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April 27, 2005

The Honorable Charles Grassley
United States Senate
Washington, D.C. 20510

The Honorable Christopher Dodd
United States Senate
Washington, D.C. 20510

Dear Senators Grassley and Dodd:

We offer our strong support for the Food and Drug Administration Safety Act of 2005. The legislation is a key step toward fundamental reform of the nation's flawed drug approval and monitoring system which has exposed millions of Americans to unsafe medicines such as Vioxx and Bextra.

The Safety Act corrects the most serious problem in FDA's drug safety program—its passive and feeble postmarket safety monitoring system that turns millions of trusting consumers into guinea pigs testing unresolved safety problems. The FDA Safety Act, by creating a strong and independent Center for Post-market Drug Evaluation and Research, will reassure Americans that drug safety will be a top priority at the FDA.

First, by removing the postmarket surveillance function from the Center for Drug Evaluation and Research, the bill helps resolve the long-standing and inherent conflicts-of-interest between those who approve new drugs and those who monitor safety once they're on the market. This conflict has resulted in a bias in favor of approved drugs, the alleged suppression of safety findings of postmarket reviewers, and FDA inaction and delay in reducing safety risks postmarket.

Second, the legislation will substantially strengthen the drug safety system by providing the independent Center for Post-market Drug Evaluation and Research with the authority to require that drug sponsors conduct additional studies at any time following approval and to take timely action to manage unreasonable safety risks.

Among the many shortcomings of the current drug safety system is the agency's lack of authority to require pharmaceutical companies to meet their postmarket study commitments, to require additional studies once a drug is approved, and to require drug companies to take timely corrective action to manage risk. Because FDA currently lacks these authorities, the agency must conduct protracted negotiations with drug sponsors prior to taking action, putting patients at risk in the interim.

FDA's reluctance to require postmarket studies at the time of approval, and inability to require them afterward, has significant consequences for the health of patients. Given the safety signals of Vioxx, Bextra and other non-steroidal anti-inflammatories identified many years ago, FDA should have required the makers of these drugs to conduct additional studies to confirm or refute suspected cardiovascular risks and managed use until those safety questions were answered. Instead, millions of consumers using these widely prescribed painkillers were left in the dark as FDA and the drug makers evaded serious safety questions. Vioxx alone is estimated to have caused up to 139,000 excess cases of cardiovascular events.

Third, by providing for consultation between the new Center and CDER, the bill will enhance communication and coordination between those who approve drugs and those who monitor safety after approval, while restoring an appropriate balance between the approval and postmarket surveillance functions.

Fourth, the bill's provision on civil penalties for sponsor noncompliance with postmarket study or risk management requirements will equip FDA with an appropriate enforcement tool. Currently, when drug sponsors fail to comply with postmarket study commitments or FDA-requested risk management steps, the agency's only recourse is seizure, injunction or withdrawal—tools FDA is reluctant to use and which may not be appropriate in all cases.

Finally, the Safety Act's requirement for greater disclosure of risk information in advertisements for drugs with significant safety concerns will help ensure that consumers have more balanced risk-benefit information. In addition, requirements for presubmission of promotional materials for new drugs will aid FDA in taking action on misleading or fraudulent ads before consumers and physicians are exposed to them. Currently, when FDA asks drug companies to pull misleading ads, it is often many months after the ads first appeared and patient preferences and physician treatment decisions have been influenced.

We also offer our endorsement of S. 470, the Fair Access to Clinical Trials Act, which dramatically improves transparency of clinical trial results so researchers, doctors and consumers have more balanced information about drug safety risks. Currently, drug companies provide study results to FDA, but they are not required to make them public, allowing them to play up positive results while burying negative ones. Taken together, the FDA Safety Act and the FACT Act will substantially improve drug safety and transparency of information.

We applaud your commitment to meaningful drug safety reform and look forward to working with you toward passage of this important legislation.

Sincerely,

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cc: Senate Committee on Health, Education, Labor and Pensions