

Opening Statement of the Honorable Joseph R. Pitts
Subcommittee on Health
Hearing on “Improving Predictability and Transparency in DEA and FDA Regulation”
April 7, 2014

(As Prepared for Delivery)

Today’s legislative hearing focuses on three bills designed to improve the predictability and transparency in Drug Enforcement Administration (DEA) and Food and Drug Administration (FDA) regulation:

- H.R. 4069, the Ensuring Patient Access and Effective Drug Enforcement Act, introduced by Reps. Marino and Blackburn, will facilitate greater collaboration between industry stakeholders and regulators in an effort to combat our nation’s prescription drug abuse epidemic;
- H.R. 4250, the Sunscreen Innovation Act, introduced by Reps. Whitfield and Dingell, seeks to expedite the FDA’s approval process for active ingredients in sunscreens that have long been approved for use in places like Europe, Canada, and other countries to ensure that U.S. consumers have access to the safest, most effective sunscreens available; and
- H.R. 4299, the Improving Regulatory Transparency for New Medical Therapies Act, which Ranking Member Pallone and I introduced.

Mr. Pallone and I 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.

It now takes, on average, well over a billion dollars and 14 years from the time a drug is discovered to the time of approval. This Committee has taken steps to provide more transparency and consistency in the drug approval process through the Prescription Drug User Fee program and a commitment to review goals embedded in the PDUFA agreements.

However, 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 begin marketing their product.

But, 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 45 days after it receives FDA’s scheduling recommendation for a new drug, allowing patients access to new therapies 45 days after FDA approval.

The DEA would retain its authority to subsequently transfer the drug between schedules under the Section 201 of the CSA.

This bill also establishes a timeline for DEA to grant approval of manufacturers’ applications to register controlled substances, not yet approved by FDA, to be used in clinical trials, allowing companies to properly plan clinical trial schedules for prospective new therapies.

This provision will get products to the market faster because innovators will be able to get clinical trials underway in a timely and predictable way; which is critical to drug developers and patients alike.

H.R. 4299 requires that if the DEA has not made a final decision on whether to approve a registration application for products in the investigational new drug (IND) phase within 180 days of submission of the application, then the DEA shall provide notice to the applicant on the outstanding issues that must be resolved in order to reach a final decision, and, an estimated date on which a final decision on the registration application will be made.

Such a solution does not force the DEA to make a particular decision but will provide transparency to the process so companies can better plan when regulatory decisions will be made.

I would like to thank all of our witnesses for being here today, and I look forward to having a constructive discussion on these legislative proposals. These bills touch on very important issues for this committee and they offer an excellent starting point for finding solutions.

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