



COMMITTEE ON DEMOCRATS  
**ENERGY & COMMERCE**  
RANKING MEMBER FRANK PALLONE, JR.

**FOR IMMEDIATE RELEASE**

May 14, 2015

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Click [here](#) to watch the markup. Additional materials, including a background memo and bill text, can be found [here](#).

**Statement by Ranking Member Frank Pallone, Jr., as prepared for delivery  
House Energy and Commerce Committee  
Subcommittee on Health Markup  
“H.R. \_\_, 21<sup>st</sup> Century Cures Act and  
H.R. 1321, Microbead-Free Waters Act of 2015”**

Thank you Chairman Pitts. And thank you Chairman Upton, Ranking Member Green, Ms. DeGette and all of the staff. Today we take another important step forward on the 21<sup>st</sup> Century Cures Act. The latest draft represents significant progress, but as with comprehensive legislation like this, we are still far from a finished product.

We’ve agreed on dozens of policies that aim to facilitate the advancement of cutting edge science and foster more efficient development and delivery of new treatments. And we have done so without sacrificing safety and effectiveness for speed. Taken together, this draft goes a long way in furthering both public and private efforts to advance health care.

The increased NIH funding is promising and essential to this effort. However, this bill is also asking the FDA to take on many new responsibilities. I’m glad to see authorizations in a

number of places, but I hope that we can ensure those become appropriated dollars moving forward.

Let me just highlight a few other notable sections.

I'm glad to see grant making authority in the draft for FDA to help advance continuous manufacturing. Rutgers in my district is a leader in this field and has built a two-story, state-of-the-art lab. Their work has shown that continuous manufacturing can revolutionize the way we make drugs, help bring manufacturing back to the United States and increase drug quality and efficiency.

Another section gives HHS the authority to participate in public-private partnerships to foster better utilization of patient registries and the best ways to gather information on the natural history of diseases, particularly rare diseases.

There is also a provision that reduces the burdens of the Paperwork Reduction Act on NIH and FDA. The requirements of that Act unfortunately sometimes serve as nothing more than a barrier to gaining valuable information that can aid the research and development of medical products. The draft also includes changes to current law to help FDA hire and retain the best scientific experts. And it includes a sense of Congress that traveling to scientific conferences is essential to the mission of NIH and FDA. It is critical we make such travel less burdensome, so government scientists can fully participate in acquiring and disseminating cutting edge science, along with their academic and industry colleagues.

Another provision will allow for meaningful incorporation of patient experience data into the drug approval process. Patients understand better than anyone else the impact a treatment has on their daily lives, and have a unique perspective to add as industry and regulators consider the benefits and risks of different therapies. Incorporating their voices in the development and review of medical products will help advance treatments that will improve the quality of life for patients.

The draft also includes a revised Section 3141. It would allow Medicare prescription drug plans to develop safe prescribing and dispensing programs to prevent fraud and abuse. I have worked on this issue in Congress for more than two years. Both GAO and HHS-OIG have found that these types of programs have the potential to improve patient safety and reduce costs in Medicare. I'm pleased to see this section now also includes critical beneficiary notification provisions and consultation with health providers.

Section 3001 includes a proposed policy on advancing interoperability within our health care system. Allowing technology systems to transfer readable and useful information can improve quality, safety and help facilitate research. But this is very complicated policy and I hope we take all the necessary time to ensure we get the policy right.

Lastly, as many will see, a provision is now included to provide an additional 6 month of exclusivity and patent extension to a drug already on the market if it gets approval for a new indication to treat a rare disease. Modelled after the successful Best Pharmaceuticals for Children

Act, I am hopeful that this limited exclusivity will provide opportunity for critical drugs to come to market. As I've said before, I do not believe that companies need more protection from competition to invest in the development of novel and innovative drugs. But I am grateful to the Chairman for his willingness to consider my views.

This is a product deserving of the Committee's support and I look forward to our continued work together.

We are also marking up another bipartisan bill – the Microbeads-Free Waters Act that Chairman Upton and I introduced together. This bill is an effort to stop plastics from personal care products from getting into our nation's waterways. It requires FDA to prohibit the sale or distribution of personal care products containing plastic microbeads beginning in 2018. We continue to make improvements to the legislation based on feedback from stakeholders, and will include further improvements before moving to Full Committee markup. I hope my colleagues will join me in supporting its advancement. Thank you.