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November 6, 2015

Dr. Kristina Thayer
Director, Office of Health Assessment and Translation
National Toxicology Program
Email: thayer@niehs.nih.gov

(1) DATA ON CURRENT PRODUCTION, USE PATTERNS, AND HUMAN EXPOSURE

A. The FDA approved fluoride toothpaste caution, “**Do Not Swallow.**” No safe dosage or amount is stated. “Do Not Swallow” is simple to understand. Use a pea or smear size and if more than used for brushing is swallowed, contact the poison control center.

A quarter milligram of fluoride is in a pea size of fluoride toothpaste, the same amount found in each 11 oz glass of 0.7 ppm fluoridated public water. Fluoridated water is dispensed to everyone without regards for other fluoride exposures, individual consent, health, or sensitivity.

The only safe amount of fluoride is, “Do Not Swallow.” Swallowing fluoride is not safe, however, many children swallow their toothpaste due to taste and the swallow reflex is part of the spitting action.

B. Fluoridated water is the primary source of fluoride for many people. Fluoridated toothpaste is considered the second primary source and for some is more than fluoridated water. Other significant sources of fluoride include bone meal, mechanically deboned meat, grape products with cryolite, several legend drugs and sulfuryl fluoride, a post harvest fumigant.

C. The FDA sent a letter to about 35 fluoride supplement manufacturers, “. . . *there is **no substantial evidence of drug effectiveness as prescribed, recommended or suggested in its labeling.*** . . .” (Drug Therapy 1975). (Emphasis supplied)

And as of November, 2015 for **efficacy** of fluoride ingestion, fluoridation, there still is not a single prospective randomized controlled trial, often socioeconomics is not controlled, studies lack adequate size, decay is difficult to diagnose especially in surveys, fluoride causes a delay in tooth eruption which is not accounted for, diet such as Vitamin D, calcium strontium, sugar variables are not controlled, variations in oral hygiene lack control, life time exposure is usually not considered, assuming the subjects actually drink the water, total water consumption is estimated, breast feeding and infant formula are not controlled, fraud or gross errors, genetics are not considered, and cost benefits assume benefit, estimate costs and assume no cost for risks.

D. Regarding the post-harvest fumigant sulfuryl fluoride, the “EPA agrees that aggregate exposure to fluoride . . . does not meet the safety standard in FFDCa section 408.”

- “The fluoride MCLG is not protective of the effects of fluoride on teeth and bones;
- The fluoride MCLG is not protective of other neurotoxic, endocrine, and renal effects of fluoride;
- EPA has not adequately protected children;
- EPA cannot determine the safety of sulfuryl fluoride and fluoride in the absence of a developmental neurotoxicity study;
- EPA has underestimated exposure to fluoride; and
- EPA has committed procedural errors in violation of the Administrative Procedures Act (APA) ([5 U.S.C. 551 et seq.](#)).”

“The Objectors [Fluoride Action Network] also argue that the 4 mg/L MCLG for fluoride does not protect against fluoride’s effects on the brain, the endocrine system, and the kidneys. The Objectors cited a study in rats allegedly showing brain damage at a fluoride exposure level in water of 1 ppm [1 mg/L] and epidemiological studies showing reductions in IQ levels in children at a fluoride exposure level of 0.9 ppm [0.9 mg/L] in iodine-deficient areas and 1.8 ppm [1.8 mg/L] in areas with sufficient iodine in the diet. (*Id.* at 25-26). As to the endocrine system, the Objectors reference the NRC Report’s conclusion that fluoride is an “endocrine disruptor” and argue that fluoride can have adverse effects on insulin secretion and on the thyroid. (*Id.* at 31-35). The Objectors argue that fluoride can affect insulin secretion where drinking water contains 4 mg/L or less of fluoride, (*Id.* at 33), and that NRC has concluded that thyroid effects can occur at exposure levels as low as 0.01-0.03 mg/kg/day for iodine-deficient humans, (*Id.* at 35). As to the kidneys, the Objectors claim that data show that adverse effects can occur when exposure levels in water are at the 1 and 2 mg/L level. (*Id.* at 38-39).

