



U.S. SENATE COMMITTEE ON

Finance

SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN

<http://finance.senate.gov>

MEMORANDUM

TO: Reporters and Editors
FR: Jill Kozeny
RE: FDA, Vioxx
DA: October 7, 2004

As part of an ongoing investigation into how the Food and Drug Administration handled information about safety issues concerning the drug Vioxx, Finance Committee investigators for Senator Chuck Grassley today interviewed FDA researcher David Graham. Dr. Graham is associate director for science in the FDA Drug Center's Office of Drug Safety. Senator Grassley is chairman of the Committee on Finance. Based on today's meeting, Senator Grassley issued the following comment.

"As my investigative staff continues looking into how the Food and Drug Administration handles drug safety issues, particularly with antidepressants and Vioxx, a picture is emerging of an agency that can't see the forest for the trees.

"Dr. Graham's study and conclusions may have triggered Merck to take necessary action on Vioxx. Dr. Graham said today that during the last month he's been fighting an uphill battle within the Food and Drug Administration to let his study see the light of day. He described an 'FDA clearance process' that was he felt was trying to block the publication of his manuscript. Dr. Graham described an environment where he was 'ostracized,' 'subjected to veiled threats' and 'intimidation.' When the Director of the Office of New Drugs suggested watering down Dr. Graham's conclusions Dr. Graham wrote, 'I've gone about as far as I can without compromising my deeply-held conclusions about this safety question.' On August 12th of this year, before his findings were presented, Dr. Graham's supervisor wrote that Merck 'needs to know before it becomes public so they can be prepared for extensive media attention that this will likely provoke.'

"So it seems that while Merck was taking a fresh look at its clinical data in search of trouble, the Food and Drug Administration was challenging its own researcher. Merck knew it had trouble on its hands and took action. At the same time, instead of acting as a public watchdog, the Food and Drug Administration was busy challenging its own expert and calling his work 'scientific rumor.'

"What Dr. Graham went through is similar to what we now know another FDA scientist, Dr. Mosholder, went through when he wanted to let the public know about a link between antidepressants and suicide in young people. In both cases, what looks like foot dragging by the Food and Drug Administration is downright alarming. Is the Food and Drug Administration dropping the ball in protecting the safety of the American people?"

