United States Senate Special Committee on Aging

Prescription for Trouble:

Drug Safety, Supply Chains, and the Risk to Aging Americans

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Good morning, Chairman Scott, Ranking Member Gillibrand, and Members of the Committee:

My name is Tony Sardella, and I serve as the founder and chairman of the API Innovation Center, a non-profit, public benefit corporation in St. Louis; API refers to active pharmaceutical ingredient, the component of medicine that makes it effective. I am also a distinguished fellow of health innovation at the Olin Business School at Washington University in St. Louis Olin Business School focused on research related to the business of health.

I am honored to be here this afternoon to share information about the work we are doing at the API Innovation Center, and how the work could be transformational in helping solve a major challenge facing our country—a vulnerable generic pharmaceutical supply chain that threatens our health security.

There are three key messages I wish to share with you today.

First, the U.S. generic drug supply chain is over-reliant on foreign sources to meet our nations' needs, placing our seniors, veterans and American citizens at risk. This over-reliance, driven by the economics of drug manufacturing, has created a fragile supply chain that leaves us vulnerable to disruption.

Second, the API Innovation Center is testing a private-public partnership model that shows promise in addressing the economic root causes that fostered this dependency. By leveraging existing idle U.S. Food and Drug Administration (FDA)-approved manufacturing capacity, APIIC is expediting U.S.-based production and supply.

Third, there are several areas of policy that can drive increased U.S. based production and investments to address our overreliance and vulnerabilities to geopolitical risks and enhance U.S. health security, where health security refers to both our national security and ensuring patient access to important medicines.

U.S. Generic Drug Supply Overreliance

Our overreliance on foreign manufacturers presents a national health security risk by leaving us highly dependent on foreign adversaries for our medicine supply, creating geopolitical vulnerabilities.

In 2019, the FDA testified that only 28 percent of the API manufacturing facilities serving the U.S. market are domestic, leaving 72 percent located overseas.[1]

My 2021 research at Washington University in St. Louis' Olin Business School— which was referenced during the last hearing on the pharmaceutical supply chain— highlighted the severity of our dependency. **83 of the top 100** generic drugs lack a U.S.-based source for their active pharmaceutical

[1] U.S. Food and Drug Administration Testimony (October 2019) - Safeguarding Pharmaceutical Supply Chains in a Global Economy: https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019.

ingredients (APIs), the critical component of a drug that provides its therapeutic effect, with 91% of all prescriptions in the U.S. being generic medicines.[2]

This year, we conducted a study focused on 40 critical medicines, that we deem the "Vital 40," that are clinically essential, frequently in shortage and have a high impact for public health and national security. Where data was available, our findings determined nearly half of the key starter materials (47%) for the vital are ***only*** sourced from China representing a single point of failure in our nations supply chain. This level of concentration creates a significant vulnerability in our national medicine supply chain.

Recently, we assessed generic medicines through the lens of those prescribed specifically to the elderly and veterans. Our analysis of the top 10 medicines most relied upon by veterans and seniors highlights a significant dependence:

- 95% of APIs are manufactured overseas.
- 84% of drug products are made abroad.
- Our dependency is concentrated in India and China which provide nearly half of our drug products and almost two-thirds of APIs.

Three of the top ten medicines for veterans and seniors are currently in shortage which include two heart failure drugs (metoprolol, losartan) and albuterol used in inhalers for asthma.

Our analysis further focused on urgent and emergent medicines that are necessary for immediate treatment in unforeseen medical situations. These medications are part of the U.S. Department of Veteran Affairs (VA) Urgent-Emergent Formulary, which allows veterans to access medications quickly at community-based pharmacies participating in the VA's Community Care Network.

The result for veterans reveals a similar severe foreign dependence and vulnerability:

- 94% of APIs are manufactured overseas.
- 83% of drug products are made abroad.

While many supply chains are global in nature and source from foreign manufacturers, there is a significant distinction relative to generic medicines. Many of the global supply chains provide low-cost products for items that drive convenience. However, access to critical medicines is an issue of survivability.

[2] U.S. Food and Drug Administration - Office of Generic Drugs 2022 Annual Report: https://www.fda.gov/media/165435/download?attachment.

The implications of this overdependence and a fragile geo-concentration of foreign suppliers include:

- Placing veterans' access to life-saving therapies at risk whenever global supply chains are disrupted.

- Making our supply vulnerable to geopolitical events such as when foreign suppliers are restricted from exporting product, as the Government of India did during COVID to ensure supply for their citizens.

- Creating price volatility with sharp and repeated price swings in cost, affordability crises and delayed access to treatment.

