOURCES BESIDES WATER.

Fluoridated water is not the only way people are exposed to fluoride. Other sources of fluoride include food and beverages processed with fluoridated water (Kiritsy 1996; Heilman 1999), fluoridated dental products (Bentley 1999; Levy 1999), mechanically deboned meat (Fein 2001), tea (Levy 1999), and pesticide residues (e.g., from cryolite) on food (Stannard 1991; Burgstahler 1997). It is now widely acknowledged that exposure to non-water sources of fluoride has significantly increased since the water fluoridation program first began (NRC 2006).

6) FLUORIDE IS NOT AN ESSENTIAL NUTRIENT.

No disease, not even tooth decay, is caused by a “fluoride deficiency” (NRC 1993; Institute of Medicine 1997, NRC 2006). Not a single biological process has been shown to require fluoride. On the contrary there is extensive evidence that fluoride can interfere with many important biological processes. Fluoride interferes with numerous enzymes (Waldbott 1978). In combination with aluminum, fluoride interferes with G-proteins (Bigay 1985, 1987). Such interactions give aluminum-fluoride complexes the potential to interfere with signals from growth factors, hormones and neurotransmitters (Strunecka & Patocka 1999; Li 2003). More and more studies indicate that fluoride can interfere with biochemistry in fundamental ways (Barbier 2010).

7) THE LEVEL IN MOTHERS’ MILK IS VERY LOW.

Considering reason #6 it is perhaps not surprising that the level of fluoride in mother’s milk is remarkably low (0.004 ppm, NRC, 2006). This means that a bottle-fed baby consuming fluoridated water (0.6 – 1.2 ppm) can get up to 300 times more fluoride than a breast-fed baby. There are no benefits (see reasons #11-19), only risks (see reasons #21-36), for infants ingesting this heightened level of fluoride at such an early age (an age where susceptibility to environmental toxins is particularly high).

8) FLUORIDE ACCUMULATES IN THE BODY.

Healthy adult kidneys excrete 50 to 60% of the fluoride they ingest each day (Marier & Rose 1971). The remainder accumulates in the body, largely in calcifying tissues such as the bones and pineal gland (Luke 1997, 2001). Infants and children excrete less fluoride from their kidneys and take up to 80% of ingested fluoride into their bones (Ekstrand 1994). The fluoride concentration in bone steadily increases over a lifetime (NRC 2006).

9) NO HEALTH AGENCY IN FLUORIDATED COUNTRIES IS MONITORING FLUORIDE EXPOSURE OR SIDE EFFECTS.

No regular measurements are being made of the levels of fluoride in urine, blood, bones, hair, or nails of either the general population or sensitive subparts of the population (e.g., individuals with kidney disease).

10) THERE HAS NEVER BEEN A SINGLE RANDOMIZED CLINICAL TRIAL TO DEMONSTRATE FLUORIDATION'S EFFECTIVENESS OR SAFETY.

Despite the fact that fluoride has been added to community water supplies for over 60 years, “there have been no randomized trials of water fluoridation” (Cheng 2007). Randomized studies are the standard method for determining the safety and effectiveness of any purportedly beneficial medical treatment. In 2000, the British Government’s “York Review” could not give a single fluoridation trial a Grade A classification – despite 50 years of research (McDonagh 2000). The U.S. Food and Drug Administration (FDA) continues to classify fluoride as an “unapproved new drug.”

SWALLOWING FLUORIDE PROVIDES NO (OR VERY LITTLE) BENEFIT

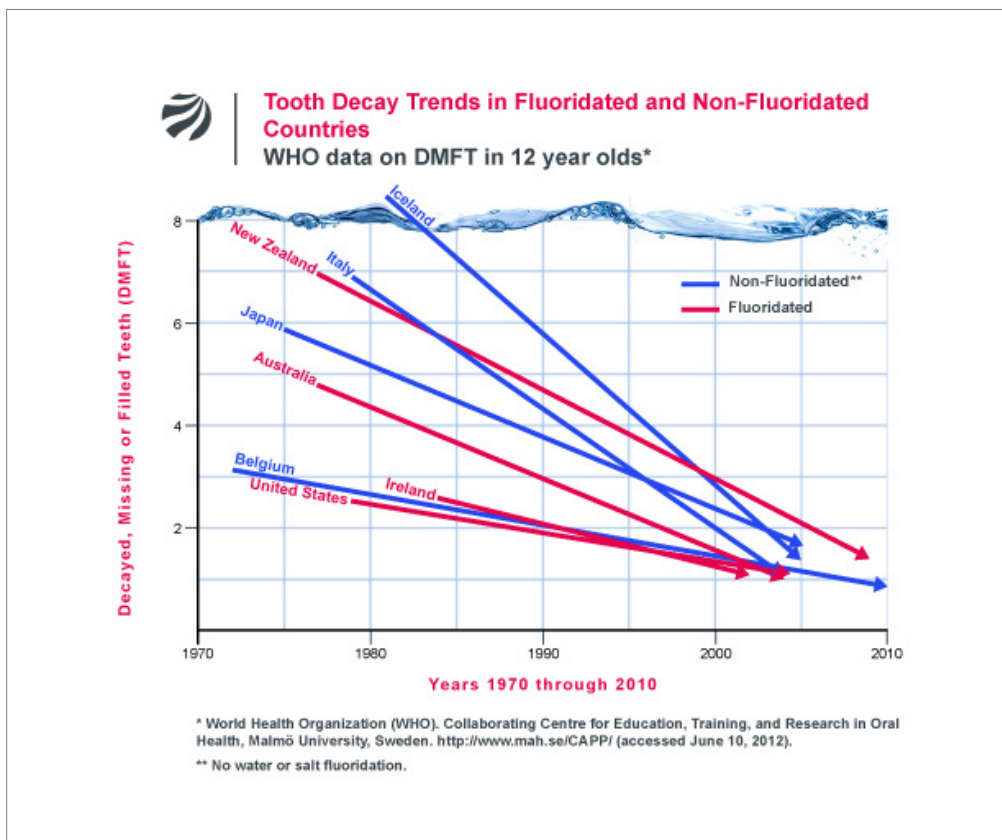
11) BENEFIT IS TOPICAL NOT SYSTEMIC. THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC, 1999, 2001) HAS NOW ACKNOWLEDGED THAT THE MECHANISM OF FLUORIDE'S BENEFITS ARE MAINLY TOPICAL, NOT SYSTEMIC.

There is no need whatsoever, therefore, to swallow fluoride to protect teeth. Since the purported benefit of fluoride is topical, and the risks are systemic, it makes more sense to deliver the fluoride directly to the tooth in the form of toothpaste.

Since swallowing fluoride is unnecessary, and potentially dangerous, there is no justification for forcing people (against their will) to ingest fluoride through their water supply.

12) FLUORIDATION IS NOT NECESSARY.

Most western, industrialized countries have rejected water fluoridation, but have nevertheless experienced the same decline in childhood dental decay as fluoridated countries. (See data from World Health Organization presented graphically in Figure).



13) FLUORIDATION'S ROLE IN THE DECLINE OF TOOTH DECAY IS IN SERIOUS DOUBT.

The largest survey ever conducted in the US (over 39,000 children from 84 communities) by the National Institute of Dental Research showed little difference in tooth decay among children in fluoridated and non-fluoridated communities (Hileman 1989). According to NIDR researchers, the study found an average difference of only 0.6 DMFS (Decayed, Missing, and Filled Surfaces) in the permanent teeth of children aged 5-17 residing their entire lives in either fluoridated or unfluoridated areas (Brunelle & Carlos, 1990). This difference is less than one tooth surface, and less than 1% of the 100+ tooth surfaces available in a child's mouth. Large surveys from three Australian states have found even less of a benefit, with decay reductions ranging from 0 to 0.3 of one permanent tooth surface (Spencer 1996; Armfield & Spencer 2004). None of these studies have allowed for the possible delayed eruption of the teeth that may be caused by exposure to fluoride, for which there is some evidence (Komarek 2005). A one-year delay in eruption of the permanent teeth would eliminate the very small benefit recorded in these modern studies.

14) NIH-FUNDED STUDY ON INDIVIDUAL FLUORIDE INGESTION AND TOOTH DECAY FOUND NO SIGNIFICANT CORRELATION.

A multi-million dollar, U.S. National Institutes of Health (NIH)-funded study found no significant relationship between tooth decay and fluoride intake among children (Warren 2009). This is the first time tooth decay has been investigated as a function of individual exposure (as opposed to mere residence in a fluoridated community).

15) TOOTH DECAY IS HIGH IN LOW-INCOME COMMUNITIES THAT HAVE BEEN FLUORIDATED FOR YEARS.

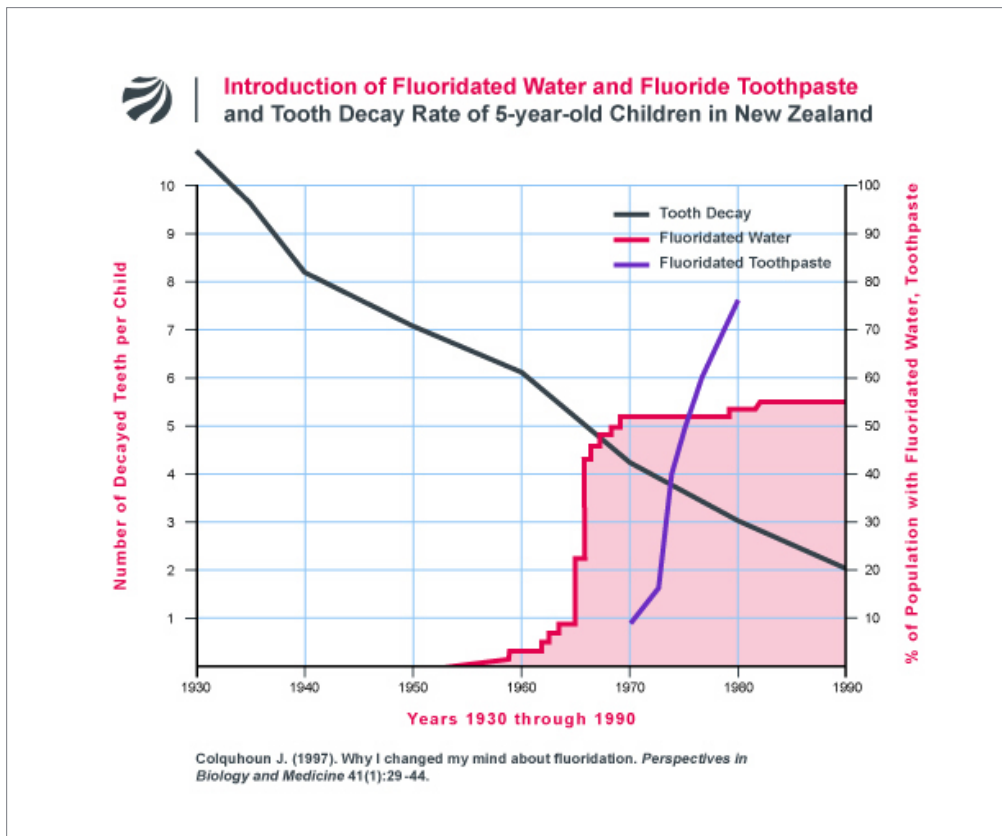
Despite some claims to the contrary, water fluoridation cannot prevent the oral health crises that result from rampant poverty, inadequate nutrition, and lack of access to dental care. There have been numerous reports of severe dental crises in low-income neighborhoods of US cities that have been fluoridated for over 20 years (e.g., Boston, Cincinnati, New York City, and Pittsburgh). In addition, research has repeatedly found fluoridation to be ineffective at preventing the most serious oral health problem facing poor children, namely "baby bottle tooth decay," otherwise known as early childhood caries (Barnes 1992; Shiboski 2003).

16) TOOTH DECAY DOES NOT GO UP WHEN FLUORIDATION IS STOPPED.

Where fluoridation has been discontinued in communities from Canada, the former East Germany, Cuba and Finland, dental decay has not increased but has generally continued to decrease (Maupomé 2001; Kunzel & Fischer, 1997, 2000; Kunzel 2000; Seppa 2000).

17) TOOTH DECAY WAS COMING DOWN BEFORE FLUORIDATION STARTED.

Modern research shows that decay rates were coming down before fluoridation was introduced in Australia and New Zealand and have continued to decline even after its benefits would have been maximized. (Colquhoun 1997; Diesendorf 1986). As the following figure indicates, many other factors are responsible for the decline of tooth decay that has been universally reported throughout the western world.



18) THE STUDIES THAT LAUNCHED FLUORIDATION WERE METHODOLOGICALLY FLAWED.

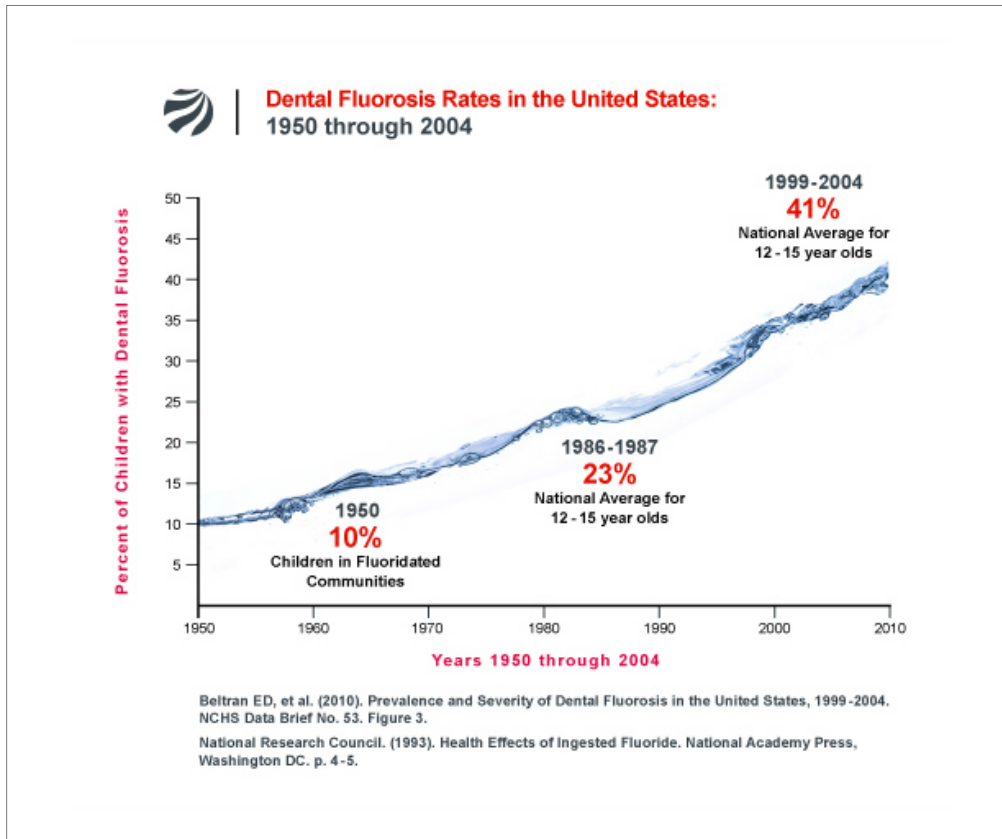
The early trials conducted between 1945 and 1955 in North America that helped to launch fluoridation, have been heavily criticized for their poor methodology and poor choice of control communities (De Stefano 1954; Sutton 1959, 1960, 1996; Ziegelbecker 1970).

According to Dr. Hubert Arnold, a statistician from the University of California at Davis, the early fluoridation trials “are especially rich in fallacies, improper design, invalid use of statistical methods, omissions of contrary data, and just plain muddleheadedness and hebetude.” Serious questions have also been raised about Trendley Dean’s (the father of fluoridation) famous 21-city study from 1942 (Ziegelbecker 1981).

CHILDREN ARE BEING OVER-EXPOSED TO FLUORIDE

19) CHILDREN ARE BEING OVER-EXPOSED TO FLUORIDE.

The fluoridation program has massively failed to achieve one of its key objectives, i.e., to lower dental decay rates while limiting the occurrence of dental fluorosis (a discoloring of tooth enamel caused by too much fluoride. The goal of the early promoters of fluoridation was to limit dental fluorosis (in its very mild form) to 10% of children (NRC 1993, pp. 6-7). In 2010, however, the Centers for Disease Control and Prevention (CDC) reported that 41% of American adolescents had dental fluorosis, with 8.6% having mild fluorosis and 3.6% having either moderate or severe dental fluorosis (Beltran-Aguilar 2010).



As the 41% prevalence figure is a national average and includes children living in fluoridated and unfluoridated areas, the fluorosis rate in fluoridated communities will obviously be higher.

The British Government's York Review estimated that up to 48% of children in fluoridated areas worldwide have dental fluorosis in all forms, with 12.5% having fluorosis of aesthetic concern (McDonagh, 2000).

20) THE HIGHEST DOSES OF FLUORIDE ARE GOING TO BOTTLE-FED BABIES.

Because of their sole reliance on liquids for their food intake, infants consuming formula made with fluoridated water have the highest exposure to fluoride, by bodyweight, in the population. Because infant exposure to fluoridated water has been repeatedly found to be a major risk factor for developing dental fluorosis later in life (Marshall 2004; Hong 2006; Levy 2010), a number of dental researchers have recommended that parents of newborns not use fluoridated water when reconstituting formula (Ekstrand 1996; Pendrys 1998; Fomon 2000; Brothwell 2003; Marshall 2004). Even the American

Dental Association (ADA), the most ardent institutional proponent of fluoridation, distributed a November 6, 2006 email alert to its members recommending that parents be advised that formula should be made with “low or no-fluoride water.” Unfortunately, the ADA has done little to get this information into the hands of parents. As a result, many parents remain unaware of the fluorosis risk from infant exposure to fluoridated water.

