



U.S. SENATE COMMITTEE ON

Finance

SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN

<http://finance.senate.gov>

MEMORANDUM

TO: Reporters and Editors
RE: FDA and Cardiac Device Recalls
DA: Wednesday, Sept. 14, 2005

Sen. Chuck Grassley, Chairman of the Committee on Finance, issued the following comment today related to the recall of cardiac devices by the Food and Drug Administration. On August 18, the FDA provided Finance Committee staff with a briefing requested by the Chairman. During the briefing, Committee staff requested additional documents from the FDA. The formal document request letter is attached.

Sen. Grassley said, "Senior FDA officials acknowledged to my staff that CDRH needed to do a better job. When a regulatory agency official says 'there's a lot of stuff going on under the table,' how can Americans rest easy?"

Sen. Grassley has conducted oversight of the Food and Drug Administration over the last 18 months and called for administrative and legislative changes to make the agency more responsive to new information about safety risks with drugs and devices. Two separate letters from Sen. Grassley to the FDA related to cardiac devices were previously posted on the Committee's website:

7-20-05 Grassley questions FDA about safety and surveillance of medical devices based on new report in the New England Journal of Medicine
<http://finance.senate.gov/press/Gpress/2005/prg072005.pdf>

7-18-05 Chairman Grassley asks FDA about disclosure of risk information for medical devices including pacemakers and defibrillators
<http://finance.senate.gov/press/Gpress/2005/prg071805.pdf>



081905 FDA
letter.pdf (54 KB)