



NOV 21 2014

Dear Ms. McElhenny:

Thank you for your correspondence concerning fluoridation of drinking water. Your letter requests that I take a number of actions related to fluoridation. These include instructing the Food and Drug Administration (FDA) to advise fluoridation manufacturers to submit New Drug Applications; instructing the Centers for Disease Control and Prevention (CDC) to stop "promotion... of any and all drugs, including the ingestion of fluoride products, not FDA CDER approved"; sponsoring a review of fluoride's neurotoxicity by the National Research Council; and supporting a prospective randomized control trial of the effectiveness of ingesting hydrofluorosilicic acid.

For nearly 70 years, community water fluoridation (CWF) has been a safe and healthy way to effectively prevent tooth decay. CDC has recognized water fluoridation as one of ten great public health achievements of the 20th century. CDC works with national partners, states, communities, and water operators to ensure that the U.S. population has access to optimally fluoridated water to prevent tooth decay.

However, fluoride ingestion while teeth are developing can result in a range of visually detectable changes in the tooth enamel, called dental fluorosis. The prevalence of mild to moderate dental fluorosis in the United States has increased in recent years. Fluoride in drinking water is one of several available fluoride sources. In 2011, the Department of Health and Human Services (HHS) proposed that the recommended level of fluoride in drinking water be set at 0.7 mg/L. This will reduce the chance for children's teeth to develop dental fluorosis, while still preventing tooth decay. The previous U.S. Public Health Service recommendations for fluoride levels ranged from 0.7mg/L to 1.2 mg/L, depending on average maximum regional air temperature. The new recommendation is based on recent findings that in the U.S., outdoor temperature does not determine water intake.

HHS expects that the final recommendations to reduce the optimal fluoride level will be publicly available soon. CDC, in collaboration with the National Institute of Dental and Craniofacial Research (NIDCR), will monitor the impact of these changes through enhanced surveillance of dental caries (tooth decay) and dental fluorosis in the National Health and Nutrition Examination Survey (NHANES).

Your specific requests are addressed below.

Instruct FDA CDER to no longer defer regulatory action. FDA CDER to send a letter to fluoridation manufacturers advising them to make FDA CDER NDA (New Drug Application) as required by Congress in the US FD&C Act.

FDA has provided the following information regarding your request:

FDA has determined that Congress did not intend for FDA to regulate the addition of fluoride to public drinking water for dental caries prevention as a drug under the FD&C Act. Instead, Congress intended that the U.S. Environmental Protection Agency (EPA) regulate fluoride in public drinking water as a potential contaminant under the Safe Drinking Water Act of 1974 (SDWA), Public Law No. 93-523, 88 Stat. 1660 (codified as amended at 42 U.S.C. 300f et seq.) to protect against adverse health effects, and that within the limits thus set by EPA, state and local governments be permitted, but not required, to fluoridate public drinking water to help prevent dental caries. Thus, FDA does not require NDAs for fluoridated public drinking water.

Instruct the CDC to stop the promotion (internet and education) of any and all drugs, including the ingestion of fluoride products, not FDA CDER approved.

Section 317M of the Public Health Service Act, codified at 42 U.S.C. § 247b-14, authorizes the Secretary of HHS, acting through the Director of the CDC, to make grants to States and Indian tribes for the purpose of increasing the resources available for community water fluoridation. This includes funds to develop educational materials on the benefits of fluoridation. CDC's Division of Oral Health leads an effort to improve the oral health of the nation and reduce inequalities in oral health. This includes encouraging the use of proven strategies to prevent oral disease, such as the effective use of fluoride products and community water fluoridation.

Sponsor a review of the scientific evidence on fluoride's neurotoxicity by the National Academy of Science's National Research Council. The review should include studies listed at www.FluorideAlert.org/issues/health/brain.

The NRC reviewed the toxicity of fluoride as recently as 2006, when it reviewed the Environmental Protection Agency's drinking water standard for fluoride as a contaminant. (See *Fluoride in Drinking Water: A Scientific Review of EPA's Standards*.) More recently and of more relevance to community water fluoridation is the systematic review undertaken by the Community Preventive Services Task Force (Task Force) in 2013. The Task Force is an independent, nonfederal, unpaid panel of public health and prevention experts that provides evidence-based findings and recommendations about community preventive services, programs, and policies to improve health. Its members represent a broad range of research, practice, and policy expertise in community preventive services, public health, health promotion, and disease prevention. In its report, *Preventing Dental Caries: Community Water Fluoridation*, the Task Force noted, "Overall, the body of evidence indicates that Community Water Fluoridation is an effective intervention for reducing caries at the population level. At the optimal fluoride concentration, associated risks are predominantly the milder forms of fluorosis that are only detectable under clinical examination." The report further stated, "In addition, there is no evidence that CWF (Community Water Fluoridation) results in severe dental fluorosis."

Sponsor a quality published independent prospective randomized controlled trial (RTC), of the effectiveness of ingesting hydrofluorosilicic acid (fluoridation), including blood serum and urine concentrations of fluoride.