EVIDENCE OF HARM TO OTHER TISSUES

21) DENTAL FLUOROSIS MAY BE AN INDICATOR OF WIDER SYSTEMIC DAMAGE.

There have been many suggestions as to the possible biochemical mechanisms underlying the development of dental fluorosis (Matsuo 1998; Den Besten 1999; Sharma 2008; Duan 2011; Tye 2011) and they are complicated for a lay reader. While promoters of fluoridation are content to dismiss dental fluorosis (in its milder forms) as merely a cosmetic effect, it is rash to assume that fluoride is not impacting other developing tissues when it is visibly damaging the teeth by some biochemical mechanism (Groth 1973; Colquhoun 1997). Moreover, ingested fluoride can only cause dental fluorosis during the period before the permanent teeth have erupted (6-8 years), other tissues are potentially susceptible to damage throughout life. For example, in areas of naturally high levels of fluoride the first indicator of harm is dental fluorosis in children. In the same communities many older people develop skeletal fluorosis.

22) FLUORIDE MAY DAMAGE THE BRAIN.

According to the National Research Council (2006), “it is apparent that fluorides have the ability to interfere with the functions of the brain.” In a review of the literature commissioned by the US Environmental Protection Agency (EPA), fluoride has been listed among about 100 chemicals for which there is substantial evidence of developmental neurotoxicity.” Animal experiments show that fluoride accumulates in the brain and alters mental behavior in a manner consistent with a neurotoxic agent (Mullenix 1995). In total, there have now been over 100 animal experiments showing that fluoride can damage the brain and impact learning and behavior. According to fluoridation proponents, these animal studies can be ignored because high doses were used. However, it is important to note that rats generally require five times more fluoride to reach the same plasma levels in humans (Sawan 2010). Further, one animal experiment found effects at remarkably low doses (Varner 1998). In this study, rats fed for one year with 1 ppm

fluoride in their water (the same level used in fluoridation programs), using either sodium fluoride or aluminum fluoride, had morphological changes to their kidneys and brains, an increased uptake of aluminum in the brain, and the formation of beta-amyloid deposits which are associated with Alzheimer's disease. Other animal studies have found effects on the brain at water fluoride levels as low as 5 ppm (Liu 2010).

23) FLUORIDE MAY LOWER IQ.

There have now been 33 studies from China, Iran, India and Mexico that have reported an association between fluoride exposure and reduced IQ. One of these studies (Lin 1991) indicates that even just moderate levels of fluoride exposure (e.g., 0.9 ppm in the water) can exacerbate the neurological defects of iodine deficiency. Other studies have found IQ reductions at 1.9 ppm (Xiang 2003a,b); 0.3-3.0 ppm (Ding 2011); 1.8-3.9 ppm (Xu 1994); 2.0 ppm (Yao 1996, 1997); 2.1-3.2 ppm (An 1992); 2.38 ppm (Poureslami 2011); 2.45 ppm (Eswar 2011); 2.5 ppm (Seraj 2006); 2.85 ppm (Hong 2001); 2.97 ppm (Wang 2001, Yang 1994); 3.15 ppm (Lu 2000); 4.12 ppm (Zhao 1996). In the Ding study, each 1 ppm increase of fluoride in urine was associated with a loss of 0.59 IQ points. None of these studies indicate an adequate margin of safety to protect all children drinking artificially fluoridated water from this affect. According to the National Research Council (2006), "the consistency of the results [in fluoride/IQ studies] appears significant enough to warrant additional research on the effects of fluoride on intelligence." The NRC's conclusion has recently been amplified by a team of Harvard scientists whose fluoride/IQ meta-review concludes that fluoride's impact on the developing brain should be a "high research priority." (Choi et al., 2012). Except for two small IQ studies from New Zealand (Shannon et al., 1986; Spittle 1998) no fluoridating country has yet investigated the matter.

24) FLUORIDE MAY CAUSE NON-IQ NEUROTOXIC EFFECTS.

Reduced IQ is not the only neurotoxic effect that may result from fluoride exposure. At least three human studies have reported an association between fluoride exposure and impaired visual-spatial organization (Calderon 2000; Li 2004; Rocha-Amador 2009); while four other studies have found an association between prenatal fluoride exposure and fetal brain damage (Han 1989; Du 1992; Dong 1993; Yu 1996).

25) FLUORIDE AFFECTS THE PINEAL GLAND.

Studies by Jennifer Luke (2001) show that fluoride accumulates in the human pineal gland to very high levels. In her Ph.D. thesis, Luke has also shown in animal studies that fluoride reduces melatonin production and leads to an earlier onset of puberty (Luke 1997). Consistent with Luke's findings, one of the earliest fluoridation trials in the U.S. (Schlesinger 1956) reported that on average young girls in the fluoridated community reached menstruation 5 months earlier than girls in the non-fluoridated community. Inexplicably, no fluoridating country has attempted to reproduce either Luke's or Schlesinger's findings or examine the issue any further.

26) FLUORIDE AFFECTS THYROID FUNCTION.

According to the U.S. National Research Council (2006), "several lines of information indicate an effect of fluoride exposure on thyroid function." In the Ukraine, Bachinskii (1985) found a lowering of thyroid function, among otherwise healthy people, at 2.3 ppm fluoride in water. In the middle of the 20th century, fluoride was prescribed by a number of European doctors to reduce the activity of the thyroid gland for those suffering from hyperthyroidism (overactive thyroid) (Stecher 1960; Waldbott 1978). According to a clinical study by Galletti and Joyet (1958), the thyroid function of hyperthyroid patients was effectively reduced at just 2.3 to 4.5 mg/day of fluoride ion. To put this finding in perspective, the Department of Health and Human Services (DHHS, 1991) has estimated that total fluoride exposure in fluoridated communities ranges from 1.6 to 6.6 mg/day. This is a remarkable fact, particularly considering the rampant and increasing problem of hypothyroidism (underactive thyroid) in the United States and other fluoridated countries. Symptoms of hypothyroidism include depression, fatigue, weight gain, muscle and joint pains, increased cholesterol levels, and heart disease. In 2010, the second most prescribed drug of the year was Synthroid (sodium levothyroxine) which is a hormone replacement drug used to treat an underactive thyroid.

27) FLUORIDE CAUSES ARTHRITIC SYMPTOMS.

Some of the early symptoms of skeletal fluorosis (a fluoride-induced bone and joint disease that impacts millions of people in India, China, and Africa), mimic the symptoms of arthritis (Singh 1963; Franke 1975; Teotia 1976; Carnow 1981; Czerwinski 1988; DHHS 1991). According to a review on fluoridation published in Chemical & Engineering News, "Because some

of the clinical symptoms mimic arthritis, the first two clinical phases of skeletal fluorosis could be easily misdiagnosed” (Hileman 1988). Few, if any, studies have been done to determine the extent of this misdiagnosis, and whether the high prevalence of arthritis in America (1 in 3 Americans have some form of arthritis – CDC, 2002) and other fluoridated countries is related to growing fluoride exposure, which is highly plausible. Even when individuals in the U.S. suffer advanced forms of skeletal fluorosis (from drinking large amounts of tea), it has taken years of misdiagnoses before doctors finally correctly diagnosed the condition as fluorosis.

28) FLUORIDE DAMAGES BONE.

An early fluoridation trial (Newburgh-Kingston 1945-55) found a significant two-fold increase in cortical bone defects among children in the fluoridated community (Schlesinger 1956). The cortical bone is the outside layer of the bone and is important to protect against fracture. While this result was not considered important at the time with respect to bone fractures, it did prompt questions about a possible link to osteosarcoma (Caffey, 1955; NAS, 1977). In 2001, Alarcon-Herrera and co-workers reported a linear correlation between the severity of dental fluorosis and the frequency of bone fractures in both children and adults in a high fluoride area in Mexico.

29) FLUORIDE MAY INCREASE HIP FRACTURES IN THE ELDERLY.

When high doses of fluoride (average 26 mg per day) were used in trials to treat patients with osteoporosis in an effort to harden their bones and reduce fracture rates, it actually led to a higher number of fractures, particularly hip fractures (Inkovaara 1975; Gerster 1983; Dambacher 1986; O’Duffy 1986; Hedlund 1989; Bayley 1990; Gutteridge 1990. 2002; Orcel 1990; Riggs 1990 and Schnitzler 1990). Hip fracture is a very serious issue for the elderly, often leading to a loss of independence or a shortened life. There have been over a dozen studies published since 1990 that have investigated a possible relationship between hip fractures and long term consumption of artificially fluoridated water or water with high natural levels. The results have been mixed – some have found an association and others have not. Some have even claimed a protective effect. One very important study in China, which examined hip fractures in six Chinese villages, found what appears to be a dose-related increase in hip fracture as the concentration of fluoride rose from 1 ppm to 8 ppm (Li 2001) offering little comfort to those who drink a lot of

fluoridated water. Moreover, in the only human epidemiological study to assess bone strength as a function of bone fluoride concentration, researchers from the University of Toronto found that (as with animal studies) the strength of bone declined with increasing fluoride content (Chachra 2010). Finally, a recent study from Iowa (Levy 2009), published data suggesting that low-level fluoride exposure may have a detrimental effect on cortical bone density in girls (an effect that has been repeatedly documented in clinical trials and which has been posited as an important mechanism by which fluoride may increase bone fracture rates).

30) PEOPLE WITH IMPAIRED KIDNEY FUNCTION ARE PARTICULARLY VULNERABLE TO BONE DAMAGE.

Because of their inability to effectively excrete fluoride, people with kidney disease are prone to accumulating high levels of fluoride in their bone and blood. As a result of this high fluoride body burden, kidney patients have an elevated risk for developing skeletal fluorosis. In one of the few U.S. studies investigating the matter, crippling skeletal fluorosis was documented among patients with severe kidney disease drinking water with just 1.7 ppm fluoride (Johnson 1979). Since severe skeletal fluorosis in kidney patients has been detected in small case studies, it is likely that larger, systematic studies would detect skeletal fluorosis at even lower fluoride levels.

31) FLUORIDE MAY CAUSE BONE CANCER (OSTEOSARCOMA).

A U.S. government-funded animal study found a dose-dependent increase in bone cancer (osteosarcoma) in fluoride-treated, male rats (NTP 1990). Following the results of this study, the National Cancer Institute (NCI) reviewed national cancer data in the U.S. and found a significantly higher rate of osteosarcoma (a bone cancer) in young men in fluoridated versus unfluoridated areas (Hoover et al 1991a). While the NCI concluded (based on an analysis lacking statistical power) that fluoridation was not the cause (Hoover et al 1991b), no explanation was provided to explain the higher rates in the fluoridated areas. A smaller study from New Jersey (Cohn 1992) found osteosarcoma rates to be up to 6 times higher in young men living in fluoridated versus unfluoridated areas. Other epidemiological studies of varying size and quality have failed to find this relationship (a summary of these can be found in Bassin, 2001 and Connett & Neurath, 2005). There are three reasons why a fluoride-osteosarcoma connection is plausible:

First, fluoride accumulates to a high level in bone. Second, fluoride stimulates bone growth. And, third, fluoride can interfere with the genetic apparatus of bone cells in several ways; it has been shown to be mutagenic, cause chromosome damage, and interfere with the enzymes involved with DNA repair in both cell and tissue studies (Tsutsui 1984; Caspary 1987; Kishi 1993; Mihashi 1996; Zhang 2009). In addition to cell and tissue studies, a correlation between fluoride exposure and chromosome damage in humans has also been reported (Sheth 1994; Wu 1995; Meng 1997; Joseph 2000).

32) PROPONENTS HAVE FAILED TO REFUTE THE BASSIN-OSTEOSARCOMA STUDY.

In 2001, Elise Bassin, a dentist, successfully defended her doctoral thesis at Harvard in which she found that young boys had a five-to-seven fold increased risk of getting osteosarcoma by the age of 20 if they drank fluoridated water during their mid-childhood growth spurt (age 6 to 8). The study was published in 2006 (Bassin 2006) but has been largely discounted by fluoridating countries because her thesis adviser Professor Chester Douglass (a promoter of fluoridation and a consultant for Colgate) promised a larger study that he claimed would discount her thesis (Douglass and Joshipura, 2006). Now, after 5 years of waiting the Douglass study has finally been published (Kim 2011) but in no way does this study discount Bassin's findings. The study, which used far fewer controls than Bassin's analysis, did not even attempt to assess the age-specific window of risk that Bassin identified. Indeed, by the authors' own admission, the study had no capacity to assess the risk of osteosarcoma among children and adolescents (the precise population of concern). For a critique of the Douglass study, [click here](#).

33) FLUORIDE MAY CAUSE REPRODUCTIVE PROBLEMS.

Fluoride administered to animals at high doses wreaks havoc on the male reproductive system – it damages sperm and increases the rate of infertility in a number of different species (Kour 1980; Chinoy 1989; Chinoy 1991; Susheela 1991; Chinoy 1994; Kumar 1994; Narayana 1994a,b; Zhao 1995; Elbetieha 2000; Ghosh 2002; Zakrzewska 2002). In addition, an epidemiological study from the US found increased rates of infertility among couples living in areas with 3 ppm or more fluoride in the water (Freni 1994), two studies have found increased fertility among men living in high-fluoride areas of China and

India (Liu 1988; Neelam 1987); four studies have found reduced level of circulating testosterone in males living in high fluoride areas (Hao 2010; Chen P 1997; Susheela 1996; Barot 1998), and a study of fluoride-exposed workers reported a “subclinical reproductive effect” (Ortiz-Perez 2003). While animal studies by FDA researchers have failed to find evidence of reproductive toxicity in fluoride-exposed rats (Sprando 1996, 1997, 1998), the National Research Council (2006) has recommended that, “the relationship between fluoride and fertility requires additional study.”

34) SOME INDIVIDUALS ARE HIGHLY SENSITIVE TO LOW LEVELS OF FLUORIDE AS SHOWN BY CASE STUDIES AND DOUBLE BLIND STUDIES.

In one study, which lasted 13 years, Feltman and Kosel (1961) showed that about 1% of patients given 1 mg of fluoride each day developed negative reactions. Many individuals have reported suffering from symptoms such as fatigue, headaches, rashes and stomach and gastro intestinal tract problems, which disappear when they avoid fluoride in their water and diet (Shea 1967; Waldbott 1978; Moolenburgh 1987). Frequently the symptoms reappear when they are unwittingly exposed to fluoride again (Spittle, 2008). No fluoridating government has conducted scientific studies to take this issue beyond these anecdotal reports. Without the willingness of governments to investigate these reports scientifically, should we as a society be forcing these people to ingest fluoride?

35) OTHER SUBSETS OF POPULATION ARE MORE VULNERABLE TO FLUORIDE’S TOXICITY.

In addition to people suffering from impaired kidney function discussed in reason #30 other subsets of the population are more vulnerable to fluoride’s toxic effects. According to the Agency for Toxic Substances and Disease Registry (ATSDR 1993) these include: infants, the elderly, and those with diabetes mellitus. Also vulnerable are those who suffer from malnutrition (e.g., calcium, magnesium, vitamin C, vitamin D and iodine deficiencies and protein-poor diets) and those who have diabetes insipidus. See: Greenberg 1974; Klein 1975; Massler & Schour 1952; Marier & Rose 1977; Lin 1991; Chen 1997; Seow 1994; Teotia 1998.

NO MARGIN OF SAFETY

36) THERE IS NO MARGIN OF SAFETY FOR SEVERAL HEALTH EFFECTS.

No one can deny that high natural levels of fluoride damage health. Millions of people in India and China have had their health compromised by fluoride. The real question is whether there is an adequate margin of safety between the doses shown to cause harm in published studies and the total dose people receive consuming uncontrolled amounts of fluoridated water and non-water sources of fluoride.

This margin of safety has to take into account the wide range of individual sensitivity expected in a large population (a safety factor of 10 is usually applied to the lowest level causing harm). Another safety factor is also needed to take into account the wide range of doses to which people are exposed. There is clearly no margin of safety for dental fluorosis (CDC, 2010) and based on the following studies nowhere near an adequate margin of safety for lowered IQ (Xiang 2003a,b; Ding 2011; Choi 2012); lowered thyroid function (Galletti & Joyet 1958; Bachinskii 1985; Lin 1991); bone fractures in children (Alarcon-Herrera 2001) or hip fractures in the elderly (Kurtio 1999; Li 2001). All of these harmful effects are discussed in the NRC (2006) review.

ENVIRONMENTAL JUSTICE

37) LOW-INCOME FAMILIES PENALIZED BY FLUORIDATION.

Those most likely to suffer from poor nutrition, and thus more likely to be more vulnerable to fluoride's toxic effects, are the poor, who unfortunately, are the very people being targeted by new fluoridation programs. While at heightened risk, poor families are least able to afford avoiding fluoride once it is added to the water supply. No financial support is being offered to these families to help them get alternative water supplies or to help pay the costs of treating unsightly cases of dental fluorosis.

38) BLACK AND HISPANIC CHILDREN ARE MORE VULNERABLE TO FLUORIDE'S TOXICITY.

