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
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

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Addressing generic drug shortages: Contributing factors and public policy recommendations

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Key: Short-term solutions | Mid-term solutions | Long-term solutions

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Introduction

With over 100 years of excellence in pharmaceutical supply chain management, Cencora is renowned for its commitment to patient care, expertise in pharmaceutical distribution, and deep understanding of market access dynamics. Our insights into the complex issues contributing to global drug shortages and their solutions are informed by our position as one of the world's largest pharmaceutical wholesale distributors of prescription drugs. Cencora seeks to partner with the U.S. Congress and the Administration to tackle these challenges, enhancing care delivery, patient access, and outcomes in the United States while harmonizing global solutions.

Drug shortages, particularly of generic drugs—including both sterile injectables and oral solids—negatively impact millions of patients and healthcare providers across the U.S. These shortages are complex and require coordinated public-private efforts to identify contributing factors and develop effective policy solutions. As a vital member of the pharmaceutical supply chain, Cencora aims to collaborate with federal and state policymakers, regulators, and the Administration to enhance care delivery, improve reimbursement processes, and increase supply chain transparency and resilience.

This white paper outlines recommended approaches to combat generic drug shortages and improve patient access and outcomes, while improving U.S. national security. It is structured to provide an executive summary, background on the issue of generic drug shortages, a snapshot of the current state of the generic drug shortages, key pillars and players involved in mitigating risks, and short-, mid-, and long-term policy recommendations to serve as solutions for providers, patients, and supply chain stakeholders.

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Executive summary

Contributing factors of generic drug shortages

Cencora's recommended public policy solutions address the contributing factors of generic drug shortages and aim to mitigate and prevent the ongoing issue. These recommendations are categorized into three main themes: sustainable and reliable manufacturing, supply assurance programs, and tax incentives. These policy initiatives are outlined in greater detail later in this paper.

Generic drug shortages contributing factors

- Challenges to diversification and sourcing of active pharmaceutical ingredients (API)
- Disruptions impacting the generic supply chain
- Uncertainty of the generic drug manufacturing market
- Limited visibility into global mapping of generic medications
- Unsustainable generic drug pricing and reimbursement

Overview of Cencora's public policy recommendations

Short-term solutions

Sustainable and reliable generic drug manufacturing

Shortage-Prone Generics (SPG) Program

This original program establishes a foundation for mitigating generic drug shortages by identifying and listing "shortage-prone generic drugs" (SPGs). Manufacturers of SPGs or SPG inputs that meet specific criteria would qualify for tax credits. Additionally, providers who purchase SPGs from these manufacturers and meet certain conditions would receive a separately payable Medicare reimbursement based on the SPG's non-aggregated Average Sales Price (ASP) plus an add-on percentage.

To effectively address the challenges faced by both provider communities and manufacturers, the SPG program must include the following components:

- **Manufacturer participant incentive:** Establish a formulary and quality bonus program for domestic manufacturers of generics, biosimilars, and "critical" drugs to stabilize drug pricing.
- **Medicaid inflation rebates:** For generic drugs that are in or at risk of shortage, the U.S. Congress should suspend Medicaid inflation rebates that discourage stable price increases. This action would decrease the rate at which generic manufacturers exit the market, thereby enhancing competition and expanding provider choices.
- **Provider reimbursement incentive:** Establish a sustainable, minimum reimbursement for providers that purchase generic drugs from SPG manufacturers and reduce inflation rebate amounts for certain shortage drugs subject to rebate waivers under the Medicare program.

Mid-term solutions

Increasing stability of supply: Supply assurance programs

Essential Medicines Reserve (EMR)

To stabilize the market, investments in a U.S. Health and Human Services (HHS) pilot program for an essential medicines reserve, and/or a pilot program to establish an essential medicines strategic stockpile (EMSS) inventory, as outlined in the Essential Medicines Strategic Stockpile Act (EMSSA) (H.R. 405 in the 118th Congress), are crucial. These initiatives will create assurances to address manufacturing redundancies and bolster reserves for provider and patient demand.

- Additionally, Cencora recommends that U.S. states collaborate with pharmaceutical logistics experts to enhance demand stability through supply assurance programs. These initiatives would incentivize generic manufacturers and help maintain supply during drug shortages and emergencies at the state level.

Medicare Conditions of Participation

New Medicare conditions of participation (CoPs) should require every provider and hospital, especially those eligible under the CMS Inpatient Prospective Payment System (IPPS) rule, to have a generic drug shortage prevention and inventory plan annually reviewed and approved by the CEO of U.S. hospitals and health systems.

Long-term solutions

Improving the resilience of the domestic supply chain and diversification of sources: Tax incentives

Tax incentives related to reserves and manufacturing capacity

Provide a tax incentive for domestic generic drug manufacturers to hold reserves and increase manufacturing capacity for drugs likely to experience shortages.

Tax incentives related to increased U.S. production

Provide tax incentives for:

- Drug manufacturers to produce generic drugs in economic opportunity zones, which have historically served as an incentive for development in rural areas of the U.S. and its territories, including the Commonwealth of Puerto Rico
- Generic drug manufacturers to increase U.S. production through a modified version of the Creating Helpful Incentives to Produce Semiconductors (CHIPS) and Science Act of 2022
- Generic drug manufacturers to seek Abbreviated New Drug Applications (ANDAs) approval to increase U.S. production

As policymakers aim to address drug shortages and strengthen the pharmaceutical supply chain, Cencora supports effective policy solutions informed by our unique supply chain perspective. We are committed to ongoing engagement with key stakeholders and the government to tackle the critical issue of generic drug shortages affecting patient access and care both in the U.S. and globally.

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U.S. generic drug shortages background

The U.S. is experiencing drug shortages of more than 130 drugs, including critical cancer drugs.[1] A 2023 survey from the Society of Gynecologic Oncology indicated that doctors in 35 states reported limited to no supply of key chemotherapy drugs at major facilities like large cancer centers and teaching hospitals.[2]

While individual drugs go into and come out of shortage status, persistent and recurring drug shortages, **specifically of generic drugs**, have been an issue in the U.S. and the global supply chain for many years. According to the U.S. Food and Drug Administration (FDA), generic drugs are "bioequivalent substitutes" for brand-name medications, providing the same dosage form, safety, strength, administration route, quality, and intended use.[3] Notably, 90% of patients in the U.S. rely on generic drugs.[4]

The reasons behind drug shortages are as complicated and multi-faceted as the drug supply chain itself. To effectively address the underlying drivers of generic drug shortages, policymakers must adopt a comprehensive approach that addresses Challenges to diversification and sourcing of active pharmaceutical ingredients (API), disruptions impacting the generic supply chain, uncertainty of the generic drug manufacturing market, limited visibility into global mapping of generic medications, and unsustainable generic drug pricing and reimbursement. In this paper, we outline the key issues that policymakers need to address, along with corresponding policy solutions, categorized into three main themes: **sustainable and reliable manufacturing, supply assurance programs, and tax incentives.**

[1] Drug Shortages Near an All Time High, Leading to Rationing The New York Times (nytimes.com)
[2] Drug Shortages Near an All Time High, Leading to Rationing The New York Times (nytimes.com)
[3] https://www.fda.gov/drugs/frequently asked questions popular topics/generic drugs questions answers
[4] IMS Institute for Healthcare Informatics. The use of medicines in the United States: review of 2011. Danbury (CT): IMS Institute for Healthcare Informatics; 2011

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The cost of drug shortages

Drug shortages have detrimental ramifications on patients' access to necessary medications. As reported by the American Society of Health-System Pharmacists (ASHP), the number of ongoing and active drug shortages reached a record high of 323 as of June 2024 – the highest since tracking began in 2001. These ongoing shortages include basic and life-saving products such as oxytocin, Rho(D) immune globulin, standard of care chemotherapy, pain and sedation medications, and ADHD medications.[5]

The drug shortage crisis continues to escalate. According to IQVIA, over the past five and a half years, approximately 25 new molecule shortages have emerged each year, totaling 160 new molecule shortages by June 2023. Of these, only 51 have been resolved. Furthermore, looking at the time frame of active shortages, three-fourths have been active for over a year, and more than half have been active for over two years.[6]

Drug shortages impose significant costs on the entire health care ecosystem – especially to patients and providers. Patients face delays in care, disease progression, and increased out-of-pocket costs for alternative medications. These challenges lead to worsened health outcomes, counteracting the intended benefits that the pharmaceutical supply chain can provide. In responding to generic drug shortages, health systems and providers face cost hurdles in logistics coordination and increased patient demand for alternative care options.

The U.S. Department of Health and Human Services' Office of the Assistant Secretary for Planning and Evaluation (ASPE) has found that drug shortages are associated with higher direct and indirect costs, including the time and effort patients spend to obtain medications. Additionally, these shortages lead to adverse changes in health outcomes and related care, such as delays in treatment, medication substitutions, lack of treatment, adverse events, and even death. Moreover, there is an equity component, as those who are uninsured or underinsured are more likely to be impacted by these shortages.[7]

A 2019 analysis revealed that due to drug shortages, health systems incur at least $359 million annually in estimated labor resources and $200 million per year to purchase alternative treatments.[8] Additionally, nearly a third of respondents to a 2023 ASHP survey described the current state of drug shortages as critically impactful, forcing patients and providers into dangerous situations where treatments or procedures are rationed, delayed, or canceled. Respondents also estimated that drug shortages add 5% to 20% to their overall budgets.[9]

[5] Drug Shortages Statistics ASHP
[6] Drug Shortages in the U.S. 2023 IQVIA
[7] ASPE Report to Congress: Impact of Drug Shortages on Consumer Costs | ASPE (hhs.gov)
[8] HHS ASPE Report to Congress Impact of Drug Shortages on Consumer Costs.
[9] ASHP 2023 Drug Shortages Survey Report

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Mitigating risks surrounding generic drug shortages

As previously mentioned, the contributing factors of generic drug shortages are multi-faceted. It is important to note that this white paper primarily focuses on generic drugs due to their widespread utilization by patients, including both generic sterile injectables and generic oral solids.

Short-term solutions

Sustainable and reliable generic drug manufacturing

As part of the debate on generic drug shortages, one factor highlighted by the U.S. Senate Committee on Finance and other industry leaders is the "race to the bottom" in generic drug prices.[10] For the purposes of this paper, we will refer to this issue as "unsustainable pricing," which may be linked to certain market dynamics and reimbursement mechanisms.[10] Cencora advocates for policies that ensure access to safe, effective, and high-quality medications, while also supporting measures that prevent generic drug prices from declining to a level that compromises patient access, drug quality, and safety.

