

Charles G. Brown, Attorney and Counselor

1725 K St., N.W., Suite 511
Washington, DC 20006
Ph. 202.884-0315; fax 822-6309
E: brownchas@starpower.net

April 9, 2007

Sheldon T. Bradshaw, Chief Counsel, FDA
Eric M. Blumberg, Deputy Chief Counsel for Litigation
Susan L. Williams, Associate Chief Counsel, Food and Drug Division
Food and Drug Administration, U.S. Dept of Health & Human Services
5600 Fishers Lane, Rockville, MD 20857
Mark B. Stern, Attorney Appellate Staff, Civil Division
Catherine Y. Hancock, Attorney, Appellate Staff, Civil Division
U. S. Department of Justice
950 Pennsylvania Ave., N.W. Room 7236, Washington DC 20530

Notice to FDA counsel of record: Retraction by key FDA staff of admissions to Court of Appeals re mercury amalgam could be evidence of fraud on the court.

Dear Chief Counsel Bradshaw, Mr. Blumberg, Ms. Williams, Mr. Stern, and Ms. Hancock:

As named counsel for FDA in the United States Court of Appeals case of *Moms Against Mercury, et al., v. FDA*, you must be aware that FDA acknowledged five times in its brief-in-chief that the issue of mercury amalgam's safety is in scientific equipoise:

- (1) "there is a lack of conclusive evidence regarding the health effects of mercury fillings" (FDA brief, p. 18);
- (2) "constantly changing scientific evidence" exists on mercury amalgam (*Id.*, p. 39);
- (3) "complex issues and intense disagreement [exist] about the scientific evidence regarding mercury and its potential health effects" (*Id.*, pp. 40-41);
- (4) "the complexity of the issue and the lack of conclusive scientific evidence on the health effects of dental amalgams" (*Id.*, p. 41);
- (5) "the lack of ... definitive scientific evidence" (*Id.*, p. 41).

This stands in marked contrast to the promotional claim of organized dentistry since it began marketing mercury-based devices as "silver" fillings in the 1840s – a claim that remains dogma to organized dentistry's advocates within FDA's Dental Devices Branch – that use over time is sufficient proof of safety.

Before this Court case and before two FDA Scientific Advisory Committees rejected outright the FDA staff's "white paper" in 2006 claiming amalgam is "safe," FDA policy on mercury amalgam was dominated by dentists at FDA's Dental Devices Branch within the Center for Devices and Radiological Health. Dr. Mary Susan Runner, Director of the Dental Devices Branch and a practicing dentist, marches in lockstep with her trade group, the American Dental Association, an organization that has commercially promoted mercury fillings since the 19th century, even owning amalgam patents, and who advertises them as "safe" – for men, women, and children of all ages – through its controversial Seal of Acceptance marketing project.

The ADA awarded its seal of safety, despite the fact that it never conducted scientific research on health risks, to manufacturers who paid ADA a hefty entrance fee and agreed to be regulated by ADA policies. Yet the “most notable” reason amalgam is safe is because, according to FDA regulator Runner, it has been used since the 19th century (see 67 Fed. Reg. 7626-27), a wholly unscientific basis for safety.

It is now a matter of public record that Dr. Runner, directed by Director Feigal to do an independent study of the literature on mercury amalgam, instead secretly collaborated with the dental interests at NIH in 2003-04, and disregarded the Federal Acquisition Regulation’s mandate of competitive bidding, of hiring qualified contractors only, and of acting in full transparency. Hence, FDA (and NIH) awarded a no-bid contract to BETAH & Associates, a conference-planning company devoid of any scientific credentials. BETAH was directed to appoint tobacco consultant LSRO as a subcontractor to conduct the “study” – redefined as a “conference” as a fig-leaf effort to make the contract appear legal, as BETAH’s existing contract centered on the mechanics of implementing government conferences. Before being handpicked to do the “study,” LSRO was provided a blueprint of its expected outcome: that mercury amalgam is “safe.” Yet, as the only way to deliver the predetermined conclusion of “safety,” LSRO actually flipped the research question, in direct violation of the specific terms of its contract with the government.

