

Marjorie H. Monteleon

From: "Marjorie H. Monteleon" <prestonbrian@acadia.net>
To: <fdadockets@oc.fda.gov>
Sent: Sunday, September 15, 2002 8:20 PM
Subject: Docket # 01N-0067-AGAINST the FDA Rule/ Mercury Dental Fillings

Docket # 01D-0064 Against the F. D. A. Rule

**Food and Drug Administration
Dockets Management Branch
5630 Fishers Lane, Room 1061-HFA-305
Rockville, MD 20852**

Dear Sirs and Mesdames:

On Thursday September 5th, 2002, 84 metric tons of mercury was finally trucked out of Maine on its way to a secure storage facility in Wisconsin. This is approximately the amount of mercury consumed by U.S. Dentists in two years of filling teeth with dental amalgam.

This Maine mercury was left behind when the now defunct Hotra Chem plant was shut down in 2000, leaving not only this 84 tons of mercury to be dealt with, but another 80 tons saturating the soil, buildings, Penobscot River as well as the town of Orrington.

On the same day in Washington DC, the Senate unanimously passed S.351 to ban mercury -- thermometers and charge a federal task force with developing a national policy to retire surplus mercury, to keep it out of commerce in order to protect the global environment.

Since mercury has and is being removed from numerous products, such as batteries, thermometers, switches, thermostats, vaccines, contact lens solutions etc., because it is such potent neuro-toxin, why would the FDA propose to make it easier to keep it in dentistry by reclassifying, encapsulated amalgam alloy, and dental mercury as a Class II device? This means you are declaring mercury safe!

If you must reclassify it, it should be a Class III, where manufacturers would be required to prove the safety of this product. That is your duty under FDA's own rules which require that "implants" be classified as a class III device.

Further, your mission clearly states that it "is to promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use. Our work is blending of law and science aimed at protecting consumers."

How can reclassifying encapsulated amalgam alloy and dental mercury as a Class II device be considered protecting consumers? Dentists are the single, largest contributor of mercury to waste water. Municipal wastewater treatment systems were not designed to treat hazardous waste. While most other anthropogenic mercury uses have declined 80% since the 1980s, this is not the case in the dental sector. Dentists are the **THIRD** largest user of mercury in the United States. Forty tons a year, most released eventually into the environment. [See the Mercury Policy Project report "Dentist the Menace?" available from MPP's website]

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Other government agencies recognize the extreme toxicity of mercury. The EPA For example, recommends that dentists hang in their offices a pledge not to use mercury of any kind.

Hospitals all over Maine have also pledged to virtually eliminate mercury from hospital waste streams by 2005 and are conducting mercury thermometer exchanges.

In August 2001, I personally watched as our governor, Angus King, signed into law that dentists would have to warn their patients that dental amalgam is 50% mercury.

In July 2002, the Maine Department of Environmental Protection said in its letter to the Joint Standing Committee on Natural Resources; "In order to fully address mercury discharges from dental offices, the Department recommends that in addition to implementing the Pollution Prevention Plan and using "The Environmental Guide for Dentistry," the following actions be taken:

1. Mercury separators be required at all dental offices. This should be accomplished through appropriate legislation. It is impossible to insure reduced mercury discharges without these devices. The Department plans to propose legislative language for your consideration."

For two years I worked on the Dental Mercury Workgroup with the Maine Department of Environmental Protection that came to the above conclusions. Our goal was to get laws and recommendations in place to stop the egregious pollution of Maine by Maine dentists.

I drove hundreds of miles in all kinds of weather, spent countless hours in meetings, did research, testified before both the Maine and New Hampshire legislatures and now you want to **PRE-EMPT** all of that? You insult the entire State of Maine and what is worse, you insult all of our hardworking lawmakers in Augusta!

Because you would not take a stand and abide by your mission to protect, you now want to pre-empt the protection each state has enacted on its own. Outrageous!

Public hearings throughout the United States are most definitely needed after the comment period closes on September 16, 2002 as well as a new Advisory Panel that can be unbiased, impartial and that has not spent its time trying to thwart all efforts by others to reduce dental mercury releases.

The positions of the A.D.A. and state dental associations are designed to undermine and discourage legislative and regulatory efforts to control mercury discharge limits for the dental industry, even though scientifically their positions are largely unfounded. They insist on obscuring substantiated scientific evidence in order to advance their objection to reforming the use of mercury in dentistry, floating a host of flawed arguments designed to reject outright the possibility of regulation.

Perhaps the Maine mercury now safely stored in Wisconsin should be placed in ½ and 1 gram dental filling packets and sent to all U.S. Dentists. In two years, there would be none to store and the owners of this mercury would be saved all those storage fees. That is about as sensible as you reclassifying dental mercury as safe.

Sincerely

9/16/02

Marjorie Monteleon,

Dental Mercury Workgroup

Maine DEP

PO Box 1302

Southwest Harbor, ME 04679

207-244-5577

The above will also be mailed from Southwest Harbor 9/16/02 to assure that these comments are in the public record.