United States Senate
Committee on Finance

Sen. Chuck Grassley · Iowa
Ranking Member

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M E M O R A N D U M

TO: Reporters and Editors
FR: Jill Kozeny, 202/2240-1308
for Sen. Chuck Grassley
RE: Prescription Drug Safety
Consumer Reports Poll
DA: April 16, 2007

Sen. Chuck Grassley issued the comment below about the poll released today by Consumer Reports about how Americans view the government's performance in ensuring the safety of prescription drugs.

In January, Sen. Grassley and Sen. Christopher Dodd reintroduced two bills to revamp and prioritize the post-market surveillance process within the Food and Drug Administration and to greatly expand public access to information about clinical trials regardless of the outcome of those trials through a clinical trials 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 (FACT) Act of 2007. Sen. Jeff Bingaman is a cosponsor of both bills. Sen. Barbara Milkulski is a cosponsor of S. 468, and Sens. Ron Wyden, Richard Durbin and Tom Harkin are cosponsors of S. 467. Sens. Grassley and Dodd authored nearly identical bills in the last Congress in the aftermath of the Vioxx and antidepressant use in children scandals.

Sen. Grassley has conducted active oversight of the FDA for three years and has put pressure on the drug-safety agency to act with more independence and transparency than it now demonstrates in order to restore public confidence and strengthen public safety. 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.

Sen. Grassley's comment:

"This survey shows that a majority of the public is worried about FDA and big drug makers looking out for their safety. It's time for bold reforms, not just nibbling around the edges. The FDA bill that's expected to be considered in the Senate HELP Committee this week doesn't shake up the status quo enough. Congress and the FDA need to make post-market review of drugs just as important as getting drugs on the market in the first place. It'd be a

terrible shame if senators missed the opportunity this year to really do something to improve the FDA. A mountain of evidence has piled up about the need to take dramatic action. Leaders in medicine like Dr. Steve Nissen, who originally opposed a separate center for post-market surveillance, have now voiced the need for a separate post-market surveillance center inside the FDA."

Dr. Nissen is the Chairman of the Department of Cardiovascular Medicine at the Cleveland Clinic. He's also the immediate past President of the American College of Cardiology.