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

FOR IMMEDIATE RELEASE
September 13, 2017

CONTACT
CJ Young — (202) 225-5735

Pallone Opening Remarks on Over-the-Counter Drugs Reform

Washington, D.C. – *Energy and Commerce Ranking Member Frank Pallone, Jr. (D-NJ) delivered the following opening remarks today at a Subcommittee on Health legislative hearing titled, "Modernizing FDA's Regulation of Over-the-Counter Drugs:"*

Mr. Chairman, I want to thank you for holding today's hearing on over-the-counter drug monograph reform and the establishment of an over-the-counter monograph user fee program. I also want to commend you, as well as Ranking Member Green, and Representatives DeGette, Latta, Guthrie, and Dingell for your work in crafting a proposal that will accomplish these goals.

The safety and effectiveness of over the counter drugs is established today through conformance with a monograph. This so-called rulebook outlines the conditions of use for a particular drug ingredient that outlines the dosage form, patient population, labeling and warnings, and other requirements. This rulebook is established through a three-phase rulemaking process that is oftentimes inflexible and time-consuming, making it difficult for FDA to quickly revise or update monographs in response to safety or other issues. We have also heard from FDA and industry that the monograph process does not lend itself well to evolving science and technology, and may have the unintended effect of discouraging the development of new formulations.

Not only is it clear that regulatory reform is needed, but the current program is drastically under resourced. Today, the OTC monograph program oversees more than 100,000 products with a staff of 30 people and a budget of just over $8 million.

It is my hope that through regulatory reform, and increased, predictable resources, we can streamline the over-the-counter process to allow for swift finalization of current monographs, timely safety updates, and encourage innovation where possible.

While we are beginning the process of making significant improvements in the review of over-the-counter products, I had hoped that we would begin taking action today on cosmetics. Millions of Americans use cosmetic products every day, but FDA's regulatory authority over cosmetics is woefully inadequate. In just the last year, millions of women and

children have been exposed to shampoos that can cause extraordinary hair loss, lip balm that can cause blistering and rashes, and eye shimmer tainted by asbestos. Unfortunately, FDA does not have the authority today to hold these manufacturers responsible and has very little ability to ensure these cosmetics are safe.

This simply cannot continue, and as we move forward with this process, we should provide adequate resourcing and authority for cosmetics. I look forward to continuing to work with my colleagues, FDA, industry, and other stakeholders to accomplish both of these goals and ensure the continued availability and safety of the millions of drug products and personal care products people use every day.

Thank you, I yield back.

###
