

June 11, 2008

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

The Honorable Andrew C. von Eschenbach M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Secretary Leavitt and Commissioner von Eschenbach:

As a senior member of the United States Senate and as Ranking Member of the Committee on Finance (Committee), it is my duty under the Constitution to conduct oversight into the actions of the executive branch, including the activities at the Food and Drug Administration (FDA/Agency), a part of the Department of Health and Human Services (HHS).

I have recently received an expert report prepared for litigation by Dr. Joseph Glenmullen, a professor at Harvard University. Based on documents from GlaxoSmithKline (GSK) and the FDA, Dr. Glenmullen concluded that GSK officials knew back in 1989 that Paxil is associated with an increased risk for suicide. I have attached his report for your review and consideration.

Furthermore, I have learned that Britain's Medicine's and Healthcare Regulatory Authority (MHRA) concluded a four year investigation of Paxil. That report found that GSK had been aware since 1998 that Paxil was associated with a higher risk of suicidal behavior in adolescents. However, the British government did not move forward with criminal prosecutions because the laws at the time were not clear enough as to whether GSK should have informed the regulatory agency.

In response to the MHRA report, Britain's public health minister, Dawn Primarolo, told the Guardian newspaper, "Companies that conduct clinical trials should not compromise people's health by withholding information." The Guardian also reported that the British government plans to introduce new legislation later this year to make clear that drug companies should not withhold safety information.

In light of this investigation by the MHRA, I would like you to take a look at the information that agency gathered and determine if the company has withheld safety information here as well. I also request a briefing for my staff on whether or not a review is being conducted by HHS or any of its departments/agencies regarding whether or not GSK withheld information from the FDA.

Should you have any questions please feel free to contact Paul Thacker or Angela Choyof my staff at (202) 224-4515.

Sincerely,

Chuck Grassley

United States Senator
Ranking Member of the Committee on Finance