

Lead Contamination in Outsourced Restorations

... a follow-up article by **10 Investigates**, a Columbus, Ohio TV Station

Chris Collier has been a patient of Dr. Dave Rummel for 30 years. When it comes to teeth, Collier is more concerned about his health than his smile. "The reason I come here is because I know I can trust the dentist I have," Collier said. "I know I can get good workmanship." Rummel is one of the few dentists in central Ohio who makes his own crowns, bridges and dentures, but most other dentists rely on outside dental labs, **10 Investigates'** Lindsey Seavert reported.

The labs can be down the street or even overseas, increasingly outsourcing work to India, Mexico and China. Chinese imports, like jewelry and toys, have been under heavy scrutiny for the last year because of lead concerns. The dental community is concerned that unsafe metals have reached their industry, too. "It's one thing if it's a toy a child plays with for 20 minutes. It's another thing if it is somebody's mouth for a lifetime," Rummel said. "There is an issue here." **10 Investigates** obtained a letter from the National Association of Dental Laboratories that outlined the concerns. The organization told the Food and Drug Administration that outsourcing would increase because dental work created overseas is cheaper.

Even more of a concern is that dental labs or mostly "mom and pop" shops are unregulated in Ohio and 46 other states. Because of that, labs can outsource and no one may ever know, Seavert reported. "Currently, laboratories that are outsourcing work overseas are required to disclose that to their dentist through existing FDA regulations but that is where it stops," said Bennett Napier of the NADL. "That disclosure does not have to pass on to the patient." **10 Investigates** learned the deception goes one step further. Sometimes labs don't tell dentists, leaving them to unknowingly place foreign products in patient's mouths.

In the U.S., the materials in dental work are FDA approved. It is supposed to be that way in foreign countries but the FDA has no way to enforce it, Seavert reported. The NADL said the FDA approached them first in 2004 and then in 2007, concerned about the increasing number of imported dental devices passing U.S. borders and acknowledged the need to better enforce dental lab regulations. With millions of products and not enough manpower, the work crosses borders to places like Ravenna, Ohio. There, a 73-year-old woman hired a lawyer to sue her dentist. It began when she received a new dental bridge last year. The pain became so severe that she could not chew. "She began to have some pretty significant complications and reactions and infection that stemmed from the restoration that ultimately had to be removed," Napier said. The woman, who requested anonymity, told **10 Investigates** that she later discovered her bridge was made in China. Worried, she had a lab test it for hazardous materials. The lab determined that the porcelain filed away in her mouth contained lead. She has since undergone two surgeries, Seavert reported.

With 300 unregulated dental labs in Ohio and an estimated 7 million crowns coming into the country each year, **10 Investigates** wondered how much a threat lead is in outsourced dental work. We ordered eight crowns from four labs in China that advertise in industry magazines. With help from Rummel's lab, we received our product 10 days later. Only one lab identified materials in the crowns. **10 Investigates** first used a device that screens for lead. Of the eight, one crown came up positive. We sent our sample to a Cleveland lab - NSL Analytics - to provide scientific proof. They specialize in testing metals and began by separating the porcelain from the metal. The crown is diluted in a test tube that becomes a solution chemists

test for lead. The machines give an instant reading of lead. **10 Investigates'** results came back at 210 parts per million. The Ravenna woman's bridge measured 160 parts per million. "We don't know what the FDA or the American Dental Association considers to be a risk as far as lead content," said Carm D'Agostino, a chemist.

With no known research on lead in dental work, the lab can only compare to toy standards. Toys leaching lead over 90 parts per million are hazardous, so what about 210 parts per million in your mouth? "I guess that tells me I need to be a little bit more concerned about other potential sources of lead," said Dr. Marcel Casavant, who runs central Ohio's lead program and poison control center. "I never would have guessed somebody would have put lead into a piece or a part installed into a human being." Casavant said adults can live with lead poisoning for years and not know it. "The symptoms are what we call non-specific - a little ache or a pain - abnormal bowel function," Casavant said. Even high blood pressure and kidney trouble could be symptoms, according to Casavant. He said he would never link lead poisoning to dental work but would have to add it to his list of questions when asking people what kind of dental work has occurred.

The NADL said that **10 Investigates'** findings prove that the FDA needs to do more. "It reinforces the concerns we have as an industry and concerns the FDA expressed to us that the potential is there," Napier said. The NADL letter asks the FDA to track dental work from foreign labs to patient records. They want the FDA to register all labs, require them to disclose where they get their dental work and label what materials are in it. The Ohio Dental Board admitted that is not sure what is happening in the state's roughly 300 labs and has no plans to regulate them. Lili Reitz, the director of Ohio's dental board, said the burden relies on the dentist. "Ignorance is not a defense when you are ultimately responsible for what is going into the mouths of the patients that you serve," Reitz said.

Rummel said that **10 Investigates'** lead findings only prove outsourcing comes with a risk. "If a medical device is made out of a foreign country, I think the patient should know," Rummel said. He recommends that people ask their dentist where their work is made. "I think you can't really get something for nothing and I think (if) we start going down that road, we all suffer," Rummel said.

In response to our story, the Ohio Dental Board on Wednesday adopted a recommendation to the dentists they regulate. They are asking dentists to give labs a form that would require the labs to disclose where their dental work is made. On a federal level, **10 Investigates** has asked the FDA for a response to our findings for the past two months. On Wednesday, they told us that they are reviewing our report and developing a strategy to address our findings on all imported dental devices. The Ohio Dental Association said that it would require their members to fill out the form in hopes of giving it a better idea of how many labs are outsourcing.

10 Investigates

February 27, 2008