May 7, 2025

**PUBLIC VERSION**

**VIA REGULATIONS.GOV**

The Honorable Howard Lutnick
Secretary of Commerce
Attention: Bureau of Industry and Security,
Office of Strategic Industries and Economic Security
U.S. Department of Commerce
14th Street and Constitution Avenue, N.W.
Washington, DC 20230

**Re: Pfizer's Comments Regarding the Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (BIS-2025-0022; XRIN 0694-XC120)**

Dear Secretary Lutnick,

Pfizer Inc. (Pfizer) respectfully submits these comments regarding the U.S. Department of Commerce's (Commerce) investigation under Section 232 of the Trade Expansion Act of 1962 (Section 232)[1] to determine the effects on the national security of imports of pharmaceuticals and pharmaceutical ingredients.[2]

The information contained in these comments is highly sensitive, and we therefore request BCI treatment of the information contained in brackets in accordance with 15 C.F.R. § 705.6(2). Specifically, we request BCI treatment because disclosure of the bracketed information would cause substantial harm to the competitive position of Pfizer. For this reason, the information contained in brackets in these comments is considered commercial information falling under the exemption from public disclosure in section (b)(4) of the Freedom of Information Act. 5 U.S.C. § 552(b)(4); 15 C.F.R. § 4.9.

We appreciate the Trump Administration's serious attention to the supply chain for pharmaceuticals, particularly as it relates to America's national security. Indeed, the COVID-19 pandemic underscored critical vulnerabilities in America's healthcare supply chain. As a patient-focused company with a 176-year legacy of medical innovation and manufacturing -- including one of the largest U.S. manufacturing networks in the industry -- Pfizer shares the

[1] 19 U.S.C. § 1862.
[2] *Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients*, 90 Fed. Reg. 15,951 (Dep't Commerce Apr. 16, 2025).

Administration's goal of ensuring that Americans have reliable access to safe, effective, and affordable medicines.

Achieving this objective requires careful attention to unique features of the pharmaceutical industry, including, for example, (1) the complex mix of regulatory policies impacting the development, manufacturing and distribution of medicines; (2) unique market conditions affecting supply that arise from different market models for industry segments (generic and non-generic in particular); and (3) the particular needs of patients who are the ultimate consumers of the products we make. In this environment, even well-intentioned policies can easily backfire, causing patients to face shortages and higher costs.

Section I of this submission describes Pfizer's current U.S. manufacturing and research and development (R&D) footprint, which includes one of the largest internal manufacturing networks in the country. Section II addresses current supply and demand trends for products manufactured by Pfizer, our approaches to ensuring resilient supply, as well as the complex regulatory and other conditions affecting timelines for validating new suppliers. Based on our extensive experience with U.S. manufacturing of both innovative and generic pharmaceuticals, in Section III below we recommend several tax, regulatory, and other policies that are likely to be effective in increasing American pharmaceutical manufacturing and supply chain security, while avoiding harms to American patients. In the same spirit, we urge the Administration not to impose additional tariffs in connection with this Section 232 proceeding. For the biopharmaceutical industry, as explained in Section IV below, tariffs are exceedingly likely to be counterproductive, leaving Americans with less access to medicines and impeding innovations that are necessary to achieve life-saving breakthroughs.

