
**VIA REGULATIONS.GOV**

May 7, 2025
Stephen Astle

Director, Defense Industrial Base Division
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
U.S. Department of Commerce
1401 Constitution Avenue, NW
Washington, DC 20230

**RE: Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (XRIN 0694-XC120)**

Dear Director Astle:

The Center for American Medicine Resiliency (the "Center for AMR" or "the Center") appreciates the opportunity to respond to the U.S. Department of Commerce's request for public comments as part of its investigation into the effect of imports of pharmaceuticals and pharmaceutical ingredients on national security.

The Center strongly supports the Trump Administration's objective to address the significant national security risks posed by overreliance on foreign sources of concern for critical pharmaceutical ingredients and products. Ensuring that Americans have uninterrupted access to lifesaving and essential medications must be a foundational pillar of U.S. national security policy.

We fully endorse the Administration's focus on strengthening medicine security and supply chain resilience. Both the brand and generic pharmaceutical sectors face critical vulnerabilities in the global supply chain, and each requires tailored solutions. However, we urge policymakers to recognize that these sectors operate under fundamentally different economic models and policy conditions. The generic industry, in particular, is uniquely strained by distorted market dynamics—such as extreme price compression, purchasing consolidation, and regulatory misalignment—that threaten its long-term viability and its essential role in providing affordable access to medicines.

For the reasons detailed below, the Center recommends a balanced, and incentive-based approach—one that builds domestic production capacity for both sectors while enacting targeted reforms to stabilize and secure the future of the generic medicine supply chain.

**Affordable Medicine-National Security Imperative.** In an increasingly unpredictable world, the United States faces the looming threat of a national crisis tied to pharmaceutical supply chain vulnerabilities. Over the last three decades, we have witnessed the gradual exodus of the U.S. affordable pharmaceutical industry and its accompanying domestic chemical production. This shift has been fueled by foreign production incentives, stringent U.S.

environmental regulations, rising labor and energy costs, and distorted pricing dynamics in the U.S. market. As a result, the U.S. has become dangerously dependent on China for our supply inputs for critical, affordable medicines.

Health is a cornerstone of American life. It fuels our thriving society, boosts our economy through improved public health outcomes and increased productivity, and reinforces military preparedness and national security. It impacts all sectors, from Wall Street to Main Street and from commerce to defense. Affordable everyday medicine stands as one of the fundamental pillars of America's infrastructure. It drives superior health outcomes, reduces the weight of healthcare costs for businesses and families alike, and promotes stronger economic participation through enhanced spending power.

Generics fill 91% of U.S. prescriptions, yet account for just 12% of pharmaceutical spending and only 1.2% of total healthcare costs. Generics contribute approximately $380 billion annually in healthcare savings, projected to reach $3 trillion over the next decade. Affordable medicines is a cornerstone of America's healthcare system, serving as the primary treatment modality trusted by millions of Americans every day to maintain health, productivity, and overall well-being. Preserving consistent access to these essential medicines is therefore critical—not only to patients but also to communities across the United States. As we know, the nation's health is intrinsically linked to our economic prosperity and security.

The global pharmaceutical supply chain—including the United States, Europe, India and Middle East —is deeply and systemically dependent on China for the raw materials and ingredients needed to produce affordable medicines. While much attention is given to active pharmaceutical ingredients (APIs), the world is even more reliant on China for generic intermediates and key starting materials (KSMs)—the upstream chemical inputs critical to API synthesis. This single-point dependency poses a growing threat to affordable medicine access, especially amid geopolitical tensions, economic instability, and global supply chain disruptions. This fragile global structure leaves the U.S. and its allies exposed—not only to supply disruptions, but to strategic manipulation by geopolitical adversaries.

Covid pandemic highlighted the global security risks and vulnerabilities. India, who supplies nearly half of America's generic medicines, finds itself deeply reliant on China for about 50% of the APIs for the national essential medicine list,[1] with this dependency reaches up to 100% for some intermediates and KSMs.[2] To mitigate their risk, India launched in 2020 its Pharmaceutical Production Linked Incentive (PLI) program aimed at rebuilding domestic production, identifying 53 molecules in phase I. Similarly, the European Commission conducted an API dependency assessment, noting that 80% of API (brand and generic) are imported coming from five countries, led by China at 45%, followed by India, the US, the UK, and Indonesia. Here in the United States, the U.S.-China Security and Economic Commission (U.S.-China Commission) first warned Congress in 2019 about the dangerous and excessive reliance on China, highlighting the deeply dependent in the affordable generic medicine sector.

Despite the risks and vulnerabilities within this sector, the U.S. government has yet to address affordable medicine security in a meaningful way. This gap in federal action is notable and increasingly unsustainable given the mounting risks. Many government officials have repeatedly stressed the importance of de-risking and re-diversifying the supply chain to reduce our reliance on China. This is not just about mitigating risk, but also about countering China's use of economic coercion against the United States and other countries. Given the deep reliance by the U.S. and allies on China for affordable pharmaceuticals, re-diversifying the supply chain for affordable everyday medicines is an urgent national imperative.

