Bristol Myers Squibb™

May 7, 2025

VIA ELECTRONIC SUBMISSION

Secretary Howard Lutnick
Department of Commerce
1401 Constitution Ave NW
Washington, DC 20230

Re: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Dear Secretary Lutnick:

Bristol Myers Squibb (BMS) appreciates the opportunity to comment on the Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients.

At BMS, we are inspired by a single vision—transforming patients' lives through science. We are in the business of breakthroughs—the kind that transform patients' lives through life-saving, innovative medicines. Our talented employees come to work every day dedicated to our mission of discovering, developing, and delivering innovative medicines that help patients prevail over serious diseases. We combine the agility of a biotech with the reach and resources of an established pharmaceutical company to create a global leading biopharma company. In oncology, hematology, immunology, cardiovascular disease, and neuroscience — with one of the most diverse and promising pipelines in the industry—we focus on innovations that drive meaningful change.

We bring a human touch to every treatment we pioneer. With great pride, we celebrate each time our patients take back their lives. Our shared values are central to who we are, what we do, and how we do it. Passion, innovation, urgency, accountability, inclusion, and integrity ground our work and unite our community. We never give up in our search for the next innovation that could mean new hope for patients who are urgently seeking new treatment options today.

BMS is supportive of the Administration's goals of increasing American innovation and investment, balancing the budget and driving economic viability, and can contribute to those goals. Currently, American patients have the best access to new and innovative medicines in the world—in fact, 94% of new medicines are available in the U.S. In other countries with similar GDPs, only 60-70% of new medicines are available.[1] The average delay in the availability of new cancer medicines in Canada, for example, is 16 months.[2] With this in mind, BMS seeks to address the following topics included in the notice of request:

[1] PhRMA. https://phrma.org/blog/new-analysis-shows-that-more-medicines-worldwide-are-available-to-us-patients.
[2] PhRMA. Global Access to New Medicines Report. April 2023. https://phrma.org/resources/global-access-to-new-medicines-report.

i. The current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States

There is a large demand for pharmaceuticals in the U.S. and a large demand for pharmaceutical ingredients sourced from out of the U.S. The use of medicines in the U.S. has grown 15% over the past 5 years. According to IQVIA, increased demand for medicines in the U.S. is a result of increased diagnoses and increased patient access over the years.[3] Further, drug shortages, which have remained a consistent problem in the U.S., are likely an indicator of large demand and may not lend themselves to trade-related supply chain solutions. Instead, drug shortages could be exacerbated by tariffs - broad-based tariffs on critical pharmaceutical inputs and finished goods, combined with foreign retaliation, could lead to shortages that could pose grave challenges for patients and healthcare providers.

Drug shortages would lead to lost revenue due to disrupted supply chains and may force U.S. companies to reduce headcount or capital and R&D investments to absorb these unfavorable financial impacts. This would be directly opposite to the objective of establishing a strong and resilient domestic system of development and supply of medicines. In fact, 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."[4] 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, Singapore, Switzerland and the United Kingdom generally have not imposed tariffs on biopharmaceuticals for several decades.[5]

ii. The extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand

Existing biopharmaceutical supply chains have been carefully established to promote resilience. Nearly two-thirds of medicines taken by U.S. patients are manufactured domestically by American workers in over 1500 manufacturing facilities across the U.S.[6] Active Pharmaceutical Ingredients (APIs) are a subset of biopharmaceutical inputs and are the components of a medicine that produce the intended therapeutic effect. The dollar value of API made in the U.S. accounted for a majority (53%) of the $85.6 billion of API used in medicines consumed in the U.S.[7] Over many years, the U.S. biopharmaceutical manufacturing sector has shown remarkable growth and resilience against economic downturns, providing important stability both to the U.S. economy and the medical supply chain.

