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U.S. Food and Drug Administration  
Center for Drug Evaluation and Research FDA-P-0346

The Food Drug and Cosmetic Act prohibits any health claims from being made for dietary minerals or supplements--such claims are reserved only for drugs. Although the fluoridationists claim fluoride is a nutrient or mineral, the FDA does not. The FDA classifies fluoride as an unapproved drug and has as recently as January 2016 ordered a manufacturer of fluoride supplements to stop proclaiming dental health benefits (Kirkman Laboratories, FDA Warning Letter SEA 16-07)

Consequently, the FDA has several options that lead to the same single conclusion regarding community water fluoridation schemes:

1. Given the FDA defines fluoride ingestion as use of a drug, then the health claims made for fluoridated water supplies by promoters would only be permitted if a New Drug Application were submitted to the FDA for those municipal fluoridated water supplies. Whereas no NDA has been forwarded for any ingestible fluoride to treat dental decay, and whereas health claims are currently widely proclaimed in writing by Federal personnel for ingesting fluoride, under law, the FDA is required to ban whole body fluoride dosing of consumers through fluoridation of water supplies.
2. If however the FDA instead re-defines ingested fluoride as use of a mineral, supplement, or dietary aid or ingredient, then the FDA must also ban fluoridation because it is unlawful to make health claims for substances other than drugs, including minerals or dietary aids or supplements, as stipulated by the FDCA.
3. If the FDA takes a third order definition for fluoride ingestion to be contamination of the population with a toxic substance in violation of the Safe Drinking Water Act and the Toxic Substances Control Act (as stated in the initial petition response letter, Janet Woodcock, Director, Center for Drug Evaluation and Research, U.S. FDA, October 27, 2010), then it is necessary for the FDA to ban fluoridation. This is because all Americans, including the FDA and its employees, are obligated to follow the SDWA and the TSCA.

I propose option three is the most appropriate FDA position based on reality that fluoridation chemicals which are byproducts of industry are invariably are harmful to many in the population, are invariably contaminated with other toxins per the NSF's own reports published by the AWWA and available on the CDC website as well as by independent analysis, and are used as a medical prophylactic rather than as a water treatment.

Any argument that the FDA does not have jurisdiction over fluoridation is without merit. The EPA fully declined any and all responsibility for regulating artificial community fluoridation schemes (CWF) decades ago because according to the EPA Office of Water, fluoridation chemicals are added intentionally into water for claimed therapeutic purpose, and only the FDA is authorized to regulate such materials.

Moreover, the PHS/DHHS confirmed their responsibility for fluoridation on April 27, 2015 with their recommendation to change their recommended fluoridation level from a range of .7 ppm - 1.2 ppm to a single limit of .7 ppm. They took this position based on a 2010 CDC report that documented 58% of African-American adolescents and 36% of white adolescents had the visible and permanent damage to

their permanent teeth, dental fluorosis enamel hypoplasia. It would be false for the Agency to continue allowing fluoridation chronic poisoning of citizens, when HHS indeed has already recognized this chronic poisoning with previous allowed levels of 1 ppm and has offered no scientific proof that the small reduction of uncontrollable mass medication in some communities would protect against this widespread damage to our population.

Lowering the level to 0.7 ppm as a recommendation, rather than a binding requirement, is an attempt to avoid liability--but no Federal agency has ever regulated water fluoridation by monitoring effectiveness, blood levels in consumers, or safety in consumers who have known common adverse health conditions. As you may know, the program has been operating on autopilot since its inception, by declaration, rather than from proven lack of harm or proven effectiveness in controlled trials with human volunteers. This act assumes liability and fully empowers the FDA as a part of the USPHS to take action regarding fluoridation.

The HHS recommendation stands as an official proclamation which is now being interpreted as HHS authorization for fluoridation, and the further chronic 'low-level' poisoning of the American population. This has been pointed out clearly in letters to HHS and the EPA by Jill Jennings-McElheney, a validated water poisoned victim of EPA negligence for not stopping use of a known contaminated water supply (see enclosed emails).

