Andrea Durkin

Vice President,
International Policy

May 7, 2025

Eric Longnecker
Deputy Assistant Secretary for Technology Security
Bureau of Industry and Security
U.S. Department of Commerce
1401 Constitution Ave. NW
Washington, DC 20230

Re: Docket numbers BIS-2025-0022 and XRIN 0694-XC120: Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Dear Mr. Longnecker:

The National Association of Manufacturers is the largest manufacturing association in the United States, representing manufacturers of all sizes, in every industrial sector and in all 50 states. Manufacturing drives American prosperity—the industry employs nearly 13 million people, contributes $2.94 trillion annually to the U.S. economy and accounts for nearly 53% of all private-sector research in the nation.[1]

The NAM appreciates the opportunity to comment on the Department of Commerce investigation under Section 232 of the Trade Expansion Act, to determine the effects on the national security of imports of pharmaceuticals and pharmaceutical ingredients, and derivative products of those items.

The NAM believes it is vital for global economic leadership and for U.S. national security to strengthen and support America's world-class pharmaceutical industry. The pharmaceutical industry, which includes producers of prescription drugs, biologics, vaccines, over-the-counter medicines and other health products, plays a large role in the U.S. economy and continues to grow. In fact, most medicines consumed in the U.S. are made in the U.S., and the industry invests more than $100 billion annually to develop new medicines for American patients and patients worldwide.[2]

For manufacturers in the U.S. to sustain our nation's global advantage in the discovery, development, production and delivery of pharmaceuticals, it is essential to safeguard a stable and reliable pharmaceutical supply chain network. Immediate and broad-based tariffs on imports of pharmaceutical inputs and finished products, many of which are sourced from allies and through related party transactions, undermines that very supply chain network. That not only harms our global advantage — it also imposes severe and preventable costs at home, particularly in the risk that undermining the pharmaceutical industry's supply chain network will in turn drive health care costs for American patients while causing shortages for American consumers.

---

[1] National Association of Manufacturers (2025), Press Releases, "Manufacturers to Trump and Congress: Act Now on Comprehensive, Commonsense Manufacturing Strategy as Tariffs Hit Manufacturing Industry," https://nam.org/manufacturers-to-trump-and-congress-act-now-on-comprehensive-commonsense-manufacturing-strategy-as-tariffs-hit-manufacturing-industry-33417/

[2] National Association of Manufacturers (2023), "Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing," https://documents.nam.org/COMM/NAM-Creating%20Cures,%20Saving%20Lives_FINAL3.pdf

To support more pharmaceutical production in the U.S., in a manner that advances the president's goal to make the U.S. the best place in the world to build, grow, and create manufacturing jobs, the Trump Administration should undertake both domestic reforms and seize trade policy opportunities that facilitate domestic investments, unlock opportunities for economies of scale through full participation in global markets, and leverage the collective advantages of America's international allies to help make pharmaceutical supply chains more resilient. These policy approaches to trade resiliency represent a pillar of a comprehensive manufacturing strategy that also includes making the 2017 tax reforms permanent and more competitive, rebalancing federal regulations, and addressing workforce challenges.

Pharmaceutical Manufacturers' Role in the U.S. Economy Is Large and Growing

The pharmaceutical and medicine manufacturing industry delivers $655 billion in U.S. economic output each year, underscoring its substantial role in the overall performance of the U.S. economy.[3] Pharmaceutical manufacturers in the U.S. range from multinational corporations that discover, develop, manufacture, and distribute a broad spectrum of prescription and over-the-counter medicines, to smaller firms that focus on biologics, vaccines, generic medications and over-the-counter health products. The industry also includes manufacturers that specialize in producing active pharmaceutical ingredients (API) and other chemical inputs, as well as contract manufacturing development and manufacturing organizations (CDMOs).

