CITY OF PHILADELPHIA
DEPARTMENT OF PUBLIC HEALTH
BOARD OF HEALTH MEETING

FEBRUARY 18, 2010

A meeting of the Philadelphia Board of Health was held on Thursday, February 18, 2010, in the Municipal Services Building, 1401 J.F.K. Boulevard, Room 1450.

Board Members Present: Jose A. Benitez, MSW; Shannon P. Marquez, MEng, PhD; Scott McNeal, DO; Susan Schewel, CRNP, PhD; Donald F. Schwarz, MD, MPH; Robert G. Sharrar, MD, MSc; Yolanda A. Slaughter, DDS, MPH

Attendees: Susan Boland; Jerry Bowman; Peter J. Carroll; Sean Connolly; Reginald Crabbe; Renee Dempsey; Sylvia Dove; Nan Feyler; Judy Gelinas; Kay Graham; John Hawkins; Caroline Johnson, MD; Freya Koss; Giridhar Mallya, MD, MSHP; Luke McConnell; Andrew Miramor; Jeff Moran; Bob Reeves; Alan Roberson; Clayton Ruley; Leslie Smith; Elaine Strunk; Kevin Vaughan; David Tekosky

Welcome and Introductions

Board President Dr. Donald Schwarz, Health Commissioner, called the meeting to order at 5:35 PM. He welcomed the members of the Board and those attending the meeting. Dr. Schwarz asked for amendments or corrections to the minutes of the meeting of December 10, 2009. Dr. Sharrar noted factual inaccuracies in the record of discussion pertaining to the efficacy of HPV vaccine. The statements have been reviewed and corrected.

Influenza Update

Dr. Schwarz introduced Dr. Caroline Johnson, Director of the Division of Disease Control, to provide the Board with an update on immunization against H1N1 and seasonal influenza.

Dr. Johnson reported that demand for seasonal flu vaccine has been much greater this season, with community based influenza immunization clinics administering nearly twice as many doses of vaccine this year over last. She speculated that the late arrival of H1N1 vaccine caused many people to opt for the seasonal vaccine, which was immediately available. 55,000 doses of seasonal vaccine have been administered through City health centers and the health department's community based program. An additional 110,000 doses have been distributed through the Vaccines for Children program. Very little seasonal influenza activity has been detected this year.

When H1N1 vaccine became available in late October, the Division of Disease focused on immunizing children. Immunization was provided in 100% of public and Catholic schools, 90% of private schools, and 70% of charter schools. Between 60,000 and 65,000 young people were immunized through the school-based effort.

At the beginning of 2010, eligibility was extended to older people and others who wanted the vaccine. In Philadelphia 450,000 doses have been distributed. The Department's influenza immunization advertising campaign concludes on March 1.

Dr. Johnson cautioned that there is still a potential for a third wave H1N1 influenza. For the next flu season, there will not be two vaccines. The trivalent seasonal influenza vaccine will include immunization against H1N1.

Dental Amalgam Review:

The Board of Health conducted its annual scientific review of amalgam as decided during the February 10, 2009 Board meeting.

The Board invited the three parties named in the amalgam ordinance—Consumers for Dental Choice, the Philadelphia County Dental Society, and the New Era Dental Society—to submit:

- Five or fewer scientific articles and/or reports published since January 1, 2009**,** that provide new evidence about amalgam, dental health, and overall health.

- A copy of the Information Sheet with any suggested changes noted and the basis for change clearly cited.

- Written testimony from one or two organization representatives that summarizes the suggested changes to the Information Sheet and the rationale for the changes.

The Philadelphia County Dental Society submitted the following reports or articles:

--FDA Final Rule and Guidance Document on Dental Amalgam, Mercury, and Amalgam Alloy

--A position paper by Steven R. Jefferies, MS, DDS, PhD, Director of Clinical Research, Kornberg School of Dentistry, Temple University

Consumers for Dental Health submitted the following reports or articles:

--Linking mercury amalgam to autoimmunity, Paolo D. Pigatto and Gianpaolo Guzzi

--Assessment of chronic mercury exposure within the U.S. population, National Health and Nutrition Examination Survey, 1999-2006, Dan R. Links, Springer Science and Business Media, published online August 21, 2009.