“With regard to the safety of children, the Objectors assert that EPA, without basis or explanation, has applied a significantly less protective RfD to infants and children than the RfD applicable to adults. The Objectors note that prior to the promulgation of the 2004 fluoride tolerances EPA had utilized a RfD of 0.114 mg/kg/day for all population age groups. (*Id.* at 59). The Objectors point out, however, that, in both the 2004 and 2005 tolerance actions, EPA increased the RfD for several of the infant and children age groups to levels that are allegedly as much as 10 times higher than the RfD for adults. This higher RfD for infants and children, the Objectors argue, is inconsistent with the statutory requirement for providing an additional margin of safety for infants and children, the basic toxicological principle that bodyweight affects the impact of a chemical, data showing adverse effects at levels below the RfD levels, and data showing that children’s bones are more sensitive to fluoride than adult’s bones. (*Id.* at 58-67). Further, the Objectors assert that EPA failed to take into account, in its decision on the safety of fluoride to infants and children, the uncertainty in the database concerning fluoride’s neurotoxic effects, and fluoride’s effects on the endocrine system. (*Id.* at 68-70).

“A developmental neurotoxicity study on sulfur dioxide, the Objectors claim, is critical to understanding the potential harmful effects of sulfur dioxide and fluoride. They argue that EPA's reasons for waiving the study lack merit and that a developmental neurotoxicity study is mandated given NRC's conclusion that fluoride is neurotoxic and that effects on the brain, including rare and severe effects, were seen in animal studies with sulfur dioxide. (Id. at 72-79).

“Turning to human exposure to fluoride, the Objectors argue that EPA has underestimated fluoride exposure and corrected fluoride values show that some people are exposed to unsafe levels of fluoride. The Objectors claim EPA made numerous errors in estimating fluoride exposure: (1) EPA underestimated average fluoride levels in water, (Id. at 81-82); (2) EPA considered only average water and food consumption levels instead of taking into account the full range of consumption amounts, (Id. at 82-84, 105-106); (3) EPA underestimated fluoride exposures from toothpaste, (Id. at 88-91); and (4) EPA had insufficient data to estimate residues of fluoride on food from fumigation with sulfur dioxide (Id. at 106). The Objectors contend that a risk assessment using corrected exposure values will show that hundreds of thousands of people exceed the 0.114 mg/kg/day RfD and that millions of people would exceed a RfD set based on an endpoint of severe dental fluorosis. (Id. at 86, 94-95).

Federal Register at <https://www.federalregister.gov/articles/2011/01/19/2011-917/sulfur-dioxide-proposed-order-granting-objections-to-tolerances-and-denying-request-for-a-stay>

Our consolidated Objections at <http://www.fluoridealert.org/wp-content/uploads/sf-nov-2006.pdf>

Although the EPA agreed with all the Objector's objections, Congress overrode the EPA and has permitted sulfur dioxide on foods.

Examples of permitted fluoride residues on foods:

beef, meat at 40 ppm;

Wheat flour 125 ppm;

cheese 5 ppm;

Coconut 40 ppm;

egg at 850 ppm; eggs, dried at 900 ppm; (Compared with Toothpaste 1,000 ppm)

Grain . . . group 16 and 17, 130 ppm;

ham at 20 ppm

milk at 3 ppm; milk, powdered at 5.0 ppm;

nut, pine, at 20 ppm;

Peanut 13 ppm;

rice flour at 98 ppm;

cocoa bean at 20 ppm;

Coffee at 15 ppm;

cottonseed at 70 ppm;

herbs and spices, group 19 at 70 ppm;

and vegetables, legume, group 6, at 70 ppm.

fluoride in or on all processed food commodities where a separate tolerance is not already established at 70 ppm;

