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Patricia Kuntze, Senior Advisor for Consumers Affairs
Office of the Commissioner
Food and Drug Administration

Request that FDA Retract and Reissue the Dec. 2002 FDA Consumer Update on Amalgam

Dear Senior Advisor Kuntze:

We ask that the December 2002 Consumer Update on amalgam be withdrawn because (1) intervening developments have made a new Update necessary, (2) even when issued it was full of misleading and false statements, and (3) the American and California Dental Associations made ex parte contacts to Dental Devices Branch Director Susan Runner requesting deletion of statements showing the health risks of mercury amalgam, whereupon Dr Runner inappropriately deleted such materials. We further ask that a new Consumer Update be prepared, this time in a transparent process including a public hearing or public meeting. We further ask that control over content be taken away from the Center on Devices and Radiological Health because that Center has twice prepared a Consumer Update on amalgam containing misleading and false information.

Consumer Update: Dental Amalgams Contains Statements That Are Misleading Or Factually Wrong

FDA's Center for Devices and Radiological Health (CDRH) publishes a consumer update where it is concerned about the safety of a particular medical device. It also may publish an update where there is substantial consumer anxiety about a medical device. This can be seen from CDRH updates on Fetal Keepsake Videos,[1] DEHP in Plastic Medical Devices,[2] and relevant here, Dental Amalgams.[3] Because these updates are meant for the consumer, they should be accurate. In order to make them more accurate, some situations may require consultation with an appropriate consumer group. The consumer update on dental amalgams presents one such situation.

[a] In the second sentence of the first paragraph, CDRH states, "…no valid scientific evidence has shown that amalgams cause harm to patients with dental restorations, except in the rare case of allergy."[4] To the contrary, valid scientific evidence published since 1997 has shown that amalgams do cause harm.[5] However, there is no indication that FDA, U.S. Public Health Service (USPHS), or NIH has looked at any studies published

[1] http://www.fda.gov/cdrh/consumer/fetalvideos.html
[2] http://www.fda.gov/cdrh/consumer/dehp.html
[3] http://www.fda.gov/cdrh/consumer/amalgams.html
[4] Id
[5] *See* pg. 28, Swedish Review

after 1997.[6] While it is possible that scientific studies publishes prior to 1997 do not conclusively show that dental amalgam causes harm, it is an overreach to say that no valid scientific evidence has shown that amalgams cause harm. In a recent review of scientific literature published between 1997 and 2002, the Swedish Government set out to "boost knowledge of health problems relating to amalgam and other dental materials…" [7] To that end, they sponsored a comprehensive review of the literature, requiring an assessment of 700 references.[8] They concluded that, *inter alia*, the "past five years' research has yielded further evidence that amalgam can give rise to side-effects in a sensitive portion of the population."[9] They also said, "the safety margin that it was thought existed with respect to mercury exposure from amalgam has been erased."[10] The Swedish report left a number of questions unanswered; nonetheless, it counters FDA's unqualified proposition that ***no*** valid scientific evidence exists.

It is true that FDA, NIH, the USPHS and others have commissioned a similar review. The LSRO/BETAH review, which was responsible for evaluating the potential human health effects of using amalgam, looked at literature published between 1996 and 2003.[11] It concluded that the data was insufficient to establish that amalgams cause adverse health effects.[12] This review was supposed to bridge the gap between a 1997 USPHS report and the most recent science. However, NIH is now investigating the review for conflicts of interest, contract irregularities, and unscientific methodologies.[13] It appears that government agencies are backing away from the LSRO/BETAH review. To date, American agencies have not been able to respond to the Swedish conclusion that amalgams cause harm, even if it is restricted to sensitive populations.

