Testimony of Stephen Colvill, MBA
Assistant Research Director and ReVAMP Drug Supply Chain Consortium Lead
Duke-Margolis Institute for Health Policy

Presented before the
United States Senate Special Committee on Aging
Hearing on:
"Truth in Labeling: Americans Deserve to Know Where Their Drugs Come From"
January 29, 2026

Summary of Testimony

Pharmaceutical Supply Chain Problem Areas

- **Clearly defining the distinct, yet overlapping, pharmaceutical supply chain problem areas is critical.** Different solutions are needed to address each area.

    - Problem Area 1: Chronic drug shortages
    - Problem Area 2: Questions around pharmaceutical quality assurance
    - Problem Area 3: Geopolitical and national health security risks
    - Problem Area 4: A desire to grow the economy through domestic manufacturing

- **My testimony focuses on the solutions needed to address chronic drug shortages**, which most frequently impact generic sterile injectable drugs that are usually administered by health care providers such as in a hospital setting.
- **Chronic drug shortages are caused by a race-to-the-bottom for critical generics.** Health care provider payment systems, which are set by CMS and private payers, encourage health care providers to seek the lowest short-term cost for generics without adequate consideration for reliable availability.

Potential Solutions

- **I propose an alternative to the race-to-the-bottom for critical generics: policymakers can adjust CMS payment policy to better align market incentives towards reliable availability, rather than focusing too much on lowest cost.**
    - Building on a 2024 bipartisan Senate Finance Committee Discussion Draft, I propose a Medicare incentive payment program that would reward health care providers when they 1) purchase through committed contracting models and 2) identify and purchase drugs that meet reliability or resiliency benchmarks. Costs from such a program would likely equate to <0.1% of total U.S. drug spending.
- **I also propose other steps that Congress could take to create more resilient and secure drug supply chains.** Congress could utilize CMS payment policy and other incentives to bolster domestic manufacturing, and Congress could support international collaboration efforts with trusted partner countries.
- **Lastly, regarding pharmaceutical labeling reforms, I outline potential positive and negative impacts and offer two important considerations:**
    - “Place of business” is likely not the best term to use when specifying what location(s) are required to be listed in pharmaceutical labeling information.
    - Legislation could require manufacturers to include unique facility identifiers for both the original API manufacturer and original finished drug product manufacturer in their digital SPL labeling information (not the physical labels).

Full Testimony

Introduction and Background

Thank you Chairman Scott, Ranking Member Gillibrand, and distinguished members of the Committee for holding this critical hearing on medicine supply chain challenges that directly impact millions of Americans, particularly seniors.

My name is Stephen Colvill, and I am Assistant Research Director at the Duke-Margolis Institute for Health Policy, where I lead the ReVAMP Drug Supply Chain Consortium. I also serve on the board of the End Drug Shortages Alliance and as a volunteer advisor for Angels for Change.

Throughout my career, I have seen the drug supply chain from many different angles. I worked at one of the largest drug manufacturing plants in the U.S. and then worked my way up the commercial business side of one of the largest generic injectable drug manufacturers in the U.S. In 2019, I co-founded RISCS, a nonprofit drug supply chain rating and certification organization with a mission to prevent drug shortages. At RISCS, I worked with health systems, group purchasing organizations, and others to help them identify reliable manufacturers of critical generic injectable drugs. I then moved to the policy side, where I have served both in the government as senior policy advisor for medical supply chains in the White House Domestic Policy Council and outside the government in my current role.

Throughout these experiences, I have witnessed drug shortages frequently inhibit patient access to life-saving and life-sustaining medications and leave health care providers unable to provide the highest level of care. As a result, one takeaway has become obvious: we need to ReVAMP how our drug supply chain works.

At Duke-Margolis, our ReVAMP Consortium brings together supply chain experts from manufacturers, group purchasing organizations, wholesalers, health systems, patient advocacy organizations, and elsewhere to develop and implement policy solutions to drug supply chain challenges, with a focus on reducing the frequency and severity of chronic drug shortages. The four tenets of the ReVAMP Consortium are: a **Re**liable Drug Supply, **V**aluing Availability, **A**dvanced **M**anufacturing Technologies, and a **P**atient-Centered Focus.

This testimony reflects my own recommendations, analysis, and perspective. As part of Duke University, Duke-Margolis honors the tradition of academic independence on the part of its faculty, researchers, and scholars. This testimony may not represent the opinions of every ReVAMP Consortium member and is not intended to limit the ability of ReVAMP Consortium members to provide their own perspective on behalf of their independent organizations.

