ConsumersUnion POLICY & ACTION FROM CONSUMER REPORTS

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Senate HELP Committee to Vote on Food and Drug Administration Safety And Innovation Act On Wednesday, April 25

Bill Includes Important Improvements Over Current Law But Lacks Critical Medical Device Patient Safety Provisions

WASHINGTON, D.C. – The Senate Health, Education, Labor and Pensions Committee is scheduled to mark-up legislation to reauthorize the Food and Drug Administration Safety and Innovation Act on Wednesday, April 25. While the legislation includes some improvements over current law, it leaves many significant flaws with the FDA's current medical device oversight system unaddressed, according to Consumers Union, the policy and advocacy arm of Consumer Reports.

"The FDA's current fast track review process has allowed too many dangerous and defective devices onto the market," said Lisa McGiffert, director of Consumers Union's Safe Patient Project. "To make matters worse, the FDA doesn't have the tools it needs to react quickly when safety problems with medical devices arise. Unfortunately, this bill doesn't fix some of the most serious flaws in our current system and leaves patients at risk."

Consumers Union has urged the Committee to strengthen the bill by prohibiting the clearance of new medical devices based on recalled ones; improving the system for monitoring devices once they are cleared for sale; providing the FDA with greater authority to require post-market safety studies; and retaining current strong conflict of interest standards.

Consumers Union is supporting an amendment to the bill by Senator Jeff Merkley that allows the FDA to reject a manufacturer's proposal to clear a new medical device based on its substantial equivalence to one that has been recalled for safety problems. The FDA can do the same if the agency is in the process of removing a device from the market. The amendment also gives the FDA the authority to ask manufacturers of new devices to demonstrate that they have corrected safety flaws when they are using recalled devices as predicates. The FDA currently does not have this authority.

Consumers Union is urging Committee members to reject four different amendments proposed by Senator Rand Paul that would undermine current FDA standards on prescription drug and medical device recalls, and an amendment by Senator Orrin Hatch that would prevent the FDA from up-classifying medical devices to require stricter safety testing.

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