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December 19, 2014

Dr. Wanda Jones
Jonathan Beeton
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
Washington, D.C. 20201

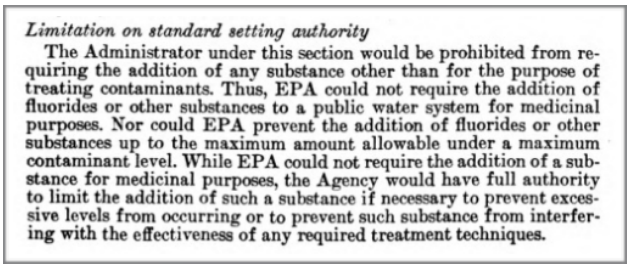
Dear Dr. Jones,

Thank you for your correspondence of November 21, 2014 responding to the requests that we had made at our in-person meeting (attached). In addition to the two of us, that meeting was attended by Jonathan Beeton, Sandra Howard, Chanya Liv, Dr. Bill Hirzy, Beth Smith, RN, Dr. Bill Osmunson, Dr. Bill Hirzy, and Jill McElheney (by phone). I anxiously awaited your response given your recognition that the materials that we presented to you and your staff were, in your own words, "compelling" however, your response fails to tackle the truly compelling nature of the issues that we have presented and simply provides further support for harming the public.

After almost 70 years of fluoridation, no federal agency admits or asserts jurisdiction over fluoridation, appropriately taking ownership of this practice; rather each continues to evade responsibility while overtly promoting it. The public continues to receive significant doses of whole-body fluoride as the science regarding the risks mounts amidst the lack of clear regulatory jurisdiction.

This circumstance begs the question which federal agency and its staff of expert toxicologists, epidemiologists, and other experts, bears responsibility for determining if, and at what levels, drinking water fluoridation should continue. However, given the fact that all stakeholders agree the addition of fluoride compounds to drinking water is done with the intent to mitigate or prevent dental caries, a disease in humans and animals, it is clear that the FDA has both jurisdiction and responsibility for approval of the addition of fluoride and the confirmation of both its safety and effectiveness.

The EPA appears to agree with this rationale. For example, February 14, 2013, the EPA Associate General Counsel Neugeboren clearly distinguished EPA's role with respect to ingredients *added* to drinking water, stating, "EPA does not have responsibility for substances added to water solely for preventive health care purposes, such as fluoride, other than to limit the addition of such substances to protect the public health…The Department of Health and Human Services (HHS) acting through the FDA, remains responsible for regulating the addition of drugs to water supplies for health care purposes." In support, Neugeboren referenced the SDWA Section 1412(b)(11) and also cited A Legislative History of the Safe Drinking Water Act, Committee Print, 97th Cong, 2nd Session 1982 at page 547. That section clearly establishes the limited role that EPA has with respect to fluoride as a "contaminant" rather than as an additive to drinking water intended to prevent caries:



Limitation on standard setting authority

The Administrator under this section would be prohibited from requiring the addition of any substance other than for the purpose of treating contaminants. Thus, EPA could not require the addition of fluorides or other substances to a public water system for medicinal purposes. Nor could EPA prevent the addition of fluorides or other substances up to the maximum amount allowable under a maximum contaminant level. While EPA could not require the addition of a substance for medicinal purposes, the Agency would have full authority to limit the addition of such a substance if necessary to prevent excessive levels from occurring or to prevent such substance from interfering with the effectiveness of any required treatment techniques.

A Legislative History of the Safe Drinking Water Act, Committee Print, 97th Cong, 2nd Session 1982, 547.

In contrast, your November response provides a quote from the FDA generally citing the 1974 SDWA et seq. without reference to a specific provision. Despite your response, there is no mention of fluoride, permitting fluoride, or dental caries in the Safe Drinking Water Act. The SDWA consistently references "contaminants" rather than anything, such as fluoride, that may be added for prevention of a disease, such as dental caries. Therefore, what legal authority is the Agency relying on for its contention that it has no responsibilities regarding fluoride that is *added* to drinking water?

As the federal agencies responsible continue passing the buck, the rate of dental fluorosis continues to increase and the impacts on the public mount. Please provide the specific basis for your Department (and its agencies) denial of responsibility as it relates to the addition of fluoride and the stated goal of caries prevention.

