

## *SILVER-MERCURY AMALGAM DISCLOSURE AND INFORMED CONSENT*

written by Dr. Michael Fleming

There is likely not one reader of this publication who is unaware of the ongoing controversy surrounding the use of dental amalgam. The dental profession continues to debate the safety and effectiveness of a material that has served dentistry's restorative needs for the better part of two centuries. However, consumer and regulatory pressure to eliminate mercury-containing products from dentistry, medicine, and the environment is at an all-time high. This makes it an entirely appropriate time to talk frankly about an issue that has too long plagued the profession.

I wear two professional hats these days. First, I have practiced general dentistry for more than 26 years. Second, I also serve as the Consumer Representative on the Dental Products Panel at the U.S. Food and Drug Administration. While my job on the panel is to represent the concerns of American consumers with respect to dental products and devices before the FDA, I also care deeply about what happens to my profession. Please understand I do not speak for the FDA or any other organization. The remarks that follow represent what I consider to be sensible opinions on this complex subject and are offered in the hope of stimulating further meaningful dialogue in the public arena. In that spirit, let's talk plainly about amalgam. I will give you a personal perspective on the results of the recent FDA hearings, discuss the problem of amalgam and informed consent, and offer some additional thoughts and recommendations regarding amalgam use for your consideration.

### **Background**

A joint meeting of the Dental Products Panel and the Peripheral and Central Nervous System Drugs Advisory Committee of the Food and Drug Administration was held in early September 2006 to review recent scientific literature on the potential neurological effects of mercury in dental amalgam. Press coverage and security for the meeting was extensive, and two documentary film production crews recorded the entire event. Some in attendance thought the meeting was the most significant gathering of its kind in the history of the dental profession.

The FDA provided a "White Paper" for the Panel's consideration that selected 34 studies out of many hundreds that fulfilled their criteria for inclusion. Following a careful review and discussion of the presentations and science, the Joint Panel voted 13-7 to reject the FDA's conclusion that amalgam was safe. By the same voting margin, the Panel also concluded 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 its safety could not be established based upon the data provided.

### **The issues**

Panel members expressed a number of concerns during the course of the meeting. These included, among other things, a lack of predictable data available on daily mercury exposure in amalgam bearers, the potential health effects of mercury in higher-risk populations, and insufficient data on mercury allergy risk.

The single most consistent concern expressed by many Panelists involved the apparent lack of informed consent obtained prior to the installation of amalgams and other dental materials. While it was acknowledged that periodontists and oral surgeons, for example, routinely explain the risks and benefits of procedures to their patients, the same could not be said for restorative dentists. Note what one Panel member said in his concluding remarks before the Panel:

*“I think the major thread, or the take-home message that I have, is that the Federal Government and the agencies need to force dentists to provide informed consent to the patient, and making sure that the patient is going to be well-informed, and making their appropriate decision toward the use of this material.*

*Having said that, I don’t know what would be the mechanism, whether ADA has to step forward, or the federal agencies. I leave it as a question open at this point. But something has to be done.”*

A recurring theme heard from consumer presenters during the meeting was: “If I had known mercury was being put in my mouth, I would never have allowed it.” Again, consider what another Panel member said about the matter in her summary statement:

*“I think it’s very important to have informed consent and I think there should be a change in the labeling of these amalgams to, if you will, ‘silver mercury,’ or ‘mercury silver amalgams,’ so people really understand what is being put in their mouths. I think also, as other people have said, from what I can understand, these [amalgams] are going to go away, and go away fairly soon. So I would recommend also that women who are of child-bearing age, especially the pregnant women, and also children, really be especially counseled on getting these in their mouths.”*

The personal recommendations of the Panel members, while not binding on the FDA or anyone else, clearly reflect misgivings about the routine use of a mercury-containing filling material in the absence of a patient’s adequate understanding of any potential health risks.

As of this writing, the FDA has not acted upon the recommendations of the Panel nor are they required to do so. There may be some sort of regulation and/or guidance proposed in the relatively near future on perhaps such matters as amalgam classification, use in higher-risk populations, package labeling, and informed consent. But, it is not clear what form that will take or exactly when or even if such changes might be imposed.

### **Changing perspectives and priorities**

Today’s consumer is far more knowledgeable about dentistry than is generally appreciated. Unfortunately, some patients who inquire about the safety of dental amalgam are often dismissed as misinformed alternative health nuts or fringe lunatics. Nothing could be further from the truth. The amalgam issue has captured the interest of a wide variety of individuals and transcends socio-economic backgrounds, political partisanship, or activist leanings. These savvy consumers rightly want and need the dentist’s guidance in making informed treatment choices.

