

**Opening Statement**  
**Health Subcommittee Chairman Michael C. Burgess, M.D., R-TX**  
**Subcommittee Markup**  
**May 18, 2017**

Today's markup of the Food and Drug Administration Reauthorization Act of 2017 is an important milestone in the work to reauthorize the FDA user fee programs. FDA began holding public meetings on these agreements in 2015, and Congress received FDA and industry's proposed commitment letters in January of this year. This subcommittee has held four legislative hearings on the substance of the bill, as well as several of the amendments we will consider today.

In other words, today's markup is just the latest step in nearly two years of work by the biopharmaceutical and medical device industry, the Food and Drug Administration, and Congress. It is a bipartisan and bicameral priority to complete this work and reauthorize the user fee programs in a timely manner.

In each of our hearings, we have heard about the tremendous success of the user fee programs in expanding access to affordable medications, supporting biomedical innovation, and maintaining high

standards at FDA for safety, efficacy, and quality. FDARA will build on these successes, as well as the achievements in 21<sup>st</sup> Century Cures, and ensure that FDA has the resources necessary to get medical treatments and cures to patients and health care providers as quickly as possible.

I want to thank Chairman Walden, Ranking Member Green, Ranking Member Pallone, and all members of the subcommittee for working in concert to improve the substance of this bill, and I look forward to sending it to the President's desk in short order.

In addition to FDARA, we will also be considering two important public health bills. Rep. Bilirakis has an amendment in the nature of a substitute to H.R. 1222; this bill will take several important steps to save and improve the lives of infants and adults affected by congenital heart disease.

Finally, I would like to speak in support of H.R. 2410, the "Sickle Cell Disease Research, Surveillance, Prevention, and Treatment Act of 2017". This bill, which was introduced by Representative Davis and me, would further our commitment to helping those with sickle cell disease by increasing our commitment to research, surveillance,

prevention, and treatment through federal collaboration with local and community-based entities.

Having cared for patients with sickle cell disease as a physician at Parkland Hospital, I've seen firsthand the devastating effect this disease can have on people. This bill provides an important step forward in ensuring that we have the resources to better understand this disease and to maintain access to services for those affected by sickle cell disease.

I would like to thank the members of our committee for the time and effort that they put into these bills, and I look forward to advancing them to the full committee.