U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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For Immediate Release
Thursday, March 25, 2004

Grassley Questions FDA's Handling of Research on Antidepressants, Suicide

WASHINGTON — Sen. Chuck Grassley has asked for an accounting of the Food and Drug Administration (FDA)'s decision to not make public the scientific report that led to the public health advisory issued this week about anti-depressants and a possible link to suicide among children and adolescents, as well as its alleged attempt to investigate FDA employees who sought to make public information about the report's findings.

"The FDA holds a vitally important public trust that must be carefully guarded," Grassley said. "Allegations have been made that the FDA may have tried to hold back information about any possible dangers associated with drugs used to treat children and adolescents. The goal of my inquiry is to get to the bottom of those allegations and help make certain that the public trust wasn't violated."

The text of Grassley's letter to the Secretary of Health and Human Services follows here. The FDA is an operating division of the Public Health Service, for which the Secretary is responsible. Grassley is Chairman of the Senate Committee on Finance.

March 25, 2004

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

Dear Secretary Thompson:

On Monday, the Food and Drug Administration (FDA) issued a Public Health Advisory on "Cautions for Use of Antidepressants in Adults and Children." The FDA's decision to issue this warning appears to be a prudent step in the right direction. At the same time, I am troubled by allegations reported to me suggesting that the FDA was not forthcoming about the dangers associated with the use of antidepressants in children and adolescents and the possible link to suicide. On

February 1, 2004, The San Francisco Chronicle reported that:

> A scientist at the [FDA] has been barred from publicly presenting his finding that several leading anti-depressants may increase the risk of suicidal behaviors among children, according to sources inside the FDA. FDA medical officer Andrew Mosholder was to present his report Monday at an FDA advisory hearing in Washington that promises to be a contentious affair involving competing medical experts and parents whose children took their own lives while on the medications. A senior FDA official said the study wouldn't be presented because it wasn't "finalized." But critics fear that the agency's action indicates it is not prepared to take stronger action against the drugs, despite warnings about their possible effects on children."

Specifically, my concerns are two-fold and inter-related. First, in recent weeks, my staff has gathered information about whether Dr. Andrew Mosholder was barred from presenting his findings. I am concerned that Dr. Mosholder did not present his findings and that his prepared and completed report was and continues to be withheld from the public. Second, I am concerned that the FDA, Office of Internal Affairs (OIA) has reportedly initiated an investigation into, among other things, who provided information to the press about Dr. Mosholder's finding that several leading anti-depressants may increase the risk of suicidal behaviors among children.

According to a notice in the October 31, 2003 Federal Register, Dr. Mosholder was to present his report on February 2, 2004, at a meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee (Meeting). The Meeting agenda posted on the FDA's website identified Dr. Mosholder's presentation. However, an amended Meeting agenda removed Dr. Mosholder's report on antidepressants, children, adolescents and suicide. The amended notice states that this topic would be covered in a second meeting to be scheduled by summer 2004.

My Committee staff reports to me that Dr. Mosholder was told he would not be allowed to present his report at the Meeting. Further, he was given a so-called script to read, explaining why he would not be presenting his findings as originally planned. Reportedly, Dr. Mosholder was even provided with prepared questions and answers to any questions posed to him at the Meeting. It is also reported that an alleged "information leak," involving one or more FDA employees, related to Dr. Mosholder's findings is presently being investigated by the FDA-OIA.

In light of the aforementioned allegations, as well as my concerns with respect to those allegations, I request that the FDA answer the following questions and provide any and all information pertinent to them.

A. REMOVAL OF REPORT ON ANTIDEPRESSANTS, CHILDREN, ADOLESCENTS AND SUICIDE FROM FEBRUARY MEETING

1. Who made the decision to remove Dr. Mosholder's report on antidepressants, children, adolescents and suicide from the meeting agenda and why?

2. It was reported to the Committee that a so-called "script" was allegedly given to Dr. Mosholder by the FDA to read at the Meeting. Is this true? If so, please provide to us a copy of the so-called "script" including the names of the author(s) of the "script." Please insure that you provide to the Committee all versions, including drafts, of the so-called "script."

3. It was reported to the Committee that questions and proposed answers were prepared for Dr. Mosholder in anticipation of the Meeting, in light of the fact that he would no longer be presenting his report findings. Is this true? If so, please provide to us a copy of the question and proposed responses, including the names of the author(s) of the questions and proposed answers. Please insure that you provide to the Committee all versions, including drafts, of the questions and proposed responses.

4. Despite the fact that Dr. Mosholder did not discuss his findings on this completed report on antidepressants, children, adolescents and suicide at the Meeting, on Monday, March 22, 2004, the FDA decided to release a national public health advisory regarding the possible link between certain antidepressants and suicide in children and adolescents. This action seems inconsistent with FDA's earlier decision to remove Dr. Mosholder's report from the Meeting. Please explain this decision in detail.

B. OFFICE OF INTERNAL AFFAIRS INVESTIGATION

1. What is the purpose of this alleged investigation?

2. Who requested that an investigation be commenced? Please provide copies of all documents, including emails, relating directly or indirectly to any OIA investigation regarding Dr. Mosholder and/or his finding that several leading anti-depressants may increase the risk of suicidal behaviors among children.

3. Why did the FDA initiate an OIA investigation? Please include in your response a chronological listing of the events, with documentation, surrounding the Mosholder report and subsequent investigation beginning with the agenda notice in the October 31, 2003, Federal Register through March 22, 2004.

4. Does FDA believe that the need to continue expending its resources on an investigation into the alleged "information leak" is necessary in light of the fact that FDA, by its recent advisory gave credibility to the Mosholder report?

5. Please identify each and every OIA investigation, review, evaluation, or audit (collectively called "reviews" for purposes of the letter) initiated by the OIA in the last five years where an "information leak" was the primary target of the review. For each matter identified please include the following information:

a. When was this review requested?
b. Who requested that a review be conducted?
c. What were the findings of the review?

d. What action(s) were taken as a result of the OIA review?

6. What policies are being enforced and violations identified by this leak investigation? Please be specific and submit copies of all materials, including internal policies and procedures, memoranda, and guidance, as applicable.

Finally, I request that the FDA provide me a copy of Dr. Mosholder's report immediately, and arrange for the following individuals to be interviewed within the next two weeks:

1. Anne Trontell;
2. Mark Avigan;
3. Andrew Mosholder; and
4. Horace Coleman.

When preparing responses to the questions identified above please be sure to re-state the question and provide a detailed response. In the event that documents or other materials are requested, please be sure to mark them accordingly.

In closing, I look forward to hearing from you no later than April 12, 2004 regarding my requests and concerns set forth in this letter. Thank you for your attention to this important matter. All correspondence should be sent via facsimile to (202) 228-2131 and original by U.S. mail.

Sincerely,

Charles E. Grassley
Chairman