U.S. SENATE COMMITTEE ON

Finance

SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN

http://finance.senate.gov

M E M O R A N D U M

TO: Reporters and Editors
FR: Jill Kozeny, 202/224-1308
RE: Bextra removal
DA: April 7, 2005

Sen. Chuck Grassley, Chairman of the Senate Committee on Finance, issued the comment below regarding the Food and Drug Administration announcement today that Bextra would be removed from the market.

Last year Sen. Grassley started conducting oversight of the Food and Drug Administration in response to concerns about the agency's handling of information about the dangers of teenager use of antidepressants and the cardiovascular risks associated with the painkiller Vioxx. In February 2005, Sen. Grassley joined Sen. Christopher Dodd in introducing legislation that would establish a mandatory clinical trial registry, in order to bring greater transparency to the drug safety review process. In addition, Sen. Grassley is working to develop legislation that would enhance post-market review of medicines by making the FDA's Office of Drug Safety independent from the FDA's Office of New Drugs.

Grassley comment —

"The burden is on the Food and Drug Administration to bring clarity to the safety concerns surrounding this class of drugs. What's happened with these painkillers has been a confusing saga for the people who need pain relief, and that can be attributed to systemic failures by the FDA and misplaced priorities of the drug industry.

"It will be good news if today's action, which goes further than the recommendations of the FDA's advisory panel, is a turning point and indicates a more independent Food and Drug Administration. Otherwise today's action may raise more questions than it gives answers for patients and their doctors. FDA officials repeatedly say that Vioxx was handled properly, and that they would act no differently today. It's hard to see how this squares with suspending the sale of Bextra and increasing the warning level for Celebrex. The FDA needs to chart a steady course for its customers, the American public."