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FDA Likely to Make Decision on Mercury Fillings by July 2009

We Think Outright Ban is Unlikely

- **This week, the FDA responded to the district court in Washington, DC, which had ordered the agency to provide a date by which it will issue classification standards for mercury (i.e. amalgam) fillings**. As a reminder, medical devices are classified under a three-tiered system (I, II, or III), with Class I being least complicated (e.g., band-aids) and III being the most complicated (e.g., implantable defibrillators). The FDA stated that it would do two things: (1) update the language for consumers on the FDA website, as it previously claimed that there are *no* safety risks associated with mercury fillings, and (2) commit to classifying amalgams by July 28, 2009, the one year anniversary of the end of the public comment period. Currently amalgams are classified as Class I, with other low risk products such as bed pans and band-aids. We believe there is a good chance that the FDA will upgrade the classification to Class II.
- **FDA issued a notice on April 28th, asking for comments on its intent to regulate mercury fillings.** The FDA has asked for 90 days of comments on an original rule issued in 2002, proposing that the agency: (1) issue a separate classification regulation for encapsulated amalgam alloy and dental mercury; (2) amend the classification for amalgam by adding special controls; and (3) reclassify dental mercury from Class I to Class II.
- **We do not believe that FDA will ban mercury fillings altogether, but it will likely restrict use in vulnerable populations.** We do believe that the agency will ask for the label to indicate that mercury is an ingredient in the filling, and that special populations should be exempt from such fillings, such as: nursing women, pregnant women, young children, and immunocompromised individuals.
- **Mercury fillings remain in the spotlight, given the link to certain neurological disorders.** In November 2006, the FDA convened an advisory committee, in which the panel generally agreed that there is little evidence that dental amalgams cause health problems in a majority of the population. However, at the time, several panelists asked for label changes, as well as more data on specific health effects of mercury fillings on pregnant women, small children, and sensitive individuals. Mercury, more broadly, has been linked to disorders such as MS and there is now growing concern about the long-term health implications associated with older fillings. While it is too early to know whether a class action lawsuit will emerge, this could clearly raise the profile of the issue. In the interim, as it relates to our companies under coverage, we see a modest positive for suppliers of CAD/CAM and related equipment (i.e. Sirona), as patients proactively seek to remove amalgam fillings, and older teeth, due to the unknown heath effects. Given that a large percentage of the patients are likely to be older (i.e. with brittle teeth), this could also drive increased volumes for bridge and crown repair work, and thereby, the need for more in-office equipment.

US Healthcare Policy

Ipsita G Smolinski[AC]
(1-202) 216-8183
ipsita.g.smolinski@jpmchase.com

Medical & Life Sciences Technology

Tycho W. Peterson
(1-212) 622-6568
tycho.peterson@jpmorgan.com

Thijs Spoor
(1-212) 622-0495
thijs.m.spoor@jpmchase.com

Healthcare Technology & Distribution

Lisa C. Gill
(1-212) 622-6466
lisa.c.gill@jpmorgan.com

Michael Minchak, CFA
(1-212) 622-6506
michael.minchak@jpmorgan.com

See page 7 for analyst certification and important disclosures, including investment banking relationships.

Ipsita G Smolinski
(1-202) 216-8183
ipsita.g.smolinski@jpmchase.com

Tycho W. Peterson
(1-212) 622-6568
tycho.peterson@jpmorgan.com

JPMorgan

FDA Action on Mercury Fillings

In February 2002, FDA published a proposed rule entitled ‘‘Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy.”

In that document, FDA proposed the following actions:

- issue a separate classification regulation for encapsulated amalgam alloy and dental mercury;
- amend the classification for amalgam alloy by adding special controls; and
- reclassify dental mercury from class I to class II.

FDA proposed that all three products would have the same labeling guidance as a special control. In addition, FDA proposed that dental mercury would have a voluntary American National Standards Institute (ANSI) standard as a special control; encapsulated amalgam alloy and dental mercury would have voluntary ANSI and International Standards Organization (ISO) standards as special controls; and the amalgam alloy products would have a voluntary ISO standard as a special control.

