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May 6, 2025

SUBMITTED ELECTRONICALLY

Mr. Eric Longnecker
Deputy Assistant Secretary for Technology Security
Bureau of Industry and Security
Office of Strategic Industries and Economic Security
Department of Commerce
1401 Constitution Ave NW
Washington, DC 20230

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BIS-2025-0022
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Re: Request for Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, 90 Fed. Reg. 15951 (Apr. 16, 2025)

Dear Mr. Longnecker:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this opportunity to provide the following comments in response to a request by the U.S. Department of Commerce ("Commerce") on the Section 232 investigation concerning pharmaceuticals and pharmaceutical ingredients as initiated on April 1, 2025.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.

This submission reflects the state and perspective of the U.S. innovative biopharmaceutical sector[1] that is very differently situated than the generic segment of the industry. The United States leads the world in researching, developing and distributing innovative medicines and the innovative biopharmaceutical industry is a major contributor to the U.S. economy. As a result of the United States's strong innovation ecosystem for biopharmaceuticals, American patients have earlier and greater access to innovative medicines than patients in any other country,[2] all the while that most prescriptions (more than 90 percent) are filled with generics and biosimilars.[3] Our sector has built resilient and secure supply chains sourced overwhelmingly from domestic sources and reliable U.S. allies. While the innovative biopharmaceutical industry certainly faces

[1] Defined as those companies investing in the innovative biopharmaceutical industry in the United States regardless of where they are headquartered.

[2] PhRMA, "Global Access to New Medicines Report," 2023, available at https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report.

[3] U.S. Food and Drug Administration, Office of Generic Drugs, https://www.fda.gov/about-fda/cder-offices-and-divisions/office-generic-drugs#:~:text=Who%20We%20Are:,those%20of%20brand%2Dname%20drugs.

trade barriers in multiple markets, those barriers are best addressed through negotiation and enforcement of robust bilateral and sectoral agreements. Biopharmaceutical innovators continue to make significant investments in the United States and stand ready to support efforts to increase domestic manufacturing of essential medicines. Specifically, we encourage Commerce to focus this investigation on targeted strategic national security concerns, rather than imposing tariffs on innovative medicines that would not advance the Administration's goal of enhancing national security nor address the trade barriers faced by the industry in foreign markets.

The innovative biopharmaceutical industry shares the administration's goal of ensuring the national and economic security of the United States. Indeed, as explained in Section I below, the innovative biopharmaceutical industry is an integral component of the United States' economic success. Unlike certain other sectors that have been subject to prior Section 232 investigations, the U.S. innovative biopharmaceutical industry is healthy and competitive, with almost two thirds of the value of medicines consumed in the United States being made in the United States. In assessing whether imports are threatening to impair the country's national security consistent with Section 232, it is critical to recognize that the innovative biopharmaceutical industry in the United States leads the world in developing and manufacturing new medicines. Further, as explained in Section II, to the extent that certain medicines and active pharmaceutical ingredients (APIs) are imported, most are imported from allied economies in Europe and Asia-Pacific (e.g., Australia, Japan, Singapore and South Korea) and innovative biopharmaceutical supply chains are diverse and resilient (Section III).

Recognizing the strength of the innovative biopharmaceutical sector in the United States, Commerce should use this investigation to identify where there are specific national security vulnerabilities (i.e., if the industry is over-reliant on supply for essential medicines and API from adversarial countries) and identify appropriate targeted solutions to address those concerns (Section IV). As explained in Section V below, tariffs are not the answer for promoting greater domestic production of these products. On the contrary, every dollar collected in tariffs would be a dollar less that innovative biopharmaceutical companies are able to invest in U.S. R&D, manufacturing facilities and infrastructure. Instead of imposing tariffs, therefore, the Administration should adopt pragmatic solutions and targeted incentives to ensure the United States' continued security (Section VI).

I. The U.S. Innovative Biopharmaceutical Industry is Healthy, Globally Competitive and a Major Contributor to the U.S. Economy

The U.S. biopharmaceutical industry leads the world in innovation and production of valuable medicines that enable people to live longer, healthier and more productive lives. Pioneering work by biopharmaceutical innovators in the United States contributes significantly to economic growth and supports good-paying jobs in all 50 states. As a key component of America's high-tech economy, the research-based biopharmaceutical sector supports over 4.9 million jobs across the economy, including more than one million jobs in the innovative biopharmaceutical industry.

The industry contributes more than $1.65 trillion in economic output on an annual basis when direct, indirect and induced effects are considered.[4]

The U.S. biopharmaceutical industry is well known as the world leader in medical research – producing more than half the world's new molecules in the last decade. Often overlooked, however, is the industry's substantial U.S. manufacturing presence. As explained below, biopharmaceutical manufacturing is one of the United States' largest manufacturing sectors, producing nearly two-thirds of all medicines consumed in the United States by value and directly employing nearly 360,000 workers, making the sector one of the largest sources of U.S. manufacturing jobs.[5]

Far from being weakened by international competition, the innovative biopharmaceutical industry has demonstrated a combination of growth, stability and economic resilience over many years, making the industry a key driver of the U.S. economy. The industry grew its U.S. workforce by 30.8 percent from 2015 to 2022 – far outpacing overall U.S. manufacturing (3.8 percent) and overall U.S. private sector (8.8 percent) employment growth over the same period.[6] The industry also attracted more new foreign direct investment into the United States than any other industry (over $148 billion from 2017 to 2022)[7] and added more than 550 new U.S. manufacturing facilities between 2018 and 2023.[8]

The men and women of America's biopharmaceutical sector strive every day to discover, develop and deliver innovative medicines to patients across the country and around the world to ensure that they can benefit from the latest treatments and cures. The industry's varied occupational base and extensive U.S. research, manufacturing and distribution infrastructure generate and support high-wage jobs, significant tax revenues and growing economic output for local communities. As explained below, the strength and ingenuity of the innovative biopharmaceutical industry, coupled with U.S. policies that support innovation and fair and open trade, have resulted in the United States being the global leader in biopharmaceutical innovation and production. The following economic metrics reflect this global and national leadership position.

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[4] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates," May 2024, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMARefresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf (last visited Jan. 26, 2025).

[5] Id.

[6] Id.

[7] U.S. Bureau of Economic Analysis, New Foreign Direct Investment in the United States, https://www.bea.gov/data/intl-trade-investment/new-foreign-direct-investment-united-states/supplemental-data. Note: New foreign direct investment includes both "greenfield projects" and acquisitions.

[8] NDP Analytics, analysis of U.S. FDA Drug Establishments Current Registration Site, as of Apr. 2023; Apr. 2022; Feb. 2021; Jan. 2020; Apr. 2019; Apr. 2018. *See* McLung, Tim, "Biopharmaceutical manufacturing companies continue to expand their economic footprint across the United States," (May 2023), available at https://phrma.org/blog/biopharmaceutical-manufacturing-companies-continue-to-expand-their-economic-footprint-across-the-united-states.

A. The Innovative Biopharmaceutical Industry is a U.S. Manufacturing Leader

The innovative biopharmaceutical industry is a global leader in U.S. manufacturing, producing $388 billion of gross output in 2023,and supplying nearly two-thirds (by value) of all medicines consumed in the United States.[9] In 2023, U.S. sales of finished biopharmaceuticals totaled $393 billion, of which 64 percent ($251 billion) was produced in the United States and 36 percent ($143 billion) was imported, primarily from Europe and other U.S. allies.[10] U.S. biopharmaceutical production has grown more than 65 percent over the past ten years, three times more than overall U.S. manufacturing.[11] Domestic production has continued to supply over 60 percent of U.S. market sales (by value) each year for the past ten years.[12]

As with finished medicines, the United States is not overly reliant on other countries for biopharmaceutical inputs. Fifty-three percent by value of the $85.6 billion of Active Pharmaceutical Ingredients (API) used in medicines consumed in the United States was manufactured in the United States as of 2021, with the remainder sourced primarily from Europe and other allies.[13]

The innovative biopharmaceutical industry is among the top five employers of U.S. manufacturing jobs, with more Americans directly employed in pharmaceutical manufacturing than in several other major industries, including each of the following: iron and steel products, aerospace products and parts, petroleum and coal products, and electric equipment and appliances.[14] In 2022, 34 percent of biopharmaceutical industry employees in the United States were engaged in manufacturing, 39 percent were engaged in biopharmaceutical R&D, 24 percent were engaged in distribution and three percent were engaged in corporate administration.[15]

Over many years, the innovative biopharmaceutical manufacturing sector has shown remarkable growth and resilience to economic downturns, providing important stability both to the U.S. economy and the medical supply chain. From 2015 to 2022, employment in the biopharmaceutical manufacturing sector in the United States increased by 22 percent.[16] Thanks to years of sustained investment by the industry, the number of biopharmaceutical manufacturing facilities in the United States grew by more than 50 percent from 2018 to 2023.[17] As of 2023,

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[9] U.S. Department of Commerce Bureau of Economic Analysis, Gross Output by Industry, 2023.

[10] Ernst & Young, Impacts of potential tariffs on the US pharmaceutical industry, April 2025.

[11] Bureau of Economic Analysis, U.S. Department of Commerce.

[12] PhRMA analysis of data from Bureau of Economic Analysis, U.S. Department of Commerce.

[13] Avalere Health, "US Makes Majority of API by Dollar Value in US-Consumed Medicines," (June 14, 2023), available at https://avalere.com/insights/majority-of-api-in-us-consumed-medicines-produced-in-the-us.

[14] U.S. Bureau of Labor Statistics, Current Population Survey (CPS) Labor Force Statistics, available at https://www.bls.gov/cps/home.htm (last visited Jan. 26, 2025).

[15] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates," May 2024, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.

[16] Id.

[17] NDP Analytics, analysis of U.S. FDA Drug Establishments Current Registration Site, as of Apr. 2023; Apr. 2022; Feb. 2021; Jan. 2020; Apr. 2019; Apr. 2018.

biopharmaceutical companies and their suppliers operated 1,580 production facilities across the country, in 48 states and Puerto Rico.[18]

The biopharmaceutical industry also is by far the largest driver of new foreign direct investment in U.S. manufacturing, accounting for more than 25 percent from 2017 to 2022. The next-highest industry, computers and electronic products, accounted for only 12 percent over the same period.[19]

B. The U.S. Innovative Biopharmaceutical Industry Leads the World in Medical Innovation

The innovative biopharmaceutical industry is the most R&D-intensive in the United States and leads the world in medical research.[20] In 2022, innovative biopharmaceutical companies invested approximately $141 billion in R&D in the United States.[21] This equates to almost 70 percent of biopharmaceutical R&D in the OECD countries.[22] Biopharmaceutical companies also account for the largest single share of all industrial R&D investment in the United States (17 percent).[23]

The heavy concentration of biopharmaceutical R&D activity in the United States provides immense benefits to the U.S. economy and workers. As of 2022, the innovative biopharmaceutical industry's R&D sector employed more than 400,000 American workers – an increase of nearly 122,000 jobs (42 percent) since 2015.[24] As of 2021, the innovative biopharmaceutical industry had more domestic R&D workers than any other U.S. industry, including aerospace and navigational instruments manufacturing, automotive and motor vehicles manufacturing, and semiconductor manufacturing.[25]

The high value-added nature of the innovative biopharmaceutical industry enables it to provide high-wage and high-quality jobs for American workers. In 2022, annual compensation for biopharmaceutical workers in the United States averaged nearly $158,000 – significantly higher

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[18] Id.

[19] U.S. Bureau of Economic Analysis, New Foreign Direct Investment in the United States, 2023, available at https://www.bea.gov/data/intl-trade-investment/new-foreign-direct-investment-united-states. Note: New foreign direct investment includes both "greenfield projects" and acquisitions.

[20] Pharmaceutical Research and Manufacturers of America, "Research and Development Policy Framework," https://www.phrma.org/policy-issues/research-development; Ezell S, "Ensuring U.S. Biopharmaceutical Competitiveness," July 2020, available at https://www2.itif.org/2020-biopharma-competitiveness.pdf.

[21] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates," May 2024, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.

[22] OECD Indicators, OECD Health. Pharmaceutical Research and Development, available at https://www.oecd.org/en/publications/2023/11/health-at-a-glance-2023_e04f8239/full-report/pharmaceutical-research-and-development_6eb5e4b8.html#OEC212_1eb40c0900.

