Opening Statement of the Honorable Michael C. Burgess, M.D.
Subcommittee on Health
Hearing on "Modernizing FDA's Regulation of Over-the-Counter Drugs"
September 13, 2017

(As prepared for delivery)

Today's hearing marks the Health Subcommittee's first public discussion on modernizing the current system at the U.S. Food and Drug Administration (FDA) to review, approve, and update over-the-counter (OTC) drugs. This hearing provides us and the American public with an opportunity to better understand FDA's regulatory framework to regulate OTC drugs and to consider a proposal to reform the OTC monograph system.

Today we will convene two panels of witnesses. First, I want to welcome Dr. Woodcock back to this Subcommittee this morning. Later, we will hear from representatives of other key stakeholders. I would like to commend all of their efforts throughout the negotiation process, and for offering their insights to Congress. Both the Energy and Commerce Health Subcommittee and the full committee have a strong record of bipartisanship on important public health issues, such as the 21st Century Cures Act and the FDA Reauthorization Act. I hope to add to that record with today's hearing.

OTC drug products treat a wide variety of ailments. Time and again, consumers seek antacids, pain relievers, eye drops, and cough products as first-line treatment options before going to see their doctor and getting a prescription. These products also include antibacterial soaps, hand sanitizers, and sunscreens commonly used by many families in the U.S. Currently, there are more than 300,000 OTC products on the market according to FDA. These products go through one of two approval processes to reach store shelves. Manufacturers can 1) submit a new drug application similar to new prescription drugs, or 2) conform to an OTC drug monograph, which is a set of specific standards created by FDA, that ensures the products' active ingredients are generally recognized as safe and effective.

The vast majority of OTC products rely on the OTC drug monograph system. Unfortunately, the current system has not had a significant update since FDA first established it in 1972 – that's over 40 years. In addition, this system requires a

burdensome, multi-step rule-making process that can take years to resolve. All of this has led to a lack of medical innovation, an inability for timely updates to address safety issues, and much work left unfinished at FDA. That is unacceptable. The good news is there is broad support from FDA, industry stakeholders, and patient groups for significant reform to regulate OTC products.

The Health Subcommittee will examine the "Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2017" discussion draft recently released by Representatives Latta, DeGette, Guthrie, Dingell, Green, and myself. This bipartisan proposal establishes the OTC Monograph User Fee Program and makes a number of meaningful modifications to the monograph process. The goal is to create a system that is more flexible and more efficient, and reflects the scientific innovations so that patients and consumers have greater access to better and safer OTC drug products.

I again want to welcome all of our witnesses and thank you for being here. I look forward to your testimony.