U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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For Immediate Release
Wednesday, Nov. 10, 2004

Grassley to Convene Hearing on Worldwide Withdrawal of Vioxx

Event: Committee on Finance Hearing, "FDA, Merck, and Vioxx: Putting Patient Safety First?"
Date/time: Thursday, Nov. 18, 2004, at 10 a.m.
Location: 215 Dirksen Senate Office Building, Washington, D.C.

Description: In the past year, Sen. Chuck Grassley, chairman of the Committee on Finance, has been examining whether the Food and Drug Administration has made fundamental mistakes in managing public health risks with antidepressants in children and, most recently, with Vioxx, the pain medication for arthritis just withdrawn from the market over concerns that it increases the risk for heart attack and stroke. Grassley is concerned that the American public has been kept in the dark. With more Americans relying on prescription drugs than ever before, and with federal programs Medicare and Medicaid poised to pay for more prescription drugs than in history, Grassley feels a critical look at drug safety and the worldwide withdrawal of Vioxx is overdue. The hearing will mark the first time the leaders of the FDA and Merck, maker of Vioxx, will testify on Capitol Hill about Vioxx's safety problems.

"Like most Americans, I've always thought that when the FDA approves a drug, it's like the good housekeeping seal of approval," Grassley said. "If the drug's not safe, the FDA would know and take it off the market. The alarming revelations about Vioxx make me a whole lot more skeptical. It looks like the FDA and Merck saw a lot of red flags from the beginning. The agency must address what looks like systemic problems when it comes to putting public health and safety first and public relations second. And Merck must stand up and set the record straight about what it knew about cardiovascular risks associated with Vioxx and when the company knew it. It appears that life-and-death decisions are being made behind closed doors. The American people should never be the last to know that their lives are at risk when taking a prescription drug."

The witness list follows.

David J. Graham, MD, MPH, Associate Director for Science, Office of Drug Safety, Center for Drug

Evaluation and Research, U.S. Department of Health and Human Services, Food and Drug Administration, Washington, D.C.

Gurkirpal Singh, MD, Adjunct Clinical Professor of Medicine, Division of Gastroenterology and Hepatology, Department of Medicine, Stanford University School of Medicine, Stanford, Calif. (via videoconference) – Dr. Singh is a former Merck consultant with extensive knowledge and expertise on Vioxx.

Bruce M. Psaty, MD, PhD, Professor, Medicine & Epidemiology, University of Washington, Cardiovascular Health Research Unit, Seattle, Wash. – Dr. Psaty has extensive knowledge of cardiovascular disease and epidemiology and will discuss various Vioxx studies and trials.

Lester M. Crawford, DVM, PhD, Acting Commissioner, U.S. Department of Health and Human Services, Food and Drug Administration, Washington, D.C.

Dr. Raymond V. Gilmartin, Chairman, President & Chief Executive Officer, Merck & Co., Inc., Whitehouse Station, N.J.

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