

# **Mercury Dental Amalgam: New Evidence Counters Old Notion that Amalgam is Safe**

Policy Options for Local Governments

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## **Summary**

Most Americans have dental restorations, and many of those restorations are dental amalgam, known as “silver” fillings. Dental amalgam, which contains about 50% mercury, was once believed to be inert. The US Food and Drug Administration (FDA) and other agencies now acknowledge that amalgam releases low levels of elemental mercury vapor. The scientific debate is now about how much is released, what levels are considered harmful, and whether this threshold varies among subpopulations. Current evidence suggests that amalgam poses a clear risk to developing fetuses and children and to people with common genetic susceptibilities. For the general population amalgam appears to add to cumulative body burden, posing a long-term risk of unknown scope.

Several countries have banned or restricted dental amalgam on both health and environmental grounds. In the US, the 157,000-member American Dental Association (ADA) supports amalgam use, while several small dental associations led by the 700-member International Academy of Oral Medicine and Toxicology (IAOMT) seek to ban it. Since 2010, the FDA states that it is “actively reviewing” the safety of amalgam, but it has provided no further information. Meanwhile, some US cities have passed ordinances aimed at discouraging amalgam use.

## **Highlights**

- A randomized, controlled, seven-year clinical trial – the highest quality human amalgam study available – found no associations between amalgam and adverse health effects as of 2006. But recent, more detailed analyses of the same dataset now reveal harm (p.20).
- Evidence suggests that a large fraction of amalgam-bearers incur mercury exposures in excess of current environmental health standards (p. 23).
- In California, existing law mandates that a fact sheet on dental materials be given to new patients, but the language on risk is out-of-date and misleading, and informal surveys suggest that few people even receive this document (p. 7).

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# 1. Introduction

Mercury is a pollutant of global concern on both health and environmental grounds.<sup>1</sup> It is a broad, systemic toxicant that is especially harmful to the developing fetus.<sup>2</sup> For most people, dietary fish and dental amalgams are the major sources of exposure.<sup>3</sup>

Current efforts by the United Nations seek to address environmental mercury on two fronts: reduce industrial pollution and reduce demand for mercury end-products.<sup>4</sup>

In the US, various mercury issues are addressed as follows:

- In the last decade, the US Environmental Protection Agency (EPA) has begun to control mercury air pollution from industry and incinerators.<sup>5</sup>
- Sport fish advisories are available from federal, state, and local authorities,<sup>6</sup> although usually not at the fishing site.

- Commercial fish toxicity is arguably underregulated by the US Food and Drug Administration (FDA). Informal surveys suggest that samples of certain fish species often exceed the FDA “action level” for mercury,<sup>7</sup> yet the FDA appears to take no action. In addition, the action level is relatively permissive. (See Appendix B: Fish mercury, p. 17.) Further, consumers receive no point-of-sale warnings, although general information is available to those who seek it.<sup>8</sup>
- Dental amalgam appears to be grossly underregulated by the FDA. (See Appendix D: Exposures exceed safety standards, p. 23.)
- Compact fluorescent light bulbs (CFLs) contain about 4 milligrams (4000 micrograms) of mercury, thus are designated as household hazardous waste.<sup>9</sup> A broken CFL can release mercury, but experiments indicate that

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<sup>1</sup> United Nations Environment Programme. Global Mercury Assessment 2013: Sources, Emissions, Releases, and Environmental Transport [Internet]. Geneva: UNEP Chemicals Branch; 2013. Available from: <http://www.unep.org/PDF/PressReleases/GlobalMercuryAssessment2013.pdf>

<sup>2</sup> Berlin M, Zalups RK, Fowler BA. Mercury. In: Nordberg G, editor. Handbook on the toxicology of metals. Amsterdam; Boston: Academic Press; 2007.

<sup>3</sup> International Programme on Chemical Safety. Elemental mercury and inorganic mercury compounds: human health aspects [Internet]. Geneva: World Health Organization, United Nations Environment Programme; 2003. Available from: <http://www.who.int/ipcs/publications/cicad/en/cicad50.pdf>

<sup>4</sup> UNEP 2013, *op cit*.

<sup>5</sup> In December 2011, EPA issued the first national standards for mercury pollution from power plants. In March 2011, the agency issued emissions limits for incinerators. In 2010, it issued emissions limits for cement plants. Source: US Environmental Protection Agency. Mercury laws and regulations [Internet]. [cited 2013 Mar 19]. Available from: <http://www.epa.gov/hg/regs.htm#air>

<sup>6</sup> Federal overview on fish advisories:

US Environmental Protection Agency. Mercury: Fish consumption advisories [Internet]. [cited 2013 Mar 19]. Available from: <http://www.epa.gov/hg/advisories.htm>.

Joint EPA/FDA brochure:

US Environmental Protection Agency and US Food and Drug Administration. Joint federal fish consumption advisories: What you need to know about mercury in fish and shellfish [Internet]. 2004 [cited 2013 Mar 28]. Available from:

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[http://water.epa.gov/scitech/swguidance/fishshellfish/outreach/upload/2004\\_05\\_24\\_fish\\_MethylmercuryBrochure.pdf](http://water.epa.gov/scitech/swguidance/fishshellfish/outreach/upload/2004_05_24_fish_MethylmercuryBrochure.pdf)

CalEPA information sheet:

Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. Methylmercury in sport fish: Information for consumers 2003. Available from: <http://oehha.ca.gov/fish/pdf/HGfacts.pdf>

CalEPA fish advisory for San Francisco Bay:

Office of Health Hazards Assessment. Health advisory and safe eating guidelines for San Francisco Bay fish and shellfish [Internet]. California Environmental Protection Agency; 2011 May. Available from: [http://www.cityofberkeley.info/uploadedFiles/Planning\\_and\\_Development/Level\\_3\\_-\\_Commissions/Commission\\_for\\_Community\\_Environmental\\_Advisory/2012-11-15\\_AGN\\_CEAC\\_Item%20V.G.pdf](http://www.cityofberkeley.info/uploadedFiles/Planning_and_Development/Level_3_-_Commissions/Commission_for_Community_Environmental_Advisory/2012-11-15_AGN_CEAC_Item%20V.G.pdf)

City of Berkeley sport fish advisory:

City of Berkeley. Fish advisory information [Internet]. [cited 2013 Mar 19]. Available from: [http://www.ci.berkeley.ca.us/Health\\_Human\\_Services/Environmental\\_Health/Fish\\_Advisory\\_Information.aspx](http://www.ci.berkeley.ca.us/Health_Human_Services/Environmental_Health/Fish_Advisory_Information.aspx)

<sup>7</sup> Hightower JM, Moore D. Mercury levels in high-end consumers of fish. Environ. Health Perspect. 2003 Apr;111(4):604–8.

<sup>8</sup> US Food and Drug Administration. Mercury levels in commercial fish and shellfish (1990-2010) [Internet]. [cited 2013 Mar 19]. Available from: <http://www.fda.gov/food/foodsafety/product-specificinformation/seafood/foodbornepathogenscontaminants/methylmercury/ucm115644.htm>

<sup>9</sup> US Environmental Protection Agency O. What are the Connections between Mercury and CFLs? [Internet]. [cited 2013 Mar 24]. Available from: <http://www2.epa.gov/cfl/what-are-connections-between-mercury-and-cfls>

worst-case scenarios yield exposures similar to those from eating one serving of a high-mercury fish.<sup>10</sup>

Policymakers face a variety of issues related to mercury. Most importantly, consumer warnings are needed for commercial fish and dental amalgam. The amalgam issue is hampered by a misperception of safety.

### Dental amalgam

Most Americans have dental restorations, and many of those are dental amalgam, known as “silver” fillings.<sup>11</sup> A 2011 study found that most posterior teeth needing restoration are filled with amalgam.<sup>12</sup> Dental amalgam, which contains about 50% mercury,<sup>13</sup> was once believed to be inert. The FDA and other agencies now acknowledge that amalgam releases low levels of elemental mercury vapor.<sup>14</sup>

## 2. Environment

Mercury is an element, thus does not degrade. It is a mobile, persistent environmental pollutant. Once released from its geologic home, mercury travels globally, taking different forms<sup>15</sup> as it

cycles through air, water, and land.<sup>16</sup> (See Appendix A: Global mercury flows, p. 13.)

Much of the existing environmental mercury burden comes from remobilization of previous releases. (See Table A-1, p.14.) Aquatic pollution is the end-point of concern, because mercury bioaccumulates in predatory fish and in species that feed on them, including humans.<sup>17</sup> The National Academy of Sciences in 2000 estimated that 60,000 infants annually may be at risk for adverse neurodevelopmental effects due to *in utero* mercury exposure from maternal dietary fish.<sup>18</sup> Another study claims the figure is five to ten-fold higher.<sup>19</sup> Marine mammals have about twelve times the mercury load today as in preindustrial times.<sup>20</sup>

According to the United Nations Environment Programme, the key to reducing mercury in the environment is to reduce the demand for mercury end-products as well as to reduce unintended emissions.<sup>21</sup> Dental mercury accounts for 16% of mercury end-products in the US, as shown in Table A-2 (p.15). Environmental concerns include:

- While all mercury products eventually reach the environment, about half of the amalgam mixed for placement immediately becomes waste, according to the East Bay Municipal Utility District (EBMUD).<sup>22</sup>

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<sup>10</sup> This worst-case scenario involved a broken CFL in a poorly ventilated room. A beater-style vacuum cleaner was used and then left in the room, along with the glass debris in a trash can. Source: Clear R, Rubinstein F, Howells J. Dangerous mercury in CFLs? One big fish story. LD+A [Internet]. 2009 Aug;53–6. Available from: <http://www.lamprecycle.org/public/images/docs/LD+A%20August%202009.pdf>

<sup>11</sup> Richardson GM, Wilson R, Allard D, Purtill C, Douma S, Gravière J. Mercury exposure and risks from dental amalgam in the US population, post-2000. *Sci. Total Environ.* 2011 Sep 15;409(20):4257–68.

<sup>12</sup> Makhija SK, Gordan VV, Gilbert GH, et al. Practitioner, patient and carious lesion characteristics associated with type of restorative material: findings from The Dental Practice-Based Research Network. *J Am Dent Assoc.* 2011;142(6):622–632. <http://www.ncbi.nlm.nih.gov/pubmed?term=PMID%3A%20%20%20%20%2021628683>

<sup>13</sup> US Food and Drug Administration. About dental amalgam fillings [Internet]. [cited 2013 Mar 19]. Available from: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/ucm171094.htm>

<sup>14</sup> *Ibid.*

<sup>15</sup> Mercury's three major forms -- elemental or metallic mercury, organic mercury compounds (e.g., methylmercury), and inorganic mercury compounds — can interconvert via bacterial action or other environmental conditions. Both elemental mercury vapor and organic mercury compounds are lipophilic, highly mobile, and well absorbed. Neither inorganic mercury nor liquid elemental mercury is well absorbed. The lipophilic forms – vapor and organomercury –

can cross cell membranes including the blood-brain barrier. They are easily oxidized into inorganic mercury, a lipophobic molecule that is more toxic but less mobile. Mercury toxicity is most severe when the mobile forms enter the cell and its organelles and then become oxidized to the inorganic form, which is thereby trapped to do ongoing damage.

Berlin, 2007, *op cit.*

<sup>16</sup> UNEP 2013, *op cit.*

<sup>17</sup> *Ibid.*

<sup>18</sup> National Research Council. Toxicological effects of methylmercury. Washington, DC: The National Academies Press; 2000, p. 325.

<sup>19</sup> Trasande L, Landrigan PJ, Schechter C. Public health and economic consequences of methyl mercury toxicity to the developing brain. *Environ. Health Perspect.* 2005 May;113(5):590–6.

<sup>20</sup> UNEP 2013, *op cit.*

<sup>21</sup> *Ibid.*

<sup>22</sup> East Bay Municipal Utility District. Dental mercury FAQs [Internet]. [cited 2013 Mar 19]. Available from:

- Dental-office releases have been the largest identifiable source of mercury discharged to US wastewater treatment plants.<sup>23</sup> As of 2002, EBMUD has mandated amalgam separators for dental offices, so that the district can meet the mercury discharge limits imposed by the state in 2001.<sup>24,25</sup> These devices reduce but do not eliminate mercury releases.
- Worldwide, global mercury emissions from human cremation are estimated at 1 to 12 metric tons per year, or about 2% of total emissions to air, and are expected to increase.<sup>26</sup>
- According to a 2007 analysis, estimated environmental mercury releases associated with dental amalgam are disproportionately high compared to those for other mercury end-products, as shown in Table A-3 (p. 15).

Both the World Health Organization and the United Nations Environmental Programme advocate a phase-down of mercury uses including dental amalgam on environmental grounds.<sup>27,28</sup>

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<http://www.ebmud.com/environment/pollution-prevention/dental-mercury-faqs>. (citing Arenholt-Binslev, 1992).

<sup>23</sup> National Association of Clean Water Agencies. Mercury source control and pollution prevention program evaluation - Final report [Internet]. [cited 2013 Mar 19]. Available from: [http://www.nacwa.org/index.php?option=com\\_content&view=article&id=366%3Amercury-source-control-and-pollution-prevention-program-evaluation-final-report&catid=10%3Awater-quality&Itemid=2](http://www.nacwa.org/index.php?option=com_content&view=article&id=366%3Amercury-source-control-and-pollution-prevention-program-evaluation-final-report&catid=10%3Awater-quality&Itemid=2)

<sup>24</sup> EBMUD, *op cit*.

<sup>25</sup> Phone conversation, March 14, 2013, Deirdre Mena, EBMUD, 510-287-1559: Different styles of separators are available. Some are settling tanks that require off-hauling of hazardous sludge. Others are returnable cartridges. The separator mandate in 2002 generated some pushback from dentists because of the cost, but the separators appear to keep the dental vacuum pumps cleaner, requiring less service, so the objections seem to be gone. Dentists probably do maintain their separators because this would keep their total costs down. Since 2002, EBMUD has observed both a reduction in mercury discharges to the bay and a reduction in mercury concentrations in their biosolids waste sludge.

<sup>26</sup> UNEP 2013, *op cit*, p. 9.

<sup>27</sup> Petersen PE, Baez R, Kwan S, Ogawa H. Future use of materials for dental restoration [Internet]. World Health Organization; 2009. Available from: [http://www.who.int/oral\\_health/publications/dental\\_material\\_2011.pdf](http://www.who.int/oral_health/publications/dental_material_2011.pdf)

<sup>28</sup> UNEP 2013, *op cit*.

