Congressman Brett Guthrie
Health Subcommittee Hearing 9.14.23
Opening Statement
As Prepared for Delivery

Today's hearing is focused on the critical topic of finding long-term solutions to preventing future shortages of key drugs for patients. For months, cancer patients, including pediatric cancer patients, have had to scramble to find the drugs recommended or use alternatives because of instability in the markets and supply chains. In 2022 alone, there were 301 drugs in active shortages according to the University of Utah. For over a decade, professionals in the medical and regulatory community have sounded the alarm on the underlying economic causes of drug shortages.

Unforeseen circumstances, like a tornado hitting a pharmaceutical warehouse in North Carolina or a manufacturing facility in India shutting down due to quality concerns, can throw a supply chain out of whack and potentially lead to shortages of vital drugs, but what's key to the supply chain's long-term sustainability is the ability to which it can bounce back in a timely manner. To do so requires strong investments to ensure that there are multiple means to develop, store, and distribute drugs. And while we can't prevent natural disasters, we can help ensure that supply chains are robust enough to withstand these types of crises.

That's why the Energy and Commerce Committee is continuing extensive work to identify the drivers of what can cause a supply chain to be unstable and lead to the shortages we've seen over the last decade. This Congress alone, we've held an oversight hearing, heard testimony on shortages at a PAHPA hearing, the Chair submitted a request for proposals, all leading to the hearing today on potential solutions that span numerous federal agencies and payers. Through this work a key theme emerged - the fundamental economics of the generic drug market, specifically sterile injectable drugs, must be reformed, if we want a more stable pipeline of drugs and investment in quality and more domestic manufacturing.

Earlier this year, the New York Times wrote, in an article diving into the complex supply chain for generic drugs, that "there is a high cost to low prices". From there, the article dives into the frailty of supply chains that operate at low costs, with these low costs oftentimes being driven by artificially deflated prices from government programs like Medicare, Medicaid, and 340B. Even Commissioner Califf agrees economics are the main driver, which he publicly shared before this committee during a previous hearing.

That's why today we'll be considering a discussion draft from Chair Rodgers that aims to improve the systemic market failures of our drug supply chain. This discussion draft includes proposals to reform reimbursement rates for low-cost drugs and includes new ideas to ensure that the FDA is appropriately prioritizing and using regulatory discretion to help get more low-cost generics to market sooner.

It is also important to note that this is only a discussion draft, and I certainly expect there to be a healthy discussion among all members today on this draft and other proposals to address

the issue of supply chains and shortages. As such, we are also continuing to actively solicit stakeholder feedback given the complexities of the supply chain.

It's my hope nonetheless that after we've had our robust discussion that we'll be able to find common-sense, bipartisan solutions to shore up our generic drug market. Doing so will keep Americans healthy and protect our national security by making us less dependent on adversarial nations for medical needs in the event of future, unforeseen natural disasters and crises. I look forward to the discussion today and our continued work over to advance long-term policies designed to address this critical issue. Thank you, and I yield back.