Pharmaceutical manufacturers directly employ around 341,800 workers nationwide.[4] At an average annual salary of $87,170, workers in the pharmaceutical sector earn higher salaries than the national average. [5] The industry generates $147 billion in labor income, illustrating its significant economic impact on workers, their families and their communities.[6] There are nearly 18,000 job openings in the industry across the country, a total which is projected to grow 7% over the next five years.[7]

Most Medicines Consumed in the U.S. Are Manufactured in the U.S.

Most medicines taken by patients in the U.S. are manufactured in the U.S. By value, nearly two-thirds ($252 billion) of U.S. medicine consumption are of products that are manufactured domestically across more than 1,500 biopharmaceutical manufacturing facilities in the U.S.[8] The dollar value of API made in the U.S. accounted for a majority (53%) of the $85.6 billion of API used in medicines consumed in the U.S. in 2021.[9]

---

[3] National Association of Manufacturers (2023), "Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing," https://documents.nam.org/COMM/NAM-Creating%20Cures,%20Saving%20Lives_FINAL3.pdf

[4]U.S. Bureau of Labor Statistics, "May 2023 National Industry-Specific Occupational Employment and Wage Estimates: NAICS 325400 - Pharmaceutical and Medicine Manufacturing," U.S. Department of Labor, https://www.bls.gov/oes/2023/may/naics4_325400.htm.

[5]Ibid.

[6] National Association of Manufacturers (2023), "Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing," https://documents.nam.org/COMM/NAM-Creating%20Cures,%20Saving%20Lives_FINAL3.pdf

[7] Lightcast, "Industry Snapshot: Pharmaceutical and Medicine Manufacturing," April 2025, lightcast.io (Subscription)

[8] PhRMA, "Biopharmaceutical manufacturing companies continue to expand their economic footprint across the United States," March 24, 2023, https://phrma.org/blog/biopharmaceutical-manufacturing-companies-continue-to-expand-their-economic-footprint-across-the-united-states

[9] Avalere Health report, "U.S. Makes Majority of API by Dollar Value in U.S.-Consumed Medicines," October 14, 2023. https://advisory.avalerehealth.com/insights/majority-of-api-in-us-consumed-medicines-produced-in-the-us

Notwithstanding decades and billions of dollars in existing U.S. investments, pharmaceutical manufacturing in the U.S. continues to expand based on the strength of the U.S. manufacturing environment. In some recent examples:

- Johnson & Johnson announced in March that the company will spend more than $55 billion on manufacturing, research and technology in the U.S. over the next four years. These investments include a $2 billion state-of-the-art biologics facility in Wilson, North Carolina, which will support about 5,000 jobs during construction and create more than 500 permanent positions in the state.

- Novartis announced in April a planned $23 billion investment over 5 years in its U.S.-based infrastructure, ensuring all key Novartis medicines for U.S. patients will be made in the United States. The investment enables Novartis to expand its current manufacturing, research and technology presence with 10 facilities, including 7 brand new facilities, and is expected to create nearly 1,000 new jobs at Novartis and approximately 4,000 additional U.S. jobs.

- Merck has made significant strides in expanding its U.S. manufacturing capabilities, with a total investment exceeding $12 billion since 2018. This includes the recent announcement of a $1 billion investment in a new 225,000-square-foot vaccine manufacturing facility in Durham, North Carolina. Additionally, in April, Merck announced a further $1 billion investment in a state-of-the-art 470,000-square-foot biologics center of excellence in Wilmington, Delaware. This investment in Delaware is part of an additional anticipated $9 billion of U.S. capital investment expected by 2028, which focuses on enhancing domestic manufacturing and R&D capabilities while creating new jobs across the country.

- Amgen announced a $900 million expansion of its biomanufacturing facility in Columbus, Ohio, bringing the total number of jobs created to 750 and the total investment in Central Ohio to more than $1.4 billion.

