AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

# MADE IN AMERICA: STRENGTHENING DOMESTIC MANUFACTURING AND THE HEALTHCARE SUPPLY CHAIN

## HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

## COMMITTEE ON ENERGY AND COMMERCE
## HOUSE OF REPRESENTATIVES

ONE HUNDRED NINETEENTH CONGRESS

FIRST SESSION

JUNE 11, 2025

**Serial No. 119–25**

Published for the use of the Committee on Energy and Commerce
govinfo.gov/committee/house-energy
energycommerce.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE
60–898 PDF WASHINGTON : 2026

## COMMITTEE ON ENERGY AND COMMERCE

BRETT GUTHRIE, Kentucky
*Chairman*

ROBERT E. LATTA, Ohio
H. MORGAN GRIFFITH, Virginia
GUS M. BILIRAKIS, Florida
RICHARD HUDSON, North Carolina
EARL L. "BUDDY" CARTER, Georgia
GARY J. PALMER, Alabama
NEAL P. DUNN, Florida
DAN CRENSHAW, Texas
JOHN JOYCE, Pennsylvania, *Vice Chairman*
RANDY K. WEBER, SR., TEXAS
RICK W. ALLEN, Georgia
TROY BALDERSON, Ohio
RUSS FULCHER, Idaho
AUGUST PFLUGER, Texas
DIANA HARSHBARGER, Tennessee
MARIANNETTE MILLER-MEEKS, Iowa
KAT CAMMACK, Florida
JAY OBERNOLTE, California
JOHN JAMES, Michigan
CLIFF BENTZ, Oregon
ERIN HOUCHIN, Indiana
RUSSELL FRY, South Carolina
LAUREL M. LEE, Florida
NICHOLAS A. LANGWORTHY, New York
THOMAS H. KEAN, JR., New Jersey
MICHAEL A. RULLI, Ohio
GABE EVANS, Colorado
CRAIG A. GOLDMAN, Texas
JULIE FEDORCHAK, North Dakota

FRANK PALLONE, JR., New Jersey
*Ranking Member*
DIANA DEGETTE, Colorado
JAN SCHAKOWSKY, Illinois
DORIS O. MATSUI, California
KATHY CASTOR, Florida
PAUL TONKO, New York
YVETTE D. CLARKE, New York
RAUL RUIZ, California
SCOTT H. PETERS, California
DEBBIE DINGELL, Michigan
MARC A. VEASEY, Texas
ROBIN L. KELLY, Illinois
NANETTE DIAZ BARRAGÁN, California
DARREN SOTO, Florida
KIM SCHRIER, Washington
LORI TRAHAN, Massachusetts
LIZZIE FLETCHER, Texas
ALEXANDRIA OCASIO-CORTEZ, New York
JAKE AUCHINCLOSS, Massachusetts
TROY A. CARTER, Louisiana
ROBERT MENENDEZ, New Jersey
KEVIN MULLIN, California
GREG LANDSMAN, Ohio
JENNIFER L. MCCLELLAN, Virginia

---

PROFESSIONAL STAFF

MEGAN JACKSON, *Staff Director*
SOPHIE KHANAHMADI, *Deputy Staff Director*
TIFFANY GUARASCIO, *Minority Staff Director*

SUBCOMMITTEE ON HEALTH

EARL L. "BUDDY" CARTER, Georgia
*Chairman*

NEAL P. DUNN, Florida, *Vice Chairman*
H. MORGAN GRIFFITH, Virginia
GUS M. BILIRAKIS, Florida
DAN CRENSHAW, Texas
JOHN JOYCE, Pennsylvania
TROY BALDERSON, Ohio
DIANA HARSHBARGER, Tennessee
MARIANNETTE MILLER-MEEKS, Iowa
KAT CAMMACK, Florida
JAY OBERNOLTE, California
JOHN JAMES, Michigan
CLIFF BENTZ, Oregon
ERIN HOUCHIN, Indiana
NICHOLAS A. LANGWORTHY, New York
THOMAS H. KEAN, JR., New Jersey
MICHAEL A. RULLI, Ohio
BRETT GUTHRIE, Kentucky (ex officio)

DIANA DEGETTE, Colorado
*Ranking Member*
RAUL RUIZ, California
DEBBIE DINGELL, Michigan
ROBIN L. KELLY, Illinois
NANETTE DIAZ BARRAGÁN, California
KIM SCHRIER, Washington
LORI TRAHAN, Massachusetts
MARC A. VEASEY, Texas
LIZZIE FLETCHER, Texas
ALEXANDRIA OCASIO-CORTEZ, New York
JAKE AUCHINCLOSS, Massachusetts
TROY A. CARTER, Louisiana
GREG LANDSMAN, Ohio
FRANK PALLONE, JR., New Jersey *(ex officio)*

# C O N T E N T S


Page

Hon. Earl L. "Buddy" Carter, a Representative in Congress from the State of Georgia, opening statement ..... 1
Prepared statement ..... 4
Hon. Diana DeGette, a Representative in Congress from the State of Colorado, opening statement ..... 10
Prepared statement ..... 12
Hon. Brett Guthrie, a Representative in Congress from the Commonwealth of Kentucky, opening statement ..... 14
Prepared statement ..... 16
Hon. Frank Pallone, Jr., a Representative in Congress from the State of New Jersey, opening statement ..... 19
Prepared statement ..... 21

WITNESSES

Patrick Cashman, President, USAntibiotics ..... 23
Prepared statement ..... 26
Answers to submitted questions ..... 207
John Murphy III, President and Chief Executive Officer, Association for Accessible Medicines ..... 35
Prepared statement ..... 37
Answers to submitted questions ..... 211
Ronald T. Piervincenzi, Ph.D., Chief Executive Officer, United States Pharmacopeia ..... 45
Prepared statement ..... 47
Answers to submitted questions ..... 215
Dawn O'Connell, Former Assistant Secretary for Preparedness and Response, Administration for Strategic Preparedness and Response, Department of Health ..... 65
Prepared statement ..... 67
Answers to submitted questions ..... 219
Josh Bolin, Associate Executive Director, Government Affairs and Innovation, National Association of Boards of Pharmacy ..... 72
Prepared statement ..... 74
Answers to submitted questions ..... 221

SUBMITTED MATERIAL

*Inclusion of the following was approved by unanimous consent.*
List of documents submitted for the record ..... 128
Report by Cencora, "Addressing generic drug shortages: Contributing factors and public policy recommendations" [1]
Letter of June 9, 2025, from Kathryn DiBitetto, Vice President, Government Affairs, Health Industry Distributors Association, to Mr. Guthrie, et al. ..... 129
Statement of the Alliance for Home Dialysis, June 11, 2025 ..... 131
Statement of StringKing by Jake McCampbell, Cofounder and Chief Executive Officer, June 11, 2025 ..... 134


[1] The report has been retained in committee files and is included in the Documents for the Record at https://docs.house.gov/meetings/IF/IF14/20250611/118366/HHRG-119-IF14-20250611-SD003.pdf.

Page

Article of April 30, 2025, "No Respect: How Misrepresenting Compounded Drugs Hurts Patients," by Scott Brunner, Chief Executive Officer, Alliance for Pharmacy Compounding, InsideSources.com ..... 137
Report by the National Association of Boards of Pharmacy, "Report of the DSCSA State Regulator & Dispenser Tracing Pilot With the United States Pharmaceutical Supply Chain" ..... 141
Report by the National Association of Boards of Pharmacy, "Serial Number Decommissioning Pilot Report" ..... 153
Report by ASOP Global Foundation, "Americans' Perception and Use of Online Pharmacies," 2023 ..... 164
Report by the National Association of Boards of Pharmacy, "RogueRx Activity Report–Injectable Weight Loss Drugs: How Illegal Online Drug Sellers Are Taking Advantage of Patients" ..... 176
Statement of Premier Inc., June 11, 2025 ..... 188
Letter of June 11, 2025, from Brian Lehman, Pharmacist, to Mr. Carter of Georgia, et al. ..... 195
Letter from Eric Axel, Executive Director, American Medical Manufacturers Association, to Mr. Carter of Georgia and Ms. DeGette ..... 198
Statement of Lynn M. Schuchter, Chair of the Board, Association for Clinical Oncology, June 11, 2025 ..... 200
Statement of the Alliance for mRNA Medicines ..... 203

# MADE IN AMERICA: STRENGTHENING DOMESTIC MANUFACTURING AND THE HEALTHCARE SUPPLY CHAIN

---

**WEDNESDAY, JUNE 11, 2025**

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
*Washington, DC.*

The subcommittee met, pursuant to call, at 10:02 a.m., in the John D. Dingell Room 2123, Rayburn House Office Building, Hon. Earl L. "Buddy" Carter (chairman of the subcommittee) presiding.

Members 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 (subcommittee ranking member), Ruiz, Dingell, Kelly, Barragán, Schrier, Veasey, Fletcher, Ocasio-Cortez, Auchincloss, Carter of Louisiana, Landsman, and Pallone (ex officio).

Staff present: Jessica Donlon, General Counsel; Sydney Greene, Director of 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 (Brimmer) 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; 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.

## OPENING STATEMENT OF HON. EARL L. "BUDDY" CARTER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

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, or 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 lifesaving 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 progrowth 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.

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

**Opening Statement for the Honorable Earl L. "Buddy" Carter**

*As Prepared for Delivery*

**"Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain."**

**June 11, 2025**

Today's hearing is critical in addressing our nation's reliance on adversarial countries for essential medications and health care 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's 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 health care system.

We saw the impacts of this reliance firsthand during the COVID-19 pandemic. According to a conversation I had with the Administration for Strategic Preparedness and Response, or 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. We didn't learn about COVID-19 until January 2020.

China knew there was an unidentified sickness in its own country, concealed it, and then 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 lifesaving

medications. There was no comprehensive effort to support American manufacturers or reduce our reliance on foreign supply chains.

That is unacceptable.

Thankfully, President Trump is taking meaningful action by demanding real investment in our domestic production base and putting an end to 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 – the No. 1 state in the nation to do business – is home to Manus Bio, who 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 reinforcing U.S. leadership in medical innovation.

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 health care 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 health care system—starting with the medicines we rely on every day.

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

**OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO**

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 hard-working 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 ensure a 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 hard-working 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:]

**Committee on Energy and Commerce**
**Opening Statement as Prepared for Delivery**
**of**
**Subcommittee on Health Ranking Member Diana DeGette**

***Hearing on "Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain"***

**June 11, 2025**

Thank you for holding this hearing, Mr. Chairman.

The COVID-19 pandemic laid bare the challenges of our medical product supply chain.

But to be clear, our reliance on foreign supply chains for critical medical products has been a problem for much longer than 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 we can always count on.

I believe my colleagues in this room want to be serious and come up with serious solutions to ensure a secure, reliable medical product supply chain.

But it's hard to take the administration seriously on this issue when they are firing hard-working public servants who support generic drug approvals, facility inspections, and initiatives that help companies make their products in America.

During the COVID pandemic, everyone in the world needed the same products at the same time and manufacturing was severely disrupted.

The problems that COVID put into sharp relief—too many single points of failure, an inability to quickly shift manufacturing to critical products, and an overreliance on unreliable foreign countries among them—have been long-simmering.

It is past time we work together to stop the endless cycle of shortages of critical medicines and ensure 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 committee, Anna Eshoo, to ensure we better understand where the active ingredients for drugs are coming from.

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

We also still need to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA), 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 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 I'm troubled by the discordance between this Committee's other work this Congress and our work today on supply chains.

The more we squeeze hospitals, particularly rural hospitals, the less able they are to spend a few extra dollars to buy American.

By kicking millions of Americans off Medicaid, the One Big Ugly Bill Act will result in an additional $42.4 billion in hospital uncompensated care costs in 2034.

That translates to hundreds of billions of dollars of care hospitals will have to swallow in the next ten years.

I don't think that is going to make hospital procurement offices more able to consider the source of the antibiotics they're buying.

Instead, it makes them even more likely to go with the cheapest option, regardless of any downstream consequences.

I implore my Republican colleagues to consider all the consequences of their Medicaid cuts.

A resilient supply chain becomes less possible as we squeeze care for hardworking Americans and especially rural and otherwise under-resourced hospitals that provide that care.

Thank you again for holding this hearing.

Securing the supply chain will require working together and examining every factor, regardless of whether it is politically convenient.

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.

**OPENING STATEMENT OF HON. BRETT GUTHRIE, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY**

Mr. GUTHRIE. 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 Mr. Guthrie follows:]

**Chairman Brett Guthrie Opening Statement**
**Subcommittee on Health**
***Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain***
**Wednesday, June 11, 2025 – 10:00 AM**

Thank you, Chairman Carter, and thank you all for being here today.

During this hearing, we'll 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 health care products for Americans.

Over the years, countries like India and China have continued to grow more influential in the 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 care 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 risks, 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 we must address.

According to recent data, around half of 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 on 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, in our doctors' offices, and are used in our hospitals.

Our health care supply chain involves many components and important players – from the groundbreaking research to the raw material suppliers, product manufacturers, distributors, and purchasers, all the way to our patients.

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 health care supply chain, bolstering our domestic manufacturing, and promoting the safety of our medicines and the security of our country.

It is also 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%, contributing more than $126 billion dollars towards U.S. advanced manufacturing. To put this into perspective – the only industry who exceeded that was motor vehicles.

In terms of innovation – the biopharmaceutical industry increased their research and development investment by more than 58 percent during

this same time frame. In fact – 46 percent of the 634 novel drugs that have been approved globally over the last decade are the direct result of American companies' involvement in the discovery, patent, or clinical research process – this is twice that of companies headquartered in Europe. The U.S. also remains the most common first-launch country for new drug products, with other country launches often lagging a year or more behind.

These are all great examples of the tremendous successes that can occur right here on American soil, when we allow for innovation to flourish.

We also have great stories of more recent domestic investments – decisions made by companies who are working to bring medicines and products back to America.

Through our One, Big, Beautiful Bill Act, tax credits like the 100 percent immediate deductibility for existing and new U.S. factories, as well as expanding small business tax benefits to more manufacturing businesses actively work to incentivize domestic manufacturing.

I look forward to hopefully hearing more about some of these District stories from the Members on this Committee, as well as our witnesses.

By taking steps to incentivize the onshoring of manufacturing and bolstering our domestic supply chain, we will promote innovation and economic growth, ensure reliable and effective products for our constituents and families, and protect the safety and security of our country.

I thank the witnesses for their participation and look forward to today's discussion. I yield back.

Mr. DUNN [presiding]. Thank you.

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

**OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY**

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 antivaccine 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:]

**Committee on Energy and Commerce**
**Opening Statement as Prepared for Delivery**
**of**
**Full Committee Ranking Member Frank Pallone, Jr.**

***Hearing on "Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain"***

**June 11, 2025**

Today, Committee Republicans want to discuss health care 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 (ACIP) – the committee that advises our nation on immunization practices. And 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's all being done so RFK Jr. can stack the panel with a bunch of anti-vaccine people.

Also on Monday, 342 of the top scientists at the National Institutes of Health (NIH) 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 this 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's taken to undermine vaccines.

Rather than demanding answers of this Administration, Congressional Republicans are plowing ahead with their Big Ugly Bill that rips health care 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 health care supply chain.

However, it's 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's 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, and 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 health care 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.

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 All-Hazards Preparedness Act (PAHPA) 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're 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 against vaccines, it's not possible to do the things supposedly this hearing is about—the supply chain. It's 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. 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 PATRICK CASHMAN, PRESIDENT, USANTIBIOTICS; JOHN MURPHY III, PRESIDENT AND CHIEF EXECUTIVE OFFICER, ASSOCIATION FOR ACCESSIBLE MEDICINES; RONALD T. PIERVINCENZI, PH.D., CHIEF EXECUTIVE OFFICER, UNITED STATES PHARAMACOPEIA; DAWN O'CONNELL, FORMER ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE; AND 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:]

**Testimony of Patrick Cashman, President, USAntibiotics**

Wednesday, June 11, 2025

Subcommittee on Health, House Committee on Energy and Commerce

Hearing: *"Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain"*

**Chairman Carter, Ranking Member Degette, and Distinguished Members of the Subcommittee:**

Thank you for the opportunity to speak before you today. My name is Patrick Cashman, and I serve as President of USAntibiotics, headquartered in Bristol, Tennessee. USAntibiotics is the last remaining end-to-end domestic U.S. manufacturer of amoxicillin, the most prescribed antibiotic in the country. [1]

The facility I lead has a proud history of supplying this critical medicine to American patients for more than 40 years. Until 2008, every dose of amoxicillin needed to treat life-threatening bacterial infections in this country was produced at our Bristol plant. By 2020, the U.S. had become entirely reliant on foreign-origin amoxicillin because our production lines had gone dark. After years of escalating subsidized competition from Indian and Chinese generic drugmakers, the facility's previous owners had filed for bankruptcy. USAntibiotics' new owners—its first American owners in history—stepped in and

[1] Georgia Public Broadcasting. (2024, September 18). The only American maker of generic antibiotics wants the government to buy local. GPB News. https://www.gpb.org/news/2024/09/18/the-only-american-maker-of-generic-antibiotics-wants-the-government-buy-local

stepped up in 2021 to revive the dormant facility, rehire and grow its staff, and restore confidence in America's antibiotic supply chain.[2]

The challenge of creating a resilient domestic antibiotic supply chain is enormous and urgent. It's not simply a question of public health but national security because a country without access to life-saving antibiotics cannot grow its economy or defend itself from threats.

My testimony today will outline the unique challenges faced by U.S. manufacturers of critical generic medicines like amoxicillin. I will also propose policy recommendations to ensure our healthcare supply chain remains secure, resilient, and American-made.

## I. The Strategic Importance of Domestic Antibiotic Manufacturing

Antibiotics are the backbone of modern medicine. Without them, routine surgeries become life-threatening, and common infections become lethal. Our nation's health security, military readiness, and emergency preparedness all hinge on reliable antibiotic access.

According to the Centers for Disease Control and Prevention, Amoxicillin alone accounts for approximately 50 million prescriptions annually in the U.S., making it the single most prescribed antibiotic.[3] It treats a wide range of infections, particularly in children. Yet, the overwhelming majority of the amoxicillin supply today is sourced from overseas—often from a small handful of producers,

---

[2] Wainer, D. (2024). America is running out of generic drugmakers. Another one is on the brink. The Wall Street Journal. https://www.wsj.com/health/pharma/america-is-running-out-of-generic-drugmakers-another-one-is-on-the-brink-dbd8bb17

[3] Centers for Disease Control and Prevention. (2022). Antibiotic use in the United States, 2022 update. https://archive.cdc.gov/www_cdc_gov/antibiotic-use/data/report-2022.html

many of which are concentrated in India and China. Today, USAntibiotics serves approximately five percent of the U.S. market, even though we have the capacity to satisfy 100 percent of the country's demand.

In recent years, we've seen how fragile global supply chains can be. The COVID-19 pandemic and geopolitical tensions have exposed our vulnerability. In 2022 and again in 2023, the United States experienced severe shortages of amoxicillin, forcing doctors to substitute less effective treatments.

We must treat antibiotic production with the same strategic urgency as energy independence or semiconductor manufacturing. Rebuilding domestic capacity is not optional—it's essential to ensure a safe, stable supply chain.

If our facility were to shutter operations permanently, it would take no less than five years and hundreds of millions of dollars to construct a new facility capable of producing amoxicillin. That would be five years in which this country would be entirely reliant on China and India, during which time one or both countries could restrict our access. A 2025 study found that Indian-made generics were 54% more likely to cause severe adverse events than made-in-America drugs.[4]

These are the stakes, and they drive me and my team to work as hard as humanly possible.

---

[4] Medical Xpress. (2025, February). Generic drugs not equal. https://medicalxpress.com/news/2025-02-generic-drugs-equal.html

## II. Unique Challenges to Domestic Generic Antibiotic Manufacturing

While all pharmaceutical manufacturing faces global competitive pressures, generic antibiotics like amoxicillin present a particularly difficult case. These challenges can be grouped into five key areas:

**1. Unfair Global Competition and Market Distortions**

Generic antibiotics are among the lowest-cost pharmaceutical products. Amoxicillin, in particular, is often sold at razor-thin margins. Indian and Chinese manufacturers benefit from significant state subsidies, lower labor costs, and less stringent environmental and regulatory standards. These advantages allow them to undercut U.S. manufacturers on price—often selling at or below the cost of production. One 2022 study found that a lack of regulatory oversight in China and India allows their drugmakers to cut as much as 25 percent off of their production costs.[5]

These price tactics sometimes resemble anti-competitive dumping practices, where foreign producers flood the market to eliminate competition. Once domestic manufacturers are driven out, prices can be raised with little oversight or recourse. Recently, some Indian drugmakers have been selling amoxicillin at a price below our chemical costs for active pharmaceutical ingredients.

On the other hand, U.S. manufacturers must comply with rigorous FDA regulations, maintain higher quality standards, and absorb higher input and operational costs. While these standards are vital for public safety, they create an uneven playing field that deters domestic investment.

---

[5] Young, C. (2022, February). America's other health care crisis: Generic medicine supply chains. American Affairs Journal. https://americanaffairsjournal.org/2022/02/americas-other-health-care-crisis-generic-medicine-supply-chains

**2. Lack of Long-Term Purchasing Commitments**

Generic manufacturers often operate without secure or long-term purchasing agreements. Most buyers—whether they are pharmacy chains, hospitals, or distributors—prioritize cost over reliability or origin. This leaves U.S. manufacturers vulnerable to market fluctuations and unable to make long-term capital investments or retain specialized labor.

Contrast this with defense or semiconductor procurement, where the federal government frequently uses multi-year contracts to ensure stability and scalability. A similar approach could transform antibiotic manufacturing.

**3. Regulatory Bottlenecks**

The FDA plays a vital role in ensuring the safety and efficacy of all medicines. However, the regulatory pathway for re-establishing domestic production can be time-consuming and opaque. Manufacturers seeking to bring production back to the U.S. must often navigate long approval timelines, duplicative inspections, and inconsistent guidance—especially when transitioning from an imported API to a domestically produced one.

Expedited pathways and regulatory incentives for essential medicines would greatly accelerate domestic production timelines.

**4. Lack of Recognition for National Security Relevance**

Generic antibiotics are not treated as strategic assets in the same way that weapons systems or critical minerals are. This means manufacturers cannot access the same financing tools, tax incentives, or industrial base support programs available to other critical infrastructure sectors.

Yet the threat posed by antibiotic shortages is just as real—and arguably more acute and more immediate. We must reclassify essential generic drugs as national security assets and build policy around that recognition.

## III. USAntibiotics: A Case Study in Resilience and Risk

As this subcommittee considers legislative solutions, I submit to you one question: how could our government—which presides over the most powerful and prosperous country in history—have allowed itself to become dependent on China and India for a critical medicine that saves millions of lives annually?

In 2021, USAntibiotics was revived by private American investors who recognized not as an economic opportunity but as a U.S. national security imperative the importance of restoring domestic antibiotic production. Since then, we have brought back high-skilled jobs, invested millions into reactivating production lines, and re-entered the commercial market. But it's neither fair nor appropriate to expect the private sector to subsidize the responsibility of the U.S. government in protecting antibiotic access.

Today, my colleagues in Bristol will manufacture approximately 700,000 doses of amoxicillin before their shift ends.

But we operate on a knife's edge.

Despite our strategic importance, we receive no federal subsidies, federal prime contracts, or protection from predatory pricing. We operate in a market dominated by foreign competitors who offer below-market prices to private-sector customers like large pharmacy chains and government purchasers. In the case of government buyers, we believe there is a higher responsibility than simply selecting the lowest bid.

Since January 2023, USAntibiotics has sold approximately $895,000 directly to government purchasers through the United States Department of Veterans Affairs and the United States Public Health Service. However, in September 2022, the U.S. Department of Health and Human Services issued an approximately $40 million award for the provision of amoxicillin for the Strategic National Stockpile. So during roughly the same period in which the last remaining end-to-end U.S. domestic manufacturer of amoxicillin sold less than $1 million of amoxicillin to U.S. government purchasers, our government spent 40 times that amount on foreign-origin amoxicillin.

We are not asking for a U.S. government subsidy or handout. But we believe that the U.S. government can and should better prioritize purchases from U.S. producers of critical, lifesaving antibiotics.

## IV. Policy Recommendations

To revitalize domestic manufacturing of generic antibiotics and protect our healthcare supply chain, I respectfully offer the following recommendations:

**1. Incentivize Long-Term Purchasing Agreements**

Encourage federal agencies to enter into long-term contracts with domestic producers of essential medicines. Multi-year agreements will provide stability and predictability for manufacturers and will help us weather the storms caused by anti-competitive pricing from foreign competitors.

**2. Implement Domestic Preference Policies, Supply Chain Visibility**

A 2023 Department of Defense review found that country of origin for API used in 22% of essential military drugs could not be identified.[6] The U.S. government should establish a "Buy American" requirement for antibiotics purchased with federal funds and a requirement for manufacturers to disclose API country origin. Just as we do for critical infrastructure and defense, our healthcare supply chain should prioritize domestic resilience over short-term savings.

**3. Create a Strategic Antibiotic Manufacturing Fund**

Provide targeted grants, low-interest loans, and tax incentives to companies investing in domestic API and antibiotic production. The CHIPS Act offers a model that could be replicated for pharmaceuticals.

---

[6] Warren, E. (2023). FY23 NDAA section 860: Risk management for DoD pharmaceuticals. U.S. Senate. https://www.warren.senate.gov/imo/media/doc/FY23%20NDAA%20sec%20860%20Risk%20management%20for%20DoD%20Pharmceuticals1.pdf

**4. Modernize Regulatory Pathways**

Direct the FDA to establish fast-track approval pathways for essential medicine facilities reopening or transitioning production to the U.S. Align regulatory oversight with national security priorities.

**5. Enforce Trade Rules to Counter Predatory Pricing**

Instruct the Department of Commerce and USTR to investigate and, where appropriate, penalize unfair trade practices in the pharmaceutical sector. We cannot allow predatory pricing to destroy our last line of defense.

## V. Conclusion

Rebuilding America's capacity to produce its own antibiotics is not just a matter of economics or public health. It is a matter of U.S. national security.

USAntibiotics stands ready to play our part. We have the infrastructure, the expertise, and the commitment. But we need this Congress and the U.S. administration to act—boldly and urgently. We cannot allow another crisis to catch us unprepared. We must reclaim our pharmaceutical security and independence, and we must do it now.

Thank you for the opportunity to testify. I look forward to your questions and working together on solutions that protect the health and safety of every American.

*Respectfully submitted,*

**Patrick Cashman**

President, USAntibiotics

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 procompetitive 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:]

**Association for Accessible Medicines**

**Statement of John Murphy III, President & Chief Executive Officer**
**House Energy and Commerce Subcommittee on Health**
**"Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain."**

Chair Guthrie, Ranking Member Pallone, Chairman Carter, Ranking Member DeGette, and the members of the Energy and Commerce Health Subcommittee, thank you for the invitation to testify today and the opportunity to comment on the critical topic of strengthening the pharmaceutical supply chain and bolstering domestic drug manufacturing. I am John Murphy III, President and CEO at the Association for Accessible Medicines (AAM).

AAM represents the manufacturers of finished generic and biosimilar pharmaceutical products, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. AAM works to expand patient access to safe, quality, and effective generic and biosimilar medicines by promoting a positive regulatory, reimbursement, and policy environment and advancing education regarding the safety and effectiveness of generic and biosimilar medicines.

Generic medicines are the backbone of the U.S. prescription drug market. They supply more than 9 out of every 10 prescriptions, but only account for 13.1% of total U.S. prescription drug spending.[1] America's patients and health care providers depend on generic medicines. However, recent hearings and legislation have highlighted Congressional concern related to the geopolitical risks of overreliance on certain countries for Active Pharmaceutical Ingredients (APIs), as well as the vulnerabilities in our pharmaceutical supply chain. Generic drug manufacturers have been driven to offshore API and some generic drug manufacturing to other countries because manufacturing generic drugs is a highly competitive, low margin industry in the U.S. In fact, in the last five years, the total dollar value of all generics sold in the U.S., including a range of new generics, has fallen by $6.5 billion.[2]

---

[1] AAM. (September 2024). "2024 U.S. Generic and Biosimilar Medicines Savings Report." Available at: https://accessiblemeds.org/resources/reports/2024-savings-report/.
[2] IQVIA Institute for Human Data Science. "The Use of Medicines in the U.S. 2023 Usage And Spending Trends And Outlook To 2027" (April 2023) (Link)

This testimony will describe in detail the challenges faced by generic drug manufacturers, and how Congress may help. It is our firm belief that with strategic support from the U.S. government, the economic footprint of the generic drug industry in the U.S. can expand, leading to increased national security, continued access to affordable medicines for patients, a reduction of dependence on any one country for key pharmaceuticals or their components, and an expanded domestic employment base.

## I. What are the Challenges to Domestic Manufacturing of Generic Drugs?

In the last five decades, pharmaceutical manufacturing has become global, first in response to tax incentives to invest in manufacturing in Puerto Rico (in the 1970s) and then with initial collaboration within Europe and later expanding to countries like India. It is a well-known fact that developing nations have offered cost savings to pharmaceutical companies due to their lower labor, energy, and transportation costs as well as differences in environmental standards (which can lead to less expensive overseas manufacturing of APIs, raw materials, fine chemicals, etc.).[3] [4] In addition, the demand side of the equation for generic medicines has increased significantly outside the United States in the past 25 years, in part due to increased economic prosperity in many previously emerging economies as well as general population growth outside the U.S.

The current global pharmaceutical supply chain relies on APIs from a variety of different sources. An April 2025 blog by the U.S. Pharmacopeia found that 12% of total API volume is made in the U.S. (excluding IV fluids, such as saline), while 43% of branded pharmaceutical API comes from the European Union.[5]

Why has the U.S. fallen behind in this regard? Generic manufacturers, far more so than brands, face key challenges that include: (1) lack of significant U.S. government financial incentives to encourage production of domestic APIs and generic drugs, (2) challenges with U.S. reimbursement, (3) labor shortages, and (4) regulatory barriers. As a result, there lays dormant significant generic drug manufacturing capacity in the United States.[6]

Given these key challenges, if the goal is to ensure that a meaningful number of generic drugs are manufactured in the United States, Congress and key agencies need to envision a decades long commitment, both in terms of overall funding but also with respect to creating legislative and regulatory pathways for success.

---

[3] Reshoring Institute. "Global Labor Rate Comparisons" Available at https://reshoringinstitute.org/wp-content/uploads/2022/09/GlobalLaborRateComparisons.pdf.
[4] USP. "Over half of the active pharmaceutical ingredients (API) for prescription medicines in the U.S. come from India and the European Union." (April 2025) Available here.
[5] Ibid.
[6] US Generic Manufacturer Available Capacity Research Survey. Center for Analytics and Budget Insights of the Olin Business School at Washington University. September 2022 (Link).

***Lack of Significant Financial Incentives.*** Unlike other countries, the United States has not coalesced around a comprehensive approach to enhance the domestic manufacture of or even the resiliency of the generic drug supply chain, as it did for the semiconductor industry with the passage of the CHIPS Act of 2022 (P.L. 117-167). The $280 billion CHIPS Act was designed to boost semiconductor manufacturing within the United States by (1) coordinating permitting for high-tech manufacturing, (2) providing funding for manufacturing incentives, and (3) establishing a 25% tax credit for necessary capital expenses, etc.[7] This sort of industrial policy is the type of commitment that engages manufacturers, particularly those in lower-margin but high value production, to see the U.S. market as attractive for investment beyond just sales. Disappointingly, HHS has only invested $60 million in domestic manufacturing of key starting materials and API,[8] and that investment did not shore up traditional generic manufacturers or ensure a continued investment in infrastructure. As such, further, continued investment is needed.

***Challenges with U.S. reimbursement.*** Current government payment policies lead to underpricing and cause generic, particularly generic sterile injectables, to leave the market. Medicare reimbursement policies for sterile injectables creates a race-to-the-bottom that drives prices below market equilibrium.[9] In many cases, this also harms generic or biosimilar adoption by rewarding providers for using higher-cost brand drugs.[10] Mandatory 340B discounts threaten the sustainability of producing low-margin, high-value generics by mandating further discounts of generics that have already been priced to unsustainably low levels. In addition, state drug takeback mandates and the Medicaid generic drug penalty also creates downward pressure and instability within the market and could potentially inhibit any federal policy to promote U.S. sourced generic drugs.

***Labor shortages.*** A 2022 HHS-sponsored report noted that the United States faces a shortage of workers with the specialized knowledge for pharmaceutical manufacturing, with 60 percent of U.S. manufacturing jobs going unfilled.

***Regulatory barriers.*** With respect to API manufacturing, there are key barriers – permitting issues and Food and Drug Administration's (FDA's) inspection of manufacturing sites. Thus, Congress may want to consider various proposals to expedite permitting processes to aid with the construction of new facilities. To ensure compliance with the current Good Manufacturing Practices (cGMP), the assessment, or review, process for new and generic drug marketing

---

[7] Frequently Asked Questions: CHIPS Act of 2022 Provisions and Implementation, Congressional Research Service, April 2023, Available at: https://crsreports.congress.gov/product/pdf/R/R47523.
[8] European Pharmaceutical Review. "Biden Administration to support resilience of US pharma supply chain." (August 2021) Available here.
[9] Gottlieb, S. "Drug Shortages: Why they happen and what they mean" (December 2011) American Enterprise Institute. Available at: https://www.finance.senate.gov/imo/media/doc/Gottlieb%20Testimony1.pdf
[10] 1 Ginsburg, P. Lieberman, S. "Medicare payment for physician-administered (Part B) drugs: The interim final rule and a better way forward" (February 2021) USC-Brookings Schaeffer On Health Policy. Accessible at: https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/02/10/medicare-payment-for-physicianadministered-part-b-drugs/

applications include FDA's assessment of whether the firm has the necessary facilities, equipment, and ability to manufacture the drug it intends to market. As noted in a 2022 report, the current process may be lengthy, with the average time to set up a new plant taking 5-7 years; adding a single line to an existing plant, 3-5 years.

In addition, complex generics represent an important but underutilized avenue of savings for U.S. patients and healthcare payors.[11] Despite recent efforts to promote the approval of complex generics, these products are still slow to be approved by the Food and Drug Administration (FDA). As a result of these delays, a 2021 analysis found that the delay in FDA approval results in annual lost savings of $1.3 billion (range of $600 million– $1.7 billion).[12] While the FDA has taken some steps to address these critical issues,[13] much more can be done.

Similarly, biosimilars face additional regulatory and reimbursement hurdles. Earlier this year, the IQVIA Institute for Human Data Science released a groundbreaking report revealing a massive void in biosimilar development. The highlight: of the 62 reference biologics without patent protection at the end of 2024, only 14 have biosimilar competition. Further, only 12 of the 118 reference biologics expected to lose exclusivity between now and 2034 currently have biosimilars in development. This means that a staggering **90 percent of biologic drugs losing patent exclusivity over the next ten years have no biosimilar competition in the pipeline**.[14]

Ensuring a vital and sustainable biosimilars market requires aligning policies affecting biosimilars–from development to intellectual property to launch and continued use. Barriers include barriers to development, including redundant and costly FDA requirements and the Inflation Reduction Act's drug pricing policies; barriers to marketing, including patent thickets; barriers to adoption, including practices by insurers and pharmacy benefit managers in favoring higher-priced brand drugs, and barriers to continued sustainability, including Medicare reimbursement policies.

