The Fluoride Letters

U.S. Food and Drug Administration

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Introduction. Synthetic industrial fluorides lacking calcium, historically used as rat poisons and insecticides or in industry to etch frosted glass and increase porosity of ceramics and dissolve metals and brick, are now diluted at 0.7-1.0 ppm into 70% of all U.S. public water supplies because ingested fluoride was falsely correlated to be associated with decreased teeth cavities without causing any adverse health effects. Both of these claims have proven to be false. Calcium in water builds strong teeth, while fluoride opposes that action and interferes with proper enamelization of teeth during growth years. In all consumers, swallowed synthetic fluoride ion alters bone density where it accumulates permanently lifetime, alters the morphology of cells lining the gastrointestinal tract, and crosses the blood brain barrier. Not surprisingly, the U.S.is paying a heavy price for these pathologic intrusions from the ingested ion. The U.S. ranks 34th in infant mortality worldwide, has no lower cavity incidence than non-fluoridated Europe, has higher incidence of low IQ, mental retardation and tooth fluorosis in fluoridated cities, among other documented fluoride effects that contribute to various illnesses.

It is often claimed by proponents of fluoridation that in this free country anyone is free to filter out the fluoride provided by municipal water suppliers before consumption. However, removal of the 2.6 Angstrom fluoride ion from water molecules, that are themselves only 2.5 x 2.7 Angstroms in size, is a nontrivial undertaking. *Particulate filtration* removes protozoa and amoeba at 10 micron typical pore size. *Microfiltration* removes bacteria at approximately 1 micron pore size. *Ultrafiltration* to 0.1 micron size removes most viruses. Nanofiltration to 0.01 micron size removes large molecules such as glucose sugar and chloramines and the silicic acid that constitutes 30% of added fluoridation chemicals in treated water. *Reverse osmosis* to 0.001 micron pore size is able to remove sodium ion that is a hydrated complex in water and is also 30% of the materials added to fluoridate water. Finally, *high pressure reverse osmosis* with tiny 0.0003 micron pore size, recently developed and only very recently made available retail, is required to eliminate the tiny fluoride ion from water. This process and the more effective but energy-demanding process of *distillation* are not practical for whole house removal for those 1% of people allergic to industrial fluoride on contact. Whole house removal requires regularly-changed, sterilized, properly packed *bone char* from aged cattle, that is difficult for most Americans to afford. Consumers pay to inject fluosilicic acid, plus Drano to neutralize acidity, and also pay to remove it. So freedom to have access to plain water is being denied, all while deceptive statements of safety, effectiveness, and it not being forced, are widely falsely proclaimed.

#1

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Public Health Service
U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Regulatory Policy
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Dear FDA Project Reviewers,

I write this letter in support of my previous petition to ban fluoridation, that is adding synthetic fluoride to public drinking water supplies. See my original petition on this issue, FDA-2007-P-0346, formerly 2007P-0400.
The FDA, with its 2010 decision that "artificial fluoride compounds used to fluoridate public drinking water...is regulated by the U.S. Environmental Protection Agency (EPA) under the Safe Drinking Water Act of 1974 (SDWA)," may have forgotten certain historical and legislative facts, which I will discuss in this letter.
The EPA does not and has never regulated the injection of fluoride compounds into water supplies (i.e. 'fluoridation') and does not authorize or accept liability or responsibility for intentionally fluoridating drinking water. In fact no Federal agency currently accepts such responsibility.

The EPA labels fluoride in water as a "contaminant" and provides levels of this contaminant that should not be exceeded in order to prevent significant, widespread adverse health consequences. However, the EPA does not and has never regulated the injection of fluoride compounds into water supplies, and this is amply proven by statements published repeatedly by the National Research Council in its report "Fluoride in Drinking Water, a Scientific Review of EPA's Standards", The National Academies Press, Washington, D.C., 2006, referred to herein as 2006 NRC Report. In the summary on page 1, second paragraph of 2006 NRC Report, the U.S. EPA is correctly stated to be required to establish exposure standards for contaminants in public drinking water systems that might cause adverse effects on human health, including the maximum contaminant level goal (at which no adverse health effects were expected to occur from fluoride contamination), the maximum contaminant level (the enforceable standard), and the secondary maximum contaminant level (a guideline for minimizing, but not preventing, significant cosmetic effects caused by drinking fluoride-containing water). Fluoride is regulated as a contaminant by the EPA, but the EPA does not regulate fluoridation, the intentional addition of fluoride into water for perceived benefit. The EPA has no means to monitor for side effects when used as an intentional ingestible prophylactic.

On page xiii line four of the 2006 NRC Report it is stated that these EPA listed exposure values

> are not recommendations for the artificial fluoridation of drinking water, but are guidelines for areas in the U.S. that are contaminated with, or have high concentrations of naturally occurring, fluoride. The goal of the EPA MCLG is to establish an exposure guideline to prevent adverse health effects, and the goal of the SMCL is to reduce the occurrence of adverse cosmetic consequences from exposure to fluoride.

On page 14 of 2006 NRC Report it is written that EPA's

> drinking water standards are restrictions on the amount of naturally occurring fluoride allowed in public water systems, and are not recommendations about the practice of water fluoridation.

Excessive contamination prevention is the goal of the EPA here; it is not to monitor side effects, subtle or otherwise, or any surmised effectiveness of fluoride compounds when used in drinking water as oral ingestibles.

Page 18 lines 8-12 and lines 17-23 of the 2006 NRC Report state that the EPA MCL for fluoride was promulgated to be the same as the MCLG of 4 ppm and EPA also established an SMCL for fluoride of 2 ppm to prevent objectionable enamel fluorosis in a major portion of the population (i.e. not everyone) and was considered adequate at that time for preventing for the most part severe enamel fluorosis that would be cosmetically objectionable. Here I quote from the 2006 NRC Report:

> EPA does not regulate or promote the addition of fluoride to drinking water.

Instead, as a known contaminant,

> if fluoride in a community water system exceeds the SMCL but not the MCL, a notice about potential risk of enamel fluorosis must be sent to all customers served by the system (40 CFR 141.208[205]).

This is not an evaluation of any and all (studied or otherwise) adverse side effects or of expected chronic toxicity from long-term continuous uptake, but rather is a rough guide to minimize severe adversity for as many people as possible.

Page 20 the last line and page 21 the first three lines of the 2006 NRC Report state that the MCLG and SMCL were merely useful "guidelines for areas where fluoridated concentrations are naturally high. They are designed with the intent to protect the public from [overt] adverse health effects related to fluoride exposure and not as guidelines to provide health benefits." In other words, the EPA was interested at the time in hoping to minimize adverse health consequences of too much of the fluoride contaminant. They had no role whatsoever in reviewing the safety or effectiveness or dosage instructions for adding artificial synthetic fluorides to be used as prophylactics.

The guidelines were not intended to be an invitation to "fill 'er up" by those who hoped the fluoridation gamble would not backfire, and that artificial synthetic fluorides when ingested might make teeth white without somehow interfering at all with any other body component or process at the same time.

Please understand however that many city and state officials have indeed interpreted the SMCL as just that, where unnatural fluorides are added into water with what is perceived as the blessing and endorsement of the EPA, since the level used is below the 4 ppm and 2 ppm levels of naturally occurring calcium fluoride that are known to be toxic by the EPA.

The long term consequences of synthetic low level fluoride consumption lifetime, and for generations, at levels under that allowed by the EPA, are not addressed by the EPA.

As required by the Safe Drinking Water Act, the EPA asked the NRC to review the water fluoride standards for naturally occurring fluoride in drinking water and told the NRC specifically not to cover the adding of artificial fluorides to drinking water, presumably because the EPA knew it had no jurisdiction to regulate the addition of artificial fluoride. Nevertheless, much of what the NRC said did apply to artificial fluoridation.

Regarding naturally occurring fluoride, the NRC on page 2, last paragraph and page 3 first paragraph, wrote

> After reviewing the collective evidence, the committee concluded unanimously that the present EPA MCLG of 4 ppm for fluoride should be lowered. Exposure at the MCLG puts children at risk of developing severe enamel fluorosis [not just minor or moderate, but severe]. The majority of the committee also concluded that the MCLG is not likely to be protective either against bone fractures.

According to the NRC, the essence of the problem is that artificially fluoridated drinking water typically contributes anywhere from 57 to 98% of total fluoride ingestion in individuals. Intake depends on naturally occurring fluoride levels, artificial fluoride added, diet, toothpaste use, total water intake, and age of the individual. Any EPA water guideline for naturally occurring fluoride in drinking water is of course useless when there are other significant additional sources of fluoride coming from other sources.

The NRC states on page 10, last paragraph of the 2006 NRC Report:

> From a cosmetic standpoint, the SMCL does not completely prevent the occurrence of moderate enamel fluorosis. EPA intended to reduce the occurrence of moderate enamel fluorosis to 15% of the exposed population.

The U.S. Health and Human Services recently requested fluoride in water be lowered to 0.7 ppm as an interim measure to help decrease the mass incidence of tooth fluorosis now evident in U.S. children aged 12-15(which demonstrates clearly that the EPA SMCL was indeed too high and has failed in its intended objective).

Why would one expect any different result? Synthetic fluorides are fully water soluble with an LD50 of only 50 mg/kg body weight single dose in tested animals (Merck Index, 1976, Rahway, N.J.) We also know that natural calcium fluoride has limited water solubility where the calcium ion tends to exert an ionic strength effect on the fluoride ion to reduce its chemical potential or activity and that calcium fluoride has a safe high LD50 of 2,500-3,000 mg/kg body weight.

For this reason, the NRC states on page 88 of the 2006 NRC Report its conclusion that further analysis should be done regarding the concentrations of fluoride and various fluoride complexes using a range of water with different hardness and mineral content, and research is needed to characterize any changes in speciation that occur when tap water is used for various beverages, and on the effects of silicon and aluminum fluoride complexes including the conditions under which the complexes occur and have biological effects.

Some 100 years ago, it was reported that natural fluoride in water in Texas and Colorado caused whitish-appearing teeth, when in fact it was the extremely high calcium level. It was not the fluoride ion which is only a toxic calcium chelator, as detailed in my original petition.

Chemists then had, and many today still have, incomplete knowledge about the fluoride ion. Fluorine, with maximum electronegativity, oxidizes, and is thus is reduced by, every other substance in the known universe. Fluoride on the other hand has no electronegativity at all and instead seeks positive charge and cannot be reduced or oxidized by any substance on earth. Fluoride is indestructible, and its toxicity depends on whether it exists in water with lots of calcium, or not.

When the EPA set the guidelines for existing fluoride contaminants in water, those guidelines were based on natural fluoride in water which is often rich in calcium, not for synthetic toxic fluorides used today without regard to calcium content to treat people through water supplies under a wide variety of conditions. Synthetic fluorides do not behave in the same way as natural calcium fluoride, and any attempt to apply the EPA guidelines to artificial synthetic fluoridated water is mistaken. This misunderstanding has caused the massive tooth fluorosis epidemic in the U.S. compared to that seen in the original Texas locale, and ultimately is the reason the vast data the NRC examined led the panel to conclude that EPA standards for fluoride concentration, which pertain to naturally occurring fluoride, must be significantly lowered.

In reality EPA should ban the addition of any kind of fluoride to drinking water. There are no EPA guidelines whatsoever authorizing adding artificial fluoride to drinking water. Existing EPA fluoride guidelines are being used as if they set the maximum amount of fluoride which legally can be added to drinking water.

No controlled clinical trials exist either to support the use of fluosilicic acid or sodium fluoride as a drug, supplement, or oral anti-caries ingestible prophylactic in water. Further, waters in the U.S. are increasingly contaminated with a wide variety of substances, some of which interact with fluoride at various body pH levels (i.e. aluminum, silicic acid, beryllium) or act synergistically with fluoride (i.e. fluosilicic acid tends to dissolve lead from water fixtures and acts together with endogenous lead and arsenic in public water systems and with the lead and arsenic in the industrial grade synthetic fluorides). Thus, adding synthetic fluorides (or any substance for that matter) as a therapeutic agent in water today (far more so than in 1945) is a false medical practice.

As is clearly evident from the NRC report, regulating the intentional prophylactic use of fluoride compounds added into public drinking water is not the job of the U.S. EPA, in spite of the Memorandum of Understanding cited by FDA in the Oct. 27, 2010 response to my original petition. That MOU, signed in 1979, could have had different meanings to the two agencies. See the MOU at http://fluoride-class-action.com/wp-content/uploads/memorandum-of-understanding-epa-fda-19791.doc .

The EPA evidently wanted to take over regulation of adding fluoride to water. However, the Safe Drinking Water Act, in a provision enacted in 1974, forbad EPA or any agency from requiring the addition of chemicals for medical purposes. This is the exact wording:

> No national primary drinking water regulation may require the addition of any substance for preventive health care purposes unrelated to contamination of drinking water.

The EPA can only make regulations requiring addition of chemicals which treat the water and make it drinkable. It cannot make regulations requiring the addition of a chemical intended for medical purposes such as artificial fluoride purports to do.

In the MOU, signed in 1979, it is evident that the FDA was under pressure to shed all responsibility for regulating the addition of fluoride to drinking water. The politics of the agencies under the Public Service is complex. The FDA administration back in 1979 was not courageous enough to ban water fluoridation. The FDA should have done so then and could still could do it today. Fluoridation of drinking water is the addition of a drug to water. Only the FDA can approve that.

The FDA will never approve the general introduction of artificial fluoride to public drinking water. For that the FDA should be praised. However, the FDA has failed to ban fluoridation, and that is its greatest error. It bans many other drugs each year, but it fails to ban the most widely used harmful drug of all, artificial fluoride.

Further, the FDA has approved the adding of fluoride to bottled water, provided it is disclosed on the bottle. It has also approved the undisclosed use of fluoridated tap water to make bottled water. The latter is a serious error, and the FDA should reverse it. For those who absolutely insist on taking fluoride internally, water containing naturally occurring calcium fluoride along with a lot of calcium should be allowed. The FDA could and should forbid the use of tap water containing artificial fluorides to make bottled water, or at minimum the FDA should require that the type and level of fluoride in bottled water or at least the calcium content of the water be disclosed on the bottle.

Moreover, the FDA should reassert its jurisdiction over adding artificial fluoride to public drinking water and should ban the practice entirely. Likewise, the EPA could and should ban drinking water fluoridation. However, this does not seem to be EPA's intent at this time. It seems that the EPA's intent is to encourage water fluoridation without requiring it and without certifying it to be effectual and harmless.

The EPA set up or reorganized a surrogate organization to do what it could not do. It reorganized the National Sanitation Foundation into a sham regulatory agency which would certify and authorize drinking water fluoridation and the artificial fluorides used to fluoridate.

Read about the NSF at http://fluoride-class-action.com/sham.

The NSF states repeatedly on its web site that toxicological studies are done on artificial fluorides. http://fluoride-class-action.com/wp-content/uploads/NSF-fact-sheet-on-fluoride-2008.pdf. However, when put on oath representatives of NSF admit that there are no toxicological studies. Yet 43 or more states allow fluoridation only if the fluoridation materials are NSF 60 certified.

Perhaps in the 1979 MOU the FDA transferred its jurisdiction over adding fluoride to drinking water with the assumption that the EPA would ban the practice. The EPA has taken no such course. The EPA allows naturally occurring fluoride in drinking water up to 4 ppm and 2 ppm levels and allows these levels to be perceived as allowing artificial fluoride to be added to drinking water.

The FDA is now in a position to walk through an obvious door that has opened to it, and to act responsibly, and without any justifiable criticism, on behalf of the country. The rationale for a ban, or temporary halt to await clinical trials data for examination, is that fluoride injections 1) have spread widely independent of endogenous local water conditions and hardness, 2) now represent only a portion of total fluoride ingestion since toothpaste fluoride use is pervasive, and 3) are complicated by the presence of contaminants in public drinking waters we now know affect fluoride toxicity (especially from commonplace injected residual aluminum). The FDA ruled in 1963 that fluoride compounds added into water would be "an uncontrolled use of a drug, where dosage cannot be controlled" (see original petition). That proclamation is even more profound today than then.

Currently, the EPA has not banned artificial fluorides in water that EPA labels as contaminants, because EPA knows the agents are being used at subacute toxic doses for most people as drugs, oral ingestibles, or supplements or dietary aids, that the Public Health Service in 1950 initially endorsed and that are not banned now by the FDA. On the other hand, the FDA has not banned artificial fluorides as drugs, because FDA has never approved these substances as oral ingestibles, supplements or dietary aids, and knows the EPA labels them as contaminants that EPA should regulate under the Safe Drinking Water Act, which strictly forbids the intentional injection into water of any contaminants (or drugs or any substance other than to sanitize water).

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Dear FDA petition reviewers,

The following material is submitted in support of the Petition for Reconsideration, 2010 and the original petition FDA-2007-P-0346 (originally assigned 2007P-0400/CP1). The first section deals with the disbanded FDA-EPA MOU of 1979 and the fact that synthetic fluorides are ingested as drugs, and the second section presents additional information on anionic fluorine chemistry and the questions that must be asked of suppliers of industrial fluorides intended for human ingestion.

I.

EPA-FDA 1979 MOU. It has come to my attention, from an attorney who is expert on Federal drug law, that the FDA-EPA MOU Memorandum of Understanding of 1979 (described in your response letter 2010) was officially revoked by the EPA in 1988. This was also confirmed by several other attorneys who recently published a summary of litigation filed in Los Angeles for a water district using fluosilicic acid fluoride, which is an unapproved drug (PRWeb, August, 2011). Moreover, the FDA officially published in 1996 that Food Drug and Cosmetic Act regulations do indeed apply for substances added to drinking water, i.e. in particular compounds or drugs to alter human tissue or treat disease. Apparently CDER at FDA was unaware, as was I, that this revocation had already taken place, and that the EPA was not in charge of regulating water additives at the time the original petition P-0346 was filed with FDA in 2007. Details follow.

Injected Fluorides in Water are Drugs. Synthetic fluorides from processed materials, not foods, when added into human drinking water to treat cavities, are classified as drugs by reason of use. All drugs are regulated, approved, banned, or not approved but allowed, exclusively by the FDA, not the EPA. All drugs (legend by prescription and over-the-counter) are given and ingested (if swallowed) based on need, and citizens who have no dental caries have *no need* for any drug used to treat caries. This description is in full agreement with the official FDA position of 1963, that fluorides added into public water supplies would be an uncontrolled use of a drug (see original petition). Moreover, the Memorandum of Understanding ("MOU"), originally made by the FDA in 1979 to have the EPA regulate chemicals added to public water systems, was discontinued in 1988 (see attached pages), thereby relinquishing any authority of the EPA to regulate chemicals being used as drugs, either FDA approved and legal, or not FDA approved and illegal, or any supplement, mineral or additive intended to treat human tissue through ingestion in water.

Fluorides Named as Supplements. Some at the FDA may yet contend that synthetic fluorides from processed materials, not foods, are 'supplements', rather than drugs, being used to prevent, rather than to cure or treat, caries. This is a fine difference philosophically, where it might be argued, since anyone without cavities would not be being 'treated with a drug', but rather is 'prevented' from suspected future cavities by 'ingesting a supplement'. This is however in contrast to the FDA ruling of 1963 that fluorides are not mineral nutrients. In any event, supplements, particularly from processed inorganic matter rather than extracted from natural foods, are also exclusively regulated by the FDA, not the EPA.

Fluorides Named as Additives. Some at the FDA may yet contend that synthetic fluoride from processed materials, not foods, are used to turn water into an 'optimal' state found in some waters naturally in the U.S. and that thus it is not a drug or a supplement but is a water-normalizing 'additive'. Understand however that there is no stated or recognized purpose for forming 'fluoride optimal' water other than to alter the structure of human teeth enamel, whether consumers have or do not have dental caries, so the designation additive still indicates its function is to alter tissue. Children during teeth development age form a fluoridated derivative of abnormal teeth enamel hydroxyapatite. Since the added chemical is introduced into water for the purpose of altering teeth to prevent disease (caries), and since the agent also alters other tissues, particularly bone and pineal gland hydroxyapatite, then Food Drug and Cosmetic Act regulations apply to this substance regardless of being labeled an 'additive'. Indeed,

FDA examined claims that fluoride strengthens bone hydroxyapatite decades ago and concluded that this is false (see petition for reconsideration, 2010), and FDA wrote that fluoride does not strengthen bone, while as we now know the National Research Council data prove ingested fluoride from treated water incorporates into bone pathologically and permanently to thousands of times that in water (National Research Council, **Fluoride in Drinking Water, A Scientific Review of EPA's Standards**, Washington, D.C., 2006).

Fluorides Claimed as Foods. The fact that synthetic processed fluorides are not foods has been amply addressed earlier (see Petition for Reconsideration, 2010; and detailed materials submitted 2010 to FDA by Dr. Bill Osmunsen). That is, the essential feature of foods is to provide calories from metabolic action to eventually produce energy for cellular needs. Fluoride can be found naturally in certain foods in certain regions of the country, but the fluoride ion itself is not an essential part of any food since fluoride itself is not metabolized and in fact cannot be oxidized or reduced or altered in its chemical form, but rather fluoride *in vivo* binds [pathologically] to calcium-rich regions, especially bone, releasing no metabolic energy or calories of any kind.

Regardless of the label one prefers to ascribe to synthetic industrial fluoride compounds injected into water, and regardless of what hazardous inorganic source material is processed to provide them, the chemical is added to treat or prevent disease by altering human tissue, either to form abnormal fluoridated enamel, or to affect caries, while it binds, and accumulates in, bone and pineal gland hydroxyapatite with a permanent, pathologic unnatural abnormal mechanism over the lifetime of the consumer. Any agent intended to alter tissues through ingestion in order to treat or prevent disease is defined by Congress as a drug (see attached summary) and must be subject to FDA regulations, as prescribed and directed by the Food Drug and Cosmetic Act.

Summary of information provided by Federal drug law Attorney Group. The U.S. Constitution Article VI cl. 2 (supremacy clause) provides that the Congressional directives, to regulate and approve/disapprove drugs and to regulate dosage of drugs, that were given to the FDA, specifically means FDA, not the EPA, has these powers that cannot be interfered with by the states. Moreover, in 1988 EPA published in the Federal Register that it terminated the agreement it made in 1979 (1979 MOU) with FDA to regulate water additives. This was effective in terminating the 1979 MOU (53 FR 25586-89 to be forwarded later). Finally, the FDA in 1996 published it would no longer avoid Food Drug and Cosmetic Act regulations for water additives in public water systems. Thus the FDA is in full charge of chemicals added to municipal drinking water as drugs for the purpose of altering tissue to treat or prevent diseases, including dental caries.

Federal law prohibits marketing any drug without FDA pre-approval. According to statutory law (United States Code 21 U.S.C. 321(ff), for foods or water swallowed with ingredients to prevent disease, such ingredients are drugs. Public drinking waters are fluoridated to prevent dental caries disease and therefore are drugs (21 U.S.C. 321(g)(1)(B)). Bulk fluosilicic acid shipped interstate to water districts by truck or railcar intended for human ingestion to alter human tissues to prevent disease are Federal drugs, whether the chemicals are approved by FDA and legal, or not approved by the FDA and thus illegal. Although bulk sodium fluoride is a prescription drug listed in the United States Pharmacopoeia and an active ingredient in some approved over the counter anticaries drugs, fluosilicic acid has never been actively regulated as either a prescription or over the counter drug or allowed active ingredient by the FDA. If fluosilicic acid ever were approved for prescription use, even then its bulk use in water supplies is not consistent with Federal drug law, because A) it is not an over the counter drug that could be used or not by consumer choice, and B) as a prescription drug prescriptions are not given by water districts to consumers. Because under the Safe Drinking Water Act, all public water systems are in interstate commerce, FDA has jurisdiction when waters in these systems are made to contain substances with drugs by the addition of fluosilicic acid or sodium fluoride with intent to prevent dental caries, a disease. Fluoridated waters that were first manufactured after 1997 (active ingredients plus excipients) that do not meet monograph conditions in 21 CFR Part 355 are not permitted by FDA to be over the counter drugs without a NDA or ANDA (60 FR 52474 and 61 FR 52285) and also are not permitted to be prescription drugs without a NDA or ANDA because these drugs (active ingredients plus excipients) are new drugs.

An important distinction to be made is that fluoride in nature that can be present in foods or water naturally is considered a mineral although FDA has stated it does not find it to be an essential mineral. As such, fluoride ion can be present naturally (as calcium fluoride which is not a recognized toxic having LD50 > 3,500 ppm) in food. The statutory provision in 21 U.S.C. 321(g)(1)(C) regarding drugs being articles intended to affect the structure of man explicitly exempts foods and minerals in foods under 21 U.S.C. 321(ff) but this definition of drugs does not apply to synthetic unnatural fluorides not found in foods, such as sodium fluoride and fluosilicic acid. The

definition of drugs as “treatment or prevention of disease” applies to both fluoride water additives and fluoridated waters as drugs under this definition because of intent of fluoridation to treat and prevent dental caries; both are anticaries drugs pursuant to the definition in 21 CFR 355.3(c) because they are a “drug that aids in the prevention and prophylactic treatment of dental cavities (decay, caries)”. It is the intent to treat or prevent disease that makes fluorides and fluoridated waters a drug independent of effectiveness. Drugs are defined in Federal case law to be both the active ingredient(s) and excipients. Therefore new implementation of fluoridated water creates a new fluoridated water drug that can only legally be used if there is a new drug application for that new drug. Further, all manufacturers and cities that use the fluoride compounds are required to register annually with the FDA (21U.S.C. 360).

Conclusion: Since 1) the FDA regulates all drugs, that is any chemical substance for ingestion to intentionally alter human physiologic or morphologic processes to treat or prevent disease, and since 2) controlled human clinical trials have not been forwarded for synthetic fluorides to the FDA for intended use as ingestible drugs, then, according to the Food Drug and Cosmetic Act it is clear that FDA must either:

1: Ban intentional injections of all synthetic fluoride compounds into public water systems in the United States; or

2: Announce requirements to provide data of proof that ingesting synthetic fluoride compounds from drinking water long-term has no significant adverse health impact on humans, including those with severe infirmities such as Alzheimer's disease, diabetes, kidney infirmity of any kind, autism and heart disease among others, and that data must be presented of controlled human clinical trials demonstrating effectiveness in its intended purpose; or

3: We request that FDA (for official records, being in charge of regulating all drugs, supplements, minerals and any chemicals other than natural foods, intended for human ingestion for the purpose of altering human physiology, pathology, or morphology to help prevent or treat disease) request from chemical suppliers, of synthetically processed inorganic fluoride compounds, any existing data that demonstrate safety and effectiveness for chronic ingestion of the materials in humans. Verbal or written endorsements and statements of safety and effectiveness do not constitute actual data of proof; and this information should be held in FDA records on such materials proposed to be continuously administered into public water systems in the U.S. for the purpose of altering human teeth, or any other purported metabolic/structural effect to help treat and prevent disease unrelated to that allowed by the Safe Drinking Water Act (i.e. to sanitize the water).

The U.S. FDA has a proud heritage for decades in maintaining correctly that anionic fluorine is not to be regarded as a normal component of fresh drinking water. We ask that you continue that tradition and actuate applicable provisions of the Food Drug and Cosmetic Act as requested above. There is no need to delay while waiting for new drug applications to arrive from those using the materials now for human ingestion purposes. No such applications will be filed, since fluorides used prior to the FD&C Act have given the false impression that the FD&C Act might not apply, unless such request is made by FDA.

II. The following information (in part from personal communications with a world expert fluorine chemist, and in part from published sources) adds to the petition and presents key questions that must be asked of chemical suppliers of synthetic fluorides sold for intentional human ingestion that is not FDA approved.

Fluorine Chemistry. As you know, fluorine is highly electronegative or electron-withdrawing, and for this reason does not exist as the uncharged element in nature. Unknown to many though, fluoride, which contains an extra electron and thus has a full negative charge, has no electro-negativity and in fact is ‘electro-positive’, the property that ensures that forces fluoride to bind positive charged calcium sites in bone in a pathologic, permanent accumulating manner.

As an employee 40 years ago of the prestigious Dr. Andrew Alm Benson, I am pleased to announce that Dr. Benson at age 94 remains brilliant and operates a laboratory to this date at the University of California, San Diego, La Jolla, CA. Benson is most notable for his elegant discovery of the actual carbon fixation reaction product in the Calvin Benson cycle of plant photosynthesis, but most do not realize Benson completed his Ph.D. at Berkeley in 1940 on the interaction of organic compounds with inorganic fluoride. Extensive discussions with Dr. Benson on the procedure of adding inorganic fluorides into public water supplies have been quite telling. In summary, Dr. Benson is appalled and is now drinking bottled water without fluoride and is attempting to avoid, with difficulty, the internal consumption of municipal water supplies containing industrial synthetic fluoride. I do not wish to apply controversy or mental pressure on the man and here provide this information for FDA private use only.

First, the metabolism and general viability of biologic cells are not compatible with the presence of even dilute amounts of inorganic fluoride. The main reason for this is that even at slight acidity (the internal fluid of cells is acidic at pH 6.9), the fluoride ion is protonated to hydrofluoric acid, HF, the most corrosive substance known which has wide use in industry to increase porosity of ceramics and to etch glass among other uses. Being a weak acid, HF corrosivity is not due to its acidity but rather to its extremely minute size and penetrability. Most organic reactions have low yield by the nature of the chemistry of carbon, but not so for fluoridated derivatives that are consistently of high yield under proper conditions. In the stomach at pH 3, ingested free fluoride in the absence of other chelators is quantitatively in the form of HF where it is able to gain access quantitatively where it does not belong, in the bloodstream.

Although 1 ppm is argued to be dilute and harmless, in actuality debridement of gastric mucosa is possible with HF in such a way as to not be sensed with any discomfort in most people. Remember that the one human controlled clinical type trials set of data that we have with cooperating regulated volunteers, summarized by the National Research Council (NRC, 2006) is the finding that drinking water with 1 ppm fluoride ion causes stomach discomfort in 1% of those tested. It is suspected that individuals with either thin stomach lining, or more nerves near the mucosal surface, or the elderly with slowed mucosa cell turnover, are those who detect discomfort from 1 ppm fluoride as HF.

Although 1 part in one million is argued to be 'safe' for human consumption, understand that one liter of water with its 32 trillion trillion molecules, at 1 ppm fluoride contains 32 million trillion fluoride ions in that liter. The kidneys eliminate half of all ingested fluoride contaminant, but are unable to prevent the remaining fluoride ion from binding to bone permanently for the life of the consumer, since calcium fluoride is insoluble at extracellular basic pH 7.4. 1 ppm fluoride water causes blood levels to be 0.21 ppm, a concentration that specifically inhibits the activity of DNA repair enzymes including glutamine synthetase about 50% (for review see: Yiamouyiannis, **Fluoride: the Aging Factor**, 1965, Health Action Press; National Research Council **Fluoride in Drinking Water, a review of EPA's Standards**, Washington,D.C., 2006; Connett, Beck and Micklem, **The Case Against Fluoride**, Chelsea Green Publishing, White River Junction, Vermont, 2010).

Benson made it clear that relying on the dental industry to determine the ingredients in public water supplies is reckless, particularly when the industry already grossly erred in its long-standing use of toxic mercury as filling for teeth caries. The ADA is heavily invested in procedures that remedy tooth morphology, but are extremely uneducated in terms of blood clinical chemistry. Benson was very pleased with the PRWeb, 2011 article on the litigation of the water district in Los Angeles for its use of fluosilicic acid for human ingestion without FDA approval. He also trusts that the FDA will act other than as a 'paper pusher' expecting others to regulate it, and instead to become actionable for the benefit of our country.

While the FDA continues to avoid regulating the injections of industrial fluorides into public water supplies, then we respectfully request that specific questions be asked by FDA of those chemicals suppliers of this material intended for ingestion without FDA approval. Example important questions are listed next.

Questions Required of Fluosilicic Acid Manufacturers.

Dear chemical supplier of fluosilicic acid materials for human consumption in municipal drinking water,

In anticipation of use of chemicals from your company sold for human ingestion by water districts in the United States, we here as overseers of citizen health and safety by Congressional statute, ask that you answer the following questions about the materials you supply for human ingestion. This information is appropriate to have on file in our records for reference.

1. Please provide written documentation that demonstrates the fluosilicic acid material when ingested by consumers from treated water supplies causes decreased teeth cavities. What percent reduction in tooth decay rate is expected from long-term consumption of diluted fluosilicic acid in municipal water?

2. Please provide written documentation that demonstrates the human experimental data that tested for safety of ingesting the fluosilicic acid materials for a continuous long-term period. Can you provide data demonstrating that long-term consumption is safe and without adverse health effect for all people, especially those afflicted with common serious illnesses such as kidney disease, diabetes, heart disease, cancer, and in particular those with Alzheimer's disease and those with autism?

3. Please provide written documents that denote the percent of increased incidence of tooth fluorosis that can occur in children consuming fluosilicic acid treated water during teeth development years, aged 5 - 8.

4. Please provide a detailed chemical analysis of all known ingredients and their percent content in the fluosilicic acid preparations that will be provided for ingestion by all citizens in a treated city.

5. The U.S. FDA has not approved any fluoride containing compound for either safety or effectiveness and has been unable to provide such data to city officials that have asked for such documentation. Can the FDA be assured freedom from litigation regarding dental fluorosis and other adverse effects known to be associated with consumption of water treated with industrial fluorides from your company?

6. As you know, the U.S. Safe Drinking Water Act prohibits any chemical, food, drug, supplement, mineral, or other, from being injected into public water supplies other than to sanitize the water. Since fluosilicic acid is added to treat human teeth, we would also like any legal documents you have that will defend FDA against those who wish to follow the Safe Drinking Water Act as initially written, and what documents you have that demonstrate specifically that diluted fluosilicic acid preparations may be exempted as exceptions to these Statutes.

7. Both the American Dental Association and the U.S. Centers for Disease Control now recommend parents not give fluoridated water to children under 5. Do you have official documents to defend against parents who complain after giving children under 5 the treated water, knowing that many parents will not be able to afford bottled untreated water in cities throughout the United States?

Final Comments. The bottom line is that un-natural synthetic fluorides without calcium, added into water to treat and prevent disease (cries) is using a fluoride compound (which happens to be a recognized poison by toxicologists, Merck Index,1976) in dilute form as a drug, and requires from the FD&CA a new drug application. The EPA has no jurisdiction over regulating fluoride compounds added into water--the FDA solely has such (in spite of the reviewers decision to the contrary in 2010). Attached is a recent letter from the EPA proving that EPA does not regulate the intentional addition of fluoride compounds into public water supplies (i.e to treat humans).

A summary copy of information gleaned from the above-mentioned attorney will be forwarded from his office to the FDA on a future date. The drug use of 140 million people is something that needs to be handled carefully while on the other hand wishing it could be done as quickly as possible.

My very best regards, and may God help you in this endeavor to return our National water supply to constitute natural, normal fresh water without added chemicals used as drugs.

If additional legal information is required to prove that fluosilicic acid requires a new drug application NDA since the grandfather clause for older drugs has been discontinued and does not apply for this agent, then please do not hesitate to ask and this will also be forwarded to FDA.

#3 **Richard Sauerheber, Ph.D.**
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November 21, 2001

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Rockville, MD 20857

Dear Reviewers,

This brief letter provides additional information, not forwarded earlier, in support of FDA petition FDA-2007-P-0346 (originally assigned 2007P-0400/CP1).

The FDA has technically been indirectly involved in water fluoridation for many years, by virtue of prescription drug labeling. The prescription drug Luride has labeling and dosage instructions required for this prescription drug. The Physician's Desk Reference, America's first and only compendium of official FDA-approved prescription drug labeling, lists Luride (sodium fluoride) as a still-legal prescription drug. The specific dosage instructions *allowed* by the FDA, include the following statement:

"Fluoride oral supplements are contra-indicated when drinking water is above 0.7 ppm fluoride" (Physician's Desk Reference, p. 838, 48th edition, Medical Economics Data Production Company, Montvale, NJ, 1994).

In spite of recommendations issued January, 2011 from the U.S. Health and Human Services to not exceed 0.7 ppm, San Diego city water is mostly treated to 0.8 ppm fluoride and Los Angeles public water is titrated to 1.0 ppm of the free fluoride ion. Water districts who inject synthetic fluoride compounds for human ingestion are in violation of FDA regulations, by either 1) dispensing a non-FDA approved drug (fluosilicic acid), or 2) in some cities dispensing an FDA *allowed* prescription drug (sodium fluoride) without a prescription, and 3) by not providing necessary FDA dosage information to consumers (i.e. as listed in the PDR above). FDA existing dosage instructions are being ignored.

Fluosilicic acid is not an FDA approved drug by either prescription or over the counter and is not listed in the PDR. Its dispensation for oral ingestion is a violation of the FD&C Act that requires, for any substance used as a drug to treat disease, a new drug application and FDA approval.

Because we are asking for a ban on fluosilicic acid in public water supplies, I should buffer perhaps this request with an additional statement. Any city with customers who wish to fluoridate their bloodstream through oral ingestion of synthetic fluorides, if the FDA were to ban the injections, may be advised to obtain prescriptions from their physicians who can prescribe Luride that is FDA *allowed*, as long as water fluoride is less than 0.7 ppm.

If you require the CFR regulations again that specifically apply to the violations listed above, I will be most happy to forward them.

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U.S. food and Drug Administration

Center for Drug Evaluation and Research
Rockville, MD 20857

Dear Reviewers,

Information here, not submitted earlier, is in support of the petition submitted to the FDA in 2007, FDA-2007-P-0346 (originally assigned 2007P-0400/CP1).

Preparations used by public water districts to treat water are obtained from various suppliers as a 23% fluosilicic acid solution. Because of the chemistry of aqueous fluorides, these solutions typically contain about 1.0 % HF (as assayed and published by Lucier Chemicals for the Metropolitan Water District, Los Angeles, CA). This is 23 grams of H_2SiF_6 and 1.0 grams HF per 100 grams of solution. This represents 18 grams of fluoride from H_2SiF_6 and therefore 5.3% of all fluoride present in the solution is in the form of HF.

The Code of Federal Regulations specifically and explicitly prohibits the marketing, interstate transport, or ingestion of any anti-caries agent that contains HF without a new drug application NDA FDA regulations provide that any anti-caries drug that includes hydrogen fluoride (HF) requires an NDA [21 CFR31O.545(a)(2) and (b).]
Fluosilicic acid hazardous waste preparations are currently diluted into nearly 70% of all U.S. water supplies without FDA approval and without a prescription, to intentionally achieve 0.21 ppm anionic fluorine (National Research Council, **Fluoride In Drinking Water, A Scientific Review of EPA's Standards**, Washington, D.C., 2006) in human blood, and such action requires an FDA ban, or an approved NDA.

The concentration of HF that would be present in a solution that is buffered to pH 7 with 1 ppm total fluoride (i.e. a public water system) is about 0.14 ppb of this corrosive substance HF. This may be un-impressive to those promoting fluoride ingestion form water, but nevertheless HF is the most corrosive substance known and is the active ingredient for industrial uses of synthetic fluorides acting on glass, ceramics, computer chips, and concrete when conditions are not buffered.