**Feasibility of Reshoring and the National Security Implications of Tariffs**

The Center appreciates the Department's thoughtful questions regarding the feasibility of reshoring pharmaceutical and ingredient production. While we support a strong, secure domestic pharmaceutical base, it is critical to approach this transition with clear-eyed realism. The current structure of the affordable medicine market—marked by extreme price suppression, purchasing consolidation, and overreliance on fragile global inputs—has left limited financial headroom for generic manufacturers to absorb new costs.

[2] https://www.downtoearth.org.in/news/health/costly-active-pharma-ingredients-from-china-create-healthcare-hurdles-in-india-78682

Without calibrated policy support and a deliberate, incentive-based strategy, imposing tariffs or other trade restrictions could exacerbate drug shortages and directly harm patients. Tariffs on affordable medicines or their components would likely raise costs, reduce supply, and further destabilize an already strained generic sector—undermining the very national security objectives this investigation seeks to achieve. As such, a targeted exemption for generic pharmaceuticals and their supply chain inputs is not only warranted—it is essential to safeguard health and maintain medicine access while longer-term solutions are developed and executed.

### A. Why Tariffs Will Worsen Shortages, Not Solve Them

Generic manufacturers face tremendous structural economic pressures that undermine the commercial viability of affordable medicines. These companies operate on razor-thin margins, and their ability to sustain production—let alone expand or reshore it—is highly constrained by distorted market conditions.

Recently, the Federal Trade Commission (FTC) and the Department of Health and Human Services (HHS) expressed concerns about the market dominance of group purchasing organizations (GPOs), warning that their contracting practices contribute to deflationary pricing spirals that discourage manufacturers from producing critical generics [3] These concerns were the subject of a comprehensive March 2023 report by the Senate Committee on Homeland Security and Governmental Affairs (HSGAC), which detailed how distorted economics have caused manufacturers to exit the market, left few incentives for new entrants, and increased the risk of shortages.[4] The report also highlighted that GPO-driven "race-to-the-bottom pricing" is a major contributor to market instability and drug scarcity.[5]

Likewise, a 2025 GAO report concluded that, *"when market conditions limit manufacturers' profitability, this reduces a manufacturer's motivation to maintain a presence in, or enter, the market and to invest in manufacturing quality and redundant capacity."* [6] It added that if the opportunity cost of producing a generic drug exceeds the potential profits, manufacturers may shift to higher-margin products or cease production entirely.[7]

This fragile situation is further compounded by the Medicaid inflation penalty: when GPOs push a drug's price below cost, and it later rebounds, the manufacturer can be penalized under Medicaid for inflationary increases—even if those increases simply bring the price back to sustainable levels.[8] Meanwhile, pharmacy benefit managers (PBMs) exert control over generic substitution and reimbursement, compounding the downward pressure on prices.

Since 2016, the sector has faced persistent deflationary pricing. Today, middlemen—PBMs, GPOs, and wholesalers—control every dimension of the generic market: procurement, reimbursement, and substitution. This dominance has created a system where market share no longer flows to the most efficient or high-quality producer, but to the entity most willing to accept unsustainable margins.

A recent Berkeley Research Group (BRG) analysis laid bare the economic imbalance: while generics account for 91% of U.S. prescriptions, generic manufacturers receive just 8.8% of total pharmaceutical revenue.[9] In contrast, nearly 50% of total spending in the pharmaceutical supply chain flows directly to middlemen.[10] This imbalance severely limits generic manufacturers' ability to reinvest in U.S. production or build redundant capacity—leaving the system vulnerable to chronic and cascading shortages.

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[3] In the retail generic market, three Buying Groups, representing collaborations among the three leading wholesalers and pharmacies, now account for nearly 80% of generic drug purchases in the U.S. See Association for Accessible Medicine Comments filed with FTC-2024-0018-6371, citing Fein, A. (2023). The 2023-2024 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors. Drug Channels Institute. FTC July report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies (The nation's three largest PBMs manage 79% of all prescription drug claims, In another agency report, "Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers," the FTC reported that the three largest PBMs drove up the price of specialty generic drugs for patients with cancer, multiple sclerosis, HIV and pulmonary hypertension by more than 1,000% in some cases and by hundreds of percent in other cases.

[4] Senate Committee on Homeland Security and Governmental Affairs (HSGAC). (2023). *Short Supply: The Health and National Security Risks of Drug Shortages*. March 2023.

[5] Id.

[6] Senate Committee on Homeland Security and Governmental Affairs (HSGAC). (2023). *Short Supply: The Health and National Security Risks of Drug Shortages*. March 2023. Available at: HSGAC March 2023 Report.