[23] Biopharmaceutical Industry-Sponsored Clinical Trials: Impacting State Economies (citing National Center for Science and Engineering Statistics (NCSES). 2024. Business Enterprise Research and Development: 2022.)

[24] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates," May 2024, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.

[25] Id.

than the U.S. private sector average of $71,000 and the U.S. manufacturing average of $96,000.[26] Value added per worker in the United States averaged $402,000 in the innovative biopharmaceutical industry, compared to $188,000 for overall U.S. manufacturing and approximately $124,000 per worker across all U.S. industries.[27]

C. The U.S. Biopharmaceutical Industry and Its U.S. Workforce Benefit from International Trade and Investment

The innovative biopharmaceutical industry's large U.S. economic footprint, and the corresponding benefits that accrue to the industry's U.S. workforce, exist precisely because the sector is an exceptionally active participant in the international trading system and benefits from global trade policies that value innovation and protect intellectual property rights. As shown above, the United States has achieved and retained the position of the world's leader in biopharmaceutical innovation and production. This leadership position, in turn, has been strengthened by the industry's robust trade and investment engagement in the global economy. For example:

- **High domestic benefits from global activity and presence.** The United States reaps an outsized share of the economic benefits of the innovative biopharmaceutical industry's global trade and investment activities. As noted above, in 2022, innovative biopharmaceutical companies invested approximately $141 billion in R&D in the United States,[28] which equates to almost 70 percent of biopharmaceutical R&D in the OECD countries.[29]

  In addition to its significant contributions to the U.S. economy and American patients, the innovative biopharmaceutical industry seeks to serve patients around the world through local affiliates. Data demonstrate that U.S. multinationals that increase their investments abroad simultaneously increase the size and strength of their manufacturing activities in the United States.[30] For example, creation of jobs by U.S. multinationals abroad and the expansion of sales by U.S. multinational affiliates abroad both lead to more production and employment at home, especially in high-wage services such as R&D. On average, a 10 percent increase in U.S. multinational firms' overseas sales by their affiliates correlates with: an 8.2 percent increase in U.S. domestic R&D spending; 2.6 percent increase in U.S. exports; and 2.2 percent increase in U.S. employment.[31] By contrast, the preponderance of net job loss in U.S. manufacturing comes from companies that do not invest abroad.[32]

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[26] Id.

[27] Id.

[28] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates," May 2024, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.

[29] OECD Indicators, OECD Health. Pharmaceutical Research and Development, available at https://www.oecd.org/en/publications/2023/11/health-at-a-glance-2023_e04f8239/full-report/pharmaceutical-research-and-development_6eb5e4b8.html#OEC212_1eb40c0900.

[30] The Peterson Institute for International Economics, The U.S. Manufacturing Base: Four Signs of Strength, June 2014, available at https://www.piie.com/publications/policy-briefs/us-manufacturing-base-four-signs-strength.

[31] Id.

[32] Id.

- **Significant foreign direct investment.** During the five-year period from 2017 to 2022, 90,000 jobs were created in the innovative biopharmaceutical industry in the United States by new foreign direct investment.[33] As noted, the biopharmaceutical industry attracts more new foreign direct investment into the United States than any other industry (over $148 billion over this five year period).[34]

- **Major U.S. exporter.** In 2023, U.S. biopharmaceutical goods exports exceeded $101 billion.[35] The biopharmaceutical sector was the largest exporter of goods among the most R&D-intensive industries in 2023 – a category that also includes navigational equipment, semiconductors and other electronic components, medical equipment and supplies, and communications equipment.[36]

II. Imports of Innovative Medicines and Inputs Are Sourced Overwhelmingly from Reliable U.S. Allies and Do Not Threaten to Impair National Security

While the United States is the primary source of innovative biopharmaceuticals and inputs consumed by U.S. patients, trade with the United States' allies – particularly in Europe and Asia – complements and supports U.S. production. Trade with longstanding U.S. allies and security partners allows U.S. patients to access the broadest possible range of treatments and cures, expands access to production inputs for U.S. manufacturers and enhances national security by mitigating the risk of domestic supply disruptions. As detailed below, U.S. allies – not adversarial nations – are by far the largest source of *innovative* biopharmaceuticals and ingredients imported into the United States.

A. Europe is the Largest Source of Biopharmaceuticals and Inputs Imported into the United States

In 2023, U.S. imports of biopharmaceutical products (including finished medicines, API and other inputs) totaled $203.2 billion.[37] By value, the European Union was the largest source of these imports, accounting for 62 percent of the total. Europe as a whole accounted for 73 percent of the total when the United Kingdom and Switzerland (which account for three and eight percent of imports, respectively) are included. Canada accounted for three percent of total imports, Israel accounted for one percent, and the following Asian countries collectively accounted for another 13 percent: Singapore (eight percent), Japan (three percent), Australia (one

[33] Financial Times Ltd, fDi Markets, available at https://www.fdimarkets.com/. Note: new foreign direct investment includes "greenfield projects" only and not acquisitions.

[34] U.S. Bureau of Economic Analysis, New Foreign Direct Investment in the United States, https://www.bea.gov/data/intl-trade-investment/new-foreign-direct-investment-united-states/supplemental-data. Note: New foreign direct investment includes both "greenfield projects" and acquisitions.

[35] U.S. Bureau of Economic Analysis, International Accounts Products for Detailed Goods Trade Data, available at https://www.bea.gov/international/detailed-trade-data.

[36] Analysis of National Science Foundation and Business Research and Development Survey (BRDIS) data by ndp | analytics.

[37] Unless otherwise stated, all figures cited in this subsection are from Ernst & Young, "Impacts of potential tariffs on the US pharmaceutical industry," April 2025. Attached hereto as Exhibit 1.

percent) and South Korea (one percent). In total, 90 percent of the value of U.S. imports of biopharmaceuticals originated from these longstanding U.S. allies.

Biopharmaceutical inputs used by American producers to make drugs here constituted approximately 30 percent by value ($60.4 billion) of total U.S. biopharmaceutical imports in 2023, whereas finished biopharmaceuticals for sale to consumers accounted for approximately 70 percent by value ($143 billion) of imports (though only 36 percent of total U.S. consumer sales). By value, Europe was by far the largest source of imports in both categories, accounting for 88 percent of imports of biopharmaceutical inputs and 73 percent of imports of finished biopharmaceuticals. In 2023, only one percent of imports of biopharmaceutical inputs and five percent of imports of finished biopharmaceuticals originated from China.

B. Europe is the Largest Source of Foreign-Origin Active Pharmaceutical Ingredients Used in U.S.-Consumed Medicines

APIs are a subset of biopharmaceutical inputs and are the components of a medicine that produce the intended therapeutic effect on the body. Europe is the primary source of foreign-sourced APIs in medicines consumed in the United States.

Medicines intended for U.S. patients are approved by the U.S. Food and Drug Administration (FDA) and manufactured in FDA-registered facilities in the United States and abroad. This includes both finished pharmaceutical products (FPP) and their API. API used in medicines consumed in the United States generally enter the supply chain in three ways: domestically manufactured API; API imported from other countries that is used in the United States to produce FPP; and API produced and manufactured into FPP in other countries, which then is imported into the United States.

As detailed below, most API manufacturing facilities that supply the U.S. market are in the United States or Europe. In addition, the vast majority of API in U.S.-consumed medicines (by value) is manufactured in the United States or Europe. As the United States considers opportunities to further strengthen biopharmaceutical supply chains, PhRMA encourages the Administration to recognize and build on the robust trade and supply chain relationships that currently exist, in terms of both finished products and their API, with partners such as those in Europe.

1. *Most API manufacturing facilities that supply the U.S. market are in the United States or Europe*

The FDA publishes data regarding API manufacturing facilities that supply the U.S. market. According to FDA data on manufacturing facilities, about 28 percent of API manufacturing facilities supplying the U.S. market are in the United States – more than any other single country – while 26 percent are in the European Union, 18 percent are in India, 13 percent are in China, two percent are in Canada and 13 percent are elsewhere in the world.[38]

[38] Testimony of Janet Woodcock, M.D. Center for Drug Evaluation and Research, FDA, "Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program" (Dec. 10, 2019), available at

2. *Most API and starter materials in U.S.-consumed medicines are manufactured in the United States or Europe*

A study performed by Avalere Health found that in 2021 more than half (53 percent) of the $85.6 billion of API and starter materials used in medicines consumed in the United States (by value) was manufactured in the United States; 29 percent was manufactured in EU Member States, three percent was manufactured in Switzerland, and one percent was manufactured in the United Kingdom. In total, approximately 85 percent of the API and starter materials used in medicines consumed in the United States in 2021 was manufactured in either the United States or these European countries. The remainder was manufactured in China (seven percent), Singapore (four percent), India (two percent) and other countries (two percent). Avalere's estimates account for all three ways in which API enters the U.S. supply chain, rather than focusing solely on U.S. imports of API that are used to manufacture FPP in the United States.[39]

One approach that should be considered by Commerce in determining whether the United States is over-reliant on specific markets for APIs in U.S.-consumed medicines would be to assess whether an API is sourced from a single foreign country. Information about FDA-regulated products imported into the United States are collected by U.S. Customs and Border Protection (CBP) to monitor compliance with FDA regulations. Through this process, the FDA in turn provides information to the public about imported products on its online compliance dashboard. An analysis of both the FDA compliance data and IQVIA data on U.S. domestic sales of medicines shows that there are very few APIs on which the United States is currently reliant on a single foreign country. On the contrary, in terms of the final sales value of U.S.-consumed medicines, APIs sourced from the United States or allied economies in Europe and Asia-Pacific represent more than 99 percent of the U.S. market, and APIs imported only from China or India represent less than 1 percent of the U.S. market.[40]

C. Imports of Innovative Biopharmaceuticals and Inputs from Europe and Other Allies Enhance U.S. National Security

The Trump Administration has previously recognized that cooperation with U.S. allies and security partners, including through trade, can enhance national security and supply chain resilience. For example, in response to President Trump's 2017 Executive Order on Assessing and Strengthening the Manufacturing and Defense Industrial Base and Supply Chain Resiliency

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https://www.fda.gov/news-events/congressional-testimony/securing-us-drug-supply-chain-oversight-fdas-foreign-inspection-program-12102019.

[39] Avalere Health, "US Makes Majority of API by Dollar Value in US-Consumed Medicines," (June 14, 2023), available at https://avalere.com/insights/majority-of-api-in-us-consumed-medicines-produced-in-the-us. The study performed by Avalere Health estimates direct U.S. imports of API and starter materials by using U.S. Department of Commerce trade data for harmonized tariff schedule (HTS) codes that are not for finished pharmaceutical products (found in Chapter 30) but have a pharmaceutical preparations end-use code (found mostly in Chapter 29 HTS codes and elsewhere). To estimate the amount of API and starter materials produced in the United States, Avalere Health uses U.S. Department of Commerce data to estimate intermediate purchases of pharmaceutical inputs by the U.S. pharmaceutical manufacturing industry and then subtracts direct imports of API and starter materials. Avalere Health estimates indirect U.S. imports of API and starter materials by analyzing the country sources of API and starter materials among countries exporting finished pharmaceutical products to the United States.

[40] PhRMA analysis of FDA compliance data and IQVIA MIDAS data.

of the United States, a Department of Defense-led (DOD) task force recommended "[w]orking with allies and partners on joint industrial base challenges" while "diversifying away from … politically unstable countries who may cut off U.S. access[.]"[41] Similarly, the Administration's 2019 Federal Strategy to Ensure Secure and Reliable Supplies of Critical Minerals recommended "[i]ncreasing trade with allies and partners" to reduce the risk of supply disruptions and dependence on unreliable sources, and President Trump's 2020 Executive Order on critical minerals recognized "the continued importance of cooperation on supply chain issues with international partners and allies …."[42] President Trump's 2020 National Strategy for Critical and Emerging Technologies further recognized that the United States "benefits from the technology ecosystems of its allies and partners" and that "[c]ooperation with allies and partners will not only promote a shared technological advantage, it will also prevent strategic competitors from obtaining unfair advantages."[43]

Congress similarly has recognized that expanding trade with allies, including in the biopharmaceutical sector, enhances national security. For example, in its March 2025 "action plan for American security and prosperity," the National Security Commission on Emerging Biotechnology chaired by Sen. Todd Young (R-IN) emphasized the need for "cross-border collaborations with allies and partners," including trade agreements that expand market access, address regulatory barriers and boost aggregate demand for biotechnology products.[44] Similarly, the bipartisan Medical Supply Chain Resiliency Act proposes to strengthen medical supply chains through sectoral trade agreements with trusted U.S. allies who maintain strong IP, regulatory and other standards and have demonstrated a commitment to open and reciprocal trade with the United States.[45]

As detailed above, the vast majority of U.S. imports of *innovative* biopharmaceuticals and inputs are sourced from countries that the U.S. government has recognized as its most reliable allies, including in the context of highly sensitive supply chains related to national defense. For example, U.S. law treats the defense industrial bases of Australia, Canada, New Zealand and the

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[41] Interagency Task Force, "Assessing and Strengthening the Manufacturing and Defense Industrial Base and Supply Chain Resiliency of the United States" (Sept. 2018) at p. 5, available at https://media.defense.gov/2018/oct/05/2002048904/-1/-1/1/assessing-and-strengthening-the-manufacturing-and%20defense-industrial-base-and-supply-chain-resiliency.pdf.

