United States Senate
Committee on Finance

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For Immediate Release
Wednesday, May 9, 2007

Grassley wins Senate passage of amendment to strengthen new FDA authority

WASHINGTON — Sen. Chuck Grassley today won an important victory in his crusade to improve the work of the Food and Drug Administration in monitoring the safety of FDA-approved drugs and devices.

Senators voted 64 to 30 for his amendment to increase the civil monetary penalties contained in the Food and Drug Administration Revitalization Act of 2007. The penalties would apply to companies that fail to comply with FDA directives that include label changes, post-approval studies, and communicating information about newly identified drug risks.

"The civil monetary penalties that were in the bill didn't pack enough punch to get the attention of corporations," Grassley said. "By approving my amendment today, senators recognized that it doesn't do much good to give the FDA new kinds of authority if the penalties designed to enforce that authority aren't meaningful."

Grassley's legislation increases the minimum civil monetary penalty from $10,000 to $250,000 that can be imposed on a drug maker that is knowingly out of compliance. It also says that the amount of the penalty will double for every 30-day period of non-compliance after that and up to $2 million. Previously, the overall bill capped the penalty at $1 million.

"These penalties need to be more than just an insignificant cost of doing business in order to affect behavior," Grassley said.

Attached in pdf is the language of Grassley's amendment no. 998, which was cosponsored by Sens. Christopher Dodd of Connecticut, Olympia Snowe of Maine, and Jeff Bingaman of New Mexico.

Grassley offered a second amendment today which was narrowly defeated 47 to 46. This measure 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 the amendment was fundamental to reforming and improving the FDA's performance and 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 an article published in last week's Journal of the American Medical Association, Grassley's arguments for the two offices carrying equal weight on post-market matters were echoed by two members of the Institute of Medicine committee that evaluated FDA's drug safety system. The authors 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."

"Defeat of this amendment is a lost opportunity when it comes to improving drug safety for American consumers," Grassley said. "The amendment responded directly to well-documented problems and expert advice on how to address those problems. Congress won't be acting responsibly if we don't continue working to strengthen post-market surveillance by the FDA."

The prestigious Institute of Medicine of the National Academies issued a report on its assessment of the nation's drug-safety system last fall. The Institute said the FDA had systemic problems and needed to exercise more vigilance over the life-cycle of drugs and provide more information to the public about drug risks. Grassley said this review validated concerns expressed by the watchdog community and added muscle to the reform effort. Last spring, the Government Accountability Office issued a separate report that said improvement was needed in the FDA's post-market decision making and oversight process.

Grassley has conducted active oversight of the FDA for the last three years and has put pressure on the drug safety agency to act with more independence and transparency in order to restore public confidence and strengthen public safety especially when it comes to drugs already on the market. Grassley 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.

In January, Grassley and Sen. Christopher Dodd introduced for the second time two bills to revamp and prioritize the post-market surveillance process within the FDA and to greatly expand public access to information about all clinical trials through a registry and results database. Their bills are S.468, the Food and Drug Administration Safety Act of 2007, and S.467, the Fair Access to Clinical Trials Act of 2007.

The FDA Revitalization Act on the Senate floor this week is S.1082. It would reauthorize the FDA's user fee authority, which collects money from drug and device companies for review of their products. The House of Representatives is expected to consider its versions of the drug safety and user fee reauthorization bills in the coming weeks.