One significant challenge policymakers encounter in addressing the prices of generic drugs is that Medicare does not directly purchase drugs typically administered in physician offices and hospitals; instead, it reimburses the providers who buy those drugs. Consequently, any effective policy solution should incorporate a mechanism ensuring that providers' reimbursement is contingent upon their purchasing behavior—specifically, purchasing drugs from resilient manufacturers at sustainable prices.

Mid-term solutions

Increasing stability of supply

In some instances, drug shortages occur due to unpredictable demand resulting from unforeseen fluctuations and events such as natural disasters, pandemics, and geopolitical crises. These disruptions send shock waves through the drug supply chain, highlighting the urgent need to stabilize and strengthen supply. For instance, when the COVID-19 pandemic began, the demand for many drugs—not just those related to COVID-19—significantly increased as patients sought longer prescription refills due to unpredictable lockdowns and increased prescribing flexibility for providers.[11] This unforeseen surge in demand strained the global supply chain, particularly affecting drugs that were not maintained in adequate strategic vendor-managed inventory or essential medicines reserves. Increasing the stability of demand would assure generic manufacturers that they have a long-term market to rely upon and encourage continued investment in the domestic supply chain and resiliency improvement.

More importantly, pharmaceutical distributors can help solve this issue through a vendor-managed essential medicines reserve. A vendor-managed essential medicines reserve and investments in additional product would help ensure a stable supply of essential generic medicines and other drugs at risk of shortage, which could help prevent shortages from harming patient access to needed essential medicines. A vendor-managed essential medicines reserve would primarily serve as a mid-term solution to the generic drug shortage issue as longer-term solutions are implemented.

[10] White Paper Preventing Drug Shortages (senate.gov)
[11] Drug shortages amid the COVID 19 pandemic. | PSNet (ahrq.gov)

Mitigating risks surrounding generic drug shortages (continued)

Long-term solutions

Improving the resilience of the domestic supply chain and diversification of sources

Addressing barriers for API

The U.S. supply chain for prescription drugs has become heavily reliant on foreign sources of basic and active pharmaceutical ingredients (API), as well as finished and near-finished drug products. Unfortunately, these foreign sources lack diversification.[12] In addition to low diversification, reliance on foreign sources raises national security concerns, particularly for generic drugs that typically have very low-price points.[13] To encourage manufacturers to establish domestic production facilities of both API and finished/near-finished drug products, policymakers must address the need to increase operations in the U.S., compared to lower-cost countries.

Legislation introduced to the 118th Congress, such as the Rolling Active Pharmaceutical Ingredient and Drug Reserve (RAPID) Reserve Act (S.2510/H.R.6802) aimed to enhance supply chain resiliency for critical generic drug products within vulnerable supply chains.[14] This legislation focuses on increasing drug manufacturing in the U.S. and allied countries, while also ensuring that reserves of essential drugs and APIs are maintained to prevent supply disruptions during drug shortages or public health emergencies.

Increasing resiliency is not the only policy justification cited for re-domesticating the U.S. generic drug supply chain. Policymakers from both parties have expressed concerns about national security, public health, and data privacy risks associated with the heavy reliance on foreign sources. This has led to strong bipartisan interest in investing in domestic capabilities and enhancing supply chain resiliency.

However, it is crucial to recognize that, given the significant dependence of the U.S. prescription drug supply chain on foreign sources, attempting to fully re-domesticate the supply chain and relocate all manufacturing to the U.S. is challenging and could lead to major disruptions in sourcing and manufacturing. Instead, the focus should be on encouraging diversification of sources and suppliers while also supporting greater investment in domestic manufacturing and promoting on-shoring and near-shoring where feasible.

Expanding supply chain transparency

To achieve true resilience, it is imperative to ensure transparency into sourcing for basic ingredients, APIs, and finished or near-finished products. Additionally, it is important to expand and standardize across government agencies the definitions of "drug shortage" and "domestic" supply chain (i.e. onshoring or near-shoring). This alignment allows stakeholders – such as the U.S. government and its private partners – to speak the same language while providing a comprehensive, uniform view into the overall U.S. pharmaceutical supply chain.

The ability to view into the domestic supply chain creates opportunities for lower-cost environments to improve resilience without replicating existing concerns related to supply chain concentration and national security or public health risks, such as the impacts of closures on Indian manufacturing facilities.[15]

Legislation such as the Mapping America's Pharmaceutical Supply (MAPS) Act (H.R. 6992/S.2364 in the 118th Congress), would enable the U.S. government, through public-private partnerships, to update the essential medicines list, establish a pharmaceutical supply chain map identifying vulnerabilities, and create a database of such drugs and their affiliated risks. This bipartisan legislation from the 118th Congress lays the foundation for enhancing real-time agility, improving cross-industry operational effectiveness, and allowing U.S. government agencies to integrate actions aimed at reducing risk.[16]

Pharmaceutical distributors, such as Cencora, are rapidly innovating to develop supply chain resiliency mapping tools. These tools leverage existing advanced technological capabilities and access to relevant data sets to look into our upstream pharmaceutical supply chain. Supply chain resiliency mapping empowers the pharmaceutical industry to proactively identify potential risks, foster improved communication and collaboration with suppliers, and inform and deploy robust risk mitigation strategies. In the face of unforeseen events, this solution facilitates rapid response through real-time data analytics and the implementation of contingency plans for agile decision-making and adaptation.

Ultimately, these efforts lead to enhanced supply chain resiliency, ensuring increased product availability, elevated service levels, and timely deliveries to various sites of care and their patients.

Supply chain resiliency mapping empowers the pharmaceutical industry to proactively identify potential risks, foster improved communication and collaboration with suppliers, and inform and deploy robust risk mitigation strategies.

Cencora encourages collaboration with government entities through public-private partnerships to define and establish an intelligent, data driven framework aimed at addressing current and future gaps, and vulnerabilities within the pharmaceutical supply chain.

[12] Geographic concentration of pharmaceutical manufacturing: USP Medicine Supply Map analysis | Quality Matters | U.S. Pharmacopeia Blog
[13] Skyrocketing Pharmaceutical Imports to the U.S. Endanger National Security Coalition For A Prosperous America
[14] S.2510 118th Congress (2023-2024): RAPID Reserve Act | Congress.gov | Library of Congress and H.R.6802 118th Congress (2023-2024): RAPID Reserve Act | Congress.gov | Library of Congress
[15] Indian regulator says 36% of inspected drug-making units had to be shut | Reuters
[16] Text H.R.6992 118th Congress (2023-2024): MAPS Act | Congress.gov | Library of Congress

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Cencora's public policy recommendations

Addressing the contributing factors of generic drug shortages requires a holistic, multi-faceted approach. It is not enough to simply address a single policy driver. For example, simply increasing reimbursement for generic drugs that are vulnerable to shortages will not address near or onshoring capabilities; there must also be policy efforts aimed at improving supply chain resiliency and stabilizing both demand and supply as mid-term solutions. Policymakers must address all contributing factors of generic drug shortages concurrently to address the problems causing supply issues for long-term success.

Cencora recommends the following public policy initiatives to address the many causes of generic drug shortages. As previously stated, these solutions are categorized into three main themes: sustainable and reliable manufacturing, supply assurance programs, and tax credits. Additionally, we have indicated whether the solutions should be implemented as short-, mid-, or long-term solutions.

To effectively address the complexities surrounding generic drug shortages, it is essential to ensure that any solution works in tandem to tackle the challenges faced by both manufacturers and providers.

Cencora's public policy recommendations (continued)

Short-term solutions

Sustainable and reliable generic drug manufacturing

"Race to the bottom" pricing and other characteristics of the generics market can render these areas unattractive and unsustainable for manufacturers, while also imposing significant costs on providers, thereby increasing the risk of shortages. To effectively address the complexities surrounding generic drug shortages, it is essential to ensure that any solution works in tandem to tackle the challenges faced by both manufacturers and providers. In 2019, an FDA-led inter-agency Drug Shortage Task Force cited a lack of incentives for manufacturers to produce less profitable drugs as a root cause of drug shortages.[17] Increasing the attractiveness of the generics market, especially for those generics that are at higher risk of shortages, could meaningfully mitigate the shortage issue. There needs to be clear market signals for manufacturers to encourage the production of more generic drugs, enabling providers to deliver equitable and timely care to patients.

To achieve this, Cencora proposes the suspension of Medicaid inflationary rebates to facilitate stable price increases. This measure would help reduce the rate at which generic manufacturers exit the market and enhance competition and provider choices.

Medicaid inflation rebates

For generic drugs that are currently in or at risk of shortage, Congress should suspend Medicaid inflation rebates that hinder stable price increases. This action would decrease the rate at which generic manufacturers exit the market and increase competition and provider choices.

Provider reimbursement incentive

Congress should create a sustainable reimbursement floor for providers purchasing generic drugs from reliable manufacturers and reduce inflation rebate amounts for certain drugs at risk of shortage that qualify for rebate waivers under the Medicare program. This approach would incentivize providers to prioritize reliability solely over the lowest price point thereby increasing demand for more reliable manufacturers and boosting production volume.

Policymakers would create a new reimbursement incentive for specific generic drugs determined as vulnerable to shortages. For example, if a drug goes into shortage, providers would be reimbursed at the average sales price (ASP) +8% rather than the standard 6% minus sequestration. Manufacturers would receive a base price plus a 10% ASP rebate, creating an incentive to increase production of the generic drug in shortage. To ensure that patients have access to a stable and diverse array of generic medications, manufacturers should be required to maintain production consistency.

[17] 2019 Drug Shortages Report, Updated February 21, 2020 (fda.gov)

Manufacturer participant incentive

Congress should create a formulary and reliability bonus program for domestic manufacturers of generic, biosimilar, and "critical" drugs (e.g., those based in the U.S. and U.S. territories). Similar to the previous policy option, this initiative could incentivize providers to prioritize reliability solely over the lowest price point, thereby increasing demand for more reliable production.

Additionally, these policy options would consider both finished and near-finished products, as well as APIs and other intermediary production; even if a final product is manufactured domestically, intermediary production may still occur elsewhere. Ideally, manufacturers would be incentivized to produce goods domestically in a manner that aligns their cost of goods sold with that of foreign-made products.

As previously noted, lawmakers on both sides of the aisle have expressed interest in enhancing domestic supply chain resilience. More importantly, the current supply chain is heavily reliant on foreign sources, making complete domestication unfeasible; however, policy options like this would stimulate increased investment in domestic capabilities and promote the diversification of sources and suppliers.

