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Docket No. BIS-2025-0022 / XRIN 0694-XC120

The Honorable Howard Lutnick
Secretary of Commerce
U.S. Department of Commerce
1401 Constitution Ave NW
Washington, D.C. 20230

Attn: Mr. Eric Longnecker
Deputy Assistant Secretary of Technology Security, Bureau of Industry and Security
U.S. Department of Commerce
1401 Constitution Ave NW
Washington, D.C. 20230

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

Dear Secretary Lutnick,

Gilead Sciences, Inc. ("Gilead" or "the Company") respectfully submits these comments in response to the notice of request for public comments on the national security investigation of imports of pharmaceuticals and pharmaceutical ingredients pursuant to section 232 of the Trade Expansion Act of 1962, as amended.[1] The notice invites interested parties to submit comments and/or other information pertinent to the Department of Commerce's ("Department") investigation.

Gilead, headquartered in Foster City, California, is a U.S. biopharmaceutical company that has pursued and achieved breakthroughs in medicine for nearly 40 years. We are committed to advancing innovative medicines and cures to address unmet medical needs in virology, oncology, and other therapeutic areas. Gilead is a leading innovator in the field of HIV, driving advances in treatment, prevention, and cure research. In viral hepatitis, we pioneered cures for

[1] Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, 90 Fed. Reg. 15951 (April 16, 2025).

hepatitis C and have helped transform other viral hepatitis into manageable conditions. During the COVID-19 pandemic, Gilead developed the first approved antiviral medicine for the treatment of COVID-19. Our efforts in oncology are especially focused on metastatic triple negative breast cancer, and through our subsidiary Kite, we are a global leader in cell therapy, treating more patients than any other cell therapy company with our own in-house manufacturing.

We share the Department's objective of protecting U.S. national security through strengthening pharmaceutical supply chains, leadership in biomedical innovation, and investment in transformative biopharmaceutical R&D. Gilead's business model is aligned with U.S. national security interests. Gilead has invested $15 billion in its U.S. R&D and manufacturing operations over the past 10 years. Over the next five years, Gilead's planned and newly committed investments as well as associated economic impact would add $43 billion in value to the U.S. economy. The majority of our U.S. workforce is focused primarily on research and development ("R&D") and manufacturing, and we essentially perform all of our R&D in the U.S. The vast majority of our intellectual property ("IP") is in the U.S., which means that over 80% of Gilead's profits are reported, taxed, and reinvested in the U.S. We have built a resilient supply chain with a group of internal and trusted external partners to ensure continuity of supply for the U.S., with certain products in our portfolio that are made in the U.S. for the U.S. market.

As we explain in Section I below, Gilead's strong U.S. footprint and planned U.S. investments support the Administration's goal of strengthening national security. Gilead's commitment to its U.S. operations and workforce contributes to the nation's economic success, disease prevention and control initiatives, global leadership in biopharmaceutical innovation, and pandemic preparedness. Prior incentives established under the Trump Administration, such as tax reform, have been integral to support Gilead's growth in the U.S. In Section II, we explain that any proposals to raise tariffs would raise the cost of our current operations and planned billion-dollar investments in the U.S. Further, tariffs could disrupt our resilient supply chain network with trusted partners, interrupt medicine supply, potentially leading to drug shortages. In Section III, we submit that the manufacturing supply chain design often begins years before a medicine is approved based on existing policy incentives. Accordingly, we urge the Administration to prioritize the development and implementation of policies that incentivize increased investments in the U.S. as it takes several years and significant resources for the investments to materialize. We expand on the type on incentives, including tax and regulatory incentives, as well as sector-specific trusted trade agreements and expanded market access, that would in turn bolster U.S. investment.

I. Gilead shares the Administration's objective to protect U.S. national security through secure supply chains and is contributing with its strong U.S. footprint and R&D competitiveness.