--A prospective study of prenatal mercury exposure from maternal dental amalgams and autism severity, David A. Geier, Janet K. Kern, Mark R. Geier, Acta Neurobiol Exp 2-009, 69: 1-9

--Affidavit: An Evaluation of Dental Amalgam and its Ability To Injure Human Health, Boyd E. Haley, PhD, February 2, 2010..

--Cadmium, mercury, and lead in kidney cortex of living kidney donors: Impact of different exposure sources, Barregard, L. et al, Environ. Res. (2009), doi: 10.1016/ j.envres.2009.10.010

Dr. Peter Carroll, D.D.S, President of the Philadelphia County Dental Society, Dental Society, addressed the Board and presented written testimony including recommended changes in the dental amalgam information sheet (**attachment A**)**.**

Dr. Carroll called upon Dr. Andrew Miramor to discuss his experiences with special needs children at an outpatient facility for patients with intellectual or developmental disabilities that often require general anesthesia for treatment. Dr. Miramor said that that the option of using amalgam is essential in these circumstances and obtaining a parental signature on the information fact sheet can be challenging. He said that he is usually able to provide clarification to a parent, but some parents refuse, which necessitates that they seek treatment elsewhere.

Dr. Schwarz noted that while the regulation and ordinance require that the fact sheet be presented they do not preclude the use of other additional, informational materials.

Renee Fennell-Dempsey, D.M.D., President of the New Era Dental Society, addressed the Board, endorsed the changes to the dental amalgam information sheet, and submitted written testimony (**attachment B**).

Dr. Yolanda Slaughter asked if the Dental Society had used a particular method in gathering information about the impact of the regulation and patient response to the information sheet, or if the information is anecdotal. Dr. Carroll said that the information is anecdotal.

Robert Reeves, Esquire, representing Consumers for Dental Choice, addressed the Board and presented written testimony including recommended changes in the dental amalgam information sheet (**attachment C**).

Susan Schewel, asked Ms. Koss for opinion of the FDA's Final Rule and Guidance on Dental Amalgam. Ms. Koss said that she is disappointed in the decision but has reason for optimism. She referred the question to Robert Reeves who reviewed for the Board his recent discussions with Dr. Joshua Sharfstein and other FDA officials under the Obama administration. He said there is reason to believe that the Final Rule and guidance will change under the new administration in Washington and urged the Commissioner to further investigate the matter.

Dr. Robert Sharrar commented that the Board must act on what is said officially by the FDA, not reports on what is being said behind the scenes.

Dr. Schwarz indicated that he would consult with the FDA prior to the next meeting of the Board.

Human Papilloma Virus (HPV):

Dr. Giridhar Mallya, Department of Public Health Director of Policy and Planning, presented the Board with information requested during the meeting of December 10, 2009:

- An article, Health and Economic Implications of HPV Vaccination in the United States, Jane J, Kim, PhD. and Sue J. Goldie, M., MPH; New England Journal of Medicine, August 21, 2008; which discusses the cost effectiveness of the vaccine and concludes that the vaccine is cost effective dependent upon the percentage of young women immunized, length of immunity, whether or not the vaccine protect against genital warts, and the frequency of pap smear screening.

-An article, Will Widespread Human Papillomavirus Phrophylactic Vaccination Change Sexual Practices of Adolescent and Young Adult Women in America; Bradley J. Monk, MD, and Dorothy J. Wiley, PhD, MPH; Obstetrics & Gynecology, Vol. 109,No. 2; August 2006; which examines the impact of sexually transmitted disease interventions on sexual behavior. Because HPV specific data is unavailable the authors review the effects of condom distribution and Hepatitis B immunization upon behavior. Between 1991 and 2001American girls reported a decline in sexual encounters, fewer sexual partners, and among the sexually active, more frequent use of condoms.

-An Amendment to Regulations Governing the Immunization and Treatment of Newborns, Children, and Adolescents, to serve as an example or model for proposed regulations.

Further discussion of a regulation governing HPV immunization was postponed for a future meeting.

Announcements: Dr. Schwarz announced that the Mayor would present his budget to City Council on March 4th. He said that the State budget has reduced funding for HIV-AIDS services by 1.7 million primarily impacting counseling and youth services.

