Citizen Petition to Amend FDA’s Mercury Amalgam Rule to Require Patient Labeling

FDA rejects proposals to provide patient labeling for dental amalgam – even though the Minamata Convention on Mercury requires each party to promote and facilitate provision of information on mercury-free alternatives to the public....even though public awareness phases down amalgam use as the Convention requires....even though international guidance from UNEP urges countries to raise public awareness of amalgam’s mercury....even though FDA’s own experts say patient labeling is needed....and even though FDA’s own Guidance on Medical Device Patient Labeling indicates that patient labeling is necessary. Consumers for Dental Choice submits 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 require patient labeling for dental amalgam.

A. Action Requested

Consumers for Dental Choice urges the Commissioner to require manufacturers to distribute patient labeling containing information about the following for parents and dental consumers:

(a) amalgam’s mercury content

(b) amalgam’s risks to children and fetuses

(c) the damage amalgam can do to tooth structure

(d) the damage caused by amalgam in the environment

(e) the benefits of mercury-free fillings

B. Statement of Grounds

1. Patient labeling is needed to comply with the Minamata Convention on Mercury’s public information requirement

Recognizing the importance of public information, Article 18 of the Minamata Convention requires that each party shall promote and facilitate provision to the public of available information on alternatives to mercury-added products like amalgam. The U.S. government signed and accepted the Minamata Convention on 6 November 2013.
But a year after the negotiations for the Convention ended, a 2014 Zogby poll finds that most Americans do not even know that mercury is amalgam’s main component, much less that mercury-free materials are available. Their dentists do not provide this information: only 11% of Americans (and 6% of African-Americans) report their dentists telling them that amalgam is mainly mercury. 3

To start bringing FDA into compliance with the Minamata Convention’s public information requirement, the Commissioner must amend FDA’s mercury amalgam rule to require patient labeling.

2. Patient labeling is needed to phase down the use of mercury amalgam, as required by the Minamata Convention

The Minamata Convention requires parties, including the U.S., to “phase down the use of dental amalgam.” 4

Raising public awareness about amalgam’s mercury content and mercury-free dental restorations phases down amalgam use. As a Zogby poll shows, 76% of American dental patients do not know that amalgam is primarily mercury. Many people even believe amalgam is mainly silver because it is frequently marketed as “silver fillings.” However, once told that amalgam contains mercury, over 75% of dental patients choose mercury-free dental restorations. 5

Nations that have already significantly phased down or phased out amalgam use cite high public awareness as an important factor in their success. For example:

- **Sweden:** The Swedish Chemicals Agency (KEMI) named “High awareness of the environmental and health risks of mercury among patients” as one of the “most important explanations” for that nation’s ability to phase out amalgam use. 6

- **Norway:** A report for Norway’s Climate and Pollution Agency explains, “The substitution of dental amalgam started as a result of public awareness and guidelines from the health authorities before the general ban on mercury in products was introduced by the environmental authorities.” 7

- **Denmark:** In Denmark, the government explains “patients ask for alternatives due to public awareness.” 8

FDA concedes that giving patients labeling with “direct information that would include the presence of mercury in amalgam” would result in “an expected reduction in mercury exposure” (i.e., a phase down in amalgam use). Yet FDA refuses to take this effective amalgam phase-down measure.

To effectively phase down amalgam use, the Commissioner must amend FDA’s mercury amalgam rule to require patient labeling.
3. Patient labeling is needed to conform to new international guidance from UNEP

The Minamata Convention requires nations, including the U.S., to “phase down the use of dental amalgam” with measures that “shall take into account the Party’s domestic circumstance and relevant international guidance.”