As outlined to Senator Grassley and Representative Chaffetz in the enclosed letter from K. Spencer, Ms. Jennings-McElheney is representative of the many susceptible subpopulations of Americans who have medical reasons for not ingesting this inflammatory drug and known endocrine disrupting toxin that is ubiquitous in food and water because of community water fluoridation schemes. Moreover, as Ms. Jennings-McElheney indicates in her many communications to EPA and DHHS, it is well documented that not only are fluoridation chemicals harmful in themselves, fluoridation chemicals are both contaminated with other toxins including lead and arsenic, they increase the lead levels in water by virtue of their ability to leach lead out of pipes, corrode pipes, and increase the tissue absorption of lead.

I petition the FDA to do its job under Section 402 and other section's of the Federal Food, Drug and Cosmetic Act which confirms their authority for banning anything that..."contain(s) any poisonous or deleterious substance that may render it injurious to health."

Thank you,

Richard Sauerheber, Ph.D.

cc: U.S. Attorney General Loretta Lynch, Senator Chuck Grassley, Senator Bill Posey, Senator Elizabeth Warren, Senator Barbara Boxer, Senator Sherrod Brown, U.S. Committee on Oversight and Government Reform Chair Rep. Jason Chaffetz and Ranking Member Rep. Elijah Cummings, Joel Beauvalis EPA Deputy Assistant Administrator for the Office of Water, President's Council of Advisors on Science and Technology (PCAST).

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#1 From: Jill McElheney  
Subject: NIH Neglect of Patient Safety Reflects Antiquated Force Water Fluoridation Culture

Dear Dr. Collins, U.S. Health and Human Services:

A year ago I organized a professional team of experts who met with NIEHS/NTP, Dr. Linda Birnbaum, and Dr. John Bucher, and EPA's Office of Water, Phil Oshida. There is an audio of this meeting available.

This important meeting was held while Flint, Michigan residents were being willfully and knowingly water poisoned from but not limited to: lead, Legionnaire's, trihalomethanes, and neurotoxic, endocrine disrupting, bone-accumulating fluoride.

It was clear from the intense agenda organizing & emails exchanged before the 2015 meeting that NIEHS/NTP actively endorsed, promoted, and represented the federal expansion of water fluoridation in New Jersey given Dr. John Bucher's pre-meeting statements to the press. It was also clear once our meeting began that the scientific weight of evidence was being co-opted. While Drs. Birnbaum/Bucher were aware, they chose not to disclose at our meeting that the Federal fluoridation panel had been meeting to adjust water levels of fluoride compounds (not doses) to continue National expansion of contaminating

municipal water supplies and exposing the American citizenry. This was to be published on May 1st in the Federal Register.

Dr. Bucher & Dr. Birnbaum participated on this Federal panel and signed their names to support the ongoing National expansion to continue forced water fluoridation representing NIEHS/NTP/NIH. This Federal fluoride exposure panel admitted over-exposure to subpopulations, while recommending that forced water fluoridation exposure should continue, implying their guarantee of scientific safety and effectiveness to States for National expansion. They unethically reiterated that data collection from victims, already known to be over-exposed to fluoride, should continue. No provisions were considered for redress, opt out, or notification to victims/caregivers.

Internal documents indicate that Federal agencies who author the Federal playbook to expand forced water fluoridation Nationally do so knowing the program is scientifically and ethically fraudulent. They cater to pressure from third party profiteers and political meddling. This has in turn compromised public health/safety, clean/safe dwindling water supplies, and National security. Known water-poisoned victims are subjected to exposure of impure, corrosive, and hazardous compounds deliberately injected into their water used for drinking, bathing, and cooking, by arguing that the infused materials are food supplements. Water ingestion is a requirement to sustain life. Intentional contamination from forced fluoridation can no longer be tolerated after its long use through government bullying and its abuse to human health.

Federal regulatory law is being toyed with and environmental health protection rights being denied to vulnerable sub-populations, including already confirmed water-poisoned victims like my family, the people of Flint, and 41% of U.S. teens who have permanent dental enamel hypoplasia from the effects of systemic fluoride on teeth development.

The EPA general counsel wrote to me on Friday speaking for HHS and its umbrella agencies who have participated in the Federal panel including the NIH.

At this time, I am deeply concerned with that response of EPA general counsel in light of NIH's current hospital patient safety situation:

Exclusive: Patient safety issues prompt leadership shake-up at NIH hospital.