The Commissioner adjourned the meeting at 6:50 PM.

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.[1] 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 re-written to remove the portions that are no longer supported by the FDA's science-based

[1]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.

ATTACHMENT B

New Era Dental Society
Philadelphia, PA

Philadelphia Board of Health Hearing
Amalgam dental Fillings Information Sheet
Renee Fennell- Dempsey, D. M.D.
Representing the New Era Dental Society
February 11, 2010

As the 2010 – 2012 president of the New Era Dental Society, I submit this testimony to the Philadelphia Board of Health Hearings on the issue of the Amalgam Dental Fillings Information Sheet.

New Era Dental Society represents minority dentists in the greater Philadelphia area. Many of our practices are in the inner city of Philadelphia and represent the underserved, the uninsured and underinsured population.

Based on our review of the current literature as well as the experiences of our members, the New Era Dental Society, along with the National Dental Association supports the findings of the Food and Drug Administration (FDA) and others that dental amalgam is a safe and effective restorative material.

From the experiences of our members, especially those serving the uninsured and underinsured population, the information brochure, impacts negatively on our patients care. We have three main issues that we would like for the Board to consider:

The Information sheet needlessly slants the patient into believing that amalgams are dangerous when the FDA says otherwise. They feel that they are going to get cancer from the amalgams and want all of their amalgams removed when the FDA recommends against this practice.

Also many patients don't understand the negative side of composite resins which are not stated in the brochure: that many times they don't last as long as amalgams, they have greater tooth sensitivity, and they are more susceptible to secondary caries.

Lastly, since most insurance does not cover posterior composites, the patients are upset about the amalgams but cannot afford to pay for alternative treatment. This has in many cases undermined the trust relationship of doctor and patient.

ATTACHMENT C

February 3, 2010

To: Kay Graham for

Donald Schwarz, MD, MPH
Health Commissioner
Philadelphia Dept of Health

Dear Dr.Schwarz:

re: Review of Risks of Mercury Dental Amalgam - Fact Sheet

Thank you for the opportunity to submit suggested revisions to the Amalgam Mercury Dental Filling Fact Sheet approved by the Department of Health during the February 10, 2009 Board Meeting.

Although the brochure is an important first step in creating public awareness about the potential harm of amalgam fillings, it does not accurately inform consumers of the health risks from placing mercury fillings into the body. Based on the evidence of toxicity contained in the scientific research submitted, the fact sheet is vague, incomplete and inaccurate. It, therefore, does not c*ontribute to a patient's ability to make an informed decision when choosing between the use of dental amalgam which contains mercury or an alternative material in a dental procedure* as stipulated in Councilwoman Reynolds Brown's bill..

We recommend that the information contained in the consumer fact sheet reflect the continual toxic exposure to mercury vapor emanating from amalgam fillings under normal chewing compression, and its toxic effect on the kidneys, immune system, pregnant women and the fetus.. As noted in the submitted Affidavit of Dr. Boyd Haley, 80% of inhaled mercury vapor is retained by the human body and that the major contributor of mercury to human body burden is from dental amalgam. This position of the World Health Organization is evidenced in their recent studies showing that released mercury vapor from dental amalgams

setting quietly in sealed test tubes is in the range of 4 to 21 ur/cm2/day. In another study, it was estimated that “The integrated daily mercury dose absorbed from amalgam was estimated up to 3 microg for an average number of fillings and 7.4 for a high amalgam load.”

Also indicated in Dr .Haley’s research, air and oral ingestion of mercury vapor primarily effect the central nervous system whereas the kidney is the major organ affected by the cationic forms of mercury. Haley notes, added to this problem is the fact that prolonged mercury vapor exposure can lead to inhibition of the mercury excretion process itself. Therefore, extended exposure to mercury from amalgams will, by itself, decrease the body’s ability to excrete mercury. See his comments re: Children’s Amalgam Trial.

