Comments of the American Dental Association Before
The Dental Products Panel of the Medical
Devices Advisory Committee
[Docket No. FDA–2010–N–0268][1]

December 2010

The American Dental Association ("ADA") is the world's largest and oldest dental association, representing more than 155,000 dentists nationwide. For nearly 150 years, the ADA has actively sought to promote the oral health of the public and promote the development of scientifically accurate information. The ADA submits these comments in support of the Food and Drug Administration's ("FDA" or "the Agency") existing rule on dental amalgam products and in response to the Federal Register notice regarding a hearing of the Dental Products Advisory Panel. We are well placed to comment on this topic.

A. The ADA Supports the 2009 FDA Ruling on Dental Amalgam

The ADA is pleased to have worked with the FDA in the past, and looks forward to doing so in the future. In fact, the ADA fully participated in the FDA proceedings which culminated just last year in the classification of encapsulated dental amalgam as a Class II device, a classification fully supported by the Association.

FDA's deliberations began more than seven years ago and involved review of hundreds of scientific studies relating to the safety of dental amalgam. After all those years of study and analysis, just last year the FDA concluded:

- "Dental amalgam has been demonstrated to be an effective restorative material that has benefits in terms of strength, marginal integrity, suitability for large occlusal surfaces, and durability."
- **"Clinical studies have not established a causal link between dental amalgam and adverse health effects in adults and children age six and older."**
- "In addition, two clinical trials in children aged six and older did not find neurological or renal injury associated with amalgam use."
- "FDA has found that scientific studies using the most reliable methods have shown that dental amalgam exposes adults to amounts of elemental mercury vapor below or approximately equivalent to the protective levels of exposure identified by ATSDR and EPA. Based on these findings and the clinical data, **FDA has concluded that exposures to mercury vapor from dental amalgam do not put individuals age six and older at risk for mercury-associated adverse health effects."**
- "FDA estimates that the estimated daily dose of mercury in *children under age six* with dental amalgams is lower than the estimated daily adult dose. **The exposures to children [under six] would therefore be lower than the protective levels of exposure identified by ATSDR and EPA."**
- "In addition, the estimated concentration of mercury in breast milk attributable to dental amalgam is an order of magnitude below the EPA protective reference dose for oral exposure to inorganic mercury. **FDA has concluded 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 vapors from dental amalgam.''**

Food and Drug Administration, HHS. Dental devices: classification of dental amalgam, reclassification of dental mercury, designation of special controls for dental amalgam, mercury, and amalgam alloy. Final rule. 74 Fed Reg. 38685-714, 38693-4 (emphasis added).

[1] Questions regarding these comments may be directed to Jerome Bowman, ADA Public Affairs Counsel at bowmanj@ada.org.

B. There Is No Scientific Reason To Revisit the 2009 FDA Ruling

These conclusions by the Agency resulted from a long and very thorough review of the scientific evidence on the safety and efficacy of dental amalgam. Since that decision, which confirmed that amalgam is both safe and effective, the ADA's Council on Scientific Affairs conducted an update of the literature review which the Association had previously filed with the FDA. We are submitting the results of that updated literature review. A copy is attached. The bottom line is that there has been no material development in the scientific literature since the FDA's decision just last year. That body of literature continues to support the Agency's 2009 decision.

The state of the science on the issue of the safety of dental amalgam is clear. The best scientific evidence continues to support the safety of dental amalgam. This evidence simply does not support a link between dental amalgam and systemic diseases or risks to pregnant women or developing fetuses. Nor does the evidence support the existence of "sensitive populations" at risk from dental amalgam.[2] And the message from the ADA is also clear: If substantial scientific evidence showed that dental amalgam posed a threat to the health of dental patients or any segment of that population, the ADA would advise dentists to stop using it. But the best and latest available scientific evidence continues to indicate that dental amalgam is safe. Now, the ADA urges the FDA advisory panel to reaffirm what is already well established and what was concluded by the Agency just last year: Dental amalgam is a safe restorative material.

C. Nothing in the NAS Report Warrants Departing from the 2009 FDA Ruling

One reason mentioned in the FDA's meeting notice for revisiting the issue of dental amalgam was the recent report on risk assessments issued by the National Academy of Sciences (NAS), entitled ''Science and Decisions: Advancing Risk Assessment.'' The ADA has reviewed that document and its application to FDA proceedings is far from clear. It expressly addresses the EPA's risk assessment process and makes recommendations with respect to that specific process. It does not address in any way how FDA does or should address risk assessment issues. Nor does it address the need to weigh both benefits and risks associated with a given material, drug or device.