In water, HF as a weak acid partially ionizes as $HF \rightarrow H^+$ and F^- with dissociation constant $Ka = 7.2 \times 10^{-4}$ (CRC Handbook for Chemistry and Physics). The calculated HF concentration that would be present in the stomach if one were thirsty and drank significant volume of 1 ppm fluoride water without food may be calculated from the equilibrium expression:

$7.2 \times 10^{-4} = [H^+][F^-]/[HF]$ where $[F^-]$ is the molar concentration of free fluoride ion after combining with stomach acid H^+ and equals 5.2×10^{-5}M - X {which is 1 ppm in molarity units minus the unknown molarity X that forms HF).

Rearranging, $7.2 \times 10^{-4}X = [10^{-3}][5.2 \times 10^{-5} - X]$ and $0.00172X = 5.26 \times 10^{-8}$
Solving, $X = 3 \times 10^{-5}$ M HF in stomach acid, which is 0.6 ppm HF.

This calculated value is in good agreement with experimental observations with a fluoride ion specific electrode at pH 3 (Sauerheber, R., Chemical Analysis of Poisoning from a Fluoridated Water Supply, submitted for publication to J. Env. Health, 2011), where 1 ppm fluoride water is detected by the electrode at only approximately 0.6-0.7 ppm because the remaining fluoride is bound as HF at that acidity, which cannot be detected by the electrode (attached data). This level of HF is a significant concentration of this uncharged tissue-penetrating corrosive, even for acid-resistant stomach mucosa and explains the ready assimilation of fluoride into the bloodstream where it does not belong, from the gastrointestinal tract. Water treated with industrial synthetic fluoride must not be used in cases of gastric ulcer or other GI abnormality. Indeed 1% of all consumers feel gastric discomfort drinking 1 ppm fluoridated water in controlled volunteer human trials (NRC, 2006).

We now know that all synthetic fluorides are fully water soluble and form HF in the stomach that freely passes through biological membranes. Ingested fluoride without sufficient antidote dietary calcium crosses the blood brain

barrier and also enters the fetus from placental circulation. This has always been the case in man and animals, but only recently has the mechanism been unraveled by which the ionic charged fluoride can cross biological membranes. It does not itself cross the membrane freely, but the associated HF (in the stomach at 0.5 ppm, in blood at 0.01 ppb and inside cells at 0.04 ppb) is nearly identical in size to the water molecule and is also uncharged, freely permeable through the lipid bilayer as is water. The membrane acts like a permeable polymer to the ultra small sized water and HF molecules, even though these polar substances do not have a significant lipid partition coefficient. The bilayer presents a barrier to most charged ions. Fluoride ion then re-dissociates from HF after it passes through the membrane. The HF concentration my be computed with the Henderson Hasselbach equation, where $pH = pK_a + \log [F^-]/[HF]$. So $7.4 = -\log (7.2 \times 10^{-4}) + \log [1.1 \times 10^{-5}]/[HF]$. Solving, $[HF] = 6.1 \times 10^{-10}$ M = 10 ppt. HF however is essentially freely membrane permeable. At pH 8.2 as in the intestines, the HF concentration would be $8.2 = -\log(7.2 \times 10^{-4}) + \log[5.2 \times 10^{-5}]/[HF]$.]HF] = 0.009 ppb.

Fluoride and Hydrofluoric Acid Levels in Various Bodily Fluids

pH	F-	HF	Bodily Location
3	0.5 ppm	0.5 ppm	Stomach
6.9	.21 ppm	0.04 ppb	Intracellular Fluid
7.4	0.21 ppm	0.01 ppb	Blood/Extracellular Fluid
8.2	0.21 ppm	0.009 ppb	Intestine

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U.S. Food and Drug Administration
Centers for Drug Evaluation and Research
Rockville, MD 20857

Dear Reviewers,

Information is presented here in support of the 2007 petition FDA-2007-P-0346 (originally assigned 2007P-0400/CP1) and the Petition for Reconsideration submitted in 2010. I apologize for having submitted a fourth letter to the FDA in one week, but 140 million American citizens, who more often than not vote against ingesting fluorides that are not FDA approved, yet now consume daily public water supplies that are injected with diluted fluoride compounds obtained from industrial synthetic unnatural hazardous waste sources (see original petition). Although acute toxicity is normally minimized so as to be unnoticed, chronic toxicity from long term continuous consumption has been well-documented in previous submitted materials.

Industrial Synthetic Fluoride in Public Water Supplies Breaks Federal Law

The purposeful injection of synthetic industrial fluoride, an EPA-recognized water contaminant, into public water supplies, with the intent to treat bacterial-induced dental caries, violates the Safe Drinking Water Act, the Water Pollution Control Act, and the Food Drug and Cosmetic Act [1]. Previous information in great detail proves that ingested fluoride from water supplies cannot decrease dental caries at continuous topical 0.02 ppm in saliva or 1 ppm in water [2], and that systemic blood fluoride is useless for this purpose (see original petition). In support of these facts, this letter summarizes the mechanism by which Federal officials have escaped regulation by the above-listed Congressional Statutes.

Water Pollution Control Act (requested and initiated by the honorable President John Fitzgerald Kennedy).

The mission of the Water Pollution Control Act (section 101a) is to maintain the natural chemistry of U.S. waterways. Pristine fresh drinking water is devoid of fluoride. Purposeful addition of fluosilicic acid or sodium fluoride to elevate fluoride content in water has escaped Federal correction under this Act in part because proponents of ingested fluoride have argued that fluoride is added at a level no higher than what is present naturally in some waters in the U.S. The Act however does not distinguish that one natural water supply is deficient compared to another. Since most (not necessarily all) water is devoid of sodium, fluoride and silicates, the injection of sodium fluoride or fluosilicic acid, plus sodium hydroxide required to neutralize acidity, violates the above mission of the Act. Furthermore, fluoride in drinking water, regardless of source, is correctly officially listed as a contaminant by the U.S. EPA. By perpetrating the opinion as 'fact', that fluorides could be part of the natural chemistry of any or all drinking waters (which is false), fluoride injections *violate the WPCA without giving the appearance of such a violation of the Act.* This constitutes deceptive practice.

Federal Safe Drinking Water Act.

The Safe Drinking Water Act provides that no Federal standard that may require that any substance be added to drinking water other than that required to sanitize the water, and that States can be no less restrictive than the SDWA. Federal officials in the Oral Health Division office within the Centers for Disease Control haves stated in writing their desire that virtually all water in the U.S. be treated with fluoride compounds to 1 ppm. To avoid liability in this action, CDC officials ask the States to accept responsibility for the decision to add fluoride into water, which sidesteps the SDWA by attempting to make the final action a State or water district decision and not a Federal decision. Although one could mistakenly accept this assertion at face value, a rational person understands that the actual definition of the term 'require' includes 'request by authority' [3]. State, city and water district operators believe there is little higher authority on dental issues than the CDC, and they regard recommendations from the CDC regarding fluoridation as synonymous with issuance of a requirement. This is so, because of the implied authority of any recommendation from an authoritative Federal office. Since the SDWA prohibits any Federal requirement, industrial fluorides injected into public water supplies as presently orchestrated violates this Congressional legislation.

Although all liability is accepted by cities, rather than by the Federal CDC, city managers routinely inject synthetic fluorides only under the auspices of State Health Departments and, in the case of California, State regulations passed which are not in keeping with the intent of the original Congressional SDWA Statute. This fact has been verified in personal communications in writing from San Diego Mayor Jerry Sanders and from Los Angeles Metropolitan Water District President Jeffrey Kightlinger, and personal discussions with Jim Barrett, former Public Utilities Director, San Diego Water and Dale Mason, former Vallecitos Water District Board member, all who uniformly have stated that "California State law requires the injections" and that all questions of safety and effectiveness be answered by the California DPH. Sadly, DPH officials have routinely requested in turn, in writing, that all questions for proof of safety and effectiveness be directed to offices of the Federal CDC. In this way, the OHD achieves its objective, *in violation of the SDWA, while giving the appearance of not being in violation of the Act.* This is deceptive practice.

U.S. Food Drug and Cosmetic Act.

The Food Drug and Cosmetic Act specifically requires that any chemical substance proposed to be used to prevent or treat disease in humans must submit a new drug application for FDA approval. FDA also now has authority to require approval for substances that had been used for long periods before the Act was passed (Petition for Reconsideration, 2010). Further, treatment of disease in humans with any chemical substance approved by the FDA requires detailed dosage instructions, as have been written for sodium fluoride (see Luride letter sent to FDA, 11/22/11). The FDA correctly ruled in 1963 that fluorides added intentionally into water to treat dental caries would be an uncontrolled use of a drug where dosage cannot be controlled (see original Petition), and it is well accepted that blood fluoride levels coming from fluoride ingestion do not decrease caries and in fact can induce abnormal tooth fluorosis. Topical fluoride in the form of toothpaste and fluoride dental gels that contain high concentrations of fluoride does not alter teeth enamel but merely briefly coats it with re-soluble calcium fluoride globules (see original petition).

Neither the CDC nor the EPA assume liability or responsibility for fluoride injections into public water supplies [1]. A 1988 Federal Register article (submitted previously) states that EPA is terminating its water additive program in 1990 which it did. EPA Region 10 in a letter States, "EPA does not provide recommendations for the addition of any substance, including fluoride, to drinking water for preventive e health care purposes and is prohibited by SDWA from setting such requirements. So, neither the EPA nor the FDA have banned the injections, and the FDA has not requested NDA's or dosage instructions from water districts that disseminate fluoridation materials, nor from the manufacturers that supply them. In this manner it is made to appear that State Public Health Departments and water districts are not violating the FD&CA. In fact fluoridation materials—which meet the definition of drugs—are added to drinking water for the purpose of treating *without either a prescription or dosage instructions, in violation of the Act.* This is deceptive drug practice.

It is necessary to obtain from the FDA a new drug application NDA for any proposed anti-caries substance that contains hydrofluoric acid HF. Hydrogen fluoride HF is labeled as fluoride by the FDA CDER but, as pointed out in 21 CFR 310.545(a)(2) and (b), an NDA is required for any over the counter anti-caries product that includes HF as an active ingredient. This Federal regulation, considered a Federal law, should prevent most or all fluosilicic acid fluoridation chemicals, and fluoridated waters with these chemicals, from being approved as OTC drugs except with an NDA. This is because *HF is an active fluoride ingredient in fluosilicic acid preparations*, typically present in fluosilicic supplied to water districts at 1.0%, or 1 gram HF per 100 grams of solution (see Lucier chemical data sheet previously submitted). Further, in a previous letter it was made clear that all synthetic fluorides in drinking water convert about 50% into HF in the acidic stomach after swallowing. In the case of fluosilicic acid, material safety data sheets are mailed to water districts that list the 1% HF, but *the content is not revealed to the public*, by either the chemical supplier, or by the water district, or by the Public Health Departments that are under the authoritative recommendation from the OHD of the CDC. This is deceptive drug practice.

Fluosilicic Acid Spreads across the Golden State and from Sea to Shining Sea.

San Francisco, CA and our Nation's Capital, Washington, D.C. began artificial fluoride injections decades ago. The greater Los Angeles basin recently began in 2007. San Diego just began in 2011. Sacramento, the State Capital, began in 2008. San Jose citizens are soon to be forced to accept water treated with non-FDA-approved fluosilicic acid for 'prevention of caries' via systemic ingestion. San Diego had opposed the injections in two city elections. The FDA should be aware that there is a chief fluoridation engineer, a Federal employee, working at the CDC and identifying himself and that he provides information on synthetic fluoride injection techniques to water

districts. He apparently does not understand that any Federal requirement to treat U.S. citizens, particularly against their will, with substances for any disease violates the Safe Drinking Water Act. The SDWA applies broadly and covers the intentional injection of chemicals such as sodium fluoride and fluosilicic acid into water It applies to added foods or other materials that do not sanitize water, regardless of whether the agents are considered legal or illegal.

We humbly request that the FDA take a public stand on this issue, that it ban injections of fluoride into drinking water, and that it buffer that ban by providing information on oral synthetic fluorides, still widely available by prescription (Luride) for those who insist on systemic blood fluoride treatment through ingestion.

Permanent chemicalization of general public water supplies with chlorines sanitizes water to be bacteria free. Additional treatment of water with fluoridation materials which purportedly prevent bacterial-induced caries is mischief initiated and individuals, educational institutions and chemical companies which are misinformed or who are defending profitable vested interests.

Federal regulations mentioned in this letter, with verbatim wording, will be provided upon request if necessary. The intent of this letter is to clarify how injections of toxic waste fluoridation materials into U.S. public water supplies, allegedly to treat humans and done so without first obtaining their informed consent, and done so in spite of the discredited malpractice it represents [1], have escaped Federal regulation.

It is anticipated that these deceptive practices will one day end. A recent objective review conducted at the London School of Hygiene and Tropical Medicine, published by Taylor & Francis, concluded that water fluoridation is ineffective and harmful and recommended its discontinuation [4]. Personal thanks go to the honorable Dr. Albert W. Burgstahler, editor of **Fluoride** (U.S.), for providing that reference free of charge (frontispiece attached).

References:

[1] Connett, P., Beck, J., and Micklem, **The Case Against Fluoride, How Hazardous Waste ended up in our Drinking Water and the Bad Science and Powerful Politics that Keep it There**, Chelsea Green Publishing, White River Junction, Vermont, 2010.

[2] National Research Council, **Fluoride in Drinking Water, a Scientific Review of EPA's Standards**, Washington, D.C., 2006.

[3] **Webster's Ninth New Collegiate Dictionary**, Merriam-Webster, Inc., Springfield, MA, 1983.

[4] Peckham, Stephen, *Slaying sacred cows: is it time to pull the plug on water fluoridation?* **Critical Public Health**, November 15, 2011, pp. 1-19 DOI:10.1080/09581596.2011.596818
To link to this article: http://dx.doi.org/10.1080/09581596.2011.596818

The following material is excerpted from a recent letter written jointly by Dr. Johns, MD and Dr. Osmunson, DDS.

State Boards of Pharmacy confirmed fluoride for ingestion is a prescription drug. Pharmacists will not sell fluoride for ingestion without a prescription. The FDA CDER has confirmed fluoride is an unapproved drug and unapproved drugs are actually illegal.

EPA scientists through their Union say fluoridation boarders on a criminal act of governments. There is not one single prospective, double blind randomized controlled clinical trial for either the efficacy or safety of fluoridation of public water supplies in the treatment of dental caries. In fact, the massive data of Ziegelbecker (Connett, The Case Against Fluoride, 2010) statistically confirm beyond doubt that ingested fluoride does not reduce dental caries, and the NRC 2006 report indicates biochemically why this is so, where fluoride in saliva is only 0.02 ppm, unable to exert topical action on teeth.

Dental caries are not the result of inadequate fluoride ingestion, and infants on fluoride free mother's milk actually have lower dental caries. On the other side of the coin, tooth damage of dental fluorosis occurs while the teeth are developing under the gums. Fluorosis repairs can cost over $100,000 in life time expenses if one wants to re-attain a normal healthy appearing smile. Other adverse effects of long term fluoride incorporation into blood at 0.21 ppm are very well documented, where the normal structure and function of bone and brain are far more important than teeth.

Sincerely, David Johns MD, Mercer Island, WA and Bill Osmunson DDS, MPH, Bellevue, WA

Note from petitioner: Effective anti-caries practices have been confirmed in personal communications with Dr. Grant Layton DDS, Encinitas, CA and in particular the WWII Battle of the Bulge survivor Victor E. Sauerheber,

Veteran 101st Airborne, U.S. Army, among countless others. That is, daily direct application of moist baking soda (50 cents per month for a family) to teeth prevents caries by neutralizing acids produced by *Streptococcus mutans* that metabolize food residues in the oral cavity. This method supercedes the outdated false practice of contaminating massive volumes of public water supplies with fluosilicic acid, hauled in 20,000 gallon rail car or truck loads to cities, which costs over a billion dollars annually in the U.S. The injections also require expensive sophisticated electronic metering to help prevent acute poisoning [as has occurred on multiple occasions, including Hooper Bay, AK with loss of life (see opening information in original petition 2007), the subject of a research article currently under review submitted to Journal of Environmental Health, 2011] and also requires the addition of massive quantities of sodium hydroxide (Drano) to neutralize acidity in a treated city, but which does not prevent the formation of hydrofluoric acid in the acidic stomach by protonation of fluoride ion after swallowing (see previous letter on HF).

Critical Public Health
Slaying sacred cows: is it time to pull the plug on water fluoridation?

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Available online: 15 Nov 2011

(Received 19 March 2010; final version received 27 April 2011)

Water fluoridation continues to be a contentious public health policy. Recent moves to introduce schemes in England raise important questions about the use of evidence in public policy. Of particular concern is how evidence is used for public health policy-making purposes. This article reviews some of the key debates about water fluoridation and examines the way evidence has been promoted and used. The background to water fluoridation is discussed and also key ideas about how evidence influences policy. While traditionally the problem of evidence is characterized as one where policy makers either accept or ignore evidence, a central concern of this article is where poor evidence is promoted by professionals and accepted by policy makers. The article then examines the evidence on the effects of water fluoridation. Drawing on the idea of the 'Gold Effect', the article shows how deeply held beliefs about public health actions shape not just policy but also the application of evidence itself by professionals and researchers. Keywords: evidence; healthy public policy; population health; water fluoridation.

In his first major speech at the National Health Service (NHS) Confederation Conference in June 2009, the then United Kingdom (UK) Secretary of State for Health, Andy Burnham MP, argued that 'We've been too timid at times on the public health agenda. Let's press ahead with fluoridation of water supplies, given the clear evidence that it can improve children's dental health'. While a welcome emphasis on public health, the choice of water fluoridation as an example is of particular interest as despite the Department of Health's long-standing commitment to extending water fluoridation,1 there is no scientific consensus that water fluoridation is either safe or effective. Despite this uncertainty, the UK Government and the NHS in England, along with governments in Australia and the USA are committed to extending community water fluoridation. However, proposals for water fluoridation remain contentious and lead to strong opposition. This article explores why water fluoridation policy is controversial within the context of how evidence is used in public health policy making. This article reviews the evidence on water fluoridation and questions whether uncritical support for this

public health policy should be continued.

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Excerpted from this article:

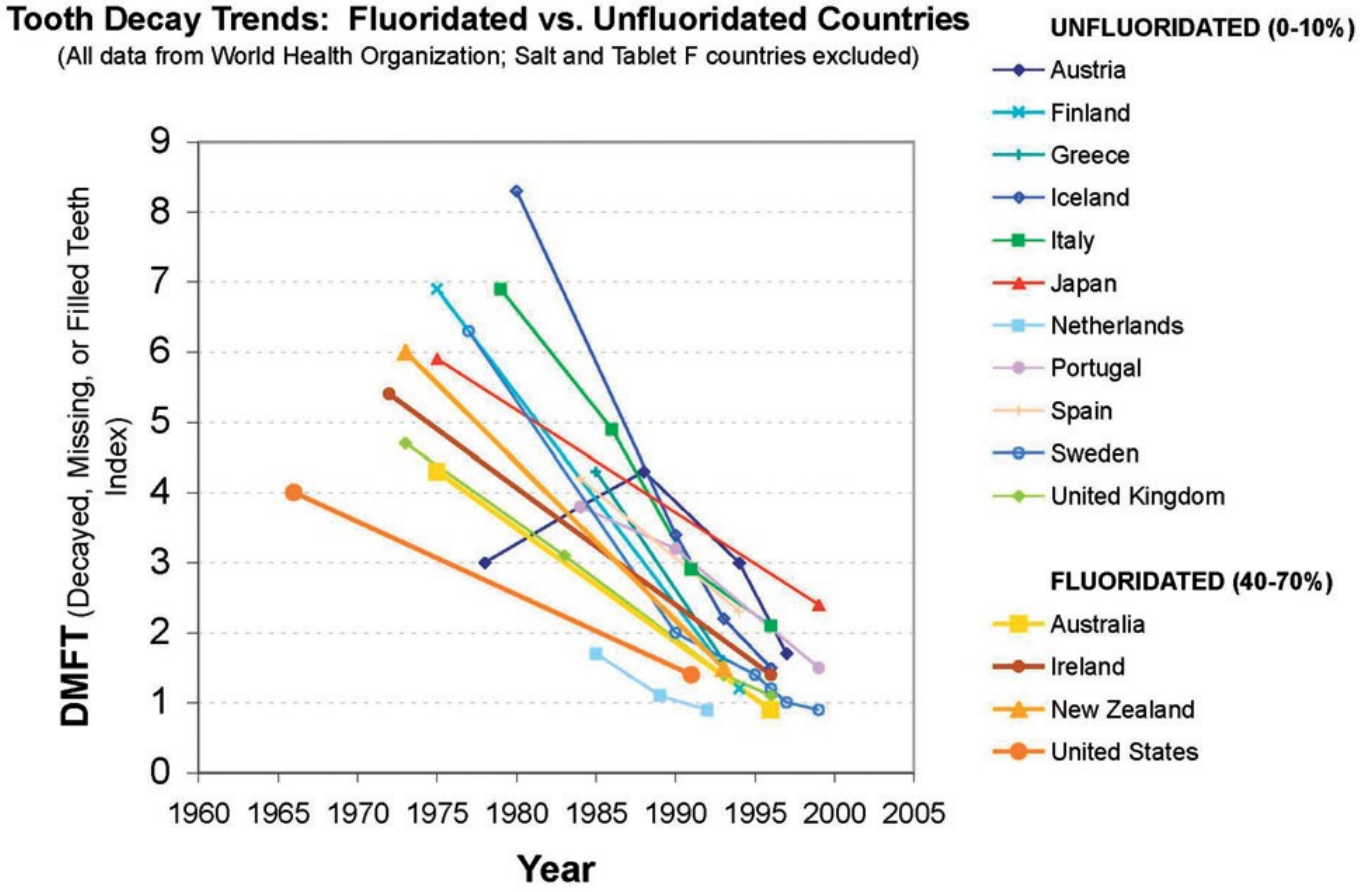

Figure 3. Comparison of decline in dental caries in fluoridated and non-fluoridated countries. Source: Neurath, C. (personal communication) amended from Neurath C., 2005. Tooth decay trends for 12 year olds in non-fluoridated and fluoridated countries. Fluoride, 38 (4), 324–325.

#6 **Richard D. Sauerheber, Ph.D.**
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November 25, 2011

U.S. Food and Drug Administration
Centers for Drug Evaluation and Research
Rockville, MD 20857

Dear FDA petition reviewers,

Any FDA petition, whether requesting a ban or regulation of a substance, requires that the petitioner explain significant opposing statements claimed by proponents for the use of the substance. To further address this need, the following material is submitted in support of the Petition for Reconsideration, 2010 and the original petition FDA-2007-P-0346 (originally assigned 2007P-0400/CP1). Deceptive statements on synthetic fluoride ingestion have been made by Federal dental officials within the U.S. Centers for Disease Control and Prevention. Scientists and other officials in the CDC appear uninvolved, inasmuch as all questions forwarded to CDC on fluorides in public water supplies are always deferred to the Oral Health Division, regardless of requests otherwise. Statements published by the OHD are henceforth referred to here as being from the CDC.

CDC claims fluoridation should be extended, awards those cities sustaining optimal levels, and trains city officials to fluoridate.

The U.S. Safe Drinking Water Act (SDWA) prohibits any national requirement for substances in drinking water other than required to sanitize the water. This legislative Congressional Statute prohibits the addition into public water of foods, natural or processed, supplements, natural or synthetic, minerals, natural or processed, or drugs, FDA approved or non FDA approved. Specifically, 42 U.S.C. §300g-1(b)(11) states

> "No national primary drinking water regulation may require the addition of any substance for preventative health care purposes unrelated to contamination of drinking water."

As published by Graham and Morin (Highlights in North American Litigation during the Twentieth Century of Artificial Fluoridation of Public Water Supplies, JOHN REMINGTON GRAHAM AND PIERRE MORIN) (http://www.keepersofthewell.org/Highlights_Litigation.pdf*), this provision was intended by Congress to prohibit the use of the Safe Drinking Water Act as a means of imposing artificial fluoridation of public water supplies throughout the United States.* Note that unscrupulous individuals have attempted to evade this Statute by inserting amendments providing for exceptions, to allow the intentional injection of synthetic industrial fluorides into public water supplies, but the original Congressionally approved Statute and its intent remain un-repealed at this time.

The current Federal CDC website on water fluoridation claims to follow the SDWA, while making statements that violate this national requirement clause by describing techniques and target water concentrations for cities to follow in order to fluoridate public water supplies, and by urging, in a Federal official capacity, that cities do so:

> "CDC has recognized water fluoridation as <u>one of 10 great public health achievements</u> of the 20th century. The CDC promotes effective public health practices, such as community water fluoridation. CDC considers comprehensive reviews by the NRC and other systematic scientific studies in its recommendation that community water fluoridation is a safe, effective, and inexpensive method to reduce tooth decay among populations with access to public water systems. *Water fluoridation should be continued in communities currently fluoridating and extended to those without fluoridation."*

<u>Awards for outstanding fluoridation efforts</u>

"CDC recognizes water systems that achieve optimal fluoridation levels for all 12 months each year with the annual Quality Award. Water systems that adjust the water fluoride level within the optimum range in a sustained manner are eligible for this award if their state documents the performance in the
CDC Water Fluoridation Reporting System."

<u>Water fluoridation training programs</u>

"CDC provides water fluoridation training designed to build the capability of state fluoridation programs and to help water treatment professionals develop and refine their skills related to operations. Courses include a 3-day annual training on the Principles and Practice of Water Fluoridation and a newly developed 6-hour water plant operator training course template designed for use by state fluoridation programs. More information on these training programs may be found at the CDC-sponsored training page."

CDC avoids liability and SDWA requirement clause, while requesting and regulating fluoridation.

To attempt to avoid responsibility and any liability for synthetic fluoride injections, and to claim the SDWA is not violated, the CDC fluoridation website makes the following statement:

> "It is not CDC's task to determine what levels of fluoride in water are safe."

This of course flatly contradicts their following statements:

> "CDC monitors the progress of the United States and individual states toward meeting the *Healthy People 2010* objective on community water fluoridation—that 75% of people on public water systems will receive water that has the optimum level of fluoride recommended for preventing tooth decay." And "My Water's Fluoride (MWF) helps consumers in participating states to learn basic information about their water system, including the number of people served by the system and the target fluoridation level. Engineering and Administrative Recommendations for Water Fluoridation, *MMWR*, September 29, 1995;44(RR–13):1–40 (PDF–338KB) provides specific recommendations for water fluoridation, including administration, monitoring and surveillance, technical requirements, and safety procedures for community public water supply systems. CDC provides technical assistance to state programs regarding engineering support, facility management, and operational support and also provides responses to public health-related questions on community water fluoridation."

In another attempt to avoid responsibility, the fluoridation site claims that the EPA is in charge of regulating water fluoridation:

> "Under SDWA, the U.S. Environmental Protection Agency (EPA) sets standards for drinking water quality and oversees the states, localities, and water suppliers that implement those standards."

It is well established that the EPA relinquished all regulatory control of water fluoridation in 1988, as published in the Code of Federal Regulations (see previous letter to FDA).

Federal Oral Health Division within CDC provides false information on fluoridation.

Information provided to the general public on fluoridation by dental officials within the CDC is false, as proven by the fact that serious adverse biologic effects such as allergy, lethal accidental overfeeds and huge levels of fluoride incorporated into bone (NRC, 2006) are dismissed from the entire fluoridation site. The only adverse effect that is acknowledged is tooth fluorosis, and CDC now pleads lack of understanding of this with the statement:

> "Recent studies have raised the possibility that mixing infant formula with fluoridated water, particularly for infants exclusively on a formula diet during the first year of life, may play a more important role in dental fluorosis development than was previously understood."

To further avoid responsibility for the current U.S. endemic of tooth fluorosis, discovered in 2004 to be at a massive 41% of all U.S. children aged 12-15, CDC provides contradictory, unintelligible information on fluoride consumption safety listed below. Here the confused CDC leaves the responsibility to parents and physicians, instead of the CDC itself who urges fluoride ingestion and argues regularly that it is "safe and natural" and a "great health achievement":

> "For children aged less than 6 years, the dentist, physician, or other health care provider should weigh the risk for tooth decay without fluoride supplements, the decay prevention offered by supplements, and the potential for dental fluorosis. Consideration of the child's other sources of fluoride, especially drinking water, is essential in determining this balance. Parents and caregivers should be informed of both the benefit of protection against tooth decay and the possibility of dental fluorosis. All fluoride supplements must be prescribed by a dentist or physician. The prescription should be consistent with the 2010 dosage schedule (PDF–756K) developed by the American Dental Association (ADA). Fluoride supplements can be prescribed for children at high risk for tooth

decay and whose primary drinking water has a low fluoride concentration."

What, pray tell, is a "low concentration" of fluoride in drinking water? Since fluoride must be given by prescription, why do CDC dental officials urge fluorides be added into drinking water, where dosage cannot be controlled? And how can any rational parent determine a dosage for a substance that could help, rather than harm, teeth, considering that CDC dental officials state elsewhere that fluoride in infant fluorosis is not understood?

The fluoridation site also argues that fluoride "strengthens bone", "decreases caries" and exerts "no adverse biologic effects on man or animals" as follows:

> "Scientists have found a lack of evidence to show an association between water fluoridation and a negative impact on people, plants, or animals."

Not addressed are the known adverse mental effects of fluoride [2] and the well documented fact that 1% of all humans are allergic to synthetic fluorides with severe rashes on bathing in 1 ppm synthetically fluoridated water and who can have severe painful face swelling and redness upon exposure to sodium fluoride in dental gels. Not mentioned are the findings of the U.S. FDA that fluoride in bone does not strengthen bone and that fluoride is not a mineral nutrient (see petition). Not mentioned is the well established fact that lifetime fluoride water consumption leads to massive unnatural fluoride levels in bone and that common levels of 3-4,000 mg/kg weakens bone, making bone more subject to fracture [3].

CDC claim disproven, that synthetic fluorides are identical to natural calcium fluoride.

It is true that anionic fluorine is the fluoride ion, whether found in solid form in natural minerals such as tourmaline aluminum fluoride and fluorite calcium fluoride, or rather in synthetic industrial compounds such as fluosilicic acid, sodium fluoride, arsenic fluoride, lead fluoride among others. The ion is identical in all substances in which it is found, even in bone hydroxyapatite and in blood where it does not belong naturally. Ionized fluoride, dis-attached from its mineral source, in the ocean at 1 ppm, surrounded by thousands of ppm calcium and magnesium, and ionized fluoride found in some waters in the Southwest detached from its mineral source at 1 ppm with several hundred ppm calcium and magnesium, is identical in form to industrial fluoride ion dissolved in pure water detached from its source compounds, including dissolved fluosilicic acid or sodium fluoride. The fluoridation website statement on this fact is accurate.

The gross deception however is in the remaining description that attempts to deceive the public into the thought that ionized fluoride from natural calcium fluoride behaves biologically and chemically no differently than ionized fluoride from industrial fluosilicic acid or sodium fluoride.

> "Three additives—sodium fluoride, sodium fluorosilicate, and fluorosilicic acid—may be used to adjust the natural fluoride levels in water to concentrations that prevent or control tooth decay."

Therein lies the mistake and the deception. The lethal acute dose in experimental animals for industrial fluorides without calcium caused all to be listed on poisons registries and use as insecticides and rodenticides with high intrinsic toxicity. This is due to the fact that the fluoride ion is soluble to an infinite degree from industrial compounds, but not from natural calcium fluoride, and that fluoride in the absence of calcium is assimilated well after ingestion. Calcium fluoride, with the same fluoride ion as for any compound with fluoride, has no acute intrinsic lethal toxicity because fluoride is not assimilated well into the bloodstream when accompanied with significant calcium ion. Calcium is the world-recognized antidote to poisoning from synthetic industrial fluorides, as occur in toothpastes, dental gels and drinking water. Deaths caused by soluble fluoride, that is well assimilated into the blood where it alters calcium metabolism and homeostasis, have never been found in the case of ingestion of calcium fluoride. For synthetic fluorides, children have had lethal heart attack after swallowing sodium fluoride in dental gels, and overfeeds in some cities have caused death from synthetic injected sodium fluoride that is fully water soluble, as in Hooper Bay, Alaska, and in kidney patients in Illinois and Maryland during overfeeds with synthetic industrial fluoride.

The claim that addition of synthetic fluosilicic acid or sodium fluoride to water duplicates natural calcium fluoride and thus that "fluoridation is natural", even from toxic hazardous diluted waste fluosilicic acid, is disproven by the fact that fluosilicic acid always contains appreciable hydrofluoric acid HF and always requires massive amounts of sodium hydroxide soda ash ('Drano') to neutralize acidity in the water. Sodium does not belong in fresh drinking water. Sodium reduces productivity of many crops.

The claim that industrial synthetic fluoride from unnatural compounds is identical to natural calcium fluoride fails to explain that synthetic fluoride biological effects are entirely dependent on the materials in the surrounding medium when ingested. Arsenic fluoride and fluosilicic acid and sodium fluoride have the exact same fluoride anion that calcium fluoride also contains, but the toxicity, whether acute lethal or chronic after long-term consumption, is widely different. Arsenic fluoride is more toxic than fluosilicic acid and sodium fluoride, which are both far more toxic than natural calcium fluoride, which is not a registered poison on any poisons registry. Calcium fluoride is water soluble to only 8 ppm maximum.

CDC explicitly exaggerates further by claiming that salmon are not harmed by 1 ppm fluoride naturally present in the ocean. This statement by itself is entirely accurate. Salmon are not adversely affected by 1 ppm fluoride ion in the ocean where calcium and magnesium are present at thousands of ppm levels as antidote. The CDC website however does not explain the entire picture. The salmon collapse in the 1970's on the Columbia River due to industrial synthetic fluoride emissions from an aluminum smelter into the fresh, calcium-deficient water at only 0.3 ppm fluoride narcotizes salmon brain and prevents navigation upstream to spawn. These data have been confirmed in prospective experiments at the University of Oregon and led the State of Oregon to pass legislation against any synthetic fluoride compounds from being injected into state water supplies. This is necessary to protect the salmon because indeed industrial fluorides in the absence of calcium allow substantial fluoride assimilation into an organism.

CDC claim, that ingested fluoride decreases caries, is explained.

The notion that swallowed fluoride decreases dental caries is a false correlation. Children in Deaf Smith County had whitish teeth with fewer cavities that were ascribed to the 1 ppm fluoride present in drinking water, without mention of the fact that the water contained 205 ppm calcium, in ionized form and as calcium bicarbonate and calcium carbonate, and also contained 123 ppm magnesium as the free ion or bicarbonate and sulfate for a total of 328 ppm divalent cation to minimize fluoride assimilation into the citizens living there. We all know the claims made in 1942 broadly published in public literature that those coming to Deaf Smith County would be assured of having cavities disappear and that babies born there had perfect white teeth with zero cavities. Hereford, Texas was referred to as the "town without a toothache" in Collier's Magazine, the Readers' Digest and also the Saturday Evening Post (A. W. Erickson, Field Notes Crop Reporting Service, Minneapolis, MN 1945, with quotes from dentist Dr. G.W. Heard).

The CDC does not acknowledge that 1 ppm fluoride in the water was accompanied with high levels of calcium, and that calcium builds strong teeth. Instead the OHD dental officials insist that the effect on teeth was due entirely to the 1 ppm fluoride alone and that all waters in the U.S. need to adjust their natural chemistry to 1 ppm synthetic fluoride, which is in violation of the Water Pollution Control Act, having the express mission that the chemistry of waters in the U.S. be maintained in their natural state.

Ironically, Dr. Heard, who first believed the false correlation, eventually after following children raised on the water concluded that fluoride incorporated into teeth dentyne make teeth interiors crumbly that required more costly dental procedures in those children in later years. Heard deplored the idea of using synthetic fluorides in public water supplies (see Buck, the Grim Truth About Fluoridation, 1965 in original petition) and wrote a detailed letter to that effect to the U.S. Public Health Service (see attached letter in original petition).

The Public Health Service believed Heard and others with the false correlation, but later did not believe Heard and others when refutations were written, likely because of ignorance, greed, stubbornness or other worse principle. The exhaustive data of Ziegelbecker [2], that eliminates false correlation due to 'cherrypicking' data, proves dramatically that ingested fluoride does not decrease cavities.

CDC promotes assimilation through ingestion of hydrofluoric acid HF.

Ingested fluoride in the stomach mostly becomes protonated at pH 3-4 to hydrofluoric acid HF (see graph in previous letter of pH dependence of ionic fluoride ppm level). It is the HF molecule that is assimilated through the cell membrane over 1,000 times more efficiently than is free ionic fluoride (Buzalaf and Whitford, 2011, see attached abstract). The fluoride ion, ionized as the free ion from synthetic sources in the absence of sufficient calcium, produces HF quantitatively in the stomach, which is assimilated well into the bloodstream. The fluoride then returns to the free fluoride ion again at blood pH of 7.4.

The Food Drug &Cosmetic Act requires that any substance used as an anti-caries treatment that contains HF must require a new drug application NDA. The Code of Federal Regulations specifically prohibits the marketing, interstate transport, or ingestion of any anti-caries agent that contains HF without a NDA [21 CFR31O.545(a)(2) and (b).]

The CDC does not seem to notice that the FD&CA is violated with any industrial fluoride compound added into water to treat caries, not simply because all fluosilicic acid preparations contain appreciable HF (to 10 grams per Liter), but also because all synthetic fluorides produce HF in the stomach anyway. This is the mechanism by which gastrointestinal distress is associated with all synthetic fluoride overfeeds; here the HF irritation of the stomach is painful.

Even at 1 ppm fluoride in water, 1% of all consumers have stomach irritation after drinking [3]. And there are 1% on average of people in a population who are allergic to the free ion from unnatural synthetic sources without calcium. Dental gels applied to teeth, even in the absence of intentional swallowing in adults, cause severe swelling and rash and redness on the face in those allergic to synthetic fluoride (personal communication). Since fluoride tends to associate with calcium ions in solution, calcium fluoride is not a known allergen, and the presence of calcium in the GI tract minimizes fluoride assimilation as stated earlier.

CDC recommends various synthetic fluorides with dosage instructions contradictory to FDA.

The current CDC public website provides information on other sources of fluoride treatments with recommended dosage instructions, which often contradict FDA dosages, all of which is contrary to the mission of the Federal CDC, which is not to provide information on supplements or minerals for consumption or other uses, but is to monitor and protect citizens from serious lethal contagious disease.

> CDC writes: "Concentrations of fluoride in toothpaste sold in the United States range from 1,000–1,500 ppm. Over-the-counter solutions of 0.05% sodium fluoride (230 ppm fluoride) for daily rinsing are available for use by persons older than 6 years of age. Solutions of 0.20% sodium fluoride (920 ppm fluoride) are used in supervised, school-based weekly rinsing programs. Fluoride gel is often formulated to be highly acidic (pH of approximately 3.0). Products available in the United States include gel of acidulated phosphate fluoride (1.23% [12,300 ppm] fluoride), gel or foam of sodium fluoride (0.9% [9,040 ppm] fluoride), and self-applied (i.e., home use) gel of sodium fluoride (0.5% [5,000 ppm] fluoride) or stannous fluoride (0.15% [1,000 ppm] fluoride). Varnishes are available as sodium fluoride (2.26% [22,600 ppm] fluoride) or difluorsilane (0.1% [1,000 ppm] fluoride) preparations. Proper application technique reduces the possibility that a patient will swallow varnish during its application and limits the total amount of fluoride swallowed as the varnish wears off the teeth over several hours, although it is <u>not currently cleared for marketing by the Food and Drug Administration (FDA) as an anti-caries agent</u>."