Examples of price volatility based on soon to be released APIIC research, include:

- **Atorvastatin:** *instability* — Prices reversed 44 times, with a spike in Q1-Q2 2022 after Dr. Reddy's Laboratories (India) recalled multiple lots for out-of-spec impurities and degradation. In Q1–Q2 2023, Accord Healthcare Inc. (sourcing from Intas Pharmaceuticals Limited, India) recalled atorvastatin and other products following an FDA Form 483 citing serious quality deficiencies. These disruptions removed significant supply and drove +40% price surges. The U.S. relies on 48 drug product suppliers for atorvastatin, but only three are domestic; of 36 API suppliers, just one is U.S.-based. The vast majority of atorvastatin supply is therefore exposed to foreign shocks.

- **Losartan:** *stress* — An approximately 60 percent price increase over months was triggered when the NMBA nitrosamine impurity was found in Hetero Labs' (India) API in 2019, sparking cascading recalls across U.S. distributors including Camber, Torrent, Teva, and Avet. With sourcing alternatives limited, Avet and Torrent discontinued losartan tablets in 2021, driving prices higher. Compounding the crisis, a nationwide "power crunch" in China shut down key chemical parks that supply ARB intermediates, leaving the U.S. market exposed and driving another sharp price spike and a shortage of all losartan from 2019-2022, with losartan and hydrochlorothiazide tablet combination still in shortage to this day. The U.S. has 37 drug product suppliers for losartan (only three are domestic) and 39 API suppliers (only four are domestic), showing again how vulnerable the market is to disruptions abroad.

- **Omeprazole:** *fluctuations* — Prices climbed steadily through 2023 as Red Sea shipping disruptions from attacks on commercial vessels extended transit times, while API costs rose in China under stricter energy and environmental rules. U.S. firms over-purchased to secure supply, but by mid-2024 this led to oversupply and weak demand, triggering a price crash, with the price halving over three months. As inventories ran down, the need to restock ahead of the Chinese Lunar New Year factory shutdowns and continued logistic bottlenecks caused prices to rebound in late 2024 with prices rising back up approximately 50 percent in December 2024. The U.S. has 27 drug product suppliers for omeprazole (five are domestic) and 37 API suppliers, none of which are U.S.-based. For omeprazole, the U.S. is entirely dependent on foreign API sources.

These cases underscore how the U.S. medicine supply is highly vulnerable to external shocks- whether it is quality-related recalls in India, disruptions from attacks on commercial vessels in the Red Sea, or China's fluctuating production capacity of key starting materials (KSMs) and Intermediates. Our nation's access to essential drugs is effectively at the mercy of foreign events beyond our control. **By investing in strong U.S. pharmaceutical manufacturing capacity, we can build a supply chain that is stable, safe, and resilient—ensuring that veterans, seniors and all patients have reliable access to the medicines they depend on.**

Further, public-private partnerships present a viable path forward.

The API Innovation Center Approach

The API Innovation Center represents a novel private-public partnership approach that is showing promise to address the two critical priorities cited by Administration for Strategic Preparedness and Response (ASPR)'s Essential Medicines Supply Chain & Manufacturing Resilience Assessment:[3]

1. Greater collaboration across key players in the supply chain to de-risk production.

2. Investment in manufacturing technology to make domestic production competitive and cost-effective.

In addition, APIIC addresses an underlying root cause. Economic instability of U.S. generic manufacturing industry is a significant cause of our fragility and overreliance on foreign suppliers for our medicine.

In research published in April 2023,[4] which analyzed the economic stability of the top 20 Global Gx manufacturers supplying the U.S., I found:

- Continued generic price pressures are contributing to unsustainable industry economics and compromise supply.
    - Since 2016 there has been 50 percent price erosion, an average high-volume 30-count bottle of medicine is now less than $1.50, the equivalent of 5 cents per tablet, further accelerated by the market consolidation of the number of drug wholesalers and group purchasing organizations.

    - Manufacturers are vying for the business of fewer, more powerful buyers. With no distinguishing product differentiation, cost reduction trends continue year after year, in what has been referred to as the 'race to the bottom,' squeezing generic manufacturer's margins further, and further degrading the economic viability of the manufacturing supply base.

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[3] U.S. Department of Health and Human Services – Public Health Supply Chain and Industrial Base One-Year Report (February 2022): https://aspr.hhs.gov/MCM/IBx/2022Report/Documents/Public-Health-Supply-Chain-and-Industrial-Base%20One-Year-Report-Feb2022.pdf.

[4] US Generic Pharmaceutical Industry Economic Instability: https://apicenter.org/wp-content/uploads/2023/07/US-Generic-Pharmaceutical-Industry-Economic-Instability.pdf.

- Decreased earnings to fund capital expenditures creating bankruptcies, asset exits and consolidation and further reduced supply, with median return on capital of the top 24 generics manufacturers being five percent in 2022.