To keep dentists instead of scientists in control, Center Director Dan Schultz, M.D., and Center Deputy Director Linda Kahan, Esq., adopt a professional courtesy posture. They rejected a petition to transfer this control to toxicologists – who are highly qualified to consider the potential health risks from exposure to mercury *via* amalgam on the neurological development of unborn and young children (as opposed to dentists, who clearly lack the requisite qualifications). As evidence that dental economics ranks above children’s health, Kahan defended the decision by claiming the key issue is “placement” of the fillings (a matter resolved since 1865) – not the potential for toxicological damage to vulnerable populations (the question, as she well knows, which is at issue).¹ It is now accepted in all the scientific research that mercury vapor continuously emanates from amalgam fillings (most notably, in the mouths of women of child-bearing age) and, like plaque, circulates throughout the vital organs of the human body.

In its application to sell amalgam products in the U.S. in 2005, a British company readily admitted that country’s ban on amalgam for children and pregnant women. But Division Director Chiu Lin just as readily approved the application for all populations, rubber stamping the ADA policy and using a scientifically unsupportable “substantial

¹ Kahan claimed on October 26, 2006, in a formal denial of the petition, “the Dental Devices Branch has consistently worked interactively with a [CDRH] toxicologist on the dental amalgam issue.” Yet in a FOIA request, both Schultz and Kahan produced no documents whatsoever, indicating a total noninvolvement in, if not outright intent to distance themselves from, the amalgam issue, and Runner produced no substantiation. Since October, Kahan has repeatedly refused to produce documentation of this implausible claim – implausible because the Center asserts that somehow mercury in dental fillings is acceptable while it is unsafe in other uses that involve much less exposure of a brain to mercury. That lawyer Kahan would make this assertion in a formal documentation without foundation or written substantiation raises the question of whether her motive is to deceive the public.

equivalence” test (no limits for amalgam), thus denying American children the protection this company must give to children in Britain.

The culmination of FDA’s pro-amalgam agenda was Associate Commissioner Norris Alderson’s presentation in September 2006 of the FDA staff’s “white paper,” which claimed that though other mercury exposures are not acceptable, dental mercury exposure is. Despite FDA’s aggressive lobbying and its hard-line public relations offensive seeking to pre-empt its own Scientific Advisory Committees, the FDA staff position on the safety of amalgam (based in part on the sham BETAH/LSRO “conference” report initiated from within the Center for Devices) was rejected by a vote of 13 to 7. Not surprisingly, the methodology was likewise rejected, 13 to 7 (www.fda.gov/cdrh/meetings/090606-summary.html).

But instead of acknowledging that a growing awareness within the scientific community of the health risks related to mercury amalgam has made the claim of safety indefensible, the Center on Devices proceeded to cover up this outright rejection, spinning yet another PR effort in support of amalgam on October 31, falsely claiming there had been no rejection of FDA’s position, and distorting the facts underlying the votes (www.fda.gov/cdrh/consumer/amalgams.html).

With their track record, we have every reason to suspect that organized dentistry’s advocates within the Center are attempting to return FDA to the position it held in the past – before FDA’s February 2007 brief containing those multiple statements confirming scientific uncertainty about whether amalgam is safe or unsafe. Any attempt to promote such a return, through word or action, would raise fundamental questions about whether FDA made the representations to the Court of Appeals about scientific equipoise better to position itself for a judicial victory instead of speaking to the Court in good faith.

It is thus incumbent on counsel to inform in writing each of the above-named persons – Alderson, Kahan, Lin, Runner, Schultz – of the position FDA took before the Court of Appeals – and that departure from this policy may put FDA or him/her in legal jeopardy. Due to the reality that mercury can permanently injure the developing brain of a child or fetus, this issue is so fundamentally serious – for women of childbearing age, the developing fetus in the mother’s womb, and young children — that Alderson, Kahan, Lin, Runner, and Schultz should be told that any behind-the-scenes activities to reassert the agency’s prior position on the safety of amalgam could be a dismissible offense.

Should there be any effort on the part of these persons, or others at FDA, to attempt to return the agency to the *status quo ante*, you have a duty to so inform the court and to cc me as counsel for petitioners. Meanwhile, we intend to monitor closely FDA communications to the public, to the scientific community, and to Capitol Hill. If any of FDA’s pronouncements are at odds with the statements made to the Court of Appeals, and if counsel does not immediately inform the Court and justify these conflicts, we will consider it evidence of commission by FDA, or by FDA counsel, of a fraud on the Court.

Sincerely,

Charles G. Brown