The FDA, of course, needs to focus not just on risks but also on the benefits inherent in the continued availability of a drug or device. This does appear to be FDA's current practice. The evidence regarding the risks *and* benefits of dental amalgam is discussed later in these comments. In any case, nothing in the NAS document calls into question the outcome of seven or more years of work by the FDA leading up to its 2009 ruling.

D. FDA Must Focus on the Benefits of Dental Amalgam and the Costs of Any Restriction on the Availability of Dental Amalgam

While the scientific evidence regarding the safety of dental amalgam is well established, and has not changed since FDA's 2009 ruling, the Agency must do more than focus on the "risk" side of the equation. The use of dental amalgam has enormous health benefits as a restorative material. Or, to look at it another way, restrictive regulation of dental amalgam would itself have a very substantial health and safety, as well as monetary, cost associated with it.

Were FDA to require a warning or limit the use of amalgam, the ADA is concerned that it would hurt efforts to address the oral health needs of both individuals and the entire population. Individually, it would deprive some patients of the freedom to choose the optimal treatment for them. In others, especially young children and those with special needs, where it may not be possible to create the dry environment required for placement of alternative restorative materials, the elimination of amalgam as a treatment option could require the use of general anesthetics. This would also create an increased risk from the use of such general anesthetics. The clinical indications for use also make amalgam one of the most

[2] The ADA does recognize, of course, that a very small segment of the population may experience localized allergic reactions to dental amalgam.

important materials for underserved populations at high risk and with high disease rates. Restrictions on use would put a disparate burden on these populations from both a health and financial perspective.

Unwarranted FDA action will also affect the entire population. As is discussed below, elimination of dental amalgam as an option, even for limited groups, will have a profound effect on the nation's public health system because of the added cost of alternative treatments. FDA also needs to be aware of the "halo effect;" how a contraindication for one population would deter others from the same treatment. These problems highlight the importance of FDA acting only on sound scientific evidence, as it did in 2009.

A 2007 peer-reviewed study examined the impact of partial and full bans on the use of dental amalgam. Among the conclusions were:

- Without amalgam, the average price of restorations would go from $278 to $330 (an 18.7 percent increase);
- As the prices increased, they estimated there would be 15,444,021 fewer restorations each year;
- A ban on amalgam would increase the use of crowns and composite resins, both of which are more expensive;
- Even limiting the ban to children would mean an increase of $1.1 billion the first year and $13 billion over a 15-year period.

Beazoglou T, Eklund S, Heffley D, Meiers J, Brown LJ, Bailit H, Economic Impact of Regulating the Use of Amalgam Restorations, Public Health Reports 2007 September-October; vol. 122, 657.

FDA action must be supported by science. Clearly, any restriction on the use of dental amalgam will affect, adversely, the health of many individuals and the population as a whole. As prices rise, some will forego treatment. *Id.* Similarly, there is a monetary cost which is significant, both individually and in the aggregate. The monetary cost is significant because of its impact, deferred treatment and the loss of funds for other treatment and prevention. Indeed, the population at greatest risk from increases in cost of alternative treatments is that which can least afford it. Any rational risk assessment must account for this side of the equation: the costs of regulation.

E. The Recent World Health Organization Report Reaffirms the Safety and Importance of Maintaining the Availability of Dental Amalgam

In October of this year, the World Health Organization (WHO) released a report of a meeting held in Geneva in 2009 in conjunction with the United Nations Environment Programme (UNEP). A copy of that report, titled "**Future Use of Materials for Dental Restoration, Report of the meeting convened at WHO HQ, Geneva, Switzerland 16th to 17th November 2009"** (WHO Report) is being provided along with these comments.

While the purpose of the report was to focus on environmental issues, WHO also addressed safety and the public health impact of an amalgam ban or restriction. First, WHO stated that "[p]roviding the best care possible to meet patients' needs should be of paramount importance," a proposition on which we are sure the FDA and ADA agree. WHO Report, p. viii. WHO went on to emphasize this point again, "It must be emphasized that providing the best care possible to patients should be of paramount importance. Patients' needs should be the top priority." Id. p. 28.