The reference below indicates that fluoride assimilation into blood differs for various brands of fluoride dental gels. Providing dosage instructions to citizens for something as minor as tooth decay is not in keeping with the original mission of the CDC, but is within the purview of the FDA.

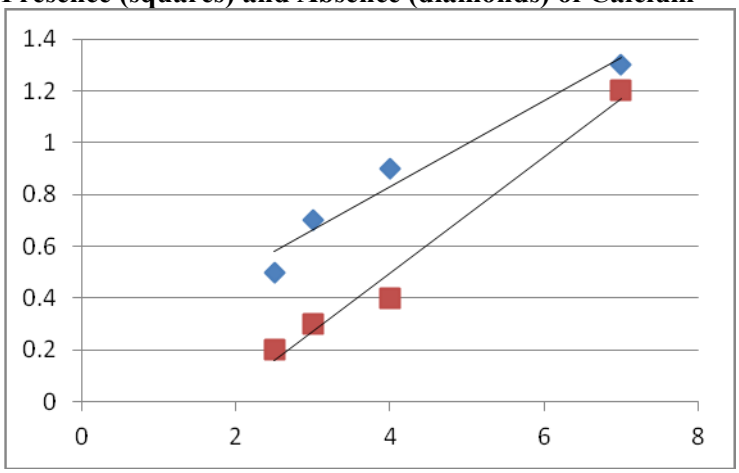
Summary.

It is clear that Federal dental officials in the Oral Health Division offices within the U.S. Centers for Disease Control and Prevention are not acting in good faith to honor the U.S. Safe Drinking Water Act that all Americans are to follow. Federal officials who openly promote, train and award State Health Departments and cities for the addition of synthetic industrial fluorides into public human drinking water supplies to treat or prevent disease, from a Federal authority, is equivalent to a national requirement, expressly forbidden by the U.S. Safe Drinking Water Act. Statements that the SDWA is being followed constitute deceptive practice.

The U.S. FDA has been here petitioned to ban fluosilicic acid and/or sodium fluoride injections into U.S. public water supplies--or in lieu of a ban to request data providing human controlled clinical trials proving safety and effectiveness for long term consumption of these materials and to prevent nevertheless their use in public water supplies where dosage cannot be regulated. Statements that Luride or any prescription fluoride must be discontinued in any city that adds synthetic fluoride, which is the current instruction to physicians who still prescribe oral Luride (Physician's Desk Reference), and statements that infants must not be given fluoridated water are minimal essential requirements.

As the truth is marching on, may you all at the FDA have a very Merry Christmas,

Fluoride Ion Concentration (ppm) as a function of pH, in the Presence (squares) and Absence (diamonds) of Calcium



This graph demonstrates the effect of acidity on the free fluoride ion level measured with an ion specific electrode that cannot sense either HF or calcium fluoride. A sodium fluoride solution in distilled water, initially at pH 7 was divided into two samples. The first sample represented by the diamonds was measured for free fluoride ion as a function of changes in pH from 7 to 2.5 in the absence of calcium ion. The squares are the fluoride ion readings of the second sample as a function of changes in pH after addition of 120 ppm calcium and 20 ppm magnesium as phosphates. There is no doubt that the progressively decreasing free fluoride ion levels occurring in the absence of calcium are caused by protonation of the fluoride ion to form HF, where $F^- + H^+ \rightarrow HF$ as the acidity increases and pH decreases. At stomach pH of 3-4, the level of free fluoride ion at 0.6-0.7 ppm indicates that about 0.6 ppm HF is present in this solution. This is the mechanism by which synthetic fluorides in the absence of calcium are efficiently assimilated in the stomach from the uncharged small HF molecule that penetrates cell membranes 1,000 times more efficiently than does the free fluoride ion [1]. These experimental observations are fully consistent with chemical calculations of the HF concentration that would form from sodium fluoride in distilled water in the absence of calcium at gastric pH determined mathematically from the known dissociation constant for HF (see previous letter to FDA).

Although fluoride does not combine with phosphate, calcium or magnesium at these cation physiologic concentrations, notice that fluoride ion concentrations are lower in the calcium solution at all pH values. Calcium prevents the assimilation of fluoride from the gastrointestinal tract into the bloodstream, and these data may indicate one possible reason. The levels of free fluoride ion are lower in the presence of calcium and magnesium, independent of pH, because the activity of the free fluoride ion is reduced by the presence of these divalent cations (Moore, **Physical Chemistry**, 1963). Not only does this impair the fluoride electrode from detecting the free fluoride ion, but also this is the likely explanation for how calcium minimizes fluoride assimilation into the bloodstream after ingestion. The drastically lower free fluoride ion readings at acidic pH in the presence of calcium and magnesium are due in part to formation of HF but also are due to decreased activity of the fluoride ion caused by these cations, where at lower pH the calcium and magnesium phosphates are expected to be fully ionized, which would then interfere more dramatically with fluoride mobility in solution.

As is evident, the interaction of fluoride ion with various foodstuffs during ingestion are complex and are likely to be responsible for the variable effects on those consuming fluoridated water. For example, although tooth fluorosis is increased without exception in any fluoridated city, nevertheless not all children succumb to this permanent adulterated abnormal enamel that produces its unsightly smile [2]. Such differences may be due to variation in diet, as much as to variation in overall fluoride uptake. The fact that the toxicology of the free fluoride ion is dependent on the chemical makeup of its surroundings is well known. Fluoride at 1 ppm in ocean water, accompanied with thousands of ppm calcium that prevents assimilation, does not affect salmon, while only 0.3 ppm fluoride in water devoid of calcium causes narcotic effects on salmon brain.

Regulation of dosage is impossible with fluoride in water, not only because water consumption is variable depending on physical activity, but also because foods alter the extent of assimilation of the agent as shown here.

Ingestion of synthetic fluoride without calcium has been legalized in the past by prescription, with accompanying dosage instructions to not be used in a fluoride-treated city. However, all synthetic fluorides quantitatively form hydrofluoric acid HF in the stomach, so Federal recommendations to permanently fluoridate consumers through drinking water to treat/prevent bacteria-induced dental caries, without a prescription, dosage instructions, or consultation with individual consumers, is not only unconscionable, but remains entirely illegal.

References:

[1] Buzalaf, MA; Whitford, GM, *Fluoride metabolism*, **Monographs in oral science** 2011;22:20-36.

[2] Connett, Micklem and Beck, **The Case Against Fluoride**, Chelsea Green Publishing, White River Junction, Vermont, 2010.

[3] National Research Council, **Fluoride in Drinking Water, a Scientific Review of EPA's Standards**, Washington, D.C., 2006.

Abstracts of references cited in the letter:

Buzalaf, MA; Whitford, GM, *Fluoride metabolism*, **Monographs in oral science** 2011;22:20-36.

Knowledge of all aspects of fluoride metabolism is essential for comprehending the biological effects of this ion in humans as well as to drive the prevention (and treatment) of fluoride toxicity. Several aspects of fluoride metabolism - including gastric absorption, distribution and renal excretion - are pH-dependent because the coefficient of permeability of lipid bilayer membranes to hydrogen fluoride (HF) is 1 million times higher than that of F-. This means that fluoride readily crosses cell membranes as HF, in response to a pH gradient between adjacent body fluid compartments. After ingestion, plasma fluoride levels increase rapidly due to the rapid absorption from the stomach, an event that is pH-dependent and distinguishes fluoride from other halogens and most other substances. The majority of fluoride not absorbed from the stomach will be absorbed from the small intestine. In this case, absorption is not pH-dependent. Fluoride not absorbed will be excreted in feces. Peak plasma fluoride concentrations are reached within 20-60 min following ingestion. The levels start declining thereafter due to two main reasons: uptake in calcified tissues and excretion in urine. Plasma fluoride levels are not homeostatically regulated and vary according to the levels of intake, deposition in hard tissues and excretion of fluoride. Many factors can modify the metabolism and effects of fluoride in the organism, such as chronic and acute acid-base disturbances, hematocrit, altitude, physical activity, circadian rhythm and hormones, nutritional status, diet, and genetic predisposition. These will be discussed in detail in this review.

Whitford, GM, *Acute toxicity of ingested fluoride*, **Monographs in oral science** 2011;22:66-80.

This chapter discusses the characteristics and treatment of acute fluoride toxicity as well as the most common sources of overexposure, the doses that cause acute toxicity, and factors that can influence the clinical outcome. Cases of serious systemic toxicity and fatalities due to acute exposures are now rare, but overexposures causing toxic signs and symptoms are not. The clinical course of systemic toxicity from ingested fluoride begins with gastric signs and symptoms, and can develop with alarming rapidity. Treatment involves minimizing absorption by administering a solution containing calcium, monitoring and managing plasma calcium and potassium concentrations, acid-base status, and supporting vital functions. Approximately 30,000 calls to US poison control centers concerning acute exposures in children are made each year, most of which involve temporary gastrointestinal effects, but others require medical treatment. The most common sources of acute overexposures today are dental products - particularly dentifrices because of their relatively high fluoride concentrations, pleasant flavors, and their presence in non-secure locations in most homes. For example, ingestion of only 1.8 ounces of a standard fluoridated dentifrice (900-1,100 mg/kg) by a 10-kg child delivers enough fluoride to reach the 'probably toxic dose' (5 mg/kg body weight). Factors that may influence the clinical course of an overexposure include the chemical compound (e.g. NaF, MFP, etc.), the age and acid-base status of the individual, and the elapsed time between exposure and the initiation of treatment. While fluoride has well-established beneficial dental effects and cases of serious toxicity are now rare, the potential for toxicity requires that fluoride-containing materials be handled and stored with the respect they deserve.

Kobayashi, CA; Belini, MR; Italiani, Fde M; Pauleto, AR; Araújo, JJ; Tessarolli, V; Grizzo, LT; Pessan, JP; Machado, MA; Buzalaf, MA, *Factors influencing fluoride ingestion from dentifrice by children*, **Community dentistry and oral epidemiology** 2011;39(5):426-32.

OBJECTIVE: This study assessed the percentage of the amount of dentifrice loaded onto the toothbrush that is ingested by children, taking into account age, the amount of dentifrice used during toothbrushing, and the dentifrice flavor. METHODS: The sample consisted of 155 children of both genders attending public kindergartens and schools in Bauru, Brazil, divided into 5 groups (n = 30-32) of children aged 2, 3, 4, 5 and 6 years old. The dentifrices used were Sorriso™ (1219 ppm F, peppermint-flavored) and Tandy™ (959 ppm F, tutti-frutti-flavored). The assessment of fluoride intake from dentifrices was carried out six times for each child, using 0.3, 0.6, and 1.2 g of each dentifrice, following a random, crossover distribution. Brushing was performed by the children or their parents/caregivers according to the home habits and under the observation of the examiner. Fluoride present in the expectorant and on toothbrush was analyzed with an ion-specific electrode after HMDS-facilitated diffusion. Fluoride ingestion was indirectly derived. Results were analyzed by 3-way repeated-measures anova and Tukey's tests ($P < 0.05$) using the percent dentifrice ingested as response variable. RESULTS: Age and percent dentifrice ingested for both dentifrices, and the three amounts used were inversely related ($P < 0.0001$). Percent dentifrice ingested was significantly higher after the use of Tandy™ under all conditions of the study when compared with Sorriso™ ($P < 0.0001$). Significant differences were observed when brushing with 0.3 g when compared with 1.2 g, for both dentifrices tested ($P < 0.05$). CONCLUSIONS: The results indicate that all variables tested must be considered in preventive measures aiming to reduce the amount of fluoride ingested by young children.

* The pharmacokinetics of ingested fluoride was studied by a 2008 study (G.M. Whitford, F.C. Sampaio, C.S. Pinto, A.G. Maria, V.E.S. Cardoso, M.A.R. Buzalaf, Pharmacokinetics of ingested fluoride: Lack of effect of chemical compound, Archives of Oral Biology, 53 (2008) 1037–1041).

Acknowledgments: I am grateful for those kind individuals, especially my students at Palomar College, who have contributed to this series of letters submitted to the FDA. Letter #1 on EPA retraction of the 1979 MOU, letter #2 on the dosage instructions for Luride by prescription only, letter #3 on the extent of conversion of fluoride to HF and the Federal regulations on HF use as an anti-caries agent, letter #4 summarizing violations of the SDWA, the WPCA and the FD&CA, and letter #5 on deceptive practices by the OHD of the CDC on the contaminant fluoride used as though it has Federal approval in public water supplies. My students understand fluoride chemistry well and the Congressional Statutes that protect public water supplies from its intentional injection or its accidental spillage, but do not understand failure to enforce these Statutes.

#7

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December 3, 2011

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Rockville, MD 20857

Dear Reviewer,

The following information is provided in support of the petition sent to the FDA in 2007, FDA 2007-P-0346 (formerly 2007P-0400/CP1) and its Petition for Reconsideration submitted 2011.

I was asked by a legal group to provide information that would clarify questions regarding the chemistry of the fluosilicic acid that is used to influence teeth through ingestion in public water supplies. The information had to be presented in the form of a numbered paragraph legal affidavit, following their required format for litigation. A copy of this affidavit, that is strictly confidential for FDA use only, is enclosed. It specifically clarifies the unusual chemistry of this synthetic fluoride compound and its associated hydrofluoric acid HF, from which fluosilicic acid is synthesized in industry.

A related letter sent earlier (11/11/2011) to the FDA presented chemical calculations of the HF content in fluoridation materials and in the stomach after ingestion, along with a copy of the CFR regulations indicating that any substance proposed to be used as an anti-caries agent containing HF requires a new drug application to the FDA.

No one in the U.S. has the right to adulterate natural water supplies with the intent to treat humans. And yet humans are being so treated, even though one of the foremost texts to advance this policy written by 5 dentists (Newbrun, E., **Fluorides and Dental Caries**, Thomas Books, Springfield, ILL, 1972) admits glaring adversity associated with the practice. For example, fluoride allergy in anyone should prevent water fluoridation on a mass scale to prevent such harm, as described extensively by Waldbott in several texts (see peitition). Newbrun attempts to discount fluoride allergy but admits that the association of fluoride with albumin (a known mechanism by which small molecules can become large enough to trigger immune reactions) is cause for 'further exploration', all while presenting 170 pages of text to convince the country to fluoridate public water supplies anyway (p. 154). The text also admits that kidney patients accumulate bone fluoride to much higher levels, and no investigation at all was made on the brain effects from the consumption of fluoride in public water supplies that has now been documented in 30 scientific publications (Connett, et.al. **The Case Against Fluoride,** 2010). The CDC admits infants should not use fluoride water because the risk of permanent abnormal enamel fluorosis is too significant. Newbrun admits fluoride at blood levels of 0.2 ppm inhibit sensitive metabolic enzymes. But rather than discussing the pathologic impact of this *in vivo*, the text turns the long discussion into how this might be beneficial as an antimicrobial.

We must all ask, who in our free country has the right to prevent access to regular public water, without added artificial perturbants documented to adversely affect many classes of people, including the infirmed, infants, and the elderly? And to also expect people in our strained economy to pay into the billions spent yearly to implement that treatment?

Affidavit enclosed.

I, **Dr. Richard D. Sauerheber**,
home address *1826 Redwing St., San Marcos, CA 92078*
solidly and sincerely affirm and declare in this affidavit on this date November 30, 2011, that:

1. I am a graduate of the University of California, San Diego with a Bachelor of Arts degree in Biology (1971), a graduate of the Department of Chemistry at the University of California, San Diego (1976) and hold a Doctorate in Chemistry, studying biochemistry and inorganic chemistry with emphases at the UCSD School of Medicine in physiology, pathology, cardiovascular science, neurochemistry, histology and pharmacology. My thesis research, under the supervision of the honorable diabetologist Dr. Arne N. Wick (Scripps Clinic, La Jolla, CA) and world

class insulin researcher Dr. Otto Walaas (University of Oslo, Oslo, Norway) led to published articles on diabetes mellitus, insulin action and the physical biochemistry of cell surface membranes and their interactions with calcium and magnesium.

2. I am of legal age and competent to testify.

3. As a Christian and citizen of the United States of America, I have the authority to make the following statements and declarations voluntarily that have been asked of me.

4. I have no commercial affiliations.

5. I completed a postdoctoral research fellowship at Scripps Clinic, La Jolla, CA (1976-1980).

6. As a Federal National Institutes of Health research grant principal investigator I supervised laboratory medical research studies at the Rees Stealy Clinical Research Foundation, San Diego, CA for one decade (1981-1991).

7. As a California Community Colleges lifetime teaching credential holder in the Life Sciences I have since 1991 been an educator in Chemistry, Physics, Biology, and Mathematics.

8. I have approximately 30 research articles published in scientific journals, including the **Journal of Biological Chemistry, Biochemistry, Science**, and **Current Therapeutics**.

9. I co-authored a review article on the role of divalent cations in the structure and function of biological membranes, published by Taylor & Francis, London in the prestigious CRC Press reference book series, **The Role of Calcium in Biological Systems**.

10. I received laboratory training at the Scripps Institution of Oceanography, UCSD, from the world re-known Dr. Andrew A. Benson of the Calvin-Benson cycle in plant photosynthesis. Not as widely known for his expertise in fluorine chemistry, Benson received his Ph.D. in 1940 from the University of California, Berkeley on the synthesis of fluoride derivatives of thyroid hormone. I currently meet regularly with Benson who at age 94 still runs a laboratory at the SIO.

11. I wrote textbooks entitled **The Calculus, Biology Introduction, The Nature of Light, the Truth Behind Relativity,** and **The Toxicity of Fluoridated Water**. I co-authored with my Pearl Harbor survivor father **Pearl Harbor, December 7th and 8th**. Each of these texts have been accepted for copyright by the Library of Congress, Washington, D.C. (www.lulu.com.)

12. I completed a chemical analysis of the Hooper Bay fluoridated water poisoning disaster, and this article has been published at www.nofluoride.com. A more extensive version is a submitted manuscript now under review at the Journal of Environmental Health.

13. I submitted a petition to ban the un-natural injection of synthetic industrial fluoride diluted fluosilicic acid hazardous waste into public water supplies in the United States. The petition was formally accepted for review by the U.S. Food and Drug Administration in 2007 (FDA2007-P-0346) and remains under consideration.

14. I had the honor of being interviewed, on three separate occasions by Dr. Stanley Monteith, orthopedic surgeon and now National radio broadcaster at www.radioliberty.com, on various aspects of the toxicology of fluoride-treated public water.

15. I am a voluntary science advisor for Washington Action for Safe Water (www.wasw.org) and for San Diegans for Safe Drinking Water (www.sdsdw.org).

16. I support clean water management practices and recognize the sanctity of U.S. waterways. I honor the mission of the U.S. Water Pollution Control Act as originally conceived by President John F. Kennedy, with the stated goal of maintaining the natural chemistry of U.S. public water supplies.

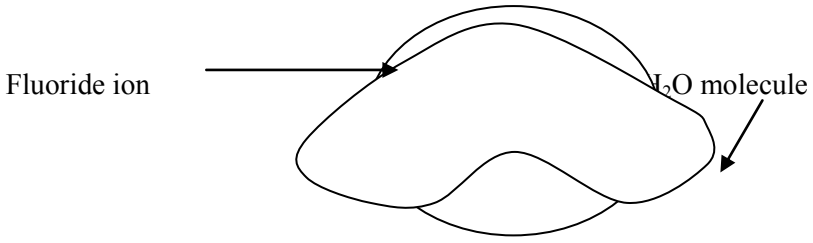
17. I honor the original mission of the U.S. Safe Drinking Water Act and the chemical meaning of its Federal requirement clause designed to prohibit the injection of any substance into water other than necessary to sanitize water.

18. Fluoride chemistry is introduced here, along with an overview of evidence that demonstrates that fluoride ion does not belong in the bloodstream or tissues of man or animal. Central is the observation that pristine fresh drinking waters, naturally formed from ocean evaporates by the sun as the essential feature of the world's hydrologic cycle (Created to provide the world's drinking water for man and animals), contain no fluoride. Moreover, several laboratories confirm this, using well controlled caged research animals raised for generations on zero fluoride water and food and proved that fluoride ion is not a mineral nutrient, as correctly decreed by the U.S. FDA in 1963 [1], and as reviewed in 1986 [1a].

19. Anionic fluorine, the fluoride ion, belongs and is present naturally in selected minerals on land [2], and as the free ion at 1 ppm in salt water of the world's oceans where it is accompanied with thousands of ppm calcium and magnesium that prevent toxicity intrinsic to the ion. Salmon for example are acutely sensitive to, and narcotized by, dilute fluoride in fresh soft river water, but are not affected by fluoride in saline ocean water [2a].

20. It is widely known that fluorine F_2 is the most electron–withdrawing of all elements on earth and thus does not exist in nature [3]. On the contrary, not widely understood is the fact that anionic fluorine, the fluoride ion F^-, has no electronegativity and in fact is electropositive, where fluoride naturally binds electrostatically to positive ions, most commonly to calcium ion in nature. Fluorine oxidizes virtually every chemical substance (listed as the most extreme oxidizing agent in all oxidation/reduction tables), but is reduced by nothing. Fluoride however can neither be oxidized (to fluorine) nor reduced (further than F^-) by any known substance and is thus indestructible, a permanent resident on earth. (For an introduction to the chemistry of fluoride one may consult the Agency for Toxic Substances and Disease Registry, 2003) [2] and for an introduction to the chemistry of fluorine, consult the CRC Press Handbook of Physics and Chemistry [3].

21. Fluoride ion is a sphere with a 267 picometer material diameter, comparable in size to a water molecule with length 275 and width 260 picometers (pictorially represented below).



22.Reaction of fluoride containing minerals, also containing silicates, with the strong acid sulfuric acid H_2SO_4 produces synthetic substances, silicon tetrafluoride SiF_4 and the toxic corrosive hydrofluoric acid HF. In acidic water these combine to quantitatively form inorganic fluosilicic acid*, H_2SiF_6. This molecule only exists when in water at low pH, because as a complex of HF with SiF_4, when water is evaporated, the molecule quickly returns to SiF_4 + 2 HF [3,4], and it ionizes at neutral pH. H_2SiF_6 cannot be stored in glass due to the constant presence of finite amounts of HF which etches glass, or in concrete which is also destroyed by HF, so water districts typically hold the substance in large rubber-lined steel or iron tanks. Large tanks of sodium hydroxide (Drano) are also on-site for neutralization of the treated water.

23. Fluosilicic acid is a recognized toxic industrial synthetic compound that does not exist in nature. The molecule must not be labeled simply as 'fluoride', but does contain the fluoride F^- ion within it. This is true for all fluoride compounds, including sodium, aluminum, calcium, stannous, and arsenic fluorides. Only natural calcium fluoride CaF_2 has such low intrinsic toxicity that it is not a recognized acute toxic compound (lethal 50% single dose LD_{50} > 3,500-5,000 mg/kg); all other fluoride compounds are artificial synthetics of industrial importance and ARE listed toxics ($LD_{50} \approx 125$ mg/kg) [4], comparable to the known acute toxicity that is intrinsic to arsenic and lead.

24. Solubility calculations mathematically demonstrate that calcium fluoride is soluble in pure water to 8 ppm fluoride maximum at 25°C with calcium also at 8 ppm (K_{sp} for $CaF_2 = 2 \times 10^{-11}$) [3]. This finite solubility is the mechanism by which calcium interferes with fluoride poisoning in acute toxicity studies in animals, and why calcium is the recognized antidote to fluoride poisoning from ingestion. The presence of calcium ion minimizes the assimilation of ingested fluoride during residence time in the GI tract. The synthetic compounds fluosilicic acid and sodium fluoride however are fully water soluble (to 6,700 ppm and 40,000 ppm respectively) [3], and a lethal fluoride concentration in blood may be achieved experimentally as above, or accidentally after oral ingestion of these compounds in man and animals [4].

25. Acute lethal poisoning with synthetic fluorides, all lacking calcium, is typically reported to occur at a blood and tissue concentration of 5 ppm [5] (whether by ingestion of 120 mg per kg synthetic fluoride without antidote calcium, or would occur by direct injection into the bloodstream at 5 ppm fluoride). This observation is *remarkably consistent* with solubility calculations for the concentration of fluoride that would precipitate calcium to 1 mM, a calcium level known to interfere dramatically with normal heart function. The concentration of fluoride that would coexist with 1 mM calcium ion is indeed $[F^-] = \{K_{sp}/[Ca^{2+}]\}^{1/2} = \{2 \times 10^{-11}/(0.001\ M)\}^{1/2} = 2.6 \times 10^{-4}$ M or 5 ppm fluoride ion. This chemically verifies the lethal mechanism by which fluoride from synthetic compounds can poison, due to hypocalcemia-induced heart attack, in its use as a rodenticide and also in accidental lethal human poisoning as in the infamous fluoridated public water overfeed disaster in Hooper Bay, Alaska in 1994 [6,7,8].

26. Fluosilicic acid dissociates in water above pH 2-3 to form hydrofluoric acid (HF), silicic acid hydrate ($H_2SiO_3H_2O$), fluoride ion and various silicofluorides (i.e. SiF_6^{-2}, etc.) in proportions depending on water acidity. Acidic conditions cause hydrofluoric acid and silicofluorides to predominate. Since HF is an extreme corrosive that dissolves many metals and frosts glass, to avoid damaging water district plumbing valves, and to avoid acidifying drinking water, fluosilicic acid is mixed with caustic soda sodium hydroxide (NaOH) or soda ash, the active ingredient in Drano drain cleaner.

The dissociation reaction when injected into neutralized water described by the National Research Council [9] is:

$$H_2SiF_6 + 4\ NaOH \rightarrow 2HF + Si(OH)_4 + 4F^- + 4Na^+ + heat$$

fluosilicic acid caustic soda hydrofluoric acid silicic acid hydrate fluoride sodium

27. In most all cases of public water supply fluoride treatment, sufficient sodium hydroxide is added to form a basic pH solution, and since the dissociation constant for HF is moderate at 7.2×10^{-4} [3] the free fluoride ion predominates and is titrated electronically to 1 ppm, while silicic acid with a small dissociation constant 1×10^{-10} [3] remains as the intact acid. The balanced reaction, with final concentrations used after dilution, may then be written:

$$H_2SiF_6 + 6\ NaOH \rightarrow H_2SiO_3 + 6F^- + 6Na^+ + 3H_2O + heat$$

(0.6 ppm) (1.0 ppm) (0.9 ppm)

Thus for every say 30 tons of 'fluoridation' chemicals employed, about 50 tons each of silicic acid, fluoride ion, and sodium ion are injected into the public water supply. Natural calcium fluoride addition into water, at one time a suggested source for water fluoridation by the CDC, does not require neutralization with sodium hydroxide.

28. The chemistry entirely changes abruptly after ingestion, as fluoridation materials arrive in the acidic stomach. Fluoride plus silicic acid in part re-form silicofluorides, and also unfortunately fluoride plus hydrogen ions (H^+), from gastric strong hydrochloric acid HCl, form hydrofluoric acid HF. Although F^- at 1 ppm in neutral water forms HF at approximately 10 ppb = 0.01 ppm, in the stomach the concentration of HF corrosive is far higher. Theoretical mathematical calculations agree precisely with direct experimental measurements. The HF concentration that would occur in the acidic stomach at pH 3, computed from $[HF] = [H^+][F^-]/K_a = (1 \times 10^{-3}\ M\ H^+)(0.001\ ppm/19\ grams/mole\ F^-)/(7.2 \times 10^{-4}) = 3 \times 10^{-5}$ M or 0.6 ppm HF. Measurements made with an electronic readout ion specific fluoride electrode (La Motte Industries, MD), that cannot detect complexed fluorides, only the free fluoride ion, have been submitted to the U.S. FDA and for publication. The data indicate that the concentration of free fluoride ion, in a solution of 1 ppm free fluoride in pure water measured at pH 7, reads, after the solution is adjusted to pH 3, only 0.5 ppm. Thus, the HF concentration that forms from the free fluoride ion is indeed 1.0 – 0.5 = 0.5 ppm HF while residing at a pH present in the stomach and the duodenum until pancreatic bicarbonate re-neutralizes gastric chyme. The importance of this is that the uncharged electrically neutral HF molecule is assimilated through the gastric cell membrane, in the absence of antidote calcium, 1,000 times more efficiently than is the free fluoride ion [10]. Assimilation of the free fluoride ion in the lower intestine is only significant because of the long length of the GI tract.

29. Synonyms for hydrofluoric acid HF are fluohydric acid and hydrogen fluoride. HF is a catalyst in the petroleum and aluminum industries, and is used to separate isotopes of uranium and in dye chemistry. Concentrated HF cannot be stored in glass because HF etches glass and forms frosted glass for light bulbs, carves computer chips, makes ceramics porous, and dissolves concrete, brick and various metals. Unknown to many biochemists however is that HF is a weak acid, since it does not dissociate well in pure water. Its destructive power is not in its acidity, but rather lies in the fact that the uncharged molecule is extremely tiny and able to penetrate solid structures with great ease. In the intestine where fluoride levels from ingested water can range from 0.21 ppm in blood to 1 ppm in ingested treated water, a fluoride gradient would exist where at pH 6.9 inside cells a calculatable level of HF may be the most likely reason that damaged goblet cells that function to assimilate dietary iron is an early morphologic alteration in humans consuming fluoride water. Dr. Susheela, world expert on fluoride-induced pathology and executive director of the Fluorosis Research and Rural Development Foundation, India, found detectable iron deficiency anemia to correlate with such cellular damage within 1 year of consuming fluoridated water [11].

30. It is evident that chemical manufacturers have perceived that HF could have an oral use in dentistry, because the U.S. FDA passed an explicit notice that any proposed anti-caries agent containing HF must submit to the FDA a new drug application. The Food Drug & Cosmetic Act requires that any substance used as an anti-caries treatment that contains HF must require a NDA. The Code of Federal Regulations specifically prohibits the marketing, interstate transport, or ingestion of any anti-caries agent that contains HF without a NDA [21 CFR31O.545(a)(2) and (b).]

31. The CDC does not seem to notice that the FD&CA is violated with any industrial fluoride compound added into water to treat caries. This is not simply because all fluosilicic acid preparations contain appreciable HF to 10 grams per liter from the equilibrium decomposition $H_2SiF_6 \rightarrow SiF_4 + 2HF$, but also because all synthetic fluorides form HF in the stomach anyway. These facts are sufficient grounds alone to abolish 'water fluoridation' in the United States. Indeed the one controlled human clinical trial type of data set that exists is that reviewed in the NRC report [9] which proved that 1% of all people on average have gastric discomfort immediately after swallowing water containing only 1 ppm fluoride from a synthetic source (i.e. sodium fluoride NaF). This is also the mechanism by

which severe GI distress is an initial symptom of synthetic fluoride overfeeds; here the HF irritation of the stomach is painful and was a chief presenting symptom, along with severe chest pain, prompting life flights to a hospital in the Hooper Bay overfeed [6].

32. Obviously from the above information, the pathologic and toxicologic behavior of a given concentration of fluoride ion is determined by prevailing conditions, such as water hardness. Soft water States in the U.S., deficient in divalent cations, have higher chemical activity or chemical potential of any added fluoride ion due to greater Brownian motion of the ion in solution. The ratio of calcium ion molarity (around 0.12 mM) to added fluoride molarity (0.05 mM) in treated soft water States, particularly in cities of the Pacific Northwest, is a low unsafe 2 to 1 or lower ratio. In hard water States the ratio is typically about 20 to one, but insufficient to prevent blood levels from reaching 0.21 ppm, the published average for consumers in cities with water fluoride regulated to 1 ppm (NRC p. 70) [9]. Hard water States are thus more protected from fluoride ion than soft water states in the U.S., since assimilation of fluoride is more marked in the latter. The mid-range for calcium ion in U.S. waters is 50 ppm.

33. Much of my research as an NIH investigator centered on the structural/functional properties of cell surface membranes, and the role of calcium in the maintenance of normal membrane properties, one being defense from extracellular toxic materials [12]. The overall biologic effect of fluoride ion in living organisms is determined by the calcium content of the water and also dietary factors that affect assimilation from the gastrointestinal tract. Fluoride tends to remain in a solution containing calcium ion, even at levels below that required for binding calcium as a precipitate. The higher the calcium concentration of a region, the less fluoride is able to diffuse away from it. This electrical attractive force is also responsible for the fact that fluoride, even at levels far below the known solubility constant K_{sp} for forming calcium fluoride, is trapped into bone, with an ion exchange mechanism due to simple substitution of fluoride for hydroxide during random collisions.

34. In contrast, fluoride accompanied in solution with Group I metal cations, such as sodium or potassium, exhibit little decline in activity over a broad range of cation concentration, because these ions are only monovalent in charge. A 1 ppm fluoride solution in pure water has only a slight activity decline as a function of added potassium ion, where electrode activity is not significantly decreased until 200 mM, a concentration at which fluoride activity would be already reduced a massive 50% by calcium ion alone [7]. Calcium and magnesium together, found in natural U.S. waters at widely varying concentrations, decreases fluoride mobility even more efficiently.

35. The actual Biologic and pathologic importance of the chemical differences between synthetic industrial fluosilicic acid (and sodium fluoride) vs. calcium fluoride are amply demonstrated: the measured dose at which lethal fluoride poisoning occurs in 50% of a tested animal group, the LD_{50}, for calcium fluoride is a safe 3,750 mg/kg single dose, whereas lethality for sodium fluoride or fluosilicic acid, as expected, compares to that for arsenic at 125 mg/kg single dose [4].

36. Toxicity during continuous chronic consumption at sub-acute levels also differs between synthetic industrial fluorides versus natural calcium fluoride. It is well publicized [13] that horses were killed in Pagosa Springs, Colorado after only 9 years drinking artificial silicofluoridated SOFT water, deficient in calcium and magnesium from nearby snowmelt. These animals drink their body weight in water every few days and all suffered severe skin reactions, crumbled hooves and browned, pitted, cracked, destroyed teeth, muscle weakness, and were eventually killed by skeletal fluorosis with severe associated tumors. A finite percentage of horses have severe allergy to synthetic fluorides.

37. Understand, if natural calcium fluoride had been the agent employed, the above lethal reaction could not have happened because the natural mineral is solubility-limited in water to only 8-13 ppm fluoride depending on water temperature. Levels of natural fluoride cannot exceed this amount. Such high water fluoride levels of approximately 10 ppm from natural sources exist in areas in India and Turkey. Natural fluorides are always accompanied with

other calcium and magnesium salts in addition to calcium fluorides. This hardness prevents acute lethality, and instead these people, with lifelong drinking, exhibit bone deformities. Prolonged continuous consumption of synthetic industrial fluorides lacking calcium at such levels in water can cause heart muscle pathology and other toxic sequelae [2].

38. Artificial fluoride, but not natural calcium fluoride, during water district overfeeds have severely poisoned and killed Americans in the U.S. In Hooper Bay, Alaska 302 people were life-flighted to a hospital after being poisoned, with one fatality by heart attack, due to fluoride assimilation into blood sufficient to decrease calcium ion concentration to block heart function [6]. Although the water fluoridation system functioned for a time at 1 ppm fluoride, metal plumbing valves and parts are no match for long-term continuous exposure to the corrosive HF molecule in un-buffered water. Natural calcium fluoride is unable to corrode metals as do artificial fluorides due to hydrolysis in neutral soft water to form HF. The net ionic reaction in the absence of calcium in soft water is $F^- + H_2O \rightarrow HF + OH^-$.

39. Fluoride ion from artificial fluorides are NOT biologically or physico-chemically the same as fluoride ion from natural calcium fluoride, at otherwise identical concentrations of the free fluoride ion. Inexperienced or amateur chemists often believe and proclaim that there is no difference between 'fluoride ion from calcium fluoride vs. fluoride ion from fluosilicic acid' because the ion is indeed identical in structure in both compounds, which has misled the CDC to claim the actions of fluoride from both compounds are the same on their current public fluoridation website, providing a false defense to continue artificial fluoridation with synthetic industrial fluorides. As stated earlier, salmon narcotized in 0.3 ppm free fluoride ion in fresh water are completely unaffected by 1 ppm free fluoride ion in the calcium-rich ocean. It is the environment in which fluoride resides that determines whether the intrinsic toxicity of the fluoride ion is expressed or not and determines that all synthetic fluorides are recognized poisons, while calcium fluoride is of low intrinsic acute toxicity.

40. The National Research Council review [9] clearly proved that 1 ppm fluoride in water on average accumulates to about 4,500 mg/kg fluoride in bone lifetime (p. 94 shows 2 year uptake), and far higher levels are expected for higher water-volume-consuming diabetics, reaching levels associated with severe bone pain requiring hospitalization (p. 35, 179) and of course with weakened bone that resist healing after fracture. Nature recently published that the U.S. currently has a well-recognized epidemic of hip fractures in the elderly. Synthetic industrial fluorides, used in over 9,000 U.S. water systems [15] to fluoridate the bloodstream of 140 million Americans permanently over lifetime consumption, are involved since fluoride accumulates and resides in bone permanently. Bone weakening is significantly detectable at levels above 3-4,000 mg/kg [9] and progresses with increasing accumulation. Accumulation below 3,000 also perturbs bone abnormally, but subtly enough to not be necessarily detected experimentally.

41. At 'low' 1 ppm fluoride in the absence of any accidental overfeed, the 0.03 mg/kg body weight fluoride ingested daily [9] would mathematically lead after 60 years, with half known to remain in bone, to 4,000 mg/kg permanently stored in the bone as a non-mobilizable fraction. As above, measurements of deceased bone from such regions contain fluoride in this calculated range. 'Low' is a very loose but nevertheless common term in toxicology. It must be made clear that even at 1 ppm, there are 30 million trillion fluoride ions in every liter of water, which contains 30 trillion trillion molecules of water (at 55.5 molar). Bone cells respond early to the perturbation from 1 ppm in drinking water by undergoing cell division [9], since a critical function of bone is to provide ionized calcium into the blood to maintain a normal heart beat [7]. Calcium ion is the exclusive agent that couples mechanical contraction of the heart with electrical excitation of the cell membrane during the plateau phase of the cardiac action potential.

42. Forcing any alteration of the chemistry of natural waters of the United States is outside the mission and scope of the United States Centers for Disease Control and in fact is in violation of the Federal Water Pollution Control

Act, section 101a, which explicitly mandates the maintenance and protection of the natural chemistry of all U.S. waterways. Fluosilicic acid, H_2SiF_6, is not present in, and is not a source for any substance present in, any natural water supply and has nothing to do with natural water chemistry--yet its use is widespread in the U.S. U.S. Food and Drug Administration spokesmen have correctly stated in writing that fluorides added into public drinking water constitutes an uncontrolled use of an unapproved drug [1]. Fluoride is not added to sterilize water, but rather to treat or prevent caries, whether a consumer has caries or not, and whether a consumer will ever develop caries or not.

43. A further complication occurs in aluminum-treated cities, where 0.05 ppm residual aluminum ion typically occurs in the water. Substantial aluminum fluoride AlF_3 forms in acidic conditions in the stomach which enhances assimilation of aluminum. Uncharged AlF_3, like uncharged HF, is assimilated more readily than ionic aluminum, and HF and AlF_3 are also expected to assimilate from a foot long section of the duodenum before acid pH is re-neutralized from pancreatic bicarbonate secretions.