[42] U.S. Department of Commerce, "A Federal Strategy to Ensure Secure and Reliable Supplies of Critical Minerals" (2019) at p. 27, available at https://www.commerce.gov/sites/default/files/2020-01/Critical_Minerals_Strategy_Final.pdf; and Executive Order 13953 on Addressing the Threat to the Domestic Supply Chain From Reliance on Critical Minerals From Foreign Adversaries and Supporting the Domestic Mining and Processing Industries (Sept. 30, 2020), available at https://www.federalregister.gov/documents/2020/10/05/2020-22064/addressing-the-threat-to-the-domestic-supply-chain-from-reliance-on-critical-minerals-from-foreign.

[43] The White House, "National Strategy for Critical and Emerging Technologies" (Oct. 2020) at p. 3, available at https://trumpwhitehouse.archives.gov/wp-content/uploads/2020/10/National-Strategy-for-CET.pdf.

[44] National Security Commission on Emerging Biotechnology, "Charting the Future of Biotechnology: An action plan for American security and prosperity," (April 2025) at pp. 136 and 142, available at https://www.biotech.senate.gov/wp-content/uploads/2025/04/NSCEB-Full-Report-–-Digital-–-4.22.pdf.

[45] The Medical Supply Chain Resiliency Act is sponsored by Senators Thom Tillis (R-NC), Chris Coons (D-DE), John Cornyn (R-TX), and Michael Bennet (D-CO). See S.998 - 119th Congress (2025-2026): Medical Supply Chain Resiliency Act, Mar. 12, 2025, available at https://www.congress.gov/bill/119th-congress/senate-bill/998.

United Kingdom as part of the United States' National Technology and Industrial Base (NTIB), as a deliberate strategy to foster "seamless integration" of the countries' respective industrial bases in support of U.S. national security objectives – including supplying military operations, conducting advanced R&D and systems development, securing reliable sources of critical materials and developing industrial preparedness to support operations in wartime or during a national emergency.[46] Under this framework, DOD is required to procure certain sensitive technologies from within the NTIB, and may exempt certain NTIB entities from restrictions on the participation of foreign entities in national security-related contracts.[47]

Similarly, most EU Member States along with Australia, Canada, the United Kingdom, Switzerland, Israel, Singapore, Japan and South Korea are parties to Reciprocal Defense Procurement Agreements (RDP) or Security of Supply Arrangements (SOSA), or both, with the United States.[48] RDP Agreements provide the parties with increased access to each other's defense procurement markets and industrial bases by waiving "buy national" requirements, duties and other requirements for covered defense procurements, whereas SOSAs allow DOD to request priority delivery for contracts, subcontracts or orders from companies in participating countries (and vice-versa).[49]

These arrangements reflect an assessment that U.S. allies in Europe and elsewhere are reliable security partners and that their participation even in critical defense-related supply chains should not only be permitted, but encouraged. That these and other close allies supply a portion of the innovative medicines and inputs consumed in the United States, in a commercial market where U.S. production satisfies the majority of demand, is thus not a national security threat but an *asset* that should be leveraged and strengthened.

III. U.S. Innovative Biopharmaceutical Manufacturers Have Built Resilient and Secure Supply Chains with Safeguards to Avoid Supply Disruptions

Research-based biopharmaceutical manufacturers are committed to ensuring safe, stable, sustainable and secure supply chains. Achieving this goal requires significant investment in time and resources to ensure that American patients receive safe and effective medicines when needed.

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[46] 10 U.S.C. § 4801. *See also* Office of the Assistant Secretary of Defense for Industrial Base Policy, "National Technology and Industrial Base (NTIB)," available at https://www.businessdefense.gov/icie/ic/ntib.html; and Congressional Research Service, Defense Primer: The National Technology and Industrial Base, (Apr. 2025), available at https://www.congress.gov/crs-product/IF11311.

[47] 10 U.S.C. § 4864; 10 U.S.C. §4874.

[48] Office of the Assistant Secretary of Defense for Acquisition, "International Contracting - Reciprocal Defense Procurement and Acquisition Policy Memoranda of Understanding," available at https://www.acq.osd.mil/asda/dpc/cp/ic/reciprocal-procurement-mou.html; and Office of the Assistant Secretary of Defense for Industrial Base Policy, "Security of Supply," available at https://www.businessdefense.gov/security-of-supply.html.

[49] See, *e.g.*, U.S. Department of Defense, Conclusion of the Renewal of a Reciprocal Defense Procurement Agreement With the Government of the Italian Republic, 90 Fed. Reg. 12712, available at https://www.federalregister.gov/d/2025-04494; and Office of the Assistant Secretary of Defense for Industrial Base Policy, "Security of Supply," available at https://www.businessdefense.gov/security-of-supply.html.

A. Existing biopharmaceutical supply chains have been carefully established to promote resilience

In developing biopharmaceutical supply chains, manufacturers consider the locations of each source facility and have extensive measures in place to manage the various elements of production processes, including ensuring sufficient access to the skilled workers and materials needed. Biopharmaceutical manufacturers must begin setting up the manufacturing supply chain for a medicine years before that medicine is even approved for patients to use. This process involves the following steps:

- **Initial development of manufacturing plans.** Designing the manufacturing process to ensure consistency and reliability is a complex activity. Manufacturing plans address operations from the receipt and manufacturing of materials to production, packaging, labeling, relabeling, storage and distribution, as well as related quality-control and testing systems.

- **Build the supply chain, including suppliers.** As large-scale manufacturing processes are developed, companies draw up plans for sourcing all the materials needed, which may be obtained in-house or through qualified vendors and suppliers. Manufacturers also develop risk-management plans to ensure redundancy in suppliers in the event of supply disruption.

- **Scale up manufacturing process.** As clinical trials progress—and assuming they show positive results—scaling up the manufacturing process to meet rigorous FDA standards at a commercial level is complex and costly. Building quality into the manufacturing process is a key focus in product and process design, including scaling up production to manufacture sufficient quantities of that medicine for the number of patients needing treatment,[50] as well as develop plans for getting those medicines to patients. This process includes, for example, contracting with various suppliers to ensure high-quality, reliable sourcing of certain materials used for manufacturing, ensuring the availability of a highly skilled labor force with the ability to manufacture the medicine and maintaining the critical quality control and testing systems needed to protect patients.

- **Build new facility or expand capacity.** Building a new facility or expanding an existing facility to produce commercial quantities of medicines requires substantial planning and resources. Constructing a new facility can cost up to $2 billion (and sometimes even more) and take five to ten years. Expanding existing facilities, transferring a single product to a new manufacturing site, or retrofitting an existing facility for a new product can take several years.

- **Comply with regulations and submit for inspections.** FDA regulations help ensure that medicines intended for patients meet quality standards that protect public health. The FDA also reviews information about the manufacturing process as part of drug applications and during pre-approval and surveillance inspections. Manufacturers must

[50] By definition, drugs for rare diseases treat far fewer patients, such that the economics often do not support more than one manufacturing location globally.

register with the FDA and list the drugs they manufacture; the agency relies on this information to plan and conduct surveillance inspections at finished drug and API sites. All facilities within the supply network implement security plans. Changes made to any supply chain component, material or design require careful consideration and planning, as well as engagement with the FDA to obtain appropriate regulatory review and approval.

Over decades, innovative biopharmaceutical manufacturers have built these robust supply chains carefully and deliberately to ensure that patients in the United States and around the world have access to safe and high-quality medicines. Biopharmaceutical companies invest significantly in the design and ongoing maintenance and modernization of manufacturing facilities and their quality systems. These efforts were successful in avoiding any major disruptions in the supply of innovative medicines during the COVID-19 pandemic.

It is important to recognize that market dynamics vary for brand or innovative manufacturing companies and generic manufacturing companies, with brand medicine manufacturers more likely to have robust business continuity plans that may include stand-by manufacturing and robust inventory to mitigate against potential disruptions including shortages. Conversely, generic manufacturers are less likely to have supply chain redundancies and, therefore, are far more likely to experience drug shortages. As a result, appropriate attention should be given to increasing resilience concerning critical generic medicines necessary to support acute care during a public health emergency.

B. Existing biopharmaceutical supply chains include important safeguards to ensure quality

The FDA regulates virtually every stage in the life cycle of a prescription medicine sold in the United States, including API for medicines available to U.S. patients. Biopharmaceutical manufacturers are required by law to report substantial information to the FDA relating to API and sourcing of API, and FPP and API manufacturers are required to register and provide certain information on each registered manufacturing facility with the FDA. The FDA's Current Good Manufacturing Practice (CGMP) requirements apply to FPP as well as API manufacturers to ensure quality regardless of where their facilities are located. In addition, biopharmaceutical manufacturers have their own robust quality control systems in place to help ensure the quality of the product throughout the entire manufacturing process. These systems include the establishment of robust supplier qualification programs to vet potential vendors to help ensure that they meet CGMP requirements.

Manufacturers have complex systems in place as a matter of course to avoid major disruptions in their supply chains. For example, they maintain robust inventory management systems that track anticipated demand by looking at historical demand and supply data. These systems allow manufacturers to continuously monitor their supply and distribution lines to ensure sufficient supply, anticipate risk and avert potential disruption. Companies put in place risk management plans that include alternate manufacturing sites, inventory reserves and/or a range of global external suppliers and logistics planning to ensure continuity in shipping of supplies. Manufacturers also have systems in place to monitor demand and work closely with the FDA to

prevent and mitigate shortages, including by reporting substantial data to the FDA regarding certain potential shortages.

C. Existing biopharmaceutical supply chains are geographically diverse

Geographic diversity is one of the most fundamental strategies for maintaining a stable, operational supply chain that can respond rapidly to public health emergencies. American patients benefit from geographic diversification, especially in the time of pandemics or other emergencies, because it provides companies with flexibility when they need it most. If an entire biopharmaceutical supply chain is dependent upon one geographic area and that area experiences a natural or national disaster or pandemic, there could be significant infrastructure and supply disruptions with global implications. Hurricane Maria in 2017 is a case in point. Approximately 50 biopharmaceutical manufacturing facilities were in Puerto Rico at the time of the hurricane, and their capacity was significantly reduced by the disaster. Because of robust supply chains and close coordination with the FDA, the industry was quickly able to shift manufacturing to facilities in other areas and prevent long-term drug shortages.

Biopharmaceutical companies must be able to adjust their supply chains in the case of an emergency that may result in disruptions, like Hurricane Maria. Building a new facility takes significant time and resources, so it is not a feasible solution in an emergency. Instead, innovative biopharmaceutical companies typically rely on a geographically diverse supply chain that includes a range of redundancies and business continuity plans to prevent and mitigate potential disruptions. Companies consider the locations of each facility and have extensive measures in place to manage the various elements of the manufacturing process, including, as appropriate, maintaining inventories of certain materials and ensuring sufficient access to the skilled workers, specialized equipment and materials needed.

Geographically diverse supply chains also allow manufacturers to access key inputs that are not readily available in every country. Coordinated global production ensures that all countries have access to the ingredients needed to produce a wide range of medicines. Manufacturers consider many factors for where raw materials, API and medicines should be sourced and produced. Some countries do not have the proximity to, or capacity to develop, the ingredients essential to the production of certain drugs. Other countries, including the United States, cannot source certain ingredients, such as rare earth minerals, either because of a lack of minable concentrations or commercial viability, or due to restrictive environmental or other regulations governing mining. Given these realities, the security of the United States' biopharmaceutical supply chain depends on maintaining both substantial domestic production and robust trade relationships with trusted allies.

