

Statement
Rep. Gene Green
Health Subcommittee Markup: 21st Century Cures Act
May 14, 2015

Thank you Mr. Chairman.

It has been a little over a year since the 21st Century Cures Initiative was launched.

Since then we have heard from the full spectrum of stakeholders within the health care world.

We have made tremendous progress toward crafting legislation that will live up to the noble goal of the Initiative, which is to bring cures to patients who need them.

The Substitute Amendment offered this morning is the result of tireless, bipartisan efforts by the Committee, the Administration, and a diverse set of stakeholders.

Thanks to these efforts, provisions of this bill take innovative approaches to long-standing challenges.

This bill will improve the innovation ecosystem for the development of life-saving medical breakthroughs, foster the development and the interoperability of health information technology, and better leverage critical resources to facilitate the discovery of new cures.

As we know, the 21st Century Cures Initiative asked what more can Congress do to promote public and private endeavors to solve today's scientific challenges and advance our health care system.

The most consistent response to that question that we received was to robustly fund the NIH and I am so pleased that this bill includes new money to move us in that direction.

NIH funded-research is essential if we are to improve our nation's health, maintain our role as the world leader in medical research, and keep a competitive edge in today's global economy.

I am particularly pleased that some of this new money will be directed toward research on neglected tropical diseases.

Beyond NIH funding, the draft includes policies to advance precision medicine, move toward continuous drug manufacturing, and foster collaboration and data sharing.

It makes improvements to the regulatory approaches for medical devices and health information technology.

The draft also includes provisions to modernize clinical trials.

This is particularly important in the context of antibiotics.

Shortly after discovering penicillin, Alexander Fleming warned of the threat of antibiotic resistance.

He gravely predicted the day when his miracle discovery would be rendered useless.

Resistance can be slowed but it cannot be stopped, and we are already seeing a rise in infections for which we have no effective treatments.

A robust pipeline of new products is necessary to maintain an advantage over ever-changing pathogens.

Yet, no new class of antibiotics has been discovered since 1987.

Antimicrobial agents are increasingly difficult to discover and develop.

Included in this bill is the ADAPT Act, which is led by myself and Congressman Shimkus.

It establishes a streamlined regulatory pathway to help bring safe and effective antibiotics to market in a faster and less costly way.

The provision encourages FDA to use alternative clinical trial methods and data sets when considering products developed for limited use in hard-to-treat infections where current therapies are inadequate.

This is critically important to address the growing global crisis of antibiotic resistance.

It also lays the groundwork for innovative trial design and targeted approaches to the development of products for other sub-populations in dire need of treatments.

I want to thank the FDA, industry stakeholders, and public health advocates for their steadfast work to help us advance this provision.

The SOFTWARE Act, led by myself and Congresswoman Blackburn, has been an ongoing effort.

I am pleased that the Cures legislation includes a new version of this bill that reflects the involvement and input of FDA, medical device manufacturers and health IT developers, and patient advocates.

This provision advances a regulatory framework for health IT that both promotes innovation and protects patient safety.

Finally, I want to highlight the provision within the Cures draft to improve the interoperability of health information technology.

Efforts are ongoing and the language is a work in progress, but its inclusion in the Amendment marks a significant step forward.

An interoperable health IT infrastructure is essential to realize the goals of the 21st Century Cures Initiative, and foundational to advancing our health care system in general.

Fully leveraging data will be the key to scientific discovery, modern clinical trials, enhanced patient safety, and improved quality of care.

We will continue to work on interoperability and I thank everyone involved for their commitment to this issue.

I want to thank Chairman Upton, Ranking Member Pallone, Congresswoman DeGette, Chairman Pitts, Members of the Committee and the countless

stakeholders who helped get us to this point in the 21st Century Cures Initiative.

This markup is the next step toward boosting research and delivering hope to patients.

There is 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 and I yield back.