44. The studies of Varner and coworkers, published in Brain Research and in Fluoride [16], summarized at www.fluoridealert.org, prove that the presence of aluminum ion and fluoride ion together in water, given chronically to experimental animals, leads to substantial accumulation of aluminum into brain and symptoms similar to human Alzheimer's disease. Consistent with the higher rate of assimilation for the complex, separately added aluminum ion without added fluoride ion at the same levels were not rapidly effective. Although aluminum lowers the amount of fluoride ion uptake (i.e. some fluoride that would form HF instead binds to aluminum), nevertheless aluminum is assimilated better because of the fluoride.

45. The CDC Oral Health Division, who are advocates for silicofluoridation, challenged the relevance of the above data. In a written response, CDC stated that fluoride and aluminum levels used in city water supplies are lower than those required to induce pathology [17]. It must be emphasized however that chemists reported in the CDC study that aluminum fluoride molecules preferentially do form at pH 5 for ion concentrations currently employed to fluoridate aluminum-treated public water supplies. The biological significance of this startling admission was apparently not understood by the study authors. Their idea defends the CDC claim that artificial fluorides biologically are 'no different' than natural calcium fluoride, but this claim is based only on chemical properties in neutral or alkaline water. No animal testing of any kind prompted these statements. Understand that the acidity of stomach contents at pH 3-4 causes (by admission of Jackson, et.al. [17]) formation of stoichometric levels of aluminum fluoride compounds that are not present in the treated water. After submitting this information to OHD CDC officials, there was no further reply. Neither has CDC commented on the fact that ingested fluoride quantitatively forms HF at stomach pH.

46. The sophisticated and systematic arguments, by vested interests at the Oral Health Division, attempt to reduce significant problems to be 'insignificant'. Continued claims that fluoride ion in hard water is the same as fluoride in soft water, and that fluoride plus aluminum behaves no differently than in the absence of aluminum because the ions remain dissociated in city water while at pH 7) is unethical misuse of chemistry. The intended implication is that the water data 'proves' biological safety after ingestion of synthetic fluoride. Sadly, after assimilation, compartmentalization of fluoride in tissue and cellular regions are well known. After assimilation in the acidic stomach, the free fluoride ion in the alkaline buffered bloodstream incorporates into calcium-rich bone and forms irreversible insoluble precipitates at extracellular fluid fluoride concentrations far below those causing precipitation of calcium fluoride from solution. Fluoride accumulates during lifelong consumption in a pathologic manner that is not saturable and not reversible (p. 94 in [9]). This alone proves to a biochemist beyond doubt that fluoride is not a mineral nutrient. All physiologic required mineral ions act in a saturable and fully reversible manner as a function of concentration present. Extracellular fluid is alkaline at pH 7.4, and since calcium fluoride is only soluble at acidic pH, fluoride is a permanent bone perturbant.

47. Ingested calcium, not ingested fluoride, can build strong teeth. 1) The statistical analysis of extensive data sets by Ziegelbecker as reviewed in Connett [18] eliminated the accidental tendency to 'cherry pick' data in favor of a particular bias and confirms that fluoride in drinking water has nothing to do with incidence of tooth decay. 2) Consistent with these observations, the original theory that water fluoride correlated with teeth health in Hereford, Texas, the storied 'town without a tooth ache', failed to include the fact that high levels of calcium and magnesium totaling 203 ppm accompany the fluoride [19]. 3) Although consumption of water with 1 ppm fluoride causes 0.21 ppm average levels in blood (which can harm teeth by commonly forming abnormal fluoridated hydroxyapetite permanent teeth enamel fluorosis, as well as other adverse pathology) [18], the U.S. CDC has published that systemic fluoride from the bloodstream after consumption from water does not reduce dental caries. 4) CDC presently argues then that fluoride must benefit teeth through a surface, direct topical mechanism. However, biochemical measurements definitively confirm the fact that ingested fluoride likewise cannot topically affect formed teeth structure-- since ingested fluoride from 1 ppm water reaches an average of only 0.02 ppm in saliva [9], a concentration that is useless in affecting teeth topically. Even at extremely high fluoride levels of 1,500 in pastes or 10-12,000 in gels and varnishes, fluoride is unable to penetrate into crystalline, rock-hard normal teeth enamel. The phenomenon known as 'remineralization' appears to be the simple formation of calcium fluoride globules on tooth surfaces [8], which are readily soluble in foods/beverages having slight acidity. 5) Finally, research animal studies, where confounding variables are fully controlled, proved that 1 ppm fluoride water does not decrease incidence of spontaneous dental decay in mammals [see 1a for review of those data].

48. The reliance, by those who promote the ingestion of diluted industrial fluorides, on data collected from innocent citizens in the city of Newburgh, N.Y. is particularly appalling. At a time of American jubilance for the U.S. military in finishing WWII, this entire city public water supply was treated with industrial synthetic sodium fluoride without obtaining permission from consumers for human experimentation. The twisted rationale for these experiments has been amply described recently [20]. In spite of many variables being un-controlled because the subjects were not volunteers who regulated their diet, etc., expert statisticians were able to demonstrate later that delayed teeth eruption occurred in children compared to the control city of Kingston and that exuberant officials falsely interpreted this as 'prevention' of caries. Other adverse biologic sequelae, summarized by several reviewers [18], were downplayed as 'minimal'. Experiments with human volunteers who agree to regulate diet and other variables, to study long term safety of ingested synthetic fluorides as required by the Food Drug & Cosmetic Act for any substance to be ingested to treat humans in the U.S., have never been published.

49. Fluosilicic acid [registry number CASRN 16961-83-4] is produced as a 23% solution from phosphate fertilizer scrubbers labeled as either technical (impure, suitable for industrial use) or CP grade (for general uses other than ingestion) [14, 15]. There is no such thing as a "pharmaceutical" U.S.P. grade of this industrial chemical, chiefly used historically as an insecticide and now in industry. A pharmaceutical grade cannot exist because fluosilicic acid is not FDA approved for oral ingestion, and a USP grade is a chemical intended to be ingested that is manufactured under current manufacturing practices which meet the requirements of the U.S. Pharmacopeia. Fluosilicic acid is instead specifically listed (on p. 85) in the EPA Toxic Substances Control Act registry for its traditional use as a pesticide/insecticide. Note however that all allowed use of this hazardous material as an insecticide has been discontinued. Its industrial uses are broad, in the electrolytic refining of lead, the removal of lime from hides during tanning, removal of molds, and as preservative for timber [3,4]. The dissociation constant K_a has not been published, but a 1% solution (0.069 M) has pH 1.2 [4], so $K_a = [H^+][HSiF_6^-]/\{[H_2SiF_6] - [H^+]\} = (10^{-1.2})^2/(0.069\text{-}10^{-1.2}) = 0.7$, indeed a relatively strong acid that would initially fully ionize, at any water or bodily pH, to $SiF6^- + H^+$.

50. Fluoride treatment of the bloodstream and every organ from heart to brain, in an attempt to decrease teeth caries, is one of the greatest public promotional mistakes of the Century. Indeed, cities who halt expensive water fluoridation operations do not report increased incidence of caries [18]. On the contrary, all cities that inject synthetic industrial fluorides into public water supplies experience increased incidence of tooth fluorosis without

exception as reported even in pro fluoridation literature. The fact that pathologic alterations caused by chronic low level continuous consumption of industrial fluoride from drinking water (i.e. bone cell division with altered calcium homeostasis, and intestinal inhibition of iron assimilation) are not readily sensed or felt by the average consumer does not defend the practice. Instead, these findings demonstrate that deceptive practices are involved when a single Federal office, the Oral Health Division within the Centers for Disease Control and Prevention, continues to recommend the widespread ingestion of diluted toxic fluosilicic acid by citizens in the United States.

51. The intentional injection into public water supplies of diluted synthetic industrial fluorides, in particular fluosilicic acid which is not FDA approved for ingestion, at levels that avoid acute toxic symptoms is in strict violation of:

the WPCA (fluosilicic acid and its dissociation products are not part of the normal chemistry of regular fresh drinking water);

the SDWA (fluosilicic acid is added with the intent to treat dental caries in humans, not to sanitize the water); and

the FD&CA (no controlled human clinical trials data for either safety or effectiveness have been submitted to the FDA; HF is not permitted by the FDA in any substance intended for human ingestion; fluosilicic acid is not an approved over the counter ingestible and is not an approved prescription drug, mineral nutrient or supplement).

All citizens, government and private agencies must honor these Federal Statutes for the protection of citizens of our country.

52. Violations of Federal water and drug law routinely escape regulation through distracting claims from parties with vested interests. For example, fluoride from hazardous waste is perceived by the OHD at CDC to become a useful 'water additive' or 'supplement' upon dilution, argued to not be the contaminant EPA lists it to be. Many at the FDA argue that the EPA, not the FDA, should regulate the injections as contaminants, rather than supplements or drugs, being non-FDA-approved for ingestion (see petition for reconsideration of FDA2007-P-0346, 2010). Some at the EPA argue it is not a spilled contaminant and thus fluoride is an intentional additive, and EPA defers to the private National Sanitation Foundation for 'certification'. NSF lists fluoride as both a contaminant and as an additive and defers questions of safety to the OHD, even though sodium fluoride (Luride) is intended to treat human caries through ingestion and is subject to regulations by the FDA through prescriptions with dosage instructions required by law. Congress ruled fluoride is not a drug, in agreement with the fact that fluorides are not FDA approved for human ingestion, but nevertheless the ingestion of this substance, which is not a food with calories or a mineral nutrient, is intended to treat human tissue, which is the legal Congressional definition of a drug, albeit an unapproved one.

53. Waters with contaminants such as fluoride or arsenic, either naturally or from accidental spillage, are subject to EPA regulation (water is not considered potable with fluoride ion alone at 4 ppm and warnings must be issued for drinking water that contains fluoride levels above 2 ppm), but EPA does not regulate, monitor or supervise in any way substances *intentionally* added into water to treat disease, *particularly when requested or recommended by Federal officials*. The OHD at CDC requests all U.S. waters to be fluoridated at 1 ppm. The U.S. Health and Human Services recently provisionally requested added fluoride not exceed 0.7 ppm, while attempting to analyze the National Research Council conclusion that current allowances for fluoride in drinking water are not protective of human health [9]. This was made because of the CDC admission that, as of 2004, 41% of U.S. children aged 12-15 have permanent abnormal tooth fluorosis (that is not a cosmetic effect these consumers requested). The Associated Press reported that toothpaste manufacturers have suggested blame for this endemic on fluoride consumption from water, since toothpaste fluoride is not designed to be swallowed. Water fluoride promoters blame toothpaste manufacturers for the endemic, because water fluoride injections began before fluoride toothpaste

was ever marketed. The NRC [9, p. 60] truthfully describes the shared blame on both, by revealing studies finding that about 45% of the fluoride in blood in a 1 ppm treated city comes from water consumption and about 20% comes from assimilation from toothpaste use in the oral cavity in 12 year olds. At the present time there is no official Federal agency that has ever supervised, tested or regulated industrial fluoride materials and their addition into public water supplies, in spite of the strong requests made by Federal officials at the OHD of the CDC that cities continue the practice [18]. The FDA ban petition, accepted for review by the FDA in 2007, remains pending as of the date of writing this affidavit.

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Acknowledgments.

I dedicate this affidavit to my father, the great American patriot and survivor of the attack on Pearl Harbor, Hawaii, who later told me to "stay in school." This is the 50 year anniversary of the University of California, San Diego.

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Dear Reviewers,

This information is sent in support of the 2007 ban petition 2007FDA-P-0346, formerly 2007P-0400/CP1, and its Petition for Reconsideration, submitted 2010. *There is now no doubt that synthetic fluoride without calcium, from ingested industrial compounds sodium fluoride or fluosilicic acid, crosses the blood-brain barrier.* In mammals, ingested fluoride, from blood where it does not belong, enters the acidic environment of cells at pH 6.9 to form small amounts of hydrofluoric acid HF [2] ($H^+ + F^- \rightarrow HF$) and in brain degrades intracellular structures and decreases protein synthesis [3, 4]. In humans, blood fluoride levels correlate with lowered intelligence and IQ [5].

In a very dramatic recent published study by Reddy [4] (see enclosed copy), synthetic fluoridated drinking water was provided to rodent mammals that produced fluoride blood levels similar to that in humans (0.21 ppm blood fluoride) when drinking 1 ppm fluoridated water [1]. A higher water concentration is required for animals that resist fluoride assimilation compared to human [6]. Mullenix found blood levels of 0.15 ppm fluoride during consumption of 100 ppm fluoride in water in these animals [6]. The Reddy study used 20 ppm water fluoride. After months of consumption, brain weights diminished 16%, and multiple types of brain and nerve cell lesions were observed with transmission electron microscopy at 3,000X magnification, not previously able to be seen by light microscopy in other fluoride brain-damaging studies. The cellular degeneration was attributed directly to fluoride ion that incorporated into tissue to 0.8 ppm [4], a level similar to that measured biochemically in brain tissue of humans in U.S. fluoridated cities [7].

Therefore, we now know that the extremely tiny fluoride ion is not simply trapped in regions of the brain that are outside brain cells, such as does occur when fluoride binds to hydroxyapetite structures in the pineal gland [5]. The ion ALSO physically crosses the blood-brain barrier, enters inside brain cells to deform intracellular structures, and inhibits metabolism in these sensitive and important cells. In those consuming fluoride lifetime, fluoride entry into brain cells would occur from infancy, when the blood-brain barrier is not developed, through adulthood, accumulating chronic bits of damage lifetime. It must be noted that in the Varner study, rodents were given water containing only 1 ppm fluoride, which after one year also produced microscopic cellular brain damage [3]. In the Reddy study, fluoride caused myelin sheath degeneration and axon deterioration in the spinal cord as well.

It is fortunate that the human brain is very large and with such capacity can withstand much chronic degeneration for very long time periods. For example, the chronic brain degeneration and volume reduction associated with alcoholism are well-documented. Further, calcium in water and foods can minimize assimilation of fluoride for many, depending on diet. Most unfortunate however is that subtle effects on brain function such as memory are not necessarily recognized by those affected. No internal control would be present to compare to mental capacity that would have existed if fluoride had never been consumed. Thus, mental adversity can be unnoticed by the consumer of the toxin, and effects that might be perceived by observers may take many decades to be significant, where fluoride logically but wrongly escapes as suspected cause. Much careful epidemiologic published work indicates there are fewer brilliant high IQ individuals and more with lower IQ in cities with higher fluoride in water supplies, as reported in numerous International studies [1, 5].

It must also be emphasized that damaged brain tissue cannot regenerate. Since fluoride ion crosses the blood-brain barrier and causes chronic brain cell damage that may not be reparable, it is imperative that public utilities again provide regular water to its citizens. Water with added chemicals used to treat people must be avoided, no matter how well-intentioned State or Federal officials may be who request water be treated. In the case of fluoride, the ion does not belong in, and has no function for, any living cell. Dosage cannot be regulated in public water, where the infirmed have higher blood fluoride levels at any given water concentration present, including kidney patients with impaired fluoride elimination, and those with diabetes where water consumption rate is high [5].

It is illegal for Federal officials to require the addition of alcohol, vitamins, foods, supplements, minerals, drugs or any ingredient into water supplies in the U.S. other than specifically to sanitize the water. Requests by Federal Centers for Disease Control officials, that the State of California 'fluoridate' water supplies, is in contrast with Federal law. *No State has legal authority to* ***require*** *industrial fluoride treatment of public water, since the U.S. Safe Drinking Water Act covers all public water supplies in the Nation and prohibits any less-restrictive State requirements.* And yet, many states have legislation, never open to public vote, with a written requirement for fluoride injections into public water supplies. San Diego, California and San Jose, California city officials this year succumbed to such sham legislation, in opposition to Federal law, and agreed (by emphatic request from Public Health officials guided by the Oral Health Division office of the U.S. CDC) to fluoridate its own citizens, who voted against such treatment.

Fluosilicic acid H_2SiF_6 is a chemical complex of silicon fluoride SiF4 and hydrofluoric acid HF that only forms in water. The substance itself cannot be purified, since at low water content it re-dissociates to hydrofluoric acid, where $H_2SiF_6 \rightarrow SiF_4 + 2HF$. The Code of Federal Regulations of the Food Drug & Cosmetic Act specifically prohibits the marketing, interstate transport, or ingestion of any anti-caries agent that contains hydrofluoric acid HF without a new drug application NDA [21 CFR31O.545(a)(2) and (b)]. Incredibly, half of all synthetic fluoride in the acidic stomach forms HF, which is fully assimilated [2] (see sworn affidavit sent to FDA November, 2011).

The treatment of citizens with industrial synthetic fluoride with high intrinsic toxicity (125 mg/kg acute lethal single oral dose, or 5 ppm acute lethal in blood plasma [8]) is a violation of human rights to access clean safe drinking water--and violates the U.S. Water Pollution Control Act mission, to maintain the normal natural chemistry of the Nation's water supplies, as conceived originally by the honorable former President John F. Kennedy (WPCA, Section 101a). As a known brain degenerative agent, it is imperative, for the success of our country, that the citizens of these United States be protected from further harm of fluoride incorporation. The false deduction from a mere anecdotal correlation, that led to claims that fluoride is a 'health achievement', must be overcome. It is necessary for the FDA to join with us citizens to ban the treatment of people with intentional ingestion of industrial synthetic fluoride.

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Attached news releases on Reddy, et.al. study enclosed.

#9

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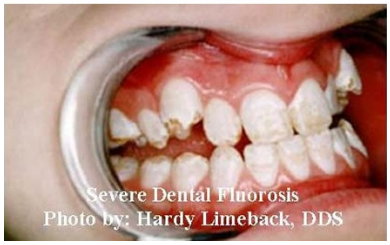
Dear Reviewer,

The assimilation from the GI tract into the blood, of both hydrofluoric acid HF and silicofluorides, should no longer be argued by anyone as a useful method to fight bacterial tooth decay. HF is 1,000 times more permeable to cell membranes than the fluoride ion from which it forms in the acidic stomach [1]. Silicofluorides may be tolerated in man, but alligators with a high water turnover rate develop silicosis of the liver and premature death when living in silicofluoridated water [2].

If we examine pictures of victims of tooth fluorosis, caused by blood fluoride after ingesting fluoridated water during infancy, there can be destroyed areas of teeth, and even in more mild cases fluorosis is a permanent abnormality that prevents a healthy normal smile [3].



The U.S. Oral Health Division, CDC finally disputes that systemic fluoride fights teeth decay, but nevertheless still promotes fluoridation of water as a useful method to fight caries [4]. The argument has long been made that the teeth structure that remains in fluorotic victims is more resistant to decay because the hydroxyapatite normal enamel has been converted into an altered form [5]. Furthermore, locations where fluorotic teeth have worn away do not have cavities, because there is no teeth structure there. This bizarre argument was used to rationalize the lack of effect on decay rate in fluoridated Newburgh, where teeth erupted one year late due to systemic fluoride ingestion in the treated city [6]. Decay rates were identical for both cities' children after teeth grew into the mouth.

In other words, let's consider that indeed fluoride in this severely fluorotic victim has done its job in decreasing incidence of tooth decay. The fact that teeth portions are ruined is considered of lesser importance. The fact that decay rates in teeth after growing into the mouth were identical in Newburgh is not considered by OHD.

It must be emphasized to those who hold those views, that people who desire fewer teeth caries also prefer to retain their teeth and to have a healthy normal smile while cavities are being fought. Since water fluoridation always increases incidence of tooth fluorosis in every city without exception, please fight teeth decay by brushing after eating sugar, or avoiding sugar, and treatment of gums to prevent inhibit *Streptococcus mutans* which produces acids causing cavities.

The CDC now argues that fluoride acts topically on teeth to reduce caries. But fluoride in saliva at 0.02 ppm [7] or water at 1 ppm cannot penetrate teeth enamel with significance, nor decrease bacterial growth [9]. This is consistent with the lack of incorporation of fluoride into teeth enamel treated with 12,000 ppm fluoride as proven by detailed electron microscopic examination [10]. Toothpaste contains 1,500 ppm fluoride, a level that does not slow bacterial growth unless the medium were acidic, where sufficient corrosive HF could form.

Water fluoridation causes assimilation of HF and silicofluorides into blood that reform fluoride ion which crosses the blood brain barrier, degrades brain tissue chronically observed in mammals [8] and decreases mental IQ in humans [5]. Water fluoridation in U.S. cities requested by the U.S. CDC in violation of the U.S. Safe Drinking Water Act is slowly but surely harming millions of Americans.

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Acute Intrinsic Toxicity of Synthetic Industrial Fluoride

It is not possible or ethical to conduct direct experiments to determine the precise single oral dose that would be lethal for synthetic fluosilicic acid in humans. However, Material Safety Data Sheets (sent to the FDA, Dec. 21, 2011) for fluosilicic acid from Brenntag Chemicals with mammalian data sheds light on this issue. Brenntag supplies the massive quantities of this material to the city of San Diego to inject continuously and indefinitely into drinking, agricultural and all public water supplies to treat consumers with the fluoride ion by ingestion. It is now clear that there is no further discrepancy regarding the true intrinsic toxicity of synthetic fluorides lacking calcium used in public water supplies.

The Merck Index lists the acute oral lethal dose LD_{50} in mammals at 125 mg/kg for sodium fluoride. Since 45% of sodium fluoride is the fluoride ion, this puts the lethal single oral dose at 56 mg/kg body weight of the fluoride ion itself. The Merck Index lists the LD_{50} for sodium fluosilicate at 125 mg/kg, which produces 76 mg/kg fluoride ion.

The Brenntag fluosilicic acid sheets however list the LD_{100} in guinea pigs at only 80 mg/kg, which amounts to 63 mg/kg fluoride ion from the Brenntag fluosilicic preparation in a single lethal oral dose. Guinea pigs may be more sensitive than other rodents, but notice this dose exerts a full 100% lethal effect in guinea pigs, not just a 50% LD_{50} lethality as reported for rats and mice in Merck.

When the 302 people were poisoned like guinea pigs, with one fatality in Hooper Bay, Alaska during a fluoride overfeed, it was thought by estimate that the water level had reached an accidental high of perhaps 150 ppm (see original petition). This number now may be re-estimated. Lethality may actually occur at lower concentrations than this during accidental overfeeds in fluoridated cities. In fact, humans assimilate ingested fluoride far more efficiently than do rodents. Typically it takes 9 ppm fluoride from sodium fluoride in water to achieve 0.2 ppm fluoride ion in blood for rats and mice. The Reddy, 2011 study used 20 ppm sodium fluoride which contains 9 ppm fluoride ion to approximate the human blood level found in humans in cities treated with 1 ppm fluoridated water (NRC, 2006). Part of this is the fact that humans also have a significant % of blood fluoride that comes from fluoridated toothpaste use, but nevertheless it is widely accepted that rodents are more resistant to fluoride assimilation. Roughly it appears that only 100 ppm fluoride in water is the level that may have killed Dominic Smith in Hooper Bay assuming he may have been using fluoridated toothpaste and is the typical 9 fold higher sensitivity than rodents. A 70 kg person who drank a gallon of this within a few hours (as Smith was reported to

have done) matches the expected lethal single oral dose in a human if the 63 mg/kg LD100 of guinea pigs were more applicable to human. If the human were 9 times more sensitive than this, then 7 mg/kg would be an expected lethal single LD_{100} dose. Indeed, 100 ppm is 400 mg in 4 liters, which for a 70 kg person is 5.7 mg/kg. The LD_{50} would be predicted to be in such a range.

Another way to estimate the lethal acute oral dose is the known fact that 5 ppm in body fluids causes death in both humans and mammals. There is good agreement on this because this is the fluoride level reached after it has been already assimilated. A 70 kg person with a 47 liter fluid volume would require 233 mg assimilated fluoride to be killed. Since half of ingested fluoride in man is typically assimilated, then 466 mg fluoride would be a single lethal oral dose. 466 mg of fluoride is contained in about 1 gram of sodium fluoride, and one edition of the Merck Index indeed reported a person was killed after ingesting an estimated 1 gram of sodium fluoride. And for a one gallon volume, this amounts to a concentration in water of 117 ppm fluoride, comparable to the above estimate.

Remember that in Madison, Wisconsin when an overfeed reached 50 ppm, the water operator told the newspaper (I now paraphrase) 'don't worry about it, it's not a dose that would seriously poison anyone because it makes you throw up the water you drink, while we get the leak repaired' (www.fluoridealert.org). It is now common knowledge that people have been killed from fluoride overfeeds because so many millions of people have been misled by CDC statements that ‘fluoride is a great public health achievement’ and ‘fluoride is safe and natural’. The term fluoride has been publicly sanitized to protect its vested use and this has led water district employees, normally in charge of keeping contaminants out of water, to put a contaminant into water that by reason of use by such individuals has become an illegal non FDA-approved drug. Congress defines a drug as a synthetic chemical substance administered to treat or prevent disease. Congress does not recognize synthetic fluorides as drugs since fluorides are not FDA approved. Fluoride however follows the stated definition of a drug, and thus fluorides are illegal drugs, or are being used as though they are drugs, specifically without FDA approval.

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This information is to support the fluosilicic acid in water ban petition, FDA2007-P-0346, formerly 2007P-0400/CP1, and its Petition for Reconsideration, submitted 2010. This is the tenth letter in a late 2011 series to the FDA.

Presented is an update on the intrinsic toxicity of synthetic fluoride compounds (acute, moderate, and chronic) that are specifically administered to humans internally for drug-like actions without a prescription. The letter is dedicated to the late American great Nobel Prize scientist Dr. Albert Schatz, who devoted his life to protect human health, discovered the recognized cure for tuberculosis that closed TB sanitariums around the world, and fought to protect the poor and malnourished from the toxic effects of synthetic fluorides taken internally. The letter is divided into two parts, one on the intrinsic toxicity of industrial synthetic fluorides and the second on fluoride-induced infant mortality in subpopulation groups.

I. Synthetic Industrial Fluoride Taken Internally Increases Infant Mortality in Population Groups

A North County Times newspaper article correctly states that U.S. infant death rates exceed those in Europe. The U.S. has dropped to 34th in the world. The article identifies Sweden, Japan, Finland, Norway being low, and Iceland having the lowest infant mortality in the world. Not mentioned is the fact that none of these countries inject the diluted toxic hazardous waste fluosilicic acid into public water supplies for its fluoride; and not mentioned is the arduous superior work of Dr Schatz who proved for any typical population group that fluoride ingestion from treated water is responsible for high infant mortality rates.

We now know that all synthetic fluorides are fully water soluble and form HF in the stomach that freely passes through biological membranes. Ingested fluoride without sufficient antidote dietary calcium enters the fetus from placental circulation and crosses the blood brain barrier. This has always been the case in man and animals, but only recently has the mechanism been unraveled by which the ionic charged fluoride can cross biological membranes. It does not itself cross the membrane freely, but the associated HF (in the stomach at 0.6 ppm, in blood at 0.01 ppb and inside cells at 0.04 ppb) is nearly identical in size to the water molecule and is also uncharged, freely permeable through the lipid bilayer as is water. The membrane acts like a permeable polymer to the ultra small sized water and HF molecules, even though these polar substances do not have a significant lipid partition coefficient. The bilayer presents a barrier to most charged ions. Fluoride ion then re-dissociates from HF after it passes through the membrane. The HF concentration may be computed with the Henderson Hasselbach equation, where $pH = pK_a + \log [F^-]/[HF]$. So $7.4 = -\log (7.2 \times 10^{-4}) + \log [1.1 \times 10^{-5}]/[HF]$. Solving, $[HF] = 6.1 \times 10^{-10}$ M = 10 ppt. HF however is essentially freely membrane permeable.

The U.S. is now very widely fluoridated (in some cities for 60 years now), with an infant mortality worse even than Cuba at 5.1 (World Health Organization latest statistics). U.S. standing in this category has progressively worsened since WWII, along with increasing prevalence of water fluoridation. Evidence this correlation is causative is presented here.

Dr. Bill Osmunson found infant mortality in the 50 U.S. states parallels the percentage of their water districts that fluoridate. Dr. Packington found that towns in England that fluoridate have 75% higher infant mortality than non-fluoridated towns (http://www.oehha.org/prop65/public_meetings/052909coms/fluoride/IPackington.pdf). Dr. Schatz, originally discovered that infant mortality in Chile increased after fluoridation began, and then declined after President Allende stopped it at the request of Schatz (www.fluoridealert.org). Schatz first presented to the U.S. Congress why many miss the connection of fluoride as cause of increased infant mortality. The reason is that fluoride ingestion harms poor undernourished people far more significantly than those with sufficient healthy food

who can withstand the toxic material. When examining a total population group, a high percentage of successful births can easily overshadow the fact that a population's undernourished can be decimated by fluoride *in utero*.

A poor section of Memphis, fluoridated for generations, has infant deaths every 43 hours and a graveyard for 1 year olds (http://tv.nytimes.com/2008/08/22/arts/television/22infa.html. Health professionals do not recognize that toxic artificial fluoride is involved, even though animal studies show it increases stillbirth rates and in humans blood fluoride shortens red cell lifespan. The original textbook that promotes water fluoridation [1] does not discuss infant mortality. Successful births for the Memphis population in total remain a high normal-appearing percentage.

Since an unborn fetus cannot breathe air and depends entirely on placenta blood for oxygen, it is not surprising then that, as has long been known (Himworth, H.E., Am. J. Phys. 135, 387, 1942), higher rates of spontaneous abortions can occur in pregnant animals given fluoridated water. It is important to consider in such studies whether a balanced diet with plentiful calcium is present since abundant calcium minimizes fluoride assimilation and also is protective in overall calcium metabolism that is affected adversely be fluoride uptake as a permanent resident perturbant in the bony skeleton.

Although U.S. infant mortality at 6.3 deaths per 1,000 means that 99.37% of births are successful, nevertheless, according to Packington in full agreement with Schatz, the premature born infant with low body weight has been found to be 70% more likely to perish in fluoridated water areas compared to non-fluoride drugged areas. The lifelong fluoride toxicology research scientist expert Dr. Susheela reported that de-fluoridation of otherwise potable water sources routinely leads to decreased infant mortality and reduced incidence of spontaneous abortion in man (see enclosed excerpts of sworn affidavit testimony for court litigation in Pennsylvania of a water supply treated with industrial flouride).

The U.S. has a reported 6.3 deaths per thousand births, worse even than Cuba at 5.1. Fluoridated Ireland is 4.9, fluoridated Canada 4.8, fluoridated Australia 4.4, somewhat better but are also less fluoridated as a % of the country's water supplies than is the U.S. Non-fluoridated Japan and Sweden are tied for 2nd best countries in the world at 3.2, behind only non-fluoridated Iceland at 2.9. There may be many causes in addition to pollutants that contribute to this, but as Schatz discovered, a country's relative population living in poverty (or overpopulation or during war) are most significant. Other levels for example are: Mexico 16.7, Vietnam, 19.5, India 55, Iraq 82, Afghanistan 157 deaths per thousand births.

References:

http://www.nytimes.com/2009/04/07/health/07stat.html (11 in 1960, 29 in 2009
http://tv.nytimes.com/2008/08/22/arts/television/22infa.html_(Memphis dead infant every 43 hours

II. Intrinsic Toxicity of Fluoride from Synthetic Industrial Fluoride Compounds

A. NRC vs. OHD/ CDC

The Oral Health Division of the U.S. CDC requests that synthetic diluted industrial fluoride compounds be taken internally by virtually all residents of the U.S. through mass treatment of the Nation's water supplies. The National Research Council 2006 Report, officially commissioned by the U.S. Environmental Protection Agency at taxpayer expense, challenges this by stating that current allowed fluoride levels in drinking water are not protective of human health [1]. OHD officials quickly disregarded the NRC findings in part because the NRC report examined cities that were both artificially fluoridated with synthetic industrial fluorides and cities that naturally had fluoride in water (from calcium fluoride) as well. The rationale for the disregard was that OHD supports adding industrial synthetic fluoride only, not natural fluoride, so all the data could be conveniently dismissed in their opinion. This contradicts earlier statements by OHD officials to public news agencies and on the CDC fluoridation website, that fluoridation with synthetic fluosilicic acid is identical to natural calcium fluoride and is thus 'safe and natural.' Asking in person a NRC coauthor, Dr. Kathleen Thiessen why CDC officials made this claim, she quickly responded that "they lied about the report" (direct, in-person communication, at Metropolitan Water District headquarters, Los Angeles, CA, August, 2007). The NRC text did not endorse fluoridation of water, but challenged it. The CDC interpreted however the lack of a NRC request to halt fluoridation as an official NRC allowance or endorsement to continue it. Adverse effects reported by the NRC on human health from water fluoride were presumed related to high natural fluoride in all cases within 3 days of the release of the lengthy detailed report, while the CDC explained they only request use of synthetic industrial fluoride in water, without realizing most of the U.S. has fluoride in water because of artificial injection that the NRC analyzed. Sadly, ingrained vested interests and acceptance of false deductions and theories can exert powerful influence.

B. Toxicity of Fluoridated Drinking Water

Dr. Paul Connett, Professor Emeritus, New York University visited us in San Diego, CA and kindly presented information on industrial synthetic fluorides in drinking water taken internally used for its drug-like properties. He spoke to the pharmacology class of a former colleague scientist of mine at San Diego State University. That scientist informed me that she lived as a child in fluoridated Evansville, Indiana and presumed that her low teeth caries incidence rate resulted from such treatment with synthetic industrial fluoride. I informed her that the absence of fluoride ion does not cause cavities, but instead allows normal teeth enamel to develop, so she graciously allowed Dr. Connett to speak to update us out West on the latest research as reviewed in a recent text [2].

A key summary of that talk is that any perceived caries reduction associated with fluoride taken internally is so exceedingly small as to be of no useful importance, especially considering that ingested fluoride crosses the blood brain barrier and is a permanent resident of bone in a consumer lifetime where it accumulates. Paul reviewed 26 studies that show decreased Intelligence Quotient (IQ) in humans as a direct function of extent of internal fluoride exposure from water supplies. Also, fluoride at first exposure can bind to high affinity sites in bone that can cause an increase in bone density, thereby deceiving those who promote fluoride as an aid to bone. The effect however is pathologic, particularly in that incorporated bone fluoride abnormally affects overall calcium homeostasis. This of course at a minimum places the heart at risk of incomplete strength or force of contraction when under extreme stress, known as high workload. Additional binding of fluoride in bone (possibly to binding sites of lower affinity) to 2,000 mg/kg causes detectable loss in bone strength and bone thickening due to bone cell division in an attempt to respond to the fluoride as a perturbant, which renders bone at that point more subject to fracture. There is now a strong known relationship between bone fracture incidence and tooth fluorosis, both caused by ingested fluoride in the affected victims [2].

C. Oral Toxicity of Synthetic Industrial Fluorides in Man and Animal

The original textbook that attempted to establish fluoride ingestion as an acceptable practice for all humans regardless of diet, genetic composition, lifestyle, or infirmed condition [3] nevertheless presented a rudimentary table on the admitted toxicology of ingested synthetic industrial fluoride at acute, moderate and chronic levels. That table of information may be presented here, updated with recently available published data. It is not possible or ethical to conduct direct experiments to determine the precise single oral dose that would be lethal for synthetic fluosilicic acid or other industrial fluoride by ingestion in humans. Animals are routinely used as guides for this purpose, and accidental human poisonings are now common enough to present a relatively accurate picture for the acute case [4]. Intermediate levels not immediately lethal are the least understood in the human but are available in mammals [5]. Chronic toxicity in man and animals [6] is better understood today than when the practice of 'water fluoridation', to internalize the fluoride ion in the human, was first begun.

Toxic Effects of Synthetic Industrial Fluoride Compounds Taken Internally in Man and Animals
(adapted from an earlier version [3])

Level:	**Acute**	**Intermediate**	**Low Level Chronic**
	76 mg/kg from sodium fluosilicate[a] 56 mg/kg from sodium fluoride[a] 36 mg/kg from fluosilicic acid[b]	10-25 ppm fluoride in water[c] (sodium fluoride or fluosilicic acid)	Intentional Fluoridated water (sodium fluoride or fluosilicic acid)
Outcome:	Death within hours	Heart failure within months	[d]Within years: fluorosis, anemia, IQ reduction, bone weakness, brain cell degeneration, increased cancer, mental retardation, heart disease, obesity, infant mortality, 1% allergy, 1% GI discomfort

[a]**The Merck Index, An Encyclopedia of Chemicals, Drugs, and Biologicals**, Twelfth Edition, Merck & Co., Inc., Whitehouse Station, NJ, 1996 for mammals [4].
[b] Solvay chemicals fluosilicic acid Materials Safety Data Sheet (80 mg/kg H_2SiF_6 or 36 mg/kg fluoride ion for guinea pig).
[c]Agency for Toxic Substances and Disease Registry, U.S. Centers for Disease Control, Fluorides and HF, 2003 [5].
[d]Various sources, including but not limited to: NRC, 2006 [1], Connett, 2010 [2], Ziegelbecker reviewed in [2], Reddy [6], Yiamouyiannis [7], Osmunsen [12], Waldbott, Burgstahler [10], Schatz [13], Varner [11], Mullenix [9], Spittle [8], Susheela: in Spittle [14].

Data in this table are taken from multiple sources on mammals including man. In all cases it is synthetic industrial fluoride compounds widely used to treat U.S. water supplies that were used as fluoride source. Values for humans are all estimates because humans exhibit very wide biologic variability. Those with kidney disease and impaired fluoride elimination, or diabetes with excess water consumption are more readily harmed from internal industrial fluoride. Moreover, there now exists in the U.S. a population subset that never existed prior to 1950, and that is people who have consumed water treated with industrial fluorides for decades of time. Fluoride bone loading in to high affinity sites interferes with fluoride removal from plasma and causes higher time average fluoride blood levels for any given assimilated dose. Such individuals are expected to be significantly more susceptible to ingested industrial fluoride than before bone loading ever took place. Effects of fluoride on autism and Alzheimer's disease patients are not listed because fluoride exacerbates these conditions without being a recognized cause.

As a medical research scientist who mainly researched laboratory animals bred for that purpose, I have not conducted research on infant mortality and industrial fluorides taken internally in animals, and instead must rely on other research experts in that field. Neither I, nor proponents of industrial fluoride consumption, can disprove the published discoveries of those experts, namely Drs. Susheela (animal and human), Schatz (human), Yiamouyiannis (animal and human), Himworth (animals) and Packington (humans) in this area. These findings are most serious, and the burden of disproof of their work lies on those who continue the willful dissemination of industrial fluorides into water to be taken internally by the unknowing, and trusting, general public.

According to my Pearl Harbor survivor father, the United States military was sucker-punched by the Empire of Japan who attacked us at Pearl while negotiating peace with President Franklin Roosevelt in person in Washington, D.C. Notice that the country overall has now been sucker-punched with industrial fluorides in drinking water, while given the argument that it is the 'greatest health achievement of the Century', now ignoring the explicit conclusion of the EPA-commissioned NRC that current levels of fluoride in public water supplies (70% treated with industrial fluoride compounds) is not protective of human health, and the CDC itself acknowledges that tooth fluorosis is endemic in U.S. children. We citizens, and the U.S. government we support, must end this adversity.

I must acknowledge that guiding me through this arduous task, with the original FDA Petition 2007 and its supplements, the Petition for Reconsideration 2010 and its supplements, culminating with the last of this 10-letter series, has been a most important statement:

"Make sure you are right, and then go ahead" (former Congressman David Crockett, Tennessee).