IV. The Section 232 Investigation Should Focus on Specific National Security Concerns

The innovative biopharmaceutical industry shares the Trump Administration's goal of ensuring U.S. national security and the supply of essential medicines. Unlike certain other sectors that have been subject to Section 232 investigations, the U.S. innovative biopharmaceutical industry is healthy, competitive and resilient (see sections I-III above). Nonetheless, to the extent that the country over-relies on markets that raise national security concerns for specific essential

products, the Administration should identify those products and tailor its actions to address those concerns.

Much work has and is being done to identify those products and inputs that should be produced domestically to ensure the nation's security. As the President stated in Executive Order 13944 of August 6, 2020 ("Essential Medicines EO"), the:

> United States must protect our citizens, critical infrastructure, military forces, and economy against outbreaks of emerging infectious diseases and chemical, biological, radiological, and nuclear (CBRN) threats. To achieve this, the United States must have a strong Public Health Industrial Base with resilient domestic supply chains for Essential Medicines, Medical Countermeasures, and Critical Inputs deemed necessary for the United States.[51]

President Trump's May 5, 2025, Executive Order on Regulatory Relief to Promote Domestic Production of Critical Medicines underscored the significance of the Essential Medicines EO and the Administration's prioritization of essential medicines in its efforts to promote increased U.S. manufacturing.[52]

In response to the Essential Medicines EO, the FDA worked in consultation with other federal partners, to develop a list of drug and biological product essential medicines and medical countermeasures:

> Generally, the essential medicines we identified are those that are most needed for patients in U.S. acute care medical facilities, which specialize in short-term treatment for severe injuries or illnesses, and urgent medical conditions. The medical countermeasures we identified are FDA-regulated products (biologics, drugs, devices) that meet the definition of a "medical countermeasure" provided in the executive order and that we anticipate will be needed to respond to future pandemics, epidemics, and chemical, biological, and radiological/nuclear threats. When identifying essential medicines and medical countermeasures, we focused on including those that are medically necessary to have available in adequate supply which can be used for the widest populations to have the greatest potential impact on public health.[53]

Since then, the Administration for Strategic Preparedness and Response (ASPR) has been working with Commerce to prioritize those medicines and APIs that are critical for patient care

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[51] Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States (Aug 6, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/executive-order-ensuring-essential-medicines-medical-countermeasures-critical-inputs-made-united-states/.

52 Executive Order on Regulatory Relief to Promote Domestic Production of Critical Medicines (May 5, 2025), available at https://www.whitehouse.gov/presidential-actions/2025/05/regulatory-relief-to-promote-domestic-production-of-critical-medicines/.

[53] *See* Criteria For Identifying Human Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs for the List Described in Section 3(c) of the Executive Order (EO) 13944 (Oct. 30, 2020), available at https://www.fda.gov/media/143407/download?attachment.

in acute settings or important for acute care, with no comparative alternative available.[54] Only last year, ASPR asked the Bureau of Industry and Security to conduct a survey on the U.S. manufacturing capacity for 83 APIs.

> This study is being performed in partnership with the Department of Health and Human Services' (HHS) Center for Industrial Base Management & Supply Chain (IBMSC). The assessment will provide IBMSC with data-driven recommendations that may include identifying opportunities for increased collaboration between the U.S. Government and industry as well as U.S. allies and partners to ensure the availability and security of the U.S. API supply chain in the U.S. and abroad.
>
> The principal goal of this survey and assessment is to gain a deeper understanding of the global supply chain network supporting U.S. API manufacturing and identify vulnerabilities such as single-source or single-region dependency, unfair trade practices, and regulatory constraints, among other issues.[55]

Building on this work, Commerce should work with industry to identify a refined and targeted list of those products on which the United States is overly-reliant on supply of these essential medicines and APIs from adversarial countries. While the Section 232 investigation is not limited to assessing imports from specific countries, prior Section 232 reports have determined that imports from "reliable foreign sources" would not threaten to impair national security.[56] As highlighted in Section II.C. above, imports from allied countries in Europe, Australia and Japan that are home to companies that have made significant investments in the U.S. innovative biopharmaceutical industry should be considered reliable foreign sources that can help the United States maintain resilient and secure supply chains, particularly for those products for which critical precursors or starting materials may not be available here.

Finally, having identified any essential products on which the country is over reliant on supply from adversarial countries, it is critical to consider the appropriate actions the President could take to sustainably support capacity to produce those medicines and API in the United States (or where appropriate, allied countries). As explained in Section V below, tariffs on innovative biopharmaceutical products will not promote greater domestic production of these products. On the contrary, every dollar collected in tariffs would be a dollar less that biopharmaceutical companies are able to invest in U.S. R&D, manufacturing and infrastructure. Innovative biopharmaceutical products, by definition, are not commodities (unlike many of the other products that have been subject to Section 232 investigations), and their complex supply chains and associated regulatory requirements would make it impossible to move production in any

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[54] That work built on a report that ASPR commissioned in May 2022 on *Essential Medicines Supply Chain and Manufacturing Resilience Assessment*, available at https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf.

[55] *See* BIS, U.S. Active Pharmaceutical Ingredient Industrial Base Assessment, available at https://www.bis.doc.gov/index.php/api-survey.

[56] *See*, *e.g.*, Department of Commerce, Bureau of Export Administration, *The Effects of Imports of Iron Ore and Semi-Finished Steel on the National Security*, Oct. 2001, at 27, available at https://www.bis.doc.gov/index.php/documents/section-232-investigations/81-iron-ore-and-semi-finished-steel-2001/file.

timescale necessary to avoid imposed tariffs. Thus, instead of imposing tariffs, the Administration should adopt pragmatic solutions and targeted incentives as outlined in Section VI below.

V. Tariffs on Innovative Medicines and Inputs Would Not Enhance National Security

PhRMA recognizes that U.S. policymakers have expressed national security concerns regarding the United States' potential over-reliance on adversarial countries for certain essential medicines. Should the Administration identify and seek to address such dependencies, it should avoid overbroad actions that would inhibit investment in innovative biopharmaceutical manufacturing and research in the United States and unnecessarily burden the U.S. health care system and patients. In particular, the Administration should refrain from imposing tariffs on innovative medicines and inputs, as such tariffs would undermine rather than strengthen national security.

A recent analysis by Ernst & Young estimates that an additional 25 percent tariff on all biopharmaceuticals and ingredients imported into the United States would increase the cost of these products by $50.8 billion annually.[57] This additional cost is equivalent to nearly 13 percent of the biopharmaceutical industry's annual U.S. sales.[58] While the innovative biopharmaceutical industry has a strong U.S. manufacturing presence and is making major investments to expand that presence,[59] setting up new facilities to manufacture medicines is a complex and costly undertaking that can take five to ten years, as shown below. Tariffs would jeopardize those investments and place significant strain on U.S. industry and the U.S. health care system, with harmful consequences for national security. PhRMA therefore urges the Administration to pursue other trade and domestic policies that would better promote biopharmaceutical manufacturing in the United States.

A. Setting Up an Innovative Biopharmaceutical Manufacturing Process and Supply Chain is a Complex and Lengthy Undertaking

As discussed in Section III.A above, innovative biopharmaceutical companies begin setting up the manufacturing supply chain for a medicine years before that medicine is even approved for patient use. This process includes determining how to manufacture the medicine, meeting all applicable regulatory requirements and developing plans for getting the medicine to patients, and

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[57] Ernst & Young, Impacts of potential tariffs on the US pharmaceutical industry, Apr. 2025 at p. 7.

[58] Id. at p. 2.

[59] *See*, *e.g.*, Press Release, Eli Lilly, Lilly plans to more than double U.S. manufacturing investment since 2020 exceeding $50 billion (Feb, 26, 2025), available at https://investor.lilly.com/news-releases/news-release-details/lilly-plans-more-double-us-manufacturing-investment-2020; Press Release, Johnson and Johnson, Johnson & Johnson Increases U.S. Investment to More than $55 Billion Over the Next Four Years (Mar. 21 2025), available at https://www.jnj.com/media-center/press-releases/johnson-johnson-increases-u-s-investment-to-more-than-55-billion-over-the-next-four-years; Press Release, Novartis, Novartis plans to expand its US-based manufacturing and R&D footprint with a total investment of $23B over the next 5 years (Apr. 10, 2025), available at https://www.novartis.com/us-en/news/media-releases/novartis-plans-expand-its-us-based-manufacturing-and-rd-footprint-total-investment-23b-over-next-5-years#:~:text=EAST%20HANOVER%2C%20N.J.%2C%20April%2010,made%20in%20the%20United%20States.; Press Release, Roche, Roche to invest USD 50 billion in pharmaceuticals and diagnostics in the United States over the next five years (Apr. 21, 2025), available at https://www.roche.com/investors/updates/inv-update-2025-04-22.

incorporating robust risk management and business continuity plans to ensure supply network security. In total, it can take five to ten years to set up a new manufacturing facility, and even longer to on-shore an entire manufacturing network. Making changes to even one element of a supply chain can take years to implement and can generate significant costs. The innovative biopharmaceutical industry has made and continues to make major investments in U.S. manufacturing, and is working to do that as quickly as possible. However, it is not possible to relocate production activities immediately in response to tariffs or other policy changes.

B. Tariffs on Innovative Medicines and Inputs Would Weaken U.S. Manufacturing and Scientific Leadership

As explained in Section I, the U.S. innovative biopharmaceutical industry is a global leader in manufacturing, producing $388 billion of gross output[60] in 2023 and supplying nearly two-thirds of all medicines consumed in the United States (by value).[61] While more than half (53 percent) of the $85.6 billion of API used in U.S.-consumed medicines (by value) is manufactured in the United States, another 33 percent is sourced from reliable European allies through carefully coordinated supply chains.[62] A 25 percent tariff on imported API and other inputs would increase production costs for U.S. manufacturers by $15.1 billion annually, reducing the United States' competitiveness as a location for biopharmaceutical manufacturing.[63] Approximately 90 percent of this cost would result from tariffs on imported API and other ingredients from Canada, the European Union, Switzerland and the United Kingdom.[64]

Similarly, while 64 percent of finished medicines consumed in the United States are produced domestically, imports of finished medicines from allied countries allow millions of U.S. patients to access a broader range of cutting-edge treatments and cures.[65] A 25 percent tariff on imports of finished medicines would increase their cost by $35.7 billion annually.[66] Approximately 70 percent of this cost would result from tariffs on finished medicines from Canada, the European Union, Switzerland and the United Kingdom.[67]

Tariffs on innovative biopharmaceutical imports would significantly inhibit investment in U.S. biopharmaceutical manufacturing and research. While the home of the innovative biopharmaceutical industry is the United States, many innovative biopharmaceutical companies operate manufacturing sites both in the United States and in other jurisdictions such as the European Union, Switzerland, the United Kingdom and Japan, simultaneously serving U.S.

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[60] U.S. Department of Commerce Bureau of Economic Analysis, Gross Output by Industry, 2023.

[61] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates," May 2024, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.

[62] Avalere Health, US Makes Majority of API by Dollar Value in US-Consumed Medicines, June 14, 2023, available at https://avalere.com/insights/majority-of-api-in-us-consumed-medicines-produced-in-the-us.

[63] Ernst & Young, Impacts of potential tariffs on the US pharmaceutical industry, April 2025 at p. 7.

[64] Id.

[65] Id. at p. 2.

[66] Id. at p. 7.

[67] Id.

patients from these U.S. and overseas facilities and supplying ingredients produced abroad to U.S. manufacturing sites. Tariffs on innovative biopharmaceutical imports would force these manufacturers to divert substantial resources to tariff payments, at the expense of further investment in biopharmaceutical manufacturing and research in the United States. By delaying and jeopardizing investments in these important areas, tariffs would undermine rather than strengthen the United States' manufacturing base and its global leadership position in biotechnology.

C. Tariffs on Innovative Medicines and Inputs Would Harm U.S. Patients

Policymakers in the United States and other developed economies have long recognized that tariffs on innovative biopharmaceuticals and ingredients can impede patients' access to medicines by increasing costs and causing shortages and supply disruptions. For example, the Trump Administration has previously recognized that "tariffs … can hinder government efforts to promote increased access to health-care products" and that "the increased expense associated with those levies is then passed directly to healthcare institutions and patients."[68] The Administration's 2025 Special 301 Report reaffirms that trade-restrictive measures, including tariffs, "have the potential to hinder market access in the pharmaceutical and medical device sectors, and potentially result in higher product costs."[69] These patient access challenges are not mere inconveniences – they can threaten the health and lives of Americans who depend on treatment. For these reasons, the United States and other developed economies including Canada, the European Union, Japan, Switzerland and the United Kingdom generally have not imposed tariffs on biopharmaceuticals and APIs for several decades.

