



U.S. SENATE COMMITTEE ON

Finance

SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN

<http://finance.senate.gov>

MEMORANDUM

To: Reporters and Editors
Re: FDA post-market studies enforcement
Da: Friday, March 3, 2006

The Food and Drug Administration reported today that drug makers failed to undertake two of every three studies they agreed to do after their products were approved for sale by the agency. Sen. Chuck Grassley, chairman of the Committee on Finance, made the following comment on these findings.

“The FDA lacks the ability to effectively police drugs on the post-market side. The agency really needs more enforcement tools. The bill Sen. Dodd and I introduced to establish an independent office of drug safety at the agency will do just that. Companies that don’t comply with their post-market commitments would face civil monetary penalties. Right now, the FDA has no teeth to enforce post-market drug safety studies. That has to change.”