According to the CDC's national survey of dental fluorosis, black and Mexican-American children have significantly higher rates of dental fluorosis than white children (Beltran-Aguilar 2005, Table 23). The recognition that minority children appear to be more vulnerable to toxic effects of fluoride, combined with the

fact that low-income families are less able to avoid drinking fluoridated water, has prompted prominent leaders in the environmental-justice movement to oppose mandatory fluoridation in Georgia. In a statement issued in May 2011, Andrew Young, a colleague of Martin Luther King, Jr., and former Mayor of Atlanta and former US Ambassador to the United Nations, stated:

“I am most deeply concerned for poor families who have babies: if they cannot afford unfluoridated water for their babies’ milk formula, do their babies not count? Of course they do. This is an issue of fairness, civil rights, and compassion. We must find better ways to prevent cavities, such as helping those most at risk for cavities obtain access to the services of a dentist...My father was a dentist. I formerly was a strong believer in the benefits of water fluoridation for preventing cavities. But many things that we began to do 50 or more years ago we now no longer do, because we have learned further information that changes our practices and policies. So it is with fluoridation.”

39) MINORITIES ARE NOT BEING WARNED ABOUT THEIR VULNERABILITIES TO FLUORIDE.

The CDC is not warning black and Mexican-American children that they have higher rates of dental fluorosis than Caucasian children (see #38). This extra vulnerability may extend to other toxic effects of fluoride. Black Americans have higher rates of lactose intolerance, kidney problems and diabetes, all of which may exacerbate fluoride’s toxicity.

40) TOOTH DECAY REFLECTS LOW-INCOME NOT LOW-FLUORIDE INTAKE.

Since dental decay is most concentrated in poor communities, we should be spending our efforts trying to increase the access to dental care for low-income families. The highest rates of tooth decay today can be found in low-income areas that have been fluoridated for many years. The real “Oral Health Crisis” that exists today in the United States, is not a lack of fluoride but poverty and lack of dental insurance. The Surgeon General has estimated that 80% of dentists in the US do not treat children on Medicaid.

THE LARGELY UNTESTED CHEMICALS USED IN FLUORIDATION PROGRAMS

41) THE CHEMICALS USED TO FLUORIDATE WATER ARE NOT PHARMACEUTICAL GRADE.

Instead, they largely come from the wet scrubbing systems of the phosphate fertilizer industry. These chemicals (90% of which are sodium fluorosilicate and fluorosilicic acid), are classified hazardous wastes contaminated with various impurities.

Recent testing by the National Sanitation Foundation suggest that the levels of arsenic in these silicon fluorides are relatively high (up to 1.6 ppb after dilution into public water) and of potential concern (NSF 2000 and Wang 2000). Arsenic is a known human carcinogen for which there is no safe level. This one contaminant alone could be increasing cancer rates—and unnecessarily so.

42) THE SILICON FLUORIDES HAVE NOT BEEN TESTED COMPREHENSIVELY.

The chemical usually tested in animal studies is pharmaceutical grade sodium fluoride, not industrial grade fluorosilicic acid. Proponents claim that once the silicon fluorides have been diluted at the public water works they are completely dissociated to free fluoride ions and hydrated silica and thus there is no need to examine the toxicology of these compounds. However, while a study from the University of Michigan (Finney et al., 2006) showed complete dissociation at neutral pH, in acidic conditions (pH 3) there was a stable complex containing five fluoride ions. Thus the possibility arises that such a complex may be regenerated in the stomach where the pH lies between 1 and 2.

43) THE SILICON FLUORIDES MAY INCREASE LEAD UPTAKE INTO CHILDREN'S BLOOD.

Studies by Masters and Coplan (1999, 2000, 2007), and to a lesser extent Macek (2006), show an association between the use of fluorosilicic acid (and its sodium salt) to fluoridate water and an increased uptake of lead into children's blood. Because of lead's acknowledged ability to damage the

developing brain, this is a very serious finding. Nevertheless, it is being largely ignored by fluoridating countries. This association received some strong biochemical support from an animal study by Sawan et al. (2010) who found that exposure of rats to a combination of fluorosilicic acid and lead in their drinking water increased the uptake of lead into blood some threefold over exposure to lead alone.

44) FLUORIDE MAY LEACH LEAD FROM PIPES, BRASS FITTINGS AND SOLDERED JOINTS.

In tightly controlled laboratory experiments, Maas et al (2007) have shown that fluoridating agents in combination with chlorinating agents such as chloroamine increase the leaching of lead from brass fittings used in plumbing. While proponents may argue about the neurotoxic effects of low levels of fluoride there is no argument that lead at very low levels lowers IQ in children.

CONTINUED PROMOTION OF FLUORIDATION IS UNSCIENTIFIC

45) KEY HEALTH STUDIES HAVE NOT BEEN DONE.

In the January 2008 issue of Scientific American, Professor John Doull, the chairman of the important 2006 National Research Council review, Fluoride in Drinking Water: A Review of EPA's Standards, is quoted as saying:

“What the committee found is that we’ve gone with the status quo regarding fluoride for many years—for too long really—and now we need to take a fresh look . . . In the scientific community people tend to think this is settled. I mean, when the U.S. surgeon general comes out and says this is one of the top 10 greatest achievements of the 20th century, that’s a hard hurdle to get over. But when we looked at the studies that have been done, we found that many of these questions are unsettled and we have much less information than we should, considering how long this [fluoridation] has been going on.”

The absence of studies is being used by promoters as meaning the absence of harm. This is an irresponsible position.

46) ENDORSEMENTS DO NOT REPRESENT SCIENTIFIC EVIDENCE.

Many of those promoting fluoridation rely heavily on a list of endorsements. However, the U.S. PHS first endorsed fluoridation in 1950, before one single trial had been completed and before any significant health studies had been published (see chapters 9 and 10 in *The Case Against Fluoride* for the significance of this PHS endorsement for the future promotion of fluoridation). Many other endorsements swiftly followed with little evidence of any scientific rationale for doing so. The continued use of these endorsements has more to do with political science than medical science.

47) REVIEW PANELS HAND-PICKED TO DELIVER A PRO-FLUORIDATION RESULT.

Every so often, particularly when their fluoridation program is under threat, governments of fluoridating countries hand-pick panels to deliver reports that provide the necessary re-endorsement of the practice.

In their recent book *Fluoride Wars* (2009), which is otherwise slanted toward fluoridation, Alan Freeze and Jay Lehr concede this point when they write:

There is one anti-fluoridationist charge that does have some truth to it. Anti-fluoride forces have always claimed that the many government-sponsored review panels set up over the years to assess the costs and benefits of fluoridation were stacked in favor of fluoridation. A review of the membership of the various panels confirms this charge. The expert committees that put together reports by the American Association for the Advancement of Science in 1941, 1944 and 1954; the National Academy of Sciences in 1951, 1971, 1977 and 1993; the World Health Organization in 1958 and 1970; and the U.S. Public Health Service in 1991 are rife with the names of well-known medical and dental researchers who actively campaigned on behalf of fluoridation or whose research was held in high regard in the pro-fluoridation movement. Membership was interlocking and incestuous.

The most recent examples of these self-fulfilling prophecies have come from the Irish Fluoridation Forum (2002); the National Health and Medical Research Council (NHMRC, 2007) and Health Canada (2008, 2010). The latter used a panel of six experts to review the health literature. Four of the six were pro-fluoridation dentists and the other two had no demonstrated

expertise on fluoride. A notable exception to this trend was the appointment by the U.S. National Research Council of the first balanced panel of experts ever selected to look at fluoride's toxicity in the U.S. This panel of twelve reviewed the US EPA's safe drinking water standards for fluoride. After three and half years the panel concluded in a 507- page report that the safe drinking water standard was not protective of health and a new maximum contaminant level goal (MCLG) should be determined (NRC, 2006). If normal toxicological procedures and appropriate margins of safety were applied to their findings this report should spell an end to water fluoridation. Unfortunately in January of 2011 the US EPA Office of Water made it clear that they would not determine a value for the MCLG that would jeopardize the water fluoridation program (EPA press release, Jan 7, 2011). Once again politics was allowed to trump science.

MORE AND MORE INDEPENDENT SCIENTISTS OPPOSE FLUORIDATION

48) MANY SCIENTISTS OPPOSE FLUORIDATION.

Proponents of fluoridation have maintained for many years— despite the fact that the earliest opponents of fluoridation were biochemists—that the only people opposed to fluoridation are not bona fide scientists. Today, as more and more scientists, doctors, dentists and other professionals, read the primary literature for themselves, rather than relying on self-serving statements from the ADA and the CDC, they are realizing that they and the general public have not been diligently informed by their professional bodies on this subject. As of January 2012, over 4,000 professionals have signed a statement calling for an end to water fluoridation worldwide. This statement and a list of signatories can be found on the website of the Fluoride Action Network. A glimpse of the caliber of those opposing fluoridation can be gleaned by watching the 28-minute video “Professional Perspectives on Water fluoridation” which can be viewed online at the same FAN site.

PROponents' DUBIOUS TACTICS

49) PROPONENTS USUALLY REFUSE TO DEFEND FLUORIDATION IN OPEN DEBATE.

While pro-fluoridation officials continue to promote fluoridation with undiminished fervor, they usually refuse to defend the practice in open public debate – even when challenged to do so by organizations such as the Association for Science in the Public Interest, the American College of Toxicology, or the U.S. EPA (Bryson 2004). According to Dr. Michael Easley, a prominent lobbyist for fluoridation in the US, “Debates give the illusion that a scientific controversy exists when no credible people support the fluorophobics’ view” (Easley, 1999). In light of proponents’ refusal to debate this issue, Dr. Edward Groth, a Senior Scientist at Consumers Union, observed that, “the political profluoridation stance has evolved into a dogmatic, authoritarian, essentially antiscientific posture, one that discourages open debate of scientific issues” (Martin 1991).

50) PROPONENTS USE VERY DUBIOUS TACTICS TO PROMOTE FLUORIDATION.

Many scientists, doctors and dentists who have spoken out publicly on this issue have been subjected to censorship and intimidation (Martin 1991). Dr. Phyllis Mullenix was fired from her position as Chair of Toxicology at Forsythe Dental Center for publishing her findings on fluoride and the brain (Mullenix 1995); and Dr. William Marcus was fired from the EPA for questioning the government’s handling of the NTP’s fluoride-cancer study (Bryson 2004). Many dentists and even doctors tell opponents in private that they are opposed to this practice but dare not speak out in public because of peer pressure and the fear of recriminations. Tactics like this would not be necessary if those promoting fluoridation were on secure scientific and ethical grounds.

CONCLUSION

When it comes to controversies surrounding toxic chemicals, vested interests traditionally do their very best to discount animal studies and quibble with epidemiological findings. In the past, political pressures have led government agencies to drag their feet on regulating asbestos, benzene, DDT, PCBs, tetraethyl lead, tobacco and dioxins. With fluoridation we have had a sixty-year delay. Unfortunately, because government officials and dental leaders have put so much of their credibility on the line defending fluoridation, and because of the huge liabilities waiting in the wings if they admit that fluoridation has caused an increase in hip fracture, arthritis, bone cancer, brain disorders or thyroid problems, it will be very difficult for them to speak honestly and openly about the issue. But they must, not only to protect millions of people from unnecessary harm, but to protect the notion that, at its core, public health policy must be based on sound science, not political expediency. They have a tool with which to do this: it's called the Precautionary Principle. Simply put, this says: if in doubt leave it out. This is what most European countries have done and their children's teeth have not suffered, while their public's trust has been strengthened.

Just how much doubt is needed on just one of the health concerns identified above, to override a benefit, which when quantified in the largest survey ever conducted in the US, amounts to less than one tooth surface (out of 128) in a child's mouth?

While fluoridation may not be the greatest environmental health threat, it is one of the easiest to end. It is as easy as turning off a spigot in the public water works. But to turn off that spigot takes political will and to get that we need masses more people informed and organized. Please get these 50 reasons to all your friends and encourage them to get fluoride out of their community and to help ban this practice worldwide.

POSTSCRIPT

Further arguments against fluoridation, can be viewed at <http://fluoridealert.org> and in the book *The Case Against Fluoridation* (Chelsea Green, 2010). Arguments for fluoridation can be found at <http://www.ada.org>

PUBLICATION HISTORY OF THE 50 REASONS

The 50 Reasons were first compiled by Paul Connett and presented in person to the Irish Fluoridation Forum in October 2000. The document was refined in 2004 and published in *Medical Veritas*. In the introduction to the 2004 version it was explained that after over four years the Irish authorities had not been able to muster a response to the 50 Reasons, despite agreeing to do so in 2000. Eventually, an anonymous, incomplete and superficial response was posted on the Irish Department of Health and Children's website (see this response and addendum at http://www.dohc.ie/other_health_issues/dental_research/). Paul Connett's comprehensive response to this response can be accessed at <http://fluoridealert.org/50reasons.ireland.pdf>. We learned on August 7, 2011 that this governmental response was prepared by an external contractor at a cost to the Irish taxpayers' of over 30,000 Euros.

Since 2004, there have been many major scientific developments including the publication of the U.S. National Research Council report (NRC, 2006); the publication of Bassin's study on Osteosarcoma (Bassin 2006), and many more studies of fluoride's interaction with the brain, that necessitated a major update of the 50 Reasons in August 2011. This update was made with the generous assistance of James Beck, MD, PhD, Michael Connett, JD, Hardy Limeback, DDS, PhD, David McRae and Spedding Micklem, D.Phil. Additional developments in 2012, including FAN's translation of over 20 Chinese studies on fluoride toxicity and publication of the Harvard team's meta-review of fluoride and IQ (Choi 2012), warranted a further update in August 2012, with the extremely helpful assistance of my son, Michael Connett.

All cited references in this article can be found at the Fluoride Action Network's Online Bibliography, available at:

WWW.FLUORIDEALERT.ORG/RESEARCHERS/FAN-BIBLIOGRAPHY/

Jeff Landry
GOVERNOR



Michael Harrington, MBA, MA
SECRETARY

State of Louisiana
Louisiana Department of Health
Office of the Surgeon General

Re: M.D.

To Whom it may concern,

Please allow this letter to serve as an exemption from your hospital's influenza vaccination requirement for Dr.

Evidence proving efficacy in prevention of infection, transmission, hospitalization, or death is far from conclusive historically and represents little more than a guess as we look toward upcoming seasonal strains. Risks associated with influenza vaccination are real and well established. Where there is risk there must be choice. In the case of Dr. risks of influenza vaccination outweigh benefits and there should be no further coercion to comply.

Masking during flu season is apparently offered as an alternative to vaccination. Conclusive evidence has not shown masks to be effective against transmission of respiratory viruses. See attached Cochrane review article for reference. Masking is therefore merely a form of punitive coercion aimed at achieving compliance. Please also allow Dr. to be exempted from compulsory masking.

<https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006207.pub6/full>

The Surgeon General's office intends to serve as an advocate for informed consent and restoration of the doctor-patient relationship as the core of medical decision making. We appreciate your hospital's cooperation with that effort.

Please feel free to contact us directly if further information is needed.

Handwritten signature of Ralph L. Abraham in blue ink.

Ralph L. Abraham M.D.
Surgeon General

Handwritten signature of Wyche T. Coleman III in blue ink.

Wyche T. Coleman III, M.D.
Deputy Surgeon General

Pharmaceutical product recall and educated hesitancy towards new drugs and novel vaccines

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Peter Rhodes^{1,2} and Peter I Parry^{3,4}

Abstract

Background: Of many pharmaceutical products launched for the benefit of humanity, a significant number have had to be recalled from the marketplace due to adverse events. A systematic review found market recalls for 462 pharmaceutical products between 1953 and 2013. In our current and remarkable period of medical history, excess mortality figures are high in many countries. Yet these statistics receive limited attention, often ignored or dismissed by mainstream news outlets. This excess mortality may include adverse effects caused by novel pharmaceutical agents that use gene-code technology.

Objective: To examine key pharmaceutical product withdrawals and derive lessons that inform the current use of gene-based COVID-19 vaccines.

Methods: Selective narrative review of historical pharmaceutical recalls and comparative issues with recent COVID-19 vaccines.

Results: Parallels with past drug withdrawals and gene-based vaccines include distortion of clinical trial data, with critical adverse event data absent from high-impact journal publications. Delayed regulatory action on pharmacovigilance data to trigger market withdrawal occurred with Vioxx (rofecoxib) and is apparent with the gene-based COVID-19 vaccines.

Conclusion: Public health requires access to raw clinical trial data, improved transparency from corporations and heightened, active pharmacovigilance worldwide.

Keywords

conflict of interest, COVID-19, clinical trials, drug-related side effects and adverse reactions, messenger ribonucleic acid vaccines, pharmaceutical industry, pharmacovigilance, safety-based drug recalls

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All pharmaceutical products are continuously experimental, observed and tracked by pharmacovigilance systems worldwide.¹

Introduction

Strong science, characterised by open mindedness, objectivity, curiosity and freedom of debate, can be corrupted by capitalist opportunism, deception, political ideology and censorship. Regulatory protections are required for good science to flourish. Corporate enthusiasm and authoritarian policy directives, such as vaccine mandates, must be balanced with humane medical ethics and protection of individual autonomy.