Defining the Problems

In efforts related to pharmaceutical supply chains, policymakers seek to address distinct, yet overlapping, problems. Clearly defining the four problem areas below is critical, as different policy steps are needed to address each area.

1) Chronic drug shortages

Severe, chronic shortages of critical generic drugs in recent decades are associated with higher mortality rates, medication errors, delays in life-saving treatment, and significant financial costs to the health care system. These chronic drug shortages have most frequently impacted inexpensive and older generic drugs, particularly generic sterile injectable drugs that are usually administered by health care providers such as in a hospital setting. Supply chain disruptions, such as from manufacturing delays, product discontinuations, and natural disasters, too frequently result in drug shortages that impact patient care. Supply chain reliability[1], which can be built and sustained through investments in modernized manufacturing infrastructure and quality culture, redundancies, buffer stocks, strong risk management plans, and other steps, is lacking for many critical generic drugs.

2) Questions around pharmaceutical quality assurance

Pharmaceutical supply chain stakeholders frequently raise questions around pharmaceutical quality assurance. In this problem area, the relevant drug is available to patients, but questions exist around whether the drug is consistently produced in accordance with Current Good Manufacturing Practices (CGMP), whether the drug is consistently produced to appropriate specifications, whether the drug might contain dangerous contaminants or defects, and/or whether the drug consistently underwent adequate quality control testing prior to each batch's release into the supply chain. These questions around pharmaceutical quality assurance are a distinct issue from chronic drug shortages. In this problem area, the relevant drug is available to patients. However, during a shortage, the relevant drug is not available (to some or all patients).

3) Geopolitical and national health security risks

The medicines that Americans rely on every day are often products of complex global supply chains. While global supply chains create efficiencies through economies of scale and increase access to global expertise and capabilities, they also create vulnerabilities to

[1] This testimony frequently refers to "supply chain reliability" (strong routine performance), but "supply chain resilience" (bouncing back from unexpected shocks) and "supply chain robustness" (withstanding unexpected shocks) are also important.

geopolitical conflict, challenges with regulatory oversight in some countries, and other risks. Some areas of foreign dependence that may represent particularly high risks include certain categories of API (for example, certain antibiotics) for which production is concentrated in China, key starting material production that is concentrated in China, and finished dosage form production for solid oral drugs that is concentrated in India. Notably, while pharmaceutical export restrictions imposed by foreign governments have been rare and have not been a major contributing factor to past shortages, foreign dependence certainly poses a risk for future shortages and other supply chain issues.

4) **A desire to grow the economy and create high-paying jobs through domestic manufacturing**

Domestic manufacturing can create high-paying jobs in the U.S., develop a skilled U.S. workforce, and potentially help to increase U.S. Gross Domestic Product.

As a nation, we obviously need to address all four of these areas. At the ReVAMP Consortium, we focus primarily on policy solutions to address chronic drug shortages. The American Society of Health-System Pharmacists has listed over 3,000 drug shortages[2] since 2001. Over one hundred studies over the past several decades have clearly documented the negative impacts to health and patient care that result from chronic drug shortages. In one example, the societal cost from hundreds of excess deaths associated with a prior shortage of norepinephrine, a drug used to treat septic shock, was estimated at over $13 billion.

Without substantive policy changes to address root causes, chronic drug shortages will likely persist. Effective solutions to chronic drug shortages would likely also have positive effects on the other problems listed above.

The Race to the Bottom

Generic drug prices are on average about 33% lower in the U.S. than in other high-income countries. In 2024, the average price of an injectable drug in shortage was $9, while the average cost of an injectable drug not in shortage was $118. The U.S. market for already-inexpensive generic drugs, which make up a small fraction of U.S. drug spending, often emphasizes achieving the lowest price at a point in time over ensuring reliable drug availability over time. While limiting costs is important, low-cost generic drugs do not benefit patients if they are not available.

[2] Many drugs have reoccurred multiple times on the ASHP drug shortage list, and those drugs are counted multiple times in this figure.

Health care providers, and the group purchasing organizations (GPOs) that contract for and wholesalers that distribute drugs on their behalf, usually have a choice of several manufacturers from which they can source a given generic drug. These generic manufacturers vary in their pricing and their ability to supply the drug reliably over time. However, the Centers for Medicare and Medicaid Services (CMS) through Medicare Part A and Part B[3], and many private payers, generally pay the same amount to providers regardless of which generic manufacturer is chosen. This payment system creates strong price competition but does not create an incentive for providers to select more reliable manufacturers.