Several countries have banned or restricted dental amalgam on the basis of both health and environment.<sup>29</sup> In the US, some cities have passed ordinances aimed at discouraging amalgam use.<sup>30</sup>

### 3. Health science: New evidence validates old concerns

Dental amalgam was once believed to be inert but is now recognized to release low levels of elemental mercury vapor.<sup>31</sup> The current scientific debate is about how much is released, what levels are considered harmful, and whether this threshold varies among subpopulations.<sup>32</sup> (See Appendix C: Health science, p. 19.)

Biochemical theory and lab science have long raised concerns about mercury exposure from dental amalgams. For example, studies of cell

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<sup>29</sup> In 2008 the governments of Norway, Sweden, and Denmark banned amalgam. Source: Dental Mercury Use Banned in Norway, Sweden and Denmark because Composites are Adequate Replacements," Reuters/PRNewswire-USNewswire Online. January 3, 2008. Available from: <http://www.reuters.com/article/idUS108558+03-Jan-2008+PRN20080103> (In some cases the bans allow dentist to apply in writing for special exceptions.)

The German government and several associations issued a consensus statement that amalgams should not be placed in pregnant women or children. Source: Working Group on Dental Amalgam for the United States Department of Health and Human Services. Dental Amalgam and Restorative Materials: An Update Report to the Environmental Health Policy Committee. (Washington, D.C.: update report, October 1997), 4-6. Available from: <http://web.health.gov/environment/amalgam2/contents.html>.

The Canadian government has stated that amalgams should not be placed in pregnant women or children. Source: Health Canada. The Safety of Dental Amalgam. 1996. Available from: [http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/hpfb-dgpsa/pdf/md-im/dent\\_amalgam-eng.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/dent_amalgam-eng.pdf)

<sup>30</sup> Local ordinances discouraging amalgam use have been passed by the US cities of:

Philadelphia, Pennsylvania  
<http://legislation.phila.gov/attachments/4696.pdf>

Costa Mesa, California  
<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/DentalProductsPanel/UCM236365.pdf>

and Malibu, California.

<http://www.malibucity.org/download/index.cfm/fuseaction/download/cid/17571/>

<sup>31</sup> US FDA. About dental amalgam fillings, *op cit*.

<sup>32</sup> Berlin, 2007, *op cit*.

cultures show clear effects on neuron growth at mercury concentrations equivalent to those found in neonatal infants of amalgam-bearing mothers with no other known exposures.<sup>33</sup>

On the other hand, epidemiological studies (studies on human populations outside the controlled lab environment) have often failed to find associations between amalgam and health effects.<sup>34</sup> Yet epidemiology is inherently rough due to confounders, biases, and measurement errors,<sup>35,36</sup> so few conclusions can be drawn.<sup>37</sup>

### Children's Amalgam Trials

In 2006, the first high-quality epidemiological studies on amalgam, known as the Children's Amalgam Trials – a pair of prospective, randomized, controlled, clinical trials, one in New England and one in Portugal – found no association between amalgam and health effects. But recent, more refined analyses of the high-quality Portugal dataset now reveal several types of harm. (See Appendix C: Health science; Children's Amalgam Trials, p. 20.)

The weight of scientific evidence now indicates that amalgam poses a clear risk to developing fetuses and children and to people with common genetic susceptibilities. In addition, for the general population, amalgam appears to add to one's cumulative body burden, posing a long-term risk of unknown scope.

### The analogy of lead poisoning

Toxic-lead researcher Herbert Needleman has warned that the trajectory of mercury science and regulation may evolve to resemble that of lead, in which chronic, low-level effects were neglected for decades, during which the population was widely exposed. Eventually, improved research involving larger sample sizes, more sensitive outcome measures, and better statistical techniques allowed detection of subtle but

serious harm at low levels.<sup>38</sup> However, regulation was delayed while industry claimed insufficient proof of harm, and in the meantime much damage was done.<sup>39</sup>

## 4. Math: Scary numbers

For the general population, most exposure to mercury derives from dental amalgams and dietary fish.<sup>40</sup> Although these forms of mercury are different, the toxicities are similar (see footnote 15).

These two sources can yield similar levels of exposure, as follows. Dental amalgam provides about 1 to 20 or more micrograms of mercury per day, with most people incurring less than 5 micrograms. (See Appendix D: Exposures exceed safety standards, p. 23)

A small serving of high-mercury fish could yield 85 micrograms of mercury.<sup>41</sup> (See Appendix B: Fish mercury, p. 17.) People with a high intake of predatory fish can and do develop mercury poisoning.<sup>42</sup> The FDA, EPA, and state and local authorities issue advisories to guide public consumption of fish (see footnote 6).

Can people with amalgams develop mercury poisoning? Based on the EPA standard and on mainstream estimates of exposure, healthy adults may safely tolerate up to about three amalgam-filled teeth. And based on the California Environmental Protection Agency (CalEPA) standard, little or no amalgam is safe. (See Appendix D: Exposures exceed safety standards, p. 23.)

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<sup>33</sup> *Ibid.*

<sup>34</sup> Mutter J, Naumann J, Sadaghiani C, Walach H, Drasch G. Amalgam studies: disregarding basic principles of mercury toxicity. *Int J Hyg Environ Health*. 2004 Sep;207(4):391–7.

<sup>35</sup> Taubes G. Epidemiology faces its limits. *Science*. 1995 Jul 14;269(5221):164–9.

<sup>36</sup> Budtz-Jørgensen E, Keiding N, Grandjean P. Effects of exposure imprecision on estimation of the benchmark dose. *Risk Anal*. 2004 Dec;24(6):1689–96.

<sup>37</sup> Mutter, 2004, *op cit.*

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<sup>38</sup> Needleman HL. Mercury in dental amalgam--a neurotoxic risk? *JAMA*. 2006;295(15):1835–1836.

<sup>39</sup> Kovarik W. Ethyl-leaded gasoline: how a classic occupational disease became an international public health disaster. *Int J Occup Environ Health*. 2005 Dec;11(4):384–97.

<sup>40</sup> IPCS (WHO), 2003, *op cit.*, p. 10.

<sup>41</sup> Assuming a 3 ounce serving (85 grams) at 1.0 parts per million mercury (the FDA "Action Level").

<sup>42</sup> Hightower JM, Moore D. Mercury levels in high-end consumers of fish. *Environ. Health Perspect*. 2003 Apr;111(4):604–8.



## 5. FDA regulation of dental amalgam

Due to historical circumstances, dental amalgam has never undergone the regulatory proof-of-safety testing required for other medical implants.<sup>43</sup> The FDA claims that amalgam is safe and effective despite concerns expressed by its science advisory panels, described below.

The current chapter in amalgam regulation began in 2002 when the FDA issued a proposed amalgam rule.<sup>44</sup> Four years later, in 2006, the agency issued a criteria document known as the draft “White Paper,” concluding that amalgam is safe.<sup>45</sup> The agency then convened a science advisory panel of dentists and scientists to review its findings.

### FDA’s 2006 science advisory panel hearing

At the 2006 hearing on dental amalgam, the FDA’s science advisory panel was asked to judge the merits of the FDA’s draft “White Paper” and its conclusions. To the question whether the White Paper “objectively and clearly presented the current state of knowledge about the exposure and health effects related to dental amalgam,” the panel voted “no” by a 13-7 margin. To the question of whether the White Paper’s conclusions were “reasonable,” the panel also voted “no” by the same 13-7 margin.<sup>46</sup>

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<sup>43</sup> Under the 1976 Amendments to the federal Food, Drug, and Cosmetics Act, Congress directed the FDA to assess the safety of medical and dental devices, and to require premarket approval of safety for any device that “is intended to be implanted in the human body”. (See 1976 Medical Device Amendments, p. 27.)

<sup>44</sup> US Food and Drug Administration. Dental devices: Classification of encapsulated amalgam alloy and dental mercury and reclassification of dental mercury; issuance of special controls for amalgam alloy. Federal Register. 2002 Feb 20;67(34):7620. Available from: <http://www.gpo.gov/fdsys/pkg/FR-2002-02-20/pdf/02-4028.pdf>

<sup>45</sup> US Food and Drug Administration. Update/review of potential adverse health risks associated with exposure to mercury in dental amalgam (Draft “White Paper”). 2006 August. Available from: <http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4218b1-01-white-paper-draft.pdf>

<sup>46</sup> According to the 2006 meeting summary, “Those voting no expressed concern that the paper contained too many research gaps and implied a safety that was not really known. Those voting yes recognized deficiencies but felt the conclusions were reasonable for the available data.”

US Food and Drug Administration. Summary minutes: Joint meeting of the dental products panel and peripheral and central nervous system drugs advisory committee. Gaithersburg, MD; Sep 7, 2006.

In response, in 2009 the FDA issued an Addendum to its White Paper,<sup>47</sup> providing additional justification for its proposed amalgam rule, but the agency did not seek additional input from its science advisory panel.

Meanwhile, in 2008, a public-interest group sued the FDA over several issues related to amalgam regulation. In court, the federal judge declined to address the substance of the FDA’s proposed rule but chastised the FDA for its 30-year delay in classifying amalgam, calling it “government at its worst.”<sup>48</sup> The FDA settled the lawsuit, agreeing to post a warning about amalgam on its website and to issue its final rule within a year.

### FDA’s 2009 Final Rule

In 2009 the FDA issued a “Final Rule,” once again reiterating the safety of amalgam. (See Appendix E: FDA regulation of amalgam; FDA’s 2009 Final Rule, p. 26.)

Several groups then petitioned the FDA to reconsider its Final Rule. (Under the federal Administrative Procedures Act, plaintiffs must exhaust all administrative remedies before suing an agency in court.)

### FDA’s 2010 science advisory panel hearing

In 2010, in response to four legal petitions for reconsideration, the FDA convened another science advisory panel and held a public hearing. This time, the FDA did not ask the panel to judge its rule or its underlying analysis, but instead pursued a series of narrow, technical questions. Nonetheless, several panel members offered unsolicited comments that amalgam should be banned for pregnant women and children. The gist of the panel’s findings was that there is an absence of scientific data to support the FDA’s conclusion that amalgam is safe.<sup>49</sup> Specific

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Available from: <http://www.fda.gov/ohrms/dockets/ac/06/minutes/2006-4218m2.pdf>.

<sup>47</sup> US Food and Drug Administration. Addendum review in response to advisory panel comments and recommendations (Addendum to White Paper). July 2009. Available from: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/ucm171117.htm>

<sup>48</sup> Moms Against Mercury *et al.* vs. Von Eschenbach *et al.*. United States District Court for the District of Columbia. May 16, 2008, transcript p. 36. Available from: <http://mpp.cclearn.org/wp-content/uploads/2008/08/transcript051508momsvfda.pdf>

<sup>49</sup> US Food and Drug Administration. 24-hour summary: Dental Products Panel, Medical Devices Advisory Committee, Center for Devices and Radiological Health. Gaithersburg, MD; Dec 15, 2010.

concerns of the panel included: the use of average exposures instead of a distribution of a range of exposures; the lack of data on human developmental effects in the face of *in vitro* and animal evidence of harm; the limitations of using urinary mercury levels within studies; the lack of data on bioaccumulation and clearance; the need to consider sensitive subpopulations; and the lack of data on the role of mercury in neurodegenerative diseases.<sup>50</sup>

Following this 2010 hearing, the FDA agreed to review its amalgam rule with attention to the current science.<sup>51</sup> The FDA has made no further comment, aside from acknowledging that it is actively reviewing its rule,<sup>52</sup> though this is not apparent on its website.

## 6. Precautionary principle

Prevention has always been a cornerstone of public health. Yet within the past decade the precautionary principle has emerged as a global force despite its apparent redundancy.<sup>53</sup>

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Available from:

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/DentalProductsPanel/UCM237211.pdf>

US Food and Drug Administration. Meeting transcript, Dental Products Panel, Medical Devices Advisory Committee, Center for Devices and Radiological Health [Internet]. Gaithersburg, MD; Dec 15, 2010. Available from:

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/DentalProductsPanel/UCM242363.pdf>

For the IAOMT summary of the hearing, and the FDA acknowledgement of its accuracy, see footnotes 190 and 191.

<sup>50</sup> *Ibid.*

<sup>51</sup> U.S. Geological Survey. 2011 Minerals yearbook: Mercury [Advance release]. [Internet]. 2011, p. 48.1. Available from: <http://minerals.usgs.gov/minerals/pubs/commodity/mercury/myb1-2011-mercu.pdf>

<sup>52</sup> FDA CDRH director Jeffrey Shuren acknowledged that the agency was actively reviewing its amalgam rule and intended to announce its results by the end of 2011 — but it failed to do so.

YouTube of FDA's Town Hall meeting in San Francisco (start at about 3 minutes): [https://www.youtube.com/watch?v=H2t0J2\\_1yr0](https://www.youtube.com/watch?v=H2t0J2_1yr0)

According to a private news service covering the FDA, the agency completed its review, but its findings were blocked by the Health and Human Services Secretary who oversees the FDA.

FDA Webview. HHS did block CDRH decision on amalgam: Center staffer. Feb. 22, 2012. Available (\$) at: [www.fdaweb.com](http://www.fdaweb.com)

<sup>53</sup> Kriebel D, Tickner J, Epstein P, Lemons J, Levins R, Loechler EL, et al. The precautionary principle in environmental science. *Environ. Health Perspect.* 2001 Sep;109(9):871–6. Available from:

### Berkeley Precautionary Principle

Definition (excerpt):

*Where threats of serious or irreversible damage to people or nature exist, lack of full scientific certainty about cause and effect shall not be viewed as sufficient reason for the City to postpone measures to prevent the degradation of the environment or protect human health.*

Right to Know (a guiding tenet):

*The community has a right to know complete and accurate information on potential health and environmental impacts associated with the selection of products, services, operations or plans.*

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Berkeley Municipal Code Chapter 12.29. Available from:

[http://www.ci.berkeley.ca.us/uploadedFiles/Planning\\_and\\_Development/Level\\_3\\_-\\_Energy\\_and\\_Sustainable\\_Development/Precautionary%20Principle.pdf](http://www.ci.berkeley.ca.us/uploadedFiles/Planning_and_Development/Level_3_-_Energy_and_Sustainable_Development/Precautionary%20Principle.pdf)

Reasons include concerns that environmental problems appear to be outpacing society's ability to address them; that industry has an excessive influence on policy; that science and risk assessment can be manipulated when issues are complex; and that some modern risks may be catastrophic.<sup>54</sup>

The precautionary principle has several components.<sup>55,56</sup>

- taking preventive action in the face of uncertainty;
- shifting the burden of proof to the proponents of an activity;
- exploring a wide range of alternatives;
- responding proportionally in relation to margins of error; and
- increasing public participation in decision-making.

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<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1240435/pdf/ehp0109-000871.pdf>

<sup>54</sup> Goldstein BD, Carruth RS. Implications of the Precautionary Principle: is it a threat to science? *Int J Occup Med Environ Health.* 2004;17(1):153–61.