NIH is also sponsoring an amalgam study called the Children's Amalgam Trial. Taking place in Portugal, Maine, and Massachusetts, the study is meant to address the continuing question of whether amalgam causes harm. Like the FDA-sponsored LSRO/BETAH review, it is being investigated. The Department of Health and Human Service's (DHHS) Office of Human Research Protections is currently scrutinizing the Trial for instances of ethical violations and conflicts of interest.[14]

In the near term, a scientific consensus regarding the safety of amalgam is unlikely. As more countries move to restrict or ban amalgam,[15] however, the CDRH position that no valid scientific evidence proves harm will become increasingly untenable. Indeed, to continue to maintain that there is an absence of evidence necessarily means that an increasing number of countries are phasing out the use of amalgams without any evidence of harm.

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[6] *See* 2002 draft regulation
[7] 4, Swedish Review
[8] Id
[9] Id, page 24
[10] Id, at 25
[11] http://www.lsro.org/presentation_files/amalgam/amalgam_execsum.pdf
[12] Executive summary, 7
[13] Case No. 2004-99. At the request of NIH Director Zerhouni the investigation is being conducted by the national CPA firm of Clifton Gunderson.
[14] Amanda
[15] see LSRO executive summary

We request that FDA and CDRH review the 2003 Swedish Report and the studies contained therein, and allow that valid scientific evidence has not shown that amalgams cause no harm.

[b] The FDA position that amalgams cause harm only in "rare cases of allergy" is misleading. First, the Agency has not issued or sponsored one study that deals with allergic reactions caused by amalgams. Therefore to say that harm only happens in "rare cases" is unsubstantiated. Second, the focus of the amalgam debate has always been mercury, and whether it is released in sufficient amounts to cause harm. Mercury itself is a potent neurotoxin, which can cause autoimmune deficiencies.[16] To simply say that mercury-containing amalgam causes harm only in rare cases of allergy suggests that mercury is not at issue, despite Agency acknowledgment that amalgams release mercury vapor. When assessing any harm caused by mercury, scientists are likely to use terms other than "allergy," terms like "toxicity," or "poisoning." To restrict the harm caused by amalgams to the misleading term "allergies" is to ignore that mercury, and not the alloy, is the source of substantial scientific disagreement. We request that FDA define a "rare case of allergy," and further, acknowledge the risks of using amalgam as Health Canada did. Rare cases of allergies do not move whole nations to recommend that amalgams not be placed in pregnant women, children, and people with kidney problems.[17]

[c] In the fourth sentence of the second paragraph, the Update states that the World Health Organization (WHO) considers amalgam "safe and effective." This language, however, was gleaned from a **draft** committee statement and does not represent the WHO's official position on amalgam safety.[18] In the most current WHO policy paper on the use of mercury in health care, it states that recent studies "suggest that mercury may have no threshold below which some adverse affects do not occur." [19] In other words, there are no safe levels of mercury; this, in light of that fact that "mercury contained in dental amalgam is the greatest source of mercury vapor in non-industrialized settings."[20] Indeed, the WHO "support[s] a ban for use of mercury containing devices and [wishes to] effectively promote the use of mercury free alternatives."

[d] In the ninth sentence of the second paragraph, FDA proposes that Sweden, Canada, and the province of Quebec agree that amalgams are safe. However, Sweden has adopted the position that for "medical reasons, amalgam should be eliminated in dental care as soon as possible."[21] Canada's official statement is ambivalent: "…current evidence does not indicate that dental amalgam is causing illness in the general population…a ban is not justified, and neither is the removal of existing sound amalgam fillings."[22] Nonetheless, it goes on to state that amalgams should not be placed in pregnant women, or in the primary teeth of children.[23] Quebec is likewise of two minds, saying, "the existing evidence [of harm] is weak, but the information base is inadequate to conclude that dental

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[16] Centers for Disease Control, *Third National Report on Human Exposure to Environmental Chemicals 2005* , http://www.cdc.gov/exposurereport/, at pp. 45-48.
[17] Health Canada statement (1996)
[18] WHO Committee Draft
[19] policy paper, at http://whqlibdoc.who.int/hq/2005/WHO_SDE_WSH_05.08.pdf
[20] id
[21] Sweden, pg. 4
[22] Canada press release
[23] id

amalgam has no effects that might be of concern."[24] These statements cannot be construed as concluding that amalgam is "safe."[25] Therefore, we request that FDA revisit international opinion of dental amalgam and revise the Update accordingly.

