



MERCURY POLICY PROJECT

1420 North St.

Montpelier, VT 05602

www.mercurypolicy.org * 802.223.9000

April 11, 2011

Mr. John E. Thompson
Bureau of Oceans and International
Environmental and Scientific Affairs (OES)
U.S. Department of State
2201 C St. N.W.
Washington, D.C. 20520

Dear Mr. Thompson,

The Mercury Policy Project has reviewed the recent submission by the United States of America to the Mercury Intergovernmental Negotiating Committee (INC) and also letters from the American Dental Association (ADA) related to mercury amalgam. For the reasons presented below, we urge the U.S. Government (USG) to not succumb to ADA's recommendations to have the Food & Drug Administration assume a leading role on mercury amalgam on behalf of the U.S. Government in the INC process.

In its April 7 letter, the ADA requested that control over mercury amalgam policy for the treaty be shifted from EPA to FDA.¹ Yet FDA is charged with regulatory measures related only to health; this treaty is more about mercury's environmental impact and the resulting impacts on human health, primarily through fish consumption. FDA admits in its rulemaking that it lacks environmental expertise. The FDA does not appreciate, nor have the expertise, to address the global threat of mercury amalgam releases.

1. FDA has no jurisdiction over environmental matters: FDA states that environmental problems caused by amalgam are not within its jurisdiction; they are EPA's jurisdiction: "FDA does not regulate the disposal of dental amalgam. The disposal of dental amalgam is regulated by the Environmental Protection Agency and state and local authorities."² When the Joint Advisory Panel of 2006 asked FDA to evaluate the environmental impact of amalgam, FDA responded that the recommendation was beyond its scope.³

2. FDA lacks environmental science expertise: FDA does not have a good understanding of the environmental health risks related to mercury amalgam releases, as demonstrated by its statement:

"Is the mercury in dental amalgam the same as the mercury in some types of fish? No... The form of mercury associated with dental amalgam is elemental mercury. The form of mercury found in fish is methylmercury, a type of organic mercury. Mercury vapor is mainly absorbed by the lungs. Methylmercury is mainly absorbed through the digestive tract. The body processes these forms of mercury differently and has different levels of tolerance for mercury vapor and methylmercury. Methylmercury is more toxic than mercury vapor."⁴

¹ http://ada.org/sections/newsAndEvents/pdfs/110408_itr_thompson_oes.pdf

² <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/ucm171115.htm>

³ <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM173908.pdf> (p.9)

⁴ <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/ucm171094.htm>

Yet this statement is inconsistent with EPA's conclusion that once amalgam is in the environment, "certain microorganisms can change elemental mercury into methylmercury, a highly toxic form that builds up in fish, shellfish and animals that eat fish... Methylmercury can damage children's developing brains and nervous systems even before they are born."⁵

3. FDA's stance is inconsistent with the current U.S. position: Contrary to the most recent U.S. submission to the Mercury Intergovernmental Negotiating Committee,⁶ FDA openly advocated in its dental amalgam rule for an increase in the use of mercury without any consideration of the public health threat of dental mercury pollution: "any change toward use of dental amalgam is likely to result in positive public health outcomes."⁷ Despite urging an increase in amalgam usage, FDA nonetheless refused to even prepare an environmental impact statement, demonstrating that the agency does not appreciate the environmental health impact of mercury products.⁸

As you know, EPA has recently decided to regulate mercury amalgam releases into the environment through a proposed effluent guideline. It has the jurisdiction to regulate dental offices release of mercury amalgam in order to significantly reduce the largest source of mercury going into municipal waste water plants today. Clearly, EPA, not FDA, has the expertise to guide the USG on global mercury releases.

We are aware that ADA and other groups have also written other letters to the Department of State. This has included two letters in February, one of which expressed "concern about potential adverse actions that might be taken by the Intergovernmental Negotiating Committee (INC) of the United Nations Environmental Program (UNEP) with respect to the continued availability of dental amalgam." The group also appealed for the U.S. Government to "assume a leadership position" on dental amalgam.⁹

We strongly support current USG leadership on global mercury issues in general, and those specifically related to mercury amalgam in its most submission to the INC. We applaud its expressed support for a mercury amalgam "...phase down, with the goal of eventual phase out."¹⁰ This position is consistent with the discussions of an expert group meeting of the World Health Organization in the fall of 2009 on the "Future of Dental Restorative Materials," as reflected in a presentation to INC1.¹¹ In addition, it is also reflective of the approach that is already occurring in many nations around the globe.¹²

Sincerely,



Michael T. Bender
Director

⁵ http://www.epa.gov/aging/press/epanews/2010/2010_0927_2.htm

⁶ <http://www.unep.org/hazardoussubstances/Portals/9/Mercury/Documents/INC3/United%20States.pdf>

⁷ <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.86)

⁸ <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf> (p.73-79)

⁹ <http://www.ada.org/news/5491.aspx>

¹⁰ <http://www.unep.org/hazardoussubstances/Portals/9/Mercury/Documents/INC3/United%20States.pdf>

¹¹ http://mercurypolicy.org/wp-content/uploads/2010/06/who_draft_presentation_final1.pdf

¹² In Sweden, where amalgam has been subject to voluntary phase downs, the consumption of mercury has decreased significantly since 1994. In Denmark, amalgam is allowed only in molar teeth where the filling is subject to wear, but the Government is poised to ban all remaining use once the Danish National Board of Health is satisfied that the non-mercury alternatives are adequate for all requirements. Norway has developed a directive (from 1 January 2003) on the use of amalgam, which encourages phase down. The European Parliament resolution on the European Environment & Health Action Plan 2004-2010 - Article 6, declared that, consistent with the "opinion of the relevant Scientific Committee, urgent consideration should be given to restricting the marketing and/or the use of mercury used in dental amalgams ... to which newborn babies, children, pregnant women, elderly persons, workers and other high-risk sections of the population are heavily exposed, as safer alternatives become available."