<sup>55</sup> Kriebel et al, 2001, *op cit.*

<sup>56</sup> Goldstein & Carruth, 2004, *op cit.*



Critics of the precautionary principle note that its application can be vague and inconsistent.<sup>57</sup> In addition, when policy is set based on incomplete information, it is inherently sub-optimal.<sup>58</sup>

Critics also claim that the precautionary principle may stifle innovation.<sup>59</sup> Indeed, there is a tension between precaution and the basic drive of economic competition. Yet the historic examples of asbestos, lead, silicosis, and vinyl chloride indicate that industry often prevails.<sup>60</sup>

Finally, critics note that proponents may appear antagonistic to science.<sup>61</sup> Yet common ground exists. Scientific findings can and should be the basis for public policy — provided their limitations and uncertainties are clearly explained and addressed.<sup>62</sup>

## 7. Current information for patients

A 2006 Zogby poll found that only 40% of Californians know that mercury is the primary component of dental amalgam.<sup>63</sup>

### FDA webpage on amalgam

The FDA's webpage, *About Dental Amalgam Fillings*, includes a section on potential risks. (See FDA's current webpage, p. 26.) The webpage discloses that dental amalgams release mercury vapor, but it cites outdated information and it downplays rather than elucidates the risks.

### State-mandated brochure

State law requires that a fact sheet written by the state Board of Dental Examiners be given one-time to each new patient.<sup>64</sup> An excerpt of the current (2004) brochure is shown in Appendix F:

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<sup>57</sup> *Ibid.*

<sup>58</sup> *Ibid.*

<sup>59</sup> *Ibid.*

<sup>60</sup> Rosner D, Markowitz G. Industry challenges to the principle of prevention in public health: the precautionary principle in historical perspective. *Public Health Rep.* 2002 Dec;117(6):501–12.

<sup>61</sup> Goldstein & Carruth, 2004, *op cit*.

<sup>62</sup> *Ibid.*

<sup>63</sup> 2006 Zogby poll <http://www.toxicteeth.org/zogby-poll--results-2006.aspx>

<sup>64</sup> California Business and Professions Code § 1648.10-1648.20

California dental materials fact sheet (p. 29). Its coverage of amalgam risks is misleading and out-of-date.

In addition, anecdotal reports indicate that most patients do not even receive this brochure.

Incidentally, the brochure was part of a 2001 scandal, in which the state enacted legislation dissolving its dental board to allow replacement with an entirely new board.<sup>65</sup> The legislature condemned the board's lengthy delays in developing a fact sheet to alert patients about the possible dangers of mercury in dental fillings.<sup>66</sup>

### Resistance to the brochure

At the 2012-2013 Berkeley commission proceedings, several dentists stated that they did not believe amalgam is a risk and that they did not believe it should require documented informed consent.<sup>67</sup> At least one commissioner noted that it would be difficult for dentists to provide patients with an informed-consent brochure that they did not believe. On the other hand, several patients reported receiving misinformation on amalgam risks in discussions with their dentists.

## 8. Alternative dental materials

Since the mid-1980s, three professional dental societies have advocated mercury-free dentistry.<sup>68</sup> According to these organizations, there is no situation in which a mercury filling is either necessary or superior to a non-mercury alternative.<sup>69</sup>

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<sup>65</sup> Sacramento Bee. Dental panel yanked. October 7, 2001.

<sup>66</sup> *Ibid.*

<sup>67</sup> Public comments at Berkeley commission hearings, December 6, 2012, January 8, 2013, and January 22, 2013.

<sup>68</sup> The International Academy of Oral Medicine and Toxicology (IAOMT website. <http://iaomt.org/>)

The International Academy of Biological Dentistry and Medicine (IABDM website. <http://iabdm.org/>)

The Holistic Dental Association (HDA website. <http://www.holisticdental.org/>)

<sup>69</sup> IAOMT 2012 Position Statement on Dental Amalgam. Available from: <https://dl.dropbox.com/u/91696587/IAOMT%20position%20statement%20on%20amalgam.pdf>

Synthetic resin (“composite”) fillings are considered more difficult to place, requiring more time and skill by the dentist. But when properly placed, composite fillings appear to be as durable as amalgam.<sup>70</sup> Although the retail price is higher than for amalgam (and exact costs vary by dentist), composites have lower total costs when societal and environmental externalities are considered.<sup>71,72</sup>

### **Bisphenol A**

Composite contains bisphenol A (BPA), a common component of epoxy resins and polycarbonates, found in many consumer products. BPA is under investigation as an endocrine disruptor. However, BPA exposures from composites appear to be less significant than exposures from canned goods and other consumer products.<sup>73</sup> A 2010 World Health Organization study found that most BPA exposure is derived from food packaging.<sup>74</sup> It found that “there was no need to collect additional data on BPA levels from dental materials, as exposure is short term and unlikely to contribute substantially to chronic exposure.”<sup>75</sup>

## **9. Political context**

### **United Nations Environment Programme**

In January 2013, over 140 nations agreed to a set of legally binding measures to curb mercury pollution, forged over the past four years by the United Nations Environment Programme.<sup>76</sup>

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<sup>70</sup> Heintze SD, Rousson V. Clinical effectiveness of direct class II restorations - a meta-analysis. *J Adhes Dent.* 2012 Aug;14(5):407–31.

<sup>71</sup> Concorde East-West. The real cost of dental mercury. Commissioned by a consortium of public-interest groups; 2012.

<sup>72</sup> Hylander LD, Goodsite ME. Environmental costs of mercury pollution. *Sci. Total Environ.* 2006 Sep 1;368(1):352–70.

<sup>73</sup> National Institute of Environmental Health Sciences. Bisphenol A (BPA) [Internet]. [cited 2013 Mar 26]. Available from: <http://www.niehs.nih.gov/health/topics/agents/sya-bpa/>

<sup>74</sup> World Health Organization. Background Paper on Sources and Occurrence of Bisphenol A Relevant for Exposure of Consumers [Internet]. Ottawa; 2010 Nov. Available from: [http://www.who.int/foodsafety/chem/chemicals/2\\_source\\_and\\_occurrence.pdf](http://www.who.int/foodsafety/chem/chemicals/2_source_and_occurrence.pdf)

<sup>75</sup> *Ibid.*

<sup>76</sup> UNEP Press release. January 19, 2013. Available from: <http://www.unep.org/newscentre/default.aspx?DocumentID=2702&ArticleID=9373>

Participants agreed to “phase down” the use of dental amalgam via a menu of strategies to discourage amalgam use and promote alternatives. The agreement still must be ratified by the participating governments and signed at a conference in October in Minamata, Japan.

### **American Dental Association**

Amalgam has been controversial since its origins in the mid-1800s. The American Dental Association was founded in 1859 by dentists who supported amalgam as the key to affordable dentistry, while the anti-amalgam dental society of the time disbanded due to loss of membership.<sup>77</sup>

According to the Wall Street Journal, the 157,000 member American Dental Association is “a heavy hitter on the Washington political scene.”<sup>78</sup> Revenues flow from its Seal of Acceptance program of product endorsements.

According to Jim Dickenson, editor of FDA Webview, a private news reporting service, “There is a hefty paper trail stretching back more than 30 years which could be used in lawsuits against dentists for covering up, with FDA help, the cause of debilitating illnesses induced by unnecessary exposure to mercury in the mouth.”<sup>79</sup> Dickinson explains the FDA’s multi-year delay in responding to the 2009 legal petitions and 2010 hearing as “Neither Democrats nor Republicans want dentists to be hurt on this issue.”<sup>80</sup>

### **International Academy of Oral Medicine and Toxicology**

The 700 member International Academy of Oral Medicine and Toxicology (IAOMT) was founded in 1984 to investigate the scientific evidence on the risks of dental mercury and to fund the research if necessary.<sup>81</sup> Its motto is “Show me

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<sup>77</sup> Hyson JM Jr. Amalgam: Its history and perils. *J Calif Dent Assoc.* 2006 Mar;34(3):215–29.

<sup>78</sup> Wall Street Journal. The health PAC to watch? Dentists. June 22, 2012. <http://online.wsj.com/article/SB10001424052702304441404577478723769027162.html>

<sup>79</sup> Dickinson J. Study: Dental amalgam isn’t cheaper after all. FDA Webview. May 31, 2012. Available from (\$): <http://www.fdaweb.com>

<sup>80</sup> *Ibid.*

<sup>81</sup> IAOMT webpage. <http://iaomt.org/about-us/iaomt-history-mission/>

the science.” It advocates mercury-free dentistry. Its stated mission is to “promote the health of the public at large,” by continually examining and compiling scientific research relating to dentistry.<sup>81</sup> In contrast, the ADA “fosters the success of a diverse membership and advances the oral health of the public.”<sup>82</sup>

The IAOMT leads the current legal challenge to the FDA’s amalgam rule.

### State gag rules

The use of ADA “ethical rules” have intimidated dentists from informing patients about the existence of mercury in dental fillings, and the risks of such fillings.<sup>83</sup> According to the ADA Code of Professional Conduct and Advisory Opinions,

*Based on current scientific data the ADA has determined that the removal of amalgam restorations from the non-allergic patient **for the alleged purpose of removing toxic substances from the body, when such treatment is performed solely at the recommendation of the dentist, is improper and unethical.***<sup>84</sup> [Emphasis added.]

The code is enforced by state dental boards. In the late 1990s the gag rules were defeated in several states<sup>85</sup> and are no longer considered a threat. Nonetheless, anecdotes of dentists being reprimanded and even losing their licenses for warning patients about amalgam risks appear to have had a powerful and lasting effect.

### Politics and scientific research

Anecdotes suggest that funding of amalgam studies may be subject to politics or other bias. (In the US, dental research is funded by the National Institute of Dental and Craniofacial Research, (NIDCR) a branch of the National Institutes of Health.) Retired mercury scientist Boyd Haley relates that after his research revealed that mercury causes pathologies

resembling Alzheimer’s, his funding was cut.<sup>86</sup> Haley contends that mercury researchers who find negative results are more likely to receive additional funding.

UC Berkeley professor Michael Bates told the Berkeley mercury subcommittee that he had received an anonymous comment from the NIDCR to the effect that his proposed study (for which funding was denied) was not worth doing.<sup>87</sup> Yet his proposed study was a follow-up to his notable 2004 study of 20,000 subjects, in which a slight association between amalgams and multiple sclerosis was found, and since this cohort was now ten years older, more associations could be expected to be found.

### Political theory and historical examples

Political theory describes the phenomenon of regulatory capture, in which agencies act on behalf of the industries they are supposed to regulate.<sup>88</sup> According to the conservative school known as public-choice theory, such behavior may be inevitable.<sup>89</sup>

The history of several key environmental health issues indicates that industry successfully employs multi-faceted public-relations campaigns to influence public ideas and opinions.<sup>90</sup> For example, industry often touts insufficient proof of harm. The amalgam myths and misinformation listed in Appendix G (p. 31) have consistently appeared in various amalgam proceedings, suggesting that they may be orchestrated.

## 10. Policy options

Regulation of mercury dental amalgam is best handled at the federal level. Yet the FDA appears to be in a long-term stall. (See footnote 52.) The optimal local policy will both prod

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<sup>82</sup> ADA webpage. <http://www.ada.org/missionandhistory.aspx>

<sup>83</sup> Duffy S. Testimony Before the Government Reform Committee, Wellness and Human Rights Subcommittee, May 8, 2003. <http://ftc.gov/os/comments/healthcarecomments2/030508duffy.pdf>

<sup>84</sup> ADA website: <http://www.ada.org/1383.aspx>, [http://www.ada.org/sections/about/pdfs/code\\_of\\_ethics\\_2012.pdf](http://www.ada.org/sections/about/pdfs/code_of_ethics_2012.pdf) “ADA Code of Professional Conduct and Advisory Opinions, section 5.A.1.

<sup>85</sup> In Arizona by the Goldwater Center; in Oregon by the American Civil Liberties Union; and in Florida and Minnesota by actions of states’ Attorneys General.

<sup>86</sup> Boyd Haley video (8 minutes). . NIH stops funding studies linking mercury to Alzheimer’s Disease.

<http://www.youtube.com/watch?v=8AQxklcXrt0>

<sup>87</sup> Michael Bates statement before Berkeley joint commission subcommittee on mercury, December 6, 2012.

<sup>88</sup> Laffont JJ, Tirole J. The politics of government decision-making: A theory of regulatory capture. Quarterly Journal of Economics. 1991 Nov;106(4):1089–127.

<sup>89</sup> Buchanan JM, Tullock G. The calculus of consent,. Ann Arbor: University of Michigan Press; 1962.

<sup>90</sup> Rosner, 2002, *op cit*.

federal authorities and provide stop-gap protection of public health.

### **Appeal to the FDA**

The city could appeal to the Health and Human Services Secretary as well as the FDA to complete the amalgam review, though this may be futile.

### **Join the legal proceeding**

The city could join the legal proceeding against the FDA to tighten amalgam regulation, led by the IAOMT.

### **Local ban**

A local ban of dental amalgam may be infeasible under state law, which prohibits local authorities from prohibiting any procedure that falls within the scope of practice of a licensed professional.<sup>91</sup> The law does allow local authorities to adopt reasonable health and safety requirements, and case law suggests that local authorities have broad authority to do so.<sup>92</sup>

### **State dental board**

The city could request the Dental Board of California to update the state-mandated fact sheet. But given the delays surrounding the 2004 release of the current fact sheet (described on p. 7), the board may be unable to respond adequately.

### **State legislature**

At present the state legislature appears to have little awareness of the issue, although in 2001 this body disbanded and replaced the stalled dental board, to compel it to issue its long-delayed fact sheet.

The legislature may need to be involved in eliminating any disincentives for amalgam use in Medi-Cal/Denti-Cal patients.

### **Signage**

The city could require signage in all dental offices, similar to that required under Proposition 65. For example:

*WARNING: This office may use dental amalgam in oral procedures. Dental amalgam*

<sup>91</sup> California Business and Professions code section 460. Available from: <http://law.onecle.com/california/business/460.html>

<sup>92</sup> Legal opinion from IAOMT attorney James Love to Berkeley officials. Available from: [https://dl.dropbox.com/u/91696587/Love\\_legal\\_opinion.pdf](https://dl.dropbox.com/u/91696587/Love_legal_opinion.pdf)

*has been widely used for over a century, but current science has not established the safety of this product. Dental amalgam releases low levels of mercury vapor. Mercury vapor is known to the State of California to cause reproductive harm.*

Mercury is listed as a reproductive toxin under Proposition 65, but this law does not apply to businesses with less than ten employees.

Signage inspection at dental offices could be coordinated with the inspections already conducted by the city Toxics Division.

