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Mercury Lawsuit Likens Von E to 'British Queen'

By Jim Dickinson, Editor, *FDA Webview & FDA Review* (www.fdaweb.com)

Attacking FDA's refusal for 31 years to act against neuro-toxic mercury in dental amalgams, a DC federal court suit by Moms Against Mercury, three other activist groups and seven individuals, likens commissioner **Andrew von Eschenbach** to "the British Queen ... chooses to reign but not rule, allowing his bureaucracy to set policy while he and deputy commissioner Lutter ignore repeated warnings of lawlessness beneath." Directed against CDRH, it's a complaint that many have informally made against this and previous agency leaders in such cases [Utah Medical Products](#), [TMJ Implants](#), [Myo-Tronics](#) and others, raising yet again the question of how effective any commissioner can be in righting wrongs at FDA — British queens are just as impotent. Indeed, one of the officials in the TMJ case, CDRH Dental Devices Branch chief **Susan Runner**, a dentist, is a named defendant in the new case.

Filed by Consumers for Dental Choice national counsel **Charles G. Brown**, the [21-page complaint](#) also names as defendants von Eschenbach, deputy commissioner for policy, planning and preparedness **Randall Lutter**, associate commissioner for science and health coordination **Norris Alderson**, CDRH director **Daniel Schultz**, CDRH director of anesthesiology, general hospital, infection control and dental devices **Chiu Lin**, and HHS secretary **Michael Leavitt**.

Contending that dental amalgam regulatory decisions are controlled by dentists who are untrained to assess mercury's neurotoxic and other effects in the body and who as a profession are historically beholden to commercial producers of mercury amalgams, Brown's complaint says amalgams are 50% mercury, a fact that is concealed from patients with FDA's complicit assent. Although there are non-mercury alternatives, the American Dental Association, he told *FDA Webview* 1/11, has been controlled from its inception by mercury-favoring dentists, who now have fallen to about half of the ADA membership but still remain firmly in charge — "The mercury-free crowd are 'political idiots' at the ADA, they have three factions, and they're dissidents, but they won't unite." Dentistry has its origins in barbering and blacksmithing, and since 1859 has shunned professional alliance with medicine in order to "march in lock step" with mercury and amalgam producers, Brown says.

Misnamed "silver fillings," his lawsuit says, amalgam arrives at a dentist's office with a skull-and-crossbones symbol beside the words "POISON, CONTAINS METALLIC MERCURY." The warning calls mercury a "potentially hazardous substance" with "neurotoxic/nephrotoxic effects" and is known the "state of California to cause birth defects or other reproductive harm." The complaint says amalgam makers have "advised dentists in writing not to place amalgam in pregnant women, nursing mothers, children under six, and anyone with kidney disease."

"Time and again," it charges, "a rogue bureaucracy inside FDA sabotages pronouncements from the Commissioner's Office that FDA will act on amalgam. FDA leaders repeatedly promise to classify — to litigants (1997), to Congressman Burton

(2002), to Senator Kennedy (2005), to the Court of Appeals (February 2007). In June 2007, facing a lawsuit by these plaintiffs, FDA promised to announce an Advanced Notice of Proposed Rulemaking. The promise was a sham to buy more time to keep mercury fillings on the market.”

Von Eschenbach, the complaint says, “promised Senator Enzi in August 2006, during his confirmation hearings, that the scientific advisory panels convening in September ‘will be asked to answer specific questions concerning any possible adverse health effects of dental amalgam.’ Such questions never took place; defendant Alderson sabotaged the order, turning the hearings instead into a referendum on a mysterious staff ‘white paper’ (a vote Alderson lost). No record exists of von Eschenbach taking corrective action when he broken that confirmation promise to Senator Enzi ... [he] remains indifferent on whether FDA complies with its legal duty to classify mercury amalgam.”

Brown’s complaint alleges that “Acting under a collectivist theory of unaccountability, where if everyone does it no one may be held to task, defendants Alderson, Lin, Runner and Schultz have abused their high-ranking positions by willfully and wantonly defying their statutory duty to regulate mercury amalgam.”

Runner, the suit says, “sabotaged a 2002 order from former Center director **David Feigal** to contract for an ‘independent literature review’ of mercury amalgam’s toxicity issues. Instead, working with dentists in other agencies, she handpicked an unqualified meetings planning company [Betah Associates] in order to avoid competitive bidding, directed that company to appoint a Beltway tobacco consultant [LSRO Inc.] to do the study with whom she or her coconspirators had conducted secret meetings to obtain an agreed-upon result.”

LSRO, Brown told *FDA Webview*, “flipped” its charge from FDA, which was to find any evidence in the scientific literature indicating that dental amalgam poses a health risk of humans, to one of determining if the literature “supported hypotheses relating to adverse health effects.” This, he said, changed the question from “one that would certainly have to be answered yes, to one that could be answered no.”

His lawsuit charges that, “Fully aware that mercury can permanently harm the fetus or the developing brain of a child, Runner nevertheless led the effort in 2002 to conceal forever from dental patients (even pregnant women and parents of young children) the presence of mercury, via a subterfuge of naming zinc as the controversial product. This outrageous conspiracy to use zinc to cover up the mercury has been joined by defendants Alderson and Schultz.”