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Associate Commissioner Randy Lutter, Ph.D., Policy
Acting Associate Commissioner Jason Brodsky, External Affairs
U. S. Food and Drug Administration -- *via e-mail to all and fax to Dr. Lutter*

Re Questions on mercury fillings to FDA Nominee from Chairman Enzi and Senator Kennedy: Panels' repudiation of staff pro-mercury position necessitates re-evaluation of FDA position

Dear Associate Commissioner Lutter and Acting Associate Commissioner Brodsky:

On September 7, two FDA panels representing distinguished scientists, physicians, and dentists decisively repudiated the staff's irrational defense of mercury fillings -- voting 13-7 that the staff's conclusion that amalgam is safe is "not reasonable." The staff "white paper" was incomplete, inaccurate, and intellectually dishonest. When the Panel pressed on why the researcher used such slipshod methodology, the staffer replied said he was just following orders. Perhaps you should find out whose orders.

The safety status of mercury fillings has now descended into a netherworld where **FDA itself is in disagreement on whether they are safe -- and for whom they are unsafe**. Panelists expressed grave concern about the safety of mercury fillings for (1) **unborn children**, (2) **children**, and (3) **hypersensitive patients**.

The action ranks as the final straw for the Center on Devices' inexplicable effort to **carve a privileged role for mercury fillings**. While the rest of FDA condemns mercury in any product, while other federal health agencies (CDC, PHS) rate amalgam as a major mercury exposure, while other modern health systems condemn mercury fillings for pregnant women and young children, the Center puts dentist economics ahead of the well-being of unborn children. Small wonder that the title of a House Subcommittee report terms the Center on Devices and Radiological Health "FDA's Neglected Child"!

For two decades, the Center has opted for mouthing out-of-date pro-amalgam rhetoric while refusing to undertake three mandated duties: (1) **refusing to classify** (despite classifying all other dental filling material two decades ago and promising to classify encapsulated amalgam four times since); (2) **no Pre-Market Approval** (hence, **no proof of safety**); and (3) **no Environmental Impact Statement**. The three are interconnected: the environmental impact statement must precede classification, as must a panel recommendation (the 13-year-old recommendation is legally deficient); an honest classification must be Class III, for which the required P.M.A. is (according to a major manufacturer's statement to shareholders) an insurmountable burden. The inaction of the staff, then, is calculated – **taking any one of these legally mandated steps results in the demise of amalgam, so the staff does none of them**.

Chairman Enzi and Ranking Member Kennedy each ask Dr. Von Eschenbach a series of incisive and thought-provoking questions about the regulation / non-regulation of amalgam. Now that a neutral panel has so decisively rejected the staff position – and note that Senator Enzi asked if the nominee will adhere to the panel's recommendations – it is essential that Dr. Von Eschenbach not take the worn-out approach used by last year's nominee, Dr. Crawford, and re-hash the Center's unscientific dogma. No longer can FDA pretend that this mercury exposure (two inches from a child's brain, with constant emission of toxic vapor) is somehow different from other mercury exposures, or that this mercury exposure causes but "allergies" while others or not, or that this mercury exposure can be concealed from the patient while others are disclosed.

With the opportunity to state its amalgam policy before confirmation, it is essential that the Commissioner nominee re-evaluate FDA's untrammeled support for mercury fillings for anyone and everyone, and reevaluate staff's opposition to mandating informed consent. (So intent is the staff in concealing mercury that in 2002 FDA actually proposed that **the zinc (non-toxic) be disclosed while the mercury (toxic) be hidden**; though that proposal is dead as a matter of law, the staff actually cited it favorably.)

- Both Senators ask **how and why FDA skirts the Pre-Market Approval system**. [We hope your solution is simply to require the P.M.A.]

- Senator Enzi, noting that most Americans don't know that amalgam is mainly mercury, and noting further that the term "silver fillings" has not been stopped by FDA, inquires what FDA is doing to educate the public about the mercury. [Up to now, I think you'll agree, the answer is nothing at all.]

- Senator Kennedy asks whether FDA will do an Environmental Impact Statement on amalgam. He cites the particular statutes and regulations that mandate an E.I.S. [We hope the answer is yes, FDA will now follow the law and do an E.I.S.]

- Both Senators inquire if FDA plans to follow what Canada has done for ten years – warn against amalgam use for pregnant women and children. Senator Enzi boldly adds, "If not, why not?"

- Senator Kennedy notes that amalgam appears to have no benefits, since other materials are available. Certainly the testimony at the hearing showed that to be so. Yet it has risks – mercury exposure. He asks the logical question: **why would FDA continue to allow on the market a product with allegedly no benefits yet certainly with risks**.

Sincerely,
Charles G. Brown
National Counsel
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