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SUBMITTED VIA WWW.REGULATIONS.GOV

Eric Longnecker, Director
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
U.S. Department of Commerce
1401 Constitution Avenue, NW
Room 3876
Washington, DC 20230

RE: Request for Comments on Section 232 Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients - XRIN 0694-XC120

Dear Mr. Longnecker:

Sanofi appreciates this opportunity to provide our perspective on the important topics raised in the Bureau's April 16, 2025 "Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients" (the "Notice").[1] These comments supplement those of Pharmaceutical Research and Manufacturers or America ("PhRMA") and Biotechnological Innovation Organization ("BIO"), both of which Sanofi is a member.

At Sanofi, we work passionately to prevent, treat, and cure illness and disease; to understand and solve health care needs of people across the world; and to transform the practice of medicine. Manufacturing and supply chains are the bridge between this innovation and the people and communities whom we serve. With sustained investment in the United States ("U.S.") and around the world, Sanofi has built a resilient global network that brings together talented people, cutting-edge technologies, and data to deliver high-quality, affordable, and sustainable pharmaceutical innovations.

Sanofi shares the administration's goal of ensuring that Americans have access to a reliable and affordable supply of critical medicines, including both generic and innovative drugs and biological products. While the vast majority of Sanofi's supply sourcing and manufacturing occur in the U.S. and allied European Union ("E.U.") countries, we also recognize U.S. interests in identifying where it may be over-reliant on certain countries for particular key medicines and ingredients, and in developing appropriate policy solutions to promote greater diversification of the supply chain for those products. However, advancing these goals in both the short-term and long-term requires carefully considering current free market dynamics and the realities of the global supply chain, so that U.S. trade and other policies are appropriately tailored and do not harm Americans' access to either existing medicines or future innovations.

[1] 90 Fed. Reg. 15951 (Apr. 16, 2025) (Docket No. 250414–0065).

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In this regard, we believe tariffing pharmaceuticals is not the right solution. Moreover, such an approach would be counterproductive to the administration's goals, potentially *impairing* national security by harming American patient access through increased costs for patients and the American healthcare system, shortages and supply disruptions, and weakened incentives for U.S.-based research and development ("R&D") and related innovation.

The U.S. pharmaceutical industry leads the world in most categories (*e.g.*, investments, exports and time-to-market). And there is already growing domestic manufacturing investment and capacity, which is appropriately integrated into a global supply chain strategically connected to allied countries. The most effective way for the U.S. to advance the national security objectives underpinning this investigation is to continue to advance open trade and other free-market policies that support U.S. investment, while recognizing the importance of a diversified and resilient manufacturing and supply apparatus that leverages both domestic manufacturing and appropriate collaboration with U.S.-allied countries.

If the Department nonetheless chooses to recommend imposing unprecedented tariffs on pharmaceuticals, any such novel policy should be applied narrowly to certain countries and limited to essential medicines and ingredients for which the U.S. is over-reliant on such countries. Moreover, preserving reliable patient access must be a guiding principle of any tariff policy. Thus, any policy arising from the present Section 232 investigation must account for:

- consideration of practical limitations, such as the limited geographic availability of certain pharmaceutical raw materials;
- the long lead time required for re-shoring or other appropriate supply chain shifts, which will require phasing in any tariffs over many years to mitigate the immediate harms that tariffs otherwise would have for patient access and affordability; and
- the need for an expeditious exemption and/or exclusion process for products in shortage or that otherwise address an unmet medical, national security or defense need.

I. <u>The Importation of Innovative Pharmaceuticals Does Not Harm National Security, Because There Is Significant and Growing U.S. Pharmaceutical Industry Investment Appropriately Augmented by an Ally-Focused Global Supply Chain.</u>

The Secretary's investigation under Section 232 of the Trade Expansion Act of 1962, 19 U.S.C. § 1862, is intended to "determine the effects on the national security of imports" subject to review, and to report the Secretary's findings to the President.[2] The Secretary also must consider the effect of a given imported article on the national economy when assessing any potential national security concern. Only if the President "concurs with the finding of the Secretary" that the "quantities" or "circumstances" of imported articles "threaten to impair the national security" may the President then "determine the nature and duration" of tariffs that may be appropriate to "adjust the imports" subject to review.[3] In the present case, the Secretary should find that imported

[2] *See* 19 U.S.C. § 1862(b)(1)(A), (3)(A).