<http://www.epa.gov/fedrgstr/EPA-PEST/2005/July/Day-15/p13982.htm>



New Label, New Opportunities

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Vikane is sulfuryl fluoride used to fumigate houses. The manufacturer warns, *“fumigated food should be discarded and should not be consumed because there are no legal tolerances for Vikane gas fumigant in food.”*

<http://www.dowagro.com/vikane/faqs/>

The new NOS (National Organic Standards) permits the use of fluoride, for example, over 1,000 ppm in bone meal. <http://www.apfn.org/apfn/fluoride.htm>

E. **Fluoride is also used as a pesticide called Cryolite.** Permissible Cryolite Content Application (Pesticide) Federal Register (1997?) Cryolite (Sodiumfluoaluminate) Fluorine=54.3%. 7 mg/kg residue is permitted for Cabbage, Citrus Fruits, Collards, Eggplant, Lettuce, Peaches, Tomatoes, etc. Potatoes 2 mg/kg to 22 mg/kg usually used in feed. <http://www.epa.gov/EPA-PEST/1996/May/Day-08/pr-685.html>

F. **Dental fluorosis, found in 41% of adolescents (58% in blacks), is a biomarker of excess human exposure.** CDC confirms, *“Dental fluorosis only occurs when younger children consume too much fluoride, from any source, over long periods when the teeth are developing under the gums.”* http://www.cdc.gov/fluoridation/safety/dental_fluorosis.htm#a2 accessed 11/6/15

PHS/HHS recently recommended lowering the concentration of fluoride in water from 0.7 ppm - 1.2 ppm to the lower level of 0.7 ppm, because too many have too much fluoride exposure. However, holding fluoride at 0.7 ppm will represent about 14% reduction in aggregate fluoride exposure.

G. In most samples of mother’s milk, fluoride is not detected. Formula made with fluoridated water subjects the infant to many times more fluoride than nature.

H. In 1950, fluoridation at 1 ppm was not expected to cause an observable effect on dental fluorosis.

*“Hodge (1950) studied children consuming fluoride in their drinking water. Fluoride levels of 0-14 ppm were investigated. Dental mottling was the parameter of interest. Fluoride levels of 2-10 ppm produced a linear dose-response curve (increasing mottling with increasing dose). **Fluoride levels of 0.1-1.0 ppm produced no observable***

effect. An assumption of 20 kg bw and 1 L/day water consumption for children was used, since the children studied were 12-14 years old. It is further assumed that a 20-kg child consumes 0.01 mg of fluoride/kg bw/day in the diet (50 FR 20164). Thus, a total intake would be approximately 0.06 mg/kg/day.”¹

I. “For ages 1.5-9 months, approximately 40% of the infants exceeded a mass-normalized intake level for fluoride of 0.07 mg/kg/day; for ages 12-36 months, about 10-17% exceeded that level (Levy et al. 2001b).” NRC 2006.

J. “Existing data indicate that subsets of the population may be unusually susceptible to the toxic effects of fluoride and its compounds. These populations include the elderly, people with deficiencies of calcium, magnesium, and/or vitamin C, and people with cardiovascular and kidney problems... Because fluoride is ubiquitous in food and water, the potential for human exposure is substantial (ATSDR, p 112, 153).” The Agency for Toxic Substances and Disease Registry (ATSDR)1993

(3) SCIENTIFIC ISSUES IMPORTANT FOR PRIORITIZING AND ASSESSING ADVERSE HEALTH OUTCOMES

A. The **toxicity** of fluoride is an important issue. The chemical added to public water is usually fluorosilicic acid and compares in toxicity to other highly toxic substances; whereas naturally occurring fluoride in water is usually calcium fluoride which is hundreds of times less toxic. Sodium fluoride (fluorosilicic acid) fits within state laws as a highly toxic substance, poison, and exempt from poison laws when regulated

