

Consumers for Dental Choice

1725 K St., N.W., Suite 511
Washington, DC 20006
Ph. 202.822-6307; fax 822-6309
www.toxicteeth.org

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Associate Commissioner Randy Lutter, Ph.D.
Acting Associate Commissioner Jason Brodsky, External Affairs
Patricia Kuntze, Senior Advisor, Consumer Affairs
Lakeysha Bryan, Office of Legislation
Diane Murphy, MD, Director, Office of Pediatric Therapeutics
Les Weinstein, Ombudsman, Center for Devices
Patty Delaney, Office of Special Health Issues
Food Drug Administration -- *via e-mail only*

Dear Associate Commissioner Lutter et al.:

It remains disconcerting to see that while **FDA opposes mercury in all human drug products**, www.fda.gov/oc/po/firmrecalls/equine05_02.html, and opposes mercury in **all veterinary products**, http://www.fda.gov/cvm/July_August.htm#2241 – yet **FDA gives the green light to large quantities of dental mercury (0.5 grams per filling) for children and pregnant women – without even providing warnings.**

A recent poll of Connecticut voters show that three in five do not believe that “silver” fillings contain mercury – and fewer than one in 20 knows it is more than a de minimis amount (the answer is 50%). The American Dental Association does not want consumers to know this – and neither does the Dental Devices Branch, which hides the fact of mercury exposure via its deceptive Consumer Updates, its proposed regulation, its barrage of amalgam-friendly rhetoric, and its choice of a user-friendly consultant for Big Tobacco (LSRO Inc.) to review amalgam literature. That **horses outrank children and human fetuses in protection from mercury exposure** defies rational explanation.

- We are filing two Citizen Petitions with FDA (sent to you in an adjacent e-mail)
- One, directed to Ombudsman Weinstein, would transfer regulatory responsibility from Dental Devices Branch to General, Restorative, and Neurological Devices. **Alone among any part of FDA, Dental Devices Branch trivializes mercury exposure, categorizing its effects as an “allergy.”** The Branch protects its ongoing use employing a rogue Amalgam Vigilance” committee.¹ Working with

¹ The dictionary definition of “vigilance committee” is “a volunteer group of citizens that without authority takes on itself powers.” In contrast to similar-named FDA groups focused on protecting consumers from bad drugs, the Amalgam Vigilance committee focuses on protecting the amalgam device from public exposure of its risks – using techniques like providing false information about amalgam phase-outs in other countries, hiding the fact of the mercury exposure from the American people, and working with the ADA while excluding consumer groups and scientists. (In one memorandum, Dental Devices Director Dr. Runner discusses her ex parte contacts with the American Dental Association and California Dental Association that led to quiet changes in the Consumer Update, while in another NIDCR’s Dr. Braveman, Director Tabak’s top assistant, jokes about how they will exclude consumer group

NIDCR, they engineered the notorious deal with LSRO and BETAH to prevent an independent inquiry into the emerging literature of mercury amalgam, and disseminate false and misleading information that prevents the public from learning that amalgam is 50% mercury and is a major source of mercury exposure. **The time for dentist control of the process is over.**

- The second petition seeks **withdrawal of the draft regulation on mercury amalgam -- for legal, scientific, and public policy reasons**, as well as **major appearances of impropriety**. The draft is hopelessly out of date, is based on ADA rhetoric rather than science; conceals rather than discloses risks; and has numerous other regulatory shortcomings. We took this legal step to protect the rights of children, fetuses, and adults exposed to mercury from amalgam. The draft regulation would maintain unfettered amalgam sales based on the spurious rhetoric of the American Dental Association -- e.g., it claims the “most notable” reason amalgam is safe is the pseudo-scientific rationale that it’s been used for over 100 years, an astonishing position for persons trained in science. It covers up the most salient fact of all: mercury amalgam is a major source of mercury exposure. The draft provides the shield for the ADA agenda of preventing consumers from even learning that amalgam contains mercury, a fact still unknown to 60% of consumers, according to the Zogby poll noted above.

We also requested a third action on an informal basis. After my discussion this week with Senior Advisor Kuntze, we wrote her to request that **FDA revoke and rewrite its false, misleading, and out-of-date Consumer Update of December 2002**. How could something be called a “Consumer Update” when it conceals that that amalgam exposes patients to mercury toxicity? It was inappropriately amended after an ex parte contact by the Director of the Dental Devices Branch with the American and California Dental Associations. Issued in 2002, it is now out of date: scientific developments about mercury toxicity in general (e.g., one young woman in six with so much mercury toxicity she is at risk of having a brain-damaged child – those women must have warnings), and about mercury amalgam in particular (e.g., the Norwegian, Swedish and German governments phasing out the product for health reasons), mandate a major re-writing.

Dental Devices Branch failed before on a Consumer Update. CDRH Director Feigal (since retired) revoked its February 2002 version for containing false information about Health Canada. Having failed the American people and this agency twice, Dental Devices Branch should be barred from participating in the re-writing of the third Consumer Update. It’s time FDA treated dental mercury with the same level of attention that it does for all other mercury products, instead of letting dentists -- those with a conflict of interest and lack of training in how mercury damages the fetus, the child’s brain, and the adult’s kidneys – make these decisions.

To understand why putting dentists in charge is so harmful, one must recognize the vested interest the American Dental Association has in protecting amalgam use – to do so, of course, they must prevent the public from learning the fillings are 50% mercury.

participation until all the “i’s” are dotted and “t’s” crossed on their secretly-negotiated contract with handpicked consultants BETAH and LSRO.

The ADA's history, and much of its present-day activities, is intertwined with amalgam. The ADA was founded as the group that used mercury fillings; their competitors, physicians of the mouth, did not. The ADA acquired patents on amalgam, a step to control the agenda on oral products. The ADA adopted a gag rule to stop dentists from discussing mercury with their patients – and ensured that state dental boards, with majority ADA dentists, would enforce it. The ADA has a notorious Seal of Acceptance program, the type of pay-to-play endorsement scheme condemned as unethical by the American Medical Association.² The ADA is engaged in such deceptive promotional activities – such as trying to convince the public that amalgam is “silver” fillings – that we filed a petition to the Federal Trade Commission.³

We look forward to working with FDA, and would be delighted to have a second meeting. Please contact us at 202.822-6307 if you need further information.

Sincerely,

Charles G. Brown

Attachments: Two petitions

² We point with pride and deep appreciation to the **many courageous dentists in this country** who defy the ADA gag rule, are outspoken against mercury amalgam, and recognize the ADA's pay-to-play Seal of Acceptance program is an anti-scientific, if not outright corrupt, enterprise.

³ Petition reported in FTC:Watch (Nov. 7, 2005).