For more than 160 years, the majority of BMS's employees, R&D investments, and manufacturing infrastructure have been based in the U.S., and BMS plans to invest $40 billion in the U.S. over the next five years, in research and development, technology and domestic manufacturing. In addition, U.S. pharmaceutical companies have made billions of dollars of capital investments in the U.S., increased our domestic capacity for

[3] IQVIA. the-use-of-medicines-in-the-us-2024-usage-and-spending-trends-and-outlook-to-2028.pdf
[4] 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; see also 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").
[5] Office of the United States Representative. https://ustr.gov/issue-areas/industry-manufacturing/industry-initiatives/pharmaceuticals.
[6] Pharma, "Biopharmaceutical manufacturing companies continue to expand their economic footprint across the United States", March 24, 2023, https://phrma.org/blog/biopharmaceutical-manufacturing-companies-continue-to-expand-their-economic-footprint-across-the-united-states
[7] Avalere Heath report, "U.S. Makes Majority of API by Dollar Value in U.S.-Consumed Medicines", October 14, 2023. https://advisory.avalerehealth.com/insights/majority-of-api-in-us-consumed-medicines-produced-in-the-us.

R&D and manufacturing and created thousands of high-paying jobs in U.S. operations since the 2017 Tax Cuts and Jobs Act (TCJA). For example:

- U.S. biopharmaceutical R&D investment grew more than 78% from 2019–2024.[8]
- Biopharmaceutical industry total capital investment was $126B+ from 2018–2022, second only to motor vehicles.[9]
- The number of U.S. biopharmaceutical manufacturing facilities has grown significantly with 1,591 facilities across the country in 2024.[10,11] However, the U.S. currently lacks sufficient domestic contract manufacturing capacity to meet domestic and global demand.
- The number of biopharmaceutical manufacturing employees grew by more than 30% from 2015–2022, to a total of more than 200,000.[12]

iii. The role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients

The pharmaceutical sector is reliant on foreign supply chains. While 64% 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.[13]

Tariffs on pharmaceutical 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 U.S. 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. patients from these U.S. and overseas facilities and supplying ingredients produced abroad to U.S. manufacturing sites. Tariffs on 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. This would weaken U.S. national security and nullify much of the benefits anticipated by the Administration's strong tax and regulatory policies.

In addition, global sourcing helps mitigate supply chain risks and ensures that Americans have a stable supply of life-saving medicines. The U.S. is well positioned to tap into established global supply chains with allies to help fill gaps and minimize U.S. exposure to supply shortages or temporary disruptions.

iv. The concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks

It is important to note that there is no national security risk associated with the imports of pharmaceuticals and pharmaceutical ingredients. In order to meet U.S. demand, the U.S. is significantly reliant on U.S. imports for precursor materials such as Regulatory Starting Materials (RSMs) and Active Pharmaceutical Ingredients

[8] IQVIA, Global Trends in R&D 2025; March 2025. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-trends-in-r-and-d-2025
[9] National Center for Science and Engineering Statistics, Business R&D Performance in the United States Nears $700 Billion in 2022; September 2024. https://ncses.nsf.gov/pubs/nsf24334
[10] PhRMA, America's Biopharmaceutical Companies Continue to Expand Advanced Manufacturing Across the United States; February 2025. https://phrma.org/policy-issues/research-development/manufacturing-supply-chain
[11] NDP Analytics, analysis of U.S. Food and Drug Administration Drug Establishments Current Registration Site, as of April 2024; April 2023; April 2022; February 2021; January 2020; April 2019; April 2018. https://dps.fda. gov/decrs
[12] TEConomy Partners, LLC. The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. May 2024. https://www.teconomypartners.com/wp-content/uploads/2024/05/The-Econ-Impact
[13] Ernst & Young, Impacts of potential tariffs on the US pharmaceutical industry, April 2025 at p. 7.

(APIs). About half of the innovative biopharmaceutical products Americans consume are manufactured domestically, and most of the rest comes from countries that are close allies. The same is true of API used to produce those medicines. According to a report by the research firm Avalere, 53% of the API used in domestically consumed medicines is produced domestically, and most of the remainder (36% of the total) is produced in Europe or Singapore. In other words, the API used to manufacture innovative pharmaceutical products consumed in the United States is overwhelmingly sourced domestically or from trusted partners. Concern in Congress about dependency on pharmaceuticals and API from China has been pronounced in recent years. However, for branded pharmaceuticals, the volume share of U.S. prescription API from China in 2024 was just 3%, according to a report from the United States Pharmacopeial Convention (USP). With the needed investment and regulatory approvals, it would take 4+ years to move these activities to the U.S.

