

As ADA's control over FDA policy collapses,
we urge FDA to keep its promise to classify

Three signs emerged in the past six weeks illustrating that the American Dental Association knows it no longer controls FDA policies on mercury fillings.

** A.D.A.'s long-time general counsel (until last year) recommended in the July 2007 Dental Practice Report that dentists disclose the mercury to avoid getting sued(!). First, they should ask every patient if they are mercury hypersensitive. Second, they should give special warnings about mercury exposure to pregnant women and parents of young children. The fear of lawsuits for implanting mercury has registered with the lawyers on the other side.

** Following a pattern in every industry which faces elimination of a product, the ADA did a study to show the impact of a ban on mercury fillings. So the ADA, folks, is now talking about the B word, Ban.

** You may recall I wrote you in July that A.D.A. advised its members in a secret memo that FDA is likely to issue some restraints, maybe warnings, maybe limitations -- or maybe even a ban.

But FDA is taking its good old time even to launch phase one. It's been two months since its lawyer promised me, in writing, that ADA would take issue a notice of proposed rulemaking to classify mercury fillings. Since we've heard nothing, I wrote Deputy Commissioner Lutter the following letter, telling him about the A.D.A.'s retreat and to request the agency get moving.

Charlie Brown
28 Aug 2007

Note our new address & ph #

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Dr. Randall Lutter, Deputy Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20847 (*via e-mail and regular mail*)

Re: ADA conceding limits or ban coming ... please issue ANPR expeditiously.

Dear Deputy Commissioner Lutter,

A consensus is growing among the former heavyweight advocate for mercury fillings, the American Dental Association, that FDA will put limits on amalgam use for pregnant women, children, and hypersensitive adults – or perhaps even ban them entirely.

Earlier, I wrote you that the A.D.A. so warned its members on July 1. Since then, two more signs have emerged.

- In the July edition of *Dental Practice Report*, the long-time general counsel of the A.D.A., Peter Sfikas (who stepped down eight months ago) advised dentists that FDA would likely contraindicate amalgam to classes of patients, and dentists must begin immediately protect their legal position by (1) asking patients if have mercury hypersensitivity, and (2) giving precise warnings about mercury exposure to pregnant women and parents of young children.
- Last week, the A.D.A. released a report by its handpicked consultant regarding the economic impact of a ban – the step virtually any industry takes when faced with a ban on a favored product or product component. When an industry pays for a study saying a product ban will hurt the public, we all know what they really mean: it will adversely affect the pocketbook of the industry. Mercury fillings are still in vogue because they are so quick and easy to place by assembly-line and old-fashioned dentists, not because of any patient demand.

For years, FDA faced intense political pressure from the A.D.A. to keep mercury fillings on the market without warnings or disclosure. And indeed, the Dental Devices Branch maintained a policy in lockstep with the A.D.A. -- neither classifying nor warning, while hiding the mercury from the American people and refusing to do an Environmental Impact Statement. But all that has changed; it's clear the A.D.A. knows FDA's *status quo ante* is no longer tenable, and is warning its members to begin the transition out of mercury fillings.

It has been two months since FDA attorney Wendy Vicente promised me in writing that FDA would issue an Advanced Notice of Preliminary Rulemaking to classify mercury fillings. We must remind you, Deputy Commissioner, that FDA made the same promise to my co-counsel Bob Reeves, in writing, in 1997. With the ANPR just the first step toward limiting or banning mercury fillings and with this Administration winding down via one official after another leaving, the pro-amalgam forces inside FDA could easily grind the process to a halt. With two months gone and FDA standing silent, we fear they are now doing exactly that.

We will not stand idly by and let the children of America, born and unborn, get poisoned by a primitive 19th-century device no longer needed in modern dentistry – nor used by any modern dentist! We request that you either issue the ANPR by September 15, or provide reasons why you need more time to act.

Sincerely,

Charles G. Brown
National Counsel
August 15, 2007

cc: Participants at May 10, 2007, meeting (Mr. McConagha, Dr. Alderson, Ms. Vicente, Ms. Chernaik, Ms. Kuntze, Ms. Warner, Dr. Fleming, Mr. Turner); Commissioner Eschenbach; Chief Counsel Bradshaw; Robert E. Reeves, co-counsel, Consumers for Dental Choice