

**Chairman Walden
Opening Statement
Energy and Commerce Subcommittee on Health Hearing
“Examining FDA’s Generic Drug and Biosimilar User Fee Programs”
March 2, 2017**

Thank you Chairman Burgess.

I can say without a doubt that this critically important FDA user fee reauthorization process is in good hands with you at the helm. I remember you leading the charge during the last reauthorization cycle in 2012 to push for a number of key process improvements at the agency that have directly benefited patients. This subcommittee hearing, and those that will follow starting later this month, are great opportunities to learn how we can build upon those efforts, as well as on the many game-changing provisions in the 21st Century Cures Act, which I am committed to ensuring is fully funded and implemented. A point I made clear to the President last month.

And, Chairman Burgess, you are exactly right that we are both committed to a timely user fee reauthorization and it is my goal, in working with the Senate, to move legislation through Congress and on to the President’s desk well in advance of the August recess. Committee staff has already hit the ground running and has been meeting frequently on a bipartisan basis with FDA and the industry negotiators to review the agreements and iron out technical issues with the legislative language.

Reauthorizing improved generic and biosimilar user fee programs will lead to timelier approvals and lower drug costs. It’s that simple.

I also want to take a minute to applaud my friend from Oregon, Rep. Schrader, and Rep. Bilirakis, for working together on pursuing additional ways to promote more generic competition, particularly in therapeutic areas where it is sorely lacking.

Thank you to Dr. Woodcock and her team at FDA, as well to the industry negotiators here today. I look forward to working with all of you in my capacity as Chairman going forward.

I yield back the balance of my time.