THE DENTAL AMALGAM FINAL RULE: MORE HEAT THAN LIGHT?

written by Dr. Michael Fleming

Aug. 4, 2009, marked the date the Food and Drug Administration released its long-awaited regulation on dental amalgam. The 116-page Final Rule will take effect Nov. 4, 2009, and is titled, "Dental Devices: Classification of Dental Amalgam, Reclassification of Dental Mercury, Designation of Special Controls for Dental Amalgam, Mercury, and Amalgam Alloy." In addition, the FDA has published a guidance document titled, "Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy."

The Final Rule formally classifies the encapsulated amalgam into Class II, reclassifies dental mercury into Class II, and designates special controls to accompany the classification changes. The entire Final Rule and Special Controls document is available for review on FDA's Web site.[1] I encourage a careful reading of these documents.

It is entirely appropriate to analyze and attempt to clarify some potentially confusing provisions of the regulation and make recommendations that transcend any requirements issuing from the Final Rule. The opinions expressed in this article are my own, but are based upon direct involvement on FDA advisory panels and the scientific, consumer advocacy, and public policy aspects of amalgam use.

Many of those closely watching the regulatory process were expecting a significantly stiffer rule than what was promulgated. For example, it was generally expected that the FDA would place limitations on the use of amalgam in young children, pregnant women, and breast-feeding mothers as part of the Special Controls. FDA did not impose such restraints and dentists appear to be free to install amalgam in virtually anyone other than those with a known allergy to the product.

There has been a good deal of confusion and frank outrage over the content of this new rule among those professionals, scientists, and consumer advocates who advocated tighter restrictions on the use of amalgam. One prominent FDA observer has stated: "Through its biased accumulation and assertion of evidentiary resources and its apparent escape from rigorous internal process validation and scientific challenge, this is the most flawed example of FDA rulemaking I have witnessed in 33 years of reporting this once-great agency."[2]

As of this writing, there are two petitions for reconsideration of the final rule before the FDA. One petition is a science-based approach requesting the agency to either ban dental amalgam from commerce or move the product into Class III. Another petition would leave the product in Class II but add substantive warnings for higher risk populations.

One of the primary thrusts of this petition centers on potential conflicts of interest involving FDA Commissioner Dr. Margaret Hamburg's prior board membership and stock holdings at the Henry Schein Corporation, one of the world's largest amalgam distributors. Significant ethical questions have been raised about the extent of her influence on the provisions of the Final Rule.

It should be remembered that FDA does not regulate the dental profession per se, only manufacturers, products, and devices. Therefore, it is important to discern where FDA's regulatory authority ends and the clinician's responsibilities (and potential liabilities) begin.

Informed consent

The need for clarity in the Final Rule is no more apparent than in the complex issue of informed consent. In the February 2007 issue of *Dental Economics*, I discussed recommendations with respect to informed consent and amalgam use (click here for the article). Confusing language in the regulation makes it necessary to revisit this matter due to the potential for significant misunderstandings about what dentists should be telling their patients about amalgam.

A number of consumer groups, clinicians, and scientists urged the FDA during the Proposed Rule's comment period to require dentists, via the package labeling, to inform patients that dental amalgam contains mercury and mandate that practitioners communicate certain health hazards believed to be associated with the use of the product. The Final Rule addresses this matter by stating the following:

> "FDA believes that the recommended labeling statements in the special controls guidance document will provide dentists with important information that will improve their understanding of the devices and help them make appropriate treatment decisions with their patients. In addition, FDA notes that dental amalgam is a prescription device and, therefore, patients cannot receive the device without the involvement of a learned intermediary, the dental professional. Based on the reasons described above, FDA has concluded that it is not necessary to require that dentists provide this information to patients in order to provide reasonable assurance of the safety and effectiveness of the device."[3]

FDA's wording has been misunderstood by many to mean that dentists are relieved of any responsibility to disclose the mercury content of dental amalgam. A careful reading of the regulation indicates the agency has only determined that informed consent with respect to dental amalgam is not necessary to establish the reasonable assurance and safety of the device itself. In other words, what has to be said to patients about dental amalgam is a separate and distinct issue from FDA's determination that amalgam is reasonably safe and effective for its intended use. FDA considers informed consent to be part of the practice of dentistry that is subject to the laws governing practitioners in their respective jurisdictions.

When it comes to a provider's duty to warn, the safest rule to follow is to be mindful of the requirement to obtain informed consent. Embedded in that duty is the obligation to disclose "material" information to patients that might cause them to make a different treatment decision. In the case of dental amalgam, FDA is instructing manufacturers what they must tell clinicians, not what clinicians should tell their patients. However, failure to disclose to patients that amalgam contains mercury would be most unwise. Such an omission misapprehends the scope and meaning of the rule and violates the basic tenets of informed consent. Clinicians should consult with their attorneys to help determine what needs to be said to patients in the jurisdiction in question.

Warnings

Prescription medical device label warnings are directed at the clinician and not necessarily the consumer of that device. It bears repeating that FDA regulates manufacturers and devices, not clinicians. While

FDA can issue direct-to-patient warnings, package label warnings are directed at the practitioner to advise of any hazards known to be associated with the use and/or improper use of the device.