[7] Id. see also https://www.americanprogress.org/article/industrial-policy-to-reduce-prescription-generic-drug-shortages/

[8] Richard Manning and Fred Selck, "Penalizing Generic Drugs with the CPI Rebate Will Reduce Competition and Increase the Likelihood of Drug Shortages," Bates White Economic Consulting, September 12, 2017, https://www.bateswhite.com/media/publication/142_CPI%20Rebate.Manning_Selck.pdf

[9] Berkeley Research Group (BRG). (2025). *The Pharmaceutical Supply Chain, 2013–2023.* January 2025.

[10] Id.

Tariffs will not reshore generic drug production. On the contrary, tariffs on generic pharmaceuticals and their ingredients—the very backbone of the U.S. healthcare system—will result in higher costs, more shortages, and direct harm to patients. They would exacerbate financial pressure on the few remaining manufacturers, forcing exits from the market and triggering avoidable downstream healthcare costs.[11] Shortages beget more shortages, and the result would be a self-reinforcing cycle of failure.

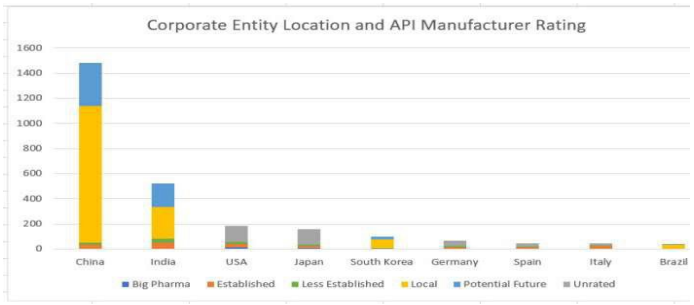
Therefore, generic medicines and their supply chain components should be exempt from tariffs until structural policy reforms are implemented to stabilize and strengthen the sector. Preserving access to these essential products requires a thoughtful, pro-growth approach—not punitive trade barriers.

### B. Domestic Production Capacity

Current U.S. production capacity for affordable pharmaceuticals and their ingredients is far from sufficient to meet domestic demand. Years of offshoring—driven by low-margin pricing, foreign subsidies, and regulatory complexity—have hollowed out the manufacturing base. While most companies are willing and eager to reshore or nearshore production, the cost of doing so at scale is prohibitive without targeted government support. Building new API and intermediate facilities requires 5-10 years on average to become fully validated, licensed, and operational. Strategic investments and public-private partnerships can close this gap—but not overnight. An uncalibrated tariff would create pressure before capacity exists, leading to avoidable supply disruption.

**C. Risks from Foreign Supply Concentration** approximately 70% of its finished affordable medicines from overseas—nearly 50% of which are supplied by manufacturers in India, followed by 11% from the Middle East, 5% from Europe, 3% from Canada, and just 2% from China.[12] However, despite these relatively diverse finished product sources, the global pharmaceutical supply chain remains dangerously dependent on a narrow set of upstream suppliers—particularly China—for key starting materials, intermediates, and active pharmaceutical ingredients (APIs).[13] and Trade Practices. The United States imports

An independent analysis by Clarivate PLC of over 3,000 API manufacturers confirms a significant global shift in API control to China. *Source: Clarivate plc analysis (2022)[iv] Corporate API Rating is a proprietary Cortellis Generics Intelligence analytic*




While this may suggest a relatively diverse set of finished dosage suppliers, it obscures a far more troubling reality: the global pharmaceutical supply chain remains dangerously concentrated at its foundation. The real chokepoint lies upstream, in the production of key starting materials (KSMs), drug intermediates (DIs), and active pharmaceutical ingredients (APIs)—inputs that are essential

[11] U.S. Food and Drug Administration, "Drug Shortages: Root Causes and Potential Solutions, As the FDA's Drug Shortages Task Force noted: "Drug shortages persist because they do not appear to resolve according to the "textbook" pattern of market response. In this more typical pattern, prices rise after a supply disruption and provide an incentive for existing and new suppliers to increase production until there is enough supply of a product to meet demand. In this respect, the market for prescription drugs and especially generic drugs differs from other markets." Id. at 5.
[12] IQVA National Prescription Sales Audit Dec. 2022; IQVIA Institute.
[13] European Parliament. Potential measures to facilitate the production of active pharmaceutical ingredients (APIs); https://www.europarl.europa.eu/RegData/etudes/STUD/2023/740070/IPOL_STU%282023%29740070_EN

for nearly every medicine, regardless of where the final product is made. China dominates this upstream supply network.

According to an independent analysis by Clarivate PLC of over 3,000 API manufacturers, 41% are "local" suppliers based in China. These companies are deeply entrenched in supplying the base chemical components for regulated pharmaceutical markets worldwide. As a result, even when finished products are imported from trusted partners like India or the EU, many of the critical raw materials still originate in China.