On the contrary, the current statutory and regulatory scheme makes it clear that the FDA does have both the responsibility and the authority to regulate the addition of fluoride, which clearly meets the FDA's own definition of "drug". Therefore, it is imperative that the FDA take ownership of this issue and determine scientifically whether the additional of fluoride to drinking water for whole-body consumption at uncontrolled or unspecified dosage rates is both "safe" and "effective" consistent with such NDA approvals for topical application in pastes.

CDC Promotion of Fluoride

During our meeting we requested that CDC discontinue promotion of adding fluoride compounds to drinking water. This is based on the fact that the agency responsible for determining the safety and effectiveness of this drug[1] has not made such an evaluation. Under these circumstances, no federal agency should be promoting fluorides use as a drug.

The CDC's promotion of fluoride is not only without legal basis, but it is also without scientific consensus. There are numerous modern, peer-reviewed studies, that fail to demonstrate that the addition of fluoride to drinking water reduces cavities. In fact, several studies show that when fluoride addition is ceased, dental health actually improves. The repeated claim that fluoridation is one of ten great public health achievements of the 20th century is without proper scientific bases. The basis for the statements made regarding the efficacy of water fluoridation need to be re-evaluated in light of the comprehensive research done on water fluoridation. The work done by the US Public Health Service in the first half of the 1900s demonstrating caries reduction in association with "mottled" enamel experienced at "relatively toxic"[2] levels of fluoride is no longer sufficient basis for claiming significant benefit from added fluoride in terms of caries reduction. Rather, more recent discussions show that, despite the large number of people ingesting added fluoride, the data demonstrating a benefit are limited at best.[3] Rather than supporting the often repeated CDC statement that fluoridation is one of the ten great health achievements of the 20th century, the data presented by Cheng et. al. demonstrate that tooth decay has decreased similarly, if not more rapidly, in countries with no water fluoridation:

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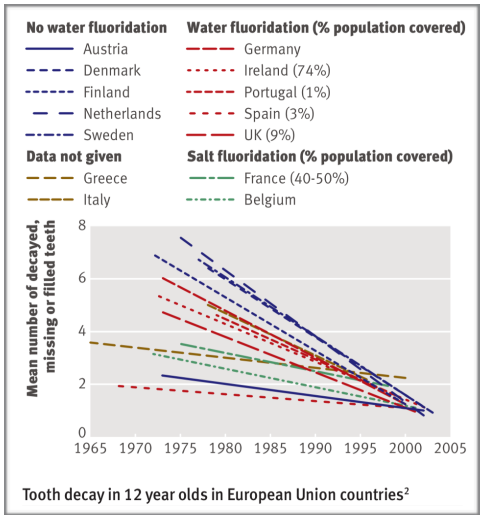
[1] "The FD&C Act defines drugs, in part, by their intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" [FD&C Act, sec. 201(g)(1)]." taken from "How does the law define a drug?" available at http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm#Define-drug.

[2] *See* H Trendley Dean, Public Health Reports - Endemic Fluorosis and its Relation to Dental Caries, at 1445 (1938) ("An analysis of these data indicates that a higher percentage of caries-free children is found in cities whose water supplies contain *relatively toxic amounts of fluorides* than in those communities with water supplies not so affected.") (emphasis added).

[3] K K Cheng, I Chalmers & T A Sheldon, ADDING FLUORIDE TO WATER SUPPLIES, 335 BMJ 699–702 (2007). ("Given the certainty with which water fluoridation has been promoted and opposed, and the large number (around 3200) of research papers identified, the reviewers were surprised by the poor quality of the evidence and the uncertainty surrounding the beneficial and adverse effects of fluoridation.").



Tooth decay in 12 year olds in European Union countries[2]

K K Cheng, I Chalmers & T A Sheldon, ADDING FLUORIDE TO WATER SUPPLIES, 335 BMJ 699–702 (2007). Given the current state of the evidence, any evaluation of the efficacy of drinking water fluoridation cannot assume, *a priori*, that adding fluoride to drinking water leads to significant reductions in tooth decay.

