There is no greater challenge in dentistry these days than accurately predicting the future of dental amalgam use and FDA regulation. Given the more restrictive trends in federal and international regulatory policy with respect to mercury in general, and dental amalgam mercury in particular, it is very timely to address the current state of amalgam regulation, discuss common misconceptions in the ongoing amalgam safety debate and offer recommendations for future amalgam use.

There is considerable confusion among health professionals surrounding the FDA’s role in the regulation of dental amalgam or any other medical device. It is worth mentioning at the outset that the agency does not regulate the actual practice of dentistry or medicine and, while this distinction is not altogether clear at times, the agency is tasked with product regulation only.

To review, the FDA regulates medical devices based upon the principle of the “reasonable assurance of safety and effectiveness.” Safety and effectiveness for a particular device are separate and distinct criteria used by the agency in the process of allowing a product or device to enter or remain in the marketplace for its intended use.

Medical devices are categorized by means of a classification system that can be generally understood as follows:

- **Class I** includes fairly simple products, such as tongue depressors;
- **Class II** includes somewhat more important devices, such as most artificial knee joints and dental amalgam;
- **Class III** includes devices most important in supporting the life or health of patients, such as heart valves.

It is a common misconception regarding device classes that the higher the classification, the greater the device’s potential risks to health. In actuality, medical devices are classified according to their complexity and intended uses, not necessarily any inherent risks to health. Misunderstandings can arise if this distinction is not appreciated.

For example, there have been concerted attempts to compel the FDA to up-classify amalgam from its current Class II designation to Class III based in part on the belief there are increased risks to health. Up-classification would then require the agency to automatically restrict its use. In fact, a Class III designation for amalgam would not necessarily achieve that end.

However, the up-classification of amalgam to a Class III for whatever reason presents a unique conundrum for manufacturers and regulators. Manufacturers would then be compelled to prove safety by means of the complex and expensive pre-market approval process. Amalgam manufacturers would likely be unwilling or unable to subject their product to such an onerous review given the expense, increasing environmental restrictions on mercury waste, escalating patient health concerns and a general decline in amalgam use worldwide. If amalgam manufacturers chose to opt out of this approval process, they would ultimately be required to cease production and distribution of their amalgam product in the U.S. market. The FDA indicated in the language of the 2009 Amalgam Rule that up-classification of amalgam to Class III was tantamount to a ban and a regulatory action the agency chose not to pursue at that time.

The FDA’s current regulatory challenges with respect to dental amalgam use surround matters of safety, not effectiveness. Here again, confusion can abound. It is very common for those on both sides of the amalgam debate to inadvertently, or by design, confuse issues of safety with those of effectiveness. However, clear distinctions between these two criteria need to be maintained whenever the subject of amalgam safety is raised. Typically, such an oversight can make for very tangled
debates, flawed research conclusions and in comprehensible public policy.

For example, traditional dental literature frequently lays claim within the context of a safety discussion to amalgam’s functional usefulness, service life or even the length of time utilized in the marketplace. The thinking seems to be, since amalgam has been so useful for so long, it has to be the best and safest option. From a strictly regulatory point of view, these kinds of arguments for or against the use of amalgam, or its alternatives for that matter, have nothing to do with whether each of these restorative materials are deemed safe for their intended uses.

“Claims of untoward health effects from amalgam are often summarily dismissed as unproven by amalgam supporters and fervently embraced by those opposed to its use.”

Safety concerns with one product or device are not related to those of a different device. Within the regulatory framework, this means that any alleged health concerns surrounding composite use are unrelated to matters of safety with amalgam. Thus, one cannot successfully argue for continuing the use of amalgam on the basis that composites may turn out to be unsafe in some way.

A classic example of confusing safety with effectiveness can be found in a very recent policy brief on dental amalgam submitted to the American Public Health Association (APHA), an influential organization representing thousands of public health professionals. This brief was authored within the oral health section of the APHA, presumably to aid in developing a policy statement to counter the international trend to phase out the use of dental amalgam. Here is a direct quote from that document:

Finally, to support the phase-out of dental amalgam, it is claimed that alternatives have been in clinical use for over 30 years, with little evidence of clinically significant adverse effects to date. While the former is true…the latter is inaccurate. Amalgam lasts longer than other materials when used for restorations in the permanent dentition and for large restorations. The aesthetics of tooth-colored alternatives, in particular RBC challenge the continued use of dental amalgam. However, scientific evidence demon-

strates that RBC are more susceptible to failure and recurrence, particularly in large multiple surface restorations and when moisture cannot be controlled. In addition, numerous studies and reviews have shown that dental amalgam outlasts RBC. Therefore, as of today, there are no dental restorative materials as cost-effective and reliable as dental amalgams. Another consideration is the fact that recent studies have found an association between RBC and adverse psychosocial outcomes among children.1

This statement muddles together issues of composite safety, amalgam functional superiority, aesthetics, restorative failure, cost-effectiveness, and concludes by alleging associations between composites and adverse psychosocial outcomes in children. While each of these separate issues can be debated on their individual merits, taken as a whole, such statements do little to clarify the core regulatory issue of dental amalgam safety. Such diverse characterizations only serve to further cloud the issues and hamper the development of a comprehensible policy on amalgam use by any organization, let alone the APHA. Again, dental restoratives are either safe or they are not, regardless of their cost, functional effectiveness or aesthetic attributes.