## II. How Can Congress Help?

---

[11] A subset of generic prescription drugs, complex generics are copies of non-biologic medicines that have a complex molecular base, route of delivery, formulation, or dosage form; are a drug-device combination product; or have other particularly complex approval requirements. Complex generics, including epinephrine auto-injectors for anaphylaxis and inhalers used to manage asthma, treat chronic and serious medical conditions, such as multiple sclerosis, schizophrenia, metastatic breast cancer and diabetes.

[12] Brill, A. "Potential Savings from Accelerating US Approval of Complex Generics" (February 2021). Available at Potential-Savings-Complex-Generics-Feb2021 pdf.

[13] Focus Area: Increasing Access to Complex Generic Drug Products | FDA

[14] IQVIA Institute for Human Data Science. (2024). *Assessing the biosimilar void in the U.S.* IQVIA. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/assessing-the-biosimilar-void-in-the-us

Several key policy proposals would help ensure more pharmaceutical manufacturing and increase the sustainability of the generics market within the United States, including: (1) guaranteed purchase of certain essential medicines; (2) expansion of the Strategic National Stockpile (SNS), (3) grants, (4) tax credits, (5) increased regulatory efficiencies, (6) creation of domestic API capacity, (7) Federal appropriations, (8) ending the use of anticompetitive tactics by brand-drug manufacturers, (9) stopping pharmacy benefit manager (PBM) and Medicare policies from denying patients access to new generics, and (10) rolling back of harmful federal policies that actively impede generic competition.

***Guaranteed Purchases***. Guaranteed fixed volume and price agreements are essential to ensuring the viability of U.S.-based generic manufacturing for essential medicines and inoculating those investments against low-priced imports of the same medicine. When engaging with the industry, however, the Department of Health and Human Services (HHS), the Department of Veterans Affairs (VA), and the Department of Defense (DoD) must encourage multiple suppliers in the market and ensure, whenever possible, that no one company supplies the entire market, given that this policy protects against supply disruptions. HHS should leverage fixed price and volume guaranteed contracts when expanding the SNS, and the VA should utilize fixed price and volume guarantees for national contracts to supply the VA and DoD.

***SNS Expansion.*** Ensuring ample supply to the most critical medicines during a national disaster, pandemic or trade dispute demands the U.S. government secure stockpiles of the medicines on the List of Essential Medicines,[15] including finished drug form and API. HHS may take possession of such purchases or may pay manufacturers an inventory management fee to produce and maintain the specified quantity on behalf of the SNS. Specific volume and price levels must be negotiated on a company-by-company basis and should factor in product expirations and inventory management costs. HHS should engage actively with the pharmaceutical industry to develop the framework and support necessary to quickly expand the SNS.

***Grants.*** HHS should provide grants to support construction, alteration or renovation of facilities for the U.S.-based manufacture of medicines included on the List of Essential Medicines. Grants should support pharmaceutical manufacturers relocating production facilities from outside of the United States back to the United States to cover expenses in moving production and include funds to offset the cost of building new factories and research centers. Such grants should be provided only to (1) manufacturers with an approved Abbreviated New Drug Application (ANDA), (2) manufacturers of an authorized generic, (3) external/contract manufacturers of approved ANDAs or authorized generics, or (4) API manufacturers with a pending or approved Drug Master File. To support a diverse and reliable supply, such grants must be available to multiple manufacturers of the same medicine. Grants could be administered by HHS/Biomedical

---

[15] Food and Drug Administration. "Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs." Available at https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs.

Advanced Research and Development Authority (BARDA). Finally, given the reliance on the List of Essential Medicines, HHS should review that list to ensure that it meets current patient needs.

***Tax credits.*** Congress could adopt new tax incentives that promote U.S. pharmaceutical companies relocating foreign manufacturing back to the United States, build new greenfield sites, refurbish already existing manufacturing facilities, or repurpose existing production lines to focus on pharmaceuticals. Specific tax incentives that will facilitate the expansion of U.S. pharmaceutical manufacturing include:

- A 50% tax credit to offset the costs of manufacturing medications on the priority medicines list in the United States. The credit should be available for as long as the medicine is on the list of priority medicines and for five years thereafter.
- An increase in the simplified Research and Development (R&D) tax credit to 20%.
- A tax credit for expenses related to bioequivalence studies via the R&D tax credit.
- A tax credit for initial and recurring FDA user fees.
- A 25% reduction in the tax rate for U.S.-manufactured medicines (modeled after the Section 199 tax reduction).
- A 20% tax credit based on wages paid to U.S. workers directly engaged in the production of essential medicines.
- An assurance that grants provided for the establishment of U.S. production of medicines are not considered taxable income.

***Increased Regulatory Efficiencies***. The FDA should streamline its regulatory review and approval processes, removing duplicative actions and reducing the time for approvals across the board. The agency should expand cooperation with the manufacturer, working collaboratively to evaluate and approve the facility and the tech transfer processes concurrently, as opposed to waiting until after the facility is built and the equipment is installed or validated.

To accomplish these goals, the FDA should create an internal, intra-agency working group focused on helping to expedite reviews and approvals to onshore pharmaceutical manufacturing. This working group should include representatives from the Office of Inspections and Investigations; the Office of Pharmaceutical Quality; the Office of Compliance; Office of Generic Drugs, and other offices as determined by the FDA. This working group should focus on reviewing for approval the transfer of production back into either U.S.-approved facilities or newly constructed facilities at new or existing sites, including those utilizing advanced manufacturing technology. This working group should grant meetings with the company to discuss the overall transfer plans. For example:

- Inspector(s) and Office of Pharmaceutical Quality staff should make site visit(s) during the construction or validation phase.
- The mechanism should be similar to a pre-ANDA meeting – that is, a developmental phase inspection and then a pre-submission inspection.

- Quality specific disciplines [e.g., Microbiology reviewer(s)] should conduct site visits to help expedite facility compliance.
- Inspections should be expedited and completed within 60 days of request for inspection.

***Investment in Domestic API Capacity.*** Countries like India have heavily invested in the necessary infrastructure for API production. Specifically, India is actively building mega-industrial parks to streamline its drug manufacturing operations, among other industries.[16] The United States could do the same, with a focus on ensuring larger domestic API production. To achieve those goals, in addition to the tools noted above, Congress should also address permitting issues. Thus, Congress should consider ways to expedite permitting processes to aid with the construction of new facilities or the modification of existing ones.

***Federal Appropriations.*** Congress could provide a multi-billion-dollar, multi-year investment for the domestic manufacturing capacity, as Congress opted to do for the semiconductor industry with a $280 billion, multi-year investment.

***Ending the Use of Anticompetitive Tactics by Brand-Drug Manufacturers***. Congress must stop the misuse of the patent system by limiting the number of patents brand-name manufacturers can assert, safeguarding the ability to enter procompetitive patent settlements, and preventing anticompetitive practices that delay access to generics.

***Stop PBMs and Medicare Policies from Denying Patients Access to New Generics.*** Medicare and Pharmacy Benefit Managers (PBMs) must stop prioritizing higher-priced brand-name drugs over generics and biosimilars. Congress and the Administration should ensure patient access to new generic and biosimilar medicines and reform PBM practices by encouraging PBM transparency and eliminating PBM profits from linking their fees to the drug list price (i.e., delinking).

***Rollback Harmful Policies***. Too many federal policies actively harm generic competition. Congress could, for example, update the Medicaid inflation penalties on generics to align with those included in the Inflation Reduction Act (IRA). Additionally, the federal government may wish to encourage states to remove barriers and amend problematic policies that run counter to the intent of great U.S. domestic supply of generic drugs, as noted above.

## III. Conclusion

[16] Swaraja. "Morning Brief: India Plans 20 Mega Industrial Parks To Streamline Manufacturing Ecosystem; Trains To Kashmir In January; RSS Mag Defends Probes Into Disputed Sites After Bhagwat's Caution." (December 2024) Located at https://swarajyamag.com/news-brief/morning-brief-india-plans-20-mega-industrial-parks-to-streamline-manufacturing-ecosystem-trains-to-kashmir-in-january-rss-mag-defends-probes-into-disputed-sites-after-bhagwats-caution.

Generic medicines are more than a healthcare innovation; they are a means of survival for millions of Americans. AAM commends Congress for its interest in addressing the longstanding concerns surrounding domestic manufacturing and the national supply chain.

The challenges to meaningfully increasing domestic pharmaceutical manufacturing are significant. The process of building new capacity, whether through new facilities or utilizing currently unused excess manufacturing capacity, takes time. It requires capital investments, acquisition of needed ingredients, validation and FDA inspection of manufacturing lines, among other requirements. Accordingly, such an effort requires not only a decades-long commitment, but the patience and endurance to see it through.

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, PH.D.**

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:]

**Statement of the U.S. Pharmacopeia**

**Submitted to the House Energy and Commerce Subcommittee on Health**

**For the Hearing "Made in America: Strengthening Domestic Manufacturing and the Health Care Supply Chain"**

**June 11, 2025**

**USP Headquarters**
12601 Twinbrook Parkway | Rockville, MD 20852, USA
+1-301-881-0666 | usp.org

The United States Pharmacopeia (USP) is pleased to submit the following statement for the record on the hearing "Made in America: Strengthening Domestic Manufacturing and the Health Care Supply Chain."

USP is an independent, scientific, global non-profit organization founded in 1820 when eleven physicians took action to protect patients from poor-quality medicines. Convening in the old U.S. Senate Chamber, they published a national, uniform set of guidelines for medicines called the U.S. Pharmacopeia. Today, USP employs 1300 staff, most of whom are scientists, and works with nearly 800 scientific experts who volunteer their time to establish quality standards for medicines. In addition, USP offers a range of programs to help ensure the supply of quality medicines for Americans, including the USP Medicine Supply Map which tracks the upstream supply chain of medicines and their ingredients, verification programs to confirm the quality of ingredients in medicines, and initiatives to accelerate adoption of advanced pharmaceutical manufacturing technologies, which can support more domestic manufacturing.

These programs reflect a core pillar of USP's work to help strengthen the global supply chain so that the medicines, dietary supplements, and foods that Americans rely on for their health are available when needed and meet quality standards as expected and required. In addition to the scientific experts on USP standard-setting committees, USP is governed by more than 500 organizations, including scientific, healthcare practitioner, consumer, and industry communities,

as well as dozens of government agencies, who together comprise the USP Convention.[1] Working with this broad base of knowledge across health care, USP creates standards for quality and safety for medicines, food ingredients, and dietary supplements.

Safe and effective medicines, consistently manufactured according to established quality standards, are essential to preventing disease, treating illness, and saving lives. USP's standards and resources are indispensable to innovation and access, providing shared, foundational platforms for industry to help accelerate the development of new technological solutions for the American marketplace. USP has over 6,000 standards for active pharmaceutical ingredients, drug products, and inactive ingredients used throughout the supply chain. USP creates these standards through an open, transparent process, offering the ability to adjust standards to adapt to new industry practices and keep up with evolving science and technology. USP also works closely with the U.S. Food and Drug Administration (FDA) and other government agencies to help ensure the quality and safety of products sold to Americans.

In addition to our work on standards, USP is an active participant in many public-private partnerships on supply chain-related issues. This includes work with the Department of Defense (DoD), the Advanced Research Projects Agency for Health (ARPA-H), the Administration for Strategic Preparedness and Response (ASPR), the Biomedical Advanced Research and Development Authority (BARDA), and the FDA.

[1] USP's governing bodies, in addition to the Council of the Convention, include its Board of Trustees and Council of Experts.

## End-to-end medicine supply chain mapping and analytics are essential for building resilience and supporting domestic manufacturing

The global medicine supply chain is a complex marketplace of manufacturers, suppliers, and distributors from many countries. While the globalization of the medicine supply chain has helped increase access to quality medicines at a lower cost, supply chains have grown longer, more complex and fragmented, leading to a lack of visibility and an increase in the risk to resilience. Moreover, market conditions for the production of some of the nation's generic medicines have become increasingly unsustainable. Unique market dynamics often drive procurement prices for these essential generic medicines below the cost of manufacturing. Under these circumstances, reliable manufacturers, particularly those operating in the United States, factor business and economic considerations into whether to maintain production in the United States, move operations outside the United States, or exit the market altogether.[2] Likewise, these circumstances influence incentives to invest in new manufacturing in the United States. These factors combine to reveal the extent of the supply chain's vulnerabilities to supply and demand fluctuation, geopolitical matters, global pandemics, natural disasters, and trade disruptions. This can have lasting impacts on patients, health systems, and national security.

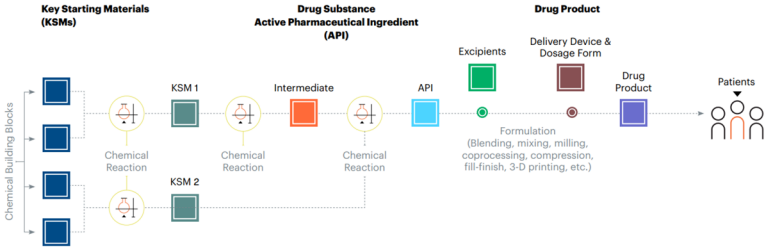
Historically, there has been little insight available into the upstream supply chain for medicines, including for key starting materials (KSMs), active pharmaceutical ingredients (APIs), and finished dosage forms (FDFs). Figure 1 is a simplified schematic depicting some of the complexity involved in the drug supply chain that begins with the KSMs needed to manufacture

[2] When market conditions limit manufacturers' profitability, this reduces a manufacturer's motivation to maintain a presence in, or enter the market and to invest in manufacturing quality and redundant capacity.

APIs, which in turn are necessary, along with excipients and other materials, to manufacture a finished drug product.

**To anticipate the impacts of policy and market forces, decision-makers need end-to-end data and mapping of entire supply chains for medicines.**

**Figure 1**: Simplified pharmaceutical manufacturing supply chain schematic.[3]




USP's Medicine Supply Map[4] – a data intelligence platform that maps where 94% of U.S. pharmaceutical drug products and their ingredients are made, and identifies, characterizes, and predicts supply chain risk – can analyze and quantify factors linked to supply chain disruptions for drug ingredients and finished drug products. Using the Medicine Supply Map, USP analyzed the location of API manufacturing facilities as well as the manufacturing volume of APIs and FDFs to better understand the geographic concentration of production for U.S. prescription medicines. These insights include actionable information for APIs and FDFs; however, blind

[3] U.S. Pharmacopeia. USP Annual Drug Shortage Report: Economic factors underpin 2023 shortages. 2024. The schematic does not provide a complete picture of the supply chain; it does not include, for example, purchasers, distributors, or healthcare providers.
[4] U.S. Pharmacopeia. USP Medicine Supply Map. www.usp.org/medicinesupplymap. 2025.

spots still exist for the excipients[5,6] and KSMs necessary for many medicines since these large data sets are not readily available. USP experts can provide end to end risk assessment analysis of specific drugs and drug classes.

## Location of API manufacturing facilities

To understand the existing concentration of manufacturing for API, USP analyzed API Drug Master Files (DMFs). API DMFs identify existing geographic locations that are manufacturing APIs and can suggest other locations that may be likely to have additional capacity.[7] Not all drug products utilize APIs referencing DMFs, but the geographic analysis of DMFs can provide a perspective on where API manufacturing capacity might be trending.

Based on this data, India maintains the greatest API manufacturing capacity with roughly 50% of API DMF filings in 2023.[8] Additionally, China's API manufacturing capacity has shown a striking rise in recent years. Between 2021 and 2023, the number of DMF filings in China increased 63%, amounting to almost one-third of all filings, while India's share of new API DMF filings decreased in 2023. The European Union (EU) saw a sizeable decrease in total active API DMF share in 2023, which was likely due to an overall increase in manufacturing activities outside the

[5] Despite being called "inactive" ingredients, excipients play a critical role in drug development, delivery, effectiveness, and stability. Excipients comprise up to 90 percent of a medicine's volume and serve important functions, including as binders, disintegrants, coatings, preservatives, colors and flavorings. Excipients are sourced from suppliers around the world and are used for more than just the manufacture of medicines. The reliance of the pharmaceutical industry on the global excipients supply chain presents challenges for supply chain resiliency as well as quality and regulatory oversight. As such, breakdowns of critical excipient supply chains can have significant downstream effects including drug recalls and patient health impacts. For example, magnesium stearate is included in 32,060 drug products according to NIH DailyMed, including those to treat high cholesterol, high blood pressure, diabetes, and bacterial infections.
[6] U.S. Pharmacopeia. USP Global Policy Position: Excipients: A Blind Spot in Ensuring Medicine Quality and Supply Chain Resilience. 2024.
[7] The proportion of DMFs in a particular location should not be interpreted as the proportion of APIs being sourced from that region. Aggregated DMF information is reflective of manufacturer site locations only, and this analysis does not contain information about the quantity produced or geographic distributions of APIs themselves.
[8] U.S. Pharmacopeia. USP Quality Matters Blog: Global manufacturing capacity for active pharmaceutical ingredients remains concentrated. 2024.

EU, rather than a decrease in its own API DMF filings. Meanwhile, the U.S. remained at 4% of API DMFs in 2023 as it did in 2021.

## Manufacturing volume of API

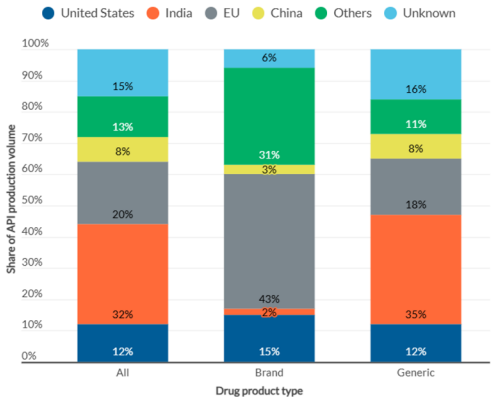
Although API DMF analysis can clarify where manufacturing facilities are based, two facilities could be producing different volumes of medicines. The USP Medicine Supply Map also determines the production volume of APIs from different geographic locations to provide a picture of where current production comes from (Figure 2).

In 2024, the analysis shows:

- Half of the API for prescription medicines in the United States come from India and the EU.
- Generic drugs, which make up 90% of U.S. prescription volume, primarily come from India.
- 43% of branded pharmaceutical API comes from the EU.
- The United States accounts for 12% of total API volume analyzed.[9]
- China contributes 8% of the total volume of API analyzed.
- There is evidence of significant dependence on China for KSMs, the building blocks of API, but further work is necessary to fully understand the supply chain of KSMs.

[9] The analysis excluded IV fluids, such as saline. If those had been included, the U.S. contribution would have been significantly higher.

**Figure 2**: API manufacturing landscape (excluding IV fluids) in 2024.[10]




All rights reserved by the U.S. Pharmacopeia ("USP"), Medicine Supply Map.

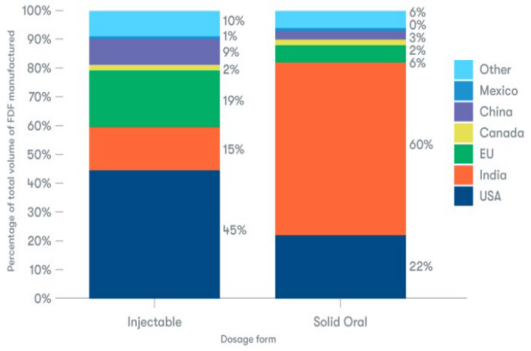
## Manufacturing volume of FDF

Using USP's Medicine Supply Map, analysis of the geographic concentration of U.S. prescription pharmaceutical finished dose forms was performed (Figure 3).

- The United States is the largest manufacturer of injectables with 45% of production volume, followed by the EU with 19% of production volume.
- For solid oral dosage forms, India has 60% of production volume, followed by the United States with 22% of production volume. Market shares have remained relatively unchanged over 2022 and 2024.

[10] U.S. Pharmacopeia. USP Quality Matters Blog: Over half of the active pharmaceutical ingredients (API) for prescription medicines in the U.S. come from India and the European Union. 2025.

**Figure 3**: Manufacturing footprint of prescription pharmaceutical FDF in 2024.[11]



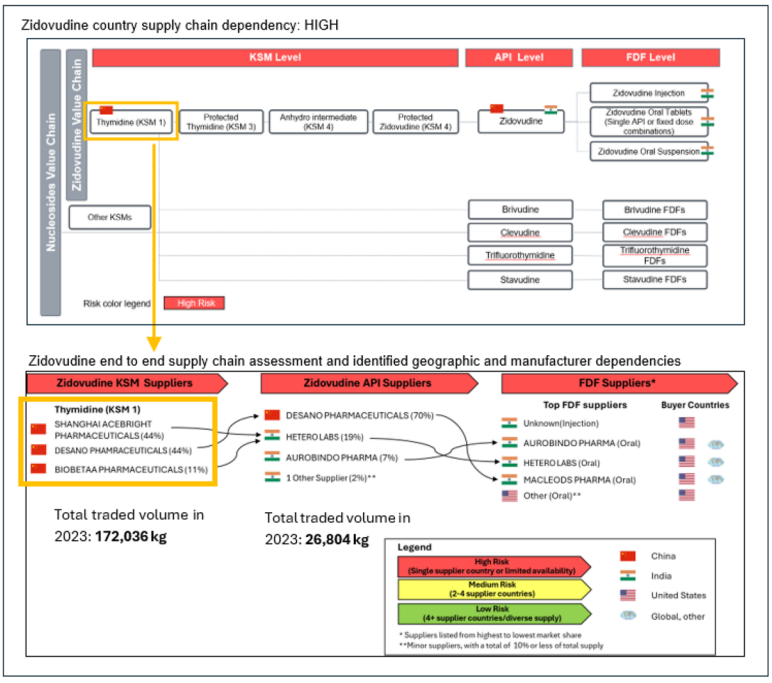

## Risk assessment analysis

In addition to the comprehensive, data-driven view of the upstream pharmaceutical supply chain provided by the Medicine Supply Map, USP is also deploying scientific experts to better understand critical blind spots that remain in our knowledge of medicine supply chains. This risk analysis can inform strategic decisions and the development of solutions. This analysis includes an evaluation of the KSM and API manufacturing pathways to identify manufacturing challenges and production bottlenecks; a geographic and technoeconomic risk analysis to assess regional vulnerabilities, economic feasibility, and supply dependencies, enabling a structured evaluation of risk potential; and resulting risk information that is specific to drugs or drug classes. For example, using zidovudine (a nucleoside-based antiviral medicine) as an example, analysis found a critical dependency on one KSM (thymidine) produced only in China, which indicates a

[11] U.S. Pharmacopeia. USP Quality Matters Blog: India and the United States manufacture most finished medicines for the U.S. market. 2025.

high vulnerability risk not just for zidovudine, but for several nucleoside-based antiviral medicines (Figure 4).

**Figure 4.** Zidovudine (and other nucleoside-based antiviral) supply chain components and geographic vulnerability risk analysis.



While the data presented above provides important insights into the U.S. medicine supply chain, neither a single government agency nor any industry entity currently has a complete view of the upstream pharmaceutical supply chain (including FDFs, APIs, and KSMs), which contributes to a limited understanding of the risks affecting the U.S medicine supply. USP is working toward more complete visibility in the Medicine Supply Map with the inclusion of additional data and insights on KSM dependence. Greater insight is needed to ensure effective deployment of resources, to strengthen our supply chain economy, and national security interests. Failing to account for upstream root causes of supply chain vulnerability paints only half the picture and leaves us susceptible to bottlenecks and geopolitical disruption.

**Efforts must continue to understand supply chain risk via initiatives like the Medicine Supply Map data and analytics coupled with extensive expertise in unraveling complicated supply chain maps to provide risk assessment and intelligence.**

USP is helping to strengthen our supply chain and economy and mitigate national security risks by identifying vulnerabilities with tools and resources. Our Medicine Supply Map and experts can currently:

- Analyze and quantify factors linked to supply chain disruptions for drug ingredients and finished drug products.
- Identify risks, including from KSMs or APIs that are made in few locations or in countries prone to supply disruption.
- Identify and characterize shortage risks at product, company, facility, and geographic levels.
- Provide end-to-end segmentation and detailed mapping from KSMs through APIs to FDFs for all U.S.-approved small molecule APIs.
- Map commercially available KSMs linked to specific APIs.

- Identify countries of origin, top suppliers, and manufacturers across each segment of the supply chain.

Only through a comprehensive, end-to-end understanding of the pharmaceutical supply chain can we truly unlock the targeted, cost-effective interventions to help make domestic manufacturing in the U.S. sustainable. This approach should cover all U.S. medicines, starting with the most critical products, and expand analysis beyond individual APIs to include related chemical and therapeutic classes. Doing so provides a holistic understanding of supply chain dependencies.

## Data- and evidence-informed policy reforms and investments can promote domestic production of medicines

Insights from USP's Medicine Supply Map demonstrate that geographic concentration of pharmaceutical manufacturing anywhere in the world increases the risk of vulnerability to disruption and drug shortages.[12,13]

A disruption in a single region can rupture multiple elements of the supply chain should it impact the reliable supply of APIs and the key starting materials essential for their synthesis, excipients, packaging materials, and other supplies. Drugs in which the API and/or FDF are made in a single or few locations are at a higher risk of shortages. The risk of drug shortages is particularly acute when a single facility is responsible for producing the entire U.S. market supply for a particular drug. While some disruptions are caused by natural events including weather or even earthquakes, some can be driven by intentional actions including trade disruptions or the potential to weaponize trade in medicine.

---

[12] United States Pharmacopeia. USP Annual Drug Shortages Report: Longstanding drug shortages persist in 2024. 2025.
[13] U.S. Pharmacopeia. USP Annual Drug Shortages Report: Economic factors underpin 2023 shortages. 2024.

Promoting geographic distribution of the manufacturing base[14] of U.S. drug products, APIs, and KSMs can help to reduce supply chain vulnerabilities and support a more reliable, resilient supply chain for these products. Multiple strategies can help to enable geographic distribution of the supply chain, such as various approaches to shoring (onshoring and near shoring), as well as exploring other considerations manufacturers assess when evaluating operation and production sites including strategic locations, regulatory risks, and economic opportunity.

**In particular, USP encourages the Committee to consider the following recommendations:**

1. **Identify medicines with a vulnerable supply chain using the USP Vulnerable Medicines List**
2. **Enable alternate pharmaceutical manufacturing processes in the United States**
3. **Incentivize resilience with a Drug Supply Chain Resilience Initiative**

## Identification of medicines with a vulnerable supply chain will help target interventions

USP recently published the USP Vulnerable Medicines List (VML),[15] which consists of medicines derived from an assessment of their essentiality, demand, and supply chain vulnerabilities and can be used to identify medicines at risk of supply chain disruption.[16,17]

Leveraging Medicine Supply Map and additional data, USP conducted an analysis to identify 100 vulnerable medicines – 49 used to manage chronic conditions and 51 for acute care – to

[14] U.S. Pharmacopeia. USP White Paper: Building geographic diversity in the medicines supply chain. 2023.
[15] United States Pharmacopeia. 2024-2025 Vulnerable Medicines List for the United States: A data-based approach to identify risks and enable interventions to increase reliability of supply. 2025.
[16] United States Pharmacopeia. USP Global Public Policy Position: Identifying and addressing vulnerabilities in the upstream medicines supply chain to build resilience and reduce drug shortages. 2023.
[17] USP's approach borrows from the framework proposed in the article: Wosinska, M., Mattingly, T., & Conti, R. A Framework for Prioritizing Pharmaceutical Supply Chain Interventions. 2023.

inform dialogue related to bolstering medicine supply chain resilience.[18] This data-driven approach accounts for the level of use by the U.S. population, the vulnerability of the medicine to supply chain disruptions, and the availability of alternative therapies. The resulting list includes a wide range of therapeutic classes of medicines, as well as a variety of product types.

The USP Vulnerable Medicines List is a practical list intended to complement other resources to identify potential drugs at risk of supply chain disruption in the United States. **USP encourages the Committee to use the Vulnerable Medicines List to help prioritize the most critical products, target investments, and inform initiatives to bolster the U.S. pharmaceutical supply chain and national security interests.**

## Alternate manufacturing processes will better enable domestic production of pharmaceuticals and pharmaceutical ingredients

As noted, the upstream pharmaceutical supply chain is complex and intricate, with myriad ingredients used commercially. Effective policy requires a deep understanding of suppliers and manufacturing locations. Additionally, the upstream pharmaceutical supply chain is a fragmented and interdependent manufacturing ecosystem, prone to unexpected vulnerabilities and often lacking efficiency and sustainability.

Enabling economically viable domestic production of prioritized APIs and KSMs is an important element of a comprehensive effort to enhance medicine supply chain resiliency. Scalable solutions to support onshoring and location production of essential drug candidates, APIs, and KSMs, and bolster rapid response capabilities within the U.S. medicine supply chain include:

- Alternative manufacturing routes: Designing economically viable alternate synthesis pathways, using KSMs that are capable of being sourced in the U.S. or allied countries.

[18] United States Pharmacopeia. 2024-2025 Vulnerable Medicines List for the United States: A data-based approach to identify risks and enable interventions to increase reliability of supply. 2025.

This work requires analysis of new ways to make a medicine that do not rely on ingredients sourced from a single country. USP has undertaken such analysis for various agencies, and urges the U.S. government to expand work on identifying alternative manufacturing routes and provide incentives for drug makers to utilize them;

- Advanced manufacturing technologies (AMTs): Emerging technologies offer promising avenues for reducing our dependence on overseas supply chains. Incentivizing acceleration of innovative approaches like continuous manufacturing and flow chemistry, are key to modernizing, localizing, and stabilizing production; and
- Scale-up and tech transfer: Supporting the transition from lab-scale innovation to commercial-scale implementation.

These innovations in manufacturing processes and technology can help to rapidly scale manufacturing capabilities, shorten supply chains while increasing manufacturing resilience, provide new ways to address drug shortages, and accelerate the development and availability of new therapies.

Many of the structural and chronic challenges with chemical manufacturing, especially chemical pharmaceutical manufacturing, have been due to low efficiency – among the major chemical industry sectors (oil refining, bulk chemicals, fine chemicals, and pharmaceuticals) pharmaceutical manufacturing generates the least product output, with about 1 kilogram of API obtained on average from a total of 25 to 100 kilograms of raw materials input.[19] Other complexities are associated with the hazardous conditions to produce chemical products at scale. Due to these complexities, over the past few decades, the manufacturing of upstream ingredients and bulk APIs has been outsourced to lower cost and less regulated countries rather

[19] Fortunak JM. Current and future impact of green chemistry on the pharmaceutical industry. Future Med Chem. 2009 Jul;1(4):571-5. doi: 10.4155/fmc.09.60. PMID: 21426025.

than tackling and solving the challenges. Therefore, today we witness these structural and chronic challenges along with dependencies on these countries.

**For these reasons, a re-imagining of the traditional chemistry processes used along the supply chains of necessary materials is essential. To advance the application of new technologies that help to mitigate identified supply chain risks, new solutions must be explored and funded.**

Building on the example of zidovudine (a nucleoside-based antiviral medicine) discussed above that found a found a critical dependency on the KSM thymidine, a key recommendation to reduce reliance on one country is to onshore API and KSM manufacturing of thymidine. This can be accomplished by leveraging continuous manufacturing technology to produce the necessary KSM thymidine. Additional AMTs can then be utilized to locally produce zidovudine more efficiently and other necessary nucleoside-based antiviral medicines while using the domestically produced thymidine. USP chemists have identified an alternate pathway to synthesize thymidine and work to optimize the new process using the AMT flow chemistry is underway.

Through a new Advanced Technologies Lab,[20] USP is supporting the development and application of AMTs, such as those for thymidine and its APIs, to foster more efficient and expanded production of quality medicines. USP will accelerate its work with industry and regulators to advance the application of new technologies and alternate manufacturing processes including developing alternate routes of synthesis for pharmaceutical KSMs and APIs and using AMTs such as pharmaceutical continuous manufacturing. These alternate manufacturing processes will help to mitigate identified supply chain risks, and this work can

[20]United States Pharmacopeia. USP announces new Advanced Technologies Laboratory to accelerate and scale pharmaceutical manufacturing innovations. 2025.

help bring quality-assured products to market more efficiently, strengthen domestic manufacturing capabilities, and build national security.

Another recent example of work to re-imagine the supply chain of pharmaceutical ingredients is the ARPA-H funded Wheat-based High-efficiency Enzyme and API Technology (WHEAT) project. The consortium of partners working on the WHEAT project aim to establish a new way to make API by leveraging cell-free protein synthesis with the aid of wheat germ extract (WGE), a key raw material derived from abundantly available agricultural wheat. This project uses WGE, in conjunction with other advanced technologies to circumvent challenges associated with traditional chemical manufacturing, such as low throughput and long, multi-step complex chemical synthesis. If successful, the team will have demonstrated a paradigm shift in domestic API manufacturing.[21] USP will support this work through USP's new Advanced Technologies Lab.

## An initiative to incentivize investment in drug supply chain resilience

In addition to the technical considerations discussed above, efforts to bolster domestic manufacturing and increase supply chain resilience must include a comprehensive assessment of the underlying market factors that influence investments in infrastructure and resilience. Economic factors play a considerable role in leading to medicine supply chain vulnerabilities and subsequent shortages of medicines.[22] Generic medicines account for nearly 90% of the medicines relied on by Americans and less than 20% of the U.S. expenditure on medicines. Yet current generic drug payment policies and practices encourage purchasers to choose manufacturers largely based almost solely on lowest price. Contracts are routinely broken, which also disincentivizes generic manufacturers to invest. This can undermine initiatives to

[21] U.S. Pharmacopeia. USP and Ginkgo Bioworks announce ARPA-H project to support production of essential medicines using innovative cell-free expression systems. 2025.
[22] U.S. Pharmacopeia. USP Annual Drug Shortages Report: Economic Factors underpin 2023 shortages. 2024.

strengthen supply chain resilience by limiting the ability of manufacturers to invest in new, alternate manufacturing processes, domestic production, manufacturing updates and necessary facility maintenance, quality assurance and management, or to build redundancy into supply chains. A fundamental shift in the market is needed to align supply and demand forces to create a more predictable, sustainable, and quality supply chain that can reliably provide medicines to American patients.

The current purchasing and payment systems, however, lack a coordinated and collaborative means to evaluate resilience and reliability and therefore minimize and mitigate risks that affect the U.S. supply of medicines. There is a need for deliberate incorporation of quality, resilience, and reliability, in addition to price, in contracting, purchasing, and inventory decisions.

**USP encourages the Committee to consider the development of a Drug Supply Chain Resilience Initiative (DSCRI),[23] which aims to foster stability in the drug supply chain by providing criteria to value the resilience and reliability of manufacturers, promoting sustainable prices for generic medicines, and incentivizing changes in purchasing practices with the goal of better meeting patients' needs through a reliable, safe, and resilient medicine supply chain.** A DSCRI must include two distinct elements:

- A data-driven system to differentiate suppliers based on reliability and resilience, such as the development of an assessment or benchmark to enable purchasers to identify resilient manufacturers.
- Establishment of meaningful value-based payment and contracting reforms to incentivize supply chain resilience and reliability.