These words mean explicitly that we only proceed after studying all the facts in detail, discern the consequences of those facts, acknowledge the difference between correlation and causation, and basically know in truth whether something is either right or wrong, before we act. That is what I have here done, and I most assuredly testify that fluoridation must be halted, not simply because it does not work, not simply because the material taken internally harms many, especially the poor and undernourished or calcium-deficient, but for the precise reason that the act itself is wrong. A ban on the injection of industrial fluorides into public drinking water is necessary, but if not instituted, then at the very least fluoride by aqueous solution administration to be taken internally must be limited by prescription only, where an individual's health status can be assessed before, not after, the agent is administered.

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[1] National Research Council, **Fluoride in Drinking Water, A Scientific Review of EPA's Standards**, D.C. 2006.

[2] Connett, P., Micklem, Beck, **The Case Against Fluoride**, Chelsea Green Publishing, White River Junction, VT, 2011.

[3] Newbrun, E., **Fluorides and Dental Caries**, Thomas Books, Springfield, ILL, 1972.

[4] Solvay Chemicals, Houston, TX, Fluosilicic Acid, **Materials Safety Data Sheet.**

[5] U.S. Centers for Disease Control, **Agency for Toxic Substances and Disease Registry**, Fluorides and HF, 2003.

[6] Reddy, P., Reddy, K., Kumar, K.*, Neurodegenerative Changes in Different Regions of Brain, Spinal Cord and Sciatic Nerve of Rats Treated with Sodium Fluoride*, **Journal of Medical and Allied Sciences** 1(1), pp. 30-35, 2011http://static.infowars.com/2011/12/i/general/2011_study-neurodegenerative_changes_from_fluoride_of_brain_spinal_cord_and_sciatic_nerve.pdf.

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[11] Varner,J, Jensen,K, Horvath,W.,Isaacson,R., **Brain Research** 784, 1998;284-98.
[12] Osmunson, B., personal communication (see materials submitted in original petition).
[13] Schatz,A., *Low Level Fluoridation and Low Level Radiation, Two Case Histories of Misconduct in Science*, 1996 http://www.fluoridation.com/schatz.htm taken from: Schatz, A. *Increased death rates in Chile associated with artificial fluoridation of drinking water, with implications for other countries.* **Journal of Arts, Science, and Humanities** 2:1-17, 1976; Sworn affidavit: http://www.fluorideinbeds.org/FIB/albertschatz.asp
[14] Spittle, B., **Fluoride Fatigue, Is Fluoride in Your Drinking Water—and from other sources—Making you Sick?,** Paua Press, Dunedin, New Zealand, 2008 http://www.pauapress.com/fluoride/files/1418.pdf.

Circuit Court Fond Du Lac County
SAFE WATER ASSOCIATION, INC.

Plaintiff,
vs.
CITY OF FOND DU LAC, Case No. 92 CV 579
Defendant.

AFFIDAVIT OF ALBERT SCHATZ, Ph.D.
IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

State of Pennsylvania
City of Philadelphia
Albert Schatz, Ph.D., being first duly sworn on oath and with personal knowledge of the information contained herein, respectfully states to the Court as follows:

BACKGROUND

1. I received my B.Sc. in 1942 in Soil Chemistry, and my Ph.D. in 1946 in Soil Microbiology, each from Rutgers University.
2. I have held numerous academic positions. Since 1980, I have been a Senior Professor at Temple University.
3. At the age of 23, I discovered the antibiotic Streptomycin. This compound was the first effective drug for the treatment of human tuberculosis.
4. I have been awarded honorary degrees and titles by the University of Chile, the Autonomous University of Santo Domingo, the Federal University of Espirito Santo in Brazil, the National University of San Antonio Abad del Cuzco in Peru, and the University of Bogota in Colombia.
5. I have been named an honorary member of the Scientific Society of Chile, the Chilean Society of Pediatrics, The Academy of Oral Dynamics (USA), the Stomatological Society of Greece, and many others.
6. I am also a Fellow of the Royal Society of Health in Great Britain.
7. I have published three books, and more than 500 articles in scientific and professional journals, and in popular magazines and newspapers.
8. On the subject of fluoridation, I have published numerous articles, including:
    a. The Failure of Fluoridation in Chile, Pakistan Dental Review, 1967; 15:83.
    b. Failure of Fluoridation in the United Kingdom. Pakistan Dental Review, 1972; 22:3.
    c. The failure of fluoridation in England. Manchester Union Leader, Jan 27, 1973.
    d. Censorship suppresses information unfavorable to fluoridation. Divulgacion Cultural Odontologica, 1975; 110:32.
    e. Increased death rates in Chile associated with artificial fluoridation of drinking water. Journal of Arts, Sciences and Humanities. 1976; 2:1.

9. From 1962 to 1965 I lived in Chile. During that time I served as a Professor at the University of Chile, and worked in the Faculty of Medicine, the Faculty of Dentistry, the Faculty of Agriculture, and the Faculty of Philosophy and Education. I was also associated with numerous projects in the Ministry of Health, Ministry of Agriculture and the Ministry of Education.

EXPERIENCE CONCERNING THE DANGERS OF FLUORIDATION

10. Chile began to experiment with artificial fluoridation in 1953. By the 1960s, it became clear to me that fluoridation was causing serious harm, and I undertook a study which showed increased death rates in Chile associated with artificial fluoridation. My dramatic findings were later published. (Exhibit____).
11. My first finding is perhaps the most disturbing. Those authorized to study and review the safety and effectiveness of fluoridation consistently distorted the data to achieve the desired results.
12. When the data for the three "test" cities in Chile were examined, Curico, F 1 ppm, San Fernando F 0.0 ppm, and La Serena 0.67 ppm, the only possible conclusion was that fluoridation was causing significant numbers of deaths.
13. Consider, for example, the deaths resulting from congenital malformations as a percent of the total number of deaths. Curico has 244% more such deaths than San Fernando, and 94% more than La Serena. (Exhibit____, table 1).
14. Infant mortality rates in Curico were 69% greater than in San Fernando and La Serena. (Id, table 2).
15. For a fuller understanding of some of the harmful effects caused by fluoridation, read exhibit____. Chile abandoned artificial fluoridation shortly after I sent copies of my report to all dental and medical officers in the Pan American Health Organization.
16. In Chile, with widespread malnutrition and high infant mortality, it was not necessary to observe a generation of people throughout their entire life-span in order to determine whether artificial fluoridation is or is not harmful. One could see the lethal effect of fluoridation within the first year of life in terms of increased infant mortality due to acute toxicity of fluoride. Some other adverse effects, like congenital malformations, may or may not cause death.
17. In the US, the harmful effects of artificial fluoridation are not so clearly revealed by large-scale, comparative studies of the total populations of fluoridated and control cities, because Americans as a whole are in a considerably better state of nutrition than Chileans.
18. Nonetheless, artificial fluoridation of drinking water may well dwarf the thalidomide tragedy, which was dramatic because it produced crippled children who are living testimonials to what that drug has done. Many victims of artificial fluoridation, on the other hand, die quietly during the first year of their lives, or at a later age under conditions where their deaths are attributed to some other cause.

EFFECTIVENESS OF FLUORIDATION

19. In 1969, the British Committee on Research into Fluoridation reported the fluoridation of water supplies is a highly effective way of reducing caries. My published analysis of the data, with Dr. Joseph Martin, shows that fluoridation does not protect against tooth decay. (Exhibit____).
20. The data clearly showed that fluoridation only delays the appearance of caries. For example, 10-year-old fluoridated and 8.8-year-old control children had about the same DMFT. A comparison of other corresponding age groups shows a similar delay of approximately 1.2 years in the appearance of caries. (Exhibit ___, figure 2).
21. Fluoridation merely postpones the appearance of caries. Fluoridated children develop the same amount of tooth decay as their non-fluoridated counter-parts over their lifetime. The only difference is that caries start developing approximately 1.2 years later.
22. There is no economic benefit for such actions. Since fluoride does not reduce caries, fluoridated and control children will develop the same amount of tooth decay. Both groups will therefore require the same amount of dental treatment. People in fluoridated areas therefore pay for the same amount of dental treatment plus the added cost of fluoridation.

REFUSAL TO CONSIDER ADVERSE EVIDENCE

23. On the strength of the data I had analyzed in Chile, I wrote L.C. Hendershot, editor of the Journal of the American Dental Association. I asked him if he would be interested in seeing my report of increased death rates, and if he would consider it for publication in JAMA.
24. When he did not reply to that letter of inquiry, I sent him three copies of the report in January, February, and March of 1965. Dr. Hendershot refused to accept all three communications, which were therefore returned to me, unopened. Copies of the certified envelopes, marked refused, are figure 3, exhibit____.

25. Such a response is typical of the proponents of fluoridation. The professional sanctions for opposing fluoridation can be severe, and it is best not to even acknowledge evidence of harm or ineffectiveness.
CONCLUSION
26. Artificial fluoridation has not been as widely accepted as its proponents imply. Many cities in the US have discontinued fluoridation after starting it. Virtually all of Europe has considered and abandoned fluoridation.
27. Because artificial fluoridation causes deaths among individuals who are for one reason or another more sensitive to fluoride toxicity than the total population taken as a whole, the controversy over whether fluoridation does or does not reduce caries is purely academic. It is criminal to implement a so-called public health measure which kills certain people even if it does reduce tooth decay in some of the survivors. As noted, the evidence is that it merely delays decay.
28. It is my best judgment, reached with a high degree of scientific certainty, that fluoridation is invalid in theory and ineffective in practice as a preventive of dental caries. It is dangerous to the health of consumers.
29. I make this Affidavit in support of the Plaintiff's Motion for Summary Judgment.

The following articles were previously submitted and are here for context.

Memphis's Bad News: The Infant Mortality Rate

By NEIL GENZLINGER Published: August 21, 2008

Every war has them: a few searing images caught on film that come to epitomize the conflict. There's a war going on in Memphis right now, and a third of the way into "Babyland," Friday's installment of "20/20" on ABC, there is such an image: workers with a steam shovel burying tiny coffins in a mass grave.

The program is about infant mortality. The United States, we are told, fares poorly among industrialized nations in its survival rate for infants, and the problem is particularly acute in Memphis. "A baby dies in Memphis every 43 hours," Elizabeth Vargas, who reports the segment, says.

This program provides fuel for several fires. The mortality rate, attributable primarily to premature births, is especially high among low-income blacks. (That mass grave, the burial of last resort, is in a public cemetery whose nickname gives the program its title.) Many of the women who lose babies are young and unmarried, and you can guess the resulting lines of argument.

But rather than dwell on these familiar and polarizing debates, the program commendably focuses on grass-roots efforts to address the problem.

There is Terry Drumwright, a white woman from the wealthy suburbs who, through a program at her church, is trying to make a difference (and walk that fine line between assistance and condescension) by working one on one with a pregnant black teenager. There is Dr. Linda Moses, who is from these poor neighborhoods and has now come back to practice there.

"How much of your job is basic education?" Ms. Vargas asks her.

She answers bluntly, "All of my job is basic education."

The program alludes to a bigger picture — of poverty, of race-based government indifference — that makes these personal crusades feel like lost causes. But the mere fact that someone is making them is wonderful to see.

Vital Statistics

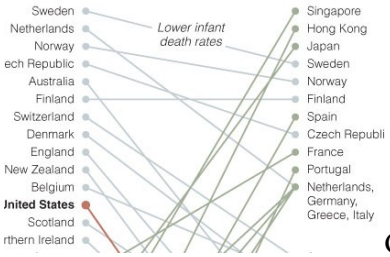
U.S. Still Struggling With Infant Mortality

By NICHOLAS BAKALAR

Published: April 6, 2009

Infant mortality has been declining slightly in the United States. But 28,000 children under the age of 1 still die every year.

Multimedia



Graphic

Infant Mortality Rates World Wide

Times Topics: Infant Mortality

The main reason for the high rate is preterm delivery, and there was a 10 percent increase in such births from 2000 to 2006, according to recent figures from the Centers for Disease Control and Prevention. (In 2007, according to preliminary data just published by the C.D.C. , that rate declined by 1 percent, mainly among late preterm infants.)

In 2004, the latest year for which worldwide data are available, the United States had a higher rate than 28 countries, including Singapore, Japan, Cuba and Hungary. In 1960, the United States had a higher rate than only 11 countries.

There are large differences by race and ethnicity. Non-Hispanic black, American Indian, Alaska Native and Puerto Rican women have the highest rates of infant mortality, while Asian and Pacific Islanders, Central and South Americans, Mexicans and Cubans have the lowest.

"We think the increase in preterm birth and preterm-related causes of death are major factors inhibiting further declines in infant mortality," said Marian F. MacDorman, the lead author of the report and a statistician at the C.D.C. "Infant mortality is a major public health problem, and it's not improving."

The following statements were excerpted from the sworn affidavit of Dr. A. Susheela, in support of litigation against the city of Fond du Lac,WI using controlled dosing of industrial fluoride in the water supply at levels recommend by the OHD. Specific fluoride levels used in her studies are not listed in the testimony, but the specific comments were intended to be relevant for water fluoridation as conducted in the United States. Susheela was first to report that consumption of 1 ppm industrial fluoride in water presents anemia as the most significant early event that is also morphologically concurrent with microscopically visible damaged cells in the intestinal villi that are known to be essential for normal assimilation of iron required for red blood cell function and prevention of anemia.

State Of Wisconsin
Circuit Court
Fond Du Lac County
SAFE WATER ASSOCIATION, INC., Plaintiff,
vs.
CITY OF FOND DU LAC, Defendant.
Case No. 92 CV 579

AFFIDAVIT OF A.K. SUSHEELA, Ph.D.
IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

Nation of India
City of New Dehli

A. K. Susheela, Ph.D., being first duly sworn on oath, under penalty of perjury, and with personal knowledge of the information contained herein, respectfully states to the Court as follows:

1. I, Dr. A. K. Susheela, have spent more than 20 years doing scientific research in the field of Fluoride Toxicity and Fluorosis.
2. I am a full Professor of Anatomy (Histocytochemistry) and Chief of the Fluoride and Fluorosis Research Laboratories, at the All India Institute of Medical Sciences, New Delhi.
3. I have held Faculty positions at the same Institute since 1969.
4. I am a Ph.D from India, with Post-doctoral training under LORD WALTON (Neurologist) of U.K. and Dr. Ade Milhorut of the Muscle Institute, New York, USA, (which no longer exists).
5. I was a Visiting Professor at the Allan Hancock Fnd. at the University of Southern California during 1974-76.

6. I am a Fellow of the Indian Academy of Sciences and the National Academy of Medical Sciences.
7. I have won the prestigious Ran Baxy Research Foundation Award (Cash Prize) for outstanding research in medical sciences.
8. I have been involved in teaching medical students of all levels and carrying out research and guiding research in the field of muscle diseases and Fluorosis for more than 20 years.
9. My field of interest for the last 20 years has been Fluoride and Health Hazards.
10. Numerous funding organizations have been calling upon me during that time for evaluating projects for funding in the field of Biomedical Research.
11. I have been a member of several National Committees since the early 1970s, where issues related to Fluoride are debated and discussed.
12. I have convened an International Conference on Fluoride and Fluorosis research in India in 1983. I edited a book on Fluoride Toxicity in 1985.
13. I have been invited to speak on my experience in the field of Fluoride Research at various scientific meetings held in: (1) Japan; (2) Denmark; (3) Switzerland; (4) Kenya; (5) U.S.A. (several times); and (6) Hungary.
14. I have guided 6 Ph.D theses in the subject of Fluoride and Health Hazards. A 7th Project is ongoing.
15. I have more than 80 scientific publications in leading Western and Indian Journals.

SAFETY OF FLUORIDATION

16. From my extensive experience, I state without hesitation and with a high degree of scientific certainty, the following evaluation of fluoridation.
17. India launched a Technology Mission on "Safe Drinking Water" in 1986 (now re-designated after the late Prime Minister Sh. Rajiv Gandhi, as Rajiv Gandhi National Drinking Water Mission) in which every drinking water source in the rural sector is checked for water quality, especially for Fluoride.
18. People are keen to defluoridate the water due to gastrointestinal problems and are adopting indigenous technology for obtaining potable (defluoridated) water.
19. Results include reduced abortions (as Fluoride is known to induce calcification of blood vessels of the fetus).
20. Reduced still births (as Fluoride is known to induce calcification of blood vessels of the fetus).
21. I am absolutely certain that large numbers of persons all around the world are suffering from Fluoride Toxicity, to one degree or another.
22. The various and frequent health complaints, caused by fluoride ingestion, are often (or invariably) over-looked due to unawareness at all levels, which include the health professionals or, perhaps, due to the prevailing ill conceived, unscientific notion that "fluoride is good for teeth."
23. Fluoride is potentially a dangerous chemical and a poisonous substance, which does no good to the human body.
24. With a high degree of scientific accuracy and certainty, I conclude that artificial fluoridation of drinking water is an ineffective means of improving dental health, and is in fact quite dangerous to those forced to consume it.
25. I make this Affidavit in support of the Plaintiff's Motion for Summary Judgment.
26. Studies on human teeth have shown that fluoride alters a chemical substance in the matrix of the tooth. The mineralization process is abnormal, leading to changes in mineral content, and cavities or pitting are known to occur.

In other words, Fluoride induces cavity formation, as well as discoloration of teeth. It is also evident that use of fluoride can lead to loss of teeth at an early age and one becomes edentulous. See The Status of Sulphated Isomers of Glycosaminoglycans in Fluorosed Human Teeth. (Exhibit____).

#11 **Richard Sauerheber, Ph.D.**
(B.A. Biology, Ph.D. Chemistry, University of California, San Diego, CA)
Palomar College, 1140 W. Mission Rd., San Marcos, CA 92069
May, 2011

Department of Health and Human Services
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Office of Regulatory Policy
Rockville, MD 20857

Dear Petition Reviewers,

It is necessary to send additional information regarding the petition to ban industrial fluoride injections into human water supplies, FDA 2007-P-0346, formerly 2007P-0400.
It has come to my attention that the FDA has taken a stern measure in warning a public broadcaster regarding claims of arsenic levels in apple juice. I commend the FDA for this action to clarify the truth, that is, when to be concerned about contaminants and when it is not necessary to be concerned, for various foods and beverages.

Along this line, it is important now also for the FDA to similarly interact with U.S. water districts and/or chemical suppliers that claim water supplies are safe to use as a vehicle to disseminate fluosilicic acid, for its fluoride to treat people without obtaining FDA approval for the ingestion of the synthetic compound employed. Total arsenic levels in water quality reports are not distinguished between methylated organic (nontoxic) or inorganic (Type Class IA certain human carcinogenic) arsenic, which is the very reason the FDA presented its stern warning mentioned above. We realize that FDA does not regulate contaminants in public water supplies. However the problem here is overlap with fluosilicic acid compounds that are indeed added to specifically elevate blood fluoride levels in consumers through water supplies as vehicle of choice.

Fluosilicic acid plus required caustic soda is injected to elevate the fluoride content of the bloodstream of citizens to 0.21 ppm (see original petition). As stated to FDA previously, in our present society this is a contraindication to human health merely for the reason that waters now in the U.S. are widely contaminated with materials that do not belong in fresh drinking water that are not tolerated particularly by the unhealthy and those with kidney and other diseases. The water quality report enclosed here from the North San Diego County region 2011 reports that industrial fluoride is added to top off the fluoride ion level to 1.0 ppm that also elevates the sodium ion level to 85 ppm, while the silicic acid level is not reported or tested. The HHS request to not exceed 0.7 ppm fluoride was honored for about one month here, but the level is now readjusted back to 1.0 ppm for intended permanent consumption without FDA approval.

The specific problem with adding blood treatment chemicals without FDA approval, and without an FDA new drug application, is that the vehicle used for this drug itself contains numerous cancer-causing agents at levels that have now exceeded that allowed by the state of CA as a Public Health Goal, and for arsenic the level in the Twin Oaks plant exceeds even Federal allowed levels at a listed maximum massive 120 ppb (allowed at 10 ppb Federal, with a non-enforced state PHG of 0.004 ppb). The number of days and the date at which these levels are reached are not reported. Many people particularly with health conditions who debate whether to drink public water in the presence of carcinogens are thus sent mixed messages, where fluoride that is perceived to be of benefit would be 'missed' if the water were not consumed, thus convincing many to consume it, regardless of other contaminants also present.

Please understand that the EPA who is in charge of water contaminants does not provide or have guidelines for water supplies that are contaminated with multiple regulated carcinogens all present in the same water at the same time, or for water treated with aluminum and fluoride intentionally for different purposes that interact in the stomach (see original petition). Lead binds to protein sulfhydryls as does arsenic, and both are present in the same water above their respective PHG's and as mentioned arsenic alone routinely exceeds Federal limits. Fluoride is a known mutagen and teratogen and a cancer promoter (see original petition) and is able to induce bone cancer when ingested for very long time periods in the genetically susceptible. (For this reason fluoride salts are now under review by the CA EPA).

Sadly, chromium Vl is here also present at more than 5 times the PHG (0.16 ppb for which no Federal level has yet been established in spite of efforts by the famous Erin Brockovich). Also lead (listed here as 'local') has been reported in excess of the Federal allowed limit of 10 ppb, depending on the local neighborhood tested, aluminum (no longer listed) is typically 0.05 ppm, arsenic (1.9 ppb average, 120 ppb highest reading, which are 400-30,000 times the PHG and 0.2-20 times the Federal allowed maximum), strontium 90 and uranium total 7.5 pCi/L (below the allowed Federal level for each as separates, but 4.7 and 7 times the PHG respectively) and halogenated hydrocarbons at a gross total of 258 ppb, 3 times the Federal allowed level for any one as a separate.

This water system is unfit to use as a vehicle to treat citizens with industrial fluoride compounds, for better or for worse. The petition has formally requested that FDA either 1) ban the dissemination of industrial synthetic fluoride compounds intended for human ingestion, or 2) announce the requirement to apply for a new drug application for synthetic fluoride compounds proposed to be ingested (that will require controlled human clinical trials data using city water as vehicle to disseminate the compound for ingestion). *It is also advisable to write letters of inquiry to one or more chemical suppliers of fluosilicic acid (Cargill, Lucier, Solvay Chemicals, etc.) requesting any available data to be presented for FDA records that demonstrate efficacy and safety for the ingestion of fluosilicic acid in humans.*

#12 **Richard Sauerheber, Ph.D.**
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January 5, 2012

U.S. Food and Drug Administration
Centers for Drug Evaluation and Research
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Dear Reviewers,

This information is provided in support of the petition to ban the intentional dissemination and ingestion of the industrial synthetic fluoride compounds fluosilicic acid and sodium fluoride, petition FDA-2007-P-0346, formerly 2007P-0400.

Definitions of Ingested Synthetic Industrial Fluoride.

Federal dental officials within the U.S. Centers for Disease Control request the injection of synthetic industrial fluoride compounds into public water supplies and claim that fluoride is not a drug and could escape the Food Drug and Cosmetic Act. Also fluoride is argued to be a 'supplement' and since it 'belongs in water' it could escape the Safe Drinking Water Act. Finally, since some waters in the U.S. contain fluoride naturally (as the nontoxic natural calcium fluoride), it is argued to escape control by the Water Pollution Control Act either.

Fluoride in proponents' opinion is basically a mineral in the diet that is believed by them to prevent or mitigate teeth caries and is given special honor to inject into virtually all U.S. public water supplies to treat humans. Not being a food (agreeable, since it has no calories) and not being a mineral nutrient (agreeable to the FDA, see original petition and Petition for Reconsideration), fluoride is presumed a 'supplement' that 'mitigates bacterial-induced teeth caries'.

Putative Rationale for Mass Injection of Industrial Fluorides into U.S. Public Water Supplies.

On one hand, teeth caries are argued to be non-communicable and thus not a serious condition. This attempts to avoid regulation of fluoride as a disease-treating agent and instead purports to merely present an innocent, unregulated 'health claim'. In contradiction to this, the CDC goal to mass inject 70% of all U.S. water supplies with industrial synthetic fluoride compounds is justified by their alternative argument that dental caries are a serious disease that can lead to crippling conditions. Which is it? If the latter is true, then claims made to justify fluoride taken internally are more than mere 'health claims' and are claims to prevent or mitigate disease. In this case fluoride is being used as a drug for drug-like properties, albeit one that is not FDA approved, that thus requires an FDA ban because it is widely used with claims of disease mitigation without controlled clinical trials or data in proof for that claim.

On the other hand, if one takes the view that caries are not a serious disease and that fluoride is a supplement that merely deserves a 'health claim', then FDA is in charge of the wording used by water districts that claim it is a teeth-improving and safe-to-consume agent. Changes in teeth structure induced by the agent taken internally by ingesting water must go through an FDA approval process with data supplied to demonstrate those claims, and obviously the purchase and use of the materials must be optional, not requested for mass dissemination through all public water supplies for such a mere health claim.

Fluoride Interactions with FDA-Approved Drugs.

A key point that has not been considered (whether one considers industrial fluorides taken internally to be drugs or not, or supplements or not) is that fluoride is known to interfere with common FDA-approved drugs that are in wide use in the U.S. Most of these drugs are designed to enhance calcium uptake and bone strength, but some are blood clot preventives and blood thinning agents. Fluoride minimizes calcium uptake from the gastrointestinal tract, just as fluoride assimilation is likewise inhibited by the presence of calcium ion. (This is the reason calcium is the antidote to fluoride poisoning, due to the affinity of fluoride for the double positive charged calcium ion). Fluoride inhibits the actions of drugs designed to enhance calcium uptake and to strengthen bone. Fluoride however potentiates the effects of blood clot inhibiting drugs by virtue of its high affinity for association with calcium, restricting the chemical potential, mobility and general physiologic action of the calcium ion.

In order to protect FDA-approved drug effectiveness and use, it is necessary to ban fluoride injections into public water supplies on the mass scale currently employed in the U.S., no matter what definition(s) one might choose to use for the fluoride ion intended to be ingested. A partial list of FDA-approved drugs that are in common use that are NOT to be used in fluoridated cities, or in conjunction with Luride tablets, or with vitamins in which fluoride is added, are:

http://www.drugs.com/drug-interactions/multivitamin-with-fluoride.htmlMultivitamin with fluoride Drug Interactions

Drug Interactions. A total of 8 drugs (18 brand and generic names) interact with multivitamins with fluoride.

- 3 major drug interactions, 4 moderate drug interactions, 1 minor drug interaction

Medications known to interact with multivitamins with fluoride include but are not limited to:

- Alli (orlistat)
- anisindione
- Calcijex (calcitriol)
- calcitriol
- colesevelam
- Coumadin (warfarin)
- dicumarol
- doxercalciferol
- Hectorol (doxercalciferol)
- Jantoven (warfarin)
- Miradon (anisindione)
- orlistat
- paricalcitol
- Rocaltrol (calcitriol)
- warfarin
- Welchol (colesevelam)
- Xenical (orlistat)
- Zemplar (parical)

Dosage instructions with fluoride-containing vitamins or with Luride tablets state that ingested fluoride is only available by prescription and are not to be taken by women intending to become pregnant and are not to be taken in cities with fluoridated water supplies. Some dosage instructions state that it is not known whether fluoride enters breast milk, while other prescription labels indicate fluoride does enter breast milk. In both cases, women are directed to consult with their doctor before taking these agents that contain fluoride.

It again must be emphasized that fluoride is not listed in the U.S. Pharmacopeia as a Congressionally-recognized legal drug, or an official FDA-approved drug. There are no human controlled clinical trials data or a drug application with the FDA that has ever been approved for any synthetic fluoride to be taken internally by ingestion. Fluoride formulations in waters (which vary from city to city in water contaminants and hardness) are being used with constantly changing suggested levels (which have recently varied from 0.7 to 1.2 ppm), rendering fluoride ingested from water an unapproved and thus illegal drug, and its intentional dissemination for ingestion must be banned.

If fluoride is defined however as a supplement or mineral allowed in the human diet, taken internally to affect teeth caries in the general population as a mass-disseminated substance for ingestion, then it must be banned as well to protect the safety and effectiveness of the above-listed FDA-approved drugs now in common use in the U.S. It is then appropriate to refer to ingested industrial synthetic fluoride as an 'anti-drug', because of known interactions with legal FDA-approved drugs that are recognized in the U.S. Pharmacopoeia, while fluoride is not.

Although synthetic industrial fluoride added into water supplies to be ingested by U.S. citizens, in an attempt to treat or prevent dental caries, may not be necessarily precisely legally defined by the FDA, as a final note please understand that the actual chemical definition of synthetic fluoride compounds, as provide in the original FDA petition, has never wavered at any time, and that is:

"Synthetic fluoride compounds lacking calcium are toxic calcium chelators" (see original petition).

Through reason of use, when these compounds at dilute concentrations of 1 ppm are considered putative anti-caries agents, it is legitimate to refer to these toxic materials as either illegal drugs, or as putative supplements that are known not to be mineral nutrients, that do not have FDA approval, and in either case require a ban by the U.S. Food and Drug Administration for intentional ingestion by citizens in the U.S.

No Regulations or Statutes Exist that Block the FDA from Issuing a Ban for the Dissemination of Synthetic Fluorides Intended for Human Ingestion.

If information is required by the FDA on Federal regulations that apply to statements made in this letter, that information will be forwarded. If the FDA argues or believes that the requested ban is 'disallowed' by Federal law, though no such legislation exists, then please issue a moratorium, injunction, or temporary cessation of the intentional dissemination of synthetic industrial fluorides for human ingestion. This is legal and required, because no clinical trials data exist, no new drug application has been filed and approved by the FDA, and no information has been provided that proves consumption of injected fluorides from synthetic compounds is a dietary supplement with benefit and that is safe for human consumption, for those using the above listed medications, or the infirmed, or even the general population for permanent lifetime ingestion that fluoridation involves. The moratorium is justified by the widespread dissemination and ingestion of synthetic fluorides that still continues in spite of lack of FDA approval or oversight.

Cessation by the FDA of the dissemination of synthetic industrial fluorides for human ingestion is additionally justified by the fact that normal drinking water is a REQUIRED consumable by all people. If fluoride were an optional purchase, such as in Luride, vitamins with fluoride, or in bottled fluoride water, then this petition would never have been submitted. It was submitted because synthetic fluorides continues to be ingested daily, without FDA approval or oversight, by most of the entire U.S. population and also continues to spread to new cities.

The interaction of fluoride, consumed from that injected into drinking water, with drugs cannot be argued to be insignificant. The dosage instructions on Luride or vitamins with fluoride clearly indicate these are contraindicated in cases where fluoride is consumed from water at 0.7 ppm or higher. In other words, the amount of fluoride from drinking water supplants that which would have been assimilated from these prescription items. Indeed, the National Research Council 2006 (Report on Fluoride in Drinking Water, A Scientific Review of EPA's Standards, Washington, D.C.) proves that the blood level of fluoride in residents of cities treated to 1 ppm fluoride averages 0.21 ppm, which is the specific concentration that fluoride proponents target to achieve through either Luride tablets, vitamins with fluoride, or fluoride treated drinking water (personal communication, Donald Nelson, Chief Fluoridation Officer, CA Department of Health Services, Sacramento; see original petition court testimony). Luride and vitamins with fluoride are listed as contraindicated for patients taking the above-listed medications, so drug interactions with fluoride from drinking water are also obviously significant.

Concluding Remarks.

Luride, and fluoride with vitamins, are contraindicated in children under four and in pregnancy, and for good reason always require prescription and use only under a doctor's oversight. Such restrictions do not exist and are not provided from either water districts, chemical suppliers of fluoridation materials, or Oral Health Division dental officials within the Centers for Disease Control who request the mass dissemination of fluoride into public water supplies to be taken internally. Taken together, all the data provided to the FDA, in the original petition and its supplements, the Petition for Reconsideration and its supplements, and the recent 12 letter series, clearly demonstrate that it is essential that the FDA stop the willful continued permanent ingestion of mass-injected industrial synthetic fluoride compounds by U.S. citizens as quickly as possible.

#13. **Richard Sauerheber, Ph.D.**
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Center for Drug Evaluation and Research
Rockville, MD 20857

Dear Reviewers,

This information is in support of the FDA petition 2007-P-0346.

I mailed the following letter to local city officials who recently were forced by State officials, at the request of Federal officials from the OHD of the CDC, to begin industrial fluosilicic acid injections into all San Diego city water supplies in spite of two city elections voting otherwise. The CA state law, that the officials claim forces them to overturn city-wide elections, does not mention fluosilicic acid or any fluoride source compound, nor mentions the water level to inject or the procedure to use, nor requires monitoring blood fluoride to check for treatment target level success, nor requires tooth decay or tooth fluorosis incidence monitoring. The language in the State bill presumes without proof that caries would decrease and that no mentionable adverse health effects would exist in any group regardless of health status or ethnicity, and regardless of calcium content of the treated water. Understand that CA Department of Health officials wrote that the State assumes zero liability for the water fluoridation it requests and that city officials freely decide whether to fluoridate and thus assume all liability. Further, the U.S. Centers for Disease Control formally wrote that States and cities take full responsibility and full liability to fluoridate public water supplies that the CDC recommends.[a]

Dear San Diego City Council and Public Utilities Officials,

As you know, the intent of the U.S. Safe Drinking Water Act is to prohibit any requirement for the addition of substances into water other than to sanitize it. You are now adding fluosilicic acid diluted hazardous waste into water to treat teeth, and you say CA State law forces you to do so in spite of wording in the SDWA.

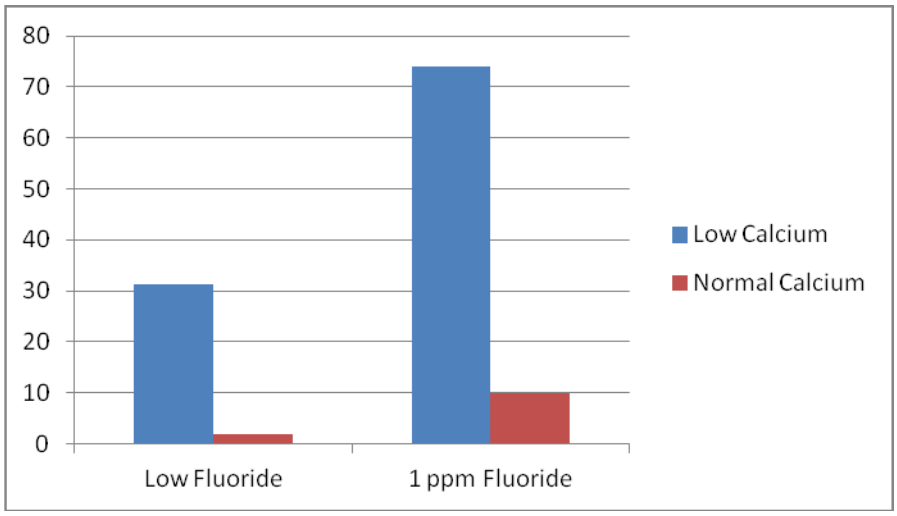
Could you then at the very least honor the mission of that State law, to improve teeth, by considering getting at the root of the problem of cavity causation, for example by providing calcium nutrition and counseling for residents with any calcium deficiency and high dental caries incidence (see graph below) -- instead of broadly treating everyone with synthetic industrial fluoride through public water? This way calcium can be provided to help build strong teeth where it is actually needed.

Fluoride has side effects including tooth fluorosis and bone weakening that calcium does not cause. After 30 years of detailed studies on four hundred thousand children [1] it was published that dental caries increase a massive 16 times higher in incidence in children with calcium-deficient diets, which occurs whether water contains appreciable fluoride or not. The authors concluded:

"The only practical and effective public health measure for the prevention and control of dental canes is the limitation of the fluoride content of drinking water to < 0.5 ppm, and adequate calcium nutrition (dietary calcium > 1 g/day)."

[1] S P S Teotia and M Teotia, Dental Caries: A Disorder of High Fluoride and Low Dietary Calcium Interactions (30 Years of Personal Research), Fluoride 1994; 27(2): 59-66.

Caries Incidence % vs. Low or Normal Calcium and Low or 1 ppm Fluoride



The percentage of dental caries are graphed as a function of the presence of dietary calcium deficiency (blue bars), accompanied with either low fluoride (left) or approximately 1 ppm fluoride levels in drinking water (right), and normal dietary calcium (red bars) accompanied with either low fluoride (left) or 1 ppm fluoride in drinking water (right). The data are from Teotia and Teotia for a 30 year study of 400,000 children. Notice that the highest incidence of caries was found in children with a calcium deficient diet where water was approximately 1 ppm fluoride. The lowest caries incidence was found in children with low fluoride water while also having adequate dietary calcium.

The reason for these results are obvious. Calcium is the chief ingredient in normal teeth enamel, and normal crystalline hard enamel that resists cavities can only form in children in the absence of fluoride-induced enamel fluorosis. Fluoride is unable to counter increased caries incidence from calcium dietary deficiency, and in fact fluoride contributes to caries incidence in this case. Fluoride also causes tooth fluorosis in children, whether on calcium-deficient or normal calcium diets (not shown for brevity).

Doesn't it make sense to use the best available mineral to help teeth? If you are planning to continue disseminating a substance to be taken internally to affect teeth, then shouldn't it be a substance like calcium, that is a normal dietary component, has a daily dietary requirement, is a mineral nutrient and an essential body component required for teeth enamel formation, and its deficiency causes conditions favorable to formation of caries? Fluoride is not a mineral nutrient according to the U.S. Food and Drug Administration, has no daily dietary requirement, from the bloodstream can cause tooth fluorosis, and after ingestion produces only 0.02 ppm fluoride ion in saliva [2] unable to affect teeth topically.

[2] National Research Council Report on Fluoride in Drinking Water, A Scientific Review of EPA's Standards, Washington, D.C., 2006.

Calcium supplementation corrects calcium deficiency, that causes inadequate enamel formation and conditions that lead to dental caries. Let's treat the causes, insufficiently developed enamel and not brushing after eating sugary foods, rather than after-the-fact attempts to treat the symptom, cavities, with fluoride in drinking water where dosage cannot be controlled, and that is of no significant value as observed in large numbers of studies [3], where the absence of fluoride in drinking water does not itself cause dental caries. Caries are caused by acid secretions from S. mutans metabolizing sugars, where insufficient enamel covering teeth dentyne is the most readily breeched.

[3] Connett, P., et.al., The Case Against Fluoride, How Hazardous Waste Ended up in our Drinking Water and the Politics that Keep it There, Chelsea Green Publishing, White River Junction, Vermont, 2010.

Although we hope for the FDA to ban fluoride water injections, or to prevent its use until a new drug application is sent to the FDA, a very useful action would be for the FDA to prohibit Federal and State officials from requesting that cities inject synthetic fluoride compounds into public water supplies. This would be a great help for the country.

[a]footnote. Letters will be forwarded on request from the CA Department of Health Services and from the U.S. Centers for Disease Control that contain these signed statements.

Enclosure on calcium deficiency and enamel hypoplasia:

http://www.identalhub.com/article_enamel-hypoplasia-370.aspx

Hypocalcaemia is a specific cause of tooth enamel hypoplasia. Recently evidence has suggested that the etiology of enamel hypoplasia is highly specific. Enamel hypoplasia is seen in children having disorders of calcium homeostasis. Low calcium level in serum is one of the major causes of enamel hypoplasia.

