U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
http://finance.senate.gov

For Immediate Release
Thursday, June 3, 2004

Grassley continues probe of FDA's handling of information about antidepressants, suicide

WASHINGTON – Sen. Chuck Grassley is asking the Food and Drug Administration a new round of questions following interviews he conducted last month with FDA scientists, and he's letting FDA employees know that they are allowed to talk directly with members of Congress despite recent instructions from FDA managers that inquiries from Congress must be routed through the office of legislative affairs.

Grassley has been conducting oversight of the FDA in the wake of allegations that there was an attempt to withhold information from the public about the findings of an FDA scientist who found a possible link between antidepressants and suicide among children. Grassley is chairman of the Senate Committee on Finance.

The text of Grassley's letter follows here.

June 2, 2004

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Mr. Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Secretary Thompson and Dr. Crawford:

Once again, I would like to express my thanks to the Food and Drug Administration (FDA) for being cooperative and making Drs. Wyzowski and Mosholder available to my staff for questioning on May 20th , May 24th , and May 28, 2004. During the course of these interviews, a number of documents were discussed that I would like the FDA to produce promptly. More specifically, I request that the FDA supply the following materials:

1. Copies of CDER Regulatory briefing minutes from September 16, 2003 through May 28, 2004 including all drafts and final versions of all such minutes;

2. Copies of all e-mails exchanged by or between Dr. Mosholder and others regarding the Adverse Event Reporting System (AERS) reporting system and/or its relationship to the February 2, 2004 Advisory Committee Meeting;

3. Copies of all draft and final versions of the February 2, 2004 Advisory Committee meeting agenda;

4. The specific date the Columbia University study on SSRIs was requested by FDA including the name of the individual or individual(s) who(m) requested that study be conducted;

5. Copies of all e-mails discussing either directly or indirectly the removal of Dr. Mosholder's presentation regarding his report on SSRIs from the Advisory Committee meeting on February 2, 2004;

6. Copies of all e-mails regarding Dr. Wyzowki's research on the effects of steroids and death certificate documentation; and

7. Copies of all e-mails exchanged with regard to Dr. Wyzowski's work on Cisapride, Cumadine and Protamine.

8. A listing of all FDA employees who have left the Office of Drug Safety in the last 5 years. Please include name, title, date of departure and contact information, if available.

In addition, the Committee would appreciate being provided with a list of meetings that took place between September 1, 2003 and February 2, 2004 that included one or more of the following individual(s) and one or more of the following drug manufacturer(s):

Individuals: Drug Manufacturers

a. Dr. Katz a. Pfizer

b. Dr. Galston b. GlaxoSmithKline

c. Dr. Jenkins c. Eli Lilly & Co.

d. Dr. Woodcock d. Bristol-Myers Squibb

e. Dr. Laughren e. Wyeth

f. Dr. Temple f. Organon

g. Dr. Seligman g. Forest

h. Solvay

At this time we are presently awaiting a privilege log from the FDA, which we requested during a meeting with FDA on May 14, 2004. We would appreciate receiving that log no later than June 7, 2004.

I also wish to emphasize that because of the seriousness of the issues being reviewed by the Committee it is imperative that the FDA/HHS keep to the time frames set forth in each of my letters. A response to the Committee's May 18, 2004 letter has not been received from the FDA and the response was due on May 28, 2004. The Committee's document requests are reasonable and specific, and delays will not be acceptable.

Finally, and perhaps most importantly I am very troubled by the attached e-mail from Terry Martin of the Center for Drug Evaluation and Research to more than 40 individuals, setting forth FDA's protocols for, among other things "Telephone Calls from Staff to the Committee" for "handling the document request on antidepressants drugs." The email states in pertinent part the following:

If you receive a telephone call from a staff member regarding this situation, please follow CDER's standard procedures which are:

Inform the caller that they should first go through FDA's Office of Legislation.

If the caller insists on speaking to you, you must first conference in the Office of Legislation.

It is apparent, based on our interviews to date, that this email effectively frightened and intimidated many FDA staff members; thereby chilling the free exchange of information by and between Congressional staff members and FDA employees. While I acknowledge the need for the systematic exchange of information between the FDA and the Committee; that need must be balanced against the need of Congress to conduct effective and unemcumbered oversight of the Executive Branch. Accordingly, I am requesting that FDA employees be advised by FDA management that they also have the right to speak directly to Congress or to a Committee of Congress without interference. (see 5 U.S.C. Section 7211)

In closing, I look forward to hearing from you no later than June 14, 2004 regarding my requests set forth in this letter. Thank you for your attention to this important matter. Should you have any questions regarding this letter, please do not hesitate to contact Emilia DiSanto or Michelle Anderson at (202) 224-4515.

Sincerely,

Charles E. Grassley

Chairman