Gilead has long-maintained significant capital investments in the U.S. This includes investments in both human capital and infrastructure. Today, Gilead employs more than 60% of its workforce in the U.S. President Trump's Tax Cuts and Jobs Act of 2017 (TCJA) significantly bolstered Gilead's U.S. footprint. Since 2017, Gilead has doubled its fulltime U.S. workforce. Nearly 65% of our U.S. workforce is currently engaged in high-value, high-paying R&D and manufacturing roles. We have over 900 full-time employees and contractors attached to our Southern California (La Verne) manufacturing and packaging facility alone.

Over the last decade, we have invested over $15 billion in U.S. projects anchored in construction and operation of nine new large-scale facilities, making deep technology investments in systems and factories, and increasing our commitments to the U.S. workforce. Over the next five years, our investments and associated economic impact would create approximately $43 billion in value to the U.S. economy. Gilead has committed to invest an incremental total of $11 billion in capital and operational investments in the U.S. to augment our planned spend of $21 billion in U.S. manufacturing and R&D through 2030, which is estimated to generate an additional $11 billion in U.S. economic impact. This investment supports the construction of three ground-up facilities and re-engineering and expansion of three existing facilities to bolster our manufacturing and R&D footprint in the U.S. Our total incremental investment of $11 billion includes $4 billion in direct U.S.-focused capital (labs, manufacturing, R&D equipment), $5 billion in increased operational investments (R&D, manufacturing, technology, workforce) and $2 billion in digital and engineering investments related to advancing innovation within our operations. These investments would expand our U.S. R&D and manufacturing footprint to 67% of our global total, and are expected to create 800 new jobs and support over 2,200 indirect jobs by 2028.

Nearly 100% of Gilead's R&D capital infrastructure is located in the U.S. We conduct the vast majority of our R&D activities in the U.S., including R&D related to our most critical and sophisticated products, bringing transformative and curative medicines to U.S. patients. Gilead has developed 12 HIV medications, including the first single-tablet regimen to treat HIV, the first antiretroviral for pre-exposure prophylaxis (PrEP) to help reduce new HIV infections, and the first long-acting injectable HIV treatment medication administered twice-yearly. Further, close to 90% of our capital investments are in the U.S. and over 80% of our real estate footprint is in the U.S. Approximately 97% of our products for the U.S. market involve at least one manufacturing step in the U.S.

Gilead's R&D-intensive U.S. workforce and significant U.S.-based R&D operations bolster U.S. national security. This combination of technical know-how and advanced infrastructure

contributes to the U.S.' ability to drive advancements and innovations in biopharmaceutical technology and enable effective disease prevention and control. As the most labor- and capital-intensive step of the pharmaceutical development process, R&D provides substantial benefits to the U.S. economy and workers, supporting national security. Cutting-edge R&D investments also drive pandemic preparedness and response. For example, in October 2020 Gilead's Veklury® (remdesivir) became the first novel COVID-19 treatment approved by the U.S. Food and Drug Administration. Gilead's prior investment, including decade-long investments in R&D, enabled us to manufacture Veklury quickly, meet real-time demand and also provide 940,000 vials of the drug free of charge to U.S. states and territories as well as various U.S. government agencies at the time. Veklury is the example of the global importance of U.S. innovation. It was invented and developed in the U.S., with its IP, know-how and finished drug product manufacturing in the U.S. for the U.S. market. Creating incentives for companies like Gilead to continue to pursue and achieve breakthroughs in medicine in the U.S. is critical for ensuring that the U.S. maintains its position as a leader in drug discovery and development of innovative medicines.

The vast majority of the Company's IP is registered and held in the U.S. [2] Past policies necessitated companies to hold IP and establish manufacturing operations in lower-tax jurisdictions to be competitive. Incentives included in the TCJA enabled the realignment of Gilead's IP holding structure such that innovative pipeline IP and commercialized IP are predominantly in the U.S. As a result, more than 80% of Gilead's profits are reported, taxed, and reinvested in the U.S. Since 2017, Gilead has completed over $40 billion in mergers and acquisitions in the U.S., continued developing the acquired technologies in the U.S., with all IP remaining in the U.S. Gilead's decision to register and hold most of its IP in the U.S. aligns both with its R&D commitment in the U.S. and U.S. national security interests. The additional tax revenue that the U.S. government receives from companies that maintain IP in the U.S. (like Gilead) enables further U.S. investment in innovation and can be used to bolster national security interests. Creating such incentives will help ensure that Americans have reliable U.S. supply of high-quality and affordable pharmaceutical products.

