U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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For Immediate Release
Friday, September 10, 2004

Grassley Seeks Complete Information from Food and Drug Administration

WASHINGTON — Sen. Chuck Grassley is keeping pressure on the Food and Drug Administration to respond fully to requests he has made during the last five months for documents related to the safety of pediatric use of antidepressants.

The senator said that the public health and safety agency has provided some information but that other important information has not yet been delivered, even after a long period of time, or it has been delivered in an incomplete form. Grassley met on July 6 with the Food and Drug Administration's acting commissioner, who provided assurances that the agency would cooperate fully with Congress.

The text of Grassley's most recent letter to the Secretary of Health and Human Services and the Acting Commissioner of the Food and Drug Administration follows here. Grassley has been conducting oversight of the Food and Drug Administration from his position as Chairman of the Senate Committee on Finance.

September 7, 2004

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
Hubert Humphrey Building, Room 416 G
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, Room 1547
Rockville, MD 20857

Dear Secretary Thompson and Dr. Crawford:

Since May 4, 2004, the Food and Drug Administration (FDA) has responded incompletely to my requests for information related to whether the FDA is effectively addressing drug safety concerns, and protecting the public health at the level expected by the American people. Specifically, for several months now my Committee staff has reviewed, among other concerns, whether the FDA suppressed an analysis completed by Dr. Andy Mosholder about the possible link between antidepressants and suicide among children and adolescents. While some information has been provided on a timely basis, quite a number of requests remain outstanding and deadlines have long ago passed.

Dr. Crawford, when we met awhile ago, you assured me that the FDA would respond completely and cooperate fully with the Committee on these matters. Further, my Committee staff reached an agreement with FDA staff that information and documents would be provided consistently on a "rolling basis." However, as I have stated previously, the FDA continues to delay and provide incomplete information and responses. Accordingly, I would appreciate your immediate attention to these outstanding requests:

1. On May 18, 2004, I requested that the FDA supply a number of documents regarding Dr. Mosholder's report on antidepressants. The FDA responded to this request on July 12th and July 28th. However, the FDA did not respond to question #6 in my letter dated May 18th. Specifically, I requested all e-mails regarding the contents and findings of Dr. Mosholder's report on SSRIs. I asked that the FDA include all e-mails written by Drs. Mosholder, Seligman, Trontell, Avigan, Temple, Jenkins, Katz, and Laughren. This response was due on May 28th—more than three months ago.

2. On June 1, 2004, I asked that the FDA advise its employees that they have the right to speak directly to Congress or to a Committee of Congress without interference. After the FDA failed to address this request, I asked again in a July 2nd letter. It is now September and I have not yet heard from the FDA whether it will notify its employees that they are free to speak to me, to my staff members and to Members of Congress without fear of reprisal.

3. On June 3, 2004, I requested that the FDA provide all documents and correspondence between the Office of Drug Safety and GlaxoSmithKline (GSK) regarding the antidepressants, Paxil. In addition, I requested all documents and correspondence between Dr. Mosholder and GSK regarding the data GSK submitted to the FDA on Paxil. The FDA has failed to respond to either of these requests that were due on June 14th.

4. On July 23, 2004, I sent the FDA a detailed list of questions and documentation requests regarding the following:

a) the Columbia University Reclassification Study;
b) FDA's July 2nd response to my May 11th letter;
c) the organizational structure of the Office of New Drugs and the Office of Drug Safety;
d) potential conflicts of interest in the Office of the Chief Counsel;
e) FDA's Independent Validation and Verification process for clinical trial data; and
f) recent news reports regarding the alleged concealment of safety data by drug manufacturers.

My letter dated July 23rd set a deadline of July 30th and the FDA has failed to respond to this inquiry entirely. In addition, some of these questions are repeated from my letter dated May 11th, which was due in full on June 7, 2004. My letter dated July 2, 2004, also brought up the issue of outstanding document requests and long overdue deadlines.

In closing, I request the aforementioned documentation immediately. While some delay may be unavoidable and even understandable, months of delay and a pattern of incomplete responses and information is not consistent with your personal assurances to me. Reasonable extensions of time may be appropriate at times, but the FDA cannot simply side-step its responsibilities to Congress. FDA's response to date and further delay is simply unacceptable.

Please have your staff coordinate with my staff regarding this letter by Friday, September 10th. Thank you in advance for your written response by September 17, 2004, unless it is available sooner. In responding to my requests, please repeat each numbered request, followed by its accompanying response. In the event that documents or other materials are requested, please be sure to mark them accordingly.

Sincerely,

Charles E. Grassley
Chairman