The overhaul is the most sweeping in decades at the nation's premier biomedical research institution. [Washington Post](https://www.washingtonpost.com/national/health-science/exclusive-patient-safety-issues-prompt-leadership-shake-up-at-nih-hospital/2016/05/10/ad1f71f6-0ffb-11e6-8967-7ac733c56f12_story.html).

[https://www.washingtonpost.com/national/health-science/exclusive-patient-safety-issues-prompt-leadership-shake-up-at-nih-hospital/2016/05/10/ad1f71f6-0ffb-11e6-8967-7ac733c56f12\\_story.html](https://www.washingtonpost.com/national/health-science/exclusive-patient-safety-issues-prompt-leadership-shake-up-at-nih-hospital/2016/05/10/ad1f71f6-0ffb-11e6-8967-7ac733c56f12_story.html)

Dr. Collins, are you in agreement with what EPA general counsel said to me on Friday? Were they authorized to speak for NIH?

Thank you,

Jill Jennings-McElheney

Verified Water Poisoned Victim by CDC While Residing in EPA Region IV Environmental Justice Community

#2 **From:** Jill Jennings-McElheney

**Subject:** BREAKING: 24 Page Judicial Order Recognizes Children as Victims with Rights Denying Motions by Government/Industries

Dear Carrie Wehling, Dawn Messier, and Gina McCarthy, U.S. EPA:

Do you hold the same personal legal interpretation as expressed by others on forced fluoridation? This being that the legal wrangling with HHS takes precedence over securing safe/clean water supplies and removing the citizenry from harm's way of this environmental hazard?

There is breaking judicial news that impacts the urgency of our nineteen month meetings/communications.

The action we need to move forward with the Federal HHS panel who recommended in 2015 the ongoing intentional neurotoxic exposure to children through fluoride-infused drinking water supplies is bolstered now with this unprecedented ruling. The recommendation by the 2015 Federal panel to allow recommend fluoride at 0.7 ppm should be rescinded immediately in the aftermath of Flint's tragic water poisoning, and our current water/lead leaching National public health crisis impacting thousands of children.

The call to meet and issue a collaborative Federal agency statement is at fever pitch given this 24 page order.

Judge Coffin's Order can be read in its entirety  
at: <http://ourchildrenstrust.org/sites/default/files/16.04.08.OrderDenyingMTD.pdf>

As you know, Administrator McCarthy, Mr. Meiburg and the Office of Water (your clients) have placed legal wrangling over enforcing Federal law while pandering to third party profiteers/political meddlers. It is also documented that large amounts of Federal dollars are peddled to promote and perpetuate a water policy that we have asked the EPA OIG to investigate as fraudulent, and the EPA OCR to investigate as discriminatory.

The Federal jurisdictional wrangling and lack of enforcement has placed National water security at risk. This half century water poisoning policy has placed generations of children in harm's way. The fallout from externalizing this industrial material used for ingestion in a futile attempt to treat dental decay as claimed through our water infrastructure will be astronomical when the costs are ultimately figured.

I hope you will contact me as soon as possible so we can resolve this ongoing Federal conflict involving water poisoned victims' rights, water security, and children's environmental public health.

This is very important in the aftermath of Flint & this Federal ruling dated yesterday.

Thank you,

Jill Jennings-McElheney  
Verified Water Poisoned Victim  
Mother to Childhood Cancer Survivor Water Poisoned Victim  
Victims' Rights Advocate for Water Poisoned People  
Children's Environmental Health Educator

#3 May 12, 2016 From: Karen Spencer [kafspencer@gmail.com](mailto:kafspencer@gmail.com):

**“Science absolutely requires independence and integrity. Without them science ceases to be science. It becomes a tool to manipulate people.” - Dr. Allison Wilson, Co-founder & Science Director of the Bioscience Resource Project (2015)**

Dear Representative Jason Chaffetz,, Washington, D.C.,

Let me try to summarize the very disturbing pattern that is detailed in the email trail below for you and Senator Grassley. I think it is important to understand in order to put the Medicaid redesign in perspective.

