21st CENTURY CURES DISCUSSION DRAFT

"If we want to save more lives and keep this country the leader in medical innovation, we have to make sure there's not a major gap between the science of cures and the way we regulate these therapies."
-- Chairman Fred Upton, April 30, 2014

Over the last year, the Energy and Commerce Committee has engaged in a public conversation with patients, innovators, providers, regulators, consumers, and researchers about what steps we can take to bridge the gap between advances in science and medicine and how we regulate those therapies. This fight to treat and cure disease is an urgent, nonpartisan, national priority. With 10,000 known diseases, 7,000 of which are rare, and treatments for only 500 of them, it's clear we have a lot of work to do. Disease management costs billions of dollars, and its personal costs are much higher, causing pain and heartbreak during the battle and with each loss of life. America has always been at the forefront of medical innovation, developing many promising treatments and cures, but despite our success, we are losing this battle with disease and risking our leadership position in health care innovation.

The yearlong 21st Century Cures listening session explored the complete cycle of cures – from the discovery of clues in basic science, to the development of new treatments, to the delivery of those cures, and back again to further discovery. This draft includes policies to help accelerate this process and ease the transition between each step in the cycle of cures. It includes policies to help find cures and treatments for the thousands of diseases, particularly rare and serious disease, without any. It includes policies to bring patients into the conversation. 21st Century Cures will bolster resources for the National Institutes of Health and help encourage young and emerging scientists. This draft includes policies to unlock the wealth of data available today to help further research and innovation. It outlines policies to modernize clinical trials. 21st Century Cures also includes policies to unleash the promise of personalized medicine. 21st Century Cures will deliver hope to patients and their families while also protecting jobs and America's leadership role in health care innovation.

DISCOVERY

Throughout the course of the 21st Century Cures initiative, we have heard from a wide-range of stakeholders about the importance of strengthening our nation's basic research enterprise. The discussion draft would provide the NIH with a robust, steady stream of funding starting in FY 2016 to strengthen the agency and its mission and improves accountability. The draft also includes provisions to foster collaboration and sharing of data in our health system.

DEVELOPMENT

The discussion draft contains numerous policies to strengthen the development of new treatments and cures and improve the transition from discovery to development and development to delivery. These include provisions to incorporate the patient perspective into the drug development process, foster the development, qualification, and utilization of biomarkers, and modernize clinical trials. Further, given the unique challenges for specific types of therapies, the discussion draft includes provisions to facilitate the development of the next line of antibiotics and a placeholder for providing incentives for repurposing drugs for serious and life-threatening diseases and disorders. Finally, the discussion draft includes a section to provide clarity for developers of software products used in health management and medical care.

DELIVERY

Successful and innovative delivery of treatments and cures to patients is the ultimate goal, and the discussion draft takes steps to improve how this is done. Our committee members continue working on two crucial policies, interoperability and telemedicine, that will be included in the final package. The committee anticipates the release of draft legislative language in both of these areas shortly.