NEW AND **NOTEWORTHY**

THE 21ST CENTURY CURES ACT

On December 13, 2016, President Obama signed the 21st Century Cures Act into law.

The Cures Act, which sailed through both the House of Representatives (392-26) and the Senate (94-5), is a massive piece of bipartisan legislation focused on advancing and accelerating medical research. Additionally, the Cures Act contains provisions devoted to fighting America's opioid abuse epidemic and improving mental health care.

Described by the House Committee on Energy and Commerce as "[a]n innovation game-changer, a once-in-a-generation, transformational opportunity to change the way we treat disease,"[1] the Cures Act is the result of "conversations with patients, researchers, innovators, and health care professionals about what steps can be taken to expedite the discovery, development and delivery of new treatment and cures and maintain America's global status as the leader in biomedical innovation."[2]

Given its sweeping scope, the White House believes that the Cures Act "will go a long way toward bringing about the medical breakthroughs we need to meet some of the biggest health challenges facing Americans today."[3] Based on the overwhelming support of Congress, the pharmaceutical and medical device industries, PhARMA, patient advocacy groups such as FasterCures, and numerous medical societies and foundations[4], it is clear that many share this view.

However, critics of the Cures Act, including Senators Bernie Sanders and Elizabeth Warren as well as consumer watchdog groups like Public Citizen's Health Research Group and the National Center for Health Research, fear that the advancements envisioned by the Act undermine the Food and Drug Administration's ability to protect patients and will ultimately endanger public health and safety.[5]

While by no means an exhaustive list, key provisions of the 21st Century Cures Act include:[6]

- Allocation of $4.8 billion over 10 years to the National Institute of Health for innovative research programs including the following:
  - Cancer Moonshot Initiative (acceleration of cancer research and availability of treatment options)
  - Precision Medicine Initiative (research of disease prevention, diagnosis, and treatment methods tailored to people's unique characteristics)
  - Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative (research of brain disorders, such as Alzheimer's and Parkinson's diseases, depression, and traumatic brain injury)
  - Regenerative medicine using adult stem cells (includes cell therapy, gene therapy, therapeutic tissue engineering products, human cell and tissue products)
- Allocation of $1 billion over 2 years for grants to states for opioid abuse prevention and treatment.
- Implementation of provisions to move drugs and devices to patients more quickly
  - Establishes a review pathway at the FDA for biomarkers and other drug development tools used to help shorten drug development time and reduce the failure rate in drug development
  - Requires the FDA to evaluate the usefulness of data collected outside of randomized clinical trials (i.e. information that is currently considered off-label) and establishes a regulatory framework that would be used to determine the usefulness of real-world data
  - Allows drug manufacturers to share off-label uses with insurance companies
  - Allows sponsors of genetically targeted or variant protein targeted drugs to rely on data for the same or similar technology from its previously approved applications
  - Requires HHS to harmonize differences between the Common Rule and the Food, Drug and Cosmetics Act with respect to protection of human subjects
  - Allows the FDA to rely on qualified data summaries to support approval of application for new indication of an approved drug
  - Requires pharmaceutical companies to establish publically accessible compassionate use policies for drugs treating serious or life threatening conditions
  - Allows the FDA to grant accelerated approval for regenerative therapeutic products
  - Establishes that devices used with a regenerative therapeutic product be considered a moderate risk unless the Secretary determines otherwise
  - Improves regulation of combination products (e.g. a product that contains a drug and a device)
  - Gives the FDA the flexibility to approve antimicrobial drugs based on a limited population if the drug treats a life-threatening condition
  - Establishes a breakthrough device approval pathway which builds on the existing priority device pathway
  - Increases the humanitarian device exemption to devices that treat diseases and conditions affecting up to 8000 individuals
  - Strikes the requirement that a sponsor of a medical device trial always use a local institutional review board
  - Requires FDA to clarify regulatory guidance to clarify the criteria for waiving CLIA requirements
  - Clarifies that FDA reviewers shall consider the least burdensome means necessary for demonstrating a reasonable assurance of safety and effectiveness when requesting additional information from manufacturers during pre-market approval
  - Encourages innovation in Medical Countermeasures and Vaccines
- Implementation of provision designed to improve quality of patient care
  - Reduces documentation burdens on providers while maintaining quality
  - Supports a model framework for electronic health records to foster exchange of health information between networks
  - Establishes authority for the OIG to investigate claims of and assign penalties for health information blocking
- Expansion of OIG's authority to use civil monetary penalties in cases of proven HHS grant or contract fraud
- Increased oversight by states for termination of Medicaid/CHIP providers
- Extension/Implementation of provisions relating to Medicare including provisions related to Rural Community Hospitals, Long-Term Care Hospitals, Hospital Outpatient Departments, and Ambulatory Surgery Centers
- Implementation of reforms for mental healthcare including:
  - Mental health parity enforcement
  - Early intervention programs
  - Suicide prevention programs

Be on the lookout in future editions of Pro Te Solutio for more in-depth analysis of the Cures Act and its potential impact on the healthcare industry. ■

1 https://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/114/analysis/20161128%20Cures%20Fact%20Sheet.pdf

2 *Id.*

3 https://wwzw.whitehouse.gov/blog/2016/12/12/3-letters-explain-why-president-obama-signing-cures-act

4 https://energycommerce.house.gov/news-center/letters/letters-support-hr-6-21st-century-cures-act

5 https://www.washingtonpost.com/news/powerpost/wp/2016/12/07/congress-passes-21st-century-cures-act-boosting-research-and-easing-drug-approvals/?utm_term=.503cb4e712cc

6 https://rules.house.gov/sites/republicans.rules.house.gov/files/114/PDF/114-SAHR34-Sxs.pdf

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