### **BACKGROUND**

Throughout 3 pregnancies, Jill Jennings-McElheney and her young family unknowingly drank well water contaminated with benzene and TTHMs. When her 4 year old was diagnosed with leukemia, she and the oncologist contacted the EPA about possible environmental contaminants. Throughout these years, the EPA pled ignorance. However, it came out that they had known all along that the well water was contaminated, but because the EPA had designated the residents a “**low target population**” the EPA was not legally obligated to inform the consumers. On top of that, there were falsified reports. They didn’t even tell the family when faced with a dying child.

Jill won her lawsuit, and her son survived. She and her family are “verified water poisoned victims.” Because of their chemical exposures, they are very sensitive to chemicals in water, such as fluoride. Since fluoridation is a problem for her family and others with multiple chemical sensitivities (MCS) and fluoride has been repeatedly proven to increase cancer rates, albeit amidst a great deal of denial from fluoridationists making it perhaps the most contested fluoridation issue, Jill is committed to doing whatever it takes and sends daily emails to government officials.

### **BAD FAITH BARGAINING**

In this email trail, Jill refers to the meetings she had during the Flint Michigan poisoning with Dr. Linda Birnbaum of NIEHS and Dr. John Bucher of NTP. The topics discussed included what needs to be done to end fluoridation because of the disproportionate harm it causes to those with health conditions, such as MCS, renal disease, cancer, etc. and the whole issue of “low target populations.” Another issue is “whose responsibility is it” which Jill refers to as “legal wrangling between EPA and DHHS.” You may remember that the EPA designated neighborhoods in Flint with the highest lead levels as “low target populations” and DHHS, the state and EPA all passed that hot potato around for months until Dr. Mona Hanna-Attisha held her Sept 2015 press conference. This is what has Jill so furious.

Dr. Bucher, who is infamous for his involvement of the EPA whistleblower case of Dr. Wm. Marcus around the issue of falsified reports on fluoride and cancer, and Dr. Linda Birnbaum, who has publicly decried endocrine disruptors and environmental toxins, were working on the April 2015 whitewash of fluoridation that lowered the “optimal” level from a range of .7-1.2 ppm to a single .7 ppm limit **during the same time frame as those meetings with Jill, and concurrent with the unfolding drama in Flint.** (Multiple studies have proven that children in fluoridated communities using HFSA have higher blood lead levels. On top of everything else, Flint was using HFSA. Any fluoride, HFSA or NaF, also increase the tissue uptake of lead.)

Jason, the 2006 National Research Council confirmed fluoride was an endocrine disruptor saying there was no evidence of any safe level of fluoride in drinking water and it could be reasonably anticipated that

those with health problems would have an adverse health impact at low concentrations. Even the EPA and DHHS as recently as the early 1990s wrote that some minority of people including the elderly or those with health conditions might be intolerant of fluoridated water, but they cavalierly dismissed those people in the footnotes while going on about the public good. Since 1999, it's been generally accepted that ingestion is unnecessary for cavity free teeth and the only benefit is "almost exclusively" or "predominantly" via toothpaste, although that hasn't stopped fluoridationists from constructing faulty studies using falsified data and computer simulations to prove otherwise... which brings us to the Medicaid push.

Dependent on your world view, it comes to one of three questions for policy makers:

1. If fluoridation has some benefit to teeth, but is harmful to some or many in the population, should we be adding it to water?
2. If fluoridation is done only for the purpose of getting specific doses into the bodies of children, why are we uncontrollably dosing everyone?
3. If fluoridation is of no benefit to teeth, why are we adding it to water at all?

The answer to all three is found in Jill's experience.... careers, prestige and paychecks are based on promoting fluoridation policy regardless of logic, science or human suffering. Using Medicaid funds is just another strategy to enrich those with vested interests.

A couple of more resources:

1. 2016 Letter to ATA includes endocrine disruption and cancer references: [http://www.ehcd.com/wp-content/uploads/2016/02/2016\\_02\\_11\\_ATATrCWF.pdf](http://www.ehcd.com/wp-content/uploads/2016/02/2016_02_11_ATATrCWF.pdf)
  - Interview with Dr. Hirzy of the EPA includes his 2001 testimony to Congress (27 min): <https://www.youtube.com/watch?v=ViNNIwmzTzI>
2. 2013 Fluoridegate: An American Tragedy (1 hr): <http://fluoridegate.org/the-film/>

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<http://www.regulations.gov/#%21documentDetail%3bD=FDA-2007-P-0346-0039>