Legislation has already been proposed to accomplish some of these concerns, specifically the American Made Pharmaceuticals Act (S. 3311 in the 118th Congress). This Act would require the U.S. Department of Health and Human Services (HHS) to conduct a program in at least 8 states that gives preference to U.S.-manufactured generic, biosimilar, and "critical" drugs under Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). This preference would affect formulary placement, cost-sharing, Medicaid rebate waivers, Part D star ratings, and Part B bonus payments to providers.

Cencora original public policy

Shortage-Prone Generics Program

Cencora has developed an original policy solution to address the generic drug shortages issue in a multifaceted manner, combining multiple policy options primarily through a reimbursement-based approach while also incorporating a tax credit component. Details on this proposed solution, the "Shortage-Prone Generics Program," are outlined below.

Shortage-Prone Generics Program

Congress should establish the "Shortage-Prone Generics Program" (SPG Program) to define what constitutes a drug "shortage" and an "at-risk" drug across several federal agencies. Additionally, the program would identify key drugs that are currently in shortage or at risk of shortage and create incentives to increase production and stabilize markets. It includes:

- The Secretary of the U.S. Health and Human Services (HHS), in consultation with the U.S. Secretaries of Commerce, Defense, Homeland Security, and Justice (the "Joint Secretaries"), would establish a list of "shortage-prone generic drugs" (SPGs). SPGs are generic drugs that have a history of shortages and are critical to the national security or public health of the United States. The SPGs list would be reviewed annually to determine any additions or deletions from the list.
- Supply chain manufacturers that agree to develop manufacturing sites for inputs or finished versions of SPGs in the U.S., U.S. territories, or other Joint-Secretary-defined "near-shore" countries would become eligible for a sliding scale tax credit ranging from 25%-50%. This credit would vary depending on the scope of the supply chain (e.g. API vs. finished product) and the manufacturing site's versatility in producing multiple SPGs. Eligibility conditions include manufacturers utilizing existing FDA-compliant manufacturing sites and all other applicable federal regulatory agencies; or establishing new manufacturing sites on domestic or "near-shore" soil, or in other countries deemed appropriate, ensuring that such facilities do not pose a national security concern as determined by the Joint Secretaries with input from private sector supply chain stakeholders. Such manufacturers could be referred to as "SPG manufacturers" or "SPGMs."

- The HHS Secretary would maintain and publicly make available a list of SPGMs and the SPGs they produce. Medicare reimbursement for SPGs purchased from SPGMs would be separately payable to providers, instead of being reimbursed through the standard inpatient prospective payment system (IPPS) bundled payment, outpatient prospective payment system (OPPS) packaged payment, or physician fee schedule (PFS) average sales price (ASP) methodologies. Reimbursement would be based on the SPG's non-aggregated ASP plus an add-on percentage (the "SPG ASP") to help offset the costs incurred by provider in complying with the conditions for receiving the SPG ASP payment.
- The SPG ASP add on would equal ASP +8% compared to the current ASP +6% minus sequestration.
- As a condition of receiving the SPG ASP, providers would be required to agree to a "sustainable contract" with the SPGM. A "sustainable contract" would include:
  - Offering the SPGM a minimum 2-year contract to purchase SPGs at the ASP price (minus the add-on, which the provider would retain) as of the contract execution date; or
  - Providing the SPGM with an alternative assurance of demand, such as a monthly subscription "Netflix" model that guarantees a fixed payment for the SPG regardless of actual utilization.
- Participating SPGMs whose SPGs experience list price increases above inflation due to the SPG Program would be exempt from inflation rebate penalties in both Medicare and Medicaid.
- SPGMs and their SPGs would be subject to the same FDA approval and inspection requirements as all other drug manufacturers.
  - SPGMs would also be subject to increased transparency requirements to provide the FDA with greater visibility into their supply chains.
- SPGMs must commit to partnering with the pharmaceutical distribution industry to ensure access to medications at all sites of care.

Cencora's public policy recommendations (continued)

Mid-term solutions

Increasing stability of supply: Supply assurance programs

Unexpected changes in demand and unpredictable events – such as natural disasters, pandemics, and geopolitical events[18] – can often lead to shortages of essential medicines. Establishing an essential medicines reserve in anticipation of supply and demand shocks would help mitigate these impacts and prevent short-term shortages.

From a national security and defense perspective, creating a vendor-managed essential medicines reserve of critical medications should be prioritized as a defense strategic priority to enhance global positioning and security. As mentioned earlier, this inventory would serve as a mid-term solution while longer-term strategies to address drug shortages issues are developed and implemented.

Additionally, while pharmaceutical distributors are well-positioned to play a key vendor role in this solution, maintaining such an inventory is feasible with external support, such as government investment and partnership.

Essential Medicines Reserve (EMR)

Until the supply chain incorporates enough manufacturing redundancy to address potential supply and demand scenarios in real-time, maintaining a reserve of essential medications for supply-driven shortages is a necessity. Given that most providers lack the necessary infrastructure and logistics expertise to effectuate medication reserves, we propose that pharmaceutical distributors serve as key operational partners to rapidly deploy secure, efficient and scalable models.

Some proposed legislation includes a policy solution designed to enhance stability by guaranteeing generic manufacturers a minimum market threshold through the establishment of an essential medicines reserve (EMR).

This approach would build on the precedent established by the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020 during the COVID-19 pandemic, which mandates continuing guidance from the U.S. Food and Drug Administration (FDA). This guidance requires pharmaceutical manufacturers to have contingency plans to respond to drug shortages, particularly of generic drugs.

A U.S. Department of Health and Human Services (HHS) pilot vendor-managed inventory program would serve this purpose, in partnership with private supply chain experts, for a reliable supply of essential medicines. Legislation has been proposed to accomplish this, namely the Essential Medicines Strategic Stockpile Act (EMSSA) (H.R. 405 in the 118th Congress). This Act would require HHS to conduct a pilot program to create such a vendor-managed inventory of generic drugs at risk of shortage through a vendor management program. HHS would enter contracts with manufacturers, wholesalers, co-op or chain pharmacy warehouses, or other eligible entities to establish a six-month stockpile of up to 50 generic drugs identified as vulnerable to shortages.

In a similar vein, a pilot program to establish an essential medicine strategic vendor-managed inventory within the U.S. Department of Defense (DoD) would play a vital role in mitigating supply-driven drug shortages, particularly of shortages caused by unexpected circumstances like geopolitical events. Policymakers could mandate that the DoD establish a pilot program that leverages the existing operations of DoD's pharmaceutical prime vendor program. This program would utilize private pharmaceutical distribution to acquire, manage, and replenish supplies of certain generic medications at risk of shortage within the military health system, ensuring stability in the face of pharmaceutical supply disruptions.

Medicare Conditions of Participation

To prevent exits from the generic market, the Centers for Medicare & Medicaid Services (CMS) should amend the Medicare Conditions of Participation (CoP) to require all providers and hospitals—particularly those identified through the CMS Inpatient Prospective Payment System (IPPS) rule—to implement an inventory and provider generic drug shortage prevention plan. This plan should be reviewed, revised, and approved annually by the CEO of U.S. hospitals and health systems. Such a requirement would promote and ensure widespread adoption, standardization, and stabilization of shortage-prone generic manufacturers (SPGMs) within the market.

The prevention plan would incorporate several specific elements to effectively address potential shortages of essential generic medications. This includes identifying a priority list of essential generic drugs at risk of shortages, establishing a vendor-managed essential medicines reserve with contracts for inventory maintenance, and developing clear contracting procedures. These procedures should consider supplier quality, diversity of supply, and committed volume, ensuring that healthcare providers are well-equipped to manage their inventories efficiently.

By implementing such a prevention plan, providers would be better prepared for unexpected disruptions to pharmaceutical inventories at their sites. Proactively addressing potential shortages would help mitigate the impact of supply chain disruptions before they escalate to critical levels, ultimately safeguarding patient care and ensuring the availability of essential medications.

In 2023, more than 99% of hospital and health system pharmacists reported experiencing drug shortages, highlighting a critical issue in healthcare.[19] Pharmaceutical distributors are uniquely positioned to address this challenge by rapidly expanding the availability and types of medications through drug shortage mitigation initiatives designed to provide health systems with reliable access to critical medications, including those at risk of shortage. Pharmaceutical distributors are willing and able to collaborate with the U.S. and state governments through a public-private partnership; however, they require increased, funding to support the sourcing, storage, and administration of shortage-prone and alternative pharmaceuticals. This funding is essential for encompassing a wide range of therapeutic classes and disease states.

To ensure that no provider has to delay or skip operationally critical treatments for patients due to supply gaps, the establishment of essential medicine reserves is vital. These reserves would guarantee providers have reliable access to necessary medications when they need them, ultimately safeguarding patient care and enhancing the overall resilience of the healthcare system. By promoting provider participation and incentivizing collaboration, the healthcare system can more effectively mitigate drug shortages and maintain continuity of care. This proactive approach would not only address immediate supply concerns but would foster a more robust framework for managing future drug shortages, ultimately benefiting both providers and patients alike.

[18] Drug shortages: A guide to policy solutions | Brookings
[19] Drug Prices and Shortages Jeopardize Patient Access to Quality Hospital Care | AHA News

Cencora's public policy recommendations (continued)

Long-term solutions

Improving the resilience of the domestic supply chain and diversification of sources: Tax incentives

Pharmaceutical manufacturing has significantly moved overseas for lower costs and greater regulatory flexibility, complicating efforts to create reserves and increase production to mitigate shortages, often due to associated costs like environmental and labor regulations.[20] Offering tax incentives to encourage manufacturers to invest in resilient and sustainable practices – especially in strengthening the domestic supply chain – would better enhance solutions to mitigate drug shortages.

Tax incentives related to essential medicine reserves and manufacturing capacity

Provide a tax incentive for domestic generic drug manufacturers to increase manufacturing capacity for drugs likely to experience shortages.

For instance, this could take the form of tax incentives for generic manufacturers based in the U.S. and its territories (and potentially other nations or regions as deemed appropriate). The proposed incentives would come with specific requirements for increasing production capacity of certain drug ingredients and finished products deemed vulnerable and critical.

Legislation has already been proposed that reflects this concept, specifically the Rolling Active Pharmaceutical Ingredient and Drug (RAPID) Reserve Act (S.2510 in the 118th Congress). This legislation leverages HHS contract awards to support drug manufacturers.

However, it could be modified to convert the HHS contracts into tax incentives for manufacturers. The Treasury could make payments of grants in lieu of tax incentives to eligible entities. This approach would provide immediate financial support particularly to generic drug manufacturers who commit to holding reserves and increasing production capacity for critical drugs and active pharmaceutical ingredients (APIs).

