May 7, 2025

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Eric Longnecker
Deputy Assistant Secretary for Technology Security
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
U.S. Department of Commerce

Re: Comments of Eli Lilly and Company Regarding the Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (Docket No. 250414-0065, XRIN 0694-XC120)

Dear Mr. Longnecker:

Eli Lilly and Company is a proudly American pharmaceutical company, founded in 1876 in Indianapolis by Colonel Eli Lilly, a former Union Army officer. For nearly 150 years, Lilly has developed quality, innovative medicines that make the lives of the American people better. As an early pioneer of pharmaceutical research and development, Lilly believes that all Americans deserve access to safe and effective medicines, manufactured under the gold standard of quality and provided through a secure supply chain.

Lilly's commitment to American manufacturing and workers is backed by real action. We employ more than 22,000 workers inside the United States, providing good pay and strong benefits to our employees. Since President Trump's signature tax reform in 2017, we have significantly increased our investment in domestic operations. Beginning in 2019, we have spent more than $6.5 billion expanding our manufacturing capacities in Indiana, North Carolina, and Wisconsin, with another $16.5 billion committed. In February of this year, at an event with Secretary Lutnick, our Chief Executive Officer Dave Ricks announced another $27 billion investment in American manufacturing, spread across four domestic sites. These new investments amount to $50 billion in total and will create more than 13,000 new jobs, increasing our domestic workforce by almost 60%.

In addition to the economic benefits that our manufacturing investments bring to an area, Lilly always provides additional investments in resources for the communities where we have a manufacturing presence. For example, Lilly is investing over $100 million in partnerships with Purdue University and Ivy Tech Community College to train students with degrees in engineering, biotechnology, biopharma manufacturing, smart manufacturing and digital integration and industrial technology.

In keeping with President Trump's comprehensive review of American trade policy, the Department of Commerce has now announced an investigation into the effects of importation of pharmaceuticals, pharmaceutical ingredients, and their derivative products. Under Section 232 of the Trade Expansion Act, the Secretary must make findings about "the effects on national security of the import of the article which is the subject of" the investigation and report to the President whether "such article is being imported into the

United States in such quantities or under such circumstances as to threaten the national security." 19 U.S.C. § 1862(b). The Secretary must then recommend to the President "action or inaction" based on these findings. *Id.*

Lilly shares this Administration's goals of protecting the American pharmaceutical supply chain, increasing American manufacturing, and ensuring that Americans have ample, secure access to safe and effective medicine. However, while conducting this investigation and making his findings, we urge the Secretary to avoid overly broad characterizations of the articles and circumstances that might affect the nation's security in ways that might harm the unique American ecosystem of pharmaceutical innovation, patient access, and quality medicine. Similarly, to the extent the Secretary believes additional measures are warranted, we urge him to recommend measures other than blanket tariffs on broad categories of pharmaceuticals to balance the many interests at stake.

I. The 232 Investigation Should Focus on Critical and Essential Medicines

While domestic pharmaceutical supply has significant implications for public health and economic impact, only a small number of pharmaceutical products directly impact national security. President Trump has already taken steps to identify and improve those supply chains, and the Secretary should focus primarily on these already identified vulnerabilities. In 2020, President Trump issued Executive Order 13,944, declaring it the policy of the United States to reduce its dependance on foreign manufacturers of essential medicines and ensuring sufficient and reliable long-term domestic production. In doing so, he ordered the Commissioner of the U.S. Food & Drug Administration (FDA) to create a list of "Essential Medicines" that were deemed "medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms." 85 Fed. Reg. 49,929, 49,932 (Aug. 14, 2020). Since that time, FDA has promulgated the Essential Medicines List, which contained approximately 227 drug and biological products.

In a subsequent review in November 2023, the U.S. Department of Defense (DOD) used this list to assess supply chain risk and its effect on military readiness. DOD's report identified 25% of the active pharmaceutical ingredients (APIs) for medicines on this list as sourced in the United States, 18% coming from countries in compliance with the Trade Agreement Act (TAA), 26% from India, 5% from China, and 1% from non-TAA-compliant countries, with 22% having an unknown source.[1] DOD also identified mitigation strategies to increase both visibility and access to these and other essential medicines. In other words, because of President Trump's actions in his first term, the key executive agencies have already identified the medicines most essential to national security and whose supply chain has a direct impact on military readiness.