A manufacturer benchmark metric should function as a tool for decision making and consist of resilience measures, reliability measures, quality measures, as well as the base vulnerability of

[23] U.S. Pharmacopeia. A drug supply chain resilience initiative will better support patients. 2025.

a drug product, which includes understanding the concentration of domestic and non-domestic manufacturing locations. Key benchmark attributes could include:

- Experts to advise on initiative details and benchmark criteria
- A menu of well-established measures that are predictive of reliability
- The ability of manufacturers to choose measures and combine values to reach the resilience benchmark
- A resilience determination per molecule, per manufacturer
- Leveraging partnership with the USP Medicine Supply Map Vulnerability Assessment and the USP Vulnerable Medicines List

Several measures are currently known and available that could be utilized, including those from the USP Medicine Supply Map; publicly available metrics from the FDA; manufacturer measures of product production, inventory, and delivery; and reputable product level quality testing data, among others.

Without significant market and policy interventions, current medicine supply chain vulnerabilities and drug shortage trends will likely continue or worsen. A solution to bolster resiliency can be facilitated by measuring and valuing reliability and quality using a comprehensive framework like the DSCRI.

## Conclusion

The USP thanks the Committee for this hearing and for the bipartisan, careful consideration of approaches to support domestic production of essential medicines and health care products. We look forward to working with the Committee and Congress to achieve practical solutions that will strengthen our supply chain, economy, and national security interests.

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:]

**Written Testimony of:**
**Dawn O'Connell**
**Former Assistant Secretary for Preparedness and Response**

**House Energy and Commerce Committee**
**Subcommittee on Health**

**Hearing on:**
**"Strengthening Domestic Manufacturing and the Health Supply Chain"**

**June 11, 2025**

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 leading the Administration for Strategic Preparedness and Response (ASPR). My job was to help the country prepare for, respond to, and recover from public health emergencies and disasters. Much of this work 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 four years it became a mission.

We must never forget 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–having last purchased it 10 years prior during the H1N1 pandemic. The amount of PPE manufactured in the United States was limited–and much of it was manufactured "just in time" with limited surge capacity. As a result, our frontline health care workers were forced to wear garbage bags and use empty soda bottles for PPE–while they waited for new shipments to cross the ocean and work their way through congested ports.

When I began my work at ASPR in 2021, two things were clear: (1) we needed enough supplies in the Strategic National Stockpile (SNS) to get the country through the first 90 days of an

emergency; and (2) we needed a manufacturing base in the United States that could quickly ramp up to meet demand

The first Trump Administration began the work of investing in domestic manufacturing of critical PPE and medical supplies using an assisted acquisitions agreement with the Department of Defense. Over the course of the COVID response, across both the first Trump and Biden 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 (Center for Industrial Base Management and Supply Chain) to manage our domestic manufacturing efforts; elevated the Strategic National Stockpile to a direct report to me; and 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 and disasters.

Expanding the health care 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 the government. For example, 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. The few levers that the government could pull were either ill timed or did not work. For example, federal

efforts to incentivize the purchase of N95s by hospitals and health systems came too late to make much of a difference in the market. Also, some departments and agencies that needed to purchase PPE chose not to buy domestically and instead sought waivers to purchase imported goods. Finally, after significant consultation with experts, tariffs were announced to push purchasers to buy US manufactured goods but their enactment was delayed to ensure there were enough domestic manufactures online to meet demand.

Despite the challenges we faced, I think we are at a moment of 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: (1) clearly identify what is in the public health and medical supply chain that needs to be available and ready to use on day one of an emergency to protect our national security; (2) invest in the domestic manufacture or near-shoring of those products; (3) work to ensure there is a market for those products in both peacetime and emergencies through government incentives; thoughtfully applied tariffs; and stockpiles of vendor managed inventory; and (4) build enough capacity that manufacturers can surge production quickly in times of emergency.

Investments made by the federal government in industrial base management should be viewed as leading examples of public-private partnerships. The country receives the benefit of the high quality manufactured supplies in times of emergency. The local community receives the benefit

of an influx of commerce and highly skilled jobs. And the company receives financial backing from the government allowing it to prove its operating plans and test innovative solutions.

Of course managing a program like this requires highly competent federal employees who understand both economics and health care. When I left ASPR on January 20, 2025, we had a small but mighty team in place. It is unclear to me from the outside how many of those team members remain. But I strongly encourage those in the Administration that are making RIF decisions to retain their expertise so the work the country needs done to expand the public health and medical supply chain's industrial base can continue. I also encourage the Department to keep ASPR as its own agency within HHS–for many reasons–but not least of which to make sure this critically important work on the supply chain receives the leadership attention and support it needs.

Ensuring a resilient and secure domestic supply chain is a non-partisan issue. In fact, it is a place, despite deep partisan divisions around public health, where the Biden and first Trump Administrations found agreement. We owe it to our frontline health care 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.

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:]

**Hearing Entitled "Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain"**
**House Energy and Commerce Subcommittee on Health**
**2123 Rayburn House Office Building**
**June 11, 2025**

Testimony of

Josh Bolin
Associate Executive Director, Government Affairs and Innovation
National Association of Boards of Pharmacy

**Introduction**

Health Subcommittee Chairman Carter, Ranking Member DeGette, Committee Chairman Guthrie, Ranking Member Pallone and Members of the Subcommittee, thank you for the opportunity to testify today about the state of the U.S. drug supply chain.

My name is Josh Bolin and I am Associate Executive Director of Government Affairs and Innovation for the National Association of Boards of Pharmacy, or NABP.

NABP is a 501(c)(3) nonprofit association that, for over 120 years, has protected public health by assisting its member boards of pharmacy in all 50 states that are responsible for regulating the practice of pharmacy and the supply chains within their states. With my testimony today, I would like to highlight the threats to regulated supply chain(s), as well as other patient safety threats posed by the internet and other emerging, un, or underregulated markets.

**Background: Drug Supply Chain Security Act (DSCSA)**

As the Subcommittee is aware, the Drug Supply Chain Security Act (DSCSA) passed into law in 2013 and provided a phased window for the pharmaceutical supply chain to achieve interoperable data sharing and electronic tracing of products to prevent suspect and illegitimate products from harming 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 should now be serialized down to the individual saleable unit—meaning there is a unique number for each product and product packaging contains a 2D barcode that can be scanned. Once scanned, trading partners and regulators can ask about the legitimacy of the product's identifiers, or who owned the product previously. (See Figure 1)

**Figure 1 – What Tools Does DSCSA Provide to Detect Counterfeit Medications?**

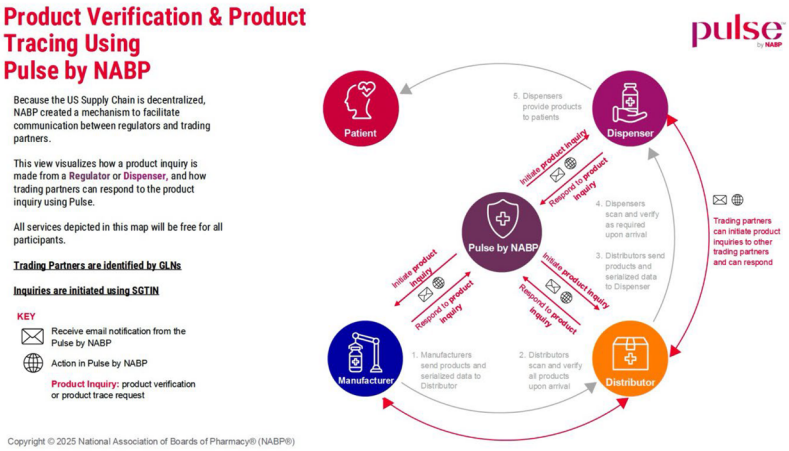
Massive amount of data is needed to communicate across the supply chain. For just a single year of supply chain data, you are talking about 16-20 *billion* transactions that need to be sifted through in order to fully utilize the DSCSA tools.

**DSCSA Implementation: Progress to Improve Supply Chain Security**

Given the 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 it. Utilizing Pulse, regulators and trading partners can scan the 2D bar code of a product and ask questions of trading partners about the product. NABP is providing the tools to our members and every pharmacy in the U.S. supply chain at no cost – because the tools of DSCSA only work if they are accessible and easy to use. (See Figure 2)

**Figure 2 – How Does Pulse Support Supply Communication?**




We rolled out Pulse to our member boards of pharmacy in mid-January. The very first scans that were conducted utilizing Pulse helped the Arkansas and Mississippi Boards of Pharmacy in identifying illegitimate/counterfeit GLP-1 medications that had made their way into our "legitimate" supply chain. From a congressional perspective, DSCSA WORKED, but it illustrated that our supply chain is susceptible to illegal actors. Since January, we have nearly 30 states utilizing the tool and not just boards of pharmacy, but non-Board of Pharmacy regulatory authorities, including Attorneys General and Drug Enforcement Administration field offices.

**Figure 3 – Illegitimate Product Identified in Arkansas Using Pulse by NABP**

**Addressing Emerging Threats to Supply Chain Security**

While we've made progress and 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 the primary highlight is that in our work, we estimate that 96% of online pharmacies in operation at any given time are illegal, violating state and federal laws. And research shows the majority of Americans falsely believe that websites offering prescription medicines have been approved by FDA or boards of pharmacy. People increasingly trust that medications on the internet are safe and regulated, but that is not always the case.

Second, NABP's members have flagged a disturbing trend in the "loosely" regulated space of medspas. For example, one state board uncovered an operation where a medspa had set up shop in their home and was "compounding" or "mixing" purported "GLP-1 medications" with vitamin B-12, in their bedroom. This medspa was "compounding" using active pharmaceutical

ingredient that was obtained not from an FDA-registered API manufacturer as required by law, but from an international online source advertising cheap weigh loss APIs. The medspa 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 has authority to regulate these entities. Unfortunately, we know that activities like this are going on in every state—but most state boards lack the authority to do anything about it.

While there are absolutely legitimate sources for obtaining medications on the internet, unfortunately, bad actors are using the opacity and capacity of internet platforms to peddle medications, putting profits over patient safety. And to be clear, legitimate compounding has an essential role in our supply chain to ensure patients have access to medicines they need that are not commercially available, but those simply mixing medications in nonsterile environments and calling it compounding are a threat to that legitimate practice. Given the popularity of certain medications – those who believe they can make a dollar over demand for a popular medication—will do just that irrespective of the impact it has on patients.

With that, I would like to thank the committee for the invitation and for your attention, and I would be happy to answer any questions.

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 weapons systems 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. OK.

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. Yes. 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 OK, 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. Yes. 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. OK. And does Moderna have manufacturing capacity in the U.S.?

Ms. O'CONNELL. They do.

Ms. DEGETTE. OK. 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 [continuing]. 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.

Mr. GUTHRIE. 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.

Mr. GUTHRIE. 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. Yes. 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.

Mr. GUTHRIE. If you have open capacity, what is preventing the price, obviously—what is preventing you from expanding your capacity?

Mr. MURPHY. Yes. 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.

Mr. GUTHRIE. But you have open domestic capacity.

Mr. MURPHY. We do. We do.

Mr. GUTHRIE. 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.

Mr. GUTHRIE. 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.

Mr. GUTHRIE. 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.

Mr. GUTHRIE. 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.

Mr. GUTHRIE. OK. Thank you. Yes, then if you—yes, the investment—and some of you just have capacity you have already invested, so that is a different animal. OK. 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.

Mr. GUTHRIE. 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. A 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 longstanding 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 moot 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 [continuing]. 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. OK. 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 national—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's 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 routes. 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.

OK. 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.

OK. Last, government strategy in terms of having manufacturing facilities. I found it so interesting that there's 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. Yes. 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. OK. 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. OK. 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. Yes. 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. Yes. 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.

Mr. CARTER OF GEORGIA. The gentleman yields back.

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

Mrs. HARSHBARGER. Yes. 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 appears at the conclusion of the hearing.]

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. Yes. 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. Yes. 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. OK.

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. OK. 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. Yes.

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

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

Dr. PIERVINCENZI. Yes, 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 invest-

ments 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. Yes, 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. Yes, 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. Yes, 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 sys-

tem 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. OK. 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?

OK. 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, OK? 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. Yes, 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. Yes, 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? OK.

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. Yes, 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. OK. 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. Yes, 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. Yes, 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?

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 back yard, 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. OK. 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 lifespans. 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. Yes, 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 appears at the conclusion of the hearing.]

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.

[Whereupon, at 1:12 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

# Documents for the Record

**Subcommittee on Health Hearing**
**"Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain"**
**June 11, 2025**

**Majority:**

1. June 11, 2025, report from Cencora [1]
2. June 9, 2025, letter from the Health Industry Distributors Association (HIDA)
3. June 11, 2025, statement from the Alliance for Home Dialysis
4. June 11, 2025, statement from StringKing CEO Jake McCampbell
5. April 30, 2025, document submitted by Rep. Harshbarger
6. June 11, 2025, submission from National Association of Boards of Pharmacy
    - June 11, 2025, report from pulse by National Association of Boards of Pharmacy (1)
    - June 11, 2025, report from pulse by National Association of Boards of Pharmacy (2)
    - June 11, 2025, survey from ASOP Foundation
    - June 11, 2025, RougeRx, (2&3) Pulse Reports
7. June 11, 2025, statement from Premier Inc.
8. June 11, 2025, letter from Brian Lehman
9. June 11, 2025, letter from American Medical Manufacturers Association
10. June 11, 2025, statement from Association for Clinical Oncology

**Minority:**

1. June 11, 2025, document from Rep. DeGette

[1] The report has been retained in committee files and is included in the Documents for the Record at https://docs.house.gov/meetings/IF/IF14/20250611/118366/HHRG-119-IF14-20250611-SD003.pdf.

HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

June 9, 2025

The Honorable Brett Guthrie
United States House of Representatives
2151 Rayburn HOB
Washington, D.C. 20515

The Honorable Earl L "Buddy" Carter
United States House of Representatives
2432 Rayburn HOB
Washington, D.C. 20515

The Honorable Frank Pallone, Jr.
United States House of Representatives
2107 Rayburn HOB
Washington, D.C. 20515

The Honorable Diana DeGette
United States House of Rep
393 Russell Senate Office Building
Washington, D.C. 20515

Dear Chairman Guthrie, Ranking Member Pallone, Chairman Carter and Ranking Member DeGette:

On behalf of the Health Industry Distributors Association (HIDA), I thank you for your leadership in working toward a stronger, more resilient healthcare supply chain. The Energy and Commerce Subcommittee on Health hearing *Made in America: Strengthening Domestic Manufacturing and Supply Chain* is a continuation of that leadership, and we thank you for elevating this important conversation.

HIDA is the trade association representing healthcare distributors, all of which deliver medical products and supplies, manage logistics, and offer customer services to nearly 300,000 points of care. Their customers include over 230,000 physician offices, 6,000 hospitals, 18,000 Emergency Medical Services agencies, and 44,000 nursing home and extended care facilities throughout the country, as well as numerous federal agencies and their healthcare facilities. HIDA members work every day to build a reliable, safe, resilient, and effective healthcare supply chain, distributing healthcare items ranging from gauze and gloves to diagnostic laboratory tests.

A resilient healthcare supply chain means one that is reliable, proactive, coordinated, and transparent. To achieve this, we need policies that support consistent demand, supply, labor, transportation, and capital investment along with strong partnerships to anticipate and mitigate any disruptions to the supply chain. Informed by industry supply chain leaders, HIDA developed a roadmap for supporting a resilient healthcare supply chain. This roadmap focuses on five pillars:

1. Diversified sourcing and domestic production strategy
2. Buffer of critical products
3. Future stockpile strategies
4. Expedite transportation of medical products

5. Public-private partnerships

As outlined in the roadmap, HIDA supports a diversified sourcing and domestic production strategy to expand our capacity to quickly ramp up critical medical supply production in support of the U.S. healthcare system. This strategy should identify areas of overreliance within the healthcare supply chain and provide government incentives to support the on-shoring or near-shoring of medical device manufacturing as appropriate.

A public health emergency can strain the healthcare supply chain through an initial spike in demand. HIDA members are well positioned to help mitigate this risk by building a buffer of core medical products in private-sector distribution centers to support up to 90-120 days of supplies. Building this buffer would require sustained investment from governmental partners.

HIDA also supports the expansion and replenishment of the Strategic National Stockpile to buffer against demand shocks within the healthcare system. Stockpiles should be dynamic resources, coordinated across all levels of government and the commercial market to ensure efficient and timely delivery of critical medical products to points of care. To achieve this, the healthcare system needs sustained and reliable funding across all levels of government.

Thank you for your commitment to this issue. If you have any questions, please feel free to contact me at 202-714-1233 or via email at dibitetto@hida.org.

Kind Regards,

Kathryn DiBitetto
Vice President, Government Affairs
Health Industry Distributors

**Statement**

**of the**

**Alliance for Home Dialysis**

**for the**

**United States House Energy and Commerce Health Subcommittee**

**"Made in America: Strengthening Domestic Manufacturing and the Health Care Supply Chain"**

**June 11, 2025**

The Alliance for Home Dialysis appreciates the opportunity to contribute a statement for the record in connection with the House Energy and Commerce Health Subcommittee hearing: Made in America: Strengthening Domestic Manufacturing and the Health Care Supply Chain. We are encouraged by the Subcommittee's interest in this important issue, which is a top concern for patients with End-Stage Renal Disease (ESRD), especially those on home dialysis. A resilient, domestic supply chain protects national health security and ensures that vulnerable patients receive the consistent, high-quality care they need.

The Alliance is a coalition of kidney dialysis stakeholders representing individuals with kidney failure, clinicians, providers, and industry. We work to drive policies that empower patient choice in dialysis and break down systemic barriers that limit access to home dialysis. Every person with kidney failure should have a fair opportunity to choose home treatment when it's right for them and their care team. Home dialysis enables patients to take charge of their health and promotes independence and self-determination.

About 815,000 Americans are currently living with kidney failure, and about 555,000 are on dialysis, whether in a dialysis center or on a home dialysis modality.[1] Kidney failure falls within the top ten causes of death in the US, but home dialysis can make a positive difference for both patient quality of life and health outcomes. Home modalities deliver striking benefits: they improve health outcomes, reduce travel and time burdens, enable patients to maintain employment or fulfill caregiving and family responsibilities, improve mental health, and expand freedom to engage in social activities, hobbies, and preserve independence.

Over the past few decades, home dialysis uptake in the US has grown—in large part due to policy changes that incentivize access and government support for the modality. We are grateful for

[1] https://www.kidneyfund.org/all-about-kidneys/quick-kidney-disease-facts-and-stats

lawmakers' support and that of the Trump Administration. From 2012 to 2022, the latest years we have data for, the percentage of incident (newly diagnosed) ESRD patients performing home dialysis increased by over 70% from 8.5% to 14.5%.[2] This growth is encouraging, but makes it even more important than ever to consider how natural disasters and supply chain interruptions can negatively impact home dialysis patients in particular.

Performing home dialysis requires specific medical supplies, like dialysis fluid, needles, tubing, and a dialysis machine, which are delivered to the patient's home at set intervals. In addition, home dialysis requires access to safe water, electricity, and ideally, the internet to allow for contact with the care team. Natural disasters can impede access to all of these things and negatively impact a patient's ability to perform their treatment. Sometimes this means patients have to go in-center to perform dialysis during the time of the disaster; other times, this is not even an option due to impossibilities in travel, challenges due to evacuations, and more.

In fact, during last year's Hurricane Helene, Baxter, a major manufacturer of both IV and dialysis solutions (and Alliance member) was significantly impacted by flooding. The factory was ultimately closed for a number of days. While Baxter moved quickly to get production lines back up and running, immediately collaborated with the FDA and other agencies, and took other action to address the devastating damage, this experience serves as a good reminder that disasters are unpredictable, can directly impact patients, and must be prepared for as best as possible.

We also want to share specific insights with you from home dialysis patients who have been impacted by natural disasters:

- Martine from California explained to us that she experienced a time when her local drinking water was unsafe to use. Due to this, she had to switch the type of fluid bags that she used for her treatments. When the water became safe again, she had a very difficult time switching back to her preferred supply option and received thousands of the incorrect item to her home.
- Shameka from Florida told us that she has lived through two hurricanes performing home dialysis with both flooding and a loss of power. No one could get to her neighborhood to deliver her home dialysis supplies and she was even forced to go in-center for treatment.
- Pedro from South Carolina said that he has been impacted by the saline shortage due to Hurricane Helene and has also had a difficult time accessing needles.

Thankfully, there are options to address many of these challenges, and Congress is in a position to do so. One major item would be federally incentivized programs to increase buffer stock, or an inventory surplus of key home dialysis supplies that manufacturers or retailers would keep either on hand or virtually managed to meet unexpected need during emergencies. Buffer stock can meet

[2] https://usrds-adr.niddk.nih.gov/2024/end-stage-renal-disease/2-home-dialysis

critical gaps during supply chain disruptions and provide a lifeline for patients who want to continue their treatments as prescribed.

In addition, the Alliance is supportive of vendor managed inventory contracts between suppliers and the federal government, which would help manufacturers respond immediately to natural disasters and ensure that access to critical supplies is not disrupted. Because it is difficult to physically stockpile fluids and other necessary home dialysis supplies, due to expiration dates, these contracting arrangements can be particularly helpful as they allow suppliers to ramp up production to meet agreed upon targets at exactly the right time.

We commend your commitment to safeguarding the health and dignity of Americans affected by kidney disease, particularly in times of crisis. The Alliance for Home Dialysis stands ready to collaborate with the Health Subcommittee to advance policies that prioritize the needs of all patients.

**Statement for the Record**

Submitted by StringKing

Hearing of the Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
*"Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain"*

June 11, 2025

Chairman Guthrie, Vice Chairman Dunn, Ranking Member DeGette, and Members of the Subcommittee:

Thank you for the opportunity to submit this statement for the record on behalf of StringKing, an American manufacturer committed to strengthening the resilience, reliability, and responsiveness of the United States health care supply chain.

Founded in Los Angeles, California in 2011, StringKing pivoted our operations during the COVID-19 pandemic to address the urgent national need for personal protective equipment (PPE). We scaled our domestic manufacturing capabilities to produce millions of masks, gowns, and other critical PPE in direct response to the vulnerabilities exposed in our nation's overreliance on foreign suppliers. Today, we continue to invest in advanced textile production, employ American workers, and support federal preparedness efforts—most notably through our current contract to manufacture surgical gowns for the Strategic National Stockpile (SNS).

**The Case for Domestic PPE Manufacturing**

The pandemic revealed hard truths: global supply chains can fracture under pressure, and frontline health care workers and patients should never have to face shortages of basic protective gear. America must not outsource its safety. To that end, a stable, domestic manufacturing base for PPE is not only a public health necessity—it is a matter of national security.

Yet, the U.S. PPE manufacturing sector continues to face existential challenges. As international suppliers re-enter the market with artificially low prices—often the result of state subsidies and unfair trade practices—American manufacturers are struggling to compete on an uneven playing field. Without sustained policy action and long-term federal procurement commitments, our domestic production capacity risks being lost—again—leaving us vulnerable in future emergencies.

**StringKing's Role in the Strategic National Stockpile**

Through our ongoing contract to supply surgical gowns to the SNS, StringKing is delivering not just high-quality, domestically manufactured products, but also supply chain security. We have invested heavily in U.S.-based manufacturing infrastructure and built partnerships across the American textile ecosystem. This allows us to respond rapidly to federal needs, maintain rigorous quality standards, and support good-paying jobs in communities across the country.

We urge Congress to recognize the Strategic National Stockpile not only as a repository of emergency supplies, but as a strategic tool to shape a resilient health care supply chain. That mission cannot succeed without sustained support for American manufacturers.

**Policy Recommendations**

To strengthen domestic PPE manufacturing and ensure the long-term viability of the SNS, we respectfully recommend the following:

1. **Establish Long-Term Federal Procurement Contracts:** Multiyear commitments, such as StringKing's current gown contract, provide the predictability manufacturers need to invest in capacity, workforce, and innovation.
2. **Enforce and Expand Buy American Requirements:** Federal procurement policies should prioritize U.S.-made PPE and materials, including through enforcement of existing domestic content standards and adoption of stronger sourcing rules for health care products.
3. **Create a Permanent Domestic PPE Reserve Program:** Modeled on the Defense Industrial Base, this initiative would sustain warm production lines and ensure surge capacity remains active even during peacetime.
4. **Address Unfair Trade Practices:** Congress and the administration must guard against predatory pricing and ensure U.S. producers are not undercut by non-market actors.

**Conclusion**

The choice before us is clear: invest in a durable, domestic manufacturing base now, or risk the consequences of foreign dependence when the next crisis strikes. StringKing stands ready to be a part of a stronger, safer, and more self-reliant America.

Thank you for your leadership on this issue and for your continued support of American manufacturers who are answering the call to protect our nation's health.

Respectfully submitted,

**Jake McCampbell**

**Co-founder and CEO**

**StringKing**

https://dcjournal.com/no-respect-how-misrepresenting-compounded-drugs-hurts-patients/

# No Respect: How Misrepresenting Compounded Drugs Hurts Patients

April 30, 2025

by Scott Brunner

Lately, compounding pharmacies have every right to feel like the late comedian Rodney Dangerfield. ***No respect.***

Maybe you recall Dangerfield as a bumptious blowhard — the uncouth jokester from *Caddyshack* and countless stand-up routines. But behind the bug-eyed delivery and loosened tie was a sharp, disciplined professional who knew exactly what he was doing.

With GLP-1 wonder drugs in prolonged shortage, it's been compounding pharmacies stepping up to ensure millions of patients had access. Yet in many ways, compounders remain as misunderstood as Dangerfield was. To some drugmakers, regulators, and even reporters, they're fringe players in a system dominated by big pharma. Like Dangerfield, that caricature hides a deeper truth. Compounders fill critical gaps in care. They deserve better than a punchline.

It's time they got a little more respect.

## Copycats? Really?

Let's talk about language. Reporters often describe compounded GLP-1s with loaded terms like "copycats" or "knockoffs" — as if they were fake handbags on a bedsheet in Times Square.

I get the appeal. Those words are punchy. Some journalists even admit their editors favor them as "grabbers." But catchy isn't the same as accurate.

Language like that distorts the truth. It trivializes the medicine and delegitimizes the profession behind it. It's not objective reporting.

Why not just call them what they are called in FDA guidance: "essentially copies" of approved drugs.

Let's also be consistent. When pediatric amoxicillin was in severe shortage two winters ago, compounding pharmacies filled the gap. Sick children got the medication they needed because compounders prepared copies of the FDA-approved drug. And it's funny: With no drugmaker profits at risk, no one called those "knockoffs."

Compounded medications aren't shady imitations. They're prescription drugs made in labs regulated by state boards of pharmacy, using ingredients from FDA-registered suppliers. They're created for individual patients in forms or dosages not available commercially. That's why they're not FDA-approved — because they're not mass-manufactured.

**"Unapproved" … and Essential**

Drugmakers — and the sock-puppet groups that echo their talking points— use the term "unapproved" to give the false impression that compounded drugs are somehow dangerous because they haven't gone through the FDA's approval process. It's a slick bit of spin. But here's the truth: "Unapproved" doesn't mean "unsafe." If it did, nearly every hospital in America would be in trouble.

Hospitals rely on "unapproved" compounded medications daily, because often there's no FDA-approved option available.

If you've had an IV in a hospital, there's a good chance it was compounded. Hospitals also rely on compounders when commercial drugs are in shortage. A pharmacist at a major Chicago hospital recently told me they had more than 250 medications on their shortage list.

Among them? Oral methadone, vital for treating opioid-dependent newborns in hard-hit communities. Another: dexamethasone, essential for reducing brain swelling. When those drugs aren't available, compounded alternatives are the only lifeline.

And it's not just hospitals. One pharmacy I know compounds a liquid form of hydroxyurea for pediatric sickle cell patients, because the only FDA-approved version is a giant pill a five-year-old can't swallow.

Or consider compounded glutathione, a preparation that was literally life-saving for firefighters who battled California's wildfires last year. It too is an "unapproved" drug.

In these and many other cases, "unapproved" doesn't sound reckless. It sounds like a necessity.

**Compounding, Counterfeiting, and Conflation**

The most dangerous tactic used to discredit compounding is conflation — lumping legitimate compounded drugs in with counterfeit and illicit substances. *Counterfeit drugs* are illegal, often manufactured overseas, and sold online by unscrupulous entities. *Compounded medications*, on the other hand, are prescribed by licensed clinicians, prepared and dispensed by licensed pharmacists, and regulated by state and federal agencies. One of these things is not like the other, right?

Drugmakers deliberately blur these lines to sow confusion and distrust. This not only undermines patient confidence, it may impede access to vital therapies for patients who rely on compounded medications to survive.

**Filling Critical Gaps in Care**

Compounded drugs were never meant to compete with brand-name products. They *complement* the pharmaceutical industry — filling gaps where

commercial drugs are in short supply or, *based on the judgment of a prescriber*, inappropriate for a specific patient.

Is there a debate to be had about how GLP-1 compounding opportunism may cross the line into competition? Yes. Let's have that debate. But let's also acknowledge that misrepresenting compounded drugs puts patients at risk.

**Time for Respect**

It's time for drugmakers, the media, and regulators to stop treating compounding like a punchline.

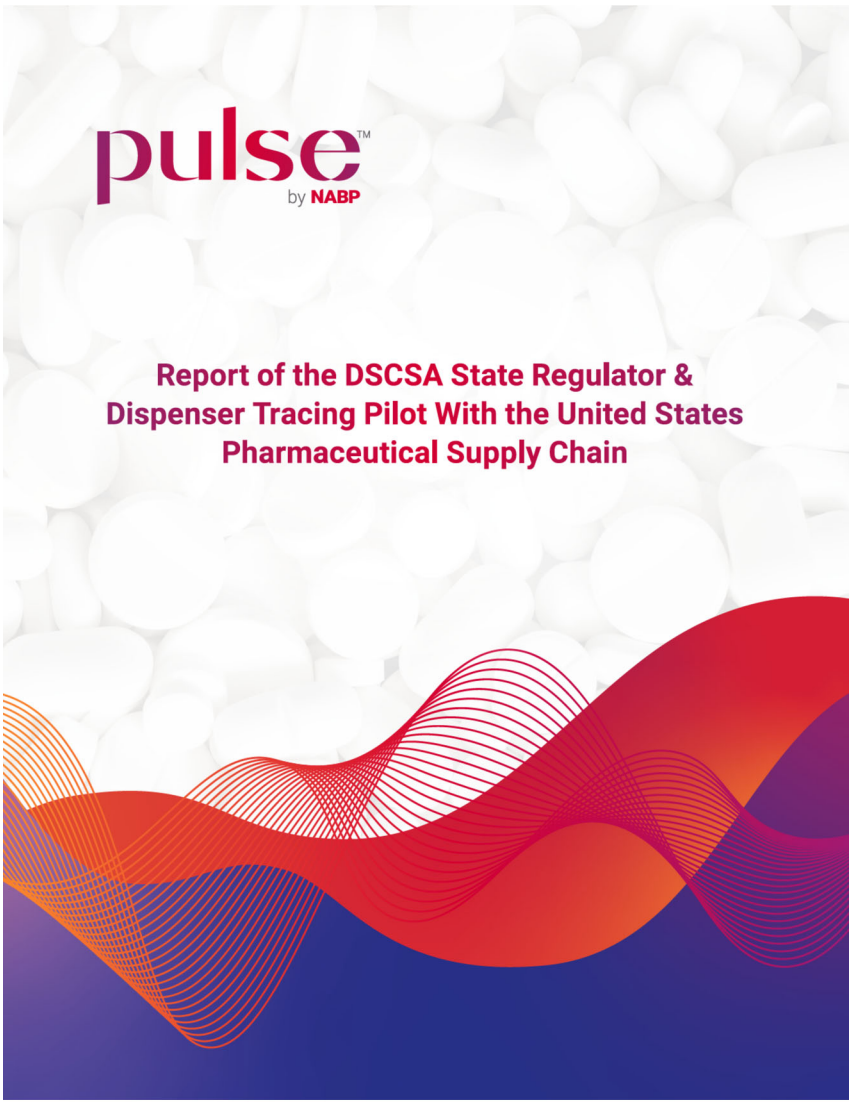
Compounded medications aren't knockoffs. They're not counterfeits. They're legitimate, highly regulated therapies that fill real, often life-saving needs.

Like Rodney Dangerfield, compounding pharmacies may not always get the respect they deserve. But without them, a lot of patients would be out of options.

And that's no joke.

*Scott Brunner, CAE is chief executive officer of The Alliance for Pharmacy Compounding. He wrote this for InsideSources.com*

# # #


pulse™
by NABP
Report of the DSCSA State Regulator & Dispenser Tracing Pilot With the United States Pharmaceutical Supply Chain

pulse™ by NABP

## NABP Members

*Participants:*

- Alaska
- Idaho
- Iowa
- Kansa
- Kentucky
- Maryland
- Massachusets
- North Dakota
- Ohio
- Virginia
- NABP Associates – Josh Bolin, Bill Cover, Gregg Jones, Eileen Lewalski, Justin Macy
- InfoNetworks – NABP Contracted Partner
- Ten Count Consulting – NABP Contracted Partner

*Observers (Stay Informed):*

- Food and Drug Administration (FDA)
- California
- Connecticut
- Florida
- Louisiana
- Minnesota
- Missouri
- Missippi
- New Hampshire
- New York
- North Carolina
- North Dakota
- Pennsylvania
- Rhode Island
- South Dakota
- Tennessee
- Texas
- Utah
- Washington
- Wisconsin
- Wyoming

## Industry and Organizations

*Manufacturer Participants:*

- Bristol Myers Squibb
- EMD Serono
- Eli Lilly and Company
- Genentech
- Ingenus Pharmaceuticals
- Johnson & Johnson
- Novo Nordisk
- Pfizer
- Sanofi

*Distributor Participants:*

- Cencora
- Capital Wholesale Drug Co
- Cardinal Health
- Hercules Pharmaceuticals
- McKesson
- Mutual Drug

pulse™ by NABP

*Dispenser Participants*

- Condo Pharmacy
- Indiana University Health
- Intermountain Health
- Rite Aid
- Thrifty White Pharmacy
- Sam's Health Mart
- Veterans Affairs (VA)
- Walgreens

*Solution Providers*

- Advasur Serialization Compliance Services
- Axway
- BirchOS
- ConsortiEX
- Gateway Checker
- SAP
- LedgerDomain
- LSPediA
- Optel Group
- RfXcel
- RxScan
- Systech
- TraceLink
- TrackTraceRx
- Trust.MED

## Observers From Across Industry

- AAM
- Amgen
- Anda Inc
- American Pharmacists Association
- Apotex
- ArentFox Schiff LLP
- Auto-ID Solutions
- BBF Consulting
- Center for Supply Chain Studies
- CVS Health
- DHL
- Excel
- Excellis Health Solutions
- Gilead Sciences
- GS1 US
- Healthcare Distribution Alliance (HDA)
- Health Mart Pharmacy
- Hikma Pharmaceuticals
- IEEE
- InfiniTrak
- Inmar
- Insolate Technologies
- Medline Industries
- Mississippi Senior Care
- Morris & Dickson co.
- Murtagh Consulting
- National Community Pharmacists Association
- Novartis
- Open Credentialing Initiative
- OFW Law
- Partnership for Safe Medicines
- Partnership for DSCSA Governance (PDG)
- Providence Health Technologies
- PMC
- Precision Dose
- Premier RX Wholesale
- RO
- Sagent Pharmaceuticals
- Smith Drug Company
- StoreMed
- Transplant Pharmacy
- Uptown Pharmacy
- United States Pharmacopeia
- Value Drug Company
- Vantage Solutions
- Vizient
- Walmart

pulse™ by NABP

## Executive Summary

NABP, working at the direction of its member state boards of pharmacy and other state regulators, undertook a second product tracing pilot to further align on requirements, systems, and integrations needed to comply with the November 27, 2023, Drug Supply Chain Security Act (DSCSA) requirements. This effort included:

1. A series of workshops to inform, assess, and outline the representative use cases required for all state regulators and the entities they oversee to meet the federal law requirements.
2. An industry-wide tabletop pilot to explore the use cases, identify findings and gaps, and develop a roadmap to implementation.

