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Consumer, Health Groups Support Tough FDA Reform Bill

Legislation establishes strong, independent safety center to reduce drug risks and eliminate conflict of interests

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(Washington, D.C.) – Consumer and health groups today supported the introduction of a tough, bipartisan drug safety bill as 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 FDA's passive and feeble safety monitoring system has turned millions of trusting consumers into guinea pigs testing unresolved drug safety issues," said Jeannine Kenney of Consumers Union, publisher of *Consumer Reports*. "Congress must pass this bill to reassure Americans that drug safety will be a top priority at FDA."

The Center for Medical Consumers, Consumer Federation of America, Consumers Union, National Women's Health Network, Public Citizen, and the U.S. Public Interest Research Group offered strong support for the Food and Drug Administration Safety Act of 2005, introduced today by Senators Grassley (R-IA) and Dodd (D-CT).

The groups have strongly criticized the FDA for its failure to aggressively monitor the safety of drugs once they are on the market despite early warning signs from clinical studies or indications of problems in patients taking the drug. The agency rarely requires drug manufacturers to study the safety of drugs once they are on the market and used by millions of consumers.

"The FDA should have required the makers of Vioxx and Bextra to conduct additional studies of suspected cardiovascular risks years ago when safety concerns were first identified, and carefully managed use of the drug until those questions were answered," the groups said in a letter to Senators Grassley and Dodd today. "Instead, consumers using these widely prescribed painkillers were left in the dark as FDA and the drug makers evaded answering safety questions."

The bill creates a proactive, independent Center for Post-market Drug Evaluation and Research that reports directly to the FDA Commissioner, rather than the division now responsible for new drug approvals (the Center for Drug Evaluation and Research). By creating the new postmarket center, the legislation resolves long-standing conflicts-of-interest in the FDA. Currently, the division that approves new drugs as safe for the market and the division that monitors them for safety once they are on the market are under the same department management.

The groups say the Office of Drug Safety currently charged with postmarket safety lacks adequate resources and authority to take action on safety concerns. Under this bill, the duties of that office would be transferred to the new Center.

The legislation also provides the postmarket Center with significant new authorities to require drug companies to conduct further safety studies of new drugs, and require them to take action to reduce risks. And it takes on direct-to-consumer drug advertising by requiring makers of new drugs to submit ads to the FDA before they are run, and to include information in the ads that promote a more accurate consumer understanding about safety risks and uncertainties.

“Today, when FDA asks drug companies to pull misleading ads, it is often many months after the ads first appeared, and sometimes long after the ad campaign was discontinued,” the groups said. “FDA needs to take action before consumers and doctors are misled by these ads. This legislation gives the new Center the authority to make that happen.”

The consumer and health advocacy organizations also support legislation introduced by Senators Dodd and Grassley that would require drug makers to register and make public the results of all their clinical drug trials so researchers, doctors and consumers would know about possible harmful side effects (S. 470 Fair Access to Clinical Trials Act). Currently, the drug companies give those drug study results to the FDA but are not required to make them public, allowing them to play up positive results but bury negative ones.

“Taken together, Senators Grassley and Dodd have put forth legislation that should substantially improve drug safety and transparency of information,” Kenney said. “We applaud the Senators for their efforts at true reform and call on the Senate to quickly take up this issue.”

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