

Consumers for Dental Choice

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May 8, 2006

Associate Commissioner Randy Lutter, Ph.D., Policy
Acting Associate Commissioner Jason Brodsky, External Affairs
Chief Counsel Sheldon Bradshaw
U. S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20847 -- -- *via e-mail and regular mail*

Re: FDA Acknowledges Privileged Legal Status for Pro-Mercury Dentists

Dear Associate Commissioner Lutter, Associate Commissioner Brodsky, and Chief Counsel Bradshaw:

In a public statement issued last week, FDA continues its policy of preserving a privileged -- and illegal -- status for the nation's remaining pro-mercury dentists. FDA's spokesperson claimed this product which is 50% toxic mercury may be sold based on a belief of safety.

"FDA spokeswoman Susan Cruzan said the agency does not comment on lawsuits. However, she noted the FDA is holding a two-day meeting in September to review scientific evidence on mercury fillings. In the meantime, Cruzan said, "**We currently believe that they are safe.**"

--- *Chicago Sun-Times*, May 2, 2006 (article is attached)

FDA may not base its actions on a "current belief." FDA must -- and for other devices does -- require proof of safety by implant manufacturers. But for mercury fillings, FDA takes the opposite tack: no proof of safety required by manufacturers, plus a sham classification scheme. Perhaps dentists at the Center on Devices -- unqualified to judge, and (documents show) lacking supervision by the Director -- "believe" amalgam to be safe, but their "belief" lacks a scientific foundation. Indeed, they hide the Canadian and Swedish national reports from the public and the Commissioner's office via their sham Consumer Updates, then handpick an unqualified meetings planner and a tobacco consultant to provide foregone conclusions posing as an independent study.

Keep in mind, we are talking about a device that is 50% mercury and which is no longer needed in oral health care. **No modern dentist still implants mercury fillings.** Mercury is the choice of the factory-line dental clinic, whose sole goal is maximizing profits (since mercury fillings are so easy to implant), and who caters to the working poor, minorities, and children.

By allowing sales of capsulated mercury amalgam, FDA is violating five sections of the FDCA:

- FDA has illegally chosen, de facto, not to classify the mercury amalgam implant.
- To allow its sale without premarket approval, FDA uses the subterfuge of calling a classified non-mercury alloy device "substantially equivalent" to the mercury amalgam capsule, even though FDA now recognizes the latter raises neuro-toxicity issues because of the mercury.

- FDA refuses to conduct an Environmental Impact Statement on the nation's #1 source of mercury in the wastewater.
- Allowing mercury amalgam capsules to be approved as a Sec. 872.3050 device makes it a misbranded device, since that device is defined as containing no mercury;
- Allowing mercury amalgam capsules to be approved as a Sec. 872.3050 device makes it an adulterated device, since mercury is a neurotoxin, a poison, being classified for sale as an alloy containing no mercury.

It's time for FDA to stop allowing mercury amalgams to be sold because of a "belief" by an unsupervised and unqualified branch of the Center on Devices. It's time for FDA to stop proclaiming the safety of mercury amalgam while never requiring what it requires of much less controversial products – proof of safety by the manufacturers.

Sincerely,

Charles G. Brown

 MS patient sues FDA over mercury fillings

Chicago Sun-Times, May 2, 2006

By Jim Ritter, Health Reporter

Convinced her multiple sclerosis was caused by the mercury in 16 silver-colored fillings, Linda Brocato asked her dentist to remove them.

Although she still is unable to walk, Brocato said her symptoms improved dramatically after she got a new set of mercury-free fillings.

Now the Prospect Heights resident is a plaintiff in a federal lawsuit demanding that the Food and Drug Administration either ban mercury fillings or show they are safe.

"The FDA is supposed to protect us, and they have not done so in this instance," Brocato said.

FDA spokeswoman Susan Cruzan said the agency does not comment on lawsuits. However, she noted the FDA is holding a two-day meeting in September to review scientific evidence on mercury fillings. In the meantime, Cruzan said, "We currently believe that they are safe."

More than 100 million Americans have received metal fillings. Mercury, which composes about half the weight of these fillings, is used to bind powders of silver, copper, tin and other metals.

MS society: no evidence of link

Mercury is a toxic metal, and metal fillings continuously release small amounts of mercury vapor that patients inhale.

Nevertheless, the American Dental Association says metal fillings have been used safely for more than 100 years. And two government studies published in the Journal of the American Medical Association last month found that metal fillings caused no ill effects in children.

The National MS Society says there is "no scientific evidence" to link metal fillings to MS or other neurological diseases.

Although mercury poisoning can damage the nervous system and cause tremors and weakness, such damage is inflicted in a different way than MS, the society said.

The lawsuit was filed on behalf of four consumer groups; a member of the California dental board; an Arizona state senator; a mercury-free dentist; a woman who believes mercury fillings caused her asthma, and Brocato.

More dentists using non-metals

Two congressmen, Dan Burton (R.-Ind.) and Diane Watson (D.-Calif.), also are demanding the FDA regulate mercury fillings.

"We fail to understand why the FDA has banned mercury in disinfectants (mercurochrome), warned against mercury in certain foods (fish), prohibited the use of mercury in all veterinary products, yet continues to allow its unregulated use inches from a child's brain," the congressmen wrote to Health and Human Services Secretary Michael Leavitt.

In recent years, more dentists have begun using tooth-colored composite fillings, which consist of materials such as glass and ceramic.

About 70 percent of fillings today are composites. But these mercury-free fillings generally cost more and don't last as long as metal fillings, a dental association spokesman said.
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