Opening Statement of the Honorable Joseph R. Pitts
Subcommittee on Health
Hearing on the "Reauthorization of PDUFA: What It Means for Jobs, Innovation, and Patients"
February 1, 2012

(As Prepared for Delivery)

Today, we will discuss reauthorizations of the Prescription Drug User Fee Act (PDUFA), the Best Pharmaceuticals for Children Act (BPCA), and the Pediatric Research Equity Act (PREA), all of which expire September 30 of this year.

We will also discuss pharmaceutical supply chain issues.

PDUFA was first authorized by Congress in 1992 with the goal of expediting human drug applications through the FDA approval process.

Under the Act and its subsequent reauthorizations, the drug industry pays user fees to FDA, and FDA commits to meet certain performance goals.

I am pleased that the industry and FDA have reached an agreement for PDUFA V, and I look forward to hearing more of the details from our witnesses.

Under the agreement, industry would pay over $700 million in FY2013, and higher amounts in the remaining four years.

The PDUFA V agreement is designed to speed new drugs to patients awaiting treatments and cures, while ensuring the highest safety standards.

It is also designed to make the approval process more timely, predictable, and certain for drug sponsors and the venture capitalists who fund new drug research.

Among the highlights, the agreement increases the communication between FDA and drug sponsors, specifically building contacts and meetings into the regulatory review process.

To increase the efficiency and predictability of the review process, a new 60-day validation period will be used for FDA and drug sponsors to communicate, interact, and plan before the clock officially starts.

We are also here to discuss the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act.

BPCA gives FDA the authority to extend a six-month period of market exclusivity to a manufacturer in return for specific studies on pediatric use.

Under PREA, a manufacturer of a new drug or biologic is required to submit studies of a drug's safety and effectiveness when used by children.

Most prescription drugs have never been the subject of studies specifically designed to test their effects on children.

Yet, when no pediatric-approved drugs exist for an illness, doctors often prescribe these medications to children, relying on the safety and effectiveness demonstrated with adults, in the absence of clinical data on how the drug may work in a child.

As a father and grandfather, I view reauthorizing BPCA and PREA as a step toward obtaining that data and ensuring that our children and grandchildren receive the correct medications and correct dosages when they are ill.

We should not forget that Americans are the most innovative people on earth, and the United States leads the world in new drug development. Some four million jobs in the U.S. are directly or indirectly supported by the drug industry.

If the goals of the PDUFA V agreement are realized, we will continue to be the world leader in new, safe, and effective life-saving and life-enhancing drugs; American patients will have timely access to treatments and cures for everyday maladies, chronic illnesses, and terminal diseases; and we will keep good, well-paying jobs here in the U.S.

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