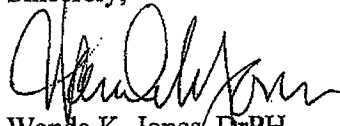
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As stated above, the effectiveness and safety of community water fluoridation was reaffirmed by the Community Preventive Services Task Force in 2013 following a systematic evidence review. Studies on the effectiveness of adjusting fluoride in community water to the optimal concentration cannot be designed as randomized clinical trials. Random allocation of study subjects is not possible when a community begins to fluoridate the water because all residents receiving community water have access to and are exposed to this source of fluoride. Furthermore, clinical studies cannot be conducted double-blind because both study subjects and researchers usually know whether a community's water has been fluoridated. In addition, it would not be possible to find control subjects with no fluoride exposure because fluorides are ubiquitous in the environment.

Although I am not able to fulfill your requests, I appreciate the information you provided to me and my staff. I will keep your concerns in mind as HHS continues to consider community water fluoridation.

A copy of this response is being shared with Dr. Hirzy, Mr. Nidel, Dr. Connett, Ms. Smith, and Dr. Osmunson.

Sincerely,

A handwritten signature in black ink, appearing to read 'Wanda K. Jones', written over a faint, illegible background.

Wanda K. Jones, DrPH
Principal Deputy Assistant Secretary for Health

Jill McElhenny

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September 4, 2014

Wanda Jones

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For the health and safety of the public:

1. Instruct FDA CDER to no longer defer regulatory action. FDA CDER to send a letter to fluoridation manufacturers advising them to make FDA CDER NDA (New Drug Application) as required by Congress in the US FD&C Act.

a. In 1975, Drug Digest reported FDA CDER (Center for Drug Evaluation and Research) protected the public by withdrawing NDA (New Drug Application) for fluoride supplements (pills). FDA CDER must do the same for artificial fluoridation drug manufacturers. There is no difference in intent or efficacy between fluoride in pills and fluoridated water. But there is a significant difference in freedom of choice, labeling, and oversight.

b. HHS would incur no cost to request FDA CDER to take regulatory action.

c. FDA CDER would incur no cost to send a letter to artificial fluoridation drug manufacturers requiring them to gain NDA as required by law.

d. FD&C Act protects the public by requiring manufacturers to gain NDA, not the FDA nor patients. The FDA CDER is to evaluate and regulate substances used with the intent to prevent disease or listed in the official US Pharmacopoeia as a drug. Fluoride is used with intent to prevent disease and listed in the USP. The FDA has testified to Congress and the public that fluoride, when used with the intent to prevent disease, is a drug.

e. CDC and Surgeon General actively promote fluoridation for the manufacturers but do not determine scientifically the safety or efficacy of fluoridation or any drugs. Cities and water districts rely on the CDC and Surgeon General assuming they are correct.

f. EPA is prohibited by Congress from regulating the addition of any substance to water intended to treat humans. Fluoride is a protected pollutant and the EPA assumes efficacy.

g. **Excess exposure:** Of greatest concern is EPA's confirming in their Dose Response Analysis (DRA) that all infants on formula with fluoridated water are at risk. The DRA reports about a third of children under the age of 7 and all infants on formula made with fluoridated water will be ingesting too much fluoride under the proposed RfD (Reference Dose) and HHS proposed 0.7 ppm artificial fluoridation. Infants and children are being harmed. Excess exposure is confirmed with 41% of children now having dental fluorosis a biomarker of excess fluoride ingestion. An NDA would provide a legend, caution, warnings, and dosage, reducing risks.

h. Over 60 requests and petitions have been made to the FDA CDER since 2009 and the requests, petitions, and complaints have been made. These have been ignored, no answer, or pending for years.

2. Instruct the CDC to stop the promotion (internet and education) of any and all drugs, including the ingestion of fluoride products, not FDA CDER approved.

3. Sponsor a review of the scientific evidence on fluoride's neurotoxicity by the National Academy of Science's National Research Council. The review should include studies listed at www.FluorideAlert.org/issues/health/brain

Of most concern are the more than 30 human studies finding harm to brains. The question is no longer whether fluoridation causes neurological damage and lower IQ, the question is how much fluoride and at what age damage is caused.

Neurological harm is one of the reasons Israel recently banned fluoridation. Most developed countries have rejected fluoridation due to ethics, lack of efficacy and risks.

4. Sponsor a quality published independent prospective randomized controlled trial (RCT), of the effectiveness of ingesting hydrofluorosilicic acid (fluoridation), including blood serum and urine concentrations of fluoride.

a. Quality research is essential and in 60 years of fluoridation, not one published prospective randomized controlled trial of fluoridation has been done. Current reviews of the low quality research available are biased, serious unknowns are not controlled and even known confounding factors are often not controlled.

b. The results of a well-designed RCT could allow HHS to tailor public health policy on fluoridation to optimize benefits and minimize costs. This is in line with the goals of "Obamacare": evidence-based public health policy.

c. Most research on fluoridation have numerous problems which include:

- Not one Randomized Controlled Trial
- Socioeconomic status usually not controlled
- Inadequate size
- Difficulty in diagnosing decay
- Delay in tooth eruption
- Diet: Vitamin D, calcium, strontium, sugar, variables.
- Total exposure of Fluoride and measured blood and/or urine fluoride concentration
- Oral hygiene habits
- Not evaluating life time benefit
- Estimating or assuming subject actually drinks the fluoridated water.
- Dental treatment expenses
- Breast feeding and infant formula
- Fraud or gross errors.
- Genetics

Sincerely,

Jill McElheney
Chris Nidel JD
Bill Hirzy PhD
Paul Connett PhD
Bill Osmunson DDS, MPH