This pilot was the first time a significantly broad representation of industry leaders, including manufacturers, distributors, dispensers, solutions providers, and state regulators, participated and collaborated to explore DSCSA interoperability. This diverse group worked together over several weeks to better understand business requirements and determine gaps in the tools and processes required to support the industry.

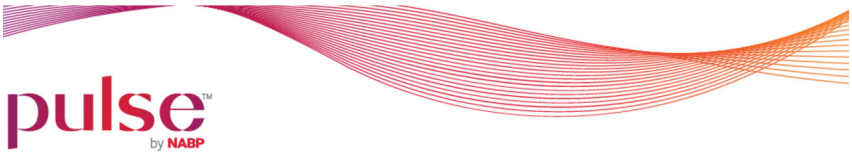
The primary goals of Pulse by NABP™ are to facilitate the creation of a trusted ecosystem to exchange DSCSA-related data, such as product tracing requests and responses for serialized drug products as required by law. The network is expected to:

- be consistent with the Uniform National Policy (Section 585 of the Federal Food, Drug and Cosmetic Act) and FDA guidance;
- implement a uniform request/response standard for state regulators and trading partners to incorporate DSCSA requirements and FDA guidance;
- create an interoperable framework for state regulator and/or trading partner communication;
- ensure that only authorized regulators can access and make requests to authorized trading partners (ATPs);
- protect the confidential and/or proprietary information of participants; and
- focus on the most critical patient safety use cases.

Following the workshops and pilot project, NABP developed this report to outline the current state of DSCSA compliance within the industry and the proposed steps required to develop an interoperable framework for the industry. This document will be published on NABP's website and proactively shared with state regulators, boards of pharmacy, industry sectors, standards groups, professional trade organizations, solutions providers, and federal entities to implement and measure DSCSA compliance.

The key findings of the completed pilot were documented in the following areas:

- **Critical Industry Alignment** – There were five key findings (outlined below) related to the need for an authoritative trading partner information source, alignment of foundational identification data, expected adoption usage growth, reasonable technological barriers to product safety (especially for small independent pharmacies), and alignment on tracing messaging formats.
- **Standards and Best Practices Alignment** – there were 24 findings that were related to topics that should be shared with industry and worked with organizations such as PDG, GS1, HDA and other industry alignment groups.




- **General Findings** – There were 20 findings that provided insights for NABP, its state members, and regulatory groups in the further development of tools such as Pulse by NABP for DSCSA compliance.

As a result, NABP intends to continue development, testing, and industry alignment in the following critical areas:

| Critical Finding | Finding Description |
|---|---|
| 1. Trading Partner Directory | Confirmed as a key functionality needed in Pulse by NABP as identified by industry in the previous tracing pilot. State regulators need an authoritative directory (licenses, registrations, identifiers, and contact information) and functional application to engage with trading partners. All stakeholders need an aligned trading partner directory confirmed by data owners (who, where, and how to connect). |
| 2. Expect Growing Tracing Volume | Expect average adoption times and request volumes to be established as paper transaction history sunsets and serialized transaction information data expands throughout supply chain. |
| 3. Achievable and Aligned Security | There is a need for equitable technological approaches that will enable adoption from the most at-risk small dispensers. Most manufacturers highlighted the importance of reducing restrictions for requestors, while others highlighted the need for more technology-enabled security. |
| 4. Foundational and Confirmed Data | Start with foundational state and federal license/registration data and allow actual trading partners (responsible) to confirm information, including identifiers assigned such as GS1's Global Location Numbers (GLNs). Based on follow-up data analysis in October 2023, NABP determined that around 6-7% of pharmacy dispensers do not have published GLNs for all locations, while most have multiple GLNs that have been created for the same locations. |
| 5. Request/ Response Messaging | PDG drafted JSON message structures for product tracing requests and response work with some suggested improvements. NABP should continue to monitor as related functions are added to Pulse. |

NABP expects to continue working with industry stakeholders and alignment groups as they continue to address these interoperability alignment findings.

pulse™ by NABP

## The Journey Remaining to Complete DSCSA 2023 Requirements

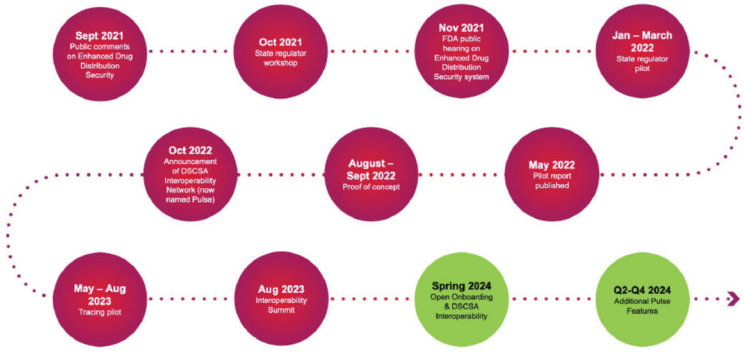
With the final DSCSA 2023 requirements now in effect and FDA confirming the need for more time with the recently announced stabilization period (effective through November 27th, 2024), there is significant work remaining for industry and state/federal agencies to fully develop, integrate, and stabilize the systems and processes required for compliance. These requirements raise several concerns for state regulators and the industry partners they regulate, including:

- ensuring that properly authorized direct and indirect trading partners are engaged for product purchases and exchange of data;
- exchanging required transaction information and related transaction statements as relevant product ownership events occur;
- establishing the systems and networkability necessary for supporting product tracing and product verification requirements; and
- ensuring the ability to demonstrate compliance with all required aspects of the law.

FDA also noted in a 2021 draft guidance titled Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act that the enhanced system "should allow FDA and other federal and state officials to communicate with trading partners' individual systems and receive relevant information upon request."

With the announcement of the Pulse by NABP platform, NABP intends to initiate a trading partner directory based on state and federal license and registration information records in first quarter 2024. All trading partners will have the opportunity to claim system profiles related to their organization, which will be based on existing accreditations and licensure address confirmation processes. This process will include the ability to confirm contact and location identification information, including email addresses, GS1 GLNs, and other widely used identifiers.

## How did we get here?



pulse™ by NABP

This diagram highlights the key events in NABP's process of engaging the industry and ensuring the Pulse by NABP platform is developed in an open and collaborative way to support the Association's mission.

## Engaging State Regulators

NABP continues to hold regular meetings with state regulatory agents to provide updates on the readiness of the Pulse platform and the related trading partner directory, each of which can be utilized for DSCSA-related communications. Once the directory is operational, evolution of the network will move toward the planned enablement of product verification and product tracing for state regulators and the dispensers they regulate.

The efforts will continue to leverage the previously established use cases that were utilized as the basis for the tracing pilots and proof of concepts conducted. These scenarios include:

1. illegitimate and suspect product investigations;
2. fraudulent activity;
3. product recalls; and
4. routine compliance audits.

## How Was the Pilot Conducted?

The goals of the pilot were developed with the engaged state regulators and reviewed by participants from across the supply chain. The goals included:

- **Basic Connectivity:** Conduct initial trial runs of trace messages in email and/or JSON message formats
- **Messages and Formats:** Explore industry needs for messaging exchange for DSCSA transactions including the Pulse by NABP trading partner directory
- **Technical Requirements:** Understand email or system-to-system communication necessary between trading partners and/or solutions providers
- **Identity and Authorization:** Economical, interoperable, and viable approaches for ensuring trusted, confidential, and secure messaging
- **Align Sectors, States, Solutions Providers, and Standards:** Understand additional needs or requests of stakeholders; provide feedback for industry work groups such as PDG & GS1

With these objectives in mind, the following use cases were developed for the pilot:

| | |
|---|---|
| 1 | Explore State Regulator Trace Requests<br>• Scenarios for key use cases (suspect/illegitimate products, fraudulent activity, recalls, and routine compliance)<br>• Methods, message formats, and technology<br>• Communication with trading partners directly and/or their solution/service providers |
| 2 | Explore Trading Partner Responses<br>• Handling within each use case with various responders<br>• Methods, message formats, and technology |
| 3 | Explore Dispenser Trace Requests<br>• To support suspicious product investigation<br>• Methods, message formats, and technology |

In each of these use cases, the assumption for the pilot was that each scenario required a product trace request to be initiated. A product information trace request, as outlined in the DSCSA and FDA guidance, is the act of collecting transaction history and transaction statement records from all owners of the product, back to the original manufacturer who created the product identifier and related human- and machine-readable labeling.

The pilot was conducted over five months through weekly status meetings and working breakout sessions. The executed pilot included the completion of:

- 19 product tracing scenarios
- 26 full test runs
- 68 trace requests and responses

## Detailed Findings

During the pilot, each participant was able to share feedback and highlight concerns to discuss with the pilot work group. After review in the work group meetings, this feedback was consolidated, updated, and formed the basis for the pilot findings.

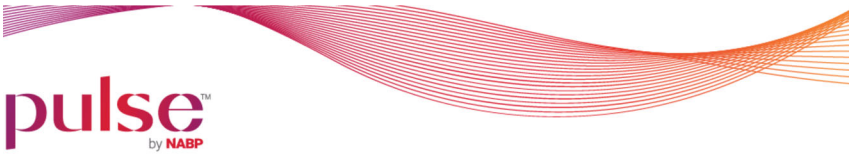
NABP has agreed to address the most critical findings, which were highlighted in the executive summary. We appreciate and value the partnership and efforts of PDG and GS1 to take the lead on other findings and gaps. NABP is committed to collaborating with these and other industry organizations as each item is addressed.

**Standards and Best Practices Alignment** – there were 24 findings related to topics that should be shared with the industry and worked on with groups such as PDG, GS1, and other industry alignment groups.

pulse™ by NABP

| Source | Description |
|---|---|
| State Regulator | **Soft Warning Message for Duplicate Requests:** It is unclear if some requests had been generated and ended up creating duplicates. Is it possible to give a soft warning if you have an active open request for that product, scan, and trace recipient combination? |
| State Regulator | **Clearer Indication of Trace Recipient:** User generated a trace request with the State Regulator and searched for profiles (licenses and GLNs) for a distributor and noticed multiple locations appeared. Unclear which one to send the trace to or if trace location will default based on company setup eventually? |
| Manufacturer | **Authority Checks:** Can it be assumed that trace requests will only come from regulators and pharmacies with valid licenses/IDs? |
| Manufacturer | **Authority Checks:** Can it be assumed that trace requests will only come from regulators and pharmacies with valid licenses/IDs? |
| Manufacturer | **Follow-Up to Requestor:** Once a trading partner submits a response to the trace, can we follow up with the regulators for more information on the investigation in the application and/or by email? |
| Manufacturer | **Negative Response:** There is a need for the ability to indicate that a National Drug Code/Global Trade Item Number/serial number did not match any transaction information on record. |
| Manufacturer | **Negative Handling:** A negative would likely lead to a possible investigation. This could either indicate a confirmed illegitimate or may be due to system issues or data entry. |
| Manufacturer | **Comments:** Could the response include the ability to comment if, for example, the responder feels it is important to provide supplemental information? |
| Manufacturer | **Electronic Product Code Information Services (EPCIS) 1.2 response:** Our solutions provider has an upcoming solution to generate transaction information/transaction statement (TI/TS) files following GS1 EPCIS Lightweight messaging standard R1.2. Is our assumption that the EPCIS file will be ingestible by Pulse? |
| Manufacturer | **3911 or Other Investigation Numbers:** Are trading partners expected to inform direct trading partners with form 3911s if a trace request was received? |
| Manufacturer | **Group Email Address:** Can we respond directly to the state regulator from a central company DSCSA mailbox we use to monitor and track DSCSA inquiries vs going into Pulse to upload TI/TS? |

| | |
|---|---|
| Manufacturer | **Security Info:** Trace request file went to spam and the address link was flagged by corporate security as needing additional clearance to utilize |
| State Regulator | **Invalid Traces:** If there are traces that are no longer valid, can requestors have the ability to cancel, void, revoke, or archive a trace request? |
| State Regulator | **Receipt Confirmation:** Is there a way to tell if a trading partner has reviewed the request? |
| State Regulator | **Repeat Request:** Is there a process to submit a repeat request if a response hasn't been received after a certain amount of time? |
| Manufacturer | **PDF File:** Is it possible to upload a PDF file as the trace response rather than a JSON file? At least initially, our system will generate a PDF trace response vs a JSON file. |
| Manufacturer | **Request download:** It would be helpful to have the ability to download the request. |
| Manufacturer | **Response Contact Information:** Include contact information in the response for follow-up by requestor (may be different than the request routing) |
| State Regulator | **Case Number:** Please add a field where state regulators can put in a "case number" that doesn't go with the request but remains visible under our "active requests" page. This is helpful when there are multiple requests made for various cases (inspections or investigations). |
| State Regulator | **Photos:** Add ability to upload .JPEGs/photos/documents and send with requests. |
| State Regulator | **Comments:** Can we add the ability to send comments with the trace request? |
| Dispenser | **Start Time of the Trace Request:** Is it possible to align on a required start time generally, or will response time always be determined on a case by case basis? |
| Manufacturer | **Incorrect Destination:** Received a trace request for another manufacturer. Is it possible to help prevent systematically? |
| Manufacturer | **Archiving:** Completed trace requests make it harder to manage queue. Is it possible to allow users to archive or filter to only see open requests? |
| Manufacturer | **Trace Request as Suspicious Product Indication:** There is concern on if a response should be given for a suspect product if the requestor is essentially saying "we have suspicious product," or should it go directly to an investigation? Would a tracing response at the manufacturer level happen without an investigation? |




**General Findings** – There were 20 findings that provided insights for NABP and state member regulatory groups in the further development of tools for an interoperable approach to DSCSA compliance. These findings are consolidated into the following topics:

- advance dashboards and reports for monitoring and managing communication;
- provide the ability for trading partners to work with state or federal regulators to initiate trace requests when required for patient safety;
- provide email alerts and summaries to minimize the need to log in to the Pulse platform;
- advance integration to allow messages to be sent system to system for users to interact with as needed (moving beyond email will be required);
- more detailed error and warning messages to minimize misunderstanding; and
- better alignment on time zones and "starting event" for tracing response time tracking.

## Next Steps

- NABP has initiated development and deployment plans to address the gaps identified during the pilot project. To help guide and inform the development process and to build on the collaborative efforts between trading partners and state regulators, NABP will convene an advisory group. The advisory group will be composed of trading partners and state regulators.
- NABP will convene regular meetings with Pulse Partner Program solutions providers to collaborate on development plans and to ensure that solutions providers are on a path toward interoperability for any required interactions with the platform, such as directory searches, license/ATP status checks, product tracing, or product verification messaging. In addition, this will allow NABP to coordinate testing and further exploration with solutions providers as systems evolve and integrate.
- NABP will continue to engage with PDG and GS1 to help inform standards development or to participate in future workshops, pilots, and other activities as necessary.

## Considerations for State Regulators

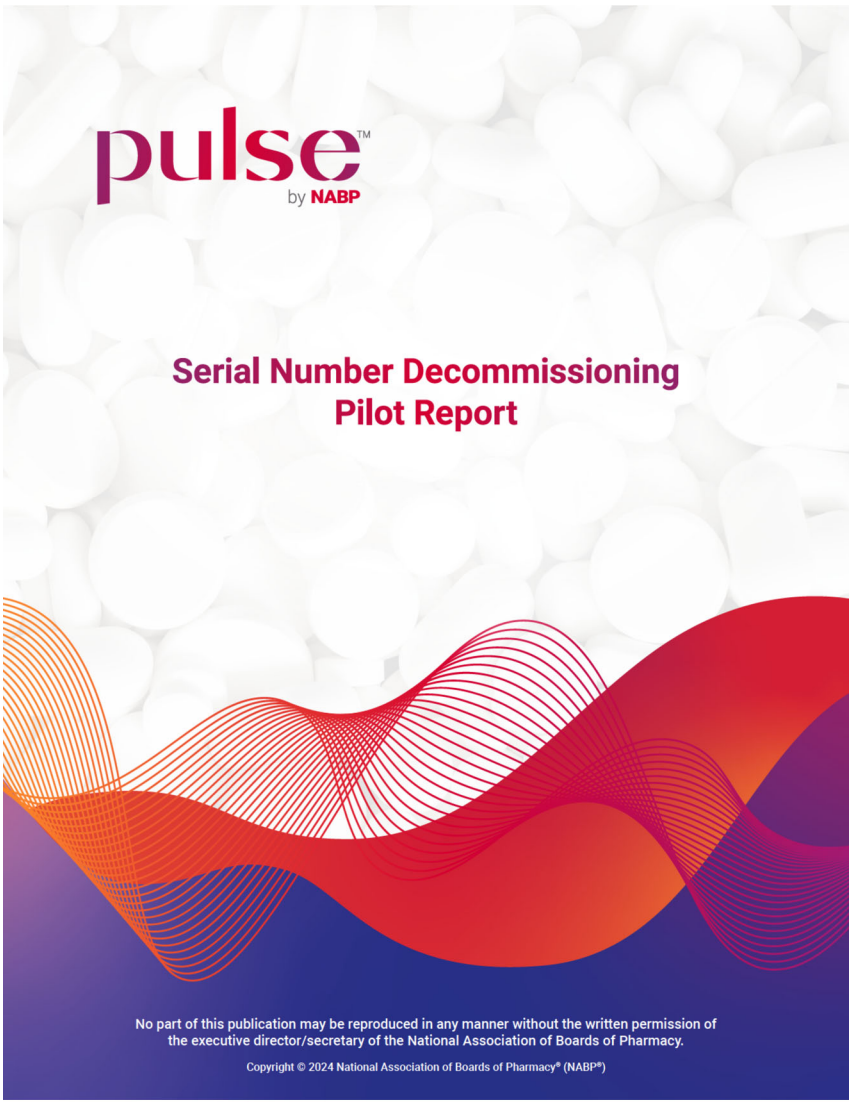
- **Sunset of transaction history:** One of the most significant impacts of the transition to electronic interoperable tracing at the unit level is that the transaction history sunsetted as 2023 requirements were met. The impact for regulators is that this transaction history is no longer available for review at the time of inspection or investigation. This was the primary purpose of conducting a pilot that would facilitate the collection of the transaction information necessary to rebuild that transaction history.
- **DSCSA is an ownership law:** While transaction histories include information about the physical movement of product(s), the November 2023 requirements mandate the exchange of transaction information showing change of ownership of the product. States may independently request information about the physical movement of product, but that is not included under the DSCSA tracing provision.
- **Impact on compliance audits and inspections:** Given the sunsetting of the transaction history and other requirements under DSCSA, regulators should consider how they will ask trading partners to verify compliance with DSCSA. In particular, how will they verify that trading partners are "authorized" under DSCSA, and how will they prove that they have systems and processes in place to comply with DSCSA?

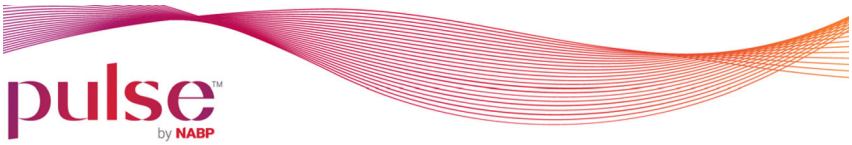
pulse™ by NABP

## Considerations for FDA

NABP is grateful that representatives from the agency were able to attend meetings and webinars as observers, and the Association is hopeful that it provided insight into areas of needed attention.

- Consistency With Uniform National Policy and FDA Guidance: As referenced in previous public comments and presentations, any solution(s) that NABP builds(s) to facilitate state regulator communication with trading partners will be built in a manner that is consistent with DSCSA, as well as any final regulations.
- State-Federal Collaboration: While it is understood that FDA will pursue its own means of facilitating communications with trading partners, NABP maintains that state regulators must have their own independent means of consistent and efficient communications with trading partners to fulfill their regulatory obligations prescribed within DSCSA.
- 3911 Form Automation: Due to the expected importance of the 3911 form and its relationship to product status, we encourage the agency to consider automating integration to the 3911 forms. This would include interaction with state and other federal agents, along with facilitating communication to/from the manufacturers as product quality owners.
- Support Existing Investigation Processes: State and other federal agents are authorized to initiate product information requests and conduct investigations as outlined in DSCSA. These agents will be required to have independent access and maintain the ability to manage this collected data in order to carry out their daily responsibilities.
- Dispenser Engagement: While the engagement in DSCSA-related work groups continues to increase, there is still a common misunderstanding of the level of effort and time needed to comply with the requirements of DSCSA. FDA and the dispenser's trade groups can help to raise awareness through training and better communication of the expectations for 2023, as well as help develop better requirements for industry governance, standards groups (like PDG and GS1), and solutions providers.
- Regulator Learning Curve: DSCSA-related systems, processes, and data are still in the early stages, and we encourage all state and federal authorities to consider conducting and participating in pilots directly with stakeholders to better understand the current conditions and prepare for the significant attention needed for DSCSA 2023.


pulse™
by NABP
Serial Number Decommissioning
Pilot Report
No part of this publication may be reproduced in any manner without the written permission of the executive director/secretary of the National Association of Boards of Pharmacy.
Copyright © 2024 National Association of Boards of Pharmacy® (NABP®)

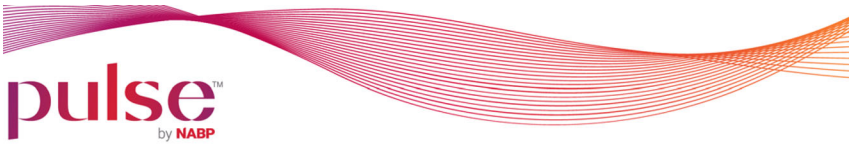



## Table of Contents

Executive Summary ..... 2
Introduction ..... 4
Background ..... 4
Pilot Objective ..... 5
Pilot Approach ..... 5
Use Case: Notification of Dispensing Events ..... 6
Pilot Results and Discussion ..... 7
Recommendations ..... 9
Pilot Outcomes ..... 9
Summary ..... 10

No part of this publication may be reproduced in any manner without the written permission of the executive director/secretary of the National Association of Boards of Pharmacy.

©2024 by the National Association of Boards of Pharmacy. All rights reserved.




## Executive Summary

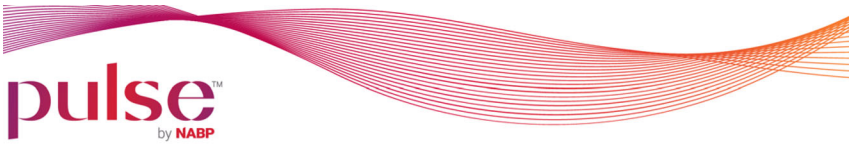
The Drug Supply Chain Security Act (DSCSA) requires the serialization of products down to the saleable unit. Serialization enables the electronic and interoperable exchange of data between trading partners, as well as other communication tools like product verification and product tracing that should help prevent counterfeit medications from infiltrating the legitimate prescription drug supply chain. While full implementation of DSCSA has been delayed to ensure that patients do not experience access issues to medications, even when fully implemented, the law has some limitations that have and will continue to be exploited. Counterfeit prescription products continue to infiltrate the legitimate supply chain. Recent counterfeit events have highlighted numerous instances where valid unique product identifiers – Global Trade Item Numbers (GTINs), or serial numbers – were duplicated or reused by bad actors to insert dangerous products into the legitimate supply chain. Further collaborative efforts are required to prevent these dangerous products from entering the supply chain.

In response, the National Association of Boards of Pharmacy® (NABP®) organized a focused, voluntary pilot that would explore the facilitation of decommissioning serial numbers as a foundational step in further preventing and detecting counterfeit medicines. The Serial Number Decommissioning Pilot explored how the industry might work together to prevent the growing tactic of counterfeiters that reuse already-dispensed prescription drug packaging with valid product identifiers. Key stakeholders from the manufacturing and dispensing communities joined the effort to see how the building blocks of DSCSA (product identifiers and 2D bar code scanning) could be leveraged to further protect the legitimate supply chain from counterfeits. The pilot design mostly revolved around the following core questions:

1. Is it possible, in any or all situations, to capture end-of-commerce event information for serial numbers that have been dispensed, damaged, destroyed, stolen, or other and translate those events into a serial number being “decommissioned”?
2. Can these events be captured in various product quantity configurations in the current “unit of sale” without a move to full “unit of dispense” for all products?
3. Could capturing and sharing with the manufacturer/repackager of such decommissioning events have helped in preventing recent types of counterfeiting events?

During the pilot, participants identified several guiding factors that should be considered as the industry weighs how to address the proliferation of counterfeit medications into the legitimate supply chain. The following guiding factors were developed before, during, and because of the pilot:

1. Only a portion of product is currently packaged and serialized at the “unit of dispense” level, but this portion includes a majority portion of recent counterfeit cases involving single-packaged vials, smaller-count pill bottles, and, more recently, auto-injection pens.
2. DSCSA provides tools that should be leveraged as foundational in preventing counterfeits, such as saleable carton serialization, data-sharing techniques, product verification, product tracing, related global standards, and the development of industry best practices.
3. DSCSA has limitations in that product verification can be performed at any time but is only required after a suspect product is identified.
4. DSCSA requires that trading partners use widely aligned DSCSA tools, such as Electronic Product Code Information Services (EPCIS) messing, product verification, and product tracking.
5. DSCSA requires that regulators, manufacturers/repackagers, and direct trading partners are efficiently notified of illegitimate product identifiers.
6. The technology and regulatory frameworks exist to scan products (or integrate them into existing scan systems) in order to verify product identifiers and decommission serial numbers at or near the point of dispense.
7. Adoption of any methods beyond clearly mandated requirements such as end-of-commerce scans will require nonregulatory incentives.
8. The variability of products, processes, and conditions present in the market requires that any solution focus on early adopters in narrow, high-counterfeit target areas, such as high-value products or other historically counterfeited product types.




9. Dispensers need a flexible approach that allows the capture of events at the most efficient points, along with options to integrate into existing workflows and systems.

At the conclusion of the pilot and based on findings outlined below, the pilot team believes that:

1. Industry should move forward in search of pathways to enable the capturing and sharing of decommissioning data while expanding the ability to verify product identifiers;
2. These efforts could have prevented or significantly limited the historical counterfeit events that involved the reuse of valid product identifiers by providing immediate visibility to unfolding threats;
3. Early efforts should focus on products most susceptible to counterfeiting; and
4. NABP should expand its work and collaboration across the supply chain to further protect patients and prevent harmful products from entering the legitimate supply chain.

## Introduction

Enacted in 2013, DSCSA established requirements for members of the United States prescription drug supply chain intended to protect the legitimate supply chain from counterfeit/falsified medicines. The requirements established that manufacturers should serialize products by affixing a unique product identifier to the lowest saleable unit of the product. The serialization would also include a global standards 1 (GS1) 2D data matrix that can be scanned throughout the product's "movement" in the supply chain. DSCSA also affords trading partners and regulators tools to identify suspect and illegitimate products by scanning the 2D data matrix to determine the authenticity of the product identifiers (product verification) and to trace the prior ownership of the product (product tracing).

Recent cases of illegitimate medicine being found in the legitimate US supply chain continue to highlight the need for increased efforts to further secure the US supply chain. While the US supply chain remains among the safest in the world, these cases emphasize how organized crime and counterfeit operations have evolved beyond the protections enabled by DSCSA (including the unique GTIN, serial number, and related 2D data matrix barcode). In these recent counterfeit cases, it has been shown that bad actors often leverage actual, existing serial numbers by reusing packaging or copying existing barcodes. In industry-wide updates with the manufacturers of the related brands, it became clear that serial number "end of commerce" capture should be explored as a preventative approach to these threats.

The Serial Number Decommissioning Pilot was performed by NABP in collaboration with participating prescription drug manufacturers and dispensers from April through May 2024. Built upon the product-tracing capabilities of Pulse by NABP™, the pilot set out to demonstrate the viability of a process that would fill a gap in medication supply chain safety, namely, to ensure that serialized products, once dispensed, cannot be reintroduced into the supply chain, thus protecting patients from receiving counterfeit medications manufactured in original packaging.

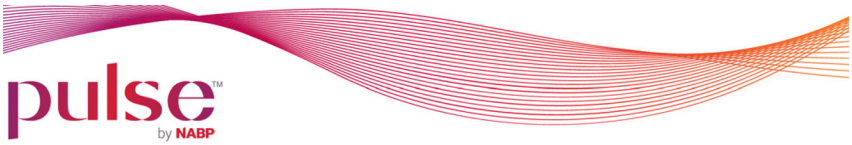
## Background

In early 2000, a series of high-profile counterfeit cases including drugs that treat cancer, renal failure, high cholesterol, and AIDS were documented through news, press releases, and investigative journalism, highlighting weaknesses in the US prescription drug supply chain. These and other historic events led to the passing of DSCSA in 2011 to facilitate the tracking of ownership changes of any applicable saleable unit to help identify the supply chain and source of detected counterfeits.

In late 2020, Janssen Pharmaceuticals (Johnson & Johnson) announced that they had been made aware that counterfeit Symtuza®, an HIV treatment medication, had been received by three pharmacies in the US. Janssen later took legal action to ensure the alleged distributor no longer introduced counterfeit products into the legitimate supply chain.

In 2021, Gilead Sciences, Inc, became the first pharmaceutical company to take direct legal action against counterfeiters manufacturing HIV counterfeits using already-dispensed original bottles. It filed its lawsuit knowing only a handful of patients received counterfeit versions of its HIV medicine but later identified through seized records from the counterfeiters that they had sold over $250 million worth of illegitimate HIV drugs into the legitimate US supply chain. The medications made their way to over 600 unique pharmacies across 36 states. In summary, findings from law enforcement show that what was most valuable to the criminals was not the medication in the bottle, but the bottle and packaging itself. While recent laws and guidance documents have helped to shape a foundation for the serialization of prescription drugs, they focus on the ability to trace the supply chain for a product after it has been identified as suspect or illegitimate and do not involve capturing the critical information of when products are removed from the supply chain (ie, product that has been dispensed and subsequently decommissioned).

Under DSCSA, prescription medicines must be serialized down to the saleable unit. In addition, product packaging must contain human-readable product identifiers that are also encoded in a 2D data matrix barcode.




To bypass the DSCSA systems, criminals obtained products in the manufacturer's original packaging and then duplicated these active product identifiers or simply cleaned the bottles, removing any identifying patient or pharmacy information to make the bottles look new. Because the packaging also contained the valid product identifiers with a serial number and 2D barcode, if a pharmacy or wholesale distributor attempts to conduct a "product verification"[1] with the manufacturer to confirm that the product identifiers on these counterfeits are genuine, the manufacturer would almost certainly confirm verification because the manufacturer would have no information that the bottle bearing those product identifiers was already dispensed.

The reason this is possible in the US is that DSCSA does not require serial numbers to be decommissioned or have related status updates when a product is dispensed. In the US, unlike the European Union's (EU's) Falsified Medicine Directive, the serialized product is **not** always packaged in a "unit of dispense" and is not required to be linked to a patient dispensing event. While the intent was to avoid creating a cumbersome dispensing event for all medicine, the impact here is that the information that a product is dispensed or otherwise decommissioned is not captured to be shared. Therefore, legitimate serialization unique identifiers can be reintroduced into the supply chain without clear detection of being duplicates. In addition, any product that is returned to a distributor or manufacturer for destruction is outside of DSCSA requirements due to the product's classification as exempt from further transaction under the non-saleable returned inventory provisions of the law and is never decommissioned. This means that if an already-dispensed product is reintroduced intentionally or accidentally, the manufacturer may also provide an affirmative response to any verification that the product identifiers are still legitimate. Both situations have been exploited in the highlighted cases, as well as in other counterfeit events, and even completely compliant implementations of DSCSA requirements will not prevent such recurrence.

## Pilot Objective

While DSCSA does not require the capturing of these decommissioning events, thought leaders from across the supply chain have suggested that a proof-of-concept pilot event could help the industry learn the benefits, challenges, and viability of dispensers capturing the dispensing and other end-of-commerce events and relay such transactions to the manufacturer or repackager of record.

The objective of the Serial Number Decommissioning Pilot was to explore the initial business processes and systems for alerting or preventing serialized product from being dispensed more than one time, thus protecting patients and providing information to manufacturers to decommission the serial number or otherwise allowing them to initiate a suspect product investigation.

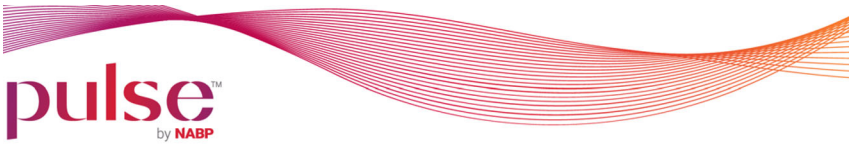
It was clear that a significant challenge in the proof of concept was helping to understand if such activity could take place without full conversion of product to "unit of dispense," as is the case in the EU and many regions of the world. This requires engaging leading manufacturers whose product was counterfeited in these highlighted cases and working with dispensers of various practice settings and sizes.

## Pilot Approach

Building off NABP's previous DSCSA pilot projects that demonstrated the product-tracing capabilities of Pulse by NABP, NABP explored the following decommissioning use case to attempt to answer the questions above. The pilot was intended to leverage the following capabilities of Pulse:

- Provide a neutral platform for any stakeholder to leverage industry-wide functions.
- Leverage the Trading Partner Directory feature of Pulse to allow connection and collaboration with any other trading partner.
- Draw from past work done on product-tracing exploration to further explore in an agile manner.
- Build on a flexible framework that facilitates direct user interactions or application programming

[1] Verifying the product identifiers (GTIN, lot number, expiration date, and serial number) with the manufacturer of the product.




interfaces (APIs) for any authorized system to integrate.
- Continue to utilize existing GS1 industry standards while flagging areas where gaps may exist for follow-up with GS1.
- Allow NABP to serve its mission as an independent agent in evolving patient safety.

