U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
http://finance.senate.gov

For Immediate Release
Wednesday, November 30, 2005

Grassley asks FDA to keep providing new information about erectile dysfunction drugs

WASHINGTON --- Sen. Chuck Grassley said the Food and Drug Administration has taken important steps to better inform consumers about the risk of vision loss from prescription medicines that treat erectile dysfunction and urged the agency to be more proactive in communicating with doctors and patients should additional concerns be identified.

Grassley's letter to the Acting Commissioner of the FDA addresses an October 20 response to him from the drug safety agency. A copy of the FDA's letter is posted with this news release at http://finance.senate.gov.

Last summer, Grassley was outspoken about the need for the FDA to provide more timely information in a user-friendly format regarding new findings that erectile dysfunction drugs could cause serious damage to eyesight. Copies of Grassley's August 24 and June 24 letters are also posted at http://finance.senate.gov, along with this news release.

Grassley is Chairman of the Senate Committee on Finance and has conducted oversight of the FDA. He has also introduced bipartisan legislation to mandate a clinical trials registry for drug makers (S.470) and to establish independence within the FDA for the office that reviews FDA-approved drugs after they're on the market (S.930).

Grassley has said that the FDA must both make available to consumers new life-saving and life-enhancing medicines as quickly as possible and be diligent in considering any new drug-safety risks that may become apparent after drugs are in the marketplace. "A commitment to transparency and letting the science prevail are the keys to the FDA's success as the world's premiere drug-safety agency," Grassley said.

Here is the text of the recent letter Grassley sent to the FDA.

November 22, 2005

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

Dear Dr. von Eschenbach:

Thank you for the Food and Drug Administration's (FDA) response to my letter dated August 24, 2005, requesting that the FDA describe actions that will be taken to ensure that patients and consumers are informed of the risks of permanent vision loss associated with the use of drugs prescribed by physicians to treat erectile dysfunction (ED).

I commend the FDA on its efforts to inform patients and consumers about the safety concerns regarding ED drugs. The FDA's letter, dated October 20, 2005, outlined a number of actions taken by the agency to date to communicate ED drug safety information to patients and their health care providers, including revising patient package inserts, partnering with groups, such as Medscape, to expand the agency's ability to disseminate safety information, and providing information to local and national media outlets and through the FDA's own Patient Safety News program and website. In addition, I applaud the FDA's initiative to improve its risk communication to ensure that patients and physicians have the most up-to-date and complete information about FDA-approved drugs on the market. However, I am also interested in knowing what action, if any, the FDA has taken to date to ensure that future safety concerns regarding ED drugs are detected and disclosed in a timely manner, including but not limited to implementing risk management plans with ED drug manufacturers to track adverse events and to conduct additional post-market safety studies.

In closing, I hope that, in the future, the FDA will take a similar approach to educating the public of new safety concerns associated with the drugs as well as medical devices and other products that are regulated by the FDA. Accordingly, as Chairman of the Committee on Finance, I request that the FDA describe in detail how the agency plans to maintain the risk communication activities and programs outlined in its October 20, 2005 letter. In addition, please describe any efforts to apply the agency's drug safety communication strategies to other areas under the FDA's jurisdiction. Finally, state whether or not the FDA has implemented or will implement risk management plans for ED drugs. If so, describe in detail what the risk management plan entails.

Thank you for your attention to this important matter. Please provide the requested information by no later than December 8, 2005.

Sincerely,
Charles E. Grassley
United States Senator
Chairman, Committee on Finance