### **City educational webpage**

A city webpage could clarify what is known and not known about the safety of dental amalgam, particularly given the evolving nature of the issue.

#### **Action by health commission**

As of February 2013, the Berkeley Community Health Commission (CHC) approved draft language to require documented informed consent each time a dentist places amalgam:

*Dental amalgam, which is approximately 50% mercury, continuously releases low levels of mercury vapor. Mercury is a neurotoxicant at low doses. Current science suggests that mercury from dental amalgams may pose a risk to the developing fetus, children, and to susceptible individuals. This statement is not intended to imply that other dental materials are without risk. These issues are currently under review by the U.S. Food and Drug Administration.*

### **Insurance incentives**

In negotiating the annual dental insurance contract for city employees, the city could prohibit any incentives for amalgam. This could also be encouraged or required for the city's major employers.



### **Informed consent**

Informed consent is a universal right with broad support.<sup>93</sup> Adding a city-mandated statement to the state-mandated fact sheet is hardly burdensome.

The informed-consent requirement should address any procedures involving amalgam, including placement, removal, and root canals.

### **Enforcement of informed consent**

If an informed-consent requirement does not address enforcement, it will not be enforced, as exemplified by both the state-mandated brochure and the Philadelphia informed-consent ordinance.<sup>94</sup>

Active enforcement is infeasible. Semi-passive enforcement could require a fine for dentists failing to show documented informed consent upon consumer complaint to the city. Passive enforcement could be attempted with language stating that failure to provide informed consent will be considered negligence, punishable by the full penalties allowable in court, although it is unclear whether a judge would find this sufficient proof of damages.

### **Proclamations and publicity**

Since one goal of local action is to prod federal authorities, proclamations that generate media attention are worthwhile.

- Evidence of amalgam safety is inadequate.
- Developing neurons are the most sensitive target for mercury, and these cells incur effects at levels consistent with exposure from maternal dental amalgams.
- Recent epidemiological findings validate long-standing concerns about risks to genetically susceptible subpopulations.
- Amalgam exposures appear to contribute to cumulative body-burden, the effects of which have not been evaluated.
- Mercury's insidious toxicity can escape detection until much damage has been done.

From a public policy perspective, these findings provide a basis for immediate action to protect public health and the environment.

## **11. Conclusion**

Industry claims that amalgam is safe. The weight of scientific evidence suggests only that it may be safe for some adults, in limited amounts, and for a limited number of years, provided the exposures during placement and removal are ignored. The FDA claims to be actively reviewing the safety of amalgam but has made no further announcement since 2010.

Policymakers have ample grounds on which to ban amalgam, particularly for pregnant women and children:

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<sup>93</sup> California Department of Consumer Affairs. Your right to informed consent. In: The Patient's Guide: Your Health Care Rights and Remedies. Available from: <http://www.calpatientguide.org/>

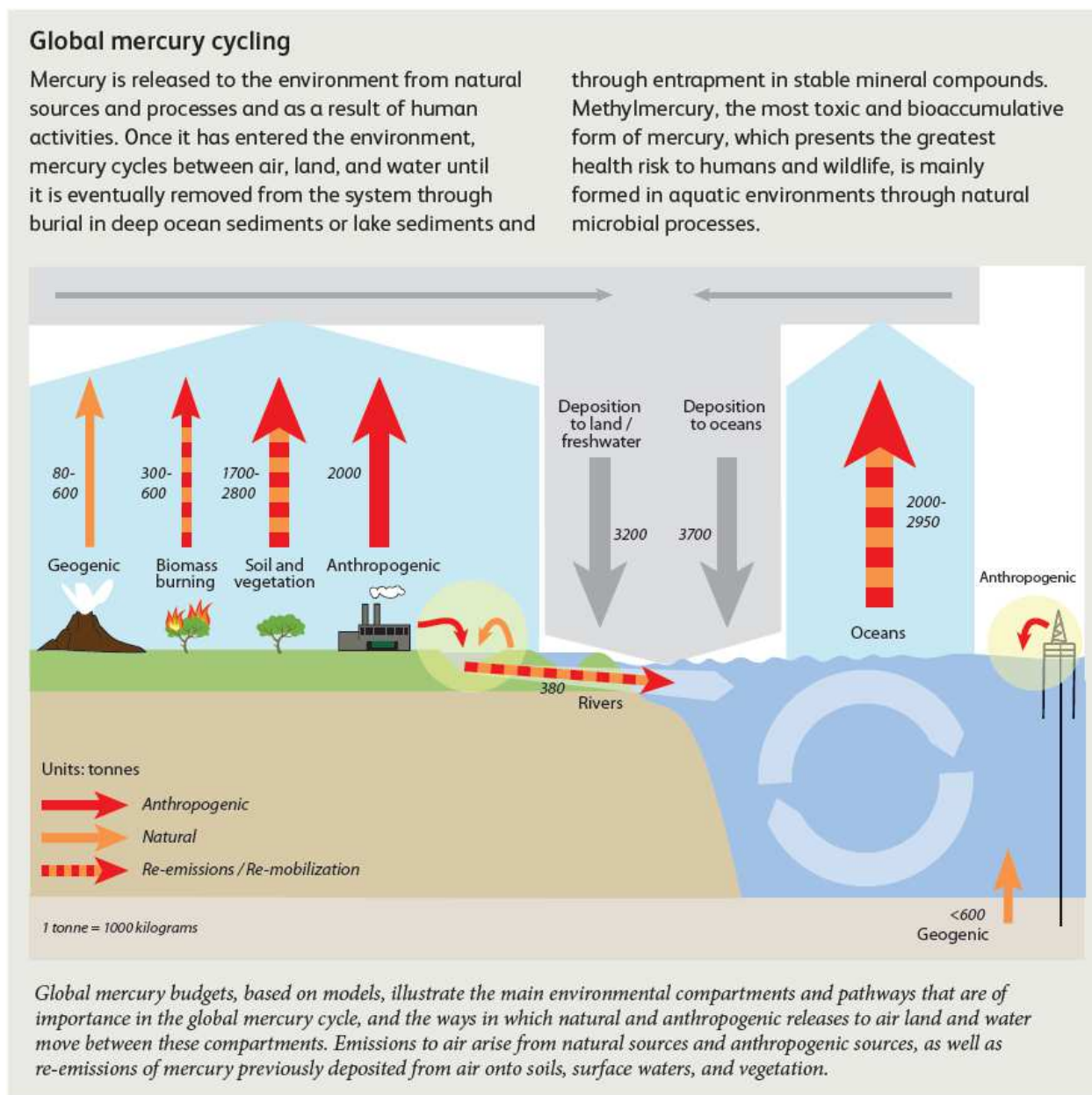
<sup>94</sup> Philadelphia informed consent ordinance available at <http://legislation.phila.gov/attachments/4696.pdf>





## Appendix A: Global mercury flows

Figure A-1: Global mercury cycling<sup>95</sup>



<sup>95</sup> United Nations Environment Programme. Global Mercury Assessment 2013: Sources, Emissions, Releases, and Environmental Transport [Internet]. Geneva: UNEP Chemicals Branch; 2013. Available from: <http://www.unep.org/PDF/PressReleases/GlobalMercuryAssessment2013.pdf>

## Global mercury flows

Much of the existing global mercury burden comes from remobilization of previous releases, as shown in Table A-1. Aquatic pollution is the end-point of concern, because mercury bioaccumulates in predatory fish.<sup>96</sup> The largest source of aquatic mercury is deposition from air.

According to the United Nations Environment Programme, the key to reducing mercury in the environment is to reduce the demand for mercury end-products as well as to reduce unintended emissions.<sup>97</sup> However, due to mercury's persistence, these reductions will not affect environmental levels significantly for many decades.<sup>98</sup>

**Table A-1: Global mercury flows, metric tons (2010)**

<b>To air: 5500 - 8900</b>		
<b>Natural (geogenic)</b> (about 10%)	80 - 600	
<b>Anthropogenic</b> (about 30%)	1960	anthropogenic breakdown:
small-scale gold mining		727
fossil-fuel combustion (98% due to coal)		484
mining and metal production		348 *
other industries (cement, chlor-alkali, oil refining)		217
consumer product waste		96 *
contaminated sites		83
cremation		4 *
total anthropogenic		1960
<b>Re-emissions</b> (about 60%)		
mobilized (recycled) from oceans	2000 - 2950	
mobilized (recycled) from biomass	2000 - 3400	
<b>To oceans: ~ 5300</b>		
<b>Natural (geogenic)</b>	< 600	
<b>Anthropogenic</b>	>1253	anthropogenic breakdown:
point sources		185 *
non-point sources		8 - 33
small-scale gold mining		> 800
mercury pesticides		no est
deforestation		260
total anthropogenic		> 1253
<b>Re-emissions</b>		
deposition from air	3700	
from rivers	380	
re-mobilized from sediments	100 - 800	
<b>To land: (large amount but less mobile than air/water emissions)</b>		
* may be amalgam-related		

Source: United Nations Environment Programme. Global Mercury Assessment 2013: Sources, Emissions, Releases, and Environmental Transport [Internet]. Geneva: UNEP Chemicals Branch; 2013. Available from: <http://www.unep.org/PDF/PressReleases/GlobalMercuryAssessment2013.pdf>

<sup>96</sup> UNEP 2013, *op cit*.

<sup>97</sup> *Ibid*.

<sup>98</sup> *Ibid*, p. 29. Mercury resides in the lower atmosphere for about a year, but it resides in the upper oceans for about thirty years and in the intermediate and deep oceans for centuries.

## Mercury in commerce

The amount of mercury in end-products may appear small (see Table A-2) relative to global mercury flows (see Table A-1). Nevertheless, demand for these end-products drives the mining portion of the unintended releases, which is the third largest source of anthropogenic emissions to air. In addition, mercury end-products release mercury throughout their life cycle in ways that are difficult to measure.<sup>99</sup>

The largest anthropogenic source of mercury releases to both air and water is small-scale gold mining. This activity is largely unregulated or illegal,<sup>100</sup> and the supply for this demand is believed to be diverted from industry and/or dentistry.

**Table A-2: Mercury in commerce. metric tons per year**

	<b>US (2002) (1)</b>	<b>Global (2005) (2)</b>	<b>Global (2010) (3)</b>
Production from mines	—	1800 - 2200	—
From stockpiles or recycling	—	1140 - 1660	—
Total supply	—	3000 - 3800	—
Total demand	190	3000 - 3900	—
Amalgam demand	30 (= 16% of total demand)	240 - 300 (= 8% of total demand)	340

(1) U.S. Geological Survey. Historical statistics for mineral and material commodities in the United States: Mercury [Internet]. 2005. Available from: <http://pubs.usgs.gov/ds/2005/140/>. As of March 2013, these are the most recent statistics available from the USGS.

(2) United Nations Environment Programme Chemicals. Summary of supply, trade and demand information on mercury [Internet]. Geneva; 2006 Nov, p. 4, 7. Available from: <http://www.unep.org/hazardoussubstances/Portals/9/Mercury/Documents/Publications/HgSupplyTradeDemandJM.pdf>

(3) United Nations Environment Programme. Global Mercury Assessment 2013: Sources, Emissions, Releases, and Environmental Transport [Internet]. Geneva: UNEP Chemicals Branch; 2013, p. 10. Available from: <http://www.unep.org/PDF/PressReleases/GlobalMercuryAssessment2013.pdf>

## Environmental emissions from amalgam

Although amalgam comprises only about 16% of mercury end-products in the US, it provides 28% of the environmental releases from end-products.

**Table A-3: US mercury emissions from mercury end-products, metric tons (2005)**

	to air	to water	to land	total
From amalgam	4.5	0.4	23.4	28.3
From all mercury-containing products	26.9	0.7	74.1	101.7
Amalgam share	17%	57%	32%	28%

Source: Cain A. Estimating mercury releases resulting from use of dental amalgam. Testimony before the domestic policy subcommittee of the oversight and governmental reform committee. May 26, 2010, citing: Cain A, Disch S, Twaroski C, Reindl J, Case CR. Substance Flow Analysis of Mercury Intentionally Used in Products in the United States. Journal of Industrial Ecology. 2007;11(3):61–75.

<sup>99</sup> Cain A, Disch S, Twaroski C, Reindl J, Case CR. Substance flow analysis of mercury intentionally used in products in the United States. Journal of Industrial Ecology 11(3). 2007.

<http://oversight.house.gov/wp-content/uploads/2012/01/20100526cain.pdf>

<sup>100</sup> UNEP 2013, op cit.





## Appendix B: Fish mercury

Fish contains methylmercury, a type of organic (carbon-containing) mercury. The toxicity of methylmercury is similar to that for elemental mercury vapor — both are lipophilic, thus travel easily throughout the body and readily cross cell membranes including the blood-brain barrier. Both oxidize into inorganic mercury ( $\text{Hg}^{2+}$ ), which is lipophobic and thus becomes trapped inside the cells.<sup>101</sup>

Fish mercury is found primarily in the muscle (protein).<sup>102</sup> Due to bioaccumulation up the food chain, the concentration of mercury in fish is one million to ten million times greater than that in surrounding waters.<sup>103</sup> Fish has one thousand to ten thousand times the mercury concentration found in other food sources.<sup>104</sup>

### Regulatory safety standards

The EPA sets a regulatory standard for mercury ingestion, and the FDA sets a standard for mercury contamination in commercial fish.

The EPA's standard for chronic methylmercury ingestion, called the reference dose, is  $1 \times 10^{-4}$  milligram per kilogram-body-weight per day<sup>105,106</sup> (or 0.1 microgram per kilogram-body-weight per day). Thus a 65 kg (143 pound) adult could consume up to 6.5 micrograms per day of fish mercury. A 48 kg (106 pound) adult could

consume up to 4.8 micrograms per day of fish mercury — which incidentally is the same level that the EPA calculates for tolerable chronic exposure to mercury vapor.<sup>107</sup>

The FDA's standard, called the Action Level, for methylmercury contamination in commercial fish, is 1 part per million (ppm).<sup>108</sup> Typical concentrations of mercury in fish range from less than 0.1 ppm for low-mercury fish to more than 1.0 ppm for high-mercury fish.<sup>109</sup> Consumption of low-mercury fish, at 0.1 ppm, would allow an intake of 65 grams of fish per day or 16 ounces of fish per week, equivalent to about three servings per week. But consumption of high-mercury fish, at 1.0 ppm, would allow an intake of only 6.5 grams of fish per day or 1.6 ounces per week, equivalent to only about one serving per month. In other words, many fish that are legally marketed, with no point-of-sale warnings, are reactively condemned, limiting safe consumption to about once per month.

Federal, state and local authorities issue fish advisories to guide public consumption, particularly for pregnant women, women who may become pregnant, nursing mothers, and young children. (See footnote 6.)