[3] *See id.* §1862(c)(1)(A)(ii).

pharmaceuticals do not raise national security concerns and are instead an integral and necessary component of the thriving and growing U.S. pharmaceutical industry.

A. Sanofi Is Part of the Global Trend of Investment in the U.S. as a Key Market.

Because of its uniquely favorable market conditions, the U.S. holds the largest share of pharmaceutical company investment globally. These conditions include timely patient access to innovative medicines; pricing that generally recognizes clinical and health system value; strong intellectual property protections; and a unique innovation ecosystem that includes leading research institutions, venture capital and a favorable regulatory environment for developing breakthrough therapies. Over time, such factors have increased the U.S. share of global pharmaceutical investment, resulting in a healthy and stable industry that supports the U.S. economy.

This makes the U.S. pharmaceutical industry a critical contributor to U.S. economic growth.[4] For example, studies show that the pharmaceutical sector supports over 4.9 million American jobs and contributes $1.65 trillion in annual economic output.[5] Biopharmaceutical companies also account for the largest single share of all industrial R&D investment in the U.S. (17%).[6]

Spending on R&D in the U.S. has been steadily increasing since 1990, growing more than tenfold from just under $7 billion in 1990 to over $75 billion in 2022.[7] These figures dwarf those of other countries and regions. For example, in 2022, pharmaceutical R&D investment across the

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[4] Teconomy Partners, *The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates* (May 2024), at 20 (explaining that "The U.S. biopharmaceutical industry's total output impact, often referred to as 'total economic impact' totaled more than $1.65 trillion in 2022. This total industry impact includes $802 billion of biopharmaceutical businesses sales (direct output effect) and $851 billion in indirect and induced output effects. These values generate a biopharmaceutical industry output multiplier of 2.06—meaning that every $1.00 in output produced by the biopharmaceutical industry supports an additional $1.06 in output in other sectors of the U.S. economy." (footnote and citation omitted)), *at* https://cdn.aglty.io/phrma/policy-issues/research-ecosystem/economy/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.

[5] *Id.* at 19 ("The U.S. biopharmaceutical industry is the world leader in the development of new small-molecule medicines, large molecule biologics, vaccines, diagnostics, and other products. While this performance provides and realizes significant benefits to U.S. citizens, it also contributes to the biopharmaceutical industry being one of the nation's most innovative industries, while driving significant contributions to the U.S. economy.").

[6] Teconomy Partners, *Biopharmaceutical Industry-Sponsored Clinical Trials: Impacting State Economies* (Mar. 2025), at i (citing National Center for Science and Engineering Statistics (NCSES) 2024 data and Business Enterprise Research and Development 2022 data), *at* https://cdn.aglty.io/phrma/fact-sheets/clinical-trials/TEConomy_PhRMA-_Biopharma-Industry-Sponsored-Clinical-Trials.2025-Report.Final_.pdf.

[7] EFPIA, *Pharmaceutical R&D Expenditure in Europe, USA, Japan and China, 1990-2022*, *at* https://efpia.eu/publications/data-center/the-pharma-industry-in-figures-rd/pharmaceutical-rd-expenditure-in-europe-usa-china-and-japan; *see also* Roman Kasianov, *Global Pharma R&D Investments Surpass $276 Billion Annually, Exceeding Previous Estimates*, BioPharmaTrend, (Oct. 24, 2024) ("The U.S. plays a dominant role, with 48% of global biopharma R&D companies based in the country. These companies are responsible for 55% of global R&D investments and 65% of development-stage funding. U.S. companies also demonstrate higher R&D intensity, reinvesting 30-34% of revenues back into research—far more than previously estimated by agencies such as the CBO."), *at* https://www.biopharmatrend.com/post/992-global-pharma-rd-investments-surpass-276-billion-annually-exceeding-previous-estimates/.

entire E.U. was just under $50 billion, and investment in China was just under $16 billion in 2022.[8] Sanofi currently is operating 125 active clinical trials in the U.S., and we aim to increase both the number of clinical studies and our U.S. R&D investment over the next 5 years.