- A low return on invested capital decreased close out rates of FDA warning letters from 24 percent in 2018 to 4 percent in 2022. Without investment in modernizing facilities or upgrading manufacturing technology, it is more difficult for manufacturers to address FDA compliance concerns when raised. Often, manufacturers conclude that it is more economical to cease manufacturing in their U.S. sites than to make the necessary upgrades.

Moreover, foreign manufacturers — supported by direct government subsidies and strategic industrial policy — can engage in aggressive pricing practices that effectively drive U.S. producers out of the market.

Recently, India's Production Linked Incentives program offers up to 20 percent financial incentives through 2027.[5] Additionally, China has poured significant investments into biotechnology parks, infrastructure and R&D, giving their manufacturers structural cost advantages that U.S. firms have not matched.[6]

Ultimately, the analysis showed the root cause of the drug supply chain fragility is not logistics, but economics.

The mission of the API Innovation Center is to drive national health security and economic growth through U.S.-based production of medicines so that every citizen, health care system and pharmacy retailer has access to critical medications by addressing the economic factors that drove offshoring.

To address supply chain vulnerability, APIIC has established a novel approach called the Invest-Contract-Partner Model, or ICP Model™, that includes:

- First, **investing** public–private secured funding to modernize the production of generic medicines. The investment develops new synthetic chemical pathways and deploys the new pathways within advanced manufacturing technology at scale. The State of Missouri has appropriated more than $24 million for API development, and ASPR has awarded APIIC $14 million under the Defense Production Act Title III and its BioMaP-Consortium to develop six new routes of synthesis for APIs.

- Second, entering **contracts** with existing U.S.-based, FDA-approved facilities with idle capacity to produce APIs using the modernized pathways and new advanced manufacturing equipment, as demonstrated by APIIC. Their expertise and experience in drug production enables domestic API production to be brought online more quickly and efficiently than if a

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[5] Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of Bulk Drugs (Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs): https://pharmaceuticals.gov.in/schemes/production-linked-incentive-pli-scheme-promotion-domestic-manufacturing-critical-key.

[6] How Innovative Is China in Biotechnology?: https://itif.org/publications/2024/07/30/how-innovative-is-china-in-biotechnology/#_edn93.

new facility was to be constructed.

- Third, entering **partnerships** with both drug product manufacturers and major purchasers of drug products, such as health care systems and national pharmacy retailers who are willing to enter into long term agreements to ensure certainty of supply and cost for domestically produced medicines.

The collaboration across the supply chain enables an end-to-end solution to source, develop, manufacture and purchase cost-competitive U.S.-produced critical drugs. The partnerships address key supply chain issues and demonstrate the following key benefits:

- U.S.-based manufacturers gain certainty of demand, revenue and price for their investments, making the investment worthwhile and the returns clear for capital allocation and lending.

- Health systems and pharmacy retailers gain certainty and stability of supply and cost within a shortened timeframe of 5-7 years versus 10-12 years with construction of new facilities.

- A reduction in supply chain risk from geographic concentration and reliance on China and India, enabling a more resilient U.S. drug supply, and reducing costs from shortages.

- API manufacturers gain modernized and innovative methods and equipment such as equipment produced by Corning to produce APIs competitively in the United States.

Currently, we have six medicines in process at the API Innovation Center with a goal to bring manufacturing of 25 medicines to the U.S. by 2030 and over 300 in the next 10 years. We have in our system over 65 U.S.-based manufacturers of key starter chemicals, APIs and drug products that are prepared to initiate production leveraging new advanced manufacturing methods.

Case Study: Metoprolol

One of the examples of the ICP Model™ in action is our work to reshore metoprolol, a widely prescribed hypertension and heart disease medication and a medicine I mentioned earlier as relied upon by our veterans and seniors.

After receiving support from ASPR, coupled with funds received through the State of Missouri, APIIC allocated funds to develop a new, continuous flow route of synthesis at our labs at the University of Missouri–St. Louis. The process will then transition to a highly experienced manufacturer with available capacity, Mallinckrodt Pharmaceuticals, to scale up large scale production for our nation.

The modernization of the process enabled production steps that would take 24/hrs per step one minute per set allowing for dramatically improving output, speed, consistency, and quality — all without the cost of building new facilities.

Case Study: Lomustine

A second case involves reshoring a low-volume, high-need medicines, lomustine, a chemotherapy used to treat glioblastoma—an aggressive brain cancer that has recently taken the life of former Rep. Mia Love, and previously the life of Senator John McCain and Beau Biden, son of former President Joe Biden. In 2018, the lone company producing lomustine had increase the cost of drug by >1500% from $5 to $768 per capsule, since 2013.[7] This includes removing the product from Medicare coverage in 2021.[8] Today, the cost of lomustine is approximately $1,390 per 100mg capsule.[9]

Through our national consortium and support by the State of Missouri, APIIC funded the development of an innovative production method that allows our nation's entire yearly requirement for lomustine to be produced in two weeks. Together, with investment by a Missouri manufacturer with available capacity, we constructed a dedicated cancer drug suite to produce not only lomustine, but future cancer medicines as well.

