

Rep. Joseph R. Pitts
Opening Statement
Energy and Commerce Subcommittee on Health
Markup of FDA User Fee Bill
May 8, 2012

(As Prepared for Delivery)

Today we will markup the latest FDA user fee package discussion draft.

This draft is the product of over a year of hard work by various parties. While the individual industries – prescription drugs, medical devices, generic drugs, and biosimilars drugs – represented in this draft were negotiating with FDA on their user fee agreements, this subcommittee was holding at least ten hearings on subjects related to the draft.

After intense negotiation between both sides of the aisle, as late as this past weekend, we have arrived at a discussion draft that I hope all members of the subcommittee will be able to support.

There are still some outstanding issues that staff continues to work on, and I hope that they can be resolved before Thursday's full committee markup.

This package is critical to patients. It will ensure that FDA has the resources and reforms needed to speed new drugs, devices, and treatments to those who are ill.

Good-paying jobs in the drug and device industries, like those in my home state of Pennsylvania, will be critical to our economic recovery, and we can't afford to outsource them.

These user fee agreements will make the approval process more transparent, more consistent, and more predictable, benefitting patients, but also keeping the United States the preeminent leader in drug and device development and manufacturing.