Sanofi plays a significant role in supporting U.S. growth in this sector, employing more than 13,000 employees across fifteen U.S. locations. Six of our sites are dedicated to manufacturing and distribution and employ over 4,000 people. Sanofi has been actively increasing our share of manufacturing in the U.S., with particular focus on biologics. The U.S. is a key market of focus for Sanofi, representing almost half of the company's entire net sales in 2024. We continue to assess our future capacity requirements and are considering additional investments in the U.S., aligning our industrial footprint to the needs of our pipeline and our expected future growth.

Sanofi also makes significant investments in patient support programs that ensure American patients have affordable access to their Sanofi medicines. In 2024, these programs saved patients in the U.S. over $1.5 billion through copay assistance and provided $1.92 billion in free medicines.

These facts fundamentally distinguish the pharmaceutical industry from other industries subject to tariffs. For example, with respect to car imports, the First Trump Administration's Commerce Department previously found in 2019 that "the present quantities and circumstances of imports … specifically engines and engine parts, [] and electrical components, … are "weakening our internal economy" and threaten to impair national security as set forth in Section 232."[9] A key finding underlying this conclusion was the decline in U.S. R&D for important automotive technologies, which the Secretary determined to weaken U.S. innovation and the country's capacity to meet national security requirements.[10] Indeed, as the U.S. Supreme Court has noted, the legislative history surrounding Section 232's predecessor statute reflected concern over "increased imports [that] were threatening to damage various domestic industries whose viability was perceived to be critical to the national security." *See Fed. Energy Admin. v. Algonquin SNG, Inc.*, 426 U.S. 548, 562 (1976).

But the U.S. pharmaceutical industry is in the exact opposite situation, as shown by sustained and growing domestic R&D investment. In fact, tariffs would unnecessarily jeopardize the U.S.' decades-long leadership in pharmaceutical R&D investment by forcing manufacturers to divert substantial resources to tariff payments, at the expense of further investment in biopharmaceutical manufacturing and research in the U.S.

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[8] *Id.*

[9] U.S. Dep't of Commerce, *The Effect of Imports of Automobiles and Automobile Parts on the National Security: An Investigation Conducted Under Section 232 of the Trade Expansion Act of 1962, As Amended* (Feb. 17, 2019), at 11.

[10] *Id.* at 11 ("[T]he U.S. military relies heavily on and adopts innovations from the commercial automotive industry, a significant decline in American-owned automotive industry investment and development also jeopardizes U.S. military leadership and its ability to fulfill America's defense requirements.").

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B. Pharmaceutical Global Supply Chains Help to Ensure Resilience and Do Not Raise National Security Concerns.

A geographically diversified and redundant supply chain, closely coordinated with trusted allies, ensures the resilience necessary for national security. To the extent Sanofi's products and API are not manufactured in the U.S., they are manufactured in long-standing U.S. allied countries (*e.g.*, Germany and France), from which imports do not present a national security risk. Strong trade relationships with allies help mitigate supply disruptions and ensure continued U.S. access. Over-concentrating manufacturing in the U.S. would undercut this supply chain diversity, thus threatening supply chain resilience and stability. For example, if an entire supply chain is dependent upon one geographic area and that area experiences a natural disaster, military conflict, or pandemic, there could be significant infrastructure and supply disruptions with global implications. Each year in the U.S. alone, hurricanes, tornados, and wildfires cause significant damage to domestic infrastructure, affecting and threatening U.S. pharmaceutical facilities.[11] For example, in 2023, tornado damage to a Pfizer factory in North Carolina, which supplied 8% of all sterile injectables used in hospitals across the U.S., risked disruption in supply of these products and caused panic at U.S. hospitals.[12] Similarly, there have been recurring shortage issues as a result of natural disasters on intravenous saline bag manufacturing both in the mainland U.S. and in Puerto Rico.[13]

Moreover, pharmaceutical products, including their derivates and ingredients, are manufactured and distributed as part of a robust global supply chain that operates under strict regulatory controls and safeguards.[14] These circumstances help ensure that only safe and effective medicines that comply with each respective jurisdiction's requirements are distributed.

II. Tariffs on Pharmaceuticals Will Harm Patients by Threatening Access and Increasing Costs.

Imposing tariffs on pharmaceuticals would harm Americans' access to important medicines by creating supply disruptions and shortages, increasing patient and health care system costs and ultimately harm U.S. pharmaceutical innovation.