Policy Considerations to Drive U.S.-Based Production and Investments

Lastly, and importantly, there are a range of policies approaches that could help address the economic challenges and obstacles facing U.S.-based manufacturers, while also encouraging greater investment in domestic production. As a non-profit, our mission is centered on national health security and the well-being of the American public, and as the government advances efforts to reshore, APIIC offers several considerations and would welcome the opportunity to discuss these pathways further in support of this shared goal.

Areas of opportunity including addressing current made-in-America language for medicines which reflect "assembled in America" and not "made-in-America."

Harmonizing conflicting definitions across the Trade Agreements Act, the *Acetris* ruling [10] and federal procurement language, is necessary to establish a clear, consistent definition of "substantial transformation" for pharmaceuticals to drive health security. The 2020 *Acetris* court decision created a loophole that allows products made with foreign APIs to be labeled as U.S.-made under federal procurement rules, undermining domestic sourcing initiatives.

The second opportunity includes placement of U.S.-sourced API/drug product onto Tier One drug formulary (state and federal level) to leverage federal purchasing power to create predictable demand.

Federal procurement is one of the most powerful market signals available to encourage private investment. By committing to long-term, volume-based contracts for medicines with domestically sourced APIs and KSMs, the federal government can de-risk the capital expenditures required to

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[7] The lomustine crisis - awareness and impact of the 1500% price hike: https://pmc.ncbi.nlm.nih.gov/articles/PMC6303421/#CIT0013.

[8] Expensive brain-cancer drug no longer an option under Medicare: https://www.cbsnews.com/news/brain-cancer-drug-gleostine-no-longer-an-option-under-medicare/.

[9] GoodRx – Gleostine (lomustine): https://www.goodrx.com/gleostine/what-is?dosage=100mg&form=capsule&label_override=Gleostine&quantity=1&sort_type=popularity.

[10] 18-2399: ACETRIS HEALTH, LLC v. US [OPINION]: https://www.cafc.uscourts.gov/2-10-2020-18-2399-acetris-health-llc-v-us-opinion-18-2399-opinion-2-10-2020_1529718/.

reshore production. These contracts should go beyond short-term price competition and instead prioritize resiliency, reliability and national security outcomes.

Leveraging the buying power of the federal government is critical, as it accounts for more than 30 percent of overall U.S. healthcare spending.[11] According to National Health Expenditure data from the Centers for Medicare & Medicaid Services, U.S. prescription drug expenditures totaled $449.7 billion in 2023[12]—an area where federal purchasing decisions, though a smaller share of overall healthcare spending (approximately $4.9 trillion in 2023), can still influence broader private market practices. For consideration, other nations, including Germany, Brazil, India and China have established sourcing policies that encourage domestic production. In the U.S., a similar approach could be explored around policies that promote domestic production, reward stronger compliance records, or otherwise align federal purchasing with long-term supply chain resilience.

Improving provider reimbursements for U.S.-made generic products and realigning preferred drug lists/formularies for Medicaid and Medicare can drive incentive for U.S.-based manufacturing.

Thirdly, investments in private-public partnerships enable the transition and adoption of advanced manufacturing technologies enabling economically competitive and sustainable U.S. production.

Ongoing investment in public–private partnerships to enable sustainable, long-term solutions that leverage advanced manufacturing technologies is critical to modernizing and expanding the capacity we already have and promises to be a more efficient and cost-effective way to scale production. This is becoming increasingly important than as foreign governments are making significant investments in their own pharmaceutical infrastructure. To remain competitive and ensure the resilience of our supply chain, the U.S. must match—and ideally outpace—these investments.

By utilizing existing U.S. FDA-approved facilities, we can dramatically improve efficiency and reduce costs in an expedited and sustainable manner. These investments can also stimulate regional economies, create new high-quality jobs and strengthen the long-term competitiveness of U.S. manufacturers. By mobilizing underutilized U.S. manufacturing capacity, accelerating adoption of advanced manufacturing and aligning federal policy with procurement, the Congress and the Administration can deliver a durable solution that protects seniors, veterans and all Americans.

Thank you for the opportunity to share our research and details of our work at the API Innovation Center as well for the committee's leadership on this critical national priority.

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[11] Centers for Medicare and Medicaid Services – National Health Expenditure Data (Fact Sheet): https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet.
[12] Ibid.