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<sup>101</sup> Berlin M, Zalups RK, Fowler BA. Mercury. In: Nordberg G, editor. Handbook on the toxicology of metals. Amsterdam; Boston: Academic Press; 2007.

<sup>102</sup> EPA Fact Sheet: Mercury Update: Impact on Fish Advisories. June 2001.  
[http://water.epa.gov/scitech/swguidance/fishshellfish/outreach/upload/2001\\_05\\_31\\_fish\\_advice\\_mercupd.pdf](http://water.epa.gov/scitech/swguidance/fishshellfish/outreach/upload/2001_05_31_fish_advice_mercupd.pdf)

<sup>103</sup> *Ibid.*

<sup>104</sup> *Ibid.*

<sup>105</sup> US Environmental Protection Agency Integrated Risk Information System. Methylmercury.  
<http://www.epa.gov/iris/subst/0073.htm>

<sup>106</sup> Regulatory safety standards are set based on studies of otherwise healthy workers who are exposed to mercury on the job, as follows. A lowest-observable-adverse-effects-level is identified, then Uncertainty Factors are applied in order to set a tolerable level of exposure for the general public, which includes less healthy members. The degree to which the workers are exposed to mercury from dental amalgams or dietary fish is unknown. Whether a person with many amalgams should reduce their consumption of fish, or whether a person with a high fish intake should avoid dental amalgams, is not addressed by the current process for setting these standards.

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<sup>107</sup> See Appendix D: Exposures exceed safety standards. The EPA standard of 0.3 micrograms per  $\text{m}^3$  is converted to a daily dose by multiplying by an inhalation rate (20  $\text{m}^3$  per day) and an absorption rate (80%), yielding 4.8 micrograms as a tolerable daily dose.

<sup>108</sup> FDA webpage: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed.  
<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ChemicalContaminantsandPesticides/ucm077969.htm#merc>

<sup>109</sup> US Food and Drug Administration webpage: Mercury Levels in Commercial Fish and Shellfish  
<http://www.epa.gov/iris/subst/0073.htm>



## Appendix C: Health science

### Lines of reasoning

#### 1. Biochemical theory raises cause for concern

Mercury is a neurotoxin at low doses. Its mechanisms of toxicity are unusually broad - it causes oxidative damage and sulfur blockage. Oxidative damage is equivalent to premature cellular aging. Sulfur is ubiquitous throughout the body, playing a key role in many biochemical reactions, thus mercury can disrupt key processes across many organ systems, depending on biochemical individuality and micronutrient status.<sup>110</sup> According to the testimony of metallobiologist Anne Summers at the 2010 FDA hearing on dental amalgam, "[T]here is almost no important system in the cell that is not hit by mercury."<sup>111</sup>

#### 2. Toxicology (lab science) confirms cause for concern

##### *Cell cultures*

The most sensitive target for mercury is the developing neuron.<sup>112</sup> Studies of cell cultures show clear effects on neuron growth at mercury concentrations equivalent to those found in neonatal infants of amalgam-bearing mothers with no other known exposures.<sup>113</sup>

##### *Lab animals*

Toxicology studies on lab animals including sheep and monkeys show that mercury from dental amalgams migrates quickly throughout the body, concentrating in organs including those of the fetus.<sup>114</sup>

Some mercury is eliminated in urine and feces, but evidence suggests that elimination slows with both exposure and aging as detoxification enzymes become impaired, yielding increasing retention and unpredictable toxicity.<sup>115</sup>

Co-exposures with other toxic metals may increase toxicity not just additively but exponentially.<sup>116</sup>

#### 3. Autopsy and biopsy studies provide limited, mixed evidence

High levels of mercury are found in brains and other organs of humans. Correlations are often but not always found between mercury concentrations in certain tissues (including certain regions of the brain) and the apparent number of amalgams — although many such studies suffer from imprecise dental histories. Finally, there is not always a close correlation between tissue burden and reported symptoms, although data are limited.

Interesting autopsy and biopsy findings include:

- Mercury levels in certain tissues of fetuses and young children correlated with maternal dental amalgams;<sup>117</sup>
- Patients with idiopathic dilated cardiomyopathy had mercury concentrations in heart tissue 10,000 times that of controls;<sup>118</sup> and

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<sup>110</sup> Berlin M, Zalups RK, Fowler BA. Mercury. In: Nordberg G, editor. Handbook on the toxicology of metals. Amsterdam; Boston: Academic Press; 2007.

<sup>111</sup> US Food and Drug Administration. Testimony of Anne Summers, 2010 meeting of the dental products panel [Internet]. Gaithersburg, MD; 2010 Dec 14. Available from: <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/DentalProductsPanel/UCM242357.pdf>

<sup>112</sup> Berlin 2007, *op cit*.

<sup>113</sup> *Ibid*.

<sup>114</sup> Lorscheider FL, Vimy MJ, Summers AO. Mercury exposure from "silver" tooth fillings: emerging evidence questions a traditional

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dental paradigm. FASEB J. [Internet]. 1995 Apr;9(7):504–8. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/7737458>

<sup>115</sup> Mutter J, Naumann J, Sadaghiani C, Walach H, Drasch G. Amalgam studies: disregarding basic principles of mercury toxicity. Int J Hyg Environ Health. 2004 Sep;207(4):391–7.

<sup>116</sup> Schubert J, Riley EJ, Tyler SA. Combined effects in toxicology--a rapid systematic testing procedure: cadmium, mercury, and lead. J Toxicol Environ Health. 1978 Nov;4(5-6):763–76.

<sup>117</sup> Drasch G, Schupp I, Höfl H, Reinke R, Roider G. Mercury burden of human fetal and infant tissues. Eur. J. Pediatr. 1994 Aug;153(8):607–10.

<sup>118</sup> Frustaci A, Magnavita N, Chimenti C, Caldarulo M, Sabbioni E, Pietra R, Cellini C, Possati GF, Maseri A. Marked elevation of myocardial trace elements in idiopathic dilated cardiomyopathy compared with secondary cardiac dysfunction. J Am Coll Cardiol. 1999 May;33(6):1578–83.

- Body burden in one subject persisted seventeen years after exposure and subsequent urinary clearing.<sup>119</sup>

#### 4. Epidemiology has given mixed results, but new, high-quality evidence counters the old notion that amalgam is safe

Epidemiology is the study of human populations in the real world, outside the controlled lab environment. In this complex and dynamic reality, it can be difficult to detect associations between a chronic, low-dose toxicant and myriad, non-specific health effects that may depend on genetic susceptibilities, nutritional status, and long time-frames. Exposure assessment is key, yet the absence of reliable exposure metrics or biomarkers causes bias toward the null, *i.e.*, underestimation of risk.<sup>120</sup> Proper exposure assessment would require quantifying years or decades of dental work and dietary fish intake for both the subject and the birth-mother. For practical reasons weak exposure proxies such as the current number of amalgams are used. In summary, proper epidemiological investigation of would require exposure metrics, time-frames, and numbers of subjects that are unrealistic. Most studies are a compromise, thus few conclusions can be drawn.<sup>121</sup>

The bulk of the amalgam epidemiology literature consists of small, retrospective, low-quality studies, that often find no association between amalgam and illness. Many of these studies use flawed measures of exposure, such as blood or urine levels as described below, thus few conclusions can be drawn.<sup>122</sup> One notable, large study of 20,000 New Zealand military personnel reviewed hospital admissions and dental records, and found a slight association between amalgam-surface-years and multiple sclerosis.<sup>123</sup>

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<sup>119</sup> Opitz H, Schweinsberg F, Grossmann T, Wendt-Gallitelli MF, Meyermann R. Demonstration of mercury in the human brain and other organs 17 years after metallic mercury exposure. *Clin Neuropathol*. 1996 May-Jun;15(3):139-44.

<sup>120</sup> Grandjean P, Budtz-Jørgensen E. Total imprecision of exposure biomarkers: implications for calculating exposure limits. *Am. J. Ind. Med*. 2007 Oct;50(10):712-9.

<sup>121</sup> Mutter, 2004, *op cit*.

<sup>122</sup> *Ibid*.

<sup>123</sup> Bates MN, Fawcett J, Garrett N, Cutress T, Kjellstrom T. Health effects of dental amalgam exposure: a retrospective cohort study. *Int J Epidemiol*. 2004 Aug;33(4):894-902.

#### Children's Amalgam Trials

Within epidemiology, the highest quality study is the prospective, randomized, controlled, clinical trial. Such a study had not been done until the Children's Amalgam Trials,<sup>124</sup> first published in 2006.<sup>125,126</sup> The original analyses showed no associations, but recent reanalyses have found harm.

A 2012 reanalysis by many from the original team of authors found significant neurobehavioral deficits associated with amalgam in boys with a common genetic variant called CPOX4.<sup>127,128</sup> The findings were remarkably consistent and significant across all types of neurobehavioral tests employed.<sup>129</sup>

These results are consistent with the emerging science on genetic susceptibilities, described below.

Another reanalysis found amalgam-associated biomarkers for kidney damage in the same genetically-susceptible subset of boys.<sup>130</sup> And

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<sup>124</sup> The New England trial followed 534 amalgam-free children who were randomly assigned to an amalgam group or a composite group, for five years. The Portugal trial followed 507 amalgam-free children who were also randomly assigned to one or the other group, for seven years. Neither was large enough or long enough to be sure of having adequate statistical power, but they are considered to be the best available.

<sup>125</sup> Bellinger DC, Trachtenberg F, Barregard L, Tavares M, Cernichiari E, Daniel D, et al. Neuropsychological and renal effects of dental amalgam in children: a randomized clinical trial. *JAMA*. 2006 Apr 19;295(15):1775-83.

<sup>126</sup> DeRouen TA, Martin MD, Leroux BG, Townes BD, Woods JS, Leitão J, et al. Neurobehavioral effects of dental amalgam in children: a randomized clinical trial. *JAMA*. 2006 Apr 19;295(15):1784-92.

<sup>127</sup> Woods JS, Heyer NJ, Echeverria D, Russo JE, Martin MD, Bernardo MF, et al. Modification of neurobehavioral effects of mercury by a genetic polymorphism of coproporphyrinogen oxidase in children. *Neurotoxicol Teratol*. 2012 Sep;34(5):513-21.

<sup>128</sup> Coproporphyrinogen oxidase (CPOX); the CPOX4 variant has a population frequency of 28% (Woods, et al, 2012).

<sup>129</sup> For the boys with the common genetic variant, of the 23 neurobehavioral tests employed, 11 tests revealed deficits associated with amalgam that were significant at  $p \leq .05$ , and 7 of those were significant at  $p \leq .01$ .

<sup>130</sup> Geier D, Carmody T, Kern J, King P, Geier M. A significant dose-dependent relationship between mercury exposure from dental amalgams and kidney integrity biomarkers: A further assessment of the Casa Pia children's dental amalgam trial. *Hum Exp Toxicol*. 2012 Aug 14;

another found elevated porphyrins<sup>131</sup> associated with amalgams, unrelated to genes.<sup>132</sup>

Scientifically, these findings support the hypothesis that amalgams contribute to a cumulative mercury body burden that may take decades to produce clinical effects. These findings also add to the evidence from recent studies in adults that supports a role for genes in mercury susceptibility.

### 5. Neglected observations and the streetlight effect

In the 1970s, the advent of synthetic resin (“composite”) dental materials allowed patients to have their existing amalgams replaced. A parade of mixed anecdotes resulted, suggesting that amalgams might cause illness in some but that removal is not necessarily a cure. This growing number of anecdotes has still not been systematically evaluated by any authority.<sup>133</sup>

According to the FDA, dental amalgam is a commonly used device with a low frequency of adverse events reported to the agency. In addition, the majority of these events have been anecdotal and lacking in specific detail, making it difficult for the agency to analyze.<sup>134</sup> Yet there is no evidence that the FDA has attempted to analyze these or any of the anecdotes of consumers testifying at its 2006 or 2010 hearings.<sup>135</sup>

The streetlight effect is a type of observational bias in which scientists study what is easiest to

see.<sup>136</sup> In the periphery of the proverbial streetlight, amalgam science may be overlooked.

## Implications

### Genetic susceptibilities may explain inconsistent findings on amalgam risk

In recent years, six common genetic variants have been identified that appear to convey increased susceptibility to mercury toxicity, including the ApoE4 allele implicated in Alzheimer's.<sup>137</sup> Because mercury attacks sulfur groups within proteins, which are coded by genes that vary among individuals, many more susceptibility genes are likely.<sup>138</sup>

A genetic component for mercury susceptibility could explain why some individuals seem unaffected by relative high exposures, while others claim to become ill from seemingly trivial doses. This could also explain why toxicology evidence gives cause for alarm, while until recently most epidemiological studies have found mixed results.

## Public policy versus science

Science – the pursuit of reliable knowledge – requires a high level of certainty. Science is by nature skeptical, deferring its conclusions until adequate certainty is achieved. Its statistical tools are meant to exclude false positives; false negatives can be corrected with time.<sup>139</sup> Thus, a

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<sup>131</sup> Porphyrins are biomarkers for metal-specific enzyme damage on the heme synthesis pathway. Woods JS. Altered porphyrin metabolism as a biomarker of mercury exposure and toxicity. *Can. J. Physiol. Pharmacol.* 1996 Feb;74(2):210–5.

<sup>132</sup> Geier DA, Carmody T, Kern JK, King PG, Geier MR. A significant relationship between mercury exposure from dental amalgams and urinary porphyrins: a further assessment of the Casa Pia children's dental amalgam trial. *Biometals.* 2011 Apr;24(2):215–24.

<sup>133</sup> Weiner JA, Nylander. Aspects on health risks of mercury from dental amalgams. In: Chang LW, editor. *Toxicology of metals*. Boca Raton: Lewis Publishers; 1996.

<sup>134</sup> US Food and Drug Administration. Dental Devices: Classification of Dental Amalgam, Reclassification of Dental Mercury, Designation of Special Controls for Dental Amalgam, Mercury, and Amalgam Alloy. Federal Register [Internet]. 2009 Aug 4;74(148):38686. Available from: <http://www.gpo.gov/fdsys/pkg/FR-2009-08-04/pdf/E9-18447.pdf>

<sup>135</sup> This author testified at the 2010 FDA hearing on dental amalgam along with dozens of other injured consumers, many of whom had also testified at the similar 2006 hearing.