- In February, Lilly announced $27 billion in new investments across four new U.S. manufacturing sites, which will create 3,000 permanent jobs and 10,000 construction jobs. This builds on previous announcements from 2020 to 2024 that totaled $23 billion, including: new sites in Research Triangle Park, Concord, North Carolina and Lebanon, Indiana; expansions of several different manufacturing facilities in Indianapolis, Indiana; and acquisition and expansion of Lilly's manufacturing site in Kenosha County, Wisconsin.

- AstraZeneca announced a further $3.5 billion investment to expand R&D and manufacturing in the U.S., including: specialty manufacturing in Texas, expanded cell therapy capacities on the West and East Coasts, a next generation manufacturing facility for biologics in Maryland, and a state-of-the-art R&D center in Massachusetts. This investment will create 1,000 new highly skilled jobs in the U.S.

The Pharmaceutical Industry Invests More Than $100 Billion Annually to Develop New Medicines. Tariffs Are a Cost That Detract from R&D Spend in the U.S.

As tariffs on inputs necessarily increase the cost of production, they would be expected to negatively impact revenue and funds available for increased R&D spend in the U.S.

R&D investments form the very foundation of the pharmaceutical manufacturing industry in the U.S., driving innovation, breakthrough discoveries and the development and commercialization of new drugs and therapies for both American patients and patients worldwide. Innovation in the pharmaceutical sector is a complex, lengthy and cost-intensive process. It typically takes 10 to 15

years of research, clinical trials and regulatory approval before a new drug can be brought to market.[10] Manufacturers in the U.S. perform the majority (52.9%) of all private-sector R&D in the nation. In the drive for continual innovation, pharmaceutical companies make up the largest share of that investment, accounting for 36.1% of all manufacturing R&D, spending $146.1 billion in 2023.[11, 12] In fact, the industry invests 20 times more than it did in the 1980s; over the last 40 years, pharmaceutical R&D investment has compounded at over 9% a year.[13]

Pharmaceutical R&D efforts are tied to and bolstered by revenue. The USC Schaeffer Center determined that reductions in revenue eventually translate into reduced rates of innovative effort. The Schaeffer Center report estimated that for every 10% reduction in expected U.S. revenues, pharmaceutical innovation — such as clinical trial starts or new drug approvals — is expected to ultimately fall by 2.5% to 15%.[14] That means the hit to company revenues that tariffs will cause will in turn hamper innovation in the industry, threatening the industry's ability to bring life-saving treatments to patients.

Sourcing of Key Inputs from U.S. Allies Is a Feature of Stable and Diversified Pharmaceutical Supply Chain Networks. Tariffs Would Unnecessarily Disrupt These Vital Trade Flows.

The strength of the U.S. pharmaceutical industry – from the jobs it supports to the economic output it produces to the innovation it drives – depends on stable and diversified supply chain networks that tariffs threaten to undermine.

Imported ingredients for the U.S. pharmaceutical industry are sourced primarily from allies including Ireland (22%), Singapore (3%), Switzerland (2%) and the U.K. (2%), with only approximately 6% coming from China.[15]

Imported inputs are vital to U.S. pharmaceutical production. In 2023, the U.S. imported approximately $60 billion of pharmaceutical inputs for further processing by U.S. manufacturing workers, resulting in $352 billion in finished pharmaceutical products for patients.[16] If tariffs are imposed on imported pharmaceutical inputs, production costs could increase by up to $15 billion —

---

[10] Derep, Maxime, N-Side, "What is the Average Time to Bring a Drug to Market in 2022?" 2022, https://lifesciences.n-side.com/blog/what-is-the-average-time-to-bring-a-drug-to-market-in-2022#:~:text=According%20to%20industry%20group%20PhRMA,initial%20discovery%20through%20regulatory%20approval.

