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Drug and Device Companies May Soon Face Less Burdensome FDA Approval Process

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On July 10, 2015, Congress passed H.R. 6, the 21st Century Cures Act, with a bipartisan vote of 344 to 77. The 352-page bill seeks to make the U.S. Food and Drug Administration (FDA) drug and device approval process less onerous to expedite patient access to new treatments and cures. The final bill aims to accomplish this goal through several provisions. During the review of a new drug, the bill requires the FDA to consider patient experience data in the drug's benefits and risks assessment.[1] The bill creates a structured framework to qualify drug development tools, such as biomarkers.[2] The bill also streamlines the institutional review board process for trials that are being conducted at multiple locations in order to eliminate duplication in the review process.[3]

The bill simplifies the review process for new purposes of previously approved drugs. The FDA must establish a program to evaluate the use of clinical data from previously approved drugs to support the potential approval of that same drug for a new purpose.[4] The bill also requires the FDA to establish a streamlined data review program which would authorize the holder of an approved application to submit a summary of clinical data intended to support the approval or licensure of the drug for a new purpose.[5]

The bill seeks to ease the development of new antibiotics by allowing approval of antibiotics for a limited population of patients based on evidence that is currently considered to be preliminary data. This data includes animal and test tube studies and trials on a small number of people.[6]

Medical device companies could also benefit from this bill. The bill clarifies that for FDA approval of medical devices, evidence such as registry data, studies published in peer-review journals, and data collected in countries other than the United States can be considered under certain circumstances.[7] The FDA must establish a program to provide priority review for breakthrough devices.[8] The bill also allows FDA-authorized third parties to certify the safety and effectiveness of device-related changes in lieu of other FDA submission requirements.[9]

Opponents of the bill warn that these changes make America's already relaxed drug and device approval process even less rigorous at the expense of consumer protection. However, supporters point out that the bill was drafted with the close consultation of the FDA, and revisions were made to earlier drafts to accommodate the FDA's concerns regarding safety standards. The bill must now be approved by the Senate, where supporters hope it will go up for a vote this fall.

1 H.R. 6, 114th Cong. § 2001 (as passed by Congress, July 10, 2015).
2 *Id.* at § 2021. In the context of this section, terms the "qualify" and "qualification" mean a determination by the Secretary of Health and Human Services that a drug development tool and its proposed context of use can be relied upon to have a specific interpretation and application in drug development and regulatory review under the 21st Century Cures Act. Besides biomarkers, drug development tools also include clinic outcome assessments and any other method, material or measure that the Secretary determines aids for purpose of this section. *Id.*
3 *Id.* at § 2261.
4 *Id.* at § 2062.
5 *Id.* at § 2063.
6 *Id.* at § 2121.
7 *Id.* at § 2222.
8 *Id.* at § 2201.
9 *Id.* at § 2221.

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