



THE 21ST CENTURY CURES ACT

An innovation game-changer, a once-in-a-generation, transformational opportunity to change the way we treat disease.

The House Energy and Commerce Committee and the Senate HELP Committee have engaged in a public, nonpartisan conversation with patients, researchers, innovators, and health care providers about what steps can be taken to expedite the **discovery, development, and delivery** of new treatments and cures and maintain America's global status as the leader in biomedical innovation. The 21st Century Cures Act ("Cures") is the product of that conversation.

DISCOVERY

- Provide the NIH with \$4.8 billion in new funding that is fully offset. These dollars will help advance the Precision Medicine Initiative to drive research into the genetic, lifestyle and environmental variations of disease (\$1.5 billion); bolster Vice President Biden's "Cancer Moonshot" to speed research (\$1.8 billion); and invest in the BRAIN initiative to improve our understanding of diseases like Alzheimer's.

DEVELOPMENT

The pace of scientific advancement over the past two decades, including the mapping of the human genome, has been impressive. Translating these discoveries into new FDA-approved treatments, however, has proven difficult. Cures will advance new therapies for patients by:

- Modernizing clinical trials and the means by which safety and efficacy data is accumulated and analyzed.
- Putting patients at the heart of the regulatory review process.
- Supporting broader, more collaborative development, qualification, and utilization of biomarkers, which help assess how a therapy is working, and on whom, earlier in the process.
- Streamlining regulations and provides more clarity and consistency for innovators developing health software and mobile medical apps, combination products, vaccines, and regenerative medicine therapies.
- Incentivizing the development of drugs for pediatric diseases and medical countermeasures, and empower FDA to utilize flexible approaches in reviewing medical devices that represent breakthrough technologies.
- Providing FDA with \$500 million for regulatory modernization and give the agency the ability to recruit and retain the best and brightest scientists, doctors, and engineers.

DELIVERY

- The development of new drugs and devices is meaningless unless they are delivered to the right patients at the right time. Cures will help improve delivery by: ensuring electronic health record systems are interoperable for seamless patient care and help fully realize the benefits of a learning health care system.
- Improving education for health care providers and help facilitate seniors' access to the latest medical technology.

HELPING FAMILIES IN MENTAL HEALTH CRISIS REFORM

Our work to advance meaningful mental health reforms has been a multi-year, multi-Congress effort. The mental health reforms included in the revised 21st Century Cures Act are based largely on H.R. 2646, the Helping Families in Mental Health Crisis Act, authored by Rep. Tim Murphy (R-PA), which passed the House in July by a vote of 422-2. This legislative effort represents the most significant reforms to the mental health system in more than a decade.

These landmark reforms will:

- Create a new Assistant Secretary for Mental Health and Substance Use to replace the Administrator at SAMHSA and coordinate mental health programs across the federal government.
- Establish the National Mental Health and Substance Use Policy Lab to drive evidence-based grant making within SAMHSA.
- Direct the Secretary of HHS to undertake guidance to clarify when communication can take place under HIPAA to help ensure communication among providers, families, and patients to improve mental health treatment.
- Improve mental health care for children with serious emotional disturbance, or adults with serious mental illness, through targeted authorizations and reauthorizations, including expansion of Assisted Outpatient Treatment.
- Strengthen the nation's mental health workforce.
- Reduce government spending by \$5 million according to a preliminary analysis from the Congressional Budget Office.