Tax incentives related to increased U.S. production

Establish tax incentives for drug manufacturers to produce drugs in disadvantaged areas in the U.S. and its territories (Commonwealth of Puerto Rico) to improve resiliency, like tax advantaged enterprise zones. Tax incentives designed to encourage manufacturers to invest in finished and near-finished products, APIs, or other intermediary production in disadvantaged areas of the U.S. would increase domestic pharmaceutical production, thereby improving the resilience of the domestic supply chain. This comprehensive approach, along with meaningful policies strives to create a sustainable manufacturing environment that benefits both the pharmaceutical industry and economically challenged communities. Ultimately improving the nation's healthcare resilience and national security.

Legislation has already been proposed to accomplish this goal, namely by the Manufacturing API, Drugs, and Excipients (MADE) in America Act (H.R. 2707 in the 118th Congress). This Act would create a "distressed zone pharmaceutical and medical device production" tax credit for pharmaceutical or medical device manufacturers operating in certain Opportunity Zones across the United States.

Similarly, providing tax incentives to generic drug manufacturers to boost U.S. production through a modified version of the Creating Helpful Incentives to Produce Semiconductors (CHIPS) and Science Act of 2022 would promote domestic production. These incentives should apply to finished and near-finished products, APIs, or other intermediary production.

The CHIPS Act established a tax credit for semiconductor manufacturers to promote increased domestic production over several years. Comparably, a modified version of the CHIPS Act would create a tax credit for domestic generic drug manufacturing, aimed at offsetting costs associated with investing in facilities that manufacture generics in the U.S. This credit should be refundable and available to generic manufacturers operating in the U.S. and its territories.

Tax incentives for generic drug manufacturers seeking Abbreviated New Drug Applications (ANDAs) approval

ANDAs are the process in which manufacturers apply to the FDA to produce generic drugs; developing an ANDA for a generic injectable drug and obtaining FDA approval costs a manufacturer roughly $3 million.[21] This can be viewed as overly costly by manufacturers, especially given the low profitability in many generics markets. Policy considerations should look at finished products, APIs, and other intermediary production.

To address the anticipated increase in ANDA applications from generic manufacturers, the FDA should establish a commission to manage application volume and develop eligibility requirements to expedite ANDA approvals. This would streamline efficiency and enhance U.S. production.

Policymakers would establish a tax incentive for generic manufacturers that agree to pursue ANDA approval for generic drugs—particularly finished products—that the U.S. Department of Health and Human Services (HHS) Secretary identifies as vulnerable to shortages. Furthermore, generic manufacturers would be required to guarantee the production of these drugs occurs within the U.S.

The proposed tax incentives are designed to address the challenges of drug shortages and bolster domestic pharmaceutical production by encouraging manufacturers to invest in resilient practices and hold essential medicine reserves to mitigate supply chain and treatment disruptions. Collectively, these strategies will strengthen the U.S. healthcare system, improve national security through a reliable supply of essential medicines, and most importantly increase patient access and sustainability without compromising provider choice and pharmaceutical quality.

[20] Safeguarding Pharmaceutical Supply Chains in a Global Economy 10/30/2019 | FDA
[21] Civica_Coukell_testimony_EandC_14SEP2023_FINAL.pdf (civicarx.org)

07

Conclusion

Combined, these policy recommendations would meaningfully address the many multifaceted factors contributing to generic drug shortages, ensuring a more stable and resilient supply chain and healthcare system.

As policymakers work to address generic drug shortages and strengthen the U.S. pharmaceutical supply chain, Cencora remains a partner of choice in developing robust policy solutions. Drawing from our integral role in the pharmaceutical supply chain, we are committed to offering valuable insights to policymakers and supply chain partners. We look forward to continuing our engagement with key stakeholders and the U.S. government as we work together to address the critical issue of the impact of generic drug shortages on patient access and care in the U.S. and beyond.

08

About Cencora

Cencora, formerly AmerisourceBergen, is a leading global healthcare company, with a foundation in pharmaceutical distribution and solutions for manufacturers, pharmacies, and providers. We create unparalleled access, efficiency, and reliability for human and animal health. Tens of thousands of healthcare providers, veterinary practices and livestock producers trust us as their partner in the pharmaceutical supply chain. Global manufacturers depend on us for services that drive commercial success for their products. Our 46,000 global team members power our purpose:

We are united in our responsibility to create healthier futures.

At Cencora, and through our family of companies, we ensure that crucial medications efficiently, reliably, and securely reach health care providers, pharmacies, hospitals, veterinary practices, and clinics every day. Cencora has a legacy of more than 100 years of excellence in pharmaceutical supply chain operations, sourcing, and distribution. **Cencora's role in the pharmaceutical supply chain and robust expertise provide us with a unique and heightened perspective on policy solutions that can help address the causes of generic drug shortages.**

cencora

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

# # #

FAH STATEMENT | MEDICAID | FAH POLICY BLOG TEAM

“A death knell to critical hospital services” – FAH Statement Following Passage of House Budget Reconciliation Bill

MAY 22, 2025

Washington, D.C. — The Federation of American Hospitals’ (FAH) President and CEO, Chip Kahn, released the following statement after the House passed the budget reconciliation bill, *H.Con.Res.14*:

“For months, Americans and the local hospitals who serve them have sent a clear warning to House leadership: don’t slash Medicaid and threaten health care access for communities across the country – in other words, ‘do no harm.’ The House budget reconciliation bill fails this test with devastating Medicaid cuts – including caps on provider taxes and state-directed payments – that will hand tie states’ abilities to fund their Medicaid programs, cause millions of Americans to lose coverage, and be a death knell to critical hospital services and entire communities’ access to care.

“There is still time to take heed and turn this ship. As the budget reconciliation process progresses, we look forward to working with lawmakers to advance policies that protect local hospitals and Americans’ health care by safeguarding Medicaid and extending the enhanced tax credits that millions of hardworking Americans rely on.”

###

pulse™ by NABP

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

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

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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

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.

The Journey Remaining to Complete DSCSA 2023 Requirements

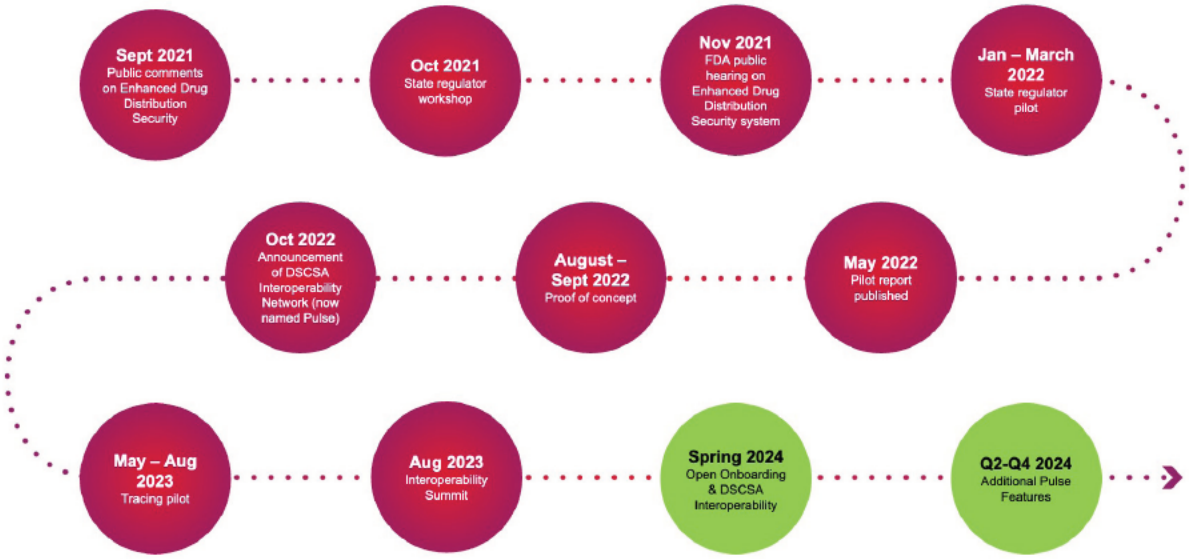
With the final DSCSA 2023 requirements now in effect and FDA confirming the need for more time with the recently announced stabilization period (effective through November 27th, 2024), there is significant work remaining for industry and state/federal agencies to fully develop, integrate, and stabilize 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?



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

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?

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

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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.

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]

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[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

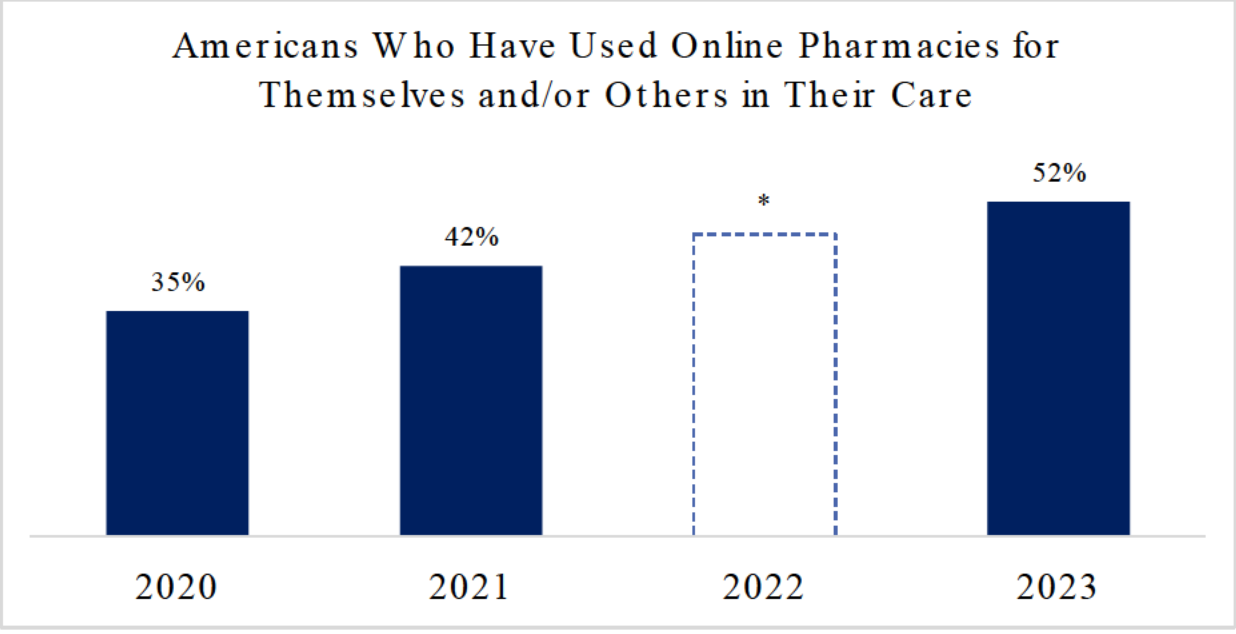
[5] Pharmaceutical Security Institute (PSI). (n.d.) *Geographical Distribution*. Retrieved November 29, 2023, from https://www.psi-inc.org/geographic-distribution

[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)

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.