New relevant international guidance on phasing down amalgam use urges countries to raise public awareness of amalgam’s mercury. The 2016 publication Lessons from Countries Phasing Down Dental Amalgam Use, produced by the United Nations Environment Programme (UNEP) and reviewed by the World Health Organization, explains that “a surprising number of people are not aware that amalgam contains about 50% mercury” and a number of people are confused by the deceptive marketing term “silver fillings.” To solve this problem, “Raising public awareness is an important factor that countries should consider because many people are not aware of the pros and cons of different dental restorations.” The publication proceeds to give examples of countries that took active steps to raise public awareness of amalgam’s mercury: “In Norway, the government adopted measures to present information on alternative dental restorative materials in a balanced manner (UNEP 2010). As a result, the move away from amalgam started even “before the general ban on mercury in products was introduced.” In Denmark, dentists were required to inform patients about the different dental restoration materials. Now “patients ask for alternatives due to public awareness.” In Sweden, the government attributes ‘high awareness of the environmental and health risks of mercury among patients’ as one of the ‘most important explanations’ for that country’s ability to virtually eliminate amalgam use.”

Contrary to international guidance, FDA has taken steps to prevent consumers from receiving direct balanced information about amalgam and its alternatives. To take into account this new international guidance, the Commissioner must amend FDA’s mercury amalgam rule to require patient labeling.

4. Patient labeling is needed according to FDA’s own experts

When the FDA asked its advisory panel to review its 2009 dental amalgam rule in December 2010, the panelists expressed concern that without patient labeling, the public was not getting the information that it needs about amalgam:

- Consumer panelist Ms. Karen Rue observed that FDA is not getting important information to consumers: “The FDA person said it was going to the dentist. There was no comment that it was going to the consumer and it needs to go also to the consumer.”

- Panelist Dr. Janine Janosky was “not even sure that the dentists read [the labeling]. I think somebody in the office opens the packages and does whatever needs to be done, the assistant or the nurse, and then that's in the trash. So I'm not sure it always gets paid enough attention to...if a doctor gives me a medication, he gives me the package to take home that he's not using, rather than putting it in the trash, and I read the insert and the box and the black box.”

- As Dr. Norman Tinanoff concludes, “A very simple thing. The consumer needs to know the risks and benefits of both products and they should be given the choice to choose which product they want to use.”
To act on these recommendations from experts, the Commissioner must amend FDA’s mercury amalgam rule to require patient labeling.

5. Patient labeling is needed to comply with FDA’s own Guidance on Medical Device Patient Labeling

The FDA’s Guidance on Medical Device Patient Labeling explains what medical devices need patient labeling – and according to FDA’s own Guidelines, amalgam requires patient labeling:

- First, patient labeling for amalgam is necessary under the Guidelines because FDA says “You should know the informational needs of your target audience in order to determine if patient labeling is necessary. Does your audience need or want specific information? Is there something unique about the device (e.g., diagnostic test) that needs to be explained to the patient? Does your audience already know the information?” Zogby polls show that 76% of people do not know that amalgam’s main ingredient is mercury. But once told that amalgam contains mercury, over 75% of dental patients choose the mercury-free fillings indicating that they not only want to know this unique fact about amalgam, but use it to decide which filling material to get.

- Second, patient labeling for amalgam is necessary under the Guidelines because FDA says “You should consider developing risk/benefit information when patients or lay caregivers need to...give personal health information to aid their health care practitioner in deciding to use or not use devices in prevention, treatment, or diagnosis of an illness (e.g., magnetic resonance imaging (MRI))...” It is critical that patients give personal health information – especially about allergies, hypersensitivities to mercury, and other significant sources of mercury exposure – to their dentists before amalgam is used. As explained in the final FDA rule on dental amalgam: “FDA concludes that existing data indicate that certain individuals with a pre-existing hypersensitivity or allergy to mercury may be at risk for adverse health effects from mercury vapor released from dental amalgam.” FDA also acknowledges that “Mercury from dental amalgam and other sources (e.g., fish) is bioaccumulative,” meaning that a person who eats a lot of high-mercury fish or is exposed to mercury vapors in the workplace might be more at risk than someone else. Consumers, not expecting to encounter mercury in a dental clinic in the absence of patient labeling, are not likely to volunteer information about their mercury hypersensitivities, mercury allergies, or other mercury exposures – putting them “at risk for adverse health effects.”