As to safety, WHO concluded that "**extensive research and clinical experience have demonstrated that amalgam is safe.**" Id. at p. 18 (emphasis added). WHO relied on and cited favorably the conclusions of the FDA from last year. Id. at p. 16 ("Following substantial reviews of evidence, the US FDA issued a final regulation on dental amalgam in 2009 to confirm that dental amalgam is a safe and effective restorative material" (citations omitted).) WHO also cited the findings of Scientific Committee of the European Commission:

> The committee concluded that dental amalgams are effective and safe, both for patients and dental personnel and also noted that alternative materials are not without clinical limitations and toxicological hazards. The Scientific Committee of the European Commission recognises that dental amalgam is an effective restorative material and may be considered the material of choice for some restorations.

Id. at p. 5. WHO even commented on the quality of data relied upon by those seeking to ban or limit dental amalgam: "Studies on adverse reactions to restorative materials lack validity as they rely on subjective and voluntary reporting, there is no robust mechanism to examine and verify reactions." Id. at p. 27. Based on its review of the evidence regarding amalgam and alternatives, WHO concluded, "[f]ollowing a review of existing evidence and much deliberation, it was agreed that dental amalgam remains a dental restorative material of choice, in the absence of an ideal alternative"). Id.

The WHO Report spends considerable time discussing the public health impact of a ban or restriction on the availability of dental amalgam. In many ways, WHO's conclusions coincide well with the points raised in the preceding section of these comments regarding the benefits of the material and the cost of any restrictions. For example, WHO noted that amalgams are far more durable than other materials and less likely to need replacement. Id. at p. 9 and 11 ("In general, composite restorations require 7 times as many repairs as do amalgam restorations"). Likewise, the primary alternative to amalgam is more expensive than amalgam. Id. WHO summarized the evidence on cost and durability, specifically as applied to North America, as follows:

> Factors that affect the cost as disseminated by private practitioners are related to "the dentist who performs the procedure, the location where it is performed, type of dental insurance (some insurance schemes do not cover composite restorations) and the number of tooth surfaces". Some clinicians claim that it takes twice as long to insert composite resins than amalgam. Typical cost of amalgam restoration in a pre-doctoral dental clinic ranges from $32 to $47 depending on complexity and from $113 to $207 if the procedure is conducted in a faculty practice clinic, compared with $42 to $62 and $129 to $275 respectively for composite resin restorations. In terms of longevity, amalgams are known to last 12 years as an average; however, there are restorations that are 40-50 years old. Composite resins have been reported to last 12-15 years.

Id. at p. 18 (citations omitted). Because of these cost factors, and as the ADA stated in the preceding section, WHO concluded that "[i]mplications for oral health are considerable if amalgam was banned. Fewer people will have access because of cost, particularly among communities in the US that are already underserved according to United States Public Health Service." Id. at p. 19.

F. There is a Lack of Sound Evidence That Amalgam Poses a Health Risk And Those Seeking to Ban It Misapply Scientific Principles

Some who support an outright ban of dental amalgam ignore or fail to understand the science supporting the conclusion that it remains a safe treatment option. Typically, they rely on non-peer-reviewed articles, studies that do not comply with Good Clinical Practice (GCP), or on studies which focus solely on sub-clinical effects at the cellular level, ignoring the dearth of evidence that amalgam causes humans any harm. In at least one prominent case, the views of one activist must be called into question due to a financial interest and resulting bias.[3]

[3] Dr. Boyd Haley is one of the primary advocates for an amalgam ban. He operates a for-profit business selling a "nutritional supplement" to treat alleged mercury toxicity. He clearly has a financial interest in creating concern over mercury in amalgam. Dr. Haley has been notified by the FDA that the sales of product by his company violate law because he has been selling an industrial chemical as a "treatment" for autism under the false claim it is a nutritional supplement. See http://www.chicagotribune.com/health/ct-met-autism-chemical-20100623,0,7088247.story.

Finally, those seeking a ban or restriction on use rely on a false reading of the precautionary principle. Under this reading, unless the negative is proven (i.e. unless there is a study which can "prove" that no one, anywhere, can ever be harmed), the use of amalgam must be ended. The problem with this approach to the precautionary principle is that it would result in the ban on almost any substance. For it is simply not possible to prove that anything is always safe. Even water cannot be "proven" safe because, at the wrong amount (dose) or ingested in the wrong way, harm is possible. While these amalgam opponents are, of course, free to advocate this or any other approach, the FDA is more constrained. As a British editor commented under similar circumstances: "But while it is one thing to debate an issue such as this…, it is quite another when a government or regulatory authority abruptly decides that it is time to ban amalgam on an emotional, or at the very least, un-critically appraised level." Editorial, Stephen Hancocks, *British Dental Journal* 204, 593 (2008) Published online: 14 June 2008 | doi:10.1038/sj.bdj.2008.492. The FDA must resist such an unscientific approach to amalgam regulation.