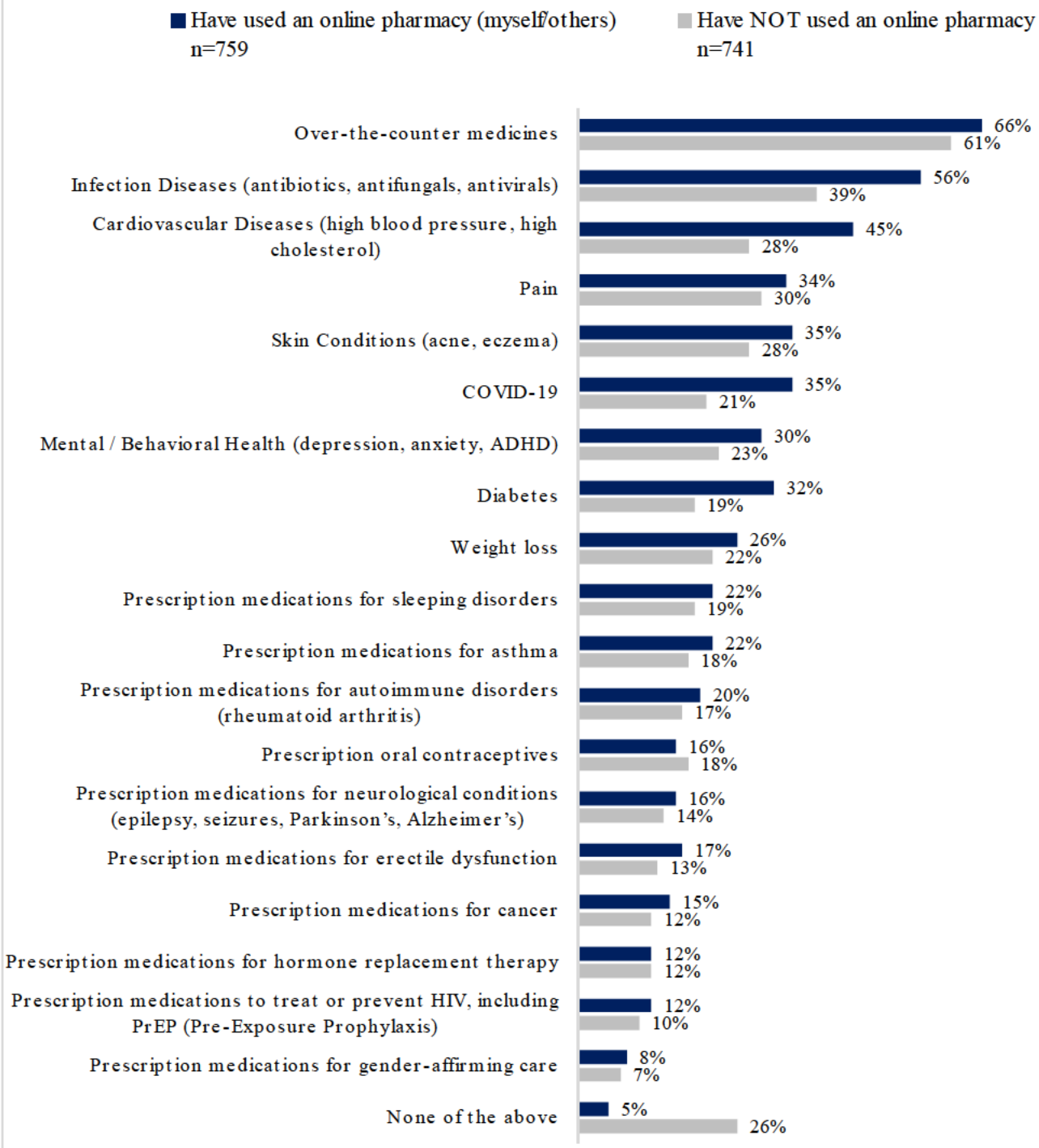
HOW DO AMERICANS FIND & USE ONLINE PHARMACIES

- **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.

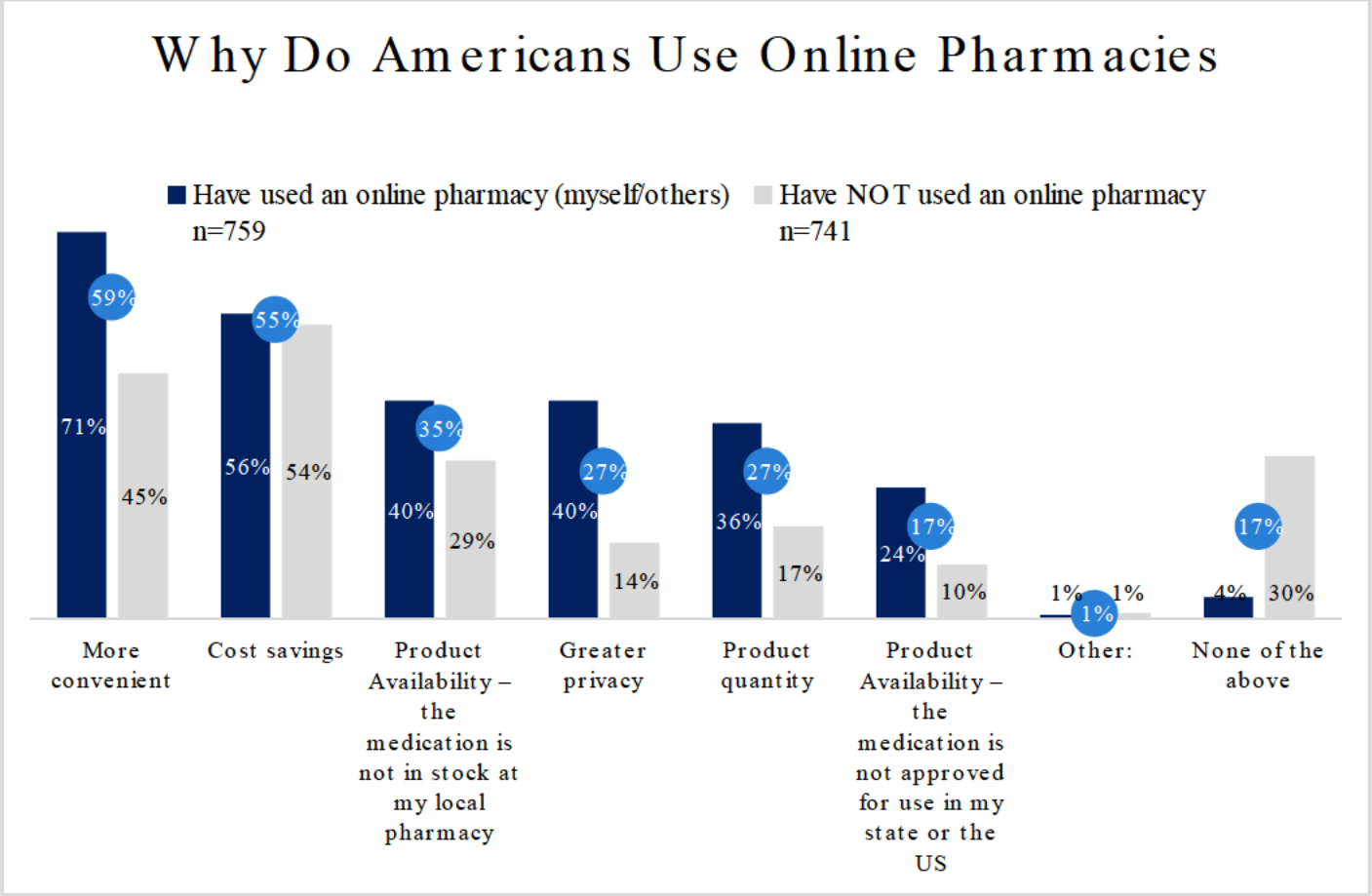
- **Most Americans who have prior experience with online pharmacies are comfortable using them to purchase multiple medications, including those that would need to be taken daily as well as those needed for acute conditions.**
    - When asked what types of prescription medications they would feel comfortable 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