This overconcentration poses a clear and present national security risk. During the COVID-19 pandemic, Chinese officials threatened to withhold critical pharmaceutical exports to the United States and European Union, underscoring the geopolitical leverage embedded in this supply chain. Since 2019, the U.S.-China Economic and Security Review Commission has repeatedly warned Congress about the strategic dangers of overreliance on China for pharmaceutical ingredients and chemical precursors. These warnings have been echoed by the White House and the Department of Defense, which have acknowledged the vulnerability but have yet to implement a coherent strategy to mitigate the threat. This structural dependence is not easily fixed. There is, in effect, nowhere else to turn in the event of a serious disruption. Even India—America's largest supplier of finished generics—is heavily reliant on Chinese imports for its pharmaceutical production, sourcing an estimated 68% of its APIs imports from China, with dependency levels reaching 90% for critical antibiotics and other life-saving medicines.

In contrast to the United States, both India and the European Union have launched targeted efforts to address their pharmaceutical vulnerabilities. In May 2020, Prime Minister Narendra Modi initiated the Aatma-Nirbhar Bharat (Self-Reliant India) campaign, aimed at reducing foreign dependence in key sectors, including pharmaceuticals. A central component of this campaign is the Pharmaceutical Production Linked Incentive (PLI) Scheme for Bulk Drugs, which incentivizes the domestic manufacture of 53 essential KSMs, DIs, and APIs. Similarly, the European Commission has conducted assessments of its supply chain dependencies, concluding that 80% of the EU's APIs are imported, with 45% coming from China. A 2020 IQVIA Institute report further revealed that 74% of the EU's total API market volume is sourced from Asia, with nearly 70% of that originating from China. These findings mirror the global overdependence and make clear that China is not just a major player—it is the linchpin supplier of the chemical ingredients that power modern medicine production around the world.

- A 2020 analysis of 68 critical APIs in India performed by PWC validates the dire dependency on China. Of the 68 APIs, 50% of them are imported directly from China. These include 6 essential APIs: Penicillin G (Pen-G), streptomycin, vancomycin, meropenem, levodopa, carbidopa and progesterone. The report further noted that while the other 50% of APIs are manufactured domestically in India, the KSMs for most of these APIs are still sourced from China.

- Examples of China intermediates used to produce APIs in India include amoxicillin, ampicillin, caffeine, azithromycin, ciprofloxacin, metformin, levofloxacin, ofloxacin, doxycycline, sulfadoxine, chloramphenicol, moxifloxacin, niacin, Vitamin B6 and cephalosporins to name a few. Lastly, the analysis noted that key therapeutic areas, such as cardiovascular, anti-infectives, oncology, hematology, and diabetology, are at high risk.

a robust approach to strengthening trade policies and regulations is crucial to safeguard the interests of domestic players in the generic pharmaceutical industry while promoting a level playing field globally.

One of the concerning strategies often employed by certain nations to dominate global markets is the "pump and dump" tactic. By heavily subsidizing specific industries—take, for example, China's robust backing of its generic antibiotic sector—countries can rapidly amass market share. Following this accumulation phase, these countries can flood global markets with competitively priced products, effectively sidelining global competition. Addressing this tactic requires a combination of vigilant monitoring and stringent regulatory countermeasures.

Beyond immediate countermeasures, the U.S. also should ensure its trade agreements reflect the values of transparency, fairness, and equitable competition. Such agreements should encompass provisions compelling partner countries to disclose pertinent information about their pharmaceutical markets. Furthermore, these provisions should guarantee that partner nations' regulatory frameworks are not designed to unduly disadvantage foreign entities. By instilling these principles in international agreements, the U.S. can play a pivotal role in fostering a more transparent and equitable global pharmaceutical marketplace.

Given these dynamics, de-risking the pharmaceutical supply chain is not optional—it is a national security imperative. Without proactive intervention, the United States remains exposed to future shocks, supply disruptions, and geopolitical coercion that could compromise health, national defense readiness, and economic stability. A coherent, well-resourced strategy is urgently needed to diversify supply, reshore essential manufacturing capacity, and build sustainable partnerships with trusted allies. As other nations take steps to mitigate their vulnerabilities, the U.S. must not remain complacent. The cost of inaction is too high—and the next crisis may not offer time to prepare.

**Tariff Implications and Trade Policy Options**

Tariffs on inputs or finished generic medicines would likely result in increased shortages, higher healthcare costs, and significant disruption in both public and private health systems. Given the current fragility of the generic sector, such tariffs would not achieve reshoring—they would accelerate **exit** from the market. Instead, the U.S. should pursue a coordinated strategy that combines:

- **Targeted exemptions** for essential and affordable medicines
- **Public-Private investment** to support domestic capacity buildup
- **Supply chain mapping** to prioritize critical vulnerabilities
- **Partnerships with allies**, such as India and Europe, to share the burden of secure supply

**Path Forward: Advancing a National Strategy for Affordable Medicine Security**

Affordable medicine security is a shared national and global challenge—one that demands coordinated strategies, targeted investments, and long-term structural reforms. Like food and energy security, the availability of reliable, affordable medicines is essential to the well-being of American families, the stability of our healthcare system, and the readiness of our military. Addressing this urgent need will require a bold, sustained public-private effort grounded in practical action. Some steps can and should be taken directly by the Administration through executive authority, while others will require comprehensive federal legislation and Congressional engagement. If the U.S. is to regain control over essential components of its medicine supply, it must make smart investments in domestic and allied production, technology innovation, and workforce development. These actions must be guided by a clear national strategy—one that mirrors successful efforts.

