Opening Statement of Republican Leader Greg Walden
Subcommittee on Health
"Improving Safety and Transparency in America's Food and Drugs"
January 29, 2020

As Prepared for Delivery

At today's hearing, we will have the opportunity to review legislation intended to improve the safety of medical products in the United States. We will also review several food-related policies. I briefly want to extend a special thanks to Dr. Doug Corey from Oregon's Second Congressional District for being here today. While it may seem tamer here in Congress than what he's used to seeing at the Pendleton Round-up back in Oregon, I can assure you we have our fair share of excitement here at these hearings. I appreciate Dr. Corey taking the time to testify and know his valued expertise will bring an important perspective to our discussions.

I am pleased that we will be considering four bipartisan priorities on the first panel that aim to improve the safety of America's drug supply, bring more transparency to the marketplace, and provide additional protection against the threat of counterfeit products.

H.R. 5663, the Safeguarding Therapeutics Act, would extend FDA's administrative destruction authority to medical devices. Under current law, FDA is authorized to destroy certain imported drugs that may pose a threat to the public health; however, this authority does not extend to medical devices, including some combination products. This legislation, introduced by Mr. Guthrie and Mr. Engel, would provide the Agency with an additional tool to protect American consumers against potentially dangerous, unapproved products.

Furthering our efforts to protect the country's medical product supply chain, we will also be considering H.R. 4866, the National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act. H.R. 4866, introduced by Chairman Pallone, would direct FDA to designate higher education institutions as National Centers of Excellence, allowing FDA to work with the centers and industry to create a national framework for the implementation of continuous manufacturing technology. At our October hearing on safeguarding the

pharmaceutical supply chain, Dr. Woodcock spoke at length about the potential advantages of continuous manufacturing, including the potential to reduce our dependence on foreign sources of active pharmaceutical ingredients, increase our manufacturing resiliency, and reduce quality issues that often trigger drug shortages. Given the potential for this technology, I am pleased we are considering this bipartisan legislation to further advance its development.

We will also be considering H.R. 5668, the MODERN Labeling Act, which allows FDA to require modifications be made to outdated labeling for generic drugs. Generic drugs are generally required to have the same labeling as the brand drug they reference, however once the brand drug is no longer on the market, the generic manufacturer is not able to update their label to reflect the most accurate and up-to-date information, often discovered through post-market use. The inability to update labeling can result in information gaps for providers and patients when discussing the most appropriate treatments. H.R. 5668 will help close those information gaps.

Additionally, we will consider H.R. 4712, the Fairness in Orphan Drug Exclusivity Act. This legislation will update the Orphan Drug Act to require drug manufacturers that receive an orphan drug designation under the cost-recovery provision of the Act to demonstrate that successor drugs eligible for the designation do not have a reasonable expectation of recouping their research and development costs. H.R. 4712 aims to balance the need to maintain existing incentives for orphan drug development, while eliminating loopholes that may allow a drug manufacturer to block competition.

I appreciate the majority's attention to these bipartisan proposals and hope that they will continue to work with us on bipartisan legislation, particularly initiatives focused on the reauthorization of critical programs set to expire at the end of this fiscal year. One of these programs is the rare pediatric priority review voucher program. Several members of this committee have already worked together, in a bipartisan manner, to introduce the Creating Hope Reauthorization Act, which

would extend this program, and I would ask that the Chairman consider its inclusion in a future hearing.

Finally, we will be considering several legislative initiatives intended to address FDA's regulation of foods. I have heard concerns from dairy and beef producers in my district related to standards of identity and I welcome the discussion on these matters today. However, I also have concerns that some of the bills being considered today may have unintended consequences and ignore the science-based approach FDA takes when regulating products under their jurisdiction.

I look forward to hearing from our witnesses and appreciate your time in being here today. I yield back.