21ST CENTURY CURES DISCUSSION DOCUMENT

In April 2014, Energy and Commerce Committee Chairman Fred Upton (R-MI) partnered with Rep. Diana DeGette (D-CO) to launch the 21st Century Cures initiative. It has been reported that among the 10,000 known diseases, 7,000 of which are considered rare, there are treatments for only 500. According to Dr. Francis Collins, Director of the National Institutes of Health (NIH), it now takes "around 14 years and $2 billion or more" to develop a new drug and "more than 95 percent of [such] drugs fail during development." Over the course of the last year, patients, providers, innovators, regulators, and researchers from around the country have provided a wide range of specific ideas on how Congress can help accelerate the discovery, development, and delivery of promising new treatments and cures for patients and maintain our nation's standing as the biomedical innovation capital of the world. While it remains a work in progress, the legislative language included in the discussion document is based on such ideas, including proposals authored by both Republicans and Democrats.

TITLE I – PUTTING PATIENTS FIRST BY INCORPORATING THEIR PERSPECTIVES INTO THE REGULATORY PROCESS AND ADDRESSING UNMET MEDICAL NEEDS

Patients are ultimately at the core of this initiative. A series of proposals are included in Title I to empower patients and foster an economic and regulatory environment more conducive to addressing their unmet needs. These include policies on patient focused drug development, biomarker qualification, antibiotic drug development, dormant therapies, and innovative device review pathways.

TITLE II – BUILDING THE FOUNDATION FOR 21ST CENTURY MEDICINE, INCLUDING HELPING YOUNG SCIENTISTS

Leveraging recent advances in science and technology, researchers have uncovered new ways to proactively diagnose and treat patients in a more precise manner based on their unique set of circumstances. Title II includes a series of proposals intended to help aid in the discovery, development, and delivery of the next generation of patient-centered solutions here in the United States, by establishing the 21st Century Cures Consortium, fostering innovation in health information technologies through the SOFTWARE Act, and helping young scientists.

TITLE III – MODERNIZING CLINICAL TRIALS

By reducing regulatory overlap and administrative inefficiency, in addition to encouraging broader utilization of efficient, flexible trial designs, provisions in Title III would help modernize the development and assessment of potential new treatments and keep clinical trials from moving overseas by improving the cost and speed of trials.

TITLE IV – ACCELERATING THE DISCOVERY, DEVELOPMENT, AND DELIVERY CYCLE AND CONTINUING 21ST CENTURY INNOVATION AT NIH, FDA, CDC, AND CMS

Title IV includes a wide-ranging series of proposals intended to streamline regulatory processes and equip our federal public health agencies with the tools needed to ensure they are able to keep pace with innovation.

TITLE V - MODERNIZING MEDICAL PRODUCT REGULATION

Finally, Title V consists of policies developed to encourage modern manufacturing technologies here in the United States as well as provisions intended to update certain medical device regulations.

CONCLUSION

This discussion document marks a new point in the conversation, but it is one that is far from over. Prior to introduction and throughout the legislative process, all interested stakeholders are encouraged to submit specific suggestions about how to improve the legislation to cures@mail.house.gov.