

United States Senate

WASHINGTON, DC 20510

November 21, 2008

Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner von Eschenbach,

I am concerned by reports that individuals in Ohio and in other areas of the country may be receiving lead-contaminated dental implants. In particular, I heard from a 73-year-old constituent from Ravenna, OH who was featured in a story on WKYC (http://www.wkyc.com/news/news_article.aspx?storyid=101067) because she received faulty dental implants that contained lead. She later found out that her dental implants were imported from China. Most recently, a member of my staff was told by an Ohio dentist that a woman from Hudson, Ohio experienced lead poisoning from one of these crowns.

I understand that the Centers for Disease Control and Prevention (CDC) worked with the American Dental Association to determine the level of harm that lead in dental implants poses. CDC determined that lead levels under 200 parts per million are safe. However, some of the dental implants tested by Ohio labs in the news story above indicate higher levels of lead than that ceiling. As reports of tainted implants increase, it is essential that FDA take action to ensure the safety of these dental products. I am therefore requesting that FDA delineate the actions it is taking to assess the prevalence, source, and impact of lead-containing dental implants in the United States.

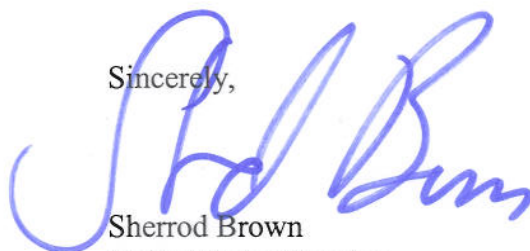
Specifically, I ask that you respond to the following questions:

- What standards exist for domestic and international dental products and the dental labs that produce them?
- What is the estimated volume of China-produced dental implants in the country today, and what is the annual volume of such products?
- What tracking mechanisms are in place to prepare for potential contamination by tainted dental implants?
- What inspection mechanisms are in place to ensure the safety of dental implants? What are the risks posed by dental implants with lead levels above those that the CDC has determined are safe?

Because of the seriousness of this matter, I ask that you respond to these questions as soon as possible. My staff will follow up with your office within the next week to determine when we may expect a response.

Thank you for your efforts.

Sincerely,

A handwritten signature in blue ink, appearing to read "S. Brown", written in a cursive style.

Sherrod Brown
United States Senator