

CONSUMERS UNION NEWS RELEASE

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Senate Passes FDA Safety And Innovation Act

Bill Makes Some Improvements to Medical Device Oversight But Important Patient Safety Protections Still Missing

WASHINGTON, D.C. – The Senate approved the Food and Drug Administration Safety and Innovation Act today. While the legislation includes some improvements over current law, it leaves significant flaws with the FDA's current medical device oversight system in place, according to Consumers Union, the policy and advocacy arm of Consumer Reports.

"Tens of thousands of patients have been seriously harmed by dangerous and defective medical devices in recent years because our current system fails to ensure they are safe and effective," said Lisa McGiffert, director of Consumers Union's Safe Patient Project. "The Senate bill makes some improvements in the law but fails to address some longstanding flaws in our medical device oversight system that endanger patient safety. Congress is missing the opportunity to fix a broken system that lets too many unsafe medical devices on the market and limits the FDA's ability to protect patients when problems arise."

Among the key patient safety provisions missing from the Senate bill:

Prohibition on clearing new devices based on recalled devices: The Senate bill does not include a provision preventing medical devices with known safety problems from being used as the basis for clearing new devices. Under the FDA's 510(k) process, the agency has to approve a new device if it is substantially equivalent to one already being sold, even when the new device is based on one that has been recalled by manufacturers due to safety problems or has a recalled device in its lineage. Currently, the FDA does not even have the authority to require manufacturers seeking clearance for new devices to demonstrate that they have addressed the flaws of the recalled device.

Consumers Union has urged Congress to prohibit recalled devices from being used as predicates for new devices. An April Consumer Reports poll found that 71 percent of Americans believe that a new medical device should not be allowed to be sold based on its similarity to an existing implant that has a safety problem or has been recalled.

A national registry for tracking medical implant problems and notifying patients: The FDA does not have all of the tools and resources it needs to adequately track and evaluate how patients with implants and other high-risk devices are faring. While the Senate bill includes some improvements in this area, it does not address the need for creating a national registry of patients with devices, which would help the FDA more quickly identify problem devices and notify patients when their device has safety problems or has been recalled.

Stronger authority for the FDA to require post market studies: The Senate bill does not give the FDA the authority to rescind clearance of a device when a manufacturer fails to comply with an order to conduct a 522 post-market safety study (that is ordered because of harm to patients) or when a post-market study reveals safety and effectiveness problems.

Retaining Existing Conflict of Interest Standards: The Senate bill weakens current standards for preventing conflicts of interest on FDA panels that review medical devices and prescription drugs. The bill eliminates existing limits on the number of waivers the FDA may grant to experts with financial ties to the medical device industry. These limits were championed by consumer advocates and adopted by Congress just five years ago. The Consumer Reports poll found that 66 percent of Americans had a high level of concern

about the safety decisions or recommendations made by expert committees that included doctors who had current financial relationships with medical device makers.

The improvements in the Senate bill include:

- A provision that would allow the FDA to more easily up-classify problematic devices so that subsequent, similar devices will receive more scrutiny before they get to patients.
- A timeframe for finalizing proposed regulations on unique device identifiers and for implementing these rules. Once these rules are in place, FDA will be better able to track problematic devices and make sure patients are warned about safety problems.
- Adds medical devices to the Sentinel Initiative, created five years ago as a mechanism to enhance post market oversight of drugs. This will assist in post market oversight.
- Codifies the requirement that approval for high-risk devices is contingent on completing required post market studies. This should make it easier to impose civil monetary penalties on bad actors, leveling the playing field for companies that comply.
- Creates a timeline on 522 post-market studies for devices that had been cleared in the fast track process, aiding the FDA in reacting more quickly when device safety issues have been identified. However, the bill allows manufacturers to delay beginning these studies for fifteen months after the FDA orders them. While these studies are being conducted, doctors can still implant these questionable devices in patients.
- Requires the FDA to do more outreach to involve more non-conflicted experts and groups – including scientific societies the Institute of Medicine, and the American Academy of Medical Colleges – in its recruitment efforts for medical device advisory committees.

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.