



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

3065 '02 JUL 19 P1:16

July 9, 2002

Charles G. Brown
Consumers for Dental Choice, Inc.
1400 Sixteenth St., N.W., Suite 330
Washington, DC 20036-2215

Dear Mr. Brown:

Thank you for your letter of June 27, 2002, petitioning me "regarding a proposed rule that would protect dentists' use of mercury fillings".

I notice that the letter referenced Docket #01N-0067 which is a Proposed Rule regarding Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy, which was published in the Federal Register on February 20, 2002. Your letter will be considered as a comment on the Proposed Rule and will be reviewed along with other comments before issuance of a Final Rule on this subject.

Sincerely yours,

Wes Weinstein
Ombudsman
Center for Devices
And Radiological Health

Cc: Dockets Management Branch

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Docket # 01N-0067 - Against FDA Proposal re Mercury Dental Fillings

Submitted to public record: fdadockets@oc.fda.gov

Les Weinstein, CDRH Ombudsman
Center for Devices and Radiological Health
FDA

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--Joseph M. Sheehan, Chief, Regulations Staff, fax 301-594-4795; jms@cdrh.fda.gov

To the Ombudsman:

On behalf of Consumers for Dental Choice, Inc., we petition the Ombudsman regarding a proposed rule that would protect dentists' use of mercury fillings on the grounds that it:

1. Is contrary to new White House policies, specifically, a recently created task force on mercury to address its health and environmental impact;

2. Conflicts with the FDA's own policies about the risks of mercury toxicity, including the recent fish warnings and the directive to cease using mercury preservatives in childhood vaccines;

3. Is opposite to other federal agencies, most recently to health risk warnings about mercury toxicity from dental fillings in the Agency for Toxic Substances and Disease Registry, U.S. Public Health Service, Toxicological Profile in Mercury, (Update) (1999), and the Environmental Protection Administration position that mercury from dental offices constitutes hazardous waste.

4. Relied on an ancient Advisory Committee, who last met fully seven years ago, and who therefore did not evaluate the plethora of developments against the use of mercury, especially for pregnant women or children;

5. Attempts to rush through a protection regulation for mercury amalgam to deflect a bill by eight Members of Congress, through the bipartisan Watson-Burton bill, H.R. 4163, that would phase out the use of mercury amalgam fillings.

6. Is acting in the absence of a Commissioner on an issue where only the ADA wants urgency, an additional sign that sufficient agency oversight is not being made on the dental materials section of the FDA.

7. Ignored or intentionally misstated studies and developments contrary to the position of the American Dental Association -- such as Health Canada reports, manufacturer contraindication warnings, peer reviewed studies, and the reason amalgam use ended in Sweden;

8. Ignored, either consciously or via gross negligence, state statutes enacted in California (1992), Arizona (2000), and Maine (2001) (and, since publication, New Hampshire), all of which require disclosures by dentists or state government agencies of the health (and in Maine and New Hampshire's case, environmental) risks of mercury fillings, a development noted even in ADA publications relied upon in the regulation;

9. May stealthily be attempting, via choosing ambiguous language, to preempt or otherwise nullify state dental practice statutes requiring dentists to give warnings about mercury fillings, a radical and unprecedented usurpation of the tradition of states regulating the professions;

10. Utilized secretive procedures leading up to the proposal intentionally excluded consumer organizations dedicated to consumer choice in fillings materials, scientists who have determined that mercury dental fillings are a health risk; and the views of the one-quarter of American dentists who no longer use mercury fillings.

11. Denies the public the right to a hearing;

12. Inexplicably suggests that the agency "inadvertently" failed to classify amalgam fillings a decade ago, whereas the truth is that the agency consciously made the choice that the dentist mixed the compound, thus absolving itself, mercury amalgam manufacturers, and the ADA from any legal responsibility for the health harms that resulted;

13. Refuses to create a new Advisory Committee which, under law, would require consultation with consumer groups and scientists opposed to mercury fillings;

Explanation of 13 Points

1. White House policy

The President recently created a task force on mercury, to examine its health and environmental implications. This regulation should await the work of the task force, which was created due to the serious problems of mercury toxicity, a factor seemingly unknown to the scribes of this regulation.

2. FDA policies

The FDA has spoken boldly and courageously to end mercury in childhood vaccines, and to warn pregnant women about mercury in fish. But when facing the powerful American Dental Association, this courage ceases, and the agency proposes a regulation to allow dentists to continue to put toxic material into children's mouths.