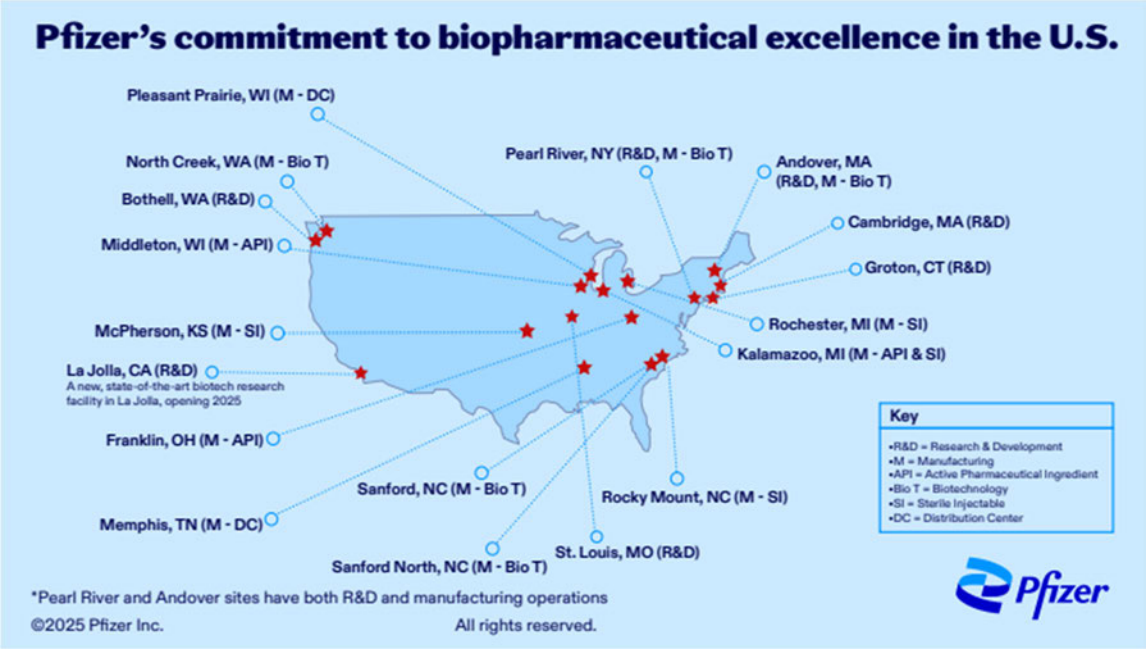
A strong American pharmaceutical manufacturing base is essential to the President's goal of unleashing an American Golden Age and achieving many of the objectives of Making America Healthy Again. The right way to further strengthen our manufacturing base and re-shore more production is to reduce tax and regulatory burdens while continuing strong enforcement of intellectual property rights. We look forward to working with the Trump Administration to make this a reality.

## I. Pfizer Has a 176-Year History of American Job-Creation, Manufacturing, and Life-Saving Innovation

Founded in 1849 in Brooklyn, New York, Pfizer is proud to be one of America's leaders in medical innovation. Our approximately 30,000 U.S.-based colleagues account for nearly 40% of Pfizer's worldwide headcount. Pfizer has a presence in 19 U.S. states, and approximately 65% of its U.S. colleagues are in highly skilled and highly paid jobs dedicated to the company's manufacturing and R&D operations.

Our U.S. operations are expansive, with 13 manufacturing sites and distribution facilities located across the United States – ranging from our largest manufacturing sites located in

Kalamazoo, MI and Rocky Mount, NC, to specialized manufacturing facilities in McPherson, KS Franklin, OH, and Middleton, WI -- that collectively represent one of the largest internal pharmaceutical manufacturing networks in the country. Pfizer's production footprint is evaluated annually and supported with capital investment to ensure that we have the manufacturing capacity to meet projected demand over the next ten years.




Our extensive domestic R&D activities complement our American manufacturing. Seven of our major R&D sites are located in the United States. Furthermore, 90% of Pfizer's R&D colleagues are based in the United States, as are 98% of our Discovery & Early Development colleagues. Our production and R&D sites focus on ensuring that all Pfizer medicines and vaccines are made to the highest standards of quality, safety, and efficacy and are available when and where they are needed. Pfizer's contributions to the U.S. economy are further bolstered by our work with approximately 30 U.S.-based contract manufacturing organizations (CMOs) that support drug substance and drug product manufacturing as well as packaging.

Pfizer has a 176-year history of developing and manufacturing groundbreaking, lifesaving medicines. Over that long period, we developed one of the most agile manufacturing infrastructures in the industry and made significant investments to get crucial medicines to patients faster – from penicillin during World War II to the COVID-19 vaccine – with the greatest focus on safety, quality, and compliance. Our U.S. sites are critical contributors to a manufacturing network that has fundamentally changed public health, paving the way for future innovations, and preparing us to take on the next public health challenge.

## II. Pfizer's U.S. Manufacturing and Supply Chains for U.S. Patients Are Resilient, Diverse and Do Not Depend on Countries of Concern

Over [ ] of the production value of medicines sold by Pfizer in the United States is generated here. Pfizer's U.S. manufacturing footprint is particularly significant with respect to large molecule drug substance and sterile injectables, which enables us to domestically manufacture a wide range of the drugs in our portfolio that are sold in the United States.

