ONE HUNDRED TENTH CONGRESS

# Congress of the United States

## House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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September 17, 2008

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane, Room 15-47
Rockville, MD 20857

Dear Dr. von Eschenbach:

I am writing to inquire about the process used at the Food and Drug Administration (FDA) to set priorities for the agency. Internal agency e-mails provided to the Committee by FDA raise questions about who is setting the agency's priorities and why.

One e-mail, dated June 15, 2007, is from Sheldon Bradshaw, who was then FDA Chief Counsel to Scott Danzis, who was then Mr. Bradshaw's special assistant. In the e-mail, Mr. Bradshaw requests that Mr. Danzis provide him a list of "the guidances/regulations you are working on or would like to work on." Mr. Bradshaw further states: "I'll send that list to the Deputy Secretary who, in turn, will send it back to the FDA as his list of priority projects. That will ensure that our projects are moved in a timely fashion."[1]

In response, Mr. Danzis provides the following list to Mr. Bradshaw:

1. Proposed rule to amend the regulations that permit companies to update drug and device labels with new safety information;
2. Guidance document on the distribution of journal articles;
3. Guidance document on off-label promotion and manufacturer dissemination of off-label information;
4. Guidance document on intended use with respect to drug and cosmetic claims;
5. Proposed amendment to FDA regulations interpreting express preemption clause in FDCA for medical devices;

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[1] E-mail from Sheldon Bradshaw to Scott Danzis (June 15, 2007). Names are redacted from the Committee's copy of the e-mail but these identifications have been confirmed with FDA Office of Legislation.

6. Final guidance on: "Help-seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms;
7. Final guidance on: "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements; and
8. Final guidance on: "Consumer-Directed Broadcast Advertising of Restricted Devices."

Mr. Bradshaw, Mr. Danzis, and the Deputy Secretary of Health and Human Services, Tevi Troy, all have ties to the pharmaceutical industry. Before joining FDA, Mr. Danzis worked for Covington & Burling, LLP where he represented drug companies. A few months after this e-mail exchange, Mr. Bradshaw left FDA to join Hunton & Williams, where he also represents the pharmaceutical industry. Prior to his time in the Bush Administration, Mr. Troy worked for the Hudson Institute and the American Enterprise Institute, two think tanks with ties to the pharmaceutical industry.[2] Mr. Troy is also the brother of former FDA counsel Daniel Troy, now general counsel for GlaxoSmithKline.

Whether coincidental or not, the list that Mr. Danzis provided to Mr. Bradshaw contains several initiatives that are known to be long-sought goals of the drug and device industries. All appear to prioritize industry desires over consumer protection by reducing FDA regulation of industry marketing practices, eliminating industry liability for injuries caused by their products, and by making it easier for drug and device companies to advertise their products directly to consumers.

There is also evidence that Mr. Danzis's list induced the agency to push these priorities through in record time. Due to current burdens and required analyses imposed by the Office of Management and Budget, the former associate commissioner for policy at FDA, William Hubbard, recently said that FDA's rulemaking process has become a "tortuous and a tortured process."[3] He warned that "public health problems don't get solved for many years" because it now takes between four and five years to complete a rulemaking process.

In contrast, the first two items on the list appear to be moving in a matter of months rather than years. The first project on the list, the proposal to amend the so-called "changes being effected" regulation in a manner that would bolster industry arguments that product

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[2] HHS, *Biography of Tevi D. Troy* (online at http://www.hhs.gov/deputysecretary/bios/index.html) (accessed Sept. 10, 2008). The Hudson Institute has a number of corporate contributors, including Eli Lilly, and the American Enterprise Institute includes the former CEO of Merck on its board of trustees.

[3] *FDA Rulemaking Has Become 'Tortuous,' Former Official Says*, FDAWebview (July 11, 2008).

liability cases filed against them should be preempted, was proposed on January 16, 2008, and finalized on August 15, 2008, seven months after the proposed rule was released.[4] The second project on the list, a draft guidance which would relax FDA's restrictions on drug company communication by allowing companies to use journal articles to promote potentially dangerous "off-label" uses of drugs and medical devices without prior FDA review or approval, was issued on February 15, 2008.[5] My understanding is that this guidance is also being forced through the agency with unprecedented speed.

