Opening Statement of Chairman Walden
Subcommittee on Health
"Modernizing FDA's Regulation of Over-the-Counter Drugs"
September 13, 2017

Thank you, Chairman Burgess, for holding this important hearing to consider long overdue reforms to FDA's inefficient and outdated framework for regulating over-the-counter (OTC) drug products.

Following the successful five-year reauthorization of several of FDA's critical medical device user fee programs, there is no better time to continue our work in this space.

From cough and cold medicines to antiperspirants and antacids, pharmacy aisles and medicine cabinets are filled with over-the-counter, or OTC, drugs that American consumers rely on daily. Unfortunately, the regulatory process in place at FDA has not been updated since the 1970s. As a result, there has been little to no innovation in this sector, and safety-related changes often take years to implement. This is simply unacceptable.

Fortunately, FDA, regulated industry, and patient and consumer groups all agree that significant reform is necessary. For several years

now, they have engaged in productive conversations about how to substantially improve upon the status quo. Informed by this ongoing dialogue, we have a bipartisan solution before us today that will ensure Americans have more timely access to innovative, safe and effective OTC medicines. Consumers will no longer have to wait years for an inflexible rulemaking process to wind its way through the bureaucracy before benefiting from product improvements.

I would like to thank my colleagues Bob Latta (R-OH), Diana DeGette (D-CO), Brett Guthrie (R-KY), Debbie Dingell (D-MI), as well as Chairman Burgess and Ranking Member Green for their hard work on getting us to this point. I look forward to hearing from our witnesses today about ways we can improve the draft legislation being considered and I yield the balance of my time to Rep. _____.