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[11] Gregory Muraski, *UMD Experts: Pharma Facilities Sit in Path of Tornadoes, Other Weather Disasters*, Maryland Today (Sep. 6, 2023), *at* https://today.umd.edu/umd-experts-pharma-facilities-sit-in-path-of-tornadoes-other-weather-disasters (finding that 42% of FDA-registered manufacturing companies are in high-tornado-risk areas and 31% are located in flood risk areas).

[12] Sydney Lupkin, *Tornado damage to Pfizer factor highlights vulnerabilities of drug supply*, NPR.org (July 27, 2023), *at* https://www.npr.org/sections/health-shots/2023/07/27/1190507719/tornado-pfizer-factory-drug-shortages (reporting disruption of intravenous painkillers and anesthetics);

[13] *Id.*; *see also* Ana Faguy, *IV fluid supplies in US disrupted by Hurricane Helene*, BBC News (Oct. 4, 2024), *at* https://www.bbc.com/news/articles/cz04nl32e7yo; *see also* Baxter, *Hurricane Helene Updates* (Feb. 17, 2025), *at* https://www.baxter.com/baxter-newsroom/hurricane-helene-updates (providing an update on intravenous saline bag manufacturing line repairs at a N.C. facility following Hurricane Helene).

[14] *See, e.g.*, 21 C.F.R. Part 211 (current good manufacturing practices for finished prescription drug products).

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A. Tariffs on Pharmaceuticals Will Create Supply Disruptions, Drug Shortages, and Threaten Access to Necessary Medicines.

Tariffs on finished pharmaceuticals and ingredient imports—which almost certainly would be met with retaliatory tariffs—pose a significant threat to American patient access. The increased costs associated with tariffs will lead to supply disruptions and worsening drug shortages.

Addressing drug shortages has been a major priority for the U.S. Food and Drug Administration ("FDA"), multiple presidential administrations of both parties and Congress in the past decades. The U.S. government addresses shortages by promoting innovation, incentivizing manufacturing of generic and biosimilar products to increase volume and ensuring a smooth import and export regime. Tariffs are likely to undermine these efforts by disrupting and destabilizing the global supply chain, creating or exacerbating shortages in the U.S., and ultimately contravening the administration's goal of ensuring that there is sufficient and reliable pharmaceutical supply to meet U.S. demand.

There are currently already around ninety (90) drug shortages reported by FDA, many caused by manufacturing discontinuations rather than spikes in demand.[15] Applying tariffs on pharmaceutical imports, which is expected to result in retaliatory tariffs on U.S. exports, will increase expenditures for all pharmaceutical manufacturers, forcing companies to assess whether it makes financial sense to continue to do business at the same level in a respective jurisdiction. As a result, manufacturers may decide to shift production lines to a different, more profitable drug in a non-tariffed jurisdiction, reduce operations in costly places of business, or take other actions that jeopardize continued supply.

Drug shortages are a particular concern for Americans with diabetes, who have had to grapple with periodic insulin shortages in recent years. In Spring 2024, two other insulin manufacturers reported shortages and manufacturing disruptions related to a number of their insulin products.[16] Additional pressure has been put on insulin supply following one of those company's discontinuation of one of its main insulin products at the end of 2024.[17] We anticipate

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[15] FDA Drug Shortages Database, *Current and Resolved Drug Shortages and Discontinuations Reported to FDA*, *at* https://dps.fda.gov/drugshortages. In 2019, during President Trump's first term, FDA released a report identifying the root causes and potential solutions for drug shortages. *See* FDA, *Drug Shortages: Root Causes and Potential Solutions* (2019), at 1 ("[A] team of FDA economists and other scientists … analyze[d] drugs that went into shortage between calendar years 2013-2017 with a view to understanding the underlying forces that were driving them. The analysts relied on the statutory definition of drug shortage, as a period of time when the demand or projected demand for the drug within the U.S. exceeds the supply."), *at* https://www.fda.gov/media/131130/download?attachment. The overall conclusion was that economic forces, such as a lack of incentives to produce less profitable drugs and a market that does not recognize and reward manufacturers for "mature quality management systems," were the cause of most shortages. *Id.* at 6.