### Use Case: Notification of Dispensing Events

In this use case, pharmacies used the Pulse platform to scan a 2D barcode of a prescription drug product that was at or near the point of dispense. The scan generated an event in the prototyped version of Pulse, and the related data was stored to show any scan performed. Manufacturers were given access to a query report that allowed the viewing of these events with data limited to the date, time, GTIN, serial number, lot number, and expiration date. Additionally, manufacturers could be sent a download of the data conclusion of the pilot to further analyze and explore.

Participants included state-licensed pharmacies and pharmacists, manufacturers, and the NABP pilot team. The following pharmacies participated in the pilot:

- Sam's Health Mart Pharmacy #1, #2, and #3 in Missouri
- Gateway Apothecary, Inc, in Missouri
- Indiana University Health

Each participating pharmacy carried products manufactured by Gilead Sciences; Genentech, Inc; and/or Johnson & Johnson.

Each participant organization assigned a user who was responsible for logging into Pulse to perform their role. Participation took place virtually, with product barcodes being scanned behind the counter in a state-licensed pharmacy.

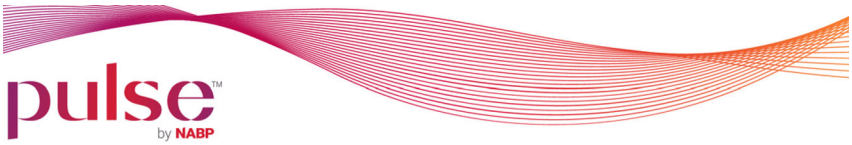
Materials for this use case included a mobile device and prescription drug products selected by the participating manufacturers that had 2D barcodes, product identifiers consistent with DSCSA, and that were ready for decommissioning (eg, an empty bottle ready for destruction or a bottle that had been dispensed intact). The technology in use was Pulse via mobile web interface and desktop web interface. No technical development, integration, or interface was required for this pilot.

The process flow was as follows:

1. A state-licensed pharmacist (user) logged into Pulse on their mobile device.
2. User selected "Decommission SN" (serial number).
3. User scanned 2D data matrix on the product.
4. Pulse displayed the following information:
    a. GTIN
    b. Serial Number
    c. Lot Number
    d. Expiration Date
5. User confirmed that the scan result matched the product identifiers and submitted.
6. The decommissioning event was received in Pulse.
7. Date and timestamp of event were recorded in Pulse.
8. The manufacturer logged into Pulse to view message.
9. Message displayed the following data elements:
    a. GTIN
    b. Serial Number
    c. Lot Number
    d. Expiration Date
    e. Date/Time the event was initiated

The pilot adhered to the following tenets:

1. No technological development, integration, or interface were required by the participants.




2. Serial numbers were not associated with any patient, patient's agent, other personally identifiable information, or personal health information.
3. Serial numbers were not disclosed to any party outside of the pilot.
4. Serial number information was purged and electronically destroyed at the end of the pilot.
5. The pilot did not disclose any event location data to manufacturers.
6. Above all, the pilot was focused on advancing patient safety by reducing the likelihood or increasing the detection capability of illegitimate products.

## Pilot Results and Discussion

**Scanning Statistics:** The total number of 2D barcode scans, the number of unique serial numbers recorded, and the success rate were collected. During a two-week period in late April 2024, a total of 282 scans were performed, and 261 unique serial numbers were scanned, resulting in a 92.55% success rate.

**Duplicate Scans and Records:** Data received from two participating manufacturers contained duplicate records that were the result of users either inadvertently scanning the same package twice or clicking "send" twice. Suggestions for reducing accidental duplicate scans included auditory cues indicating when a scan has successfully registered a serial number in the system or system techniques to reduce inadvertent duplicates.

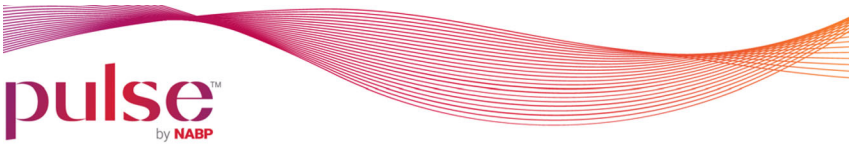
These duplicates pointed to a need to distinguish between records that are erroneously duplicated and products that are potentially counterfeit. Participants noted that if the duplication occurs within a certain timeframe, it can be discounted, but if it occurs at multiple time points, it will indicate a potential problem. The question was raised whether the system would alert users that a serial number has already been decommissioned. One suggestion was to add the capability to sort records by timestamp proximity. It was also highlighted that there may be occasions of duplicate scans that simply show that a product was accidentally scanned twice or was a controlled return that may be determined as normal and not suspicious product.

**Factors Affecting Scanning:** Some participants had trouble scanning 2D barcodes, either because the barcodes were small or blurred or because the scanners being used (eg, cellphone cameras) were not sufficiently high-resolution. Dispensers noted that larger barcodes could be scanned without a problem. The size of the barcode, however, varies with the size of the package. The pilot dispenser participants noted that there may be an opportunity to integrate with pharmacy scanners, which would increase the volume and accuracy of scans and help to scale the pilot more broadly.

**When to Decommission:** Questions arose about the process, such as the circumstances in which to decommission a product. Participants agreed that a package that has been opened should not be dispensed, but questions remained as to other use cases, such as when product is a salable return or sent for destruction and whether that would warrant a second decommissioning. Some dispensers indicated that they would prefer to scan the serial number at the time of receipt, internal distribution, or shelf/cabinet stocking.

Pharmacies scanned products that were dispensed in the manufacturer's original packaging, as well as products for prescriptions that were filled out of a larger stock bottle and placed into a smaller vial. Manufacturers with large stock bottles indicated that they preferred that products be scanned at the point that the stock bottle is opened. Their thinking is that, at that point, the product should not be dispensed from another location or otherwise processed as a saleable return.

**User Interface:** Manufacturers indicated that additional data fields and functionality would be useful. This includes further functionality to visually or systemically distinguish between new records and those that have been read or forwarded. Additional fields that manufacturers had asked about and will need more industry alignment to include consist of the product name, pharmacy that scanned the product, time zone when the record was entered, and the type of event (if scanning is done at earlier points of the handling processes). Also, it was mentioned that capturing who is performing a scan (potentially connecting with Pulse by NABP profiles) and in what geographical location the scan was performed would help to distinguish between inadvertent duplicate scans and potential nefarious activity that requires further analysis.




**Reporting/Exporting Data:** Manufacturers asked for flexibility in how the captured information is obtained. Some wanted the ability to download or export data into a spreadsheet to share with others in their organization, while many suggested integrations would be needed to send the events either in batch or real-time transmission. Additional functionality might include standard reports for monitoring activity, such as duplicate serial numbers, a new dispenser source, or serial numbers in a inactive state.

**Workflow:** Different workflows in pharmacies presented other potential use cases. Central fill, for instance, may involve the automated scanning of products being distributed to pharmacies. The timing of when product scanning occurs (eg, in batches) may also vary by pharmacy.

While scanning to dispense/decommission as soon as possible after opening the serialized bottle/box is preferred, there is a need to address situations in which this scan can only happen at different points in the workflow. For example, some pharmacies may remove the serialized box when stocking product into a dispensing cabinet, some may only consider scanning serialized barcodes at the point of receipt to the pharmacy dock or central fill location, or there may be automated scanning at central fill only. This issue will require further exploration with system providers and dispenser stakeholders to understand and determine if there is a need to systemically identify at what point in the workflow and in what location this scan is occurring.

**EPCIS Structure:** Manufacturers expressed a desire to move toward a GS1 standard – namely, an EPCIS structure – to help facilitate the interoperability of data among trading partners. It was noted that the GS1 1.3 US implementation guide includes scenarios for events including dispense, partial dispense, and decommission. The pilot team indicated that, while the information collected through the pilot project establishes a firm foundation for potential future standardization, the pilot intends to determine whether the platform helps to prevent prescription drug counterfeiting. If this is established, it may lead to informing a process for standardization. Others noted that the existing product VRS (verification routing service) may be leveraged for a lighter message format that could include a “dispense” reason code.

**Demonstration:** NABP staff demonstrated the pilot’s functionality while participating in the Drug Enforcement Administration (DEA) Diversion Control Division’s Supply Chain Conference in late April. DEA agents at the conference reported the diversion of promethazine, which is sometimes sold illegally and used recreationally. Staff was able to scan the 2D bar code on a case of stolen product and immediately determine the appropriate person with the appropriate manufacturer to initiate an investigation, thus demonstrating a valuable use case for the Pulse platform and its decommissioning capabilities.

**Future Developments:** Unless dispensers, and, in particular, small independent pharmacies widely utilize product verification, DSCSA may never reach its full potential. While DSCSA requires pharmacies to verify a product if it is considered to be suspect, participants noted that a gap still exists. The group agreed that an effective serial number decommissioning process would require verification of every product dispensed. Pilot participants discussed future developments that would be needed to expand the Serial Number Decommissioning Pilot process on an industry-wide scale. Toward this end, participants expressed the importance of providing pharmacies with access to product verification tools, as this will facilitate the development of pharmacy best practices that include scanning products at the point of dispensing and verifying products with manufacturers prior to dispensing. They noted that payers could play a role in normalizing product verification at the point of dispensing by requiring pharmacies to submit the serial numbers of products dispensed.

The group recognized that statutory and regulatory changes to require verification and/or scanning at the point of dispensing are highly unlikely. Accordingly, without a regulatory mandate, other factors would be needed to incentivize pharmacies to scan products at the point of dispensing. Participants agreed that dispensers would need to see a return on investment beyond patient safety. It was noted that revenue, such as compensation for the service of scanning and the resulting data product, may be an effective driver. Participants noted that some manufacturers have direct dispensers, in which case the manufacturers could require the dispensers to comply with the process through their contracts. Gaining compliance from the multitude of indirect dispensers, however, would be much more challenging. Participants also considered whether scanning at the dispenser level could be tied to incentive methods such as manufacturer rebates to help offset costs incurred at the dispenser and

drive adoption.

It was suggested that the group consider the commercialization and commoditization of data as a path forward. Manufacturers can assign a value to granular and timely data and determine the value of a serial number scan at the point of dispensing. This value may vary across products.

## Recommendations

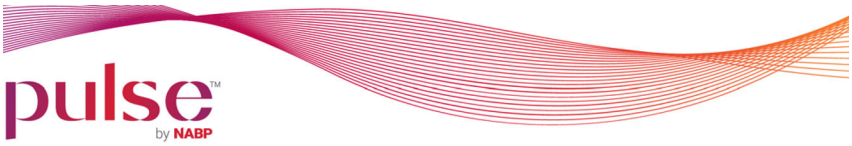
After several weeks of testing, discussion, and deliberation, the pilot team made the following recommendations for improvements to the Pulse serial number decommissioning system and process:

1. Share pilot findings with additional members of the prescription drug supply chain, including distributors, chain pharmacies, and other stakeholders, to collect further feedback for consideration in follow-on efforts.
2. Continue to expand follow-on pilot trials with a broader range of dispensers to further identify variability in other environments, such as large retail, mail order, institutional and governmental, and other environments.
3. Explore integrating pharmacy information systems with the Pulse platform to enable pharmacy scanners to be used for 2D barcode scanning at the point of dispensing.
4. Work with industry to advance the creation of a neutral and business confidential network that will include methods to incentivize dispensers' voluntary participation.
5. Clarify methods for identifying dispensers (either anonymized, permission-based named, cryptographically linked, or other).
6. Improve API integration with manufacturer systems to make the information easily available and accessible.
7. Implement auditory cues indicating when a scan has successfully registered a serial number in the system to reduce the likelihood of accidental duplicate scans.
8. Add the capability to sort records by timestamp.
9. Add the following data elements: product name, the pharmacy that scanned the product, the time zone when the record was entered, the type of event, who performed the scan, and in what geographical location the scan was performed.
10. Add functionality to create reports and export data to begin monitoring, or enable trading partners to share information with others in their organization.
11. Confer with system providers and dispenser stakeholders to determine whether there is a need to systemically identify at what point in the workflow and in what location the barcode scan should occur.

## Pilot Outcomes

The pilot demonstrated that it is possible to capture product identifier (including serial number) information at the point of dispense and relay this information to the manufacturer of record, thereby allowing the manufacturer to decommission the serial number. Based on historical and recent high-profile counterfeit cases, it is believed this is one step in potentially reducing or preventing counterfeit product from being dispensed through the following ways:

- Manufacturers could monitor for duplicate or suspicious serial scanning information to more quickly identify suspicious product.
- Dispensing or other end-of-commerce events of serial numbers could be shared and updated in verification and other systems to improve the ability to give a warning if the same serial numbers are re-scanned.
- Distributors could begin to see if any product identifiers that are processed through returns show records of being dispensed to avoid excess credit.
- Dispensers could increase assurance that any dispensed and matching product is legitimate.




- Dispensers need a flexible approach that allows the capture of events at the most efficient points, along with options to integrate into existing workflows and systems.
- Enablement of this approach should include incentives to encourage adoption and offset resources required by dispensers.

The pilot team's primary observation was that the decommissioning process has the potential to warn or alert of a potentially suspect product. The goal of the process is to prevent a suspect serial number from being dispensed to a patient. If all members of the supply chain are verifying products, then dispensed serial numbers can be successfully decommissioned, and product verification could stop or significantly limit suspect serial numbers from being dispensed.

## Summary

DSCSA provides foundational tools (serialization, product verification, and product tracing) that prevent counterfeit medications from entering the supply chain. The law, however, has limitations in that verification is not widely required and serial numbers are not required to be decommissioned. DSCSA will only work if the tools it provides are widely used, and if the industry continues to evolve to stay ahead of bad actors. At present, barriers exist for widespread adoption by the pharmacy community – in particular, the independent pharmacy community, which is most susceptible to counterfeiters and criminals.

To remove barriers to participation, NABP is providing all dispensers with access to DSCSA tools at no cost (eg, product verification and product tracing) and could facilitate decommission scanning with continued collaboration from industry leaders. Nonregulatory incentives must be explored to increase the utilization of product verification and to facilitate the sharing of decommissioning events at the point of dispensing.

Building on the pilot, NABP will continue to work with industry stakeholders to explore nonregulatory pathways that enhance patient safety and protect the prescription drug supply chain.

ASOP GLOBAL FOUNDATION | abacus data

# AMERICANS' PERCEPTION AND USE OF ONLINE PHARMACIES

## ASOP Foundation 2023 Consumer Survey

## EXECUTIVE SUMMARY

In September 2023, ASOP Global Foundation commissioned Abacus Data to survey 1,500 Americans about their perceptions and use of online pharmacies. The survey also measured the factors that influence consumer buying decisions. This is the third survey that ASOP Global Foundation has undertaken in the past four years, allowing ASOP to track year-over-year changes in Americans' exposure to online pharmacies and the factors that influence their decision to buy their medications online.

- More Americans are buying prescription medication online than ever. Most are new to online pharmacies within the last 3 years and have become regular customers who use them to meet the majority of their medication needs.
    - 52% of Americans aged 18 and older have previously used an online pharmacy - a 10-percentage-point increase compared to 2021 and a 17-percentage-point increase compared to 2020.
    - 71% of Americans report they first started using online pharmacies in the past 1-3 years.
    - 85% of Americans with online pharmacy experience are currently using an online pharmacy to fill one or more medications.
    - 61% of Americans with online pharmacy experience report using them to purchase most or all their prescription medications.

- Recent nationwide drug shortages and changes in access are two key factors likely to fuel a continued rise in online medication purchasers.
    - 66% of Americans say they would likely purchase medication unavailable at their local brick-and-mortar pharmacy if they found it online. 49% of those *without* prior online pharmacy experience say they would be likely to purchase a medication online if unavailable at their local pharmacy, indicating access could be a strong motivator for those who haven't yet purchased medications online.
    - 59% of Americans say they would be comfortable ordering controlled substances from an online pharmacy if unavailable at their local pharmacy.
    - 47% of Americans with online pharmacy experience would be open to purchasing prescription medicines from an online source not approved by a U.S. regulator if it *gave access to medicines they couldn't otherwise access*.

- Driven by cost and convenience, Americans are willing to take what they believe are calculated risks.
    - Convenience (59%) and cost-savings (55%) remain the most frequently cited reasons Americans have or would use online pharmacies – and both trump safety concerns.
        - 60% of Americans with online pharmacy experience would be open to purchasing prescription medicines from an online source not approved by a U.S. regulator if it made ordering medicines *more convenient*.
        - 55% of Americans with online pharmacy experience would be open to purchasing prescription medicines from an online source not approved by a U.S. regulator if it *offered more cost savings*.

- This is particularly alarming because even as harms resulting from medication bought online are increasing among those who report using online pharmacies, most Americans are unaware of these risks, and their awareness is decreasing.
    - 24% of Americans with prior experience using online pharmacies report having previously been exposed to harmful, counterfeit, or substandard medication received from an online pharmacy, a 7-percentage-point increase from 2021.
    - Yet, even as more consumers are buying prescriptions online, fewer (44%) Americans describe taking medication purchased online as risky, a 10-percentage-point decrease from 2021.

- Americans who purchase their medications online often make dangerous, false assumptions about the safety, oversight, and compliance of online pharmacies.
    - 44% of Americans falsely believe that online pharmacies do not need a prescription from a healthcare provider to dispense the medication for certain prescription medicines. This number jumps to (53%) among those who have previously purchased prescription medicines online.
    - 54% of Americans – up from 45% in 2021 – falsely believe all websites offering healthcare services/prescription medications to Americans via the Internet have been approved by the FDA or state regulators. This misperception is even higher (68%) among those who have previously purchased prescription medicines online, up from 59% in 2021.
    - 47% of Americans falsely believe that only safe, verified websites selling prescription medications appear on the first page of search engine results. Again, this misconception is higher (61%) among those who have previously purchased prescription medicines online.

- When it comes to Controlled Substances, Americans are comfortable establishing a relationship with a healthcare provider solely through telehealth appointments but many Americans believe there should be some limitations on the circumstances in which healthcare providers can prescribe controlled substances virtually.
    - 69% of Americans are comfortable being prescribed a controlled substance by a healthcare provider whom they meet exclusively through telehealth appointments.
    - 34% of Americans support telehealth prescribing of controlled substances after a patient-provider relationship has been established and 20% of Americans would support telehealth prescribing but not of all controlled substances.

## INTRODUCTION

In the past three years, the U.S. healthcare landscape has rapidly and dramatically changed. In this short time period, Americans have not only lived through the first pandemic in over a century (COVID-19), they've also observed the creation of novel vaccines and antiviral medications in record time, the swift adoption of telehealth platforms by most healthcare providers, and the temporary loosening of federal laws mandating what were previously tight controls over the remote prescribing of controlled substances. These events have fundamentally transformed Americans' perception of how and where they can safely source healthcare and medical products, in some ways to their benefit and in other ways to their detriment.

Initially forced to accept virtual healthcare providers and online medical product retailers out of necessity, Americans have since become more trusting of these new technologies, and many have become repeat customers, swayed by the convenience and cost-savings they provide. However, Americans' perception of risk has also been redefined by the pandemic. To find medications and other healthcare products in high demand, Americans had to become resourceful, often looking online for answers. And while some of the impacts of the COVID-19 pandemic have abated, the strain on the US pharmaceutical supply chain remains, creating what is now a devolving drug shortage crisis. As of 2Q 2023, the US had 209 active, ongoing drug shortages, the highest in over a decade.[1, 2] Among the drugs in shortage were essential medicines, including chemotherapy drugs and antibiotics, as well as transformative new therapies for obesity and diabetes.[1, 2, 3] Multiple reports have demonstrated the long-term impact just one medication shortage can have on patients. The average drug shortage impacts at least half a million consumers and lasts 1.5 years, with shortages of critical medicines often lasting longer.[2]

What few Americans also realize is that counterfeit and illegal drug sales are also on the rise, and the U.S. is far from immune. Incidents of pharmaceutical counterfeiting, illegal diversion, and theft across 141 countries increased by 50% from 2018 to 2022, and North America ranked highest for such incidents.[4, 5] While Americans benefit from a highly regulated system of drug distribution designed to prevent these medicines from entering the supply chain, online there is significantly less transparency and accountability, which means greater risk for the growing number of Americans who have recently turned to ordering their prescription medications online. And when medicines are inaccessible, patients may discontinue treatment, seek alternatives, or turn to grey market sources, including illegal online pharmacies, where they are more likely to be exposed to counterfeit, substandard, or unapproved products.

To better understand this rapidly changing landscape and the impact it has on the prevalence and patterns of online pharmacy usage, consumer awareness of associated risks, and other trends, the ASOP Global Foundation conducted a survey of 1,500 Americans. This is the third such survey that the Foundation has undertaken in the past four years, allowing ASOP to track year-over-year changes in Americans' exposure to online pharmacies and the factors that influence their decision to buy online. [6] [7]

---

[1] American Society of Health-System Pharmacists (ASHP). (2023). *Severity And Impact of Current Drug Shortages.* https://www.ashp.org/-/media/assets/drug-shortages/docs/ASHP-2023-Drug-Shortages-Survey-Report.pdf

[2] United States Senate Committee on Homeland Security and Governmental Affairs. (2023). *Short Supply: The Heath and National Security Risks of Drug Shortages*. https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf

[3] Blum, D. (2023, October 5). The Wegovy Shortage Drags On, Leaving Patients in Limbo. *The New York Times*. https://www.nytimes.com/2023/10/05/well/live/wegovy-shortage-ozempic-fda.html.

[4] Pharmaceutical Security Institute (PSI). (n.d.) *Incident Trends*. Retrieved November 29, 2023, from https://www.psi-inc.org/incident-trends

[5] Pharmaceutical Security Institute (PSI). (n.d.) *Geographical Distribution*. Retrieved November 29, 2023, from https://www.psi-inc.org/geographic-distribution

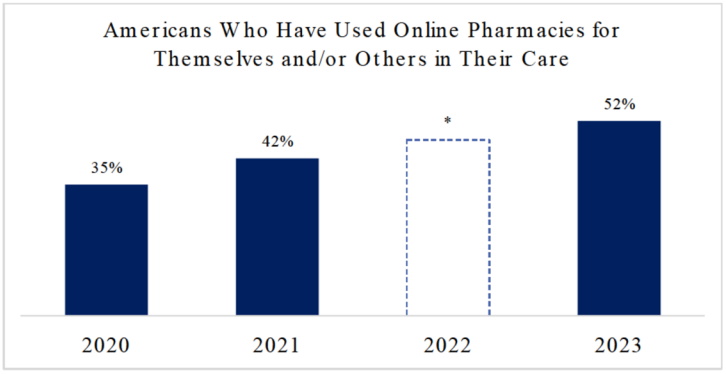
[6] Alliance for Safe Online Pharmacies Global Foundation (ASOP Global Foundation). (2021). *2021 Survey: American Perceptions and Use of Online Pharmacies*. ASOP-Global-Foundation-2021-Consumer-Behavior-Survey-Key-Findings_Final-7.9.2021.pdf (asopfoundation.pharmacy)

[7] Alliance for Safe Online Pharmacies Global Foundation (ASOP Global Foundation). (2020). *2020 National Survey On American Perceptions of Online Pharmacies*. Survey-Key-Findings_October-2020.pdf (asopfoundation.pharmacy)

## RESULTS

### HOW MANY AMERICANS USE PRESCRIPTION MEDICATIONS AND ONLINE PHARMACIES

- While prescription medication use in the US has remained relatively unchanged for the last three years, the number of Americans who are buying their medication online has risen quickly. For the first time in the history of this survey, the number of Americans with prior experience using an online pharmacy outnumber those without.
    - 68% of Americans 18 years old and above currently take prescription medications (a 6-percentage-point increase compared to 2021), with the average American taking 3.5 prescription medications daily.
    - As expected, the prevalence of prescription medication use and the number of prescription medications taken daily increases with age. Prescription medication use is also more prevalent among those with a higher level of education and those who report a higher household income. However, prescription medication use did not differ significantly based on gender, region, or community.
- This year, 52% of Americans aged 18 and older report having previously used an online pharmacy either for themselves and/or someone in their care, which is a 10-percentage-point increase compared to 2021 and a 17-percentage-point increase compared to 2020.
- Of those Americans actively using online pharmacies, 71% report they first started using online pharmacies in the last 1-3 years, suggesting that online pharmacies have seen a recent surge in popularity and most Americans who are currently using them are relatively inexperienced.




** No ASOP Foundation conducted in 2022..*

## WHO USES ONLINE PHARMACIES

- Consistent with 2021 survey results, online pharmacy use is not concentrated in just one group. Men and women of all ages, geographical locations, communities, education levels, and socioeconomic status have used online pharmacies.

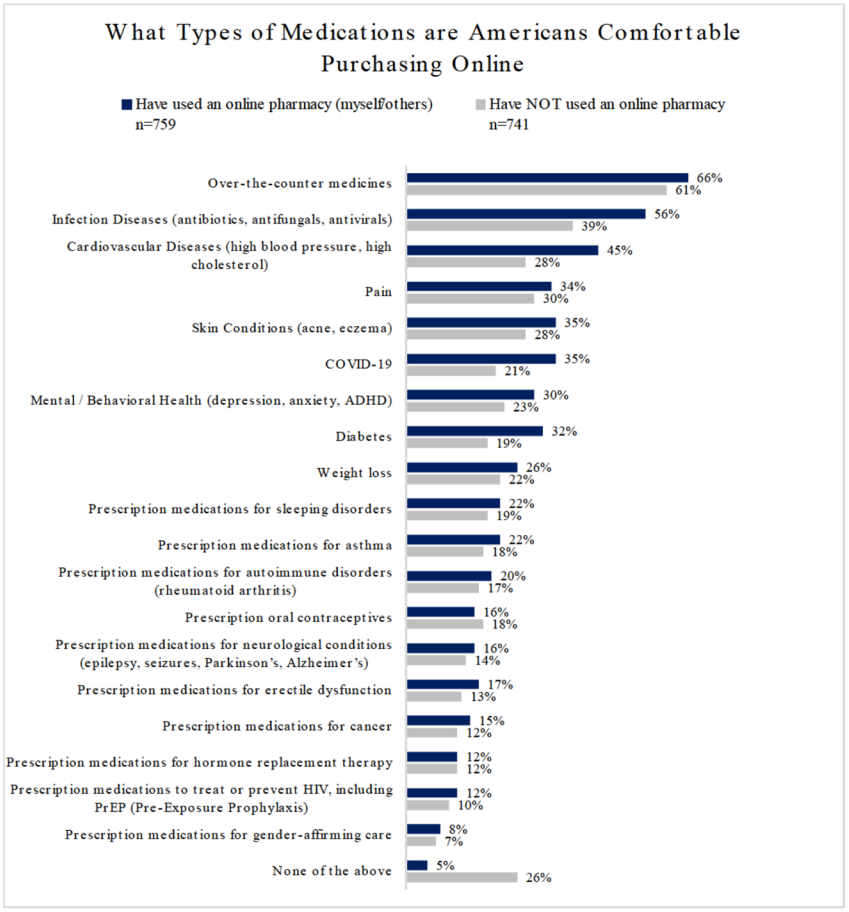
- Exposure to online pharmacies has also increased across all these groups.

## HOW DO AMERICANS FIND & USE ONLINE PHARMACIES

- **Americans use multiple resources (2.5 on average) to find their online pharmacy but most rely on healthcare providers, with pharmacists playing an increasingly important role.**
    - Consistent with 2021 survey results, healthcare providers remain one of the most popular resources for Americans to find their online pharmacies (36%).
    - However, this year, over half (53%) of online pharmacy users credited pharmacists with helping them find their online pharmacy.

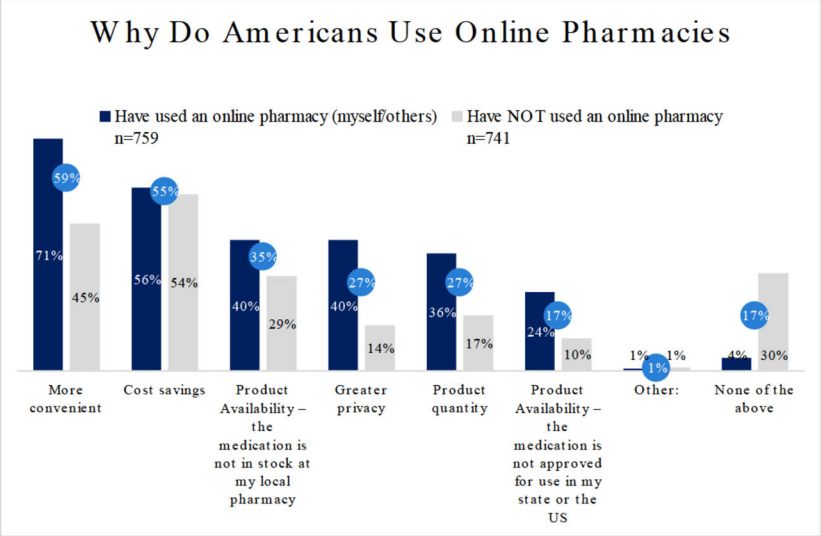
- **Once Americans use online pharmacies, most become regular customers and use them consistently.**
    - 85% of Americans with online pharmacy experience are currently using an online pharmacy to fill one or more medications.
    - 61% of Americans with online pharmacy experience report using them to purchase most or all of their prescription medications.

- **Most Americans who have prior experience with online pharmacies are comfortable using them to purchase multiple medications, including those that would need to be taken daily as well as those needed for acute conditions.**
    - When asked what types of prescription medications they would feel comfortable purchasing online, those with prior online pharmacy experience selected an average of 4.7 different types of medications.
    - Many express comfort using online pharmacies to fill medications they would need to take daily, such as medications for cardiovascular diseases, pain, mental and behavioral health, and diabetes, as well as medications to treat acute conditions, such as infectious diseases and COVID-19.


What Types of Medications are Americans Comfortable Purchasing Online
Have used an online pharmacy (myself/others) n=759
Have NOT used an online pharmacy n=741
Over-the-counter medicines 66% 61%
Infection Diseases (antibiotics, antifungals, antivirals) 56% 39%
Cardiovascular Diseases (high blood pressure, high cholesterol) 45% 28%
Pain 34% 30%
Skin Conditions (acne, eczema) 35% 28%
COVID-19 35% 21%
Mental / Behavioral Health (depression, anxiety, ADHD) 30% 23%
Diabetes 32% 19%
Weight loss 26% 22%
Prescription medications for sleeping disorders 22% 19%
Prescription medications for asthma 22% 18%
Prescription medications for autoimmune disorders (rheumatoid arthritis) 20% 17%
Prescription oral contraceptives 16% 18%
Prescription medications for neurological conditions (epilepsy, seizures, Parkinson's, Alzheimer's) 16% 14%
Prescription medications for erectile dysfunction 17% 13%
Prescription medications for cancer 15% 12%
Prescription medications for hormone replacement therapy 12% 12%
Prescription medications to treat or prevent HIV, including PrEP (Pre-Exposure Prophylaxis) 12% 10%
Prescription medications for gender-affirming care 8% 7%
None of the above 5% 26%

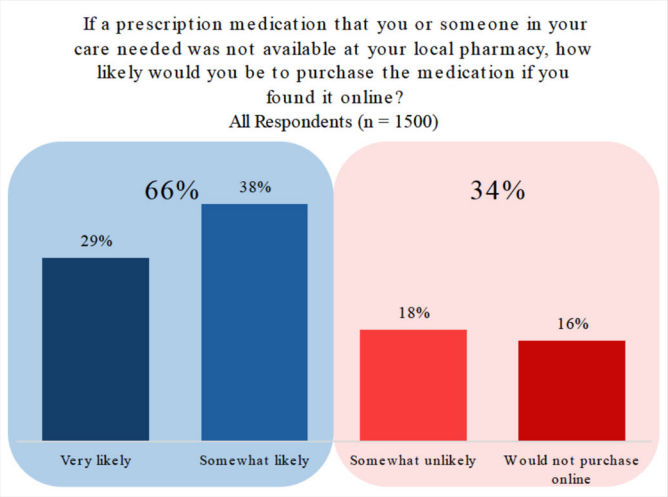
## WHY DO AMERICANS USE ONLINE PHARMACIES

- **Consistent with 2021 survey results, convenience (59%) and cost-savings (55%) remain the most frequently cited reasons Americans have or would use online pharmacies, but most Americans cite multiple reasons.**
    - Convenience is by far the most frequently cited reason (71%) those with prior online pharmacy experience have purchased medications online.
    - In contrast, cost-savings is the most frequently cited driver (54%) those who haven't yet used an online pharmacy would consider using one.




## MEDICATION SHORTAGES ALSO LIKELY TO MOTIVATE AMERICANS TO BUY ONLINE

- **While only a third of Americans count local shortages of their medication as a reason they have or would buy medication online, the vast majority of Americans would buy online if their medication were not available locally.**
    - 66% of Americans say they would be likely to purchase medication that was unavailable at their local pharmacy if they found it online.
    - Notably, 49% of those *without* prior online pharmacy experience reported they would be likely or very likely to purchase medication that was unavailable at their local pharmacy if they found it online.

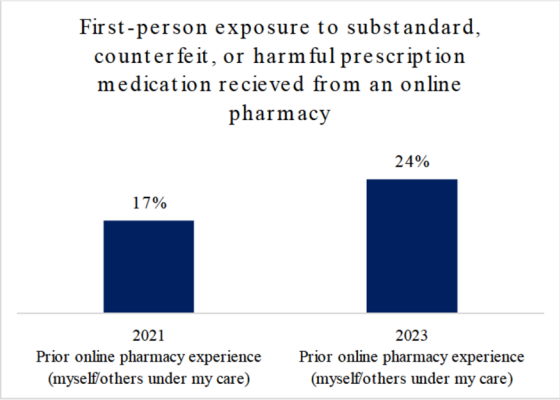



## AWARENESS OF AND EXPOSURE TO RISKS

- **Most Americans who use online pharmacies don't consider them very risky.**
    - Approximately half (53%) of Americans with online pharmacy experience describe the risk of using medications purchased online as not too risky or not risky at all. In comparison, 33% of Americans without prior online pharmacy experience describe using medications purchased online as not risky or not too risky.
    - When asked how much risk they would be willing to accept in exchange for the convenience and savings of purchasing online, 23% of those who have previously used online pharmacies said they would accept high to very high levels of risk.
- **Americans who use online pharmacies are open to taking certain risks in exchange for convenience, cost-savings, and access.**
    - 60% of Americans who have used online pharmacies would be open to purchasing prescription medicines from an online source not approved by U.S. regulators if it made ordering medicines more **convenient.**
    - 55% of Americans who have used online pharmacies would be open to purchasing prescription medicines from an online source not approved by U.S. regulators if it offered more **cost-savings.**

- 47% of Americans who have used online pharmacies would be open to purchasing prescription medicines from an online source not approved by U.S. regulators if it **gave access to medicines they couldn't otherwise access.**
- Americans who use online pharmacies may be willing to take these risks because the majority believe the most likely risk of using an online pharmacy is not receiving the medication on time (39%), compared to 31% who say it's likely their medication will be falsified.

