

Honorable John Kerry, Secretary of State  
United States Department of State  
2201 C Street NW  
Washington, DC 20520

September 21, 2015

Dear Secretary Kerry,

In 2013 the United States took the important step of being the first country to ratify the Minamata Convention on Mercury.<sup>i</sup> We appreciate your leadership on reducing global mercury pollution and are writing to strongly urge the U.S. to reverse an outdated federal policy that is both impeding mercury reduction efforts domestically and contrary to the position taken by the U.S. during the negotiations.

The goal of controlling the anthropogenic releases of mercury throughout its lifecycle is the primary driver that shaped obligations under the Convention. These obligations, which will be phased in over time, include: supply and trade controls on mercury; mercury-added product phase outs and phase downs; reducing mercury use in processes; and air emission controls for major sources of mercury pollution.

Dental amalgam is now one of the largest consumer uses of mercury in the U.S. today. According to the latest U.S. Geological Survey report, 18-30 tons of mercury is used in dental amalgam each year accounting for between 35% and 57% of mercury use in 2010.<sup>ii</sup>

During the treaty negotiations, the Department of State expressed support for reducing and eventually phasing out dental amalgam use:

“The United States supports further consideration of dental amalgam by the Intergovernmental Negotiation Committee such that the agreement is able to achieve the phase down, with the goal of eventual phase out by all Parties, of mercury amalgam upon the development and availability of affordable, viable alternatives.”<sup>iii</sup>

This Department of State (DoS) position is reflected in the final Convention text, as Annex B of the Convention requires Parties to “phase down the use of dental amalgam”, using two or more measures identified in the Annex.<sup>iv</sup>

However, the Food & Drug Administration (FDA) apparently takes the opposite view, as expressed when it reclassified dental amalgam as a Class II medical device in a rule published on August 4, 2009. In assessing the potential impacts of the reclassification, the FDA states:

“We are unable to estimate possible changes in exposure that may result from this rule. Dentists may use dental amalgam for some patients for whom they may not have used the device previously, and decide not to use the device for other patients for whom they have used the device. However, any change away from use of dental amalgam is likely to result in negative public health outcomes (delayed dental treatments or increased costs of treatment); while there would be a decrease in mercury exposure, there is no evidence that there would be any reduction in adverse effects associated with mercury.”<sup>v</sup>

Accordingly, FDA's position as articulated in 2009 and unaltered since that time is fundamentally at odds with the Convention's provisions to "phase down the use of dental amalgam," as well as the U.S. Government's position taken during the negotiations. The difference in approach reflects the Convention's consideration of dental amalgam's full life cycle, and the comprehensive approach in the Convention "to protect the human health and the environment from anthropogenic emissions and releases of mercury..."<sup>vi</sup>

Announcing support for the Convention, the DoS said that, "The United States has already taken significant steps to reduce the amount of mercury generated and released into the environment, and can implement Convention obligations under existing law."<sup>vii</sup> However, unless the FDA's views and associated policies toward the phase down of dental mercury are changed, it may undermine comprehensive mercury reduction efforts in the U.S. and also could send the wrong message to other Parties to the Convention.

Therefore, we respectfully recommend that DoS take a leadership role in encouraging FDA to reduce amalgam use. With the Environmental Protection Agency proposing a rule to reduce dental mercury pollution,<sup>viii</sup> the responsibility for phasing down amalgam use squarely falls on FDA.

Thank you again for being a strong leader on reducing mercury pollution. We look forward to meeting with you or your staff to discuss this further. Please feel free to contact Michael Bender (email: [mercurypolicy@aol.com](mailto:mercurypolicy@aol.com)) if you or your staff have questions.

Sincerely,

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## Endnotes

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<sup>i</sup> *Minamata Convention on Mercury*, <http://www.mercuryconvention.org/>

<sup>ii</sup> *Changing Patterns in the Use, Recycling, and Material Substitution of Mercury in the United States*(2013), U.S. Geological Survey ,p.26, <http://pubs.usgs.gov/sir/2013/5137/>

<sup>iii</sup> *Submission of the United States Government*, Mercury Intergovernmental Negotiating Committee, page 6 <http://www.unep.org/hazardoussubstances/Portals/9/Mercury/Documents/INC3/United%20States.pdf>

<sup>iv</sup> *Minamata Convention on Mercury*, page 46, <http://www.mercuryconvention.org/>

<sup>v</sup> 74 Fed. Reg. 38707-08 (August 4, 2009)(emphasis added).

<sup>vi</sup> *Minamata Convention on Mercury*, page 6, <http://www.mercuryconvention.org/>

<sup>vii</sup> *The United States joins Minamata Convention on Mercury, Hails Agreement as a Tremendous Step Forward in Protecting People in the United States from Transboundary Mercury Pollution*  
<http://www.state.gov/e/oes/eqt/mercury/>

<sup>viii</sup> 79 Fed. Reg. 63258 (October 22, 2014).