[16] Erin Poche, *The 2024 Insulin Shortage and What You Need To Know*, T1D Guide, (Aug. 2, 2024), *at* https://www.type1strong.org/blog-post/the-2024-insulin-shortage-and-what-you-need-to-know.

[17] *Breakthrough T1D Statement and Update on Insulin Shortage*, Breakthrough T1D (Apr. 10, 2024), *at* https://www.breakthrought1d.org/for-the-media/press-releases/jdrf-statement-and-update-on-insulin-shortage/ (noting that Eli Lilly discontinued manufacturing certain vials of Humalog).

continued impacts on demand as certain other manufacturers continue to shift manufacturing capacity away from insulin and toward other products, such as GLP-1s.[18]

Sanofi considers the U.S. a key market, and we remain committed to sustaining American patients' access to their prescribed Sanofi insulins. We continue to invest in strengthening manufacturing capacity and supply resilience to meet demand in the U.S. and elsewhere. Additionally, Sanofi recently received FDA approval for Merilog, a rapid-acting insulin biosimilar to Novolog, which is expected to be available in the U.S. market beginning in July 2025. Sanofi intends to price Merilog to optimize access and affordability and provide Americans with diabetes an additional option to mitigate the risk of patient access issues from shortages of other rapid acting insulins.

As demonstrated by the insulin example, drug shortages can be prompted by increased demand but also by changing market conditions, such as price caps placed on insulin and increased profitability of GLP-1 medications—both manufactured by the same companies in several instances. This example serves as an instructive warning about how changing market dynamics can lead to shifting supply priorities, disruptions, and shortages. Tariffs also would impact market dynamics, potentially with the same negative consequences for U.S. patient access.

B. Tariffs on Pharmaceuticals Will Raise Costs for Patients.

President Trump has expressed a strong commitment to identifying ways to reduce patient and system costs for pharmaceuticals. Sanofi is also deeply committed to that goal. But tariffs on pharmaceuticals undermine this objective and will increase costs for manufacturers and others in the supply chain, which ultimately will increase costs for patients and the U.S. healthcare system. A recent analysis by Ernst & Young estimates that an additional 25% tariff on all biopharmaceuticals and ingredients imported into the U.S. would increase the cost of these products by $50.8 billion annually[19]—this additional cost is equivalent to nearly 13% of the biopharmaceutical industry's annual U.S. sales.[20]

Despite sustained investment in U.S. manufacturing, manufacturers currently and will continue to rely on inputs and finished products from the global supply chain. Moreover, establishing additional U.S. manufacturing capacity takes significant time, money, and coordination with appropriate regulatory authorities. In President Trump's May 5, 2025 Executive Order titled "Regulatory Relief to Promote Domestic Production of Critical Medicines," (hereinafter the "Pharmaceutical Manufacturing EO") he acknowledged "the length of time it takes to build pharmaceutical manufacturing facilities in the United States today," citing "[i]ndustry estimates [which] suggest that building new manufacturing capacity for pharmaceuticals and

[18] Elaine Chen, *As GLP-1 sales surge, insulin users fear Novo Nordisk and Eli Lilly will move on without them*, STAT, (Jul. 17, 2024), *at* https://www.statnews.com/2024/07/17/insuln-novo-nordisk-eli-lilly-weight-loss-drugs/.

[19] Ernst & Young, "Impacts of potential tariffs on the US pharmaceutical industry" (Apr. 22, 2025), at 1.

[20] *Id.* at 2, 9.

critical inputs may take as long as 5 to 10 years[.]"[21] Although a number of the policies in the executive order aimed at streamlining regulatory processes are likely to encourage additional domestic manufacturing over the long term, the actions required by the order are unlikely to quickly shorten the expected time to bring a new manufacturing facility onboard. In the meantime, patients will face higher costs for their medicines.

Even if Sanofi were to absorb these increased costs, other manufacturers (including generic manufacturers with small margins who supply a large percentage of all medicines in the U.S.) are likely to pass the additional cost on to consumers. In any event, if even a subset of products increase in price, those increases are likely to have broader implications for patients and the U.S. healthcare system. Based on our experience, we anticipate that pharmacy benefit managers ("PBMs") and insurance plans will shift much of the cost of any price increases to patients in the form of higher premiums, deductibles, and cost-sharing across all products – and not just those products with a higher list price.

