

## ATTACHMENT A



**Philadelphia Board of Health Hearing  
Amalgam Dental Fillings Information Sheet  
Peter Carroll, D.D.S.  
Representing the Philadelphia County Dental Society  
February 11, 2010**

My name is Dr. Peter Carroll and I practice general dentistry in Philadelphia. I am the current President of the Philadelphia County Dental Society and have been designated as its representative to the Board of Health in order to submit testimony on this issue.

Philadelphia dentists welcome the opportunity to share what we have learned in the past year since we last met to discuss the issue of dental amalgam. There have been two important developments that bear consideration by the Board, the first being the major Food and Drug Administration ruling with conclusive findings that render portions of the information sheet as unnecessary at best, and the second being that dental practitioners in the city have had nearly a year to measure the information sheet's impact upon the care of our patients.

Our first attachment is our suggested revisions to the information sheet. With one minor exception, all changes are tied directly to the FDA decision.<sup>1</sup> Also attached is a one page summary of the FDA's final rule classifying dental amalgam as Class II, the same classification as gold, porcelain and composite (i.e. tooth-colored) fillings. This summary clearly sets forth the FDA findings, in its own language.

The Food and Drug Administration is the federal agency with both the expertise and the responsibility to regulate dental materials. The FDA reviewed all of the scientific literature on this topic, and concluded that "the scientific evidence adequately demonstrates the absence of unreasonable risk of illness or injury associated with the intended use of dental amalgam." Given this definitive review of the science by the federal agency with responsibility over this topic, we believe that the Philadelphia information sheet must be rewritten to remove the portions that are no longer supported by the FDA's science-based

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<sup>1</sup>The one exception is a correction to the original fact sheet's statement that waste amalgam must be handled as a hazardous waste. Hazardous waste is a technical, legal term under environmental regulation and dental amalgam in general does not fall within that definition. Moreover, even if it were "hazardous waste", under EPA regulations it would not be handled as hazardous waste because those regulations exempt very low levels of such waste from the rules. As you can see, this quickly becomes quite complex. Our suggested clarification still reflects our desire to handle waste amalgam safely and appropriately.

conclusions. As currently written, the fact sheet does not reflect the conclusions so carefully reached by the FDA.

The past year has been very helpful in understanding the impact of the information sheet on dental care. Attached also please find a letter from Dr. Amid Ismail, the Dean of Temple University's Kornberg School of Dentistry, raising serious concerns about the information sheet because it implies serious and, as the FDA has definitively concluded, unfounded risks from amalgam. The Temple faculty have also helpfully provided their own review of the literature on the topic, and that is attached as well.

I also wanted to share with you the experiences of Dr. Andrew Mramor, the Clinical Director of General Dentistry at Special Smiles, LTD, a North Philadelphia outpatient facility for patients with intellectual and/or developmental disabilities that often requires general anesthesia for dental treatment. As he put it, "at our clinic, we have had several parents refuse amalgam thereby limiting access to care. When providing full mouth rehab to patients under general anesthesia, it is imperative that we have the option of amalgam in our armamentarium. Generally, we can clarify the situation and proceed but if a guardian flatly refuses amalgam and will not sign the information sheet, we will not see the patient. The patient must then find another dental home which is a challenge as few facilities are equipped to treat these individuals."

The combined force of the FDA ruling and the experiences of our dentists with the information sheet reinforces our long-held belief that this document is unnecessary and unnecessarily intrudes on the relationship between dentist and patient. For this very reason, combined with the lack of any unreasonable risk, the FDA declined to require any type of document to be provided to patients.

However, we certainly understand that the Board is required to comply with the city ordinance to produce an accurate information sheet, and so therefore we suggest the attached changes and strongly urge the Board to adopt them as suggested. The residents of Philadelphia deserve no less than to be educated with valid, peer-reviewed scientific information. We thank you for your patience with this difficult issue and for your consideration of our suggestions.