Enamel Hypoplasia and Caries. Enamel hypoplasia is clinically significant not only because it is disfiguring and the restorative treatment costly, but because it may affect caries susceptibility. There was a strong correlation between hypoplasia in the teeth of British schoolchildren and caries susceptibility. Out of a collection of 1,500 extracted teeth, 74% of very hypoplastic teeth were carious, whereas 80% of the nonhypoplastic teeth were caries–free. Caries has also been associated with hypoplasia in many parts of the Third World. There is no information about the chemical composition of hypoplasia enamel so the exact reason for its greater proneness to caries is uncertain, but it is possible that its irregularity and pits may favor the development of more plaque compared with smooth well-formed enamel.

Enamel hypoplasia is due to many causes. It can be due to high fluoride level or due to some medicines or if the child becomes ill when the teeth which are affected by enamel hypoplasia are being formed. The treatment depends on degree of hypoplasia. Intially the composite restorations are done and if it is more (i.e. whole of enamel is hypoplastic) then veneers or crowns are indicated in later age when the teeth are fully formed.

#14. **Richard D. Sauerheber, Ph.D.**
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U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Rockville, MD 20857

Dear Reviewers,

The following information should be of help in evaluating the fluoride water ban petition, FDA2007-P-0346.

As provided to the FDA earlier, detailed statistical analyses by Ziegelbecker [12] indicate a wide variation in teeth caries incidence among people in a large U.S. population that is unrelated to fluoride levels in drinking water. Vitamin D and calcium, rather than fluoride, is important for normal teeth health and development. Variation in caries incidence found among people may be explained by variation in vitamin D and dietary calcium.

It has long been known that vitamin D, necessary for the proper assimilation of dietary calcium through the intestines, decreases dental caries. [Dr. Anthony Norman, world expert on the mechanism of action of vitamin D, is a former colleague.] The late Dr. Linus Pauling, a former mentor, founded the Orthomolecular Medicine organization, and the following description is paraphrased from a published article by that organization. The U.S. Public Health Service in 1950 ignored well-published data and accepted the idea that fluoride added to water might fight tooth decay.

Orthomolecular Medicine News Service, February 19, 2009

Vitamin Deficiency Underlies Tooth Decay

There is especially strong evidence for a relationship between vitamin D deficiency and cavities. Dozens of studies were conducted in the 1930's and 1940's [1-11] that concluded that supplementing children with vitamin D prevents cavities. Between 5,000 and 15,000 IU of vitamin D may be obtained from modest exposure to sunshine in the middle of the day. Recommending that people regularly use the capacity of their skin to make vitamin D is common sense. 1,000 to 2,000 IU per day of vitamin D in supplemental form is safe to help prevent tooth decay.

References:

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12] Connett, P., et.al., **The Case Against Fluoride, How Hazardous Waste Ended up in our Drinking Water and the Politics that Keep it There**, Chelsea Green Publishing, White River Junction, Vermont, 2010.

#15 **Richard Sauerheber,Ph.D.**
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U.S. Food and Drug Administration
Centers for Drug Evaluation and Research
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Dear Reviewers,

This information is provided in support of the petition to ban the intentional dissemination and ingestion of the industrial synthetic fluoride compounds fluosilicic acid and sodium fluoride, petition FDA-2007-P-0346, formerly 2007P-0400.

The U.S. Centers for Disease Control and Prevention, Oral Health Division desires that water fluoridation be conducted in most all U.S. water supplies, as described on the CDC fluoridation website. State Public Health Departments under the authority of the CDC promote and require fluoridation of city water supplies. City administrators instruct water districts to fluoridate under the authority of their State Health Departments.

However, questions regarding proof of safety and effectiveness of the ingestion of industrial fluorides from water, or procedures used to monitor the injections to determine effectiveness for a given water supply containing various local contaminants and differing water hardness, all the above groups deny authority and responsibility and do not provide answers to such questions. The CDC and State Health Departments go so far as to deny liability and responsibility for the injection of fluorides into public water supplies that they themselves request! CDC lays liability on State Health Departments, which officially give liability to city officials, who themselves claim are required to do so by State Health Departments, who defer authority and all questions to the CDC.

Enclosed as proof of this endless circle are letters from the Metropolitan Water District, Los Angeles, CA the CA State Department of Public Health, and the U.S. Centers for Disease Control and Prevention. Each were asked for data they possess that demonstrates that ingested industrial fluoride, from public water supplies, decreases caries and exerts no adverse health effects in consumers long-term and without such data to please halt its use. In response, the MWD President denied any authority or knowledge of either safety or effectiveness of fluosilicic acid injections into Los Angeles water supplies and wrote that MWD completely relies on the authority of the CA Department of Public Health for answers to questions of safety and effectiveness of the injections that DPH officials request of them. On the contrary, in the same segment in time, the CA Department of Public Health denied liability or responsibility for the injections, and writes that all liability and responsibility lies with city officials themselves whether to inject fluoride compounds or not into public water.

Further, in an e-mail from the CA Department of Public Health chief fluoridation officer I was told that it is the CDC who decides what the State Health Department requests and how to inject fluoride compounds into water and answers all questions of safety and effectiveness. Finally, notice however the letter from the CDC, which clearly contradicts this and states that CDC is a non-enforceable, non-regulatory investigative agency, and thus accepts no responsibility or liability for fluoride injections into water supplies. My request to the CDC for data demonstrating the safety and effectiveness of the ingestion of fluoride compounds from water supplies was thus denied when I was told to write to the CA State Health Department (who had already told me to write to the CDC!). The only response to questions of effectiveness was the usual endorsement by the Surgeon General that it is a great 'public health achievement'. The CDC denies liability and responsibility and gives such to the States, which in turn insist on being accepted by the cities, which in turn give authority back to the States, which give such to the CDC…...

The fruit of this deceptive practice, where fluoridation is not being regulated or monitored (for accuracy among various types of water supplies) by any Federal agency, is well documented. Illness and adversity caused by

fluoride ingestion. When proven and brought to suit, requires lengthy trials, where routinely cities claim the State has liability for requiring the injections, while the State claims cities have full liability because the cities decided to fluoridate. The lawsuit is still ongoing now for years for the tragic death of Dominic Smith during the Hooper Bay, AK fluoride water overfeed poisoning disaster (the first topic discussed in this original FDA 2007 petition).

When will this endless circle be broken? Only when the HHS and FDA order that CDC and State officials cease and desist in requesting or endorsing the injection of fluoride compounds into public drinking water supplies in the U.S. The order is necessary because industrial fluoride compounds, disseminated into public water supplies for ingestion to treat humans, is an uncontrolled use of an un-approved drug or drug-like substance. Fluorides have never been *formally approved* for ingestion in the U.S. for any purpose, and have been *allowed by prescription only* but only in cities that do NOT fluoridate public water supplies to 0.7 ppm fluoride or higher. *It is necessary for the CDC, the U.S. Surgeon General, and all State Health Departments to withdraw public endorsement of industrial fluoride injections into public drinking water to treat humans with its internal ingestion.* It will require the Center for Drug Evaluation and Research, U.S. FDA to achieve this withdrawal of endorsement by the OHD of the CDC, being another agency now part of Health and Human Services.

Copies of letters in response to request for data demonstrating long-term consumption safety and effectiveness of industrial fluoride compounds added into public drinking water and to halt such additions in the absence of such data (letters are in sequential series according to date of receipt and reflect communication from local, to State, to Federal level in succession). Original signed letters can be forwarded if necessary.

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Letter from Chief Donald Lyman, CA Department of Public Health, 2007.

Letter from President Jeff Kightlinger, Metropolitan Water District, Los Angeles, CA, 2009.

Letter from Associate Director for Communication, U.S. Centers for Disease Control and Prevention, 2010.

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Dear Reviewers,

This information is sent in support of the 2007 ban petition 2007FDA-P-0346, formerly 2007P-0400/CP1, and its Petition for Reconsideration, submitted 2010. Scientific facts are now clear today that were not known in the 1940's, 50's, 60's or 70's when fluoride injections into public water supplies began and spread to many U.S. cities. One of the most significant new findings is, as stated in an earlier letter, *there is now no doubt that synthetic fluoride from ingested industrial compounds sodium fluoride or fluosilicic acid, crosses the blood-brain barrier* [1,2,3,4,5].

This letter provides additional supporting data that indicate the absolute urgency for the FDA to halt water fluoridation in the U.S. or at the very least to request that Federal officials withdraw all endorsements for fluoride injections into water to treat people through internal ingestion. A widely employed American Water Works Association procedure is to add aluminum-based alum into raw water as a flocculant to remove dissolved solids. Unfortunately, this treatment chemically always leaves behind detectable levels of aluminum ion in the product water due to aluminum intrinsic finite chemical solubility. A typical residual level reportted by many water districts is 0.05 ppm aluminum ion. In the presence of added fluoride ion at 0.7 ppm, it is well accepted that aluminum fluoride complexes form in the acidic stomach, enhancing aluminum uptake into the blood after ingestion.

Aluminum loading in the brain is twice as high in rodents given aluminum fluoride water at concentrations comparable to the above, compared to aluminum water alone since aluminum ion itself is not assimilated well. The effect is due to formation of uncharged aluminum fluoride complexes at acidic pH. Although fluoride assimilation is somewhat reduced in the presence of substantial aluminum ion, sadly aluminum uptake is far greater as a result. Mammals given aluminum fluoride water develop abnormal brain function, and the abnormal brain tau proteins in human Alzheimer's disease bind aluminum ion efficiently to exacerbate the condition.

Please understand that of all the leading causes of death due to disease in the United States, only Alzheimer's disease has neither a cure nor an effective treatment. Moreover, of the top 6 leading caues of death, only Alzheimer's continues to rapidly rise in incidence while all others are either declining or holding steady. Notice below the graph of U.S. data on incidence of lethal diseases as a function of year in the U.S. The incidence of Alzheimer's continues to escalate exponentially since first recording in 1978. These data have been confirmed in publications printed by the Alzheimer's Association. Presently, California leads the nation in per capita incidence of Alzheimer's disease, and San Diego County leads CA in its incidence. Southern CA aluminum treatment of water supplies is now coupled with fluoride injections, in Los Angeles since 2007 and in San Diego since 2011.

In non-fluoridated cities that treat drinking water with aluminum, where aluminum assimilation is minimal, industrial fluoride injections must be blocked, and use of Luride, particularly in the elderly, is contraindicated on first principles. There are in fact no valid reasons to excuse and allow the continuous internal ingestion of any industrial fluoride by citizens of the United States. It is necessary for government agencies to immediately stop requesting industrial fluoride injections into U.S. water suplies and to withdraw all endorsements for the internal ingestion of fluoride.

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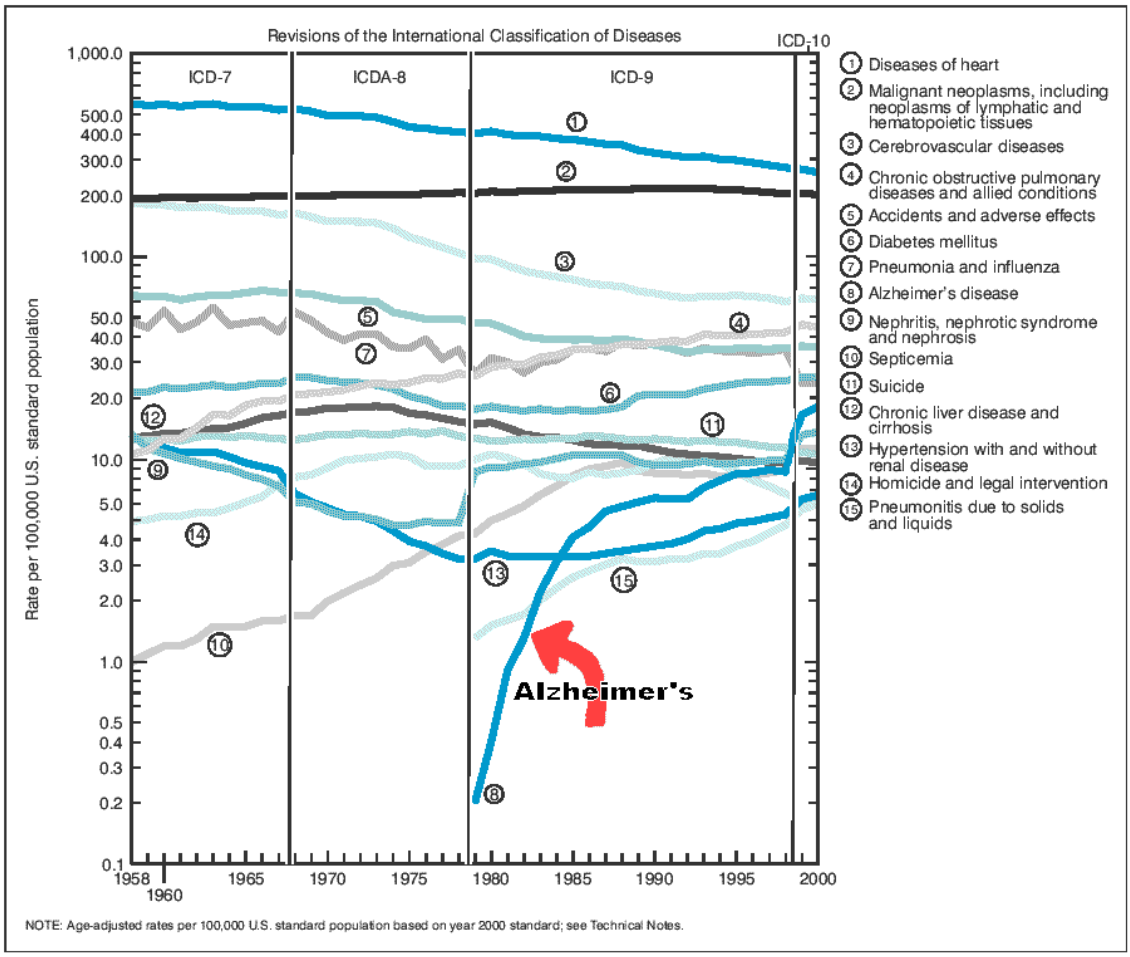

Figure 5. Age-adjusted death rates for the 15 leading causes of death: United States, 1958–2000

(Chart taken from CDC National Vital Statistics 2000 report page 9)

ALZHEIMER'S DISEASE AND DEMENTIA – IMPORTANT NEW STUDY SHOWS GRAVE IMPLICATIONS FROM INTERACTION OF ALUMINUM AND LOW DOSE FLUORIDE

The latest edition of the peer-reviewed medical journal, Brain Research, (vol.784:l998), reveals that aluminum-induced neural degeneration in rats is greatly enhanced when the animals were fed low doses of fluoride. The presence of fluoride enhanced the bio-availability of aluminum (Al) causing more aluminum to cross the blood-

brain barrier and become deposited in the brain. The aluminum level in the brains of the fluoride-treated group was double that of the controls.
http://www.actionpa.org/fluoride/aluminum.html

Acknowledgments:
Much appreciation is here extended to Moms Against Fluoridation (www.momsagainstfluoridation.org) for providing careful data analysis and for extensive letter writing to the U.S. Surgeon General to ban industrial fluoride treatment of public drinking water. Thanks also to San Diegans for Safe Drinking Water (www.SDSDW.org) for the graph employed in this letter.

p.s. Although the FDA may be officially un-interested in animal welfare, the following letters regarding the famous Wild Animal Park show elephants, living on aluminum fluoride water since 2005, are included for context.

ZOO ELEPHANTS WERE EUTHANIZED AFTER 6 YEARS OF ALUMINUM FLUORIDE WATER CONSUMPTION

Dear Anthony Young, San Diego City Council,

As a concerned San Diego native I write again to help you understand your rights regarding the use of substances in water to treat citizens of the city. All Water Districts in the U.S. who treat people with industrial fluorides for any putative effect on teeth via the bloodstream after ingestion are responsible for measuring the fluoride level in the blood of citizens they decide to treat. The burden of quality control is on the utilities that administer the agent, not the consumer who is forced to ingest it. The target blood level stated by the Oral Health Division dental officials within the CDC is 0.2 ppm fluoride [1], but neither the OHD dentists nor most city utilities understand that blood fluoride levels depend on water hardness. People consuming Seattle ultra-soft water (10 ppm calcium) have levels above 0.2 ppm in blood, and water chemists there add calcium chloride along with the fluoridation chemicals to help minimize assimilation [2]. In hard water Texas (safe 300 ppm calcium antidote), where the idea of 'water fluoridation' first began, the blood level is below 0.2 ppm. San Diego water (labeled 'soft' by water districts) has a calcium to fluoride ratio of only about 60 mg calcium per 0.8 mg fluoride. Animal studies show the blood level of fluoride was lowered 4 fold when calcium was administered along with sodium fluoride, compared to sodium fluoride alone.

Those who believe the false claim, that fluoride consumption is harmless long-term, regardless of all the published human and animal studies proving otherwise, do not explain how fluoride, that crosses the blood brain barrier [3] and accumulates in bone permanently [4], somehow magically avoids having any effect on systemic biologic functions. How does this happen? The answer of course is that fluoride indeed causes harm. Look at the 41% of 12-15 year olds in the U.S. having permanent abnormal tooth fluorosis that prevents a normal smile [4]. They are not smiling, and neither are San Diego residents voting against the injections who know the truth, that industrial fluorides are all toxic calcium chelators [5].

Unfortunately after 6 years of consuming aluminum fluoride treated municipal water, the former show elephants of the Wild Animal Park were finally euthanized at the San Diego Zoo this week [6]. One was unable to walk and the other had also deteriorated after both became mentally unstable and unable to follow tasks in the shows that were canceled a few years after the Park began accepting treated municipal water in 2005. The Park was told in 2005 they would not receive the treated water, but the Park's utility, the San Pasqual Water District, arranged for the city of Escondido to provide the water that is treated with aluminum and with industrial fluoride [7], thinking without evidence that the water would be healthy for elephants, not realizing their large body to brain volume ratio.

Show elephants consume copious amounts of water because of their daily activity level, over 60 gallons daily, and do not have kidneys designed to remove aluminum fluoride at an intake rate that high. They developed mental aberrations that are known to occur in laboratory animals given aluminum fluoride water at such levels for long time periods [3, 4], including inability to walk from motor brain degeneration. The problem is that aluminum and fluoride together in the acidic stomach form complexes that are assimilated into the bloodstream, causing aluminum accumulation in brain [4]. Aluminum in water without industrial fluoride is not assimilated. The elephants were transferred to the San Diego Zoo and have been treated with industrial fluoride water again since January of last year. The elephants' mental deficiencies, being unable to wander around freely in the enclosure, never improved

until they were euthanized. Zoo veterinarians do not acknowledge the role played by aluminum fluoride in these animals' demise, nor are they trained in fluoride toxicology, and neither has a satisfactory explanation for this been found by them.

It is necessary for city officials to request blood testing of citizens in San Diego that are under your care to verify that the target fluoride blood level is maintained with this new radical water district treatment. Remember that the CA law, that requests 'fluoridation,' does not mention the fluoride source of choice nor does it provide protocols for our local water, having only 60 ppm calcium, to achieve a desired blood level of 0.2 ppm fluoride. The CA Dept. of Health merely suggests what the OHD suggests, to use synthetic industrial hazardous waste fluosilicic acid diluted to '1 ppm' free fluoride, making no mention of adjustments for water calcium or aluminum content! It must be emphasized again that both the CDC and the CA Dept. of Health, in detailed letters to me, made it perfectly clear that the city itself bears all responsibility and all liability for the injections designed to treat citizens in San Diego; and monitoring the health effects of animals by either agency is out of the question.

Is it time to halt these injections? Of course it is. The FDA has never approved ingestion of fluoride because it is not a mineral nutrient and in water is an uncontrolled use of a non FDA-approved drug. When added intentionally into water, the FDA decreed fluoride is an unapproved drug. When accidentally or naturally found in water, both the FDA and EPA rule fluoride is a contaminant. We expect the FDA to ban the intentional injection of fluorides, or to bar the OHD from requesting the injections, soon. But nevertheless in the meantime, cities bear all liability for the injection of fluoride into citizens through public water supplies and because of that fact alone have full legal authority to halt the injections.

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[7] Freedom of Information Act request answered by the Escondido Public Works Department, 2010.

Dear San Diego City Council,

Continuing, we have data from the 50 U.S. states that rank disease incidence as a function of percent of water districts that fluoridate. The data indicate yet again that water fluoridation does not influence teeth decay, but has significant associations with increased tooth fluorosis, mental retardation, cancer and cardiovascular deaths [1]. There was no correlation of increased incidence of Alzheimer's disease with fluoridation, but cities were not separated between those that treat water also with aluminum from those that do not.

Please let me be clear. It is possible that the elephants from the Wild Animal Park that were mentally degraded and euthanized at the Zoo this week may have presented with some form of dementia independent of aluminum and fluoride in their water. ***However*,** there is little doubt that the massive amounts of aluminum and fluoride, ingested together that causes uptake into brain, hastened their complete demise. The abnormal *tau* proteins synthesized in brain in human dementia for unknown reasons have very high affinity for aluminum. Many Alzheimer's victims have aluminum in large concentrations in brain at time of death.

The Alzheimer's Association is currently confused and does not know the cause of the high incidence of Alzheimer's in the U.S. or why San Diego leads the nation in this category of death per capita. It is no longer assumed by this organization that aluminum is the causative agent. San Diego Water facilities indeed do not inject their own aluminum but report levels on water quality reports. Metropolitan Water, Los Angeles has injected aluminum as a clarifying agent long before fluoride injections were begun that enhance aluminum assimilation, and this water is imported to North San Diego County. However, the city of San Diego and Escondido are fully culpable for contributing to the demise of these prize animals by providing no option other than water treated with fluoride that also contained aluminum. There is little doubt that aluminum uptake in brain enhanced the mental condition the animals suffered. Aluminum taken up into the brain where it does not belong cannot hide to exert zero

effects on structure and function. Numerous studies by Varner and coworkers over the last many decades [2] prove fluoride plus aluminum forms AlF3 complexes that are assimilated into brain that cause microscopically observed brain degeneration during long term chronic consumption. The question is why is this seemingly not more dramatic in the human population than what seems to exist, but remember the human brain is of very high capacity (200 billion cells per brain). Further, lack of effect is merely an impression, not a fact, since Alzheimer's now is the 6th leading cause of death in the U.S. [3] and in San Diego County is now astoundingly 3rd [4]!! The time to death after Alzheimer's first appears is relatively quick in many cases and there remains no cure.

It is time to halt the inane practice of injecting industrial synthetic fluoride compounds into human drinking water in an attempt to find a child's cavity, when nonfluoridated Europe has experienced the same rate of decline in caries incidence that the U.S. has seen during this water ingested fluoride program [5]. Understand again that CA AB733 was based on a false assumption, that swallowed fluoride was assumed to decrease caries, when biochemical measurements prove it cannot--it is present from swallowing in the saliva at only 0.02 ppm [6], unable to affect teeth topically though CA dental officials with vested interests attempt to ignore this [7]. And again, no protocols are provided in CA AB733; it merely asserts basically to 'go forth and fluoridate', without details of any kind, as though it were some sort of higher proclamation, when it is a corrupt order that violates the Safe Drinking Water Act (which prohibits any Federal requirement for drugs, supplements, or any chemicals added other than to sanitize water), the Food Drug and Cosmetic Act (requires FDA approval for any substance used as a putative treatment in humans) and the Water Pollution Control Act (section 101a). No State law can be legally binding that attempts to supercede these and other Federal laws covering public waterways that are Federal property. The Colorado River originates as far North as Western Wyoming (Wind River Mountain Range), and CA aqueduct water originates as far North as creek drainage in Southern Oregon. The Oregon State legislature barred any State requirement for fluoride in Oregon waterways, to protect salmon from the known gross mental narcotic effect fluoride exerts that causes salmon run collapse.

As a medical research scientist and native San Diegan, I request that you order the Public Utilities Director, San Diego to stop titrating this illegal, unapproved, useless, harmful industrial substance lacking calcium into the water supply that is ingested by the innocent animals and people who reside here in our otherwise fair city. My brother was offered the position of head computer systems operator by the San Diego Padres. However, due to concerns over water fluoride (my brother has slight tooth fluorosis from a one-time Luride dose) he has chosen to remain in his home in Morgan Hill, CA. Morgan Hill is listed as a 'fluoridated city' but this is false. The water district chemists there stopped ordering drums of fluosilicic acid hazardous waste decades ago and refuse to inject synthetic fluorides into innocent people that, as a toxic calcium chelator, accumulates into bone permanently lifetime. Many people can remain rational about this, and I think you can also.

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Dear FDA Project Reviewers,

This letter is in support of the petition to ban the addition of synthetic industrial fluoride compounds into public drinking water supplies, original petition FDA-2007-P-0346, formerly 2007P-0400. The letter contains three principle sections: I. Cardiovascular effects of ingested industrial fluorides and the recent data from the Veterans' Administration Healthcare System, Los Angeles indicating fluoride preferentially incorporates into atherosclerotic plaque and diseased heart tissue. II. A discussion of the withdrawal of a fluosilicic acid chemical supplier from the city of Selmer, Tennessee that could not provide data demonstrating either caries reduction or safety of use in the infirmed for consumers who ingest the chemical they provided. III. Direct communications with the U.S. EPA Office of Drinking Water, Region 9, San Francisco proving that EPA has no intention of regulating the procedures or chemicals used to treat humans with industrial fluoride compounds to be taken internally through public water supplies, which confirms the Petition for Reconsideration 2010 that the FDA, not the EPA, is exclusively in charge of regulating/prohibiting the dissemination of fluoride compounds to be taken internally through ingestion by citizens in the U.S.

I.Cardiovascular Effects of Systemic Industrial Fluoride.

The National Research Council 2006 Report [1] avoided discussion of the effects of industrial fluoride ingestion on cardiovascular function because comparatively so much more data existed for review on other organ systems (personal communication with Dr. K. Thiessen, coauthor of NRC Report). This is most unfortunate, since the mechanism of acute high level fluoride toxicity is known to be heart block due to inhibition of calcium ion mobility and related sequelae [2], the cause of death in the Nation's worst water fluoride disaster in Hooper Bay, Alaska (see original petition). Further, at lower, intermediate blood levels of fluoride, research animals during long-term consumption develop heart muscle degradation and weakening [3]. Finally, for 'low' fluoride levels in consumers in U.S. treated cities, 0.2 ppm in blood, it has been long known that heart attack incidence increases in fluoridated cities. In Newburg, N.Y., heart attack incidence increased 1.7 fold after fluoridation began, which exceed the National average for the first time in city history, far in excess of incidence in the control city of non-fluoridated Kingston [5].

Fluoride in soft water is assimilated more than from hard water, and a clear correlation between percent of fluoridated water districts and heart attack incidence for the 50 U.S. States [4] is even more significant for those States in soft water regions [2]. Dr. A.L. Miller submitted data to the U.S. Congress regarding the increased incidence of cardiovascular deaths after fluoridation of Newburgh, N.Y. and Antigo, Wisconsin [5]. Electrocardiogram abnormal heart rhythms and reduced myocardial function are found in an unusually large percentage of patients having dental tooth fluorosis [6]. This is supported by recent studies indicating that patients with chronic fluorosis have detectably decreased aortic elasticity and left ventricular function [7, 8].

Although I do not support the injection of any fluoride compound into humans for any purpose, note that the study enclosed below, approved and conducted on heart disease victims for various assessment purposes, proves *fluoride preferentially incorporates into damaged heart tissue and into coronary and femoral arteries and aorta in patients with cardiovascular disease.* The study was conducted at the VA Health Care System in Los Angeles, CA, published in Nuclear Medicine Communications, 2011 [9]. There is no doubt that the fluoride ion when present systemically incorporates directly and selectively into heart tissue and various major arteries of patients who had suffered previous heart conditions, including coronary arteries, the aorta and the leg femoral artery where calcium has long been known to accumulate during atherosclerosis. The incorporation of fluoride, fully expected as a toxic calcium chelator, was directly observed by Positron Emission Tomography (PET) scans after injection of radioactive fluoride as sodium fluoride.

The precise concentration in the bloodstream during the incorporation was not listed, but could be calculated by contacting the authors to determine the specific activity of the isotope employed. Acute heart attack was obviously not induced by the injections, so the concentration was a tolerable level that did not exceed the known solubility for calcium fluoride. At such concentrations that compare to that in U.S. citizens in fluoridated cities, the incorporation must occur by an ion exchange mechanism, similar to that in bone where fluoride binds permanently to calcium even when below the K_{sp} for the formed precipitate. The composition of the calcium ingredient in atherosclerosis remains unknown but is most likely calcium carbonate or phosphate, or a lipid complex. The ion exchange mechanism in bone is not opposed by fluoridation proponents (see attached graph from Newbrun, **Fluoride and Dental Caries**, 1975, indicating in England long before fluoridated pastes, gels and rinses, and before widespread fluoridation corrupted foods and beverages, that bone calcium levels in fluoridated cities accumulate lifetime to levels causing weakening by age 40-50 for water fluoride between 0.8 and 1.9 ppm). Predictably though, fluoridation proponents have claimed without experimental data to back it up, that fluoride as a perennially-excused substance might clean or prevent atherosclerotic plaque buildup. The VA study however indicates that any such claim by proponents must land on deaf ears, since plaque is not removed by fluoride but rather fluoride incorporates so efficiently into tissue that it is detected as solids on the PET scan.

Fluoride is a toxic calcium chelator and thus incorporates into tissue where calcium is enriched, including calcium-rich atherosclerotic plaque. The authors of the VA study suggested that blood fluoride is expected to increase pathologic risk in patients with cardiovascular disease and that fluoride is a component feature of atherosclerosis. To be more accurate, fluoride itself is not a normal body component and its presence is thus an aberration. Atherosclerosis in the absence of fluoride is composed chiefly of cholesterol, calcium and fatty acids in the original fatty streak. These are normal constituents of the bloodstream and are always components of atherosclerotic plaque. Fluoride when present, not a normal body component, incorporates as an abnormal ingredient.

These charges are extremely serious. The presumption that 'fluoridation' is safe is based on the fact that populations with normal health, regularly drinking fluoridated water in the U.S., can live full lives to a reasonably long age. However, Dr. Albert Schatz cautioned against this mistaken assertion, since it is not the healthy with good nutrition who are noticeably most susceptible to ingestion of industrial fluorides, but rather the undernourished and infirmed who are. Specifically, the population of American citizens who suffer with atherosclerosis or cardiovascular disease are at increased risk from continuous exposure to industrial fluoride taken internally to elevate the blood fluoride level to 0.2 ppm (or higher in soft water cities). Unusual stress in heart patients is expected to be more dangerous when all organs are invested with continuous levels of the fluoride ion where it does not belong.

Atherosclerosis is still considered to be the most common underlying cause of heart disease in the U.S., particularly in cases of angina pectoris substernal chest pain due to coronary artery reduced blood flow and ischemia. Incorporation of fluoride into atherosclerotic plaque is an insidious and unnecessary abnormality that complicates atherosclerosis, the most widespread disease entity in the U.S. Consumption of industrial fluorides from public drinking water is contraindicated in humans afflicted with either atheroscelerosis or cardiovascular disease. Much recent data, not known when the idea of 'systemic fluoridation' was unveiled, now prompts the elimination of industrial fluoride compounds from being intentionally and indiscriminately injected further into public water supplies without a prescription. Cardiovascular disease remains the Nation's leading killer, and regulation and enforcement is regarded as immediately necessary. As Buck pointed out long ago, indiscriminate dissemination of fluoride compounds into public water supplies is an act of violence, and today we must add that it is nothing short of elder abuse, with the known widespread prevalence of atherosclerosis, and the bone weakening that occurs after lifetime fluoride consumption, in the U.S. elderly.

The widespread treatment of water with industrial fluoride compounds, in a worthless attempt to decrease dental caries through internal ingestion of fluoride ion, is not the fault of the U.S. FDA. FDA decreed in 1963 that fluoride is not a mineral nutrient and that its addition into public water supplies constitutes an uncontrolled use of a non-FDA-approved drug where dosage could not ever be regulated. Fluoridation is the fault of zealots who have routinely and completely ignored FDA statements on the matter, and the FDA is commended for not approving the ingestion of fluoride compounds and for only allowing ingestion by prescription in non-fluoridated cities. It is now time to impose regulations since currently no Federal agency assumes responsibility for the dissemination into public water supplies.

Please understand that there is no such action that can be simply called 'fluoridation.' Fluoride cannot exist without the presence of other elements. Since 1939 when the original false correlation was made that fluoride,

rather than the accompanying, responsible calcium ion, reduced teeth caries, fluoridation proponents have switched from using calcium fluoride (originally promoted as a fluoridation agent by the CDC) to sodium fluoride and then to the cheaper hazardous waste fluosilicic acid fluoride. The Safe Drinking Water Act was written to prevent using public water supplies as a medium in which to disseminate any fluorides for human ingestion, but yet fluoridation promoters have sidestepped the Act by adding tacked-on regulations along the way since 1974, designed to make allowances for ill-defined 'fluoridation'. Fluosilicic acid supplies have now become depleted, and the next fluoride compound to be proposed to be used as source material will again be fully expected by promoters to go unnoticed and unregulated by any Federal agency.

It is simple to claim that 'fluoridation' is natural—simply use an agent that is known to be a natural ingredient in the earth's crust, such as sodium, silicon, lithium, aluminum or arsenic. The first two ingredients have already been in use for 'fluoridation', the former for over 69 years in the U.S. Any proposed use of lithium fluoride, aluminum fluoride or arsenic fluoride for water 'fluoridation' could also again be argued to be 'natural', fully expecting complete lack of Federal agency repudiation or a ban as long as the MCL for the extra component is not exceeded. The U.S has already entered down this slippery slope by 'fluoridating' water supplies with toxic industrial sodium fluoride and then with toxic hazardous waste fluosilicic acid, marketed to water districts and State public health departments as a water purifying agent with dental caries benefit as an ingestible. The industrial fluoride compounds are argued by the CDC as being 'identical' to natural calcium fluoride and thus deserving of the continued support and proclamation from the U.S. Surgeon General as the 'greatest public health achievement of the 20th century'. How long this scheme continues is entirely up to the FDA, and no one else. We beg the FDA to oversee these injections, and if a ban is not instituted, then it should be possible to request that all fluoride compounds proposed to be ingested must be given *by prescription only*, rather than by forced injection into public water supplies used by everyone, having caries or not.

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Original Articles

Association of vascular fluoride uptake with vascular calcification and coronary artery disease

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Abstract

Objective: The feasibility of a fluoride positron emission tomography/computed tomography (PET/CT) scan for imaging atherosclerosis has not been well documented. The purpose of this study was to assess fluoride uptake of vascular calcification in various major arteries, including coronary arteries.

Methods: We retrospectively reviewed the imaging data and cardiovascular history of 61 patients who received whole-body sodium [^{18}F]fluoride PET/CT studies at our institution from 2009 to 2010. Fluoride uptake and calcification in major arteries, including coronary arteries, were analyzed by both visual assessment and standardized uptake value measurement.

Results: Fluoride uptake in vascular walls was demonstrated in 361 sites of 54 (96%) patients, whereas calcification was observed in 317 sites of 49 (88%) patients. Significant correlation between fluoride uptake and calcification was observed in most of the arterial walls, except in those of the abdominal aorta. Fluoride uptake in coronary arteries was demonstrated in 28 (46%) patients and coronary calcifications were observed in 34 (56%) patients. There was significant correlation between history of cardiovascular events and presence of fluoride uptake in coronary arteries. The coronary fluoride uptake value in patients with cardiovascular events was significantly higher than in patients without cardiovascular events.

Conclusion: sodium [^{18}F]fluoride PET/CT might be useful in the evaluation of the atherosclerotic process in major arteries, including coronary arteries. An increased fluoride uptake in coronary arteries may be associated with an increased cardiovascular risk.

Introduction

Cardiovascular disease remains the leading cause of morbidity and mortality in the world [1]. The major pathophysiologic change of cardiovascular disease is atherosclerosis in critical arteries. Atherosclerosis is a slow, progressive, and cumulative process that results in atheromatous plaque formation in vascular walls and eventually leads to narrowing of the arterial lumen, occlusion, or aneurysm formation. The development of atherosclerotic plaque is characterized by subendothelial fatty material accumulation, a chronic inflammatory process, and vascular calcification [2,3]. To predict and prevent any deadly cardiovascular events, extensive studies have been conducted to evaluate the risk of cardiovascular disease. Over the past decade, many cardiovascular studies focused on the calcification process in atherosclerosis [4–7].

Calcification in atherosclerosis occurs through an active process that resembles bone formation and is controlled by complex enzymatic and cellular pathways [8,9]. Coronary artery calcification parallels atherosclerosis progress and is strongly and linearly correlated with the total atherosclerotic burden [10]. Coronary calcification can be measured by computed tomography (CT) studies and is one of the most important predictors of future cardiovascular events. The level of coronary artery calcium can also help to reclassify asymptomatic individuals into high-risk or low-risk categories [4]. Currently, sodium [^{18}F]fluoride positron emission tomography (PET)/CT is the most sensitive imaging modality to detect active bone formation [11]. Recently, Derlin *et al.* [12] reported the feasibility of sodium [^{18}F]fluoride PET/CT for imaging atherosclerotic calcification in major arteries, including carotid, aorta, iliac, and femoral arteries. They also found that the mineral deposition in the carotid plaque detected by sodium [^{18}F]fluoride PET/CT significantly correlates with atherogenic risk factors [13]. Although atherosclerosis is a systemic disease, and evaluation of vascular calcification may potentially predict cardiovascular events, studies have shown that direct assessment of coronary arteries is superior to surrogate imaging for evaluating the risk of cardiovascular events [14]. Some recent studies have demonstrated that evaluation of coronary arteries by PET is feasible [15–22]. Most of these studies investigated fluorodeoxyglucose (FDG) uptake in coronary arteries. However, the clinical significance of [^{18}F]fluoride uptake in coronary arteries has not been documented.

In this study, we evaluated sodium [^{18}F]fluoride uptake in major arteries, including coronary arteries, in 61 patients. The relationship between [^{18}F]fluoride uptake and cardiovascular history and/or multiple risk factors was also evaluated.

Materials and methods

This study has been approved by the institutional review board of the Greater Los Angeles VA Healthcare System.

Patients

We retrospectively reviewed sodium [^{18}F]fluoride PET/CT bone studies conducted at Veterans Affairs Greater Los Angeles Healthcare System from April 2009 to June 2010. There were 58 male patients and three female patients. Detailed clinical histories and the presence of cardiovascular risk factors, such as hypertension, diabetes, hypercholesterolemia, smoking history, obesity, and history of cardiovascular events, were obtained for all patients. The clinical characteristics of the patients are summarized in Table 1.

Table 1

Image Tools

Positron emission tomography/computed tomography protocols and imaging reconstruction

PET/CT scans were performed using a Philips Gemini TF 64-channel time-of-flight PET/CT scanner (Philips Healthcare, Andover, Massachusetts, USA) with spatial resolution of 4.5 mm at West Los Angeles VA Medical Center. Sodium [^{18}F]fluoride was injected intravenously at a dose of 10±2 mCi (370±74 MBq). Participants were comfortably seated in a private, quiet, cozy room. Forty minutes after the injection, patients were subjected to a low-dose CT scan of the whole body without contrast at 50 mA, 120 kV_p, 0.5 s/rotation, a pitch of covering 0.83 mm, and a slice thickness of 5 mm [23,24]. The subsequent PET data were acquired continuously for 90 s and at 180 mm per bed position with 50% overlap between consecutive bed positions using a matrix of 140×140, followed by reconstruction corrected for attenuation using low-dose CT scans. No cardiac or respiratory gating was performed.

