

Statement of Ranking Member Frank Pallone, Jr.
Committee on Energy and Commerce
Subcommittee on Health
Public Health Markup

February 4, 2015

Thank you, Chairman Pitts, for holding this markup on four important public health bills.

The Improving Regulatory Transparency for New Medical Therapies Act, would speed up Drug Enforcement Administration (DEA) decisions on scheduling of new FDA-approved drugs containing controlled substances, so that they could get to patients more quickly. It also would speed up the DEA registration process allowing the manufacture and distribution of controlled substances for use only in clinical trials. The bill aims to bring better reliability and transparency to breakthrough therapies, while continuing to ensure that they reach patients in need both safely and effectively. I want to thank Chairman Pitts for working with me on this bill last Congress, and committing to move forward early this Congress. Thank you to Mr. Green as well for joining us on this important bill.

The Ensuring Patient Access and Effective Drug Enforcement Act, would add two definitions to the Controlled Substances Act to better focus DEA's enforcement activities. It also would require DEA to provide registrants an opportunity to submit an action plan to correct any violations for which DEA is considering revoking or suspending their controlled substance registration. The goal of the bill is to help drug distributors, pharmacies, and others work with DEA to achieve the difficult balance between keeping controlled substance prescription drugs away from drug abusers but not from patients who need them. I thank Representatives Blackburn, Marino, Welch and Chu for introducing this legislation.

I know that Senators Whitehouse and Hatch are working to incorporate technical assistance they received from FDA and DEA on their melded version of these two bills. It is critical that the agencies responsible for implementing these programs have this input so that the intended policy goals we share are properly executed. I look forward to working with the Administration, the Senate and my House colleagues on a perfected version we can markup at full committee, after we pass these today.

We are also considering two bills reauthorizing a number of trauma programs. The Trauma Systems and Regionalization of Emergency Care Reauthorization Act, which passed the House last year, is aimed at planning and implementing trauma care systems in the States and establishing pilot projects for innovative models of regionalized trauma care. The second bill, the Access to Life-Saving Trauma Care for All Americans Act, reauthorizes two additional trauma programs that expire this year that aim to increase the availability of trauma services.

Traumatic injury is the leading cause of death for children and adults under the age of 45, and it is critical that States are equipped to deliver these medical services. But none of these programs have received funding during the appropriations process in recent years. I hope that

our consideration of these measures signals the importance of these programs to Members of Congress. I would like to thank Mr. Green and Mr. Burgess, who are both leaders on trauma care, for their work on these bills.

Many of these bills passed our Committee and the House last Congress with broad bipartisan support. I look forward to working with my colleagues to do the same this year.

Thank you.