

We sue FDA top brass for defying federal law

We have filed a federal lawsuit against FDA here in Washington, seeking a court order to force FDA to move forward and asking that mercury fillings be taken off the market until FDA deigns to act.

The specialized press has begun writing about the case; see, from *FDA Website and FDA Review*, www.toxicteeth.org/Mercury%20Lawsuit%20Likens%20Von%20E%20to%20British%20Queen.pdf -- which highlights our argument that the Commissioner of FDA reigns over, but does not actually run, his agency.

Here's the background on why we had to sue: Last May, we notified FDA lawyers that, due to the agency's decades of (illegal) intransigence in classifying mercury amalgam, we were preparing a complaint in the US District Court, pursuant to the guideposts from the US Court of Appeals ruling in April. FDA asked us for a meeting instead. At that meeting with top FDA officials, Dr. Mike Fleming, lawyer Jim Turner, and I were told that FDA realized it needed to move forward; we said we would wait 30 days.

At the end of that 30 days (in June 2007), the FDA Commissioner's office phoned and said with enthusiasm, "You will like our plan," promising details the next day. The next day, FDA counsel phoned me and said FDA intended to begin the classifying process, by issuing an Advanced Notice of Proposed Rulemaking (ANPR). I asked the lawyer to put that promise in writing, which she did. I then immediately contacted two reporters (from *FDA Week* and the *Bureau of Nat. Affairs Medical Devices Reporter*), both of whom called FDA's press office, which confirmed the agency would issue such an Advanced Notice of Proposed Rulemaking, by the end of the calendar year at the latest.

Month after month, we waited. No ANPR issued. In November, FDA witness Norris Alderson, FDA's lead scientist (his degree is in veterinary medicine), appeared before Congress and stonewalled, repeatedly misleading Congress and refusing even to commit to doing an Environmental Assessment (legally required). Over the past 15 years, FDA repeatedly promises (to courts, to Congress, to petitioners) to classify mercury fillings -- then doesn't. Fool me once, shame on you; fool me repeatedly, shame on me. So I guess the shame is on me for, in my naiveté, actually believing FDA when the agency lawyers make a written promise.

FDA lied to us and to the American people -- again. Accordingly, on the last workday of the calendar year (Fri. Dec. 28, 2007), my co-counsel Bob Reeves and I, with substantial assistance from lawyer Johann Wehrle, sued. The lawsuit is at www.toxicteeth.org/Complaint_Dec282007.pdf

The malfeasance at FDA -- this sequence of illegal actions to shield dentists' pocketbooks instead of showing any concern with children's health, unborn children's lives, or the environment -- extends deep into the agency. Accordingly, we sued six individuals at FDA (not just the Commissioner), going several layers deep into the agency. We are going to stop these autocratic bureaucrats from hiding behind each other.

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