Opening Statement
Rep. Gene Green
Health Subcommittee Hearing "21st Century Cures Initiative"
April 30, 2015

Good morning and thank you all for being here today.

I particularly want to thank our witnesses and their colleagues for their expertise, and for the countless hours of work they have put in to help us in this effort.

It has been one year since the 21st Century Cures Initiative was launched by my colleagues, Chairman Upton and Congresswoman DeGette.

Yesterday's release of a discussion draft marked continued progress toward boosting research and delivering hope to patients.

As we know, FDA-approved treatments are the global gold standard for safety and effectiveness. It is what physicians, patients and families trust when making decisions about their health.

Recently, Congress has enacted additional tools - like the breakthrough designation for drugs - to facility the development effective, innovative treatments.

The NIH, the world's leading biomedical research institution, is one of the great success stories of the federal government.

Our investment in basic and translational research has led to advances that have profoundly improved the health and quality of life of millions of Americans.

The 21st Century Cures Initiative nobly asked what more can Congress do to further public and private efforts to address today's most difficult scientific challenges, and advance our health care system.

Additional funding for NIH is tantamount to this effort.

It is so important that the Initiative includes increased funding for NIH, both through reauthorization and $10 billion over five years in mandatory funding.

On the regulatory side, the draft includes policies to incorporate the patient perspective in the development process, facilitate the use of biomarkers, and breakdown barriers to collaboration and data sharing.

The draft also includes provisions to modernize clinical trials.

I want to particularly highlight the ADAPT Act, which Congressman Shimkus and I are working on, to provide a streamlined approval pathway for the next generation of antibiotics.

FDA, and Dr. Woodcock in particular, has been an incredible partner on this issue.

I thank the agency for their continued commitment to combat the global crisis of antibiotic resistance.

We are working hard to incorporate recent feedback and will have a new draft of ADAPT to share in the coming days.

The draft also includes a new version of the SOFTWARE Act, which I have been working on with Congresswoman Blackburn.

This provision will provide clarity for developers of software products used in health management and care.

Dr. Shuren and his colleagues at FDA have been instrumental to this effort, and I look forward to continuing to work with you all to foster innovation, provide regulatory certainty, and promote patient safety.

The draft recognizes the importance of improving the interoperability of health IT systems.

Interoperability is foundational to realizing the goals of the 21st Century Cures Initiative.

An interoperable health care system can advance and facilitate research, and dramatically improve patient care and safety.

I thank my colleagues for their commitment to continuing this effort.

The Cures draft is a work in progress.

There is a lot of work left to do, but we will continue to move forward and iron out policies to advance our health care system and live up to the goals of the 21st Century Cures Initiative.

Thank you again to our witnesses, and I yield the remainder of my time to Congresswoman DeGette.