Health care providers care deeply about providing quality care to their patients. They also are rational economic actors that often operate in challenging financial environments with significant economic constraints. Health care providers have some financial incentives to prevent shortages, but these financial incentives are limited and uncertain. For example, providers experience some increased costs from shortages, such as costs from additional labor spend[4], longer patient stay times, and negative impacts to health care quality incentive payment programs. Providers may also experience decreased revenue if shortages lead to reduced patient volumes. However, shortages sometimes impact patient care without having a significant impact on provider costs or revenue. For example, a patient who received a suboptimal therapy due to a shortage may experience complications that are not identified or apparent in the short-term, and health care quality incentive payment programs may not fully internalize some patient impacts from shortages. Patients bear the brunt of the impact of many shortages in the form of worse health outcomes.

Because the financial impacts on providers from shortages are limited and uncertain, the demand signal for reliability transmitted from many providers to others upstream – such as GPOs, wholesalers, and manufacturers – is weak and ambiguous. The result is a race-to-the-bottom for many generic drugs: manufacturers compete intensely on price but too frequently do not supply reliably and consistently.

While the totality of financial and patient care impacts from shortages is uncertain and very challenging to measure, it is clear that current market incentives driven by the current drug

[3] In Medicare Part A, providers receive Diagnosis Related Group (DRG) payments that include a set rate for cases based on the patient's diagnosis. In Medicare Part B, providers receive a payment based on the drug's Average Sales Price (ASP), which is a blended rate across all generic suppliers of the particular drug.
[4] The average cost to U.S. hospitals from the additional labor spend needed to manage drug shortages has been estimated at $900 million per year ($150,000/hospital/year). This is small compared to the societal cost from hundreds of excess deaths associated with one prior shortage of norepinephrine, a drug used to treat septic shock, which has been estimated at over $13 billion.

reimbursement and provider payment structure have not been sufficient to address the chronic drug shortage crisis.

An Alternative: Aligning Incentives Towards Reliable Availability

Drug shortages are not inevitable. Policymakers can shift the market to focus more on ensuring a reliable supply of generic drugs, while keeping costs low. CMS payment policy is the most appropriate and influential tool that policymakers can use to accomplish this aim.

Addressing chronic drug shortages is clearly aligned with CMS' mission to improve the health outcomes of CMS beneficiaries. CMS, as the primary source of revenue for many U.S. hospitals, is well-positioned to meaningfully change market incentives. CMS influence is particularly pronounced in the inpatient setting – in 2023, Medicare accounted for 48% of all inpatient days in the U.S., and Medicaid accounted for another 26%.

Recognizing the need for CMS to play a central role in addressing drug shortages, the Senate Finance Committee released a bipartisan Discussion Draft in 2024 that proposed a Medicare Drug Shortage Prevention and Mitigation incentive payment program designed to combat shortages of critical generic drugs. Importantly, participation in this Program would be entirely voluntary, and providers could choose not to participate or to participate for only a subset of their purchases.

Building on the Senate Finance Committee proposal, we at Duke-Margolis recently published a white paper on "Addressing the Root Causes of Drug Shortages: Next Steps for Congress". In this white paper, we propose a simplified version of the Medicare Drug Shortage Prevention and Mitigation incentive payment program that would reward health care providers when they 1) purchase through committed contracting models and 2) identify and purchase drugs that meet reliability or resiliency benchmarks.

1) Purchase through committed contracting models

In recent years, some health care providers have begun entering into new committed contracting models, such as through Civica Rx or other similar programs. These committed contracting models are designed to offer greater assurance of demand for manufacturers and assurance of supply for providers. The committed nature of these models creates a greater incentive for purchasers to vet suppliers and for manufacturers to ensure reliable delivery of products over time. However, while such committed contracting models have demonstrated some success, they currently represent a small share of generic drug contracts in the U.S., and drug shortages persist as many resource-constrained providers continue to seek out the lowest cost short term suppliers. Our proposed Medicare Drug

Shortage Prevention and Mitigation Program would incentivize health care providers to more frequently purchase their generic drugs through committed contracting models.

2) Identify and purchase drugs that meet reliability or resiliency benchmarks

Our proposal also would tie Medicare Drug Shortage Prevention and Mitigation Program incentive payments to purchases of drugs that meet reliability or resiliency benchmarks. The first step in accomplishing this is assessing which manufacturers and drugs actually have reliable supply chains. To that end, we propose that Congress should direct CMS, in collaboration with other relevant HHS operating divisions, to authorize one or multiple drug supply chain reliability (DSCR) benchmarking programs for this purpose. To qualify for our proposed Medicare incentive program payments, providers would need to buy products that have been evaluated through at least one of the CMS-authorized benchmarking programs. At the outset, qualification for these incentive payments could be binary (either the product was evaluated or it was not). As the accuracy and utility of benchmarking programs are assessed and potentially verified over time, CMS could adjust the incentive payments to provide higher payment amounts for products that are deemed more reliable through the benchmarking programs.

