CONSUMERS UNION NEWS RELEASE

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Senate HELP Committee OKs Food and Drug Administration Safety And Innovation Act

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 approved the Food and Drug Administration Safety and Innovation Act today. While the legislation includes some improvements over current law, it leaves many significant flaws with the FDA's current medical device oversight system unaddressed (http://safepatientproject.org/press_release/consumers-union-medical-device-bills-missing-critical-protections-for-patients), 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 had 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.

For more details, see Consumers Union's news release outlining these concerns (http://safepatientproject.org/press_release/consumers-union-medical-device-bills-missing-critical-protections-for-patients).

PLEASE NOTE: Consumers Union can connect reporters with patients who have been harmed by defective medical devices. For more information, please contact Michael McCauley at mmccauley@consumer.org, or 415-902-9537.

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