

Opening Statement of the Honorable Joseph R. Pitts
Subcommittee on Health
Hearing on “FDA User Fees 2012: Hearing on Issues Related to
Accelerated Approval, Medical Gas, Antibiotic Development and
Downstream Pharmaceutical Supply Chain”
March 8, 2012
(As prepared for delivery)

Today we are taking a more in-depth look at several issues related to the FDA user fee programs.

First, we will hear about FDA’s accelerated approval process for certain new drugs that treat serious or life-threatening illnesses and provide a greater therapeutic benefit over existing drugs and therapies.

Accelerated approval has been successful in speeding cancer and HIV/AIDS drugs to market, and I am particularly interested in how the process can be better utilized for rare diseases.

Earlier this week, Rep. Stearns, along with Reps. Bilbray and Towns, introduced the Faster Access to Specialized Treatments (FAST) Act to help expedite new drugs through the approval process.

We will also hear about FDA’s regulation of medical gas and the need for targeted regulations for these substances, due to their differences from most drugs.

Rep. Lance has introduced H.R. 2227, the Medical Gas Safety Act, which would reform the current FDA regulation of medical gases to create an appropriate process for medical gases to be approved.

It would also remove the current regulatory uncertainty for medical gases by establishing targeted regulations that take into account the unique characteristics of medical gases.

Rep. Lance’s bill is bipartisan and is cosponsored by members of the full committee from both sides of the aisle.

Next, we will address the lack of new antibiotics in the pipeline and how Congress and FDA can act to incentivize new antibiotic development.

Dr. Gingrey’s Generating Antibiotic Incentives Now Act, or the GAIN Act, H.R. 2182, targets this problem.

This bill would extend the exclusivity period for new prescription antibiotics and add an additional six-month period of exclusivity for a manufacturer if the new antibiotic identifies a companion diagnostic test.

The GAIN Act also has bipartisan support, including eight Democrats and 15 Republicans from the full committee.

Finally, the subcommittee will hear about the dangers and weaknesses to the current pharmaceutical supply chain – from manufacturers, to distributors, to pharmacies –

and how best to ensure that counterfeit, adulterated, or stolen drugs do not end up in the hands of patients.

Rep. Bilbray and Rep. Matheson are currently working in this area, and Dr. Cassidy's Online Pharmacy Safety Act, H.R. 4095, aims to educate the public about which internet pharmacies are known to be safe and legitimate.

I would like to thank our witnesses for being here, and I look forward to your testimony.

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