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Subject: Written comment for the Joint Meeting of the Dental Products Panel of the Medical Devices Advisory Committee of the Center for Devices and Radiological Health and the Peripheral and Central Nervous System Drugs Advisory Committee of the Center for Drug Evaluation and Research, September 6 and 7, 2006

Dear FDA Committee:

Thank you for holding this important hearing on mercury neuro-toxicity and use of mercury in dentistry.

My expertise is as a professional congressional staff member serving Congressman Istook on the Labor-HHS-Education appropriations subcommittee as associate staff for 10 years, from 1995 to 2004. I am now a registered lobbyist and have no clients on either side of this issue. I'm providing this comment because of what I learned overseeing the health and humans services and education infrastructure of the nation for 10 years.

Most of my time was spent dealing with healthcare issues, and I became professionally acquainted with the entire NIH, CDC, AHRQ, and CMS infrastructures at HHS, as well as worked extensively with the agencies dealing with welfare and criminal justice issues. I also handled the FDA work in the office and have had numerous professional meetings there at the FDA, especially with the medical devices division.

As I've dealt with all of the agencies, including the FDA, I have found professionalism and a genuine desire to do things in the interests of the American people. Conflicts do exist, but repeatedly I found professionalism prevailed. I was heartened to learn this hearing was being held, and I'm hopeful that the committee can take a step back as they examine the evidence and do the right thing for the American people.

In 2004, the last hearing we had was on mercury preservatives in vaccines. Julie Gerberding, the CDC Director, made a statement that really had an impact on me. She stated, "...let us just get to the basics. And the basics are that mercury is a heavy metal. It is not

something that anyone wants to have in their body if they don't have to. The decision to use thimerosal as a preservative was made a long time ago because it was important to protect the safety of the vaccines....And I think that the steps that we have all recommended to remove the thimerosal [25% mercury] from vaccine supplies as quickly as possible is a prudent commonsense approach to a situation...because we cannot prove a null hypothesis [that it is not harmful.]”

(Hearings before the Labor HHS Education subcommittee of the Committee on Appropriations, 108<sup>th</sup> Congress, 2<sup>nd</sup> session, Part 8 “Influenza Vaccine.” Page 19)

In preparation for this hearing, I read a great deal of scientific literature from the schools of public health, especially Harvard, and from the CDC's ATSDR toxicology website. The CDC is very concerned that 1 of 6 women of childbearing age are toxic for mercury according to the NHANES study. Mercury poisoning has about 200 symptoms, differing from person to person. It is a terrific enzyme disruptor, which is why it has been used as an antiseptic and preservative. It is toxic in parts per billion. Look at most of your toxic substances; most of them are toxic at parts per million. Few are toxic at parts per billion.

So, can something that is toxic at parts per billion be generally regarded as safe? Please, look at a package insert for any of the dental amalgam products on the market today and see if anything says, “Generally regarded as safe.”

When dentists started using mercury in dentistry 150 years ago, we did not know much about mercury or other heavy metals. The option was to have molten silver poured into a tooth. “Ouch! Bad! Please try something a little less dangerous.” Today modern dental filling material has been invented since the Vietnam War that is indeed less dangerous and has all been approved by the FDA.

It is my understanding that mercury fillings never have been approved. They were grandfathered in like so much other stuff. In my career I met with the dentists every year, and I actually helped save the dental school from closing in Oklahoma. I'm proud of that work, and proud of the caring dentists that help us with our teeth and oral health. Many are frightened of having dental amalgams banned because of liability issues. It has nothing to do with the issue of mercury itself. I don't think dentists should be held liable, any more than we should hold doctors liable for using mercurochrome, which everyone thought was safe until you, the FDA, took it off the market. It had been “grandfathered” as well. Believe it or not, I just met a retired pharmacist who still has some in his medicine cabinet and has been using it, unaware that it had been pulled off the market by the FDA.

As I worked with CDC, I worked extensively with the environmental health sciences lab and Jim Pirkle, MD, PhD. Dr. Pirkle is the head toxicologist at CDC. He briefed me many times over our ten years of working together. The last time we met he told me, “The more I have studied the effects of mercury, arsenic and lead, the more concerned I have become about the health impact of these metals in humans.” Mercury is the most toxic of these metals.

One of the things I learned from Dr. Pirkle is that most physicians are trained in infectious disease, but few receive training in toxicology. When CDC responds to a

request to find out what is causing an epidemic, they always send both the infectious disease team and the toxicology (environmental medicine) team. Another thing that Dr. Pirkle taught me is that, “There is no such thing as a genetic epidemic. Everything is either being caused by an infectious agent or an environmental toxin.”