In the 2009 study by Dr. Lars Barregard**,** *Cadmium, mercury, and lead in kidney cortex of living kidney donors: Impact of different exposure sources* ,it indicated that the kidneys is a major target of mercury from amalgams:

> "Kidney Hg increased by 6% for every additional amalgam surface, but was not associated with fish consumption. Lead was unaffected by the background factors surveyed. CONCLUSIONS: In Sweden, kidney Cd levels have decreased due to less smoking, while the impact of diet seems unchanged. Dental amalgam is the main determinant of kidney Hg."

Haley also points to the connection between exposure to mercury and immunotoxicity. “Namely, mercury can serve as a co-factor in autoimmune disease in the presence of other triggering events, either genetic or acquired.” He notes that mercury toxicity is a retention toxicity, where mercury is extracted from the blood and retained in certain tissues, leading to elevated levels that can cause illnesses.

In the Laks 2009 study submitted: "The results indicate that due to chronic mercury exposure, inorganic mercury deposits accumulate in organs of the human body, in a time dependent manner. This study indicates that I-Hg deposition within the human body is significantly associated with biomarkers for the main targets of chronic mercury exposure, deposition and effect: the liver, immune system, and pituitary. ,,,,The evidence presented in this study indicates that effects of chronic mercury exposure within the US population may result in a significant rise over time in the population risks of associated neuro-developmental and neurodegenerative diseases."

The scientific evidence presented in Haley's paper and several others found that only mercury could cause a major biological abnormality in a major brain protein when added to normal human brain tissues or in rat brain on exposure to mercury vapor, a major pathological diagnostic hallmark of Alzheimer's disease.

Further, Haley presents studies indicating that mercury in dental amalgams in a pregnant mother increases
The exposure of the in utero infant to elevated mercury vapors as it dramatically increases the mother's blood mercury levels. He notes, that "there can be little doubt that the exposure of a pregnant mother to mercury vapor by aggressive dental amalgam treatment could cause harm to her infant in utero."

Considering the submitted evidence of risk, it would be prudent for the Dept of Health to revise the Amalgam Patient Fact Sheet to include, at the very least, the Warnings and Contraindications included in the Amalgam Materials Safety Data Sheet as follows:

Prop 65

- This product contains mercury, which is known by the state of California to cause birth defects or other reproductive harm.

Contraindications:

The use of amalgam is contraindicated:

- In proximal or occlusal contact to dissimilar metal restorations.

- **In patients with severe renal deficiency.**
- In patients with known allergies to mercury amalgam.
- For retrograde or endodontic filling.
- As a filling material for cast crown.
- **In children 6 and under.**
- In expectant and nursing mothers.

Precautions:
The number of amalgam restorations for one patient should be kept to a minimum.

Side Effects and Warnings
- Mercury may also be a skin sensitizer, pulmonary sensitizer, nephrotoxin and neurotoxin.
- Removal of clinically acceptable amalgam restorations should be avoided to minimize mercury exposure, especially in expectant mothers.

- Health hazards (acute and chronic). Mercury poisoning is usually chronic.
- The number of amalgam fillings for one patient should be kept to a minimum.
- Exposure to mercury may cause irritation to skin, eyes respiratory tract and mucous membranes.
- Mercury expressed during condensation and unset amalgam may cause amalgamation or galvanic effect if in contact with other metal restorations. If symptoms persist, the amalgam should be replaced by a different material.

Dental personnel should also be made aware of their occupational exposure to mercury vapors. It has been well documented that among other symptoms, female dental personnel have a high percentages of miscarriages, infertility and neurological problems.

Considering these warnings, we strongly recommend that the current brochure be amended to include these facts, and any other necessary information to afford patients the ability to make educated decisions. We encourage patients to read and understand the information presented in the brochure before agreeing to any dental treatment. If they have concerns related to the use of mercury fillings or they would prefer composite fillings, we suggest conferring with their dentist, but to ultimately make their own decision.

We also request that disadvantaged patients be informed that Medicaid insurance does pay for white composite fillings. This fact had been eliminated by

the Dept of Health from the original adopted brochure. We ask that the following be reinstated in the brochure: “There may be a cost difference between resin composite and dental amalgam, however, many insurance providers, including Medicaid provide coverage for resin composite fillings,”.. Patients should be made aware of this.

Sincerely,

Freya B.Koss
For Consumers for Dental Choice