In the case of dental mercury, the 2009 Special Controls Guidance Document under Part 8 C. contains the following language:

> **"WARNING-CONTAINS MERCURY"**
> "*may be harmful if vapors are inhaled*"

The original 2002 Special Controls Document (Draft) upon which the provisions of the current rule are based contained under 3.2.4. **WARNINGS** the following language:

> "If the Encapsulated amalgam, Amalgam Alloy, or Dental Mercury device contains a material which may cause a sensitivity reaction (e.g., beryllium or nickel), a warning statement should be displayed identifying the component(s) and the potential adverse reaction(s). If the product contains zinc, the following warning should be provided (in bold type):
>
> **"THIS PRODUCT CONTAINS ZINC; THE AMALGAM MADE FROM ZINC MAY SHOW EXCESSIVE EXPANSION IF MOISTURE IS INTRODUCED DURING MIXING OR COMPACTING"**[4]

Zinc is one of the metals included in some alloys to reduce corrosion potential. One of the justifications for the continued use of amalgam is its utility in high moisture environments, but it seems evident zinc-containing amalgams should not be used in such situations.

It is not clear why FDA eliminated this additional warning in the 2009 Final Rule. It may be because there are a number of class action lawsuits pending against the manufacturers of FDA-approved denture adhesive creams and cold remedies owing to neurological impairments allegedly resulting from the zinc content of these products.

Contraindications

Almost without exception every drug, biologic and medical device label includes a generic contraindication warning regarding known allergy to any of the ingredients.

The Final Rule's Special Controls Guidance Document under Part 8 D. lists the sole contraindication language for the use of the device:

> "do not use in persons with a known mercury allergy"

FDA makes no attempt to quantify the extent of allergy to mercury in the Final Rule. The Joint Panel in 2006[5] was most concerned about this lack of quantification of allergy risk and called upon FDA to investigate the matter further. One pro-amalgam presenter provided data to the Joint Panel that indicated mercury allergy was at least 6% of the population.[6] Most patients have no idea what dental products they might be allergic to. Therefore, the warning regarding known mercury allergy is of limited value to the clinician let alone potentially allergic patients who unwittingly receive the device.

Precautions

Precautions for use are designed to provide the clinician with special instructions related to the installation and handling of the device.

Under Part 8 E. of the Special Controls is listed the following:

> "do not place the device in direct contact with other types of metals"
> "use with adequate ventilation"
> "single-use only"
> "store in a cool, well ventilated place"

The first precaution advises against the installation of amalgam adjacent to, underneath, or possibly opposing other unlike metals. This language could be interpreted to mean that a zinc-free amalgam should not be placed next to one that contains zinc, for example. Since so many patients already have a variety of metals installed in one form or another, treatment decisions now become much more challenging.

Information for use

The most controversial provision of the Final Rule deals with the use of amalgam in young children, pregnant women, and breast-feeding infants. Section 8 F. of the Special Controls document states, in part:

> "The developing neurological systems in fetuses and young children may be more sensitive to the neurotoxic effects of mercury vapor. 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."

The FDA's claim that amalgam remains reasonably safe and effective in these groups is questionable given the apparent dearth of scientific evidence to support their conclusion. This part of the Final Rule is already hotly contested and will likely subject FDA to numerous consumer-driven lawsuits. I recommend against the use of amalgam in these populations.

Final thoughts

In my opinion, FDA regulators have essentially dropped the amalgam "hot potato" squarely into the laps of dental professionals. Dentists are left to navigate a confusing regulatory maze somehow managing to discern their duties and legal liability risks under this rule. However, the story does not have to end here.

I believe FDA regulation alone is entirely inadequate to address the multitude of complexities surrounding the use of a dental material that has been the mainstay of restorative dentistry for the better part of two centuries. The consumer public rightly expects FDA to take the lead in the substantive regulation of a wide range of food, medical, and dental products. In the case of dental amalgam, the agency appears to lack the necessary resources or capability to produce a rule that contains clear and comprehensible guidance.

I happen to believe the dental profession is far better equipped to accomplish for the consumer public what FDA is either unwilling or unable to provide on its own. Dentists have a narrow window of

opportunity to act responsibly and respond swiftly to the public's increasing demands for information about amalgam safety and substantive action during this critical time in the history of dentistry. This will require individual clinicians to decide for themselves whether the continued use of amalgam is advisable.

Nothing about this rule compels dentists to use amalgam or any other material in the armamentarium. Moreover, the provisions of the regulation do not apply to dentists who no longer use amalgam. Currently, dentists remain free to embrace the use of amalgam or abandon it as individual conscience and understanding of the current science directs. However, given the trajectory of the emerging science, congressional regulatory pressure and the potentially litigious environment surrounding amalgam use, this is an excellent time for dentists to consider eliminating amalgam from their practices altogether. For those who continue to use the product, dental amalgam can be offered as the restoration of last resort, not the first.