

**Opening Statement
Chairman Fred Upton
Subcommittee on Health Markup
Tuesday, May 8, 2012**

(As Prepared for Delivery)

Thank you, Chairman Pitts. I want to start by commending you for your tremendous leadership on this issue.

At the beginning of this user fee process, I set three basic goals. First, I expected the process to be bipartisan. Second, I wanted the user fee bill enacted by the end of June. Third, I believed the user fee bill needed to foster American innovation so we could help get new treatments to American patients and create jobs here at home. I am proud to report that we are on track to accomplish all three goals.

First, I want to thank Mr. Waxman, Mr. Pallone, Mr. Dingell and members on both sides of the committee for their bipartisanship through this process. The bill before us today is a reflection of their hard work and their willingness to put partisanship aside to look at issues together. Because of their hard work and dedication, the bill is much improved, which will help American patients and American innovators.

My second goal was to get this user fee bill enacted into law by the end of June. We are on track to accomplish this goal as well. The full committee will mark up this bill on Thursday, and I expect the bill to be on the floor this month. That will give us time to work with our good friends in the Senate to have this bill to the president before the 4th of July.

Finally, I want to this bill to foster American innovation, which is essential in getting new treatments to patients and creating American jobs. Because of the hard work of the committee members, I think we have done that. Let me highlight some of these provisions.

The user fee titles of the bill contain important metrics that will hold the FDA accountable for its performance. Because of the efforts of Mr. Barton, we will get FDA data down to the review division level and have the independent, third party assessments of FDA's performance for drug and devices written into the statute.

Due to the leadership of Mr. Rogers, Ms. Eshoo and Mr. Markey, Title V of the bill makes the Best Pharmaceuticals for Children Act and Pediatric Research Equity Act permanent. This will help in getting new therapies to our nation's children.

Through the efforts of Dr. Burgess and Mr. Guthrie, Title VI contains provisions that will significantly improve scientific exchange at FDA's advisory committees and ensure transparency and public input in the development FDA's guidance documents.

Title VII will significantly improve FDA's regulation of medical devices. Because of the hard work of Mr. Shimkus, we will fix the current problems with the investigational device exemption and the device modifications guidance. Fixing these problems will bring clinical trials back to the United States and reduce regulatory uncertainty and delay that is hurting American medical device innovators.

Title VIII will foster American innovation because of Dr. Gingrey's GAIN Act, Mr. Stearns and Mr. Towns' Fast Act, and Mr. Lance's medical gas bill.

Finally, Title IX will help our nation's patients, doctors, hospitals and nurses as they deal with drug shortages. I would like to thank Ms. DeGette, Mr. Walden, Dr. Gingrey, Mr. Bass and Mr. Latta for their leadership on this issue.

Thank you again for your leadership, Mr. Chairman. I yield back.