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Petition: The Philadelphia Board of Health Must Get Legal Advice from City Solicitor Smith Before Proceeding with Amalgam Information Sheet Revisions

At the meeting of the Board of Health on February 18, 2010, the Pennsylvania Dental Association (PDA) and the Philadelphia County Dental Society (PCDS) presented an extraordinary take-it-or-leave-it threat to Philadelphia's children with disabilities, and a similar implicit threat to this Board. To the parents of children with disabilities in North Philadelphia, the PDA and PCDS endorse an ultimatum that they would refuse to provide dental care – no teeth cleaning, nothing – as a tactic to strong-arm “consent” to this implanting of a mercury device in their children's teeth.

The representative advocating this joint withdrawal of services, Dr. Andrew Mramor, was trained by the PDA to be an official “spokesperson” to protect the marketing of mercury amalgam. Such no-holds-barred tactics continue what last year's PCDS president David Tecosky calls “amalgam wars” against those opposed to mercury in the mouth.

The actions are a last-ditch effort by these trade groups to protect the use of dental amalgam, a primitive pre-Civil War device that is composed of 50% neurotoxic mercury and that long sustained the coffers of their parent trade group the American Dental Association as it held amalgam patents and accepted kickbacks from amalgam manufacturers. Now that consumers are learning the risks of this neurotoxin that dentists had refused to disclose to them – risks recently confirmed by the Food and Drug Administration – the trade groups are struggling to shield themselves from liability.

1. The Board may not base its revisions to the amalgam information sheet on the threats PDA/PCDS directs at people with disabilities and must take steps to address the discrimination that came to light in the course of its proceedings

By threatening a denial of dental services to people with disabilities, PDA and PCDS are clearly attempting to intimidate the Board, bullying it into weakening the warnings in the amalgam fact sheet. If left unaddressed, this issue will undermine public confidence in the Board, leave the Board open to legal liability, and encourage other health professionals to threaten minority groups in order to influence Board decisions.

If these dental trade groups are as concerned about the relationship between dentists and patients as they claim to be, perhaps they should not have declared “war” on their patients and the ever-growing coalition that supports them. Those opposed to amalgam include the rising field of mercury-free dentists, research scientists who have demonstrated the health risks, environmentalists shocked by the dental mercury's devastating role in our planet's water and air pollution problems, consumers who insist upon their right to control what materials are implanted into their own bodies, minority advocates fighting against “choice for the rich and mercury for the poor” (are parents on the Main Line forced to submit to amalgam for their children or are only children in North Philadelphia subjected to this neurotoxin?), and those North Philadelphia parents who are exerting their right to alternative filling materials for their children with disabilities.

As a war tactic, the PDA and PCDS have singled out the most defenseless of patients – disabled, children, and minority – to say that the parents must “consent” to mercury fillings, or else. While they claim to promote choice of filling materials for the able-bodied (“Many factors may affect *your choice* of filling material”¹ and “This fact sheet outlines the alternatives available and will help *you decide on the right choice for you.*”²), the dental associations publicly advocate discriminatory punishment for people with disabilities who exercised this right. In their written testimony of 11 February 2010 and in their comments before the Board at its 18 February 2010 meeting, PDA and PCDS threaten to continue pushing dentists to withhold dental treatment – even teeth cleanings that would prevent tooth decay in the first place – from these people with disabilities who exercise their right to refuse amalgam. Boasting that the associations have the economic power to force amalgam onto these non-consenting people with disabilities, PDA/PCDS spokesman Dr. Mramor reinforced this threat by emphasizing that after a family is expelled from one of the only clinics equipped to treat people with disabilities, finding dental care is a “challenge.” To confirm the power of the associations to carry out this threat, Spokesman Mramor announced that he has already denied dental care to several children with disabilities when their parents refused to consent to amalgam.

The experiences of dentists confirm that any claim that amalgam is the only option for a sedated child with disabilities is patently false. Dr. Chester L. Yokoyama is a former Member of the Dental Board of California and co-founder and former director of Aiding the Medically Compromised, Inc., a non-profit organization established to promote awareness of dental issues for persons with disabilities. Having spent ten years as a dentist treating children with disabilities in the operating room, Dr. Yokoyama clarifies the situation now facing children with disabilities in Philadelphia: “Composites can be done under general anesthesia or IV sedation. If the dentist is unwilling to provide composites for children with disabilities, it raises questions about denying such children access to dental treatment. If the dentist is unable to provide composites for children with disabilities, then he or she can seek further training.”

2. The Board may not rely on misleading testimony to revise the amalgam information sheet

Appearing before this Board, the PDA and PCDA bring their monopoly economic power to bear, raising the specter of pulling services out of North Philadelphia to corral the Board into repealing the disclosures that the ordinance mandates. With truth as the first casualty of war, the PDA and PCDS apparently have decided that they have the right to make the patently false claim to this Board that the Food and Drug Administration issued no warnings about amalgam. But in fact, upon learning of the trade group’s proposed changes to the information sheet, the FDA wrote a letter stating that its rule did contain warnings about amalgam, citing the specific warnings, and

¹ The Pennsylvania Dental Association, Dental Filling Facts, <http://www.padental.org/AM/Template.cfm?Section=Search&TEMPLATE=/CM/HTMLDisplay.cfm&CONTENTID=4472> (emphasis added).