There are many questions raised by this e-mail. The process for setting priorities described in the e-mails appears designed to bypass normal channels. Moreover, there is a major disconnect between the priorities identified by Mr. Danzis and the issues that public health experts have said should be FDA's top priorities. Mr. Danzis's list — and FDA's subsequent actions — put initiatives that benefit the pharmaceutical industry at the top of FDA's priority list.

By contrast, your own FDA Science Board identified a very different set of issues in dire need of attention. The Science Board concluded in November 2007 that "American lives are at risk" because limitations in resources leave the agency unable to attend to a frightening number of critical regulatory and public health responsibilities.[6] According to the report:

> We found that FDA's resource shortfalls have resulted in a plethora of inadequacies that threaten our society — including, but not limited to, inadequate inspections of manufacturers, a dearth of scientists who understand emerging new technologies, inability to speed the development of new therapies, an import system that is badly broken, a food supply that grows riskier each year, and an information infrastructure that was identified as a source of risk in every Center and program reviewed by the Subcommittee.[7]

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[4] FDA, *Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices*, 73 FR 2848 (Jan. 16, 2008); FDA, *Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices*, 73 FR 49603 (Aug. 22, 2008).

[5] FDA, *Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on napproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Feb. 2008) (online at www.fda.gov/ c/op/goodreprint.html).

[6] *FDA Science and Mission at Risk, Report of the Subcommittee on Science and Technology*, at 6 (Nov. 2007) (online at www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf).

[7] *Id.* at 7.

None of these Science Board priorities are reflected in Mr. Danzis's list.

To assist the Committee's investigation into these issues, I ask that you provide the Committee with the following information related to Mr. Danzis's list:

1. The status of implementation for the draft reprint guidance, including the current point in the agency decisionmaking process for this item;

2. The status of each of the remaining items contained on Mr. Danzis' June, 2007, list above, including the current point in the agency decisionmaking process for each of these items;

3. An explanation for the public health objective underlying each initiative as well as an explanation for why FDA would need to act on each initiative at this point in time, given the other public health challenges and priorities you have identified;[8]

4. A list of all outside individuals or entities with whom FDA (including Mr. Danzis) or HHS officials conferred regarding the formulation of Mr. Danzis' June 2007 list, including the date of any such communications and any documents relating to such communications;

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[8] As Commissioner, you have acknowledged that FDA's current resources are overextended. The FDA Amendments Act: Reauthorization of the FDA, Remarks by Andrew C. von Eschenbach, M.D. Commissioner of Food and Drugs, Annual Conference, Food and Drug Law Institute, Washington, DC (Mar. 26, 2008); *Tools for the FDA: The Food and Drug Administration finally asks Congress for more money*, Washington Post (May 19, 2008). You have further recognized that rapid changes in FDA regulated marketplaces are imperiling the agency's ability to carry out its "mission to protect and promote the health of every single American." To respond to this situation, you indicated that the agency must focus its limited resources on activities that are "of critical importance to the mission of FDA":

> We cannot do everything at once, but issues of drug safety, food protection, the scientific foundation for regulatory decisions, work force development and essential infrastructure including facilities and information technologies *are our immediate priorities*.

Remarks by Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs, "FDA at a Turning Point: Meeting the Challenge of a Rapidly Changing World," National Press Club (Feb. 29, 2008).

5. Information on whether Mr. Bradshaw or any other FDA official forwarded some or all of Mr. Danzis' list of priorities to the Department and the date of any such transmittal;

6. All communications related to what was transmitted to the Department, including whether FDA received a list of the Department's priorities after the list was sent and a copy of that list of the Department's priorities if such list exists; and

7. The number of FTEs that have been dedicated toward the priorities included on Mr. Danzis' list.

I also want to reiterate my concerns regarding the first two items on the list and urge you to reconsider taking any further steps toward implementing those proposals. Further, I urge you to carefully consider the propriety of moving forward with the remaining items on the list. At a time in which FDA's own Science Board warns that "American lives are at risk" due to chronic underfunding of the agency, I am deeply concerned that these industry priorities are being promoted at the expense of the agency's core public health mission.

The Committee on Oversight and Government Reform is the principal oversight committee in the House of Representatives and has broad oversight jurisdiction as set forth in House Rule X. Enclosed with this letter are instructions on how to respond to the Committee's document request.

Please submit your responses by October 6, 2008. If you have any questions about this request, please contact Stephen Cha of the Committee staff at (202) 225-5056.

Sincerely,

Henry A. Waxman
Chairman

Enclosure

cc: Tom Davis
Ranking Minority Member