G. Treatment of Pregnant Women

The Association understands that treatment of pregnant women is an area of concern to FDA. Just last year, FDA fully evaluated the evidence on this point and concluded, "the existing data do not suggest that fetuses are at risk for adverse health effects due to maternal exposure to mercury vapors from dental amalgam." Food and Drug Administration, HHS. Dental devices: classification of dental amalgam, reclassification of dental mercury, designation of special controls for dental amalgam, mercury, and amalgam alloy. Final rule. 74 Fed Reg. 38685-714, 38691. Since that determination was made, there have been no material developments in the science on this topic.

The attached literature review from the ADA's Council on Scientific Affairs also addresses this issue, with a review of literature published since the Life Sciences Research Office (LSRO) study, and concluded, "There is no reliable evidence from controlled studies that this exposure is associated with any adverse pregnancy outcomes or health effects in the newborns and infants".

Some key findings from the literature review follow:

> Studies investigating the *in utero* effects of low-level elemental mercury exposure.
> Summary: Maternal amalgam fillings result in *in utero* exposure to low levels of elemental mercury. **There is no reliable evidence from controlled studies that this exposure is associated with any adverse pregnancy outcomes or health effects in the newborns and infants.** [Emphasis added.]
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> > Effect of amalgam fillings on the mercury concentration in human amniotic fluid.
> > Luglie PF, Campus G, Chessa G, Spano G, Capobianco G, Fadda GM, Dessole S.
> > Arch Gynecol Obstet. 2005 Feb;271(2):138-42. Epub 2003 Dec 20.
>
> Seventy-two pregnant women took part in the prospective study examining the effect of the number and surface areas of amalgam fillings on the mercury concentration in amniotic fluid. The investigators found that the number and surface areas of amalgam fillings positively influenced the mercury concentrations in amniotic fluid, but not at a statistically significant level. **The authors concluded that mercury levels detected in amniotic fluid were low and they observed no adverse outcomes during the pregnancies (incidence of hypertension, premature rupture of membranes, caesarean section rate, postpartum hemorrhage) or in the newborns (Apgar scores, hypocalcemia, hypoglycemia, hyperbilirubinemia, sepsis, respiratory distress syndrome, asphyxia, seizures).** [Emphasis added.]
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> - Maternal amalgam dental fillings as the source of mercury exposure in developing fetus and newborn.
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> Palkovicova L, Ursinyova M, Masanova V, Yu Z, Hertz-Picciotto I. J Expo Sci Environ Epidemiol. 2008 May;18(3):326-31. Epub 2007 Sep 12.

This study assessed the relationship between maternal dental amalgam fillings and exposure of the developing fetus to mercury. The study subjects were 99 mother-child pairs. Questionnaires were completed after delivery and mercury levels in maternal and cord blood were recorded. **The authors report that none of the cord blood samples contained mercury at levels considered to be hazardous for neurodevelopmental effects in children exposed to mercury *in utero* using the EPA reference dose (5.8 µg/l in cord blood).** [Emphasis added.]

- Mercury Exposure from Dental Filling Placement during Pregnancy and Low Birth Weight Risk.

Hujoel PP, Lydon-Rochelle M, Bollen AM, Woods JS, Geurtsen W, del Aguila MA. Am J Epidemiol. 2005 Apr 15;161(8):734-40.

This population-based, case-control study evaluated the risk of a low birth weight pregnancy outcome associated with placement of amalgam fillings. The study was conducted by linking dental utilization data from Washington Dental Service to Vital Records birth certificates from Washington State. The study included women between the ages of 12 and 45 years with a dental treatment between January 1, 1993, and December 31, 2000. 1,117 women with low birth weight infants were compared with a random sample of 4,468 women who gave birth to infants that were not low birth weight. 4.9% of the women had at least one amalgam filling placed during pregnancy. These women were not found to be at higher risk for a low birth weight infant and neither were women who had from 4 to 11 amalgam fillings placed.

- Maternal dental history, child's birth outcome and early cognitive development.

Daniels JL, Rowland AS, Longnecker MP, Crawford P, Golding J; ALSPAC Study Team. Paediatr Perinat Epidemiol. 2007 Sep;21(5):448-57.

