

**Joseph R. Pitts**  
**Opening Statement**  
**Energy and Commerce Subcommittee on Health**  
**Markup of H.R. 4299, the Improving Regulatory Transparency for New**  
**Medical Therapies Act; H.R. 4709, the Ensuring Patient Access and Effective**  
**Drug Enforcement Act; and H.R. 4631, the Combating Autism**  
**Reauthorization Act**  
**May 28, 2014**

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

Today, we are considering three important, bipartisan bills:

- H.R. 4709, the Ensuring Patient Access and Effective Drug Enforcement Act, introduced by Reps. Marino, Blackburn, Welch, and Chu, which will facilitate greater collaboration between industry stakeholders and regulators in an effort to combat our nation's prescription drug abuse epidemic;
- H.R. 4631, the Combating Autism Reauthorization Act, introduced by Reps. Chris Smith and Doyle, which is important for all persons with an autism spectrum disorders and their families. In addition to reauthorizing existing provisions, the bill will require a study on the needs of autistic youth transitioning into adulthood and the available services to help them as adults. We have worked closely with our Senate colleagues to strengthen this bill and continue the important research to identify better prevention strategies, diagnostics, treatments, and even a cure; and
- H.R. 4299, the Improving Regulatory Transparency for New Medical Therapies Act, which I and Ranking Member Pallone introduced.

H.R. 4299 seeks to improve the transparency and consistency of DEA's scheduling of new FDA-approved drugs under the Controlled Substances Act (CSA), and its registration process for manufacturing controlled substances for use in clinical trials. Ultimately, this will allow new and innovative treatments to get to patients who desperately need them faster.

This Committee has worked diligently in the last several years to ensure that the FDA has the resources it needs to move new drugs more quickly through its approval process.

However, newly-approved drugs that contain substances that have not been previously marketed in the United States and that have abuse potential must also be scheduled under the CSA by the DEA before they can be marketed.

Unfortunately, under the CSA, there is no deadline for the DEA to make a scheduling decision, and the delays in DEA decisions have increased nearly five-fold since 2000.

This lack of predictability in the timing of DEA scheduling decisions leads to unnecessary uncertainty in the drug development process and needless delays in patients' access to new therapies.

H.R. 4299 simply requires DEA to issue an Interim Final Rule no later than 45 days after it receives FDA's scheduling recommendation for a new drug, allowing patients access to new therapies while still ensuring that appropriate controls are in place.

I would urge all of my colleagues to support these three bills, and I yield back the remainder of my time.

Thank you.