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The global pharmaceutical industry has grown in recent decades and now represents one of the most valuable in the world. Revenue of the worldwide market in just 2 decades has risen from 390 billion USD (2001) to 1482 billion USD (2022).²

New additions to the global marketplace appear with entrepreneurial enthusiasm. Yet withdrawals of these products are also significant. In the last 7 decades, from 1953 onwards, more than 462 medicinal products have had to be recalled from sale because of adverse drug effects that frequently include fatalities. The median interval between the first reported adverse reaction and the year of first withdrawal for a drug is 6 years (IQR, 1–15).³

Globally, whether drugs are recalled or not, pharmaceutical industry violations have become a multibillion-dollar industry of litigation, legal fees, and court penalties. Some of the most impressive corporate criminal trials include⁴:

- **Cardinal Health, McKesson, AmerisourceBergen, Johnson & Johnson (2022)**, inappropriate opioid prescription, addiction crisis, settlement of \$26 billion USD;
- **GlaxoSmithKline (2012)**, unlawful promotion of Paxil (paroxetine), Wellbutrin (bupropion) and Avandia (rosiglitazone), and failure to report safety information, settlement of \$3 billion USD;
- **Eli Lilly, Takeda Pharmaceuticals (2015)**, concealment of data on carcinogenicity of Actos (pioglitazone), settlement of \$2.4 billion USD;
- **Pfizer (2009)**, false promotion of Bextra (valdecoxib) tablets, Geodon (ziprasidone) capsules, Lyrica (pregabalin), and Zyvox (linezolid), payment of financial kickbacks, submission of false claims to government, illegal drug promotion, settlement of \$2.3 billion USD;
- **Johnson & Johnson (2013)**, misbrand of antipsychotic drug Risperdal (risperidone), payment of financial kickbacks, settlement of \$2.2 billion USD.

Direct to public commercials in the USA for legal support are now widespread, e.g.⁴:

“Call a Dangerous Drug Attorney at O’Connor, Acciani & Levy.

If you believe you were harmed after using a certain pharmaceutical product, call a skilled dangerous drug attorney for help in starting a personal injury claim.”

In this selective narrative review, our goal is to consider some of the milestones in drug recall from the market, litigation for, and republication of, hidden data, and potential lessons that may be learnt. We assess recall of various pharmaceutical agents, proven over time to be monumental events. In particular, we focus on the cases of Merck’s Vioxx (rofecoxib), and the new gene-based COVID-19 vaccines.

Results

Diethylstilbestrol (DES)

Marketed widely in the 1950s and 1960s, diethylstilbestrol (DES) (Eli Lilly), prescribed by the medical profession for prevention of miscarriage, led to extensive harm that would prove fatal for some and would span generations. Supplied to millions of pregnant women over 3 decades, DES became the first identified cause of “prenatal drug-induced cancer in humans”. The drug was recalled in 1971. The full intergenerational impact of these prescriptions is still not known.⁵

Thalidomide

Thalidomide is one of the saddest chapters in pharmaceutical history and an example of how premature safety claims can have tragic consequences. Created as a sedative and marketed in Germany in 1957 by Chemie Grünenthal, thalidomide would soon be launched in the UK (Distillers, UK), and many other countries would follow. At this stage, the first thalidomide-affected baby had already been born in Germany, 25 December 1956, to a Chemie Grünenthal employee. By 1958, thalidomide was licensed and promoted in the UK as a “wonder drug” to treat headaches, insomnia, and nausea in pregnant women – advertisements emphasised safety, with catch phrases such as “non-toxic” and “no known toxicity”.

The first publication to link thalidomide and birth defects appeared in 1961 in *The Lancet*, as a letter from an Australian, William McBride.⁶ This same year the drug was formally withdrawn in Germany and in the UK, the Thalidomide Society was established in the UK, and efforts began to secure compensation for victims. In 1968, Chemie Grünenthal was brought to trial in Germany, charged with intent to commit bodily harm and involuntary manslaughter, but in 1970 this trial was ended prematurely by the German government, who stated that it was “not in the public interest”.⁷

Efforts have continued in the UK to secure compensation from the 1970s through to the present. It was only on 29 November 2023 that the Australian Prime Minister announced a “formal national apology to all Australians impacted by the Thalidomide Tragedy”, more than half a century on from the earliest harms.⁸

Through the diligent work of FDA scientist Frances Kelsey, who demanded further safety trials prior to market authorisation, thalidomide was never approved for release in the USA. She protected an entire nation.⁹

Paroxetine

The Selective Serotonin Reuptake Inhibitor (SSRI) antidepressant, paroxetine, became a very successful commercial product for SmithKlineBeecham (SKB) (later GlaxoSmithKline, GSK). In the late 1990s, the company conducted two randomised, controlled trials in adolescents with depression (Study 329 & Study 377). Company documents, subpoenaed through litigation, reported that Study 377 “failed to demonstrate any separation from placebo” and consequently the company had “no plans to publish data from Study 377”. Study 329 showed “trends in efficacy” but the differentiation from placebo “was not statistically significant”.¹⁰ This Study 329 was ghost written and then published by Keller and 21 co-authors in 2001, with the conclusion that paroxetine was “generally well tolerated and effective” for adolescents with depression.¹¹ Although SKB/GSK decided not to present the studies’ data to the FDA for a label change to treat adolescent depression, they used the Keller et al. publication to promote off-label prescriptions for depressed teens. Later, independent researchers gained access to raw data from Study 329 and found increased suicidality and no significant efficacy.¹² Despite calls for retraction of the original Study 329 publication, the *Journal of the American Academy of Child and Adolescent Psychiatry (JAACAP)* has refused to do so.¹³

GSK suppressed negative data about their drug paroxetine and effects on depression and suicide. An internal GSK document advised staff to withhold data that indicated paroxetine had no beneficial effect in adolescents.¹⁴ In 2012, GSK pleaded guilty to fraud allegations and failure to report safety data, with payment of \$3 billion in criminal fines, the largest fraud settlement in US history at the time.¹⁵

There have been further disputes over the increased suicidality caused by SSRIs in adolescents and young adults, with calls to remove the FDA Black Box label. However, both Study 329 data re-analysis¹³ and separate further data support continuation.¹⁶

This GSK paroxetine chapter is by no means an isolated case of hidden data. In 2015, Eli-Lilly and Takeda Pharmaceuticals were fined \$2.4 billion USD for concealment of the carcinogenic effects of pioglitazone (Actos).¹⁷

Avandia (rosiglitazone)

Avandia (rosiglitazone) gained FDA approval for management of diabetes in May 1999 and was widely prescribed for control of blood glucose, until it was shown to increase risk of myocardial infarction by 43% and increase risk of death from cardiovascular causes by 64%.¹⁸ In May 2007, Steven Nissen of the Cleveland Clinic published controlled trial data that showed, in the rosiglitazone group, as compared with control, the odds ratio for myocardial infarction was 1.43 (95% confidence interval (CI), 1.03 to 1.98; $p = 0.03$), and the odds ratio for death from cardiovascular causes was 1.64 (95% CI, 0.98 to 2.74; $p = 0.06$).¹⁹

In July 2007, a panel of FDA advisers voted 22 to 1 against removal of Avandia from the marketplace. As late as 2009, GSK continued with promotion of Avandia as “safe and free from cardiovascular side effects”.²⁰ In contrast, by February 2010, a US senate finance committee was able to conclude that GSK had “full knowledge of the cardiac risks of Avandia in late 2004 or early 2005”. David Graham, FDA scientist, has estimated combined US heart attacks, strokes and deaths caused by Avandia to be in the order of 100,000 events.²¹ The drug was removed from the European market in September 2010, based on cardiovascular risks, and remains banned to this day.

Pursuit of surrogate end points can be dangerous, exemplified here with a focal target of blood glucose control, yet accompanied by significant adverse events.

While such corporate products and medical prescriptions as diethylstilbestrol, thalidomide, paroxetine and rosiglitazone are now infamous chapters in medical history, still greater events loom over more recent history, and we consider two of these, Merck’s Vioxx (rofecoxib) scandal, and the roll out of gene-based COVID-19 vaccines.

Vioxx (rofecoxib)

Developed by Merck, the cyclooxygenase-2 (COX 2) inhibitor Vioxx (rofecoxib) marketed as a non-steroidal anti-inflammatory drug (NSAID) for pain relief in 1999, obtained FDA approval (21 May 1999) based on equivalence to other

NSAIDs in short term use. Efforts to explore long term value in rheumatoid arthritis further supported sales, with fewer gastrointestinal side effects when compared with typical NSAID naproxen.²²

In this VIGOR paper,²² Merck concealed adverse cardiovascular events in the Vioxx arm of the study that would prove to be a serious statistical signal. Just prior to publication, Merck informed the FDA of three adverse cardiovascular events, published on an FDA website, but *The New England Journal of Medicine (NEJM)* article was neither retracted nor corrected.

The full VIGOR data unmasked high rates of cardiovascular events with Vioxx (rofecoxib) compared to naproxen, with a relative risk of 2.38 (95% CI 1.39–4.00) for rofecoxib against naproxen over a 12-month study period.²³ The time lag between initial FDA approval and the appearance of this more complete VIGOR trial data in print was over 18 months.

Initial responses to this data from Merck included claims that naproxen had a protective effect against heart attacks and strokes, that was not possessed by Vioxx, and that the increased cardiovascular risks seen with Vioxx occurred only in people with known cardiovascular disease.²⁴ This was later found to be untrue, once data for healthy individuals who had suffered harm on Vioxx had been uncovered.

Merck tried to influence lead American physicians with support and finance for research, and they defamed, withdrew support, and tried to discredit or “neutralise” those who failed to promote use of Vioxx, a matter uncovered by the Federal Court in Melbourne, Australia.²⁵ In contrast, the Chair of the Study Data and Safety Board (SDSB) for the study, Michael Weinblatt, owned \$72,000 in Merck stock and was on a \$60,000 contract for 12 days’ work for the company.²⁶

Internal Merck emails are now known to have shown as early as 18 November 1999 (unblinded minutes), that an interim safety analysis of VIGOR showed excess deaths and cardiovascular adverse experiences – 79 cardiac events for rofecoxib compared with 41 for the control group on a traditional NSAID, naproxen.^{26,27} Yet Merck made a press release on 22 May 2001, entitled “*Merck Reconfirms Favourable Cardiovascular Safety of Vioxx*”. Merck even created a “fake journal” with the medical publisher Elsevier: *The Australasian Journal of Bone and Joint Medicine*, with six issues between 2002 and 2005, that collated articles favourable to Merck’s drugs Vioxx and Fosamax.²⁸

The FDA appears to have been complicit with Merck in early suppression of the adverse event data of VIGOR. Eventually the FDA did instruct Merck (April 11th, 2002) to include a precaution about cardiovascular risks in their package insert.²⁴ Dr David Graham, an FDA scientist in its Office of Drug Safety, revealed this interplay in his testimony to the US Senate (below).

Vioxx remained on the market until the completion of the APPROVE study in 2004. The intention was to promote use of Vioxx to treat polyps of the colon. But again, the drug demonstrated at least double the cardiovascular risk compared with placebo, this time in a patient population considered to be at low risk of cardiovascular disease.²⁹

Merck announced withdrawal of Vioxx on 30 September 2004, the largest prescription drug recall in history to date.

Over 20 million people in the US are believed to have taken the drug, of whom an estimated 88,000 to 139,000 suffered myocardial infarctions, with 30–40% fatality rate (testimony of Dr Graham to the US Senate).³⁰ His figures on estimated cardiac arrests were also published in *The Lancet*, despite opposition from the FDA.³¹ Dr Graham further testified to the Senate that conflicts of interest at the FDA had delayed the Vioxx recall.³² Discovery documents in litigation reveal corporate pharma may conceal data early, at any cost to achieve market growth.^{33,34} Here the FDA appeared complicit and slow to withdraw the product.^{24,35} Published in the *NEJM*, prominent cardiologist Eric Topol included strokes as well as myocardial infarctions to estimate 160,000 events per 10 million people prescribed Vioxx, and he noted a global cohort of up to 80 million had been prescribed Vioxx.²⁴

By August 2005, 13,000 class action lawsuits had been filed against Merck. By November 2007, Merck had created a settlement fund of \$4.85 billion USD, the largest ever in US history at the time. Merck agreed to compensate victims in exchange for a no-fault agreement – specifically, no legal admission of fault. Yet payment of \$4.85 billion USD in compensation to claimants could clearly be interpreted as an admission of fault.^{25,26}

When the Vioxx scandal broke, Merck had a capital market value of between \$40 and \$50 billion USD. Despite the greatest drug scandal in the world, enormous fines and atrocious damage to image, Merck has continued to grow in the last 2 decades and has increased its value six-fold to over \$300 billion USD.

COVID-19 gene-based vaccines

Initially marketed December 2020, as Emergency Use Authorisation (EUA) in the USA, and provisional authorisation in Australia and other nations, the gene-based COVID-19 vaccines of modified mRNA type, (Pfizer-BioNTech’s BNT162b2, Moderna’s mRNA-1273) and viral-vector-DNA type (AstraZeneca’s ChAdOx1-S, Janssen’s Ad26.COV2.S, Gamaleya’s Sputnik V) have constituted the majority of over 13 billion doses of all COVID-19 vaccines.^{36–41} In contrast, COVID-19 vaccines that employ traditional well-tested inactivated virus or

recombinant protein antigen-based technologies have been utilised mainly in a few non-Western nations (e.g., Bharat Biotech's Covaxin, Sinovac's CoronaVac, Cinnagen-Vaxine's SpikoGen, Cuba's Genetic Engineering and Biotechnology Centre's Abdala).⁴²

Purposed for protection against transmission of the SARS-CoV-2 virus and reduced disease severity, official sales narratives included – “safe and effective”, and “millions of lives saved”. Indications of serious harm appeared from 2021 with record high adverse event reports to pharmacovigilance. These included suspected death reports as indicated by VAERS data⁴³ (Figure 1), peer-reviewed VAERS and EudraVigilance data,⁴⁴ excess mortality above expected from collation of official death statistics by Our World in Data⁴⁵ and insurance data for excess mortality and disability⁴⁶ correlated with COVID-19 vaccination. Montano (2022) compared COVID-19 vaccines (Janssen, Moderna, Pfizer-BioNTech) with influenza vaccines, and found extremely high elevated relative risk for serious and fatal adverse events across most organ systems [⁴⁴, in Table 3b]. Excess mortality is defined as mortality above normal background rates at ourworldindata.org which is under the jurisdiction of Oxford University, UK.

Market restrictions on recommendations began September 2022, with COVID-19 booster vaccines generally limited to over age 50 and the vulnerable in Nordic nations and Switzerland, e.g., the Danish Health Authority declared it was “no longer possible ... for children and adolescents aged under 18” to get the COVID-19 vaccine “from 1 September 2022”.⁴⁷ By contrast, the USA, Canada, Australia and some other nations still market for children. The key failure is to have mandated injections in young and healthy adults; these mandates correlate with excess mortality.^{44–46} A recent peer-reviewed study in *BMJ Public Health* on excess mortality from 47 Western nations, finds over three million excess deaths from January 2020 to December 2022. Notably, when stratified by year, the highest number of excess deaths was reported in 2021, the year in which mass vaccination began. Especially in late 2021 which saw imposition of vaccine mandates in many nations (first graph p. 5).⁴⁵ Additional lessons potentially are that rushed “warp speed” development of novel technologies is unwise; narrative and groupthink can distort judgement; suppression of clinical trial data is harmful; heightened active pharmacovigilance must be encouraged.^{48–50}

Use of the term “vaccine” for novel experimental agents that deploy gene codes may convey a false sense of assurance in the absence of supportive data and thus may mislead. In pharmacological design terms, these products are “pro-drugs”.⁵¹ They must enter cells and undergo translation of genetic code before intended outcomes

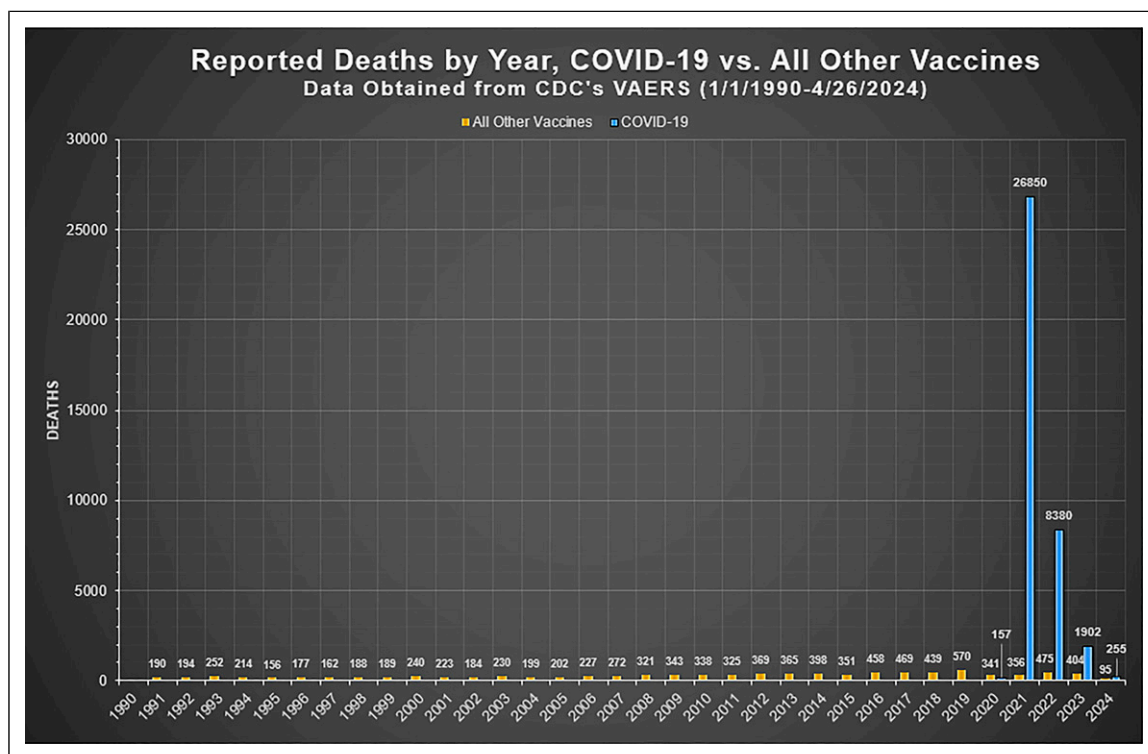


Figure 1. Reported suspected deaths from vaccines to VAERS since 1990 comparing all other vaccines combined with COVID-19 vaccines. From VAERS Analysis⁴³ (with permission).

unfold⁵² (Figure 2), and in this sense they operate as “synthetic viruses”.⁵³ Unintended consequences are thus possible.^{53–57}

A systematic review of the peer-reviewed literature: “Serious harms of the COVID-19 vaccines: a systematic review” by Gotzsche and Demasi (2024) [⁵⁸ preprint] found that with the notable exception of Fraiman et al.,⁵⁹ “most studies were of poor quality” (abstract) and used methodologies such that “serious harms are vastly underreported” (p. 7). They conclude:

Adenovirus vector vaccines increased the risk of venous thrombosis and thrombocytopenia, and the mRNA-based vaccines increased the risk of myocarditis, ... serious neurological harms (occurred), which are likely due to autoimmune reaction. ... Severe harms were underreported in the randomised trials [published in the NEJM].