We strongly support the recent actions taken by the Administration to address vulnerabilities in the pharmaceutical supply chain—most notably the April 30, 2025 Executive Order to advance domestic pharmaceutical manufacturing

and the April 16, 2025 Executive Order to lower prescription drug costs. These directives mark important steps toward improving the FDA's review timelines for generic medicines and accelerating the approval of domestically manufactured pharmaceutical products. Streamlining regulatory pathways is critical to ensuring that high-quality, affordable medicines can be produced quickly, reliably, and at scale within the United States.

Building on this momentum, the Administration should now take additional steps to lay the foundation for long-term resilience. First, the President should issue a broader Executive Order under the Defense Production Act of 1950, prioritizing the domestic production of key components such as APIs, KSMs, intermediates, and other essential chemical inputs. A new Technology Security and Innovation Council should be launched to coordinate federal agencies, expedite regulatory processes, and foster collaboration with private manufacturers and state and local governments. The FDA, in partnership with the Department of Commerce, should establish an Affordable Generic Medicine Advanced Manufacturing Program to promote cutting-edge technologies while maintaining rigorous quality standards. A joint Everyday Medicine Innovation and Technology Institute (EMITI) would help build a skilled domestic workforce, support R&D, and enable knowledge-sharing with trusted allies.

To reinforce these efforts, federal procurement power should be aligned to support domestic and ally-based manufacturers through agencies such as DOD, VA, FSS, and FMAP. The Administration should also deploy additional tools—including commercial insurance incentives, support from DFC and EXIM, and sustained emergency stockpile funding—to drive a more resilient, affordable, and secure generic medicine ecosystem.

As we rebuild domestic capacity, the United States must simultaneously deepen cooperation with trusted international partners. Bilateral and multilateral trade agreements, coupled with interim joint statements, should be pursued with allies such as India, to facilitate the co-production of affordable medicines, ensure mutual transparency, and align on quality standards. These alliances can reinforce supply chain resilience and serve as a critical counterweight to adversarial dependencies.

**In Conclusion:** These steps represent a comprehensive path forward to close the dangerous vulnerabilities that continue to threaten America's health and national security. A **tariff exemption for essential generic medicines and components** is necessary to prevent further erosion of the market and to relieve pricing pressures that harm both manufacturers and patients. But relief alone is not enough. **Structural reforms to the generic market** must be paired with **decisive government action**—including a new **Executive Order**, full deployment of **Title VII of the Defense Production Act**, and new legislation to establish the infrastructure, funding, and incentives needed to rebuild and sustain a resilient domestic production base. These combined measures can restore confidence in the supply of essential medicines, insulate the U.S. from geopolitical shocks, and secure the long-term viability of a sector critical to public health, military readiness, and economic stability. With focused leadership and bipartisan support, the United States can once again lead the world in ensuring reliable access to affordable medicine.

## I. Consider Executive Order to Stimulate the Manufacturing of Affordable Generic KSMs, APIS and Critical Inputs

Given the urgency surrounding our nation's inability to ensure a steady, sustainable, and affordable supply of essential medicines for everyday life, the White House should consider immediately issuing an Executive Order to commence manufacturing of affordable generic components here at home. Following the precedent set by President Trump's Executive Orders on other domestic industries, we strongly urge the White House to make a similar order for the manufacturing of affordable generic KSMs, Apis, and Critical Inputs. The Executive Order would aim to stimulate domestic manufacturing of affordable generic components, reduce dependency on foreign suppliers, create job opportunities, and ensure that affordable medicines will be available for all Americans.

The Rationale for the Executive Order is:

**National Security**: Similar to previous Executive Orders, this initiative will bolster America's health system and economic prosperity and protect communities against potential international disruptions or crises.

**Revival of Manufacturing and Innovation.** Restoring domestic production of affordable generic components can spur innovation, supporting key sectors. It ensures the health of workers across various critical sectors.

**Economic Growth and Job Creation**. Reviving domestic manufacturing can create high-quality jobs, stimulating the economy and offering opportunities nationwide.

**Affordability and Accessibility**. This initiative will ensure the widespread availability of crucial generic medicines, improving quality of life and reducing disparities.