BMS 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 biopharmaceutical manufacturing and research in the U. S. and unnecessarily burden the U.S. health care system and patients. In particular, the Administration should refrain from imposing tariffs on medicines and inputs sourced from reliable U.S. allies, as this would undermine rather than strengthen national security.

v. The impact of foreign government subsidies and predatory trade practices on United States pharmaceuticals industry competitiveness

The imposition of tariffs on pharmaceuticals would substantially harm U.S. interests, and therefore would not be a productive means of addressing unfair trade practices abroad. 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. The pharmaceutical 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 rules-based international trading system and benefits from U.S. trade policies that historically have valued innovation, protected IP rights and championed open trade. Over a period of several years, the United States' pro-innovation trade policies, combined with strong domestic policies, have resulted in the United States achieving and retaining the position of the world's leader in pharmaceutical innovation and production. This leadership position, in turn, has been strengthened by the industry's robust trade and investment engagement in the global economy.

Other countries are trying to replicate our model, grow private investment in the sector and learn from our innovation and infrastructure. The U.S. healthcare ecosystem needs to continue to reward American innovation, support the economy and create new jobs, while also ensuring that Americans are not being unfairly burdened with the costs of innovation that benefit the world.

The Administration should work to make other countries pay their fair share for U.S. innovation, so that the ecosystem continues to allow our sector to grow, thrive and maintain our winning position in the world. For example, the Administration could encourage ex-U.S. countries to increase prices for U.S.-associated drugs to solve the "freeloading" problem. Some potential solutions to encourage ex-U.S. countries to increase prices for U.S.-associated drugs are:

- Pushing other countries to price drugs relative to their per capita GDP
    - Structuring pricing around a drug's GDP per capita adjusted price would yield a larger adjustment ratio than the GDP-adjusted price.
    - This would be a "carrot and stick" approach that involves pharmaceutical manufacturers as well:

        - Carrot: Office of the United States Trade Representative (USTR) supports the Company's ability to negotiate higher prices via trade agreements by including provisions in bilateral trade negotiations.
        - Stick: Companies would provide the U.S. government a rebate if a drug's ex-U.S. price is greater than or equal to its GDP per capita adjusted price.
    - Using unique tools like Oval Office meetings, state dinners, Mar-a-Lago visits, etc. to reward countries that raise prices for U.S. products.
    - Using the "bully pulpit" to publicly "name and shame" countries and companies that refuse to increase prices in ex-U.S. markets.
    - Penalizing countries that do not raise prices.

vi. The economic impact of artificially suppressed prices of pharmaceuticals and pharmaceutical ingredients due to foreign unfair trade practices and state-sponsored overproduction

While the United States is the primary source of innovative biopharmaceuticals and inputs consumed by U.S. patients, trade with the United States' most reliable 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. Reliable U.S. allies are by far the largest source of innovative biopharmaceuticals and ingredients imported into the United States – not adversarial nations.

However, BMS agrees with the Administration that "foreign freeloading" is an issue that needs to be addressed. As outlined above, the Administration should work to make other countries pay their fair share for U.S. innovation, for example by structuring pricing around a drug's GDP per capita adjusted price. At the same time we need to be aware of the competitive landscape and ensure that while we are trying to address issues in the U.S., we don't destroy the ecosystem that has enabled the industry to endure. Tariffs will disrupt supply chains, increase costs and reduce America's appeal for new therapies. These added costs will not only be passed down to patients, but to states and private insurers, which will be forced to absorb higher healthcare expenses. Further, the 2017 TCJA was pivotal in reducing the differential of certain foreign countries offering competitive income tax rates and incentives to attract manufacturing. Extending the 2017 TCJA will continue to ensure a level playing field.

vii. The potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over pharmaceuticals supplies

Imports of innovative medicines and inputs are sourced overwhelmingly from reliable U.S. allies and do not threaten to impair national security. Imports from allied countries in Europe, Australia and Japan should be considered reliable foreign sources that we should partner with to ensure resilient and secure supply chains, particularly for those products for which critical precursors or starting materials may not be available in the United States.

