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

**FOR IMMEDIATE RELEASE**
January 17, 2018

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# Pallone Opening Remarks at Health Subcommittee Markup

**Washington, DC** – *Energy and Commerce Ranking Member Frank Pallone, Jr. (D-NJ) delivered the following opening remarks today at a Health Subcommittee Mark-up on H.R. 1876, Good Samaritan Health Professionals Act of 2017; H.R. 2026, Pharmaceutical Information Exchange Act; and H.R. __, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018:*

Thank you, Mr. Chairman. Today we are considering three health bills. One will expand protections for volunteer health professionals who provide their services during a national disaster. The second bill will expand manufacturer communication about unapproved drugs and devices. And the third bill will establish a user fee program for over-the-counter drugs while also modernizing the over-the-counter monograph system.

H.R. 1876, the Good Samaritan Health Professionals Act, would limit the civil liability of the volunteer health professionals that provide their services during disaster response. Our volunteer health professionals are a crucial resource in major disasters, which unfortunately are happening with greater and greater frequency due to climate change. Last year, the U.S. endured 16 separate weather and climate disasters with total costs to our economy of $306 billion, a new record for this country. I have reservations about preempting state laws and do not think Congress should ever do this lightly. However, with the growing frequency of natural disasters, I think we must do what we can as lawmakers to support medical volunteers at the federal level, and encourage volunteers to offer their services in future disasters.

H.R. 2026, the Pharmaceutical Information Exchange Act, would allow drug and device companies to communicate health care, economic and scientific information about their unapproved products as well as unapproved uses of their products with insurance companies and similar entities. This means that economic analyses or clinical studies of products never reviewed by the FDA could be freely discussed. As drafted, the FDA would be hamstrung to act against any inappropriate actions by the manufacturers because the legislation prohibits the FDA from considering this information exchange as false, misleading, misbranding, or a violation of law. This shielding of companies from such

misconduct could threaten patient safety. While I respect the interest of insurance companies and other similar entities to want greater information about drugs that are in FDA's review pipeline, this legislation has great potential to undermine FDA's approval process. It could also lead to the coverage of wholly unapproved drugs, something that I cannot support.

The Subcommittee is also considering the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018. This bill would reform the current OTC monograph process and would also establish an OTC monograph user-fee program. Reform holds the promise to provide FDA with increased, predictable resources that will allow the agency to streamline the current monograph process to allow for swift finalization of current monographs, timely safety updates, and encourage innovation where possible.

I am disappointed that we are not also considering legislation today that would address the FDA's authority over cosmetics. Today, the laws that regulate cosmetics sold in the U.S. are obsolete. They were enacted in the original Food, Drug and Cosmetic Act of 1938. While all other product categories regulated by the agency have been updated to keep pace with innovation and consumer expectations, the laws for cosmetics have been left untouched for nearly 80 years. That is simply unacceptable, and we really should be taking this opportunity to consider legislation to give FDA the authority and the resources to ensure cosmetics are safe for the American people. I look forward to discussing the need for cosmetic reform and hope to see this Committee address this issue soon.

Thank you – I yield back.

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