House Voting Today on FDA Reform Act

The Associated Press

The House is scheduled to vote on the Food and Drug Administration Reform Act today. The House bill is weaker than similar legislation passed by the Senate last week. Neither bill includes important provisions needed to protect patients from unsafe medical devices, according to Consumers Union, the policy and advocacy arm of Consumer Reports.

"The FDA is hamstrung by a weak medical device law that leaves patients at risk of serious injury and even death," said Lisa Swirsky, senior policy analyst for Consumers Union. "While both bills include some provisions that will improve the FDA's ability to track devices once they are on the market, only the Senate offers a provision that may improve safety before devices reach consumers. Both bills lack key consumer protections needed to help ensure devices are safe and effective before, not after, patients use them." The House bill does not include a number of important provisions that were included in the Senate legislation last week: -- A provision that would allow the FDA to more easily re-classify problematic devices so that subsequent, similar devices will receive more scrutiny before they get to patients.

-- A timeframe for implementing proposed regulations on unique device identifiers. Once these rules are in place, the FDA will be better able to track problematic devices and make sure patients are warned about safety problems.

-- A provision that 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.

-- A timeline on 522 post-market studies for devices that had been cleared in the fast track 510k process, aiding the FDA in reacting more quickly when device safety issues have been identified.

Neither the House nor the Senate bill include a number of critical patient safety protections, including: -- Providing the FDA with the authority to reject new devices based on their similarities to devices recalled by manufacturers for safety reasons -- A national registry for tracking medical implant problems and notifying patients when problems arise. Similar registries are used in Australia and the UK that have allowed them to track and evaluate how patients with implants and other high-risk devices are faring.

-- Stronger authority for the FDA to require post market studies; and -- Keeping existing conflict of interest limitations for people serving on FDA advisory panels that approve drugs and devices.

For more details on these important patient safety provisions, see Consumers Union's news release on last week's Senate vote on the FDA Safety and Innovation Act.

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