

**Opening Statement of Chairman Greg Walden**  
**Subcommittee on Health**  
**Markup on H.R. 1222, H.R. 2410, and H.R. 2430, the FDA**  
**Reauthorization Act of 2017**  
**May 18, 2017**

*(As prepared for delivery)*

Today, we will markup three bills. Two are public health bills that received hearings last Congress and garnered strong bipartisan support. The other bill is the Food and Drug Administration Reauthorization Act of 2017, which I introduced earlier this week along with Ranking Member Pallone, Chairman Burgess and Ranking Member Green.

This legislation is critically important for patients, drug and device manufacturers, and the entire health care sector.

We've all read about medical innovations that once seemed like wishful thinking, coming to fruition. And at a recent hearing, the FDA told us that more advancements are on the horizon – but not without the legislation we will consider today.

Now that 21<sup>st</sup> Century Cures has become law, the FDA Reauthorization Act is more important than ever. We must continue to build on these successes and improvements for patients – delivering hope for new treatments and cures.

The FDA Reauthorization Act would reauthorize the agency's critically important drug and medical device user fee programs, making improvements to each of them based on lengthy deliberations involving FDA, industry, patient groups, and other stakeholders. These agreements were submitted to Congress in January, pursuant to a process laid out in statute, and we have been working on a bipartisan, bicameral basis since then to translate the agreements into legislative language, which was first circulated several weeks ago.

Under the leadership of Dr. Burgess, the Health Subcommittee has held multiple hearings for members to better understand how the updated and improved user fee programs will provide FDA with the tools it needs to ensure that patients have timely access to safe and effective new drugs and devices, including generics and biosimilars, which will increase competition and bring lower cost alternatives to the marketplace.

This subcommittee also examined additional medical device provisions, some of which have been updated and are before us today as amendments.

I fully support the agreements that are included in this legislation and, along with Chairman Alexander, remain committed to a timely reauthorization.

Let me be clear: if we do not have this bill to the President's desk in July, not only will thousands of FDA employees be seeking new employment, but desperately needed treatments and cures will not reach patients. We cannot – and will not – stand for that.

I do want to take a moment to thank my colleagues on both sides of the aisle for working on thoughtful ways to improve the legislation. I understand there will be several bipartisan amendments offered today and that there are a host of additional issues that will continue to be discussed and hopefully resolved by our full committee markup. I appreciate everyone's commitment to better this important bill.

In addition to the FDA Reauthorization Act, we are considering two public health bills that address two relatively common, but life-threatening diseases.

H.R. 2410, the Sickle Cell Disease Research, Surveillance, Prevention, and Treatment Act of 2017, sponsored by Rep. Danny Davis and Chairman Burgess, reauthorizes the Sickle Cell Disease Treatment

Demonstration Program. Sickle cell disease is red blood cell disorder that causes life-long illness. It is the single most common inherited blood disorder in the United States and yet still has no cure. Through research, surveillance, prevention, treatment, and enhanced collaboration with community-based organizations, this bill will help lead to better interventions, and eventually a cure to this debilitating disease.

Lastly, we are considering an amendment in the nature of a substitute to H.R. 1222, the Congenital Heart Futures Reauthorization Act of 2017, sponsored by Rep. Bilirakis. By improving the CDC's Congenital Heart Disease Surveillance System and enhancing biomedical research with respect to congenital heart disease, this legislation will help us better understand and improve long-term outcomes for children and adults with this condition.

I look forward to advancing these important bills and would like to thank the entire committee for its dedication to identifying important ways to help patients.