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<sup>136</sup> Freedman D. Why scientific studies are so often wrong: The streetlight effect. *Discover Magazine* [Internet]. 2010 Aug. Available from: <http://discovermagazine.com/2010/jul-aug/29-why-scientific-studies-often-wrong-streetlight-effect#.UUtUxxfvjTQ>

<sup>137</sup> Genes with common variants that appear to convey increased susceptibility to mercury toxicity include: coproporphyrinogen oxidase (CPOX); brain-derived neurotrophic factor (BDNF); the serotonin transporter gene known as 5-HTT (5-hydroxy-tryptamine transporter); catechol O-methyltransferase (COMT); glutamyl-cysteine ligase (GCL); and apolipoprotein E (Apo E); the latter of which has been implicated in Alzheimer's. See Woods 2012 *op cit.*; and Mutter J. Is dental amalgam safe for humans? The opinion of the scientific committee of the European Commission. *J Occup Med Toxicol.* 2011;6(1):2.

<sup>138</sup> Berlin M, Zalups RK, Fowler BA. Mercury. In: Nordberg G, editor. *Handbook on the toxicology of metals*. Amsterdam; Boston: Academic Press; 2007.

<sup>139</sup> Scientists avoid making statistical Type I errors (errors of commission; *i.e.*, accepting spurious relationships as true), but don't mind making Type II errors (errors of omission; *i.e.*, dismissing true relationships as spurious). See: Needleman H. Current status of childhood lead exposure at low dose. In: Chang LW, ed. *Toxicology of metals*. Boca Raton: Lewis Publishers; 1996, p 412. (editorial comment at end of chapter)



large gray area exists in which suspected associations between risk and disease may be *more likely than not*, yet do not meet an adequately high level of scientific certainty.

Traditional scientific methods of conducting studies and communicating results may seem at odds with the precautionary principle and with optimal public policy.<sup>140</sup> Policy, unlike science, requires balancing risks and benefits amidst evolving uncertainties, and policymakers, unlike scientists, incur consequences for failing to act. But there is common ground in recognizing the value of reliable scientific knowledge, the limitations of scientific conclusions, and the uncertainties that may remain unaddressed by current science.<sup>141</sup>

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<sup>140</sup> Grandjean P. Non-precautionary aspects of toxicology. *Toxicol. Appl. Pharmacol.* 2005 Sep 1;207(2 Suppl):652–7.

<sup>141</sup> Kriebel D, Tickner J, Epstein P, Lemons J, Levins R, Loechler EL, et al. The precautionary principle in environmental science. *Environ. Health Perspect.* 2001 Sep;109(9):871–6. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1240435/pdf/ehp0109-000871.pdf>

## Appendix D: Exposures exceed safety standards

Many people incur unhealthy exposures to mercury vapor from their dental amalgams, based on a simple comparison of estimated exposures versus regulatory safety standards. See Table C-1 below.

### Exposures from amalgam

The World Health Organization estimates that typical mercury exposures from amalgams range from 1 to 27 micrograms per day (mcg/d), with the absorbed dose ranging from 1 to 22 mcg/d, and with most subjects incurring exposures of less than 5 mcg/d.<sup>142</sup> Considerable variation exists among individuals, with an upper range of approximately 100 mcg/d associated with gum-chewing and bruxism.<sup>143</sup> Exposure variables include the total amalgam surface-area, the physical and chemical composition of the amalgam, the mechanical stresses of chewing and bruxism, the proximity to other metals, and the oral conditions of temperature, pH, and negative air pressure.

The US Food and Drug Administration (FDA) assumes an exposure of 1 to 5 mcg/d in its current amalgam rule,<sup>144</sup> based on a 1999 Public Health Service report.<sup>145</sup> The amalgam rule does not address individuals with above-average exposures.

**Table C-1:** The mid to upper range of exposures to mercury vapor from amalgam exceeds many safety standards. The CalEPA standard appears to preclude amalgam fillings.

	micrograms of mercury per day	micrograms of mercury per cubic meter of air
<b>Exposures (chronic)</b>		
estimated chronic intake from amalgam for most people (FDA; ATSDR)	1 to 5	—
estimated range of chronic intake from amalgam (WHO; ATSDR)	1 to 22	—
high-end chronic intake from amalgam	~ 100	—
<b>Regulatory standards (chronic):</b>		
US EPA RfC for chronic mercury inhalation (1995)	4.9* (equivalent)	0.3
US ATSDR MRL for chronic mercury inhalation (1999) **	3.2* (equivalent)	0.2
Cal EPA chronic REL (2008)	0.5* (equivalent)	0.03
* assuming a ventilation rate of 16.2 m <sup>3</sup> per EPA.		
** not applicable for occupational settings covered by OSHA; the value is shown only for comparison.		

### Regulatory safety standards

The US Environmental Protection Agency (EPA) provides a Reference Exposure Level (REL) for chronic mercury inhalation, set in 1995, of 0.3 mcg/m<sup>3</sup>.<sup>146,147</sup> As shown in Table C-1, this can be converted to a tolerable daily exposure in units of mcg/d — and the value is virtually the

<sup>142</sup> International Programme on Chemical Safety. Elemental mercury and inorganic mercury compounds: human health aspects [Internet]. Geneva: World Health Organization, United Nations Environment Programme; 2003. Available from: <http://www.who.int/ipcs/publications/cicad/en/cicad50.pdf>

<sup>143</sup> Agency for Toxic Substances and Disease Registry. Toxicological profile for mercury [Internet]. Public Health Service, US Department of Health and Human Services; 1999. Available from: <http://www.atsdr.cdc.gov/toxprofiles/tp46.pdf>. Appendix A covers derivation of the Minimum Risk Level.

<sup>144</sup> US Food and Drug Administration. Dental Devices: Classification of Dental Amalgam, Reclassification of Dental Mercury, Designation of Special Controls for Dental Amalgam, Mercury, and Amalgam Alloy. Federal Register. 2009 Aug 4;4(148):38686. Available from: <http://www.gpo.gov/fdsys/pkg/FR-2009-08-04/pdf/E9-18447.pdf>

<sup>145</sup> Public Health Service. Dental amalgam: A scientific review and recommended public health service strategy for research, education and regulation [Internet]. Department of Health and Human Services; 1993. Available from: <http://web.health.gov/environment/amalgam1/ct.htm>

<sup>146</sup> US Environmental Protection Agency, Integrated risk information system -- Mercury, elemental: Reference concentration for chronic inhalation exposure (RfC) (1995) Available from: <http://www.epa.gov/iris/subst/0370.htm#revhis>

<sup>147</sup> The US EPA's chronic inhalation Reference Concentration (RfC) is an estimate of a continuous inhalation exposure concentration to people (including sensitive subgroups) that is likely to be without risk of deleterious effects during a lifetime. The chronic inhalation RfC for mercury vapor is based primarily on a 1983 occupational study with a Lowest Observable Adverse Effects Level of 25 mcg/m<sup>3</sup>, which was converted to a continuous exposure of 9 mcg/m<sup>3</sup>. An Uncertainty Factor of 30 was applied (10 to cover sensitive subpopulations and 3 to cover lack of data, particularly developmental and reproductive studies).

same as the FDA's assumption for typical amalgam exposure.

The FDA acknowledges that amalgam exposures are in the same range as the EPA standard, but notes that the standard was derived to be protective. Thus, the FDA argues that the average person is not harmed by amalgam even though anyone with more than an average exposure will effectively exceed the safety standard.

The FDA also claims that the levels of exposure from amalgams are well below levels actually known to cause adverse effects — even though these data are gleaned from occupational studies of healthy workers and are not intended to apply to the general population.

The US Agency for Toxic Substances and Disease Registry (ATSDR) provides a similar safety standard — the Minimal Risk Level (MRL) — of 0.2 mcg/m<sup>3</sup> (set in 1999).<sup>143,148</sup> However, the standard set in 2008 by the California Environmental Protection Agency (CalEPA) is 0.03 mcg/m<sup>3</sup><sup>149,150</sup> — ten-fold stricter than the US EPA standard. Indeed, a scientific debate exists regarding whether the EPA standard, which was set in 1995, is too lax.<sup>151</sup>

A 2011 analysis presents these comparisons and concludes that many Americans with amalgams incur mercury exposures in excess of the EPA standard, and most or all incur exposures in excess of the CalEPA standard.<sup>152</sup> (Under the CalEPA standard, almost no amount of amalgam is safe.)

Finally, several significant sources of dental mercury exposure have not yet been considered by regulatory agencies. Little published data exist on mercury vapor exposures to patient, dentist, and staff during amalgam removal — though they are known to be high. And particulate matter generated during amalgam removal, which is not addressed by mercury vapor measurements, appears to be the largest source by far of exposures for dentists and staff.<sup>153</sup>

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<sup>148</sup> The US ATSDR develops toxicological profiles for hazardous substances as well as health guidance levels known as Minimum Risk Levels -- estimates of the daily human exposure that is likely to be without appreciable risk of adverse noncancer health effects. The MRL for chronic mercury vapor inhalation is based on occupational studies showing a Lowest Observable Adverse Effects Level of 26 mcg/m<sup>3</sup>, then extrapolating to a continuous exposure and applying an Uncertainty Factor of 30 (10 for inter-individual variation and 3 for extrapolation from a Lowest Observable Effects Level to a No Observable Effects Level).

<sup>149</sup> The CalEPA Reference Exposure Level (REL) was derived using more recent occupations studies that yielded a similar Lowest Observable Adverse Effects Level of 25 mcg/m<sup>3</sup>, which was converted to a continuous concentration of 9 mcg/m<sup>3</sup>. But CalEPA used a larger Uncertainty Factor of 300 (10 to extrapolate from a Lowest Observable Effects Level to a No Observable Effects Level; √10 for inter-individual variability; and 10 for developmental susceptibilities), thus the CalEPA standard (unlike the EPA and ATSDR standards) explicitly consider developmental toxicities.

<sup>150</sup> California Environmental Protection Agency. Mercury reference exposure levels: Technical support document for noncancer RELs, Appendix D.1.F, Mercury. Office of Environmental Health Hazard Assessment; 2008. Available from: [http://oehha.ca.gov/air/hot\\_spots/2008/AppendixD1\\_final.pdf#page=214](http://oehha.ca.gov/air/hot_spots/2008/AppendixD1_final.pdf#page=214)

<sup>151</sup> Several members of the 2010 FDA science advisory panel thought that the uncertainty factors used by the EPA to set its standard may be too lenient.

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US Food and Drug Administration. Meeting transcript, Dental Products Panel, Medical Devices Advisory Committee, Center for Devices and Radiological Health, Gaithersburg MD [Internet]. Dec 15, 2010. Available from:

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/DentalProductsPanel/UCM242363.pdf>

IAOMT attorney James Love summarized the hearing in a letter to the FDA:

Love JM. Letter from IAOMT to FDA CDRH director Jeffrey Shuren summarizing the 2010 hearing. Jun 23, 2011. Available from:

<https://dl.dropbox.com/u/91696587/Love%2011-06-23%20Ltr%20to%20%20FDA.pdf>

FDA CDRH director Jeffrey Shuren responded, calling Love's summary "a detailed and accurate analysis of the record."

Shurne J. Letter from FDA CDRH director Jeffrey Shuren responding to IAOMT attorney James Love. Jul 29, 2011. Available from: <https://dl.dropbox.com/u/91696587/Shuren%2011-07029%20response.pdf>

<sup>152</sup> Richardson GM, Wilson R, Allard D, Purtill C, Douma S, Gravière J. Mercury exposure and risks from dental amalgam in the US population, post-2000. *Sci. Total Environ.* 2011 Sep 15;409(20):4257–68.

<sup>153</sup> Richardson GM. Inhalation of Mercury-Contaminated Particulate Matter by Dentists: An Overlooked Occupational Risk. *Human and Ecological Risk Assessment: An International Journal.* 2003;9(6):1519–31.

## Appendix E: FDA regulation of amalgam

Wide use of amalgam pre-dates the establishment of the US Food and Drug Administration (FDA). In 1976, the Medical Device Amendments to the federal Food, Drug, and Cosmetics Act brought amalgam under FDA authority.

### 1976 Medical Device Amendments

The 1976 Amendments directed the FDA to assess the safety of medical and dental devices.<sup>154</sup> As set forth below, Congress established three classes of devices: Class I is generally recognized as safe; Class II is of moderate risk; and Class III requires proof of safety from manufacturers.<sup>155</sup>

Congress mandated that devices should be classified as Class III (thus requiring premarket approval of safety) when insufficient information exists to provide reasonable assurance of safety. Yet the FDA has avoided classifying amalgam as Class III. The law states:

*(C) Class III, Premarket Approval.*— A device which because —

(i) it

*(I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and*

*(II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and*

(ii) [sic]

*(I) is purported or represented to be for a use in supporting or sustaining human life or for a*

*use which is of substantial importance in preventing impairment of human health, or*

*(II) presents a potential unreasonable risk of illness or injury,*

*is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.*<sup>156</sup> [Emphasis added.]

Further, Congress mandated that implants be categorically placed in Class III:

*(c) In the case of a device which has been referred under paragraph (1) to a panel, and which —*

*(i) is intended to be implanted in the human body or is purported or represented to be for a use in supporting or sustaining human life, and*

*(ii) [sic]*

*(I) has been introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or*

*(iii) is within a type of device which was so introduced or delivered before such date and is substantially equivalent to another device within that type,*

*such panel shall recommend to the Secretary that the device be classified in class III unless the panel determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. If a panel does not recommend that such a device be classified in class III, it shall in its recommendation to the Secretary for the classification of the device set forth the reasons for not recommending classification of the device in such class.*<sup>157</sup> [Emphasis added.]

Further, FDA rules implementing this law state:

*Although no device can be regulated adequately in Class I or Class II unless there are adequate data and information establishing its safety and effectiveness, a device for which there are such data and information may nevertheless require regulation in Class III because of the public health concerns posed by its use.*<sup>158</sup> [Emphasis added.]

<sup>154</sup> Wizemann T. Legislative History of the Medical Device Amendments of 1976. In: Public Health Effectiveness of the FDA 510(k) Clearance Process: Balancing Patient Safety and Innovation: Workshop Report. Washington, DC: National Academies Press. 2010.

[http://www.nap.edu/openbook.php?recaord\\_id=12960&page=3](http://www.nap.edu/openbook.php?recaord_id=12960&page=3)

<sup>155</sup> US Food and Drug Administration. Medical devices: Premarket approvals [Internet]. [cited 2013 Mar 24]. Available from: <http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/default.htm>

<sup>156</sup> 21 U.S.C. §§360a, et seq.

<sup>157</sup> 21 U.S.C. §§360c, et seq.

<sup>158</sup> 42 Federal Register 46030, [13 Sep 1977]



## FDA's 2009 Final Rule

The FDA's current position that amalgam is safe, was promulgated in its 2009 Final Rule:<sup>159</sup> The rule classifies both mercury and amalgam into Class II (moderate risk) and mandates labeling requirements on packaging provided to dentists but does not mandate information for patients. The rule acknowledges that amalgam releases mercury vapor but downplays this risk.