Thus, where the statutory command is to evaluate the effects on national security, the Secretary should evaluate and make recommendations as to those set of medicines already identified under E.O. 13,944. As detailed below, outside of this core group of medicines, pharmaceutical medicines can affect national security indirectly by improving overall

[1] Dep't of Def., *Report on the Department of Defense Pharmaceutical Supply Chain Risks* 9 (Nov. 2023), https://tinyurl.com/522yfxy6.

economic stability or public health. But significant measures like tariffs placed on pharmaceutical products more broadly would actually undermine national security more than they would benefit it, given the negative ripple effects in other areas.

II. Increasing the Cost of Medicines by Imposing Tariffs will Harm National Security

Lilly agrees that American interests are promoted by increasing the security and stability of the pharmaceutical supply chain. At the same time, some measures—like tariffs—that increase the cost of medicines or decrease the capital available to manufacturers will actually worsen the problem this Administration seeks to address. Thus, to the extent the Secretary concludes that public health and the economics of medicines impact national security, tariffs will cause more harm than good to those interests.

A. Tariffs will decrease access for patients, lowering public health and increasing costs

First, by immediately increasing the cost of medicines—both imported and manufactured domestically using imported materials—tariffs will decrease patient access through immediate disruption of the supply chain, potential shortages, and higher end-costs to patients and insurers.

In the short term, tariffs decrease the security and stability of the national supply chain as market actors change behaviors in the face of uncertainty. Stockpiling and hoarding behaviors by hospitals, pharmacies, or individuals are common in high-tariffs environments and lead to serious problems: artificial scarcity, inconsistent geographic distribution of medicines, increased prices, inability to accurately forecast patient demand, and waste from unneeded medicines expiring on the shelf or in stockpiles.[2] Around 90% of hospital supply chain professionals estimated "major disruptions" in procurement processes and supply shortages as a result of pharmaceutical tariffs.[3] These shortages and disruptions can have significant consequences: Drug shortages in cancer treatments have caused difficulties in finding substitute medications and even treatment delays and insurance coverage issues, with Medicaid recipients most likely to be affected.[4]

In addition, the price to patients and insurers would increase, decreasing patient access and lowering the nation's economic health. Some researchers have suggested that a pharmaceutical tariff of 25% would increase the cost of medicine to American households by 8-10% and—as a share of income—have an impact three times as severe on the lowest-

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[2] https://www.forbes.com/sites/stephenbrozak/2025/03/04/as-tariffs-begin-what-will-they-do-to-drug-prices-and-availability/

[3] https://blackbookmarketresearch.newswire.com/news/double-digit-tariffs-disrupt-u-s-healthcare-costs-and-supply-chain-22513308

[4] American Cancer Society. https://www.fightcancer.org/sites/default/files/national_documents/survey_drug_shortages_biomarkers_1.pdf

income households than the highest.[5] Another survey concluded that "[a]bout 7 in 10 experts predict drug costs will rise by at least 10%."[6] Around half of payer executives estimate that insurance premiums will also rise to account for increased supply chain expenses.[7] These effects are directly at odds with this Administration's stated goal of ensuring more affordable medicine for Americans.[8]

Lastly, tariffs will increase costs to the federal government and harm the overall economic health of the country. Because the federal government is the largest purchaser of pharmaceutical products in the United States, higher prices for medicine will increase federal spending, which could be better allocated to other national security priorities and to decrease the national debt held by foreign entities. Combined, Medicare and Medicaid account for about 40% of spending on drugs nationwide, with Medicare alone accounting for nearly a third.[9] Where charging higher prices are prohibited by law, costs will be redirected to other portions of the economy, like private insurers, hospitals, and employers. Researchers estimate that GDP growth resulting from 25% tariffs in this area will slow "equivalent of the U.S. economy being permanently smaller $24-25 billion annually in 2024 dollars."[10] Whatever revenue the government obtains from tariffs, it will lose in larger economic detriments.

B. Tariffs will deprive manufacturers of necessary capital to both innovate and invest in reshoring

Second, increasing the costs of manufacturing will deprive pharmaceutical manufacturers like Lilly of critical capital that it needs to produce existing medicine, discover innovative medicine, and engage in the domestic manufacturing investment that this Administration ultimately wants to encourage.