Grams to kill a person of average weight

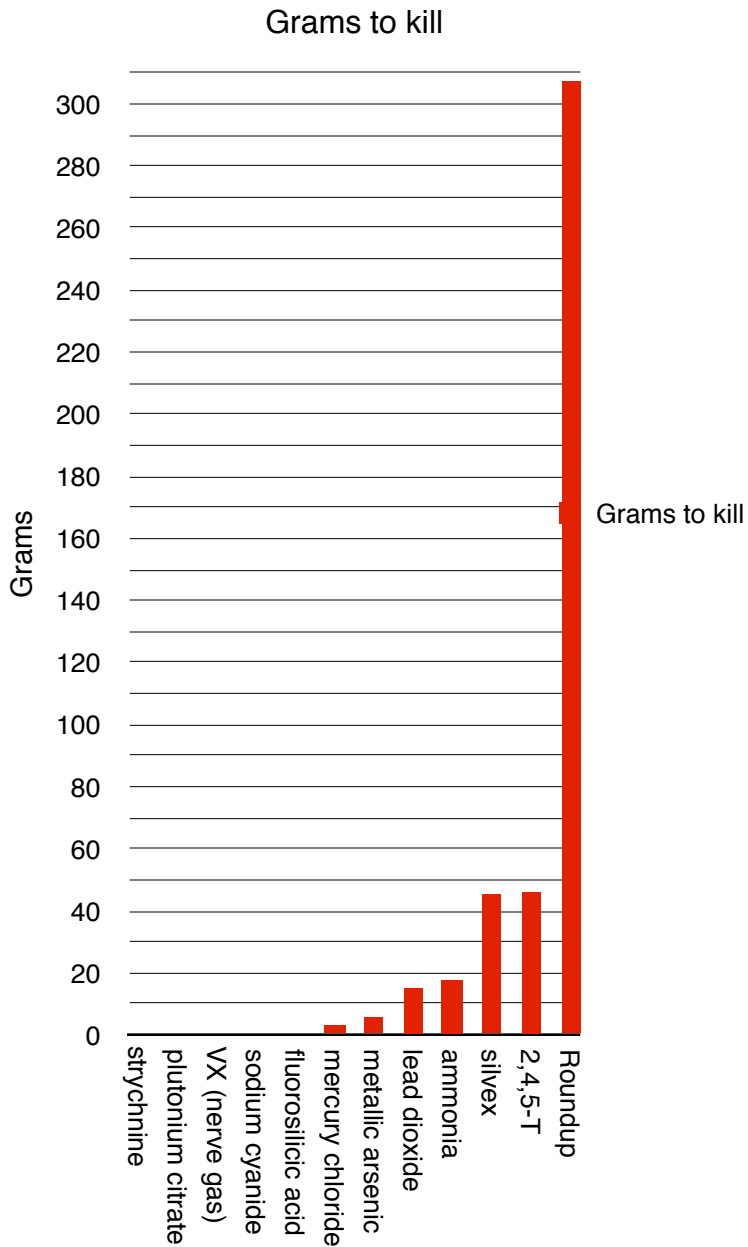
strychnine	0.002
plutonium citrate	0.021
VX (nerve gas)	0.70
sodium cyanide	0.154
fluorosilicic acid	0.56
mercury chloride	2.87
metallic arsenic	5.34
lead dioxide	14.9
ammonia	17.5
silvex	45.5
2,4,5-T	46.4
Roundup	307.0

Source: Gerald Judd, PhD., chemist, professor of chemistry, Johns Hopkins.



¹ <http://www.epa.gov/IRISsubst/0053.htm#oralrfd>

under pesticide or drug laws. Fluoride is a poison, drug or pesticide depending on the intent of use. Dr. Judd's data is graphed below. Fluoride added to public water is an extremely toxic substance.