[11] U.S. Bureau of Economic Analysis, "Table 5.6.5. Private Fixed Investment in Intellectual Property Products by Type," U.S. Department of Commerce, https://apps.bea.gov/iTable/?reqid=19&step=2&isuri=1&categories=survey&_gl=1*s8r6xc*_ga*MTAzNzYwOTg4OC4xNzA3NzY0NTQz*_ga_J4698JNNFT*MTcwOTA2MzE0NS40LjEuMTcwOTA2NTMzMC42MC4wLjA.#eyJhcHBpZCI6MTksInN0ZXBzIjpbMSwyLDNdLCJkYXRhIjpbWyJjYXRlZ29yaWVzIiwiU3VydmV5Il0sWyJOSVBBX1RhYmxlX0xpc3QiLCIzMzEiXV19.

[12] National Association of Manufacturers, "Facts About Manufacturing," https://nam.org/mfgdata/facts-about-manufacturing-expanded/

[13] National Association of Manufacturers (2023), "Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing," https://documents.nam.org/COMM/NAM-Creating%20Cures,%20Saving%20Lives_FINAL3.pdf

[14] USC Schaeffer Center white paper, "The Elasticity of Pharmaceutical Innovation: How Much Does Revenue Drive New Drug Development?" Feb. 18, 2025 https://schaeffer.usc.edu/research/the-elasticity-of-pharmaceutical-innovation-how-much-does-revenue-drive-new-drug-development/

[15] Avalere Health (2022), "Majority of API in US-Consumed Medicines Is Produced in the U.S.," https://advisory.avalerehealth.com/insights/majority-of-api-in-us-consumed-medicines-is-produced-in-the-us-2020#:~:text=Ireland%20(22%25)%2C%20China%20(,medicines%20consumed%20in%20the%20US.

[16] EY report, "Impacts of Potential Tariffs on the U.S. Pharmaceutical Industry," April 22, 2025

threatening to disrupt vital trade and supply chain flows that support access to critical health solutions for millions of Americans.[17]

Some of these inputs are not produced in the U.S. or not produced in sufficient quantity or quality. Lack of availability can occur for a variety of reasons, including because the U.S. lacks sufficient domestic contract manufacturing capacity to meet domestic demand or because the input is not available in the U.S. despite efforts to manufacture domestically. For example, a manufacturer of a dietary supplement produced in the U.S. can only source psyllium husk, an API, from India. While the manufacturer has sought other sources of psyllium, including attempting to grow the husk domestically, they have not been successful with alternative sourcing. Similarly, another U.S. manufacturer, and the last western producer of the API ibuprofen, relies on a critical raw material input from India because domestic producers of the raw material have exited the market. Immediate tariffs on this critical input would disrupt domestic manufacturing and jobs, and reduce U.S. competitiveness with foreign producers, such as China, in both the U.S. and export markets. Secure and consistent availability and access to these key inputs is imperative for these manufacturers to continue producing these products in the U.S.

Another NAM member has developed a strong and vibrant North America supply chain as a result of the U.S.-Mexico-Canada Agreement. They manufacture capsules (the medicine's delivery mechanism) in Canada, which are then sent to North Carolina for the medicine to be inserted into the capsule. North American production creates a competitive environment with an integrated regional supply chain. Tariffs on capsules would increase production costs for this American manufacturer for inputs even though these inputs do not pose a national security risk. Such a move would hamper this manufacturer's ability to invest further in manufacturing and R&D in the U.S.

Chemical Inputs in Pharmaceuticals Have a Wide Variety of Applications

Given the nature of chemistry, many chemical products are used in a wide range of supply chains. For example, propylene glycol can be used as a food stabilizer, a moisturizer in skin care cosmetics and shampoos, and a solvent in drug formulas. These products are often difficult to distinguish both in their production and when categorizing or classifying such products, especially by their Harmonized System codes. This means that trade measures designed to impact their use in one industry can have a broad ripple effect across the economy.

While domestic chemical producers have made specific investments to reshore domestic production, some are simply unavailable in the U.S. at this time. As such, the scope of this investigation and any resulting actions could have direct effects on chemical production for both pharmaceutical supply chains as well as other supply chains such as agriculture and food production, healthcare, information technology and other industrial products. The NAM urges the administration to work closely with industry to discuss the scope of this investigation as it affects inputs that go well beyond pharmaceutical supply chains.