We operate in an industry where establishing supply chains requires considerable time, effort, and expense. In contrast to many other industries, pharmaceutical inputs are not inherently substitutable. Regulatory requirements for medicines, including manufacturing site changes, are complex and may take years to implement. For example, moving the manufacture of active pharmaceutical ingredients (APIs) typically involves long cycle times that may extend well over two years after appropriate excess capacity is identified or after significant time and resources are spent to build new capacity, including the following approximate timeframes for critical steps:

- six months or more to procure starting materials;
- another six months or more to manufacture APIs through several synthesis steps and ensure this process is validated;
- another three months or more to ensure that using this API in a given drug product results in no change to product properties;
- another six months or more to generate stability data to ensure there is no change to the finished goods product specification over shelf life;
- another three months, in certain cases, to generate relative bioavailability data (rBA) to ensure the product with the new API has the same pharmacokinetic profile in patients; and
- another three months-plus, depending on U.S. Food and Drug Administration (FDA) resources, to compile data in a regulatory submission and wait for FDA approval.

In this context, Pfizer has a well-diversified supply base for raw materials and APIs that provides stability and continuity of supply. We currently have over [ ] suppliers qualified for raw materials and API, with over [ ]. Overall, about [ ]% of the value of Pfizer's imports come from allies like [ ]. Developing this supply base has been costly and time-consuming, given the stringent requirements that Pfizer and regulators impose for qualifying suppliers.

Pfizer is also capable of increasing domestic pharmaceutical production as appropriate to meet the demands of American patients. We [ ]. Nonetheless, Pfizer has available unused U.S. production capacity relative to U.S. demand in a number of pharmaceutical categories including: [

]. Our domestic manufacturing capacity is also bolstered by our extensive network of U.S. CMOs, with which we partner to manufacture our portfolio across a wide range of delivery platforms, handling tasks like large-scale manufacturing, packaging, labeling, and supply chain management.

Pfizer has also diversified its supply base to mitigate the risk that foreign country export restrictions or other unexpected events disrupt supply. Specifically, many of our products are dual-sourced in the [ ] from suppliers currently validated by Pfizer. For example, many of Pfizer's hospital essential medicines have multiple validated API sources both in the U.S. and the rest of the world. Pfizer further notes that other API suppliers also exist outside of Pfizer's production network. In response to the survey issued in Commerce's recent "United States Active Pharmaceutical Ingredient Industrial Base Assessment", Pfizer reported that alternative suppliers exist for [ ] of the [ ] surveyed API sourced by Pfizer, and [ ].

These facts demonstrate that Pfizer's supply chain is resilient and does not depend on countries of concern. These facts also underscore how tremendously costly and disruptive it would be for Pfizer – and American patients – if we were forced to undertake a major reorientation of our supply chain.

## III. Domestic Tax, Regulatory and Targeted Stockpiling Policies are the Best Means of Promoting American Pharmaceutical Manufacturing, Supply Chain Security, and Innovation

In this Section 232 investigation, the Secretary of Commerce is required to consider an array of factors specified in the statute[3] in determining whether imports of pharmaceuticals and pharmaceutical ingredients threaten to impair national security.[4] In considering these factors, the Secretary of Commerce, like the President, is required to "recognize the close relation of the economic welfare of the Nation to our national security."[5] In this vein, Pfizer explains below why tax policy and regulatory reform are the best available policies for promoting American pharmaceutical manufacturing and supply chain security. Tariffs, by contrast, will likely be counterproductive for the reasons explained in Section IV.

### A. Tax Policy

Pro-growth tax policies are critical to ensuring that the U.S. pharmaceutical industry is robust, innovative, and efficient. This is evident from the success of the Tax Cuts and Jobs Act of 2017 (TCJA), which was enacted thanks to President Trump's leadership.

[3] 19 U.S.C. § 1862(d).
[4] *See* 19 U.S.C. § 1862(b)(3)(A).
[5] 19 U.S.C. § 1862(d).

America is more competitive and innovative thanks to the TCJA. Since its passage, Pfizer has invested heavily in capital, R&D and manufacturing in the United States:

- Pfizer has increased its U.S. manufacturing headcount by over [ ]%;
- We invested close to $100 billion in new investments in the United States, including more than $6.4 billion in our domestic manufacturing footprint; and
- We have spent $24 billion in U.S. manufacturing operating expenses and more than $50 billion in R&D expenses in the U.S.

