



World Alliance for Mercury-Free Dentistry  
Alliance Mondiale pour une dentisterie sans mercure  
Всемирный альянс за стоматологию без ртути  
Alianza Mundial por una Odontología Sin Mercurio  
التحالف العالمي لطب أسنان خال من الزئبق  
世界无汞牙科联盟



**Mercury  
Policy Project**



CAMPAIGN FOR  
**MERCURY FREE DENTISTRY**  
A PROJECT OF CONSUMERS FOR DENTAL CHOICE



## **Citizen Petition to Revoke and Replace FDA’s Mercury Amalgam Rule So That the U.S. Government Will Conform with the *Minamata Convention on Mercury***

Date: 20 October 2015

Three times in its mercury amalgam regulation, FDA says “any change away from use of dental amalgam is likely to result in negative public health outcomes.” And three times in its mercury amalgam regulation, FDA states “any change towards use of dental amalgam is likely to result in positive public health outcomes.”<sup>1</sup> The World Alliance for Mercury-Free Dentistry and its co-petitioners submit this petition under the Federal Food, Drug, and Cosmetic Act to request the Commissioner of the Food and Drug Administration to amend its mercury amalgam rule at 74 FR 38686 to revoke FDA’s official support for “change towards use of dental amalgam” – which is contrary to the *Minamata Convention on Mercury*’s requirement to “phase down amalgam use.”

### **A. Action Requested**

The World Alliance for Mercury-Free Dentistry and its co-petitioners – Asian Center for Environmental Health, African Center for Environmental Health, Mercury Policy Project, and Consumers for Dental Choice – urge the Commissioner to make the following changes to FDA mercury amalgam rule so that the United States government will conform with the *Minamata Convention on Mercury*:

- 1) Revoke the sections of the mercury amalgam rule promoting amalgam use, namely “any change towards use of dental amalgam is likely to result in positive public health outcomes.”<sup>2</sup>
- 2) Revoke the sections of the mercury amalgam rule opposing the phase down of amalgam use, namely “any change away from use of dental amalgam is likely to result in negative public health outcomes.”<sup>3</sup>
- 3) Replace these sections with “To reduce the use of mercury-added products in line with the intentions of the *Minamata Convention*, the FDA recommends against the use of mercury amalgam dental fillings. Mercury-free dental filling materials should be the first choice.”
- 4) Promote the FDA’s support for mercury-free dental filling materials with a media and education campaign.

## **B. Statement of Grounds**

### **1. The Commissioner must amend FDA's mercury amalgam rule in order to comply with the *Minamata Convention on Mercury's* required phase down of amalgam use**

The *Minamata Convention* requires nations to “phase down the use of dental amalgam.”<sup>4</sup> The U.S. government signed and accepted the *Minamata Convention* on 6 November 2013.<sup>5</sup> FDA's official support for “change towards use of dental amalgam” and its rejection of “any change away from use of dental amalgam” is contrary to the *Minamata Convention's* requirement that parties “phase down the use of dental amalgam.”<sup>6</sup>

To start bringing the U.S. government into conformity with the *Minamata Convention on Mercury*, the Commissioner must amend FDA's mercury amalgam rule.

### **2. The Commissioner must amend FDA's mercury amalgam rule in order to maintain the leadership role of the United States on mercury issues**

FDA's push for phasing up amalgam use has already raised major concerns in the international community:

- Numerous non-governmental organizations from around the globe are pointing out the discrepancy between the U.S.'s obligation to phase down amalgam use and FDA's policy of promoting the phase up of amalgam use. Most recently, sixty environmental organizations wrote the State Department, urging Secretary Kerry to bring FDA into line with the *Minamata Convention's* amalgam phase down requirement.<sup>7</sup>
- The press is covering this discrepancy, running articles describing how “The FDA is speaking out of both sides of its mouth, on the one hand participating as part of the U.S. delegation supporting the amalgam phase-down, and on the other hand standing behind their 2009 rule.”<sup>8</sup>
- Other nations look to the amalgam issue as a litmus test. Does the U.S. government view the *Minamata Convention* as a soapbox to lecture other nations about their mercury uses or as a serious commitment to phase down dental amalgam, its own leading intentional mercury use? After all, the U.S. cannot effectively call for China to reduce industrial mercury use ... advise Burkina Faso and Indonesia to eliminate mercury use in gold mining ... urge Mexico to stop its wildcat mercury mining ... and suggest India decrease mercury from power plants ... while FDA thwarts the *Minamata Convention* by urging a “change towards use of dental amalgam.”

To maintain the leadership role of the United States on mercury issues, the Commissioner must revoke and replace FDA's mercury amalgam rule.

### C. Environmental Impact

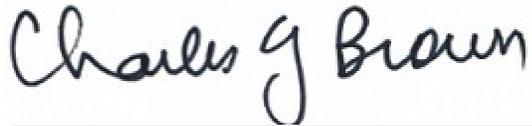
The FDA is required to prepare an environmental assessment for each action not categorically excluded. Categorically excluded devices “do not ordinarily require” an environmental assessment.<sup>9</sup> But this is not an ordinary circumstance. With the need for action now recognized by the *Minamata Convention on Mercury*, FDA can no longer categorically dismiss mercury amalgam’s negative environmental impact. The requested action in this petition will benefit the environment by:

