United States Senate
Committee on Finance

Sen. Chuck Grassley · Iowa
Ranking Member

http://finance.senate.gov
Press_Office@finance-rep.senate.gov

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Grassley urges conferees to support strong FDA reforms

WASHINGTON — Sen. Chuck Grassley said the upcoming September 30 anniversary of Vioxx being pulled from the market is a good reminder about the need for Congress to embrace reforms passed by the Senate and House earlier this year in separate legislative proposals for the Food and Drug Administration.

In a letter to the leaders of the conference committee that's crafting a final bill, Grassley said, "Both houses of Congress passed FDA reform bills that attempt to address serious problems at the FDA. Let's not undo those efforts by reporting a weaker bill out of conference."

Grassley has conducted active oversight of the FDA and documented shortcomings and conflicts with the drug safety agency's pre-market review and post-marketing surveillance of drugs, biologics, devices and veterinary medicines. He has called the FDA's relationship with the drug industry "too cozy" and revealed how agency leaders have acted to suppress scientific dissent regarding agency actions and drug-safety recommendations.

"Public safety is at stake," Grassley said. "Congress needs to do everything it can with this legislation to make the FDA more independent, rigorous and responsive in its work. Unfortunately, the case for reform gets stronger all the time, as new questions continue to emerge about FDA actions and inaction."

One of the reforms Grassley urges congressional negotiators to include in their final conference report is a Grassley amendment that senators approved in May with a vote of 64 to 30. The measure would improve pharmaceutical companies compliance with FDA directives, including label changes, post-approval studies and communicating important patient information such as newly identified risks.

A separate amendment offered by Grassley during Senate debate on the FDA Revitalization Act lost by just one vote. This initiative would have made the FDA office that studies drugs after they're on the market an equal partner with the FDA office that initially approves drugs for all post-approval decisions related to the safety of drugs that are on the market. Grassley said again today that this reform is fundamental to improving the FDA's

ability to monitor the safety of FDA-approved drugs and devices.

Strengthening the Office of Drug Surveillance and Epidemiology has been a central focus of Grassley's effort to fix problems at the FDA. In a commentary published earlier this year in the Journal of the American Medical Association, two members of the Institute of Medicine committee that evaluated FDA's drug safety system wrote, "the IOM identified the imbalance in authority between the Office of New Drugs and the Office of Surveillance and Epidemilogy (formerly the Office of Drug Safety) as a major weakness in the drug safety system. In an effort to facilitate a collaborative and constructive team approach, the IOM recommended joint authority for the Office of New Drugs and Office of Surveillance and Epidemiology in the post-approval setting."

The text of Grassley's letter this week to the Chairmen and Ranking Members of the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce follows here.

September 17, 2007

Dear Chairmen Kennedy and Dingell and Ranking Members Enzi and Barton:

Over the last year, I have written to you regarding my concerns about how the Food and Drug Administration (FDA or Agency) handles the pre-market review and post marketing surveillance of drugs, biologics, devices and veterinary medicines. As the House and Senate go into conference and work to resolve differences between S. 1082, the Food and Drug Administration Revitalization Act, and H.R. 2900, the Food and Drug Administration Amendments Act of 2007, I urge you to keep in mind the public's interest. It is essential that Congress maintain provisions within the two bills that will improve drug safety at the FDA and enable the Agency to better protect the health and safety of all Americans.

I appreciate the efforts of the Senate Committee on Health, Education, Labor, and Pension and the House Committee on Energy and Commerce to address some of the major problems at the FDA. In particular, S. 1082 and H.R. 2900 would provide FDA with the much needed authorities to require labeling changes and post-approval clinical trials, among other things. However, I believe we need strong civil monetary penalties in order for these new authorities to be effective, which is why I had offered Amendment No. 998 to S. 1082. That amendment increased the minimum and maximum amounts of civil monetary penalties in S. 1082 that could be imposed for violations of approved Risk Evaluation and Mitigation Strategies. Amendment No. 998 passed by a vote of 64 to 30, showing that a large majority of the Senate also agreed that strong civil penalties are necessary to deter bad behavior. Monetary penalties would be meaningless if they were nothing more than the cost of doing business.

I would also like to reiterate my concerns regarding the imbalance between the office that approves new drugs at the FDA, the Office of New Drugs (OND), and the office that monitors the safety of drugs once they are on the market, the Office of Surveillance and Epidemiology (OSE). Although neither the Senate nor the House bills would give post-marketing surveillance the equal footing it deserves with drug approval, I welcome the provision in H.R. 2900 that

would require FDA to report to Congress on drug safety recommendations received in consultation with the Office of Surveillance and Epidemiology (OSE). If the FDA does not act on an OSE recommendation or it takes a different action, the Agency would be required to provide its justification to Congress.

In addition, I welcome the requirement in S. 1082 that the Secretary assess and implement the Risk Evaluation and Management Strategies in consultation with OND and OSE. While this requirement does not necessarily change the status quo, I hope it will encourage the FDA to give the drug safety office a greater voice on post-marketing drug safety matters.

I have seen time and time again in my investigations that serious safety problems that emerge after a drug is on the market do not necessarily get prompt attention from the Office of New Drugs, the office that approves drugs to go on the market in the first place. We saw this with Vioxx and over the last few months with the diabetes drug Avandia. My current review of FDA's handling of Avandia has unearthed concerns similar to those we have seen in the past-a situation where FDA ignored its own post-marketing safety experts and once again left the public in the dark regarding potential, serious health risks. Not only did the FDA disregard OSE's recommendations that the Avandia labeling be revised to include a "box warning" for congestive heart failure and stronger warnings about the drug's possible negative effects on eyesight, but the Agency also allegedly reprimanded a senior agency scientist for signing off on those recommendations.

The amendment that I offered in May, Amendment No. 1039, was intended to curb delays in FDA actions when it comes to safety. Although that amendment lost by one vote, the narrow margin demonstrates that many members of the Senate also recognized the seriousness of the imbalance between OSE and OND and believed action by Congress is necessary.

The deadline for renewing the Prescription Drug User Fee Act is rapidly approaching, but it is not too late for Congress to do what is right by the American people. Both houses of Congress passed FDA reform bills that attempt to address serious problems at the FDA. Let's not undo those efforts by reporting a weaker bill out of conference.

Sincerely,
Charles E. Grassley
Ranking Member

cc: Members of the Senate HELP Committee
Members of the House Committee on Energy and Commerce