



## 21st Century Cures is Moving Quickly Through the Legislative Process - Here's What You Should Know

**Today the 21st Century Cures Act was unanimously voted out of committee. Act creates a cohesive, efficient, effective & patient-centered path to cures.**

*The 21st Century Cures Act*, a substantial piece of legislation that touches on all aspects of medical innovation - from basic research to regulation, from biomarkers to patient data - was spearheaded by House Energy and Commerce Committee Chairman **Fred Upton (R-MI)** and Oversight and Investigations Subcommittee Ranking Member **Diana DeGette (D-CO)**.

Earlier today, the *Act* was unanimously approved by the Energy and Commerce Committee. Said Chairman Upton, "This historic day marks a big bipartisan step forward on our path to cures. . . The time for 21st Century Cures is now." Said Rep. Diana DeGette, "21st Century Cures will make a real difference in the lives of patients and their families."

There are many exciting opportunities this bill creates to improve the systems that serve patients. Below are a few of the bill's most promising measures.

### Investment in Critical Science & Research

- ***The National Institutes of Health (NIH)*** ([Section 1002](#))
  - The National Institutes of Health has lost almost 25% of its purchasing power over the last ten years, severely limiting basic research. This bill will increase NIH funding by \$10 billion over the next-five years, bolstering America's investment in medical innovation.
- ***The U.S. Food & Drug Administration (FDA)*** ([Amendment](#))
  - To ensure the execution of its many exciting new tools and programs to enhance patient input and the scientific capacity of the FDA, the bill increases FDA funding by \$550 million over 5 years.
- ***High Risk, High-Reward Research*** ([Section 1028](#))
  - When budgets are tight, researchers are sometimes limited to cautious projects. The bill will ensure that funding exists for high risk research with the potential to lead to medical breakthroughs.
- ***Supporting Young Scientists*** ([Title I Subtitle C](#))
  - NIH will improve its loan repayment programs and develop new programs to ensure that opportunities are being extended to a new generation of elite researchers.

## Building a Framework to Better Involve and Incorporate Patients Throughout the Drug Development Process

- **Putting Patients at the Center of Drug Development** ([Section 2001](#))
  - This provision creates a series of new steps that operationalize the incorporation of direct patient feedback and assist advocacy organizations, medical researchers, FDA, and industry to realign drug development programs with this important information.

## Strengthening the FDA: Streamlining Clinical Trials, Improving Efficiency, and Laying the Groundwork for the Future

- **Precision Medicine: Biomarker Qualification** ([2021, Title II Subtitle C](#))
  - *The 21st Century Cures Act* will create a process by which the FDA could work with researchers and drug developers to qualify new biomarkers, allowing future researchers to measure drug activity and safety more efficiently.
- **Accelerated Approval Development Plans** ([Section 2022](#))
  - Accelerated Approval Development Plans will be established to help FDA and drug sponsors to better plan and predict the use of Accelerated Approval.
- **Streamlined Data Review** ([Section 2063](#))
  - Supplemental new drug applications (sNDA) are submitted to FDA to expand the safe and effective use of a drug beyond its original setting. *The 21st Century Cures Act* will expedite this process for drugs that are already well understood, saving time and resources.
- **Approval of Drugs for Limited Patient Populations** ([Section 2121](#))
  - FDA will be empowered to offer experimental drugs approval for narrow patient populations, expanding options for patients without established alternatives.
- **Priority Review for Breakthrough Devices** ([Section 2201](#))
  - Medical devices that more effectively treat or diagnose serious or life-threatening diseases will benefit from a new, more efficient FDA review pathway.
- **Keeping and Recruiting the Best & Brightest to FDA** ([Section 2281](#))
  - As FDA's responsibilities have grown, it has often found it difficult to hire and retain qualified employees. This bill will better enable FDA to pursue and retain top talent.

A full copy of the most recent draft of *The 21st Century Cures Act* is available [here](#).