Pharmaceutical Tariffs Should Not Apply to Related Party Transactions, Which Are a Prevalent Form of Trade in the Chemical and Pharmaceutical Industries

Some of the United State' largest pharmaceutical companies have longstanding operations in allied countries where they conduct R&D, diversified sourcing and manufacturing for global patient populations.[18] It is common in the chemical and pharmaceutical sectors for companies with operations in the U.S. and in other jurisdictions, such as the U.K. and the European Union, to

[17] Ibid

[18] Ibid

engage in related party transactions wherein a company purchases inputs and other products from itself.

For example, a chemical manufacturer that makes a base chemical at their facility in India subsequently sends it to France to be transformed into an intermediary product at their French subsidiary, which is ultimately sent to the U.S. for manufacturing into a final, advanced manufactured good with strong intellectual property rights protections. Related party imports such as these should not be subject to tariffs as they are an integral part of how these companies are set up and operate, as such they ultimately support and enable manufacturing in the U.S.

Tariffs on Pharmaceuticals Could Have Adverse Impacts in the Form of Higher Health Care and Food Costs and Shortages.

Tens of millions of Americans rely on imported medicines. The established norm in decades of trade policy was to avoid tariffs on medicines out of the recognition that tariffs increase the final cost of medicines and could impair patients' access to medicines. Global trade agreements made progress to establish **"zero-for-zero" reciprocal tariff terms. The Trump Administration should pursue this approach in its current negotiations.**

Prices for Patients: Tariffs on pharmaceutical imports would be borne by patients and consumers. A study conducted by Ernst & Young showed that a 25% tariff would increase drug costs by approximately $51 billion annually, 12.9% of which will be passed on to end users.[19] Further, patients' and consumers exposure to these higher costs is expected to increase over time.[20] Patients are at an extremely high risk of seeing cost increases to over-the-counter medications as well as generic drugs, which account for more than 90% of prescriptions in the U.S. and have slim profit margins.[21] As such, suppliers would be unable to absorb the costs of tariffs and would likely pass increased costs along to consumers. Case studies of countries that have placed tariffs on pharmaceuticals show that when tariffs were applied, the final prices to patients and consumers, in Brazil for example, increased by as much as 80%, along with diminished availability as medicines made their way instead to tariff-free markets.[22]

Health Care Costs: Tariffs may also increase overall health care costs. Manufacturers care about the health of their workers and know that providing health insurance is good for employee recruitment and retention. That is why 93% of NAM members offer employer-sponsored insurance to their employees. However, the rising cost of health care is a primary challenge for more than 58% of manufacturers.[23] Small and medium-sized manufacturers are even more concerned — 68% consider rising health care costs a key business challenge. As tariffs increase the cost of prescription drugs, health plans will likely pass along those increases through higher out-of-pocket costs for employers and employees. As manufacturers have to pay more for health care, they will have fewer dollars to invest elsewhere in their companies, including for onshoring or expanding domestic manufacturing capabilities.

---

[19] EY report, "Impacts of Potential Tariffs on the U.S. Pharmaceutical Industry," "April 22, 2025

[20] Beasley (2025), Reuters, "Pharma companies expected to absorb any tariff hit in short term," https://www.reuters.com/business/healthcare-pharmaceuticals/pharma-companies-expected-absorb-any-tariff-hit-short-term-2025-04-16/

[21] Association for Accessible Medicines "2020 Generic Drug & Biosimilars Access and Savings in the U.S. Report," https://accessiblemeds.org/resources/reports/2020-generic-drug-biosimilars-access-and-savings-us-report/

[22] Lee (2025), "Number Analytics, A Detailed Study of Tariff Influences on Global Drug Pricing," https://www.numberanalytics.com/blog/global-drug-pricing-tariff-trends

[23] Bloom & Holland (2025), NAM Manufacturers Outlook Survey, https://nam.org/wp-content/uploads/securepdfs/2025/03/Q1_2025_Outlook_Survey.pdf