3. Federal agencies

The report relies more upon a 1993 report of the Agency for Toxic Substances and Disease Registry than the 1999 report which superceded it! Probably not at all coincidentally, the American Dental Association in its pro-mercury propaganda takes the same tact. The 1999 report says that the two major causes of mercury toxicity (except for workplace exposure) are dental fillings and fish. (The FDA, as noted above, proposes diametrically opposed solutions for fish compared to fillings.) It says mercury goes through the placenta to the fetus, and through the breast milk to the infant. It says children are most at risk for mercury fillings, because the toxicity from the fillings goes first to the brain and their brains are still developing. All of these claims by a federal agency should be taken most seriously by the FDA. The public has a right to expect that when federal agencies make decisions, risks to children's health must trump dental economics.

The EPA has a longstanding policy of reducing mercury at the source, and of treating dental fillings as hazardous waste.

4. Obsolete Advisory Committee

The decision to use an Advisory Committee who last met seven years ago -- an eon in terms of scientific research -- allows the FDA to ignore those very developments that would lead an objective agency to classify mercury fillings as a Class III material. For example:

- The many peer-reviewed studies condemning mercury dental fillings, by Professors Haley, Lorscheider, Vimy, Summers, Aposhian, Chang, etc.;
- The Health Canada report, recommending no mercury fillings for children, pregnant women, and those with kidney problems, braces, or mercury allergies;
- The contraindication warnings by the manufacturer Dentsply, advising dentists to stop giving mercury fillings to children, pregnant women, and those with kidney problems, braces, or mercury allergies;
- The case directing that Proposition 65 warnings (California) issue for mercury dental fillings;
- The ending of mercury in other health care uses, such as in vaccines, thermometers and contact lenses.
- The Watson-Burton bill, H.R. 4163, with six more co-sponsors to date, which would abolish mercury dental fillings (although not introduced until 2002, announced by Congresswoman Watson in November 2001 and well reported in dental publications);

- State bills, similar to Watson-Burton, introduced in, to date, Alabama, Arizona, California, Georgia, and Illinois.
- The 1999 report of the Agency for Toxic Substance and Disease Registry.
- The resolution of the California Medical Association (2000) favoring phasing out of all health care products that contain mercury;
- The resolution of the American Public Health Association (1999) favoring phasing out of all health care products that contain mercury;
- The official paper of the American Pediatric Medical Association advising physicians to recommend mercury-free dentists to patients concerned about exposure to mercury;
- The emergence of Health Care Without Harm as an organization opposed to mercury in health care products;
- The creation of Consumers for Dental Choice (1996), a consumer group favoring, first, informed consent, and second, an end to mercury dental fillings;
- The creation of the Coalition to Abolish Mercury Dental Fillings (2001), an umbrella group supporting policies ending mercury in dentistry;
- State laws directing specific warnings issue: Arizona (2000), Maine (2001), and New Hampshire (2002);
- The implementation of a 1992 California statute requiring a "fact sheet" on the risks of mercury fillings, so blithely ignored by the Dental Board that the Legislature shut down the Board in 2001;

Organized dentistry is fully aware of these developments, and the scribes of this rule either know about them or used gross negligence to keep themselves in the dark.

5. H.R. 4163, the Watson-Burton bill

A bill by Congresswoman Watson (D-Calif.) and Congressman Burton (R-Ind.), since joined by Congresswoman Carson (D-Ind.), Congressman Hinchey (D-N.Y.), Congressman Ford (D-Tenn.), Congresswoman Davis (R-Va.), Congresswoman Millender-McDonald (D-Calif.), and Congressman Conyers (D-Mich.), would immediately stop the use of mercury fillings for children, pregnant women, and nursing mothers, would give health warnings to all, and would prohibit the use of mercury in dentistry starting in 2007. This regulation tried to jump-start the forces opposed to the bill, a meddling in Congressional prerogatives that is not appropriate.

6. No Commissioner

Until the President appoints and the Senate confirms a new Commissioner, the agency should focus on urgent decisions. The only private parties seeing urgency in the FDA acting on this regulation are the ADA and the mercury manufacturers. We believe that lower levels of the FDA engineered this rule without appropriate review, not a surprising action when the agency has had no Commissioner for so long. This regulation can wait her or his arrival.

7. Ignoring or misstating studies and developments contrary to ADA position

Health Canada recommended back in 1996 that children, pregnant women, and people with kidney problems, braces, or mercury hypersensitivity not receive mercury fillings. In 1997, a major manufacturer, Dentsply, issued contraindication warnings for children, pregnant women, and people with kidney problems, braces, or mercury hypersensitivity. In 1999 and 2000, respectively, the American Public Health Association and the California Medical Association passed resolutions calling for a phase-out of all health products containing mercury. All of these developments were plainly known to the FDA, or with any reasonable effort could have been.

Web sites listing numerous studies include www.altcorp.com/amalgmpage.htm; www.home.earthlink.net/~berniew1; and <http://www.vimy-dentistry.com/>

The FDA falsely suggests that Sweden ended amalgam use for environmental reasons. As a letter to the agency explains, the decision was made for health as well as environmental reasons. Rather than learn the facts, the FDA chose to rely on ADA folklore.