Imaging and statistical analyses

CT and PET images were coregistered by the Philips Extended Brilliance workstation (Philips Healthcare). CT, PET, and fused PET/CT images were evaluated visually and semiquantitatively simultaneously using the same workstation. All images were analyzed by two independent nuclear medicine physicians blinded to all patients' clinical information. Inter-reader reproducibility was excellent and was evaluated using an intraclass correlation coefficient (0.89). Vascular calcification was identified as positive on CT images if the target was visually detectable with a greater than 130 Hounsfield units. CT-attenuated PET images were evaluated for fluoride uptake in major arteries. Background activity was based on the standardized uptake value (SUV) of the blood pool, which was calculated from the mean SUVs of three circular regions of interest (ROIs) placed in the left atrium, mid lumen of the aortic arch, and abdominal aorta at the level of the celiac trunk on axial images. The sizes of ROIs were 2 cm in diameter for the left atrium and 1 cm for the aortic arch and the abdominal aorta. Maximum SUVs (SUV_{max}) from target arteries were obtained by manually placing an individual circular ROI of 1 cm diameter in the target artery wall. All three orthogonal images were assessed for focal lesions in major arteries with an increased fluoride uptake. Positive fluoride uptake was identified if the target lesion was visually detectable with a greater than or equal to 1.5 target-to-background ratio in all three orthogonal image planes. For either CT or PET evaluation, the arterial territory was categorized as positive if at least one lesion was detected and agreed upon by both readers. The percentages of positive studies on both CT and PET of each arterial territory were calculated. Correlation between fluoride uptake and CT calcification was analyzed by Fisher's exact test. Correlation of PET results and the number of cardiovascular risk factors were analyzed by the Wilcoxon rank-sum test. Significance was defined as *P* value of less than 0.05 in two-tailed studies.

Results

Patients' age and reasons for sodium [^{18}F]fluoride PET/CT imaging are summarized in Table 1. Most patients were men with a median age of 66 years (27–91 years). The majority of patients (69%) had more than one risk factor for coronary artery disease.

Arterial sodium [^{18}F]fluoride uptake and calcification

Arterial wall sodium [^{18}F]fluoride uptake and calcification were evaluated in major arteries, including carotid arteries, the thoracic ascending (including aortic arch) aorta, the thoracic descending aorta, the abdominal aorta, femoral arteries, and major branches of coronary arteries. Iliac arteries were not evaluated because of frequently observed urinary and occasional bowel uptake in the pelvis, which interferes with the accurate assessment of iliac vessels. For coronary arteries, four major branches were evaluated. An example of fluoride uptake in femoral arteries is shown in Fig. 1. Orthogonal views of fluoride uptake in the aorta and coronary arteries are shown in Figs 2 and 3.

Fig. 2 Fig. 3

Image Tools Image Tools

Fig. 1

Image Tools

Both fluoride uptake and calcification were common in major arteries as summarized in Table 2. In general, fluoride uptakes in vascular walls were observed in 361 vascular territories of 59 (97%) patients, and calcifications were observed in 317 vascular territories of 49 (88%) patients. Only two patients did not demonstrate fluoride uptake in any of the vasculatures (one patient aged 27 and one aged 61). In thoracic aortas, the abdominal aorta, and femoral arteries, fluoride uptake was observed more frequently compared with calcification. In contrast, calcification was more common than fluoride uptake in carotid and coronary arteries (Table 2). Except for the abdominal aorta, fluoride uptake and calcification were significantly correlated in the same vascular territories, as evaluated by Fisher's exact test. It should be noted that the fluoride uptake and calcification were not necessarily overlapped in the exact same anatomic locations. At calcification sites that did not demonstrate prominent overlapping fluoride uptake, fluoride uptake was frequently observed in the adjacent area within the same arterial territories (Fig. 2).

Table 2

Image Tools

Relationship between coronary fluoride uptake and cardiovascular risk factors

The coronary arteries were also investigated for fluoride uptake. Four major branches of coronary arteries, including left main artery (LMA), left anterior descending (LAD), left circumflex (LCA), and right coronary arteriy (RCA) were evaluated. Fluoride uptake was more frequently observed in the LAD and LCAs. A similar pattern was also identified in coronary artery calcification. In each individual coronary branch, calcification was more frequently observed than fluoride uptake (Table 2). Among 10 patients who had significant three-vessel coronary calcifications, 80% demonstrated fluoride uptake in at least one coronary branch (data not shown).

Cardiovascular risk factors including hypertension, obesity, diabetes, hypercholesterolemia, smoking history, and history of coronary artery disease were reviewed in all patients (Table 3). The majority of the patients (69%) had more than one cardiovascular risk factor; however, neither the individual cardiovascular risk factor nor the number of risk factors was significantly correlated with coronary fluoride uptake (Table 3). Nine patients had a history of cardiovascular events. Among them, eight demonstrated identifiable coronary fluoride uptake. There was significant correlation between coronary calcification and fluoride uptake in this group evaluated by Fisher's exact

test (Table 3). All nine patients also demonstrated coronary calcification on CT images. We also compared the SUV_{max} in coronary arteries between patients with and without a history of cardiovascular events. The average coronary SUV_{max} in patients with a history of cardiovascular events was 1.70, significantly higher than 1.39 for patients without a history of cardiovascular events (P=0.029, two-tailed Student's t-test). No correlation was observed between cardiovascular risk factors and fluoride uptake in other vascular territories (noncoronary).

Table 3

Image Tools

Discussion

Vascular calcification, in particular coronary calcification, has been shown to predict vascular events [25–27]. Recent utilization of multidetector CT has made the assessment of coronary calcium feasible and reproducible [7,28]. However, CT can only evaluate structural change, which usually represents later stages of the disease's process. Given the assumption that fluoride uptake represents dynamic atherosclerotic calcification, we would expect that fluoride uptake occurs at the stage before the formation of detectable calcium deposition. Consistent with this theory, Derlin *et al.* [12] reported that only 12% of the calcification sites demonstrated prominent overlapping fluoride uptake, whereas 12% of fluoride-positive lesions did not show concordant calcification. In our study, fluoride uptake and CT calcification are significantly correlated in the same arterial territories, except in the abdominal aorta. This is because of the extremely high positive rate (97%, only one patient demonstrated negative uptake) for fluoride uptake in the abdominal aorta. Fluoride uptake either overlaps with calcification or locates adjacent to the detectable calcium deposits, suggesting that fluoride uptake and detectable calcification represent different stages of the atherosclerotic process.

In large arteries, such as the thoracic aorta, abdominal aorta, and femoral arteries, fluoride uptake is more commonly observed than calcification. This finding is different from results published by Derlin *et al.* [12], which demonstrated that fluoride uptake is less frequently observed than calcification in all major arteries. The discrepancy may be due to different PET/CT scanners. In our study, we used a time-of-flight PET/CT scanner with better spatial resolution (4.5 mm vs. 8 mm) and higher sensitivity. In addition, differences in patient populations may also contribute to the discrepancy. Most of our patients were older male veterans with multiple cardiovascular risk factors. Consistent with this, our data demonstrated notably higher incidents of calcification compared with the data published by Derlin *et al.* [12]. Recently, they also reported that fluoride uptake in carotid arteries significantly correlated with cardiovascular risk factors. We found that 43 (right) and 48% (left) of patients have carotid calcifications, whereas 34 (right) and 38% (left) of patients have fluoride uptake, compared with 32 (right) and 37% (left) with calcification and 25 (right) and 28% (left) with fluoride uptake according to the results from Derlin *et al.* [13]. However, we did not observe any correlation between carotid fluoride uptake and cardiovascular risk factors, probably because of the limited number of patients in our study.

In contrast to the results of the aorta and femoral arteries, fluoride uptake was less commonly observed than calcification in coronary arteries. This phenomenon could be due to the following reasons: (a) the limited spatial resolution of PET reduces the sensitivity to detect fluoride uptake in smaller arteries; (b) the combination of cardiac and respiratory motions further reduces the sensitivity of PET in the evaluation of coronary arteries; (c) the proximal coronary arteries are surrounded by vascular structures that are highly susceptible to calcification. These include aorta, pulmonary artery, and heart valves. All these structures may affect the interpretation of fluoride uptake in coronary arteries; and (d) the partial volume effect on the small size of the ROIs is also a possible reason.

Coronary motion is greatest in the RCA, followed by circumflex coronary artery, LAD, and LMA in descending order [29]. Our study demonstrated that fluoride uptake was more frequently observed in LAD and circumflex coronary artery than in the RCA and LMA. Motion artifact reduces the sensitivity to detect fluoride uptake in the RCA. The short length of LMA and its short distance to the aorta, which frequently demonstrates fluoride uptake, may attribute to the low frequency of fluoride uptake in the LMA. Despite the feasibility of fluoride PET evaluation of coronary calcification, coronary imaging with fluoride PET/CT remains challenging because of small artery size, motion artifact, and interference of surrounding vasculature calcifications. All of these factors will potentially cause either false-negative or false-positive results. The recent development of cardiac–respiratory gating technology in PET scans may increase the accuracy of coronary imaging [30–32]. In addition to the technical difficulties in evaluating coronary arteries, the limited number of patients and the unvarying nature of the patient population in this study may be skewed and may not apply to the general population.

We found that fluoride uptake in coronary arteries is significantly correlated with a patient's history of cardiovascular events, and the uptake value in patients with cardiovascular events was significantly higher than that in patients without cardiovascular events. These results further support the fact that higher fluoride uptake in coronary arteries indicates increased cardiovascular risk. Recently, several studies have demonstrated the feasibility of FDG-PET/CT in detecting plaque inflammation in coronary arteries [15–22]. Nevertheless, fluoride PET/CT detects active mineral deposition, which represents the distinct pathophysiologic process of atherosclerosis. Derlin *et al.* [33] reported that uptake of FDG and sodium fluoride in vessel wall alterations was rarely coincident, supporting the suggestion that these two studies evaluate different functional and morphologic changes of the atherosclerotic process. The FDG uptake and fluoride uptake of atherosclerotic plaques could have complementary roles in evaluating the cardiovascular risk of patients. The combination of sodium [^{18}F]fluoride PET and CT is a promising imaging modality that provides both metabolic and anatomic information in evaluating vascular calcification. However, large-scale studies are needed to evaluate the clinical significance of fluoride PET/CT for imaging atherosclerosis.

Conclusion

Our study demonstrates that vascular calcification and fluoride uptake are significantly correlated in the same arterial territory, although not necessarily overlapping in the same anatomic locations. An increased fluoride uptake in coronary arteries may be associated with an increased cardiovascular risk. Combined anatomic and metabolic imaging with sodium [^{18}F]fluoride PET/CT offers a promising, noninvasive method to evaluate atherosclerosis.

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II.Fluosilicic Acid Industrial Fluoride Removed from Fluoridated Selmer, Tennessee.

The letter below was sent to San Diego Mayor Sanders, in an attempt to appease San Diego citizens, and myself, by asking the Mayor a favor that is not unreasonable. David Robinson, the Mayor of Selmer, Tennessee asked a few questions of the fluosilicic acid suppliers for his city and found the supplier could not provide such answers, and instead ceased to provide any further the specific fluosilicic acid formulation that had been used in Selmer for years, and then removed all fluoridation equipment and chemicals from Selmer (see Robinson letter attached). Mayor Robinson has agreed to send the correspondence he has to Mayor Sanders, if it is requested. Here is an attempt to obtain that information to have on file for the city of San Diego for reference because of use by San Diego of the same fluoridation materials used in Selmer.

Dear Mayor Sanders,

I am writing to ask a simple specific favor of you. You are fully aware of my feelings on this, but this request is not related to either the support of, nor the opposition to, water fluoridation and is not dependent on scientific data. David Robinson, the Mayor of Selmer, Tennessee wrote to me that he will provide information he obtained that resolved this issue in Selmer, that is similar to that in San Diego. Selmer City officials in the fully fluoridated state of Tennessee found itself in a position similar to here in San Diego, where citizens opposed a measure that is nevertheless required, as here by the CA State fluoridation bill. It is a great story and I'm certain you will be happy that you contacted him, in particular because in so doing you will have the latest information that will fulfill your obligations of due diligence for duty of care for citizens here.

Thank you for your consideration of this request, for the benefit of our city.

Robinson is a good and effective mayor and he wrote that he will be more than happy to forward the brief correspondence he has if you ask. His contact information he sent me is:

David Robinson

Mayor, Town of Selmer

City Hall 731-645-3241

Cell 731-610-7016

Fax 731-646-1462

III.Correspondence with the Office of Drinking Water, U.S. Environmental Protection Agency, Region 9, San Francisco.

The FDA 2010 response to the 2007 petition stated that "artificial fluoride compounds used to fluoridate public drinking water...is regulated by the U.S. Environmental Protection Agency (EPA) under the Safe Drinking Water Act of 1974 (SDWA)." To clarify for you the actual official belief held by the EPA, enclosed please find letters of communication with Jill Korte, U.S. EPA, Region 9, San Francisco, CA, Office of Drinking Water.

The following letters were recently exchanged with U.S. EPA Region 9. In summary, the EPA mistakenly proposes that fluoride is a contaminant and as long as the level is not in excess of the MCL of 2 ppm, EPA does not take action. In the letter it was admitted that no Federal requirement is allowed for agents added into water to treat people, but that EPA is not concerned with this because the EPA itself does not recommend or support the injections. Intentional injections, although in violation of the SDWA, will not be enforced until the level exceeds the allowed level for fluoride pollution at 2 ppm. In other words, EPA will do no regulating of the procedures by which fluoride compounds are titrated into water, and EPA basically views the MCL as an invitation to 'fill 'er up' with a substance that is not allowed by the SDWA.

Notice my response to the EPA indicates that we all need to follow the SDWA and prohibit adding any purported medicaments or other agents into water supplies other than to sterilize the water, and that adding a fluoride compound violates the Act. No industry or private agency or citizen is allowed to add any contaminant or other substance into water simply because the total concentration after dilution is kept below the MCL that EPA has decided to allow for a pollutant. The EPA is using the MCL as though it is a value assigned for an ingestible substance approved with proper regulations required by the Food Drug & Cosmetic Act. Understand though that only proper prospective controlled human clinical trials data may be used to arrive at a daily dose for any purported ingestible compound to be taken internally, as required by the FD&CA.

I apologize for the unnecessary side topic of arsenic being mistakenly typed in a wrong column on a Water District report, rather than being an actual water error, as you will see in the exchange.

Richard D. Sauerheber, Ph.D.
Palomar Community College
1140 W. Mission Rd., San Marcos, CA 92069
E-mail: richsauerheb@hotmail.com Phone: 760-402-1173

U.S. Environmental Protection Agency
Region 9, San Francisco, CA
Drinking Water Office

Dear Jill Korte,

The U.S. EPA of course is not itself directly violating the U.S. Safe Drinking Water Act. I realize that the EPA is not adding fluosilicic acid and is not recommending its addition either. But what you fail to see is that the State of California is in violation of the SDWA because indeed the State, under the direction of Federal dental officials at the Oral Health Division of the Centers for Disease Control by their request, is indeed adding an agent to treat humans through the public water supply, in violation of the Act.

You have claimed in your letter that the EPA allows the INTENTIONAL injection of chemical substances to treat humans through drinking water as long as the final dilution level remains below the EPA MCL for fluoride. This is absurd. Understand that the 2 ppm MCL you mention is the allowed level for fluoride as an accidental or naturally-present contaminant. It is NOT an invitation to 'fill 'er up' with fluoride on purpose, as long as it remains below 2 ppm when you are done. Intentionally adding a contaminant violates the SDWA just as much as intentionally adding a substance to treat humans violates the Act. Remaining below 2 ppm does not give one the right to willfully place any substance into public water supplies.

If you as a public servant feel this way and interpret the original Congressionally-approved statutes of the SDWA that way, then please consider this:

The next time someone dumps barrels of pure arsenic into a public water supply, you have no right whatsoever to arrest him or prohibit his actions, as long as he carefully titrates it in so that the final level does not exceed the MCL for these materials that is allowed by the EPA.

Do you understand how absurd your thinking is? EPA Region 9 is a basically useless entity in helping spare the people of this country and our State from the intentional treatment of the human blood supply with industrial fluoride through drinking water. Why do you support such nonsense? EPA scientists are currently in litigation over this very matter (Connett, et.al., **The Case Against Fluoride**, 2010). EPA has every right to order the halt of intentionally-injected contaminants into public water supplies because the EPA is entrained to follow and enforce the SDWA as much as public citizens and anyone else in this country is obligated to honor. Indeed, as you may know, EPA scientists have published that we must stop using our Nation's water supplies as a vehicle to dispose of toxic hazardous waste fluosilicic acid. How long does the public need to wait for help from EPA administrators?

Finally, as a chemist who is fully aware of methodology required to eliminate fluoride contamination from drinking water, please understand that the CA Department of Public Health routinely 'certifies' reverse osmosis units as 'reducing fluoride by 90%.' This is a deceptive and evil practice. In detailed interviews, chemists who perform the tests admitted that this type of reduction cannot be obtained when starting with fluoride concentrations present by intent in public water supplies. 90% reduction is only obtained when starting with fluoride levels in excess of the K_{sp} solubility for calcium fluoride. In other words, at 8-9 ppm fluoride where calcium fluoride precipitates as particles, of course RO easily removes them. The same instrument however is incapable of but a mere 30% or less reduction when the input water is 1-2 ppm fluoride. Fluoride removal from treated public water under conditions of current use is an expensive and non-trivial issue. Engineers have recently developed special ultra tiny pore size membranes that under high pressure can separate water from fluoride by forcing the oblong water molecule through a pore that tiny fluoride ion cannot enter, but only recently have these become available retail. Also animal bone char (Brimac), only available from facilities in Scotland, is capable of eliminating fluoride by ion exchange much like live bone can, so one's own bones do not incorporate it. These are the only two methods that work for drinking water, and only the latter method is usable for whole house use for those who cannot shower with fluosilicic acid water due to fluoride allergy. RO wastes far too much water for every gallon produced. And whole house bone char is very expensive to maintain, particularly with Brimac shortages that already exist.

It would greatly benefit you if you could please examine the above Connett text and also the National Research Council **Report on Fluoride in Drinking Water, A Scientific Review of EPA's Standards**, Washington, D.C., 2006 that the EPA commissioned to investigate this specific issue. The NRC concluded without reservation that the current allowed EPA MCL for fluoride is not protective of human health. This is consistent with the current CDC-documented epidemic of tooth fluorosis we now have in 41% of American children aged 12-15 as of 2001 that prompted the U.S. Health and Human Services to request water levels not exceed 0.7 ppm as an interim measure until the issue of 'water fluoridation' is resolved. FDA has never approved ingestion of fluoride compounds from public water supplies and has never allowed sale of fluoride compounds to be taken internally without a prescription. The petition to ban fluosilicic acid injections into water supplies in the U.S., accepted for review by the FDA in 2007 (FDA-2007-P-0346), is still pending.

We again ask the EPA to enforce the SDWA in the meantime, in particular for us here in Carlsbad, CA. The National Sanitation Foundation private organization Standard 60 'certification' mark is devoid of controlled human clinical trials data to back it up, as the FDA recognizes. EPA has a long way to go to catch up on this National abuse of a substance that continues without regulation by any Federal office that agrees to accept liability or responsibility for the treatments.

You might also want to contact Mayor David Robinson of Selmer, Tennessee who will provide letters indicating that fluosilicic acid suppliers do not have any data demonstrating caries reduction in those who consume their product and have no evidence of safety for long-term consumption, particularly in the infirmed. An EPA MCL is not an allowance to ingest a substance intentionally for its drug-like effects. Food Drug and Cosmetic Act regulations must be satisfied for any such substance used as an ingestible. If you seek, you will find that the FDA ruled fluoride in water is an uncontrolled use of an un-approved drug and is not a mineral nutrient.

The FDA is not in an as easy a position as is the EPA to ban the injections or to prohibit them for selected locations in honor of the SDWA. And this is why we are asking you to act on this request instead of dismissing it on paper.

To: richsauerheb@hotmail.com

CC: Jones.Joel@epamail.epa.gov; Pringle.Everett@epamail.epa.gov; Sylls.Gene@epamail.epa.gov

Subject: Fw: (SDWA - FY12-91141-3715-CV) Referred to Region – California

From: Korte.Jill@epamail.epa.gov

Date: Wed, 8 Feb 2012 09:22:55 -0800

Dear Dr. Sauerheber,

Thank you for your e-mails of 1/10/2012 regarding the Metropolitan Water's (MWD) treated drinking water supply that is provided to Carlsbad Water District. You asked that EPA request that Carlsbad water not be treated with fluoridation materials by MWD due to your health concerns about fluoride and potential impurities in hydrofluosilicic acid, such as arsenic. The drinking water supplied by Carlsbad Water District is in compliance with the federal and state standards for both fluoride and arsenic. Furthermore, the State of California meets its obligations under the Safe Drinking Water Act for the delegation of primary enforcement authority for the public water supply supervision program with respect to the fluoride standard. The U.S. EPA cannot request that MWD stop fluoridation of its water supply.

The Safe Drinking Water Act (SDWA), 42 USC §300g-1(b)(11), does prohibit the federal government from adopting any *national* primary drinking water *regulations* that "require the addition of any substance for preventive health care purposes unrelated to contamination of drinking water." The U.S. EPA has not adopted any *national* regulations requiring the addition of fluoride or any other substance for preventive health care.

The SDWA, 42 USC §300g-2(a)(1), requires states such as California that have been granted primacy enforcement responsibility for public water systems to "adopt drinking water regulations that are no less stringent than the national primary drinking water regulations." With respect to fluoride, the U.S. EPA has adopted a health-based, enforceable, primary standard of 4.0 mg/l and a secondary standard of 2.0 mg/l that is based on the cosmetic effects of dental fluorosis. Under federal regulations, public water systems with fluoride levels greater than 2.0 mg/l but less than 4.0 mg/l are subject to specific public notification requirements, but are not required to treat to levels 2.0 mg/l or less. California's enforceable, primary standard for fluoride is 2.0 mg/l, making the state regulation more stringent than the federal regulation. Although California does require its larger public water systems to fluoridate, they are assigned an optimal fluoride level and must operate within a control range, the upper limit of which is less than the more stringent, state enforceable maximum contaminant level (MCL) of 2.0 mg/l.

Metropolitan Water District's Skinner Water Treatment Plant provides water to Carlsbad Water District and consistently produces water that is well below the MCLs for both the state and federal fluoride and arsenic MCLs. Arsenic is not detected in the MWD supply from the Skinner Treatment Plant. In addition, treated water provided to Carlsbad Water District by the San Diego County Water Authority also meets both federal and state standards for fluoride and arsenic.

Any questions you have on fluoridation or home treatment units for fluoride removal should be directed to the California Department of Public Health in Sacramento at (916) 449-5600.

Thank you for your interest in this topic.

Sincerely,

Jill Korte, P.E.

Environmental Engineer
CA PWSS Project Officer
U.S. EPA Region 9
Drinking Water Office
75 Hawthorne St. (WTR-6)
San Francisco, CA 94105
(415) 972-3562 (415) 947-3549 (fax)

01/10/2012

SUBJECT: FWD: (SDWA - FY12-91141-3715-CV) Referred to Region – California
FROM: sylls.gene@epa.gov
TO: jones.joel@epa.gov
CC:
See complaint #91144. The following tip is from the National Tips Database. This information is being provided to you for whatever action you deem appropriate. Please follow up or notify the appropriate agency.

1/4/2012 8:46 PM

HQ LEAD NUMBER: FY12-91141-3715-CV

SUBJECT: Referred to Region - California

FROM: richsauerheb@hotmail.com

TO:

Name: Dr. Richard Sauerheber

Address: 1826 Redwing. St.

City: San Marcos

State: California

Zip: 92078

Phone: 760-744-2547

Alleged Violator's Name: Carlsbad Water District

Alleged Violator's Address: 5950 El Camino Real

Alleged Violator's City: Carlsbad

Alleged Violator's State: California

Alleged Violator's Zip: 92008

Tip or Complaint:

I here raise a formal complaint against the Carlsbad Water District, San Diego County for its use of water with high arsenic levels, and for not reporting this clearly. A value of 120 ppb arsenic detected was listed on their water quality report 2011 with an average of 1.9 ppb. As you know, the EPA allowed MCL for arsenic since Jan., 2011 has been 10 - 50 ppb. The CA State MCL is 10 ppb and the State Public Health Goal is zero. A small amount of arsenic is diluted into water from added fluosilicic acid crude preparations that use the excuse of fighting cavities with the fluoride contained in it. Again, the As PHG is zero. Further, it is a violation of the Safe Drinking Water Act for any State to be less restrictive than its clause that prohibits any National requirement for any substance added into water other than to sanitize the water. This makes it illegal to add arsenic, fluoride, or any substance other than to kill bacteria, into water and yet the practice of adding both has now spread even here to Southern CA

recently against the voting willl of the public. These were the typed data in the Carlsbad Water Quality Report, 2011. Arsenic: CA MCL 10 ppb; PHG .004 Sample 1.9 Range ND - 120 I was told by an employee of CWD that the 120 number was not a reading, but an 'allowed range'. But again the Fed and State allowed ranges do not include a number as high as 120 ppb. I told him that and he said he wasn't sure and that I need to talk with the supervisor who is not available. The 120 number was printed in the report in the column in which measurements were reported, not in the column which lists the allowed MCL's, as shown above.

If you could look into this we would appreciate it here in Carlsbad. We have had a terrible history with elementary school children perishing with cancers of various types and we are aware of the problem with schoolhouses being built on farms (as here) where arsenic pesticides had been used and that allowed arsenic emissions are detected from the Carlsbad emission stacks from a utility. The last thing Carlsbad children need is an extra dose of arsenic from their local water supply and yet that is what they are getting, from fluosilicic acid diluted waste and obviously additional unknown sources responsible for these readings. Carlsbad should be placed on a moratorium for the addition of crude hazardous diluted fluosilicic acid waste, out of sheer courtesy to the parents of these children as well as for the safety of the children themselves.

We in So CA have had enough of fluosilicic acid waste that actually adds, for every 30 tons of added materials, 10 tons of sodium in fresh water where it does not belong, 10 tons of fluoride unwanted by the citizens, and 10 tons of silicic acid, all labeled as 'water fluoridation.' When does drugging the people of a city end, and who has the right to alter the bone density of citizens with fluoride that we now know crosses the blood brain barrier and injects arsenic when we are trying to remove it under our specific problematic circumstances?

Violation Still Occurring? Yes

State DEP/DEQ/DEM Notified? No

01/10/2012

SUBJECT: FWD: (SDWA - FY12-91144-3715-CV) Referred to Region – California
FROM: sylls.gene@epa.gov
TO: jones.joel@epa.gov
CC:

See complaint #91141. The following tip is from the National Tips Database. This information is being provided to you for whatever action you deem appropriate. Please follow up or notify the appropriate agency.

1/4/2012 11:10 PM

HQ LEAD NUMBER: FY12-91144-3715-CV

SUBJECT: Referred to Region - California

FROM: richsauerheb@hotmail.com

TO:

Name: Dr. Richard Sauerheber

Address: 1826 Redwing St.

City: San Marcos

State: California

Zip: 92078

Phone: 760-744-2547

Alleged Violator's Name: Metropolitan Water District

Alleged Violator's Address: Alameda St.

Alleged Violator's City: Los Angeles

Alleged Violator's State: California

Alleged Violator's Zip: 90054

Tip or Complaint:

I earlier submitted a complaint against Carlsbad Water District, CA on behalf of children in that city. Upon reading the Vallecitos Water Report that shares the same water source, it became clear that the Carlsbad Water

Quality Report made a simple clerical error and typed in a value of 120 ppb for arsenic that was actually that for barium, which is an acceptable number. The remaining part of the original complaint then is directed to Metropolitan Water, Los Angeles, because Carlsbad does not inject the fluosilicic acid materials, but rather MWD does. MWD is unaware of the arsenic issue in Carlsbad, where arsenic in schoolyard soils and from the city power plant stack parents believe is causing the high incidence of childhood cancers here. The type and class IA human carcinogen arsenic is present in small amounts in the fluosilicic acid injected for its fluoride by MWD and we ask the EPA to request that Carlsbad water not be treated with fluoridation materials by MWD, particularly inasmuch as fluoride in blood at 0.2 ppm inhibits DNA repair enzymes involved in cancer cell removal (Yiamouyiannis, Fluoride, The Aging Factor, 1985; National Research Council, Report on Fluoride in Drinking Water, 2006; Connett, The Case Against Fluoride, 2010) and because Carlsbad Water has arsenic and lead at levels approaching their respective MCL's both at the same time.

Fluosilicic acid waste injections are requested by Federal dentists at the CDC, which is prohibited by the Safe Drinking Water Act since no National requirement may be made for any substance added into water other than to sanitize the water, and States can be no less restrictive. Ingested fluoride is not FDA approved, and States cannot require consumption by citizens of a substance that is not FDA approved. Carlsbad citizens are being disserved by EPA allowance of fluosilicic acid hazardous waste injections into city water supplies that violates the SDWA. The National Sanitation Foundation is a private agency that 'certifies' the injection materials without having data demonstrating it is effective at caries reduction or that it causes no harm to anyone upon long term consumption. The chemical supplier Lucier Chemicals and Brenntag Chemicals likewise have no such data demonstrating safety or effectiveness of the materials they sell and deliver to MWD and to San Diego (personal communication, Brenntag CEO, water chemicals division).

Carlsbad water also contains injected aluminum at 0.05 ppm which forms complexes with fluoride in stomach acid. Fluoride crosses the blood brain barrier, affects calcium homeostasis and induces bone cell division as a result. These children with high incidence of various lethal cancers in Carlsbad are being subject to unnecessary risk with fluoridation waste materials that is inconsistent with current conditions here. Thank you for your attention.

Violation Still Occurring? Yes

State DEP/DEQ/DEM Notified? Yes

#18 **Richard Sauerheber, Ph.D.**
(B.A. Biology, Ph.D. Chemistry, University of California, San Diego, La Jolla, CA)
Palomar College, 1140 W. Mission Rd., San Marcos, CA 92069
March 24, 2012

Department of Health and Human Services
Public Health Service
U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Regulatory Policy
Rockville, MD 20857

Dear FDA Project Reviewers,

This letter is in support of the petition to ban the addition of synthetic industrial fluoride compounds into public drinking water supplies, original petition FDA-2007-P-0346, formerly 2007P-0400. It has come to my attention that Metropolitan Water District, Los Angeles has been conferring with and advised by officials from the U.S. Environmental Protection Agency to determine dosages in public water supplies for the treatment of consumers with fluoride to be taken internally.

This treatment has nothing to do with environmental protection, but is instead a medical health procedure with the goal of treating the bloodstream of consumers to 0.2 ppm fluoride in an attempt to affect dental tissue through systemic ingestion. This medical procedure has been labeled a dietary supplement (CDC) or as an unapproved drug (FDA) where nevertheless the EPA has no Congressional authority to set dosages for any substance to be taken internally by man in the U.S. That is the sole role of the FDA. Below is correspondence from the President of MWD indicating the role EPA officials are playing in determining dosages. Unfortunately, the EPA MCL's of 4 and 2 ppm fluoride for water are to indicate when water is not to be consumed (4 ppm) and when citizens are to be warned to avoid it (2 ppm) because of known adverse effects on bone during long-term consumption at these levels. Sadly, using these levels as though they were guidelines from volunteer, prospective controlled human clinical trials is a miscarriage of justice that has given MWD board members the false impression that such trials have been conducted, when in fact they have not. FDA ruled in 1963 that fluoride in drinking water is an uncontrolled use of a drug and in 1993 that taking fluoride internally through intentional ingestion is an unapproved drug.

I understand the former claim (2010) by the FDA regarding the 1979 MOU, that has since been repealed, where the EPA was asked to regulate water fluoridation chemicals and procedures, but that memo never intended for the EPA to be responsible for determining or contributing to decisions regarding dosages to be given to consumers for fluoride to be taken internally under conditions with purported benefit but without adverse effect in consumers. The EPA has no such data of safety or effectiveness, or has expertise to determine such dosage in human consumers, particularly in patients who are missing kidneys and rely on dialysis equipment for survival, and in diabetics who typically consume twice as much water daily as similar-weight non-diabetics, and mental retardation victims now that it is certain fluoride crosses the blood brain barrier where it alters brain cell calcium metabolism. The EPA is unaware of such sequelea from fluoride taken internally and is unaware of fluoride-drug interactions, fluoride allergies, or fluoride and HF effects on those with stomach ulceration, Crohn's and other digestive diseases. As a case in point as to how uninformed the EPA and the general public is on fluoride toxicology, the following is a description of a museum display on fluorotic bone vs. normal bone that may be used as an instructional tool. It is intended to introduce the fact that fluoride is both an acute poison (lethal at 5 ppm in blood) and an insidious chronic poison when present at blood levels long-term that are sub-acute, with widely different deleterious effects.

The Associated Press recently reported that hip, knee and elbow replacement surgeries have risen dramatically in the U.S.in recent years. It is inexcusable under these conditions, knowing that fluoride accumulates pathologically into bone permanently during lifetime ingestion, for any human public drinking water to be treated with industrial fluoride compounds to be taken internally. The treatment is an attempt to solve one problem, tooth caries, but

instead introduces other problems, including bone weakening, impaired brain cell calcium metabolism, incorporation into atherosclerotic plaque in cardiovascular disease patients, and in fact ingested synthetic fluoride does not decrease teeth caries systemically at 0.2 ppm in blood and 0.02 ppm in saliva (see previous letters).

Sincerely, Richard Sauerheber, Ph.D.

March 22, 2012

Dear Mayor Sanders,

I understand this is the final year for you as Mayor of San Diego. I believe it would be good if you could examine the correspondence below with Jeff Kightlinger, President of Metropolitan Water, Los Angeles. Kightlinger informed me that no State official ever forced MWD to inject fluosilicic acid, but that the MWD Board itself made that choice. This means that the fluoride treatment of San Diego will be one of the legacies of your administration, if left as is.

The fluosilicic acid chemical suppliers have no data demonstrating caries reduction when the product is ingested. I am certain you would be a virtual hero to the people of San Diego (and elsehwere) by looking into this and fulfilling the voting will of San Diegans. I fully expect that Kightlinger will correct this, now that we have data, unknown when the practice started in 1945, that proves fluoride crosses the blood brain barrier and incorporates into atherosclerotic plaque in cardiovascular disease patients (found on PET scans by physicians at the VA hospital, Los Angeles, published in: Yuxin, **Nuclear Medicine Communications**, Jan., 2012).

As you will see below, MWD has been relying on advice from the EPA for fluoride dosage instructions. EPA regulates contaminant, not supplements or medicaments, for which only the FDA has Congressional authority. In fact it was for this reason that litigation was filed this year against MWD in Federal court.

Richard Sauerheber, Ph.D.

Correspondence (arranged in order for simpler reading):

Dear Jeff Kightlinger, Metropolitan Water, Los Angeles,

Thank you for the editorial you submitted to the North County Times. I do not condone the claims of North County Supervisors that San Diego water is being more unfairly charged for water delivery than other cities are.

On the other hand, one of the sources of unnecessary costs that all overlook is fluosilicic acid/caustic soda injections that treat people, rather than sanitize water. *I must inform you that an MWD spokesman incorrectly told a news reporter (France 24 television) that MWD has 'authority to inject fluosilicic acid from the EPA'.* I have a letter from EPA Region IX San Francisco, Office of Drinking Water, Jill Korte, that states the opposite! EPA does not authorize the injection of fluosilicic acid for its fluoride in public water supplies. That is fully the responsibility of the city itself who chooses to do so. EPA only limits the amount present as a hazardous waste in water to 4 ppm for acute safety concerns. EPA has no ability to regulate procedures or ingredients used to treat people, as fluoride is used. The EPA MCL is not a license to fill up water supplies to that known hazardous level as though it were a value from human clinical trials--that, it is not.

The CA Department of Public health also wrote to me that they do not take any responsibility for, or force fluoride injections--all liability belongs to the cities alone. Further, the FDA has never given approval for any fluoride compound to be ingested, taken internally. The FDA ruled fluoride in water is an uncontrolled use of a drug in 1963 and is an unapproved drug in 1993. Although FDA has not yet banned the injections, it does not approve them and an FDA petition to ban the injections is still pending.

A recent study from the Veterans Administration Health Care Center, Los Angeles is particularly disturbing, that fluoride from the blood incorporates into atherosclerotic plaque in coronary arteries in cardiovascular disease patients, observed directly in PET scans (Yuxin, **Nuclear Medicine Communications**, Jan, 2012). This information has been forwarded to the FDA. Inasmuch as the ban petition is still under consideration, it advisable for you to reprimand the MWD official who is making false statements to public reporters regarding the EPA on

fluosilicic acid. The statement is not only false but also projects a blatant disregard of the public welfare and lack of due diligence in duty of care by MWD.

These unlawful, wasteful, harmful injections will one day end, with or without the blessing of MWD.

Richard Sauerheber, Ph.D.

From: jkightlinger@mwdh2o.com

To: richsauerheb@hotmail.com

Date: Tue, 20 Mar 2012 14:57:15 -0700

Subject: Re: questions from reporters

Dr. Sauerheber

Thank you for your email. I'm glad you understand the real issues on rates.

I will speak with my staff so we are very clear on the fluoride issue so that we communicate clearly that MWD was never mandated or required to fluoridate its water supply. Rather our Board voted to take the action at the urging of numerous medical, county and state officials. There were also many that spoke in opposition as well. That vote was years ago and has been the Board direction to staff since that time. Since that vote staff has worked with the U.S. EPA and health officials on how best to set the right dosage levels and on various technical issues.

Thank you for your continued interest.

Jeffrey Kightlinger

Dear President Kightlinger,

Thank you for your quick response. I want you to know that the EPA does not have data or expertise on what water or blood level of any substance to use to induce a biologic effect in humans while also preventing any associated adverse symptoms, especially in the infirmed (and when other exposures are prevalent for that substance, as true for fluoride). Such regulation of dosage for anay chemical to be taken internally is the exclusive jurisdiction of the U.S. FDA. The EPA deals with preventing contaminants from being too high in water, which is a completely unrelated issue. Officials from the EPA who are advising you have no authority to regulate substances that treat consumers internally through oral ingestion as a supplement.

In short, for the fluoridation of the bloodstream of millions of Southern Californians, MWD is placing its trust in officials who are advising you to treat people with a substance ruled by the FDA as an unapproved drug (where dosage is uncontrolled for this substance ruled to be not a mineral nutrient in 1963). The material has no volunteer controlled human clinical trials data for safety or effectiveness and thus has never been FDA approved. Industrial synthetic fluoride is scientifically un-tested for either safety or effectiveness. An EPA MCL is not a dosage--it is a level not to exceed to help minimize adverse bodily effects known to occur on long term exposure when other sources are absent. The current MCL allowed by the EPA was deemed unprotective of human health by the National Research Council in 2006 in their study requested by the EPA. NRC is expecting a full lowering of this level from the EPA as soon as possible since fluoride exposure from other sources coupled with that in water has resulted in the current endemic of fluorotic abnormal teeth in 40% of U.S. teens as of 2004. This amounts to 9 million U.S. teens who now in 2012 are in their 20's with permanent fluorotic enamel. The next crop of 9 million more are already now being so treated.

