

**Opening Statement of Chairman Fred Upton  
Reviewing FDA's Implementation of FDASIA  
November 15, 2013**

Mr. Chairman, thank you for holding today's hearing on the implementation of the Food and Drug Administration Safety and Innovation Act. As many of you know, this was one of the committee's significant bipartisan achievements last Congress, and I thank Dr. Woodcock and Dr. Shuren for coming today to provide an update on implementation.

Last Congress, the committee held at least 10 hearings on subjects related to the legislation. At these hearings, we focused on improving the predictability, consistency and transparency of FDA's regulation of drugs and medical devices. Improving FDA regulation is essential to fostering innovation, which brings life-saving, life-improving drugs and medical devices to American patients and boosts job creation across the country, including southwest Michigan.

I am very proud of the bipartisan work we did last Congress, and I am pleased to hear that initial reports on implementation, especially at the Drug Center, are promising.

Today is an opportunity to get an update on whether FDA is meeting its commitments related to the various user fees we reauthorized, as well as the independent assessment of the device center. It also is a chance to hear about how FDA is implementing provisions related to rare diseases, drug shortages, prescription drug abuse, and drug imports. These were provisions important to Republicans and Democrats, and we look forward to working with FDA on these issues. Our drug and device makers are global leaders in innovation and job growth, and we will continue working to ensure that they remain on top.