PhRMA members are committed to advancing public policies that ensure innovative medicines are accessible and affordable for U.S. patients – a goal shared by the Administration. Tariffs run counter to this shared goal by imposing direct costs on biopharmaceuticals and the various inputs used to invent, manufacture and distribute them. This not only threatens patient access to existing medicines, but diverts resources that could instead be directed to research and development, including clinical testing, of new treatments and cures for the most pressing health challenges Americans face.

As explained in Section I, the biopharmaceutical sector is one of the most research-intensive in America, annually investing an estimated $141 billion in researching and developing new medicines.[70] As a result of these investments, new medicines projected to launch in the coming years have the potential to address some of the most serious health challenges Americans face

[68] Office of the U.S. Trade Representative, 2017 Special 301 Report at p. 20, available at https://ustr.gov/sites/default/files/301/2017%20Special%20301%20Report%20FINAL.PDF.

[69] Office of the U.S. Trade Representative, 2025 Special 301 Report at p. 30, available at https://ustr.gov/sites/default/files/files/Issue_Areas/Enforcement/2025%20Special%20301%20Report%20(final).pdf (citing an October 2021 Geneva Network Report on "How Tariffs Impact Access to Medicines").

[70] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates," May 2024, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.

including cancer, Alzheimer's disease, multiple sclerosis and obesity, among others.[71] Many medicines currently in development have the potential to address previously unmet medical needs: for example, more than 2,000 gene therapies are in the pipeline with the potential to provide greater treatment options for approximately 6,500 rare diseases that currently lack an FDA-approved treatment.[72] With an estimated annual cost of more than $50 billion, a 25 percent tariff on the biopharmaceutical sector would seriously inhibit the ability of the U.S. innovative biopharmaceutical industry to invest in these promising technologies, to the detriment of American patients and public health.

D. The Administration Should Address Unfair Trade Practices Through Ambitious, Pro-Innovation Trade Agreements, Rather Than Tariffs

As the Administration has recognized, many foreign countries engage in unfair trade practices that deny adequate and effective protection of intellectual property rights or deny fair and equitable market access to U.S. biopharmaceutical innovators.[73] For decades, PhRMA has encouraged the U.S. government to engage with trading partners to address these unfair practices, which inhibit the ability of our member companies and their workers to develop, manufacture and export life-saving treatments and cures.[74]

As explained above, the imposition of tariffs on innovative biopharmaceuticals would substantially harm U.S. interests and would not be a productive means of addressing unfair trade practices abroad. Such tariffs also are unnecessary to protect U.S. national security. Indeed, as explained in Section I, the U.S. biopharmaceutical industry is healthy and globally competitive, leads the world in innovation, and has a large and growing U.S. manufacturing presence. Foreign trade barriers, while significant in many markets, have not prevented the industry from achieving and maintaining this global leadership position and do not threaten U.S. national security.

Rather than imposing tariffs on biopharmaceuticals, PhRMA urges the Administration to negotiate with foreign governments to secure the elimination of unfair trade practices that inhibit U.S. biopharmaceutical innovation, production and exports. PhRMA members support the following trade initiatives to bolster the competitiveness of the biopharmaceutical sector in the United States:

- **Negotiate new bilateral and sectoral trade agreements.** PhRMA encourages the Administration to pursue bilateral and sectoral trade agreements, as envisioned in President Trump's America First Trade Policy Memorandum, to eliminate unfair trade practices abroad. Such agreements should strengthen the U.S. biopharmaceutical industry by: (1) including strong intellectual property provisions that reflect a standard of protection similar to that found in U.S. law; (2) ensuring fair and equitable market access

[71] PhRMA, A New Era of Biopharmaceutical Innovation, Feb. 2025, available at https://innovation.org/wp-content/uploads/2025/02/PhRMA-InnovationReport.pdf.

[72] Id.

[73] Office of the U.S. Trade Representative, 2025 National Trade Estimate Report on Foreign Trade Barriers, available at https://ustr.gov/sites/default/files/files/Press/Reports/2025NTE.pdf.

[74] PhRMA, 2025 Special 301 Comments, Jan. 27, 2025, available at https://phrma.org/resources/phrma-special-301-submission-2025.

through requirements that pricing and reimbursement policies abroad appropriately value patented medicines and are fair, reasonable and non-discriminatory; (3) eliminating foreign tariffs on U.S. biopharmaceuticals and APIs; and (4) fostering transparency, due process and good regulatory practices, and regulatory cooperation.

In addition to pursuing new trade agreements, the Administration should consider modernizing and building on existing agreements, including through negotiations with China for a second phase of the Economic and Trade Agreement. The Administration also should use the upcoming Joint Review of the USMCA to strengthen the Agreement's intellectual property chapter, ensuring that Canada and Mexico afford reciprocal intellectual property protections to the United States consistent with President Trump's original vision for the Agreement.

PhRMA also supports targeted U.S. government engagement to eliminate foreign tariffs on biopharmaceuticals, APIs and other inputs. While most countries that play a major role in the innovative biopharmaceutical supply chain already provide reciprocal, tariff-free treatment to U.S. biopharmaceutical exports, emerging economies such as Argentina, Brazil and India apply significant tariffs in the sector. The Administration should engage with these trading partners to seek the elimination of tariffs on biopharmaceuticals exported from the United States.

- **Trusted trading partner agreements.** PhRMA encourages the Administration to pursue bilateral or sectoral trade agreements with trusted trading partners, such as the European Union, Japan, Switzerland and the United Kingdom, to formalize and affirm commitments to reciprocal, tariff-free trade in biopharmaceuticals, eliminate other trade barriers in the medical sector and promote strong IP, regulatory and other standards. Such agreements can strengthen U.S. biopharmaceutical supply chains by incentivizing trade and investment among reliable allies that have demonstrated a commitment to open and reciprocal trade with the United States. PhRMA encourages the Administration to partner with Congress, including through such initiatives as the bipartisan Medical Supply Chain Resiliency Act, to negotiate and implement such agreements.

Regrettably, the previous Administration demonstrated no ambition in addressing foreign intellectual property and market access barriers that impede U.S. biopharmaceutical research, manufacturing and exports, failing to implement a single commercially meaningful trade agreement with a new or existing partner. Instead, it departed from longstanding and bipartisan U.S. trade objectives by deprioritizing, and in certain instances proactively opposing, the very trade policies that best protect and support U.S. workers in this important sector. Ambitious new trade agreements that deliver strong intellectual property protection and market access for U.S. biopharmaceutical exports would provide strong incentives for manufacturing and innovation in the United States.

VI. The Innovative Biopharmaceutical Industry Continues to Make Significant Investments in the United States and Stands Ready to Support Efforts to Manufacture Essential Medicines in the United States

As outlined above in Section I, the home of the innovative biopharmaceutical industry is the United States. Not only does the U.S. innovative biopharmaceutical sector lead the world in the development of new medicines, it also generates high-quality jobs and powers economic output and exports for the U.S. economy, serving as the foundation upon which one of the United States' most dynamic innovation and business ecosystems is built. As noted above, in 2022, innovative biopharmaceutical companies invested approximately $141 billion in R&D in the United States,[75] which equates to almost 70 percent of biopharmaceutical R&D in the OECD countries.[76] Moreover, several significant new investments in U.S.-based manufacturing and R&D initiatives have been announced in 2025 alone.[77]

To the extent that this investigation identifies certain essential medicines on which the United States' innovative biopharmaceutical industry is over-reliant on supply from adversarial countries – thereby raising national security concerns – the innovative biopharmaceutical industry stands ready to partner with the U.S. Government to determine the best path forward to incentivize and sustainably support capacity to produce those medicines and APIs in the United States (or where appropriate in allied countries). While it is challenging to propose specific policies or incentives without knowing the products at issue, there are a broad range of policies that could be considered to expand and scale biomanufacturing capacity and infrastructure:

- The biopharmaceutical industry, like other advanced manufacturing industries, continues to face substantial increases in raw material, energy and transportation costs. It is important to recognize that there are often substantial differentials in the cost of raw materials and energy-related expenditures in the United States versus other countries. China, for example, has lower electricity, energy and water costs than the United States. Supporting the development of new technologies to increase efficiencies to help bring down some of these cost differentials are key to spurring increased investment in the United States.

- To help defray higher costs and level the playing field, tax and other investment incentives for new manufacturing facilities, expansions of facilities and enhancements of existing facilities in the United States and Puerto Rico are also needed. The U.S. tax code has supported R&D primarily through two policies: 1) expensing of R&D costs; and 2) tax credits for certain R&D expenses. The disparity in the tax treatment of R&D performed in the United States compared to the rest of the world now places the United States almost last among the OECD and BRIC nations in terms of tax incentives for

[75] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates," May 2024, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.

[76] OECD Indicators, OECD Health. Pharmaceutical Research and Development, available at https://www.oecd.org/en/publications/2023/11/health-at-a-glance-2023_e04f8239/full-report/pharmaceutical-research-and-development_6eb5e4b8.html#OEC212_1eb40c0900OECD Indicators, OECD Health.

[77] *Supra* n. 59.

R&D.[78] The R&D credit is currently at least three times more generous in China than in the United States.[79] Adjustments to R&D tax credits should seek to expand manufacturing in the United States irrespective of the current location of a company's operations or place of organization.

- Given the significant time and resources needed for expanding or building new facilities and innovating manufacturing processes, consideration must also be given to policies that expedite and streamline required regulatory approvals and processes.[80] Changes in federal, state or local government regulations or business-related policies also are a substantial driver of increases in the costs of doing business in the United States. Incentives and enhancements in key advanced manufacturing infrastructure provide opportunities for innovations that will increase efficiencies and potentially lead to cost savings in R&D and manufacturing that will allow the United States to offset some of the cost differentials with other countries.

- Significant workforce gaps exist across sectors with implications for national security and the bioeconomy from health care providers to construction engineers to transportation workers, cybersecurity and more. It is estimated that the STEM skills gap alone will leave 2.4 million positions unfilled in the United States between 2018 and 2028, with a potential economic impact of $2.5 trillion. India and China produce almost half of all science and engineering bachelor's degrees, compared to the U.S. which comprise only 10 percent of the global total.[81] In addition, U.S. students continue to fall behind other countries in terms of STEM standings and despite calls to shore up STEM education in the United States. At the same time, R&D-intensive industries such as the biopharmaceutical industry continue to make substantial investments in communities across the country to enhance K-12 STEM education and teachers' skills and grow interest in STEM fields and STEM education at all levels.[82] The gaps in the STEM work force are impacting biopharmaceutical companies' ability to initiate new clinical research efforts and impacting the ability to expand manufacturing in areas of scientific promise due to lack of access to qualified STEM workers.

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[78] ITIF, To Do: Double the R&D and Alternative Simplified Credits (Feb. 8, 2025), available at https://itif.org/publications/2024/04/01/to-do-double-the-rd-and-alternative-simplified-credits/.

[79] ITIF, China Is Rapidly Becoming a Leading Innovator in Advanced Industries, New Report Finds (Sept. 16, 2024), available at https://itif.org/publications/2024/09/16/china-rapidly-becoming-leading-innovator-in-advanced-industries-new-report-finds/.

[80] In this regard, the industry looks forward to further engaging with FDA, the Environmental Protection Agency and other relevant agencies as they work to implement the Executive Order on Regulatory Relief to Promote Domestic Production of Critical Medicines (May 5, 2025), available at https://www.whitehouse.gov/presidential-actions/2025/05/regulatory-relief-to-promote-domestic-production-of-critical-medicines/.

[81] Nat'l Sci. Found., Higher Education in Science and Engineering (Nov. 16, 2023), available at https://ncses.nsf.gov/pubs/nsb202332/international-comparisons-of-s-e-higher-education.

[82] TEConomy Partners, The Biopharmaceutical Industry's Sustained Commitment to Enhancing the Nation's STEM Education and Workforce, 2024, available at https://cdn.aglty.io/phrma/global/resources/import/pdfs/TEConomy-PhRMA%20STEM%20Ed%20Backgrounder%20Report%202024.pdf.