Claims of untoward health effects from amalgam are often summarily dismissed as unproven by amalgam supporters and fervently embraced by those opposed to its use. However, health effects resulting from the use of amalgam have been very difficult to scientifically support to the FDA’s satisfaction. Nevertheless, since the standard for agency regulators is the reasonable assurance of safety, proof of harm or the lack thereof are not necessarily required for the FDA to impose future restrictions.

The FDA could choose to take restrictive action based simply upon an agency belief that there is little to no evidence to support safety in whatever populations or circumstances they have identified. This approach underscores the need to understand that reasonable assurance of safety in the regulatory environment is not synonymous with the proof or disproof of harm. Under these circumstances, the FDA is not compelled to affirm or deny any health effects if the agency thinks the current science does not support such admissions.

From a public policy point of view, the imposition of regulatory restrictions without the admission of health effects would serve to partially mollify both sides of the amalgam safety debate – no ban for the pro-amalgam side and some restrictive activity for the anti-amalgam side. Such an approach would also signal to the profes-

1. LB1: Dental Amalgam—Preserving a Proven Dental Material, proposed policy statement for the American Association of Public Health, prepared by the Oral Health Section of the AAPH, October 30, 2012
sion and consumer public the FDA’s future direction in policy making and leave the door open for additional restrictive guidance for amalgam over the longer term.

There is an emerging consensus among some expert agency observers that the FDA is poised to implement a more restrictive policy on amalgam use. However, proposed changes in guidance with an issue as politically sensitive as amalgam use inevitably go through an extensive inter-agency review, particularly when a more restrictive policy is contemplated. As of this writing, it is unclear exactly what form any changes might take and when or even if any new guidance on amalgam use will be forthcoming.

Beyond increased regulatory pressure there are two other noteworthy trends at work that are affecting a precipitous decline in amalgam use. First, many dentists have ceased using amalgam for a number of reasons to include aesthetics, anticipated regulatory restrictions and perceived risks to operator and patient health. Second, and perhaps the most underestimated force for change, is escalating consumer demand for alternatives to amalgam.

Dentists who choose to eliminate amalgam from their armamentarium do so for a variety of personal and practical reasons. There is nothing whatsoever unethical about the decision to cease offering dental amalgam as a restorative option. Clinicians can also ethically refuse to remove the product for health reasons even at the patient’s request or a physician’s recommendation. These are decisions made by the practitioner based entirely upon what he or she believes to be the safest and most effective treatment options.

While the FDA has not yet promulgated any new guidance on amalgam use beyond what is contained in the 2009 Rule, sensible decisions regarding amalgam use can be made in advance of the FDA imposing further restrictions. Given the current regulatory climate, practitioners who still use the product may want to consider amalgam the restorative option of last resort, not the first.

Consistent with the 2009 Rule, the use of amalgam in patients with a demonstrated allergy to any of its component metals is contraindicated. The FDA also recommends against the installation of amalgam adjacent to dissimilar metals. Dental Products Advisory Panel members at the December 2010 meeting on amalgam safety concluded that certain subgroups of the population may be at higher risk of health effects and should not receive dental amalgam restorations. While none of the following restrictions have been imposed by the FDA, it would be advisable for dentists to carefully consider whether to continue installing amalgam in young children, pregnant and nursing women, immune-compromised patients, and those with impaired renal and neurological function.

Consumers of dental services are clearly demanding dental products that are safe, effective and aesthetic for themselves and their children. It is very common for patients to express concerns to their dentists about exposures to fluoride, BPA resins and metals of any kind. It is very distressing to patients for a dentist or staff member to thoughtlessly dismiss these concerns out of hand. There is little to commend in behaviors that exhibit condescending and patronizing responses to entirely legitimate and important questions. Strategies for addressing these concerns can be considered – which are reasoned, compassionate and implemented with a focus on substantive informed consent.

Finally, FDA regulation alone is insufficient in addressing all of the complexities surrounding the continued use of a dental material that has been the mainstay of restorative dentistry for the better part of two centuries. Working jointly, health professionals and researchers on both sides of this important issue of amalgam safety have the capacity and the obligation to clearly and objectively interpret the emerging science to each other and the consumer public. Proactive ways can be found for all involved to formulate and offer meaningful guidance on restorative choices in an atmosphere of trust and mutual respect. ■

Comment on this article! Visit www.towniecentral.com/Dentaltown/Magazine.aspx and search for “Predicting the Future of Dental Amalgam Use and FDA Regulation”

Author’s Bio

Dr. Michael D. Fleming is the former consumer representative on the FDA’s Dental Products Panel and acting consumer representative on the Circulatory System Devices Panel. He currently is an appointed consultant to the Center for Devices and Radiologic Health (CDRH) (term expires August 2014). He was a panel member at the September 2006 and December 2010 FDA advisory panel meetings on amalgam safety. Dr. Fleming is a former marine pilot and Vietnam veteran and has practiced dentistry in Durham, North Carolina, for more than 30 years. Dr. Fleming’s remarks and recommendations reflect his personal opinions only and not necessarily those of the Food and Drug Administration.