- **Reducing mercury use:** According to the U.S. Geological Survey, “[d]ental amalgam constituted the largest amount of mercury in use in the United States,” accounting for between 35% and 57% of mercury consumption in 2010. In 2009, an estimated 28.5 tonnes was released into the environment through cremation, dental clinic emissions, human waste, burial, and other pathways.<sup>10</sup> Any change away from use of dental amalgam will reduce the large amount of mercury in use in the United States.
- **Decreasing environmental mercury:** The large amount of dental mercury used in the U.S. enters our air, water, and land via numerous pathways including cremation, dental clinic emissions, sludge incineration, human waste, burials, and landfills. The U.S.’s dental mercury is not contained within the boundaries of the United States. As the *Minamata Convention* recognizes, “mercury is a chemical of global concern owing to its long-range atmospheric transport,” among other reasons.<sup>11</sup>
- **Protecting environmental health:** According to the U.S. Environmental Protection Agency, when amalgam is in the environment, certain microorganisms can change its elemental mercury into methylmercury, a highly toxic form that builds up in fish, shellfish, and animals that eat fish.<sup>12</sup> Methylmercury can damage children’s developing brains and nervous systems even before they are born.<sup>13</sup>
- **Lowering environmental costs:** Due to the high costs of dental mercury pollution, amalgam is recognized as “more expensive than most, possibly all, other fillings when including environmental costs.”<sup>14</sup> Taking into account these high environmental costs, an amalgam filling costs up to \$87 more than a composite filling.<sup>15</sup>
- **Leading on mercury policy:** Under President Obama and his well-known anti-mercury policy, the U.S. led the negotiations for the *Minamata Convention on Mercury* – from jumpstarting negotiations to supporting robust terms to ratifying the *Convention* first. But now at the implementation stage, the U.S. government punts by pushing for “change towards use of dental amalgam” – which is already the largest intentional mercury use. In order to continue to lead, FDA must withdraw its official opposition to the *Minamata Convention*’s requirement to phase down amalgam use.

By failing to take into account these negative public health consequences of dental mercury in the environment, FDA reached the paradoxical conclusion that an increase in this mercury use will result in a “positive public health outcome.” Unlike FDA, the *Minamata Convention*’s framers did consider amalgam’s full life cycle. Informed by this more comprehensive analysis, the nations agreed that the phase down of amalgam use is necessary to achieve the *Convention*’s objective “to protect the human health and the environment.”<sup>16</sup> To account for the known negative public health impact of dental mercury in the environment, the Commissioner must revoke and replace FDA’s mercury amalgam rule.

#### **D. Certification**

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



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*Joined by the following co-petitioners:*

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African Center for Environmental Health

Mercury Policy Project

Consumers for Dental Choice

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<sup>1</sup> Federal Register / Vol. 74, No. 148 / Tuesday, August 4, 2009, pp. 38706, 38707-38708, 38710-38711, <http://www.gpo.gov/fdsys/pkg/FR-2009-08-04/pdf/E9-18447.pdf>

<sup>2</sup> Ibid.

<sup>3</sup> Ibid.

<sup>4</sup> *Minamata Convention* (2013)

<sup>5</sup> <http://www.mercuryconvention.org/Countries/tabid/3428/Default.aspx>

<sup>6</sup> *Minamata Convention* (2013)

<sup>7</sup> *Letter to Secretary John Kerry* (21 September 2015), [http://mercurypolicy.org/wp-content/uploads/2015/09/sec\\_state\\_kerry\\_ngo\\_letter\\_sept\\_21\\_2015.pdf](http://mercurypolicy.org/wp-content/uploads/2015/09/sec_state_kerry_ngo_letter_sept_21_2015.pdf)

<sup>8</sup> Greg Gordon, *State Dept. urged to press FDA to curb mercury dental fillings*, SUN HERALD (22 September 2015), [http://www.sunherald.com/2015/09/22/6428727\\_state-dept-urged-to-press-fda.html?rh=1](http://www.sunherald.com/2015/09/22/6428727_state-dept-urged-to-press-fda.html?rh=1)

<sup>9</sup> 21 CFR 25.30

<sup>10</sup> U.S. Geological Survey, *Changing Patterns in the Use, Recycling, and Material Substitution of Mercury in the United States* (2013), p.1, 26

<sup>11</sup> *Minamata Convention* (2013)

<sup>12</sup> Stone, M.E., Cohen, M.E., Liang, L., et al.. 2003. *Determination of methyl mercury in dental-unit wastewater*. *Dental Materials* 19:675–679. (“Environmentally important levels of MMHg were found to be present in dental-unit wastewater at concentrations orders of magnitude higher than seen in natural settings.”); EPA, *EPA Will Propose Rule to Protect Waterways by Reducing Mercury from Dental Offices* (2010), <http://yosemite.epa.gov/opa/admpress.nsf/e77fdd4f5afd88a385257%206b3005a604f%20/a640db2ebad201cd852577ab00634848!OpenDocument>

<sup>13</sup> EPA, *EPA Will Propose Rule to Protect Waterways by Reducing Mercury from Dental Offices* (2010), <http://yosemite.epa.gov/opa/admpress.nsf/e77fdd4f5afd88a385257%206b3005a604f%20/a640db2ebad201cd852577ab00634848!OpenDocument>

<sup>14</sup> Lars D. Hylander & Michael E. Goodsite, *Environmental Costs of Mercury Pollution*, *SCIENCE OF THE TOTAL ENVIRONMENT* 368 (2006) 352-370.

<sup>15</sup> Concorde East/West, *The Real Cost of Dental Mercury* (March 2012), [http://www.zeromercury.org/index.php?option=com\\_phocadownload&view=file&id=158%3Athe-real-cost-of-dental-mercury&Itemid=70](http://www.zeromercury.org/index.php?option=com_phocadownload&view=file&id=158%3Athe-real-cost-of-dental-mercury&Itemid=70), pp.3-4

<sup>16</sup> *Minamata Convention* (2013)