



U.S. SENATE COMMITTEE ON

Finance

SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN

<http://finance.senate.gov>

MEMORANDUM

TO: Reporters and Editors
FR: Jill Kozeny
202/224-1308
RE: Institute of Medicine Report
"Safe Medical Devices for Children"
DA: Friday, July 15, 2005

Sen. Chuck Grassley, Chairman of the Committee on Finance, issued the following comment about a report to be released on Monday, July 18, at 4 p.m. by the Institute of Medicine. **Sen. Grassley's comment is embargoed until the release of the IOM report.** The report assesses postmarket surveillance and safeguards on medical devices used for pediatric care. 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.

"This report exposes a fissure in the FDA's safety mission when it comes to surveillance of medical devices for children. It documents how the FDA is neither properly monitoring postmarket studies nor making important postmarket research publicly available. These are the same kinds of problems we've seen with postmarket review of medicines. The Institute of Medicine spells out remedies that should be pursued to better protect children who rely on FDA-approved medical devices, and I intend to work to help improve the situation."