January 22, 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 wrote to you on November 30, 2007, to express significant concern about a draft FDA proposal to allow drug and device companies to use journal articles to promote potentially dangerous uses of drugs and medical devices without prior FDA review and approval. My letter requested documents relating to the draft proposal as well as answers to specific questions.

In response to my letter, you provided just one document: a memorandum of an April 2007 meeting including you and other senior FDA officials; Dan Troy, who is a former FDA chief counsel now representing drug companies; and other drug company representatives. According to this memorandum, Mr. Troy and the other drug company representatives urged you to issue FDA guidance allowing the distribution of journal articles promoting off-label uses to protect the drug companies from "Federal prosecutors pursuing distributors of this information for criminal conduct."

This document raises questions about the rationale for the draft guidance. It is also troubling that FDA initially resisted providing the document to the Committee and did so only after my staff informed FDA that we knew of its existence.

In your December 21 letter, you state that you are not providing the Committee with other documents or answering the Committee's questions because this information is "pre-decisional."[1] This is no basis for withholding from the Committee communications about the use of journal articles that FDA received from private drug companies. This is also no basis for withholding internal FDA communications where — as in this case — there is evidence that FDA's actions may be unduly influenced by regulated companies.

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[1] Letter from Acting Assistant Commissioner for Legislation Stephen R. Mason to Rep. Henry A. Waxman (Dec. 21, 2007).

Minutes of April 2007 Meeting

FDA originally informed my staff that no documents would be provided in response to my request and that there were no agency records of outside contacts concerning the proposed guidance. My staff responded that they were aware of a relevant document in FDA's possession that described an April 2007 meeting with drug industry representatives about the new guidance.[2] Your staff claimed that the document did not involve the proposed guidance, but instead concerned "the sunset of the FDAMA provision on journal reprints." After my staff insisted on production of the document, it was included as the sole responsive document provided to the Committee with your December 21 response to my letter.

This document summarizes an April 13, 2007, meeting between FDA officials and industry representatives. According to the document, you personally attended the meeting, as well as top officials in your office, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health. Dan Troy, the former FDA chief counsel, attended the meeting representing drug and device industry clients, along with several other representatives of the drug and device industry.

The subject of the meeting was "peer-review journal articles." The minutes show that the industry representatives (1) were concerned because a statutory provision allowing the legal distribution of reprints has now expired,[3] and (2) were seeking protection from prosecution for illegal marketing, possibly in the form of an FDA guidance sanctioning dissemination of reprints. According to the memorandum, "FDAMA allowed the practice of distributing this information, but the provision has now sunset." Industry representatives spoke about the "effect and consequences of the sunset" and "the problems companies face" as a result. In particular, the industry representatives "expressed concerns about Federal prosecutors pursuing distributors of [journal reprints] for criminal misconduct. There is confusion about the rules, possibly an FDA guidance could clarify the rules."[4]

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[2] *See* Inside CMS, "Draft Version of FDA Guide on Journal Dissemination Sparks Debate." (Dec. 13, 2007).

[3] Until the FDA Modernization Act of 1997, FDA considered distribution of reprints on unapproved uses to be evidence of illegal marketing except when directly requested by a physician. FDAMA permitted such distribution under very limited conditions (if the manufacturer had already applied for FDA approval of the unapproved use and submitted the reprints to FDA for review). This safe harbor under FDAMA expired in 2006 and FDA currently has no policy in place that protects distribution of reprints from being considered evidence of marketing.

[4] FDA, Memorandum of Meeting (Apr. 13, 2007).

The April 2007 minutes are short and provide little detail about what transpired at the meeting. But they do raise significant questions about the origins of the draft proposal. The minutes reflect no discussion about the public health impacts of new guidance. Instead, the rationale urged by the industry representatives was to protect drug and device companies from prosecution for illegally promoting unapproved uses, not to advance public health.

Your Response

In my November 30 letter, I raised serious concerns about the draft guidance.[5] The guidance would shelter drug companies from responsibility for dissemination of articles on unapproved uses to a far greater extent than at any other time in FDA's history and would undermine the law requiring companies to seek approval before marketing a drug or device. As my letter pointed out, there have been multiple recent examples in which drug companies have used journal articles in ways that misled physicians or consumers about the true risks of their products.

In your response, you stated that "materials requested in your letter contain deliberative pre-decisional information."[6] You offered to provide a briefing on background information and previous statutory guidelines but stated that "we are not providing materials that reflect these ongoing deliberations."[7]

Your response is not satisfactory. Under FDA's own regulations, the Committee is entitled to any relevant agency record, regardless of whether it is pre-decisional.[8] The need for pre-decisional documents is especially important in a case like this where there is evidence that the agency's actions may be unduly influenced by the interests of regulated entities. Moreover, many potentially responsive documents, such as communications between agency officials and drug company representatives, cannot properly be considered pre-decisional.

To enable the Committee's investigation to proceed without further delay, I request that you provide the following documents to the Committee:

1. All documents since January 26, 2001, relating to communications between FDA and persons outside the executive branch relating to (a) the new draft guidance on

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[5] Letter from Rep. Henry A. Waxman to FDA Commissioner Andrew C. Von Eschenbach (Nov. 30, 2007).

[6] Letter from Acting Assistant Commissioner for Legislation Stephen R. Mason to Rep. Henry A. Waxman (Dec. 21, 2007).

[7] Letter from Acting Assistant Commissioner for Legislation Stephen R. Mason to Rep. Henry A. Waxman (Dec. 21, 2007).

[8] 21 CFR 20.87.

dissemination of reprints and textbooks or (b) the issue of the dissemination of reprints and textbooks.

2. All documents between January 26, 2001, and April 13, 2007, including internal FDA communications, relating to the dissemination of reprints and textbooks.

These documents should be provided to the Committee by February 5, 2007. In addition, you should know that the Committee is reserving its right to request additional documents from FDA on this issue, including any internal FDA communications about the draft guidance occurring after April 13, 2007.

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.

If you have any questions about this request, please contact Stephen Cha at (202) 225-5056.

Sincerely,

Henry A. Waxman
Chairman

Enclosure

cc: Tom Davis
Ranking Minority Member