Statement of Ranking Member Frank Pallone, Jr.
House Committee on Energy and Commerce
Subcommittee on Health
"Examining FDA's Prescription Drug User Fee Programs"
March 22, 2017

Thank you, Mr. Chairman. I appreciate the opportunity today to discuss the reauthorization of the Prescription Drug User Fee Act. PDUFA has been incredibly successful at bringing reviews of new drug applications down by more than half, and providing patient access to treatments more quickly, and often before any other country.

PDUFA has also encouraged innovation by bringing stability and predictability to the review of new drug applications. FDA has been able to hire the review staff and scientific and technical experts needed to keep pace with science and increase the efficiency of the review process. However, more work needs to be done and I am encouraged by how PDUFA VI builds off of the successes of this user fee program.

I am therefore disappointed to see what can only be referred to as a disclaimer in the testimony today from FDA. While it is true that the reauthorization proposals were negotiated under a previous Administration, the goals of the PDUFA program and the drug approval process remain the same – a fully resourced and staffed FDA, and an efficient and timely drug review process that is keeping pace with the scientific and regulatory advancements in this field. It is my hope that the Administration would understand how carefully crafted the current agreement is, and recognize that the reauthorization process started nearly two years ago.

The agreement before us today is the result of many negotiations with industry and stakeholders, consultations with patients and consumers, and solicitation of public input. The resulting recommendations were transmitted to Congress in meeting the January 15, 2017 statutory deadline. Transmitting new recommendations at this point would go against this requirement, and run the very real risk of PDUFA not being reauthorized before the program expires on September 30, endangering the review of innovative new drug treatments and threatening the jobs of thousands of FDA employees.

I intend to continue to work with my colleagues on the Committee and across the Capitol, as well as industry, to ensure that we do not let this happen. This is a strong agreement, and one that deserves our support.

Thank you.