RDLA Policy Primer:
21st Century Cures Act & Cures 2.0

The 21st Century Cures Act (Cures Act) was signed into law (P.L. 114-255) on December 13, 2016. The law authorized $6.3 billion in funding, primarily to the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). The Cures Act was designed to encourage development of medical products and devices, and to streamline the process of getting them into the market.

"The signing of the 21st Century Cures Act into law, codified Patient Focused Drug Development as a part of FDA's mission." ~ Janet Woodcock, December 13, 2016

The Cures Act consists of five main sections:

1. Division A: Research and drug development
2. Division B: Behavioral health
3. Division C: Healthcare access and quality improvement
4. Qualified Small Employer Health Reimbursement Arrangement (QSEHR)
5. Electronic health records information blocking

Under Division A, the Cures Act supports several areas that are particularly relevant for the rare disease community. These include streamlining the FDA drug approval process, support for targeted drugs for rare disease, and additional funding for medical research advances in the rare disease space at the NIH.

Of particular note was section 3001 which focused on the inclusion of patient experience data within product development and review and established a Patient Experience Data checklist as a formalized part of the regulatory review. 21st Century Cures also required that FDA develop Guidance on patient engagement and data collection throughout the product development lifecycle. While the Act was ultimately passed with bipartisan support, stakeholders such as consumer protections groups opposed the Act, claiming that the provisions were in the interest of the pharmaceutical industry and would bypass the gold standard of randomized controlled trials.

Cures 2.0: On April 27, 2020 representatives Diana DeGette (D-CO) and Fred Upton (R-MI) released a concept paper describing a "Cures 2.0" legislation. The draft builds on the framework of the Cures Act and aims to further modernize the nation's healthcare pipeline in the hopes of avoiding some of the burdens that the system has faced during the COVID-19 pandemic. Some of the proposed areas for policy include public health and pandemic preparedness, healthcare delivery systems, patient engagement in healthcare decision-making, caregiver integration into the care team, modernizing CMS, and increasing diversity in clinical trials.

Resources:

- National Institutes of Health: The 21st Century Cures Act
- Congress.gov: H.R. 34 – 21st Century Cures Act
- 21st Century Cures 2.0 Concept Paper
- EveryLife Comment on Cures 2.0
- RDLA Monthly Webinar (May 2020) with presentation on 21st Century Cures