² *Id.* (emphasis added).

observing that the information sheet proposed by the trade groups did not accurately describe any of the risks found by FDA.³

Even though it failed to reflect scientific studies that indicate even more extensive safety problems, the facts spelled out in FDA's 2009 dental amalgam rule fail to even remotely resemble the rosy PDA/PCDS summary of the rule. The FDA rule admits that there is no scientific basis for concluding that amalgam is safe for children under six, for pregnant women's fetuses, or for lactating mothers' nursing babies: "Very limited to no clinical information is available regarding long-term health outcomes in pregnant women and their developing fetuses, and children under the age of six, including infants who are breastfed." In fact, FDA admits that amalgam could cause severe harm: "The developing neurological systems in fetuses and young children may be more sensitive to the neurotoxic effects of mercury vapor." Additionally, in its white paper addressing dental amalgam (released along with the rule), FDA conceded that its rule does not take into account the reality that many people are already affected – or even disabled – by a high mercury bioburden from other sources (such as tuna and vaccines), a condition that makes them even more susceptible to amalgam's neurotoxic effects: "This type of comprehensive analysis of exposure to multiple species of mercury from multiple sources was beyond the scope of the review."

This is not the first time PDA and PCDS have intentionally made inaccurate statements to protect amalgam – after all, they have deceived consumers about the product's risks for years (and their highly misleading proposed information sheet makes clear that they intend to do so again). The Board may not rely on the blatantly inaccurate PDA/PCDS claims to revise the amalgam information sheet.

3. The Board may not rely on non-responsive testimony to revise the amalgam information sheet when it denies other stakeholders both the opportunity to present relevant testimony that did not satisfy its narrow requirements and the opportunity to reply to the non-responsive testimony

The Board's actions on February 18 suggest it has already decided to cave in to the PDA and PCDS's demands. The Board requested only a "concise set of 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 suggested changes, and written testimony summarizing them. Additionally, the Board stressed that "Testimony will NOT be provided orally" (emphasis in original).

PDA and PCDS submitted testimony that did not respond to the Board's narrow request. It dwelled on old studies published years before the 1 January 2009 cut-off date, anecdotal dentist complaints about the rule, and an FDA rule that could hardly be mistaken for a scientific study since the agency admits that its decision was based on such non-scientific factors as the costs of periodic manufacturer testing, FDA administration, and alternative materials (and no doubt lobbying from the American Dental Association was an additional non-scientific factor).

³ See

<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/DentalAmalgam/UCM174024.pdf>

Meanwhile, Consumers for Dental Choice complied with the Board's request, submitting new scientific studies that reinforced the need to warn consumers about this hazardous product. In light of the Board's restrictions, we did not cite older science, we did not relate stories heard from consumers, we did not present unscientific government decisions, and we did not make arrangements for scientists, dentists, or consumers to testify orally. Then, at its 18 February meeting, the Board not only failed to address any of the new scientific studies we raised, but it focused on the non-responsive PDA and PCDS testimony and permitted trade association spokesmen who did not submit written testimony the opportunity to present oral testimony. By the time we realized that the Board had suddenly decided to permit just anyone to orally testify, it was too late – our representatives who had not submitted written testimony, relying on the Board's restrictions, were not in attendance and so could not testify.

Having granted special favors to the trade associations (i.e. the opportunity to orally testify and to submit written testimony that did not satisfy Board restrictions) the Board may not now make any information sheet revisions to the detriment of consumers who demand the information that dentists have so long withheld from them – the risks of neurological damage, the dearth of scientific proof of safety for children and the unborn, and the dangers of bioaccumulation.

Requested Action

In these circumstances, this Board must get legal advice from the City Solicitor, the Honorable Shelly R. Smith. It should not take a vote on amending the brochure until several legal questions are answered about whether strong-arm tactics by a monopoly economic power can be used as part of a scheme to remove warnings about the product this monopoly forces onto the public.

As a statutory stakeholder, Consumers for Dental Choice petitions that – before proceeding with revisions to the amalgam information sheet – the Board of Health seek the written legal opinion of City Solicitor Smith, with regard to these five critical issues:

1. May the Board base its revisions to the amalgam information sheet on threats directed at people with disabilities?
2. Should the Board ask the state Attorney General to investigate this conduct under laws addressing (a) discrimination against the handicapped, or (b) restraint of trade by monopolies, or (c) Medicaid regulations?
3. What are the Board's legal options when an organization with monopoly power threatens to cut off services as a means of obtaining its desired result from the Board?
4. In considering revisions to the fact sheet, may the Board rely on false and misleading testimony, in this case, the claim by the PDA and PCDA that the FDA has no neurological warnings in its amalgam rule?
5. May the Board rely on non-responsive testimony to revise the amalgam information sheet even though it denied other stakeholders both (a) the opportunity to present relevant testimony that failed to respond to its narrow requirements and (b) the opportunity to reply to the non-responsive testimony?

Charles G. Brown, National Counsel

Date