

## We Win -- FDA Must Classify Mercury Fillings

We have won our ten-year battle to get the Food and Drug Administration to comply with the law and set a date to classify mercury amalgam.

On Monday, we settled our lawsuit, *Moms Against Mercury et al. v. Von Eschenbach, Commissioner, et al.* FDA will finish classifying within one year of the close of the public comment period on its amalgam policy, that is, by July 28, 2009.

There's more good news. During a several hour negotiation session, FDA agreed to change its website on amalgam -- dramatically. Gone, gone, gone are all of FDA's claims that no science exists that amalgam is unsafe, or that other countries have acted for environmental reasons only, or that the 2006 Scientific Panel vote affirmed amalgam's safety. Instead -- see <http://www.fda.gov/cdrh/consumer/amalgams.html> -- FDA has moved to a neutral course, while recognizing the serious health concerns posed by amalgam in particular for children and unborn children, for pregnant women, for those with mercury immuno-sensitivity or high mercury body burdens. FDA now states, for example:

“Dental amalgams contain mercury, which may have neurotoxic effects on the nervous systems of developing children and fetus.”

“Pregnant women and persons who may have a health condition that makes them more sensitive to mercury exposure, including individuals with existing high levels of mercury bioburden, should not avoid seeking dental care, but should discuss options with their health practitioner.”

Perfect? No. A 180-degree reversal from FDA's 30-year policy of protecting mercury fillings? Absolutely.

To change FDA policy, we tried petitions, Congressional hearings, state fact sheet laws, Scientific Advisory Committee hearings, and letters galore -- to no avail. So in the great American tradition, we sued. The case came to a head this spring. On April 22, working with Johann Wehrle and Gwen Smith, I filed a motion for an injunction before Judge Ellen Huvelle. Three sets of briefs later, the government and I presented our oral arguments on May 16. In a crucial ruling, Judge Huvelle ruled that our 11 plaintiffs -- the diverse group listed below -- have standing. She said FDA should classify, and invited the two sides to mediate. On May 30, before Magistrate Judge John Facciola, we hammered out an agreement with FDA officials and lawyers.

The impact of the re-writing of its position on amalgam can hardly be understated. FDA's website will no longer be cited by the American Dental Association in public hearings. FDA shows awareness of the key issues involved. As it prepares to classify amalgam, FDA has moved to a position of neutrality. Indeed, having repeatedly raised the question of amalgam's risk to children, young women, and the immuno-sensitive persons in its website, I find it inconceivable that FDA will not in some way protect them in its upcoming rule.

Charlie Brown  
3 June 2008

PS 1: Our talented (and *pro bono publico*) legal team includes Johann Wehrle, Sandra Keech, Mike McClory, and Gwen Smith; Larry Pilot served as legal advisor on the FDCA.

PS 2: Great appreciation to our gutsy plaintiffs, a team of nonprofit groups, public officials, dental professionals, and consumer victims: Moms Against Mercury (Amy Carson and Angela Medlin), Connecticut Coalition for Environmental Justice (Dr. Mark Mitchell), Oregonians for Life (Mary Starrett), mercury expert Michael Bender (in his capacity as Commissioner of a Vermont advisory board on mercury), Arizona Senator Karen Johnson, Dr. Andy Landerman, consumer advocates Linda Brocato and Anita Vazquez Tibau, and (of course) Consumers for Dental Choice.

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