



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

October 29, 2008

Barbara J. McNeil, M.D., Ph.D.
Ridley Watts Professor and Head
Department of Health Care Policy
Harvard Medical School
180 Longwood Avenue
Boston, MA 02115-6092

Dear Professor McNeil:

As you know, allegations of improper and undisclosed conflicts of interest have been made regarding Professor Martin Philbert, PhD, of the University of Michigan, who is currently serving as Chair of the subcommittee of FDA's Science Board that is tasked with evaluating the safety of BPA in food contact substances like baby bottles. I have read a thorough review conducted by William McConagha of FDA's Office of Accountability & Integrity, which has responsibility for oversight and management of FDA's Advisory Committees. His team has contacted Professor Philbert, senior officials at the University of Michigan, Mr. Charles Gelman (a donor to the university mentioned in press articles), the FDA staff who conducted the initial screening of Professor Philbert, as well as the ethics office at FDA and legal counsel at the HHS Office of General Counsel, Ethics Division. Based on that review, I have concluded that the donations to the University of Michigan from Mr. Charles Gelman and an unrestricted grant to the University from Dow Chemical for a risk study of dioxin do not necessitate Professor Philbert's recusal or a waiver of conflict of interest under 18 USC 208 b(3) or Section 712 of the Food Drug and Cosmetics Act.

Given the attention that now embroils this issue, however, I think it might be wise to have Professor Philbert present the results of the subcommittee report to the Board, answer related questions, but refrain from voting on the questions before the Board relating to BPA. I recommend that course of action to you.

We are grateful for Dr. Philbert's leadership of the Science Board subcommittee and his service in support of FDA.

Sincerely,

A handwritten signature in black ink, appearing to read "Randall W. Lutter", written over a white background.

Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy