Drug Shortage Health and National Security Risks:

Underlying Causes and Needed Reforms

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I would like to thank Chairman Peters, Ranking Member Paul, and the distinguished Members of the Committee for holding this hearing and for the privilege of speaking with you. My name is Dr. Andy Shuman, and I am a cancer surgeon and medical ethicist. I have a surgical practice and leadership roles at both the University of Michigan Hospital System and the Veterans Affairs Ann Arbor Healthcare System. Please note that I am not speaking on behalf of either institution today.

My personal experience with drug shortages began fifteen years ago during a routine surgical case. At the time, there was a national propofol shortage, an anesthetic we need to perform surgery, that required anesthesiologists to improvise how to keep patients safe and comfortable during their procedure. And you do not need to be a cancer surgeon to realize how important it is that patients remain asleep during their operation.

Since that first experience, colleagues and other hospitals have continuously asked me to help them respond to the never-ending game of drug shortage whack-a-mole. Hundreds of drug shortages affect our country each year. Drug shortages have wide-ranging, and at times, devastating consequences for patients. My goal for next few minutes is to share some examples from my experience trying to protect patients from the terrible consequences of not having access to the drugs they need.

Almost two million Americans are diagnosed with cancer each year. We are lucky enough to live in a country where cutting-edge research has massively reduced cancer-related deaths. But cancer drug shortages represent a tragedy happening in slow motion.

For example, etoposide is a cancer drug that has been on the market for over 40 years and typically costs less than $50 per vial. It is given to patients for nearly a dozen different types

of cancer. But in 2018 due to manufacturing delays, etoposide was on shortage at hospitals across the country. This left us in an awful position. Which of our patients with cancer should receive this potentially lifesaving drug? How can we prioritize between American lives? Should our limited vials go to an older woman who was just diagnosed with lung cancer? To a young man who had already been successfully taking it for his testicular cancer? Or a baby with neuroblastoma, an aggressive cancer for which this drug is part of the standard of care, but others might work too despite limited studies?

Our hospital, like other hospitals across the country, struggled to make these decisions based on the drug's projected availability, which patients were already under our care, and our best guess at how many new patients would be diagnosed in the coming weeks. We could not spread our limited supplies across all the patients that needed it. As a doctor who has devoted my life to fighting cancer, it is hard to express how horrible it is to face this kind of tragedy. In this case, after we offered the patients with lung and testicular cancer our limited supplies, a heroic pharmacist was able to scrape together enough etopocide from the bottom of the leftover vials to also treat our infant patient. But our pharmacists should not be desperately trying to squeeze out a few last drops when a life might be on the line.

Another ongoing shortage involves injectable anesthetic drugs such as lidocaine, which are used for everything from epidurals during labor, to dental procedures, to the cancer surgeries I perform every week. This shortage is one that has not received quite as much media attention because, in many cases, alternative drugs and doses are available. But often, these alternates require more clinical work, and increase the risk for errors. Many of these products come in a vial that is ready to use, but sometimes the alternative product may need to be made

by a pharmacist, or mixed right before use. We already have a shortage of nurses and supplies. For clinicians who are perpetually overworked and understaffed, these additional tasks also increase the risk of inadvertent errors in dosing or administration.

The role of geopolitics and our reliance on foreign products is a major cause of such drug shortages. For example, last year, a GE plant in Shanghai stopped making the contrast used for many radiology tests, literally threatening half of the country's supply, including that which VA hospitals relied upon. At that time, we had no idea how soon another shipment would come in or when the factory would reopen, leading to decisions such as whether to prioritize scans for cancer, or for heart disease. No American who proudly served our country should be told that they cannot have a necessary medical test because a single foreign factory stopped production.

While cancer patients not being able to get treatment is heartbreaking, drug shortages impact almost every field of medicine. For example, Senator Paul has dedicated his professional career to preserving and restoring his patients' vision. There are eyedrops that literally keep people from going blind that cost a few dollars a month. But these miracle drops are sometimes completely unavailable. Professional organizations of eye doctors have pleaded for help. Some patients with glaucoma require additional surgeries that would be avoidable if they had these drops. These patients also deserve better.

And I would be remiss not to bring up how the COVID pandemic has exacerbated drug shortages in our country. My colleagues and I have worked tirelessly over the past three years to take care of patients with COVID. We have also learned quite a bit about how to conserve and ration health resources, doing so equitably by making sure that that diverse patient

communities have access to the best care possible. We know that supporting clinicians in making tough decisions with clear objective criteria can help limit subjectivity and variance between doctors to ensure decisions are consistent and fair.

But all hospitals do not have access to the same resources. Michigan Medicine has multiple pharmacists focusing on predicting, mitigating and avoiding drug shortages. Some smaller hospitals are not so lucky. Patients should not have better access to scarce drugs than other people across the state purely based on which hospital they use, particularly because access is driven by differences in demographics and health disparities. This is why I and my team have studied how institutions across regions and states can better communicate about ongoing drug shortages, such as prioritization approaches, patient volumes, and existing supplies to *predict* drug shortages, and in so doing, better *prepare* for them. One key role for lawmakers is to improve drug shortage monitoring and information sharing nation-wide.

Information sharing is a critical component of health care emergency preparedness, where we often think of important resources in terms of staff, space and stuff. For example, in April 2020, we desperately tried to make sure we had enough ventilators and were relieved when we believed we had secured a sufficient supply. But a ventilator is just an expensive metal box if we do not have enough respiratory therapists to operate it. At Michigan Medicine, we had to train our medical students to help use the ventilators when we ran out of respiratory therapists. And, even if we have enough ventilators and the personnel, we still need enough hospital beds, which remain in short supply even today. Finally, the patient on the ventilator needs the proper medications to keep them sedated and comfortable … ironically the same medication, propofol, that began my passion for fighting drug shortages so many years ago.

We know what causes drug shortages. FDA issued a roadmap in 2019 demonstrating the root causes and potential solutions to this problem. This Committee issued a detailed report as well. Americans are too dependent upon drugs and drug precursors from abroad. We need to diversify where these supplies come from, including increasing production on American soil. If there are shortages, we need companies to disclose the reasons why – otherwise we will not know where to focus resources. In addition, drug pricing structures are not always reflective of their value to patients. We should incentivize and/or subsidize companies to make high-quality, critical-need drugs like the ones I have mentioned, even if they have been less profitable. My fellow witnesses today are experts in the supply side and pharmacy approaches, and I welcome their further wisdom and advice.

We can all agree that sick Americans deserve access to life-saving medications. Telling someone with cancer that they cannot receive a drug that was developed during the Johnson administration and costs less than my Uber ride from the airport is not acceptable. I thank the Committee for highlighting this critical issue and the importance of finding creative legislative solutions.