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MADE IN AMERICA: STRENGTHENING DOMESTIC MANUFACTURING AND OUR HEALTH CARE SUPPLY CHAIN

WEDNESDAY, JUNE 11, 2025

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:02 a.m., in Room 2123, Rayburn House Office Building, Hon. Earl L. Carter [chairman of the subcommittee] presiding.

Present: Representatives Carter of Georgia, Griffith, Bilirakis, Dunn, Crenshaw, Joyce, Balderson, Harshbarger, Miller-Meeks, Cammack, Obernolte, James, Bentz, Houchin, Langworthy, Kean, Guthrie (ex officio), DeGette, Ruiz, Dingell, Kelly, Barragan, Schrier, Veasey, Fletcher, Ocasio-Cortez, Auchincloss, Carter of Louisiana, Landsman, and Pallone (ex officio).

Staff Present: Jessica Donlon, General Counsel; Sydney Greene, Director, Finance and Logistics; Jay Gulshen, Chief Counsel, Health; Emily Hale, Staff Assistant; Annabelle Huffman, Clerk,

Health; Megan Jackson, Staff Director; Sophie Khanahmadi, Deputy Staff Director; Brayden Lacefield, Special Assistant;; Molly Lolli, Counsel, Health; Sarah Meier, Counsel and Parliamentarian; Joel Miller, Chief Counsel; Jake Riith, Staff Assistant; Jackson Rudden, Staff Assistant; Chris Sarley, Member Services/Stakeholder Director; Emma Schultheis, Policy Analyst, Health; Matt VanHyfte, Communications Director; Katie West, Press Secretary; Lydia Abma, Minority Policy Analyst; Sam Avila, Minority Health Fellow; Jacquelyn Bolen, Minority Counsel, Health; Keegan Cardman, Minority Staff Assistant; Waverly Gordon, Minority Deputy Staff Director and General Counsel; Tiffany Guarascio, Minority Staff Director; Una Lee Minority Chief Counsel, Health; and Destiny Sheppard, Minority Intern.

Mr. Carter of Georgia. The subcommittee will come to order. The chair recognizes himself for 5 minutes for an opening statement.

Welcome, everyone.

Today's hearing is critical in addressing our Nation's reliance on adversarial countries for essential medications and healthcare products. This dependence not only jeopardizes our national security and patient safety, but also highlights the urgent need to increase domestic and friend-shored manufacturing.

Let me be clear: The United States should never be dependent on the Chinese Communist Party for the antibiotics and essential medicines. But that is exactly the dangerous position we are in today.

In 2002, the United States manufactured 72 percent of the pharmaceuticals it consumed. By 2023, that number had dropped to just 37.5 percent. We didn't just outsource manufacturing -- we outsourced the sovereignty and safety of our healthcare system.

We saw the impacts of this reliance firsthand during the COVID-19 pandemic. According to a conversation I had with the Administrator for Strategic Preparedness and Response, our ASPR, under the Trump administration the United States saw a downtick in the amount of PPE and pharmaceuticals coming to our country from China in the fall of 2019 -- in the fall of 2019. We didn't learn about COVID until January of 2020. They knew what was going on. They started hoarding this stuff and not sending it to us.

China knew there was an unidentified sickness in its own country. They concealed it, and then they withheld medical supplies so the United States was less prepared when COVID-19 hit our shores.

As both a pharmacist and a Member of Congress, I know how critical these medicines and supplies are, especially for our national security. Under the Biden-Harris administration, over 323 drugs were in shortage during the first quarter of 2024, an all-time high, and cancer patients were often forced to switch treatments, adjust dosage regimens, or, in extreme cases, unable to receive their life-saving medications. There was no comprehensive effort to support American manufacturers or reduce our reliance on foreign supply chains.

That is simply unacceptable.

Thankfully, President Trump is taking meaningful action by demanding real investment in our domestic production base and putting it into decades of failed "America Last" policies that left our supply chains hollowed out and put our patients, constituents, and families at risk.

Under the leadership of President Trump, we are bringing manufacturing back to America. Since the start of this year, the start of President Trump's second term, Johnson & Johnson broke ground on a new $2 billion facility in North Carolina, Amgen announced a $900 million manufacturing expansion in Ohio, AbbVie committed $10 billion to invest in the United States, and Sanofi announced plans to invest at least $20 billion.

And these are just a few examples. This is just the start.

I look forward to hearing from my other colleagues about the recent investments in their districts and States during this hearing today, and I am thrilled to see what additional investments continue to flow and thrive under an administration focused on unleashing innovation and bringing capacities back home.

Along those lines, I commend recent efforts by this administration to bolster domestic production. But we must do our part in Congress as well.

This hearing will make it clear that more can be done to eliminate burdensome regulatory barriers, streamline processes that impede our competitiveness on the global stage, and establish the proper incentives to ensure we are creating the environment to allow innovation to flourish.

It is no coincidence that Georgia, my home State, the number one State in the Nation to do business, is home to Manus Bio, which has invested nearly $60 million and created over 100 jobs with the acquisition of a new manufacturing facility in Augusta. We need more policies at the Federal level that mirror the pro-growth examples we have in the State of Georgia.

That is why House Republicans passed the One Big Beautiful Bill Act, which incentivizes domestic medical supply production by rewarding companies that build their products in America, like USAntibiotics, who is the last remaining end-to-end domestic U.S. manufacturer of amoxicillin, the most prescribed antibiotic in the country.

This is about protecting American lives, empowering American workers, restoring American sovereignty, and reenforcing U.S. leadership in medical innovation.

China is not our friend. Ladies and gentlemen, China is not our friend. Every product component that then turns into a vial of medicine or a piece of medical equipment that is made in China is a missed opportunity to strengthen our economy and protect our people.

It is time to act. We need to view pharmaceutical and healthcare supply chain independence just as we are viewing energy independence.

I am proud to stand with President Trump and all those committed to putting America first in our healthcare system, starting with the medicines we rely on every day.

I now recognize the gentlelady from Colorado, Representative DeGette, for 5 minutes for an opening statement.

[The prepared statement of Mr. Carter of Georgia follows:]

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Ms. DeGette. Thank you so much, Mr. Chairman.

I do agree with you that China is not our friend. But, however, it is hard to take this administration seriously on this issue when they are firing hardworking public servants who support generic drug approvals, facility inspections, and initiatives that help companies make products in America because that will just cause a longer delay.

I do want to say the COVID-19 pandemic laid bare the challenges of our medical supply chain, but, unfortunately, Mr. Chairman, as you mentioned, our reliance on foreign supply chains for critical medical products has been a problem for decades, as you said, much longer since 2020.

We have a system that is great at producing cheap generic drugs and basic supplies, but we do not have a system that is great at encouraging a resilient supply chain that we can always count on.

I believe everybody in this room wants to be serious and come up with serious solutions to a ensure secure, reliable medical supply chain.

During the COVID pandemic, everybody in the world needed the same products at the same time, and manufacturing was severely disrupted. The problems with COVID put this problem into sharp relief because there were too many single points of failure, there was an inability to quickly shift manufacturing to critical products, and, as you said, there was an overreliance on unreliable foreign countries among them. That has all been long simmering.

So I think it is past time we work together to stop the endless cycle of shortages of critical medicines and ensure that we will have a reliable supply of medical products.

This committee considered legislation last Congress to address the supply chain and how it relates to drug shortages. This includes legislation from the former chairwoman of this

subcommittee, my predecessor, Anna Eshoo, to ensure that we better understand where the active ingredients for these drugs are coming from.

The bill, the Drug Origin Transparency Act, is so important because only 12 percent of active pharmaceutical ingredients globally are made in the United States.

We also, of course, need to reauthorize the Pandemic and All-Hazards Preparedness Act, one of the major tools we have to invest domestically in medical countermeasures.

Some PAHPA-authorized programs, like the Biomedical Advanced Research and Development Agency, have made it possible for innovative manufacturers to help the American people prepare for public health emergencies.

And I know I have friends on the other side of the aisle who are working very closely to try to get this PAHPA reauthorization into this committee for hearing and markup and onto the floor.

And the Strategic National Stockpile can be used to help support domestic manufacturers and secure the supply chain by focusing on resiliency.

Our hospitals can also be part of the solution. Hospitals are major medical supply purchasers, and they need to be at the table to encourage and reward domestic production and secure supply chains.

But, frankly, as I mentioned, I am troubled by the discordance between this committee's other work this Congress and our work today on supply chains. For example, the more we squeeze hospitals, particularly rural hospitals, the less they will be able to do to spend a few extra dollars on buy American.

If we kick off millions of people from Medicaid under the Republicans' reconciliation bill, that will result in an additional $42.4 billion in hospital uncompensated care costs in 2034.

Let me say that again. If this bill actually passed the way it passed from this committee in the House, there would be an additional $42.4 billion in hospital uncompensated care costs in 2034. That would translate into hundreds of billions of dollars of care hospitals will have to swallow in the next 10 years.

I don't think that that is going to make hospital procurement offices more able to consider the source of the antibiotics they are buying. Instead, what it does is it makes them even more likely to go with the cheapest option regardless of where it came from or any downstream consequences.

So I implore my Republican colleagues to consider all of the consequences of their Medicaid cuts, not just throwing 16 million, or however many, people off of healthcare.

A resilient supply chain will become less popular as we squeeze care for hardworking Americans, and especially rural and otherwise underresourced hospitals that provide us with that care.

So I want to thank you again, Mr. Chairman, for having this hearing. And I will yield back.

[The prepared statement of Ms. DeGette follows:]

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Mr. Carter of Georgia. The gentlelady yields.

The chair now recognizes the chairman of the full committee, Chairman Guthrie, for 5 minutes for an opening statement.

The Chair. Thank you, Chairman Carter and Ranking Member DeGette, for this hearing.

I appreciate all the witnesses for being here today.

During this hearing, we will be hearing from expert witnesses regarding the current state of our supply chain and opportunities and challenges to strengthen our domestic manufacturing capacities and infrastructure.

Efforts to bring capacity back home to the United States are critical to protecting our national security as well as ensuring access to safe, secure, and reliable medicines and healthcare products for Americans.

Over the years countries like India and China have continued to grow more influential in research, development, and manufacturing of medical products. Globally, this has led many countries, including the United States, to be reliant on international sources for the production of certain medicines and other health products and supplies.

The reasons for this evolution are incredibly complex, involving both workforce and development and manufacturing cost considerations, differing incentive structures, strategic location selections, operational risk, as well as associated regulatory burdens or corresponding flexibility, just to name a few.

While the reasons are complex, the staggering reality that our current domestic supply chain is largely reliant on international forces is remarkably clear and one that we must address.

According to recent data, about half of all the APIs, or Active Pharmaceutical Ingredients, for prescription medicines in the U.S. come from India and the European Union. In addition, India controls the majority of production volume for most oral tablets and capsules.

Meanwhile, China is an exclusive manufacturer of certain APIs and essential medicines, while remaining a dominant supplier of key starting materials, the pieces of the puzzle that often go to contribute to API.

Thus, it is fair to say the U.S. remains reliant on several international partners for many, varied pieces of the supply chain that eventually come together to produce the products that land in our medicine cabinets, our doctors' offices, and are used in our hospitals.

Our healthcare supply chain involves many components and important players, from the groundbreaking research to the raw material suppliers, product manufacturers and distributors and purchasers, all the way to the patient.

We look forward to hearing from the experts in front of us today to provide their perspective and shed light on the nuances of this supply chain and the role their entities play, shed light on vulnerabilities, and discuss possible opportunities and solutions.

With decreased reliance on China and other nations, we can help to foster a more sustainable, resilient, and predictable healthcare supply chain, bolstering our domestic manufacturing and promoting the safety of our medicines and the security of our country.

It is important to remember the national advancements in medicine already being made right here at home. For example, from 2018 to 2022, the biopharmaceutical industry increased capital investments in their facilities, equipment, and infrastructure by more than 72 percent, more than $126 billion towards U.S. advanced manufacturing.

To put this into perspective, the only industry who exceeded this was motor vehicles.

In terms of innovation, the biopharmaceutical industry increased their research and development by more than 58 percent at the same time.

In fact, 46 percent of the 643 novel drugs that have been approved globally over the last decade are as a result of American companies' involvement in the discovery, patent, or clinical research process. This is twice as much as Europe.

I look forward to hopefully hearing more about some of these district stories from members of the committee as well as our witnesses, and I look forward to having our witnesses testify today.

And I yield back.

[The prepared statement of The Chair follows:]

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Mr. Dunn. [Presiding.] Thank you.

I now recognize the ranking member of the full committee, Mr. Pallone, for 5 minutes for an opening statement.

Mr. Pallone. Thank you, Mr. Chairman.

Today committee Republicans want to discuss healthcare supply chains while the Trump administration is unleashing chaos and harm on our public health infrastructure.

The latest dangerous action by this administration came on Monday when Secretary Kennedy fired all 17 medical experts of the Advisory Committee for Immunization Practices, the committee that advises our Nation on immunization practices.

This action puts the health and well-being of the American people, especially our Nation's children, at extreme risk. It undermines vaccine safety and politicizes research and also politicizes science. And it is all being done so RFK, Jr., can stack the panel with a bunch of anti-vaccine people.

And also on Monday, 342 of the top scientists at the National Institutes of Health signed a letter to the NIH Director detailing unprecedented waste, abuse, and illegality at NIH under the Trump administration.

The letter also addresses the harmful consequences of these actions on our Nation's ability to improve and save lives through scientific breakthroughs.

This was really an unprecedented action by these employees who must feel they have no other options at this point than to go public.

Now, each of these actions warrants a hearing here in this committee, and yet Republicans on the committee remain silent, blindly following the Trump administration as it decimates our public health infrastructure.

This committee has yet to hear from the Secretary of HHS. We have yet to hear from the NIH Director. I know Republicans plan a budget hearing with Secretary Kennedy later this month, but he has caused so much destruction at HHS already that one hearing focused on the budget is not going to be sufficient. He must answer separately for the dangerous actions he has taken to undermine vaccines.

And rather than demanding answers of this administration, congressional Republicans are plowing ahead with their Big Ugly Bill that rips healthcare away from 16 million people so they can give giant tax breaks to billionaires.

Committee Republicans want to talk about strengthening domestic manufacturing and the healthcare supply chain. However, it is difficult to have a discussion about the supply chain without acknowledging the disruption, confusion, and uncertainty that the Trump tariff policies have caused, as well as the deep budget cuts the administration has proposed to the FDA.

I don't understand how congressional Republicans intend to square their desire to onshore manufacturing and bolster the domestic supply chain while eliminating nearly 2,000 jobs at FDA and proposing an 11 percent budget cut.

FDA employees are the ones who inspect foreign and domestic manufacturing facilities, approve branded and generic drugs, and ensure that medical products are safe and accessible for the people who rely on them. FDA staff have said the layoffs have resulted in drug safety work being stalled and inspections falling behind.

And that is the hearing we should be having. We should be conducting robust oversight on the implications of these actions, what it means in the short term for preparedness and response, what it means in the long term for American innovation and our ability to lead on a global scale. Both are threatened under the Trump administration's policies.

And if Republicans are really interested in strengthening domestic manufacturing and the healthcare supply chain, they would work with Democrats to ensure FDA has the resources and authorities it needs to ensure the medical products Americans rely on are safe, effective, and available.

FDA needs additional tools, resources, and authorities, not less, to address drug shortages and strengthen the supply chain.

Now, last Congress, Democrats put forward several bills that would bring greater transparency and resiliency to the supply chain, but Republicans refused to act on them. They also walked away from a bipartisan reauthorization of the Pandemic and All-Hazards Preparedness Act after Elon Musk blasted the overall package it was included in.

There is a lot of work to be done here, Mr. Chairman, to protect our supply chain, mitigate drug shortages, and ensure we are better prepared for the next pandemic.

However, unless and until the Trump administration chooses to end its dangerous crusade against public health, against biomedical research and vaccines, it is not possible to do the things that supposedly this hearing is about with the supply chain.

It is time that the administration and Republicans understand that these policies and solutions are all intertwined. You can't separate them. You can't talk about the supply chain and mitigating drug shortages and at the same time fire people at FDA, limit the resources that go to FDA, and all the other chaos that this administration is creating.

And with that, I yield back the balance of my time, Mr. Chairman.

[The prepared statement of Mr. Pallone follows:]

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Mr. Dunn. This concludes member opening statements. The chair would like to remind members that, pursuant to committee rules, all members' opening statements will be made part of the record.

We want to thank all of our witnesses for being here today and taking time to testify before the subcommittee.

Our witnesses today are Mr. Patrick Cashman, President, USAntibiotics; Mr. John Murphy, President and Chief Executive Officer of the Association for Accessible Medicines; Dr. Ronald T. Piervincenzi, Chief Executive Officer, United States Pharmacopeia; Ms. Dawn O'Connell, former Assistant Secretary for Preparedness and Response; and Mr. Josh Bolin, Associate Executive Director, Government Affairs and Innovation, of the National Association of Boards of Pharmacy.

Per committee custom, each witness will have the opportunity for a 5-minute opening statement, followed by a round of questions from members. The light on the timer in front of you will turn from green to yellow when you have 1 minute left.

I now recognize Mr. Patrick Cashman for 5 minutes to give an opening statement.

STATEMENTS OF MR. PATRICK CASHMAN, PRESIDENT, USANTIBIOTICS; MR. JOHN MURPHY III, PRESIDENT AND CHIEF EXECUTIVE OFFICER, ASSOCIATION FOR ACCESSIBLE MEDICINES (MINORITY); DR. RONALD T. PIERVINCENZI, PH.D., CHIEF EXECUTIVE OFFICER, UNITED STATES PHARAMACOPEIA; MS. DAWN O'CONNELL, FORMER ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE (MINORITY); AND MR. JOSH BOLIN, ASSOCIATE EXECUTIVE DIRECTOR, GOVERNMENT AFFAIRS AND INNOVATION, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

STATEMENT OF PATRICK CASHMAN

Mr. Cashman. Chairman Carter, Ranking Member DeGette, distinguished members of the subcommittee, thank you for the opportunity to speak today. My name is Patrick Cashman. I serve as President of Bristol, Tennessee-based USAntibiotics, which is the last remaining end-to-end U.S. manufacturer of amoxicillin.

The facility I lead has supplied life-saving medicine to American patients for more than 40 years. Until 2008, every U.S. prescription of amoxicillin was produced at our Bristol plant. But after years of escalating subsidized competition from Indian and Chinese generic drugmakers, the facility's previous owners filed for bankruptcy in 2020. By the time our production lines went dark that year, the U.S. had become entirely reliant on foreign-origin amoxicillin.

In 2021, USAntibiotics was rescued from bankruptcy by private American investors who recognized the national security imperative of antibiotic production. Since then, we have created new jobs, invested tens of millions of private capital into reactivating production lines, and reentered the commercial market.

I feel privileged to play a role in this important story, and I look forward to sharing more with you about our experience.

Without antibiotics, routine surgeries and common infections can become fatal. Our Nation's health security, military readiness, and emergency preparedness all hinge on reliable antibiotic access.

Amoxicillin alone accounts for approximately 50 million U.S. prescriptions annually, making it the most prescribed antibiotic. After dropping to zero in market share in 2020, USAntibiotics now has about 5 percent market share.

If our facility were to shut down permanently, it would take no less than 5 years and hundreds of millions of dollars to construct a new facility capable of producing amoxicillin. That would be at least half a decade in which the U.S. would be entirely reliant on other countries for the most commonly prescribed antibiotic.

Our company and other U.S. generic drugmakers like us face three primary challenges.

One, unfair foreign subsidies, labor practices, and lax regulatory oversight. One 2022 study found that a lack of Chinese and Indian regulatory enforcement allows their drugmakers to cut as much as 25 percent off their cost.

Two, a lack of long-term government purchasing commitment. Most buyers prioritize cost over reliability or origin. Unlike defense contractors, which often operate under multiyear contracts, U.S. drugmakers of critical generic medicines are vulnerable to market fluctuations.

Three, a lack of recognition for critical drugs' national security relevance. Generic antibiotics are not treated as strategic assets like weapon systems or critical minerals. This means manufacturers cannot access all of the same financing tools, tax incentives, or industrial base support programs available to other domestic producers of critical goods.

Today, my colleagues in Bristol will manufacture approximately 700,000 doses of amoxicillin before their shift ends, but we operate on razor thin margins. Despite our strategic importance, we receive no Federal subsidies, Federal prime contracts, or protection from predatory pricing.

Since January 2023, the U.S. Government has spent $900,000 on USAntibiotics products through the Federal Supply Schedule system. However, during roughly the same period, HHS spent approximately $40 million to purchase foreign-origin amoxicillin for the Strategic National Stockpile.

To ensure the U.S. is never again dependent on China and India for amoxicillin, I humbly submit four policy recommendations for your consideration:

One, incentivize long-term purchasing agreements. To establish predictable demand companies like USAntibiotics require to scale and grow, encourage Federal agencies to enter a multiyear contract with domestic producers of essential medicines.

Two, implement domestic preference policies. The U.S. Government should establish a buy American requirement for antibiotics purchased with Federal funds when a U.S. manufacturer exists.

Three, create a strategic antibiotic manufacturing fund. Provide targeted grants, low-interest loans, and tax incentives to companies investing in domestic production.

Four, enforce trade rules to counter predatory pricing. The Department of Commerce and USTR should leverage existing authorities to penalize unfair trade practices in the antibiotic sector.

We support the ongoing Section 232 investigation regarding national security effects of imports of pharmaceuticals and pharmaceutical ingredients.

USAntibiotics stands ready to play its part to secure the U.S. antibiotic supply chain for the 21st century. We have the infrastructure and we have the expertise. But we need this Congress to act.

Thank you for the opportunity to testify. I look forward to your questions.

[The prepared statement of Mr. Cashman follows:]

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Mr. Carter of Georgia. [Presiding.] Thank you, Mr. Cashman.

The chair now recognizes Mr. John Murphy III for 5 minutes to give an opening statement.

STATEMENT OF JOHN MURPHY III

Mr. Murphy. Chairman Carter, Ranking Member DeGette, members of the subcommittee, thank you for inviting me to discuss how we can strengthen domestic pharmaceutical manufacturing and secure our supply chain.

My name is John Murphy, President and CEO of the Association for Accessible Medicines. We represent the companies that supply more than 90 percent of U.S. prescriptions to American patients while accounting for just over 13 percent of total U.S. drug spending.

American families depend on affordable generic and biosimilar medicines. Yet the supply chain that delivers these medicines is under increasing pressure and in some parts is already fracturing.

The total value of sales of generic and biosimilar medicines has stagnated for more than a decade and the economic footprint of U.S. generics has shrunk by $6.5 billion over the past 5 years despite growth in volume and the availability of many new medicines.

Production has increasingly evolved globally due to the competing economies seeking to bolster their own health security and access and the declining incentive structures and reimbursement potential here in the United States.

To be more specific, four key challenges face our industry and its growth in the United States.

We have no comprehensive national strategy or real incentives for production. The CHIPS Act, as an example, incentivized domestic manufacturing of semiconductors and showed what a bold industrial policy looks like.

Reimbursement policies continue to underprice essential drugs. For sterile injectables in particular, a race to the bottom competitive environment drives prices for indispensable medicines below sustainable levels and often rewards higher price brands over generics.

We have labor shortages. According to a recent HHS-sponsored report, the U.S. faces a shortage of workers with the requisite expertise to work in our sector, and more than half of specialized manufacturing jobs go unfilled.

Slow permitting and regulatory barriers also add. It can take 5 to 7 years to build a new plant and 3 to 5 years to add a single production line.

That is the bad news.

The good news is that Congress can help. Congress can reverse these trends with commitments built on nine pragmatic steps.

First, we should create guaranteed purchase contracts for essential medicines. Fixed-volume, fixed-price agreements, structured to encourage multiple suppliers, would give manufacturers the revenue certainty to build or reopen capacity here in the United States.

Second, we should expand the Strategic National Stockpile to include finished drugs and other active ingredients.

Third, fund grants to defray relocation and retrofitting costs of existing dormant capacity.

We should provide targeted tax incentives. A 50 percent credit on capital costs for domestically producing essential medicines, a simplified 20 percent R&D tax credit, relief for

bioequivalent studies and FDA user fees, and wage credits for U.S. production would narrow the cost gap with overseas labor and energy.

We should streamline FDA regulatory review of new complex generics and biosimilars.

We should look to invest in domestic API capacity. Many other countries, like Austria and South Korea, have invested heavily to support their own API production. The U.S. can and should pursue similar strategies that cluster suppliers and reduce barriers to scale.

We should appropriate multiyear funding equal to the strategic value of medicines to the United States, comparable to commitments made in the CHIPS Act.

We should look to curb anticompetitive brand patent tactics that delay generic entry by limiting serial patents and preserving the ability to reach pro-competitive settlements.

And last, we should reform Medicare and PBM practices that steer patients to higher price brands and protect prolonged brand monopolies.

These measures are not theoretical. They mirror the tools that secured domestic production of semiconductors and personal protective equipment. Applying them to medicines will expand U.S. manufacturing, enhance national security, and preserve access to affordable treatments for every patient.

Let me close with two realities.

First, the United States has dormant capacity. With the right incentives, existing facilities can restart lines faster than we can build new plants.

Second, rebuilding resilience will require some patience. Capital investments, ingredient qualification, validation, and FDA inspections take time. But the sooner we begin, the sooner patients, hospitals, and our military will benefit.

Generic and biosimilar medicines are not just cost savers. They are lifelines. With strategic, sustained support, we can reenforce that lifeline at home, reduce reliance on any single foreign source, and create skilled jobs across our communities.

I appreciate the subcommittee's attention to this urgent issue and look forward to working with you to turn these proposals into law.

Thank you.

[The prepared statement of Mr. Murphy follows:]

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Mr. Carter of Georgia. Thank you, Mr. Murphy.

The chair now recognizes Dr. Ronald Piervincenzi. Is that pretty good?

Dr. Piervincenzi. That is pretty good. Thank you.

Mr. Carter of Georgia. You know, I try to get staff to get Smith and Jones, but they get all these other people here. So, I have directed them, "Don't have any witnesses unless it is a Smith or a Jones."

[Laughter.]

STATEMENT OF RONALD T. PIERVINCENZI

Dr. Piervincenzi. Thank you, Chairman Carter, and thank you, Ranking Member DeGette, members of the committee, for this opportunity to provide testimony on strengthening the domestic manufacturing and the healthcare supply chain.

I am Ron Piervincenzi, Chief Executive Officer of the United States Pharmacopeia, better known as USP.

USP is an independent scientific global nonprofit organization founded on January 1 of 1820 when 11 physicians concerned about patient safety and poor-quality imported medicines from England came together to create the first national Pharmacopeia in the world.

Today, USP works with hundreds of independent experts to set 6,000 -- over 6,000 quality standards for the entire medicine supply, including dietary supplements -- and also their ingredients, importantly. In addition, we have developed verification services to ensure the quality of ingredients, a program to test the quality of pharmaceutical products from the marketplace, and initiatives to accelerate adoption of advanced pharmaceutical manufacturing technologies.

All of this work is in service of USP's mission to help strengthen the global supply chain so that medicines people rely on are available when needed and meet quality standards as expected and required.

USP launched an ambitious initiative in 2019 to map and analyze the global medicine supply chain. The resulting data platform, known as the Medicine Supply Map, now tracks 94 percent of U.S. drug products and ingredients wherever they are manufactured in the world. It identifies

vulnerabilities in our supply chain and helps guide smarter investments by both the private sector and, hopefully, targeted interventions by policymakers.

So what have we learned from this extensive mapping? Globalization has indeed enabled the manufacture of generic medicines at lower cost, but it has clearly made our supply chains longer, more fragmented, and more opaque.

So a few facts.

Over 80 percent of key ingredients and raw materials used in U.S. medicines are manufactured abroad today, and many in just a handful of locations. India supplies more than a third of all U.S. prescription drug APIs. But China's API filings have risen 63 percent just over a 2-year period from 2021 to 2023, now comprising a third of new global filings on a go-forward basis.

This geographic concentration is one key driver of vulnerability.

Using our data, USP has identified 100 vulnerable medicines that are both at high risk for disruption and difficult to substitute therapeutically. Pharmacists will understand that one.

Right now, the supply of our most essential medicines, nearly all of which are generics, remain highly sensitive to geopolitical tensions, disasters, pandemics, and, importantly, market dynamics that drive often the most reliable manufacturers to exit the market for individual drugs.

The result is an increasingly fragile supply chain that jeopardizes not just patient care but national security.

To reduce these risks and improve resiliency, we have identified four key recommendations which can also serve as pillars to guide Congress' support for domestic manufacturing.

The first is to continuously identify the Nation's most vulnerable medicines, to leverage that data to pinpoint the factors most responsible for supply risk, and target interventions where the data shows the risk is most imminent.

The second is supporting the innovation in U.S. manufacturing technologies, reducing the barriers for new novel methods for producing pharmaceutical ingredients, including key starting materials as well as APIs.

The U.S. is actually quite well positioned to lead on breakthrough technologies, including advanced manufacturing, and to find alternative synthesis pathways for those APIs. That can help reduce our reliance on overseas suppliers and enable us to domestically manufacture medicines and their ingredients more efficiently and more competitively.

A third is to establish a resiliency benchmark for the purchase of vulnerable medicines. We must rethink how we value essential generic drugs, which account for more than 90 percent of medicines that Americans rely on but represent less than 20 percent of our spending on medicines.

USP and other stakeholders have proposed establishing a resilience benchmark to help shift the paradigm to empower and incentivize public and private sector purchasers to value resiliency and predictability.

Fourth, expand the supply chain visibility by leveraging tools like the USP Medicine Supply Map. Expertise like this is essential to unravel complicated supply chains and provide the risk management intelligence. We can pinpoint vulnerabilities so that we can also pinpoint solutions.

The fragile supply chain is a problem we can and should solve, and with confidence. In fact, we must work to forge a more resilient, adaptable, and secure future for America's medicine supply because the well-being of millions of people and our Nation's security does depend on it.

USP thanks the committee for convening this discussion on this urgent issue that affects so many of my fellow Americans and their healthcare providers.

I look forward to answering your questions. Thank you.

[The prepared statement of Dr. Piervincenzi follows:]

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524 ******** COMMITTEE INSERT ********

Mr. Carter of Georgia. Thank you, sir.

The chair now recognizes Ms. Dawn O'Connell for 5 minutes for an opening statement.

STATEMENT OF DAWN O'CONNELL

Ms. O'Connell. Thank you, Chairman Carter and Ranking Member DeGette. I am pleased to have this opportunity to testify before you today on the need to strengthen domestic manufacturing and the public health and medical supply chain.

I served in the previous administration as the Assistant Secretary for Preparedness and Response. My job was to help the country prepare for, respond to, and recover from public health emergencies and disasters.

Much of this work was focused on making sure the country had the tools it needed to respond to whatever emergency was at hand. As a result, having a resilient public health and medical supply chain was always a concern of mine, but over the last 4 years it became a mission.

We must never forget what Ranking Member DeGette mentioned, those early days of COVID when the whole world needed the exact same medical supplies at the exact same time, and most of them were manufactured somewhere else.

The Strategic National Stockpile had limited stores of usable PPE, the last pieces purchased 10 years prior during the H1N1 outbreak. Also, the amount of PPE manufactured in the United States was limited, and much of it was manufactured just in time with little surge capacity.

As a result, our frontline healthcare workers were forced to wear garbage bags and used empty soda bottles for PPE.

When I began my work at ASPR in 2021, two things were clear to me.

First, we needed enough supplies in the Strategic National Stockpile to get the country through the first 90 days of an emergency.

And second, we needed a manufacturing base in the United States with enough capacity that could quickly ramp up to meet demand after those first 90 days.

And so we got to work.

The first Trump administration began the work of investing in domestic manufacturing of critical PPE and medical supplies. We continued that work when we came in.

And over the course of the COVID response across both administrations, ASPR invested in the domestic manufacture of masks, gloves, gowns, tests, as well as ancillary equipment, such as swabs and vials.

Under my leadership, I established ASPR's supply chain office to manage our domestic manufacturing efforts. I elevated the Strategic National Stockpile to direct report to me, and I restocked its depleted shelves with domestically manufactured supplies whenever possible.

As the country emerged from the acute COVID PPE and medical supply shortages, our team expanded its efforts to invest in the domestic manufacturing of active pharmaceutical ingredients and key starting materials for the medicines that are most needed in public health emergencies.

Expanding the healthcare manufacturing base in the United States takes time, attention, and a coordinated effort across the government. We ran into several challenges that ASPR and HHS alone could not solve but required the support and engagement of other parts of government.

And despite our efforts, some of the companies we invested in were unable to survive the waning demand for PPE that quickly followed the ending of the acute phase of the COVID response.

But despite these challenges, I think we have an opportunity. The previous two administrations initiated much of their supply chain work during times of emergency and acute

shortage. There is an opportunity now that we are not in a crisis to take a look at what has worked and what has not and consider a comprehensive framework for securing our public health and medical supply chain.

This framework should first clearly identify, what is the public health and medical supply chain? What is in it that needs to be available and ready to use on day one of an emergency?

It should promote investment in the domestic manufacture or near-shoring of whatever those products are.

It should have a strategy to ensure there is a market for those products in both peacetime and times of emergency.

And the strategy should take into account government incentives, thoughtfully applied tariffs, and stockpiles of vendor-managed inventory, and it should build enough domestic manufacturing that manufacturers can surge production quickly in times of emergency.

Ensuring a resilient and secure domestic supply chain is a nonpartisan issue. In fact, it is a place, despite deep partisan divisions around public health, where both the Biden and first Trump administrations found agreement.

We owe it to our frontline healthcare workers to make progress on this important issue before the next public health emergency so they never have to wear garbage bags for PPE again.

Thank you, and I look forward to your questions.

[The prepared statement of Ms. O'Connell follows:]

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Mr. Carter of Georgia. Thank you, Ms. O'Connell.

The chair now recognizes Mr. Josh Bolin for 5 minutes to give an opening statement.

STATEMENT OF JOSH BOLIN

Mr. Bolin. Health Subcommittee Chairman Carter, Ranking Member DeGette, members of the subcommittee, thank you for the opportunity to testify today about the state of the U.S. drug supply chain.

NABP is a 501(c)(3) nonprofit association that for over 120 years has protected public health by assisting our member boards of pharmacy in all 50 States that have the responsibility for regulating the practice of pharmacy as well as the prescription drug supply chains within their States.

With my testimony today, I will highlight some of the emerging safety threats to both the regulated and unregulated supply chains for products as they move closer to patients.

As the subcommittee is aware, the Drug Supply Chain Security Act passed into law in 2013 and provided a phased window of implementation for the pharmaceutical supply chain to achieve interoperable data sharing and electronic tracing of products to prevent dangerous products from reaching patients.

The DSCSA provides essential tools that trading partners in the supply chain and State and Federal regulators can utilize to detect unsafe medications.

First, products now have to be serialized down to the individual saleable unit, meaning that there is a unique identifier for each product, and product packaging contains a 2D barcode that can be scanned.

Once the product is scanned, trading partners and regulators can ask about the legitimacy of that product's identifiers or who owned that product previously.

The U.S. supply chain now generates 16 to 20 billion transactions per year, and given this massive amount of data, NABP started working with our member boards of pharmacy and all sectors of the supply chain to conduct pilots that led to the development of Pulse by NABP, which is NABP's digital platform for DSCSA that we launched in January.

The best way to think about Pulse is that it is a directory for all the manufacturers, distributors, and pharmacies in the supply chain as well as all the products that move through the supply chain.

Utilizing Pulse, regulators and trading partners can scan the 2D barcode of a product and ask questions of trading partners about that product.

NABP is providing the tools to our members and to every pharmacy in the supply chain at no cost. We are doing so because the tools of DSCSA only work if they are accessible and easy to use.

We rolled out Pulse to our member boards in mid-January, and as it happens, the very first scans that were conducted out in the field utilizing Pulse helped the Arkansas and Mississippi Boards of Pharmacy in identifying illegitimate and counterfeit GLP-1 medications that had actually made their way into our legitimate supply chain.

From a congressional perspective, DSCSA worked, but it illustrated that our supply chain is still susceptible to illegal actors.

Since January, we have nearly 30 States utilizing the tool, and not just boards of pharmacy but other regulatory authorities, such as attorneys general and Drug Enforcement Administration field offices.

While we have made progress, and implementation of DSCSA helps, we still face challenges and threats to supply chain security.

First, regarding medications offered over the internet. NABP has a host of resources we can share about the dangers of purchased medications over the internet.

But our primary highlight is that in that work we estimate that 96 percent of online pharmacies in operation at any given time are illegal and in violation of State and Federal law. And research shows that the majority of Americans falsely believe that websites offering prescription medications have been approved by the FDA or by the boards of pharmacy. People increasingly trust that medications on the internet are safe and regulated, but, unfortunately, that is not always the case.

Second. NABP's members have flagged a disturbing trend in the loosely regulated space of med spas. For example, one State board uncovered an operation where a med spa had been set up in an individual's home where compounding -- and I use that loosely -- or mixing of purported GLP-1 medications with vitamin B12 in their bedroom, hardly a sterile environment.

The med spa was compounding, using active pharmaceutical ingredient that was obtained not from an FDA-registered API manufacturer but from an international online source advertising cheap weight loss APIs. The med spa simply mixed these ingredients, drew it up in syringes, and then mailed them to individuals in plastic bags.

This is just one example from a State that actually has authority to regulate these types of entities. And, unfortunately, we know activities like this are going on in every State, but most State boards lack the authority to actually do anything about it.

So while there are absolutely legitimate sources for obtaining medications over the internet, unfortunately, bad actors are using internet platforms to peddle medications, putting profits over

safety. And to be clear, legitimate compounding plays an essential role in our supply chain to ensure patients have access to medications they need that aren't commercially available.

But those that are simply mixing medications in their bedroom or in their bathroom in nonsterile environments and calling it "compounding" are a threat to legitimate practice.

Given the popularity of certain medications, those who believe they can make a dollar over demand for a popular medication will do so irrespective of the harm it causes to patients.

I would like to once again thank the committee for their time and attention. I will look forward to your questions.

[The prepared statement of Mr. Bolin follows:]

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Mr. Carter of Georgia. Thank you, Mr. Bolin.

And thank all of you for your testimony.

We will now begin questioning, and I will recognize myself for 5 minutes of questioning.

As has been established here already, America has found itself entrenched in an issue that poses a threat to our safety and our national security. China has become our pharmacist. I practiced pharmacy for almost 40 years. Now I have been replaced by China.

Seriously. China has become our pharmacist. China decides whether Americans have the prescription and over-the-counter drugs we need to get and stay healthy.

That is why we are having this hearing today, so that we can examine the policies that bolster our domestic pharmaceutical supply chain.

Before our committee today is USAntibiotics, who is the only -- the only -- U.S. manufacturer of amoxicillin and Augmentin.

Based in Bristol, Tennessee, USAntibiotics operates a world-class antibiotic production facility with the sole focus of affording patient access to quality life-saving medications and antibiotics, securing critical domestic supply chains, and creating good-paying jobs.

Despite USAntibiotics' critical importance to our supply chain and national security, previous administrations didn't prioritize these American-made products. In fact, previous administrations prioritized foreign-sourced amoxicillin over American-made amoxicillin.

Thankfully, President Trump has prioritized American-made medicines and issued an executive order promoting American-made pharmaceutical manufacturing to reduce our reliance on adversarial countries.

Mr. Cashman, in your testimony you mentioned that we should treat generic drugs the same way as we treat military weapon system or critical minerals. Can you explain the rationale for that?

Mr. Cashman. Thank you, Chairman Carter.

Yes, absolutely. Approximately 45 percent of the global amoxicillin API production --

Mr. Carter of Georgia. Can you bring that microphone closer to you?

Mr. Cashman. Excuse me.

Approximately 45 percent of the global amoxicillin API production capacity is concentrated in China. Even though China isn't the leading global exporter of our finished form of amoxicillin, they supply upwards of 70 percent of the amoxicillin API that Indian drugmakers use.

In addition, one should note that 80 percent of the key starting materials used for the production of API, amoxicillin API, is also produced in China.

So China has a stranglehold on amoxicillin production globally.

Mr. Carter of Georgia. Let me ask you something. There was a study done in 2025 that found that Indian-made generics were 54 percent more likely to cause severe adverse effects than made-in-America drugs.

Can you describe any documented quality differences between domestic and foreign manufactured antibiotics?

Mr. Cashman. Yes. In this study that was done by Ohio State that you mentioned, Chairman Carter, 54 percent effect was -- there were 54 percent more severe adverse events in medications from China than medications -- the same -- very same medications produced in the United States.

In addition, there have been cases of contamination with carcinogens. In 2019, there was a case of carcinogens being in blood pressure medications. And there have been numerous other situations like this.

Mr. Carter of Georgia. And this is one thing we want to look at in the future on this committee as well, on this subcommittee and this committee, and that is the FDA investigating and looking at these foreign manufacturers.

If Congress would act on the recommendations today, how quickly could we -- could our domestic capacity expand? If we were to act on this, how quickly could we get this up and running?

Mr. Cashman. With the right policy framework, we could significantly expand production within 18 to 24 months. And let me explain that a little bit.

We are currently running three active production lines. We have two crews on first shift and another crew on second shift. By simply adding new crews, adding shifts, so we can have three shifts per day on each line, we could dramatically increase our production.

In addition, we have over 11 production lines -- or excuse me -- nine production lines. So we can add additional new production lines as well.

So in a time period of 18 to 24 months, we could increase our production significantly.

Mr. Carter of Georgia. So can we work with our allies to reduce dependence on China without going totally domestic? I mean, friend-shoring, offshoring, that would help as well, correct?

Mr. Cashman. Absolutely that would help. But we have to keep in mind here that in working with our allies, that many of them have supply chain vulnerabilities as well. They don't have the capacities to supply all of the U.S. market as well as the European market, for example.

Mr. Carter of Georgia. Right.

Mr. Cashman. So those are situations we have to look at each specific case.

Mr. Carter of Georgia. Okay.

I am out of time. Thank you very much for that, Mr. Cashman.

I now recognize the ranking member of the subcommittee, Representative DeGette, for 5 minutes of questioning.

Ms. DeGette. Thank you so much, Mr. Chairman.

Well, I have got to say, we are all alarmed about this issue. I was alarmed to find out that my local hospitals didn't have IV fluids and other essential medications. And we can easily see how tenuous this makes our whole healthcare system.

So I want to start with you, Dr. Piervincenzi.

In the 2025 Annual Drug Shortages Report, the USP identified four factors that contribute to and drive medication shortage. Can you briefly restate what those risk factors are?

Dr. Piervincenzi. Thank you, Ms. DeGette. I appreciate that question.

So the report did a retrospective analysis of that broad --

Ms. DeGette. And what the four -- briefly -- what were those four areas?

Dr. Piervincenzi. Yeah. So first was price. And by first, I mean the thing that was most highly correlated to supply disruptions. In this case, of course, low price for generic drugs, too low of a price.

The second was quality. In this case, it was quality disruptions. Bad inspections, poor quality medicines that resulted in discontinuities.

Third was geographic colocation. So this has different factors, including geopolitical, but also, of course, weather, weather events. We are familiar with many examples.

And the -- excuse me -- on the fourth -- oh, and of course complexity. You were mentioning the IV bags. The higher the complexity, the more things that can go wrong. So, unsurprisingly, that becomes also highly correlated.

Ms. DeGette. Right.

Dr. Piervincenzi. Now, the last thing I will say is that the four factors aren't independent, meaning any one of those perhaps might be okay, but it is when they come together is when you have really serious risk.

Ms. DeGette. When they all work together.

So does USP call for deregulating domestic pharmaceutical manufacturing as a solution?

Dr. Piervincenzi. Deregulating?

Ms. DeGette. Deregulating as a solution. That is not in the four factors you talked about.

Dr. Piervincenzi. Oh. I am sorry. Yes.

So the U.S. FDA's inspections are critical. And we talked about a couple of the factors, including quality. The assurance of quality is one of those factors. So deregulating the quality would, I think, work against the --

Ms. DeGette. So that is not one of your recommendations.

And what about reducing inspections domestically? Would that help, if we reduce domestic inspections?

Dr. Piervincenzi. Would it help resilience?

Ms. DeGette. Yeah. Would it help solve these problems?

Dr. Piervincenzi. So the FDA's role -- and this is, we know, from working with our partners in industry -- that strong inspections result in higher resilience.

Ms. DeGette. Thank you.

Now, so the reason I am asking you these questions, the Trump executive order pretty much tells companies they can avoid inspections if they manufacture in the United States. But as you said, the FDA's involvement assures quality and safety, and thereby it averts drug shortages caused by subpar drugs.

I want to move quickly to you, Ms. O'Connell.

You are so right about replenishing the stockpile now instead of waiting, like we always do, until a crisis. And the chairman is nodding because he agrees with me.

So I want to ask you, HHS recently canceled $766 million in contracts with Moderna to develop vaccines against influenza strains with pandemic potential, including the H5N1 avian flu.

Moderna utilizes mRNA technology that has important advantages over older methods of vaccine development. This technology was developed over three decades with $337 million of Federal Government investment prepandemic. It saved millions of lives when Operation Warp Speed resulted in multiple safe and effective vaccines for COVID-19 in less than a year.

So I want to ask you, can you explain why the strengths of mRNA technology matter in a pandemic context?

Ms. O'Connell. Absolutely. At this point, the mRNA platform is the only vaccine that we can use to meet our 100-day mission. Our biosecurity strategy requires that we are able to, at the first identification of an outbreak, have a vaccine ready to go.

The mRNA platform, because it is very flexible and quick to manufacture, is the only platform at this point that will provide the country that protection within the first 3 months of an outbreak.

Ms. DeGette. What would happen if we had a massive bird flu outbreak or other strain of influenza if we didn't have the mRNA platform?

Ms. O'Connell. Well, at this point, we do have other vaccines -- egg-based, cell-based -- but they take 6 months to manufacture.

Ms. DeGette. Okay. And does Moderna have manufacturing capacity in the U.S.?

Ms. O'Connell. They do.

Ms. DeGette. Okay. And does cancelling this contract help offshore the medical supply chain?

Ms. O'Connell. No.

Ms. DeGette. The Moderna contract? No.

So I just want to say, is this platform, the mRNA platform, safe, and is it reviewed?

Ms. O'Connell. Absolutely. It has been studied, as you mentioned, over 30 years, and it was licensed by FDA and been through several clinical trials in the process.

Ms. DeGette. Under both --

Ms. O'Connell. Absolutely.

Ms. DeGette. -- under Republican and Democratic administrations?

Thank you. I yield back.

Mr. Carter of Georgia. The gentlelady yields.

The chair now recognizes the chairman of the full committee, Chairman Guthrie, for 5 minutes of questioning.

The Chair. Thank you. Thank you, Mr. Chairman. Thank you for yielding the time.

And I just want to talk about advanced manufacturing technologies. Actually, I want to go back. I want to talk about H.R. 1 for a couple minutes.

So, Mr. Cashman, H.R. 1 has several tax credits involved. Can you speak to the benefit of the provisions of the USAntibiotics specifically, and if the Senate were to pass the bill with these incentives in tax, how quickly could USAntibiotics expand production to serve more of the American market?

Mr. Cashman. Thank you, Chairman Guthrie. Great question.

I can only speak to the impact of specific limited provisions of the legislation on companies like ours.

As stated, we serve only 5 percent of the U.S. amoxicillin market despite having capacity to scale to serve 100 percent. The immediate expensing of new product production equipment and facility improvements, as well as domestic R&D expensing provisions, could better position us to make capital investments. So, it would help us.

The Chair. Thank you.

And so, Mr. Murphy, would you explain how your member companies could use the provisions in H.R. 1 to move production back domestically?

Mr. Murphy. Yeah. Mr. Chairman, thank you for that question.

We have often talked about the need to have tax credits and the ability to have flexibility in the Tax Code to make the investments necessary in the United States.

I would say we have a significant amount of dormant capacity in the United States too that could be turned back on, which would require some capital investments to get things online. And our members have been very, you know, pleased to hear that there is more attention being paid to this sector of the market from a tax perspective that could help the industry.

The Chair. If you have open capacity, what is preventing the price, obviously -- what is preventing you from expanding your capacity.

Mr. Murphy. Yeah. So, I would say predominantly -- and Dr. Piervincenzi said this as well -- price in the generic market is the primary driver to make more investments. And we have a long history of working with this committee on solutions to that. But, ultimately, tax provisions help as well.

The Chair. But you have open domestic capacity.

Mr. Murphy. We do. We do.

RPTR SEFRANEK

EDTR ZAMORA

[11:01 a.m.]

The Chair. Because there is a -- I used to do supply chain, so it is not pharmaceutical but automotive, but -- so you have a couple of things. One, if you are going to try to bring it back, you got to build a new plant.

You are saying you can bring this back if the -- without big capital investments. You don't have capacity -- you have to do some, I get it, but you just need the right price signal to do it, which the Tax Code can help you get there.

Mr. Murphy. The Tax Code can help, and then the price signal that, you know, we could work on with PBM reform and other areas that this committee has worked on could certainly help.

But, yes, there is finish-fill capacity in the United States that could be turned on, and as Mr. Cashman said, would take, you know, far less than the 5 years that it would take to build a new facility.

The Chair. So, Mr. Cashman, you have the capacity as well or you would have to build new facilities to bring production back?

Mr. Cashman. Yes, we have significant capacity. We have over 390,000 square feet, and we are using a fraction of that at this point.

The Chair. So being a supply chain person, as I just said, if somebody says, hey, we are going to bring this back, it can be short term or long. You said you can do it pretty quickly if the right pricing or the right investment opportunity was there, right? Which the Tax Code gives you that.

Mr. Cashman. Yes, Chairman Guthrie, with the right pricing and the right economic incentives, we can bring this production capacity back online.

The Chair. In your testimony, is the current -- what we passed out of the House is sufficient for you to start making those decisions?

Mr. Cashman. Well, Chairman Guthrie, I am an expert on production. I live and breathe producing amoxicillin. I believe it is going to be helpful to us to allow us to deduct these investments more quickly, yes.

The Chair. Okay. Thank you. Yeah, then if you -- yeah, the investment -- and some of you just have capacity you have already invested, so that is a different animal. Okay. I understand.

So, Dr. Piervincenzi, I am looking at advanced manufacturing technologies. Could you provide some examples of how AMTs, or advanced manufacturing technologies, have been or could be utilized successfully to modernize and localize and stabilize your domestic production and, therefore, reduce our overseas dependence?

Dr. Piervincenzi. Thank you, Chairman Guthrie. And I think this is a question that maybe goes to the second half, the first half being dormant capacity. But at some point, that runs out.

The next step is, how do we build new capacity? And I think that is where the advanced manufacturing comes into play, to create a system that produces even better, higher quality medicines with a lower labor rate and a lower footprint, which gives it an advantage, especially in countries with higher income levels.

The second piece to that is that where the U.S. lags the furthest behind is in API and then even more so in the Key Starting Materials. And in those spaces, it is probably the only solution that would be able to domestically increase the production is through these advanced techniques. And they are advanced for pharmaceutical industry. They are not really advanced in the world. The automotive industry has been doing it for many decades now.

And the last thing I would say is, where is it happening? It is happening with innovator medicines that have higher margins and able to make the capital investments. Where it is not happening is for generic drugs where we see the shortages.

The Chair. Right. Thank you.

And my time has expired, and I yield back.

Mr. Carter of Georgia. The gentleman yields back.

The chair now recognizes the ranking member of the full committee, Representative Pallone, for 5 minutes of questioning.

Mr. Pallone. Thank you, Mr. Chairman.

It is difficult for me to have a discussion about the medical supply chain in the midst of the chaos and destruction that the Trump administration and the Republican big ugly bill is causing to our public health infrastructure.

I mean, the chairman talks about how, you know, the big ugly bill is going to help manufacturing more drugs, but the CBO says 16 million -- more than 16 million Americans aren't even going to have health insurance. How are they going to buy any? How are they going to, you know, get any drugs or get any healthcare if they have no health insurance? So I don't understand -- you know, these things are intertwined, and you can't talk about them separately.

I wanted to ask the Former Assistant Secretary O'Connell, you noted in your testimony that bolstering domestic manufacturing requires highly competent Federal employees who understand both economics and healthcare.

I had two questions. Why are highly skilled and trained Federal workers so critical to this mission, and impact -- what impact does it have when that expertise and experience are lost? And, second, do the Federal layoffs make us more vulnerable to shortages or supply chain challenges?

I have more questions, so briefly, if you will.

Ms. O'Connell. Absolutely. Just to say that that is a highly specialized skill that we had within HHS to be able to understand market dynamics, economics, push/pull incentives across the health supply chain, and to have staff that understood both and are able to work across both and pick the right investments has been really important and a unique skill set that we were pleased to have in ASPR and is necessary.

Mr. Pallone. Well, thank you, Ms. O'Connell.

I would also like to briefly touch on the Hospital Preparedness Program, which is operated by ASPR, and is one of the key preparedness programs typically reauthorized as part of the Pandemic and All-Hazards Preparedness Act. However, as I noted earlier, congressional Republicans walked away from an agreement to reauthorize PAHPA last year.

Hospitals, obviously, play a key role in securing the supplies, medicines, and equipment necessary to care for patients -- I guess that is pretty obvious -- and they are important actors in the supply chain. However, in just another example of how the Trump administration is decimating public health, the fiscal year 2026 budget proposed to eliminate funding for the Hospital Preparedness Program.

So, again, Ms. O'Connell, can you provide some examples for how HPP has been utilized in response to past public health emergencies and disasters, and what would be the impact of eliminating the Hospital Preparedness Program?

Ms. O'Connell. Well, HPP is the only source of Federal funding that hospitals and healthcare coalitions have to be prepared, and they have used that funding to run exercises and to be prepared for hurricanes, for cyber attacks.

We saw recently in October there was a case of Lassa fever that was imported to Iowa. The hospital, because it had its preparedness mechanisms in place, was able to contain the Lassa to the one patient, and it didn't spread throughout the hospital or into the community.

So having hospitals that can identify challenging pathogens is critically important and to know how to respond in those times. And this healthcare funding, the HPP funding, is the only source of Federal funds that allows them to do that.

Mr. Pallone. And, of course, I saw this vividly during the COVID epidemic, right. I mean, I literally -- I am sure most members of this committee on both sides of the aisle spent so much time trying to, you know, get our hospitals so that they had the equipment, they had the, you know, supplies that were necessary which were in such shortage during COVID.

And so, you know, this idea of having no Hospital Preparedness Program, to me, I can't imagine anything that is as destructive in the event of a natural disaster or another epidemic. I mean, to me, it makes absolutely no sense to have a level of preparedness. But, again, I go back to the same thing again. We are talking about the tax implications of this big ugly bill and how they are going to provide more domestic manufacturing, but at the same time we are firing people who are going to run the programs. We are saying that we don't need our hospitals to be prepared.

You know, what I don't understand -- and I know I keep saying it over and over again -- is these hearings -- not that there is anything wrong with the hearing, but you have to recognize that these things are all intertwined, right. You can't say we are going to increase supply chains and domestic manufacturing when you don't have the people available to actually do the work, you know, to make sure that we are prepared.

And I just -- I just -- I don't expect you to respond because I think you already have, but I just -- I have to say, Mr. Chairman, I just don't understand how there is so much silence on the

Republican side to all these concerns about people losing their health insurance and not being -- hospitals not being prepared. Cuts that come from the Medicaid, Medicare, ACA cuts that are going to occur with this big ugly bill.

I yield back the balance of my time, Mr. Chairman.

Mr. Carter of Georgia. The gentleman yields back.

The chair now recognizes the vice chair of the subcommittee, Dr. Dunn, for 5 minutes of questioning.

Mr. Dunn. Thank you very much, Mr. Chair, and thank you to our witnesses for being here today.

Over a 30-year career of medicine, I have become familiar with the complex healthcare supply chain that produces our essential drugs and products that Americans rely on. Reliable domestic supply chain not only serves to ensure the health of American people, it is a national security priority.

As a member of the House Select Committee on China, I am very aware of the extent to which Americans become reliant on foreign entities to supply our country's medical needs. The Chinese Communist Party has made an intentional and coordinated effort to become a force in the biomedical production world.

The United States has been a long-standing leader on research and development, and that did not happen by accident. It was driven by policy choices that reflect our values, that promote continued discovery. It is clear to me that those values also mean that the United States should be a leader in the production of those critical medicines. We must ensure that America remains at the forefront in biopharmaceutical manufacturing to protect our supply chain and bring American innovative cures to our patients in a safe and reliable manner, especially at a time when China is fast on our heels.

Mr. Cashman, it seems to me that domestic antibiotic manufacturing should be a fundamental priority for this committee. I also believe that the Federal Government can play a role in ensuring a domestic supply of other critical products. I find it troubling that under the former administration, the HHS made a $40 million award to a foreign amoxicillin producer when there was a domestic manufacturer available.

In your experience, do Federal contractors appropriately take into account made in America when determining Federal awards?

Mr. Cashman. Thank you, Vice Chairman Dunn. That is an excellent question. Let me respond to that.

The focus is primarily on pricing by the Federal Government, but I think it is something that the Federal Government has to take a much broader view and look at security of supply, national security issues, and to ensure America has access to quality medicines made in the United States.

So I think it is something that needs to be reevaluated and perhaps put more emphasis on the sourcing of medications from manufacturers within this country.

Mr. Dunn. By the way, I want to make a side comment here. I think the source is important, the supply chain is important, the control of it, but also the quality is. And I don't think we do enough independent -- and I mean independent third-party testing on all these products.

I have seen reports on this -- DOD is doing a study on it -- that actually is pretty clever in showing some very wide disparities in quality, both quantitatively and qualitatively, in generic drugs that are produced by different manufacturers and are being sold legally -- legally in this country. So that is just a side comment.

I also want to make a final comment, if I may, to Ms. O'Connell. Having previously served as the ASPR, the Assistant Secretary for Preparedness and Response, and the person in

comment -- rather, in charge of the Strategic National Stockpile, I am troubled, but it was your team in the Biden administration who chose not to support the last remaining end-to-end domestic manufacturer of amoxicillin.

It is a story that I heard too many times during the last 4 years in which it looks like we mismanaged the Strategic National Stockpile, repeatedly misaligned our contract decisions. And, honestly, I think the Office of ASPR repeatedly was slow in awarding Federal contracts to delays -- you know, which leads to delays, unreliable supply chains for the manufacturers.

And I believe our Federal agencies can play a critical role in ensuring that markets for the key medical products remain viable. I also believe it is necessary for our safety and our national security.

I see my time is up. Mr. Chairman, I yield back.

Mr. Carter of Georgia. The gentleman yields.

The chair now recognizes the gentleman from California, Dr. Ruiz, for 5 minutes of questioning.

Mr. Ruiz. Thank you, Mr. Chairman.

As an emergency medicine physician, it has always been my top priority in Congress to improve patient access to high quality and affordable healthcare. We have made great strides towards this goal, but these efforts are mute if we cannot ensure a readily available supply of medications patients desperately need.

In the emergency room, I have witnessed firsthand the dire implications that shortages of key medications have on the lives of my patients. For patients suffering from infections or trauma or fighting against cancer, this can be a matter of life and death. In fact, I remember times where we have a patient with respiratory distress after a trauma and we didn't have succinylcholine, a paralytic that we use to intubate a patient. And when you are used to using succinylcholine and have to use

another drug that has a higher side-effect profile and more contraindications, then you have to think for a moment and take time to assess what you are doing. And in the emergency department, time is of the essence, as you all know. So it definitely creates complications.

And even if medications are not in short supply, affordability remains a significant barrier to care, and safety is paramount. So that is why we need to act in order to strengthen the supply chain for critical medications. This includes bolstering domestic production, but it is crucial that we do so in a way that will not raise costs for patients and will not jeopardize the safety of these medications. It is important to think about geographic diversity in manufacturing.

Let's remember the alarming impact on the availability of IV fluids back in late 2024 due to the critical damage the Baxter facility in North Carolina sustained during Hurricane Helene. Baxter supplies roughly 60 percent of the IV fluids used in North America. When just one manufacturing facility was damaged, supply was restricted, and hospitals across the country faced shortages. And I remember speaking to desperate CEOs of the hospitals in my district very concerned about patient quality care during that shortage.

Ms. O'Connell, can you share some lessons learned from your experience as Assistant Secretary for Preparedness and Response during the aftermath of Hurricane Helene, particularly with respect to the importance of geographic diversity and manufacturing critical medical supplies?

Ms. O'Connell. Absolutely. Thank you, Congressman.

So, of course, we were not invested in Baxter. Baxter was a private company. But when we were making investments in domestic manufacturing, we made sure that we had regional diversity in the investments that we made, so we weren't putting the manufacturers of similar products in the same regions that could potentially be impacted by either a hurricane down South, ice storm up

North, wildfires out West. It was critical that we had our investments spread out across the country. That was one of the things that we tried to do.

When it came to Baxter, we did a couple of things. We helped them import their IV solutions that were manufactured in other parts of the world. We --

Mr. Ruiz. So what can we do as legislatures to help --

Ms. O'Connell. Right.

Mr. Ruiz. -- with the geographic diversity?

Ms. O'Connell. So I think it would be important to encourage the private industry, those that we don't have levers with, but that act on their own to seek geographic diversity.

I think Baxter would absolutely agree -- I know they are not here today -- that it would be important moving forward that they don't have just one plant manufacturing 60 percent.

Mr. Ruiz. Okay. So we have talked about the importance of geographic diversity and safeguarding medical supply chains, but how do we do that on American soil while also ensuring the safety and affordability of medications?

So the answer is certainly not dismantling FDA and firing thousands of Federal workers that support key roles and responsibilities in ensuring the safety and efficacy of medications Americans rely on, like the Trump administration has done. The answer is not slashing protections and inspections to ensure the safety. And tariffs will raise prices on the components of the supply chain, vials and tubings, et cetera, which will raise prices.

So the Trump administration is calling for looser regulations or weaker protections that are in place to keep patients safe within that executive order. Inspections and safety standards are vital to ensuring the safety of medicines we rely on.

Mr. Murphy, do you believe that we should have fewer inspections of manufacturing facilities, and how does that lead to better quality? And does the Association for Accessible Medicines and your member companies want clear regulatory guidance from Federal regulators?

Mr. Murphy. Thank you, Dr. Ruiz.

We support a strong FDA with a strong inspections division. It provides certainty to the marketplace that there is quality built into the overall inspection process. And so we support FDA having more resources in the inspection space to do their work.

Mr. Ruiz. And you do not support reducing the inspections?

Mr. Murphy. Certainly, we -- certainly, we understand that there are different priorities across the agency, but from an inspections standpoint, that is a very critical component of our work.

Mr. Ruiz. Thank you. I yield back.

Mr. Dunn. [Presiding.] The gentleman yields back.

I now recognize the gentleman from Virginia, Mr. Griffith.

Mr. Griffith. Thank you very much, Mr. Chair.

Ms. O'Connell, a nitrile glove manufacturer in my district is aiming to create the first domestic facility to create both the base nitrile glove ingredients and production of the final nitrile glove.

Their initial application was just for glove production, but it is my understanding from them that HHS and DOD encouraged them to expand their production capabilities to do both the final production of gloves and base ingredients for the glove manufacturer, which they did. However, HHS only provided a grant for a period of the expanded capabilities cost and has not provided additional assistance to help with the completion of the dual project, which is necessary for them in order to begin production.

Does HHS not view it as their responsibility to see this project fully through?

Ms. O'Connell. Thank you, Mr. Griffith.

The investments in glove manufacturing were extraordinarily challenging. The grant that you mentioned was made by the first Trump administration, and they did it in accordance with an assisted acquisitions relationship they had with DOD.

So DOD competed and then managed that contract. They set it up as a firm-fixed-price contract, which means as there were cost overruns in the development of the manufacturing site, no additional money could be added to that contract. DOD decided at the completion of the contract that it was done and complete. And if we were going to add additional money, we would have to recompete in an entirely new contract. We -- and I think everybody is aware of this. I have come to Congress many times to talk about the funding that was needed in order to make those additional investments.

At this point, the office that is managing our supply chain has $10 million identified in the next budget. That is not enough to be able to bring that glove manufacturing on board.

Mr. Griffith. So you will work with me to figure out ways that we can get that plant finished? Because we have got this beautiful facility that is not finished and, therefore, no jobs and no real asset for the community. All right. Thank you.

I truly believe that having a real buy American policy for government agencies on masks, gowns, and other PPE will stimulate American manufacturing and decrease the likelihood of shortages if we have another situation similar to COVID.

Does any witness disagree with me on that? Raise your hand if you disagree. I will give you a minute.

All right. I didn't think you would, and I do appreciate that.

Again, Ms. O'Connell, as we have heard today, the U.S. is incredibly too reliant for active pharmaceutical ingredients from foreign countries, specifically China and India. This is a serious national security threat.

One solution is from a company in the Richmond area named Phlow, P-h-l-o-w, who is in partnership with the Federal Government to bring the U.S. to a competitive advantage with foreign countries to produce fully domestic essential medicines.

What other incentives and policies can be implemented to not only support these efforts but also encourage other companies to follow suit?

Ms. O'Connell. Thank you, Congressman.

So the Phlow contract is one that we spent a lot of time with and were very pleased with the outcome of what they have been able to do. I think that is a perfect example of some of the ways we need to work moving forward.

Bringing the incentives there to Richmond was critical, and the proposal to have some sort of stockpile of those active pharmaceutical ingredients, I think, is something that the U.S. Government should pursue moving forward.

Mr. Griffith. I appreciate that. I am going to switch gears a little bit on you. Has HHS considered starting a pilot program where they would ship close to expiring PPE, et cetera, in the Strategic National Stockpile to a rural hospital, so instead of throwing them away, we can actually get some benefit out of it?

Ms. O'Connell. Well, we looked at that, and I think that is absolutely right. We are trying to encourage the SNS to think in innovative ways. Some of what we found was not everybody was interested in just-about-to-be-expired PPE. They wanted new PPE. But we continue to push on that.

Of course, I am not in a position to make those decisions now but would, you know, encourage my former colleagues to consider it.

Mr. Griffith. I appreciate that greatly.

Mr. Cashman, it is great to see you again. While your operation is technically in Mrs. Harshbarger's district, I would suspect that at least 40 percent of your employees are probably living in my district since you are so close to the line that you could probably walk from your facility to my district without any great difficulty.

At the meeting that we had previously, you mentioned how HHS awarded a company a contract that might not have been a fully domestic manufacturer. Can you explain that briefly, because my time is about up?

Mr. Cashman. Congressman Griffith, effectively, yes, you could walk from our plant to Virginia.

Yes -- regarding that contract, yes, the best of our knowledge, we understand that that company imported API, active pharmaceutical ingredient, from China, and we don't know where it was manufactured, but it was effectively the only company that was awarded a contract for the SNS.

Mr. Griffith. And you don't do that. Is that correct? You don't import your API from China?

Mr. Cashman. No, sir. We import our API from Europe. Thank you.

Mr. Griffith. All right. I appreciate it. My time is up. I must yield back.

Mr. Dunn. The gentleman's time has expired.

And I now recognize the gentlelady from California, Ms. Kelly.

Ms. Kelly. I am from Illinois, but thank you. I am Illinois. Thank you, Mr. Chair and Ranking Member DeGette, for holding today's hearing.

The stability of our healthcare supply chain is not only an economic issue but one deeply tied to national security and public health. Health systems, providers, and patients alike have all felt the strain caused by the waves of drug shortages.

Over the past decade, we have witnessed chronic underinvestment in public health infrastructure, notably during both of the Trump administrations. In 2019, the Strategic National Stockpile faced budget constraints even as warnings mounted about supply vulnerabilities.

Now, in his second term, under his bill is an attempt to reduce Food and Drug Administration funding by $200 million. The Trump administration and RFK are actively undermining our ability to support supply chain resiliency by gutting the Federal workforce and dismantling key responsibilities within the FDA. This uncertainty poses a significant risk to the FDA's ability to effectively oversee critical functions and threatens the integrity of our healthcare supply chain.

Ms. O'Connell, thank you for your work on equity and access to care during your time under the Biden-Harris administration.

Apart from the devastating impact to America's R&D and innovation, how will cuts to our public health agencies impact our ability to strengthen our domestic supply chain and reduce our dependence on China, who is actively supporting R&D and innovation?

Ms. O'Connell. Well, as we have talked about today, Congresswoman, the innovation is going to be critical to us being able to afford to reshore some of the production that has left our shores over the last 50 years. And in order to invest in that innovation, we need to have the research and development in place.

Cuts to the administration -- you know, to what we are seeing in HHS are impactful in a lot of ways in our preparedness and response efforts. You know, in order for us to have the tools we need ready to go, we need to be able to invest both in the advanced research and development of those

tools, as well as the stockpile and procurement of those tools. And with limited funds, we are unable to do what we were able to do before.

I continue to say "we." Of course, it is not we anymore; it is they. But just a reflection on what the U.S. Government is going through right now.

Ms. Kelly. Thank you so much.

A recent Brookings report titled, The Wild East of semaglutide, raised concerns about the safety of compounded GLP-1 products, particularly those sourced from overseas manufacturers that have not been inspected by the FDA. Some of these products were found to contain unidentified impurities with limited regulatory oversight in place.

Given these findings, can you also speak to the risks those pose to patient safety and whether stronger safeguards are needed in the supply chain? Ms. O'Connell.

Ms. O'Connell. I am sorry. Can you please --

Ms. Kelly. What I was asking about is, there was a question about the safety of compounded GLP-1 products, particularly those sourced from overseas. How safe are those? Because there is questions around FDA and their ability to inspect.

Ms. O'Connell. Absolutely. So seeing these FDA cuts is -- you know, one of the impacts of that is that we are not able to secure and make sure that our products are as safe as they should be. And I think that is extraordinarily impactful for the country.

Ms. Kelly. It is very scary. Thank you.

According to the DOGE Terminated Contracts Dashboard, on April 25, DOGE canceled four major contracts with U.S.-headquartered genomic sequencing companies who are responsible for tracking coronavirus variants in the United States and from 25 other nations around the world.

Ms. O'Connell, do you believe that cutting the laboratories that provide over 80 percent of the CDC's critical data for public health response enhances our safety and preparedness? Excuse my voice.

Ms. O'Connell. Making those cuts does not enhance our safety and preparedness. We need that surveillance to know what is coming next, and it is critical that we are able to do the genomic sequencing in order to see what is coming.

Ms. Kelly. Thank you very much. Thanks to the witnesses.

And I yield back.

Mr. Dunn. The gentlelady yields back.

And I recognize the gentleman from the great State of Florida, Mr. Bilirakis.

Mr. Bilirakis. Thank you very much. Appreciate that, Mr. Chairman. Thank you again for holding this hearing on this very critical issue.

The healthcare supply chain is incredibly complex, and we need to do more to protect our supply chains from vulnerabilities. This is not only a health issue but a national security issue. Public health and wellness should not depend on foreign adversaries, plain and simple.

I am proud to be a founding member of the American-Made Medicines Caucus with my good friend, Chairman Buddy Carter, and look forward to advancing key policies on this particular issue.

I am also encouraged to hear that we are already making progress to invest in domestic manufacturing. Last year, I had the privilege to visit Med-Nap, a company in my district that specializes in saline and medical-grade wipes. This company has recently expanded and has significant plans to expand further but struggles to compete with China, unfortunately.

We must protect American leadership and innovation with regulatory and market certainty. I look forward to learning from you today, the witnesses, and already have.

But the first question is for Dr. Piervincenzi. Your organization has unique visibility into the domestic pharmaceutical supply chain. Your testimony mentions, and I quote, a fundamental shift in the market is needed to align supply and demand forces.

Can you provide more detail on the types of incentives needed to make this shift, please?

Dr. Piervincenzi. Thank you, Congressman. I appreciate that opportunity.

Mr. Bilirakis. Of course.

Dr. Piervincenzi. USP is working in a public-private partnership to address two sides of this: the incentives that you describe on the one hand and then the capacity on the other.

On the incentives side, the incentives really come back to the buyers. We need -- the buyers need to be incentivized to make the investments in resilience, which means to purchase medicines where they can rely on the quality, where they can have a higher expectation of consistency, and not only purchase on price. However, those buyers today don't have the data that they need to make that choice, and simply paying more for the same medicine achieves nothing except wasting patients' money.

And, therefore, what we also need -- the second part of this -- are a set of benchmarks that can describe what does consistent quality look like. How do we consider things upstream? For example, a manufacturer who buys their API from trusted sources in Europe or from two locations rather than from an adversary. These become factors. And a variety of those factors can result in something that would be rewarded through a better contract.

So these are the two pieces that we are putting forward when we talk about our supply chain resilience initiative -- benchmarking initiative. Sorry.

Mr. Bilirakis. Thank you. Again, sir, would it be helpful for the Federal Government to conduct a national security assessment on the location and volume of APIs and Key Starting Materials in countries of concern that are used to make drugs for the U.S. market?

Dr. Piervincenzi. Absolutely. Yes. And, fortunately, we are in a position to be able to do that now. We wouldn't have been able to 5 years ago.

USP has already completed mapping nearly all locations for APIs for 94 percent of U.S. medicine. We are in the process and only need a few more months to complete the KSM analysis, which is essentially where are the current Key Starting Materials coming from for those APIs.

The typical medicine today, if you randomly pick something off a shelf in a pharmacy, would probably be a solid oral dosage, a pill, made in India with an API or at least a Key Starting Material coming from China.

And so this mapping has to go upstream to that last step. And then -- then we are not done. Then we have assessed risk. Next step, we begin the process of fixing the problem, which partly could be figuring out different ways to make those APIs.

And so perhaps the only Key Starting Material in the world for a certain antibiotic is from China. Well, let's make it a different way. Chemistry will allow different pathways, and new technologies for manufacturing allow us to use those new pathways.

And then the final thing is that the benefit of chemistry is it doesn't change. So we only have to do that work once, and then we have a permanent database that we can use for the entire medicine supply to find alternative roots. And this is within our reach, in a couple of years, for fractions of a billion, less than 100 million. It is right here, and it is available today.

Mr. Bilirakis. Very good. Thank you.

I yield back, Mr. Chairman.

Mr. Dunn. The gentleman yields back.

I now recognize the gentlelady from Washington State, Dr. Schrier.

Ms. Schrier. Thank you, Mr. Chairman. Thank you to all of our witnesses. This has been such an interesting discussion.

Before I start, I just need to make a couple comments. I want to open today just about recent news and to voice my deep frustration with HHS Secretary RFK, Jr., for unilaterally and just unjustifiably firing all 17 members of the Advisory Committee on Immunization Practices. And, Mr. Chairman, I would like to know if you will commit to having a hearing on this issue.

Mr. Dunn. I will take that up with the chairman.

Ms. Schrier. Thank you. In addition, on the same topic, as a pediatrician, I cannot help to mention that these policies of RFK, Jr., to discourage vaccinations may well decrease or eliminate the U.S. production of vaccinations, which I would consider just as, if not in some cases, more important than having all medications developed and manufactured here in the United States. And I just shudder to think about this in the context of a future pandemic, which will probably not take too long to arrive on our shores.

And then I also want to mention -- because we have been talking a lot about antibiotic shortages in particular, and I wanted to tie vaccines to that. Because although there are some diseases that just cannot be treated -- I mean, we are talking about measles and polio and others -- they can't be treated with medications.

Like, I personally have seen what the HIB, Haemophilus influenzae B, vaccine has done in terms of preventing, not just ear infections, but meningitis and something called epiglottitis, where the epiglottis swells so much that kids cannot breathe until they get intubated. That is virtually gone

now. I have never seen a case of that. And that would have required the antibiotics we are talking about today.

I think about the pneumococcal vaccine and what that has done. Also for sepsis, meningitis, pneumonia, ear infections, and how that has, not only decreased deaths, but has also decreased our reliance on some of these medications.

So I just had to close that loop and make it clear that vaccinations also need to be part of our healthcare strategy and domestic manufacturing.

Okay. On the topic that we are talking about today about having domestic manufacturing, and also, you know, we don't want to depend on our adversaries. I would say nearshoring is another important strategy when we are talking about this.

And I love the concept of the buy American incentive. I think that will work well, especially because Medicaid, Medicare, VA, TRICARE make up such a big part of our healthcare system that if we only did that on the governmental level and dealt with PBM reform, I think that would go a long way to achieving what we are all hoping for today.

I also like that you talked about the other incentives, and I think Operation Warp Speed is really a perfect example of how government incentivized manufa- -- research development, manufacturing of vaccines that have saved millions of lives. I think that has been forgotten in this country, but that that was incredible.

I also will mention that ACIP also vetted those vaccines and is directly tied to saving millions of lives.

Ms. O'Connell, it is great to see you again. I was wondering if you could first just discuss how Federal research over decades led to development of the COVID vaccines in less than a year, record time?

Ms. O'Connell. Well, that is exactly right. And one of the things I think people forget is that when the Trump administration first started Operation Warp Speed, they invested in several -- an entire suite of candidates of various platforms, and each of those platforms came through some early research work that NIH did and some advanced research and development that BARDA did.

So the government was critical in helping to see the success of each of those platforms come through. It turned out that the mRNA platform was the one that moved us quickly. You know, you mentioned the one that was done within 11 months. That was -- we were able to -- the Trump administration at that time was able to push that research through and develop that vaccine, and it did provide significant protection for millions of Americans.

Ms. Schrier. Thank you. And just to double-click on that, NIH research over 10 years led to that, and China is currently seeking access to that technology.

Okay. Last, government strategy in terms of having manufacturing facilities. I found it so interesting that there is all these retired manufacturing facilities out there that aren't being used that could be rehabilitated that could speed this path. And I just wanted to just drill down a little.

Is it possible for, like, a given manufacturing facility to kind of shift lines to produce different kinds of medications, and has there been a strategy developed about which facility could manufacture what car facility produced ventilators?

Go ahead and answer. Anyone.

Dr. Piervincenzi. Sorry about that, Dr. Schrier.

So to some degree, within a type of medicine. So physically, rather than how it treats. So solid oral dosage form, a sterile injectable, saline; these will be quite different. However, switching from one type of -- within a similar bucket becomes much more feasible and faster.

Ms. Schrier. That is great. I have to yield back, but I like that reassuring answer. Thank you.

I yield back.

Mr. Dunn. The gentlelady yields back.

I now recognize the gentleman from Pennsylvania, Dr. Joyce.

Mr. Joyce. Thank you, Mr. Chairman. And thank you to our panel for appearing here today on such an incredibly important topic.

With President Trump's executive orders aimed at increasing domestic manufacturing and more resilient supply chains, we have seen a multitude of new investment announcements in the U.S., specifically in the pharmaceutical space. It is for this reason that I am glad this subcommittee is reviewing the issue today.

Access to generic drugs is critical to American patients, as generic medications make up 90 percent of the prescriptions filled in the U.S. And they are essential to keeping costs down across the healthcare system.

During the 118th Congress, this committee put forward a number of ideas to strengthen the supply chain and address drug shortages. One core provision in that legislation was to finally fix the Medicaid generic drug inflation penalty. The incorrect application of an inflation penalty to the generic drug market has resulted in drug discontinuations, shortages, and further instability in the generic drug supply chain. This financial penalty can drive low-margin essential medicines into negative territory, forcing manufacturers to leave markets, which ultimately leaves the patient without the medicines that they need.

Mr. Murphy, you mentioned this penalty in your testimony. Can you elaborate on how it creates uncertainty for generic manufacturers and why reform is necessary in this specific area?

Mr. Murphy. Well, Dr. Joyce, thank you for the question.

And as, you know, we have said across our testimony, the generic marketplace has a number of critical factors facing it that are negative. I would think from a -- at a broader level, though, when we talk about domestic manufacturing, one of the things we really want to talk more about is how we can move the markets to more appropriately treat generic medicines in the reimbursement system.

So we talk about PBM reform, we talk about domestic manufacturing incentives, because it is really -- it is a critical component of the U.S. market that we don't do enough for. And so we would love to follow up with your office and talk more about concrete steps we can take, but I think we look at the overall picture of this hearing to say there are lots of structural problems in the market that we need to address, and we hope to work with Congress collaboratively on a suite of reforms that we can get to to ultimately make this market a more predominant force in the U.S. manufacturing base.

Mr. Joyce. And I would welcome that, to open that dialogue, so we can make those concrete steps forward.

So as we talk about strengthening our pharmaceutical supply chain, I urge my colleagues to also consider reforms that address the market challenges in the generic drug supply chain. We need policies that reflect the realities of the market and support, not to stifle, access to affordable medications. It is also important to acknowledge existing barriers that exist to reshoring manufacturing in this space.

Mr. Murphy, can you walk me through the average timeline and process to establish and construct a facility in the U.S., starting from the initial decision to invest, permitting, inspection, to fully opening and operating? How long does that generally take?

Mr. Murphy. So based on our conversations with our manufacturing members, once you have raised the capital, which is in and of itself a barrier in the generic market, you are looking at

close to 5 to 7 years if you are going to build a new facility. And there are State laws that actually come into play too that we really think we should talk about.

Mr. Joyce. And do you have any estimate on the costs that are associated with these processes, as well as the corresponding delays which occur because so many inputs have to be taken into consideration?

Mr. Murphy. Yes. So what we understand, in new facilities, right, a new API facility, you are talking a couple hundred million dollars. And that is, you know, at a small scale. If we wanted to start really scaling up, you know, it is a significant investment for our manufacturers.

Mr. Joyce. That is a significant cost, and that is a long time. I must imagine that these burdens play a role in making decisions about where companies should invest, especially when facing those daunting costs.

With my remaining time, Mr. Murphy, what are the top three regulatory burdens that we in Congress could change to improve this process?

Mr. Murphy. Yeah. Thank you for that question, Dr. Joyce.

So, one, I think we need to streamline the regulatory review process both on the environmental, the water quality, as well as the FDA inspections process. It doesn't mean limiting the safety and effectiveness of FDA, but figuring out ways for more complex generic development to be streamlined and prioritized at the agency.

I think PBM reform, to try and take the stranglehold over pricing that is occurring in this country back and put it back in the driver's seat for generic manufacturers is another.

And then I think also prioritizing generic access once they become available on the market. Too often products remain in a predominant position to provide access to patients over top of generic approvals.

And we could fix all three of those with this committee's help.

Mr. Joyce. I look forward to beginning this process and to work with you. This committee is dedicated to making sure our patients have access to affordable, efficient medications. I thank the entire panel for presenting here today.

Mr. Chairman, I yield back.

Mr. Dunn. The gentleman yields back.

I now recognize the gentlelady from Michigan, Mrs. Dingell.

Mrs. Dingell. Thank you, Mr. Chair. Thank you for holding this important hearing.

We have really realized -- the COVID-19 pandemic really showed the world how our supply chains were disrupted significantly and how we must focus on bringing production home. It is a public health safety issue and it is a national security issue, which too many people do not realize.

Congress needs to ensure that we are prepared for what is to come, increase our ability to onshore healthcare manufacturing, as we have very clear bipartisan agreement on, and respond effectively to disruptions.

It is critical to ensure healthcare providers have access to the medical supplies and the prescription drugs that their patients rely on. And I think too many people do not understand how drug shortages in this country are leaving thousands of patients in distress. No one should have to panic and fight to find the medications their doctors know are necessary for their treatment.

We must work, as everybody is talking about, to onshore pharmaceutical supply chains, incentivize the production of generics, find ways to ensure we understand why shortages are happening, getting earlier alerts, helping with broad distribution and many other issues.

I am going to -- so I actually have more questions from some of your answers, but I will go to my first one that I do want to say because one of our concerns -- my concern is the ability to achieve

these solutions is extremely difficult, if not impossible, as a result of the drastic reductions in force of $400 million in budget cuts at the FDA proposed by the Trump administration. Without a strong FDA workforce, we can't ensure we are safely and effectively doing the critical work needed to maintain the safety of our drug supply chain.

So, Mr. Murphy, the Trump administration has made these drastic reductions in the FDA workforce. How have large-scale staff reductions affected the ability of the FDA to maintain this prescription drug supply chain, and what long-term effects can we anticipate on our drug supply and resulting costs for American patients?

Mr. Murphy. Thank you for that question, Mrs. Dingell.

We have seen delays already this year in the release of what are called product-specific guidances, which are the critical components that generic manufacturers need to develop the products to get them approved by FDA. And so that was, I think, the first backlog we saw at a very material level. I will say, just last week, the FDA did start releasing those product-specific guidances again, and so we are hopeful that we will continue to see that backlog eaten away at.

But, you know, I will say as a representative of the generic industry, every month's delay of a generic drug getting to market is a month that patients are paying more for branded drugs than they should be for generic drugs.

Ms. Dingell. I do have a question. And I am probably going to have to do a lot more questions for the record. I am mainly concerned about the drug shortages that patients are currently facing, and some just don't make sense to me.

An example, an asthma drug that many pulmonologists now want to use has gone to generic, but the generic is taking months. And you have got -- the supply chain is so complicated. But pulmonologists are talking to me about how their patients can't get the generic, and the generic is

more -- I wish I could remember the name of it. And it doesn't make sense. And yet it is a real problem. And that is just one. There are about 20 other drugs I could name off the top of my head.

Can you speak to how these cuts to our supply chain infrastructure will specifically impact the ability to address existing and prevent future drug shortages?

Mr. Murphy. Yes. So certainly, FDA's inspection capacity is critical to ensuring that products can get to market. And, you know, we hope to see, as staff are added back to FDA -- which we understand is occurring -- that those inspections will pick up.

But I don't want to discount the fact that, in the drug shortages space, just for purposes of clarity, that, you know, price in the generic market is a huge driver of drug shortages, and that is something we would love to work with the committee to address.

Ms. Dingell. We would love to get some specific recommendations on that.

You know, Mr. Chairman, I am down to 29 seconds. So I guess what I am going to do -- I have a lot of questions for the record, and we will -- and this is my partner in PBM reform, so we both totally agree in a bipartisan way.

Mr. Carter of Georgia. [Presiding.] Absolutely.

Mrs. Dingell. I will yield back.

Mr. Carter of Georgia. Thank you. The gentlelady yields.

The chair now recognizes the gentleman from Ohio, Representative Balderson, for 5 minutes of questioning.

Mr. Balderson. Thank you, Mr. Chairman.

Thank you all for being here today. I am looking forward to hearing some responses for my questions, and I appreciate the innovation of quality care that is available to all Americans.

I am proud to represent Ohio. Mr. Bolin talked about Ohio, a State that continues to support innovation, investment, and domestic development, clearly impacting the patient community.

Recently, I had the privilege of attending a groundbreaking in my district for Amgen's new advanced manufacturing facility in New Albany, Ohio. And with Central Ohio being home to McKesson's largest and most advanced pharmaceutical distribution center as well, I can proudly say that the world's leaders in medicine are investing right here at home.

The policies we work on should continue to support companies we choose to do business here in the United States, allowing for innovations to be accessible to all Americans.

Mr. Bolin, my first question is for you, and thank you for being here. And I apologize for running back and forth between meetings.

I have led bipartisan letters to the FDA twice, raising question about the industry's ability to comply with the drug chain supply security act and warning of possible drug shortages and supply chain disruptions if the FDA fails to act ahead of the enforcement deadline of the DSCSA. I know progress has been made since the implementation process began, and as of 2024, the FDA announced a set of phased exemption periods that will expire on different dates this year.

Given your background, I am curious to hear from you about the importance of this process, as well as the importance of ensuring the supply chain remains uninterrupted as the exemption periods come to an end.

Mr. Bolin. Sure. Thank you, Congressman.

So as you mentioned, last year, FDA has implemented this more of a phased implementation process for full implementation of drug traceability throughout the supply chain. The manufacturer exemption actually just expired less than a month ago, and so manufacturers now have to fully comply with the law.

The next expiration period comes up for both distributors and for pharmacies later this summer. And FDA has been holding a number of townhall meetings and listening sessions from each of the sectors to try to understand where each of the sectors stand moving toward implementation.

The manufacturing community, I think, by and large is and was ready. Major distributors are well on their way. And there are going to be some questions about where the pharmacy community is when it comes to compliance. Many of the larger chain pharmacies have already, you know, come into compliance, by and large. The smaller independent community pharmacies are likely going to be leaning on their small dispensary exemption that they have, which gives them until next year.

Of course, the concern with that is that the longer it is for the supply chain to come into full compliance, the more susceptible it is for illicit products making their way into the legitimate supply chain, as we have seen with the GLP-1 medications in Arkansas and in Mississippi. And we have seen more recently HIV -- counterfeit HIV medications making their way into pharmacies in New York.

So the longer the implementation takes, the more concern there certainly is.

Mr. Balderson. Okay. Thank you. Appreciate that.

Dr. Piervincenzi -- I hope I said that correctly, sir. I mean no disrespect -- thank you for being here today also.

We know that a recent analysis showed that around half of the active pharmaceutical ingredients, APIs, for prescription medications in the U.S. come from India and the EU, with around 12 percent being manufactured domestically here in the U.S.

From your perspective and with your great experience, how do you believe we can increase this share in a sustainable way?

Dr. Piervincenzi. Thank you, Congressman Balderson, for that question.

It is two layers to it. I think the first layer is to increase production of API will require new facilities and substantial new investments and time. There are shorter term ways to bridge the gap and to create a more secure supply chain, including through friendshoring and other purchasing opportunities.

And, finally, also considering the potentially even higher vulnerability to the starting materials upstream of the API, which may be even more highly concentrated in adversary countries and coming to us through India and Europe.

So we talked earlier about the good news being there is new return opportunity and some untapped potential for some production. But for API production, unfortunately, we are going to have to do this from -- mostly from scratch. And that is why USP is talking about creating easier access to the advanced manufacturing technologies, especially for generic companies, who today are struggling to be able to make any capital investments like that in the U.S.

Mr. Balderson. Okay. Thank you very much.

Mr. Bolin, you got -- I had another question. We are out of time.

Mr. Chairman, I yield back.

Mr. Carter of Georgia. The gentleman yields.

The chair now recognizes the gentleman from Texas, Representative Veasey, for 5 minutes of questioning.

Mr. Veasey. Mr. Chairman, thank you very much.

And I am glad that we are here having this conversation today about this supply chain of drug supplies. I think it is very important, and I too am worried about the U.S. losing ground to this area. I don't want to cede anything, whether it is solar, pharmaceutical drugs, whatever, to the Chinese. I think that is bad.

And one of the things that worries me and we will fall even further behind in the race is the fact that the Trump administration has laid off more than 3,500 FDA employees, and many of them performed very essential functions, like drug inspections, generic drug reviews, oversight roles funded directly through user fees.

And at the same time, the administration is imposing these sweeping tariffs on these pharmaceutical ingredients and manufacturing equipment, and we don't even make that manufacturing equipment, for the most part, here in America. A lot of this manufacturing equipment, if you have visited any of these facilities, they come from places like Germany. And it is -- all of these things are going to mean that the American consumer could end up paying more for these tariff taxes.

And so I wanted to ask Ms. O'Connell, we have seen firsthand how fragile this pharmaceutical supply chain can be. How do the current administration's actions, including unleashing these tariff taxes, serve to further undermine our pharmaceutical supply chain, and what are some specific effective ways the Federal Government can strengthen supply chain resiliency?

Ms. O'Connell. Thank you, Congressman.

I think one of the challenges with, you know, a policy initiative like the tariffs we have seen is it should be accompanied by investments in domestic manufacturing. Just putting tariffs on various products increases the price and likely decreases access for the American people to those products.

What is important is that any tariff actions -- and, you know, they are a really good tool to be able to use thoughtfully. Any tariff action should be accompanied by investments to make sure that there is adequate domestic manufacturing so the American people continue to have access to the products that they need.

Mr. Veasey. Yeah. No, absolutely.

Mr. Murphy, you noted in your testimony that there is a structural challenge that generic manufactures face, including a lack of significant U.S. Government financial incentives to encourage domestic production of generic drugs.

Can you expand on how this strategic stockpiling, either at the national or State level, can help encourage manufacturers to invest in U.S.-based production even when there are high costs and market uncertainties that are involved?

Mr. Murphy. Yeah. Mr. Veasey, thank you for your question. Thanks for your support on the stockpiling act that you are working on.

One of the things we talk with our manufacturers about is what are creative ways to sustain supply commitments across the U.S. as we work on market challenges, like PBM reform and reimbursement. And one of those areas we talked about is, can the government provide a more stable supply market at a fixed price for a period of time that gives some certainty to producers who may be looking to invest in the United States and could get preference in that regard while we work across the market to sustain, you know, the overall generic supply chain in a more holistic way.

So, you know, we view that as a critical interim gap that both secures the supply chain for American patients by having some supply at the ready given pandemic or other challenges, but also helps bridge the market and gives some certainty to manufacturers who are producing either, you know, in the U.S. or friendshore countries while we work on other structural reforms to the marketplace.

Mr. Veasey. Yeah. No, absolutely. And I really appreciate you mentioning the bill that I have, the State Strategic Stockpile Act, which will provide States with financial assistance to establish, expand, or maintain their own strategic stockpiles. I think that that would really help in raising some of the concerns that you have. So I really appreciate that.

Mr. Chairman, with that, I yield back the remainder of my time.

RPTR KRAMER

EDTR CRYSTAL

[12:01 P.M.]

Mr. Carter of Georgia. The gentleman yields back.

The chair now recognizes the youngest pharmacist in Congress, Representative Harshbarger, from Tennessee.

Mrs. Harshbarger. Yeah. Thanks for that, Mr. Chairman. I appreciate that. Thank you.

And thank you to the witnesses for being here today.

And I am especially pleased to see you, Mr. Cashman.

He is president of USAntibiotics, and his facility is a magnificent facility in my district of east Tennessee. And if you don't know the story of how USAntibiotics was resurrected, you need to read it, talk to me or talk to Mr. Cashman, because it is a remarkable story. It is a critical infrastructure facility.

So thank you for being here.

But before I get to questions, I do want to -- I think I need to talk about -- I am a compounding pharmacist. So I want to talk about strengthening the safety and security and quality of our healthcare product supply chains.

