The 21st Century Cures Act (H.R. 34 now P.L. 114-255) received broad, bipartisan support from the U.S. Congress and the White House. It passed the Congress on Dec. 7 and was signed into law by President Barack Obama on Dec. 13. P.L. 114-255 consists of three divisions:

- Division A: 21st Century Cures
- Division B: Helping families in mental health crisis
- Division C: Increasing choice, access, and quality in health care for Americans

Division A, “21st Century Cures,” contains the provisions relevant to biomedical innovation and seeks to make improvements throughout the entire R&D system.

**New Funding**

The act provides new funding over a 10-year period for initiatives that have the potential to significantly advance our understanding of disease and identify opportunities for new therapies.

- $500 million total for the Food and Drug Administration (FDA)
- $4.8 billion total for the National Institutes of Health (NIH):
  - $1.8 billion for the Beau Biden Cancer Moonshot
  - $1.5 billion for the Precision Medicine Initiative®
  - $1.5 billion for the Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative
- The act includes changes to other programs that would fully pay for this funding so that appropriators will not have to find new offsets each year.

**Policy Reforms**

The 21st Century Cures Act addresses the entire biomedical innovation system across discovery, development and delivery of new medical products. Here are examples of policy reforms in this act, which are also aligned with FasterCures’ recommendations developed during our Rx for Innovation project:

- Strengthens patient centricity in biomedical product development and regulatory approval (sections 3001-3004).
- Bans information blocking between health data systems and provides the Department of Health and Human Services the authority to levy civil penalties against offenders (sections 4001-4006).
- Reforms FDA hiring authorities to fill vacancies by enabling it to compete more effectively with industry to hire and retain the best and brightest experts to review medical product applications (sections 3071-3074).
- Enhances NIH’s ability to support innovative research by, for example:
  - Establishing a new research prize authority (section 2002).
  - Providing flexible contracting tools to support high-risk, high-reward research (section 2036).
  - Expanding the translational work done by the NIH’s National Center for Advancing Translational Sciences (section 2037).
- Catalyzes innovation in clinical trials and regulatory approval, without diminishing FDA’s authority to determine what constitutes a safe and effective medical product by, for example:
  - Promoting FDA qualification of biomarkers and other drug development tools (section 3011).
  - Having FDA study how best to use innovative clinical trial designs and real-world evidence generation during product development and regulatory approval (sections 3021, 3022).

FasterCures will monitor the progress of these provisions and looks forward to working with the Congress and the administration to help implement the 21st Century Cures Act.