

Committee on Energy and Commerce

**Opening Statement
of
Ranking Member Frank Pallone, Jr.**

Implementing the 21st Century Cures Act: An Update from FDA and NIH

November 30, 2017

Thank you Mr. Chairman. I want to welcome Dr. Collins and Dr. Gottlieb here today to discuss implementation of the 21st Century Cures Act. While the law addressed several different issues facing our healthcare system, such as the opioid epidemic and mental health, today we'll be focusing on the ongoing work at NIH and FDA to implement the provisions of the law aimed at improving the discovery and development of new treatments and cures.

The Cures Act provided new funding to advance cutting edge research at NIH. I'm particularly proud that the law included funding for the Beau Biden Cancer Moonshot Initiative. This initiative aims to accelerate cancer research in America and improve our ability to prevent and detect cancers early on; with the hope that one day we might find cures for the many different cancers, such as pancreatic cancer, afflicting patients today. I'm interested in hearing how NIH is working to achieve this admirable goal. I'm also pleased that the Cures Act invested new funds in the BRAIN Initiative and the Precision Medicine Initiative, which is now known as the All of Us Research Program. The BRAIN Initiative funds important research on brain disorders such as Alzheimer's, epilepsy and traumatic brain injury. The All of Us Research Program funds a historic effort to gather data from at least 1 million people that will help lead to the development of personalized therapies rather than one-size-fits-all treatments.

At FDA, the Cures Act aims to bolster the medical product review process in order to get treatments to patients faster while also maintaining FDA's gold standard for safety and effectiveness. For example, the law granted FDA added authority to develop and utilize new tools to facilitate drug development, provide greater flexibility in the clinical trial process, and support the development of continuous manufacturing. It also invests in increased patient engagement by encouraging the use of patient experience data in the review process. The law also provided FDA with \$500 million in new funding to ensure the agency has the necessary resources to recruit the best and brightest scientists and effectively implement the law. I look forward to hearing more about the progress the agency has made to date.

The Cures Act marked an important step toward the development of new treatments and cures and I'm pleased that this Committee was able to work together last Congress to pass this monumental law. It's critical that we hold hearings like these to ensure the law is working as it should and achieving its goals. I look forward to hearing from our witnesses today and to further discussions on the implementation of other provisions of the law.

Thank you, and I would like to now yield the remaining balance of my time to Representative Lujan.