This study evaluated prenatal exposure to mercury from amalgam fillings and adverse reproductive outcomes: preterm delivery, low birth weight and delayed neurodevelopment. Maternal dental history prior to and during pregnancy was documented for 7375 offspring born in Britain between 1991 and 1992. Nearly 90% of the women in this study received dental care during pregnancy. Of these women 31% had amalgams placed or removed. 71% of the women had 4 or more amalgams in place prior to conception. **Dental care was not associated with gestational age or birth weight. The odds of term low birth weight or preterm birth were not associated with maternal history of any dental care during pregnancy or with having an amalgam filling placed or removed. Having more fillings in place at time of conception did not negatively affect pregnancy or birth outcome. Early communicative development scores were not associated with receiving dental care or with placement or removal of amalgam fillings. In addition, the odds of scoring low were not associated with maternal dental history.** [Emphasis added.]

- A prospective study of prenatal mercury exposure from maternal dental amalgams and autism severity.

Geier DA, Kern JK, Geier MR. Acta Neurobiologiae Experimentalis. 2009;69(2):189-97.

H. This study examined the relationship between *in utero* mercury exposure from maternal dental amalgams and severity of autism or an autism spectrum disorder (ASD) in 100 subjects. No control group was utilized and the study design appears to be retrospective, not prospective. The outcome (autism or ASD) was determined at the start of the study, and the exposure was ascertained from past records. After adjusting for age, gender, race, and region, the mean difference of maternal amalgams was not statistically significant between DSM-IV (severe) and ASD (mild) groups. Further analysis found that the number of maternal amalgams increased the odds of being diagnosed with autism (severe) relative to ASD (mild) however only the group with 8+ maternal amalgams were statistically significant. Changing the statistical model to determine if

> there were greater odds of being diagnosed with autism compared to ASD between subjects whose mothers had 5 or fewer amalgams vs. those with 6 or more resulted in a statistically significant 3.2 fold increase for the group with 6+ maternal amalgams. The authors did not control or account for maternal methylmercury exposure and did not compare the number of maternal amalgams in children with autism or ASD with healthy controls.[4]Literature Review

The ADA's Council on Scientific Affairs is made up of scientific experts from across the country. This body guides the Association's work on all matters scientific. The Council is a body of independent, scientific experts and has no interest in the outcome of scientific debate other than to provide dentists with the best available scientific information on which to base their treatment decisions. Individuals who serve on the 17-member Council are chosen at large from among the ADA membership for their scientific expertise in a wide variety of fields affecting oral health. Most members of the Council hold academic appointments and are involved in active research. This provides the Council with the experience and expertise to read and assess the scientific evidence according to accepted standards of scientific rigor. This year, the Council updated an existing literature review on the issue of dental amalgam safety. A copy of this updated review is attached to this submission.

The Council's reviews date back to 2004, the date of the last comprehensive literature review by LSRO. In its review, the Council concluded that:

> [A] number of studies have added to the growing body of literature on the topic of amalgam safety. The findings of the studies published between January 1, 2004 and June 15, 2010 showed no consistent evidence of harm associated with dental amalgam fillings, including for infants and children. There is some evidence that mercury excretion may be affected by gender. There was no evidence demonstrating that some individuals are genetically susceptible to harmful effects from exposure to the low doses of mercury associated with dental amalgam fillings. Overall, **studies continue to support the position that dental amalgam is a safe restorative option for both children and adults.** (Emphasis added.)

I. Summary of Key Studies

1. Scientific Committee on Emerging and Newly Identified Health Risks

In addition to the comprehensive review provided in the attached document from the Association's Council on Scientific Affairs, a few key studies merit special attention. A review of the evidence conducted by the Scientific Committee on Emerging and Newly Identified Health Risks of the European Commission (SCENIHR) addressed safety concerns for patients, professionals and the use of alternative restorative materials. See http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_016.pdf. The committee concluded that dental amalgams are effective and safe, both for patients and dental personnel. The Committee's report states, "SCENIHR concluded that dental amalgams are an effective restorative material and may be considered the material of choice for some restorations. While some local adverse effects are seen, the incidence is low and usually readily managed. The current use of dental amalgams does not pose a risk to health apart from allergic reactions."

According to SCENIHR, alternative materials are not without clinical limitations and toxicological hazards. Allergies to some of these substances have been reported, both in patients and in dental personnel.

2. Children's Amalgam Trials[5]

[4] Please see the written submission from the Autism Science Foundation: "The bulk of scientific evidence to date finds no association between dental amalgam and autism."

