### By the Numbers: Policy Changes from the 21st Century Cures Act

Section Editor: The ISPOR Student Network

# TIMELINE FOR THE 21ST CENTURY CURES ACT<sup>3</sup>

2013

House Energy and Commerce Committee hearings started

1/6/2015

Introduced in the House

1/7/2015

Passed the House

10/6/2015

Passed the Senate with an amendment

11/30/2016

The House agreed to Senate amendment with further amendment

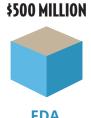
12/7/2016

The Senate agreed to House amendment

12/13/2016

Signed into law by President Barack Obama

# FUNDING CATEGORIES UNDER THE 21ST CENTURY CURES ACT<sup>1,2</sup>



FDA OPIOID ABUSE PREVENTION AND TREATMENT

# Cancer Moonshot \$1.8 Billion BRAIN (Brain Chemistry) \$1.5 Billion All of Us (Precision Medicine) \$1.5 Billion Regenerative Medicine \$30 Million ENIH RESEARCH

\$4.8 BILLION

### FDA GUIDANCE MILESTONES<sup>5</sup>

### DRAFT GUIDANCE ISSUED

- 12 Jun 2018: Patient-Focused Drug Development: Collecting Comprehensive and Representative Input - Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders
- 13 Jun 2018: Limited Population Pathway for Antibacterial and Antifungal Drugs - Guidance for Industry
- 13 Jun 2018: Humanitarian Device Exemption (HDE) Program Draft Guidance for Industry and Food and Drug Administration Staff

### **GUIDANCE TO BE RELEASED**

- 13 Dec 2019: Protection of human research subjects
- 13 Dec 2019: Qualification of drug development tools
- Date to be announced: Novel clinical trial designs
- Date to be announced: Real world evidence

## SOME NUMBERS ON THE 21ST CENTURY CARES ACT4

**PROGRAMS** 



\$1 BILLION

VOTES IN THE HOUSE: 392 IN FAVOR – 26 AGAINST



VOTES IN THE SENATE: 94 IN FAVOR – 5 AGAINST (1 NOT VOTING)



SECOND-MOST LOBBIED HEALTHCARE BILL IN THE HISTORY



MORE THAN 1,400 REGISTERED LOBBYISTS WORKED ON THIS BILL



REGISTERED LOBBYISTS REPRESENTED MORE THAN 400 DIFFERENT ORGANIZATIONS



APPROXIMATELY HALF A BILLION DOLLARS WAS SPENT ON LOBBYING

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- Barlas S. 21st Century Cures Bill May Lead To Faster Drug/Device Approvals: But Moving Away from Clinical Trials Worries Some. Pharmacy and Therapeutics. 2017;42(2):76-77.
- <sup>2</sup> 21st Century Cures Act: Actions Overview, Available from: https://www.congress.gov/bill/114th-congress/house-bill/34/actions
- 3 National Institutes of Health, Implementation of Funding Plan for the NIH Innovation Projects Under the 21st Century Cures Act, Available from: https://www.nih.gov/research-training/medical-research-initiatives/cures
- 4 Sydney Lupkin, A Frenzy Of Lobbying On 21st Century Cures, Kaiser Health News; 2016. Available from: https://khn.org/news/a-frenzy-of-lobbying-on-21st-century-cures/
- <sup>5</sup> FDA.gov, US Food and Drug Administration 21st Century Cures Act Deliverables, Available from: https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/ 21stCenturyCuresAct/ucm562475.htm