- Federal investments, including increased public-private partnerships, can serve a key role in enhancing U.S. manufacturing infrastructure and increasing U.S. competitiveness in areas ranging from accelerating the development and adoption of new, more-sustainable technologies and practices, to research into new technology platforms as well as supporting additional manufacturing capacity.

- To help the United States retain its global leadership in biopharmaceutical innovation and production, policymakers must maintain and foster the types of policies that contributed to the United States' current leadership position. For example, the United States should retain payment and coverage policies that appropriately value innovative medicines and the potential offsets they can bring elsewhere in the health care system, and robust protections and enforcement of intellectual property.

- Finally, as detailed in Section V.D above, multiple opportunities exist for the U.S. Government to promote biopharmaceutical R&D, manufacturing and exports through global cooperation. To maximize these opportunities, the Trump Administration, unlike its predecessor, should engage with U.S. trading partners to negotiate and conclude ambitious and comprehensive trade agreements. These agreements should include strong intellectual property protections and predictable and transparent market access, regulatory and other provisions that incentivize and reward innovation, dismantle trade barriers and facilitate manufacturing and distribution of medicines.

* * *

PhRMA appreciates this opportunity to respond to Commerce's request for comments and provide input on this Section 232 investigation. PhRMA looks forward to working with Commerce and other relevant government agencies on these issues.

Sincerely,

/s/ Jay Taylor

Jay T. Taylor

Executive Vice President, International

EXHIBIT 1

Impacts of potential tariffs on the US pharmaceutical industry

Prepared for PhRMA

24 April 2025

Table of contents

Key findings

$393b
in total US pharmaceutical sales

Total US consumer sales of finished pharmaceutical products were $393 billion in 2023, with 64% ($251 billion) domestically produced and sold inside the US and 36% ($143 billion) imported.

73%
of imports from Europe

Europe is the largest supplier of pharmaceuticals and inputs imported into the United States, accounting for 73% of total imports.

$50.8b
in tariff costs for highest scenario

The 25% tariff scenario assessed in this report would increase the cost of imported pharmaceuticals by $50.8 billion annually, with tariffs on imports from Europe accounting for the majority of this cost.

13%
of sales

The tariff cost is equivalent to 13% of the US pharmaceutical industry's annual domestic sales.

$15.1b
increase in production costs

The tariff on pharmaceutical industry inputs increases US production costs by $15.1 billion, increasing domestic production costs and reducing the competitiveness of the United States as a location to produce drugs for export.

$35.7b
increase in cost of imported finished medicines

Tariffs on imports of finished pharmaceuticals intended for sale to healthcare providers or patients would increase costs of those imports by $35.7 billion

1. Summary and overview

Tariffs on US imports including those enacted and proposed by President Donald Trump could materially increase US pharmaceutical costs, as well as impact economic activity. EY was commissioned by the Pharmaceutical Research and Manufacturers of America (PhRMA) to conduct an analysis of potential tariffs on the US pharmaceutical industry and economic activity.

The key findings of this analysis are summarized below.

Potential tariff scenario evaluated. The analysis examines the potential impact of a 25% tariff on pharmaceutical products.

Potential tariffs on US pharmaceutical imports. Based on the scenario, Table ES-1 shows tariffs on pharmaceutical imports to the United States would total $50.8 billion annually, at 2023 levels.

- The driver of the overall tariff cost is the tariff rate applicable to imports from the EU, due to its significance as a major source of US pharmaceutical imports.
- A portion of these tariffs would be levied on finished goods that are intended for sale to healthcare providers or patients. The remainder of the tariffs would be levied on pharmaceutical products that are further processed by the US pharmaceutical industry and then resold as domestic goods or exported abroad.

Table ES-1. Tariffs on US imports of pharmaceutical goods, by trading partner
(Tariffs in billions of dollars at 2023 levels)

Tariff scenario	Canada	China	EU	Mexico	Switzerland	United Kingdom	Rest of World	Total tariff	Effective rate on imports
25% tariff on pharmaceutical imports	$1.4	$1.8	$31.4	$0.2	$4.0	$1.7	$10.3	$50.8	25%

Source: EY estimates based on US Census Bureau USA Trade data and hypothetical tariff scenario.

US pharmaceutical import profile. Total US imports of pharmaceutical products were $203 billion in 2023, with high reliance on a small number of country trading partners.

- Total 2023 US pharmaceutical imports of $203 billion were sourced from 147 countries, but just 12 countries (six of which are in the EU) account for 80% of total imports.
- The EU was the largest source of these imports, accounting for 62% of total pharmaceutical imports in 2023. Ireland was the largest country source of US pharmaceutical imports, accounting for 25% of total US imports in 2023, followed by Germany (9%). Europe, including the United Kingdom (3%) and Switzerland (8%), accounted for 73% of total US pharmaceutical imports.
- Canada, Mexico, and China are relatively minor sources of US pharmaceutical imports, with 4% of total imports sourced from China, 3% from Canada, and less than 1% sourced from Mexico.
- Breaking down pharmaceutical imports by type, Europe is the dominant supplier of imported medicines. China is the largest supplier of antivirals, antibiotics, provitamins and vitamins by value, but these substances account for only 3% of total US pharmaceutical imports.

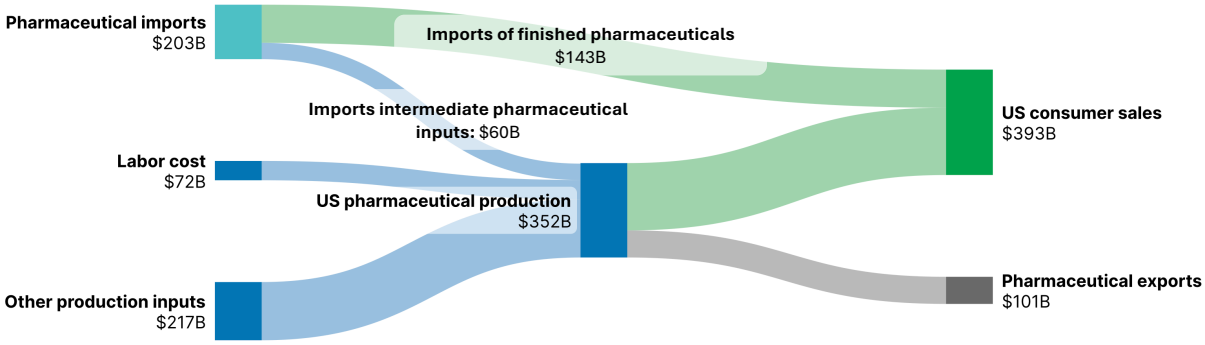
US pharmaceutical flows. Imports of pharmaceuticals are used in one of two ways, as shown in Figure ES-1 below:

- Approximately 30% of pharmaceutical product imports are ingredients for products manufacturered in US facilities and then exported or sold to US consumers. As described below, tariffs on these inputs increase US pharmaceutical production costs.
- Approximately 70% of pharmaceutical imports are finished products which are packaged and sold to consumers through distributors. Tariffs on these products are initially costs to the importer, which could be a distributor or a pharmaceutical company.

US pharmaceutical sales. Total US consumer sales of finished pharmaceutical products were $393 billion in 2023, with 64% ($251 billion) domestically produced and sold inside the US and 36% ($143 billion) imported.

- Approximately 24% of US consumer sales of finished products are imported from Europe.
- Approximately 3.2% of US consumer sales of finished products are imported from Canada (1.3%), Mexico (0.2%%), and China (1.7%).

Figure ES-1. Flow of pharmaceutical goods and production output through the US economy, 2023



Source: EY analysis based on US Census Bureau and US Bureau of Economic Analysis data
Note: Pharmaceutical production excludes production of pharmaceutical products that are consumed by the pharmaceutical industry as inputs for further processing.

Impact of tariffs on US pharmaceutical industry production costs. The US pharmaceutical industry would face higher production costs in relation to its US production activities due to tariffs levied on its purchased active pharmaceutical ingedients used in US production.

- In 2023, the US pharmaceutical industry imported an estimated $60.4 billion of pharmaceutical products for further processing in domestic production facilities. In some cases, pharmaceutical companies may locate different stages of processing in different countries, such that active ingredients used in US production may be produced abroad. These imported ingredients become production inputs in the US, combined with other production inputs and the labor and capital of the US pharmaceutical industry, to produce $352 billion of products for consumption by patients or export abroad.
- The EU is the largest source of imported pharmaceutical inputs, especially biological products. Therefore, the tariff rate applied to EU imports drives the overall input tariff cost.
- Expressed as a share of the $352 billion of economic output of the domestic pharmaceutical manufacturing industry, tariffs on imported inputs is 4.3% of output.

Tariff costs relative to US pharmaceutical sales. Production costs are only one factor shaping the price of newer medicines and it is unclear to what extent tariffs on imported intermediate inputs or imported finished products would be passed forward to consumers. Tariffs on imported finished products could be passed through to consumers by the wholesale or retail distributors paying the tariff.

- Given the pharmaceutical industry's estimated $393 billion in 2023 US domestic sales, and tariff costs of $50.8 billion, tariffs on production inputs and finished medicine products could amount to 12.9% of US pharmaceutical industry domestic sales. Of this amount, tariffs on imported finished medicines are 9.1% and tariffs on imported production inputs are 3.8%.

Impact on employment and economic activity. The US pharmaceutical industry is a significant and growing industry, which produces a significant share of the pharmaceuticals consumed in the US. Over the past 10 years, its contribution to US gross domestic product (GDP) has grown 81% compared to 41% for manufacturing overall. Tariffs on industry inputs would effectively increase production costs for US

domestic pharmaceutical production, reducing the competitiveness of the United States as a location to produce drugs for domestic consumption and export.

- A significant share of US production activity is related to export sales, which could be negatively impacted by higher US production costs. In 2023, $101 billion of pharmaceuticals were exported from the United States. Due to higher US production costs arising from intermediate input tariffs, US producers of pharmaceutical goods for export could face a reduction in demand for these products, with a corresponding decline in US employment.
- If tariffs are imposed on pharmaceutical industry inputs, production costs will increase by up to $15.1 billion, posing a competitive disadvantage for export sales. These incremental costs are equivalent to 4.1% of sales.
- US pharmaceutical production activity supported approximately 1.7 million total US jobs in 2023, of which an estimated 490,000 are related to export sales and some portion of these could be at-risk due to tariffs on production inputs.

2. Current US pharmaceutical import profile

The effects of the tariff scenario analyzed in this report are highly dependent on the type of product and sourcing of imported products from specific trading partners, which are described in this section and analyzed in the following sections.

2.1 Total imports of pharmaceutical products by trading partner

Table 1 shows the annual customs value of imported end-use pharmaceutical products in 2023. Ireland accounted for 25% of total US imports of pharmaceutical products – a share which has remained relatively stable for several years. The EU accounts for 62% of total US imports – a figure which grows to 73% if the United Kingdom and Switzerland are included as a European trading bloc.

Table 1. Pharmaceutical product imports by country, 2023
(Total customs value of imported end-use pharmaceutical goods in billions of dollars)

Country	2023	% of 2023 US imports
Ireland	50.9	25%
Germany	19.0	9%
Switzerland	15.9	8%
Singapore	15.5	8%
India	11.3	6%
Netherlands	10.7	5%
Italy	8.8	4%
China	7.2	4%
Belgium	6.9	3%
United Kingdom	6.8	3%
Japan	6.6	3%
Denmark	5.9	3%
Canada	5.8	3%
France	4.3	2%
Austria	3.8	2%
Spain	3.0	1%
Sweden	3.0	1%
Slovenia	2.9	1%
Hungary	2.8	1%
Korea, South	2.6	1%
Portugal	1.4	1%
Israel	1.3	1%
Australia	1.2	1%
Finland	1.0	0%
Mexico	0.9	0%
Other countries	3.5	2%
Total US imports	**$203.2**	**100%**
Addendum:		
European Union	$125.5	62%

Source: US Census Bureau USA Trade
Notes: Pharmaceutical products are defined as US Bureau of Economic Analysis end-use pharmaceutical products

The definition of pharmaceutical products analyzed in this report is set by the US Bureau of Economic Analysis (described as "end-use pharmaceutical products") to include a set of 293 Harmonized Commodity Description and Coding System (harmonized system, or "HS") product codes, most of which are found in Chapter 29 and Chapter 30 of the harmonized system. The harmonized system is a multipurpose international product nomenclature developed by the World Customs Organization (WCO), which includes more than 5,000 commodity groups, is used by more than 200 countries and economies

as a basis for their customs tariffs and for the collection of international trade statistics. Over 98% of the merchandise in international trade is classified in terms of the HS.

