U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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For Immediate Release
Wednesday, May 12, 2004

Grassley continues review of FDA's handling of research on antidepressants, child suicide

WASHINGTON — Sen. Chuck Grassley has asked the Food and Drug Administration and the Department of Health and Human Services for detailed information about an FDA contract with Columbia University as part of his larger review of allegations that the government initially withheld information from the public about risks for children given antidepressants.

Grassley said he wants to make sure that the Food and Drug Administration is not attempting through an outside evaluation underway by Columbia University to undermine the findings of the scientist who identified a possible link between child suicide and antidepressants.

The text of Grassley's letter to the FDA and the Department of Health and Human Services follows here.

May 11, 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 Mr. Crawford:

On March 25, 2004, I requested that the Food and Drug Administration (FDA) answer a series of questions related to its March 22, 2004 Public Health Advisory on “Cautions for Use of Antidepressants in Adults and Children.” As you know, my inquiry is in response to allegations that the FDA has withheld very important information from the public regarding the risks

associated with children and their use of antidepressants. In the FDA's April 14, 2004 response, it states "Agency staff determined that an independent panel of experts in suicidology should be convened to carefully evaluate and reclassify the reported adverse events. DNDP (Division of Neuropharmacological Products) arranged for this work to be performed under a contract with Columbia University and this review is ongoing."

In light of my concerns, I request that the FDA provide detailed responses to the following questions:

1. On what date was it decided that these data needed to be analyzed by non-FDA reviewers?
2. Who decided to have these data analyzed by a third party? Please provide the name of each individual who engaged either directly or indirectly in this decision, including their title and division assignment.
3. Describe in detail the rationale behind the decision to have non-FDA reviewers analyze these data?
4. How was Columbia University selected as the non-FDA reviewer of these data?
5. What is the dollar amount of the contract awarded to Columbia University?
6. Provide a list of all similar instances in the past five years where the Division of Neuropharmacologic and Psychiatric Drug Products contracted with non-government parties with the expressed purpose of having safety data from new drug application (NDA) clinical trials reviewed and analyzed using patient-level data from these studies. Provide a similar list of all such instances within the Center for Drug Evaluation and Research (CDER). This request is specific to the analysis of NDA clinical trial safety data and excludes any instances of analysis of safety data from observational, phase 4, or other non-pre-approval studies.
7. Provide the names, qualifications and curricula vitae of all personnel from Columbia University who will be participating in the analysis of SSRI data under contract to the FDA. Provide all documents related to FDA's evaluation of Columbia University personnel for potential conflicts of interest.
8. Provide the names, qualifications and curricula vitae of all personnel working on this analysis that are not affiliated with Columbia University.
9. For each member of the Columbia University group that will be participating in the SSRI analysis, provide a list of all work done with the pharmaceutical industry either directly or indirectly or its representatives covering the past five years. This list should include the nature of the work, the company for which it was performed and the amount of money received. This includes all consultative work, speaking engagements and any other type of arrangement with the pharmaceutical industry, as well as, stock holdings or other investments.

I understand further that the FDA referred the "details" (narrative summaries) of suicides from SSRI clinical trials in minors to Columbia University for review. The following series of questions relate to these "details."

1. What data is included in these "details"? Please be specific.

2. Who developed the data included in the "details" provided to Columbia University? Please provide a copy of their respective CVs.
3. Please describe the methodology used to determine the date included in these "details"? Please identify whom developed the methodology and what the rationale was behind the methods used.
4. Please describe in detail, the process used to develop the narrative "details." Among other things, address the following for each "detail" prepared and proved to Columbia University:
    a. whether or not the subject was interviewed;
    b. whether or not the subject's parent(s)/guardian(s) were interviewed;
    c. whether or not the subject's treating physician was interviewed; and
    d. whether or not those subjects who left the trial were included in the details.
5. How much time lapsed between an adverse event and each "detail" written and provided to Columbia University for the study?

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 June 7, 2004 regarding my requests and concerns set forth in this letter. Thank you for your attention to this important matter.

Sincerely,

Charles E. Grassley
Chairman