Since 2002, a 2006 joint meeting of the Dental Products Panel and the Peripheral and Central Nervous System Drugs Advisory Committee raised the need for FDA to further consider scientific issues that are potentially relevant to this classification. The FDA provided a “White Paper” for Panel consideration, which selected 34 studies out of many hundreds that fulfilled the criteria for inclusion. Following a review and discussion, the Joint Panel voted 13-7 to reject the FDA conclusion that amalgam was safe. By the same voting margin, the panel also concluded that the paper did not objectively and clearly present the current state of knowledge about mercury exposure and health effects of dental amalgam. The panel did not say amalgam was unsafe, only that safety could not be established based upon data provided.

As a result, on April 28th, the FDA issued a federal register notice seeking 90 days of additional comments on the proposed classification
The comment period closes on July 28th. In response to a district court case, the FDA this week stated that it will issue a classification by July 28, 2009.

The FDA comment period closes on July 28th. The FDA has stated it will classify mercury fillings by July 28, 2009. We believe the agency will limit usage of mercury fillings, but not ban use altogether.

FDA is now asking for comments concerning whether these devices should be classified into class II (special controls). Also, if class II is the appropriate classification for these devices, FDA requests comment on whether the two types of special controls proposed by FDA in 2002 (i.e. materials and labeling) provide reasonable assurance of the safety and effectiveness of the devices, and on whether the proposed special control guidance document should be revised in light of the recommendations and with respect to the discussions by the 2006 joint committee.

- **Controls on the Materials.** For example, should the material controls proposed by FDA address conformance to recognized consensus standards that make

Ipsita G Smolinski
(1-202) 216-8183
ipsita.g.smolinski@jpmchase.com

Tycho W. Peterson
(1-212) 622-6568
tycho.peterson@jpmorgan.com

recommendations for testing, compressive strength, and identifying the mercury vapor released by the device?

- **Labeling Controls.** For example, how should labeling controls, if any, address the disclosure of composition, including mercury content, and precautions regarding use of the device in sensitive subpopulations composed of individuals who respond biologically at lower levels of exposure to mercury than the general population? If so, which subpopulations should be included (e.g., children under age 6, pregnant and lactating women, hypersensitive, immunocompromised individuals)? Should the labeling controls require more specific patient labeling (e.g., informing patients of identified sensitive subpopulations of the mercury content, the alternatives to the device and their relative costs, and health risks associated with the failure to obtain dental care)?

On April 28, FDA also requested comments, including available data, on the following questions:

(1) How many annual procedures use mercury amalgams? What are the trends?

(2) What are the differences in cost between amalgams and alternative materials (e.g., composite, other metals, ceramics, etc.)? Are there differences in replacement lives?

(3) What are reimbursement rates for dental amalgam and the alternative materials?

(4) How would labeling describing the risks of amalgam for certain subpopulations (e.g., children under age 6, pregnant and lactating women, hypersensitive or immunocompromised individuals) affect the demand for, and use of, mercury amalgam? How would the risks included in the labeling be communicated to those subpopulations?

(5) What is the current exposure to mercury for patients? For professionals? What would be the reduction in exposure associated with the alternatives described previously?

SOURCE: Federal Register, v73, n82

Other Jurisdictions

In Asia, Japan remains the only country to regulate the use of amalgam fillings. Within Europe, the use of amalgam fillings varies greatly by country, with unrestricted use in certain countries (UK, France, Italy) and as such, and there is no clear precedent for the U.S. Other countries, notably Austria and Germany, have some restrictions on dental amalgam, such as permitting use for the general population, but not for children, pregnant women, people with kidney problems, when in contact with other metals (such as braces), and in people with mercury sensitivity. Sweden and Finalnd have banned or regulated the use of mercury in dental amalgams, citing health or environmental concerns, while amalgam use in Norway has been banned as of January 1, 2008. Of note is that the Swedish rationale is that “there are strong grounds for banning amalgam for environmental reasons. From a health point of view there is every reason to apply a precautionary approach.”