Talking about compounding, there is an indispensable role for pharmacy compounding. And for 25 years, I came to the Hill to beat that drum about my profession and the overburdensome regulations to where we couldn't get patients the medications they needed.

And compounding starts with a problem. For whatever reason, there are a lot of people that can't take mass-produced medications, and these compounding medications will provide a solution.

And not all compounders are the same. Let me make that perfectly clear. But there have been recent reports -- wrong reports, basically -- that have referred to compounded drugs as counterfeit or knockoffs or copycats.

And let me assure you, they are produced legally, they are regulated, and they serve as a critical lifeline for millions of patients. And many times have we stepped in when there are drug shortages and we have to provide that to patients to save their lives.

So you are going to have bad actors, and you are going to have those compounders that are lifesavers.

So, Mr. Chairman, for the record, I would like to submit an article that corrects the record and discusses how misrepresenting compounded medications hurts patients, undermines trust, and are a vital part of modern healthcare.

Mr. Carter of Georgia. Without objection.

[The information follows:]

******** COMMITTEE INSERT ********

Mrs. Harshbarger. Thank you, sir.

Now I will get to the questions, the good stuff.

Mr. Cashman, you said that the U.S. Government needs to prioritize made-in-America medication acquisitions over and beyond price comparisons. Do you think this approach will lead to higher drug prices for American patients and taxpayers?

Mr. Cashman. Thank you, Congresswoman Harshbarger. And good to see you as well.

It is a valid concern. But I think it is something we really need to look at more broadly.

When shortages occur, as they did in 2022 and 2023, physicians are forced to use less effective alternatives -- you know that very well as a pharmacist -- leading to longer hospital stays, the potential for antimicrobial resistance in the case of antibiotics, treatment failures, and eventually higher overall healthcare costs.

The economic disruption from supply chain failures far exceeds any premium for domestic production. More importantly, we are not asking for subsidies or price guarantees. We are asking for purchasing policies that factor in more than just price, things like supply chain security, national security, public health, and welfare, alongside costs.

A slightly higher upfront price is a small insurance premium against catastrophic costs of shortages or supply disruptions.

Mrs. Harshbarger. Yeah. To me, it is a national security issue. When you know that it is really closer to 90 percent of your APIs come from an adversarial nation and 70 percent of India's APIs come from China, there is a problem, and there has been. And that is why I am here.

So you mentioned that USAntibiotics serves about 5 percent of the market despite having capacity to serve 100 percent of the market. You got 390,000 square feet. I have been there. And it

is not just your amoxicillin you could do. You could venture into cephalosporins or other drug therapies within that plant.

So what prevents you from scaling up, sir?

Mr. Cashman. Our plant can produce any beta-lactam antibiotic, Congresswoman. And what prevents us from scaling up is really long-term agreements with both commercial and government buyers.

That would really help our business. It would allow us to make appropriate business decisions and make investments and scale up when it is appropriate.

Mrs. Harshbarger. Yeah. Because we are hearing from physicians and healthcare providers all over the country about antibiotic resistance and things of that nature, and you want to make sure that those antibiotics you are receiving, in a finished product even, is exactly what it says it is. And when you have healthcare facilities testing their finished product, that shows you that not everything that says it is, is really what it says it is.

You mentioned the government spent 40 million on foreign-origin amoxicillin while buying less than $1 million from USAntibiotics. Isn't the government supposed to take the lowest bids?

We need those origins of what they are buying. Aren't they supposed to take the lowest bid? You are only getting a million dollars worth of a $40 million business, and you are a domestic manufacturer.

Mr. Cashman. So, Congresswoman, let me understand your question. Please, can you rephrase the question so I better understand?

Mrs. Harshbarger. Well, you are a domestic supplier. The government spent 40 million on foreign-origin amoxicillin. And they only -- you only -- I guess, you have less than a million dollars

spent on your market of amoxicillin. Is it because of the price? Or why would you be excluded from that contract?

Mr. Cashman. Thank you, Congresswoman. Now I understand.

Mrs. Harshbarger. Okay.

Mr. Cashman. The contract for the SNS was focused on small businesses. We are not considered a small business because of our ownership structure. So we weren't allowed to compete for that contract, that specific contract.

Mrs. Harshbarger. Okay. Got you.

Mr. Cashman. Yes, price is part of the government's decision, but we would ask that they take a broader view and look at other factors as well.

Mrs. Harshbarger. Yeah.

Mr. Carter of Georgia. The gentlelady's time has expired.

Mrs. Harshbarger. Thank you. I yield back.

Mr. Carter of Georgia. The gentlelady yields back.

The chair now recognizes the gentlelady from Texas, Representative Fletcher, for 5 minutes of questioning.

Mrs. Fletcher. Well, thank you, Mr. Chairman.

And thank you to all of our witnesses today for your testimony. I have appreciated it. And I think that your prepared testimony and answers to the questions today have been really helpful on this important topic.

This has long been an area of bipartisan agreement, and I do hope we can move forward on some of the thoughtful recommendations and ideas that we have heard, not only today but over the last several years, about this issue.

But once again, I caution everyone on this committee and everyone participating that these are not normal times. And we can't pretend that they are. To the extent that holding this hearing suggests that they are, we have to acknowledge that they are not.

Like my colleagues who have spoken before me, I can think of more than a dozen topics that this subcommittee should be holding a hearing on about unprecedented and tremendously damaging recent actions in the Trump administration, like the announcement that the Secretary of Health and Human Services just fired all of the members of the Advisory Committee on Immunization Policies; or the staff reductions and delayed and cancelled research at the National Institutes of Health; or pauses in funding for grants at institutions that do critical medical research, undoing decades and decades of work that this country has invested in to lead the world in medical research and in scientific research more broadly.

These are just not normal times. And these are huge issues in my district where so many people work at the Texas Medical Center, the largest medical complex in the world, doing the groundbreaking research that we are talking about in this country, including development for new vaccines for diseases threatening people here at home and around the world.

So I appreciate the importance of making our healthcare supply chains more resilient, but we cannot have this conversation without acknowledging that the Trump administration is today taking steps to gut our Federal agencies that are directly responsible for making these supply chains function properly and result in safe and effective medical products for Americans.

It was only 2 months ago that HHS fired 10,000 workers across the agency, including 3,500 at the FDA. The mass layoffs were done so haphazardly, as many of us in the room know, that the FDA had to hire some of those people back because they were critical to food and drug safety and work at the agency.

Another example. Firing all 13 of the Division of Policy Development staffers in the Office of Generic Drug Policy at FDA. This team drafts, reviews, approves the policy guidance that we are talking about, gives instructions on how generic versions of branded medicines can be developed and brought to the market, the kinds of things we are talking about today. The administration is gutting these agencies that do absolutely critical work.

And so I am glad that the administration realized its mistake and that some of these FDA employees have been rehired. But it is another example of a "shoot first and ask questions later" approach that is a huge threat to our healthcare supply chain.

So for months, guidance documents outlining the approval of pathways for generic drugs were put on pause. Mr. Murphy, I know that your agency -- or your organization -- put out a press release expressing concern about this in early April, about the staffing cuts at FDA.

Can you share with us how has the confusion from the firing and rehiring of this team and the subsequent delays in issuing new guidance impacted generic drug development and approvals?

Mr. Murphy. Yeah. Thank you, Mrs. Fletcher, for the question.

As you noted, obviously, we view FDA as a very critical component of the drug supply chain both in ensuring safety and making sure patients understand what they are getting. It is effective.

We did see a number of delays this year that thwarted the ability of manufacturers to request product-specific guidance. It does appear that that is starting to come back online. And I think we were very heartened to hear that the agency is starting to look at the Office of Generic Drugs to rehire individuals because it is a component of the agency that I think could benefit from more capacity versus less capacity.

And so we were glad to see Commissioner Makary announce they were going to bring those folks back to the Office of Generic Drug Policy. But we now have a backlog that we have to work

through. And from a generic drug standpoint, that inhibits the ability to bring more affordable medicines to patients sooner.

So we hope and we look forward to working with the agency to try and address that backlog.

Mrs. Fletcher. Well, thank you, Mr. Murphy.

And I just want to reiterate, it doesn't have to be this way. It doesn't have to work this way. This is an approach the administration has chosen and there are other things the administration has chosen to do.

I am going to submit a question for the record to you, Mr. Bolin, because another thing that this administration has chosen to do is impose tariffs on all kinds of imports. We talked about it a little bit earlier. But I want to ask you and will submit for the record a question about how those tariffs are impacting pharmacies.

I am hearing and seeing reports particularly that tariffs on pharmaceuticals might impact pharmacies, and I know that that is a concern certainly for our chairman and for all of us for access to drugs for our constituents.

So I thank you all very much for your work and for your time today.

And I thank you, Mr. Chairman, for letting me go over just a minute. And I will yield back.

Mr. Carter of Georgia. The gentlelady yields back.

The chair now recognizes the gentlelady from Iowa, Dr. Miller-Meeks, for 5 minutes of questioning.

Mrs. Miller-Meeks. Thank you, Mr. Chair. I will try to stay on time.

Let me just say that nothing could be more important than this hearing today. I recall last term that the now-minority party held up the reauthorization of PAHPA because we didn't address drug shortages with more regulation on the FDA, which is certainly not the answer.

This is a pressing issue that impacts all Americans regardless of demographic and geographic location, which is our healthcare supply chain. It includes pharmaceuticals, medical device components, bandages, and other lifesaving products which everyone in this room has either used, currently uses, or will use at some point.

And I applaud recent efforts by the Trump administration to boost American supply chain production, such as the recent announcement of the opening of a facility in North Carolina to produce carbon black well ahead of schedule.

Examining our supply chain is essential not just to ensure patients have the resources they need but also to ensure we are not too reliant on other countries like China for supplies.

As has already been addressed, only 19 percent of active pharmaceutical ingredients, for example, are produced in the United States, 13 percent from China, and 21 percent from India.

The reliance on other countries for generic drugs, which comprise the majority of prescriptions filled in the United States, is even higher, presenting additional and concerning challenges.

Having robust U.S.-based manufacturing is also essential to combating drug shortages, which a number of our health systems in my district are currently facing.

In addition to boosting manufacturing capabilities, there need to be appropriate incentives to support innovation, which is why I am concerned about the damage that government price controls from the Democrats' Inflation Reduction Act has done to U.S. biopharmaceutical research and development, especially in areas like orphan drugs and small molecule medicines, and I have even heard this from pharmaceutical manufacturers abroad.

And, Mr. Murphy, thank you for mentioning PBM reform. My first PBM reform bill was in 2019 as an Iowa State senator. It has been a long time coming for PBM reform.

Since 2021, small molecule development has decreased by 70 percent, which led to fewer cures coming to the market, meaning less new drugs being manufactured and fewer options for patients who depend on innovation. It is why I also support fixing the pill penalty, which will support domestic manufacturing of new and advanced drugs.

Mr. Piervincenzi, do you agree that creating new government price controls could worsen the harm being done by the IRA in terms of discouraging more R&D, and if so, by how much?

Dr. Piervincenzi. Thank you, Congresswoman, for the question.

The important distinction, I think, in the supply chain resiliency is that between the branded medicines and the generics. And we are getting a really much better understanding now. It has been known, I think, to some degree.

On the branded side, what we have is a much higher production of medicines in the U.S. We also have more onshoring going on right now, as we have discussed during this hearing. And this is quite encouraging, and I think this is even more opportunity.

Unfortunately, on the generic side, just the economics and the incentives are just not there. And it is solvable. And, in fact, because the prices are so low, the cost of solving it is actually reasonable. But we don't have any mechanisms to make sure that when people maybe pay more or have a better contract that they are rewarded with something more resilient and they are not just paying for the same thing with more money.

Mrs. Miller-Meeks. And this question is for you again, or for Mr. Murphy.

There has been a lot of talk already about active pharmaceutical ingredients, or APIs, key starting materials, or KSMs, finished dosage forms, and the like.

I want to make sure we are all on the same page. But instead of going through what the ingredients are, let me just say, understanding that there is more to learn based on what we currently know, where are most KSMs extracted and/or produced? Either of you.

Dr. Piervincenzi. Yeah. I am happy to take that, Mr. Murphy.

So we are very close to being able to actually answer that question. The worry has been, as we have gone upstream, we have discussed quite a bit about APIs because we kind of knew that, and that gave us, I think, some concern. But we had a lot more concern in discussions with industry in India, in particular, when we said: Where are you getting your KSMs from for your API production? And the answer was: Mostly "from China.

This was a concern even in India where there are policies -- government policies to incentivize production of KSMs in office parks in India. And this is one piece of the solution. But USP believes we should be looking at that in the U.S. as well to create our own resilience, especially for KSMs.

Mrs. Miller-Meeks. And quickly, where do finished doses come from, both injectables and solid oral doses?

Dr. Piervincenzi. Yeah. So injectable doses we produce much more as a percentage in the U.S., over 50 percent are U.S.

Mrs. Miller-Meeks. Okay. And then, as a whole, what country or countries are we most reliant on, and which products are particularly vulnerable?

Dr. Piervincenzi. Yeah. The simplest answer to that is that most medicines for the U.S. come from India.

Mrs. Miller-Meeks. Thank you. I yield back.

Mr. Carter of Georgia. The gentlelady yields back.

The chair now recognizes the gentlelady from New York, Representative Ocasio-Cortez, for 5 minutes of questioning.

Ms. Ocasio-Cortez. Thank you so much, Mr. Chair.

And thank you to all of our witnesses for offering your testimony here today.

I would love to spend some of this time honing in on the issue of drug shortages. Drug shortages, of course, are more than just an inconvenience for a lot of people, but they can have deadly consequences for people in urgent medical situations.

And one of the most common drugs in the United States right now facing a shortage is the liquid form of Albuterol, which is used by hospitals to treat asthma.

Albuterol has been in short supply since 2022, and this is an issue that hits particularly close to home in my community. In the South Bronx in particular, we face one of the highest childhood asthma rates in the United States.

And when these kids and their parents show up at a hospital and they are unable to breathe, they may not be able to access the medicine that they need if there is a shortage.

Ms. O'Connell, can you help the general public understand why is it that in such a common condition such as asthma, and with such a broadly available drug like Albuterol, how can we get to a place -- and how do we get to a place -- where there is a shortage of it in the United States?

Ms. O'Connell. Thank you so much, Congresswoman.

Albuterol wasn't one of the issues that we dealt with directly in ASPR, but observationally, I think it is a perfect example, as you have laid out, of the fragility of the generics market.

Albuterol is a generic drug, had two manufacturers in the United States. One of them declared bankruptcy and left the market. That left a shortage. And there have been very few

incentives, as has been discussed already at the table, to encourage generic manufacturing of Albuterol in the country.

Ms. Ocasio-Cortez. Thank you.

And I think to kind of disentangle this a little bit more, there is a lot of talk about incentives. But at the end of the day, the United States healthcare system is a for-profit system. And largely, an incentive is about if making it is profitable.

And in the for-profit system, manufacturers need to know that their drugs will be profitable. If it is not profitable, the incentive doesn't exist, it becomes difficult to manufacture.

But if manufacturers can't afford to operate, they will leave the market altogether, as you noted, or move their operations abroad.

Meanwhile, drug shortages are costing hospitals at least $360 million annually in labor costs alone for making up for some of these shortages.

And so what all of these pieces put together are pointing to is a market failure. And, ironically, this market failure is emerging because the drug is affordable, because the price is very low.

My understanding is that the Federal Government has effectively acted in the past to address drug shortages. And in particular, both Republican and Democratic administrations have used the Defense Production Act to address past drug shortages. There has been some discussion today about almost, like, a strategic reserve of sorts but for medicine.

Ms. O'Connell, what is the Defense Production Act, and has the Federal Government used it in the past -- how has the Federal Government used it in the past to address drug shortages?

Ms. O'Connell. Absolutely. Thank you so much for the question.

So the Defense Production Act is an authority that allows the government in times to secure the defense of the Nation or in times of emergency to priority rate contracts to ensure that the supplies that are in the supply chain go to whatever is needed to secure the country.

So in a case of shortages, it would go to the manufacturing of the particular item that is in shortage, to be able to provide that item to the American people.

We used it multiple times, dozens of times throughout the COVID response, both the Trump and Biden administrations. And then outside of the COVID response, we also used it for the infant formula shortage. And we used it most recently for the Baxter IV shortage.

Ms. Ocasio-Cortez. Thank you. Yes. And those are all excellent points because we are hearing talk today of moving manufacturing to the United States, and it is not to give short shrift to that point, but some of those examples that you named -- well, Albuterol is manufactured in the United States. IV fluid, manufactured in the United States. Even a couple of years ago, baby formula also produced in the United States. All three of those things are produced in the United States. All three have had chronic shortages.

Ms. O'Connell, could the Federal Government play a role in manufacturing some of these drugs where we are seeing persistent market failures? I am interested in some of your thoughts to that point.

Ms. O'Connell. Well, this is a question that we always come back to. Should the government be responsible for the manufacture of, say, vaccines? That was a question we asked ourselves during COVID.

And what it comes down to is a commitment from the government to fund both the capacity for the government to do the manufacturing as well as the capability for the government to do that manufacturing.

And over the course of our analysis in looking into this, and over many generations of others in similar situations needing to answer that question, what is needed most is a sustained commitment in funding. And that has not been something that has been demonstrated from previous Congresses.

And so we always went to the public-private partnership, which is a perfect thing that BARDA does, which is invest in the capacity that the private companies have, reserve that capacity for the United States. But the United States doesn't own the actual physical structure and do the manufacturing itself.

Ms. Ocasio-Cortez. Thank you.

Mr. Carter of Georgia. The gentlelady yields back.

The chair now recognizes the gentleman from Michigan, Representative James, for 5 minutes of questioning.

Mr. James. Thank you, Mr. Chairman.

COVID was a clear wake-up call that our Nation, for far too long has been reliant on unstable and adversarial supply chains for our critical medicine and healthcare supplies. When we are relying on China for lifesaving supplies to defend against a Chinese-made virus, something is horribly wrong.

Only 12 percent of active pharmaceutical ingredients, APIs, for prescription medicines in America are manufactured domestically. Half our APIs come from India and the European Union. While China only contributes around 8 percent of APIs, they are a dominant supplier of the key starting materials utilized to produce APIs. They are also the exclusive manufacturer of APIs in essential medicines controlling much of the antibiotic API production.

While we have been asleep at the wheel, the CCP has engaged in a concentrated and strategic effort to become the global leader in biomedicine development and production. I am gravely

concerned over the growing role of the Chinese industry in our medicinal supply chains. Even India, which has made significant investments in carving out a major role in the medical supply chain, is dependent on China, an estimated 70 percent of their APIs.

The warning lights are flashing red, and it is time for Congress to take action. The health of our citizens is a national security imperative, and too many lives are at stake. We must take action, and we must do it now.

So I appreciate you all being here today. And we are trying to look at things different. It is a bipartisan issue to address our medical supply chain. But I believe that Michigan and the Great Lakes region is in a specific and very special position to be able to contribute in new and innovative ways.