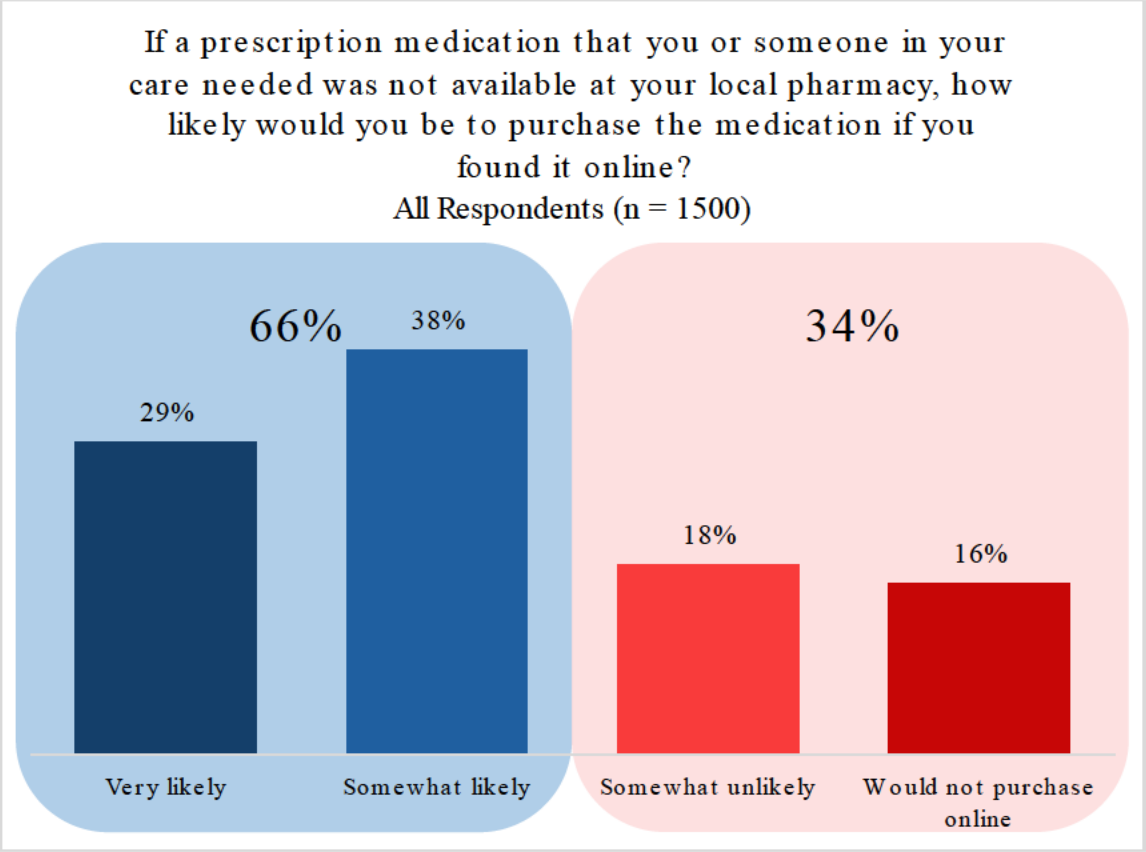
WHY DO AMERICANS USE ONLINE PHARMACIES

- **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.**

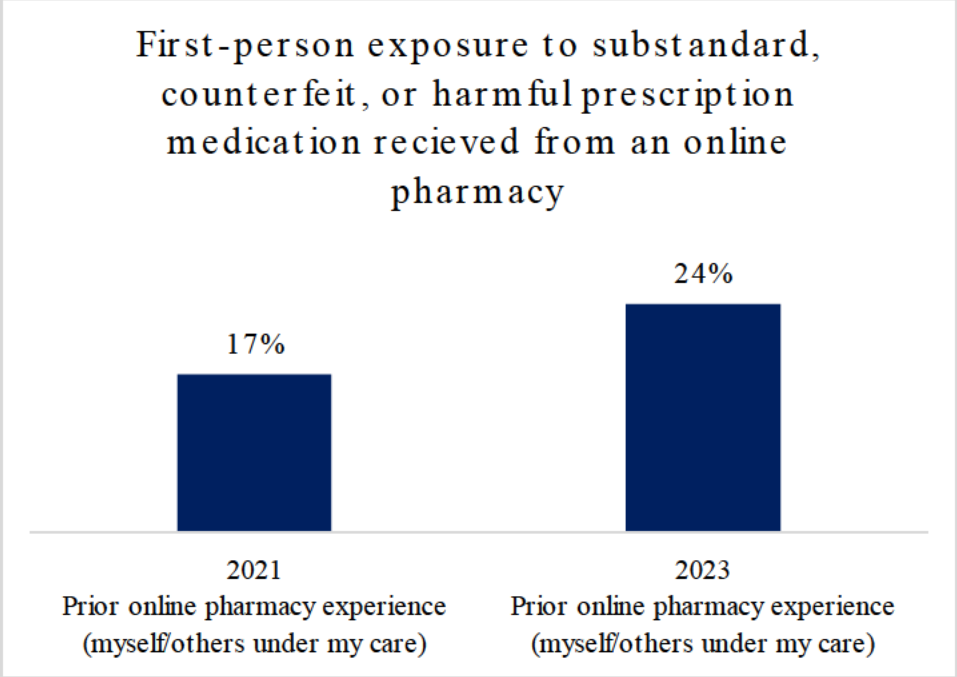
- 47% of Americans who have used online pharmacies would be open to purchasing prescription medicines from an online source not approved by U.S. regulators if it **gave access to medicines they couldn't otherwise access.**

- 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

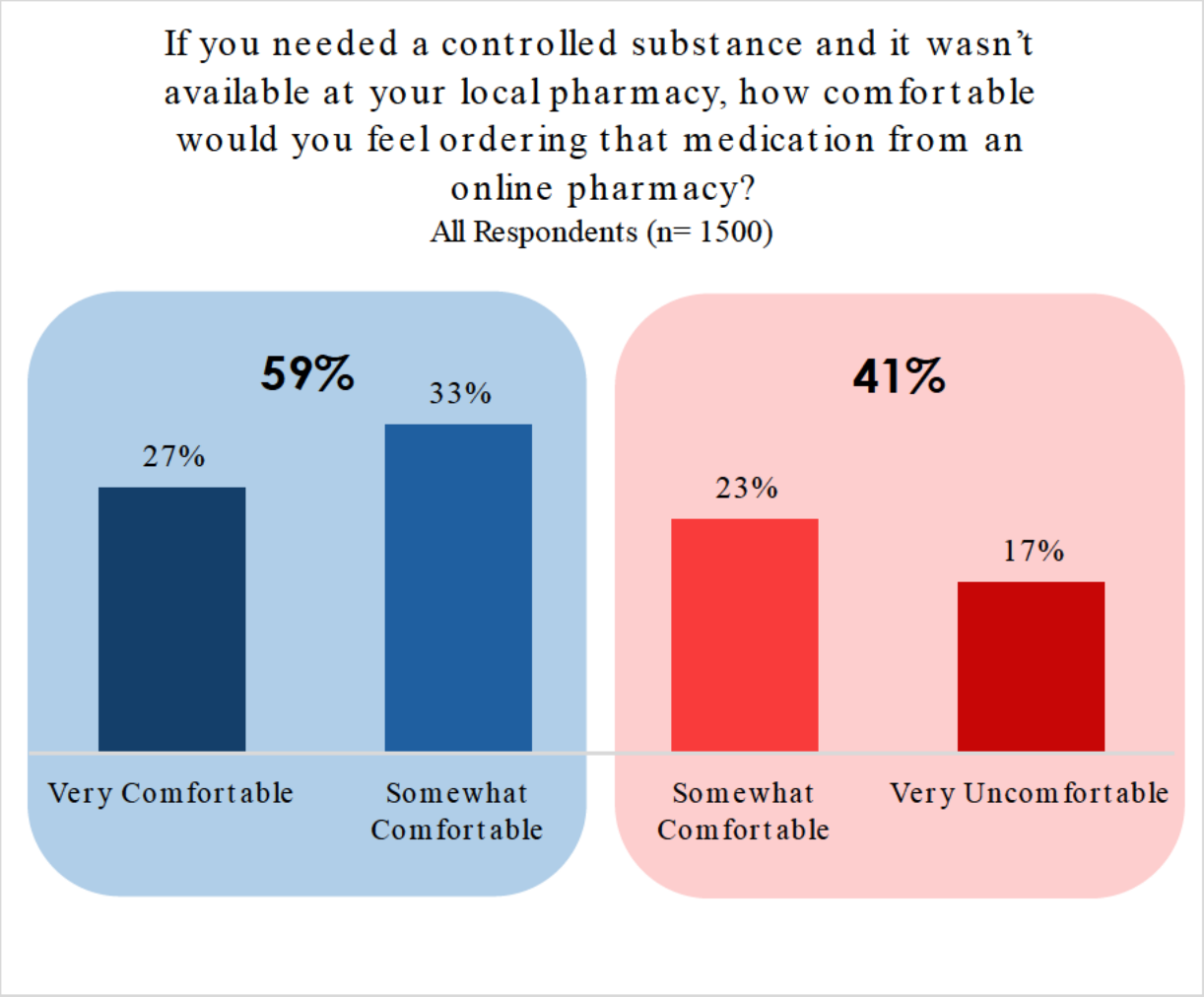
AMERICANS' REACTIONS TO CHANGING CONTROLLED SUBSTANCE REGULATIONS

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

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.

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.

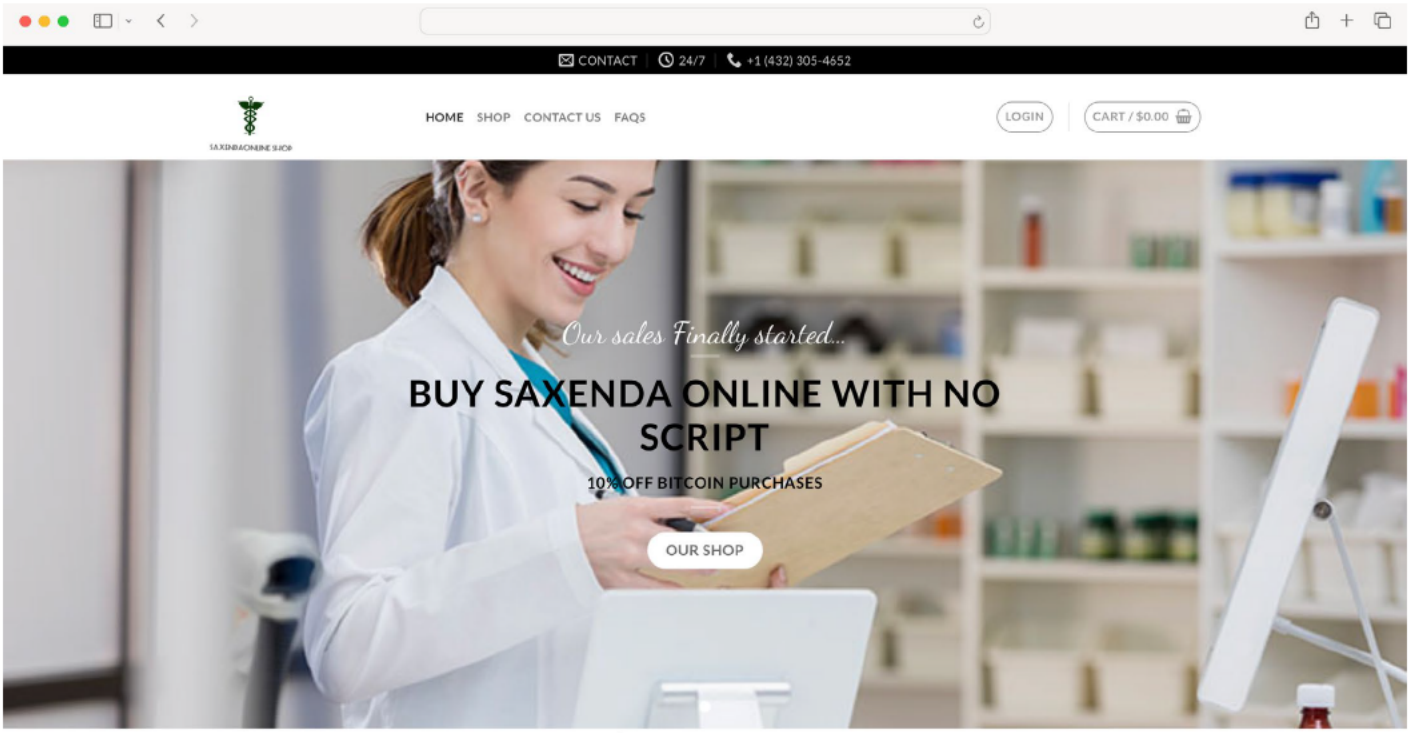


FIGURE 1: Illegal online pharmacy offering Saxenda, a GLP-1 agonist, without requiring a prescription.

