U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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For Immediate Release
Wednesday, August 4, 2004

Grassley asks drug makers what they told the FDA about anti-depressants and suicide among young people

WASHINGTON — Sen. Chuck Grassley has asked eight major pharmaceutical drug makers to describe the kind of information they provided to the Food and Drug Administration during the government's review of the safety of pediatric use of anti-depressants. Last year, the Food and Drug Administration asked these manufacturers for pediatric trial data regarding their antidepressant drugs.

Grassley made his request of the drug companies as part of his ongoing investigation into whether or not safety information was withheld from the public by the Food and Drug Administration. Today's letter asks questions to determine if the drug companies withheld any safety information from the Food and Drug Administration about their antidepressant drugs. The text of the letter he sent to Pfizer, Inc., Wyeth Pharmaceuticals, GlaxoSmithKline, Bristol-Myers Squibb Company, Organon Pharmaceuticals USA Inc., Solvay Pharmaceuticals Inc., Eli Lilly & Company, and Forest Pharmaceuticals, Inc. follows here.

August 3, 2004

Dear _____,

Several months ago, I initiated an investigation into the decision by the Food and Drug Administration (FDA) to remove Dr. Andy Mosholder from the agenda for an FDA Advisory Committee Meeting (ACM) that was scheduled on February 2, 2004. A number of additional matters have come to light since my Committee staff began its investigation, which require clarification and information from your company.

In June 2003, Dr. Mosholder was charged by the Office of New Drugs (OND) at the FDA to conduct an analysis of the data from clinical trials of selective serotonin reuptake inhibitors (SSRIs) and other antidepressant drug products in pediatric patients. Dr. Mosholder's analysis concluded that a "link" existed between the use of antidepressants by children and suicidal

behavior. However, the FDA did not allow him to present his analysis at the ACM.

In preparing his analysis, Dr. Mosholder relied, in part, upon clinical trial data your company provided to the FDA about your company's drug, _____. Additionally, FDA officials contracted last fall with Columbia University (Columbia) to re-examine and classify data from the pediatric depression trials. It is my understanding that this study was led by a team of three Columbia research scientists, who convened a panel of 10 independent members to review the data. The Columbia study reportedly applied standardized terminology for suicidal acts and behavior to over 400 case descriptions from the 25 pediatric antidepressant trials. These independent reviewers, as I understand it, reviewed descriptions that your company, among others, used in reporting adverse events that occurred in its studies.

Hopefully, the Columbia study will add another important piece of the puzzle that will lead to a better understanding of the effects of antidepressant use among children and adolescents. It is essential, however, to ensure that all available information on pediatric antidepressant trials has been made available to the FDA. The Columbia Study and Dr. Mosholder's expert analysis are undoubtedly of interest to millions of parents whose children are using antidepressants throughout the United States. My position is, and continues to be, that doctors and patients need to be given the fullest picture possible - they deserve to know more, not less - about the effectiveness of drugs.

In recent news reports, I have seen that some drug manufacturers of antidepressant are being accused of concealing important information about the safety and efficacy of antidepressants. Specifically, it has been reported that some drug manufacturers have allegedly withheld negative information and misrepresented data concerning the safety and efficacy of antidepressants when prescribed for depression in children and adolescents.

I am concerned that some drug companies may not have provided the FDA with all information at their disposal. In light of these concerns, please respond to the following requests for information:

ANTIDEPRESSANTS

1. From January 1, 1990 through July 23, 2004, provide a list of all clinical trials and/or studies initiated by your company relating to the pediatric use of antidepressants. Please identify each trial/study by name and provide a summary of the results of the study. This request encompasses any trial/study -- including, but not limited to all randomized placebo-controlled trials, open trials, and active-controlled trials -- conducted by your company relating to any New Drug Application (NDA), Investigational New Drug (IND) application, or for any other reason. In addition, provide the following information with respect to each trial/study:

1a. State the date it was initiated and the date it was completed. If it was not completed, state in detail why it was not completed, who made the decision not to complete it, and at what

point it was terminated.

1b. State when and where it was published. If it was not published, state in detail why it was not published.

2. State when and for what purpose the trial/study was submitted to the FDA. If it was not submitted, state in detail why it was not submitted.

OTHER DRUG STUDIES

1. From January 1, 2000 through December 31, 2003, provide a list of all INDs and NDAs submitted by your company to the FDA. Please provide a brief summary for each IND and NDA.

2. From January 1, 2000 through December 31, 2003, provide a list of all clinical trials and/or studies initiated by your company relating to the INDs and NDAs identified in Question 1. Please identify each trial/study by name and provide a summary of the results of the study. This request encompasses any trial/study -- including, but not limited to all randomized placebo-controlled trials, open trials, and active-controlled trials -- conducted by your company relating to any NDA, INDs, or for any other reason. In addition, provide the following information with respect to each trial/study:

2a. State the date it was initiated and the date it was completed. If it was not completed, state in detail why it was not completed, who made the decision not to complete it, and at what point it was terminated.

2b. State when and where it was published. If it was not published, state in detail why it was not published.

3. State when and for what purpose the trial/study was submitted to the FDA. If it was not submitted, state in detail why it was not submitted.

Please provide the information requested by August 27, 2004, unless it is available sooner. In addition, please provide the name and contact information of a person who will act as your company's point of contact by August 11, 2004. In complying with this request, respond by repeating the enumerated request, followed by the accompanying response. In the event that documents or other materials are responsive, please be sure to mark them accordingly. Finally, in complying with this request, _____ means its corporation, or one or more of its divisions, subsidiaries or affiliates, or related entities, including any other companies or corporations with which _____ entered into a partnership, joint venture or any other business agreement or arrangement. Also, the terms "relating," "relate," or "regarding" as to any given subject means anything that discusses, concerns, reflects, constitutes, contains, embodies, identifies, deals with, or is any manner whatsoever pertinent to that subject.

Any questions or concerns should be directed to our Committee staff, Emilia DiSanto or Michelle Anderson at (202) 224-4515. All correspondence should be sent via facsimile to (202) 228-2131 and original by U.S. mail. All document deliveries should be coordinated with the Chief Clerk for the Committee, Ms. Carla Martin, at (202) 224-4992, and delivered in accordance with her instructions. In order to comply with Committee deadlines, certain delivery information must be submitted to the Chief Clerk at least 24 hours ahead of the anticipated delivery day.

Sincerely,

Charles E. Grassley
Chairman