Given the push for reshoring and diversifying supply chains, should Congress direct HHS, DOT, and Commerce to study the feasibility of routing APIs and KSMs through U.S. ports in the Great Lakes to reduce reliance on congested coastal ports? Any of you have an opinion?

Yes, sir.

Dr. Piervincenzi. Thank you, Congressman.

It is true we haven't discussed this piece of the supply chain in particular. And in the USP's Medicine Supply Map, most of the U.S.' imported medicines come through the East Coast. And it is something to be considered because that is a vulnerability itself through weather conditions and others.

And so it is something that, if it is of interest, we could utilize the data to try to get you some more information about that.

Mr. James. I would like to follow up with you on that, to at least have a feasibility study. Coming in through St. Lawrence and through the Great Lakes, the ports in Ohio and in Michigan and in Illinois could provide us a very good opportunity to diversify our risk levels in, say, New York, New

Jersey, with that port, or maybe even further south in Jacksonville or Atlanta -- I am sorry -- or Savannah and Charleston and the like.

Mr. Cashman, as the head of the only U.S.-based manufacturer of certain critical antibiotics, you understand logistical hurdles in sourcing both active ingredients and distributing finished drugs.

This is the time to start considering regional shipping infrastructure, again, like Port of Detroit. Is there any targeted investment in port distribution infrastructure that can help firms like USAntibiotics scale domestic manufacturing and create a new route to distribute drugs and ingredients to drug short areas?

Mr. Cashman. Thank you, Congressman.

I am not an expert on that subject. We route all our ingredients coming from Europe through an East Coast port as well. It is something to take a look at. And, again, I am not an expert on that particular topic, so I will pass.

Mr. James. But additional routes might help with resilience and potentially lower cost?

Mr. Cashman. Yes, it would help. Definitely.

Mr. James. Perfect.

Dr. Piervincenzi, USP has done a lot of work mapping supply chain vulnerabilities and drug shortage risks. Has your analysis explored the concentration of pharmaceutical transportation channels? And do you see value in restructuring transport sourcing routes? For example, APIs or KSMs, as we mentioned.

Could USP's Medicine Supply Map incorporate port of entry and regional manufacturing hub data to help us understand how we could mitigate shortages and work through the Midwest?

Dr. Piervincenzi. Thank you, Congressman.

We actually do incorporate, for most products, the port of entry. But your question opens up something that we would be very interested to explore, which is that is only one step in that process.

How else, what are the other links between that the map does not currently contain? But it is an answerable question. So I would be interested to follow up on that.

Mr. James. Thank you for your feedback and advice. I look forward to following up with you.

Mr. Chairman, that is all I have. I yield.

Mr. Carter of Georgia. The gentleman yields back.

The chair now recognizes the gentleman from Massachusetts, Mr. Auchincloss, for 5 minutes of questioning.

Mr. Auchincloss. Thank you, Mr. Chairman. I am going to change my name to Mr. Jones for you.

I appreciate the expert testimony this afternoon.

Mr. Murphy, I want to engage with you, please. And first just by stating there is so much debate in Congress, rightfully so, on expanding access to prescription drugs. And one of the best answers is staring us right in the face, which is genericization of drugs. It is the most effective way to ensure that people have affordable access to medications.

And if I am correct, actually, Americans -- unlike with brand prices -- Americans actually pay less for generic drugs than people overseas.

So it is a real success story. There is debate in this committee, of course, about maybe the right amount of time before drugs go generic. But they should go generic without undue delay. And we want to see a successful generics and biosimilars sector.

I appreciated the commentary you provided at the front end of this about maybe an industrial policy surrounding generics manufacturing.

I will be candid. I am not sure I agreed with the middle parts of your recommendations, which sound more like subsidies and tax breaks. But the first and last thing you said I really liked, and I want to dig into those a little bit.

The first was basically demand signal for enhanced production of generic drugs, particularly sterile injectables.

Can you talk about proposals that have been made around having DSH hospitals aggregate as group purchasing organizations and providing a premium for those sterile injectables for a sustainable supply chain? What is your view on those?

Mr. Murphy. Yeah, Mr. Auchincloss. Thank you for the question.

I think the current state of the market demands any creative solution that will help provide certainty to manufacturers that there is going to be a market at a sustainable price for them to invest in the kind of domestic manufacturing we would like to see.

Mr. Auchincloss. Is that sort of DSH premium approach something that you would be amenable to?

Mr. Murphy. So I would have to talk with our manufacturer. I would love to follow up with your office. I haven't explored that in depth, though.

Mr. Auchincloss. Great. It would build on some examples that we have already seen with hospitals grouping together in group purchasing organizations for a sustainable supply chain.

The last thing you talked about was PBMs and, basically, the role of these intermediaries, these drug-pricing middlemen in distorting healthy incentives. And I want to dig into that, particularly on biosimilars, because the biosimilar market has been working better but not working well enough.

I believe 86 percent of brand biologics that are eligible for biosimilar competition still don't have a biosimilar under development. And there are a lot of reasons for that. But that is a big opportunity cost. That is probably about $100 billion of spending that could have been genericized.

Talk a little bit about how PBMs are playing the rebate game to try to keep biosimilars out of the market.

Mr. Murphy. Yeah. This is an issue we have studied extensively because we are missing a lot of opportunity. And we are ceding ground to Europe, candidly.

The PBM environment has favored those manufacturers that can afford to pay very large rebates or have a large product portfolio that is rebatable that can prevent generic access. In one of the most famous examples of a product right now that has multiple biosimilar competitors, the brand manufacturer retains over 80 percent market share multiple years after. And it is infecting investment in the future.

Mr. Auchincloss. Right. Providing the safe harbor to the anti-kickback provision does not seem like it was great policy from the 1990s. Maybe we should rethink that.

Mr. Murphy. We would love to work with the committee on a number of areas to get that out of the way.

Mr. Auchincloss. Now, the PBMs are also starting to do their own biosimilar manufacturing. Give us, like, 30 seconds on that and whether that is a good idea.

Mr. Murphy. So it is challenging because in the one hand, we want to promote biosimilar adoption, but we also want to promote the investment that is necessary to bring new biosimilars to market. And if standalone generic and biosimilar manufacturers don't see a signal that investing in that next generation of biosimilars is going to be worthwhile from a portfolio standpoint, they will stop investing in that.

And so if we see follow-on products that don't help the market but, in fact, favor particular individual companies, it is going to be a challenge to the overall market.

Mr. Auchincloss. I am not sure I fully tracked on that. Are you saying that the PBMs running their own biosimilar manufacturing is a net negative for biosimilar competition?

Mr. Murphy. I think it is a challenge for those folks who are trying to innovate new biosimilars.

Mr. Auchincloss. Got it.

Quickly, in our last 30 seconds, FDA's role, given the staffing cuts in biosimilar interchangeability studies?

Mr. Murphy. Yeah. So we are pretty much in agreement with FDA that we need to optimize that process and take costs out of the system. And we look forward to working with Congress to try and codify that over the years.

Mr. Auchincloss. Do you have confidence, given the radical reorganization and cuts at the FDA, that they have the personnel and expertise to do that?

Mr. Murphy. I think they could always use more support.

Mr. Auchincloss. I yield back.

Mr. Carter of Georgia. The gentleman yields back.

The chair now recognizes the gentleman from Oregon, Mr. Bentz, for 5 minutes of questioning.

Mr. Bentz. Thank you, Mr. Chair.

And thank all of you for being here.

Mr. Cashman, I am interested in balance. And, I guess, the question is, is there a restriction that we can impose on China if they choose to impose a restriction on us?

And this is a broad general question because, as I listen to this, I am trying to figure out whether the issue is fear of someone withholding stuff or price.

But go ahead and just tell me, are we currently in balance or out of balance?

Mr. Cashman. Congressman Bentz, that is a very interesting question. I think we have to think as a Nation how much dependence do we want on a foreign nation like China?

Right now, in the case of amoxicillin, 80 percent of the starting material used to make the API -- it is called 6-APA -- comes from China. We are very, very dependent. And therefore, I think, things are very much out of balance. We are so dependent upon China in the case of amoxicillin.

Mr. Bentz. I think you indicated earlier that the challenge for you is what in expanding your footprint in that space from 5 percent to something higher? Is it price? You said something about contracts, and I wasn't quite clear on what the restriction was when it came to contracts.

Mr. Cashman. One of the challenges we face is contracts, yes. Contracts give us consistency. It gives us stability. It allows us to make investments in personnel and in equipment.

So those long-term contracts -- and we have had some success on the commercial side with that, but we haven't had success yet on the governmental side.

Mr. Bentz. And why not?

Mr. Cashman. I can't explain that, sir.

Mr. Bentz. Does it have something to do with the bid process preventing long-term contracts? Is it on the government side of the equation or is it on your side of the equation?

Mr. Cashman. I think it is on the government side of the equation. The government's focus is very much on price. There are some structural issues. For example, in cases they are looking for purchasing from small business entities and things like that. Through our organizational structure, we are not a small business.

Mr. Bentz. Let me hop ahead. The issue -- the tradeoff seems to be price versus everything else. So if China is going to be subsidizing everything that they do in China, then is our market system such that we cannot compete because everything is all about price? Is that what you are really saying?

The only way we can ever get even is if we decide we want to pay a higher price because we can certainly get it for less from China, but we lose the security situation. That is what you are trying to call out, isn't it?

Mr. Cashman. Well, price is an important aspect and that I think it affects all of us. And, yes, China and India have different ways of looking at the economic market than we do. They made decisions to have much lower prices. And in some cases, we are dealing with competition that is below our cost of production.

Mr. Bentz. Right. Well, it seems to me we face this situation in any space that China chooses to focus upon, which is a lot of them. Steel is a good one to talk about for a moment. They can produce steel, what, 30 percent more than everybody actually needs.

So what I am trying to get at here, the common theme seems to be if we want to be secure, we are going to have to pay more. Is that a correct statement?

Mr. Cashman. Congressman, I think in general that is the case. We will have to pay more.

Mr. Bentz. Okay. Let me flip over to Mr. Piervincenzi.

What prevents China right now from withholding stuff that we actually need? Is it world opinion? We see it happening now in the context of negotiations with China. They are withholding rare earth minerals, and we have chips and perhaps certain types of stuff we use in fracking. So there is kind of a little bit of a balance there, not much.

But what prevents us from right now being in real trouble in this space?

Dr. Piervincenzi. I am not sure anything prevents it at the moment.

I would say that the key starting materials that we talk about here in medicine are probably the most equivalent to your rare earth metals. And most of those are probably going to India for production, but these routes and channels are well understood if you are the owner of those key starting material plants.

I would say that here in the U.S., we actually don't know where these key starting materials are yet. And that is why we are working on that data source.

We hope to be done with that in the next few months, and we will finally have the answer as to where we are vulnerable, and then we can start to try to correct it one drug at a time. I don't think there is a shortcut to it.

Mr. Bentz. To what do you attribute our current -- I don't want to say "lack of preparedness," but it appears that we are. Are we not prepared?

Dr. Piervincenzi. The key starting material topic is really chemicals. And the chemicals industry has mostly left the U.S. decades ago. And while there are also API dependencies, and that is not without some challenge, it is even more of an issue upstream, just as Mr. Cashman has described.

Mr. Bentz. Thank you so much. Yield back.

Mr. Carter of Georgia. The gentleman yields back.

The chair now recognizes the gentleman from Ohio, Mr. Landsman, for 5 minutes of questioning.

Mr. Landsman. Thank you, Mr. Chair and to the ranking member, for today's hearing.

The importance of strengthening domestic manufacturing in the healthcare supply chain is hugely important to all of us, certainly in southwest Ohio.

We have -- and I want to just share -- a company called Emerge Manufacturing in southwest Ohio. It is led by a woman named Cynthia Booth. She was this incredible entrepreneur and was going to retire and then realized that we had this issue during COVID and that we should be doing more of the PPE manufacturing here in the United States and, in her mind, in a community where folks don't really have access to these good-paying jobs.

So she sort of emerged out of what was retirement to build Emerge Manufacturing, and it is now up and running. They are producing PPE, all kinds of other things for the healthcare space.

And it is in a neighborhood called Bond Hill, historically Black neighborhood, predominantly Black neighborhood where she grew up, and now they are manufacturing all of this. And the majority of people who work there are from Bond Hill, which is just an incredible story, and I wanted to share.

And if you are ever interested in coming and spending time in Cincinnati and seeing Emerge Manufacturing, we would love to have you; anyone from the committee too.

She and others rely on the FDA to get their PPE approved. And that is why the FDA's job, as it relates to the domestic supply chain, is so important.

In April of 2025, the GAO released a report to Congress about drug shortages entitled "HHS Should Implement a Mechanism to Coordinate Its Activities." Makes perfect sense. In the report, the GAO stated that the FDA, Congress, and academic experts have reported that collaboration across Federal agencies is important to address drug shortages and enhance supply chain resiliency because each agency has a unique role in the supply chain.

HHS then creates a Supply Chain Resilience and Shortages Coordinator -- not a great name but a great cause, makes all the sense in the world -- somebody who is going to lead the coordination

across the agencies. They do this in 2023, November 2023, a position within the Office of the Assistant Secretary for Planning and Evaluation.

It was funded through 2027. Last month, however, the Trump administration eliminated the role. HHS no longer has the mechanism to coordinate drug shortage activities across the Department.

Ms. O'Connell, question. As Assistant Secretary for Preparedness and Response, how was the office working with other agencies within HHS, including the FDA, to strengthen the domestic supply chain?

Ms. O'Connell. Thank you, Congressman.

I think that is a great example of the need to coordinate within the Department that we always were dealing with.

But the role of the supply chain coordinator was extraordinarily important during my tenure there. You have lots of independent agencies within HHS, each having their own agenda, each having their own constituencies that they are working towards. We needed someone sitting on top of all of that, tying the threads together, to ensure that we were moving forward in the way that we needed to, in a unified way, on behalf of the Department and on behalf of the White House.

Mr. Landsman. Can anyone on the panel give a reason for why they would just eliminate the position?

Okay. None.

It doesn't seem like it was a smart idea.

But the position is now gone. HHS also has identified something like 10,000 employees to be fired.

Is the Department equipped to coordinate a response in the case of a supply chain issue, as we had one several years ago?

Ms. O'Connell. So it is hard for me to know, since I am on the outside now, what it feels like on the inside. But what I can say is that the role of the coordinator was important.

And the coordinator didn't just coordinate within the Department. They coordinated across departments. And there are lots of other pieces of the supply chain, departments and agencies throughout the government, that have roles to play. We have talked about tariffs and other incentives.

So having somebody sitting on top of all of that was really important. And we need somebody, I think, who can do that again.

Mr. Landsman. I agree. And this maybe is something that this committee could take up. It seems like a simple enough thing to do to say: Hey, why don't we put the coordinator back on the job? Because we all agree that increasing the domestic supply and domestic manufacturing is really important.

That is my time. Thank you very much. I yield back.

Mr. Carter of Georgia. The gentleman yields back.

The chair now recognizes the gentleman from Texas, Mr. Crenshaw, for 5 minutes of questioning.

Mr. Crenshaw. Thank you, Mr. Chairman. Thank you for holding this hearing.

Thank you to our witnesses.

I think too often we don't treat domestic drug manufacturing like the national security issue it is. But it is one, especially when we are depending on foreign nations, often adversarial ones, for

critical medicines or their ingredients. We are handing them leverage. That is not good. It is a dangerous game to play.

And it leaves us vulnerable when we are in crisis, whether it is a pandemic, a supply chain disruption, geopolitical tensions, whatever it is.

And in my district, I am proud to say our citizens are not waiting around. They are acting. San Jacinto College, Lone Star College leading the way, training the next generation of biomanufacturing and biomedical engineering professionals. These students will fill those gaps in the workforce, help build the domestic capability that we really should have prioritized a long time ago.

We are seeing investments too. Bionova is a company that recently put $100 million into a new plasma DNA manufacturing facility in my district in The Woodlands.

And it isn't a coincidence. It is a signal. I think companies are choosing Texas because they see the promise of a strong, skilled workforce and a business environment that supports innovation and growth.

But we have got a long way to go. Nearly 80 percent of biopharma companies, many of them small and emerging biotech firms, still have to rely on contract manufacturing or contract manufacturers in China. That should set off a lot of alarm bells.

If we are serious about building biomanufacturing capacity here, then we have got to take a hard look at the regulatory and policy roadblocks that are standing in the way. We have to fix what is making the U.S. less competitive. And we should do it now before we are caught flat-footed again in the next crisis.

Mr. Murphy, we have seen Congress move pretty quickly, actually, to streamline permitting specifically for semiconductors under the CHIPS Act, carving them out from the National Environmental Policy Act, NEPA.

Given the strategic importance of -- and I bring that up because that was a recent bill, and it was something that Democrats and Republicans came together on. NEPA reform but just for this one thing that we can agree on because we need more chips. Okay? Seems like a -- that is interesting. That is a pathway to agreement.

Given the strategic importance of pharmaceutical manufacturing, do you think similar carve-outs for pharmaceutical facilities are warranted? Would removing these regulatory hurdles, while also protecting the environment through pared-back, I think more efficient review processes, would that help accelerate domestic buildouts?

Mr. Murphy. Yeah. Mr. Crenshaw, thanks for the question.

We certainly agree that permitting is one thing that can delay significant investments and really stand in the way of getting our domestic manufacturing base back online, particularly in the generic pharmaceutical space where cost is such a significant driver.

And so I think we saw in the President's executive order that talked about permitting reform in the medicine space is something that we could work collaboratively with Congress to try and ensure that we both protect our environment but also not let the abnormally long permitting processes stand in the way of getting that domestic investment online.

Mr. Crenshaw. Yeah. I appreciate that. And, again, we have done it before in a bipartisan way, and I hope we can do it again in this Congress. Even if we can't get full NEPA reform, at least we could do it for certain industries.

Dr. Piervincenzi -- did I get that? Okay.

Dr. Piervincenzi. Thank you.

Mr. Crenshaw. USP has worked on digital quality infrastructure advancing manufacturing mapping. What capabilities exist right now today for really understanding and fully mapping the U.S. pharmaceutical supply chain using that technology?

Dr. Piervincenzi. So we are a lot closer than 2019 when we started. Many of the things that -- the supply chain is complex, we don't know what it is. We can answer most of those questions already today. And in just a few months, we will be able to talk about that even on down to the level of key starting materials, which means we are getting very close to having the information of what is where, and we start to have to do the next thing, which is what we do about it.

And that is not a dead-end because there are additional analyses we can do that open up those opportunities for domestic manufacturing. So how else can we make those medicines? How else can we produce an API through different key starting materials that maybe are available either near shore or domestically?

And they are one at a time. There are solutions. But they are solvable. They are solvable one time. And then we can think about the incentives and the other things we have talked about here today to reduce the barriers to those investments that are very hard for generic companies today to make those commitments. We see it, the lack of investment in advanced manufacturing. It is almost at zero within the generic industry today.

Mr. Crenshaw. I want to get one more question in for Mr. Murphy.

