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Industry Asks FDA to Improve Regulation of Dental Restorations to Protect Patient Safety

National Association of Dental Laboratories Finds Cause for Concern in Lax Regulation of Imported and Domestic Dental-Restoration Products

TALLAHASSEE, Fla.--(BUSINESS WIRE)--The National Association of Dental Laboratories – the leading trade group for the \$5.5 billion U.S. dental-restoration products industry – has formally asked the Food and Drug Administration to implement more stringent regulations governing the dental restorations affixed into the mouths of millions of Americans each year.

Dental-restoration products – the porcelain crowns, provisionals, dentures and bridges that American dental patients have permanently seated in their mouths – are under-regulated, with few legal requirements for technicians to be certified and no mandates for dentists to document or disclose the source of dental work to patients, the association asserted in a Sept. 10 letter to the Presidential Interagency Working Group on Import Safety.

Although dentists prescribe the type of device they need for a dental patient, the product is actually manufactured by a dental technician employed by a dental laboratory, which could be located in the United States or anywhere in the world. Due to the growing number of Americans seeking dental restorative treatment and the growing pressure by dentists to cut costs and increase profit margins, much of the dental work Americans carry in their mouths is now imported from countries such as China, Pakistan, the Philippines and India.

Those products are not tested or inspected for sterilization, for the long-term safety or quality of their components, or for the precision of the fit as required for proper dental care. Even for products manufactured within the United States, most domestic dental laboratories are exempt from registering with the FDA, and most typically employ just 3.5 people.

To protect public confidence in the industry, the association asserted that the FDA must act to protect Americans and:

- Promote certification of dental technicians employed at both domestic and foreign labs.
- Require that dentists label and disclose to patients the source of dental devices, so all dental-restoration products can be traced back to the laboratory that made them.
- Step up inspections of the content and quality of imported dental-restoration products.
- Mandate that dental labs register with the FDA or with state health departments.

- Require that dentists include the registration number of their contracting dental laboratory on a prescription that is kept in patients' dental records; so that dental devices can be traced even long after they have been implanted in patients' mouths.

"Such common-sense regulations are critical because in many cases, the dental technician – not the prescribing dentist – makes the selection of dental materials that will be used for a particular patient's restoration," said Bennett Napier, CAE co-executive director of the National Association of Dental Laboratories. "Without having some requirement for the person or manufacturer creating the device to have the appropriate knowledge and training, the issue of material selection and/or safety is left to chance."

Many of the dental crowns and bridges imported into the United States are either porcelain fused to metal or metal-alloy devices. If manufactured incorrectly, these products could be contaminated with lead or other toxic heavy metals that could make patients sick.

"If a problem occurs with a U.S. patient due to a dental restoration that contains a toxic material, chances are that the patient would report their health issue to a medical doctor and not their dentist to determine the root of the health problem," Napier said. "It is unlikely that the problem would be immediately traced back to the dental device, as most patients are unaware of what materials are in their dental restoration and even less likely to know where it was manufactured."

Anecdotal evidence has pointed to contamination problems with products imported from emerging markets such as China, but there is no comprehensive data about the scope of the problem because there have been no large-scale inspections of such products.

The National Association of Dental Labs is a trade association with 43 affiliated state and regional commercial dental laboratory associations representing more than 1,400 members. For more information, please visit www.nadl.org.