Ipsita G Smolinski
(1-202) 216-8183
ipsita.g.smolinski@jpmchase.com

Tycho W. Peterson
(1-212) 622-6568
tycho.peterson@jpmorgan.com

Moms Against Mercury vs. FDA

In mid-May 2008, a District Court in Washington, DC, required the FDA to respond with a date certain that it will classify mercury fillings.

This week, the FDA settled the court case in Judge Huvelle's courtroom with the following commitments:

(1) The FDA will classify mercury fillings by July 28, 2009 and

(2) The FDA will update the information to consumers on its website (see link below).

As a reminder, Class I devices are subject to the least regulatory control. They present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. Class I devices are subject to "General Controls" as are Class II and Class III devices.

Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances. In addition to complying with general controls, Class II devices are also subject to special controls. Special controls may include special labeling requirements, mandatory performance standards and post-market surveillance.

We believe that the FDA is likely to classify mercury fillings as Class II devices
Class III is the most stringent regulatory category for devices. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls. Examples include drug eluting stents and defibrillators.

Next Steps

Stakeholders will provide comments to the FDA as per the April 28th Federal Register notice. The comment period will close on July 28, 2008.

The FDA will have one year – until July 28, 2009 – to decide how it will classify mercury fillings, e.g., class I, II or III. Currently they are classified as Class I, with other low risk products such as bed pans and band-aids. We believe there is a good chance that the FDA will upgrade the classification to Class II.

In the meantime, the FDA has updated the website, as the old website language for consumers stated that mercury fillings are safe and contain no health risks: http://www.fda.gov/cdrh/consumer/amalgams.html. Notably, the FDA took only a few hours to update the website after the case was settled this week.

Background

Amalgam

Amalgam is a mixture of mercury (43-54%), silver, tin and copper with trace amounts of zinc indium and palladium added to increase strength and to reduce corrosion. While the integrity of the filling comes from the silver, mercury (as the

Ipsita G Smolinski
(1-202) 216-8183
ipsita.g.smolinski@jpmchase.com

Tycho W. Peterson
(1-212) 622-6568
tycho.peterson@jpmorgan.com

only metal liquid at room temperature) is required to activate the reaction to form the amalgam so that it can conform to the shape of the cavity and then set. Amalgam was first introduced in 1826 with 8 times the mercury content, with the current mercury levels stable since 1963.

Amount of Mercury Released From Amalgam

Over the past several years, there has been growing concern over the use of mercury in dental amalgams, which make up nearly half the content of fillings, along with silver, tin and other elements, due to concerns over both patient safety (i.e. neurological, MS, teratogenic potential), as mercury is a known neurotoxin, with known environmental hazards. At issue is not whether the fillings are effective, but the fact that amalgam releases mercury vapor. While the scientific community generally agrees that amalgam fillings expose patients to a daily dose of mercury, different studies reviewed by the FDA have concluded that the exposure may be as low as 1-3 µg/day or as high as 27 µg/day, with compounding variables related to location and number of fillings, gum chewing and the frequency of teeth grinding.

The World Health Organization (WHO) has also reviewed the issue, with daily mercury exposure estimates ranging from 3 µg/day to 9 µg/day, with spikes in mercury release after chewing, eating or brushing teeth although it is unknown what portion of an inhaled dose is ingested rather than exhaled. A study by Berglund (J Dent Res 69:1646, 1990) measured the intraoral vapor levels over a 24-hour period in patients with at least nine amalgam restorations. The average daily dose of inhaled mercury vapor was 1.7 µg (range from 0.4 to 4.4 µg), which is approximately 1% of the threshold limit value of the 2µg/kg/day established by the World Health Organization, based on a maximum allowable environmental level of 50 µg/day.

Peer reviewed literature differs in the conclusions reached, with the range of opinions from “the current data are insufficient to support an association between mercury release from dental amalgam and the various complaints that have been attributed to this restoration material” (Life Sciences Research Office) to “removal of dental amalgam leads to permanent improvement of various chronic complaints in a relevant number of patients in various trials”(Freiburg University Institute for Environmental Medicine). Given what appears to be, at the very least, growing concerns over the link between mercury and diseases such as MS, we feel that this could drive a large number of patients proactively removing older fillings.

