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Group Seeks to Force FDA Move on Dental Mercury

by Jim Dickinson, Editor

Alleging seven CDRH stalls on regulating dental mercury since 1997, Consumers for Dental Choice 3/17 offered to settle litigation it has filed against the agency if FDA will issue an advanced notice on proposed rulemaking (ANPR) within 40 days. Filed 12/28/07 for Moms Against Mercury, the lawsuit alleges consistent CDRH efforts to conceal the presence of neuro-toxic mercury in dental amalgams.

In his 3/17 offer to Department of Justice attorney Drake Cutini, Consumers for Dental Choice attorney Charles G. Brown says that when an ANPR to classify encapsulated mercury amalgam is issued, “We would consent to move the case to the inactive calendar.” Otherwise, FDA’s response to the lawsuit is due 4/14.

“Six months ago,” Brown’s letter to Cutini says, “defendant Mary Susan Runner [CDRH Dental Devices Branch chief, a dentist] told members of the science advisory committee of the International Academy of Oral Medicine that the ANPR was written, and that she was surprised it had not issued. If the ANPR is available, why is FDA holding it up? This sequence mirrors a well-worn tactic on mercury fillings — promising, then stalling, promising, then stalling — that FDA’s Center for Devices has repeatedly employed: Promise to classify, then fail to do so.

“From 1997 to the present, this pattern has repeated itself seven times. FDA has made the same promise to Senators at confirmation time, Representatives at oversight hearings, petitioners seeking classification — even (in a February 2007 brief) to the United States Court of Appeals.”

It’s happening again, Brown complains — “That’s why our offer is to put the case on inactive status. If we dismissed it outright, we believe FDA’s mercury fillings defenders have the power, particularly during a change in Administration, to block action again.

“At FDA’s other Centers, mercury is banned, limited in use, or warned against. The Center for Devices stands alone in keeping mercury secret from consumers. The most likely explanation is this: the old-school dentists and assembly-line dentists still using mercury fillings (barely half of U.S. dentists) don’t want consumers to know that their ‘silver fillings’ are about 50 percent mercury. Inside FDA, the regulatory decision is handed over to dentists with long-standing professional ties to pro-amalgam entities. The conflict of interest is patent. The people controlling the process are the very people who understand that the disclosure of the mercury in amalgam, and the application of FDA general standards to mercury-based products, will doom mercury fillings.”

Brown’s letter says that FDA’s “real scientists,” in this case toxicologists, have been

shut out of the decision and that Runner “remains a leader in blocking disclosure to consumers about the main element in amalgam implants — mercury.”