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Pallone Remarks at Health Hearing on Compounding Quality Act

Washington, DC – *Energy and Commerce Ranking Member Frank Pallone, Jr. (D-NJ) delivered the following opening remarks today at a Subcommittee on Health hearing on "Implementation of the Compounding Quality Act"*

Thank you, Mr. Chairman, for holding today's hearing on the Compounding Quality Act, which passed with broad support from stakeholders and bipartisan, bicameral support in Congress in 2013.

Passage of the Compounding Quality Act was about patient safety. Congress came together in response to the horrible tragedy of actions by the New England Compounding Center (NECC) that led to 64 people losing their lives. Despite a history of complaints and investigations by both the FDA and the Massachusetts State Board of Pharmacy, NECC was allowed to continue compounding products given to patients on a scale and in a manner that should have never been allowed. The new law was meant to clarify drug compounding laws. It was also supposed to make clear the lines and requirements for traditional pharmacies that want to compound and those pharmacies that compound on a larger scale.

I think we all agree and support maintaining patient access to compounded drug products. Undoubtedly there are patients with unique medical needs for which a traditional prescription drug product is not appropriate, whether for pediatric patients, seniors, or those with allergies. However, we must all remember that compounded drug products are not without risk. Compounded drug products are not reviewed by FDA prior to coming to the market for safety and effectiveness. Traditional compounding pharmacies are also not required to report on the compounded drug products they produce or report adverse events.

And while this law was intended to prevent another tragedy like the one at NECC, adverse events associated with compounded drug products are still occurring. Since passage of the law, there have been more than 140 recalls associated with compounded drugs. We've also seen reports of serious health events. For example, just last summer, 43 patients suffered vision impairment after receiving compounded eye injections of a drug containing a combination of a steroid and an anti-infective agent. Also last year, three infants received a

compounded morphine preparation that was 25 times the strength that was indicated on the label resulting in at least one hospitalization. These are just two examples of why clearly identified standards and requirements must be maintained if we are going to protect patient health.

Recently FDA released the agency's 2018 Compounding Policy Priorities Plan identifying next steps the agency will be pursuing in regards to implementing the Compounding Quality Act, including revisions to current guidance.

As FDA moves forward, I would caution the agency to ensure that any revisions that it makes does not enable an environment that could allow for another NECC to occur. We must maintain appropriate patient safeguards and clear lines between what activities are permissible for traditional pharmacies and what activities are permissible for outsourcing facilities. Patient safety and the protection of public health must be at the forefront of any guidance revisions FDA considers. The American people deserve confidence that the drug products they receive are safe and held to strong quality standards.

I want to thank Commissioner Gottlieb and all of our witnesses for being here today. I look forward to a robust discussion about the implementation of the Compounding Quality Act. Thank you.

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