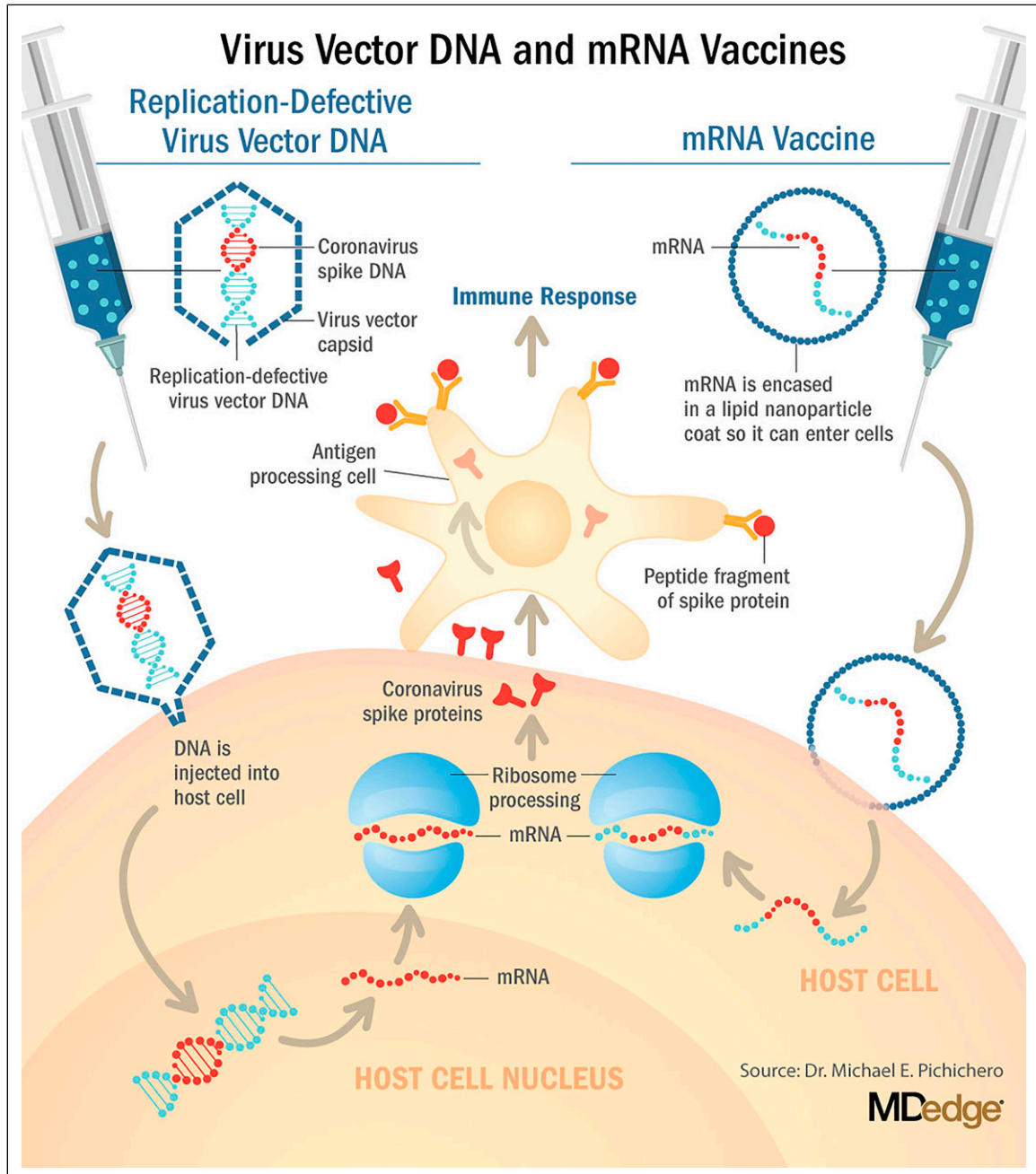


Figure 2. COVID-19 virus vector DNA and mRNA vaccines: mechanism of action. From Pichichero ME (with permission).⁵¹

As authorisation and promotion of the COVID-19 mRNA vaccines continue, the authors call for randomised trials of COVID-19 booster doses in high-risk groups that thoroughly examine serious adverse events.⁵⁹ The authors also state that “Authorities ... do not consider that the balance between benefits and harms becomes negative in low-risk groups such as children [and those with natural immunity]” (abstract). This point has been well made by Bardosh et al. (2024)⁶⁰ who argued against universal vaccine mandates and noted that based on the Pfizer-BioNTech vaccine booster trial data,⁶¹ to prevent one COVID-19 hospitalisation, 18.5 students would suffer a serious adverse event.⁶⁰

These products are novel and experimental, whether modified mRNA gene codes encased in lipid nanoparticles (LNP) (Pfizer-BioNTech and Moderna), or viral-vector-DNA gene codes encased in adenovirus shells (AstraZeneca, Janssen, Sputnik V). These gene sequences produce the spike protein antigen of the SARS-CoV-2 virus, which must be extruded from the cell surface as foreign protein to stimulate an immune response. This is a new mechanism for public vaccination, completely distinct from traditional vaccine technologies.

Moreover, rigorous assessment of long-term safety of these experimental gene-based products has been effectively sabotaged by the early dissolution of the placebo arm in phase III clinical trials.⁶² Despite this, the interim and extensive publication of these abbreviated clinical trials in the *NEJM* has been used to support marketing and the public health message of “safe and effective”.

In terms of efficacy, failure to prevent infection or transmission of the COVID-19 variants^{63–66} eventually led the US Centers for Disease Control and Prevention (CDC) to reinvent their definition for “vaccine” as no longer the provision of “immunity,” but as “protection” against disease severity^{67,68} – now a narrative challenged by more recent data. Promotion of the belief that millions of lives would be saved by these agents has been based on hypothetical, predictive epidemiological models which have a track record of miscalculation.^{46,53,73} Official data from New South Wales state in Australia by late 2022 during the omicron variant wave did not concord with the message that these agents prevent serious disease or death, and even suggested the opposite.⁵³

For the wealthy western nations who have utilised these novel agents in particular, the haste and scale of development, production, distribution, and administration is unprecedented.⁶⁹ Yet haste, especially at “warp speed”, should be alien to good medical science. It is likely that novel technology, haste in vaccine development and mass production all contributed to the reported phenomenon of “batch toxicity” based on official pharmacovigilance data.⁷⁰

Key failures – Coercion and mandates, ridicule of educated hesitancy

Perhaps the greatest failure of gene-based vaccine use is the political act to mandate therapy. Mandates are relatively rare in medical history. Vaccine passports to engage in normal life resemble measures under totalitarian rule. The deadlines for COVID-19 vaccine mandate compliance correlated closely with excess morbidity and mortality.^{1,44,46}

Given the novel nature of gene-based COVID-19 vaccines, it may be no surprise that “vaccine hesitancy” among those with tertiary qualifications was highest with PhD doctorates (January–April 2021, 14.6%),⁷¹ and among healthcare workers was highest for “emergency medical technicians/paramedics” (April–May 2021, 45.4%).⁷² Reflective of both research and coalface clinical experience. This could thus be referred to as “educated hesitancy”, found in a cohort most familiar with the imperfections of corporate sponsorship, market authorisation and medical literature, and a cohort on the frontline. Educated hesitancy towards these products has been ridiculed. It is particularly tragic that mandates have been applied to the young, fit, and healthy in our workforce, at minimal risk from the coronavirus itself, some of whom have paid the ultimate price with loss of life.^{43–46} In fact, at a global level the median pre-vaccination infection fatality rate (IFR) was estimated at 0.03% for the 0 – 59-year-old population, while for children aged 0–19 years the median IFR was 0.0003%.⁷³ These observations indicate that children and adolescents are essentially at zero risk of COVID-19 mortality.

The limitations in the peer-reviewed literature to identify and quantify the harms of the gene-based COVID-19 vaccines [58, preprint], means greater consideration must be given to analyses of public datasets of passive and active pharmacovigilance and insurance and actuarial data. A graph of Western Australian Vaccine Safety Surveillance (WAVSS) (Figure 3 in our prior paper)¹ illustrates this, and it should be noted that due to remote geography and border closures, the state of Western Australia was essentially free of the SARS-CoV-2 virus in 2021.¹

Similarly, a strong temporal correlation was evident between the imposition of COVID-19 vaccine mandates for employment in the third quarter of 2021 in the USA and high excess mortality for working age (25–64 years old) Americans, in the data collated by the US Society of Actuaries Research Institute, as shown in the table from *Cause Unknown* by Edward Dowd⁴⁶ (p. 80) (Figure 3).

With Vioxx, the key publication of the VIGOR clinical trial in the *NEJM* excluded three subjects with severe cardiovascular adverse events, a data suppression that obscured the true risk. Similarly with the phase III clinical

Table 5.7
EXCESS MORTALITY BY DETAILED AGE BAND

Age	Q2 2020	Q3 2020	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	4/20-3/22	% COVID	% Non-COVID	% Count
0-24	116%	124%	104%	101%	119%	127%	110%	91%	111%	3.3%	8.1%	2%
25-34	127%	132%	121%	118%	131%	178%	131%	125%	133%	13.3%	19.6%	2%
35-44	123%	134%	128%	129%	133%	200%	156%	136%	142%	23.1%	19.2%	4%
45-54	123%	127%	129%	133%	119%	180%	151%	143%	138%	27.4%	10.8%	9%
55-64	117%	123%	130%	130%	114%	153%	141%	137%	131%	24.0%	6.7%	18%
65-74	117%	115%	133%	130%	108%	131%	125%	122%	122%	18.6%	3.9%	17%
75-84	114%	114%	133%	123%	106%	119%	121%	121%	119%	14.0%	4.6%	20%
85+	112%	103%	124%	111%	92%	104%	105%	103%	107%	10.3%	-3.5%	27%
All ¹¹	116%	115%	129%	123%	107%	134%	126%	122%	121%	17.1%	4.3%	100%

Figure 3. Table 5.7 Excess mortality by detailed age band. From p.80 Dowd E (2022)⁴⁶ (with permission).

trials for the Pfizer, AstraZeneca and Moderna COVID-19 vaccines it is now known that three subjects with serious adverse events were excluded [49,58 preprint, 74] from key papers^{36,37,39} in the *NEJM*, which influenced health policy globally. These omissions occurred in the context of a non-random excess of 251 exclusions from the vaccine arm compared to placebo arm (311 vs 60) in the Pfizer clinical trial⁷⁵ and reported unblinding at one of the clinical trial sites.⁷⁶

Two phase III clinical trials subjects who suffered severe adverse events from the vaccine arms of the Pfizer-BioNTech trial and the AstraZeneca trial [49,58 preprint], and one from the Moderna trial⁷⁴ came forward to say their adverse event data was not published in the *NEJM* peer-reviewed papers of the clinical trials, and likely not reported to the FDA either. In the case of AstraZeneca, this was despite appeals to the journal.⁴⁹ A further case of a 12-year-old in the adolescent Pfizer COVID-19 clinical trial, suffered permanent severe polyneuropathy and is wheelchair bound [58 preprint, 77,78], is recorded in the *NEJM* paper as “functional abdominal pain”.

Additionally, the Pfizer-BioNTech phase III trial report submitted to the FDA for Emergency Use Authorisation listed 2 deaths in the mRNA vaccine arm and 4 deaths in the placebo arm. However, documents released under court order revealed a further 4 deaths in the vaccine arm and 1 death in the placebo arm, to give the total number of deaths before the data cut-off date actually 11 (6 vaccine, 5 placebo) versus the 6 disclosed. Closer examination of relevant documentation available for each patient showed a pattern of delay in death notification, a clear violation of trial protocols and legal requirements.⁴⁸ By the end of the truncated Pfizer phase III trial there were 21 deaths in the vaccine arm and 17 in the placebo arm and the difference was accounted for by cardiovascular mortality.

Discussion

In this selective narrative review, we have chosen some of the most well-known drug recalls and data suppression scandals. We have sought insights from these events that may help better appraise the current gene-based COVID-19 vaccines, which have together formed the largest ever launch of novel pharmaceutical product in history.

Medical research

Quality of research in medical science is problematic. The scientific “replication crisis”, which is also a publication crisis, has been studied, debated and recognised in surveys of scientists^{79,80} ever since Ioannidis’ highly cited 2005 paper asserted that at least half the published medical literature may simply be wrong.⁸¹ The crisis rests on pressure to publish, failure to publish negative and/or unfavourable data, lack of data transparency, poor methodological design of studies, statistical errors, carelessness, inexperience of peer reviewers and editors, commercial interest, ideological biases, failure to declare conflicts of interest and fraud.^{81,82} Tanver et al. noted lack of data transparency in the COVID-19 vaccine trials⁸³ and cast doubt on their use in public health, as did senior and chief editors of the *BMJ*.⁵⁰

Distorted data, particularly due to commercial bias, is regularly published in medical journals. A Cochrane Review meta-analysis found odds ratios exist for a *sponsored* drug trial to find results, (OR 2.05) and provide conclusions (OR 2.69) in favour of the drug versus an *independent* trial for the same agent.⁸⁴

Corporate integrity and data transparency

Concerns exist related to data transparency, access to raw data, and the potential for hidden data, deleted data or indeed failure to record data.^{10,12,15,24,30,33,34,49,50,74–90} The track record of the pharmaceutical industry in these areas has been weak. Internal industry documents released after criminal convictions of the companies concerned, reveal a systemic pattern geared towards “marketing-based medicine” that is at odds with “evidence-based medicine”.³³

Among many examples, an internal AstraZeneca email discussed “*burial*” of data from four clinical trials. We quote John J A Tumas, Publications Manager, AstraZeneca, 6 December 1999,

There is pressure from outside the industry to provide access to all data from clinical trials conducted by the industry; thus far we have buried trials 15, 31, 56 and are now considering COSTAR.⁹⁰

Illusion of evidence-based medicine

Jureidini and McHenry, in a prominent article in the *BMJ* asserted that Medicine has been “corrupted by corporate interests, failed regulation and commercialisation of academia”, to cause an “illusion of evidence-based medicine”.⁸⁵ The evidence base for clinical and public health decisions has long been corrupted, in the view of former chief-editors of *The Lancet*,⁹¹ the *BMJ*⁸⁶ and *NEJM*.⁸⁷ Peer review cannot possibly police commercial and ideological conflicts of interest.

Pharmaceutical companies, publication and statistics

Manipulation of statistics in the medical literature has been lamented.¹⁸ Widespread promotion of relative rather than absolute risk and use of surrogate endpoints are examples.^{18,75}

Concerns exist over the transparency of COVID-19 mRNA vaccine trial data. Available figures from Pfizer and Moderna trials listed at clinicaltrials.gov have been evaluated (NCT04368728 and NCT04470427). As originally published in *NEJM*, the Pfizer and Moderna mRNA COVID-19 vaccine interim phase III clinical trial reports suggested a favourable risk/benefit ratio. Based on exactly the same data, Fraiman and colleagues publish in *Vaccine* that:

mRNA COVID-19 vaccines were associated with an excess risk of serious adverse events of special interest of 10.1 and 15.1 per 10,000 vaccinated over placebo baselines of 17.6 and 42.2 (95% CI –0.4 to 20.6 and –3.6–33.8), respectively.

From which they conclude a need for formal risk-benefit analyses.⁵⁹

The FDA has been publicly criticised for their slow response to follow up potential increases in serious adverse events in elderly people related to Pfizer’s mRNA COVID-19 vaccine [⁵⁸ preprint,^{92,93}].

There are even indications that initial clinical trial work, published in the *NEJM*, may have been performed with mRNA products that differed from those eventually mass-produced. The clinical trial mRNA gene codes were created by PCR “Process 1” technology, but the vials for the public were produced by “Process 2” E. coli plasmid DNA manufacture, which has led to plasmid DNA contamination of vaccine vials.⁹⁴

Beyond any clinical trial data and the process required to obtain initial approval from regulatory authorities, is the absolutely vital need to recognise that all therapeutic agents must be continuously monitored and subject to the red flags of vigilant surveillance.

Lack of recognition of pharmacovigilance data

Historic precedence in pharmacovigilance, safety and product recall has not been followed with respect to the COVID-19 gene-based vaccines, as shown by reports on <https://www.vaersanalysis.info/> which collates weekly updates of data from the US CDC’s Vaccine Adverse Event Reporting System (VAERS) (Figure 4). The methodology used by vaersanalysis.info is presented in the [supplemental materials](#).