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.

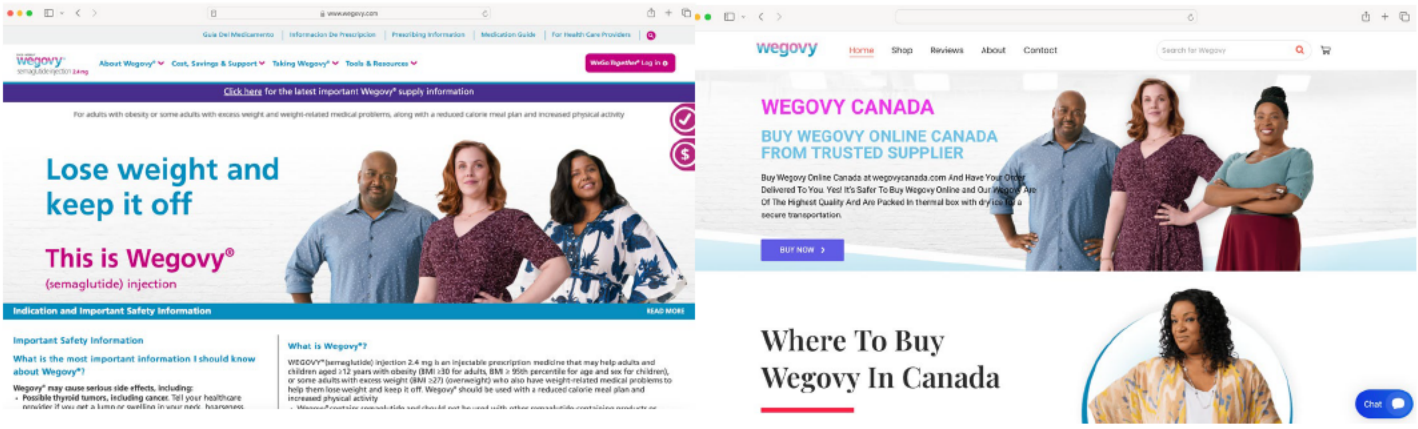


FIGURE 2: Manufacturer's website (left) versus an illegal online pharmacy (right).

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.

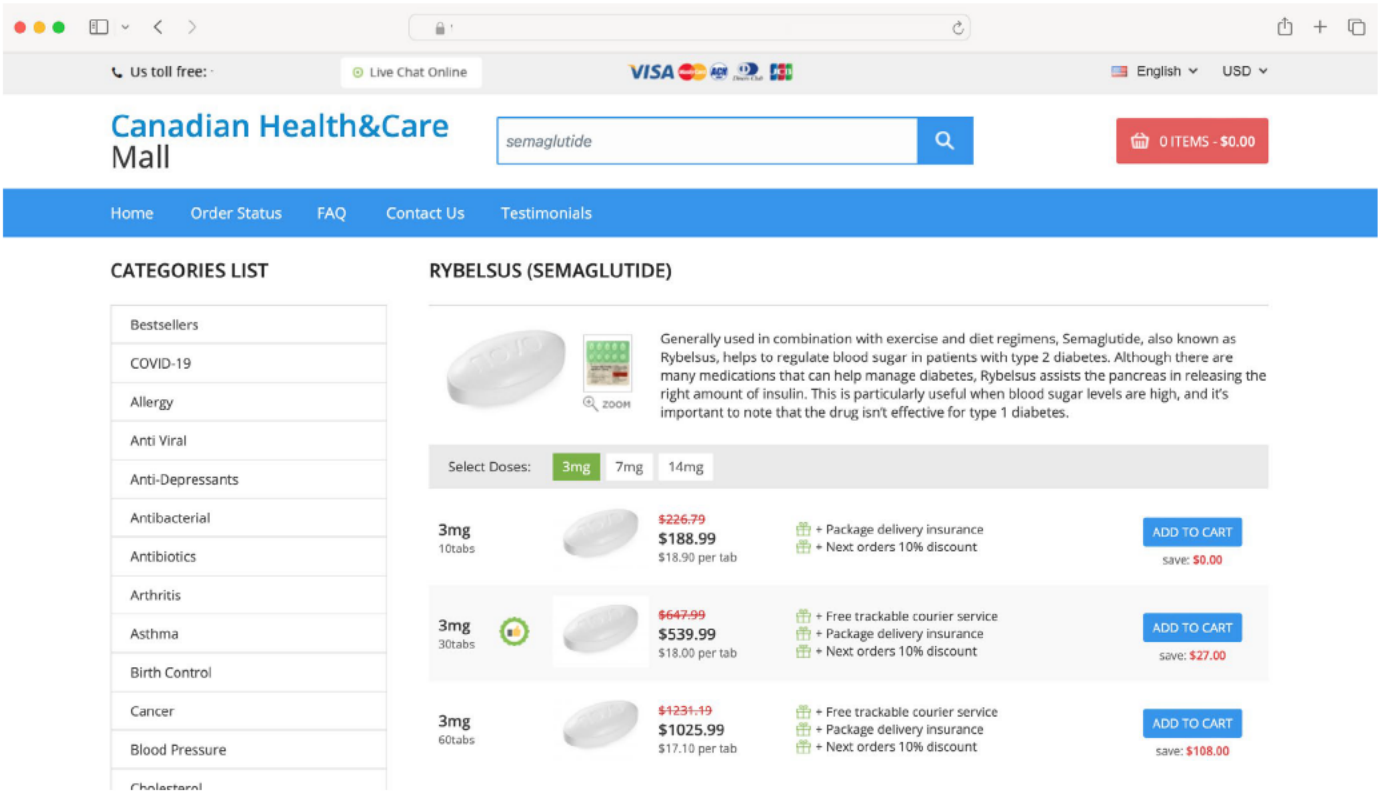


FIGURE 3: Website belonging to a large rogue internet pharmacy network that sells oral semaglutide.

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]

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.

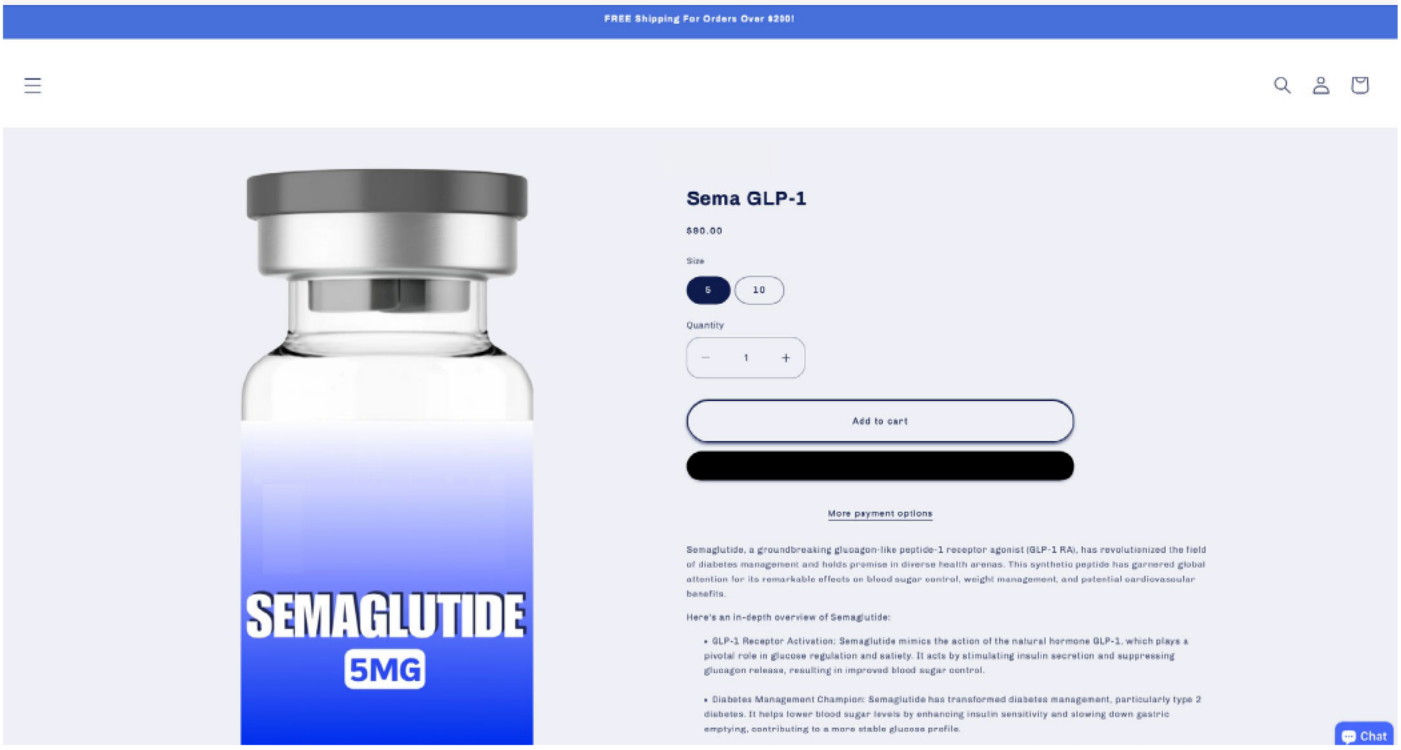


FIGURE 4: "Sema GLP-1" is advertised on a peptide website.

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."