The United States leads the world in pharmaceutical innovation and development, filing nearly 38% of all global biotechnology patents between 2015 and 2020.[11] And Americans benefit first from most new-drug launches: One 2021 study concluded that more than 60%

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[5] https://budgetlab.yale.edu/research/fiscal-economic-and-distributional-effects-automobile-semiconductor-and-pharmaceutical-tariffs.

[6] https://www.forbes.com/sites/stephenbrozak/2025/03/04/as-tariffs-begin-what-will-they-do-to-drug-prices-and-availability/

[7] https://blackbookmarketresearch.newswire.com/news/double-digit-tariffs-disrupt-u-s-healthcare-costs-and-supply-chain-22513308

[8] Lowering Drug Prices by Once Again Putting Americans First, E.O. 14,273 (Apr. 15, 2025), 90 Fed. Reg. 16,441.

[9] *See* Juliette Cubansk et al., *How Does Prescription Drug Spending and Use Compare Across Large Employer Plans, Medicare Part D, and Medicaid?*, KFF (May 20, 2019), https://tinyurl.com/2p83ddze; https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet

[10] https://budgetlab.yale.edu/research/fiscal-economic-and-distributional-effects-automobile-semiconductor-and-pharmaceutical-tariffs

[11] https://www.csis.org/analysis/understanding-us-biopharmaceutical-innovation-ecosystem

of all new medicines were first launched in the United States.[12] Sustaining this level of innovation requires extraordinary investments of time and money. Only 0.02% of therapies in development receive FDA approval for use—and only one-third of those will ever recoup its development costs.[13] Lilly, for instance, invested more than $10 billion *for each* new FDA-approved molecular entity it brought to market from 2006 to 2014.[14] Every year, Lilly re-invests around 25% of its revenue into research and development of future medical breakthroughs, including more than $10 billion in 2024 alone. As one example, Lilly spent 30 years and billions of dollars pursuing treatments for Alzheimer's disease—an arena in which the failure rate for potential new medicines is more than 99%—until finally in 2024, it received FDA approval for Kisunla®(donanemab) as a breakthrough therapy.[15]

Analysts project that a 25% U.S. tariff on pharmaceuticals will deprive the pharmaceutical industry of as much as $76 billion per year.[16] That does not count any additional lost revenue as a result of other countries imposing retaliatory tariffs. Revenue loss of this magnitude directly correlates to lower research and development on new medicines: Academic studies indicate that every 1% drop in pharmaceutical revenues leads to a 1.5% decrease in research and development spending, which in turn translates to 1.5% fewer drugs being developed.[17] At a time when countries like China are investing significant resources in incentivizing pharmaceutical innovation—and have been closing the gap with the United States on shares of value added[18]—the government should not take steps that would significantly reduce the resources American pharmaceutical companies need to remain the leaders in innovation and research.

In addition, as noted in President Trump's recent Executive Order,[19] the process of reshoring takes time and significant capital as well: "Building a new manufacturing facility,

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[12] IQVIA, *The Global Use of Medicines 2021: Outlook to 2025* (2021).

[13] *See* Sandra Kraljevic et. al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps., no. 9, 2004, at 837, https://tinyurl.com/525p87tp; John A. Vernon & Joseph H. Golec, *Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence* 7 (2008), https://tinyurl.com/2k3hfyw5; U.S. Food & Drug Admin., *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective* (Nov. 24, 2017), https://tinyurl.com/32xnaus2.

[14] A. Schuhmacher et al., *Changing R&D models in research-based pharmaceutical companies*, J. Transl. Med. 14, 105 (2016), https://tinyurl.com/53rkbh9a.

[15] Shawn O'Neail, *Privately funded pharmaceutical innovation deserves support, not punishment*, The Hill (June 3, 2022), https://tinyurl.com/y9y6eps2; *see also* Alzheimer's Ass'n, *Alzheimer's Disease Facts and Figures*, https://tinyurl.com/s57afk6k; *FDA approves treatment for adults with Alzheimer's disease*, U.S. Food & Drug Admin. (July 2, 2024), https://tinyurl.com/ywcmzndn.