A key change with TCJA that helped enable this increased U.S. employment, investment, and expenditure has been the ability of companies like Pfizer to access foreign-generated cashflow and deploy it domestically to support American jobs.

The TCJA also counteracted the assault on American businesses, as U.S. biopharmaceutical and medical device companies were being acquired by foreign competitors at an alarming rate prior to its enactment. Foreign companies and foreign governments were winning. U.S. companies, U.S. workers, and U.S. tax collections were losing. That all changed thanks to the TCJA. Post-TCJA most acquisitions of large biopharmaceutical and medical device companies were made by U.S. companies. Indeed, over the past four years, Pfizer has acquired six companies (three U.S.-based, and three foreign) with an aggregate value of over $70 billion. These companies were developing new approaches to treating significant disease areas such as cancer and migraines.

These facts confirm the power of smart tax policy to drive domestic manufacturing and innovation, with consequent benefits for America's fiscal position. In fact, as a result of the TCJA, Pfizer and other U.S. multinationals pay U.S. tax on a *larger* portion of their worldwide income than they did before the law was enacted.

Pfizer looks forward to working with the Trump Administration to build on this success, including by pursuing the following policies:

- <u>Retaining the permanent corporate income tax rate of no more than 21%.</u> This will help to ensure that American biopharma companies have funds available for new investments in innovation and domestic manufacturing.

- Supporting a tax code that does not put U.S. multinationals at a disadvantage relative to non-US peers. Tax proposals that would subject a transaction to tax based on whether or not the parent company is U.S. based would effectively unwind benefits achieved by the TCJA and once again put U.S. parented multinationals at a competitive disadvantage, which could negatively impact U.S. employment and U.S. manufacturing.

- <u>Ensuring the effective Global Intangible Low-Taxed Income (GILTI) rate does not exceed 15%</u>. Most other countries have adopted a global 15% minimum tax rate

consistent with the OECD "Pillar 2" framework; it makes sense to keep U.S. companies from suffering a higher U.S. tax rate on their foreign affiliate's earnings. Immediate expensing for R&D investment. The absence of immediate expensing puts U.S. biopharma companies at a disadvantage to competitors in foreign jurisdictions, where immediate expensing is standard. Restoring immediate expensing of R&D investment will help incentivize innovation and, by extension, the production of new pharmaceuticals.

- Retaining tax incentives for owning IP in the United States, including the current deduction under the Foreign-Derived Intangible Income (FDII). This will promote American manufacturing and exports by maintaining a competitive tax rate on income derived from the export of products tied to IP held in the United States.

- Supporting stability and certainty in the tax rules. This is critical for decision-making by biopharma companies, given that their investment cycle involves long lead times and high costs.

These tax policies, and the regulatory reforms discussed immediately below, are key to ensuring that America's pharmaceutical supply chain is both secure and at the leading edge of innovation.

### B. Regulatory Reform Related to Manufacturing

As President Trump has acknowledged, U.S. pharmaceutical manufacturing will not grow significantly without a hospitable regulatory environment. Creating biopharmaceutical manufacturing capacity and fulfilling all the related regulatory and logistical steps is a complex and lengthy process.

For example, bringing a new manufacturing facility online can cost up to $2 billion and take 5 to 10 years,[6] in large part because of the time and costs associated with regulatory processes. Such an effort includes the following regulatory and logistical steps, among others: site selection; facility design, construction, and equipment qualification; regulatory compliance, permitting, and approvals; workforce recruitment and training; FDA validation, registration, and facility licensing; and production start-up and quality control. As a business works through these steps, additional complications can arise, including permitting delays, infrastructure constraints, regulatory inspections, and workforce shortages — all of which can significantly impact timelines. As a result of all these factors, building a new U.S. manufacturing facility and bringing its production online is challenging.

Similar challenges arise in connection with the expansion of an existing facility or transferring production of a single product to a new manufacturing site. These efforts require

[6] *See* Fact Sheet: Donald J. Trump Announces Actions to Reduce Regulatory Barriers to Domestic Pharmaceutical Manufacturing (May 5, 2025) (noting that "estimates suggest that building new manufacturing capacity for pharmaceuticals and critical inputs may take as long as five to ten years.").

process transfer and scale-up, validation, stability protocols and regulatory filings, which can take several years.