- **This is concerning because while exposure to adverse events is *increasing* among those who purchase prescription medication online, awareness of and perception of these risks among the general U.S. population is *decreasing*.**
  - 24% of Americans with prior experience using online pharmacies report having previously been exposed to harmful, counterfeit, or substandard medication received from an online pharmacy, a 7-percentage-point increase from 2021.[†]
  - Despite this increase in first-hand exposure to harms, only 17% of respondents report hearing about adverse effects from drugs purchased online via the news media—relatively unchanged from 2021.
  - 44% of respondents describe taking medication purchased online as very or somewhat risky, a 10-percentage-point decrease from 2021.




[†] *2021 survey results were retroactively analyzed to determine the prevalence of self-reported exposure to substandard, counterfeit, or harmful medication received from an online pharmacy among those with online pharmacy experience.*

## WHAT DO AMERICANS KNOW ABOUT ONLINE PHARMACIES

- **The majority of Americans who use online pharmacies make dangerous assumptions about the general safety, oversight, and compliance of the prescription medicine sellers they encounter on the Internet.**
    - 54% of Americans falsely believe all websites offering healthcare services/prescription medications to Americans via the Internet have been approved by the FDA or state regulators. This misconception is even higher (68%) among those who have previously purchased prescription medicines online.
    - 47% of Americans falsely believe that only safe, verified websites selling prescription medications appear on the first page of search engine results. This misconception is even higher (61%) among those who have previously purchased prescription medicines online.
    - 44% of Americans falsely believe that for certain prescription medicines, online pharmacies do not need a prescription from a healthcare provider to dispense the medication. This misconception is even higher (53%) among those who have previously purchased prescription medicines online.

## WHAT AMERICANS WANT TO KNOW ABOUT THEIR ONLINE PHARMACY

- For the majority of Americans, it is important that online pharmacies dispense medicines approved for use in the U.S., are licensed to operate in at least one U.S. state, and are transparent about from where their medications ship. This is even more important among those who have previously used online pharmacies.
    - 86% of those who have used online pharmacies say it is important that the medicines they purchase are **approved for use in the U.S.** vs. 72% of those who have never used an online pharmacy
    - 83% of those who have used online pharmacies say it is important to them that their online pharmacy is **licensed in at least one U.S. State** vs. 72% of those who have never used an online pharmacy
    - 60% of those who have used online pharmacies say **knowing from where their medication ships** is important to them vs. 52% of those who have never used an online pharmacy

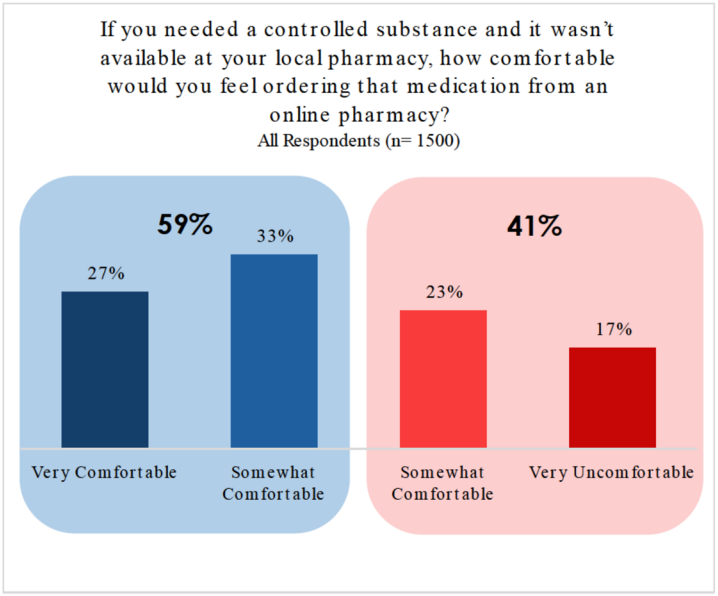
## AMERICANS' REACTIONS TO CHANGING CONTROLLED SUBSTANCE REGULATIONS

In light of recent shortages of several controlled substances and the anticipated introduction of new Drug Enforcement Agency (DEA) regulations concerning telehealth prescribing of controlled substances,[8, 9] survey respondents were asked several questions about their comfort receiving virtual services for controlled substance prescriptions as well as what restrictions, if any, should exist on healthcare providers operating virtually.

[8] United States Food and Drug Administration (FDA). (2023, August 1). *FDA Announces Shortage of Adderall*. https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-shortage-adderall

[9] United States Drug Enforcement Administration (DEA). (2023, October 6). *DEA and HHS Extend Telemedicine Flexibilities through 2024*. https://www.dea.gov/documents/2023/2023-10/2023-10-06/dea-and-hhs-extend-telemedicine-flexibilities-through-2024

- As expected, the vast majority of Americans support the continuation of the same flexibility allowed during the COVID-19 Public Health Emergency. However, approximately half of Americans support the introduction of some minimum requirements, such as establishing a provider-patient relationship first, and limitations to certain controlled substances.
    - 69% of Americans are comfortable being prescribed a controlled substance by a healthcare provider whom they meet exclusively through telehealth appointments.
    - 26% of Americans believe that a healthcare provider should be allowed to rely solely on telehealth appointments to prescribe any controlled substance (without any caveats). However, 34% of Americans support telehealth prescribing only after a patient-provider relationship has been established and 20% of Americans would support telehealth prescribing but not of all controlled substances.
    - Consistent with survey respondents' willingness to purchase their medications online when in shortage at their local pharmacy, the majority (59%) of Americans expressed comfort in ordering a controlled substance from an online pharmacy if unavailable at their local pharmacy.



## ABOUT ASOP GLOBAL

The Alliance for Safe Online Pharmacies (ASOP Global), a 501(c)(4) nonprofit organization headquartered in Washington, D.C. with activities in the U.S., Canada, Europe, Latin America, and Asia, is dedicated to protecting consumers around the world, ensuring safe access to medications, and combating illegal online drug sellers.

## SURVEY OBJECTIVE & METHODS

The ASOP Global Foundation conducted this survey to gain perspective into Americans' experience with and perceptions of online pharmacies. To allow for longitudinal analysis of trends, questions asked of respondents in similar surveys conducted in 2020 and 2021 were repeated in this survey.

Consistent with surveys conducted in 2020 and 2021, Abacus Data surveyed 1,500 American adults from September 7 to 10, 2023. A random sample of panelists was invited to complete the survey from a set of partner panels based on the Lucid exchange platform. These partners are typically double opt-in survey panels, blended to manage out potential skews in the data from a single source. The data was then weighted according to census data to ensure that the sample matched America's population. The margin of error for a comparable probability-based random sample of the same size is +/- 2.53%, 19 times out of 20.

Respondents were asked to answer questions based on the following definitions:

- **Prescription medication** – A medicine that can only be dispensed to those who have received a prescription from a licensed healthcare provider based on an in-person assessment, virtual assessment, or review of a patient questionnaire. This does NOT include medicines or supplements that can commonly be bought off-the-shelf in stores without prior consultation with a licensed healthcare provider.
- **Online pharmacy** – A website, app, or other electronic communication platform that sells prescription medications exclusively over the Internet and delivers them direct to consumers. Online pharmacies DO NOT include apps, websites, or other electronic communication platforms you may use to schedule the pickup or delivery of your prescription medications from a local brick-and-mortar pharmacy.
- **Controlled Substance** – Prescription medications that are classified as controlled substances by the Drug Enforcement Agency (DEA) because of their potential to cause physical and/or mental dependence that may lead to addiction. Common examples include medications for ADHD, opioid use disorder, or pain.
- **Telehealth Appointment** – A phone call or video visit with a licensed healthcare provider.

NABP
National Association of Boards of Pharmacy

# RogueRx Activity Report

*Injectable Weight Loss Drugs: How Illegal Online Drug Sellers Are Taking Advantage of Patients*

*No part of this publication may be reproduced in any manner without the written permission of the executive director/secretary of the National Association of Boards of Pharmacy.*

**©2024 by the National Association of Boards of Pharmacy. All rights reserved.**

NABP

## INTRODUCTION

Almost 75% of Americans are clinically defined as overweight or obese.[1] Therefore, it is unsurprising that glucagon-like peptide-1 receptor agonists (GLP-1 agonists) have gone viral. This class of drugs – which includes semaglutide, liraglutide, and tirzepatide – is well-known for its effectiveness in promoting weight loss. Some celebrities, including Elon Musk and Tracy Morgan, have admitted to using semaglutide for weight loss – and dozens of other suddenly-slender celebrities have vehemently denied its use. These drugs are so popular that Walmart has noted a correlated reduction in food purchases.[2] Meanwhile, weight-loss chain Jenny Craig filed for bankruptcy, and WeightWatchers acquired a telehealth platform that offers GLP-1 agonists.[3, 4]

GLP-1 agonists stimulate the receptor for the hormone glucagon-like peptide-1, which increases insulin production and satiety. Approved GLP-1 agonist medications are used to treat type 2 diabetes and obesity. Regarding the latter, semaglutide (under the brand name Wegovy®) was approved by Food and Drug Administration (FDA) in 2021 for chronic weight management in adults with obesity or overweight with at least one weight-related condition (such as high blood pressure, type 2 diabetes, or high cholesterol).[5] More recently, tirzepatide was approved by FDA (under the brand name Zepbound™) for chronic weight management in adults with obesity or overweight with at least one weight-related condition.[6] However, other GLP-1 agonists – including Ozempic®, Rybelsus®, Mounjaro®, and Saxenda® – are frequently used off-label for the same purpose. Most of these drugs are injectable, and they must be refrigerated prior to first use. Common side effects include nausea, vomiting, diarrhea, constipation, and abdominal pain. Currently, certain dosages of these FDA-approved drugs are on FDA's Drug Shortage List; this means that the total supply of the commercially available product cannot meet the current demand.[7]

Of course, bad actors are taking advantage of these drugs' popularity and shortage; their unlawful actions put patients at risk. In this report, NABP highlights the methods used by illegal actors to sell substandard or falsified GLP-1 agonists without holding required pharmacy licensure and without requiring a valid prescription. The Association also reports on the actions taken by government agencies around the world to prevent the illegal sale of these drugs and prosecute bad actors. Finally, NABP encourages third-party platforms to continue monitoring for these illegal products and recommends that pharmacists and patients report these illegal sellers to FDA's Office of Criminal Investigations (FDA-OCI), state boards of pharmacy, state attorneys general, and NABP.

## ILLEGAL ONLINE PHARMACIES CAPITALIZE ON GLP-1 AGONISTS' POPULARITY AND SHORT SUPPLY

Illegal online pharmacy operators have always been opportunists, from their heavy promotion of lifestyle drugs (eg, Viagra®, Cialis®, Propecia®) to their focus on hydroxychloroquine and ivermectin during the COVID-19 pandemic. As rational economic actors, these criminals are now actively selling GLP-1 agonists – without requiring a valid prescription and without the required pharmacy licenses – to vulnerable patients.

NABP

Illegal online drug sellers are focusing on GLP-1 agonists for many reasons. These drugs are extremely popular, expensive, and often not covered by insurance. This means that desperate patients will pay out of pocket and will be highly motivated to find cheaper options online. In addition, because several FDA-approved GLP-1 agonists are not readily available in the legitimate market, patients are more likely to explore options outside of their local retail pharmacy.

NABP has identified thousands of websites that promote the illegal sale of GLP-1 agonists. In some cases, these websites are connected to domain names that include GLP-1 agonist brand names, including Ozempic and Wegovy.[8] An example can be found below.

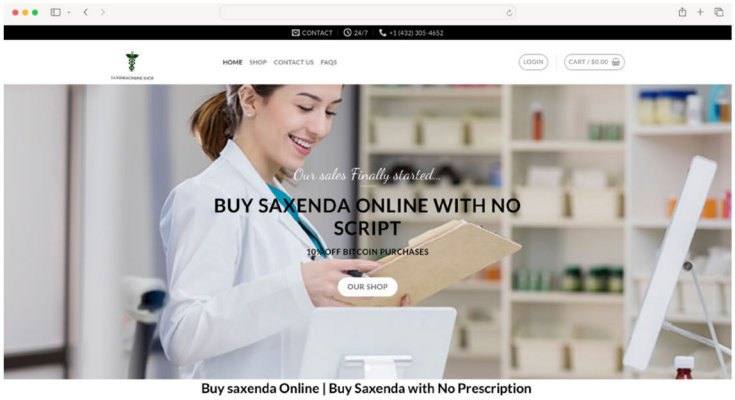



**FIGURE 1: Illegal online pharmacy offering Saxenda, a GLP-1 agonist, without requiring a prescription.**

NABP

Although some illegal online drug sellers, like the example in Figure 1, make it obvious that they are selling GLP-1 agonists without requiring a prescription (a clear indicator of illegality), others try to mimic legal sellers. One online seller has even copied the manufacturer's website for Wegovy. See below.

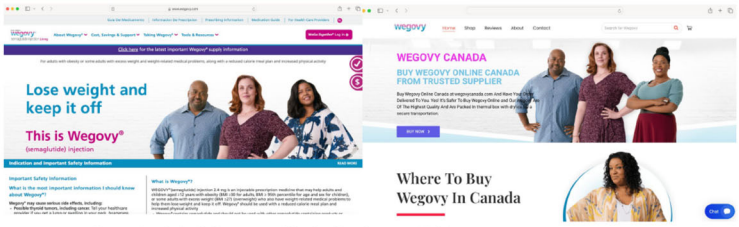



**FIGURE 2: Manufacturer's website (left) versus an illegal online pharmacy (right).**

As NABP has discussed in previous reports, many illegal online pharmacies belong to large, rogue online pharmacy networks. At this time, these large networks appear to be selling *only* oral semaglutide, marketed as Rybelsus; they do not sell the injectable versions, which require refrigeration prior to first use. For example, see Figure 3 below. However, many smaller networks and isolated actors *do* sell injectable GLP-1 agonists without requiring a prescription. That said, pharmaceutical manufacturers are actively developing new oral GLP-1s intended for weight loss, which experts predict will be cheaper to produce and will be better tolerated by patients; as such, NABP predicts that the large criminal networks will soon be promoting oral GLP-1s as actively as they currently promote erectile dysfunction drugs.[9]

**WHAT IS A ROGUE INTERNET PHARMACY NETWORK?**

Most illegal internet pharmacies belong to organized criminal networks, many of which have been the recipients of FDA warning letters. These networks are often complex, global operations that include hundreds – or even thousands – of related websites. The network operators create website templates and run back-end services (eg, payment processing and pharmaceutical shipping). They offer these templates and services to "affiliate marketers" who: (1) operate websites on behalf of the network; (2) drive traffic to those websites; and (3) take a small cut of the profits. Illegal pharmacy networks typically sell prescription-only drugs without requiring a prescription, sell unapproved drugs, and do not hold proper licensure in the jurisdictions where they offer shipping.

NABP

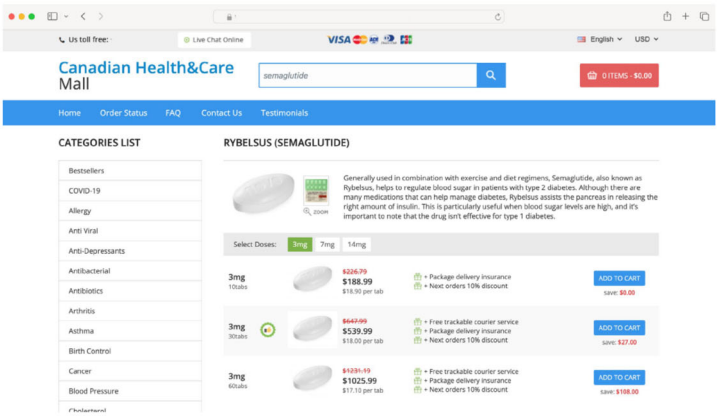



**FIGURE 3: Website belonging to a large rogue internet pharmacy network that sells oral semaglutide.**

Some illegal websites offer GLP-1 agonists as part of "non-delivery schemes."[10] A non-delivery scheme is a financial crime where a buyer pays for goods or services online, but never receives them. NABP has received reports directly from patients regarding this issue. For example, one patient reported that a website "took my money out from my bank account and no contact. Missing $640." Another stated, "[l]ong story short, via a series of text messages and naiveté on my part, they stole $700 from me."

## ILLICIT PEPTIDE DEALERS ADD GLP-1 AGONISTS TO THEIR PRODUCT CATALOGS

To avoid enforcement, some illegal online drug sellers advertise drug products as "peptides." Although these bad actors knowingly sell their products for consumer use, they claim that these products are for "research purposes only" and "not for human consumption." The "peptides" are typically delivered as lyophilized (freeze-dried) powder, and users are required to reconstitute the product with bacteriostatic water.

Illegal peptide sellers have been around long before Ozempic. They typically offer a limited product catalog of investigational new drugs, unapproved drugs, and prescription-only drugs that are popular among bodybuilders (eg, melanotan 2, CJC-1295, clomiphene). The United States Department of Justice, in collaboration with FDA-OCI, has prosecuted several of these illegal peptide sellers.[11]

NABP

In response to consumer demand, these bad actors have recently added GLP-1 agonists – including semaglutide and tirzepatide – to their product catalogs. Because they are claiming the products are for research purposes, they do not use brand names. Instead, NABP has seen peptide websites label their products with the following names: GLP-1 analogue, GLP-1, Tirz, and Sema GLP-1. One such example can be found below.

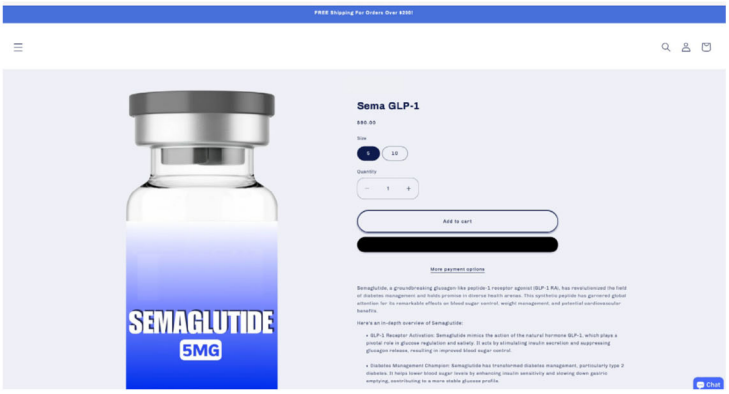



**FIGURE 4: "Sema GLP-1" is advertised on a peptide website.**

In an article focusing on peptide websites selling GLP-1 agonists, the *Wall Street Journal* identified more than 50 websites selling semaglutide and tirzepatide. Nearly all of them included disclaimers that the substances were "not for human consumption."[12] These sellers likely offer, at best, research-grade versions of these drugs, which do not eliminate impurities at the same level as pharmaceutical-grade versions.[13]

In recent months, illicit peptide websites have begun offering retatrutide, a GLP-1 agonist that is currently classified as an investigational new drug.[14] For example, in Figure 5 below, the seller notes, "[a]ll products purchased are for laboratory & research use ONLY, this means we cannot provide any further instructions on reconstitution and/or dosing."

NABP

According to George Karavetsos, former director of FDA-OCI, "[i]t's unprecedented to see a drug that is in late-stage clinical trials being so flagrantly advertised for sale online."[13]

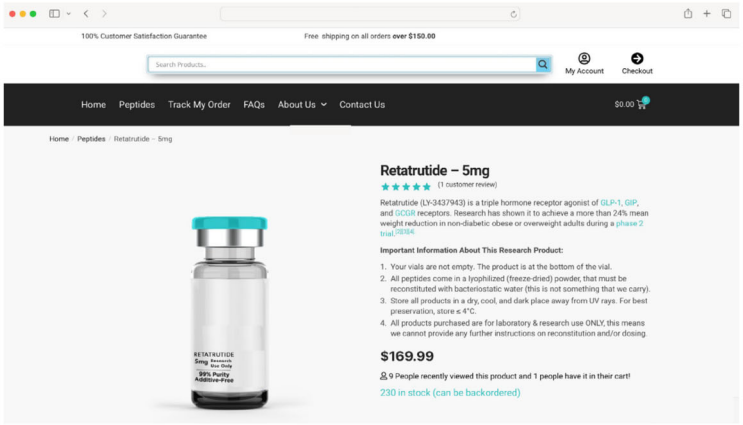



**FIGURE 5: A peptide website is marketing retatrutide, an investigational new drug.**

## CRIMINAL ACTORS TAKE ADVANTAGE OF ONLINE MARKETPLACES AND AD PLATFORMS

Illegal online drug sellers are also taking advantage of online marketplaces to sell substandard or falsified GLP-1 agonists.

In some cases, bad actors intentionally misspell or nickname the product to avoid detection by the platform's automated compliance tools. For example, on one platform, an illicit seller described tirzepatide as "Tirz" (see Figure 6). In another example, an illegal seller intentionally placed spaces between the letters in the words "semaglutide," "Ozempic," and "Wegovy" (see Figure 7). In a third example, the word "semaglutide" is misspelled (see Figure 8).

NABP

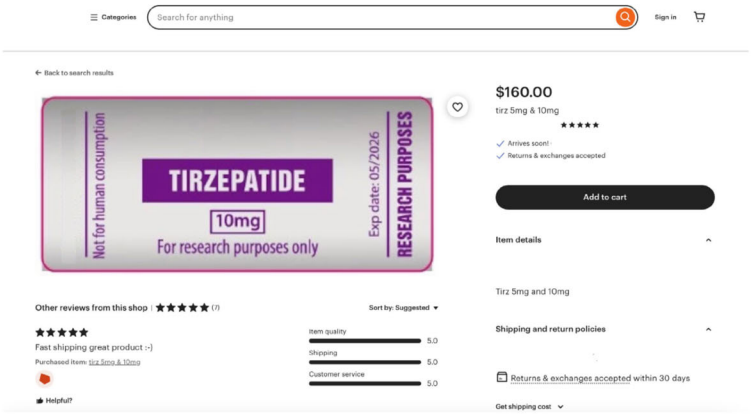



**FIGURE 6: Tirzepatide is marketed on an online marketplace as "Tirz."**

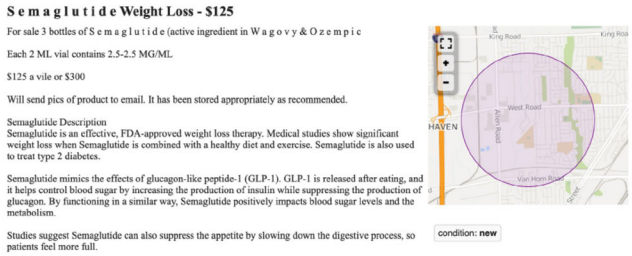



**FIGURE 7: Semaglutide is promoted for sale with spaces between the letters in the words "semaglutide," "Ozempic," and "Wegovy." Wegovy is also misspelled.**

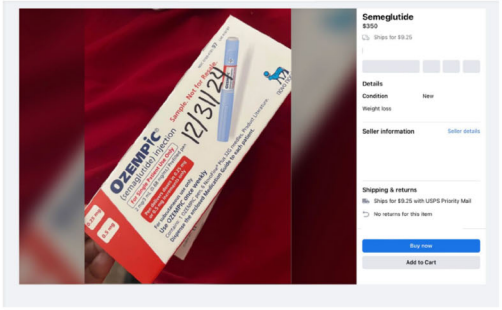



**FIGURE 8: Semaglutide is misspelled, possibly to avoid detection by automated compliance solutions.**

Illegal sellers have also advertised on major online ad platforms and social media.[15, 12, 13] Often, these sellers are peptide websites that are marketing GLP-1 agonists as research chemicals.

## GOVERNMENT AGENCIES IDENTIFY SUBSTANDARD AND FALSIFIED GLP-1 AGONISTS AND TAKE ACTION AGAINST ILLEGAL SELLERS

Medicine regulators around the world have identified substandard and falsified GLP-1 agonists in the supply chain. In the US, FDA has seized thousands of units of fake Ozempic.[16, 17] In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that, since January 2023, they had seized 369 potentially fake Ozempic pens. MHRA also stated that they had "received reports of fake Saxenda pens that have been obtained by members of the public in the UK through non-legitimate routes (any route that does not require a prescription from a qualified prescribing healthcare professional)."[18, 19] Germany's Federal Institute for Drugs and Medical Devices identified wholesale batches of counterfeit Ozempic 1 mg in German packaging.[20] Australia's Therapeutic Goods Administration also detected fake semaglutide being illegally imported into Australia.[21] Ireland's Health Products Regulatory Authority detained 254 units of products claiming to contain semaglutide between January and September 2023, compared to just 32 units in 2022.[22] According to the Partnership for Safe Medicines, substandard and falsified Ozempic has been found in at least 16 countries to date.[23]

These fake medicines have resulted in patient harm. For example, in October 2023, Austria's drug regulatory authority reported that several people suffered hypoglycemia and seizures after using what was suspected to be a falsified version of Ozempic.[24] "Due to the untested quality of the counterfeit drug, possible impurities and unknown ingredients, these counterfeits can also be life-threatening," the Austrian agency said. In Lebanon, 11 people suffered bouts of dangerously low blood sugar, one of whom required hospitalization, after injecting

NABP

suspected fake versions of Ozempic.[25] According to information gained from FDA's Adverse Event Reporting System, 42 people around the world were hospitalized after being injected with substandard or falsified semaglutide. Of the reports, 28 are classified as "serious" with outcomes that include death. Three of these hospitalizations happened in the US.[26]

Regulators are taking action to stop the unlawful sale of GLP-1 agonists. In addition to seizing fake Ozempic and alerting pharmacists and patients about fake lot numbers,[16] FDA is regularly issuing warning letters to peptide website operators and illegal online pharmacy operators who engage in the illicit sale of GLP-1 agonists.[27, 28, 29] Likewise, the European Medicines Agency is assisting European Union member states in their investigations of falsified versions of Ozempic.[30]

Meanwhile, Canada has taken a different approach. To ensure availability for Canadian patients and to protect the legitimate supply chain, the Canadian province of British Columbia passed legislation to restrict the shipment of semaglutide to US patients.[31] After enacting the regulation, the number of dispenses to US residents dropped by more than 99%.[32]

Regulators are also collaborating internationally to take down sellers of substandard and falsified GLP-1 agonists. According to Jim Mancuso, director of the US Department of Homeland Security's Intellectual Property Rights Coordination Center (IPR Center), "[t]hese weight loss drugs are a hot topic right now because they're on TV and getting a lot of media attention. If I'm a criminal organization, that's the next opportunity I go ahead and exploit." According to Reuters, the IPR Center is "working with Europol, INTERPOL, and around 23 other law enforcement agencies on tracking weight-loss drugs to quell what they believe could become the worst tide of counterfeit lifestyle medicines since erectile dysfunction drugs like Viagra."[33]

## CONCLUSION

In 2023, the American Association for the Advancement of Science declared that GLP-1 drugs were the "Breakthrough of the Year."[34] By all accounts, these medications are critical for public health. Unfortunately, illegal actors are taking advantage of high demand and short supply in order to sell substandard and falsified versions of these products to patients around the world.

To stop these bad actors, government agencies and private actors need to stay alert, take aggressive action, and, where possible, work together. NABP applauds the work of government agencies around the world that are actively investigating illegal sellers of substandard and falsified GLP-1 agonists. NABP also supports the efforts of online marketplaces and e-advertising platforms, whose leaders are working hard to remove illegal online drug sellers from their ecosystems. To protect the supply chain and promote public health, NABP strongly encourages pharmacists and patients report illegal sellers to FDA-OCI,[35] state boards of pharmacy,[36] state attorneys general,[37] and NABP.[38]

*For information about NABP's RogueRx Activity Report or the Association's research and reporting capabilities, please contact Senior Digital Health & Policy Expert Niamh Lewis at nlewis@nabp.pharmacy.*

NABP

## ENDNOTES


1 Center for Disease Control and Prevention. Obesity and Overweight. https://www.cdc.gov/nchs/fastats/obesity-overweight.htm. Published on Jan. 5, 2023. Accessed on March 19, 2024.

2 Bloomberg. Ozempic Is Making People Buy Less Food, Walmart Says. https://www.bloomberg.com/news/articles/2023-10-04/walmart-says-ozempic-weight-loss-drugs-causing-slight-pullback-by-shoppers. Published on Oct. 4, 2023. Accessed on March 9, 2024.

3 Salon. Why Jenny Craig couldn't last in the Ozempic Age. https://www.salon.com/2023/05/06/why-jenny-craig-couldnt-last-in-the-ozempic-age. Published on May 6, 2023. Accessed on March 9, 2024.

4 Fierce Healthcare. WeightWatchers buys Sequence to expand into remote prescribing of hot weight loss drugs. https://www.fiercehealthcare.com/digital-health/weightwatchers-acquisition-sequence-allows-expansion-remote-prescribing-hot-weight. Published on March 8, 2023. Accessed on March 9, 2024.

5 FDA. FDA Approves New Drug Treatment for Chronic Weight Management, First Since 2014. https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014. Published June 4, 2021. Accessed March 9, 2024.

6 FDA. FDA Approves New Medication for Chronic Weight Management. https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management. Published on Nov. 8, 2023. Accessed March 9, 2024.

7 FDA. FDA Drug Shortages. https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm. Accessed on March 9, 2024.

8 Eg, buyozempiconlinecanada.com. https://web.archive.org/web/20240309191930/https://buyozempiconlinecanada.com; ozempicchemist.com. https://web.archive.org/web/20240309184831/https://ozempicchemist.com.

9 The Economist. Expect a bumper year for weight-loss drugs. https://www.economist.com/the-world-ahead/2023/11/13/expect-a-bumper-year-for-weight-loss-drugs. Published on Nov. 13, 2023. Accessed on March 9, 2024.

10 Therapeutic Goods Administration (TGA). Consumers Warned About Ozempic Scams. https://www.tga.gov.au/news/media-releases/consumers-warned-about-ozempic-scams. Published on March 1, 2023. Accessed March 9, 2024.

11 See, eg, FDA. New Jersey Husband and Wife Admit Selling Misbranded and Unapproved New Drugs. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/new-jersey-husband-and-wife-admit-selling-misbranded-and-unapproved-new-drugs. Published on March 23, 2022. Accessed March 9, 2024; see also Department of Justice, Owner of Bodybuilding Drug Companies Sentenced for Selling Misbranded Drugs. https://www.justice.gov/usao-md/pr/owner-bodybuilding-drug-companies-sentenced-selling-misbranded-drugs. Published on May 9, 2016. Accessed March 9, 2024.

12 Wall Street Journal. How Dozens of Websites Sell Knock-Off Drugs, No Prescription Required. https://www.wsj.com/health/healthcare/ozempic-mounjaro-no-prescription-websites-726b3928. Published on Aug. 16, 2023. Accessed on March 9, 2024.

13 Wall Street Journal. This Drug Could Be the Next Ozempic. Bootlegs Are Already Selling Online. https://www.wsj.com/health/pharma/the-next-hot-obesity-drug-wont-be-approved-for-years-online-sellers-hawk-it-anyway-e04d7cc3. Published on Oct. 20, 2023. Accessed on March 9, 2024.

14 ClinicalTrials.gov. A Study of Retatrutide (LY3437943) in Participants Who Have Obesity or Overweight (TRIUMPH-1). https://www.clinicaltrials.gov/study/NCT05929066. Published July 3, 2023. Accessed on March 9, 2024.

15 Futurism. Google Seems to be Running a Lot of Ads for Black Market Semaglutide. https://futurism.com/neoscope/google-ads-semaglutide. Published on Aug. 24, 2023. Accessed on March 9, 2024.

16 FDA. FDA warns consumers not to use counterfeit Ozempic (semaglutide) found in U.S. drug supply chain. https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-use-counterfeit-ozempic-semaglutide-found-us-drug-supply-chain. Published on Dec. 21, 2023. Accessed on March 9, 2024.

17 Novo Nordisk. Novo Nordisk Warns of Counterfeit Ozempic® (Semaglutide Injection) Pen Found in US. https://www.novonordisk-us.com/media/news-archive/news-details.html?id=166119. Published on June 15, 2023. Accessed on March 9, 2024.

18 MHRA. Falsified Ozempic (semaglutide) pens identified at two wholesalers in the UK. https://www.gov.uk/government/news/falsified-ozempic-semaglutide-pens-identified-at-two-wholesalers-in-the-uk. Published on Oct. 18, 2023. Accessed on March 9, 2024.

19 MHRA. MHRA warns of unsafe fake weight loss pens. https://www.gov.uk/government/news/mhra-warns-of-unsafe-fake-weight-loss-pens. Published on Oct. 26, 2023. Accessed on March 9, 2024.

20 Federal Institute for Drugs and Medical Devices. BfArM takes over coordination in the case of counterfeiting of the diabetes drug Ozempic. https://www.bfarm.de/SharedDocs/Pressemitteilungen/DE/2023/pm05-2023.html?nn=468782. Published on Oct. 11, 2023. Accessed on March 9, 2024.

21 Therapeutic Goods Administration. Counterfeit semaglutide vials. https://www.tga.gov.au/news/safety-alerts/counterfeit-semaglutide-vials. Published May 25, 2023. Accessed March 9, 2024.

22 Health Products Regulatory Authority (HPRA). HPRA reports increase in detentions of Semaglutide products sold illegally online. https://www.hpra.ie/homepage/medicines/news-events/item?t=/hpra-reports-increase-in-detentions-of-semaglutide-products-sold-illegally-online&id=18091526-9782-6eee-9b55-ff00008c97d0. Published on October 25, 2023. Accessed on March 9, 2024.

23 Partnership for Safe Medicines. Counterfeit GLP-1 agonists: Injected Diabetes and Weight Loss Medicine. https://www.safemedicines.org/2023/06/fake-semaglutide.html. Published June 2023. Accessed March 9, 2024.

24 Federal Office for Safety in Health Care (BASG). Warning of counterfeit Ozempic® - Update 31.10.2023. https://www.basg.gv.at/en/market-surveillance/official-announcements/detail/update-zur-warnung-vor-gefaelschtem-arzneimittel-ozempicr-1. Published on Oct. 31, 2023. Accessed on March 9, 2024.

25 Reuters. Suspected fake Ozempic causes hypoglycemia in 11 in Lebanon. https://www.reuters.com/business/healthcare-pharmaceuticals/suspected-fake-ozempic-causes-hypoglycemia-11-lebanon-2023-11-28. Published on Nov. 28, 2023. Accessed on March 9, 2024.

26 CBS News. FDA investigating reports of hospitalizations after fake Ozempic. https://www.cbsnews.com/news/fda-ozempic-counterfeit-weight-loss-drugs-hospitalizations. Published on Nov. 7, 2023. Accessed on March 9, 2024.

27 FDA. Warning Letter to Synthetix Inc. DBA Helix Chemical Supply. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/synthetix-inc-dba-helix-chemical-supply-668918-02072024. Published on Feb. 7, 2024. Accessed on March 9, 2024.

28 FDA. Warning Letter to www.gorillahealing.com. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/wwwgorillahealingcom-664245-10022023. Published on Oct. 2, 2023. Accessed on March 9, 2024.

29 FDA. Warning Letter to US Chem Labs. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/us-chem-labs-669074-02072024. Published on Feb. 7, 2024. Accessed on March 9, 2024.