A polio vaccine was withdrawn after just 10 death reports,⁹⁵ the Swine Flu vaccine of 1976 was recalled after just 25 of the ultimate 53 death reports.⁹⁶

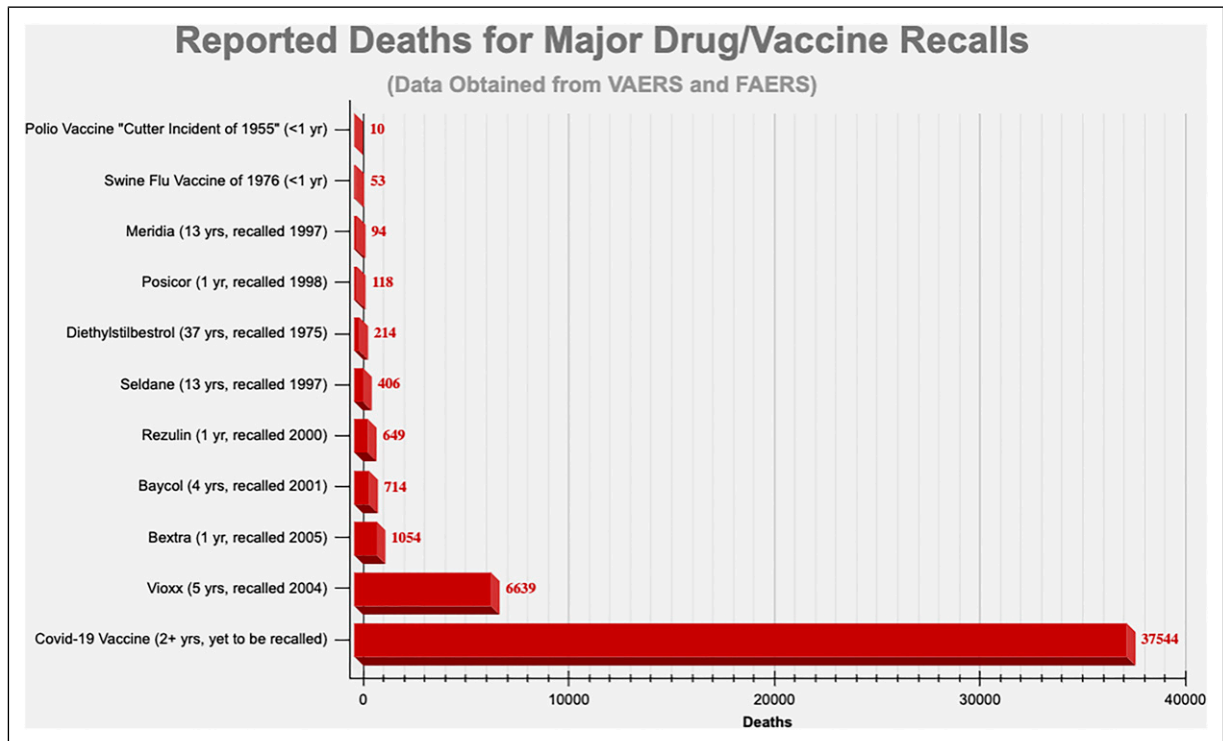


Figure 4. Reported suspected deaths for major drug/vaccine recalls versus COVID-19 vaccine reported suspected deaths. From VAERS Analysis⁴³ (with permission).

Not only are adverse events exceedingly high for the COVID-19 vaccines compared to all other vaccines (Figure 1), but deaths related to vaccines based *per million doses* show an unprecedented performance for the COVID-19 gene-based agents. Comparison with the influenza vaccine for which more doses have been dispensed is noteworthy (Figure 5).

The red bars provide a comparison of ratios of adverse events/distributed doses of vaccines. The COVID-19 vaccines have data for both distributed doses (solid bar) and administered doses (taller dotted line bar) which might be a more accurate comparison given the reported high proportion of non-used COVID-19 vaccine doses.^{97,98}

Pharmacovigilance underestimation factor

Vioxx data suggests the FDA's adverse event database (FAERS) *underestimates deaths by a factor of 5- to 9-fold*.^{88,99} With deaths from strokes added to heart attacks, the under-estimation factor is likely to have been greater.²⁴ Yet, since the advent of the COVID-19 vaccines, health authorities have strenuously suggested the unprecedented adverse events are over-reported and thus overestimated. For example, the Australian Therapeutics Goods Administration (TGA) claim of overestimation by its *passive* system Database of Adverse Event Notifications (DAEN) is directly contradicted by the Australian National Centre for Immunisation Research and Surveillance (NCIRS), who operate the *active* prompted submissions to the AusVaxSafety database. While active AusVaxSafety data for Pfizer,¹⁰⁰ Moderna,¹⁰¹ and AstraZeneca¹⁰² vaccines failed to question around severe adverse events, and is thus incomplete, it still reflects far greater numbers of adverse events than the passively collected TGA DAEN figures.

In the US, government quality assurance suggests that the CDC's VAERS *under-reports by a factor of 10- to 100-fold* – that only 1%–10% of all serious vaccine injuries are recorded.¹⁰³ VAERS sensitivity to capture serious adverse events well-known to be caused by vaccines, namely anaphylaxis and Guillain-Barré syndrome, ranged from 12% to 76%, but mostly around 25% for several vaccines. In other words, an *underestimation factor of 4-fold*.¹⁰⁴

These pharmacovigilance databases err decidedly on the side of underestimation, not overestimation.

In this context, the TGA confirms 14 of 1004 deaths (to 29 October, 2023) reported as potentially associated with the COVID-19 vaccines authorised in Australia,¹⁰⁵ which implies the other 990 deaths (98.6%) reported, mostly by clinicians,

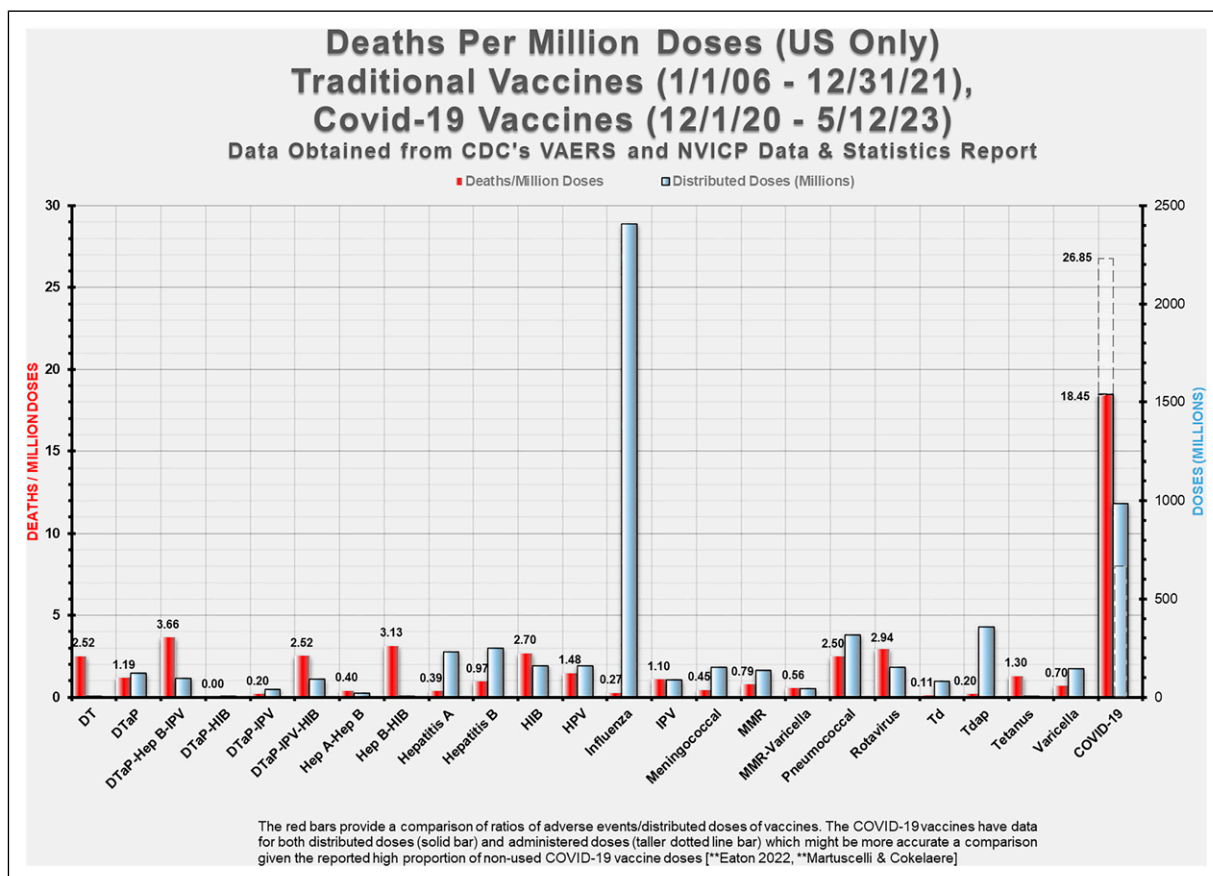


Figure 5. Suspected deaths per million doses of vaccine. Distributed doses in millions. Traditional versus COVID-19 vaccines. From: VAERS Analysis⁴³ (with permission). See also supplementary materials for further information on this graph.

are attributable to an *overestimation factor*. The TGA dismissal of the severity of its own DAEN data is at odds with all prior research and with the active surveillance systems.

The active surveillance AusVaxSafety survey data showed a dose response effect of increased mRNA in the higher ratio of adverse events from Moderna than Pfizer COVID-19 vaccines and in the higher rate after the second dose that follows soon after the first. Graphical representations of the statistics reveal high rates of “missing work, study or routine duties”. A graph from the AusVaxSafety survey for the Moderna vaccine¹⁰¹ is presented in Figure 6. AusVaxSafety had a limited range of adverse events typical of reactogenicity to vaccines for respondents to select. Inability to perform normal activities is generally considered a criterion for serious adverse events, even though the survey did not specifically list them.

Educated hesitancy has been mocked. Figure 7 from the VAERS analysis data shows that the rate of adverse events per vaccine dose reported did not vary substantially across the age range. This contrasts with the severity of COVID-19 viral illness which was a relatively mild illness for younger age cohorts.

Pharmacovigilance and the future

Broadly, all pharmaceutical products are continuously experimental, observed and tracked by pharmacovigilance systems worldwide. The population ultimately becomes the long-term experiment.¹

Gene-based medicine in blanket form, with mass production at extremely low cost, is expected to become a significant market trend.¹⁰⁶ With the many gene-based therapeutic technologies planned, a vast new era of pathology may lie ahead.

Time honoured medical ethics and the precautionary principle must be reasserted. Commercial pressure, distortion of evidence base, authority bias and groupthink bureaucratic lockstep policy, all mitigate against cautious, safe-practice medical science.

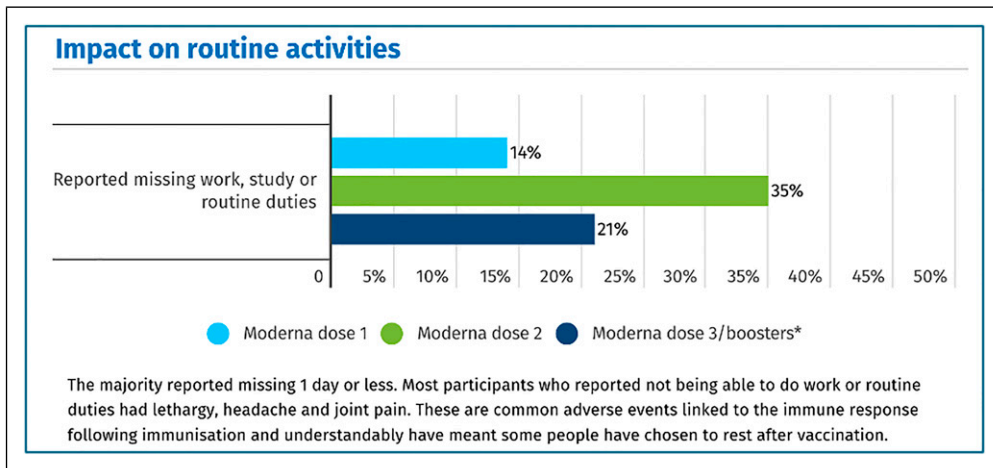


Figure 6. Impact on routine activities of Moderna doses 1, 2 and booster. AusVaxSafety data as January 26, 2023.¹⁰¹

Access to raw data, open discussion, freedom from censorship and heightened, active pharmacovigilance must be nurtured, if the health of humanity is to be better protected and if trust in the medical profession is to be fully restored.

Limitations

In this selective narrative review, limitations are embodied in the very nature of our subject matter – an exploration of conflicts between scientific integrity, data transparency and timely action on pharmacovigilance and adverse events, versus corporate ambitions to advertise, compete and market pharmaceutical agents for financial gain. The authors acknowledge limitations of free access to confidential data, a reliance upon Freedom of Information requests (themselves dependent upon

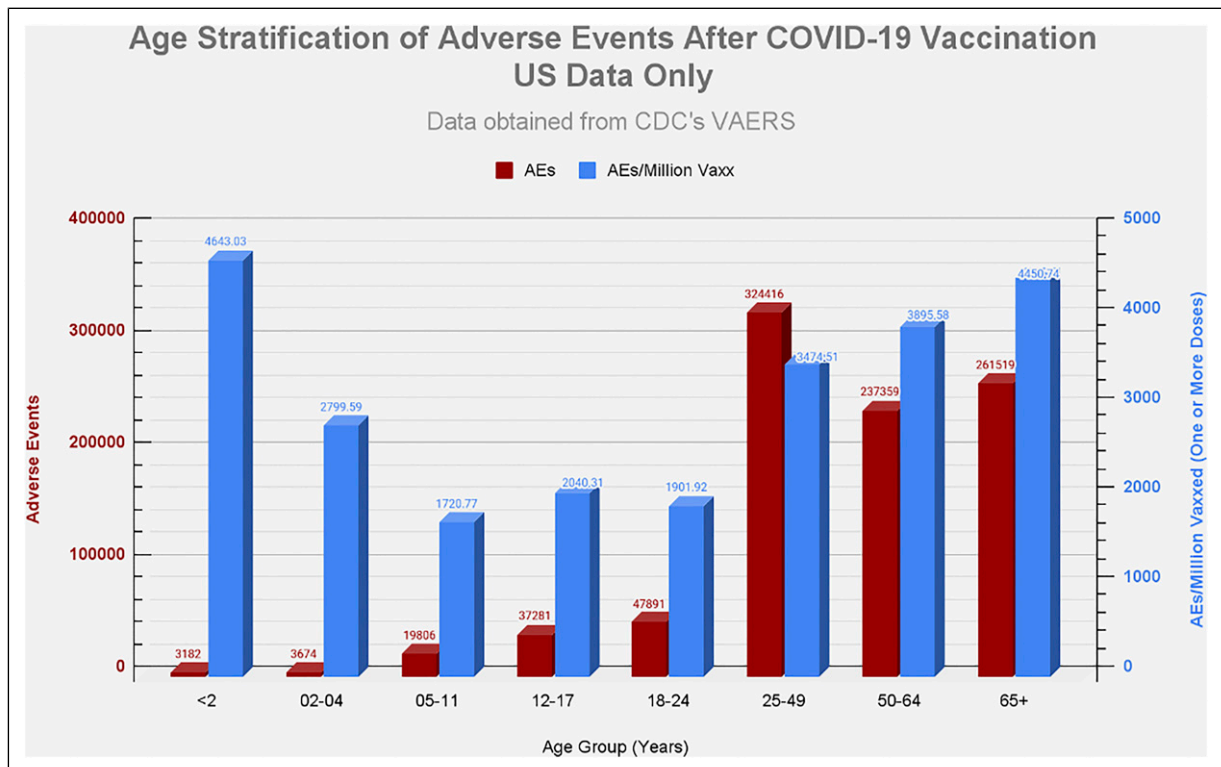


Figure 7. Age stratification of adverse events after COVID-19 vaccination. From: VAERS Analysis⁴³ (with permission).

the time, will and energies of interested parties), and of course dependency upon peer reviewed medical literature, an uncertain proportion of which has been shown to be unreliable, either because of exuberant optimism, publication haste or by deliberate design.^{25–28,30,32–35,57–74}

The methodology for the graphs from <https://www.vaersanalysis.info/> used in this paper, and limitations in the raw data used to compile those graphs, are described in the [supplemental materials](#).

Conclusion

The fullest context is one in which the pharmaceutical industry has provided many remarkable drugs for the benefit of humanity. From this backdrop, we have selected a few of the most significant events in pharmaceutical recall history, in which commercial interest has dominated market strategy, and we have sought to derive key lessons from these.

A host of mechanisms are used by the pharmaceutical industry to promote and market their products. These include changes to the definitions or boundaries of disease, introduction of bias long before data collection begins, concealment of raw data, failure to collect safety data, or decisions not to report negative or unfavourable results.^{33,89,90}

Gene codes for foreign protein production throughout the body are particularly novel. Close attention to pharmacovigilance data is imperative. Failure to withdraw the gene-based COVID-19 vaccines from the market, despite clear indications of harms, is not without precedent – as has been seen with Merck's Vioxx (rofecoxib).

Excess mortality figures are high at present in many countries that have deployed the novel and experimental gene-based COVID-19 vaccines. As open-mindedness, objectivity and curiosity are essential to good science, we must immediately include new corporate products in our discussions about excess mortality and its possible causes. Drug recalls have been significant and numerous over recent decades. It may well be high time for the recall of still more.