Longer lead times translate into higher investment costs for American pharmaceutical manufacturing, and these can become so high as to make the costs of a new facility prohibitive at the outset. The time and cost obstacles to increased U.S. production capacity could be reduced if the United States: (1) streamlines data stability requirements; (2) uses some of the learnings from Operation Warp Speed and risk based techniques such as bracketing to reduce validation time and expense; (3) suspends unnecessary data requirements that can delay manufacturing change approvals; (4) simplifies lot release for vaccines; and (5) simplifies environmental permitting. Other areas of needed regulatory reform include more reasonable approaches to FDA reviews, inspections, and approvals; and State and local permitting and regulations. Together, these targeted policy changes could reduce the time necessary to establish new, or transfer existing manufacturing capacity to, facilities in the U.S. by up to 2 years. President Trump's May 5, 2025 Executive Order announcing actions to reduce regulatory barriers to domestic pharmaceutical manufacturing recognizes many of these challenges and will hopefully result in the above needed regulatory reforms.[7]

### C. Regulatory Reform Related to Healthcare Price Transparency and Affordability

The security of the U.S. pharmaceutical supply chain is also heavily influenced by the regulatory environment surrounding healthcare pricing, since bad policy in this area will tend to limit the availability and affordability of medicines for American patients. In this regard, Pfizer appreciates the patient-centered focus of President Trump's Executive Order 14221[8] and supports the Administration's efforts to promote cost transparency in the healthcare markets.

We agree that, to make fully informed decisions about their healthcare, patients must know the price and quality of a good or service in advance. To achieve this goal, the Administration should continue the work from the President's first Administration by fully implementing the hospital and health plan price transparency regulations issued in 2019 and 2020. Specific objectives include ensuring that hospitals and health plans publicly disclose actual prices of all items and services, requiring that pricing information is standardized and easily comparable across hospitals and health plans, and updating enforcement policies.

Pfizer also shares the goal of ensuring that American patients get access to prescription drugs at lower costs, which the President articulated in Executive Order 14273.[9] We partner and

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[7] *Executive Order of May 5, 2025: Regulatory Relief to Promote Domestic Production of Critical Medicines*, available at https://www.whitehouse.gov/presidential-actions/2025/05/regulatory-relief-to-promote-domestic-production-of-critical-medicines/'

[8] *Executive Order 14221 of February 25, 2025: Making America Healthy Again by Empowering Patients With Clear, Accurate, and Actionable Healthcare Pricing Information*, 90 Fed. Reg. 11,005 (Feb. 28, 2025).

[9] *Executive Order 14273 of April 15, 2025: Lowering Drug Prices by Once Again Putting Americans First*, 90 Fed. Reg. 16,441 (Apr. 18, 2025).

advocate with payers, governments, and others in the healthcare system on behalf of patients to relieve their financial burdens and provide access to our medicines at a cost they can afford. We also offer patient assistance and donation programs when insurance or reimbursement systems fail to provide affordable access to our medicines.

In addition, Pfizer fully aligns with the President's goal to lower the cost of complex biologic medicines. Building on our 30-years of experience manufacturing biologics, our robust portfolio of biosimilars offers additional treatments at potentially lower costs, which can create savings and efficiencies for the healthcare system. Biosimilars help broaden access to highly effective treatments for millions of people living with life-threatening and chronic diseases – including cancer, diabetes, rheumatoid arthritis, and many others. In this way, biosimilars contribute to much-needed competition in the biologics market and can drive dramatic cost savings for patients, providers, payers, and health systems, as shown by the $36 billion in estimated savings already achieved between their introduction in 2015 through 2023.[10]

Lowering costs to patients also requires taking on all the middlemen in the supply chain – pharmacy benefit managers (PBMs), insurers, Group Purchasing Organizations (GPOs), 340B providers, and other for-profit companies that have inserted themselves into the market. Half of every dollar spent on brand medicines goes to entities that play no role in the research, development, or manufacturing of those medicines. Those dollars must be redirected towards lowering costs for patients.