Moreover, increased operational costs due to tariffs mean that manufacturers will have fewer resources to devote to manufacturer-sponsored affordability programs that currently offset the high cost-sharing imposed by PBMs and insurance plans. Sanofi, as demonstrated through its commitment to patient access, would attempt to minimize such effects on its affordability programs, but tariffs would make some increases in patient costs likely unavoidable.

The recognition that tariffs on pharmaceuticals and ingredients would impede patient access is why the U.S. government and other jurisdictions with the world's leading innovative pharmaceutical industries—such as the E.U., U.K., Singapore, and Switzerland—do not impose tariffs on pharmaceutical products, including U.S. exports.[22] Additionally, recent experience suggests that imposing tariffs on pharmaceuticals from these (and other) regions and countries may inspire reciprocal and retaliatory tariffs. Such retaliatory tariffs threaten to impair the health of Americans by further exacerbating patient and system costs.

C. Tariffs on Pharmaceuticals Threaten Americans' Early and Broad Access to Innovative Medicines.

Tariffs also would undermine the current U.S. market dynamics and financial incentives that allow Americans to enjoy earlier and better access to innovative medicines. Currently, over half of new drugs are launched first in the U.S. before being launched in other countries, with an average lag of about one year between launch in the U.S. and launch in another country.[23] Patients in Organization for Economic Cooperation and Development ("OECD") countries—which

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

[22] *See generally* Ernst & Young, "Impacts of potential tariffs on the US pharmaceutical industry" (Apr. 22, 2025).

[23] Ass't Sec'y for Planning & Evaluation, U.S. Dep't of Health & Human Servs., *Comparing New Prescription Drug Availability and Launch Timing in the United States and Other OECD Countries*, (Feb. 2024), at v, 15, *at* https://aspe.hhs.gov/sites/default/files/documents/430a3e61c234f06270b04414e797ad3a/new-drug-availability-launch-timing.pdf.

represent around 40 of the world's wealthiest countries—have access to just 29% of new medicines via a government health plan, versus 85% in the U.S.[24]

As noted above, applying tariffs on pharmaceutical imports will increase the costs for supplying pharmaceuticals in the U.S., which will change the financial incentives that currently drive better access in the U.S. Tariffs may force manufacturers to change their new product launch strategies, particularly if other countries seek to leverage the changing dynamics in the U.S. to their benefit.

D. Increased Costs from Tariffs Will Strain Resources for R&D and Harm Innovation.

U.S. pharmaceutical R&D is the engine for scientific breakthroughs that transform how we treat and prevent diseases. It is also one of the U.S.' most R&D-intensive domestic industries, as it is supported by a U.S. policy framework and free market incentives that encourage innovation and competition. "In the last 10 years alone, the U.S. pharmaceutical industry has developed over 470 medicines to treat diseases such as cancer, cardiovascular diseases, and diabetes."[25]

Many medicines currently in development have the potential to address previously unmet medical needs: for example, Sanofi's pipeline includes 86 clinical-stage projects, with a strong focus on difficult-to-treat diseases.[26] However, with an estimated annual cost of more than $50 billion, a 25% tariff on the biopharmaceutical sector would seriously inhibit the ability of the industry to invest in these promising technologies, to the detriment of American patients, public health, and the U.S. economy.

III. The Administration Should Advance Policy Solutions That Incentivize U.S. Investment and Resilient Supply Chains while Strengthening Patient Access.

Sanofi is committed to advancing public policies that ensure innovative medicines are accessible and affordable to U.S. patients. As described above—and as long recognized by U.S. policymakers, including the Trump Administration—tariffs on pharmaceutical imports run counter to this shared goal.[27] Tariffs not only threaten access to existing medicines, they also divert resources that could instead be directed toward U.S. manufacturing investment and R&D.

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[24] *Id.* at v, 3, 24.

[25] IFPMA, *#AlwaysInnovating: The pharmaceutical innovation journey* (2024), *at* https://www.ifpma.org/initiatives/alwaysinnovating-the-pharmaceutical-innovation-journey/.

[26] Sanofi, *Our Pipeline* (last updated Apr. 24, 2025), *at* https://www.sanofi.com/en/our-science/our-pipeline.