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]

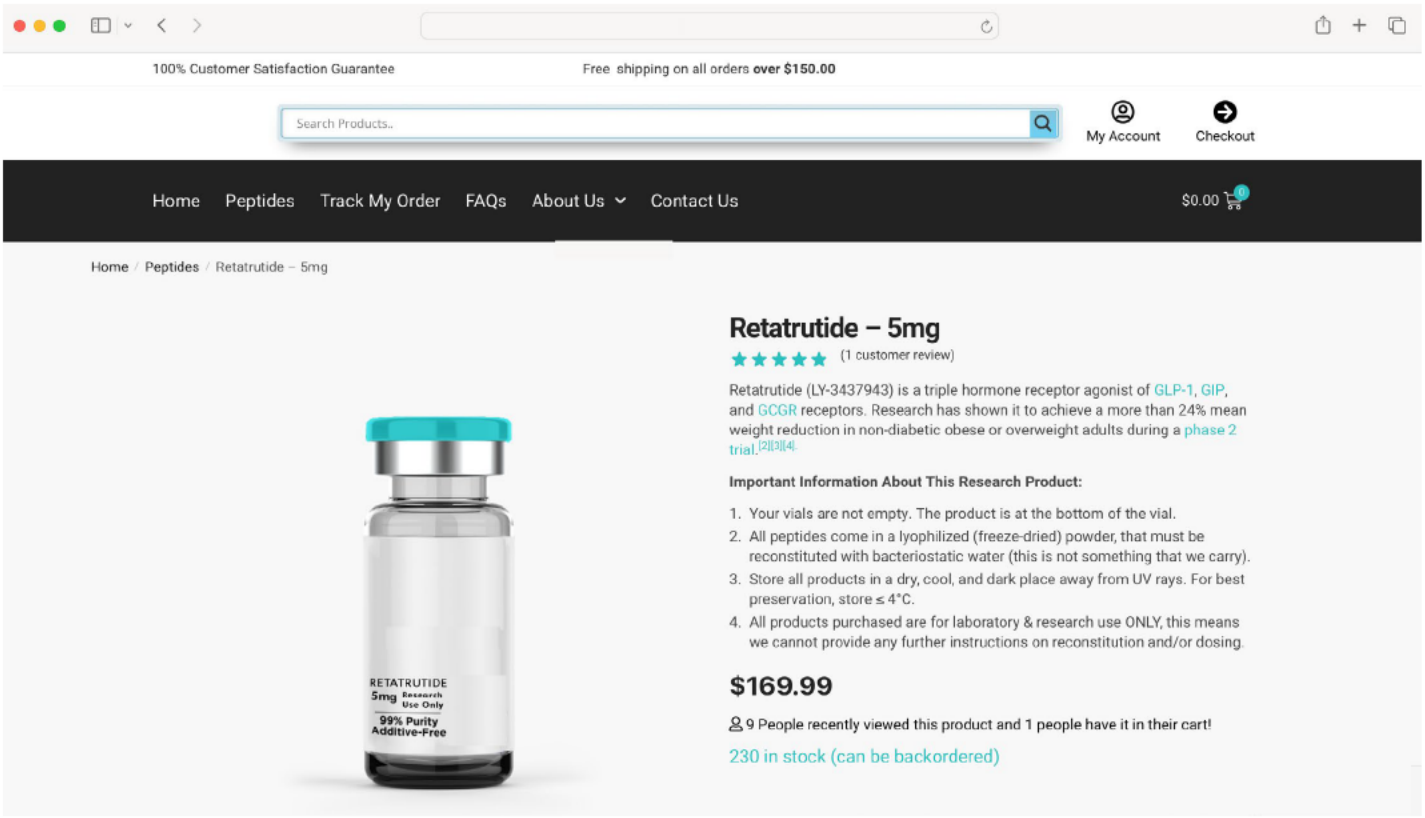


FIGURE 5: A peptide website is marketing retatrutide, an investigational new drug.

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).

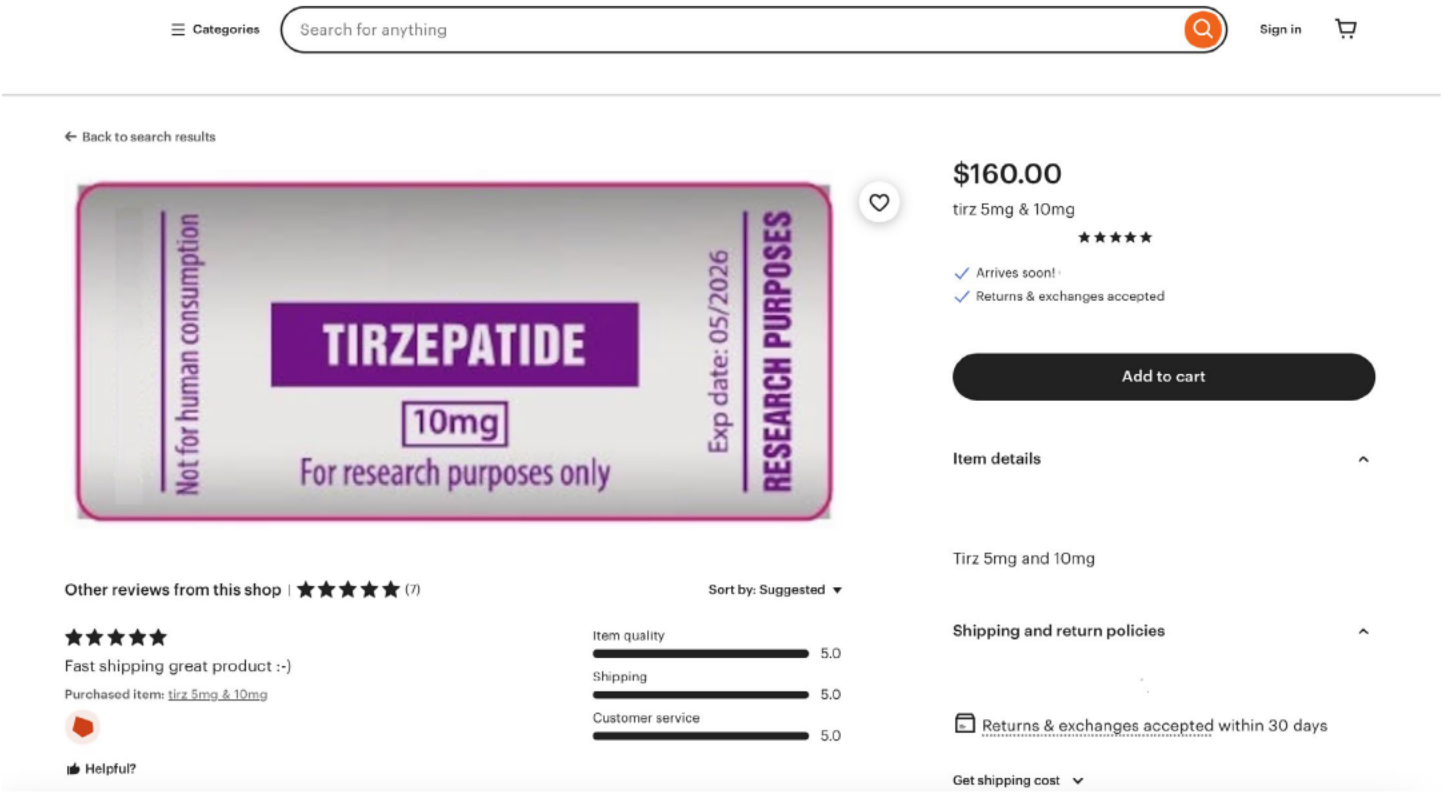


FIGURE 6: Tirzepatide is marketed on an online marketplace as "Tirz."

S e m a g l u t i d e Weight Loss - $125

For sale 3 bottles of S e m a g l u t i d e (active ingredient in W a g o v y & O z e m p i c

Each 2 ML vial contains 2.5-2.5 MG/ML

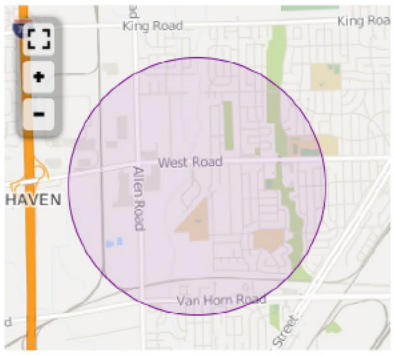
$125 a vile or $300

Will send pics of product to email. It has been stored appropriately as recommended.

Semaglutide Description
Semaglutide is an effective, FDA-approved weight loss therapy. Medical studies show significant weight loss when Semaglutide is combined with a healthy diet and exercise. Semaglutide is also used to treat type 2 diabetes.

Semaglutide mimics the effects of glucagon-like peptide-1 (GLP-1). GLP-1 is released after eating, and it helps control blood sugar by increasing the production of insulin while suppressing the production of glucagon. By functioning in a similar way, Semaglutide positively impacts blood sugar levels and the metabolism.

Studies suggest Semaglutide can also suppress the appetite by slowing down the digestive process, so patients feel more full.



condition: **new**

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

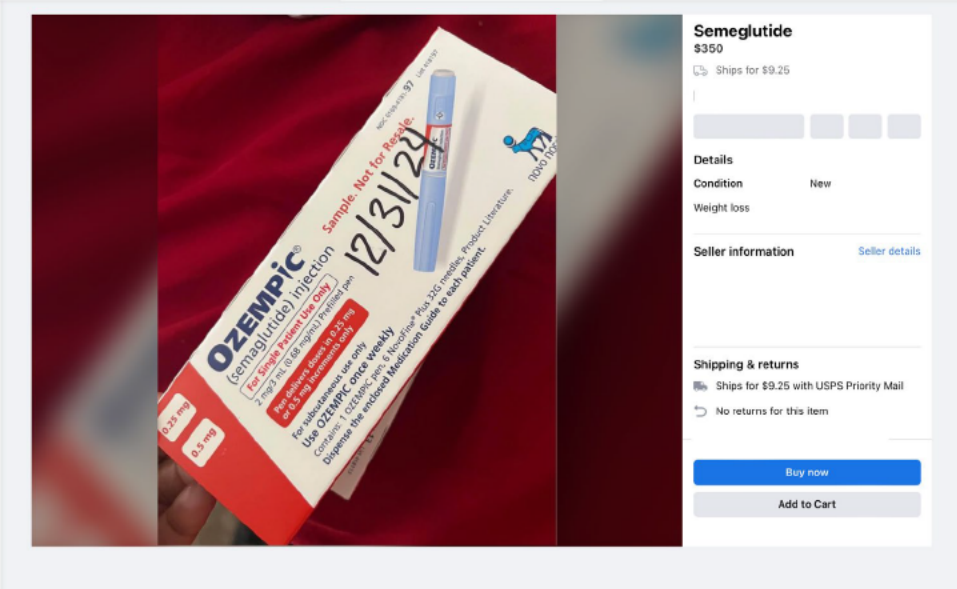


FIGURE 8: Semaglutide is misspelled, possibly to avoid detection by automated compliance solutions.

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

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.

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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

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[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, ALM, MHA, RPh

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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.

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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

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.

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

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.