



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

FOR IMMEDIATE RELEASE

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**Statement by Ranking Member Frank Pallone, Jr. on the Manager's Amendment,
as delivered
House Energy and Commerce Committee
Full Committee Markup
“H.R. 6, 21st Century Cures Act”**

Thank you, Mr. Chairman. And let me start out by thanking you. It's been a pleasure working with you on this bill, and, in my opinion, you really epitomize what it's all about to be an outstanding member of Congress, Republican or Democrat. You worked with us constantly and were always willing to entertain our concerns and ideas. I know you're very proud of this bill, and you should be.

I also want to thank Congresswoman DeGette. From day one when she trekked around the country with Chairman Upton, and promoted this bill—you know, we're here, it's almost anti-climactic today because the amount of work that was put into this by so many people, but particularly the Chairman and Ms. DeGette, is unbelievable. I think the only one I went to outside of Washington was when I went to Lancaster with Mr. Pitts. I also want to thank Chairman Pitts and our Ranking Member, Mr. Green, for all the work they put into it. Not only did I get a chance to go to Lancaster with you, which I always wanted to, but, again, that hearing and all the hearings just showed a tremendous amount of bipartisanship and willingness to work together, which is kind of an example, in my opinion, of what this Congress and, obviously, what this Committee is all about.

I also want to thank all the staff who have worked so hard. This is really an incredible achievement that we have here today.

Let me just talk a little bit about the specifics in the Manager's Amendment before us. It reflects a bipartisan effort to address several outstanding issues of importance to Members of this Committee, and includes a number of Democratic priorities that I would like to highlight.

Following release of the 21st Century Cures draft, one message that we all heard loud and clear is the need for resources for FDA to implement the new authorities and programs included in the 21st Century Cures Act. The Manager's Amendment would provide \$550 million over five years to enable the agency to set up or expand over a dozen new programs.

These programs will help speed up and improve the process by which new medical products are developed. They will enable FDA to make better use of patients' knowledge and experiences in its approval decisions on new treatments. Under these programs, FDA will help facilitate the development and use of biomarkers to improve and shorten clinical trials. And they will enable FDA to create a new pathway for the development of critically needed new antibiotics for limited populations, to mention only a few, and I am glad to see this included in the amendment.

I am also pleased that the Manager's Amendment will address the unfortunate sequestration of FDA user fees. I have not supported a piecemeal approach to addressing the sequester in the past. However, FDA was uniquely impacted in 2013 when \$85 million in user fees were sequestered.

As members of this Committee know well, the user fee agreements are carefully negotiated by industry and the FDA to support the review of drugs and medical devices. These fees by law cannot be used for any other purpose than to support the approval of drugs and devices. The inability of the agency to access this funding prevents FDA from meeting the goals laid out in these agreements, and, ultimately, impacts timely access to safe and effective medical treatments.

While Congress addressed this issue in 2013, we did not exempt these user fees from any future sequestration. I am pleased that the Committee has done so in this Manager's Amendment, providing certainty to industry and FDA that those fees will continue to be available for use.

I also want to note my support for the inclusion of proposals of importance to my colleague, Mr. Rush, which would encourage the National Institute of Minority Health and Health Disparities to consider ways to increase the representation of underrepresented communities, including minorities, in clinical trials as well as in the biomedical workforce.

The Manager's Amendment also includes offsets for the underlying bill. The included offsets were carefully negotiated by both sides, and I am glad that they reflect a Democratic proposal offered by Ranking Member Green that would change the timing of reinsurance payments to Medicare Part D drug plans and is based on recommendations from the HHS-OIG. Overall these proposals represent a compromise that will ensure the successful implementation of H.R. 6, and provide much-needed resources to the NIH and FDA.

While Members and staff on both sides of the aisle have been working hard on the underlying bill and the Manager's amendment, I do want to note that I received a copy of a letter sent yesterday to Chairmen Upton and Pitts from ten prominent public health organizations, including the March of Dimes, the American Academy of Pediatrics, and ACOG. They ask that the sections in the bill that address vaccines and immunization practices be revised to ensure that they don't have the unintended effect of undermining or impairing the processes by which the CDC makes vaccination recommendations. I know that would be the exact opposite of our intent, so I hope that the Chairmen will work with us as we move forward to ensure that we get these provisions right.

Before I close I also want to take a moment to recognize two of my staff members – Ziky Ababiya and Brendan Hennessey – both of whom have served this Committee, and its members, ably. I thank you for your hard work and your service, and wish you well as you move on to new opportunities. While you may be leaving the Committee, you will always be a part of Team Pallone.

Again, thank you Mr. Chairman. I can't say enough about your efforts in moving this bill forward.

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