

Congress of the United States

Washington, DC 20515

June 6, 2024

Dear Stakeholder:

Eight years ago, the 21st Century Cures Act was enacted, marking a pivotal moment in the advancement of medical research and health care delivery in the United States. This groundbreaking legislation has played a critical role in areas such as biomedical research funding and innovation, mental health care reform, drug development, and health information technology. Today, we are still witnessing the profound effects of the law, a testament to its far-reaching impact and the enduring relevance of its initiatives. However, we know that there is still more work to do. As a result of the impact of the 21st Century Cures Act, we have a strong foundation upon which to build and consider a new set of reforms under the banner of the broader 21st Century Cures initiative.

The Cures 2.0 Act, first introduced in November 2021 by Representative Diana DeGette and Representative Fred Upton, proposed provisions to further accelerate medical research, increase patient access to novel therapeutics, and enhance telehealth services. It called for the creation of a new agency that would prioritize funding for high-risk, high-reward research, targeting diseases like cancer, diabetes, ALS, and Alzheimer's; a long-term study of COVID-19 impacts; preparedness planning initiatives; and increased diversity in clinical trial participants. Additionally, the language also called for changes to FDA operations, Medicare reimbursement, and coverage of innovative health technologies.

Cures 2.0 aimed to build on the success of 21st Century Cures by focusing on ways we can modernize coverage and access to life-saving cures. In crafting legislation to build on existing work in the 21st Century Cures initiative, we are reminded that a modernized system of developing new cures will require a delivery system capable of getting them to patients in need.

Thanks to your continued advocacy and support, we are pleased to report that several original objectives of Cures 2.0 are already in motion, demonstrating our collective commitment to transformative health care improvements. These advancements include:

The establishment of the Advanced Research Projects Agency for Health (ARPA-H) within the National Institutes of Health, focused on novel treatments for challenging diseases.

Comprehensive reforms to the FDA, including guidance on cell and gene therapy, expedited drug approval processes, and the integration of real-world evidence in regulatory decision-making.

1. Development of TCET guidance, enhancing Medicare coverage for breakthrough medical devices and improving patient access to cutting-edge technologies.
2. Bolstering our national preparedness and response infrastructure, including establishing strategies for testing and response mechanisms for future public health security threats.
3. Policies to address Long COVID in the National COVID-19 Preparedness Plan and the establishment of the Office of Long COVID Research and Practice (OLC) to enhance our understanding and management of the long-term effects of the virus.

Each of these advancements plays a crucial role in shaping a more dynamic, patient-centered health care system, driving research, and improving treatment options.

While it is encouraging to see these policies taking shape, we are mindful that these are just the initial steps towards our broader objectives.

To ensure we are moving in the right direction and fully realizing the goals of the 21st Century Cures Act and Cures 2.0, we seek your input on key questions:

1. Do the policies included in Cures 2.0 that have advanced through legislation or executive action meet the needs that the original Cures 2.0 bill aimed to address?
2. What elements might be missing that are essential for further progress?
3. What additional reforms, support mechanisms, or incentives are needed to enhance or improve the effectiveness of the steps already taken, including any structural reform to agencies, offices, or programs involved?

Please send your input and feedback to cures.rfi@mail.house.gov by close of business on August 2, 2024.

Your responses to these questions are crucial, as they will guide us in refining our strategies and ensuring the path we are on is the one most beneficial to patients and the health care system.

The 21st Century Cures initiative is an ongoing process of reform, one that depends on continuous stakeholder input and collaboration. Your contributions are vital in this journey, helping to shape a health care landscape that is innovative, responsive, and patient-focused.

Thank you for your continued engagement and support in this vital endeavor.

Sincerely,



Diana DeGette
Member of Congress



Larry Bucshon, M.D.
Member of Congress