[27] 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." Office of the U.S. Trade Rep., *2017 Special 301 Report* (Apr. 2017), at 20, *at* https://ustr.gov/sites/default/files/301/2017 Special 301 Report FINAL.PDF; *see also*, Office of the U.S. Trade Rep., *2025 Special 301 Report* (Apr. 2025), at 30, *at* https://ustr.gov/sites/default/files/files/Issue_Areas/Enforcement/2025 Special 301 Report (final).pdf (citing an October 2021 Geneva Network Report on "How Tariffs Impact Access to Medicines").

Even if tariffs were to eventually result in increased U.S. manufacturing of pharmaceutical products—a process that takes many years of building and regulatory hurdles—such a shift would not necessarily lead to more affordable or better patient access. For most products in this industry, shifting the manufacturing location would be a monumental undertaking measured in many years and billions of dollars, rather than months and millions.[28] Moreover, as described above, tariffs would undermine current market dynamics that provide Americans with the best and earliest access to innovative medicines in the world.

There are a number of more effective ways that the President can work with the pharmaceutical industry to encourage increased domestic manufacturing and decrease reliance on adversarial countries. Ultimately, manufacturing and other investment is determined by several factors including tax conditions, infrastructure, availability of local talent, supportive regulatory environment and a thriving local economy.

Below, we highlight just a few policies that would better achieve our shared goals:

A. Tax Reforms and Other Incentives Can Achieve the Same Goal of Increasing U.S. Investment without Harming Patients.

President Trump has made tax reforms that support individuals and corporations a central tenet of both of his presidential terms. The President has urged Congress to pass "the largest tax cuts in history to the American people."[29] One of the results promised from the President's proposed tax plan is a long-run GDP boost of 2.6%-3.2% and a short-run boost of 3.3%-3.8%[30] and extending provisions from the 2017 Tax Cuts and Jobs Act ("TCJA") that reoriented the corporate tax system.[31] Extending such provisions is one way to further incentivize U.S. pharmaceutical investment without harming patients.

For example, the TCJA cut the corporate tax rate by 14% (*i.e.*, from 35% to 21%), which increased the attractiveness of the U.S. for investment.[32] President Trump's economic advisers note that this action "further enhanced the competitiveness of American corporations and removed tax barriers to repatriating foreign earnings."[33] This type of tax reform works, as evidenced by

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[28] FDA requires drug and biologic sponsors to submit a prior approval supplement for major manufacturing changes such as opening a new facility. *See* 21 C.F.R. 314.70. This supplement is required to include validation and other testing information set forth in the CGMPS (*e.g.*, 21 C.F.R. Parts 210, 211 and 600-680), in addition to needing an FDA inspection prior to approval. *See also* FDA, *Guidance for Industry: Changes to an Approved NDA or ANDA* (Apr. 2004).

[29] The White House, Articles, *ICYMI: President Trump's Largest Tax Cut in History* (Apr. 30, 2025).

[30] *Id*.

[31] White House Council of Economic Advisers, *The Economic Impact of Extending Expiring Provisions of the Tax Cuts and Jobs Act* (Apr. 2025), at 1.

[32] *Id*.

[33] *Id*.

increasing U.S. investment by pharmaceutical companies.[34] If the President wants to encourage companies to move manufacturing to the U.S., further reducing the corporate tax rate is a proven method of doing so.

Additionally, we encourage the administration to consider tax incentives specifically for new, expanded, or upgraded manufacturing facilities, including establishing a 15% tax rate for U.S.-manufactured pharmaceuticals. We also recommend that the U.S. make adjustments to R&D tax credits to better align and compete with tax treatment for R&D in the rest of the world.[35]

Although it is clear that tax incentives play a key role in incentivizing U.S. leadership in pharmaceutical investment, other financial incentives that will maintain and extend U.S. domination in this space include federal grants and/or subsidies relating to R&D costs, as well as federal investments in public-private partnerships for new manufacturing facilities, expansions of facilities, and enhancement of existing facilities. These efforts would help defray the overall higher cost of doing business in the U.S. compared to other countries, which levels the playing field and encourages further investment in U.S. manufacturing infrastructure, thereby increasing U.S. competitiveness.

These policy approaches also avoid creating patient access issues because they would not impact existing pharmaceutical supply chains in the short run. These policies also mitigate the risk of manufacturers passing on any increased costs associated with moving manufacturing to patients.