Three prominent examples of such benchmarking programs include the Healthcare Industry Resilience Collaborative's resiliency badging program, US Pharmacopeia's resiliency benchmarking program, and FDA's Quality Management Maturity program. Uptake of approaches such as these has thus far been limited, especially among generic injectable drug manufacturers and products, but could be significantly increased through government funding and support.

The proposed Medicare Drug Shortage Prevention and Mitigation Program would be a logical extension of other Medicare quality and safety measures that are adequately reflected in Medicare provider payments today. After the incentive payments are incorporated in baseline purchasing prices in the future, the payments could potentially be discontinued – similar to Medicare payments for important new technologies or previously for electronic heath record adoption.

The Potential Cost of a Medicare Drug Shortage Prevention and Mitigation Program

Health care providers spend about $15 billion per year on physician-administered generic sterile injectable (GSI) drugs. Assuming a 20% bonus incentive payment (based on Average Sales Price) and inclusion of all GSI drugs, the proposed Medicare Drug Shortage Prevention and Mitigation Program could cost less than $3 billion per year.

If targeted towards the top 50 most essential GSIs[5], the proposed Medicare Drug Shortage Prevention and Mitigation Program would likely cost **less than $1 billion per year[6].**

Because not all purchases would qualify for the incentive, program costs would likely be well under $1 billion per year. Costs to administer the program would need to be considered as well but could be negligible. $1 billion in incremental spending is equal to ~0.1% of total annual drug spending in the U.S.

Other Potential Reforms

Supporting Domestic Pharmaceutical Manufacturing

A critical and bipartisan priority, bolstering domestic pharmaceutical manufacturing capabilities can help to reduce geopolitical and national health security risks, ensure a sustained industrial base for emergency events, reduce regulatory oversight challenges, increase economic growth, create jobs, and more. While increased domestic manufacturing could have positive spillover effects in reducing chronic drug shortages, other steps described above are likely more well-targeted to address the misaligned economic incentives driving chronic drug shortages. Some of the most significant past drug shortages have resulted from manufacturing issues in U.S. plants.

The drugs for which increased domestic manufacturing would be the most beneficial are not necessarily the same drugs that pose chronic drug shortage risks. For example, while increasing domestic manufacturing for some innovative branded drugs may be beneficial for sensitive intellectual property and economic impact reasons, innovative branded drugs are historically unlikely to experience shortages. On the other hand, IV fluids have been notoriously prone to shortage, both due to hurricanes and other issues. However, IV fluids are largely already produced in the U.S. and thus likely do not need domestic manufacturing support.

To bolster domestic drug manufacturing, policymakers need to prioritize the most important drugs for onshoring and then create incentives for purchasers to select domestically-made versions of those drugs. As described previously, Medicare and Medicaid together account for ~75% of all inpatient days in the U.S. Congress could partner with CMS to incentivize purchasers to source from domestic manufacturers of critical medical supplies such as personal protective equipment and essential medicines. For example, CMS could revise their existing Domestic N95 Respirator Payment Adjustment policy, including by expanding the policy to essential medicines. While the existing policy

[5] The ASPR Downselected Essential Medicines Needed for Acute Patient Care List includes 66 essential generic sterile injectable drugs.
[6] Author's analysis.

has had limited uptake thus far, Duke-Margolis recently released three recommendations that could significantly increase uptake: simplify the reimbursement and reporting methodology, expand to other product types (including essential medicines), and publish a list of eligible domestically-made products. Congress could also direct CMMI to pilot various approaches to preference domestically-made drugs as proposed in the American Made Pharmaceuticals Act.

Although direct federal procurement accounts for less than 10% of the total pharmaceutical market, creating a federal buyer's market that prioritizes domestically-made drugs would be another important step. While maintaining preference for drugs sourced from Trade Agreements Act (TAA) compliant countries over non-TAA compliant countries is important, Congress could prioritize preference for drugs that meet Buy American Act requirements over any foreign-made drugs from TAA compliant and non-TAA compliant countries. Legislation could also close the "Acetris loophole" by directing revision of the Federal Acquisition Regulation definition such that country-of-origin would be determined only by where a drug is "substantially transformed" rather than where a drug is "manufactured". This would refocus country-of-origin determinations for the purposes of direct federal procurement on the most important production step.