Also note that Table 1 shows pharmaceutical products, which include active pharmaceutical ingredients (finished medicines or bulk medicines in need of further processing and packaging), organic and inorganic chemicals, biological materials, and excipients. Note that pharmaceutical products does not include non-pharmaceutical production inputs used by the US domestic pharmaceutical manufacturing industry. These products include plastics, paper products, petroleum products, and other commodities used as inputs in the production process.

2.2 Imports of key pharmaceutical products by trading partner

Tables 2 and 3 present a breakdown of 2023 imports by major trading partners and regions. The EU accounted for 62% of total US imports of pharmaceutical goods in 2023, with Switzerland and the United Kingdom adding another 11% combined, meaning that 73% of total US imports of end-use pharmaceutical products originate from Europe.

Table 2. Pharmaceutical product imports by country, 2023
(Total customs value of imported BEA end-use pharmaceutical goods in millions of dollars)

HS	Country	Canada	China	EU	Mexico	Switzerland	United Kingdom	Rest of World	Total US Imports
3004	Medicaments Nesoi, Mixed Or Not, In Dosage Etc Fm	4,764	4,454	45,164	575	9,868	3,242	18,829	86,896
3002	Human Blood; Animal Blood; Antisera, Vaccines Etc	665	448	58,310	24	5,054	3,244	13,676	81,421
2937	Hormones; Derivatives & Steriods Used As Hormones	7	143	8,529	5	48	5	2,277	11,015
2933	Heterocyclic Comp, Nit Hetero-atoms Only	11	114	5,371	2	336	5	252	6,090
2934	Nucleic Acids & Salts, Heterocyclic Comp Nesoi	3	18	2,092	13	76	67	3,214	5,483
3006	Pharmaceutical Goods In Note 4 To Chapter 30	190	63	2,368	77	127	78	729	3,631
3003	Medicaments Nesoi Of Mixtures, Not Dosage Etc Form	34	154	1,619	0	66	31	465	2,369
2935	Sulfonamides	0	118	949	0	17	4	156	1,244
2936	Provitamins And Vitamins & Derivatives & Intermixs	6	812	157	1	89	39	107	1,210
2941	Antibiotics	2	199	438	3	4	3	84	733
	Other	106	709	485	248	228	94	1,232	3,102
	Total imports of end-use pharmaceuticals	**$5,788**	**$7,231**	**$125,482**	**$948**	**$15,913**	**$6,811**	**$41,020**	**$203,194**

Source: US Census Bureau USA Trade
Note: Amounts in table reflect 10-digit harmonized system commodities identified as end-use pharmaceuticals by the US Bureau of Economic Analysis, aggregated by 4-digit harmonized system section – amounts are not inclusive of all 10-digit codes included in each 4-digit harmonized system section shown.

Table 3. Pharmaceutical product imports by country, 2023
(Share of total customs value of imported BEA end-use pharmaceutical product categories imported from selected trading partners)

HS	Country	Canada	China	EU	Mexico	Switzerland	United Kingdom	Rest of World	Total US Imports
3004	Medicaments Nesoi, Mixed Or Not, In Dosage Etc Fm	5%	5%	52%	1%	11%	4%	22%	100%
3002	Human Blood; Animal Blood; Antisera, Vaccines Etc	1%	1%	72%	0%	6%	4%	17%	100%
2937	Hormones; Derivatives & Steriods Used As Hormones	0%	1%	77%	0%	0%	0%	21%	100%
2933	Heterocyclic Comp, Nit Hetero-atoms Only	0%	2%	88%	0%	6%	0%	4%	100%
2934	Nucleic Acids & Salts, Heterocyclic Comp Nesoi	0%	0%	38%	0%	1%	1%	59%	100%
3006	Pharmaceutical Goods In Note 4 To Chapter 30	5%	2%	65%	2%	3%	2%	20%	100%
3003	Medicaments Nesoi Of Mixtures, Not Dosage Etc Form	1%	6%	68%	0%	3%	1%	20%	100%
2935	Sulfonamides	0%	9%	76%	0%	1%	0%	13%	100%
2936	Provitamins And Vitamins & Derivatives & Intermixs	1%	67%	13%	0%	7%	3%	9%	100%
2941	Antibiotics	0%	27%	60%	0%	0%	0%	11%	100%
	Other	3%	23%	16%	8%	7%	3%	40%	100%
	Share of imports of end-use pharmaceuticals	**3%**	**4%**	**62%**	**0%**	**8%**	**3%**	**20%**	**100%**
	Total imports of end-use pharmaceuticals	**$5,788**	**$7,231**	**$125,482**	**$948**	**$15,913**	**$6,811**	**$41,020**	**$203,194**

Source: EY calculations based on US Census Bureau USA Trade
Note: Amounts in table reflect the share of 10-digit harmonized system commodities identified as end-use pharmaceuticals by the US Bureau of Economic Analysis, aggregated by 4-digit harmonized system section imported from each trading partner. The percentages are calculated at a more detailed level and are not inclusive of all 10-digit codes included in each 4-digit harmonized system section shown.

3. Tariff scenario and estimated tariff costs for imported pharmaceutical products

The analysis examines the potential impact of a 25% tariff on pharmaceutical products. While there would also be minor effects from other tariffs levied by the US on imports of non-pharmaceutical production inputs, separate estimates show those impacts to be relatively small (less than $500 million).

Based on the value of 2023 pharmaceutical imports from each trading partner, Table 4 presents the estimated dollar value of tariffs that would be levied on imports from each country under the tariff scenario, which total $50.8 billion. The driver of the overall result is the tariff rate that applies to pharmaceutical imports from the EU, due to its great significance as a source of US pharmaceutical imports.

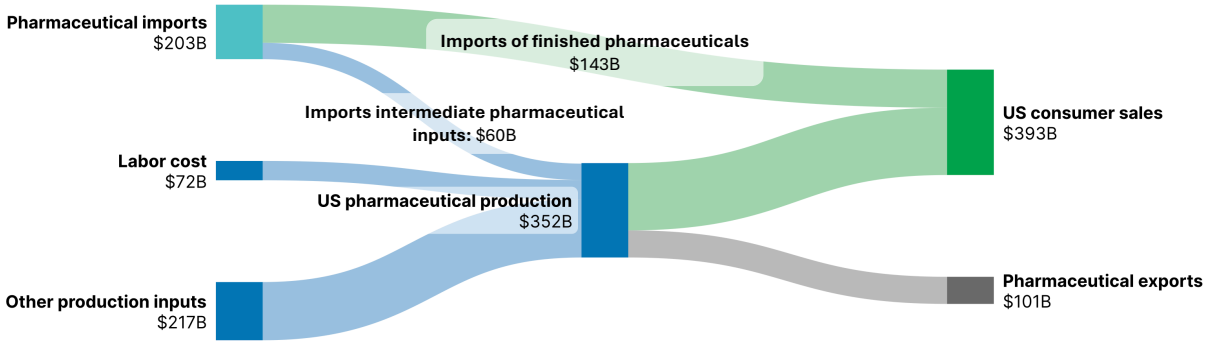
Table 4. Tariffs on imported pharmaceutical goods
(Assumed tariff rates applicable to all imported end-use pharmaceutical goods from each trading partner)

Tariff scenario	Canada	China	EU	Mexico	Switzerland	United Kingdom	Rest of World	Total tariff	Effective rate on imports
25% pharmaceutical rate	$1.4	$1.8	$31.4	$0.2	$4.0	$1.7	$10.3	$50.8	25%

Source: EY estimates based on US Census Bureau USA Trade import data and hypothetical tariff scenario.

As illustrated in Figure 1, a portion of these tariffs would be levied on $143 billion of finished pharmaceutical products that are sold to healthcare providers or patients. The remainder of the tariffs would be levied on $60.4 billion of pharmaceutical products that are further processed by the US pharmaceutical industry and then resold as domestic goods or exported abroad.

Figure 1. Flow of pharmaceutical goods and production output through the US economy, 2023



Source: EY analysis based on US Census Bureau and US Bureau of Economic Analysis data
Note: Pharmaceutical production excludes production of pharmaceutical products that are consumed by the pharmaceutical industry as inputs for further processing.

The sourcing of active pharmaceutical ingredients (API) and finished pharmaceutical products varies somewhat, with the EU supplying 74% of pharmaceutical inputs and 57% of finished pharmaceutical products. This is mostly due to the high share of biological products used as ingredients in US pharmaceutical production that are sourced from the EU (75%), which are a smaller share of US finished product imports. The shares of imported active pharmaceutical ingredient production inputs and finished product imports from each major trading partner are shown in Table 5.

Table 5. Sourcing of imported pharmaceutical production inputs and finished products
(Assumed tariff rates applicable to all imported end-use pharmaceutical goods from each trading partner)

Type of import	Canada	China	EU	Mexico	Switzerland	UK	Rest of World	Total
Imported production inputs (API)	2%	1%	74%	0%	10%	4%	10%	100%
Imported finished products	3%	5%	57%	1%	7%	3%	25%	100%
Total imported pharmaceuticals	**3%**	**4%**	**62%**	**0%**	**8%**	**3%**	**20%**	**100%**

Source: EY analysis based on US Census Bureau and US Bureau of Economic Analysis trade flow data

Based on the amount of imported pharmaceutical products sold directly to patients and hospitals for final use or used by pharmaceutical companies for further processing and production in the United States, Table 6 presents the estimated tariff on each category of sale of imported pharmaceutical product.

Table 6. Allocation of pharmaceutical tariffs on sales to final users and intermediate inputs

Tariff scenario	Tariff on imports used as intermediate inputs	Tariff on imports for sale to final users	Total tariffs on imports
25% on pharmaceutical imports	$15.1	$35.7	$50.8

Source: EY analysis

4. Tariffs on US pharmaceutical industry production inputs and finished products

The prior section examined the value of tariffs that would be levied on pharmaceutical product imports in total. This section examines the tariffs that would be levied on pharmaceutical products that are further used by the US domestic pharmaceutical industry in the production of products for sale in the United States or for export abroad.

Table 7 shows the use of imported pharmaceutical products by the US pharmaceutical industry. The US domestic pharmaceutical industry in 2023 produced $387.9 billion of gross economic output, of which $351.7 billion was products for final use (sales to patients or for export). To produce this output, the US industry consumed an estimated $62.5 billion of imported intermediate intermediate inputs, of which $60.4 billion were pharmaceutical products. These production inputs include active pharmaceutical ingredients in bulk or unfinished form that require further processing or packaging, organic and inorganic chemicals, biological materials, and excipients as well as basic inputs such as packaging materials.[1]

Table 7. Imported pharmaceutical industry production inputs and industry output, 2023
(Total customs value of key categories of imported pharmaceutical inputs, NAICS basis categories and output measures)

Imported production inputs	Total
Biological product (ex. diagnostic) manufacturing	$60.0
Medicinal and botanical manufacturing	0.1
Other basic organic chemical manufacturing	0.2
Pharmaceutical preparation manufacturing	0.0
Other commodities	0.8
Trade, services and other	1.3
Total imported intermediate inputs	**$62.5**
US pharmaceutical industry gross economic output	**$387.9**
Less: output re-used in domestic production as pharmaceutical inputs	-36.2
US gross industry economic output for final uses	**$351.7**

Source: EY calculations and estimates based on Bureau of Economic Analysis 2017 and 2023 input-output use matrix.
Note: The intermediate input categories and amounts shown are presented on a NAICS industry classification basis, consistent with the presentation of the Bureau of Economic Analysis input-output tables from which the amounts are derived.

Table 8 presents the sourcing of the imported pharmaceutical inputs used by the US pharmaceutical industry, by trading partner. The EU accounts for a significant majority of most intermediate inputs, including biological product inputs, which are the largest input category by value.

Table 8. Sourcing of imported pharmaceutical industry production inputs, 2023
(Share of total customs value from each trading partner of key categories of imported pharmaceutical inputs, NAICS basis categories)

	Canada	China	EU	Mexico	Switzerland	United Kingdom	Rest of world	All imports
Biological product (ex. diagnostic) mfg.	1%	1%	75%	0%	10%	4%	9%	100%
Medicinal and botanical mfg.	0%	7%	65%	0%	3%	1%	24%	100%
Other basic organic chemical mfg.	10%	15%	37%	2%	8%	2%	28%	100%
Pharmaceutical preparation mfg.	5%	5%	52%	1%	11%	4%	22%	100%
Other commodities	14%	14%	19%	15%	2%	2%	35%	100%
Total commodity intermediate inputs*	2%	1%	74%	0%	10%	4%	10%	100%

Source: US Census Bureau USA Trade data, NAICS-basis imports.
Note: The intermediate input categories and amounts shown are presented on a NAICS industry classification basis, consistent with the presentation of the Bureau of Economic Analysis input-output tables from which the amounts are derived.