Furthermore, as you are well aware, any demonstrated efficacy of added fluoride in drinking water needs to be critically weighed against the cost of doing so, which includes the risk of dental fluorosis as well as fluoride's effect on the thyroid, pineal gland, and the brain as well as calculations to determine the appropriate margin of safety.

Scientific Review of Neuro-cognitive Effects of Fluorides

During our meeting, we presented a brief summary of recent epidemiological evidence demonstrating low-level impacts of fluoride on brain function and IQ. Much of this evidence has become available since the NRC's 2006 review of fluoridation, and therefore has not been considered by the Committee. In your written response to our request, you mention the Community Preventative Services Task Force from 2013 (the "Task Force"). However, the Task Force did not review studies regarding the neurotoxicity of low level exposures to fluoride. This is clear from the Task Force's summary of its included studies:[4]

> **The Community Preventive Services Task Force recommendation on community water fluoridation is based on evidence from the following:**
>
> - **28 studies about the effect of CWF on caries; 16 about oral health disparities, and 117 about dental fluorosis -- most of which were included in an existing systematic review (McDonough 2000, search period 1966-1999; 26 studies on caries; 13 on oral health disparities; 88 on fluorosis)**
> - **2 studies on caries; 3 on oral health disparities and 29 on fluorosis (search period 1999-2012)**

To the contrary, the Task Force specifically recognized the existing data gaps including the possibility of neurotoxic effects.[5]

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[4] From "Preventing Dental Caries: Community Water Fluoridation" available at http://www.thecommunityguide.org/oral/supportingmaterials/is-waterfluoridation.html.

[5] The Task Force lists "other potential positive or negative health effects" as an area where "more research is needed" under a section entitled "Evidence Gaps". Available at http://www.thecommunityguide.org/oral/supportingmaterials/RRfluoridation.html.

Furthermore, the Task Force's work is not entirely credible on its face. As you quote, the Task Force concluded that there is "no evidence that CWF (Community Water Fluoridation) results in severe dental fluorosis." I am not sure what this means given CDC's own data showing the incidence of severe fluorosis in the United States population. Does HHS have a basis for attributing the incidence of severe fluorosis to well water, or sources of fluoride specifically other than CWF?

The bottom line is that your response does nothing to address the recent scientific support that demonstrate the neurotoxic effects of ingested fluoride. There *must* be some agency in the federal government that has responsibility to consider the impact that ingesting added fluoride is having on the public, including the science of neurotoxicity. As long as the HHS continues to promote water fluoridation and ingestion of fluoride it is not just HHS's legal obligation to properly weigh this evidence, but it is also their human, moral obligation. Your response is a frightening indication that the Department is not willing to address the science that should be the basis for any Department action and instead has chosen to bury its head and rely on limited, outdated modes of safety evaluation.

Water Fluoridation Should be Held to Same Rigor as any Drug

Given that the use of fluoride added to drinking water is akin to a drug, it should be held to the same scientific rigor as would the approved use of any drug. In light of that, we requested that HHS sponsor a prospective randomized control study of adding fluoride to drinking water. In response, you indicate that such studies are not possible. While a pure double-blind randomized control trial may not be achievable, there are prospective studies that can be done to determine the efficacy of water fluoridation. Perhaps the most effective way to approach optimal conditions for study would be to provide bottled water (some containing fluoride and some without) to the study population and follow the dental health of both groups. There can be no question that, despite that large number of people drinking water with added fluoride and the vast number of studies that have been done, there remains sound science that demonstrates both fluoridation's ability to reduce cavities and the lack of such an ability. Without conclusive evidence, the likes of which could come from a prospective study, an appropriate public health assessment of the costs and benefits simply cannot be done.

In closing, it seems that the HHS has taken some responsibility for recommending how to safely "use" fluoridated water ("HHS expects that the final recommendations to reduce the optimal fluoride level will be publicly available soon.") but refuses to take ownership of the ultimate public health issues that are endemic to the issue of water fluoridation; ultimately passing regulatory authority to the EPA, which itself has denied having the authority. The public needs public health leadership from the federal government and that starts with knowing where the responsibilities lie.

I hope that you will re-think your November 11th dismissal of our concerns and take a leadership role in confronting the scientific and public health issues before you and the nation.

Sincerely,

Chris Nidel

Bill Osmunson DDS, MPH

Jill McElheney

cc:
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