The proposed Executive Order could include:

- **Activation of Defense Production Act.** The Act should be implemented to speed up domestic production of affordable generic components, similar to prior applications in clean energy and critical minerals. This includes granting section 303 waivers for the affordable pharmaceutical industry, ensuring a stable supply of critical components, and encouraging the use of cutting-edge technology for affordable generics production.

- **Establishment 4 Year Transfer Bridge.** To support domestic manufacturing during its expansion phase, a two-year transfer bridge should be created. This would allow for the temporary importation of key knowledge and know-how and components from countries such as India, the UK, South Korea, Canada, and Israel duty-free for this time period. This would provide a sufficient supply of goods while domestic production scales up.

- **Federal Procurement Utilization.** The full power of federal procurement should be leveraged, particularly by agencies such as HHS, VA, DOD, and ASPR. These agencies should prioritize the procurement of affordable medicines with several defined, critical domestically produced components, thus driving demand and incentivizing manufacturers.

**II. Enactment of Federal Legislation:**

**Proposed Title -- The MEDICINES ACT** – The Manufacturing Expansion and Domestic Independence Through Critical Investments in National Economic Security Act

Mirroring other critical industry programs that bolstered our nation's technological defense and commercial systems, we can strengthen our health, economy, and security by passing robust legislation, tentatively titled the "Manufacturing Expansion and Domestic Independence through Critical Investments in National Economic Security" Act of 2023 (MEDICINES ACT). The proposed act would be comprehensive in nature and be designed to drive public-private investments, incentivize partnerships and more, with the goal of regaining affordable pharmaceutical component production and associated chemical manufacturing creation.

Recent federal policies - including federal procurement restrictions, country-of-origin requirements, addressing product shortages, and the "Made in America" initiative provided direction. These well-intended policies each carry their own limitations and address symptoms of the broader issue.

Our nation's approach must be comprehensive, addressing the root causes of our nation's vulnerabilities and dependencies regarding generic medicine production and the global supply chain. It should incorporate lessons from past policy impacts, such as the fallout of chemical tariffs and the COVID-19 pandemic, to guide a strategic reboot of our industrial base. To

this end, we should fuel and fully fund a resurgence in research and development and critical component production and build a resilient supply chain for affordable generic medicines, ensuring the today's families and tomorrow's grandchildren and their families have consistent and reliable access to everyday medicines.

Just like the semiconductor, battery and energy industries, our nation's journey towards creating robust, access to everyday medicine is not about short-term fixes; it's about transformative measures that fortify our national health security and independence. It's about more than just "Made in America" - it's about "Produced with America's Trusted Allies." The commitment lies in strengthening resilience, self-reliance, and future readiness for both America and our dependable partners.

Below are the actions we recommend for consideration, with more detail information provided on the proposed legislation in Appendix I below.

ENACTMENT OF NATIONAL ECONOMIC, HEALTH AND SECURITY INVESTMENTS

1. **Federally-Funded Center for Affordable Everyday Medicine Security.** Deploy the Defense Production Act or enact federal legislation to establish a joint venture between the DOD and the Department of Commerce (DOC). This center would focus on investing in domestic and allied manufacturing for APIs, KSMs and critical inputs of everyday generic medicines.

2. **Affordable Everyday Medicine for American Defense Fund:** Create a fully funded DOD initiative to establish public-private partnerships aimed at fast-tracking domestic and allied manufacturing of critical therapeutic agents and components for use in the military readiness and national security (starting with WHO's 500 plus essential medicine list).

3. **U.S. Affordable Everyday Medicine Independence & Security Supply Chain Disruption Institute.** Create an institute run by DOD to develop a National Supply Chain Database, leveraging technology and industry knowledge to provide transparency in the supply chain for affordable medicine.

4. **Affordable Everyday Medicine for America Technology Security and Innovation Council & Funding.** Launch an interagency council to expedite regulatory approvals and ensure collaboration across federal agencies, the private sector, and state and local governments for federally funded projects.

5. **Advance Manufacturing & Inspection Program.** Establish a program focusing on advancing technology in the manufacturing of domestic and allied generic medicines and ensure (1) the quality of the medicines; and (2) a level competitive playing field.

6. **Everyday Medicine Innovation & Technology Institute (EMITI).** Establish a joint DOC and FDA institute focusing on workforce education in advanced technology and manufacturing capabilities pertinent to generic medicine R&D and production. Employ where possible reciprocity with allies of R&D knowledge transfer and workforce talent and education programming.

5. **Affordable Generic Medicine Manufacturing Investment Tax Credit.** Implement a 40% tax credit for investments in affordable API, KSM, and advanced chemical manufacturing to negate the cost advantages of foreign adversarial subsidy regimes and incentivize domestic and trusted allied production.

6. **Federal & State Procurement Programs.** Leverage federal procurement power to support domestic and allied production of preferred critical medicines (WHO's essential medicine list) and components (which are free of foreign adversaries components) by creating a stable demand for these products through federal program procurement

requirements (DOD, VA, FSS) and Federal Medical Assistance Percentage program (FMAP) with States, and providing private sector incentives for investments.