International Collaboration

Collaboration with trusted international partners (with important safeguards in place for national security and emergency preparedness) should be a critical complement to onshoring efforts. Duke-Margolis recently published a white paper on "Building a Resilient and Secure Pharmaceutical Supply Chain: The Role of International Collaboration" that proposes how the U.S. should prioritize international regulatory harmonization and international economic partnerships to effectively and cost-efficiently secure our pharmaceutical supply chain. International regulatory harmonization can create efficiencies and reduce barriers to sourcing from trusted sources, which can reduce risks associated with concentrated production in more adversarial countries. International economic partnerships, such as through the Bio-5 Consortium model, can also reduce these risks through purchase commitments and coordination among partner countries. For example, if one partner country is specializing in building resilient alternate sources of antibiotics, another could specialize in a different product class, such as oncology drugs, rather than duplicating efforts. Rather than taking an antagonistic approach towards allied countries, the U.S. should focus on these kinds of international collaboration efforts.

Pharmaceutical Labeling Reform

Pharmaceutical labeling reforms, if effectively designed, could have a positive, yet limited, impact. Americans deserve to know where their drugs come from, and better availability of information about manufacturing locations of drugs might, over time, cause more drugs to be sourced domestically. However, for provider-administered drugs, impacts of labeling reforms are likely to be limited, as many decision makers already know where API and finished drug products are made or can acquire this information if desired. For retail drugs, impacts of labeling reforms are also likely to be limited, as patients have minimal influence over what drugs the retail pharmacies and retail GPOs decide to stock.

The Committee should carefully weigh any negative consequences that may arise from labeling reforms and consider how to mitigate them. Just because a drug is made in the U.S. does not necessarily mean that it is the best choice – some of the most significant past shortages have resulted from manufacturing issues in U.S. plants. Site location alone is not necessarily indicative of reliability or quality. Other assessments of reliability and quality, such as through the benchmarking programs described previously, are also needed. Pharmaceutical labels also may illuminate certain stages of production while obscuring other risks, such as from upstream key starting material (KSM) dependencies. KSM mapping and vulnerability assessment exercises will remain critical. The Committee should also consider that any labeling reforms may impact the information that is ultimately available to institutional buyers, health care providers, and patients in different ways. Other potential negative consequences include increased regulatory burden, potential impacts to patient medication adherence, and potentially more easily enabling bad actors to identify potential targets[7].

As the Committee considers potential pharmaceutical labeling reforms, I offer two additional specific considerations:

- **"Place of business" is likely not the best term to use when specifying what location(s) are required to be listed in pharmaceutical labeling information.** Current labeling requirements in the Federal Food, Drug, and Cosmetic Act dictate that a drug label must include the name and "place of business" of the manufacturer, packer, or distributor. Requiring only the "place of business" of a manufacturer to be listed on a label enables the actual location of manufacturing to be obscured. For example, the "place of business" listed on a drug label may be a company's U.S. corporate headquarters, while that drug's manufacturing facility might be in a foreign location. If any new requirements only require a "place of business" to be listed, those new requirements may result in limited to no additional transparency.

- **Legislation could require manufacturers to include unique facility identifiers, such as the FDA Establishment Identifier (FEI) number or the DUNS number, for both the original API manufacturer and original finished drug product manufacturer in their labeling information[7],** as FDA requested in the prior Administration's legislative proposals and again in the current Administration's FY26 legislative proposals. Requiring unique facility identifiers only in digital Structured Product Labeling (SPL) metadata, and not on the physical labels, could eliminate the complexities that would arise from the updating of physical labels and product inserts whenever a manufacturing location changes or is added, while still enabling online public access to data that for the first time could be easily used to connect National Drug Codes with unique manufacturing facilities.

As mentioned previously, the most critical step that is needed, both in the provider-administered and retail drug settings, is to implement financial incentives for pharmacies and other purchasers to select more reliable and/or domestic suppliers.

Conclusion

I encourage the Committee to prioritize financial incentive reforms that can meaningfully address the various drug supply chain challenges we face, particularly by partnering with the Senate Finance Committee on Medicare payment reforms to address chronic drug shortages. I also encourage the Committee to prioritize international collaboration opportunities and to consider incentives that would encourage drug purchasers to select domestically-made drugs. The Committee should carefully think through important considerations around pharmaceutical labeling reforms to ensure positive impact and mitigate any negative consequences. Absent new incentives to encourage pharmacies and other purchasers to select reliable and/or domestic manufacturers, any positive impacts from pharmaceutical labeling reforms are likely to be limited.

Thank you to the Committee for holding this hearing on this critical topic and for inviting me to testify. I look forward to your questions.

[7] The Committee could consider whether FDA should be provided with the authority to exempt some drugs from a requirement to disclose unique facility identifiers if there is a compelling safety or national security reason to do so, such as for some controlled substances.