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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
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MEMORANDUM

November 28, 2017

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Implementing the 21st Century Cures Act: An Update from FDA and NIH"

On **Thursday, November 30, 2017, at 10:00 a.m., in room 2123 of the Rayburn House Office Building**, the Subcommittee will hold a hearing titled "Implementing the 21st Century Cures Act: An Update from FDA and NIH."

I. THE 21st CENTURY CURES ACT

The bipartisan 21st Century Cures Act (CURES Act) was signed into law on December 13, 2016.[1] The law consists of three divisions: Division A – 21st Century Cures Act; Division B – Helping Families in Mental Health Crisis; and Division C – Increasing Choice, Access, and Quality in Health Care for Americans. The purpose of the hearing is to discuss the status of Division A provisions being implemented by the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). These provisions aim to advance the discovery and development of new treatments and cures through increased research and an improved drug approval process. Please refer to the bipartisan summary of the 21st Century Cures Act for more information on each section of the law.[2]

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[1] Pub. L. No. 114-255.

[2] Summary of the 21st Century Cures Act prepared by bipartisan Committee staff (https://rules.house.gov/sites/republicans.rules.house.gov/files/114/PDF/114-SAHR34-Sxs.pdf); *See also* Congressional Research Service, *The 21st Century Cures Act, Division A of P.L. 114-255* (Dec. 23, 2016) (http://www.crs.gov/Reports/R44720?source=search&guid=7b425d8813284929a0dd74dbc7947b80&index=0).

A. NIH Provisions

The CURES Act provided NIH with $4.8 billion in new funding to advance several cutting edge research initiatives including: $1.8 billion in funding to support the Beau Biden Cancer Moonshot Initiative which aims to accelerate cancer research and improve our ability to prevent and detect early-stage cancers; $1.5 billion in funding for the Obama Administration's Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative to help discover new ways to treat, cure, and prevent brain disorders such as Alzheimer's, epilepsy and traumatic brain injury; $1.45 billion in funding for former President Obama's Precision Medicine Initiative, which seeks to help researchers develop medicines tailored to individuals, rather than one-size-fits-all treatments; and $30 million in funding for the Regenerative Medicine Innovation Project to support clinical research to advance the field of regenerative medicine.

B. FDA Provisions

The CURES Act provided FDA with $500 million in new funding over ten years to foster innovation and to help implement certain provisions in Title III of the bill. These provisions aim to improve FDA's medical product review process and expedite patient access to drugs and medical devices while maintaining the same standards for safety and effectiveness. The law also grants FDA added authority to develop and utilize new tools to facilitate drug development, provide for flexibility in the clinical trial process, encourage the development of regenerative medicine and combination products, and improve FDA's ability to recruit and retain scientific and technical personnel. FDA's proposed work plan for 21st Century Cures outlines the agency's implementation activities.[3]

II. WITNESSES

Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration

Francis S. Collins, M.D., Ph.D.
Director
National Institutes of Health

[3] FDA, *Proposed FDA Work Plan for 21st Century Cures Act Innovation Account Activities* (https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/UCM556618.pdf).