MWD has entered into a fray that is completely unnecessary and again the Board should re-vote to halt the injections, not simply to cut out unnecessary expenses that eventually will be paid by consumers, but also because the treatments are harming our youth. There is no excuse for officials who continue to avoid understanding the data we now have and to encourage you to violate the Safe Drinking Water Act that prohibits using public waters as a vehicle to treat consumers of broad and varying need or lack thereof.

You need not feel you have to respond if you do not wish to do so.

Sincerely, Richard Sauerheber, Ph.D.

Dear Mr. Kightlinger,

I am requesting that you write a brief letter to Mayor Robinson of Selmer, Tennessee who has agreed to supply information to you regarding fluosilicic acid chemicals used by cities in public water supplies. This letter to Mayor Sanders I now address to you also. Mayor Robinson asked a few questions of the fluosilicic acid suppliers for his city and found they could not provide such answers, and instead ceased to provide their specific fluosilicic acid formulation and then removed all fluoridation equipment and chemicals from Selmer. Robinson agreed to send the correspondence he has to anyone who asks for it. This is an attempt to collect that information to have on file for reference because we at MWD use the same materials as Selmer did (our supplier for fluosilicic acid as you know is Lucier Chemicals, which like the Brenntag supplier for San Diego has no data demonstrating caries reduction after the material is ingested (personal communications from two Brenntag officials, water additives division).

January 8, 2012

Dear Mayor Sanders,

I am writing to ask a simple specific favor of you. You are fully aware of my feelings on this, but this request is not related to either the support of, nor the opposiiton to, water fluoridation and is not dependent on scientific data. David Robinson, the Mayor of Selmer, Tennessee wrote to me that he will provide information he obtained that resolved the issue in Selmer, that is similar to that in San Diego and in Los Angeles. Selmer City officials in the fully fluoridated state of Tennessee found itself in a position similar to here in San Diego, where citizens opposed a measure that is nevertheless required (here by the CA State fluoridation bill). It is a great story and I'm certain you will be happy that you contacted him, in particular because in so doing you will have the latest information that will fullfill obligations of due diligence for duty of care for citizens here.

Thank you for your consideration of this request, for the benefit of our city.

Robinson is a good and effective mayor and he wrote that he will be more than happy to forward the brief correspondence he has if you ask. His contact information he sent me is:

David Robinson

Mayor, Town of Selmer

City Hall 731-645-3241

Cell 731-610-7016

Fax 731-646-1462

Email david.robinson@selmercityhall.com

website www.townofselmer.com

From: jkightlinger@mwdh2o.com

To: richsauerheb@hotmail.com

Wed 21, Mar 2012

Subject: great information from Mayor David Robinson

Dr. Sauerheber,

Thank you. I will have my staff look into this.

Jeff Kightlinger

From: Richard Sauerheber To: Mr. Kightlinger

Thanks, Mr. Kightlinger.

I really don't want to be pushy, but there is another item that should be mentioned, now that the Water Board is placing its trust in dosage instructions suggested from EPA officials. The EPA does not have expertise or authority in setting dosage for dietary supplements or medicinal ingredients, in particular for people with diabetes who drink more water daily, or patients with missing kidneys living on dialysis machines that cannot process fluoride taken internally.

We included a supplement in the FDA petition describing cases where fluoride consumption is a contraindication, for example for patients with stomach ulcers, since HF forms in stomach acid from ingested fluoride and is far too corrosive for these victims. There is a long list of medications that various patients take that cannot be taken with fluoride because fluoride either potentiates or interferes with their intended actions. Attached are two letters sent to the FDA, one on luride that is an unapproved but allowed drug by prescription in cities that are not fluoridated (as per dosage instructions) and the other on drugs that are not to be taken with fluoride.

The original petition in 2007 is about 80 pages, the Petition for Reconsideration in 2010 another 80 pages, and these are two of 17 supplementary letters relevant to industrial fluoride ingestion from water. We are all hoping the FDA will act and either ban the injections for you or request from chemical suppliers information on 1) what % caries reduction to expect when the material is ingested and 2) that consumption has no adverse side effects for all consumers, even the infirmed. These data do not actually exist. At the very least we expect the FDA to request that Federal officials stop endorsing fluoride ingestion without having controlled volunteer human clinical prospective trials data to back it up.

Thanks again for your consideration, Richard Sauerheber, Ph.D.

Normal and Severely Fluorotic Human Leg Bones, Museum of Man, Balboa Park, San Diego, CA

The detailed history or mechanism by which fluorosis occurred in the individual from which these leg bones were obtained is not described. However, it is nevertheless instructive to ask: if one of these were from a victim of acute fluoride poisoning, which set of leg bones would that have been?

If you guessed the bone with fluorosis damage, you would not be correct! Acute fluoride poisoning does not alter the structure of bone, but instead causes heart block when blood fluoride reaches 5 ppm, which prevents blood calcium from coupling the heart beat with electrical excitation (**ATSDR**, 2003; Gessner, **New England Journal of Medicine**, 330, 1994; Sauerheber, **J. Environmental Health**, submitted 2011). Intermediate blood levels of 1 ppm over a chronic period cause heart muscle weakening

Leg bone is in part responsible for delivering calcium into the blood to support heart function, where normal bone has a smooth surface. The bones with fluorosis are severely spiculed with calcium fluoride deposits, abnormally thickened due to bone cell replication to help maintain normal whole body calcium homeostasis in response to the poisonous insult of the calcium chelator fluoride. Fluoride accumulates into bone permanently during lifetime consumption only when at levels low enough to not be acutely lethal. Uptake is a linear dependence on concentration (**National Research Council**, *Report on Fluoride in Drinking Water,* Washington, D.C., 2006) and is pathologic, not physiologic, and is virtually non-saturable, where human bone in the U.S. has been found with 12,000 mg/kg fluoride. Two years drinking water with 1 ppm fluoride accumulates 2,000 mg/kg. At 3,000 mg/kg, bone is detectably weakened and more subject to fracture. The extent of incorporation is determined by water hardness that minimizes fluoride assimilation, as well as the fluoride concentration in water.

The Museum claims that fluorosis results from exposure to 'high concentrations' of fluoride, but high is a relative term with little meaning in fluoride toxicology. A 'high' concentration of 5 ppm fluoride in blood is acutely lethal within minutes from heart block, without effects on bone. For fluoride to accumulate into bone, lower blood levels of fluoride, not acutely lethal, are necessary so accumulation can occur over many years without killing the individual. A 'low' blood level of 0.21 ppm fluoride, the average for 150 million U.S. citizens consuming 1 ppm fluoride water, causes lifetime bone accumulation to 3-4,000 mg/kg (range from 1610 – 4,921 mg/kg) (p.73). The U.S. now has an epidemic of hip fractures in our elderly population (1/3 million cases yearly) while knee, elbow and hip replacements are on the rise, and there is little reason to wonder why. The NRC reported that drinking 2.6 ppm fluoride water lifetime leads to 10,800 mg/kg with bone/joint pain, and 4 ppm water leads to 11,000 ppm associated with immobility, so bone fluorosis is not limited to cryolite and other industrial workers.

Fluoride is not a mineral nutrient and has no place or function in any living animal or man. Technically any blood fluoride level above zero, where fluoride does not belong, is thus a 'high' level. Industrial fluoride from human drinking water in the U.S. is fully assimilated, crosses the blood-brain barrier and lowers IQ in children raised on such water (Connett, **The Case Against Fluoride, How hazardous Waste ended up in our Drinking Water and the Politics that Keep it There**, Chelsea Green Publishing, White River Junction, VT, 2010), does not decrease dental caries, but instead increases tooth fluorosis in all treated cities, and can incorporates into aorta (**ATSDR**, CDC, Washington, D.C., 2003) and coronary artery atherosclerotic plaque (Yuxin, **Nuclear Medicine Communications**, January, 2012).

#19

Richard D. Sauerheber, Ph.D.
Palomar Community College
1140 W. Mission Rd., San Marcos, CA 92069
E-mail: richsauerheb@hotmail.com Phone: 760-402-1173
April 4, 2012

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Rockville, MD 20857

Dear reviewers,

This letter is in support of the petition to ban the addition of synthetic industrial fluoride compounds into public drinking water supplies, original petition FDA-2007-P-0346, formerly 2007P-0400.

The France 24 international television news broadcast entitled 'In Deep Water' (aired March, 2012, http://www.france24.com/en/20120318-2012-in-deep-water-india-california-fluoride-drinking-clean-france-mineral) interviewed Dr. Kennedy, myself, and Mr. Stewart, general manager of Metropolitan Water District, Los Angeles on water treated with industrial fluoride. According to Stewart, the entire Los Angeles basin and also the North San Diego County region of Southern California began injecting fluorosilicic acid/caustic soda into all human drinking water a few years ago because of health agency recommendations that MWD entrusts. Previously, Jeff Kightlinger, MWD President, stated that Federal officials from the EPA instruct MWD on procedures and dosages of industrial fluoride to administer to consumers through public water supplies. Taken together, it is clear that MWD officials and employees themselves do not understand the biologic effects of fluorosilicic acid in humans, and instead rely on Federal agencies other than the FDA to determine treatment protocols with fluorides used as though they are safe and effective when taken internally.

In fact, the original plan to use toxic hazardous waste fluorosilicic acid, that the EPA classes as hazardous waste, was delineated by Rebecca Hamner of the EPA years ago. She wrote that a solution to the disposal of toxic hazardous waste fluorosilicic acid is to allow it to be injected into public water supplies as a source of fluoride (see petition and Connett, et.al., **The Case Against Fluoride, how Hazardous Waste ended up in our Drinking Water and the Bad Science and Politics that Keep it There**, Chelsea Green Publishing, White River Junction, VT, 2010).

The U.S. Safe Drinking Water Act forbids any Federal requirement for any substance added into water other than to sanitize water. The U.S. Surgeon General's announcement in past years that fluoridation is a public health achievement begs the question of why chemicals that contain fluoride are allowed to violate the SDWA. Placing calcium fluoride, a nontoxic material, into water supplies does not compare with adding hazardous waste industrial fluorides lacking calcium, which the EPA Hamner decision authorized. The CDC recommends the injections, the EPA and CDC overlook SDWA statutes, and both allow hazardous industrial waste injections into public water supplies, advise, encourage and in fact orchestrate dosages and mechanisms.

It is commendable in the TV interview that Stewart admits that science about fluoridation is changing and that a public discussion of the injections is good to have. Indeed, Dr. Kennedy, D.D.S. was able to point out that the ingestion of industrial fluoride represents a poisoning, where tooth fluorosis permanent abnormal enamel hypoplasia occurs when systemic ingested fluoride is present when teeth develop under the gums at ages 5-8. Abnormal dental fluorosis is exclusively caused by consumption of fluorides, including sodium fluoride and fluorosilic acid fluoride, and the chief source of fluoride in the bloodstream of consumers in a fluoridated water region is from ingestion of fluoride water (**National Research Council**, 2006, Washington, D.C.). Fluorosis afflicts approximately 5 million teenagers aged 12-15 in the U.S. In 2004, 41% of 12-15 years olds had tooth fluorosis according to published figures from the CDC. Government statistics indicate there are 13 million teens today in the 12-15 year age group. Those teens in 2004 are now in their 20's, still with the permanent abnormality except for those who have paid large sums for tooth restorations. The next population of children are now developing fluorosis, since 70% of all water districts continue to inject fluorosilicic acid (and, as well, toothpaste with industrial fluoride intended for topical treatment only is not declining in use).

Dosage instructions for, and handling procedures for, hazardous toxic waste fluorosilicic acid is provided to water districts by the CDC and now also the EPA (see previous letters #6 and #18). In the U.S., neither of these Federal agencies has authority to regulate, request, recommend, promote, advertise, require or provide dosage and treatment instructions for any substance intended to be taken internally to affect human tissue. Such Federal actions lie only within the purview of the U.S. FDA. For example, the EPA Maximum Contaminant Level for fluoride at which water becomes non-potable is not an invitation to inject fluoride on purpose to that level, and certainly is not a 'dosage' obtained from clinical trials. The MCL does not take into account that people vary widely in daily water consumption and health conditions. Those with tooth fluorosis in particular are not candidates for further, continuous lifelong fluoride ingestion, nor individuals who have been fluoride poisoned in industry or through intentional ingestion of fluoride toothpaste or other sources. Injection of chemical treatments for internal ingestion on a mass scale are based on a theoretic average, healthy person, when no additional sources of fluoride other than from drinking water are available. No person in such a situation in the heavily fluoridated U.S. is known to exist.

The FDA is commended for requesting recently that fluoride mouthwash advertisers cease from claiming that fluoride taken topically promotes gum health, as there is no evidence in support of this. It is now time to also order water districts, industrial fluorosilicic acid chemical suppliers, and CDC and EPA officials to stop advertising that the ingestion of fluoride from industrial compounds decreases teeth caries, as this gives the impression that no adverse health effects of any kind occur along with its ingestion by all consumers, even diabetics (who drink twice normal water volumes daily) and kidney disease patients with impaired ability to eliminate the fluoride ion. And it further continues the myth that industrial fluoride taken internally can decrease caries, when the CDC published that systemic fluoride does not do so (in: **Morbidity and Mortality Weekly Report**, August, 2001).

A disturbing N.Y. Times article last week went so far as to reprimand parents for providing bottled regular water to children who developed cavities, when in fact normal water without fluoride does not cause cavities. Caries are caused by sugars in the mouth that are not brushed away after eating that *S. mutans* metabolizes to acid that can degrade enamel. Fluoride, in the bloodstream systemically at 0.2 ppm or in saliva at 0.02 ppm, after ingestion from fluoridated water does not prevent caries (see letters #9, #13). The accusation that normal drinking water is suddenly now unhealthy, and that parents using it should be denounced, is false. It is an extension of much incorrect information provided by the Oral Health Division of the CDC (see letter #6) that is also supported by certain officials in the EPA. One is free not to oppose fluoride injections, but no one has a moral right to make false claims of effectiveness or safety of its long-term consumption by humans, particularly the infirmed. Natural God-given pristine drinking water (without injected synthetic industrial fluoride) is not to be denigrated, but in fact must be valued and protected.

Richard Sauerheber, Ph.D.

Letter # 6 sent to FDA Nov. 25, 2011
Letter #8 sent to FDA Dec. 17, 2011
Letter # 9 sent to FDA Dec. 22, 1011
Letter #13 sent to FDA Jan. 14, 2012
Leter #18 sent to FDA March 24, 2012

#20 **Richard Sauerheber, Ph.D.**
(B.A. Biology, Ph.D. Chemistry, University of California, San Diego)
Palomar College, 1140 W. Mission Rd., San Marcos, CA 92069
Email: richsauerheb@hotmail.com Phone 760-744-1150 xt 2448
April 14, 2012

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Rockville, MD 20857

Dear Reviewers,

This letter is in support of the petition to ban the addition of synthetic industrial fluoride compounds into public drinking water supplies, original petition FDA-2007-P-0346, formerly 2007P-0400.

Enclosed please find an article submitted for publication entitled *Physiologic Conditions Affect the Toxicity of Ingested Industrial Fluoride*. Although it is a privileged communication that is now under review, it is appropriate for the FDA to have a copy. The brief paper describes the interaction of synthetic industrial fluoride with calcium ion at physiologic concentrations and body temperature. The level of fluoride required to induce acute poisoning is computed and agrees favorably with known fluoride levels in tissues of persons with acute fluoride poisoning.

The calcium fluoride paradox is described, where high calcium levels in the GI tract are able to prevent fluoride toxicity by inhibiting assimilation, but once inside the bloodstream the opposite scenario exists where higher calcium levels are more easily saturated with lower levels of fluoride. An explanation of biologic variability in both chronic and acute fluoride toxicity is indicated, and the significance of the data are briefly presented in context of the treatment of water supplies with industrial fluoride.

Thank you again and if you have any questions please do not hesitate to contact me preferably by E-mail where thoughtful answers could be best provided as I am able.

Richard Sauerheber, Ph.D.

Physiologic Conditions Affect Toxicology of Ingested Industrial Fluoride

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Abstract. The effects of calcium ion and pH over broad ranges on the free fluoride ion aqueous concentration were determined. Solubility calculations indicate that blood fluoride concentrations that occur in lethal poisonings would decrease calcium below normal physiological levels. Acute lethal poisoning, and also many of the chronic 'low' level effects of fluoride, are mediated by calcium binding by fluoride ion. At a pH typical of gastric juice, approximately 50% of fluoride is protonated as hydrofluoric acid HF, with 50% remaining the free fluoride ion. The significance of these observations is discussed in terms of potential hazards, both acute and chronic, associated with consumption of water treated with industrial fluorides.

Synthetic industrial fluoride compounds lack calcium and are listed toxic substances (Buck, 1964, Gleason, 1969, Blakiston, 1960, Merck, 1976). Calcium fluoride is found in nature and is not considered a toxic compound because of its comparatively high lethal oral acute dose in rodents (LD_{50} = 3,750 mg/kg). The fluoride compounds sodium fluoride and fluosilicic acid, added into municipal water for human ingestion purposes, are synthesized artificially by industrial reaction and are classed as rodenticides, insecticides and pediculicides, with acute oral lethal doses in experimental animals comparable to arsenic and lead (Merck, 1976) (NaF and H_2SiF_6 LD_{50} = 125 mg/kg).

Waters in the U.S. can contain natural calcium fluoride along with other calcium salts (ATSDR, 2003). Although fluoride has been debated to be an agent that alters teeth by ingestion, natural fluoride is accompanied with calcium, which is the chief ingredient in normal teeth enamel hydroxyapatite, not fluoride. The principal effect of ingested fluoride on developing teeth is to alter the structure of enamel to cause fluorosis, a permanent mottling reported to afflict 5 million teens aged 12-15 in the U.S. as of 2004.

Acute Toxicity. The concentration of fluoride is here calculated that would cause calcium fluoride precipitates to first form, from the known solubility product constant for calcium fluoride (K_{sp} = 8 x 10^{-11} at 37°C) and the known concentration of calcium ion in normal human blood (2.2 mM) (Davidsohn, 1962). The K_{sp} varies slightly with temperature and may be computed at 37°C (310 Kelvin) from the relation $\ln(K_{sp}) = -\Delta G/(RT)$ (Lide, CRC**,** 2008) for calcium fluoride with the free energy for the dissociation of calcium fluoride ΔG = 59 kJ/mol and K_{sp} = 3.4 x 10^{-11} at 25°C (298 Kelvin).

The computed fluoride level at which an aqueous solution containing physiologic calcium (3 mM) at physiologic temperature (37°C) is 0.11 mM fluoride or 2 ppm. Here the concentration of fluoride is: $[F^-] = (K_{sp}/[Ca^{2+}])^{1/2}$ from the definition of the solubility product constant for insoluble salts where $CaF_2 \rightarrow Ca^{2+} + 2F^-$ and $K_{sp} = [Ca^{2+}][F^-]^2$. The concentration of blood fluoride where the blood calcium level would be lowered to the lethal low level of about 1 mM is 0.2 mM fluoride (3.8 ppm).

The calculated calcium levels that would coexist in fluid with a given fluoride level from solubility considerations are compared with actual measurements of blood levels of calcium and fluoride ion in victims of fluoride poisoning (Gessner, 1994) in Hooper Bay, Alaska during an accidental overfeed. Note the good agreement, between theoretically calculated fluoride levels that would lower blood calcium ion to levels below normal, and the actual calcium and fluoride ion levels measured in the blood of victims poisoned with fluoridated municipal water. The victim of heart failure from fluoride poisoning had a measured fluoride level of 0.18 mM and another victim that was able to survive had blood fluoride at 0.48 mM that caused calcium levels to plummet to a typically-lethal low level of 1 mM. These concentrations of fluoride from solubility considerations produce calcium ion lowering to levels reported to decrease beat rate in isolated rodent heart cells (Wang, 1998).

The fact that fluoride lethality occurs at concentrations known to compare with saturation and sequestration of calcium ion brings forth an aspect of fluoride toxicity that is counter-intuitive. Ionized calcium levels in human

plasma can vary in some cases from 1.5 mM in hypocalcemia to 4.5 mM in hypercalcemia (as in hyperparathyroidism or excessive Vitamin D intake) (Davidsohn, 1962). The assimilation of ingested fluoride is minimized by calcium ion in the gut, which usually suggests that once inside the bloodstream fluoride toxicity would be lowered in any individual with a higher blood calcium level, but this is false. K_{sp} calculations prove that higher blood calcium levels are associated with lower blood fluoride levels required to achieve calcium sequestration. Lower blood calcium levels require higher fluoride blood levels to begin precipitation. The effect is quite substantial, varying from 2.5 to 5 ppm fluoride lethal levels for subjects with 4.5 and 1.5 mM calcium, respectively. This may help explain the broad variability in reported blood and tissue fluoride levels in lethal fluoride toxicity from ingestion in humans.

Chronic Toxicity. The mechanism by which fluoride from blood at desired 'low' levels irreversibly accumulates in bone (NRC, 2006) does not involve precipitation of ionized calcium because fluoride is below the K_{sp} for direct precipitation. Instead an ion exchange mechanism occurs at extremely minute fluoride levels, where the fluoride ion merely by diffusion exchanges with hydroxide on bone hydroxyapatite. A fluoride ion solution made in soft or distilled pure water has a very high chemical activity, or chemical potential, compared to the activity of the ion at the same concentration when accompanied also by calcium or magnesium ion in solution. Although much less sensitive and exquisite than an actual biological cell membrane, a fluoride specific electrode senses such a difference.

In the following graph for example are fluoride electrode measurements of a solution of sodium fluoride fixed at 0.8 mg/L (ppm) (0.042 mM) actual concentration, in pure de-ionized water at various calcium levels over a wide range. 30 mM calcium (Figure 1) causes substantial inter-ionic interactions with fluoride that significantly lower diffusion or Brownian motion of the fluoride ion because of the relatively massive divalent positive charge on the compact calcium ion. Addition of calcium from 0.1 to 2.5 molar causes progressive decreases in the free ion level due to precipitation of calcium fluoride particles that the electrode cannot detect. The calcium level calculated to first begin fluoride precipitation at 0.80 ppm fluoride is 0.03M.

This phenomenon applies to Group II cations including magnesium ion, prevalent in all foods and natural hard waters. In contrast, fluoride accompanied in solution with Group I metal cations, such as sodium or potassium, exhibit no decline in activity over a broad range of cation concentration, because these ions are only monovalent in charge (not shown).

The ratio of calcium ion molarity (around 0.12 mM) to added fluoride molarity (0.05 mM) in soft water states, particularly in the Pacific Northwest, in an artificially fluoridated city is very low. In moderate hardness water States the ratio is typically about 80-100 to one or more, but still insufficient to prevent blood levels from reaching 0.21 ppm (NRC, 2006) (p. 70). Hard water states are more protected from fluoride ion assimilation than are soft water states in the U.S.

Activity coefficients for the fluoride ion are substantially reduced in the presence of calcium and magnesium divalent cations (Moore, 1965). This effect may be compared to the phenomenon of attraction between fluoride ion and hydrogen atoms in water known as hydrogen bonding which decreases the Brownian motion and diffusion of the ion. These factors determine the overall biologic effect of fluoride ion for living organisms, where calcium decreases assimilation through the gastrointestinal tract, but calcium in the bloodstream lowers the fluoride level associated with calcium sequestration. Further, membranes exhibit complex structural and functional features that are calcium-determined (Sauerheber and Gordon 1982). Fluoride diffusion from a solution containing calcium ion may be impaired, even though far below the level required for binding as calcium fluoride precipitate. The higher the calcium concentration of a region, the less fluoride is able to diffuse away from it. This electrical attractive force is also responsible for the fact that fluoride, even at levels far below the known solubility constant K_{sp} for forming calcium fluoride precipitates, is trapped in bone by ion exchange due to directed collisions.

The effects of pH on the percent of fluoride that converts to HF is shown in Figure 2. As HF, fluoride gains entry into the bloodstream because HF is a neutral small molecule comparable in size to the water molecule and is freely permeable through the biologic membrane (Whitford, 2008). The K_a for HF indicates it is a weak acid but as a small molecule HF is a penetrating corrosive, and its assimilation is most efficient at gastric low pH.

All artificial fluoride compounds are toxic calcium chelators and the allowed levels in drinking water in the U.S. have been found by the National Research Council to not be protective of human health (NRC, 2006). Moreover, the level of fluoride in saliva, that filters from the bloodstream after swallowing, is a miniscule 0.02 ppm (NRC, 2006), unable to influence teeth cavities (as oral topical toothpaste synthetic fluoride at 1,500 ppm fluoride is argued to do). Systemic fluoride at subacute levels incorporates into atherosclerotic plaque in coronary vessels in cardiovascular disease patients (Yuxin, 2012), weakens heart muscle in chronic animal studies (ATSDR, 2003) and exhibits alterations in heart function in humans (Vatrol, 2010a, 2010b).

Consistent with this, as found in the largest taxpayer funded study we have, fluoridated cities have comparable caries incidence as non-fluoridated (Hileman, 1989), and the U.S. CDC published findings that though high levels of topical fluoride might have a caries effect, systemic blood-borne fluoride from swallowing does not (MMWR, 2001). In fact systemic fluoride plays the most major role in causing the current U.S. high incidence of tooth fluorosis in children that prompted the U.S Health and Human Services to request in 2011 that water fluoride be lowered.

Water districts most commonly now inject artificial unnatural industrial synthetic compounds into water to increase fluoride levels to treat consumers (Connett, 2010), using mostly fluosilicic acid H_2SiF_6. Controlled human clinical trials for safety and effectiveness have never been completed with water treated with either sodium fluoride or fluosilicic acid as source of fluoride, and the U.S. Food and Drug Administration has thus never formally approved fluoride compounds for ingestion in the U.S. The FDA has written that fluoride is not a mineral nutrient and labeled fluoride in water is an uncontrolled use of an unapproved drug. Fluosilicic acid is not a source for fluoride in any natural water supply.

Finally, in Figure 3 notice the particular situation in Southern California public drinking water supplies where sodium levels in fresh drinking water had increased from industrial emissions, along the source Colorado River, to 85 ppm in 2006 prior to artificial fluoridation. After fluosilicic acid injections began in 2007 with sodium hydroxide required to neutralize acidity, the sodium level reached 93 ppm. Many plant species that have thrived in this region, including the widely grown avocado crop, are known to be saline intolerant (Musyimi, Netondo and Ouma, 2007). Avocado leaf number, chlorophyll content, chloride content, root weight and transpiration water loss rate are all altered by sodium in irrigation water. At 345 ppm sodium, chlorophyll content is reduced in leaves by 40%, chloride content increased 42% and transpiration rate of water loss decreased as a result of the high salt content by 21% after only 7 days treatment of avocado with the saline water.

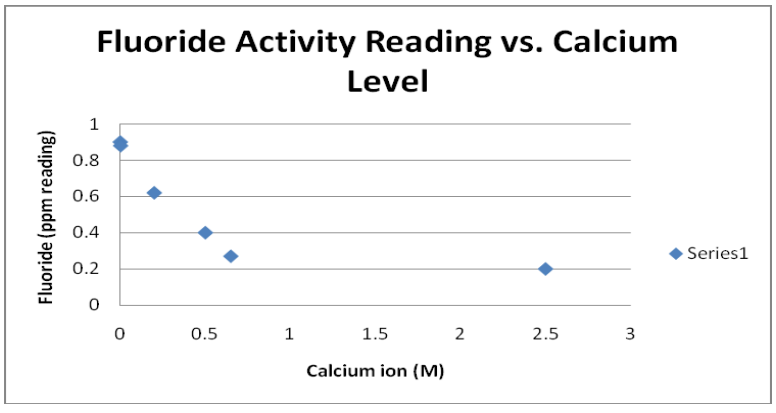

Figure 1. A 0.9 ppm fluoride solution in distilled water was measured for fluoride level with a LaMotte fluoride specific electrode calibrated with 1.00 ppm sodium fluoride in distilled de-ionized water at room temperature. Calcium ion was adjusted over a wide range by

addition of aliquots of calcium biphosphate. Fluoride readings progressively decrease with increasing calcium concentration over the range 20 mM to 3 M.

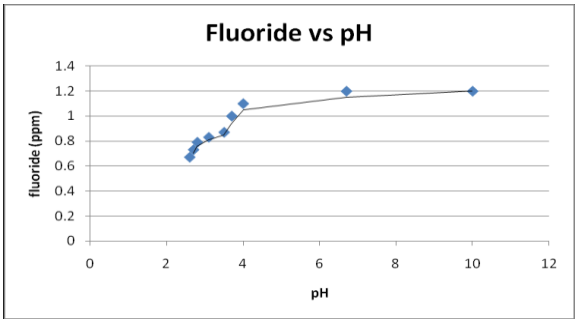

Figure 2. All readings were from a LaMotte fluoride specific electrode (calibrated with a 1.00 ppm fluoride standard solution in distilled deionized water at room temperature). Readings for the 1.2 ppm true concentration solution progressively decrease as pH decreases. Acidity was adjusted with dilute acetic acid. At stomach acid pH readings the fluoride is about 50% protonated, as hydrofluoric acid HF, and 50% free fluoride.

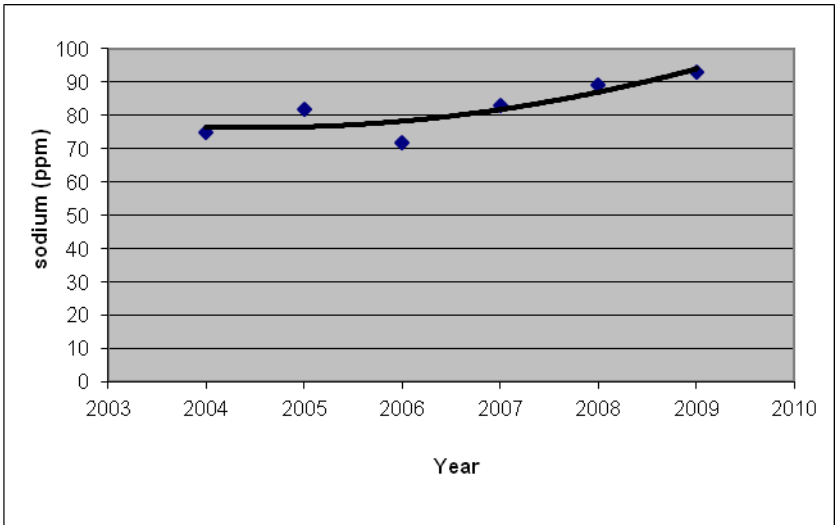

Figure 3. Data are from public published water quality reports from the Metropolitan Water District, Los Angeles for sodium as a function of year. The curves increase progressively after 2007 when industrial fluosilicic acid with caustic soda injections began. Every 24 tons of industrial fluosilicic acid requires 14 tons of sodium hydroxide to maintain pH at 8.4 (two H^+ ions from H_2SiF_6 requires two sodium ions). Sodium at 116 ppm has been found to decrease yields and affect vegetable and fruit quality. Sodium is released into the Colorado River by scores of industries lining the river. The EPA Salt Abatement Program limits releases to one ton daily per site, but with so many sites has led to this level. The EPA secondary standard for TDS (500 ppm) is exceeded but is not enforced--plants can tolerate natural TDS from 800-1000 ppm. No MCL standards have been developed by EPA for sodium, since fresh water has historically been low in sodium. Sodium in blood is 3,000 ppm but is 0-10 ppm in pristine fresh drinking water with a national average at 15 ppm.

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April 15, 2012

U.S. Food and Drug Administration
Centers for Drug Evaluation and Research
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Dear Reviewers,

This information is provided in support of the petition to ban the intentional dissemination and ingestion of the industrial synthetic fluoride compounds fluorosilicic acid and sodium fluoride, petition FDA-2007-P-0346, formerly 2007P-0400.

It is important to emphasize that most individuals involved in the treatment of public water supplies with industrial fluorides are not well-versed in the consequences of fluoride ingestion on those with selected illnesses. Conditions that are particularly exacerbated by systemic fluoride from ingestion are briefly mentioned here, where fluoride crosses the blood brain barrier, accumulates irreversibly into bone, and incorporates into atherosclerotic plaque as found in human heart disease patients (Yuxin, **Nuclear Communications**, January, 2012) and in research animals (**Agency for Toxic Substances and Disease Registry**, 2003).

Cardiovascular Disease. According to the Health and Human Services, San Diego there are 4,000 heart disease deaths every year in San Diego, where the leading contributor to the condition is coronary artery atherosclerosis. The known accumulation of systemic fluoride ion into atherosclerotic plaque in coronary arteries in cardiovascular disease victims (Yuxin,) is an unnecessary chemicalization risk, knowing that the chief source of fluoride in the bloodstream in fluoridated cities is fluoride ingested from treated public water supplies (**National Research Council, Report on Fluoride in Drinking Water**, Washington, D.C., 2006).

Brain Disease. There are 50,000 victims of Alzheimer's disease in San Diego County (Alzheimer's Association). Aluminum and fluoride treated water are contraindicated in this disorder as the aluminum fluoride complex at stomach pH heighten their assimilation and incorporation into brain.

In California there are typically 10,000 new cases of autism every four years (as found between 1996-2000). With 44,000 births yearly in San Diego there are 270 new cases annually. Fluoride consumption exacerbates symptoms in these children (personal communication, Washington Action for Safe Water advocate testimony).

Bone Disease. I was interviewed by Dr. Stanley Monteith on Liberty Radio (www.libertyradio.com) in three one hour segments discussing the adverse effects on human health from long term fluoride ingestion. Dr. Monteith testified as a former orthopedic surgeon that bones are abnormal and chalky in appearance in patients living in fluoridated cities for prolonged periods. 95% of all ingested fluoride that is retained (50% of that ingested) resides permanently lifetime in bone (NRC,2006) where bone becomes significantly weakened and more subject to fracture at 3,000 ppm. There are now 10 million victims of bone weakening due to osteoporosis in the U.S., and in all fluoride consumption is unwarranted and a harmful contributor to additional weakening and calcium metabolic alterations that already plague these victims.

Sincerely,

Richad Sauerheber, Ph.D.

Physicians Group, Sharp Hospital, San Diego description of osteoporosis and its treatments attached

Thanks go to physicians at Scripps Hospital, San Diego for the following invaluable information on the problems that victims of osteoporosis face, whether caused by calcium deficiency or other unknown reasons, where fluoride consumption is an obvious contraindication. It is important to understand the difficult symptomatology that victims face with this insidious condition.

Osteoporosis

Definition

Osteoporosis is the thinning of bone tissue and loss of bone density over time.

Alternative Names

Thin bones

Causes, incidence, and risk factors

Osteoporosis is the most common type of bone disease. There are currently an estimated 10 million Americans suffering from osteoporosis, as well as another 18 million who have low bone mass, or osteopenia.

Osteoporosis occurs when the body fails to form enough new bone, or when too much old bone is reabsorbed by the body, or both.

Calcium and phosphate are two minerals that are essential for normal bone formation. Throughout youth, the body uses these minerals to produce bones. If calcium intake is not sufficient, or if the body does not absorb enough calcium from the diet, bone production and bone tissues may suffer.

As people age, calcium and phosphate may be reabsorbed back into the body from the bones, which makes the bone tissue weaker. Both situations can result in brittle, fragile bones that are subject to fractures, even without trauma.

Usually, the loss occurs gradually over years. Many times, a person will sustain a fracture before becoming aware that the disease is present. By the time this occurs, the disease is in its advanced stages and the damage is severe.

Researchers estimate that about 20% of American women over the age of 50 have osteoporosis. In addition, another 30% of them have osteopenia, which is abnormally low bone density that may eventually deteriorate into osteoporosis, if not treated.

About half of all women over the age of 50 will suffer a fracture of the hip, wrist, or vertebra (bones of the spine).

Recognized risk factors include smoking, eating disorders, low body weight, too little calcium in the diet, heavy alcohol consumption, early menopause, and use of certain medications, such as steroids and anticonvulsants.

Symptoms

There are no symptoms in the early stages of the disease.

Symptoms occurring late in the disease include:

- Fractures of the vertebrae, wrists, or hips (usually the first indication)
- Low back pain
- Neck pain
- Bone pain or tenderness
- Loss of height over time
- Stooped posture

Signs and tests

- Bone mineral density (BMD) testing -- as performed in dual-energy x-ray absorptiometry (DEXA) -- measures the demineralization of the bones. This has become the gold standard for osteoporosis evaluation.
- A spine CT can show demineralization. Quantitative computed tomography (QCT) can evaluate bone density, but is less available and is more expensive.
- A spine or hip x-ray may show fracture or vertebral collapse in severe cases.
- Measuring the amount of calcium in urine can provide some evidence of increased bone turnover, but is of limited value.

Treatment

Treatments for osteoporosis focus on slowing down or stopping bone loss, preventing bone fractures by minimizing the risk of falls, and controlling pain associated with the disease.

There are several different kinds of drugs used to treat osteoporosis. They vary in their side effects, benefits, and costs. **Bisphosphonates** are a type of drug used for both the prevention and treatment of osteoporosis in postmenopausal women. The two bisphosphonates currently approved for osteoporosis -- Fosamax and Actonel – help prevent bone loss and reduce the risk of spinal and hip fractures.

A woman's body produces less estrogen during and after menopause, which may affect her bone strength. Based on early studies, many physicians used to believe that **hormone replacement therapy** (HRT) might be beneficial for reducing the risk of heart disease and bone fractures caused by osteoporosis in addition to treating menopausal symptoms. The results of a new study, called the Women's Health Initiative (WHI), has led physicians to revise their recommendations regarding HRT.

In July 2002, one component of the WHI, which studied the use of estrogen and progestin in women who had a uterus, was stopped early because the health risks exceeded the health benefits. A second component of the study, which studied estrogen-only therapy in women who no longer had a uterus, was stopped early in March 2004.

The WHI study showed that women taking HRT had 34% fewer hip fractures and 24% fewer fractures than women not receiving hormones. However, the main reason for stopping the estrogen-progestin study was a 26% increase in breast cancer in women taking HRT, as well as increases in heart attacks, strokes, and blood clots.

Calcitonin, marketed under Calcimar (injectable), is a medication that slows the rate of bone loss and relieves bone pain. While calcitonin slows bone loss and reduces the risk of fractures, it appears to be less effective than bisphosphonates.

A **diet** that includes an adequate amount of **calcium, vitamin D**, and protein should be maintained. While this will not completely stop bone loss, it will guarantee that a supply of the materials the body uses for bone formation and maintenance is available.

Supplemental **calcium** can be taken as needed to achieve recommended daily calcium dietary intake.

Response to treatment can be monitored with a series of bone mineral density measurements taken every 1-2 years, though such monitoring is controversial and expensive.

There are no surgeries for treating osteoporosis itself. However, a procedure called **vertebroplasty** can be used to treat any small fractures in the spinal column due to osteoporosis. The procedure involves injecting a fast-hardening glue into the regions that are fractured or weak. A similar procedure, called kyphoplasty, uses balloons to widen the spaces that need the glue. (The balloons are removed during the procedure.)

Expectations (prognosis)

Progression of the disease can sometimes be slowed or stopped with treatment. Some people become severely disabled, as a result of weakened bones. Hip fractures, which are frequently sustained by people with osteoporosis, leave about 50% of victims unable to walk independently.

This is one of the major reasons people are admitted to nursing homes.

Complications

- Compression fractures of the spine
- Hip fractures and wrist fractures
- Disability caused by severely weakened bones
- Loss of ability to walk, due to hip fractures

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