



Documented Cases of Lead Contamination in Off Shore Dental Laboratory Restorations

Feb. 26, 2008

Recently, NADL was contacted by a dental patient in Ohio who has documentation of lead contamination in her dental restoration. The affected patient, a senior citizen, received a three-unit dental bridge from a dentist in Ohio. After having an adverse reaction to her dental work, and having it removed, the dentist disclosed that the prescription was sent to an offshore dental laboratory and disclosed to the patient that the restoration was made in China. The patient then had the restoration sent to a chemical laboratory for analysis. The documentation of the dental material analysis of this patient's restoration showed unsafe levels of lead in the porcelain on the restoration.

This case has attracted the attention of an Ohio television reporter who was already working on a story about offshore dental laboratory work. As part of the reporter's investigative research for the story, the TV station ordered a series of crowns from several offshore dental laboratories. One of those restorations contained 210 parts per million of lead in the materials. The U.S. Congress, in response to the toy recalls in 2007, lowered the acceptable levels of lead in toys to 90 parts per million.

The testing of these restorations for the reporter's investigation was conducted by a chemical research laboratory in Ohio and, at the suggestion of NADL, at the Boston University School of Dental Medicine. In addition to the documentation of lead, the chemical analysis revealed the restoration contains traces of radioactive isotopes.

The reporter contacted NADL and interviewed co-executive director, Bennett Napier, CAE, for this story. Others interviewed include the attorney for the patient in Ohio; a lead expert; a spokesperson from the Ohio Dental Board, a Columbus dentist and laboratory owners from central Ohio. The TV report contains position statements or quotes from the American Dental Association and the U.S. Food and Drug Administration.

WBNS 10 TV in Columbus, Ohio, will broadcast this story Wednesday. You can view the full investigative report Wednesday evening at the station's Web site www.10tv.com. The owners of the regional television station also own the Columbus Dispatch, the local

daily newspaper. An article about the story will be run in that paper's Thursday, February 28th edition.

It is likely that with the significance of this story it may be picked up by other media outlets in large metropolitan areas by the end of this week and possibly may be picked by national news media outlets as well.

NADL's Position:

NADL has worked with the U.S. Food and Drug Administration to promote patient safety and ensure laboratories have a voice in any regulation of the industry. NADL is on record supporting regulations that assure patients their restorations are safe for use, regardless of where they are manufactured. NADL's position has been presented consistently to the American Dental Association since 2003.

The National Association of Dental Laboratories believes that every dental patient has a reasonable expectation that the dental restoration placed in his or her mouth is safe, regardless of where it is manufactured. Therefore, in an attempt to provide the necessary documentation for disclosure as well as to document competency, the NADL strongly supports the following:

- The necessity of at least one Certified Dental Technician (CDT) in each dental laboratory.
- The necessity that all dental laboratories register with either the U.S. Food and Drug Administration or an appropriate state governmental agency.
- The written documentation of all materials included in a final restoration and the point of origin (country and laboratory) where the restoration was manufactured.
- The necessity that each of these items be documented in the patient's record.

Additional Information:

NADL informed the American Dental Association's executive leadership so they could tell their members about this pending story and possible outcomes including the public's response.

The ADA will be sending out an alert to its members this week sharing guidance about what questions to ask dental laboratories relative to outsourcing activity and statements of assurance on material content of dental restorations. NADL member's laboratories should be prepared for such requests.

Additionally, it is expected that state dental societies will be discussing possible regulatory options to address this issue at the state level in state dental practice acts. State dental societies may be contacting your state's dental laboratory association about possible collaborative efforts or to seek additional information. NADL members are encouraged to share NADL's model bill for state regulation with state dental

societies or inquiring dental clients that may request a template for state regulation. Members of the laboratory industry may download this document from NADL's Web page at www.nadl.org.

Dental laboratories should be prepared for increased calls from your dental clients and possibly local media outlets during the next few weeks as this news story circulates the country. NADL will be providing up-to-date guidance documents to our members on the member section of our Web site www.nadl.org to assist you when answering questions. We are committed to keeping our members well informed and prepared.

Sincerely,

NADL Board of Directors and Executive Staff

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