30 European Medicines Agency. EMA alerts EU patients and healthcare professionals to reports of falsified Ozempic pens. https://www.ema.europa.eu/en/news/ema-alerts-eu-patients-healthcare-professionals-reports-falsified-ozempic-pens. Published on Oct. 18, 2023. Accessed on March 9, 2024.

31 British Columbia Government News. Province takes action to protect supply of diabetes drug in B.C. https://news.gov.bc.ca/releases/2023HLTH0046-000554. Published on April 19, 2023. Accessed on March 9, 2024.

32 British Columbia Government News. Regulation protects supply of diabetes drug in B.C. https://news.gov.bc.ca/releases/2023HLTH0085-000957. Published on June 16, 2023. Accessed on March 9, 2024.

33 Reuters. Demand for weight-loss drugs fuels global rise in counterfeits. https://www.reuters.com/business/healthcare-pharmaceuticals/demand-weight-loss-drugs-fuels-global-rise-counterfeits-2023-10-20. Published on Oct. 10, 2023. Accessed on March 9, 2024.

34 Science. 2023 Breakthrough of the Year. https://www.science.org/content/article/breakthrough-of-the-year-2023. Published on Dec. 14, 2023. Accessed on March 9, 2024.

35 FDA Office of Criminal Investigations. Field Office Contact Information. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/criminal-investigations/field-office-contact-information

36 NABP. Boards of Pharmacy. https://nabp.pharmacy/about/boards-of-pharmacy

37 National Association of Attorneys General. Find my AG. https://www.naag.org/find-my-ag

38 NABP. Report a Suspicious Internet Pharmacy Site. https://nabp.pharmacy/forms/report-a-site.

PREMIER

**Statement for the Record**

**Submitted by Premier Inc.**

***"Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain"***

**Committee on Energy and Commerce Subcommittee on Health**

**June 11, 2025**

Premier Inc. commends the Committee on Energy and Commerce Subcommittee on Health for its bipartisan leadership and ongoing commitment to supporting a resilient healthcare supply chain, including opportunities to strengthen domestic manufacturing of critical medical supplies. Securing our nation's healthcare supply chain has been a long-standing priority for Premier from both a policy perspective and market-based approach. As the Subcommittee considers policy reforms to address critical healthcare supply chain issues, Premier urges the Subcommittee to consider:

- Leveraging tax credits as a mechanism to incentivize manufacturers to invest in domestic production while also ensuring that domestically manufactured goods are price competitive with globally sourced products.
- Taking action to strengthen domestic manufacturing of essential medicines by:
  - Requiring federal agencies to purchase domestically manufactured medical supplies when available;
  - Providing CMS with statutory authority to implement payment adjustments for domestically manufactured critical medical supplies and pharmaceuticals in a non-budget neutral manner; and
  - Adapting the Food and Drug Administration (FDA) regulatory framework for approval to expedite review of applications and inspections of manufacturing facilities for new domestic entrants.
- Passing the bipartisan and bicameral Medical Supply Chain Resiliency Act (S. 998/H.R. 2213) to establish trade agreements with trusted trade partner countries to diversify sourcing for critical medical devices and pharmaceuticals, protect public health and bolster national security.

Given the witness panel, our policy recommendations focus primarily on creating resiliency in the pharmaceutical supply chain but are equally applicable to all critical healthcare supplies. Our recommendations are described in greater detail below.

## I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,350 hospitals and approximately 325,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost.

Premier has continued to bring resiliency to the market by incenting the domestic manufacture of essential generic medications through investments in VGYAAN (Skillman, NJ) and Exela Pharma Sciences (Lenoir, NC), which combined are working to bring new, domestic sources of 20 different essential generic medications to market, with more anticipated. Premier will continue to innovate and collaborate across diverse stakeholders to address pharmaceutical supply chain resiliency and increase domestic manufacturing.

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way healthcare is delivered nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

## II. THE FRAGILITY OF THE PHARMACEUTICAL SUPPLY CHAIN IMPACTS PATIENT CARE

Premier believes that true supply chain resiliency requires a holistic approach as part of a larger strategy to address the challenges in healthcare – particularly access to products during a shortage, natural disaster, public health crisis or national security threat.

A 2024 Premier survey of healthcare providers found that 67 percent spent 10+ hours per week mitigating supply chain challenges and shortages, while nearly 40 percent were forced to cancel or reschedule cases at least quarterly due to shortages of standard and critical healthcare products.

Despite the foregoing efforts by Premier and others to diversify the pharmaceutical supply chain, there are many essential medicines that continue to be overly reliant on a single supplier, country, or region for manufacturing, leading to potential shortages and disruptions to patient care. It is important to note the following:

- All medications are not created equal. While all medications provide a level of clinical benefit to patients, few are considered to be essential such that an inability to access such medications would result in catastrophic outcomes for Americans and threaten our national security. From this perspective, Premier urges the Subcommittee to focus its initial efforts to bolster pharmaceutical supply chain resiliency on the medications identified in:
    - The FDA List of Essential Medicines, Medical Countermeasures, and Critical Inputs as required by Executive Order 13944; and
    - The Department of Defense (DOD) List of Essential Medicines, Medical Countermeasures, and Critical Inputs as required by Executive Order 13944.

  Most medications deemed essential by the FDA and DOD are generic medications that are often prone to drug shortages due to many reasons, including manufacturing and quality problems, delays, and discontinuations. Therefore, the pharmaceutical supply chain for essential medicines is vulnerable and requires additional investment to create true resiliency.

- The manufacturing of pharmaceuticals is a highly regulated and complex process that takes significant financial investment and time. On average, a new U.S.-based manufacturing facility takes five years to come online and retooling of an existing domestic manufacturing facility takes at least 18 months. Therefore, the repatriation of the pharmaceutical supply chain cannot occur overnight, and any policies must account for the length of time necessary to ramp up domestic production of these essential medications.

- In addition to the medication itself, it is important to note that the availability of a medication is also dependent on the availability of the delivery mechanism associated with that medication – such as needles, syringes, glass vials, rubber stoppers, metal crimps, IV fluid bags, etc. Therefore, policies to spur domestic manufacturing of medications must also account for policies to spur the domestic production of the delivery mechanisms associated with medications. For example, making a medication domestically does not produce the intended results if the availability of that drug for patient use is contingent upon the ability to procure a syringe that is manufactured overseas.

- It is not feasible to manufacture all essential medicines on U.S. soil and have a true end-to-end domestic supply chain as many raw materials are not available in the U.S. While Premier recognizes a need to incentivize domestic manufacturing, we also recognize a need to ensure global diversity in manufacturing. For example, moving all manufacturing onshore would create a similar overreliance on a single geographical region. Therefore, Premier recommends that there be at least three global suppliers of the final form, ancillary products and raw materials for critical medical supplies and drugs. Global suppliers should be from geographically diverse regions, including at least one domestic supplier.

Based on Premier's extensive data regarding the country of origin for drugs and their corresponding active pharmaceutical ingredients (APIs), below are several case studies to highlight challenges with critical medications, ingredients, and geographic footprints.[1] Premier urges the Subcommittee to further study the current manufacturing landscape of all essential medicines when weighing the establishment of targeted and thoughtful policies to spur domestic manufacturing.

- Case Study #1a – Essential Medicines with Sufficient Domestic Manufacturing Footprint for Both API and Finished Dose: Sodium Bicarbonate

  Sodium bicarbonate injection is most commonly used for urgent treatment of cardiac emergencies, such as cardiac arrest, heart attacks, strokes and other life-threatening emergencies. The medication is also used to treat excessive acid or potassium in the blood stream, metabolic acidosis, hyperkalemia, dehydration and certain drug overdoses.

  Sodium bicarbonate has been on and off the FDA drug shortage list since 2017 when supply constraints were so dire that the FDA permitted the import of Australian product which was priced 300 percent higher than U.S.-approved products. To help create a consistent and reliable supply for this essential medication, Premier invested in and worked with U.S.-based manufacturer Exela Pharma Sciences to bring a new domestic source of sodium bicarbonate – both the API and finished dose - to market. Premier's investment helped enable the total domestic manufacturing of sodium bicarbonate to now account for over 97 percent of U.S. patient utilization.

  However, it is important to note that while sodium bicarbonate is predominantly manufactured in the U.S., the product remains at risk of shortage. ***This is a key example to demonstrate that domestic manufacturing alone does not equate to product availability and more investments from public and private partners are necessary to create quality, resilient and sustainable domestic manufacturing sources for essential medicines in quantities that can meet our nation's needs***.

- Case Study #1b - – Essential Medicines with Sufficient Domestic Manufacturing Footprint for Both API and Finished Dose: Intravenous (IV) Fluids

  IV fluids are essential medications used to rehydrate the body, provide essential electrolytes and mixed with other medications to assist in their delivery. IV fluids have been on and off the FDA drug shortage for many years.

  When Hurricane Helene hit Western North Carolina, it severely damaged a production facility solely responsible for 60 percent of IV fluid market share in the U.S. – a disruption which led to shortages for over 86 percent of providers and postponed medical procedures nationwide. While other manufacturers were willing to help increase production to ease the burden of the shortage on the healthcare industry, one rate limiting step was the availability of IV fluid bags. This serves as an example where not only is additional resilience and redundancy needed for products that already

[1] The information provided is based on data that Premier has access to and may not be exhaustive of all available supply options. This information is provided for illustrative purposes only.

have a significant domestic manufacturing footprint, but the delivery mechanism associated with the medication also needs sufficient resiliency and redundancy.

- Case Study #2 – Essential Medicines with Sufficient Domestic Manufacturing Footprint for Finished Dose and API but Not for Key Starting Materials: Fentanyl Citrate

  Fentanyl citrate is an essential medication used for its analgesic and anesthetic properties, particularly in connection with surgery. Fentanyl has been on and off the FDA drug shortage list since 2012.

  While there are several domestic manufacturers of the finished dose and API, the key starting materials necessary for the manufacture of fentanyl API are derived overseas. Specifically, poppy seeds are primarily grown in Afghanistan and Australia which are then transported primarily to China for processing. This creates an upstream overreliance on, and production bottleneck by, foreign countries. In this scenario, addressing resiliency associated with fentanyl will require investments to move key starting material processing to the U.S. as well as agricultural investments to grow poppy seeds in the U.S.

- Case Study #3a – Essential Medicines with Insufficient Domestic Manufacturing Footprint for Finished Dose and API: Cephalosporin Antibiotics

  Cephalosporin antibiotics refers to a class of medications that are used to treat a wide variety of bacterial infections, including pneumonia, skin infections, urinary tract infections and ear infections. Cephalosporin antibiotics have been on and off the FDA drug shortage list since 2015.

  Cephalosporin antibiotics have no known domestic manufacturers of the finished dose. In addition, there are two predominant API manufacturers for these products located in Italy and China. Although Italy is traditionally considered a U.S. ally, it imposed export embargoes on key medical supplies during the COVID-19 pandemic, affecting the availability of essential products in the U.S. This example demonstrates that overreliance on foreign countries for our essential medicines extends beyond China.

- Case Study #3b – Essential Medicines with Insufficient Domestic Manufacturing Footprint for Finished Dose and API: Heparin

  Heparin is an anticoagulant that prevents the formation of blood clots that can ultimately lead to venous and arterial thromboembolic events if not properly treated. It is also used to treat pediatric patients with leukemia. The drug has been on and off the FDA drug shortage list since 2017.

  Heparin has historically experienced supply volatility due to difficulties associated with obtaining the raw materials necessary to make it, which are derived from pig intestines. Currently, the two major porcine cell lines for heparin are located in China and Spain and there is little U.S.-based source of raw materials available. In addition, over 75 percent of finished dose heparin is manufactured outside of the U.S.

  In 2020, Premier partnered with Fresenius Kabi to help diversify sourcing of heparin API out of China. More recently, Premier has partnered with Sagent Pharmaceuticals to further diversify sourcing of heparin out of China. In addition, there is a domestic manufacturer of heparin; however, their current manufacturing capacity is unable to meet U.S. patient demand absent additional private and public sector investments.

  Heparin serves as an example where investments must be made to move more finished dose and API manufacturing to the U.S. as well as agricultural investments to create a domestic source of the necessary raw materials from porcine intestines.

These examples show some of the challenges manufacturers and providers experience in the pharmaceutical supply chain and the need to look at medications individually when formulating policies. The U.S. needs a balanced policy to ensure a resilient, globally diverse supply chain.

## III. TAX INCENTIVES ARE REQUIRED TO STRENGTHEN DOMESTIC MANUFACTURING OF ESSENTIAL MEDICINES

To reduce the dependence on overseas manufacturing and drive domestic manufacturing, there are five major barriers that policy proposals must address. These barriers include: 1) capacity; 2) environmental regulations; 3) labor costs; 4) availability of raw materials; and 5) historical policy decisions that advantaged offshoring.

The roadmap to resilience requires multi-sourcing critical inputs, geographically diversifying supply chains, investing in domestic manufacturing, and fully utilizing advanced forecasting technologies. The private sector has already taken steps towards these, but Congress and the White House hold the dual tax and trade policy levers that can rapidly modernize America's healthcare supply chain resiliency. The President outlined important policies in a recent executive order titled "Regulatory Relief to Promote Domestic Production of Critical Medicines" which directed FDA, Environmental Protection Agency (EPA), and others to streamline various methods to speed review for domestically manufactured medications. While this is a positive step forward, it alone is not enough to spur domestic manufacturing and more must be done to create the necessary incentives.

***To stimulate domestic manufacturing, Premier has thought critically about how to incentivize manufacturers to invest in domestic production while also ensuring that domestically manufactured goods are price competitive with globally sourced products. To that end, Premier recommends a two-part approach that leverages tax credits as a mechanism for achieving these goals.***

**Part I:**

- A 30 percent tax incentive for investments to support the domestic manufacturing of critical medical supplies and drugs, including their raw materials. Examples of how the tax incentive could be applied include, but are not limited to:
  - Investments in advanced manufacturing equipment or machinery
  - Investments to upgrade facilities to meet EPA requirements
- The tax incentive should be reevaluated in five years to determine its ongoing necessity and whether the incentive level can be lowered or eliminated.

**Part II:**

- A 10 percent tax credit on the income generated from the sale of domestically manufactured goods to reward manufacturers who have already invested in domestic manufacturing. This would also help lower the cost of goods manufactured domestically and make them price competitive with globally sourced products.
- To be prudent, companies found to be price gouging or selling counterfeit products by the Department of Justice, Federal Trade Commission, or other agency should not be eligible for the tax credit. Guardrails would help ensure companies aren't artificially increasing their prices to take advantage of the tax credit from higher sales prices and support the integrity of the supply chain.

Tax incentives should be limited to products on the FDA and DoD lists of Essential Medicines, Medical Countermeasures, and Critical Inputs, the FDA List of Critical Medical Devices, and the DoD Joint Deployment List. By applying these credits to a select subsection of the most critical for national security, Congress can help to bolster redundancies in the medical supply chain and insulate America from geopolitical supply chain risk.

In addition, manufacturers should be eligible to receive the tax incentives regardless of where they choose to manufacture as long as it is on U.S. soil. This is important so that current U.S.-based manufacturers can take advantage of the credits to expand their existing production capacity without having to move their entire manufacturing production to an eligible zone. Another key factor that often necessitates the need to locate manufacturing in certain areas is the ability to recruit skilled labor which is essential for advanced and highly specialized manufacturing, such as for sterile injectables and large molecule biologics and biosimilars.

Finally, tax incentives legislation should ensure Congress is receiving frequent reports regarding the uptake and utilization of the credits and the downstream impact to creating a more resilient supply chain.

## IV. ADDITIONAL POLICY CHANGES ARE REQUIRED TO STRENGTHEN DOMESTIC MANUFACTURING OF ESSENTIAL MEDICINES

***To truly create a long-term domestic manufacturing infrastructure that is sustainable, tax incentives for onshoring manufacturing must be coupled with committed purchasing volumes so new entrants to the market have a guaranteed sales channel.*** To accomplish this goal while cultivating global diversity, Premier recommends that government purchasers be required to contract for critical medical supplies and pharmaceuticals from a mixture of onshore, near-shore (such as Central and South American countries) and offshore countries. Purchase thresholds based on a geographical region can help prioritize domestic manufacturers while ensuring global diversity and sustainability of the supply chain. In addition, longer-term contracts (at least three years in length) will help provide ongoing volume commitments and assurance for suppliers entering the marketplace.

While purchasing requirements for government agencies (e.g. Department of Defense, Department of Veterans Affairs, etc.) exist under The Buy American Act and Berry Amendment, there are many loopholes that permit these agencies to continue to buy globally sourced medical supplies and drugs even when a viable domestic option exists. We must hold agencies accountable for compliance with domestic purchasing of healthcare supplies to support a sustainable domestic manufacturing footprint. ***Premier recommends Congress study these policies and require that federal agencies purchase domestically manufactured medical supplies when available.***

Premier also recommends that Congress consider incentives for healthcare providers to purchase domestically manufactured critical medical supplies and drugs through programs such as differential reimbursement, CMS bonus payments, etc. to create committed purchasing volume for domestic suppliers and offset higher acquisition costs. For example, CMS instituted a Premier-supported payment adjustment to compensate hospitals for the increased cost of domestically produced N95 masks, however, absent Congressional action – the payment policy was implemented in a budget-neutral manner, impacting its ability to be applied broadly to additional domestically manufactured critical medical supplies. Therefore, ***Premier recommends that Congress provide CMS with statutory authority to implement payment adjustments for domestically manufactured critical medical supplies and pharmaceuticals in a non-budget neutral manner.***

Finally, ***to truly support domestic manufacturing, the FDA regulatory framework for approval must be adapted to expedite review of applications and inspections of manufacturing facilities for new domestic entrants.*** As manufacturers seek to invest in onshoring the manufacturing of critical medical supplies and pharmaceuticals, it is essential that our nation's regulatory framework support, and not inhibit or deter, repatriation. As such, Congress should consider policies that bolster the recent Presidential Executive Order and expedite FDA review for domestically manufactured critical medical supplies and pharmaceuticals such as prioritizing inspections and regulatory approvals for products manufactured domestically. Currently, no formal expedited pathway exists for domestically manufactured products, and they are reviewed in a first-in, first-out manner meaning that if a Chinese application was submitted first, it would be reviewed before a domestic application. Absent prioritization for domestic manufacturers, on

average a new U.S.-based manufacturing facility takes five years to come online and retooling of an existing domestic manufacturing facility takes at least 18 months.

## V. TRUE SUPPLY CHAIN RESILENCY REQUIRES TRUSTED TRADE PARTERS

True supply chain diversification requires a balanced approach of onshoring on U.S. soil, nearshoring with trusted trade partners and offshoring with a diverse global geographic footprint to achieve greater redundancy and minimize disruptions. A strong and sustainable healthcare supply chain is essential for quality patient care and requires a multifaceted strategy that bolsters domestic manufacturing while cultivating trusted trade partnerships. The bipartisan and bicameral Medical Supply Chain Resiliency Act (S. 998/H.R. 2213) would help address the vulnerabilities in the U.S. supply chain by enabling the establishment of trade agreements with trusted trade partner countries to diversify sourcing for critical medical devices and pharmaceuticals, protect public health and bolster national security.

More than 50 healthcare organizations support The Medical Supply Chain Resiliency Act as a comprehensive approach that will strengthen the healthcare supply chain and promote high-quality, lower cost care for patients.

***Premier urges Congress to act swiftly to pass the Medical Supply Chain Resiliency Act, securing uninterrupted access to essential healthcare supplies for providers and patients alike.***

## IV. CONCLUSION

Premier appreciates the opportunity to comment on the Subcommittee's work. A secure America needs reliable supply chains – with redundancies and fail safes to prevent bottlenecking and balance demand pressure. Solutions require focus across policy areas, government agencies, industries, and constant concentration to face evolving challenges.

If you have any questions regarding our comments, or if Premier can serve as a resource on these issues, please feel free to contact John Knapp, Vice President, Advocacy at john_knapp@premierinc.com, 240-839-0739.

June 11, 2025

The Honorable Buddy Carter
Chairman, Subcommittee on Health
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Neal Dunn
Vice Chairman, Subcommittee on Health
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Diana DeGette
Ranking Member, Subcommittee on Health
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

RE: Hearing – Made in America: Strengthening Domestic Manufacturing and the Health Care Supply Chain

Dear Chairman Carter, Vice Chairman Dunn, Ranking Member DeGette, and Members of the Subcommittee:

Thank you for holding the upcoming hearing, "Made in America: Strengthening Domestic Manufacturing and the Health Care Supply Chain." This discussion is both timely and vital to addressing one of the most pressing national security challenges we face today: the United States' overdependence on foreign—particularly Chinese—sources of active pharmaceutical ingredients (APIs) and finished pharmaceuticals, especially generics.

As noted in the Office of the Director of National Intelligence's March 2025 Annual Threat Assessment, the People's Republic of China (PRC) has established a dominant position in the global pharmaceutical and medical supply chains. This dominance is bolstered by lower regulatory standards for safety and environmental practices, creating vulnerabilities that extend beyond economics into the realms of national security and defense.[1]

The scale of this problem is immense. Approximately two-thirds of Americans—and the majority of U.S. military service members—rely on prescription medications, 90% of which are generic. The PRC's control over key nodes in the pharmaceutical supply chain,

---

[1] Office of the Director of National Intelligence. Annual Threat Assessment of the US Intelligence Community. March 2025. Accessed on June 6, 2025 at https://www.dni.gov/files/ODNI/documents/assessments/ATA-2025Unclassified-Report.pdf

alone or in collaboration with India,[2] gives it potential leverage in trade disputes or geopolitical crises. This leaves U.S. healthcare delivery and defense preparedness dangerously exposed.

It is clear that the current trajectory is untenable. A more deliberate, coordinated, and actionable policy framework is urgently needed. I respectfully submit the following recommendations for your consideration:

**Advance a Dual Strategy: Align Supply-Side Incentives with Demand-Side Reforms**

A sustainable solution requires pairing production incentives with structural market corrections:

Supply-Side Incentives

- Reduced tax rates and direct grants to lower the cost of domestic manufacturing.
- Low-interest loans to support infrastructure, technology, and facility upgrades.
- Regulatory modernization that maintains safety while improving operational efficiency.
- Strategic tariffs to offset market distortions caused by adversarial trade practices.

Demand-Side Interventions

- Increased reimbursement rates for American-made and allied-produced generics.
- Long-term purchasing commitments from both public and private payers.
- Reforms that address the pricing pressures, especially on generic drugs, created by large Group Purchasing Organizations (GPOs), large retail generic buying consortia, and Pharmacy Benefit Managers (PBMs).

**Support Bipartisan Legislative Solutions**

Several bills introduced in the 118th Congress align with this dual-incentive framework, including:

- Our Nation's Supply Chain for Healthcare has Over-Reliance Elsewhere (ONSHORE) Act
- Providing Incentives for Long-term Production of Lifesaving Supply of Medicines (PILLS) Act
- The Manufacturing of API, Drugs, and Excipients (MADE) in America Act

These proposals deserve prioritized consideration, particularly those that integrate procurement-driven demand signals into policy design.

In addition, I urge the Subcommittee to:

- Reintroduce the Rolling Active Pharmaceutical Ingredients and Drug (RAPID) Reserve Act

---

[2] Stephen Schondelmeyer, Stephen. 2024. "Witness Statement - Ways & Means Committee Hearing on Examining Chronic Drug Shortages in the United States." https://gop-waysandmeans.house.gov/wpcontent/uploads/2024/02/Schondelmeyer-Testimony.pdf.

- Advance companion legislation to the Further Strengthening America's Supply Chain and National Security Act

**Reform Healthcare Intermediaries**

To support the long-term success of domestic pharmaceutical manufacturing, it is essential that Congress also addresses the influence of market intermediaries. I encourage the Subcommittee to continue advancing legislative reforms targeting the practices of PBMs, large retail generic purchasing groups, and GPOs. Specifically, reforms should address harmful behaviors such as aggressive downward pricing pressures and reliance on short-term contracts—both of which undermine the viability and growth of U.S.-based manufacturing for generic drugs and APIs.

**Recognize the Strategic Timeline**

Restructuring global pharmaceutical supply chains will not happen overnight. A phased transition from China to domestic and allied production will realistically require four to five years. FDA review timelines, capital investments, and workforce development demand a long-term strategy that begins immediately.

In closing, I commend the Subcommittee for its leadership in addressing this critical issue. A secure and resilient pharmaceutical supply chain is not merely a matter of industrial competitiveness—it is a cornerstone of our national security. I urge you to move forward with bold, bipartisan action that strengthens domestic manufacturing, safeguards affordability, and protects the health and readiness of the American people.

Thank you for your attention to this vital matter.

Sincerely,

Brian Lehman

Brian Lehman, ALM, MHA, RPh

**American Medical Manufacturers Association**
*1405 S Fern St #91671 Arlington, VA 22202*
972-863-7878
info@medicalmanufacturers.org

The Honorable Buddy Carter, Chairman, Subcommittee on Health
The Honorable Diana DeGette, Ranking Member Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

**RE: For the Record - Subcommittee on Health Hearing: "Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain"**

Dear Chairman Carter and Ranking Member DeGette:

I write to commend the House Subcommittee on Health for its continued bipartisan leadership in addressing the critical vulnerabilities in America's personal protective equipment (PPE) and critical medical supplies supply chain and strengthening domestic manufacturing capabilities for these essential medical products.

**Commending the Subcommittee's Leadership**

The Subcommittee's focus on Made in America and the health care supply chain demonstrates essential oversight at a pivotal moment for American health security. Your examination of the complex healthcare supply chain network highlights the sophisticated understanding needed to address the unique challenges facing PPE and critical medical supplies production and distribution.

The Subcommittee's recognition that our healthcare supply chain must ensure PPE, critical medical supplies, and protective equipment "are delivered to patients and healthcare workers in a safe and efficient manner" reflects the comprehensive approach required to build resilience into this critical infrastructure.

**The Imperative for Domestic PPE and Critical Medical Supplies Manufacturing**

Domestic PPE and critical medical supplies manufacturing must be a national priority:

**Strategic Vulnerabilities:** The dangerous over-reliance on China and other foreign suppliers represents a critical national security vulnerability. When PPE and critical medical supplies supply chains are disrupted, Americans are left defenseless, especially those on the front lines, compromising our entire healthcare system's ability to function.

**Lessons from Global Disruptions:** Recent global events have exposed the fragility of extended, fragmented PPE and critical medical supplies supply chains. When disruptions occur, American healthcare workers are left without adequate protection and essential medical products, directly compromising patient care and public health response capabilities.

**Economic and Security Benefits:** Domestic PPE and critical medical supplies manufacturing creates high-skilled American jobs while simultaneously strengthening our national security posture. It reduces our vulnerability to supply disruptions and ensures we can meet critical needs during emergencies.

**American Medical Manufacturers Association**
*1405 S Fern St #91671 Arlington, VA 22202*
972-863-7878
info@medicalmanufacturers.org

**Supporting Congressional Action**

The Subcommittee's work aligns with and supports several critical legislative initiatives that deserve continued attention:

- **CMS Reimbursement Policies:** Supporting Medicare and Medicaid reimbursement structures that incentivize hospitals to purchase domestically manufactured PPE, critical medical supplies, and protective equipment
- **NIOSH and NPPTL Support:** Maintaining robust funding and operations for the National Institute for Occupational Safety and Health and its National Personal Protective Technology Laboratory to ensure rigorous safety standards and certification processes that protect American workers
- **Make PPE in America Act Implementation:** Ensuring robust oversight of federal agencies' compliance with domestic procurement mandates
- **Strategic National Stockpile Management:** Strengthening domestic sourcing requirements for emergency preparedness

**The Path Forward**

The Subcommittee's work is particularly vital as we consider how to compete effectively against heavily subsidized foreign producers while building a resilient manufacturing base that can respond to both routine needs and emergency situations.

**Conclusion**

The American people benefit immensely from the Subcommittee's diligent oversight and forward-thinking approach to healthcare supply chain security. By addressing these challenges proactively, you are helping to ensure that our nation will never again face critical shortages of basic protective equipment and essential medical supplies during times of crisis.

Thank you for your leadership in strengthening America's medical manufacturing base and protecting our healthcare workers and patients. The importance of this work cannot be overstated, and your continued bipartisan efforts provide hope for a more secure and resilient healthcare system.

I look forward to the Subcommittee's continued leadership on these vital issues affecting America's health security and industrial strength.

Respectfully submitted for the record,

Eric Axel

Executive Director

ASCO®
ASSOCIATION FOR CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

**ASSOCIATION CHAIR OF THE BOARD**
Lynn M. Schuchter, MD, FASCO

**ASSOCIATION TREASURER**
Mark A. Henderson, MD

**ASSOCIATION DIRECTORS**
Fredrick Chite Asirwa, MD, MBChB, FASCO
Carolyn B. Hendricks, MD, FASCO
Elizabeth A. Mittendorf, MD, PhD, MHCM, FASCO
Kathleen N. Moore, MD, MS, FASCO
Ann H. Partridge, MD, MPH, FASCO
Eric J. Small, MD, FASCO
Ashley Love Sumrall, MD, FACP, FASCO
Karen M. Winkfield, MD, PhD, FASCO
Robin T. Zon, MD, FACP, FASCO

**NON-VOTING DIRECTOR**
**Chief Executive Officer**
Clifford A. Hudis, MD, FACP, FASCO

**Lynn M. Schuchter, MD, FASCO**
**Chair of the Board**
**Association for Clinical Oncology**

**Statement prepared for:**
**U.S. House of Representatives**
**Committee on Energy and Commerce**
**Subcommittee on Health**

**Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain**

**June 11, 2025**

The Association for Clinical Oncology (ASCO) is pleased to submit this statement for the record for the hearing entitled, "Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain." ASCO appreciates the U.S. House of Representatives' Committee on Energy and Commerce Subcommittee on Health's focus on this critical issue.

ASCO is the world's leading professional organization representing over 50,000 oncologists and other oncology professionals who treat people with cancer. We are committed to advocating for policies that provide and increase patient access to high-quality cancer care and support a robust clinical trials system.

For more than a decade, the oncology community has experienced cancer drug shortages. These shortages are caused by a multitude of factors, including quality issues, manufacturers' business decisions, disruptions to supply of raw ingredients and excipient supplies, and natural disasters. Most oncology drugs in shortage are older generic sterile injectables, many of which do not have alternatives. Shortages impact both the pediatric and adult populations. The lack of predictability in the generic cancer drug supply chain can disrupt or delay treatment, potentially leading to irreversible disease progression. Both Congress and the Administration need to intervene to secure the pharmaceutical pipeline and address drug shortages.

ASCO believes a multi-faceted approach is necessary to tackle the oncology drug shortage crisis effectively and remains committed to working with policymakers, regulatory bodies, drug manufacturers and the health care community to identify solutions. The goal is to ensure long-term stability and patient access to lifesaving and life-prolonging oncology treatments.

ASCO
ASSOCIATION FOR CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

Securing the pharmaceutical supply chain is an important component of a comprehensive solution to mitigate existing and prevent future shortages of lifesaving and life-prolonging cancer drugs. ASCO supports the need to address economic factors that drive generic manufacturers out of the market and consider stabilizing the market with long-term contracts and guaranteed prices as well as reward reliable U.S. manufacturing of critical and supportive medications and raw materials through price stabilization and investment in continuous manufacturing or other advanced manufacturing for critical drugs and active pharmaceutical ingredients (APIs).

Recent and ongoing shortages in oncology drugs have made clear that while data signals exist that can help predict upstream pharmaceutical supply chain risk, they are not integrated in a way that provides actionable insights for preventing or mitigating drug shortages.[1] Although the Food and Drug Administration (FDA) possesses information about finished product manufacturers and APIs, it is not always aware of which API supplier(s) a manufacturer utilizes, or the quantities involved. Moreover, visibility into earlier stages of the supply chain, such as key starting materials (KSMs) and refined chemicals, is severely limited. This opacity extends to manufacturers' quality improvement initiatives and investments in production quality. Many chemotherapy drugs, especially generics, rely on global supply chains for both manufacturing and the production of APIs, which makes the supply chain unpredictable. Today, over 72% of APIs used in U.S. generic drugs are produced overseas, primarily in countries like China and India.[2]

These vulnerabilities demonstrate a clear need for information that can support early identification and mitigation of risks in the pharmaceutical supply chain. The *Mapping America's Pharmaceutical Supply Act or MAPS Act (S.1784)* would create a system to monitor and map the supply chain for APIs and finished dosages of vulnerable drugs, enabling allocation of resources to areas where they are most needed. Strengthening supply chain resiliency in this way would help prioritize medicines vulnerable to shortage and safeguard access to critical medications that cancer patients depend on for their treatment.

Although the MAPS Act would improve efforts to spot and mitigate risk, persistent disruptions in drug supply also have prompted consideration of on-or nearshore manufacturing. Shortages of important chemotherapy agents delay care or force switching to alternative therapies—if they are available. These actions may worsen toxicity or side effects, reduce effectiveness, or introduce unknown long-term consequences. Domestic production could mitigate some of these impacts and ASCO has supported this concept. While increased production closer to home should be considered, it should also be noted that production of chemotherapeutic agents present significant challenges for manufacturers, including resources and time needed to satisfy special requirements associated with manufacturing and handling of toxic substances.

ASCO supports a multi-layered approach to the ongoing drug shortage crisis. We support efforts to stabilize the pharmaceutical supply chain, including the adoption of advanced manufacturing technology and development of continuous manufacturing, or other advanced

[1] https://www.usp.org/sites/default/files/usp/document/drug-shortage-task-force/call-to-action-on-drug-shortages.pdf
[2] https://qualitymatters.usp.org/geographic-concentration-pharmaceutical-manufacturing

ASCO
ASSOCIATION FOR CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

manufacturing for critical drugs and APIs. We support policies that would encourage multiple suppliers for key drugs, geographic diversification of manufacturing, and component supply redundancies, which could help improve supply chain resiliency and incentivize domestic production.[3] Congress could use its authority to incentivize advanced manufacturing technology and develop new continuous manufacturing technology for critical drugs and APIs, including support for advanced manufacturing grant appropriations. The focus needs to be on advancing drug manufacturing quality and focus on outcomes that improve the overall resilience of our nation's medication supply chains.[4]

Congress should work on a comprehensive solution to securing our pharmaceutical supply chain, preventing future drug shortages. This includes: 1) passing MAPS Act, 2) increasing transparency across the supply chain through communication between manufacturers, regulators, and physicians; 3) facilitating adoption of advanced manufacturing technology and the development of continuous manufacturing for critical drugs and APIs and 4) use of financial and purchasing frameworks that incentivize value, supply chain quality, resilience, and reserves for drugs vulnerable to shortages.[5]

ASCO thanks you for holding this important hearing. We welcome the opportunity to engage with the House Committee on Energy and Commerce Subcommittee on Health in a meaningful dialogue about these issues as you develop bipartisan solutions to mitigate existing and prevent future drug shortages. Thank you for your commitment to increasing access to lifesaving and life-prolonging oncology medications. If you have any questions, please contact Jeremy Haines, Associate Director of Congressional Affairs, at Jeremy.Haines@asco.org.

