Chairman Michael C. Burgess, MD
Opening Statement
Energy and Commerce Subcommittee on Health Hearing
"Implementing the 21st Century Cures Act:
An Update from FDA and NIH"
November 30, 2017

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

The 21st Century Cures Act (Cures) was a monumental achievement. Cures was the product of a bipartisan, multi-year effort by the Energy and Commerce Committee that brought our laws into a modern era of medicine. It has been nearly one year since Cures was signed into law. Today's hearing marks the Health Subcommittee's first look into the implementation of what many in the healthcare community called a transformational bill that would positively impact not only the researchers and scientists who are developing the latest breakthrough therapies, but physicians seeking treatments for their patients – giving hope to them, their loved ones, and other advocates.

This morning we will hear from two leaders responsible for implementing the drug development and biomedical research provisions included in Cures. I want to welcome Dr. Francis Collins, Director of the National Institutes of Health, and Dr. Scott Gottlieb, Commissioner of the Food and Drug Administration, back to this

subcommittee. All of us know the demands of your schedules and appreciate both of you coming before us today.

At the time of the Energy and Commerce Committee's launch of the 21st Century Cures Initiative, there were only 500 cures or treatments to address the 10,000 known diseases. Certainly, more progress was needed to alleviate the agony of an incurable disease.

While the U.S. had maintained its global leadership in biomedical innovation, there existed a potential to bridge the growing divide between the revolutionary advances in science and technology over the last decade and a less-than-adequate system for discovering, developing, and delivering new therapies. Members of the committee and the Senate HELP Committee held numerous public hearings, forums, and roundtables in Washington, D.C. and across the nation, bringing together leading scientists and medical experts, patient and disease group advocates, and researchers across multiple sectors. The primary objective of these events was to uncover opportunities to strengthen and streamline the process by which cures are discovered and made available to patients. Cures accelerated the cycle of discovery, development, and delivery of new treatments and ensured our nation remained at the helm of biomedical innovation.

At the NIH, the 21st Century Cures Act authorized resources to support biomedical research and reduce administrative burdens and provided almost $5 billion dollars in new funding to support the agency's four innovation projects. The Precision Medicine Initiative was authorized over $1.4 billion for NIH to build a national biomedical data set in order to accelerate health research and medical breakthroughs. Cures also authorized $1.5 billion dollars for the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative to better understand the brain's physiology and coordinate efforts across multiple federal and private groups to expedite research for diseases like Alzheimer's. Cures also authorized $1.8 billion dollars for cancer prevention, diagnosis, treatment and care through the Beau Biden Cancer Moonshot. Finally, the Regenerative Medicine Innovation Project was authorized $30 million dollars to support clinical research in the field of regenerative medicine in coordination with the Food and Drug Administration (FDA).

The 21st Century Cures Act helped the FDA modernize the regulation of medical products throughout its lifecycle. It established an "FDA Innovation Account" and authorized $500 million dollars in funding to implement Title III of the law, which included a broad range of deliverables from the FDA. These include creating a mechanism for the collection and incorporation of patient perspective in regulatory decision-making; updating the way medical products are reviewed and approved;

advancing new drug therapies through a review pathway for biomarkers and other drug development tools to help shorten drug development time while maintaining the same rigorous standard for safety and effectiveness; and requiring the FDA to establish standards and definitions necessary to develop regenerative medicines.

Before I close, I recognize that the 21st Century Cures Act also touched upon other critical healthcare priorities, such as mental health and health IT. Both of these areas should have their own, separate hearings because of their importance to the medical community and I look forward to holding them in the near future.

I again want to welcome our witnesses and thank you for being here. I look forward to your testimony.

I would like to yield the balance of my time to Ms. Blackburn of Tennessee, for a statement.