It is important that the Consumer Update reflect the latest information, both in science and regulatory developments. Because it is meant for consumers, the Update should be as accurate as possible. Many consumers rely on FDA for information on a variety of health topics, and may make crucial decisions after reading a consumer update, or the "Hot Topics" portion of the Agency's home page. This information should not be misleading or incomplete. The benefits of a particular medical device should not be praised when unwarranted; likewise, the risks of a particular medical device—like amalgam—should not be obscured. The Update need updating.

(2) **Mercury-Free Dentistry Should Have Input In Any Consumer Update On Dental Amalgam**

According to the American Dental Association (ADA), seven of ten dentists are members.[26] Christensen Research Associates estimates that a third of dentists practice mercury-free dentistry. As of 1999, there were approximately 165,000 practicing dentists in the United States.[27] Almost all mercury-free dentists are not affiliated with ADA, as ADA continues to consider mercury amalgam a safe and viable filling option. Upwards of 50,000 dentists, then, do not use amalgam and are not affiliated with ADA. Even so, the mercury-free dental profession has had little input in FDA decision-making, including the information contained in the Consumer Update.

Dental Devices Branch Chief Susan Runner, D.D.S., is responsible for content contained in consumer updates regarding dental devices. As such, she has the power to write, revise, and scrap the Update where circumstances require. The update in question was published in February of 2002. The prior version contained what she deemed, "inaccuracies [that] could be taken the wrong way."[28] At the request of the ADA and the California Dental Association, she removed language indicating a U.S. trend of restricting the use of amalgam.[29] That the dominant dental association can call FDA's Dental Devices Branch and readily change consumer information is troubling, although perhaps not unprecedented. Runner was able to keep this activity secret for three years, as CDRH stonewalled (for reasons that are increasingly obvious) wave after wave of freedom of information act requests from Consumers for Dental Choice.

While prompt to accede to requests by the ADA, Runner took the opposite approach on a request to include information unfavorable to amalgam. No record exists of Runner replied to a request by Norm Braveman of NIH's dental arm to incorporate the Swedish study, the one calling for a ban.[30] The 2002 Update remains in place, two years after the

[24] Information contained in draft regulation.
[25] Update
[26] ADA home page
[27] http://bhpr.hrsa.gov/healthworkforce/reports/factbook02/FB302.htm
[28] E-mail, Runner, Mary S. to Braveman, Norman, March 5, 2002, re "News."
[29] id
[30] E-mail, Norman Braveman to Runner, Mary S., December 1, 2003, re "Swedish information"

Swedish study said it's time to ban mercury fillings, with the ADA-inspired fiction that the Swedes support a ban only for environmental reasons.. Runner and her Amalgam Vigilance committee ensure that the Swedish information never reaches the American public.

Competing associations like the International Academy of Oral Medicine and Toxicology, and the American Academy of Biological Dentistry have as much an interest in the responsible dissemination of information on amalgam as ADA. They also represent the interests of thousands of mercury-free practitioners. Therefore, we request that mercury-free dentistry, like the ADA, have the ability to suggest revisions to consumer information on amalgam, and further, see that its input is accorded a similar deference as ADA's.

The first Consumer Update, released in February 2002, was so laudatory of amalgam, and contained such patently false information about mercury amalgam, that CDRH Director Feigal revoked it. The second one also contains false, misleading, and laudatory information. No reason exists to give CDRH a third try. This time, the matter should be addressed by the Commissioner's office of consumer affairs, an agency focused on providing information to consumers, not withholding it.

Sincerely,

Charles G. Brown
National Counsel
Consumers for Dental Choice
November 8, 2005