[16] https://www.pwc.com/us/en/tax-services/publications/insights/assets/pwc-us-tariff-industry-analysis-pharmaceutical-life-science-and-medical-device.pdf

[17] https://cpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/08/Issue-Brief-Drug-Pricing-in-HR-5376-11.30.pdf

[18] Barbosu, S. *How Innovative is China in Biotechnology?* ITIF. July 2024. https://itif.org/publications/2024/07/30/how-innovative-is-china-in-biotechnology/

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

for example, can cost between $2 billion and $10 billion and take 5 to 10 years before it is operational, including the time and costs related to comply with various regulatory requirements."[20] Depriving pharmaceutical companies of capital thus fundamentally undermines their ability to invest that capital in domestic manufacturing processes.

C. *Tariffs will disproportionately harm generics, the best deal in U.S. healthcare, which will have negative consequences for innovators*

Nor will research or domestic manufacturing investment by innovator pharmaceutical companies like Lilly be the only process affected. The reason the United States leads the world in pharmaceutical development turns on its recognition of the symbiotic relationship between innovators and generic manufacturers. Because developing new medicine requires such extensive outlays of time and money on the front end—with little guarantee of success—innovators require intellectual property protections and an exclusivity period to recoup the costs of development and create the capital necessary to invest in new research enterprises. But, as Congress recognized with the Hatch-Waxman Act, creating an accelerated pathway for generic manufacturers after exclusivity dramatically expands patient access and lowers drug prices for patients. Now, according to the FDA, approximately 91% of all U.S. prescriptions are filled with generic medicines, with more than 32,000 generic medicines approved as of 2021.[21] Lilly relies on generic manufacturers satisfying patient demand after its exclusivities end to transition its resources to developing the next innovative breakthrough.

Yet these generic manufacturers will be severely undercut by pharmaceutical tariffs, leading directly to reduced patient access. One 2021 report concluded that "83 of the top 100 generic medicines consumed in the U.S. have no domestic API manufacturing source. Additionally, 97% of the most prescribed antivirals and 92% of antibiotics lack a U.S.-based source for their API."[22] Yet because generic manufacturers operate on slim profit margins in any event, the American Society of Health-System Pharmacists has warned that "for a generic drug, if [an increased tariff] pushes them over the line to no longer being profitable, they may just drop out of the market, and then we have a shortage."[23] At least one generic vendor has warned that a 25% percent tariff would cause it to stop selling 60 medicines in America.[24] If generic manufacturers cannot provide low-cost medicines to patients while

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[20] https://phrma.org/policy-issues/research-development/manufacturing-supply-chain

[21] FDA. Office of Generic Drugs 2022 Annual Report. https://www.fda.gov/media/165435/download?attachment

[22] Wall, M., Seetharaman, S., Sardella, A. *Revitalizing U.S. Pharma: Evaluating the Economic and Social Impacts of Advanced Manufacturing in Missouri*. September 2024. Page 4. https://apicenter.org/wp-content/uploads/2024/10/APIIC-EconomicImpactReport.pdf

[23] https://thehill.com/policy/healthcare/5245652-trump-tariffs-pharma-drug-shortages-trade-war-hhs-kennedy/

[24] https://thehill.com/opinion/healthcare/5265790-pharmaceutical-tariffs-national-security/; https://matsui.house.gov/sites/evo-subsites/matsui.house.gov/files/evo-media-document/20250409_letter-to-ustr-and-commerce-on-tariffs-on-essential-medical-supplies.pdf

still retaining profit, they will cease operations in the United States, which will cause a ripple effect on both patient access and innovator resources.[25]

D. Imposing tariffs threatens to draw retaliatory tariffs, which will exacerbate these negative effects

As we observed during the imposition of tariffs earlier this year, other countries are likely to respond to any imposition of pharmaceutical tariffs with retaliatory tariffs of their own. Each such tariff will only exacerbate the negative impacts on American patients, economy, and innovation, as they will make it even harder for pharmaceutical companies to recoup the necessary revenues and ensure patient access. And because foreign countries often also impose price limitations on medicines manufacturers can sell in their jurisdictions, the impact of each new layer of tariffs will rebound on the United States, both as a matter of price and in decreasing the capital available to invest in American manufacturing and development.