Our supply chains have proven to be resilient, providing Americans with reliable U.S. supply of our critical medicines, even during the COVID-19 pandemic. Gilead's supply chains for U.S. products are intertwined with a diverse set of partners located in the U.S. and in countries that have strong rule of law, including Canada, the European Union, Korea, and Japan. Our supply chains are optimized to source and process ingredients efficiently, increase volumes as needed, and to allow for redundancies to shift production during unforeseen events. In addition, our diverse supplier base helps ensure that we have adequate supplies to meet U.S. demand, and we are not exposed to the risks associated with being overly reliant on a small number of suppliers.

[2] David Wainer, Wall Street's New Tariff Safe Haven: High-Tax Biotech Stocks, Wall Street Journal (April 27, 2025).

In this way, our supply chains enhance U.S. national security. By leveraging our internal manufacturing and packaging facility in California and working closely with partners primarily based in countries allied with the U.S., the pharmaceutical products and ingredients on which we rely are not susceptible to weaponization (e.g., through export controls) by other countries. This comports closely with the Trump Administration's recognition that cooperation with U.S. allies and security partners can enhance national security and supply chain resilience.[3]

Kite, a Gilead subsidiary and global leader in cell therapy has made significant investments in establishing innovative manufacturing processes and a highly specialized workforce in the U.S., which supplies U.S.-made therapies to the U.S. market, as well as several international markets. CAR T-cell therapy is a custom-made, one-time treatment that re-engineers a patient's own white blood cells and harnesses their immune system to treat certain kinds of blood cancers. This is truly an individualized medicine with curative potential. Kite's manufacturing is state-of-the-art with an end-to-end process and customized for on-demand manufacturing of each patient's individualized product. Kite's supply chains are designed to ensure that they are resilient and capable of providing reliable supply of high-quality products to patients. There are many factors that influence how we structure particular supply chains for specific products, including products that we manufacture in the U.S. For example, for Kite's novel autologous cell therapies, logistics and manufacturing processes are integral to the delivery of these precision therapies to terminally ill cancer patients. These supply chains need to operate under severe time limitations, as the successful manufacturing of these therapies is contingent on the rapid transportation of patients' cells and biologic material to our manufacturing facilities. Therefore, Kite's manufacturing facilities are strategically located in close proximity to U.S. patients to quickly address their medical needs.

In summary, Gilead's business model supports U.S. national security interests. We have responded to the incentives offered by the U.S. government, such as those provided in the TCJA, by making significant investments in both human capital and capital infrastructure in the U.S., which includes both R&D and manufacturing. Based on such incentives, we are already committed to investing substantial resources over the next five years in the U.S. These investments contribute to the U.S. being a global leader in developing biopharmaceutical products, which enhances U.S. national security and contributes to disease prevention, pandemic preparedness and response, and secure supply in the U.S. In addition, having most of our IP registered and held in the U.S. provides tax revenue that can be used to fund policies that incentivize additional investments in the U.S., which advances U.S. national security interests by helping to ensure that Americans have a reliable supply of medicines. Finally, we have built

[3] Assessing and Strengthening the Manufacturing and Defense Industrial Base and Supply Chain Resiliency of the United States, Report to President Donald J. Trump by the Interagency Task Force in Fulfillment of Executive Order 13806 (Sept. 2018), p. 5, available at https://media.defense.gov/2018/oct/05/2002048904/-1/-1/1/assessing-and-strengthening-the-manufacturing-and%20defense-industrial-base-and-supply-chain-resiliency.pdf.

diverse and resilient supply chains that are intertwined with trusted partners located in U.S.-allied nations and are designed to prevent supply chain disruptions.

II. Proposals to raise tariffs will impact Gilead's competitiveness, as more capital is used to cover increased costs, and have knock-on effects on patient access.