7. **Private Commercial Insurance Program.** Create policies incentivizing commercial purchasers to prioritize preferred generics and components manufactured domestically or with trusted allies, rewarding supply chain quality and resilience.

8. **Leverage Federal Financial Agencies.** Utilize agencies like the U.S. Development Finance Corporation (DFC) and Export-Import Bank (EXIM) to support the resilience of the generic medicine supply chain, focusing on development, research, and manufacturing projects.

9. **Emergency US Stockpile Funding.** Allocate sufficient funds to ensure the operational efficiency of the U.S. stockpile, covering emergency medicine for a segment of the U.S. population, while still pursuing other initiatives for a comprehensive approach.

Together, these steps represent a comprehensive path forward to close the dangerous vulnerabilities that continue to threaten America's health and national security. A tariff exemption for essential generic medicines and components is necessary to prevent further erosion of the market and to relieve pricing pressures that harm both manufacturers and patients. But relief alone is not enough. Structural reforms to the generic market must be paired with decisive government action—including a new Executive Order, full deployment of Title VII of the Defense Production Act, and new legislation to establish the infrastructure, funding, and incentives needed to rebuild and sustain a resilient domestic production base. These combined measures can restore confidence in the supply of essential medicines, insulate the U.S. from geopolitical shocks, and secure the long-term viability of a sector critical to public health, military readiness, and economic stability. With focused leadership and bipartisan support, the United States can once again lead the world in ensuring reliable access to affordable medicine.

Please feel free to reach out if you have any questions or require additional information.

Sincerely,

Kathleen Jaeger, President & CEO

Center for American Medicine Resiliency

CENTER FOR AMR

VISION: Empowering America's Healthcare and National Security through Resilient and Diversified Medicine Supply Chains.

MISSION: Ensuring a Future Where Americans Have Access to Affordable, Reliable Medicine.

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MISSION: Ensuring a Future Where Americans Have Access to Affordable, Reliable Medicine.

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**Appendix I: Proposed Enact Federal Legislation**

## CALL IT --- The MEDICINES ACT
## The Manufacturing Expansion and Domestic Independence through Critical Investments in National Economic Security Act

**A. National Economic, Health & Security Investments:**

- Federally-Funded Center for Affordable Medicine Resiliency: Immediately deploy the Defense Production Act (DPA), or enact federal legislation and corresponding funding, under the tentatively titled the "Bipartisan Medicines Act" to regain US and allied production capabilities and capacities to establish a *fully-funded Center for Affordable Medicine Resiliency, joint venture between Department of Defense (DoD) and the Department of Commerce (DOC)* aimed at authorizing D0D/DOC to provide funds for affordable generic everyday manufacturing investments, including financial assistance and incentives to transfer technology and know-how back to the U.S. from trusted allies; refurbish and modernize existing manufacturing facilities or build new facilities, which includes upgrading quality, green technology, innovative equipment for the development, advance manufacture, testing of pharmaceutical APIs, KSMs, and advanced chemicals, which includes direct loans costs and loan guarantees.

  To accomplish this goal, the Center should aim to advance public-private partnership to conduct advanced manufacturing technology innovations and invest in new cost-effective technologies to manufacture affordable generics and other essential medicines and expand workforce training and development opportunities. Partnerships can be between government, industry, startups, and outside funding organizations to increase funding opportunities for domestic and allied research, development, manufacturing, accelerate manufacturing technologies for affordable medicines.

- Affordable Generic Medicine for America Defense Fund. Establish a fully funded DOD military initiative to create public-private partnerships like the Center above, with an aim of expediting the domestic and trusted allied manufacturing of KSMs, APIS, critical chemicals, inputs, and affordable medicine for critical therapeutic agents for use to national security (starting with WHO's 500 plus essential medicine list) and to military readiness.

- U.S. Affordable Medicine Independency & Security Supply Chain Disruption Institute. Establish a fully funded Institute to be run by DOD, using state of the art technology, AI, and critical industry knowledge by leveraging the Center's partnerships and current U.S. suppliers to create a National Supply Chain Database for affordable medicine. This database will provide transparency and assist the U.S. military, manufacturers, hospitals, pharmacies, and clinics in the U.S. with non-China supplier scouting and procurement of finished dosage forms, APIs, KSM, and advanced chemicals of critical affordable medicine to minimizing supply chain disruptions and shortages. DOD also would be authorized to work with counterparts who are trusted trade partners.

  To drive transparency and national security, the U.S. will require each manufacture selling affordable generic and OTC therapeutic products in interstate commerce to share critical sourcing information with DOD as it relates to APIs, KSMs, and advanced chemicals of affordable and OTC medicines.

