

Below: Consumers' letter re perjurious testimony by FDA Assoc. Commissioner Norris Alderson. If you agree with our concerns, write Alderson's boss, Deputy Commissioner Randall Lutter and Lutter's assistant William McGonagha (randall.lutter@fda.hhs.gov, william.mcconagha@fda.hhs.gov) to inquire why FDA continues to give false and misleading information to Congress and the American people about mercury amalgam.

Consumers for Dental Choice

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Re: FDA lawyers should give immediate legal counsel to FDA Associate Commissioner regarding consequence of perjurious testimony to Congress

Wendy Vicente, Esq., and Beverly Chernaik, Esq.
Office of the General Counsel
US Food and Drug Administration
via e-mail only-- beverly.chernaik@fda.hhs.gov; wendy.vicente@fda.hhs.gov

Dear Attorney Vicente and Attorney Chernaik:

In defending FDA's illegal refusal to classify encapsulated mercury amalgam and FDA's illegal refusal to do an Environmental Assessment on dental mercury, Associate Commissioner Norris Alderson repeatedly made false claims to the House Government Reform's Domestic Policy Subcommittee, on November 14, 2007.

At this point, we believe counsel for FDA has a duty to advise Dr. Alderson of draconian consequences that could inure if he fails to withdraw and correct his testimony before the record closes -- which under Chairman Kucinich's ruling occurs in five legislative days from November 14.

At least three times, Dr. Alderson, who testified under oath, made claims that are false and that he knows or should know to be false. Two were in his written testimony, the third in answer to a question from Congressman Burton:

- Regarding a joint meeting of the Dental Products Panel and the Peripheral and Central Nervous System Drugs Advisory Committee in 2006, Alderson first deceived the House Subcommittee in his written testimony by claiming the joint committee "asked FDA to expand its literature review to include additional data bases and searches for information on special protections." In fact, the joint committee's two votes, and only two votes, were a rejection of an Alderson-engineered "white paper" claiming that mercury fillings. The joint committee voted 13 to 7 to reject the methodology used by Alderson et al., then voted 13 to 7 to reject the result. That claim is plainly deceptive, but not so plainly false as to be one of the three false claims.
- After misleading the Subcommittee about the FDA panel's vote, Alderson made two false claims in his written testimony:

“[1] The 2006 joint committee generally agreed, however, that there is no evidence that dental amalgam cause health problems in the vast majority of the population. [2] The 2006 joint committee also agreed that the most recent well-controlled clinical studies showed no evidence of neurological harm from the dental amalgam.”

In fact, those were the claims in Alderson’s “white paper” that the joint committee overwhelmingly rejected. The joint committee took just two votes (described above); both were negative to Alderson’s position. www.fda.gov/cdrh/meetings/090606-summary.html. The committee never voted in favor of the two “generally agreed” Alderson assertions, nor did they issue a consensual statement or take other action indicating unanimity on any issue. In short, there were no “general agreements” -- a fact Alderson well knows.

Alderson knows the truth, because ... he presided at the entire two-day hearing. After his position was resoundingly repudiated by the joint committee, he stood before them, humbly, and conceded that the staff position was rejected, announced that he had heard the joint committee’s position, and the staff would respond. (We are still waiting, fourteen months later.) If Alderson is relying on an apologia for mercury written by the Center for Devices months later, trying to protect the latter’s do-nothing position on mercury fillings, his confidence is misplaced. Alderson knows what the joint panel did, and cannot throw in secondary sources who mischaracterize it. Alderson lost the vote, and he now tells the Subcommittee he won the vote.

- In response to a question by Congressman Burton that FDA recalled a horse lotion [Miracle Leg Paint II] because of its mercury content, Dr. Alderson categorically denied that the mercury in the lotion was the reason for the recall. His denial is false; a point made clear in FDA’s own description of the recall; “Nationwide Recall of Miracle Leg Paint” FDA Veterinarian Newsletter, July/Aug. 2002, Volume XVII, No. IV, http://www.fda.gov/cvm/July_August.htm#2241 (fifth item). FDA’s sole stated reason for the recall was the mercury in the blistering agent:

“the use of mercury blistering agents to treat lameness in horses is outdated, unsafe for animals and humans, and outside the scope of modern veterinary medicine.”

The company who did the recall fully understood that the reason their product was being recalled is the mercury; see its announcement, “Nationwide Recall of Miracle Leg Paint Veterinary Drug Because of Potential Health Risk to Animals and Humans,” www.fda.gov/oc/po/firmrecalls/equine05_02.html

That Alderson knew about the recall, and knew the reason, is beyond doubt. Alderson’s academic degree is in the field of veterinary science, and he worked for the Center for Veterinary Medicine, the center which made the recall.

As with other false claims to Congress, issues of knowledge and intent loom large. We have explained that Alderson knows the truth. But what motive would he have to deceive Congress?

The answer may well lie on a decision to protect his career, his high position at FDA, and his reputation. He has come from a Center where mercury is banned for horses and dogs, to a high-ranking position where he is called on to defend a 19th-century device is still implanted in America's children. The maintenance of this primitive mercury device is upheld at the instance of a powerful special interest group, and FDA is notorious for being unable to withstand the heat from the rich and powerful economic forces in society.

Being trained in veterinary science, Dr. Alderson well knows the harm to animals of mercury exposure, and he prudently was part of a Center that banned mercury from any medicinal use for animals. But now he chooses, or is forced, to defend agency inaction (and agency silence) about extending that same benefit of stopping mercury exposure to children of an implant just inches from their brain -- even though alternatives to mercury fillings are available for any kind of cavity. Likewise, Alderson chooses, or is forced, to defend agency inaction (and agency silence) about extending that same benefit of stopping mercury exposure to unborn children when mercury, a highly vaporous material, is implanted in pregnant women and which toxic vapors go to the fetus -- again, even though alternatives to mercury fillings are available for any kind of cavity.

Wearing his veterinary hat, Alderson helped develop or maintain a policy of "no approved veterinary drug products that contain mercury as an active ingredient"; see newsletter cited above. Now promoted, he must defend the opposite policy for American children and unborn children. Unable to extricate himself from an absurd, and in fact immoral policy -- protecting horses and dogs but turning his back on America's children -- he chose the wrong route, the unacceptable route, the route of making false claims to Congressman Burton about a recalled product, and to entire Subcommittee about the votes of an FDA Scientific Advisory Committee.

Sincerely,

Charles G. Brown
National Counsel
16 November 2007

cc, at FDA: Associate Commissioner Alderson; Deputy Commissioner Lutter; William McConagha, Assistant to Dr. Lutter; Dan Schultz, Director, Center for Devices; Patricia Kuntze, Consumers Affairs Advisor

cc, on Capitol Hill: Jaron Bourke, for the Subcommittee; Brian Fauls, for Congressman Burton; Richard Butcher and Valerie Van Buren, for Congresswoman Watson