While Gilead supports the Administration's objective of increasing pharmaceutical manufacturing capacity in the U.S., we submit that the most effective way to accomplish this is through the development and implementation of policies that make it easier to invest in the U.S. We believe that tariffs, on the other hand, will increase costs, threaten patient access to medicine, and stifle investments in R&D and manufacturing.

The Department has requested comments on "whether additional measures, including tariffs or quotas, are necessary to protect national security[.]" We submit that imposing tariffs will have the opposite effect. Specifically, imposing significant additional tariffs on pharmaceutical products and ingredients will impair national security by increasing costs, creating shortages, jeopardizing patient access to pharmaceutical products, and reducing investment in R&D, which will delay pharmaceutical development. Additionally, when shortages occur, there is increased risk of grey-market and counterfeit suppliers that create further risk to product quality and patient safety.

Establishing a pharmaceutical production facility in the U.S. could take anywhere between 5 to 10 years because of the complexity of manufacturing and the regulatory approvals required. Therefore, imposing broad tariffs will lead to increased costs throughout pharmaceutical supply chains and may lead to supply disruptions. Any decision to impose tariffs should be made thoughtfully on a product-by-product and country-specific basis in ways that support robust supply chains and minimize disruptions to support national security interests.

For example, as described above, the products that we import are sourced from multiple suppliers located in countries that the U.S. counts among its closest and most trusted trading partners. There is ample and diverse supply of these products to meet U.S. demand, with no risk of export restrictions being used to weaponize the supply of these products. Accordingly, based on the criteria set forth in the Federal Register notice, the products we import do not threaten U.S. national security.

If the Department recommends imposing tariffs on pharmaceutical products and/or ingredients, it should be accompanied by a product exclusion process for companies to obtain relief for specific products manufactured in specific countries by trusted partners. Factors to consider in deciding whether to approve an exclusion could include, for example, whether the product and the

materials required to make the product are currently available in the U.S. or overreliance on a single-source or nation, which may threaten U.S. national security interests.

In certain other Section 232 investigations, including under the prior Trump Administration, where the Department found that imports threaten to impair national security, the Administration did not impose tariffs. Instead, the Administration established a working group that it directed to, among other things, examine the state of domestic production of the subject articles and provide policy recommendations and incentives to bolster domestic industry.[4] Further, some prior Section 232 reports have concluded that imports from "reliable foreign sources" would not threaten to impair national security.[5] We would urge the Department and the Administration to adopt a similar approach here by establishing a working group with members of the pharmaceutical industry to identify measures that are likely to be effective in reviving domestic production and certain criteria to work with reliable partners as appropriate, while minimizing, or avoiding entirely, the increased costs and potential shortages that would result from imposing tariffs. In addition, such a working group could be beneficial to unpack the understudied complexity of pharmaceutical supply chains, to elicit best practices.

III. Gilead believes that the Administration's national security objectives could be further strengthened by coordinated tax, trade, and regulatory policy incentives.

Imposing broad and significant tariffs on pharmaceutical ingredients and products will not strengthen U.S. national security and, instead, may very well undermine U.S. national security. We submit that strengthening national security requires creating incentives for companies to invest in the U.S. This should be effectuated through policies that offer favorable tax incentives, reduce unnecessary and/or inefficient regulatory obstacles, and focus on educating U.S. children in math and science, in addition to pursuing bilateral or sectoral agreements with like-minded and trusted trading partners and expanding market access.

President Trump's negotiated trade agreements, including the U.S.-Mexico-Canada Agreement, as well as other plurilateral treaties such as the WTO Pharmaceutical Agreement, have resulted in pharmaceutical tariffs already being reciprocally very low among major economies whose companies Gilead works with. In general, the trusted trade partners we work with have not imposed tariffs on biopharmaceuticals for several decades. Therefore, we particularly support incentive-based non-tariff measures designed to encourage companies to invest in the U.S.

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[4] See, e.g., Memorandum on the Effect of Uranium Imports on the National Security and Establishment of the U.S. Nuclear Fuel Working Group, Presidential Memorandum, July 12, 2019; and Memorandum on the Effect of Titanium Sponge Imports on the National Security, Presidential Memorandum (February 27, 2020).

