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Pallone's Opening Remarks at FDA User Fee Markup

"We should move forward with this bipartisan bill that will allow the FDA to meet its mission of ensuring the medical products that patients and American families use are safe and effective."

Washington, D.C. – Energy and Commerce Ranking Member Frank Pallone, Jr. (D-NJ) delivered the following opening remarks at a Health Subcommittee markup of three legislative bills including the FDA Reauthorization Act of 2017:

Thank you, Mr. Chairman. Today we are considering three bipartisan bills that will reauthorize CDC's congenital heart disease programs, HRSA's sickle cell disease prevention and treatment demonstration program, and FDA's medical product user fee programs.

H.R. 2430, the Food and Drug Administration Reauthorization Act of 2017, would reauthorize FDA's user fee programs in the areas of prescription and generic drugs, biosimilars, and medical devices.

This bill is the product of considerable discussion and negotiation between FDA, industry, and additional stakeholders, and also incorporates the bipartisan, bicameral work of this Committee and the Senate. Swift passage of the user fee reauthorization package will ensure that FDA lay-offs will not occur, and that the medical product review process will continue uninterrupted—ensuring patient access to the medical treatments they need.

I am disappointed that the Trump administration is pushing at the last hour to reopen negotiations on the user fee reauthorizations in order to withhold federal government support for the critical work that is at the heart of FDA's public health mission. The Trump administration should seriously reconsider any reopening of these negotiations. Instead, we should move forward with this bipartisan bill that will allow the FDA to meet its mission of ensuring the medical products that patients and American families use are safe and effective. I hope that all of my colleagues will reject this proposal, and continue the process to reauthorize the user fee programs as agreed to by FDA and industry.

Mr. Chairman, I want to raise the issue of drug pricing in the time I have left. Prescription drug prices are rising at an alarming pace and the problem is widespread. Annual drug spending in the United States is estimated to reach more than \$500 billion by 2018, and in 2014 spending grew by 12 percent—faster than any year since 2002.

Throughout the country, and even from our President, there is bipartisan support for action to lower the costs of prescription drugs and make treatments more affordable for patients and their families.

Yet, despite this commitment from the President, this Committee has yet to take serious look at what can be done to address the high costs of prescription drugs.

I urge the Chairman to hold a hearing on this issue, and to begin a process where we can work together in a bipartisan manner as we are today to learn more about what can be done to make prescription drugs affordable for patients and their families.

Thank you.

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