

Senate to Vote on Final FDA User Fee Bill As Early As Today

The Associated Press

The Senate is expected to vote as early as today on a final version of the FDA Safety and Innovation Act, which was passed by the House last week.

While the bill provides critical user fees to fund FDA oversight and makes some medical device safety improvements, it falls short of what is needed to protect patients, according to Consumers Union, the policy and advocacy division of Consumer Reports.

"Americans are counting on the FDA to make sure that medical devices have been thoroughly reviewed so they don't harm the patients they are designed to help," said Lisa McGiffert, director of Consumers Union's Safe Patient Project (www.SafePatientProject.org). "Unfortunately, too many dangerous medical devices have been allowed on the market because our current weak oversight system fails to protect patients.

This bill gives the FDA some new tools so it can better monitor medical devices once they are on the market, which could make it easier to notify patients when things go wrong and require more timely testing when safety problems are uncovered.

But it does not give the FDA the stronger authority it needs to more thoroughly assess the safety of devices before they are allowed on the market." While the bill does allow for easier reclassification of devices, which may allow the FDA to prevent some problematic devices from hitting the market, on balance it does more on the back end than the front end when it comes to improving oversight. It doesn't provide the FDA with the authority it needs to thoroughly assess the safety of devices before they are allowed on the market.

Consumers Union had urged lawmakers to adopt a number of critical patient safety protections, such as requiring stricter safety testing for all high risk and implantable devices and prohibiting devices recalled from manufacturers for safety reasons from being used as the basis for clearing new devices. In the end, the politically powerful medical device industry succeeded in blocking these common sense reforms.

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