8. State statutes

It strains credibility to suggest that the framers of this proposed rule either did not know about the state statutes or thought them irrelevant. That the regulation calls for "uniform" disclosures suggests that they indeed do know about the laws and are trying, *sub silentio*, to overturn them. In fact, a veritable revolution against amalgam use has begun in the states. Four states have passed laws: Arizona, California, Maine, and New Hampshire. Bills were proposed this year in Alabama, Georgia, Illinois, and Ohio to stop dentists from using mercury fillings in children and pregnant women.

The National Black Caucus of State Legislators passed a resolution. The NAACP of Los Angeles, the Children's Advocacy Institute, and the Mercury Policy Project have all called for an end to the use of mercury in fillings. Health Care Without Harm, the American Public Health Association, and the California Medical Association have all called for a phase-out of ALL mercury products in health care, and did not exclude mercury fillings.

9. The preemption question

Before proposing such an important rule for public comment, the FDA needs to unambiguous: Does the proposed regulation pre-empt state laws? Pretending no such laws exist only begs the question. Members of Congress from states where such laws are passed, and who likely support their home states' right to legislate, need to know this before the rule is finalized. This is yet another reason to withdraw and rewrite the rule.

If preemption is attempted, it would mark a radical, unprecedented, and perhaps unconstitutional step by the FDA to preempt the states' traditional role in regulating the practice of health professionals.

10. Secretive procedures

The decision to unveil this regulation and rely upon an Advisory Committee that hasn't convened for seven years, without any recent public hearings, sent a shock wave through the growing public movement to abolish mercury dental fillings. The regulation was timed to pre-empt actions in Congress and the states, and contains no consumer protection at all. Consumer comment, overwhelmingly against the rule, is enormous, leading to an agency agreement to allow more time for public comment.

One trade group, and only one, is delighted with the FDA action: the American Dental Association. The FDA has given *carte blanche* to dentists to make crucial decisions about dental issue, re-enforcing organized dentistry's position that it is entirely appropriate for dentists to profit by putting grams of mercury into the bodies of unsuspecting children and pregnant women, even hiding the presence of mercury by calling it "silver." Ignored by the FDA is that the ADA's control over dentistry is itself disintegrating: fully 27% of all American dentists are now mercury free.

11. No public hearing

The regulation allowed neither for public hearings nor for a right of reply. It would allow the ADA, with its pseudo-scientific system of product endorsements fed by money from product manufacturers, to go unchallenged in its comments.

On an issue of this magnitude, a public hearing and the right of reply are essential.

12. "Inadvertent" failure to classify

A "mistake" unchecked for ten years deserves an explanation. None is given. That is no surprise: it was no mistake. In the early 1990s, the FDA relegated the amalgam decision to the ones "mixing" the material, the dentists. Now, with dentists being sued for putting mercury in the mouth without warning, the FDA is trying to protect them by saying the decision was inadvertent. It was not. If we are wrong, then we call on the agency to explain its silence.

13. Refusal to create new Advisory Committee

Consumers for Dental Choice was created in 1996. By refusing to have a new Advisory Committee, we were bypassed. Three national dental societies oppose mercury fillings: International Academy of Oral Medicine & Toxicology (Dr. Michael Ziff, Orlando, telephone 407.298-2450); American Academy of Biological Dentistry (Carol Arana, Carmel, telephone 831.659-5385), Holistic Dental Association (Dr. Jim Kennedy, Denver, telephone 303.399-4550). They would likewise need to be consulted, instead of reliance upon the pro-mercury American Dental Association. Finally, the emergence of prominent scientists who have studied and condemned the use of mercury fillings - e.g., Professors Haley (University of Kentucky), Summers (University of Georgia), Aposhian

(University of Arizona), and Lorscheider (University of Calgary-retired) – calls for their views to be heard.

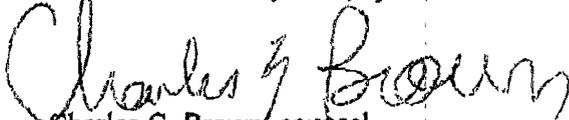
Instead, the FDA chose to record the ADA viewpoint only, then ratify it into a regulation.

Remedy requested

Petitioner asks for that the FDA:

- Withdraw the rule outright. *Failing that,*
- Appoint a new advisory panel who will review the colossal developments over the past seven years against mercury dental fillings. *Failing that,*
- Postpone action until Congress can consider the Watson-Burton bill. *Failing that,*
- Postpone the rule until a Commissioner is appointed. *Failing that,*
- Have a public hearing and right of reply. *Failing that,*
- Classify amalgam fillings as Class III. *Failing that,*
- Issue a warning that, immediately, children, pregnant women, and nursing mothers not receive mercury dental fillings.

Submitted June 27, 2002, by Consumers for Dental Choice, Inc.



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