Good morning, everyone and welcome to today's hearing before the Subcommittee on Oversight and Investigations.

This morning's hearing will be examining the very serious and growing problem of prescription drug shortages. Americans need better, more reliable access to life saving drugs. We've all seen the headlines about shortages of critical drugs. According to the American Society of Health System Pharmacists we currently have over 247 active drug shortages.[1] A recent Senate found that the number of active drugs shortages could be as high 295 and that between 2021 and 2022 new drug shortages increased by almost 30%.[2]

It is unbelievable that in our great country there is a shortage of drugs to treat childhood cancer. It's unbelievable that patients suffer because our healthcare system cannot figure out how to produce enough saline bags.

[1] https://www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=CurrentShortages&loginreturnUrl=SSOCheckOnly

[2] https://www.hsgac.senate.gov/wp-content/uploads/Drug-Shortages-HSGAC-Majority-Staff-Report-2023-03-22.pdf

It's even more galling when you consider that most shortages are in the generic drug space where there should be competition. The median price of drugs in shortage between 2013 and 2017 was less than 9 dollars per treatment dose. Generic drugs are a tremendous success story. They account for 90% of all prescriptions, but only 17% of drug spending. Generics are perhaps the only significant segment of our healthcare industry where costs haven't increased faster than inflation.

However, instead of the thriving industry you would expect with multiple drug manufacturers competing to deliver reliable, quality generics at the best possible price and a shortage is quickly met with new companies entering the market. The generic pharmaceutical industry is plagued with recurrent and prolonged shortages of key treatments. We have an economic environment so unappealing to manufacturers that life-saving drugs are produced by one, or at most, two companies worldwide, often at an unsustainable, artificially low price.

There is a broad consensus that the root cause of drug shortages is a profound market failure caused by economic forces unique to the drug

market. When a drug goes into shortage, its price should rise until other companies enter the market. In many instances the increase needed to entice a generic drug company to begin production is just a few cents, less than a dollar.

However, this isn't happening in the generic drug market. Instead, when a generic drug goes into shortage, the price stays the same. Companies that could start production stay out of the market. The drug remains in shortage for longer, perhaps indefinitely. The average drug shortage now lasts 1.5 years. There are more than 15 critical drug products that have been in shortage for more than a decade.[3]

Prices don't rise to alleviate shortages in large part because middlemen don't care about shortages. By one count, for every 100 dollars spent spent on a generic prescription drug 44 dollars go to middlemen.[4]

The three largest PBMs control around 80% of the commercial drug sales. The largest Group Purchasing Organizations control a huge

[3] https://www.hsgac.senate.gov/wp-content/uploads/Drug-Shortages-HSGAC-Majority-Staff-Report-2023-03-22.pdf
[4] https://healthpolicy.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/

percentage of all drug sales to healthcare providers. They have massive market power.

They could help end drug shortages by prioritizing generic drugs availability and quality. Instead, they use their market power to force "race to the bottom pricing" which pushes generic drug prices to unsustainable, artificially lows price.

The result is consolidation and offshoring. Over the past 10 years the United States has seen dozens of generic drug manufacturing facilities close. Thousands of good paying jobs lost. And the problem isn't limited to closings. We don't fully use the factories we have, as Professor Sardella's notes, we only use about half of our current generic manufacturing capacity.

We now have fewer manufacturing facilities both in the U.S. and globally and the supply chain is not only longer but more fragile. The typical generic drug has just two manufacturing facilities. Forty percent

(40%) are made at just a single facility.[5] Thus, even the temporary shutdown of a single facility triggers a shortage.

We are far too dependent on foreign countries for generic drugs and active pharmaceutical ingredients (API), especially India and China. Indian drug manufacturers have a long history of quality control problems and recalls. Our dependence on China represents a serious national security risk. China's new interpretation of its national security law may make FDA's already anemic inspection program in that country a crime.[6]

As we are holding this hearing, FDA Commissioner Califf is appearing before our Health Subcommittee. All too often his agency has made drug shortages worse and left us more vulnerable. The FDA's response to shortages is to waive through foreign made generics and API. The FDA is so focused on collecting information when it doesn't effectively use the information it already has. We need an FDA operates a robust foreign inspections program. We need an FDA that prioritizes

[5] https://www.fda.gov/media/131130/download
[6] https://www.wsj.com/articles/china-confirms-campaign-against-alleged-spying-by-foreign-consulting-companies-fef48e16; https://www.wsj.com/articles/china-locks-information-on-the-country-inside-a-black-box-9c039928

applications from U.S. manufacturers and to give companies the flexibly to address shortages with resources based here.

Solving drugs shortages is going to require an all of the above approach. We must rein in middlemen. We must figure out how U.S. based manufacturers can realize their full potential. Purchasers of generic drugs must incentivize quality and reliability in generic drugs.

And we must always keep in mind the human toll of drug shortages. I look forward to hearing from our witnesses today who are all working in innovative ways to help solve drug shortages. Thank you all for being here and I yield back.