B. The **source** of most human fluoride exposure is an important issue. As of 2012 CDC estimates approximately 200 million people in the USA are fluoridated. A reduction to 0.7 mg/L from 1 mg/L will represent about a 14% reduction in total fluoride intake, based on children at the 90th percentile of drinking water intake which accounts for 40%-70% of total fluoride intake.²

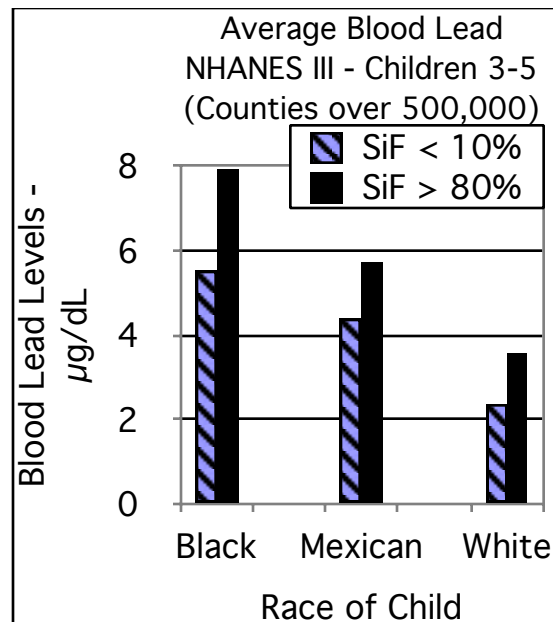
The source of the fluorosilicic acid (hydrofluorosilicic acid) for public water is predominantly a contaminated waste product (byproduct) of the phosphate fertilizer industries. The fluorosilicic acid is not a pharmaceutical grade and contains small amounts of a contaminated product and may contain Arsenic, Lead, Mercury, Beryllium, Vanadium, Cadmium, Radium, Silicon, Bauxite, and Radioactive Materials. (National Sanitation Foundation)

Water and toothpaste are the primary source of fluoride for most in the USA, however, significant amounts of fluoride can be found bone meal, tea, canned foods with fluoridated water, beer, soda, some bottled water, deep wells, volcanoes, industry such as copper, steel, aluminum, Teflon, Goretex, pesticides, fertilizers, coal, drugs, anesthetics, vitamins, and post harvest fumigants.

C. Increased blood lead levels in fluoridated communities is an important issue. The reason the average **blood lead** level in fluoridated communities is higher than non-fluoridated communities is not fully understood. Although the lead in the fluorosilicic acid is present, the amount would theoretically not be sufficient in itself to cause a significant increase in blood lead concentrations. Dissolved lead out of the pipes and brass faucet fittings is an additional likely source.³

Coplin provides a graph (right) comparing low and high fluoridated communities and race.

When FSA was added “lead concentrations spiked to over 900 ppb”⁴



² (US PHS Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries. Public Health Reports, July-August 2015 Vol 130)

³ Coplan MJ, Patch SC, Masters RD, Bachman MS. Neurotoxicology. 2007 Sep;28(5):1032-42. Epub 2007 Mar 1. “Prevalence of children with elevated blood lead (PbB>10µg/dL) is about double that in non-fluoridated communities”

⁴ Effects of fluoridation and disinfection agent combinations on lead leaching from leaded-brass parts. Maas RP, Patch SC, Christian AM, Coplan MJ. Neurotoxicology. 2007 Sep;28(5):1023-31. Epub 2007 Jun 30

D. The FDA's position on fluoride is an important issue. Although the FDA has ruled fluoride for ingestion in pills is not effective or approved, **fluoridation of water is in a regulatory void**. The FDA has said they are deferring regulatory action and most recently suggested Congress's intent is for the EPA to regulate the intentional addition of fluoride to water. No Federal, state or local government accepts jurisdiction over determining the "benefit vs risk" with appropriate dosage and label of fluoride added to public water.

Congress defined drugs as "Articles intended for use in the . . . prevention of disease. . .",⁵ FDA testified to Congress that fluoride is a drug,⁶ and the EPA Water Law Office Ass. General Counsel Steve Neubeboren confirms, "The FDA, remains responsible for regulating the addition of drugs to the water supply for health care purposes," the FDA claims EPA has jurisdiction.

