Opening Statement of the Honorable Michael C. Burgess, M.D.
Subcommittee on Health
Markup on H.R. 1876, H.R. 2026, and H.R.__, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018
January 17, 2018

(As prepared for delivery)

Today, the Health Subcommittee will mark up three public health bills led by members of this committee. The policies within each of these bills exemplify our shared commitment to improve and strengthen public health policy for all Americans.

First, we will consider an amendment in the nature of a substitute to H.R. 1876, the Good Samaritan Health Professionals Act of 2017, which was introduced by Representative Blackburn. This bill seeks to ensure victims in federally declared disasters have access to medical care by providing limited civil liability protections to licensed healthcare professionals when they volunteer their services during such an event. It will address gaps in federal and state laws that have been developed to encourage volunteer action by healthcare professionals.

Next, the subcommittee continues its steadfast commitment to bring federal regulation into the modern era of medicine – from the 21st Century Cures Act to last year's FDA Reauthorization – by reviewing an amendment in the nature of a substitute to H.R. 2026, the Pharmaceutical Information Exchange Act of 2017. This legislation, authored by Health Subcommittee Vice Chairman Guthrie, will clarify how drug and medical device companies share healthcare economic or scientific information with certain entities responsible for coverage, reimbursement, or healthcare management decisions of drugs or medical devices if it is based on competent and reliable evidence.

As a physician, I know firsthand the importance of cutting-edge information in medicine and science to optimize patient care and

outcomes, particularly at a time when the Food and Drug Administration (FDA) is reviewing and approving innovative drugs, for example, around gene therapy. Ensuring that public and private payers and formulary review committees have access to reliable information related to investigational use of drugs or devices is critical and could have the potential to save patient lives or cure rare diseases.

Lastly, we will consider draft legislation authored by Representatives Latta, DeGette, Guthrie, Dingell, Green, and myself, the "Over-the Counter Monograph Safety, Innovation, and Reform Act of 2017." This bipartisan proposal establishes an over-the-counter (OTC) Monograph User Fee Program and makes a number of meaningful modifications to the way these products are brought to market, which has not been updated in more than 40 years. The goal is to create a system that is more flexible and more efficient, and encourages scientific innovations so that patients and consumers have greater access to better and safer OTC drug products.

I would like to thank the members of our committee for their contributions to these bills, and I look forward to advancing them to the full committee.