**Chairman Walden**
**Opening Statement**
**Energy and Commerce Subcommittee on Health Hearing**
**"Examining Improvements to the Regulation of Medical Technologies"**
**May 2, 2017**

Thank you Chairman Burgess.

As I have previously stated and will reaffirm today, the Energy and Commerce Committee is fully committed to a timely reauthorization of FDA's vitally important user fee programs. The good news is that we are well on our way.

The Health Subcommittee held hearings on each of the proposed agreements that were initially submitted to Congress in January. Since that time, we have translated those agreements into legislative language which the committee released with the Senate HELP committee several weeks ago.

As part of that release, I noted that as the legislative process proceeds I look forward to continued discussions with my colleagues in the House on other member priorities that could strengthen this important legislation.

Today's hearing is a great opportunity for us to learn more about four bipartisan medical device bills that could potentially be included.

H.R. 1652, the Over-the-Counter Hearing Aid Act, introduced by Reps. Kennedy, Carter, and Blackburn would require FDA to issue regulations establishing a category of OTC hearing aids for adults with perceived mild to moderate hearing loss. Both the President's Council of Advisors on Science and Technology and the National Academies have called for this approach. I understand that some patient

safety concerns have been raised and I look forward to hearing more about that from FDA and our witnesses on the second panel.

H.R. 2118, the Medical Device Servicing and Accountability Act, introduced by Reps. Costello and Peters, would require both original medical equipment manufacturers and third-party service providers to register with the FDA and submit adverse event reports. Several small businesses have raised concerns about the costs they would incur in registering. I am committed to ensuring patient safety while minimizing regulatory burden and look forward to learning more about this bill going forward.

H.R. 2009, the Fostering Innovation in Medical Imaging Act, also introduced by Reps. Costello and Peters would clarify FDA's regulation of imaging devices and contrast agents. This bill includes common-sense changes that would streamline the regulatory review of these important technologies.

Last but not least, Reps. Buschon, Brooks, Peters, and Butterfield have introduced H.R. 1736, which would improve FDA's risk-based approach for inspecting medical device manufacturing facilities both domestically and abroad.

Thank you to all of our witnesses for their testimony and I yield back the balance of my time.