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

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Statement of Ranking Member Frank Pallone, Jr.
House Energy and Commerce Committee
Subcommittee on Health
"Legislative Hearing on 21st Century Cures"

April 30, 2015

Thank you Chairman Pitts. And let me thank Chairman Upton, Ms. DeGette and Ranking Member Green. Today's hearing will examine a draft released yesterday that is the result of months of discussions. It has changed significantly from the draft the Chairman released earlier this year. While it is by no means perfect, it does reflect hard work by staff, true collaboration between Republicans and Democrats, stakeholders, and the Administration and I am hopeful we can bring this legislation to a successful conclusion.

Let me also thank HHS for the expert advice and help along the way. I know how many resources have been spent on this effort as well, and this draft is a better product because of their guidance.

Now I would have liked Members and their staff, and our witnesses, to have had more time with the draft before a legislative hearing. The ambitious timeline has been a challenge. I

want to be clear that I am committed to ensuring that every Member is comfortable as this process moves forward so that a final product gains broad support.

There are a large number of policies in this draft – and not a lot of time to cover all of them. But let me highlight just a few things.

Most notable in the new draft, and the one that I am most proud to see, is $10 billion in mandatory funding for NIH over the next five years. It also includes a $1.5 billion increase in NIH discretionary authorization over the next three years. This is a real win for researchers, patients and industry alike. I believe federal funding is the foundation of our biomedical ecosystem and is one of the most promising ways to spur economic prosperity and treatments and cures for the 21st Century.

While this a great development, I hope that we can also ensure that FDA has the needed resources to implement the many additional policies put forth in this draft. We cannot divert already scarce resources nor impede the progress FDA has already made to advance the development and review of medical products.

We also need to ensure that policies in this draft do no harm. I have said all along that broadly extending drug exclusivity will not solve the problems 21st Century Cures sets out to address. So I am glad to see that this new draft includes placeholder language for a much more tailored approach at solving a targeted problem. We are going to continue discussions on how we can incentivize development of a narrow class of drugs that have been abandoned because of

inadequate remaining patent life. Dr. Collins has spoken about the need to provide limited additional exclusivity for drugs that have been found to be safe in clinical trials. Even though they failed the trials for effectiveness, it may be possible to repurpose them for a different indication or for a different population for which they may be effective. If such drugs fill an unmet medical need for treating a serious or life threatening disease, it may be appropriate to provide companies with limited additional exclusivity for companies to spend the resources needed to determine if they work. I appreciate the Chairman's commitment to me to continue to discuss this policy and ensure that it is targeted only to where it is needed.

Mr. Chairman, with the hard work of staff, I believe we have come a long way. However, there are other complicated policies, like interoperability and telehealth, which still need thorough vetting and further consideration.

As I've said since I became Ranking Member, I am serious about finding common ground on important issues. True bipartisanship is critical to achieving successful and broadly supported policies. I am confident that this much improved collaborative process can continue. There is still much more work to be done, but today's hearing is an important step and I look forward to our continued partnership on this initiative.