Safety of Mercury

Two recent randomized clinical trials in children showed no statistically significant differences in adverse neuropsychological or renal effects observed over the five-year period in children whose caries were restored using dental amalgam or composite materials, although one study could not rule out the possibility of a small adverse effect on IQ in children with amalgam. In contrast, another study showed a trend of higher dental treatment need later in children with composite dental fillings, and thus, claimed that amalgam fillings are more durable. However, a subsequent study published in JAMA cites increased mercury blood levels in children with amalgam fillings. The study states, “during follow-up [blood mercury levels were] 1.0 to 1.5 µg higher in the amalgam group than in the composite group.” EPA considers high blood mercury levels to be harmful to fetus, and also states that “exposure at high levels can harm the brain, heart, kidneys, lungs, and immune

Ipsita G Smolinski
(1-202) 216-8183
ipsita.g.smolinski@jpmchase.com

Tycho W. Peterson
(1-212) 622-6568
tycho.peterson@jpmorgan.com

system of people of all ages." Currently, EPA has set the "safe" mercury exposure level to be at 5.8 micrograms of mercury per one liter of blood.

In the longer term safety analysis in children there has been a drop in mercury excretion in urine, which also has resulting in conflicting opinions as some attribute this to a decrease in mercury in children's bodies, whereas a response in JAMA says that this is evidence that children are losing the ability to excrete mercury with increased levels of exposure, and therefore mercury in the blood and muscle are better assessments of cumulative dose.

An analysis of the data collected during the studies showed that the authors of the studies ignored the drop in mercury excretion, after two years, in the urine in the children with amalgam fillings, even though the mercury exposure from amalgam remained the same or increased. This is explained in a response by Dr. Boyd Haley, to the 2006 publication, in JAMA, of the NIDCR-funded children's amalgam study. According to Haley, this is evidence that these children are losing the ability to excrete mercury with increased exposure. This observation points to a strong limitation in the use of mercury concentrations within urine as an indicator of mercury exposure from amalgam (and, potentially, as an indicator of mercury concentration within the bloodstream).

Impact on the Dental Market

As a result, while mercury-based amalgams have been the preferred restoration material for fillings for nearly a century and a half, and an estimated 30-50% of dentists are now "mercury free", a large population of patients are increasingly looking to remove older fillings. Perhaps more importantly, the ADA, FDA and various advocacy groups are actively revisiting the issue as well, with a chance that the FDA could look to re-classify dental amalgam as a higher level (Class II or III) device, as due to the neurotoxic effects.

While it remains unclear whether mercury fillings will ultimately be banned, we expect an increasing shift toward crowns (using composite materials), as patients look for a longer-term replacement for fillings. We expect this could also drive higher demand for chair-side CAD/CAM procedures, as patients (in particular, elderly patients) seek the additional convenience of a single-visit approach. The American Dental Association has held that dental amalgam was safe since its foundation in 1859 as amalgam is durable, cheap, and easy to use although up until 1984 their position had been that no mercury could ever be released from amalgam as it was permanently bound. Resin composites are thought to be less durable than amalgam, however the gap between amalgam and composites durability appears to be closing as seen in follow up work published in JADA in 2007 which showed that in a study of 5000 children that resin based restorations had greater replacement rates than amalgam but was only statistically significant in patients with recurrent cavities. As a caveat however, there are concerns as well in the literature about the estrogen-mimicking effects of the plastic chemicals such as Bisphenol A used in some composite resins.

Ipsita G Smolinski
(1-202) 216-8183
ipsita.g.smolinski@jpmchase.com

Tycho W. Peterson
(1-212) 622-6568
tycho.peterson@jpmorgan.com

JPMorgan

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Ipsita G Smolinski
(1-202) 216-8183
ipsita.g.smolinski@jpmchase.com

Tycho W. Peterson
(1-212) 622-6568
tycho.peterson@jpmorgan.com

Ipsita G Smolinski
(1-202) 216-8183
ipsita.g.smolinski@jpmchase.com

Tycho W. Peterson
(1-212) 622-6568
tycho.peterson@jpmorgan.com

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