Medical Device Bills Missing Critical Protections For Patients

The Associated Press

Key House and Senate Committees will vote next week on legislation to reauthorize the statute governing medical devices at a time when the law has come under increasing criticism for failing to ensure devices are safe and effective. While the Senate legislation is stronger than the House version, neither bill includes critical reforms needed to protect patients from dangerous or defective devices, according to Consumers Union, the policy and advocacy arm of Consumer Reports.

"Our system for overseeing medical implants and other high risk devices is clearly broken and allows too many dangerous devices on the market," said Lisa McGiffert, director of Consumers Union's Safe Patient Project. "Tens of thousands of patients have been injured or died in recent years because current law fails to ensure medical devices are safe. Unfortunately, these bills don't fix the most serious flaws in our current system and leave patients at risk." The Senate Health, Education, Labor and Pensions Committee will hold a mark-up of its bill to reauthorize the Medical Device User Fee Act on Wednesday, April 25. The House Energy and Commerce Committee's Health Subcommittee will mark up its bill on Thursday, April 26.

Despite the fact that 78 percent of high-risk medical devices are reviewed through the FDA's fast track 510(k) process, industry lobbyists have urged Congress to ease federal oversight in order to promote innovation and speed up new device approvals. But according to a March 2012Consumer Reports poll, 82 percent of Americans believe that preventing safety problems is more important than limiting safety testing in order to prevent delays and encourage innovation.

"We all want patients to get timely access to effective new medical technologies," said Lisa Swirsky, senior policy analyst for Consumers Union. "But Congress needs to make sure that patient safety isn't sacrificed in the drive to speed up medical device approvals." The House bill is particularly weak, according to Consumers Union.

Among other things, it diverts the FDA's mission of protecting public health to include job creation and innovation and constrains the FDA's ability to get needed clinical data from manufacturers. The Senate bill includes some important reforms, including streamlining the process for "up-classifying" devices so they can be subject to more rigorous review. But a number of critical protections are missing from both the House and Senate bills, including: Prohibition on clearing new devices based on recalled devices: The FDA clears more than 90 percent of all medical devices without requiring any clinical testing. These devices are cleared based on whether they are "substantially equivalent" to existing devices already on the market. Under the 510(k) process, the FDA has to approve a new device if the

manufacturer proves it is similar to a previously cleared one, even when the existing device has been recalled because of safety problems.

The Senate and House bills do not include a provision preventing medical devices with known safety problems from being used as the basis for clearing new devices. 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. The 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 system to monitor devices after they are cleared for sale: The FDA does not have the tools and resources to adequately track and evaluate how patients with implants and other high-risk devices are faring.

The Senate bill provides some improvement in this area while the House bill does not. Five years ago, Congress required the FDA to create a Unique Device Identifier (UDI) system to monitor what happens to implants once they are on the market, but it is still not in place.

UDIs are essential for including devices in the Sentinel Initiative, a surveillance system currently being implemented that monitors how prescription drugs perform once on the market. The Senate bill officially includes medical devices in the Sentinel Initiative and reaffirms the importance of implementing the existing UDI requirement by establishing a December 31, 2012 deadline for promulgating the UDI regulations.

UDIs coupled with a national registry of patients with devices would help the FDA more quickly identify problem devices and notify patients when their device has safety problems or has been recalled. The Senate and House bills do not address the need for a national registry. The Consumer Reports poll found that 95 percent of Americans believe that effective consumer protections for medical implants should include a nationwide system for tracking medical implants so patients can be notified about safety problems or recalls.

Stronger authority for the FDA to require post market studies: The FDA currently does not have the authority to require post market studies of new devices as a condition for clearing them through the 510(k) process. Further, if the agency issues an order for a "522 study," which can now be required when safety concerns arise after a device is cleared for the market, it doesn't have the authority to rescind the clearance of the device if the device maker fails to comply with the order or if the study shows that the device is unsafe or ineffective. Neither the House nor the Senate bill provides the FDA with these needed powers.

The Senate bill improves current law by establishing a timeline for 522 studies.

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.

Retaining Existing Conflict of Interest Standards: Both the House and Senate bills weaken current standards that aim to prevent conflicts of interest on FDA panels that review medical devices and prescription drugs. The bills eliminate 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 House bill also eliminates certain disclosure requirements for FDA advisory panelists.

The FDA has provided no substantial evidence to demonstrate a problem with finding experts without conflicts. 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.

SOURCE Consumers Union -0- 04/19/2012 CO: Consumers Union ST: District of Columbia IN: HEA MEQ MTC SU: LEG AVO PRN -- DC90916 -- 0000 04/19/2012 15:43:25 EDT http://www.prnewswire.c

Source URL (retrieved on *11/21/2014 - 8:55pm*):
http://www.mdtmag.com/news/2012/04/medical-device-bills-missing-critical-protections-patients