Furthermore, Pfizer shares the President's goal of fixing the Inflation Reduction Act's (IRA) pill penalty, which unfairly subjects small molecule drugs (pills) to price controls earlier than biologics and thereby discourages investment in additional research. We appreciate the Administration's efforts to improve transparency and reduce the complexity of the IRA's price-setting process.

### D. National Stockpile of Identified National-Security-Critical Medicines and API

Recognizing that some regulatory changes could take time to implement, appropriately designed stockpiling mechanisms could provide a shorter-term solution to addressing national security concerns for certain products. Physical and virtual inventory stockpiles or buffers have been recommended in several recent policy proposals to address issues related to shortages and U.S. supply chain dependencies. Government financing of surpluses is needed to support surge manufacturing capacity in the event of a shortage, including for API and other inputs. These inventories should be aggregated and reported at an anonymized industry level. Finished product buffer inventories should also be established. Wholesalers or distributors are best positioned to hold and manage finished goods buffer inventory given their existing warehousing and distribution capabilities. On the other hand, buffer inventory requirements for suppliers or

[10] *See* https://biosimilarscouncil.org/news/biosimilar-medicines-saved-12-4-billion/.

hospitals could create financial exposure and unintentionally incentivize excessive stockpiling by hospitals which could exacerbate supply challenges.

In sum, Pfizer agrees with the Trump Administration that reasonable tax and regulatory policies are critical to enable greater American pharmaceutical manufacturing and a more secure supply chain. The following section discusses how trade policy can support supply chain resilience and why broad tariffs on medicines and inputs could undermine the President's objectives with respect to improving American healthcare and strengthening supply chains.

## IV. An Effective Trade Policy to Support U.S. Manufacturing and Innovation Should Avoid Counterproductive Tariffs on Medicines and Inputs

Although President Trump has imposed tariffs on imports of other articles using Section 232 authority, tariffs are not a viable solution to national security concerns in the pharmaceutical sector. Other trade policies that the Administration has identified – such as sectoral agreements to strengthen trade with allies in a manner that promotes U.S. competitiveness[11] – would be more effective at addressing supply chain weaknesses and would complement the policies described in Section III above. To summarize, tariffs would likely:

- increase healthcare costs for Americans while decreasing their access to medicines;
- degrade the ability of American biopharma manufacturers to innovate new treatments by reducing the funds available for R&D; and
- reduce the global competitiveness of U.S. pharmaceutical manufacturers – and thus the American innovations and manufacturing jobs they create – particularly in relation to competitors from countries of concern.

Tariffs would likely have these adverse effects because they would clash with the distinctive conditions in our industry, as discussed below.

### A. Tariffs Risk Delayed or Degraded Delivery of Critical Medicines to Patients

Patients are the focus of Pfizer's work, and reliable supply chains are essential to ensuring that patients get the medicines they need. However, tariffs would impose burdens on this supply chain that would likely lead to increased drug prices and, in some cases, delayed or degraded drug delivery.

To take just one example, production for the active ingredient for [ ], starts in [ ].

[11] USTR 2025 Trade Policy Agenda, at 3 ("USTR will also identify opportunities for bilateral or sector-specific plurilateral agreements that might be negotiated to open new market access for U.S. exports and reorient the trading system to promote U.S. competitiveness.").

It is then shipped to [ ]. If approved by the FDA, the first batches will then be sent to a partner in [ ] where it will be packaged and then shipped to Pfizer distribution site in [ ]. Once this product has gone through the FDA approval process, Pfizer cannot immediately make changes to it, including with respect to the sites where it is produced. Any proposed change would require additional FDA reviews and approvals. Thus, imposing tariffs on any article in this supply chain would impose immediate costs without resulting in near-term increases in U.S. manufacturing.

Moreover, because some of the most promising innovations in oncology rest on combination therapies utilizing more than one molecule, the risk of access delays could potentially be multiplied as each drug in a combination has a separate supply chain at the outset of the manufacturing process. For example, the breast cancer treatment Tukysa is indicated in combination with capecitabine and trastuzumab, which Pfizer largely sources from [ ] Similar situations exist for another treatment for certain types of metastatic breast cancer, Ibrance, and for prostate cancer, Xtandi.