[5] Dr. DeRouen has submitted comments in response to misguided criticism of these trials. The ADA supports those comments and they are included as separate documents filed with these comments.

The findings of two clinical trials, widely known as the Children's Amalgam Trial, were published in April 2006 in the Journal of the American Medical Association, with a number of additional publications drawn from data generated during these trials. Neurobehavioral effects of dental amalgam in children: a randomized clinical trial. DeRouen TA, Martin MD, Leroux BG, Townes BD, Woods JS, Leitão J, Castro-Caldas A, Luis H, Bernardo M, Rosenbaum G, Martins IP. JAMA. 2006 Apr 19;295(15):1784-92; and Neuropsychological and renal effects of dental amalgam in children: a randomized clinical trial. Bellinger DC, Trachtenberg F, Barregard L, Tavares M, Cernichiari E, Daniel D, McKinlay S. JAMA. 2006 Apr 19;295(15):1775-83. See attached literature review for a discussion of the follow up publications.

These important, randomized clinical trials, funded by the National Institutes of Health (NIH), continue to be among the best studies of the safety of dental amalgam ever conducted. They were designed to examine the effect of mercury released from amalgam on the central and peripheral nervous systems and kidney function in children. The researchers looked for signs of damage to the brain and kidneys because these organs are thought to be the most sensitive to mercury toxicity.

The investigators found no adverse health effects related to neuropsychological function (IQ), memory, attention, visuomotor function, nerve conduction velocities or renal function arising from the placement of amalgam restorations in children. While the safety of dental amalgam has been the subject of a number of previous publications, expert panel meetings and national and international conferences, these two new clinical trials are the first to compare overall health effects in children treated with amalgam restorations and children treated with resin composite restorative materials.

3. LSRO Literature Review

The Children's Amalgam Trials follow a long line of studies on dental amalgam's safety. The safety of dental amalgam was confirmed by a 2004 LSRO review commissioned by the NIH, U.S. Department of Health & Human Services and FDA. See Brownawell AM, Berent S, Brent RL, Bruckner JV, Doull J, Gershwin EM, Hood RD, Matanoski GM, Rubin R, Weiss B, Karol MH.. The Potential Adverse Health Effects of Dental Amalgam. Toxicol Rev. 2005;24:1-10.

LSRO undertook its review in consultation with a panel of scientific experts selected from outside the dental research community to ensure a fresh, comprehensive look at the literature. These included experts in immunotoxicology, immunology and allergy, neurobehavioral toxicology and neurodevelopment, pediatrics, developmental and reproductive toxicology, toxicokinetics and modeling, epidemiology, pathology and general toxicology. The report concluded:

> [T]here is insufficient evidence to support a correlation between dental amalgam exposure and kidney or cognitive dysfunction; neurodegenerative disease, specifically Alzheimer's disease and Parkinson's disease; or autoimmune disease, including multiple sclerosis.

4. New England Journal of Medicine

An article published in 2003 in the New England Journal of Medicine, one of the most prestigious medical journals in the world, stated:

> Current concern arises from claims that long-term exposure to low concentrations of mercury vapor from amalgams either causes or exacerbates degenerative diseases such as amyotrophic lateral sclerosis, Alzheimer's disease, multiple sclerosis, and Parkinson's disease. However, several epidemiological investigations failed to provide evidence of a role of amalgam in these degenerative diseases…Patients who have questions about the potential relation between mercury and degenerative diseases can be assured that the available evidence shows no connection.

Clarkson TW, Magos L, Myers GJ. The Toxicology of Mercury – Current Exposures and Clinical Manifestations. N Engl J Med 2003;349:1731-7.

J. Conclusion

Dental amalgam remains a valuable restorative option for dentists and their patients. At present, there is no direct restorative material that works as well as amalgam for large fillings in the back teeth, in very deep fillings, or in fillings below the gum line. Alternatives are often less effective in these situations.

Amalgam is also an excellent restorative material for placement in a wet environment. This is critical when working with patients such as children or persons with developmental disabilities who might have difficulty sitting still in the dental chair. Without amalgam, dentists would be required to administer higher risk forms of anesthesia, to treat these patients with other restorative materials or by extraction.

The ADA is a science-based organization and bases its comments solely on the scientific evidence. Based on that evidence, the ADA strongly urges the FDA advisory panel to support the well researched and thoughtful conclusions reached by the FDA only last year, after years of study.

We appreciate the opportunity to share these views with you.