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Harkin Welcomes FDA's Release of Proposed Rules to Protect Consumers Using Generic Drugs

WASHINGTON, D.C.—U.S. Senate Health, Education, Labor, and Pensions (HELP) Chairman Tom Harkin (D-IA), along with a coalition of lawmakers, today welcomed the Food and Drug Administration's (FDA) [release](http://harkin-press.ews.senate.gov/mail/util.cfm?mailaction=clickthru&gpiv=2100110006.12477.3&gen=1&mailing_linkid=95249) (http://harkin-press.ews.senate.gov/mail/util.cfm?mailaction=clickthru&gpiv=2100110006.12477.3&gen=1&mailing_linkid=95249) of a proposed rule to ensure that generic manufacturers of prescription drugs can update their warning labels to provide better patient safety information to consumers.

Chairman Harkin, along with Senate Judiciary Chairman Patrick Leahy (I-VT), Senator Al Franken (D-MN), Senate Aging Committee Chairman Bill Nelson (D-FL), and Representatives Henry Waxman (D-CA), Chris Van Hollen (D-MD), Bruce Braley (D-IA), Matthew Cartwright (D-PA), and other lawmakers have long called for the FDA to act on this important patient safety issue.

The rulemaking follows two Supreme Court cases in which patients who were gravely injured by a prescription drug were unable to seek relief from the drug manufacturer because they had taken the generic version of the drug. The Court held that generic manufacturers could not be held responsible for inadequate labeling because they lack independent authority to update their warning labels, even if they become aware of new safety problems, unless the counterpart branded drug has first updated its warning labels. This issue would be addressed by the proposed rule released today.

“Consumers and health care professionals should have access to the most up-to-date product labeling information, regardless of whether they choose to use a name-brand or a generic drug,” Harkin said. “I applaud the FDA for working to ensure that important generic drug safety information reaches consumers and health care professionals in the most timely manner possible, and hope this rule can be finalized quickly.”

“A consumer should not have her rights foreclosed simply because she takes the generic version of a prescription drug,” Leahy said. “I welcome this action by the Food and Drug Administration to ensure that generic manufacturers can improve their patient safety labels. Responsible brand-name and generic manufacturers alike should have the ability, and the obligation, to give doctors and patients the information they need to avoid injuries.”

“A senior in Minnesota may have no idea that a prescription drug they're taking could cause devastating complications because generic drug manufacturers aren't allowed to update their labels to accurately reflect all side effects or risks,” Franken said. “Last year, we introduced a bill to fix this problem. And today, after our urging, the FDA took a

critical step forward to right this wrong. I'll be pushing to get the FDA's labeling fix implemented as soon as possible."

"This new guidance will give consumers clear, safe and accurate drug information—regardless of whether a drug is brand-name or generic," Nelson said.

"Today's action by FDA will not only allow patients and physicians to have access to the newest safety information about all drugs at the earliest possible time, but it will grant patients who take generic drugs the same right to access the courts as those who take a brand drug," Waxman said. "I am also glad to see that FDA is carefully evaluating ways to preserve the 'sameness' principle between generic and brand drugs that has been so critical to the success of the U.S. generic drug system. Patients need to have confidence that the generic drugs are the same as their brand counterparts in all significant respects, including risk information on the drug labeling."

"I applaud the FDA's action today to ensure that consumers are armed with the most accurate information about new risks and side effects of all drugs. This will help ensure that generic manufacturers have the ability to independently add or strengthen the warning on their products, like brand name manufacturers do. It is a critical change that we've been fighting for, and it will improve safety and help Americans make the best decisions for their families," Van Hollen said.

"I'm glad to see this important step forward for patient safety," Braley said. "This is a common sense solution to protect American patients who deserve to know the risks of the drugs they're taking. American consumers don't want multiple sets of rules when it comes to the accuracy of drug labels. Today's announcement is an important step towards preventing the misuse of prescription drugs, and keeping Americans safer and healthier."

"I applaud the FDA's decision to allow generic drug manufacturers to update labels with the latest safety information," Cartwright said. "This proposal will help equip health care providers and consumers who depend on generic drugs with the best possible information to avoid adverse outcomes."

Harkin and the lawmakers sent letters urging the FDA to act on this issue in [June 2013](http://harkin-press.ews.senate.gov/mail/util.cfm?mailaction=clickthru&gpiv=2100110006.12477.3&gen=1&mailing_linkid=95248) (http://harkin-press.ews.senate.gov/mail/util.cfm?mailaction=clickthru&gpiv=2100110006.12477.3&gen=1&mailing_linkid=95248) and [May 2012](http://harkin-press.ews.senate.gov/mail/util.cfm?mailaction=clickthru&gpiv=2100110006.12477.3&gen=1&mailing_linkid=95247) (http://harkin-press.ews.senate.gov/mail/util.cfm?mailaction=clickthru&gpiv=2100110006.12477.3&gen=1&mailing_linkid=95247). Action on this issue has been supported by a broad coalition of patient safety and consumer groups, including the AARP, Public Citizen, Breast Cancer Action, and the National Women's Health Network.

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