ONE HUNDRED TENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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June 26, 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:

On May 14, 2008, the Committee held a hearing examining the issue of preemption of state liability claims relating to FDA-approved drugs and medical devices. Deputy Commissioner for Policy Randall Lutter testified regarding FDA's current position on preemption. According to his testimony, FDA believes that "State product liability lawsuits that challenge the Agency's careful determination of safety, efficacy, and appropriate labeling can have detrimental effects on public health in a number of ways."

In contrast, former FDA Commissioner David Kessler and other witnesses at the hearing testified that, under previous administrations, FDA's position was that product liability lawsuits in state court complemented the agency's regulation of drugs and medical devices, providing an important additional layer of consumer protection against unsafe products.

This reversal of FDA's long-standing position on preemption raises important questions. To assist the Committee in examining these questions, I request that you provide the Committee with the following information:

1. All documents since January 20, 2001, relating to communications between FDA officials and private persons, including representatives of drug or medical device companies, about preemption, including documents related to: (a) FDA intervention in specific product liability cases; (b) the development of Section D "Comments on the Product Liability Implications of the Proposed Rule" in the preamble to the 2006 drug labeling rule;[1] and (c) policy documents and guidance relating to preemption.

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[1] Food and Drug Administration, *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products and Draft Guidances and Two Guidances for*

2. All documents since January 20, 2001, relating to internal communications among FDA officials about preemption, including documents related to: (a) FDA intervention in specific product liability cases; (b) the development of Section D "Comments on the Product Liability Implications of the Proposed Rule" in the preamble to the 2006 drug labeling rule; and (c) policy documents and guidance relating to preemption.

3. All documents since January 20, 2001 relating to communications between FDA officials and officials in the Department of Health and Human Services (HHS), the White House, or other federal agencies about preemption, including documents related to: (a) FDA intervention in specific product liability cases; (b) the development of Section D "Comments on the Product Liability Implications of the Proposed Rule" in the preamble to the 2006 drug labeling rule; and (c) policy documents and guidance relating to preemption.

4. All amicus briefs since January 20, 2001, filed by or on behalf of FDA in product liability cases.

5. All drafts since January 20, 2001, of the final drug labeling rule.[2]

6. All documents relating to compliance with Executive Order 13132 (requiring consultation with state and local officials in the development of regulatory policies with federalism implications) in connection with the issuance of the final 2006 drug labeling rule.[3]

7. All documents relating to FDA's proposed rule modifying the "changes being effected" regulation,[4] including all drafts of the proposed rule and all communications between FDA or HHS officials and private persons, including representatives of drug or medical device companies, about the need for modifications to the "changes being effected" regulation.

Industry on the Content and Format of Labeling for Human Prescription Drug and Biological Products; Final Rule and Notices, 71 Fed. Reg. 3921, 3933 (January 24, 2006) (final rule).

[2] *Id.*

[3] *Id.*

[4] Food and Drug Administration, *Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices*, 73 Fed. Reg. 2848 (January 16, 2008)(proposed rule).

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 July 11, 2008. If you have any questions about this request, please contact Stephen Cha with the Committee staff at (202) 225-5056.

Sincerely,

Henry A. Waxman
Chairman

Enclosure

cc: Tom Davis
Ranking Minority Member