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Supplemental Material

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Subject: Concerns Regarding WSDOH Recommendation on Water Fluoridation

Dear WSBOH,

I am writing to express my concerns regarding the current WSDOH recommendation to fluoridate drinking water.

It seems unthinkable for a physician to prescribe a lifelong dosage of a potentially toxic substance, with no proven clinical benefit, to someone they have never met, interviewed, or examined. Such an approach disregards individual medical histories and informed consent. Even more troubling, this recommendation effectively suggests that the public consume an unspecified amount of this substance indefinitely, not because of their individual needs, but because some children may suffer from tooth decay.

This one-size-fits-all approach is not only unscientific but also illegal, unethical and unacceptable.

On September 24, 2024, the U.S. District Court for the Northern District of California issued a landmark ruling, determining that water fluoridation at 0.7 mg/L poses an “unreasonable risk” to children’s health by reducing IQ. This decision underscores the urgent need to reevaluate the continued recommendation of fluoride at these levels, as it is no longer justifiable in light of the demonstrated harm.

In addition to my concerns, I would like to share the attached Top 50, Top 10, and Top 3 Reasons to Discontinue Fluoridation for your consideration. These reasons encapsulate a range of ethical, scientific, and public health perspectives that I believe warrant serious reflection.

The recommendation to fluoridate drinking water is in violation of numerous state and federal laws.

The Department of Health is complicit in encouraging violations of RCW 69.41.030, which governs the distribution and administration of legend drugs. Fluoride, classified as a legend drug, is being recommended for unauthorized delivery to the public without prescriptions, medical oversight, or the involvement of licensed professionals. This circumvention of lawful distribution channels and medical oversight constitutes a breach of RCW 69.41.030.

Additionally, under RCW 69.38.010, sodium fluoride meets the state's definition of a poison. The intentional addition of poison to the water supply contravenes RCW 69.40.030, which criminalizes the willful mingling of poisons in water supplies and carries penalties of imprisonment and substantial fines.

The Department also fails to ensure compliance with WAC 246-290-220, which mandates adherence to ANSI/NSF Standard 60 & 61. These standards limit the leaching of harmful contaminants into drinking water and ensure the additives are safe. Moreover, the

recommendation violates RCW 70A.125.060 by failing to prioritize the safety of the public water system, thereby compromising water quality and endangering public health.

Further, the promotion of fluoridation by the Department infringes upon federal regulations under CFR Title 21. Specifically, it violates 21 CFR 202.1(e) by failing to disclose side effects and making false or misleading claims about fluoride. This also constitutes a breach of the Food, Drug, and Cosmetic Act by promoting and distributing an unapproved drug without proper oversight or informed consent.

Finally, by recommending the addition of fluoride to water supplies without informed consent or medical oversight, the Department of Health is in violation of ethical standards set by the Nuremberg Code and the Belmont Report. These actions infringe upon constitutional rights, including the right to bodily integrity and freedom of medical choice.


Under federal law, fluoridation qualifies as medical experimentation. Fluoride is an unapproved drug being administered to human subjects without their consent, in violation of 21 CFR § 312.3(b). The Department has not ensured "legally effective informed consent" as required by 21 CFR § 50.20 and 21 CFR § 50.25(a)(1). Furthermore, no Investigational New Drug (IND) application has been filed, as required under 21 CFR § 312, nor has Institutional Review Board (IRB) approval been sought, as mandated by 21 CFR Part 56.

Lastly, under the Food, Drug, and Cosmetic Act (FD&C Act), the recommendation to fluoridate constitutes the unlawful introduction of an unapproved drug into interstate commerce without the required New Drug Application (NDA) or IND, in violation of 21 U.S.C. § 355. These actions amount to illegal medical experimentation and a failure to protect public health.

I urge the Department of Health to reconsider this recommendation in light of these legal, ethical, and public health concerns. Thank you for your attention to this matter.

Sincerely,

Derek Kemppainen
31404 NE 142nd Ave
Battle Ground, WA 98604
360-975-2011



10 **FACTS** ABOUT FLUORIDE

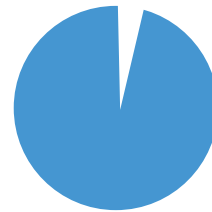


FLUORIDEALERT.ORG
Fluoride Action Network

FACT 1 MOST DEVELOPED COUNTRIES DO NOT FLUORIDATE THEIR WATER

In the United States, health authorities call fluoridation “one of the top 10 public health achievements of the 20th century.” Few other countries share this view. In fact, more people drink artificially fluoridated water in the U.S. alone than in the rest of the world combined.¹ Most advanced nations do not fluoridate their water. In western Europe, 97% of the population has water without a single drop of fluoride added to it.² Fluoridation proponents will sometimes say this is because Europe adds fluoride to its salt. Only five nations in western Europe, however, have any fluoridated salt.³ The vast majority do not.

WESTERN EUROPE

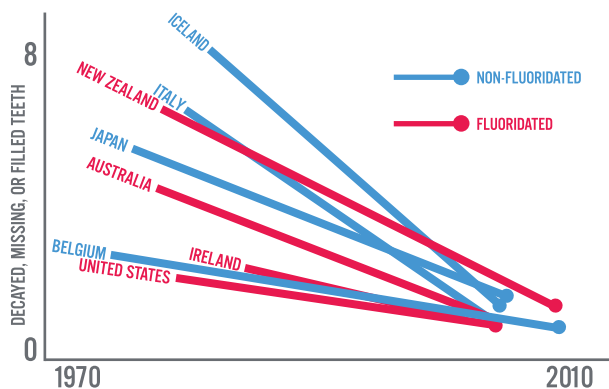


97%
DO NOT DRINK
FLUORIDATED WATER

DID YOU KNOW?

MORE PEOPLE DRINK ARTIFICIALLY FLUORIDATED WATER IN THE U.S. ALONE THAN IN THE REST OF THE WORLD COMBINED

It is often claimed that fluoridated water is the main reason the United States has had a large decline in tooth decay over the past 60 years. This same decline in tooth decay, however, has occurred in all developed countries, most of which have never added any fluoride to their water.⁴ Today, according to data from the World Health Organization, there is no discernible difference in tooth decay between the minority of developed countries that fluoridate water, and the majority that do not.⁵



SOURCE: WORLD HEALTH ORGANIZATION (2013)

FACT 2

FLUORIDATED COUNTRIES
DO NOT
HAVE LESS
TOOTH DECAY THAN
NON-FLUORIDATED COUNTRIES

FACT 3 FLUORIDE AFFECTS MANY TISSUES IN THE BODY BESIDES THE TEETH

Fluoridation advocates have long claimed that the safety of fluoridation is beyond scientific debate.⁶ However, according to the well-known toxicologist, Dr. John Doull, who chaired the National Academy of Science's review on fluoride, the safety of fluoridation remains "unsettled" and "we have much less information than we should, considering how long it has been going on."⁷ In 2006, Doull's committee at the NAS published an exhaustive 500-page review of fluoride's toxicity.⁸ The report concludes that fluoride is an "endocrine disruptor" and can affect many things in the body, including the bones, the brain, the thyroid gland, the pineal gland, and even blood sugar levels.⁹

Far from giving fluoride a clean bill of health, the NAS called upon scientists to investigate if current fluoride exposures in the United States are contributing to chronic health problems, like bone disorders, thyroid disease, low intelligence, dementia, and diabetes, particularly in people who are most vulnerable to fluoride's effects.¹⁰ These recommendations highlight that—despite 60 years of fluoridation—many of the basic studies necessary for determining the program's safety have yet to be conducted.

DID YOU KNOW?

"It is apparent that fluorides have the ability to interfere with the functions of **the brain**."

"The possibility has been raised by studies conducted in China that fluoride can lower **intellectual abilities**."

"Fluoride is an **endocrine disruptor**."

"Several lines of information indicate an effect of fluoride exposure on **thyroid function**."

"Sufficient fluoride exposure appears to . . . increase the severity of some types of **diabetes**."

"The relationship between **fertility** and fluoride requires additional study."

"Further research on a possible effect of fluoride on **bladder cancer** risk should be conducted."

"These changes have a bearing on the possibility that fluorides act to increase the risk of developing **Alzheimer's disease**."

SOURCE: National Research Council. (2006). Fluoride in Drinking Water: A Scientific Review of EPA's Standards. National Academies Press, Washington D.C.

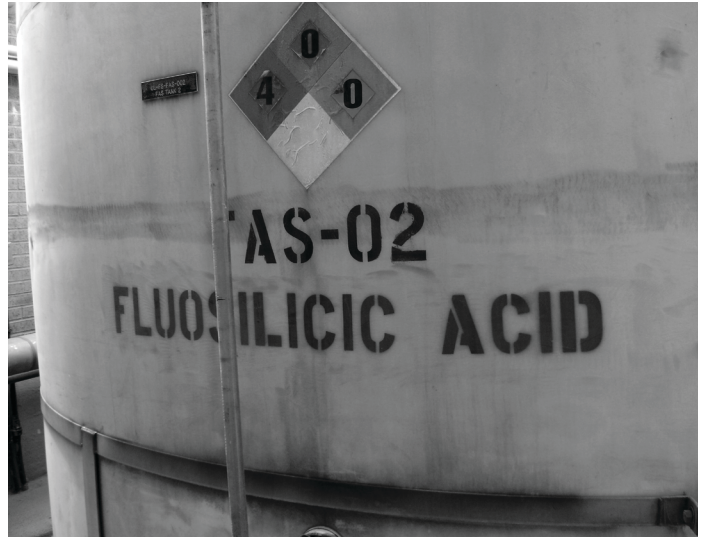
FACT 4 FLUORIDATION IS NOT A "NATURAL" PROCESS

Fluoridation advocates often say that "nature thought of fluoridation first." By this, they mean that fluoride occurs at naturally high levels in some water supplies.¹¹ Lots of toxic substances, however, like arsenic, and even some medicines, like lithium, can occur at naturally high levels. This doesn't mean they're safe.¹² Further, the level of fluoride added in artificial fluoridation programs is far higher than the level of fluoride that occurs in the vast majority of (unpolluted) fresh surface waters.¹³

Also the main fluoride chemical (fluorosilicic acid) that is added to water is not what most people would call

Fact 4 continued

a naturally occurring compound. It is a corrosive acid captured in the air pollution control devices of the phosphate fertilizer industry.¹⁴ Fluoride is captured in air pollution control devices because fluoride gases are hazardous air pollutants that cause significant environmental harm.¹⁵ This captured fluoride acid is the most contaminated chemical added to public water supplies,¹⁶ and may impose additional risks to those presented by natural fluorides. These risks include a possible cancer hazard from the acid's elevated arsenic content, and a possible neurotoxic hazard from the acid's ability--under some conditions--to increase the erosion of lead from old pipes.¹⁷



DID YOU KNOW?

THE FLUORIDE CHEMICAL (“FLUOSILICIC ACID”) ADDED TO MOST TAP WATER IS A CORROSIVE ACID CAPTURED IN AIR POLLUTION CONTROL DEVICES

FACT 5

40%

OF AMERICAN TEENAGERS SHOW
VISIBLE SIGNS
OF FLUORIDE OVER-EXPOSURE

According to a recent national survey by the CDC, about 40% of American teenagers have a condition called dental fluorosis.¹⁸ Fluorosis is a defect of tooth enamel caused by fluoride's interference with the tooth-forming cells. The condition shows as cloudy spots and streaks and, in more severe cases, brown stains and tooth erosion.¹⁹ In the 1950s, health officials claimed that fluorosis would only affect 10% of children in fluoridated areas.²⁰ This prediction has proven false. Today, not only do 40% of American teenagers have fluorosis, but, in some fluoridated areas, the rate is as high as 70 to 80%, with some children suffering advanced forms of the condition.²¹

“Virtually all authors have noted that some children could ingest more fluoride from [toothpaste] alone than is recommended as a total daily fluoride ingestion.”

- Dr. Stephen Levy, et al.,
Journal of Public Health Dentistry (1999).

The high rate of fluorosis in the U.S. reflects the fact that **children now receive fluoride from many sources besides tap water.** When fluoridation first began, there was not a single tube of toothpaste that contained fluoride. Today, over 95% of toothpastes are fluoridated. Although fluoride toothpastes carry poison warnings on them, studies show that children can swallow large amounts of fluoride when they brush, particularly when using toothpaste with bubble gum and candy flavors.²²

Fact 5 continued

And there are other sources of fluoride as well, including processed beverages/foods,²³ fluoride pesticides,²⁴ tea,²⁵ Teflon pans,²⁶ and some fluorinated pharmaceuticals.²⁷ The concern today, therefore, is not just the safety of fluoridated water by itself, but the safety of fluoridated water in combination with all the other sources to which we're now exposed.

Dental Fluorosis >
Photograph by Hardy Limeback, DDS, PhD



DID YOU KNOW?

36 STUDIES HAVE FOUND A CORRELATION BETWEEN FLUORIDE AND LOWER IQ

FACT 6 FOR INFANTS, FLUORIDATED WATER PROVIDES NO BENEFITS, ONLY RISKS



Up until the 1990s, health authorities advised parents to give fluoride to newborn babies. This is no longer the case. Today, the Institute of Medicine recommends that babies consume a minuscule 10 micrograms of fluoride per day.²⁸ This is roughly the equivalent of what babies ingest from breast milk, which contains virtually no fluoride.²⁹

Infants who consume formula made with fluoridated tap water consume up to 700 to 1,200 micrograms of fluoride, or about 100 times more than the recommended amount. According to the CDC, these early spikes of fluoride exposure during infancy provide no known advantage to teeth.³⁰ These spikes can, however, produce harm.

Recent studies show that babies who are given fluoridated water in their formula develop significantly higher rates of dental fluorosis.³¹ Because of this, a number of prominent dental researchers now advise that parents should not add fluoridated water to baby formula.³²

And teeth are not the only concern. In July of 2012, scientists from Harvard University warned that **the developing brain may be another target for fluoride toxicity.**³³ The Harvard team based their warning on a large number of studies from China that have found reduced IQ scores among children exposed to elevated fluoride during their early years of life. Twelve of the studies the Harvard team reviewed found IQ loss at fluoride levels deemed safe in the U.S. and a study sponsored by UNICEF found IQ loss in iodine-deficient children at the so-called "optimal" fluoridation level.³⁴ The possibility that fluoridated water can reduce IQ is a matter that "definitely deserves concern."³⁵



FACT 7

FLUORIDE SUPPLEMENTS HAVE NEVER BEEN APPROVED BY THE FDA

Fluoride “supplements” are designed to provide children the same dose of fluoride they would receive by drinking fluoridated water.³⁶ Unlike other dietary supplements, however, you can’t just walk into a grocery store and buy a fluoride supplement. Because of fluoride’s toxicity, you can only buy a fluoride “supplement” if you have a doctor’s prescription. Yet, although federal law requires that prescription drugs be approved as safe and effective by the FDA,³⁷ the FDA has never approved fluoride supplements for the prevention of tooth decay.³⁸ In fact, **the only fluoride supplements the FDA has reviewed, have been rejected.**³⁹ So, with fluoridation, we are adding to the water a prescription-strength dose of a drug that has never been approved by the FDA.

FACT 8 FLUORIDE IS THE ONLY MEDICINE ADDED TO PUBLIC WATER

Fluoride is the only chemical added to water that doesn’t actually treat the water. Chlorine, for example, is added to kill bacteria so that we can drink the water without getting sick. Fluoride, by contrast, is added to prevent a disease (tooth decay) that is not caused by drinking water.

Fluoridation proponents claim that fluoridated water is not a medication because, in their view, it’s no different than adding iodine to salt or vitamin D to milk. What proponents fail to acknowledge, however, is that iodine and vitamin D are both essential nutrients; but fluoride is not.

An essential nutrient is something the body has a physiological demand for. If we don’t have enough



Fluoridation adds a prescription-strength dose of a drug to the water supply.

Fact 8 continued

iodine, for example, our thyroid gland won't function properly. Although fluoride advocates sometimes claim that fluoride is a "nutrient," the National Academy of Sciences has repeatedly confirmed that this is not the case.⁴⁰ Because fluoride is not a nutrient, the FDA has defined fluoride as a medicine when used to prevent disease.⁴¹ Since tooth decay is a disease, adding fluoride to water to prevent tooth decay is -- as a matter of logic -- a form of medication. This is one of the reasons why most European nations have rejected fluoridation: because, in their view, the water supply is an inappropriate way to deliver medicine.⁴² **With other medicines, it is the patient, not the doctor, who has the right to decide** which drug to take.⁴³ Fluoridation denies people this right.

“Fluoridation goes against all principles of pharmacology. It's obsolete.”

- Dr. Arvid Carlsson,
Nobel Laureate in Medicine/Physiology.

FACT 9

SWALLOWING FLUORIDE PROVIDES LITTLE BENEFIT TO TEETH

When water fluoridation first began back in the 1940s, the medical profession believed fluoride needed to be ingested to be most effective in preventing cavities.⁴⁴ This was why fluoride was added to water and pills—because these are things that people swallow. Today, however, it is now widely recognized that fluoride's main benefit does not actually come from ingestion, it comes from fluoride's **topical contact** with teeth⁴⁵—a fact that even the CDC has now acknowledged.⁴⁶ So, not only does fluoridation add a medicine to water, it adds a medicine that does not actually need to be swallowed.



DISADVANTAGED COMMUNITIES ARE THE MOST DISADVANTAGED BY FLUORIDE

In the United States, there is a serious shortage of dentists who will treat low-income patients.⁴⁷ The claim, however, that we can compensate for this lack of care by forcing poor populations to consume fluoridation chemicals in their water is a dangerous one.