E. "It is not CDC's task to determine what levels of fluoride in water are safe."
<http://www.cdc.gov/fluoridation/safety.htm> Accessed 5/26/2012

F. Determining the percentage of the population to be protected is an important issue. Do we protect up to the statistical mean as practiced by some? 90th percentile as chosen by the EPA Dose Response Analysis? Or do we protect 100% and add a margin of safety and uncertainty factor?

Subpopulations consume more water, foods, toothpaste, and other sources of fluoride than the statistical mean. Although the statistical mean water consumption is about 1 liter a day, some ingest over 10 liters a day. The EPA for fluoridation uses a 1:1 margin of safety and uncertainty factor. In contrast, the EPA usually recommends a 1:1,000 for animal studies. The EPA protects fluoride.

G. Fluoride is not needed for any normal physiologic function. The lack of fluoride does not cause dental caries. Fluoride is not an essential element, mineral, or food.

⁵ 21 USC 321 (g)(1)(B)

⁶ Congressional Investigation 2001



NOV 21 2014

Dear Ms. McElheney:

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,
[Redacted]

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

Jill McElhenny

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September 4, 2014

Wanda Jones

Jonathan Beeton

Office of the Assistant Secretary for Health

U.S. Department of Health and Human Services

Sandra.Howard@HHS.GOV

202-690-7778

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



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

[Enclosure 2] -

OFFICE OF
GENERAL COUNSEL

February 14, 2013

Gerald Steel, PE
7303 Young Road NW
Olympia, WA 98502

Dear Mr. Steel:

This is in response to your letter of December 28, 2012 to EPA Administrator Lisa Jackson in which you asked several questions about the status of an MOU between EPA and the Federal Drug Administration (FDA) published in 1979. I am replying on behalf of her.

Your first question is whether, from the viewpoint of EPA, the purpose of a 1979 Memorandum of Understanding (MOU) between EPA and the Federal Drug Administration (FDA) was "to take away from FDA, and give to EPA, responsibility for regulating public drinking water additives intended for preventative health care purposes and unrelated to contamination of public drinking water?" Your second question is whether, if that was the purpose of the 1979 MOU, the MOU was terminated through a subsequent Federal Register notice.

The answer to your first question is no, so there is no need to address your second question. The purpose of the MOU was not to shift any responsibilities between the Agencies. Rather, it was to help facilitate effective coordination of our respective legal authorities. Under the Safe Drinking Water Act (SDWA), EPA is the lead federal agency with responsibility to regulate the safety of public water supplies. EPA does not have responsibility for substances added to water solely for preventative health care purposes, such as fluoride, other than to limit the addition of such substances to protect public health or to prevent such substances from interfering with the effectiveness of any required treatment techniques. SDWA Section 1412(b)(11); see also A Legislative History of the Safe Drinking Water Act, Committee Print, 97th Cong, 2d Session (February 1982) at 547. 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.

The 1979 MOU was intended to address contamination of drinking water supplies as a result of direct or indirect additives to drinking water, not to address the addition of substances solely for preventative health purposes. 44 Fed. Reg. 42775 (July 20, 1979) ("EPA and FDA agree: (1) that *contamination* of drinking water from the use and application of direct and indirect additives and other substances poses a potential public health problem...")(emphasis added). It was intended to avoid potentially duplicative regulation of "food", which FDA had, in the past, considered to include drinking water. 44 Fed. Reg. 42775 (July 20, 1979). The MOU did not address drugs or other substances added to water for health care purposes.

Gerald Steel, PE
February 14, 2013
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I hope that this has adequately answered your inquiry. Please do not hesitate to contact Carrie Wehling of my staff (202-564-5492) if you have further questions about this.

Sincerely,
[Redacted]

Steven M. Neugeboren
Associate General Counsel
Water Law Office