As I prepared for the 2004 hearing and read of symptom after symptom of mercury poisoning, I was literally stunned. I remember suddenly thinking back on the entire series of disease group representatives I’d met with over 10 years, and all of the physicians, and all of the lectures I’d attended on various disease processes. There were so many like chronic fatigue syndrome, and Alzheimer’s disease, and autism, which had no “known” cause. Autoimmune diseases are a real puzzle. I’d watched stroke and diabetes and cancer rates rise over those 10 years. When I looked at the CDC data, you can imagine my surprise at seeing that mercury causes cancer, strokes, heart attacks, and neurological disorders. This is known. It is not disputed data.

Yes, the kind of mercury does matter. Methyl, ethyl and elemental mercury all have differing effects and differing toxicities, but all of them are toxic, and various processes in the body can cause types to switch back and forth. So before my comment is discounted because I don’t “understand” the chemistry, I understand it well. Mercury preferentially replaces selenium, copper and manganese and attaches to S-H groups in the body. It interferes with mitochondria and enzymatic functions in multiple organ systems, and with RNA and DNA replication.

The puzzle for physicians is that mercury poisoning may manifest as psoriasis in one patient, and cause a stroke in another or chronic fatigue syndrome in another, while someone else has a heart attack. Someone else may manifest an autoimmune disease. Someone else may be irritable and violent, while another loses the ability to think. I read about all of these different symptoms in the literature. I also discovered that is difficult to remove mercury from a poisoned patient and the most prudent public health practitioners work hard to prevent poisoning in the first place. All of the 29 schools of public health are dedicated to preventing mercury poisoning, from mining, or broken thermometers at school, or coal fired power plants.

And realized Dr. Gerberding, the Director of the CDC was absolutely right. “the basics are that mercury is a heavy metal. It is not something that anyone wants to have in their body if they don’t have to. ....And I think that the steps that we have all recommended to remove the thimerosal [mercury] from vaccine supplies as quickly as possible is a prudent commonsense approach to a situation...because we cannot prove a null hypothesis [that it is not harmful.]”

According to the World Health Organization, dental amalgams account for most of the mercury in people’s bodies. When 1 out of 6 women of child bearing age are toxic for mercury, that has a direct impact on any children they bear and has a direct impact on the cost of educating these children in our school system. Mercury as an environmental factor has clearly implicated autism in a recent article from *Environmental Health Perspectives* published by the National Institute for Environmental Health Sciences at the NIH.

So please, examine this clearly. It is impossible to explain how a classroom is cleared because a mercury thermometer broke, and becomes an EPA cleanup site, and yet that same amount of mercury can be implanted into a tooth of a patient and it is somehow “generally regarded as safe.” The amalgams are dangerous before they are even put in (see any package insert.) Check the OSHA rules where they are manufactured. They have to be disposed of as hazardous waste when they’re removed from the mouth, but are somehow safe in a tooth? Clearly there is a logic gap of immense proportions.

The FDA is filled with intelligent people. I truly believe your panel wants to come to the correct decision. Examine the facts and I am sure you will discover, as I have, that nothing about mercury is “safe.” All exposure to mercury that can be reduced should be reduced. Even the CDC has stated this clearly. As Dr. Gerberding stated, the prudent and commonsense approach to the situation should be to remove mercury exposure from humans as quickly as possible. The CDC’s ATSDR website has hundreds of studies that confirm this. CDC’s environmental health sciences lab has confirmed this. The schools of Public Health are trying to limit mercury exposure. The EPA removed mercury from indoor paint because of toxic exposure, and has issued warnings not to eat fish. The FDA removed mercurochrome and substitutes for thimerosal in vaccines are being sought and some have been approved by the FDA. The precedent is there for this FDA panel to also recommend that amalgams no longer be used in patients.

I hope that this FDA panel will examine mercury for the hazard that it is to human health and make the decision to protect the U.S. population. The liability issue that dentists have can be dealt with separately and I expect Congress would move to do that quickly if it were necessary. Until mercury is removed from dental practice, we will continue to have significant exposure to mercury from amalgams. Amalgams are the single largest source of mercury in sewage treatment plants because of this heavy metal in fecal matter (which in turn gets back into the environment and water supply.)

Please remove this additional source of mercury from the United States population by disallowing its use in the future as a tooth restorative compound.

Sincerely,

A handwritten signature in cursive script that reads "Dr. William A. Duncan". The signature is written in black ink and is positioned above the printed name.

DR. WILLIAM A. DUNCAN