Tariffs also will increase costs to the federal government, which is the largest purchaser of pharmaceutical products in the United States. Combined, Medicare and Medicaid account for about 40% of spending on drugs nationwide, with Medicare alone accounting for nearly a third.[24]

Drug Supply Shortages: Tariffs on pharmaceuticals risk inducing drug shortages. According to the American Society of Health-System Pharmacists, since March 2025, the U.S. is experiencing 270 active drug shortages, down from its peak of 323 shortages in 2024.[25,26] As noted by the Office of the Assistant Secretary for Planning and Evaluation at the Department of Health and Human Services, the average drug shortage impacts approximately 500,000 people.[27] Examples include critical cancer treatments and blood pressure medications, as well as antibiotics. [28] **Placing immediate and broad-based tariffs on imported medicines could exacerbate drug shortages, particularly for generic medications.** Drug shortages make it more difficult and more expensive for Americans to get the medications they need, impacting both Americans' health and ability to work .

Global sourcing helps mitigate supply chain risks and ensures that Americans have a stable supply of life-saving medicines. Global, resilient supply chains were essential during the pandemic and other national emergencies such as in the aftermath of natural disasters. The U.S. is well positioned to tap into established global supply chains with allies to help fill gaps and minimize U.S. exposure to supply shortages or temporary disruptions.

Supply of Orphan Drugs: Tariffs could have serious implications for patients' access to drugs that treat rare diseases. Also known as orphan drugs, these drugs treat conditions that affect fewer than 200,000 Americans and are often the only treatment option for individuals living with severe, progressive, and life-threatening illnesses.[29] These patients would be impacted disproportionately by shortages and disruptions caused by tariffs due to the lack of alternative treatment options. Flexibilities should be prioritized for such patients, as there are fewer options for reshoring or shifting supply chains for specialized and rare disease medicines due to high barriers for conducting R&D, clinical trials and small-batch manufacturing. Disruptions or shortages for patients with such conditions could worsen health outcomes and disease progression and potentially have even more serious consequences.

Ranchers/Farmers Impacted: Tariffs on the pharmaceutical industry would also negatively impact the agricultural industry and lead to shortages or increased costs of food for Americans. Ranchers and farmers operate on slim margins and a tariff caused increase in the cost of livestock pharmaceuticals, including vaccinations, antibiotics, and other medications, may be passed on to consumers or lead farmers to delay or skip certain preventive health measures that could impact animal health and hurt domestic food supply.

Additionally, disruptions in the animal pharmaceutical supply chain because of tariffs could also cause ranchers and farmers to miss important vaccination windows, which could in turn lead to disease outbreaks and impact food supply.

---

[24] Centers for Medicare & Medicaid Services, NHE Fact Sheet, https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet

[25] ASHP (2025), "National Drug Shortages January 2001-March 2025," https://www.ashp.org/-/media/assets/drug-shortages/docs/Drug-Shortages-Report.pdf

[26] ASPE Report to Congress (2023), "Impact of Drug Shortages On Consumer Costs," https://aspe.hhs.gov/reports/drug-shortages-impacts-consumer-costs

[27] Ibid

[28] Ibid

[29] *See* 21 U.S.C.S. § 360bb(a)(2) (LexisNexis 2025).

Trade Policy Solutions

Tariffs on pharmaceuticals and production inputs risk serious unintended consequences, including supply disruptions, lowering U.S. producers' competitiveness, escalating costs to patients, and long-term damage to the R&D foundation that drives competitiveness of pharmaceutical manufacturers in the U.S.

Trade policy can be better leveraged to **secure preferential access to allied markets that are a source of critical inputs, partners in related party transactions, and the backstop against shortages in emergencies**. This includes sectoral agreements as proposed for example in the Medical Supply Chain and Resiliency Act which aims to strengthen the U.S. medical supply chain by enhancing trade partnerships, diversifying sources, and improving overall resilience. The administration should also continue to pursue intellectual property protections and high IP standards in these markets to protect the greatest source of national security — R&D and innovation by manufacturers in the U.S.

The administration should consider hosting a **public-private consortium to discuss and engage the private sector in collaborative approaches to address unmet domestic pharmaceutical needs.** This could be broadened to include chemicals and other critical inputs for pharmaceutical production to meet the needs of American patients and consumers.

A Comprehensive Manufacturing Strategy Is Necessary to Support More U.S. Pharmaceutical Production

The administration is right to look to increase domestic pharmaceutical production capabilities and ensure sufficient supply of pharmaceuticals for Americans, and manufacturers stand ready to partner with the administration on these important goals. **However, tariffs on pharmaceutical products will not help the U.S. achieve those objectives** and instead would lead to negative unintended consequences. The NAM instead encourages a comprehensive manufacturing strategy that includes strategic trade policy solutions, as discussed above, as well as domestic reforms that support the growth of the pharmaceutical industry in the U.S.

Manufacturers encourage the administration to foster a domestic policy environment that supports and encourages pharmaceutical innovation here at home:

- **Make President Trump's 2017 Tax Reforms Permanent and More Competitive:** Pharmaceutical companies depend on a competitive tax code to support life-saving innovation. Congress and the administration should preserve crucial innovation and investment incentives—including immediate R&D expensing, the FDII deduction, full expensing for capital equipment purchases, and more—and maintain tax reform's reduced corporate rate in order to empower the industry to innovate and grow in the U.S.

- **Advance Workforce Reform:** Pharmaceutical innovation requires high-skilled workers at a time when manufacturing is facing more than 400,000 open jobs across the industry. As such, the government should focus on workforce training and upskilling solutions to close the skills gap.

- **Expedite Permitting Reform**: The federal government should be making it easier for biopharmaceutical manufacturers to expand domestic capabilities by reforming the lengthy process of building new facilities. Streamlining permitting processes, cutting red tape, requiring federal agencies to make timely decisions, and reducing the potential for baseless litigation will reduce the burdensome process and enable increased domestic manufacturing. Similarly, expedited approvals to change labels and manufacturing processes (e.g., to

change registered source materials) would also allow greater manufacturer flexibility to adjust suppliers, as needed, to increase reliability and create efficiencies.

- **Fully Resource the FDA:** FDA reviews and approvals of life-changing and life-saving treatments, as well inspections of pharmaceutical facilities, require a fully resourced and staffed agency. Manufacturers encourage the administration to ensure that under-resourcing at the FDA does not lead to unnecessary delays that could slow down companies' efforts to manufacture and deliver medicines to patients.

- **Reform PBMs:** PBMs, underregulated middlemen in the prescription drug system, contribute to the skyrocketing cost of health care by tying patient cost-sharing to list prices, pocketing manufacturer rebates, and obscuring their concerning business models. Reforms to their business practices would lower health care costs.

- **Fight Counterfeit Products**: Counterfeit pharmaceuticals pose significant risks to consumers and undermine pharmaceutical companies' efforts to produce safe and effective products. The NAM encourages the U.S. government to work more closely with foreign counterparts and private sector actors, including online platforms, to strengthen penalties for counterfeiters, tackle counterfeit shipments, and improve capacity to fight counterfeiting.

Conclusion

This investigation is complex and could have adverse impacts on both patients' healthcare costs as well as on the ability of pharmaceutical manufacturers to produce life-saving treatments in the U.S. The NAM's recommendations herein offer several alternative paths to achieving national security and economic resiliency and competitiveness in the pharmaceutical sector.

The NAM appreciates the opportunity to comment on this investigation and looks forward to engaging BIS in this investigation as well as working with the administration to bolster a resilient pharmaceutical supply chain and enhance manufacturing of biopharmaceutical products in the U.S.

Sincerely,

Andrea Durkin
Vice President, International Policy