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October 14, 2008

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

Dear Commissioner von Eschenbach:

A recent report in the Milwaukee Journal Sentinel contained information about a \$5 million donation from a known opponent of regulation of the chemical bisphenol A (BPA) to a science center founded and co-directed by the chairman of the Food and Drug Administration (FDA) panel responsible for making a determination on BPA's safety ("Donation raises questions for head of FDA's bisphenol A panel", Milwaukee Journal Sentinel, October 11, 2008). As FDA prepares to issue its BPA determination, it is essential that its findings are grounded in objective scientific evidence based solely on the facts. Accordingly, I would appreciate FDA's responses to the following questions.

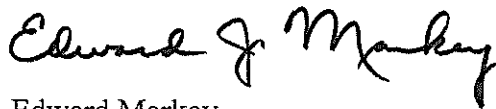
1. According to the Journal Sentinel report, FDA was unaware of the \$5 million donation from Mr. Charles Gelman, an opponent of BPA regulation, to an organization founded and co-directed by Dr. Martin Philbert, the current chairman of the FDA's subcommittee on bisphenol A, until it was contacted by the Journal Sentinel. Is this accurate? If not, when did the FDA become aware of this donation and from whom?
2. Should Dr. Philbert have disclosed Mr. Gelman's \$5 million donation to the center when it occurred, reportedly in July 2008? Does such a failure to disclose this information violate FDA policy? If not, why not? If FDA had been aware of this donation prior to making its selection of chairperson to head the BPA panel, would it still have selected Dr. Philbert? Now that FDA is aware of Dr. Philbert's involvement with Mr. Gelman, will it require Dr. Philbert either to return the \$5 million his center received from Mr. Gelman or recuse himself from the decision-making process? If not, why not?
3. The FDA's "Conflict of Interest Disclosure and Acknowledgement for Participation at the Subcommittee Public Meeting on the Draft Assessment of BPA (Bisphenol A) for Use in Food Contact Applications" states, in pertinent part, that "individuals invited to participate at the subcommittee public meeting to

discuss the draft assessment of BPA...will be asked to disclose to the subcommittee any financial relationship that they may have with any company or group that may be affected by the topic of this meeting.” Does this policy apply to the members of the FDA BPA subcommittee? If not, why not?

4. According to the Journal Sentinel report, the FDA’s associate commissioner for science asserted that the \$5 million donation did not pose a conflict of interest for Dr. Philbert because the gift does not fund Dr. Philbert’s salary at the center. Is this accurate? Is this assertion consistent with FDA policies intended to prevent conflicts of interest and with its view that the agency “believe[s] in a transparent process for information gathering and decision-making”?

I am concerned that these recent revelations represent an apparent or, at minimum, a perceived conflict of interest that will cast doubt on the objectivity of the FDA panel’s BPA determination. Therefore, before the panel makes its determination, I urge the FDA to conduct a thorough review of the issues raised in the Journal Sentinel report, as well as an overall review of the BPA panel’s activities to ensure that its work has not been colored by conflicts of interest. I further urge FDA to either require Dr. Philbert to return the \$5 million donation or recuse himself from further participation on the BPA panel. As the panel’s BPA determination is expected shortly, I appreciate your prompt response to these questions. If you have questions about our inquiries, please have a member contact Mark Bayer or Angela Coggins of my staff.

Sincerely,



Edward Markey