## FDA's current webpage

As part of the 2008 legal settlement, the FDA posted a warning about the neurotoxic risk from amalgam on its web site, noting that the agency would be reviewing the issue.<sup>160</sup> Following the release of its 2009 Final Rule, the FDA changed its website to its current iteration, which downplays the risk:<sup>161</sup>

*Dental amalgam contains elemental mercury. It releases low levels of mercury vapor that can be inhaled. High levels of mercury vapor exposure are associated with adverse effects in the brain and the kidneys.*

*FDA has reviewed the best available scientific evidence to determine whether the low levels of mercury vapor associated with dental amalgam fillings are a cause for concern. Based on this evidence, **FDA considers dental amalgam fillings safe for adults and children ages 6 and above.** The amount of mercury measured in the bodies of people with dental amalgam fillings is well below levels associated with adverse health effects. Even in adults and children ages 6 and above who have fifteen or more amalgam surfaces, mercury exposure due to dental amalgam fillings has been found to be far below the lowest levels associated with harm. Clinical studies in adults and children ages 6 and above have also found no link between dental amalgam fillings and health problems.*

*There is limited clinical information about the potential effects of dental amalgam fillings on pregnant women and their developing fetuses, and on children under the age of 6, including breastfed*

*infants. However, the estimated amount of mercury in breast milk attributable to dental amalgam is low and falls well below general levels for oral intake that the Environmental Protection Agency (EPA) considers safe. FDA concludes that the existing data support a finding that infants are not at risk for adverse health effects from the breast milk of women exposed to mercury vapor from dental amalgam. The estimated daily dose of mercury vapor in children under age 6 with dental amalgams is also expected to be at or below levels that the EPA and the Centers for Disease Control and Prevention (CDC) consider safe. Pregnant or nursing mothers and parents with young children should talk with their dentists if they have concerns about dental amalgam.*

*Some individuals have an allergy or sensitivity to mercury or the other components of dental amalgam (such as silver, copper, or tin). Dental amalgam might cause these individuals to develop oral lesions or other contact reactions. If you are allergic to any of the metals in dental amalgam, you should not get amalgam fillings. You can discuss other treatment options with your dentist. [Emphasis added.]*

### Comments on the FDA webpage:

The reader is assured that the FDA has reviewed the best evidence and has concluded that amalgam is safe for adults and children aged six and above. This language declines to address amalgam safety in fetuses and children below age six, advising patients to confer with their dentists. This presumes that individual practitioners can assess and convey the current and evolving science on risk despite conflicts with present and past practices.

The FDA's claim that "the amount of mercury measured in the bodies of people with dental amalgam fillings is well below levels associated with adverse health effects" is based on occupational studies of healthy adults.<sup>162</sup> This does not mean that such levels are safe for the general, uninformed population or for vulnerable subpopulations. In addition, these occupational studies measured obvious, clinical, observable harm and may not have detected subtle or subclinical harm. Finally, long-term effects may not have been captured by these studies.

Similarly, regarding the FDA's use of the US EPA standard to judge whether mercury levels in breast milk are harmful, this standard is ten-fold

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<sup>159</sup> US Food and Drug Administration. Dental Devices: Classification of Dental Amalgam, Reclassification of Dental Mercury, Designation of Special Controls for Dental Amalgam, Mercury, and Amalgam Alloy. Federal Register [Internet]. 2009 Aug 4;4(148):38686. Available from: <http://www.gpo.gov/fdsys/pkg/FR-2009-08-04/pdf/E9-18447.pdf>

<sup>160</sup> US FDA 2008 webpage on amalgam risk: [https://dl.dropbox.com/u/91696587/FDA\\_2008\\_website.pdf](https://dl.dropbox.com/u/91696587/FDA_2008_website.pdf)

<sup>161</sup> US Food and Drug Administration. About dental amalgam fillings [Internet]. 2012 [cited 2013 Mar 19]. Available from: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/ucm171094.htm>

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<sup>162</sup> US Environmental Protection Agency. Integrated risk information system -- Mercury, elemental: Reference concentration for chronic inhalation exposure (RfC) [Internet]. 1995. Available from: <http://www.epa.gov/iris/subst/0370.htm#revhis>



more lenient than the newer, CalEPA standard, which explicitly consider developmental toxicities. (See **Error! Reference source not found.**, p. 23.) In fact, the FDA's 2010 science advisory panel expressed concern that the EPA standard (set in 1995) may not be adequately health protective. (See footnote 151.)

The FDA's claim that "Clinical studies in adults and children ages 6 and above have also found no link between dental amalgam fillings and health problems," is *no longer true* since the Children's Amalgam Trial, to which this quote refers, has now found harm (see p. 20).

The FDA's claim that "The estimated daily dose of mercury vapor in children under age 6 with dental amalgams is also expected to be ... safe," makes no sense on several grounds. Developmental toxicities occur at levels far lower levels than for the adult toxicity levels studied;<sup>163</sup> the estimated daily dose varies widely such that many individuals exceed the regulatory safety standards;<sup>164</sup> and the FDA admits it has data only for populations aged six and older.<sup>165</sup>

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<sup>163</sup> Berlin M, Zalups RK, Fowler BA. Mercury. In: Nordberg G, editor. Handbook on the toxicology of metals. Amsterdam; Boston: Academic Press; 2007.

<sup>164</sup> See Appendix D: Exposures exceed safety standards, p. 23.

<sup>165</sup> FDA, 2009, *op cit*.



## Appendix F: California dental materials fact sheet

The following excerpt from *The Facts About Fillings*, issued in 2004 by the California Dental Board comprises page 3 within the 8-page, 5" x 8" brochure. (The controversy in issuing this brochure is described on p. 7.)

### Toxicity of Dental Materials

#### Dental Amalgam

Mercury in its elemental form is on the State of California's Proposition 65 list of chemicals known to the state to cause reproductive toxicity. Mercury may harm the developing brain of a child or fetus.

Dental amalgam is created by mixing elemental mercury (43-54%) and an alloy powder (46-57%) composed mainly of silver, tin, and copper. This has caused discussion about the risks of mercury in dental amalgam. Such mercury is emitted in minute amounts as vapor. Some concerns have been raised regarding possible toxicity. Scientific research continues on the safety of dental amalgam. According to the Centers for Disease Control and Prevention, there is scant evidence that the health of the vast majority of people with amalgam is compromised.

wording  
down-  
plays  
risk

The Food and Drug Administration (FDA) and other public health organizations have investigated the safety of amalgam used in dental fillings. The conclusion: no valid scientific evidence has shown that amalgams cause harm to patients with dental restorations, except in rare cases of allergy. The World Health Organization reached a similar conclusion stating, "Amalgam restorations are safe and cost effective."

out of date  
-- e.g.,  
Portugal  
Children's  
Amalgam  
Trial shows  
harm.

A diversity of opinions exists regarding the safety of dental amalgams. Questions have been raised about its safety in pregnant women, children, and diabetics. However, scientific evidence and research literature in peer-reviewed scientific journals suggest that otherwise healthy women, children, and diabetics are not at an increased risk from dental amalgams in their mouths. The FDA places no restrictions on the use of dental amalgam.

out of date  
-- the WHO  
reversed  
its position  
in 2005.

#### Composite Resin

Some Composite Resins include Crystalline Silica, which is on the State of California's Proposition 65 list of chemicals known to the state to cause cancer.

**It is always a good idea to discuss any dental treatment thoroughly with your dentist.**



## Appendix G: Myths and misinformation

The following myths and misinformation, presented by members of the California Dental Association at the 2012-2013 Berkeley mercury hearings, and the American Dental Association at the 2006 and 2010 FDA hearings, distract from the key issue that dental amalgam has never been proven safe and that from a public-policy perspective the current weight of evidence supports a ban.

Myths and misinformation:	Facts:
Dental amalgam is safe and effective. <sup>166</sup>	Mercury dental amalgam has never been proven safe — it has never undergone proof-of-safety testing required of other medical implants. (See 1976 Medical Device Amendments, p. 25.)
Many authorities claim that amalgam is safe and effective, as described in the 2008 American Dental Association document, <i>What Others Say</i> . <sup>167</sup>	A full rebuttal to this outdated information is available from Californians for Green Dentistry (2012), <i>What Others NOW Say: A Response to the ADA's "What Others Say."</i> <sup>168</sup>
The World Health Organization concluded in a 1997 consensus statement, "No controlled studies have been published demonstrating systemic adverse effects from amalgam restorations." <sup>169</sup>	In 2005, the World Health Organization stated, "Recent studies suggest that mercury may have no threshold below which some adverse effects do not occur." <sup>170</sup> In addition, as of 2011 and 2012, three reanalyses of a controlled study known as the Portugal Children's Amalgam Trial demonstrate clear adverse effects from amalgam. <sup>171</sup>
Use of the term "mercury dental amalgam" is inappropriate and amounts to unwarranted scaremongering. <sup>172,183</sup>	"Mercury" is an adjective that adds meaning to the phrase "dental amalgam," and is intended to counter the misleading term, "silver fillings."

<sup>166</sup> Lewis, Bill (California Dental Association). Letter to the Berkeley Community Environmental Advisory Commission, October 31, 2012. Available from: [http://www.cityofberkeley.info/uploadedFiles/Planning\\_and\\_Development/Level\\_3\\_-\\_Commissions/Commission\\_for\\_Community\\_Environmental\\_Advisory/2012-11-15\\_AGN\\_CEAC\\_Item%20V.%20I.pdf](http://www.cityofberkeley.info/uploadedFiles/Planning_and_Development/Level_3_-_Commissions/Commission_for_Community_Environmental_Advisory/2012-11-15_AGN_CEAC_Item%20V.%20I.pdf)

<sup>167</sup> American Dental Association. *What Others Say*. 2004. Available from: <http://www.ada.org/sections/publicResources/pdfs/others.pdf>

<sup>168</sup> Californians for Green Dentistry. Response to 'What Others Say'. 2012. Available from: [http://mercuryandmore.weebly.com/uploads/1/7/6/6/176627/response\\_to\\_ada\\_what\\_others\\_say\\_2008.pdf](http://mercuryandmore.weebly.com/uploads/1/7/6/6/176627/response_to_ada_what_others_say_2008.pdf)

<sup>169</sup> Lewis, Oct 2012, *op cit*.

<sup>170</sup> World Health Organization. Policy paper: Mercury in health care. 2005. Available from: [http://www.who.int/water\\_sanitation\\_health/medicalwaste/mercurypolpap230506.pdf](http://www.who.int/water_sanitation_health/medicalwaste/mercurypolpap230506.pdf)

<sup>171</sup> See Children's Amalgam Trials, p. 20.

<sup>172</sup> Lewis, Bill (California Dental Association). Letter to the Berkeley commissions, Jan. 30, 2013. Available from: [http://www.cityofberkeley.info/uploadedFiles/Planning\\_and\\_Development/Level\\_3\\_-\\_Commissions/Commission\\_for\\_Community\\_Environmental\\_Advisory/2013-01-30\\_AGN\\_CEAC\\_Item%20X.A.pdf](http://www.cityofberkeley.info/uploadedFiles/Planning_and_Development/Level_3_-_Commissions/Commission_for_Community_Environmental_Advisory/2013-01-30_AGN_CEAC_Item%20X.A.pdf)



Myths and misinformation:	Facts:
Dental amalgam is an inert alloy. <sup>173</sup>	Whether amalgam is an alloy or a solid emulsion is debated. Regardless, the FDA acknowledges that amalgam releases mercury vapor throughout the life of the filling. <sup>174</sup>
Dental amalgam is like salt, in which a toxic element becomes nontoxic when combined with another element. <sup>175</sup>	Unlike salt, amalgam emits toxic vapor.
Dental amalgam is like cake made with salmonella-containing eggs — the toxicity disappears from the final product. <sup>183</sup>	Unlike cake, amalgam if baked will kill the baker. <sup>176</sup>
Measurements of mercury vapor from amalgam cited by opponents use flawed technology. <sup>177</sup>	Estimates of mercury release from amalgams cited by the FDA use incremental urine studies that underestimate exposure by neglecting retained mercury. The best means of estimating mercury exposure from amalgam is part of the scientific debate that should be elucidated rather than dismissed.
It is impossible for a dental amalgam to release mercury vapor indefinitely. <sup>178</sup>	Mercury is continuously released from amalgam fillings. <sup>179,180</sup>
Amalgam opponents use junk science. They cite questionable studies as if they were fact. <sup>181,182</sup>	Junk science may be found on both sides of the issue, and it has no place in the discussion.

<sup>173</sup> Noblett, W. Craig (Berkeley endodontist). Letter to the Berkeley commissions. Stamped February 7, 2013. Available from: [http://www.cityofberkeley.info/uploadedFiles/Planning\\_and\\_Development/Level\\_3\\_-\\_Commissions/Commission\\_for\\_Community\\_Environmental\\_Advisory/2013-01-30\\_AGN.CEAC.Item%20X.B.pdf](http://www.cityofberkeley.info/uploadedFiles/Planning_and_Development/Level_3_-_Commissions/Commission_for_Community_Environmental_Advisory/2013-01-30_AGN.CEAC.Item%20X.B.pdf)

<sup>174</sup> US Food and Drug Administration. About dental amalgam fillings [Internet]. 2012 [cited 2013 Mar 19]. Available from: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/ucm171094.htm>

<sup>175</sup> Terlet, Ariana (California Dental Association). Statement to the Berkeley mercury subcommittee, November 15, 2012.

<sup>176</sup> In 1989 four adults died of acute mercury poisoning in Lincoln Park, Michigan, apparently due to heating dental amalgam in an attempt to recover the silver content. See: Zumdahl SS, Zumdahl SA. Chemistry: Media Enhanced Edition [Internet]. Cengage Learning; 2007, p. 975. Available from: [http://books.google.com/books?id=ldhYqXy37KIC&pg=PA975&lpg=PA975&dq=michigan+four+deaths+mercury+lincoln+park+1989&source=bl&ots=2\\_4KXiRcBV&sig=l4hC-qg5lyVlxpiS52v4guL5cVE&hl=en&sa=X&ei=741LUcuvAuOM2qXT24GoBQ&ved=0CEsQ6AEwBQ#v=onepage&q=michigan%20four%20deaths%20mercury%20lincoln%20park%201989&f=false](http://books.google.com/books?id=ldhYqXy37KIC&pg=PA975&lpg=PA975&dq=michigan+four+deaths+mercury+lincoln+park+1989&source=bl&ots=2_4KXiRcBV&sig=l4hC-qg5lyVlxpiS52v4guL5cVE&hl=en&sa=X&ei=741LUcuvAuOM2qXT24GoBQ&ved=0CEsQ6AEwBQ#v=onepage&q=michigan%20four%20deaths%20mercury%20lincoln%20park%201989&f=false)

<sup>177</sup> Noblett, 2013, *op cit*.

