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June 2, 2009

The Honorable Margaret A. Hamburg
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Madam Commissioner:

The Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations have been investigating the possible dangers of the chemical Bisphenol A (BPA) in consumer products and food product containers, particularly in infant formula containers and other items used by infants and children.

Under the Bush Administration, FDA concluded that BPA was safe at current exposure levels. We are writing to ask that you reconsider this conclusion in light of longstanding questions about the scientific data relied on by FDA under the previous Administration, as well as new press accounts detailing the influence of industry lobbyists on FDA's scientific analyses.

On February 25, 2008, FDA sent a letter to the Committee declaring that BPA "exposure to adults and infants is safe."¹ The letter explained that FDA's conclusion was based predominantly on "two pivotal multigenerational oral studies," both of which were sponsored by the American Plastics Council.² Although many other studies have raised serious concerns with BPA, FDA did not address these studies in detail. Instead, FDA's letter to the Committee stated

¹ Letter from Stephen R. Mason, Acting Assistant Commissioner for Legislation, Food and Drug Administration, to Rep. John D. Dingell, Chairman, House Committee on Energy and Commerce (Feb. 25, 2008).

² *Id.* (referencing Rochelle Tyl, *et al.*, *Two-Generation Reproductive Toxicity Study of Dietary Bisphenol A (BPA) in CD-1 (Swiss) Mice*, Toxicological Sciences (Apr. 29, 2008); and Rochelle Tyl, *et al.*, *Three-Generation Reproductive Toxicity Study of Dietary Bisphenol A in CD Sprague-Dawley Rats*, Toxicological Sciences (July 2002)).

only that “FDA considers the findings of all such analyses seriously and will continue to monitor these data.”³

On May 16, 2009, the *Milwaukee Journal-Sentinel* reported that when FDA conducted its review of BPA, it “relied on chemical industry lobbyists to examine bisphenol A’s risk, track legislation to ban it, and even monitor press coverage.”⁴ E-mails obtained by the *Journal-Sentinel* reportedly reveal that FDA regulators “relied on the trade association to do much of their work for them.”⁵ In the e-mails, FDA “sought information from the [American Chemistry Council] to discredit a Japanese study that found [BPA] caused miscarriages;” asked the American Chemistry Council to provide its “opinion of a study by the U.S. Centers for Disease Control and Prevention on the prevalence of BPA;” and invited the American Chemistry Council “to come to its headquarters several times since 2000 to make presentations on BPA,” and “to give their opinion on various independent studies on the effects of BPA.”⁶

In addition, over the past week, both the *Washington Post* and the *Journal-Sentinel* have reported on a recent meeting at the Cosmos Club in Washington D.C. during which industry officials discussed a public relations strategy to counter efforts to regulate BPA. Internal notes from the meeting obtained by the *Post* state that industry representatives discussed “using fear tactics [e.g. ‘Do you want to have access to baby food anymore?’].”⁷ The notes also state that the group focused on “befriending people that are able to manipulate the legislative process.”⁸ According to the *Journal-Sentinel*, industry officials “hammered out” a public relations strategy they hoped would include the “holy grail” of “showcasing a pregnant woman to talk about the chemical’s benefits.”⁹

These new press accounts raise serious questions about the extent to which FDA relied on the industry for independent scientific advice under the previous Administration.

On October 30, 2008, for example, FDA’s own Science Board Subcommittee on Bisphenol A criticized the agency’s conclusion that BPA exposure was safe. The Subcommittee

³ *Id.*

⁴ *FDA Relied Heavily on BPA Lobby*, *Milwaukee Journal-Sentinel* (May 16, 2009).

⁵ *Id.*

⁶ *Id.*

⁷ *Strategy Being Devised to Protect Use of BPA*, *Washington Post* (May 31, 2009).

⁸ *Id.*

⁹ *BPA Industry Seeks to Polish Image*, *Milwaukee Journal-Sentinel* (May 29, 2009).

found that FDA's conclusions were "not supported by the available data and science."¹⁰ The Subcommittee also warned that "the studies excluded from the quantitative analysis raise additional and unsettling concern about potential effects from exposure to BPA."¹¹ The Subcommittee concluded that FDA's "lack of consideration of the totality of exposures from other sources severely limits the usefulness of the safety assessment with respect to food contact applications."¹²

Similarly, in March 2009, a consortium of international experts from academia, government, and industry characterized FDA's safety assessment of BPA as "incomplete and unreliable" because it failed to consider the totality of scientific work relating to BPA.¹³ The consortium warned that the two industry studies relied on by FDA "were too limited in their scope to be considered benchmarks" and "failed to consider serious dangers posed by BPA," including "effects on behavior and the development of the brain and prostate."¹⁴ The consortium raised questions with the "methodology and accuracy" of the studies and concluded that "government regulators need to greatly expand the universe of studies that they consider."¹⁵

Finally, last month, a study by the Harvard School of Public Health found that BPA concentrations increased by 69% in the urine of subjects who drank from plastic bottles containing BPA.¹⁶

¹⁰ Food and Drug Administration, Science Board, Subcommittee on Bisphenol A, *Scientific Peer-Review of the Draft Assessment of Bisphenol A for Use in Food Contact Applications* (Oct. 30, 2008) (online at www.fda.gov/OHRMS/DOCKETS/ac/08/briefing/2008-4386b1-05.pdf).

¹¹ *Id.*

¹² *Id.*

¹³ *Consortium Rejects FDA Claim of BPA's Safety*, Milwaukee Journal-Sentinel (Apr. 11, 2008) (online at www.jsonline.com/watchdog/watchdogreports/42858807.html).

¹⁴ *Id.*

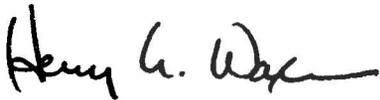
¹⁵ *Id.*

¹⁶ Jenny L. Carwile, *et al.*, *Use of Polycarbonate Bottles and Urinary Bisphenol A Concentrations*, *Environmental Health Perspectives*, (May 12, 2009).

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Based on this information, we request that FDA reconsider the Bush Administration's position that BPA is safe at current estimated exposure levels. We also request that FDA examine its processes to determine whether its interaction with and reliance on industry groups was appropriate in this case, and whether changes are needed going forward. We ask that you keep the Committee staff informed of your activities relating to BPA. If you have any questions, please have your staff contact Paul Jung of the Committee staff at (202) 226-2424.

Sincerely,



Henry A. Waxman
Chairman



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

cc: Joe Barton
Ranking Member

Greg Walden
Ranking Member
Subcommittee on Oversight
and Investigations