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Medical Cures Bill Moving Through Congress

Author: Allison Gilchrist, Associate Editor, July 10, 2015

The US House of Representatives today passed the 21st Century Cures Act by a wide 344-77 margin.

This legislation would allocate more funding to both the FDA and the National Institutes of Health and enact dozens of reforms to speed the development and approval process for new drugs.

Currently, it could take up to 15 years for a new treatment to progress from the development stage to a fully approved, ready-to-dispense drug.

The 21st Century Cures Act also includes provisions to incentivize pharmaceutical companies to develop treatments for rare diseases. For instance, it would extend exclusivity periods and patent protections for currently marketed drugs that treat rare conditions.

Throughout the bill's journey, from its introduction in the Health Subcommittee of the House Energy and Commerce Committee to its approval in the House, different stakeholders in the pharmaceutical industry have voiced praise and grievances about different provisions.

The National Association of Chain Drug Stores (NACDS) celebrated the legislation's passage through the House, noting that the bill would "accelerate the pace of cures and medical breakthroughs in the United States and position pharmacy to play an important role in the delivery of new drug treatments to patients."

"Pharmacies and pharmacists everywhere in every community stand ready to help foster access to promising cures and treatments that can save and improve patients' lives," stated NACDS President and CEO Steve C. Anderson, IOM, CAE.

In an earlier press release, Academy of Managed Care Pharmacy (AMCP) CEO Edith A. Rosato, RPh, IOM, applauded the House Energy and Commerce Committee's unanimous passage of the legislation. However, she stated that the AMCP is "concerned that several onerous requirements in the

bill's proposal to combat prescription drug abuse for at-risk Medicare beneficiaries may discourage Medicare Part D plans from pursuing these programs."

For instance, the legislation requires Medicare Part D plans to provide two notices to beneficiaries and two levels of appeal to follow each notice. "AMCP believes that the notice and appeal time periods [included] will hamper the ability of the health plan to provide critical assistance to an [at-risk] beneficiary," Rosato said.

Generic Pharmaceutical Association (GPhA) president and CEO Ralph G. Neas described the 21st Century Cures Act as "a bipartisan achievement that should enhance the drug approval process and significantly boost critical research and development efforts."

Despite this endorsement, he also indicated that "GPhA will continue working toward the inclusion of policy that limits the misuse of Risk Evaluation and Mitigation Strategies, a mechanism designed for patient safety that some companies use to delay generic competition."

The bill will now move to the US Senate, though many expect the Senate to pass its own version of a medical cures bill.