<sup>178</sup> *Ibid*.

<sup>179</sup> Health Canada. The safety of dental amalgam. 1996, p.4. Available from: [http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/hpfb-dgpsa/pdf/md-im/dent\\_amalgam-eng.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/dent_amalgam-eng.pdf)

<sup>180</sup> David Kennedy, DDS, spokesperson for the IAOMT demonstrates mercury off-gassing from a 25-year old filling. Available from: <http://www.youtube.com/watch?v=9ylnQ-TZoiA>

<sup>181</sup> Noblett, 2013, *op cit*.

<sup>182</sup> Lewis, 2013, *op cit*.

Myths and misinformation:	Facts:
The Children's Amalgam Trials provide evidence that amalgam is safe. The recent reanalyses are flawed. <sup>183,184</sup>	All epidemiological studies are flawed and must be weighed carefully. See rebuttal to Noblett letter. <sup>185</sup> Such potentially important findings from the reanalysis of the Children's Amalgam Trial should be viewed with curiosity and concern, rather with dismissal.
The 2011 Richardson study that concluded that adults can only tolerate up to three amalgam fillings is at best controversial. <sup>186</sup>	The Richardson study is a more detailed version of the simplified data presented in Appendix D: Exposures exceed safety standards (p. 23). Incidentally, the ADA has critiqued the Richardson paper, and Richardson has rebutted the critique. <sup>187</sup>
The 2010 FDA science advisory panel found that the FDA acted appropriately when it ruled in 2009 that dental amalgam is a safe and effective treatment option for the general population. <sup>188</sup>	According to the US Geologic Survey, "[I]n response to consumer petitions and letters, the FDA and an advisory panel decided to review the existing scientific evidence that resulted in the FDA's earlier pronouncement that dental fillings containing mercury do not cause harm to patients." <sup>189</sup> In addition, IAOMT attorney Jim Love wrote to the FDA's CDRH director, Jeffrey Shuren, objecting to the ADA's false spinning of the 2010 hearing, and providing IAOMT's interpretation of the hearing. <sup>190</sup> Dr. Shuren responded, thanking Love for his "detailed and accurate analysis". <sup>191</sup>
The state mandated brochure provides accurate and balanced information.	The brochure is misleading and out of date. (See Appendix F: California dental materials fact sheet, p. 29.)
Amalgam is hardly used anymore.	A 2011 study found that most posterior teeth needing restoration are filled with amalgam. <sup>192</sup>

<sup>183</sup> Noblett, 2013, *op cit*.

<sup>184</sup> Lewis, 2013, *op cit*.

<sup>185</sup> Homme, Kris. Critique of Noblett letter. March 2013 Available at: [https://dl.dropbox.com/u/91696587/Noblett\\_markup%202013-01-30\\_AGN.CEAC.Item%20X.B.pdf](https://dl.dropbox.com/u/91696587/Noblett_markup%202013-01-30_AGN.CEAC.Item%20X.B.pdf)

<sup>186</sup> Lewis, 2013, *op cit*.

<sup>187</sup> Richardson G Mark. Rebuttal to ADA critique, provided as Exhibit 3 of the June 23, 2011 letter from IAOMT attorney James Love to FDA CDRH director Jeffrey Shuren. Available from: <https://dl.dropbox.com/u/91696587/Richardson%20rebuttal%20in%20JML%20FDA%20Ltr.pdf>

<sup>188</sup> Lewis, 2012, *op cit*.

<sup>189</sup> USGS Minerals Yearbook, 2011, available at: <http://minerals.usgs.gov/minerals/pubs/commodity/mercury/myb1-2011-mercu.pdf>

<sup>190</sup> Love, James. Letter from IAOMT to FDA CDRH director Jeffrey Shuren. June 23, 2011. Available from: <https://dl.dropbox.com/u/91696587/Love%2011-06-23%20Ltr%20to%20%20FDA.pdf>

<sup>191</sup> Shuren, Jeffrey. Response letter to IAOMT. Stamped July 29, 2011. Available from: <https://dl.dropbox.com/u/91696587/Shuren%2011-07029%20response.pdf>

<sup>192</sup> Makhija SK, Gordan VV, Gilbert GH, et al. Practitioner, patient and carious lesion characteristics associated with type of restorative material: findings from The Dental Practice-Based Research Network. J Am Dent Assoc. 2011;142(6):622-632.  
<http://www.ncbi.nlm.nih.gov/pubmed?term=PMID%3A%20%20%20%202021628683>

Myths and misinformation:	Facts:
Patients prefer composites for aesthetic reasons.	While aesthetics may play a role, patients receive little reliable information on the health aspects of dental materials. According to the IAOMT, there is no situation in which an amalgam filling is either necessary or superior to a mercury-free alternative. <sup>193</sup>
In some situations, amalgam is the only viable option. <sup>194</sup>	The three mercury-free dental societies have many members who have practiced dentistry for decades without needing to use amalgam.
Composites are risky too. Why single-out amalgam?	Risk information for all materials should be provided to patients. The risks related to amalgam appear to have been inappropriately downplayed for too long.
This low-cost option is needed for poor people. <sup>195</sup>	Low-income patients are more likely to have exposures to other toxicants, so they are in greater need of protection from mercury. They certainly deserve full disclosure.
Dentists should not be asked to present something they don't believe.	This is precisely why the city needs to become involved.

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<sup>193</sup> IAOMT 2012 Position Statement on Dental Amalgam. Available from:  
<https://dl.dropbox.com/u/91696587/IAOMT%20position%20statement%20on%20amalgam.pdf>

<sup>194</sup> Lewis, 2013, *op cit*:

<sup>195</sup> *Ibid.*.

## Appendix H: Timeline

1800s	Amalgam allows low-cost dental restorations for the masses.
1859	American Dental Association founded.
<hr/>	
1920s-1930s	German chemist Alfred Stock writes extensively about amalgam toxicity but his warnings are subsumed by World War II.
<hr/>	
1970s-1980s	The availability of synthetic resin composite materials allows amalgam replacement, sparking the current round of the amalgam debate.
1976	Congress directs the FDA to evaluate all medical (and dental) devices and to classify them according to risk.
1996	Health Canada states that amalgam fillings should not be placed in or removed from pregnant women.
1997	The German government states that amalgam fillings should not be placed in or removed from pregnant women.
2002	FDA proposes its amalgam rule
2004	California Dental Board brochure discloses mercury content but downplays risk.
2005	World Health Organization reverses its position that amalgam is safe, instead advocating a phase-down and long-term ban.
2006	Two amalgam studies of the highest quality to date (prospective, randomized, controlled) called the Children's Amalgam Trials, find no association between amalgams and health effects.  An FDA science advisory panel on dental amalgam declines to validate the FDA's amalgam rule.
2004-2012	At least six genes are identified that convey increased susceptibility to mercury toxicity.
2008	Norway, Sweden, and Denmark ban amalgam.  The city of Philadelphia, PA, passes an ordinance requiring that an informational brochure be written by the city health department and provided to all dental patients.  The FDA settles a lawsuit, agreeing to issue a Final Rule on amalgam within a year.
2009	FDA reiterates the safety of amalgam in its 2009 Final Rule.
2010	The city of Costa Mesa, CA, passes a resolution requesting dentists to voluntarily refrain from using dental amalgam.  In response to several legal petitions challenging its Final Rule, the FDA convenes another science advisory panel, holds a public hearing, and agrees to review its amalgam rule with attention to current science.
2011	The city of Malibu, CA, passes a resolution supporting efforts to reduce mercury use and asking dentists to educate patients about alternatives to amalgam.  FDA CDRH director Jeffrey Shuren announces an intent to finish the amalgam review by year-end, but fails to do so.
2011-2012	Three reanalyses of the Portugal Children's Amalgam Trial find harm to children.





## Appendix I: Chronic mercury poisoning

Chronic mercury poisoning is described in the toxicology literature<sup>196,197,198</sup> but is not yet recognized by most physicians or institutions. Medical textbooks typically give the issue minimal coverage and fail to acknowledge that some individuals may incur harm from their dental amalgams.<sup>199</sup> Diagnostic criteria often require a finding of elevated blood or urine mercury levels,<sup>200</sup> even though these do not reflect body burden or symptoms.<sup>201</sup>

No reliable diagnostic test exists for chronic mercury poisoning.<sup>202</sup> Individuals with poor excretion and a high body burden may counterintuitively show low mercury levels in blood, urine, hair and nails due to impaired detoxification enzymes.<sup>203</sup>

The porphyrins panel can reveal the toxic footprint unique to many toxic metals including mercury, but since porphyrins are easily damaged,<sup>204</sup> the risk of false negatives is high.

Symptoms of chronic mercury poisoning are variable and nonspecific. In the early stages they may be intermittent.<sup>205</sup> The catch-all list of symptoms includes twitching, tremors, numbness, tingling, short-term memory deficits, poor concentration, vision problems, tinnitus,

hearing loss, mood disorders, headaches, muscle pains, sleep disorders, skin problems, reduced immunity, autoimmunity, fatigue, diarrhea, gingivitis, loose teeth, excessive salivation, thyroid and adrenal problems, food intolerances, chemical sensitivities, fatigue, and reduced work capacity.<sup>206,207</sup> The most specific symptom may be erethism – the mercury personality – a combination of shyness, irritability, emotional lability, and hypersensitivity to stimulation.

A 1977 review of clinical symptoms asserts that chronic mercury poisoning is often misdiagnosed due to its insidious onset of vague symptoms and to the unfamiliarity of the disease by members of the health professions.<sup>208</sup>

Not only is diagnosis difficult, but effective treatments are nonexistent. Even removal of the exposure can be problematic. Preliminary evidence suggests that transient exposures to patients and staff during amalgam removal may routinely exceed the regulatory ceiling of 100 mcg/m<sup>3</sup><sup>209</sup> set by the US Occupational Health and Safety Administration.<sup>210</sup>

While it may be difficult to prove that a case of illness is due to chronic mercury poisoning, it may also be difficult to prove that it is not, since the scope of known symptoms is so broad. Many developmental and neurodegenerative diseases appear to be multifactorial, involving some combination of genetic and environmental

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<sup>196</sup> Berlin M, Zalups RK, Fowler BA. Mercury. In: Nordberg G, editor. Handbook on the toxicology of metals. Amsterdam; Boston: Academic Press; 2007.

<sup>197</sup> Gerstner HB, Huff JE. Clinical toxicology of mercury. J Toxicol Environ Health. 1977 Jan;2(3):491–526.

<sup>198</sup> Trakhtenberg IM. Chronic effects of mercury on organisms. [Bethesda Md.]: U.S. Dept. of Health Education and Welfare Public Health Service National Institutes of Health; 1974.

<sup>199</sup> Fauci AS. Harrison's principles of internal medicine. 17th ed. New York, London: McGraw-Hill Medical; 2008.

<sup>200</sup> Goldman L, Sshafer AI. Cecil medicine. Philadelphia: Elsevier Saunders; 2011.

<sup>201</sup> Berlin, 2007, *op cit*.

<sup>202</sup> *Ibid*.

<sup>203</sup> Mutter J, Naumann J, Guethlin C. Comments on the article "The toxicology of mercury and its chemical compounds" by Clarkson and Magos (2006). Crit. Rev. Toxicol. 2007;37(6):537–49.

<sup>204</sup> Woods JM. Presentation on mercury and porphyrins. IAOMT conference. San Antonio. 2009. Available from: <http://www.youtube.com/watch?v=eW0kDV-jmF4>

<sup>205</sup> Trakhtenberg, 1974, *op cit*.

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<sup>206</sup> Agency for Toxic Substances and Disease Registry. Toxicological profile for mercury [Internet]. Public Health Service, US Department of Health and Human Services; 1999. Available from: <http://www.atsdr.cdc.gov/toxprofiles/tp46.pdf>

<sup>207</sup> Gerstner, 1977, *op cit*.

<sup>208</sup> *Ibid*.

<sup>209</sup> The Permissible Exposure Level (PEL) is a ceiling exposure level not to be exceeded at any time. Occupational Safety and Health Administration website. <http://www.osha.gov/SLTC/healthguidelines/mercuryvapor/recognition.html>

<sup>210</sup> Richardson GM. Inhalation of Mercury-Contaminated Participate Matter by Dentists: An Overlooked Occupational Risk. Human and Ecological Risk Assessment: An International Journal. 2003;9(6):1519–31.

factors.<sup>211</sup> Evidence suggests that mercury may play a significant role in such conditions. The diseases for which the evidence of a link appears strongest are Alzheimer's,<sup>212</sup> autism,<sup>213,214,215</sup> and Multiple Sclerosis.<sup>216,217,218</sup>

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<sup>211</sup> Sears ME, Genuis SJ. Environmental determinants of chronic disease and medical approaches: recognition, avoidance, supportive therapy, and detoxification. *J Environ Public Health*. 2012;2012:356798.

<sup>212</sup> Mutter J, Curth A, Naumann J, Deth R, Walach H. Does inorganic mercury play a role in Alzheimer's Disease? A systematic review and an integrated molecular mechanism. *J Alzheimers Dis*. 2010 Aug 30;

<sup>213</sup> Bernard S, Enayati A, Redwood L, Roger H, Binstock T. Autism: a novel form of mercury poisoning. *Med. Hypotheses*. 2001;56(4):462–471.

<sup>214</sup> Desoto MC, Hitlan RT. Blood levels of mercury are related to diagnosis of autism: a reanalysis of an important data set. *J. Child Neurol*. 2007;22(11):1308–1311.  
<http://www.ncbi.nlm.nih.gov/pubmed?term=18006963>

<sup>215</sup> Desoto MC, Hitlan RT. Sorting out the spinning of autism: heavy metals and the question of incidence. *Acta Neurobiol Exp (Wars)*. 2010;70(2):165–176.  
<http://www.ncbi.nlm.nih.gov/pubmed?term=20628440>

<sup>216</sup> Aminzadeh KK, Etminan M., Dental amalgam and multiple sclerosis: a systematic review and meta-analysis. *J Public Health Dent*. Winter;67(1):64-6. Review, 2007.

<sup>217</sup> Bangasi D, Ghadirian P, Ducic S, Morisset R, Ciccocioppo S, McMullen E, Krewski D. Dental amalgam and multiple sclerosis: A case-control study in Montreal, Canada *Int J Epidemiol*. 27:667–71, 1998.

<sup>218</sup> Bates MN, Fawcett J, Garrett N, Cutress T, Kjellstrom T. Health effects of dental amalgam exposure: a retrospective cohort study. *Int J Epidemiol*. 2004 Aug;33(4):894–902.