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). Tariffs will not be the answer for promoting greater domestic production of these products. On the contrary, every dollar collected in tariffs would be a dollar less that pharmaceutical companies are able to invest in U.S. research, manufacturing and infrastructure. Innovative pharmaceutical 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

timescale necessary to avoid imposed tariffs. Instead of imposing tariffs, it will be critical to develop pragmatic solutions and targeted incentives.

Securing the U.S. supply chain does not mean abandoning global operations. Instead, policymakers should strengthen alliances with friendly trading partner countries to enable U.S. businesses to form partnerships, share costs, reduce duplication, and secure diversified components of their supply chains. Manufacturing in allied countries also enables U.S. companies to meet global demand while at the same time having assurances that their intellectual property, contractual relationships, and commercial partnerships will be respected and protected.

viii. The feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance

Over decades, innovative pharmaceutical manufacturers have built robust supply chains carefully and deliberately to ensure that patients in the U.S. and around the world have access to safe and high-quality medicines. Pharmaceutical companies invest significantly in the design and ongoing maintenance and modernization of manufacturing facilities and their quality systems. This includes determining how to safely and efficiently manufacture the medicine, meeting all applicable regulatory requirements and developing plans for getting the medicine to patients, and incorporating robust risk management and business continuity plans to ensure supply network security. Making changes to even one element of a supply chain can take years to implement and can generate significant costs.

Despite their interest in doing so, pharmaceutical companies are limited in their ability to quickly relocate manufacturing due to complex global supply chains and highly technical and stringent regulatory requirements. 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 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.

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 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. To comply with product security regulations, 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 substantial engagement with the FDA to obtain regulatory review and approval.

Therefore, while the U.S. pharmaceutical industry has made and continues to make major investments in U.S. manufacturing, it is not possible to relocate production activities immediately in response to tariffs or other policy changes.

ix. The impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security

Tariffs will threaten America's ability to lead the world in R&D as companies will be forced to spend money on tariffs that could be spent on innovation and patient access and stall the Administration's goal of bringing high value jobs back to America that would be eliminated instead with the imposition of tariffs.

1. Innovative medicines are not fungible and interchangeable. As a result, imposing tariffs on medicines, and/or the materials used to manufacture them, will undoubtedly harm patient access to lifesaving treatments.
2. Tariffs will disrupt supply chains, increase costs and reduce America's appeal for new therapies. These added costs will not only be passed down to patients, but to states and private insurers, which will be forced to absorb higher healthcare expenses.
3. Pharmaceutical research is essential to the American economy. Tariffs will undermine investment, innovation and job growth, while also making it more costly to conduct clinical trials in America.
4. We need to ensure the imposition of tariffs does not inhibit U.S. manufacturers from remaining global leaders in the sector. The Administration should further work to make other countries pay their fair share for U.S. innovation, as outlined in response to Question V above.

BMS also asks the Administration to keep the following implementation considerations in mind:

1. Exempt U.S. pharmaceutical manufacturers that are investing in U.S. infrastructure, innovation and R&D from any tariff on medicines.
2. If a tariff is imposed on the sector, include a tariff deferral of 3–4 years. This will provide time to build out new sites, obtain necessary government permits and move complex operations from their current location to the U.S.
3. For U.S.-based companies, a tariff could serve as a significant second tax on products brought into the country from a foreign affiliate. Given the U.S. system already applies a tax on related income, there must be adjustments to prevent double taxation and preserve the global competitiveness of U.S. companies.
4. Consider exempting medicines that are best- or only-in class and treat serious diseases to ensure that U.S. patients continue to have access to critical medicines without interruption.
5. Given the significant export volumes from the U.S. to other markets, imposing tariffs is likely to result in retaliatory tariffs that will not only impact innovation but also lead to workforce reductions.

x. Any other relevant factors

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BMS appreciates the opportunity to comment on the Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients.

Thank you for considering BMS' comments. We would be pleased to discuss these comments in further detail. Should you have any questions or concerns, please contact Katie Verb (katie.verb@bms.com).

Sincerely,

/s/

Martin Whalen
Senior Vice President
Global Policy and International Government Affairs