COMMITTEE ON
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DEMOCRATS
RANKING MEMBER FRANK PALLONE, JR.
NEWS

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Pallone Calls for Swift Reauthorization of MDUFA

"Any delays would endanger the review of innovative medical devices and threaten the jobs of thousands of FDA employees"

Washington, D.C. – *Energy and Commerce Ranking Member Frank Pallone, Jr. (D-NJ) spoke of the importance of a prompt reauthorization of the Medical Device User Fee Amendments (MDUFA) today at a Health Subcommittee hearing titled, "Examining FDA's Medical Device User Fee Program:"*

Thank you, Mr. Chairman. I appreciate the opportunity today to discuss the reauthorization of the Medical Device User Fee Amendments.

I am pleased to see the progress that has been made under MDUFA in reducing review times for medical devices, as well as ensuring that the Center for Devices and Radiological Health (CDRH) is well-resourced and well-staffed. I would also be remiss if I did not acknowledge the positive response from industry in terms of how MDUFA III is working, a dramatic shift from where things stood prior to reauthorization in 2012.

A lot has been accomplished in meeting the goal of reduced review times under the MDUFA program. Average total review times for 510(k)s are down by 11 percent, and average total review times for pre-market applications are down by 35 percent or 150 days. Importantly, CDRH also approved the highest number of novel devices in the history of the MDUFA program in 2016, approving 91 new devices. While more work needs to be done, this progress has resulted in patient access to safe and effective medical devices more quickly, which is a goal I think we all share.

MDUFA IV will build on these successes by working to improve the medical device user fee program. It will advance the use of the patient perspective in the risk-benefit assessment of medical devices. It also establishes a system called the NEST to utilize real world data for premarket approval of new indications and post-market safety monitoring. It tailors the use of the Third Party Review program, and improves pre-submission communication with sponsors. All of these actions will help to improve the consistency, efficiency, and effectiveness of medical device reviews.

Just as I have said before on the other user fee agreements, 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 MDUFA not being reauthorized before the program expires on September 30. Any delays would endanger the review of innovative medical devices and threaten 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, and I look forward to continuing our work on all of the user fee agreements to ensure they are signed into law as soon as possible.

Thank you.

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