The risks of negative effects of tariffs on drug delivery are most acute for drugs that are already susceptible to shortages. Shortages are a continuing problem in our healthcare system and have impacted a wide range of therapies, both branded and generic, over the past decade. While drug shortages can occur in all areas of the pharmaceutical supply chain, Pfizer's experience is that they occur most frequently in the generic sterile injectable (GSI) market. As a major supplier of over 600 generic sterile injectable medicines, including chemotherapies, antibiotics, parenteral nutrients, anesthetics, and many others, Pfizer is keenly aware of the market dynamics that contribute to sterile injectable drug shortages. While GSI medicines are both crucial and ubiquitous in our healthcare system, they are complex, challenging, and expensive to manufacture. Despite the investment required to reliably supply these important and complex products, GSI medicines are often sold at a relatively low price. Consequently, high manufacturing costs coupled with low prices often create unsustainable market dynamics that make the GSI market more susceptible to drug shortages. Given this delicate interaction between prices and costs, tariffs would likely have outsized – and possibly catastrophic – adverse effects in the GSI market. GSI shortages would be far better addressed by non-tariff measures such as (1) improving the long-term sustainability of the generic sterile injectables market; (2) establishing GSI manufacturing incentives; (3) continuing FDA regulatory modernization; and (4) ensuring flexible and resilient global supply chains.

### B. Tariffs Create Disincentives to Innovate New Medicines

Pfizer prides itself on its portfolio of innovative products, and this innovation depends on having the right incentives in place. Broad tariffs on pharmaceuticals and their ingredients would create disincentives to innovation by increasing both the front-end costs of the materials used in R&D and the anticipated costs of producing a drug once it is approved for manufacture.

The impact of these tariff-induced disincentives could be reflected in reduced clinical trials, diminished therapeutic area portfolios and priorities, and diversion of resources from research and development – which could have serious implications for important therapeutic areas like oncology. Tariffs could also force pharmaceutical manufacturers to make difficult decisions about the feasibility of continued investment in post-approval R&D. Furthermore, the financial headwinds and uncertainty created by tariffs could dissuade private investment in biopharmaceutical R&D, which would undermine U.S. leadership and competitiveness in this critical sector. In sum, tariffs could force American companies to shift resources from R&D and slow the innovation engine that gives patients hope for cures to cancer and other diseases.

### C. Tariffs Risk Lower American Pharmaceutical Manufacturing, Employment, and Production

As discussed above in Section II, Pfizer's supply chains for U.S. patients are resilient, diverse and do not depend on countries of concern. In this context, tariffs would undermine Pfizer's ability to supply the market, manufacture in America, compete with foreign suppliers, and employ American workers, all without addressing the Administration's national security concerns.

As discussed, moving existing pharmaceutical, biopharmaceutical, and API manufacturing to the United States would require companies to transform existing operations, rework global supply chains, and make significant financial, operational, and personnel investments while running duplicative plants as U.S. production ramps up. Increased costs for specialized equipment manufactured outside of the U.S. could make this situation more challenging. For example, over $1 billion would be required to shift [ ], currently supplied from [ ] to the United States. In addition, the [ ] is a specific Pfizer design that is only available from our strategic equipment vendor, which does not have a U.S. location.

U.S. tariffs will also likely precipitate retaliatory tariffs from foreign countries that would reduce U.S. pharmaceutical exports, including for materials that are further processed abroad and then returned here. For example, Pfizer's Kalamazoo, Michigan site is one of the largest in its internal network, producing active pharmaceutical ingredients API and drug products (DP) that are shipped to more than 100 countries around the world. In addition, our McPherson, Kansas site specializes in manufacturing sterile injectable medicines used daily in hospitals around the world. These range from pain management treatments and medicines that enable sedation during surgery to life-saving antibiotics, critical blood pressure regulators and some of Pfizer's first biosimilars.

Ultimately, tariffs risk harming Pfizer's U.S. innovation, manufacturing, and employment in ways that could reduce the pipeline of future innovative medicines and increase costs to American patients.

## V. Conclusion

Pfizer is committed to working with the Administration to identify strategies to promote viable domestic manufacturing, strengthen supply chains, and make them more resilient. To maintain strong domestic investment in pharmaceuticals, the United States must continue to appropriately value innovation, promote greater regulatory harmonization and flexibility and enact pro-investment policies to enable more efficient allocation of supplies across borders.

Sincerely,

Jennifer Walton

Senior Vice President U.S. Policy & Government Relations