- Third, patient labeling for amalgam is necessary under the Guidelines because FDA says “You should consider developing risk/benefit information when patients or lay caregivers need to...select among similar devices or device procedures...” There are many different types of filling materials for patients to choose from – including composite, glass ionomer, compomer, and amalgam.

- Fourth, patient labeling for amalgam is necessary under the Guidelines because FDA says “You should consider developing risk/benefit information when patients or lay caregivers need to...be involved in deciding whether to have a procedure involving the device...” It is unethical not to involve patients in deciding which filling material will be implanted in their teeth, so they will be involved. As the World Dental Federation’s Dental Ethics Manual
saying, “The right of patients to make decisions about their health care has been enshrined in legal and ethical statements throughout the world.”24

- Fifth, patient labeling for amalgam is necessary under the Guidelines because FDA says “You should consider developing risk/benefit information when patients or lay caregivers need to... understand the effect or influence of the device on the patient or others (e.g., orthopedic rods, screws, and fixation devices; genetic screening).”25 Amalgam’s environmental impact – including the environmental health risks to children and fetuses – is so severe that the Minamata Convention requires the phase down of amalgam use. Consumers need to understand that amalgam has a negative effect on others too.

- Sixth, patient labeling for amalgam is necessary under the Guidelines because FDA says “You should consider developing instructions for use when patients or lay caregivers need to... know how to safely dispose of the device.”26 Specifically, it explains that patient labeling should “explain how to safely dispose of the device (e.g., mercury containing devices, sharps). Include your take-back information, recycling options, and refurbishment options.”27 It is not uncommon for amalgam fillings or primary teeth filled with amalgam to fall out outside of the dental clinic, leaving consumers to dispose of them. The U.S. Environmental Protection Agency provides a label for dentists that says, “Capture mercury amalgam waste using gray bags and amalgam separator. Send to a RCRA-permitted mercury recycler.”28 But consumers do not see these labels or any other label telling them how to properly handle and dispose of this mercury product; as Zogby polls indicate, most consumers do not even know they are handling a mercury product. Without patient labeling, it is unlikely that these mercury amalgam fillings will be properly disposed of.

- Seventh, patient labeling for amalgam is necessary under the Guidelines because this is not a situation when patient labeling is not needed. FDA explains “Medical device patient labeling is not usually necessary when: a patient will have no opportunity to benefit from the labeling” (i.e., the device is a tool of the health care practitioner) or “a patient’s opportunity to benefit from patient labeling is outweighed by the risk of allowing him the opportunity in an emergency.”29 Neither of these situations apply to amalgam. Amalgam is not just a tool of the health practitioner, the choice of which would not affect the patient – it is a material that is implanted into the patient’s body. Nor does the placement of a filling rise to the level of an emergency with no time to read patient labeling.

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.30 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. Patient labeling for mercury amalgam would have positive environmental impacts, including:

- **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,
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.

- **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. Methylmercury can damage children’s developing brains and nervous systems even before they are born.

- **Lowering environmental costs:** Due to the high costs of dental mercury pollution, amalgam is now recognized as “more expensive than most, possibly all, other fillings when including environmental costs.” Taking into account these high environmental costs, an amalgam filling costs up to $87 more than a composite filling.

- **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. is pushing for “change towards use of dental amalgam” – its own 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.

To account for the known negative public health impact of dental mercury in the environment, the Commissioner must amend 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.

Charles G. Brown  
National Counsel and Executive Director  
Consumers for Dental Choice  
316 F St. NE, Suite 210, Washington, DC 20002  
202-544-6333  
charlie@toxicteeth.org
Available Substitutes

Environmental Costs of Mercury Pollution

than seen in natural settings.

Environmentally important levels of MMHg were found to be present in dental-unit wastewater at concentrations orders of magnitude higher than in natural settings.


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FDA transcripts (15 December 2010),


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FDA transcripts (15 December 2010),


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FDA, Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers (19 April 2001).

The Real Cost of Dental Mercury (March 2012),