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.