Chairman Michael C. Burgess, MD
Opening Statement
Energy and Commerce Subcommittee on Health Hearing
"Examining Implementation of the Compounding Quality Act"
January 30, 2018

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

Today's hearing marks the Health Subcommittee's first look at the Compounding Quality Act which passed under Title I of the Drug Quality and Security Act (DQSA) nearly five years ago. Before then, the last time Congress examined the drug compounding issue was in 1997 when it passed the Food and Drug Administration Modernization Act, touching upon the Food and Drug Administration's (FDA) authority to regulate compounded drugs and establishing section 503A in the Federal Food, Drug, and Cosmetics Act (FFDCA). However, the tragic outbreak of fungal meningitis in 2012, when the New England Compounding Center shipped over 17,000 contaminated vials of a compounded steroid medication throughout the country, resulted in one of the worst and most fatal drug safety incidents in U.S. history, where more than 750 people developed fungal infections in 20 states and over 60 people died subsequently. This outbreak prompted Congress to act, with the Energy and Commerce Committee taking the lead in the House through a series of investigations and hearings on the issue.

Today we will convene two panels of witnesses. First, I want to welcome Dr. Gottlieb, Commissioner of FDA, back to the Subcommittee this morning. The agency has been very active over the last several months on drug compounding, most recently releasing the 2018 Compounding Policy Priorities Plan. Your insights today are certainly appreciated.

Later, we will hear directly from representatives of pharmacies, physicians, patients, and manufacturers who will share their perspective of the implementation of Title I under DQSA thus far. We will also have a patient of the New England Compounding Center to share her personal story from the 2012 incident and her experience since that time. All of the testimonies from today's hearing are critical in our understanding of the compounding issue as FDA works to strike the proper balance that would continue to advance patient safety while ensuring patients' access to compounded medicines.

Being a physician who has worked with compounding pharmacists during my practice, I know the important role and value these individuals serve in the healthcare delivery system. Compounded drugs serve a unique need of patients that cannot utilize an FDA-approved product due to, for example, an allergy to one of the product's ingredients or the primary route of the product's administration. Because of the process involved in creating a compounded medication, we all

acknowledge the fact that proper oversight is necessary, whether by FDA or by a state's regulatory body, such as its board of pharmacy. Preventing poor compounding practices that can lead to contaminations or erroneous product strength, quality, and purity, is the goal we adhere to so that another New England Compounding Center does not happen again. Thinking back to that fungal meningitis outbreak, I was not only heartbroken by the patients' lives lost or harmed, but also troubled by what seemed as missed opportunities that could have prevented this tragedy.

Title I of DQSA accomplished two things. First, the law further clarified FDA's authority to regulate traditional pharmacy compounding practices under section 503A which saw several court challenges. Second, it added section 503B to FFDCA creating a new category of drug compounders know as outsourcing facilities. These outsourcing facilities engage in larger-scale, national distribution of sterile drugs in bulk quantities and thus have heightened statutory requirements, such as complying with current good manufacturing practices and being subject to certain registration, reporting, and inspection requirements.

Over the last four years, FDA has issued numerous draft and final guidance documents, proposed and final rules, and a draft memorandum of understanding (MOU) to implement the Title I provisions. There has been much discussion and

debate over the manner the agency has implemented Title I of DQSA. In my home state of Texas, there already exist in statute the framework and manner in which a compounding pharmacy should conduct its practice. Other stakeholders have also expressed concerns around "office-use" compounding and the prescription requirement. I hope these and other issues in the drug compounding space will be discussed today. So, I am encouraged by the interest of all of the stakeholders involved in this important debate – many of whom are represented here today – and the commitment of FDA to work with Congress in ensuring patients have access to products that are tailored to their clinical needs while also equipping agency officials with the requisite tools to protect public health.

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