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

Such incentives include maintaining the corporate tax provisions of the TCJA that continue to incentivize the realignment of IP structures to the U.S. We also advocate for a cohesive national economic policy that harmonizes regulatory overlap, automates reviews, and accelerates permitting processes to avoid lengthy delays in ways that continue to maintain patient safety and environmental standards, while encouraging building in America. The Administration should also consider other tax incentives and benefits for companies that manufacture pharmaceutical products and ingredients and perform R&D in the U.S. (e.g., investment tax credits, reduced tax rate on manufacturing income, accelerated depreciation), in addition to attractive terms to build factories, expand advanced manufacturing capabilities, and federal funding to bolster a STEM workforce in the U.S. Further, the U.S. does not necessarily have the full domestic capacity to develop certain pharmaceutical inputs because of a lack of minable concentrations or commercial viability. Incentives, rather than tariffs, to analyze these gaps would boost supply chain resiliency among trusted trade partners.

We also support the Administration's interest in tariff-free sectoral trade agreements with countries that are aligned with the U.S. on security and rule of law.[6] The bipartisan, bicameral Medical Supply Chain Resiliency Act[7] provides a strong framework to negotiate medical sectoral agreements with our most trusted trade partners as the Trump Administration engages in new trade negotiations and frameworks with certain allies and friendly nations. Negotiating such agreements would help link our medical supply chains through reciprocal market access provisions, alignment of standards and regulations, respect for IP rights, and prohibit export restrictions. While Gilead agrees with the Administration's objective to increase U.S. pharmaceutical and pharmaceutical ingredient production capacity, we submit that global supply chains that involve trusted trading partners based on certain criteria[8] are equally critical to U.S. national security, as this allows for the manufacture of products to shift quickly in response to unforeseen events, thereby mitigating the risk of shortages.

Finally, Gilead supports the Administration's goal to address unfair trade practices and secure mutually advantageous terms. We welcome the Trump Administration's Special 301 Report and the National Trade Estimate Report, which provide a strong roadmap to address foreign IP issues, market access challenges, and tax burdens. We welcome the Administration's position that IP waivers could weaken IP standards and impact the development of new treatments and

[6] The President's 2025 Trade Policy Agenda, Office of the U.S. Trade Representative (March 3, 2025) ("USTR will also identify opportunities for bilaterial or sector-specific plurilateral agreements that might be negotiated to open new market access for U.S. exports … .").
[7] Tillis, Colleagues Introduce Bipartisan Bill to Strengthen Medical Supply Chains, Press Release (March 12, 2025): https://www.tillis.senate.gov/2025/3/tillis-colleagues-introduce-bipartisan-bill-to-strengthen-medical-supply-chains.
[8] Covid-19 Demand Shock and Preparedness Response, Securing Medical Supply Chains: The Trusted Trade Partner Network, Center for Strategic & International Studies (December 21, 2020): https://www.csis.org/analysis/covid-19-demand-shock-and-preparedness-response.

cures[9] and undermine U.S. R&D investments. Securing IP standards similar to U.S. standards along with fair and equitable market access commitments could boost U.S. exports and economic competitiveness, which could in turn provide more resources to deepen U.S. investment. However, we believe that nontariff policy tools tailored to such individual barriers and trading partners can most optimally drive the U.S. trade policy agenda, manage domestic economic impact, and avoid unintended impacts such as higher medicine costs or supply interruptions.

Thank you for considering these comments. Gilead welcomes the opportunity for further engagement with the Department as this investigation progresses. If you have any questions about this submission, please contact the undersigned at (202) 615-9850 or at michael.boyd1@gilead.com.

Respectfully submitted,

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Gilead Sciences

[9] 2025 Special 301 Report, Office of the U.S. Trade Representative (April 29, 2025): https://ustr.gov/about/policy-offices/press-office/press-releases/2025/april/ustr-releases-2025-special-301-report-intellectual-property-protection-and-enforcement.