

**Chairman Michael C. Burgess, MD**  
**Opening Statement**  
**Energy and Commerce Subcommittee on Health Hearing**  
**“Examining the Drug Supply Chain”**  
**December 13, 2017**

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

The multifaceted nature of the current U.S. drug supply chain system is complex and interwoven with multiple stakeholders involved in each step of the process. Improving access to life-saving treatments for consumers should be a non-partisan priority for all of us. Two weeks ago, the Health Subcommittee held a hearing on the implementation of the 21<sup>st</sup> Century Cures Act and heard testimonies from officials at the helm of the National Institutes of Health and the Food and Drug Administration about the law’s transformative impact on maintaining our nation’s global leadership in biomedical innovation. Built into that very concept is the expectation that innovative and breakthrough treatments will get developed, approved, and introduced into the therapeutic market to cure diseases or effectively manage chronic conditions, so people can lead healthier, fuller lives.

Today’s hearing will serve as an important educational opportunity to better understand the intricacies of our nation’s drug supply chain. To help us work

toward that goal, we will hear from a diverse group of representatives – ten to be exact – that represent the many facets of the supply chain process. I want to welcome each of you to the subcommittee this morning. It is my hope our discussion today is substantive and largely focused on the patients who are prescribed these medications because, at the end of the day, they are who matter most in this conversation.

Practicing medicine, I cared most about prescribing my patients a drug that was efficacious and safe without thinking too much about whether they would be able to fill their prescription at the pharmacy. Now, the conversation has shifted to a complicated back-and-forth between doctors, patients, insurance companies, and pharmacies about drug copays, prior authorizations, and drug formularies, among other things. Over the last few years, we have also learned about acquisitions and mergers within and amongst the various drug supply chain as companies seek out increased integration of their operations with an eye towards more efficiencies over the larger continuum of the system.

Prescription drugs continue to play a vital role in the United States health care system, from significantly improving patients' lives to producing health care savings through fewer hospitalizations and medical procedures. A patient's access

to prescription drugs is a key healthcare issue for Americans, and within that context is the debate over affordability.

Now, I also expect disagreement. But, while there are legitimate differences of opinion, I recognize that every participant here this morning does aspire to the common goal of saving lives and alleviating human suffering. And so out of these areas of disagreement – I hope to begin to identify areas of consensus so that we can begin delivering solutions to the problems identified this morning.

These stakeholders include pharmaceutical manufacturers that primarily research, develop, and produce brand-name and generic drugs, biologics, and biosimilars. These medicines treat a spectrum of diseases and conditions, such as allergies, infections, and hypertension to cancer, diabetes, and rheumatoid arthritis.

Next, pharmaceutical wholesalers purchase these drugs and store them in regional distribution centers for delivery points that include pharmacies, supermarket retailers, hospitals, physician groups, and other healthcare providers. Wholesalers also provide other ancillary services such as repackaging, consulting, inventory management, and patient discount programs.

Overall, pharmacy benefit managers (PBMs) manage prescription drug benefits on behalf of employer-sponsored health plans, health maintenance

organizations, state and federal health programs, including Medicare Part D and Medicaid managed care plans. PBMs impact the lives of 266 million insured Americans, with most them enrolled in private health plans. They have a special role in the drug supply chain that include determining payments and pricing for drugs, processing pharmacy drug claims, negotiating rebate and discounts from drug manufacturers, designing drug plan formularies, and operating mail-order and specialty pharmacies.

Retail pharmacies have a large neighborhood presence, representing large drug store chains, pharmacy departments in local supermarkets and big-box retailers, and independent (community) pharmacies that occupy a unique and essential role within the drug supply chain. Many drug stores contract with payers and PBMs to join health plan pharmacy networks; some larger pharmacy chains have also entered into joint ventures with PBMs and insurers.

Finally, private health insurance plans are likely recognized by most Americans to have a direct impact on their ability to access prescription drugs, largely due to the dictates of federal laws, such as the Affordable Care Act, on benefit requirements and out-of-pocket spending limits. They employ utilization controls to manage costs, such as multi-tiered drug formularies, step therapies, and prior authorizations for certain high-cost brand-name medicines.

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