Regarding the FDA's current good manufacturing practice enforcement, what tools, if any, exist within FDA's own compliance and inspection regime to tip the scales towards domestic production?

Mr. Murphy. Yeah. I mean, certainly, FDA could signal their willingness to speed up inspections for newly brought online generic manufacturing facilities in the United States.

I think understanding that that inspection paradigm is on the horizon and set up stably would give folks the understanding that that investment has a timeframe at the end of it which requires FDA inspection is more certain.

Mr. Crenshaw. Okay. I appreciate that.

And yield back.

Mr. Carter of Georgia. The gentleman yields back.

The chair now recognizes the gentleman from Louisiana, my first cousin, Representative Carter, for 5 minutes of questioning.

Mr. Carter of Louisiana. Thank you, my dear cousin. Thank you, Chairman and Ranking Member, for holding this hearing.

Thank you all for being here.

As the only member of the committee from Louisiana, I know how important a resilient supply chain and resources, like the Strategic National Stockpile, are for States like mine, especially during natural disasters and public health emergencies.

In fact, I am proud to share that Louisiana has been and continues to be a leader in this space. In 2020, during the COVID-19 pandemic, Ochsner Health and SafeSource Direct, a U.S.-based PPE manufacturer, formed a partnership to step up and address the Nation's shortages of gloves, masks, and other critical PPE needed to protect our healthcare workers on the front lines.

Efforts like this and the Federal investments allow to expand domestic manufacturing and bolster the supply chain to ensure we are all well prepared for when the next -- not if -- but when the next natural disaster or public health emergency hits.

I look forward to hearing from our witnesses today and discussing how Congress can strengthen our medical supply chain and expand domestic manufacturing.

Ms. O'Connell, we know that the -- from this committee, Louisiana -- and what I have mentioned to you earlier, Louisiana is paving the way for domestic manufacturing in the healthcare space through Ochsner and SafeSource Direct. They are also currently in the process of standing up a rubber facility to fill the U.S. gap in domestic raw materials, such as rubber, which is needed to create gloves and PPE.

From your perspective, as someone who previously served at HHS, how can the Federal Government work to ensure there is a domestic market to support the sale of domestic raw materials and end products?

Ms. O'Connell. Congressman, thank you so much for that question. And I think the SafeSource example is one that we have been trying to -- or that the Federal Government should think about replicating in other places.

What is important about what SafeSource was able to do, they were able to solve one of the problems that we continued to run into in other situations, which was making sure that there was a market for the PPE that was manufactured even after the emergency.

And because a hospital system like Ochsner committed to purchasing SafeSource's PPE, we were able to keep SafeSource in business, and Ochsner had the high-quality, domestically manufactured PPE that it needed.

Finding similar hospital partners across the country with other investments we have made should be a priority of the current --

Mr. Carter of Louisiana. Proud to have Louisiana leading the way there.

The Strategic National Stockpile is important to States like Louisiana. To what extent does the stockpile support and utilize domestically manufactured products, such as gloves and PPE?

Ms. O'Connell. Whenever possible, we tried to restock with domestically manufactured goods. It is important, and as I said in my opening testimony, that we have 90 days of this emergency supply to be able to get us through those first early days of anything that comes next.

Mr. Carter of Louisiana. Thank you.

Ms. O'Connell. Yes.

Mr. Carter of Louisiana. Mr. Murphy, thank you for being here with us here today and talking about the challenges with domestically manufactured generic drugs.

As you know, FDA reviewers are tasked with conducting inspections, and new manufacturing facilities and manufacturers are required to comply with good manufacturing practices.

How would RIFs at FDA impact the agency's mission to carry out this work and exacerbate the challenges you shared?

Mr. Murphy. Yeah. Mr. Carter, thank you for the question.

And early on, when the initial RIFs were announced, we saw that it was a lot of support staff in the Inspections Division, which raised a lot of concern in the industry, because it is one thing to have qualified inspectors, and a sufficient amount of them, but you also need that support staff to help FDA conduct all of the inspections and the logistics associated with that.

We have been tracking very closely whether or not there have been deficits in inspections. But I would point out the fact that, from a foreign inspection standpoint, FDA is still not getting back to the levels they had pre-COVID of being able to conduct foreign inspections. And the industry, actually, would like to see more capacity in that space.

Mr. Carter of Louisiana. So what happens, how does this continue to slide down the slope if we don't do something differently?

Mr. Murphy. Yeah. So I think right now it is affecting the ability to get more product in the market at a lower price. I think we are seeing FDA trying to triage that. But, ultimately, we need to see FDA funded at a level that allows it to have a fully functioning inspection force.

Mr. Carter of Louisiana. Either of you can answer this.

And how have the on again/off again tariffs impacted manufacturing? We will start with you, Mr. Cashman, and then we will go down, if we can. I have got about 13 seconds, so can you -- whoever wants to answer, answer quickly. You can, if you are ready, Mr. Murphy.

Mr. Murphy. I will just say it creates uncertainty and it requires companies to make --

Mr. Carter of Louisiana. And uncertainty kills business, doesn't if? It hurts our economy. The uncertainty of not knowing if we are able to do business or not is one of the leading factors of why businesspeople complain, they don't have the certainty of being able to conduct business.

My time is over. I yield, Mr. Chairman.

Mrs. Cammack. [Presiding.] The gentleman yields.

The gentleman from New Jersey, Mr. Kean, is recognized for 5 minutes.

Mr. Kean. Thank you, Madam Chairwoman.

I want to thank our witnesses for being here today. I am very interested in learning about our medical supply chains, especially in the biotechnology space.

New Jersey has a thriving biotech industry for both brand name and generic drugs. I have been pleased to see several companies make investments in the Garden State. These include Ferring, Roche Diagnostics, Amneal, Novartis, and BeOne Medicines, amongst others.

I am also a member of both the Energy and Commerce Committee as well as the House Foreign Affairs Committee. In that committee, we are working on legislation to be to reauthorize the State Department.

I look forward to learning if I can use that work to build resilience and transparency in our medical supply chains.

Mr. Bolin, the med spa case that you cited in your testimony involved active pharmaceutical ingredients sourced from an unregulated international online supplier.

What challenges does NABP face in tracking and preventing the importation of counterfeit or substandard APIs or GLP-1 drugs?

And what can Congress and the U.S. Government do to strengthen international partnerships, such as with custom agencies or to better address this issue?

RPTR SEFRANEK

EDTR ZAMORA

[12:56 p.m.]

Mr. Bolin. Sure. Thank you for the question, Congressman.

So on the issue of med spas, I will say first there are legitimate operators that do things the right way and compound correctly, but our members are seeing that most of the scary and egregious things that are happening are happening in these largely unregulated facilities.

So you have instances where you have unlicensed practitioners that are never inspected, are setting things up in their homes or, you know, scarily, in their bathtubs. And, frankly, a lot of the boards of pharmacy actually lack the jurisdiction to go in and inspect these facilities, so they will at times have to work with the board of nursing or work with the medical board or refer to the attorney general's office.

So from a congressional perspective, any sort of visibility Congress can continue to shine on this issue will help, because there are, we believe, thousands of these locations that will never see a regulator come in the door. And so when you think about them obtaining this API from unregistered forces, like, that is really, really scary when you think that people are injecting these things into their body.

Mr. Kean. Thank you.

Mr. Cashman, my district has a number of pharmaceutical manufacturers, both brand name and generics space. Can you speak to the challenges you have faced operating domestically? And, additionally, what can Congress do to ensure that the companies that are choosing to do manufacturing domestically can continue to do so?

Mr. Cashman. Thank you, Congressman. Great question.

I think, you know, I talked about the issue of prices before. And I just want to emphasize that the difference in prices between us and many other foreign -- foreign generic suppliers is not very big. It is somewhere between 10 and 20 percent in many cases. And in a few cases in government contracts where we have checked that, we can actually offer better prices than the government paid through the government contracting suppliers.

So we could do better on some of the prices, but we do -- we have and we have lost business for 10 cents a bottle on the commercial side. So that is very challenging.

But I think one of the things that would definitely help everyone, I think, in the generic industry have more stability and have the ability to have long-term contracts, which will allow us to plan and -- plan our capital and expansion and scale up businesses in an efficient way.

Mr. Kean. Thank you.

Dr. Piervincenzi and Mr. Murphy, the FDA recently announced its plans to expand the use of unannounced inspections at foreign manufacturing facilities. Can you explain how this policy change will impact efforts to increase supply chain resilience and even domestic manufacturing?

Mr. Murphy. So thank you for that question, Mr. Kean. Actually, I think there are net positives in the ability to ensure that FDA has the flexibility to get in the facilities overseas and provide the public with assurances of the safety of the medicine supply chain. So, you know, I think we look forward to working with the agency to try and expand inspection capacity both domestically and overseas to help ensure that we have a stable flow of medicines that come in to patients.

Mr. Kean. Thank you. Doctor?

Dr. Piervincenzi. Thank you for that question. Very much like FDA, USP has set up facilities with teams in India and in China for specifically that purpose, which is a risk-based approach to all assurance of quality medicines. You have to show up where you think the risks are and you have got

to have enough resources. Otherwise, you are just inspecting in your backyard, and that is not only not effective, but it is actually not fair to domestic manufacturers.

Mr. Kean. Thank you to all the panel of witnesses.

I yield back.

Mrs. Cammack. Thank you. The gentleman yields.

The chair now recognizes herself for 5 minutes. I know that is strange.

So by now it has been made clear, as we come to the conclusion of the hearing, that depending on adversarial nations like China for lifesaving medicines, it is dangerous. So I am not going to repeat what has already been said here today. Instead, I want to talk about some solutions.

So we have American manufacturers ready to produce the antibiotics, the generics, the APIs that our system depends on, but they are getting crushed by subsidized competition from China and India, while navigating a U.S. system that buries them in red tape and rewards the lowest bidder no matter where it is made. This is a problem.

So if we are serious about fixing this, we need to reward resilience. That means long-term Federal purchasing contracts for essential medicines. It means fast-tracking approvals for domestic facilities, and it means treating pharmaceutical manufacturing like the national security issue that it is.

And we also need to think bigger. Reshoring can't just mean the final pill or vial. It has to include the full chain, starting from key intermediaries and chemical inputs. If we are still importing the ingredients from China, we are still vulnerable.

It should be about incentivizing domestic production of these early stage materials to truly rebuild them from the ground up. And that means working closely with trusted allies as well,

especially in Western Europe, to diversify our sourcing and to build in redundancy. So with one facility going offline, it doesn't mean that we are putting other people at risk.

The bottom line is that we cannot defend American lives with a drug supply chain that depends on the goodwill of Beijing or New Delhi.

So I want to thank you all for being here as witnesses before this committee and for speaking on what is working, what is not, so that we can finally get this straight.

Mr. Bolin, you have been highlighting the early successes of the Pulse platform. Now, as we work to bring pharmaceutical manufacturing back to the United States and rebuild resilience into the supply chain, I am very concerned about the counterfeit and substandard drugs slipping through the cracks, particularly from overseas sources.

Since Pulse has launched, what are the most alarming trends that you have seen, whether in product type, origin, or distribution patterns, and what does that tell you about where the biggest vulnerabilities lie?

Mr. Bolin. Thank you, Madam Chair. I think the most disturbing thing that we have seen is the fact that the very first scans that we conducted utilizing the tool found illegitimate and counterfeit products. And that is just in a handful of States that are using the tool so far.

The reality is that where there is money to be made, bad actors are going to find ways to insert things into the supply chain. So it is going to require vigilance on the part of the State boards of pharmacy, as well as the pharmacies themselves, to really think about where they are purchasing their medications.

I think one of the other challenges is when you have -- you know, we have talked today a lot about what happens as products are being manufactured. We still have issues within the supply

chain from the point a product enters the supply chain to the point it is dispensed. There is not a lot of visibility and transparency in the supply chain.

And so I would encourage Congress to think about ways that you can start to unlock some of the capabilities that do exist. The fact that this law -- and you can track a product down to the saleable unit, that unlocks the ability to really trace medications and address issues like drug shortages, keeping illicit medications out of the supply chain.

So I think let's leverage the investments that has already been made. That would be what I would recommend for Congress.

Mrs. Cammack. And you mentioned the States that have adopted it. What are the States that are currently utilizing the platform?

Mr. Bolin. So we have over 30 States that are currently utilizing the platform.

Mrs. Cammack. I am not going to make you name them all.

Mr. Bolin. Thank you for that. But we are finding good and early success with that, so we are going to continue to help support our members so that they -- and provide additional tools to help them detect counterfeit medication.

Mrs. Cammack. Okay. In the interest of time -- I have got about a minute left. So you talked about the -- needing transparency in the supply chain, and you said Congress needs to do more in that space.

So as we are effectively working to reshore the production and reinforce the supply chain, how can we ensure that some of the regulatory tools, like Pulse, don't detect -- that just don't detect threats but actually help eliminate them as well?

Mr. Bolin. And so when you speak about that supply chain visibility, it is really getting members of the supply chain to be more transparent and communicate with each other. There is so

much information that is moving from the point of manufacture to distribution to dispensing, but no one shares that. It is only when they have to share it.

And so I think the supply chain being incentivized to actually do something, like the national control tower that existed back during COVID, that was some of the most widespread visibility that the supply chains had after the point of manufacture, and I think that is another opportunity to consider.

Mrs. Cammack. I would have more for you that I would like to follow up on, but I have run out of time. So my time has expired.

I yield to the gentleman from California, Mr. Obernolte. You are recognized for 5 minutes.

Mr. Obernolte. Thank you very much. I want to thank our witnesses. This has been a really valuable hearing for me.

I represent, obviously, a district in California. But because of all the biopharmaceutical research and innovation that occurs in California, particularly at our public institutions, it is obviously of critical interest that we make sure that our supply chains are resilient.

If I could start with Mr. Cashman, I was really interested in your testimony about how to make our supply chains more resilient. And I thought it was poignant, you know, the story that you told about when we allow our supply chains to be opaque and complex, how when we have an unforeseen shortage, those supply chains can't respond. And you offered, I thought, some really meaningful suggestions for improving that situation.

But one of the things I was curious about, it seems like -- as a free market guy myself, it would seem like market reactions would catalyze some of the solution to that problem. For example, one of the things you suggested was long-term supply contracts. But if you are someone that has consistent demand for a drug like amoxicillin and you have experienced a situation where supply is

constrained and, therefore, the market reacts by raising prices up to astronomical levels, you would think that would incentivize you, just from a financial perspective, to diversify your supply chains.

Why is that not the case?

Mr. Cashman. Congressman, it is exactly that. We have had commercial -- people in the commercial market, customers of ours, approach us for long-term contracts because of the instability of supply during 2022 and 2023. Those are, I think, very knowledgeable and innovative people who want to avoid problems for a critical drug like amoxicillin.

Unfortunately, much of the market is still very much focused on price. And as I said earlier, 10 cents a bottle for a product that sells for $3.40, sometimes people walk away from us as a U.S. supplier for a foreign supplier.

Mr. Obernolte. It would just seem to me that there is a commercial incentive to not do that when you are aware that locking yourself into a foreign supply might mean a lack of availability, and paying just a couple cents more now for a long-term contract would ensure that that doesn't happen, just from a dollars and cents standpoint would seem like people would be incentivized. But thank you for the response.

Dr. Piervincenzi, one of the things that I thought was really interesting about your testimony is the criticality of manufacturing innovation here in the United States and, obviously, that is something that would make our domestic manufacturers more competitive, it would simplify our supply chains, it would incentivize domestic production.

But, I mean, just to play devil's advocate for a moment, even if we came up with innovation here, in short order, isn't that going to be duplicated elsewhere in the country? It doesn't seem to me like -- although it is a desirable thing, it doesn't seem to me like that is a long-term solution to the problem.

Dr. Piervincenzi. So 100 percent, we should assume so. I think that is safe to say for just about any innovation anywhere ever. However, the advantage of advanced manufacturing in the U.S., it is a bigger advantage in the U.S. domestically, meaning it offers you lower environmental footprint, it works with lower labor costs. These are bigger advantages here than they will be in a lower-cost environment.

And so while it is just as useful a technology, the benefit compared to the older technology is higher in the U.S.

Mr. Obernolte. Interesting. So it gets right at some of the things that make U.S. manufacturers uncompetitive. That is interesting.

Dr. Piervincenzi. It is true. And if I might just add one thing. The challenges at the facilities that we currently have, they are 20-, 25-year life spans. The cost of a new facility, including for advanced manufacturing, doesn't seem extremely high when you look at an innovator drug and the potential for revenue. But for generic companies, it is out of reach at the moment.

And so USP, we are working with some other partners to try to reduce that barrier at least somewhat, but it is going to take something more. It is going to take some incentives to get over that hurdle --

Mr. Obernolte. Sure. I think Mr. Cashman was talking about hundreds of millions of dollars.

Mr. Murphy, if I could end with you. In your testimony, you said that one of the things that is constraining domestic -- our domestic ability to create supply, to manufacture supply is labor shortage. What can we do about that?

Mr. Murphy. Yeah. That is the most long-term problem that we have, right. Because we have to start imbuing more STEM education and more embodiment of trade-type education into our system.

I mean, I don't like always talking about that because it is the one that is the most difficult to address. We had a long discussion in this country earlier last year about H-1B visas because we realized so much high-skilled manufacturing was necessary, and we didn't have the supply. But I think we need a mobilization of how we educate and how we prioritize the education that is in the United States to show what the job of the future will look like.

Mr. Obernolte. Right. I completely agree. And it is not just pharmaceutical manufacturing that is suffering with this problem. It is lots of different fields that we want to keep America at the forefront of.

I want to thank everyone for their testimony. I have really enjoyed the hearing.

I yield back.

Mrs. Cammack. The gentleman yields.

The chair will yield to the ranking member for a few brief comments.

Ms. DeGette. Thank you. It looks like we are about to end. I really want to thank you, Madam Chair, and also the actual chair of the subcommittee, Mr. Carter.

Listening to this panel, it is really clear that these are issues, they have always been bipartisan issues, they are American issues, and I think we can all work together to solve them. We need to recognize the situation we are being faced with right now and then work on that.

I just do want to expand on the record a minute. The gentlelady from Iowa talked about a North Carolina facility that is being built right now, and that is for pipette tips. That was funded with $79.9 million from the American Rescue Plan. And so we all think that there is a role for government in this, and we should really work together to figure out how we can make it happen.

And I yield back.

Mrs. Cammack. The ranking member yields.

At this time, I ask unanimous consent to enter into the record documents included on the staff hearing document list.

Without objection, so ordered.

[The information follows:]

******** COMMITTEE INSERT ********

Mrs. Cammack. And I would like to thank again all our witnesses for being here today. Members may have additional written questions for you all.

I will remind members that they have 10 business days to submit questions for the record, which really means staff. And I ask the witnesses to respond to the questions promptly. Members should submit their questions by the close of business Wednesday, June 25.

So without objection, the subcommittee is adjourned.

[The information follows:]

******** COMMITTEE INSERT ********

[Whereupon, at 1:13 p.m., the subcommittee was adjourned.]