



Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

September 9, 2009

SENT VIA FAX AND
REGULAR MAIL

Charles G. Brown
National Counsel
Consumers for Dental Choice
316 F. St., N.E., Suite 210
Washington, D.C. 20002

Dear Mr. Brown:

We received your letter to Commissioner Hamburg dated August 31, 2009, regarding her stock holdings in Henry Schein and her recusal from the dental amalgam rulemaking. The accusations you make in that letter regarding the Commissioner's stock holdings are without merit. Further, the Commissioner did not "personally and substantially" participate in the dental amalgam rulemaking, and therefore complied with applicable law. Finally, your personal attacks against the Commissioner are unproductive as well as unseemly, unfair, and inappropriate. If your organization wishes to mount a serious challenge to the *substance* of the agency's dental amalgam rule, there are formal steps that you can take to do so.

First, with respect to the Commissioner's stock holdings, you assert that she still held stock in Henry Schein when she took office. This is incorrect. As the FDA made clear in an August 18th statement to FDA Webview, on May 20th, six days before taking office, the Commissioner sold all of her Henry Schein stock and exercised all in-the-money Schein stock options, and sold all the resultant shares. All her remaining options were out of the money and non-transferable. Because they were non transferable, she was unable to sell them as you suggest. On July 16th, after learning that some of those remaining options had come into the money, she exercised those options and sold the resultant stock. On the same date, July 16th, she also asked Schein if there was some way that her remaining out-of-the money options could be terminated before their August expiration date. In response to this request, Schein examined whether this would be possible to accomplish and, on July 27th, Schein canceled all her remaining options. As you can see, the Commissioner fully complied with her obligations under her ethics agreement (attached) to divest her vested stock options and stock in Henry Schein within 90 days of confirmation.

Second, the Commissioner did not "personally and substantially" participate in the dental amalgam rulemaking, in full compliance with her ethics agreement. Separately, we are mailing today a partial response to your request under the Freedom of Information Act ("FOIA"), which our FOIA office officially received on August 11, 2009. Although we have deleted certain

material from the records furnished to you because that material is exempt from disclosure, we are producing documents that show that the Commissioner attended a briefing session for the dental amalgam rule on July 1, 2009, which was her only exposure to the issue. Her minimal level of exposure to the draft rule on that date -- a draft rule that had already been received by the Office of Management and Budget ("OMB") on June 23, 2009 -- does not qualify as "personal and substantial" participation in the rulemaking.

Everything that I told you in my letter dated July 24, 2009, is correct: the Commissioner did not take any action with respect to the rule before it was sent to the Department of Health and Human Services ("HHS"); the Commissioner did not take any action with respect to the draft rule before it went from HHS to OMB; and the Commissioner did not take any action with respect to the draft rule while it was at OMB -- or at any other time.

We hope that this letter addresses the concerns in your August 31, 2009 letter. If you wish to administratively challenge the final rule, please follow the formal procedures in our regulations.

Sincerely,

A handwritten signature in black ink that reads "Michael M. Landa /js". The signature is written in a cursive style and is positioned above the typed name.

Michael M. Landa
Acting Chief Counsel
Food and Drug Administration

Attachment