[1] Overall, slightly less than half (45.7%) of pharmaceutical industry goods and services inputs are imported, meaning that the effective tariff rate across all inputs (domestic and imported) is approximately half of the effective import tariff rate. Inputs account for 35% of the value of final industry gross output, with the remaining 65% of industry production value coming from domestic pharmaceutical industry labor and capital.

As shown in Table 9, the tariff scenario results in $15.1 billion of tariffs on active pharmaceutical ingredients at the 25% rate.[2]

Tariffs under the scenario analyzed are 4.1% of gross economic output for final uses. Given the significance of active pharmaceutical ingredients in the production of finished pharmaceuticals, the pharmaceutical tariff rate is the driver of the result rather than country-specific tariff rates that apply to other production inputs.

Table 9. Estimated input tariff costs as a share of US pharmaceutical industry economic output, 2023
(Dollars in billions)

Imported intermediate input category	Tariff scenario
Biological product (except diagnostic) manufacturing	$15.0
Medicinal and botanical manufacturing	0.0
Other basic organic chemical manufacturing	0.1
Pharmaceutical preparation manufacturing	0.0
Other commodities	**
Trade, services and other	-
Total tariff cost on intermediate inputs	**$15.1**
Economic output for final uses	$351.7
Input tariffs as a % of industry gross output	**4.1%**

Source: EY estimates
Note: 0.0 values reflect positive amounts of less than $50 million. "-" reflects $0. Pharmaceutical industry economic output has been reduced to remove output that is re-used and consumed by the industry. ** While not presented or included in these totals, tariffs on non-pharmaceutical inputs used in pharmaceutical production are estimated to be $400 million.

[2] Note that in addition to the tariff on pharmaceutical productinputs (i.e., active pharmaceutical ingredients), there would also be an estimated $400 million in tariffs on other types of production inputs such as packaging and filler ingredients.

5. Scale of tariffs relative to US pharmaceutical sales

Production costs are only one factor shaping the price of newer medicines and it is unclear to what extent tariffs on imported intermediate inputs or imported finished products would be passed forward to consumers. Tariffs on imported finished products could be passed through to consumers by the wholesale or retail distributors paying the tariff.

In other sectors, empirical studies indicate that a significant portion of import tariff cost is passed on to consumers through higher prices. Amiti, Redding, and Weinstein (2019) analyzed the tariffs imposed on Chinese imports in 2017-2018 and found that approximately 100% of the tariff burden was passed on to consumers through higher prices of imported goods.[3] Similar findings by Fajgelbaum et al. (2020) also suggest consumers face increased prices for both imported goods and domestic substitutes.[4] In sectors such as consumer electronics, household goods, and automobiles, tariffs have been shown to translate almost directly into retail price increases. US businesses also experience significant costs from tariffs, particularly those reliant on imported intermediate goods. According to a study by Cavallo et al. (2021), US manufacturers that depend on foreign inputs face increased production costs, reducing competitiveness both domestically and internationally.

Table 10 presents the total tariff on imported pharmaceutical products as a share of US sales. Note that since the US pharmaceutical industry exports approximately one quarter of its US production output, some of the tariff cost is related to imported production inputs that are used to produce pharmaceuticals for export. These tariffs may be harder to pass forward to consumers in foreign markets. In addition, there are unique considerations that may impact the ability for import tariff costs on pharmaceutical products to be passed on through higher prices, including pricing limitations that may be in place for commercial and government contracts. However, if all tariffs are fully passed forward through higher prices on domestic sales, prices would rise by 12.9%. This assumes the only change in the price for domestically produced pharmaceuticals is related to the tariffs on imported inputs. [5]

Table 10. Tariffs as a share of US pharmaceutical sales, 2023
(Dollars in billions)

	Tariff amount
Tariffs on pharmaceutical imports and production inputs	$50.8
US pharmaceutical sales	$393
Tariffs as a % of US domestic sales	12.9%

Source: EY estimates

[3] See Amiti, M., Redding, S. J., & Weinstein, D. E. (2019). *The Impact of the 2018 Trade War on US Prices and Welfare.*

[4] Fajgelbaum, P. D., Goldberg, P. K., Kennedy, P. J., & Khandelwal, A. K. (2020). *The Return to Protectionism.*

[5] The reader should note the following limitations: The imposition of tariffs may impact the level and sourcing of imports such that domestic imports and imports from lower-rate countries would be preferred, which could reduce the tariff amount from what is presented in this analysis. Pharmaceutical products are often protected by patent, which results in fewer substitutes for any particular drug. For differentiated products like patented pharmaceuticals, price changes due to tariffs are less clear since treatments may not be easily substituted. This analysis assumes no change in price for domestically produced pharmaceuticals. Commercial contractual obligations and limitations as a result of government programs and policies are not considered and could limit price changes. This may limit the degree to which prices are passed forward to consumers. Businesses may locate US production facilities in a foreign trade zone to purchase production inputs tariff-free if used to produce products meant for export. Production facilities located in these zones could avoid at least some of the tariffs on imported production inputs, which would reduce the overall amount of the tariffs. Currency effects have not been considered but could partially offset tariff costs.

6. Impact of tariffs on pharmaceutical industry employment and economic activity

The pharmaceutical industry employed approximately 300,000 workers in production facilities and other functions in the United States in 2023, which supported additional economic activity elsewhere in the US economy through indirect effects related to supplier activity and induced effects related to consumption spending. Based on the IMPLAN economic model of the United States, this analysis estimates that the US pharmaceutical industry's production activities supported 610,000 additional jobs at US suppliers (indirect jobs) and 800,000 jobs at businesses that sell to the employees of pharmaceutical industry employees (induced jobs). Table 11 presents the overall impact of the production activity of the US pharmaceutical industry including contributions to jobs, labor income, gross domestic product (GDP), and economic output.

As shown in Table 11, total industry gross output for final uses was approximately $350 billion. Of this amount of US production, approximately $101 billion was exported. Based on this share, 29% of US pharmaceutical production activity is related to export sales and would be at-risk if import tariffs are levied on inputs, due to the inability of US producers to pass forward these costs to foreign markets.

This analysis does not estimate the specific reduction in US production activity that could occur due to a tariff on pharmaceutical imports, but some portion of the 490,000 jobs that support US production of pharmaceutical products for export would be at risk due to higher input costs that the industry would likely be unable to pass forward to foreign markets due to price controls imposed by governments in those markets. Given input cost increases due to tariffs that equal 1.7% to 3.5% of the industry's gross output for final uses, the total economic impact would likely be less than 10% of the export-related activity.

Note that the tariff scenario included in this report does not include retaliatory tariffs. If such tariffs were imposed, the economic impact for US producers of pharmaceuticals would be much more significant.

Table 11. Economic contribution of US pharmaceutical industry production activity
(Billions of dollars, jobs at 2023 levels)

Impact	Jobs	Labor income	GDP	Output
Direct industry footprint	300,000	$70	$190	$350
Indirect economic activity	610,000	60	110	210
Induced economic activity	800,000	50	100	160
Total US pharmaceutical manufacturing contribution	**1,710,000**	**$170**	**$400**	**$730**
% of industry producing exports	29%	29%	29%	29%
At-risk export-related economic activity	**490,000**	**$50**	**$110**	**$210**

Source: EY analysis
Note: amounts are rounded to the nearest 10,000 jobs and $10 billion

7. Appendix 1: Detailed imports of pharmaceutical products

A-1. Detailed pharmaceutical product imports by country, 2023
(Total customs value of imported BEA end-use pharmaceutical goods in billions of dollars)

	Country	Canada	China	EU	Mexico	Switzerland	United Kingdom	Rest of World	Total US Imports
510	Ambergris, Castoreum Etc; Glands Etc For Pharmacy	0	0	0	0	0	0	0	0
1507	Soybean Oil & Its Fractions, Not Chemic Modified	0	0	0	0	0	0	0	0
1704	Sugar Confection (incl White Chocolate), No Cocoa	43	0	6	0	54	1	2	106
2106	Food Preparations Nesoi	0	0	0	0	30	0	0	30
2710	Oil (not Crude) From Petrol & Bitum Mineral Etc.	0	0	1	0	0	0	0	1
2914	Ketones & Quinones & Halogenatd, Sulfonatd Der Etc	0	102	0	0	0	0	7	109
2916	Unsat Acyclic & Cyclic Monocarbox Acid & Anhyd Etc	0	29	0	0	0	0	2	31
2918	Carboxylic Acid, Added Oxygen & Anhy Etc, Hal Etc	0	8	18	3	0	0	38	67
2921	Amine-function Compounds	0	0	5	0	0	1	3	9
2922	Oxygen-function Amino-compounds	1	26	47	0	10	8	611	703
2923	Quaternary Ammonium Salts Etc; Lecithins Etc.	0	0	5	0	0	0	7	12
2924	Carboxyamide-function Comp; Amide-function Com Etc	0	16	24	0	63	0	54	158
2925	Carboxyimide-function Comp; Imine-function Com Etc	1	0	3	0	0	0	1	5
2926	Nitrile-function Compounds	0	0	0	0	0	0	0	0
2928	Organic Derivatives Of Hydrazine Or Hydroxylamine	0	2	2	0	10	0	2	16
2930	Organo-sulfur Compounds	0	18	1	0	0	0	8	27
2931	Organo-inorganic Compounds Nesoi	0	0	0	0	0	0	0	0
2932	Heterocyclic Compounds, Oxygen Hetero-atom(s) Only	0	0	1	0	0	0	1	2
2933	Heterocyclic Comp, Nit Hetero-atoms Only	11	114	5,371	2	336	5	252	6,090
2934	Nucleic Acids & Salts, Heterocyclic Comp Nesoi	3	18	2,092	13	76	67	3,214	5,483
2935	Sulfonamides	0	118	949	0	17	4	156	1,244
2936	Provitamins And Vitamins & Derivatives & Intermixs	6	812	157	1	89	39	107	1,210
2937	Hormones; Derivatives & Steriods Used As Hormones	7	143	8,529	5	48	5	2,277	11,015
2938	Glycosides, Natural Or Synth & Salts, Ethers Etc.	1	177	15	0	6	1	89	290
2939	Veg Alkaloids, Nat Or Synth & Salts, Ethers Etc.	2	101	137	3	46	59	99	447
2941	Antibiotics	2	199	438	3	4	3	84	733
2942	Organic Compounds Nesoi	0	0	8	0	0	0	3	11
3001	Glands Etc Dry & Ext; Heparin; Hum Etc Subst Nesoi	28	164	115	2	2	12	131	454
3002	Human Blood; Animal Blood; Antisera, Vaccines Etc	665	448	58,310	24	5,054	3,244	13,676	81,421
3003	Medicaments Nesoi Of Mixtures, Not Dosage Etc Form	34	154	1,619	0	66	31	465	2,369
3004	Medicaments Nesoi, Mixed Or Not, In Dosage Etc Fm	4,764	4,454	45,164	575	9,868	3,242	18,829	86,896
3006	Pharmaceutical Goods In Note 4 To Chapter 30	190	63	2,368	77	127	78	729	3,631
3306	Preparations, Oral Dental Hygiene; Dental Floss	1	16	6	224	0	1	27	275
3407	Modeling Pastes For Child Etc; Denta Impr Cp Etc	0	4	56	1	3	0	28	92
3822	Diag/lab Reagents Incl Kits, Excl Head 3006;crm	0	0	32	0	6	10	8	57
9602	Veg Molded Resin Etc Carving Material, Nesoi	29	44	4	15	0	0	112	202
	Chapter 29 goods	34	1,883	17,801	30	705	193	7,014	27,660
	Chapter 30 goods	5,681	5,283	107,577	678	15,116	6,607	33,829	174,772
	Other goods	73	65	104	240	92	12	177	762
	Total imports of end-use pharmaceuticals	5,788	7,231	125,482	948	15,913	6,811	41,020	203,194

Source: US Census Bureau, EY analysis