[3] https://www.usp.org/sites/default/files/usp/document/drug-shortage-task-force/call-to-action-on-drug-shortages.pdf
[4] https://www.usp.org/sites/default/files/usp/document/drug-shortage-task-force/call-to-action-on-drug-shortages.pdf
[5] https://www.usp.org/sites/default/files/usp/document/drug-shortage-task-force/call-to-action-on-drug-shortages.pdf

**Statement for the Record, U.S. House Energy and Commerce Committee Health Subcommittee Hearing "Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain"**

The Alliance for mRNA Medicines (AMM)[1] commends the members of the Health Subcommittee of the House Energy and Commerce Committee for holding this hearing to examine current challenges and opportunities to bolster U.S. manufacturing and foster a resilient health care supply chain. mRNA has and will transform the lives of U.S. patients if the U.S. advances pro-mRNA policies, including those related to manufacturing. Below we present the case for why Congress and the Administration should robustly support mRNA product development as part of the strategy to strengthen domestic manufacturing:

- **As Evidenced by the Recent News on "Baby KJ", mRNA Will Save Lives and Improve the Health of Millions of Americans**
- **mRNA Manufacturing Offers Significant Benefits Over Current Technologies**
- **The U.S. Is Currently a Leader in mRNA Manufacturing**
- **However, Due to Recent State and Federal Government Actions, U.S. Leadership on mRNA Is Under Threat**
- **To Bolster this Innovative Area of Medicine, Congress Should Advance Pro-mRNA Manufacturing Policies in the United States to Help U.S. Patients and Create U.S. Jobs**

## I. As Evidenced by the Recent News on "Baby KJ", mRNA Will Save Lives and Improve the Health of Millions of Americans

mRNA is a revolutionary technology with therapeutic applications in serious and complex diseases, with high potential to save lives and improve the health of millions of Americans. It is already being tested in the clinic for patients with diseases that present significant challenges to living a healthy and enriching life. These are American patients who have no effective treatment options – diseases as diverse as pancreatic cancer and melanoma, cystic fibrosis, and cardiovascular, autoimmune, and neurological conditions. mRNA technology is also a critical—and proven—component of America's leadership position in biotechnology and pharmaceutical industries, in academic leadership, and as a key factor in our national security strategy.

Advancements in mRNA technology are improving American lives today, demonstrated by the recent announcement of the successful treatment of an infant, Baby KJ. **Baby KJ successfully**

[1] The Alliance for mRNA Medicines (AMM) is the leading global organization dedicated to advancing and advocating for mRNA and next-generation encoding RNA therapeutics and vaccines for the benefit of patients, public health, and society. Our mission is to propel the future of mRNA medicine, improve patients' lives, and advance scientific knowledge by convening and empowering mRNA industry leaders, innovators, scientists, and other key stakeholders. AMM's membership, which is composed of nearly 80 organizations, consists of biotechs, pharmaceutical companies, contract development and manufacturing organization (CDMOs), suppliers, and academic researchers. Learn more at https://mrnamedicines.org

**received a personalized (N of 1) mRNA-CRISPR gene therapy treatment for severe carbamoyl phosphate synthetase 1 (CPS1) deficiency, which (until now) was an incurable, rare disease**. This most recent story shows the potential of mRNA technologies and the importance of U.S. mRNA manufacturing to patients. There are many other stories like this in the making, including advances in treating pancreatic cancer, melanoma, breast cancer, and brain cancer. An unprecedented 2022 study using an mRNA technology resulted in an effective cure for some patients with pancreatic cancer (a five-year survival rate). Thus, mRNA technology is transforming health care and saving American lives from previously devastating diseases.

## II. mRNA Manufacturing Offers Significant Benefits Over Current Technologies

mRNA manufacturing offers the following benefits over other pharmacological technologies:

- **Scalable and Modular Manufacturing:** the same process can be used for multiple products and using modular systems enabling fast implementation and multiple scales (n of 1 or billions)
- **Quality and Consistency:** cell-free system simplifies and shortens production process; it also reduces risk of contamination
- **Smaller Footprint, Lower Infrastructure Needs:** mRNA facilities require less space and lower capital investment
- **Rapid Development and Production:** from sequence to manufacture moves much faster than other modalities – new mRNAs can be made in weeks vs. years for other technology
- **Continuous Manufacturing Potential:** fosters real-time quality control and thus efficiency and higher quality
- **Hospital-Based / Point-of-Care Manufacturing:** enables individualized cancer treatments for patients
- **Lower Cost of Goods:** allows for broader implementation
- **Easily Adaptable for New Indications:** fosters agility which will help in rare disease, infectious disease, and cancer, among other diseases

## III. The U.S. Is Currently a Leader in mRNA Manufacturing

As with many of the most innovative areas in medicine, the U.S. has led the way in mRNA product development and manufacturing, which creates jobs in the U.S. and supply chain security. Just a few of the many examples of U.S. leadership in manufacturing include:

- **New England Biolabs (NEB)** has pioneered the discovery and production of innovative products tailored for molecular biology research for over 50 years. NEB domestically manufactures enzymes for use in basic and applied research, molecular diagnostics, and nucleic-acid therapeutics manufacturing. In addition to their Ipswich, MA, headquarters, in 2019 NEB opened a facility in Rowley, MA, capable of large-scale mRNA synthesis enzyme manufacturing with the quality systems required for use in GMP mRNA production. NEB employs over 500 full time employees in the US.
- **NTx Bio** is strengthening America's pharmaceutical supply chain by manufacturing distributed mRNA production systems, critical RNA precursors, and high-purity RNA entirely in the United States. NTx Bip's benchtop NTxscribe® platform is actively being

used by U.S. cancer centers, CDMOs, and pharma companies to reduce dependence on foreign suppliers and accelerate domestic biomanufacturing for research and critical medicines. NTx instruments and consumables are assembled in New Mexico, with expansion underway in Plano, Texas. Critical raw materials for mRNA are traditionally sourced through complex global supply chains and several key materials are fully dependent on China. To protect U.S. interests and offer consistent and stable supply to customers, NTx developed a line of proprietary biomaterials —including n1-methylpseudouridine triphosphate, enzymes, and polymerases— that are produced in the U.S. using 100% U.S.-sourced materials. NTx's technology enables rapid, distributed manufacturing to bolster U.S. supply chain resilience and reduce reliance on overseas production.

- **ReciBioPharm's** Advanced Bio business operates an 80,000 sq. ft. development and manufacturing facility in the Greater Boston Area that manufactures mRNA therapeutics and live biotherapeutic microbiome products for clinical trials and commercial use. The site employs between 150 and 200 people ranging from interns and technicians to seasoned scientists and manufacturing operations professionals. All of which bolster the U.S. as a leading manufacturer of the most advanced therapeutic products for rare and chronic illnesses.
- **Maravai Lifesciences** helps life sciences companies overcome their biggest development and manufacturing challenges, to streamline and scale from research through clinical trials to commercialization. Maravai does all its manufacturing in the San Diego, California area, including RNA research in all clinical phases and commercial manufacturing.

## IV. However, Due to Recent State and Federal Government Actions, the U.S. mRNA Leadership, Including Manufacturing, Is Under Threat.

Recent policy developments, at both the federal level and in certain states. jeopardize the progress that has been made on mRNA innovation. Researchers and industry are already experiencing the impacts of overall funding cuts to research, targeting of mRNA, and the negative policy climate. Taken together, these represent a critical threat to the biomedical leadership of the U.S., as they would:

- cause U.S. research and manufacturing jobs to move to Europe and Asia
- delay therapeutic advances in cancer, rare disease, and other diseases by years
- force the loss of billions in potential healthcare savings
- forfeit U.S. biomedical leadership to Europe and Asia, and
- put U.S. National Security in the hands of other countries.

The consequences were demonstrated in a recent AMM survey of 106 industry leaders where 81% of the respondents expressed concern that anti-mRNA policies would cause manufacturing, research, and related jobs to leave the U.S. in favor of pro-innovation environments in Europe and Asia. Key findings of the survey included:

- **66% of mRNA-related jobs are located in the U.S**. and up to **45% of those U.S. positions** are potentially at risk, with **21%** of organizations indicating *all* such U.S. roles could be eliminated under hostile policy conditions, based on survey results.
- **48% of surveyed mRNA organizations have already experienced direct impacts from recent policy disruptions and funding cuts**. Those impacts include:
  - 54% were forced to cut back on mRNA R&D and postponed studies
  - 46% experienced budget freezes and reductions
  - 46% cancelled collaborations
  - 46% delayed capital investments
  - 30% initiated hiring freezes or layoffs among specialized scientific personnel
  - 20% are relocating projects, divisions or entire company, particularly moving from the U.S. to Europe or Asia

## V. Congress Should Advance Pro-mRNA Manufacturing in the United States to Help U.S. Patients and Create U.S. Jobs

U.S. biomedical leadership in mRNA was catalyzed by U.S. government support, including investments from DARPA over a decade ago to support from President Trump in his first term. Continuing U.S. policy support is critical to sustaining this leadership, helping U.S. patients, and creating U.S. jobs. Congress can continue this support by advancing these policies:

- Continue funding mRNA research at NIH, BARDA, ARPA-H, and NSF
- Incenting infrastructure investment in the U.S.
- Investing in production of high-quality raw materials in the U.S.
- Requiring FDA to further advance the regulatory framework for platform technologies
- Enhancing FDA's regulatory capacity for mRNA products
- Supporting workforce development

## VI. Conclusion

AMM thanks the Members of the Committee for holding this hearing to explore this important issue.

August 8, 2025

The Honorable H. Moran Griffith
Chairman
Subcommittee on Health
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Griffith:

I was honored and privileged to appear before the House Subcommittee on Health to discuss the enormous challenges facing American manufacturers of critical generic drugs. Your attention to this urgent matter is essential to protecting the integrity of the U.S. pharmaceutical supply chain.

As requested, I have enclosed my answers to the six additional questions for the record from Representatives Carter and Harshbarger.

Thank you again for the opportunity to tell the story of USAntibiotics, America's last domestic amoxicillin manufacturer, before your esteemed subcommittee.

Sincerely,

Patrick Cashman

Attachment

**Questions for the Record from the Honorable Earl L. "Buddy" Carter**

**Question 1**: How does the price delta for U.S.-vs-foreign origin amoxicillin compare to other sectors where the federal government already pays premiums for American-made products for national security reasons?

> **Answer**: USAntibiotics' pricing is highly competitive with other prime or subcontractors supplying amoxicillin to the federal government, as evidenced by the Federal Supply Schedule. The federal government would not have to pay significantly more to buy American-made amoxicillin because we've worked extremely hard to optimize our production processes.
>
> While it's true we have lost commercial sales when outbid by 2.5 percent (a 10-cents bottle difference) from subsidized foreign competitors, even that modest premium would be wholly consistent with federal government procurement in other critical sectors. For example, the government routinely pays premiums to avoid Chinese technology solutions in favor of American alternatives for cybersecurity reasons. There's a reason that the federal government pays more for U.S.-made operating systems and computer hardware. Similarly, the Defense Department regularly pays higher prices for American-made equipment and components under Buy American requirements.
>
> Essential antibiotics deserve the same treatment as computer systems, semiconductors, and defense equipment. A fractional premium for amoxicillin—the most prescribed antibiotic in America—is a small insurance policy against the catastrophic costs of supply chain failure.

**Question 2**: You mentioned that USAntibiotics was excluded from the $40 million Strategic National Stockpile contract because it wasn't classified as a small business for reasons of its ownership structure. Given that national security and supply chain resilience were stated priorities of the previous administration, does it make sense to prioritize small business status over domestic manufacturing capability for critical medicines?

> **Answer**: This contradiction highlights a fundamental misalignment in government priorities. While small business programs serve important economic goals, excluding the only domestic manufacturer of a critical antibiotic from Strategic National Stockpile contracts defeats the purpose of maintaining emergency medical supplies.
>
> National security should take precedence over contracting categories for truly critical medicines. The irony is that even as USAntibiotics is a small business by every financial metric aside from our ownership structure, we wouldn't be able to sustain the enormous losses of the last four years unless a larger company stepped in to subsidize our operations, thereby excluding us. Any policy prioritizing business size over supply chain security for essential medicines must be re-examined.

**Question 3**: How would predictable, multi-year government purchasing commitments for domestic manufacturers compare in cost-effectiveness to the emergency spending required when foreign supply chains fail and the government must source alternatives at premium prices during shortages?

> **Answer:** Multi-year government purchasing commitments for domestic manufacturers would be far more cost-effective than the current cycle of emergency procurement during shortages. Predictable demand allows us to make efficient capital investments, maintain steady production, and offer competitive pricing.
>
> During the 2022-2023 amoxicillin shortage, emergency sourcing cost significantly more than normal procurement. Some buyers paid 3-5 times the typical pricing for available supply. Meanwhile, USAntibiotics had untapped capacity that could have prevented the shortage entirely if we had long-term commitments that justified scaling up production beforehand.
>
> This is exactly how defense procurement works—multi-year contracts provide stability for manufacturers and better pricing for taxpayers. The same approach would work for essential medicines and would be far more economical than crisis-driven emergency spending.

***

**Questions for the Record from the Honorable Diana Harshbarger**

**Question 1**: Are you aware of other critical sectors where the federal government prioritizes domestic suppliers over the lowest foreign bid for national security reasons?

> **Answer**: Yes, there are numerous precedents. The Berry Amendment has required the Defense Department to buy American textiles, food, and hand tools since 1941. The Trade Agreements Act restricts government purchases to U.S. and designated country products. Federal agencies routinely avoid Chinese telecommunications equipment despite lower costs. The government pays premiums for American-made vehicles, construction materials, and technology solutions.

**Question 1a**. How should pharmaceutical procurement policies align with these existing practices?

> **Answer**: Pharmaceutical procurement should align with these existing practices. If we won't buy Chinese routers for government networks due to security concerns, why would we fill the Strategic National Stockpile with foreign-made antibiotics that our military and emergency responders depend on? The principle is identical—critical infrastructure requires trusted, domestic sources.

**Question 2**: When a government agency awards a contract for strategic national stockpile antibiotics to a foreign supplier while a domestic alternative exists, what risks does this create for supply chain resilience during future emergencies?

> **Answer**: Principally, it creates supply chain vulnerability by feeding dependence on foreign sources at the expense of domestic industry. This is particularly dangerous in military or trade conflicts where exports are restricted, or a potential bacterial pandemic in which antibiotics will become highly prized commodities. Second, there are enormous quality control risks because we have less oversight and transparency in foreign manufacturing processes. Lastly, it forces domestic manufacturers to exit the market when their own government refuses to support American industry. Taken together, it undermines the very purpose of a strategic stockpile, which is supposed to provide security during emergencies, not create additional vulnerabilities.

**Question 3**: Mr. Cashman, you referenced a 2025 study showing Indian-made generics were 54 percent more likely to cause severe adverse events than American-made drugs. When government agencies procure pharmaceuticals, should quality metrics and regulatory oversight standards be factored into procurement decisions alongside price?

> **Answer**: Absolutely. The 2025 Ohio State study showing 54% higher rates of severe adverse events from Indian-made generics compared to American-made drugs should be a wake-up call. Quality isn't just about patient safety—it's about healthcare costs. When patients experience adverse events, it means additional medical treatment, needlessly extended hospital stays, and higher overall costs to the system.
>
> Government procurement should factor in the regulatory environment where drugs are manufactured. American facilities operate under rigorous FDA oversight with regular inspections. We have transparency and accountability that's simply not possible with foreign manufacturing. When the government purchases pharmaceuticals, it should consider the total value proposition: quality, safety, oversight, and supply chain security—not just the lowest unit price.

***

The Honorable Morgan Griffith
Chairman, Subcommittee on Health
House Committee on Energy & Commerce
2110 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
Ranking Member, Subcommittee on Health
House Committee on Energy & Commerce
2111 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Griffith & Ranking Member DeGette:

Below are my answers in response to additional questions for the record submitted by members following my appearance before the Subcommittee on Health on Wednesday, June 11, 2025 at a hearing entitled, *"Made in America: Strengthening Domestic Manufacturing and the Health Care Supply Chain."*

**The Honorable Erin Houchin**

*1. Mr. Murphy, the speed to onshore pharmaceutical manufacturing is largely determined by the speed with which manufacturers can construct and qualify a facility in the United States with the Food and Drug Administration (FDA). Can you give any suggestions to accelerate U.S. pharmaceutical domestic manufacturing and minimizing regulatory roadblocks while maintaining high safety standards?*

> *a. For example, how can Congress encourage the FDA to think creatively to facilitate earlier FDA involvement with new or recapitalized U.S.-based sites to speed the availability of medicines made in the U.S.?*

**Mr. John Murphy, III**

We believe there may be several considerations and opportunities for the FDA, the states, and the elected officials to work collaboratively on this issue.

Before we focus on FDA, we should point out that incentivizing public-private collaboration for U.S. sites through grants, tax credits, or guaranteed purchase programs, would greatly help accelerate U.S. pharmaceutical domestic manufacturing.

Once a manufacturer has made the decision to build a new manufacturing facility or repurpose existing manufacturing sites/lines, there are several actions the FDA could take to help accelerate this process.

**Enable Earlier FDA Engagement and Pre-Approval Collaboration**

1. Encourage FDA to meet with manufacturers during the planning and construction phase, rather than waiting until facilities are fully built and validated.
2. Establish a "pre-construction/pre-validation inspection program" to identify compliance gaps early.
3. Consider developmental-phase and pre-submission inspections, allowing FDA to sign off on key quality systems in parallel with construction and tech transfer.
4. It would be helpful if the FDA collaborate with states on inspection activities to limit the need redundant inspections.
5. It would be helpful if the FDA work with EPA on certain environmental issues related to new facility construction.

**Create a Dedicated FDA Domestic Manufacturing Task Force**

- Congress can request FDA form an intra-agency working group to fast-track domestic manufacturing projects, involving:
  - Office of Pharmaceutical Quality (OPQ)
  - Office of Compliance and Office of Inspections
  - Office of Generic Drugs
- This team would coordinate reviews, inspections, and tech transfer approvals to compress the typical 5–7 year timeline for a new facility.

**Regulatory Flexibility with Safety Maintained**

- If a manufacturer has a strong compliance record, the FDA should consider certain changes be permitted without potentially having to inspect every proposed change.

- If a manufacturer has a strong compliance record, consider use of alternate inspectional tools that may fall under the Remote Regulatory Assessment (RRA) paradigm.

**As mentioned briefly above, Congressional Support to Encourage FDA Creativity**

- Statutory authority or appropriations can support early engagement programs and inspection resources to avoid delays caused by limited FDA staffing.
- Incentivize public-private collaboration for U.S. sites through grants, tax credits, or guaranteed purchase programs.

**The Honorable Jake Auchincloss**

*1. The 340B program has grown substantially since its inception – the number of participating provider organizations has increased by 600 percent since 2000. It is now one of the largest federal prescription drug programs. What concerns do you have about how reimbursement policies affect generic manufacturing and supply-chain resilience?*

**Mr. John Murphy, III**

In 2023, generics continued to demonstrate their value proposition -- representing 90 percent of all prescriptions filled but only 13 percent of all prescription drug spending. Generic and biosimilar medicines are the only segment of healthcare that consistently delivers lower costs. In fact, generic prices continue to experience severe deflation; the overall value of all generic sales in the U.S. has declined by $6.4 billion since 2019, despite increased volume and new generic launches.[1] Generic drugs save patients money. In 2024, the average out-of-pocket cost for a generic was $6.95; while the average out-of-pocket cost for a brand drug was nearly five times higher – at $28.69.[2]

A recent analysis by RAND found that generic prices in the U.S. average 16 percent less than other countries, and between 30 to 50 percent less than nations such as the U.K., Mexico, France and Japan.[3] This difference is the result of a hyper-competitive U.S. generic

---

[1] IQVIA Contributors. (May 2023). The Use of Medicines in the U.S. 2023. Accessible at: https://www.iqvia.com/insights/the-iqviainstitute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023

[2] IQVIA Institute. (April 2025). *Understanding the Use of Medicines in the U.S. 2025.* Accessible at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/understanding-the-use-of-medicines-in-the-us-2025/iqvia-institute-iqi-us-use-of-medicines-04-25-forweb.pdf

[3] RAND. (February 2024). International Prescription Drug Price Comparisons. Accessible at: https://www.rand.org/pubs/research_reports/RRA788-3.html

drug market in which prices can rapidly fall by 40 percent on average, and as much as 95 percent upon generic entry.[4]

With respect to 340B, in particular, as you are likely aware, the formula utilized for creating the Medicare drug pricing is carried over into the 340B program. In 2017, a new penalty was imposed on generic manufacturers participating in the Medicaid program. Targeting price increases exceeding the rate of inflation, the Medicaid Generics Penalty (MGP) ignores important market differences between generics and brand-name drugs. To better understand the impact of this penalty on generic manufacturers, AAM requested an in-depth analysis by Avalere Health, and the following includes their findings.[5]

According to Avalere Health, the rule unfairly penalizes manufacturers for price fluctuations outside of their control, increases the risk of drug shortages, and threatens the continued availability of low-cost generics to patients. Generic manufacturers may have price increases for items outside the manufacturer's control (e.g., purchasing pattern fluctuations, including changes in customer base and seasonal changes in product usage).

Further, pricing for generic drugs is highly affected by the commoditized nature of the multi-source generic market. Price competition in many generic markets has driven prices down to just above production costs, with minimal margins to absorb any fluctuations (e.g., increases in manufacturing or ingredient costs). This downward pressure may result in price increases for generic manufacturers when input costs increase or when there is a shortage. This is particularly likely when the benchmark is low, which occurs when a manufacturer enters the market after others or if it is an older generic drug (where there has been sustained price competition).

Given these problems, Congress should refine the Medicaid drug inflationary penalty and model it after the Medicare inflationary penalty, which takes into account the multi-source nature of the generic drug market.

While the U.S. generic market is clearly in peril, solutions are not far out of reach. In addition to changes to the MGP, policymakers must streamline FDA processes, curb patent abuse, stop PBMs and Medicare policies from denying patient access and rollback harmful federal policies – including IRA price controls.

The time to act in the best interest of America's patients is now!

---

[4] FDA. (December 2019). Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. Accessible at: https://www.fda.gov/media/133509/download

[5] Avalere. (February 2025). *The Medicaid Drug Rebate Program and Considerations for Generic Markets*. *https://advisory.avalerehealth.com/wp-content/uploads/2025/02/The-Medicaid-Drug-Rebate-Program-and-Considerations-for-Generic-Markets.pdf*

BRETT GUTHRIE, KENTUCKY
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED NINETEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-3641
Minority (202) 225-2927

July 29, 2025

Dr. Ronald T. Piervincenzi, PhD
Chief Executive Officer
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Dear Dr. Piervincenzi:

Thank you for appearing before the Subcommittee on Health on Wednesday, June 11, 2025, to testify at the hearing entitled "Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Tuesday, August 12, 2025. Your responses should be mailed to Annabelle Huffman, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Annabelle.Huffman@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

H. Morgan Griffith
Chairman
Subcommittee on Health

cc: Diana DeGette, Ranking Member, Subcommittee on Health

Attachment

**Attachment — Additional Questions for the Record**

**The Honorable Diana Harshbarger**

1. Having naloxone as an over-the-counter (OTC) has been lifesaving for countless people but recent reporting highlights some of the inefficiencies at the Food and Drug Administration (FDA) in need of improvement. A recent study on Narcan's OTC switch found that FDA's review of the proposed tradename took 8 months, its review of the human factors study (HFS) protocol (assessing how well participants could use the NNS device) took 6 months, and the protocol revision took 4 more weeks. Narcan was supposed to meet a public health emergency.

    a. Why would it take so long for the FDA to act and what changes could be made at the agency to improve our healthcare supply chain?

2. The report also notes that despite FDA's verbal appeal to manufacturers in 2017, FDA denied the Sponsor's request for fast-track designation and priority review of the OTC application. The FDA only granted this request after the Sponsor went through an appeals process. How do you think these sorts of delays impact getting these products to market?

    a. How long does it take?

**QFR**

1. *Having naloxone as an over-the-counter (OTC) has been lifesaving for countless people but recent reporting highlights some of the inefficiencies at the Food and Drug Administration (FDA) in need of improvement. A recent study on Narcan's OTC switch found that FDA's review of the proposed tradename took 8 months, its review of the human factors study (HFS) protocol (assessing how well participants could use the NNS device) took 6 months, and the protocol revision took 4 more weeks. Narcan was supposed to meet a public health emergency.*

   *Why would it take so long for the FDA to act and what changes could be made at the agency to improve our healthcare supply chain?*

   The availability of naloxone over-the-counter (OTC) has expanded access to this lifesaving intervention and continues to serve as a critical tool in preventing opioid-related deaths across the country.

   As you note, the FDA plays a central role in administering the complex evaluations needed to ensure such products are safe and effective and can be used safely and effectively by the general public without the supervision of a healthcare provider.

   It is hard to know, in the case of naloxone, how the emergence of COVID impacted the review process or contributed to regulatory delays, particularly with respect to the human factors protocol. Ensuring that these pathways function as intended or are updated to be appropriately responsive to the health needs of the nation is critically important.

   As FDA and industry begin their next round of user fees agreements, in earnest, there is likely to be debate over enhanced transparency, defined performance goals, and review predictability. Your questions are timely and represent important considerations. USP stands ready to work with your office ahead of Congress' review and authorization process.

2. *The report also notes that despite FDA's verbal appeal to manufacturers in 2017, FDA denied the Sponsor's request for fast-track designation and priority review of the OTC application. The FDA only granted this request after the Sponsor went through an appeals process. How do you think these sorts of delays impact getting these products to market? How long does it take?*

   The naloxone example raises important questions about how regulatory tools like Fast Track and Priority Review might be applied in future cases when the barrier is not the product itself, but the mode of access.

Continued dialogue between FDA, Congress, and public health stakeholders could help clarify whether existing expedited pathways are sufficient—or whether new mechanisms are needed—to better align regulatory processes with urgent public health needs.

Looking ahead, continued collaboration between FDA, industry, and public health stakeholders can help identify areas for process improvement while preserving the rigor that underpins public trust in the agency's decisions.

Dawn O'Connell
Former Assistant Secretary for Preparedness and Response
Answers to Additional Questions for the Record
Hearing: June 11, 2025

The Honorable Diana Harshbarger

1. **During your tenure overseeing the SNS did our office ever undertake any market surveillance on critical medicine acquisitions to determine if any domestic end-to-end manufacturers existed?**

    a. **If not, why?**

    b. **Was your department aware that your decision to compete the September 2022 amoxicillin award as a small business set-aside meant the last US manufacturer of the drug would be excluded from bidding?**

ANSWER:

During my tenure, ASPR's Center for Industrial Base Management and Supply Chain (IBMSC) conducted regular market surveillance of critical medical supplies. This surveillance informed their investments in strengthening domestic manufacturing of several key medical supplies including Personal Protective Equipment (PPE), active pharmaceutical ingredients, and key starting materials. The SNS used IBMSC's market research, when applicable, to inform their purchases of critical medical supplies. The decision to use the small business set aside to purchase amoxicillin was made at the Department-level, not by ASPR or the SNS.

**2. Did your office conduct risk assessments regarding supply chain vulnerabilities when sourcing critical antibiotics from foreign manufacturers, particularly given the concentration of active pharmaceutical ingredient production in China and India?**

    a. **If so, why did it continue to purchase foreign-origin amoxicillin when domestic supply existed?**

ANSWER:

Yes, ASPR conducted risk assessments regarding supply chain vulnerabilities which is why IBMSC invested in the domestic production of active pharmaceutical ingredients and key starting materials. The decision regarding which procurement vehicle to use to purchase amoxicillin was made at the Department-level, not by ASPR or the SNS.

**3. During your time leading the Administration for Strategic Preparedness and Response, was a comprehensive cost-benefit analysis conducted that weighed the potential costs of supply chain disruption against any price premium for domestic sourcing when making SNS procurement decisions?**

ANSWER:

SNS procurement decisions are informed by several factors including cost, quality, mission-readiness, and availability. Whenever possible, the SNS has purchased domestically manufactured supplies including PPE. I believe the SNS should continue to prioritize domestically manufactured goods whenever feasible.

**NABP Responses to E&C QFRs from June 11 Hearing**
**Due Aug 12, 2025**

**The Honorable Erin Houchin**

**Mr. Bolin, in your testimony you discussed how Pulse by the National Association of Boards of Pharmacy enabled the identification of counterfeit GLP-1 medications that had made their way into our supply chain. Can Pulse trace the origin of illicit active pharmaceutical ingredients (APIs), particularly those from China, when verifying or tracing products?**

The DSCSA enables tracing and verification of finished dosage forms of products, but not the active pharmaceutical ingredients (APIs) that are used to manufacture the products. Pulse by NABP is a directory of legitimate trading partners (manufacturers, distributors, and pharmacies) in the supply chain, as well as the pharmaceutical products that move through the supply chain. Utilizing Pulse, regulators and trading partners can scan the 2D bar code of a finished, saleable unit of product and ask questions of trading partners about the product.

Accordingly, Pulse can scan products that are in finished dosage forms and have been affixed with a GS1 Data Matrix. Due to the limitations of the DSCSA, Pulse would not trace the origin of APIs – legitimate, illicit or otherwise, but, it would enable trading partners and/or regulators to ask that question about the legitimacy of the product and the prior ownership of that product.

**a. If not, what enhancements to Pulse or the Drug Supply Chain Security Act would be needed to better identify and block China-sourced counterfeit APIs?**

As discussed above, the DSCSA does not require serialization or tracking of APIs – for manufacturing of FDA-approved products, or for compounding, but Pulse can help regulators ask questions about the legitimacy of a product and the prior ownership of that product.

A recent report by the Partnership for Safe Medicines, conveys that there is visibility into APIs coming into the US, but FDA and Customs and Border Patrol (CBP) resources and enforcement authority may be lacking. Based on publicly available data for April - May 2025, the PSM report details that 74.5% of shipments of API manufactured in facilities **not known to FDA** were being allowed into the country.

FDA's Report on the State of Pharmaceutical Quality released last week (August 8, 2025) reveals a concerning trend related to illicit APIs used in compounded products: "During the past five years, 72% of actions (e.g., warning letters, import alerts, and regulatory meetings) taken against API manufacturers were for sites that only supply compounding pharmacies, even though these sites represent just 18% of API manufacturers in the Site Catalog."

FDA ensures that drug manufacturers utilize API from legitimate FDA-registered sources via the requirement that manufacturers follow current good manufacturing practices (CGMPs) and associated inspections, recall authority, and oversight. However, as cited in the recent FDA report, section 503A compounding pharmacies are not subject to CGMP requirements and might not test their API prior to use. To assist regulators in knowing the source of API used by both finished product manufacturers and compounding pharmacies, it could be required that the original FDA-registered API manufacturer be listed on the certificate of analysis (COA).

There may also be an opportunity for more information sharing between FDA Office of Criminal Investigation and state boards of pharmacy and state Attorney General Offices. Our understanding is that FDA OCI has details on *where* API shipments are being sent, which would help inform state investigative and enforcement activities.

Congress should maintain oversight of FDA, CBP, and other agencies and ensure they have the resources and enforcement authority needed.

Additionally, not particular to DSCSA, there are several policy approaches that can help identify and block counterfeit API from China and other countries, and NABP supports the FDA's FY2026 legislative proposals to require labeling to include original manufacturer and supply chain information and require the destruction of imported products that pose a significant public health risk. Senators Grassley and Hassan and Reps. Moore and Schneider also recently introduced legislation to detect and halt counterfeit and pirated imports (S. 2677 and H.R. 4930). A major source of illegitimate product in the U.S., including with China-sourced counterfeit APIs, is social media. Thus, NABP supports the Protecting Patients from Deceptive Drugs Act (S.652), enhancing the FDA's enforcement capabilities against social media platforms.

**The Honorable Robin Kelly**

**Following my question during the House Committee on Energy and Commerce Subcommittee on Health Hearing on counterfeit and compounded glucogen-like peptide-1 receptor (GLP-1) products, as well as your comments on the potential dangers of these products in your opening statement, I wanted to submit additional questions on the Food and Drug Administration's (FDA) role and responsibilities:**

**a. How have recent workforce cuts impacted the FDA's ability to inspect foreign drug manufacturers and their facilities?**

FDA's ability to conduct its business to ensure that drugs in the U.S. supply chain are safe and effective is critical. This includes FDA's ability to inspect foreign drug manufacturers and their facilities, inspect imported shipments of finished dosage forms and active pharmaceutical ingredients (APIs), and inspect domestic manufacturing and 503B facilities.

For the inspection of domestic 503A compounding pharmacies, FDA relies on partnership with state boards of pharmacy, who hold the primary enforcement authority over state-licensed 503A compounding pharmacies.

NABP has not yet experienced the impacts of FDA workforce cuts in its ability to conduct inspections, but a further reduction in inspection ability would be concerning. FDA has historically been understaffed for this critical function, and we would encourage more robust resources for foreign inspections. However, we are encouraged by FDA's recent announcement to utilize limited resources better by expanding unannounced inspections at foreign manufacturing facilities.

**b. How is the FDA coordinating with other federal agencies to enforce the May 22, 2025, compounding prohibition for GLP-1 drugs? Specifically, how is the FDA coordinating with the Federal Trade Commission (FTC) to regulate online advertising of these products?**

FDA has declared that GLP-1s are no longer in shortage, so the authority to compound due to shortage should no longer be available. Now, GLP-1s may only be compounded based on a documented patient-specific clinical need. While the shortage was in effect, it unlocked a new market for "compounding" in med spas and wellness clinics.

This is one of the most troubling patient safety threats that NABP's member boards are seeing—the rapid proliferation of un-regulated or under-regulated compounding outside of licensed pharmacies, including in med spas. Many of these entities are engaged in aggressive local marketing campaigns using social media that mislead patients.

The regulation of med spas is fragmented, with most states lacking a comprehensive statutory or regulatory framework tailored to med spas. All states regulate the individual practitioners providing the professional services at the med spas – nurses are overseen by professional nurse licensure boards, doctors by boards of medicine, etc.

Only four states currently require specific licensure or registration of a med spa facility depending on types of services provided – Mississippi, Ohio, Tennessee, and Utah. Given the concerns raised, additional states are considering action and Colorado, Nevada, Rhode Island, and Texas have recently passed legislation or enacted regulations touching on med spas regulation. Overall, most states still lack the authority to regulate med spas, let alone conduct robust inspections.

NABP and our member boards of pharmacy are actively working to address these gaps by collaborating with boards of medicine and nursing, gathering inspection data from states that have authority over med spas and preparing legislative proposals to help address existing gaps in state law and regulation.

Given the risk of illegal online drug sales, NABP supports the FTC's efforts to address deceptive marketing practices of medications sold on the internet. However, regulatory

authority to take action against the social media companies that allow illegitimate actors to market illegitimate products is limited. To help close this loophole, Senators Durbin and Marshall introduced the Protecting Patients from Deceptive Drugs Online Act (S.652). The legislation would hold influencers and providers—including telehealth providers—accountable for making false or misleading claims, such as omitting side effects, presenting inaccurate information, or failing to disclose key facts.

NABP is not privy to particular information and cannot comment on whether FDA and FTC are coordinating on these issues. Provide

○