Floor Statement of U.S. Sen. Chuck Grassley of Iowa
on Amendment No. 1039

Mr. President, I am here today to offer Amendment No. 1039 to S. 1082, the Food and Drug Administration Revitalization Act. I ask unanimous consent that Senators Mikulski,

Brown, Snowe, and Bingaman be added as cosponsors to my amendment, no. 1039. I am offering Amendment No. 1039, because S. 1082 does not sufficiently address the underlying problem that exists at the Food and Drug Administration. That problem is the lack of equality between the Office of New Drugs, which reviews drug applications and decides whether or not to approve a drug for marketing, and the Office of Surveillance and Epidemiology, the office which monitors and assesses the safety of a drug once it's on the market. The Institute of Medicine recognized this problem. The Institute of Medicine recommended joint authority between the two offices for post-approval regulatory actions related to safety. Having equality between the pre-approval and post-approval offices at the FDA is fundamental to real reform of the FDA. Concentrating on the entire life-cycle of drugs is critical. After all, the vast majority of a drug's life-cycle is spent post-approval. In essence, S. 1082 promotes the status quo when it comes to the role played by the Office of Surveillance and Epidemiology-that means the Office of Surveillance and Epidemiology will remain nothing more than a "mere" consultant to the Office of New Drugs. This is not acceptable. Amendment No. 1039 gives the Office of Surveillance and Epidemiology "sign-off" authority. They are the experts on post-marketing safety. Even the Institute of Medicine recognized that through their recommendation. Let me be clear here, this is a lesser amendment than what Senator Dodd and I originally proposed. I still believe an independent post-marketing safety center is the best solution to the problem, but, that will not happen. At least joint post-marketing decision-making between the Office of Surveillance and Epidemiology and the Office of New Drugs will allow the office with the post-marketing safety expertise to have a say in what drug safety actions will be taken by the FDA. The problem here is not only about FDA having enough tools, it's about FDA managers disregarding the concerns raised by FDA's own scientists in the Office of Surveillance and Epidemiology and not taking prompt action. This amendment makes common sense when you weigh the evidence I have presented over the last three years. Opponents to this amendment say that this amendment is unnecessary because S.1082 includes a dispute resolution process with strict deadlines. But that process is for disputes between FDA and the drug company, not internal disagreements between FDA offices. I also want to add that this amendment provides an approach with checks and balances between the office that approves a drug for marketing and the office that watches a drug once it is on the market. I ask that each Senator ask himself or herself one question before voting on this amendment today: Since the Institute of Medicine recommends equality between the pre-approval and post-approval offices at the FDA, why not vote for this amendment and improve post-marketing safety for the American people?

Floor Statement of U.S. Sen. Chuck Grassley of Iowa
on Amendment No. 998

Mr. President, I am here today to offer Amendment No. 998 to S. 1082, the Food and Drug Administration Revitalization Act. I ask unanimous consent that Senators Dodd, Snowe, and Bingaman be added as cosponsors to my amendment, No. 998. Amendment No. 998 provides for the application of stronger civil monetary penalties for violations of approved risk evaluation and mitigation strategies. Currently, S. 1082 contains penalties but those penalties won't mean much to large global corporations. In fact, the penalties amount to nothing more than the cost of doing business. This amendment is intended to give FDA, the watch-dog, some bite along with its bark. There is opposition to having strong civil monetary penalties. But that just does not make sense to me. The reality here is this: Drug companies provide life-saving pharmaceuticals to the world. They make miracles happen. Before a drug is approved, a drug sponsor has an incentive to provide evidence of a drug's effectiveness to the FDA. Without it,

they can't sell the drug to Americans. However, once a drug is already being sold in the marketplace, drug companies have almost no incentive to look for and evaluate safety issues. The bottom line is that, sometimes, market forces guide businesses in ways that may be contrary to the public interest. We have seen this happen. For FDA's new authorities to be meaningful, there must be strong civil monetary penalties. If fines are nothing more than the cost of doing business, you can't change behavior. More importantly, you can't deter bad behavior. After all, if a company does what it is supposed to do, a drug company doesn't need to fear any penalties. It's just that simple. In closing, I ask that Members of the Senate support Amendment No. 998 and add some teeth to the FDA's bite. I thank Senators Kennedy and Enzi for the tremendous efforts that went into bringing this bill to the floor. And I again thank them for incorporating a number of the provisions set forth in the two bills filed by Senator Dodd and me.