The conditions that make people more vulnerable to fluoride toxicity are more prevalent in poor communities than affluent ones (e.g., nutrient deficiencies, infant formula consumption, kidney disease, and diabetes).⁴⁸ This likely explains why African American and Mexican American children suffer significantly higher rates of dental fluorosis.⁴⁹ These disparities in fluoride risk have led several prominent civil rights leaders—including Andrew Young and the nation’s largest Hispanic civil rights organization—to call for an *end to fluoridation*.⁵⁰

Despite claims that fluoridation can prevent the high rates of tooth decay seen in poor areas, the vast majority of poor urban communities have been fluoridated for over 30 years, and yet are still suffering from a severe oral health crisis.⁵¹ In fluoridated Cincinnati, the dental director described the state of oral health among poor children as “absolutely heartbreaking and a travesty,”



DID YOU KNOW?

- In (fluoridated) Detroit, 91% of 5-year-old black children have tooth decay, with 42% suffering from “severe” decay.⁵⁴
- In (fluoridated) New York City, 34% of pre-school black children from low-income families have rampant tooth decay, with a staggering 6.4 cavities per affected child.⁵⁵
- In (fluoridated) Chicago, 64% of third graders have tooth decay.⁵⁶
- In San Antonio, annual head start surveys show that fluoridation failed to reduce the high rate of tooth decay among the city’s head start children. After eight years of fluoridation, the tooth decay rate did not decrease—it increased.⁵⁷
- A national survey by the CDC found that the most fluoridated state in the U.S. (Kentucky) suffers the highest rate of tooth loss (44%) while the least fluoridated state (Hawaii) suffers the lowest rate of tooth loss (16%).⁵⁸
- Untreated tooth decay in fluoridated urban areas has led to several deaths, including a 12-year-old child in Prince Georges Maryland, and a 24-year-old father in Cincinnati.⁵⁹

adding that “people would be shocked to learn how bad the problem has become.”⁵² Many other cities have experienced the same fate. (See sidebar)

The simple fact is that **poor populations need dental care, not fluoridation chemicals in their water.** The millions of dollars spent each year promoting fluoridation would be better spent advocating for policies that provide real dental care: like allowing dental therapists to provide affordable care to populations with little access to dentists.⁵³ In short, fluoridation provides good PR for dental trade associations, but bad medicine for those it’s supposedly meant to serve.

REFERENCES:

NOTES FOR FACT 1: “MOST DEVELOPED COUNTRIES DO NOT FLUORIDATE THEIR WATER”

- 1) See data at: www.fluoridealert.org/content/bfs-2012/
- 2) See data at: www.fluoridealert.org/content/water_europe/
- 3) For data on the number of countries in Europe that allow fluoridated salt, see: Gotzfried F. (2006). *Schweiz Monatsschr Zahnmed* 116: 371–75. Unlike water fluoridation (which applies fluoride to an entire water supply), salt fluoridation in Europe is limited to household salt that people have the option to purchase. In two of the five European countries that allow salt fluoridation, only 6% to 10% of household salt is actually fluoridated). Salt fluoridation is thus a far less intrusive application of fluoride than water fluoridation.

NOTES FOR FACT 2: FLUORIDATED COUNTRIES DO NOT HAVE LESS TOOTH DECAY THAN NON-FLUORIDATED COUNTRIES

- 4) See extensive compilation of published research and data at: www.fluoridealert.org/studies/caries01/
- 5) World Health Organization Collaborating Centre for Education, Training, and Research in Oral Health, Malmö University, Sweden. Data available at <http://www.mah.se/CAPP/> (accessed on March 30, 2013).

NOTES FOR FACT 3: FLUORIDE AFFECTS MANY TISSUES IN THE BODY BESIDES THE TEETH

- 6) A representative example of this viewpoint was expressed by Dr. Robert Kehoe in 1957: “The question of the public safety of fluoridation is non-existent from the viewpoint of medical science.”
- 7) In a January 2008 article published in *Scientific American*, Dr. Doull was quoted as saying: “[W]e’ve gone with the status quo regarding fluoride for many years—for too long, really—and now we need to take a fresh look. In the scientific community, people tend to think this is settled. I mean, when the U.S. surgeon general comes out and says this is one of the 10 greatest achievements of the 20th century, that’s a hard hurdle to get over. But when we looked at the studies that have been done, we found that many of these questions are unsettled and we have much less information than we should, considering how long this has been going on. I think that’s why fluoridation is still being challenged so many years after it began.”
See: www.fluoridealert.org/researchers/nrc/panelists/
- 8) National Research Council. (2006). *Fluoride in drinking water: a scientific review of EPA’s standards*. National Academies Press, Washington D.C. Available online at: www.nap.edu/catalog.php?record_id=11571
- 9) See excerpts of NAS’s findings at: www.fluoridealert.org/researchers/nrc/findings/
- 10) See excerpts of NAS’s recommendations at: www.fluoridealert.org/researchers/nrc/recommendations/

NOTES FOR FACT #4: FLUORIDATION IS NOT A “NATURAL” PROCESS

- 11) Most fresh surface waters (e.g., lakes/streams) contain very little fluoride. When fluoride is obtained from deep ground water supplies, however, fluoride contamination can become a significant problem. See *infra* note 13.
- 12) High levels of naturally occurring fluorides have wreaked havoc on tens of millions of people’s health around the world, particularly in developing countries where water shortages force many rural communities to obtain water from deep in the ground. Consumption of fluoride-laden well water causes serious health ailments, including tooth loss, bone disease, ulcers, brain damage, heart disease, and thyroid disease. See: www.fluoridealert.org/issues/health/. Because of this, international organizations like UNICEF assist developing nations in finding ways of removing fluoride from the water. For a review by UNICEF on the worldwide scope of fluoride poisoning, see: www.fluoridealert.org/uploads/UNICEF-1999.pdf
- 13) In Canada, the average level of fluoride in fresh surface water is just 0.05 ppm, which is 14 to 24 times less fluoride than added to water in fluoridation programs. See: Environment Canada. (1993). *Inorganic Fluorides: Priority Substances List Assessment Report*. Government of Canada, Ottawa. p. 14. Fresh vegetables, fruits, milk, and eggs contain even lower levels of fluoride (unless they’re sprayed with fluoride pesticides). See: www.fluoridealert.org/content/fresh_foods/. In the rare circumstance where rivers or ponds contain the same level of fluoride that is added to tap water, salmon and frogs have been found to suffer serious harm, including bone disease, changes in behavior, and increased mortality. See: Shaw SD, et al. (2012). *Journal of Zoo & Wildlife Medicine* 43(3):549-65; Damkaer DM, Dey DB. (1989). *North American Journal of Fisheries Management*. 9: 154-162.
- 14) As noted by the U.S. Environmental Protection Agency, “By recovering by-product fluosilicic acid from fertilizer manufacturing, water and air pollution are minimized, and water authorities have a low-cost source of fluoride available to them.”
See: www.fluoridealert.org/uploads/hanmer1983.pdf.
- 15) In 20th century, fluoride pollution caused more harm to livestock than any other pollutant. In Polk County, Florida (the capital of America’s phosphate industry), cattle downwind of the phosphate industry suffered “mass fluoride poisoning.” Between 1953 and 1960, “the cattle population dropped 30,000 head,” and “an estimated 150,000 acres of cattle land were abandoned.” As one farmer explained, “Around 1953 we noticed a change in our cattle... We watched our cattle become gaunt and starved, their legs became deformed; they lost their teeth. Reproduction fell off and when a cow did have a calf, it was also affected by this malady or was a stillborn.” For discussion and documentation, see: www.fluoridealert.org/articles/phosphate01/
- 16) See: Weng C, et al. (2000). Treatment chemicals contribute to arsenic levels. *Opflow (AWWA)*, October, p. 6-7. Available at: <http://www.fluoridealert.org/uploads/opflow-2000.pdf>
- 17) Hirzy JW, et al. (2013). *Environ. Sci. Policy* <http://dx.doi.org/10.1016/j.envsci.2013.01.007>. On the lead/neurotoxic risk, see: Coplan MJ, et al. (2007). *Neurotoxicology* 28(5):1032-42; Maas RP, et al. (2007). *Neurotoxicology* 28(5):1023-31.

NOTES FOR FACT #5: 40% OF AMERICAN TEENAGERS SHOW VISIBLE SIGNS OF FLUORIDE OVER-EXPOSURE.

- 18) Beltran-Aguilar ED, et al. (2010). *Prevalence and Severity of Dental Fluorosis in the United States, 1999–2004*. NCHS Data Brief No. 53.
- 19) For photographs and discussion, see: www.fluoridealert.org/issues/fluorosis/
- 20) Spzunar SM, Burt BA. (1988). *J. Dent. Res.* 67(5):802-06; Hodge HC. (1950). *J. Am. Dent. Assoc.* 40:436-39.
- 21) See: www.fluoridealert.org/studies/dental_fluorosis01/
- 22) See: www.fluoridealert.org/issues/sources/f-toothpaste/
- 23) See: www.fluoridealert.org/issues/sources/processed/
- 24) See: www.fluoridealert.org/issues/sources/f-pesticides/
- 25) See: www.fluoridealert.org/issues/sources/tea/
- 26) See: www.fluoridealert.org/issues/sources/teflon-pans/
- 27) See: www.fluoridealert.org/issues/sources/pharmaceuticals/

NOTES FOR FACT #6: FOR INFANTS, FLUORIDATED WATER PROVIDES NO BENEFITS, ONLY RISKS

- 28) Institute of Medicine. (1997). *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride*. p. 302.
- 29) Ekstrand J, et al. (1981). *British Medical Journal* 283: 761-2.
- 30) In a May 15, 2012 letter to Senator Barbara Boxer, the CDC wrote:
“We are **unaware of data** . . . about the additional protection from tooth decay that could result from [intakes greater than 10 micrograms/day of fluoride].” See: www.fluoridealert.org/uploads/cdc-2012.pdf
- 31) See: www.fluoridealert.org/studies/infant02/
- 32) See: www.fluoridealert.org/studies/infant01/
- 33) Choi AL, et al. (2012). *Environmental Health Perspectives* 120:1362-68.
- 34) For a discussion of these studies, see: www.fluoridealert.org/articles/iq-facts/. For a listing of all studies that have found an association between fluoride and reduced IQ, see: www.fluoridealert.org/studies/brain01/.
- 35) Dr. Philippe Grandjean, the senior scientist who authored the Harvard review, has stated that: “Chemical brain drain should not be disregarded. The average IQ deficit in children exposed to increased levels of fluoride in drinking water was found to correspond to about 7 points – a sizable difference. To which extent this risk applies to fluoridation in Wichita or Portland or elsewhere is uncertain, but **definitely deserves concern**.” See: www.braindrain.dk/2013/02/fluoridated-water-and-brains/.

NOTES FOR FACT #7: FLUORIDE SUPPLEMENTS HAVE NEVER BEEN APPROVED BY THE FDA

- 36) Under current fluoride supplementation guidelines, two-year-old children living in non-fluoridated areas are prescribed 0.25 mg of fluoride per day. This is the same amount of fluoride contained in just one 8 ounce glass of water fluoridated at 1 ppm. To learn more about current fluoride supplementation guidelines, see: Rozier RG, et al. (2010). *J. Am. Dent. Assoc.* 141(12):1480-89.
- 37) 21 U.S.C. § 355(a). Although an exception to this rule exists for drugs that were on the market prior to 1938, fluoride supplements did not enter the market until the 1950s. Accordingly, the “grandfather clause” exception does not apply to fluoride supplements. For a detailed discussion on this point, see: www.fluoridealert.org/researchers/fda/explanations/
- 38) To access FDA’s letters confirming this fact, see: www.fluoridealert.org/researchers/fda/not-approved/
- 39) The two fluoride supplements that FDA has rejected are Enziflur (a fluoride/vitamin combination) and prenatal fluoride supplements. See: www.fluoridealert.org/uploads/enziflur-1975.pdf and www.fluoridealert.org/articles/fda-1966/.

NOTES FOR FACT 8: FLUORIDE IS THE ONLY MEDICINE ADDED TO PUBLIC WATER

- 40) According to the NAS, “fluoride is no longer considered an essential factor for human growth and development.”
See: www.fluoridealert.org/studies/essential-nutrient/
- 41) According to the FDA: “Fluoride, when used in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal, **is a drug** that is subject to Food and Drug Administration (FDA) regulation.” See: www.fluoridealert.org/researchers/fda/drug/
- 42) In Germany, for example, “the argumentation of the Federal Ministry of Health against a general permission of fluoridation of drinking water is the **problematic nature of compulsion medication**.” See this and other statements from European authorities at: www.fluoridealert.org/content/europe-statements/.
- 43) Under the principle of “informed consent,” the patient has the “right to self decision.” See: *AMA Ethical Opinion 8.08*. While the doctor has an “obligation . . . to present the medical facts accurately to the patient,” it is the patient (or the patient’s caregiver) who has the sole right to decide what medical treatments to use.

NOTES FOR FACT 9: SWALLOWING FLUORIDE PROVIDES LITTLE BENEFIT TO TEETH

- 44) Fejerskov O. (2004). *Caries Research* 38:184 (“The hypothesis was that increased intake of fluoride during tooth formation raises the fluoride concentration in enamel and hence increases acid resistance. As a consequence fluoride had to be taken systemically and artificial fluoridation of drinking waters became the ‘optimal’ solution.”).
- 45) For an extensive compilation of quotes from dental researchers discussing this consensus, see: www.fluoridealert.org/studies/caries04/
- 46) According to the CDC, “fluoride prevents dental caries predominately after eruption of the tooth into the mouth, and its actions primarily are **topical** for both adults and children.” Centers for Disease Control (1999). *Morbidity and Mortality Weekly Report* 48: 933-40.

NOTES FOR FACT 10: DISADVANTAGED COMMUNITIES ARE THE MOST DISADVANTAGED BY FLUORIDE

- 47) In Maryland, 84% of dentists do not accept Medicaid patients. Similar rates exist in other states, including Alabama (82%), Colorado (79%), and Ohio (72%). As a result, most low-income children are not able to receive treatment from a dentist. See data and reports at: www.fluoridealert.org/content/dental-care/
- 48) See: www.fluoridealert.org/issues/sources/ej/
- 49) Beltran-Aguilar ED et al. (2005). *MMWR Surveillance Summaries* 54(3): 1-44. For a discussion of other studies that have found racial disparities in fluorosis rates, see: www.fluoridealert.org/studies/dental_fluorosis02/
- 50) See: www.fluoridealert.org/issues/ej/statements/
- 51) For a compilation of reports, see: www.fluoridealert.org/studies/caries07/.
- 52) See: www.fluoridealert.org/news/cincinnati-dental-crisis/
- 53) Allowing access to dental therapists represents an important strategy for expanding dental care services to underserved populations. Dental therapists are specially trained to provide dental care, such as tooth cleanings and fillings. According to a recent review, “the quality of technical care provided by dental therapists (within their scope of competency) was comparable to that of a dentist, and in some studies was judged to be superior.” Nash D, et al. (2012). *A Review of the Global Literature on Dental Therapists*. W.K. Kellogg Foundation. p. 6. Despite these findings, dental trade associations (such as the American Dental Association) are vigorously lobbying against efforts to allow dental therapists to serve underprivileged populations. See: Levine D. (2011). *Why Are Dentists Opposing Expanded Dental Care?* Available at: www.governing.com/topics/health-human-services/gov-why-are-dentists-opposing-expanded-dental-care.html
- 54) Ismail AI, et al. (2006). Severity of dental caries among African American children in Detroit. Presentation at ADEA/AADR/CADR Conference, March 11. Abstract available at: http://iadr.confex.com/iadr/2006Orld/techprogram/abstract_73168.htm
- 55) Albert DA, et al. (2002). *Dental caries among disadvantaged 3- to 4-year-old children in northern Manhattan*. *Pediatric Dentistry* 24:229-33.
- 56) Bridge to Healthy Smiles. Cook County Oral Health Crisis. Available at: <http://www.bridgetohealthysmiles.com/ISDSBrochure.pdf>
- 57) Bexar County Head Start Dental Screenings Program. See data at: www.fluoridealert.org/uploads/san_antonio_caries.pdf
- 58) Centers for Disease Control. (1999). Behavioral Risk factor Surveillance System. Data summarized at: http://drc.hhs.gov/report4_3.htm
- 59) For a discussion of these tragic outcomes, see: Carrie Gann, *Man Dies from Toothache, Couldn't Afford Meds*, ABC News, Sept. 11, 2011, and Laura Owings, *Toothache Leads to Boy's Death*, ABC News, March 5, 2007.

STATEMENTS ON FLUORIDATION FROM CIVIL RIGHTS LEADERS

“I am most deeply concerned for poor families who have babies: if they cannot afford unfluoridated water for their babies’ milk formula, do their babies not count? Of course they do. This is an issue of fairness, civil rights, and compassion. We must find better ways to prevent cavities, such as helping those most at risk for cavities obtain access to the services of a dentist.”

-Andrew Young



“I support the holdings of Fluoridegate hearings so we can learn why we haven’t been openly told that fluorides build up in the body over time, why our government agencies haven’t told the black community openly that fluorides disproportionately harm black Americans, and why we’ve been told that decades of extensive research show fluoridation to be safe, when the National Research Council in 2006 listed volumes of basic research that has never been done.”

-Rev. Gerald Durley

“This is a civil rights issue. No one should be subjected to drinking fluoride in their water, especially sensitive groups like kidney patients and diabetics, babies in their milk formula, or poor families that cannot afford to purchase unfluoridated water. Black and Latino families are being disproportionately harmed.”

-Alveda King

