ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

October 15, 2008

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

Dear Dr. von Eschenbach:

Under Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are continuing to investigate the use of the chemical Bisphenol A (BPA), particularly in products intended for use by infants and children.

When we began our investigation in January 2008, we were interested in the potential health effects of BPA on infants and children, primarily through liquid infant formula. Since then, several reports and new scientific studies have added to the cascade of data pointing to the negative health effects caused by BPA. The largest manufacturers of liquid infant formula in the U.S. have begun to find alternatives to BPA with the goal of replacing it with a safer alternative. Manufacturers such as Nalgene have begun to remove BPA from their products. In addition, retailers such as Wal-Mart and Toys "R" Us have announced plans to remove BPA-containing products from their shelves. Most recently, the attorneys general from Connecticut, New Jersey, and Delaware requested that 11 companies stop using BPA in their baby bottles and baby formula packaging. Evidently, the scientific evidence has convinced some commercial industries, but not the Food and Drug Administration (FDA), that BPA may be unsafe.

Although the FDA Science Board met on Tuesday, September 16, 2008, to re-evaluate the agency's position on BPA's safety, we are concerned that FDA still has not given due attention to all of the available science on BPA since FDA continues to rely primarily on two industry-funded studies to assess BPA's safety. In addition, summary assessments of BPA were created for FDA's BPA panel by ICF Consulting, a private contractor that has done prior work for BPA manufacturers, and whose board members have ties to BPA manufacturers.

Now we have learned of a potential conflict of interest relating to an undisclosed $5 million donation to the research center of the BPA advisory panel chair by a medical device manufacturer who believes that BPA is "perfectly safe." This appearance of a conflict of interest raises serious concerns about FDA's ability to protect our Nation's infants and children from a potentially dangerous chemical.

Therefore, we ask that you respond to the following requests in writing:

1. Please provide the names of those who specifically made the decision to base FDA's safety assessment of BPA on the two industry-funded studies mentioned in our previous letters.

2. Will FDA continue to use good laboratory practices (GLP) as the standard by which studies are examined for their appropriateness in the development of regulatory decisions?

3. Norris Alderson, FDA's associate commissioner for science, is reportedly satisfied that there is no conflict of interest in the Philbert/Gelman matter because Philbert's salary is not paid by the undisclosed $5 million donation to his center. Is this an accurate statement? If so, why is this the standard for determining conflict of interest at FDA?

In addition, we ask that you provide the following documents:

1. All conflict-of-interest disclosures for the Science Board's BPA panel; and

2. All records of communication between FDA and ICF Consulting relating to their BPA work for the agency.

Finally, we ask that you appear for an interview by Committee staff in order to explain your agency's decisionmaking relating to Bisphenol A—specifically, why industry-funded studies provide the basis of your regulatory decisions and why the totality of science around the chemical continues to be ignored by your science-based agency.

Please deliver copies of the requested records to the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, Room 316, Ford House Office Building, no later than two weeks from the date of this letter. Please note that for the purpose of responding to this request, the terms "record" and "relating" should be interpreted in accordance with the attachment to this letter. After review of the records, we may require additional records and/or staff interviews with FDA staff.

Thank you for your prompt attention to this matter. If you have any questions related to this request, please contact us, or have your staff contact Paul Jung or David Nelson of the Committee staff at (202) 226-2424.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.