Research

# The Importance of PDUFA Reauthorization

**MAY 21, 2012**

The conditions within PDUFA V have been agreed upon by the FDA, industry, and stakeholders. Due to the expiration of both the Medical Device User Fee Act and the Prescription Drug User Fee act, several additional provisions have been attached to the reauthorization bill to ensure that they are passed. The bundle of reauthorizations is referred to as the "Food and drug Administration Safety and Innovation Act" in the Senate and includes several improvements to the FDA.

Not only have the industries, FDA, and stakeholders agreed upon the conditions within the bill, the add-ons have garnered bipartisan support. As such, the set of FDA reform measures has passed committee votes in both the Senate and the House nearly unanimously. The wisest step for the rest of Congress would be to pass PDUFA V and its accompanying safety and review enhancements quickly so that the FDA can begin preparing for its new set of duties to patients and medical innovators.

Read the full paper by clicking below.