B. Other Intellectual Property and Regulatory Incentive Programs Will Also Support U.S.-Based Innovation and Fair Trade.

In addition to the recommendations above to encourage U.S. investment, we also believe the following approaches should be implemented to support continued U.S.-based innovation and fair trade.

As we have described throughout, it is vitally important to maintain and foster current pro-innovation policies that have led to U.S. global leadership in innovative pharmaceutical products. Current policies that contribute to the strength of U.S. innovation include payment and coverage policies that appropriately value innovative medicines, robust protections and enforcement of intellectual property ("IP"), and streamlined (and consistent) regulatory approval processes. For example, we are supportive of the policies outlined in the Pharmaceutical Manufacturing EO to

[34] *See supra*, Section I.A; *see also* White House Council of Economic Advisers, *The Economic Impact of Extending Expiring Provisions of the Tax Cuts and Jobs Act* (Apr. 2025), at 5 (explaining that a "jump in the growth rate of investment emerges as a result of the reduction in the statutory corporate tax rate and introduction of full expensing for equipment investment, both of which lower the user cost of capital. This jump in investment, in turn, results in a growing capital stock that pushes up GDP and wages.").

[35] The U.S. is almost last among the OECD and BRIC nations in terms of tax incentives for R&D. ITIF, *To Do: Double the R&D and Alternative Simplified Credits* (Feb. 8, 2025), *at* https://itif.org/publications/2024/04/01/to-do-double-the-rd-and-alternative-simplified-credits/.

streamline review and permitting processes at FDA, the Environmental Protection Agency, and the U.S. Army Corps of Engineers related to the manufacturing of pharmaceutical products.

Additionally, we recognize and support the President's overall objective of ensuring fair trade agreements. As such, in lieu of tariffs, the administration should focus on modernizing existing trade agreements, negotiating new sectoral agreements, and setting up new trading partner agreements to eliminate unfair trade practices. Such agreements must include strong IP protections, fair and equitable market access conditions, good regulatory practices, and elimination of foreign tariffs, clawbacks, and other counterproductive fees imposed on the pharmaceutical industry that impact U.S.-manufactured exports.

C. Any Tariff Action Should Be Narrowly Tailored to Address Discrete National Security Threats and Mitigate Harm to Patients, Health Systems, and the Economy.

If the U.S. Commerce Department nonetheless chooses to recommend imposing unprecedented tariffs on pharmaceuticals, any such novel policy should narrowly address specific national security threats, in order to minimize harming American access to current medicines and hampering future innovation. The vast majority of imported pharmaceuticals and their ingredients do not raise the national security concerns that animate Section 232. Generally speaking, there is no need for the U.S. to impose new tariffs on pharmaceuticals in the name of "national security," because sufficient domestic manufacturing capacity already exists, it is growing every day, and that capacity is appropriately integrated into a resilient global supply chain anchored in countries that are longstanding U.S. allies. To that end, we recommend that the administration take a risk-based approach to its investigation to identify vulnerabilities with respect to particular countries of concern (*e.g.*, countries subject to U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC") sanctions) and essential medicines and ingredients for which the U.S. is over-reliant on such countries.

Above all else, continued, reliable patient access must be a guiding principle of any tariff policy. Thus, any policy arising from the present Section 232 investigation must account for:

- consideration of practical limitations, such as the limited geographic availability of certain pharmaceutical raw materials;

- the long lead time required for re-shoring or other appropriate supply chain shifts, which will require phasing in any tariffs over many years to mitigate the immediate harms that tariffs otherwise would have for patient access and affordability; and

- the need for an expeditious exemption and/or exclusion process for products in shortage or that otherwise address an unmet medical, national security or defense need.

* * *

For all of these reasons, we strongly believe that tariffs on pharmaceuticals are not an appropriate or effective means for addressing our shared goal of maintaining and protecting U.S. patient access to medicines and, in fact, would harm access to current medicines and future innovation. Instead, we encourage the Trump Administration to work with Sanofi and other manufacturers to develop free market policy solutions that will encourage further growth of the U.S. pharmaceutical industry and drive continued innovation.

Sincerely,

Adam Gluck
Head, U.S. and Specialty Care Corporate Affairs