While there may be some form of dialogue with patients in restorative practices over matters such as esthetics and cost of treatment, very little information seems to be conveyed regarding any potential health risks of the various dental materials contemplated for use. In the case of amalgam, this likely stems

from the fact that major dental, medical, and government agencies currently endorse its continued use. As well, many dentists simply do not believe amalgam is unsafe and see no reason to discuss the matter with their patients. Moreover, state boards of dentistry have generally looked unfavorably on a dentist's unsolicited discussion of amalgam health risks and removal options. Even when such information and treatment is requested by patients, many dentists are still reluctant to talk about amalgam issues for fear of jeopardizing their licenses. While a few states require some form of informed consent prior to amalgam placement, there still remains an overall restrictive environment for dentists and patients to exchange needed information to make adequate treatment decisions.

Many patients have no idea to which dental products they might be sensitive. Still, informed consent discussions ought to include asking patients if they have any known allergies to mercury, resins, and other dental materials. The risks and benefits of amalgam removal also should be thoroughly discussed. The patient's proper informed consent can then be obtained before treatment commences.

Children and women of childbearing age are of particular interest to regulatory agencies, and thought by some investigators to be at higher risk for mercury exposure effects. In these cases, informed consent is essential particularly in high-volume pediatric, Medicaid, and public health settings. Whole-mouth restorative care, including composites, amalgams, pulp treatments, and stainless steel crowns, is often rendered on children in these settings during one appointment.

### **Disclosure, decisions, and options**

The burden to obtain the necessary information to make informed treatment choices does not rest solely on the patient. It is the dentist's legal duty to inform patients of the known risks and benefits of proposed treatments, including restorative procedures. Providing answers only when patients ask about amalgam or any other material is only part of the informed consent process. The greater challenge before the profession is establishing what needs to be said when patients do not ask. Silence is a poor option given the current litigious environment and the persistent doubts about amalgam safety.

Dentists do not need to place themselves in the position where their patients have little or no idea what was installed in their mouths. Patients do not necessarily need or want to know everything, but they can know more than what they are typically told - that they just got a root canal, a filling, or a crown. When patients ask for information, dentists and staff members cannot afford to respond in a dismissive or condescending manner simply because they are asking hard questions. In this regard, the need to listen carefully and compassionately to patients cannot be overemphasized. Yes, it takes time to answer the questions and participate in active dialogues with patients on matters that concern them. Is it worth it? Absolutely! Patients will admire and respect a dentist for it.

One of the most important decisions a dentist can make is whether or not to reduce or abandon amalgam altogether. These are bold steps but they are steps many practices have successfully taken for a variety of reasons. The most common reason for reduction in amalgam use has to do with esthetic concerns, but a growing number of practices have also eliminated amalgam to control occupational mercury exposure and limit potential health effects in their patients. Whatever the reasons, such changes can be made in dental practices that maintain the highest ethical standards and provide wonderful service for patients.

Currently, dentists remain free to offer dental amalgam as a restorative choice, but the time may come when that treatment option will no longer be available. Whatever the FDA or other regulatory authorities decide, steps can be taken now to address the use of amalgam in potentially higher risk populations under the precautionary principle. Dentistry has very good alternative materials for most restorative needs and, if amalgam installation or removal is contemplated, treatment can be agreed upon in a collaborative atmosphere with the patient.

On a more personal note, I decided to stop using amalgam more than 20 years ago. It was very unpopular to question amalgam safety back then, and a number of my colleagues were mystified and occasionally enraged that I would do such a thing. Some still don't understand it. Nevertheless, I decided long ago that conviction had to trump popularity. In retrospect, it was a great decision for me and, in all the years since, I have never had a patient ask for an amalgam. Do I enjoy the respect and admiration of my colleagues? It depends on whom you ask. Some dentists are very supportive; others would just as soon put me out of their misery. Yes, there was a price to pay for following my conscience, but it was well worth the cost.

### **Stage three**

The philosopher Arthur Schopenhauer once said that all issues of truth pass through three stages. First, it is ridiculed; second, it is violently opposed; and finally, it is accepted as self-evident. While reasonable minds can differ on the truth and meaning of the current scientific evidence, I believe the amalgam issue is emerging from stage two and entering stage three of this evolution. This is an excellent time for all the stakeholders in the matter to lower the gun barrels, come out of the trenches, and begin the process of meaningful engagement on the issues.

These times of change offer opportunities for the profession to grow and transform itself and do not represent the ominous portents of doom some have imagined. To be sure, the inevitable transition out of amalgam will be challenging and confusing to both regulators and dentists. But, there is absolutely no reason the profession cannot accomplish a great deal on its own to responsibly navigate these troubled waters. Throughout all of this, dentistry can continue to respect the law, uphold the highest ethical standards of patient care, and honor the emerging science.

Dr. Michael D. Fleming is a former Marine pilot and Vietnam veteran, and is currently serving as the Consumer Representative on the Dental Products Panel at the Center for Devices and Radiologic Health of the Food and Drug Administration. He maintains a private dental practice in Durham, N.C.