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July 28, 2006

Associate Commissioner Randy Lutter, Ph.D.
Acting Associate Commissioner Jason Brodsky, External Affairs
Food Drug Administration -- *via e-mail*

Re: **Von Eschenbach heads for confirmation hearings while Center on Devices sabotages FDA policies by protecting mercury amalgam**

Dear Associate Commissioner Lutter and Acting Associate Commissioner Brodsky:

As Dr. Andrew Von Eschenbach prepares for confirmation hearings on August 1, the Center on Devices and Radiological Health continues to sabotage positive FDA policies by signing secret contracts with witnesses, ignoring conflict of interest rules on panels, and, worst of all, adopting a pro-mercury policy on dental fillings while the agency condemns mercury in other products.

The most controversial issue in dentistry today is whether mercury fillings should continue to be used. **Mercury is no longer needed in oral health care**; all modern dentists use alternative materials to fill any kind of cavity. But **old-fashioned and factory-line dentists still place them in children and low-income Americans**, because it is so easy – and profitable. Incredibly, FDA's Center on Devices has handed the issue, *carte blanche*, to its in-house dentists – persons (1) absolutely unqualified to determine the impact of poisonous mercury on the fetus, the child's brain, and the adult's kidneys, and (2) with a brazen conflict of interest. Both points were raised in a letter three years ago by Senator Lautenberg; his concerns were ignored. These FDA dentists defend amalgam on the pseudo-science that it is safe because it's been used for a long time (like cigarettes?); they handpick biased allies to do "literature reviews" to ratify their position.

We emphasize our belief that you two Assistant Commissioners have tried to turn the Center on Devices to a new direction regarding mercury amalgam. But the recalcitrant Center on Devices remains – as it has been called in the title of a House committee report and in a Supreme Court opinion – "FDA's Neglected Child."

A 2006 Zogby poll shows 76% of American voters cannot identify the main component of amalgam. FDA – in league with pro-mercury dentists – refuses to correct the deceptive promotion of this device as "silver fillings." FDA condemns mercury in virtually all other products – even banning mercury in all veterinary products. By blocking mercury products in animals but allowing it in children's mouths and in pregnant women, **the Senate could well ask the Commissioner whether FDA puts a higher priority on protecting horses than protecting children and unborn babies**.

The Center on Devices is violating several federal statutes:

- It refuses to classify encapsulated mercury amalgam, thus violating the Food, Drug and Cosmetic Act;

- To allow sales without classifying, the Center adopts a subterfuge system of deeming amalgam "substantially equivalent" to a non-mercury powder -- thus **allowing sales of a device that is 50% mercury that no manufacturer has ever proved to be safe**.

- Ordered to do an independent review of the amalgam literature but determined not to allow the science to emerge, the Center violated the Federal Acquisition Regulation (FAR) statute by handpicking an unqualified meetings planner as strawperson contractor, then directing that a consultant for Big Tobacco actually write the report – for which the Center provided a blueprint in advance!

- The Center violates the National Environmental Policy Act by repeatedly refusing to do an Environmental Impact Statement on amalgam – **America's 3rd largest source of mercury**.

Here is the latest: **the Center is blocking a fair and balanced inquiry by the joint committee assigned to investigate amalgam's neurotoxicity**. On April 3, you ordered that a joint committee, on September 6 and 7, 2006, "review and discuss peer-reviewed scientific literature on dental amalgam and potential mercury toxicity, specifically as it relates to neurotoxic effects." Those putting together the event – Chu Lin, Director of the Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices; Mary Susan Runner, Director of the Dental Devices Branch; and Michael Adjodha, Executive Secretary, Dental Products Panel – are creating a one-sided presentation to promote their in-house position and to marginalize the independent scientists, the mercury-free dentists, and the consumers injured by mercury toxicity:

- They signed secret contracts with guest panelists whom they refuse to identify. Mr. Adjodha justifies this closed door because it is "FDA policy"; when questioned, he says the policy is not in writing and he refuses to say how he learned it. An <u>oral</u> policy? One that says FDA may sign secret contracts with unnamed persons to testify at a public meeting? **Here is another example why you must stop the Center on Devices from controlling amalgam regulation**.
- The program is intentionally one-sided – Lin, Runner, and Adjodha refuse to contract with any independent scientist who has researched mercury's toxicity. By using government funds to bring forward only the Center's position, they are biasing the panel by suggesting only their position is credible.
- All three key decision-makers – Dan Schultz, Director of the Center, Director Lin, and Director Runner – refuse to testify. Instead, they are delegating low-level staff (unidentified, of course) to give "background." It's time for accountability: those who uphold this policy disaster – Schultz, Lin, and Runner – must come before the panel and justify their actions.
- One invited speaker with government funds, Timothy DeRouen, calls into question FDA's new policy on conflicts of interest with panels. DeRouen headed the highly controversial <u>mercury experiment on Portuguese orphans</u>, now under investigation by the Office of Human Research Protection for implanting mercury without disclosures and fuzzy clearance procedures for orphans. Long before writing the report, DeRouen was an outspoken proponent of mercury amalgam; he testified at a public hearing in Seattle in 2002 that amalgam is safe. Such manifest evidence of bias should have been cause to yank his contract.

Mercury amalgam policy at the Center on Devices could well be called “FDA’s Neglected Child’s Neglected Child.”

Sincerely,

Charles G. Brown

cc--at FDA: Daniel Schultz, Chu Lin, Michael Adjodha, Les Weinstein, Patricia Kuntze

cc--Senator Mike Enzi, Chairman; Senator Ted Kennedy, Ranking Member; and Senator Members, H.E.L.P. Committee