By contrast, the prior approach of collaborative trade engagement with foreign countries has proven substantially beneficial. Since 1994, the United States, the European Union, and 10 other nations have been parties to the so-called "Pharma Agreement" under the General Agreements on Tariffs and Trade, which eliminated customs duties on pharmaceutical products. As a result of that agreement, the United States has benefited from medicines from these partner countries in shortage emergencies, including during Hurricane Helene and COVID-19. For the 106 medicines on the US FDA shortage list, 71% (75/106) of shortage mitigation supplies come from outside the U.S. – including from the European industry.[26]

III. The Secretary Should Recommend Non-Tariff Alternatives to Secure America's Supply Chain and Incentivize Reshoring of Pharmaceutical Manufacturing

Fortunately, to the extent the Secretary's investigation results in concerns that the pharmaceutical supply chain is negatively affecting national security, a variety of non-tariff measures can both improve supply chain stability and benefit patients. Specifically, the Secretary should recommend incentives for onshoring and improving domestic manufacturing, as well as benefits and exemptions for pharmaceuticals manufactured within the United States.

Some of these alternative measures could include:

- Selectively increasing payments or reimbursement rates in federal health programs for companies meeting certain criteria of supply chain resilience, trade compliance, or manufacturing investments;

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[25] Cheaper is not always better: Drug shortages in the United States and a value-based solution to alleviate them - PubMed

[26] https://www.medicinesforeurope.com/wp-content/uploads/2025/04/Medicines-for-Europe-Position-Paper-US-Tariffs-7-April-2025-1.pdf

- Easing or accelerating federal regulatory review for domestic onshoring, such as site permitting, environmental reviews, federal construction rules, advanced manufacturing or process changes, or other approvals;
- Extending or expanding cuts to corporate tax rates for companies engaged in onshoring domestic manufacturing, such as lowering the manufacturing corporate tax rate to 15%;
- Incentivizing base chemical manufacturing in the United States to strengthen pharmaceutical manufacturers' access to raw materials to make API;[27]
- Creating regulatory pathways for domestic manufacturing facilities to transition to manufacture critical medicines during periods of shortage or national disaster;
- Ensuring that American domestic policy does not reinforce other countries' lack of rewards for innovation, through the use of harmful tools like price controls, drug importation, or international reference pricing;
- Collaborating with allies who produce materials used in manufacturing API and finished pharmaceuticals to enable domestic onshoring of the latter manufacturing while ensuring a stable supply chain of key materials; or
- Encouraging other countries to allow pharmaceutical companies to bring parity to drug prices globally, to reduce friction with regulatory action, and to engage in mutual recognition agreements with strong good manufacturing practices.

Broadly speaking, because tariffs decrease profitability of overseas operations, they are essentially punitive measures to convince companies to move their operations to domestic locations. But with the intricacies of the pharmaceutical industry—and particularly the uniqueness of the American intellectual property and innovation engine—the same measures operate differently in this industry than others. When profitability is reduced—and the time to onshore operations will take many years and billions of investment—tariffs actually decrease the stability of the supply chain in the interim period. Moreover, they will externalize their negative effects on American patients, who will likely pay higher drug prices, receive fewer groundbreaking new medicines, and lose access to affordable generic medications while the lengthy onshoring process occurs.

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This Administration can promote the important goals of incentivizing American manufacturing and onshoring operations through measures that do not impose these external costs on the American public. Lilly has already demonstrated its commitment to American manufacturing—to the tune of $50 billion in investments—and it stands ready to further assist this Administration in finding better, more effective solutions to concerns identified in the Secretary's investigation.

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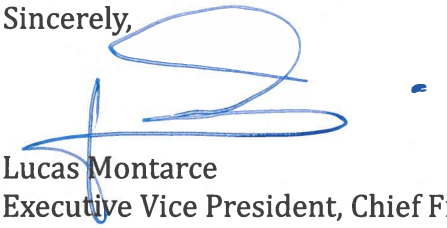
[27] Business Roundtable. Resilient, Diverse and Secure: Improving Critical Supply Chains. July 2024. Page 19. https://www.businessroundtable.org/resilient-diverse-and-secure-improving-critical-supply-chains; Roads, T., Colvill, S., McClellan, M. *Pharmaceutical Tariffs: Potential Impacts and the Need for Vulnerability Assessments. Health Affairs.* March 26, 2025. https://www.healthaffairs.org/content/forefront/pharmaceutical-tariffs-potential-impacts-and-need-vulnerability-assessments

Please feel free to contact me at montarce_lucas@lilly.com directly if you have any questions or need any additional information. Thank you for your attention to this very important matter.

Sincerely,



Lucas Montarce
Executive Vice President, Chief Financial Officer