- Affordable Generic Medicine for America International Technology Security and Innovation Council & Funding: Establish a council aimed to launch a sector-specific interagency council aimed to expedite regulatory approvals or permits in accelerated fashion and ensure collaboration and coordination across federal agencies, the private sector, and the state and local governments to facilitate timely and effective reviews of all federally funded projects under the Center. It also will provide resources to the DOD,

DOS, HHS, EPA, USTR. on international trade or related initiatives to advance the security of components of and affordable medicines for allied partners. It also will require FDA, and EPA to a lesser extent, to re-evaluate their procedures, assessments, protocols, and requirements to address technology advances and system-wide changes resulting in a rapid evolving landscape for affordable pharmaceutical and related chemical manufacturing.

- FDA Enhanced Affordable Generic Medicine Advance Manufacturing & Inspection Program. Establish a program aimed at two critical imperatives:

  a. Establish FDA-manufacturing partnerships to advance the use and approval of advance technology, innovation, enhanced instrumentation, quality and testing, and manufacturing capabilities as it related to the development, production and testing of APIs, KSMs, advanced chemicals and finished dosage forms of generic medicines;

  b. Create a fair and level global competitive playing field by ensuring that manufacturers that import into the U.S. are held to the same inspections and audits requirements, which would include the elimination of inspection notification to Chinese facilities, and an expansion of well-trained FDA inspectors who reside in China and are fluent in both languages. This program also aims to create inspection standardization between and among trusted allied parties, as set forth in memoranda of understanding regarding allied facility inspections and audits and the reciprocity thereof.

- Affordable Generic Medicine Innovation & Technology Institute (AGMITI). Establish an Institute as part of that Center above where DOC and FDA jointly aim to educate commercial skill labor and agency workforce on advance technology, innovation, measurement science, enhanced instrumentation, testing, and manufacturing capabilities as it related to the development, production and testing of APIs, KSMs, advanced chemicals and finished dosage forms of generic medicines.

**B. Financial & Related Incentives:**

- Affordable Generic Medicine Manufacturing Investment Tax Credit: Establish a 40% percent tax credit for investments in the production of affordable APIs, KSMs and advanced chemical manufacturing. The credit should cover both construction of manufacturing facilities and manufacturing equipment. It also includes incentives for the manufacturing of the specialized component equipment required in the manufacturing process.

  Such a tax credit would erase the difference with foreign subsidy regimes, and cost difference for leading-edge production for restoring domestic manufacturing, allowing the grant funding to be focused on those components and chemicals for affordable medicine production critical to our economic and national security. Foreign government subsidies and monopolistic tactics in conjunction with U.S. labor and environmental costs drive a substantial cost difference for producing generic medicines overseas. These dynamics must change if the United States is to strengthen its national security and the security of others.

- Federal DOD, Medicare & Veterans Administration Procurement Programs and State Medicaid Program Mandates. Leverage the U.S. government's role as a purchaser of and investor to create robust, domestic and trusted allied affordable generics and chemical sectors. Federal procurement has the potential to support U.S. and allied production of critical a vast array of referred, critical medicine and indispensable components thereof from antibiotics to analgesics to cardiac and diabetic medications by creating a stable source of demand for these products—thereby providing an incentive for the private sector to invest in manufacturing. This also includes closing loopholes in the Buy
  America Act thereby shoring up federal agencies procurement mandates, such as DOD's non-China procurement policy to transcend to products with APIs, KSMs and some advanced chemicals made in China. Lastly, establish policies that provide procurement preference in all federally funded or assisted programs to

domestic manufacturers who use federally funded domestic APIs, KSMs and process chemicals in the manufacturing of affordable medicine and who are reliable, high quality product suppliers. Such policies will increase the economic sustainability of the U.S., including volume of goods solid along with manufacturing costs.

- Private Commercial Insurance Programs
  Develop policies that incentive commercial purchasers to shift to preferential generics with components manufactured domestically and thus reinforce and reward supply chain resilience and thereby eliminate the impact of "low-price" contract clauses.

- Leverage Federal Financial Agencies
  Leverage the U.S. Development Finance Corporation (DFC), Export –Import Bank (EXIM) of the U.S., and other financing tools to underwrite or support generic medicine supply chain resilience. Specifically, the DFC should increase capacity for investments in development, research and manufacturing projects that will expand production capability for critical medicines and their indispensable components, with an expansive view of the depth and breadth of critical medicines to maintain and improve the nation's health and economic prosperity. U.S. development and international finance tools can offer a powerful avenue for working with allies to strengthen supply chains for key products. The U.S. can use trade agreements and financial tools to ensure that the manufacturing that takes place with partners supports supply chain resilience and provides a percentage guarantee of product supply to the U.S.

- Sufficiently Fund – An Emergency US Stockpile. Funds to ensure that the U.S. stockpile is operational and functioning at the highest level. Yet, providing funding for this initiative does not negate the need to execute the other initiatives above since it is a costly endeavor that only covers a small segment of emergency medicine, and it only is intended to cover a fraction of the US population.