Genentech
A Member of the Roche Group

May 7, 2025

Via Electronic Submission

Mr. Eric Longnecker
Deputy Assistant Secretary for Technology Security
Bureau of Industry and Security
Department of Commerce
1401 Constitution Ave. NW
Washington, DC 20230

RE: Federal Register docket number BIS-2025-0022 (XRIN 0694-XC120)

Dear Mr. Longnecker,

Please find below Genentech's comments on the Department of Commerce Section 232 national security investigation of imports of pharmaceuticals and pharmaceutical ingredients.

Genentech is a leading biotechnology company dedicated to pursuing groundbreaking science to discover and develop medicines for people with serious and life-threatening illnesses. We are committed to improving patients' lives through new innovations. In the past ten years, we have delivered to patients 19 new medicines that treat diseases like cancer, multiple sclerosis, and hemophilia. In addition to our over 40 approved medicines, we have 70 potential new medicines in clinical or preclinical development, and have been granted 40 FDA Breakthrough Therapy Designations for medicines with the potential to provide substantial improvement over currently available treatments.

In 2009, Genentech was purchased by Roche and is now a wholly-owned subsidiary of the Roche Group. When Roche purchased Genentech, it did something unheard of - it kept all of Genentech's intellectual property in the US and it expanded the U.S. manufacturing footprint instead of moving it overseas. Consequently, Roche and Genentech have substantial manufacturing capacity in the United States and as a corporation we are a significant corporate tax payer. Roche and Genentech already have a significant U.S. presence with more than 25,000 employees, 15 R&D centers, and 13 manufacturing sites. Additionally, last year alone, Roche invested over $15 billion in R&D, over half of which was spent in the U.S. The U.S. is Roche's largest business footprint.

We remain committed to ensuring U.S. biopharmaceutical and medtech manufacturing innovation continues to thrive, and we are making a major investment in our U.S. footprint - $50 billion over five years – in order to deliver on the promise of our strong pipeline for the benefit of American patients and worldwide. Roche and Genentech are very proud to be creating new U.S.

jobs that build on our leadership in manufacturing and R&D innovation. In addition to the 25,000 people we currently employ across several states, over the next five years, we plan to add 1,000 high-paying jobs across R&D and manufacturing. These investments are projected to create more than 12,000 new jobs: 1,000 at Roche and Genentech and more than 11,000 in support of new U.S. manufacturing capabilities.

Genentech understands President Trump's goal of protecting national and economic security. We are aligned that by maintaining a competitive market for pharmaceuticals and addressing specific vulnerabilities in the supply chain, the U.S. can grow its domestic manufacturing capacity and build on existing relationships with allied countries so the U.S. can continue to be the global leader in delivering innovative medicines to patients.

Onshoring of pharmaceutical manufacturing and R&D can and should be accomplished through the Administration working with industry and providing the necessary incentives, rather than by imposing harmful tariffs. Combined, Genentech and other biopharmaceutical manufacturers have pledged to invest more than $150 billion in US manufacturing and R&D this year.[1] These substantial industry commitments to U.S. pharmaceutical R&D and manufacturing serve to support the Administration's goals of ensuring national security, fostering a pro-innovation and pro-manufacturing business environment, improving supply chain resiliency, and avoiding disruption in patient care. In light of the Administration's significant progress on its goals, we urge the Administration to carefully consider the negative and lasting harms to national security and the U.S. pharmaceutical supply chain and potential disruption in patient care of broad tariffs or restrictions.

Robust and resilient supply chains are necessary for national security

Genentech shares the Department's national security goals, including the urgent need to bolster domestic manufacturing to safeguard the U.S. supply of medicines and enable rapid response to defend against biothreats and meet the healthcare needs of the US population. However, making changes to global supply chains takes time, investment, and a rebalancing of current global networks. Geographic diversity of biopharmaceutical supply chains are what enable redundancies and resilience that prevent and mitigate disruptions and help us remain prepared for emergencies. By disturbing these well established and resilient channels, there is a risk of creating a dangerous gap in supply that could make the U.S. more vulnerable as well as impede our industry's ability to develop and deliver breakthrough treatments for patients.

Trade with U.S. allies and security partners allows U.S. patients access to the broadest possible range of treatments and cures, expands access to production inputs for U.S. manufacturers, and enhances national security by mitigating the risk of domestic supply disruptions. The U.S. should be evaluating opportunities to further strengthen supply chains by building on the existing trade relationships with key partners, rather than creating barriers to the free movement of goods. Both Congress and this Administration have recognized that cooperation with U.S.

[1] The White House, "100 Days of Investment" (April 2025), available at https://www.whitehouse.gov/articles/2025/04/100-days-of-investment-5-trillion-in-new-investment-fuels-americas-future/

allies and security partners reduces the risk of supply interruption, allows the U.S. to benefit from shared technological innovations, and prevents strategic competitors from obtaining unfair advantages.[2]

In conducting this investigation, the Department of Commerce should consider actions to incentivize sustainable capacity to produce medicines in the U.S. in partnership with, and not to the exclusion of, allied countries. Tariffs are not the best tool for promoting increased domestic capacity for biopharmaceuticals because they will force companies to redirect resources from research and development, manufacturing and infrastructure. Innovative biopharmaceutical products are not commodities and the complex supply chains and regulatory frameworks required to support innovation necessitate incentives to onshore manufacturing and work constructively with allies, rather than redirection of capital to tariffs.

Supply chain disruption without adequate transition time could harm patient access to medicines

Although Roche and Genentech already have a significant U.S. manufacturing footprint and are expanding domestically, the sophisticated technology and complex manufacturing required to produce biopharmaceutical products means that moving the manufacturing to U.S. facilities will take time. Imposing tariffs while we and other manufacturers are working to onshore new facilities and increase capacity will jeopardize investments, undercutting the Administration's overall aim to bring biopharmaceutical manufacturing to the U.S. Opening a new manufacturing facility can take 3-4 years before it is producing medicines. Transferring technology to existing production sites can take 24-26 months. It is imperative that manufacturers be given adequate time to allow them to scale up production, navigate regulatory requirements, and reduce reliance on foreign sources for the long term.

A careful and strategic assessment of the biopharmaceutical supply chain should also seek to minimize negative impacts of the availability of medications to American patients and to avoid potential shortages of critical medicines. Abrupt changes to the sourcing of medicines or critical supplies could disrupt ongoing treatment. At a minimum, a phased-in timeline to safeguard the continuity of care is imperative to avoid jeopardizing the health of U.S. citizens.

Incentivizing Domestic Production

In addition to our existing 15 R&D centers and 13 manufacturing sites, Roche's $50 billion in potential new investments is planned to expand and upgrade U.S. manufacturing and distribution capabilities for our innovative medicines and diagnostics portfolio in Kentucky, Indiana, Massachusetts, New Jersey, Oregon and California. These facilities and expansions include:

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[2] The White House, "National Strategy for Critical and Emerging Technologies" (Oct. 2020) at p. 3, available at https://trumpwhitehouse.archives.gov/wp-content/uploads/2020/10/National-Strategy-for-CET.pdf
National Security Commission on Emerging Biotechnology, "Charting the Future of Biotechnology: An action plan for American security and prosperity," (April 2025), available at https://www.biotech.senate.gov/wp-content/uploads/2025/04/NSCEB-Full-Report-–-Digital-–4.22.pdf.

- A state-of-the-art gene therapy manufacturing facility in Pennsylvania
- A new 900,000 square foot manufacturing center to support Roche's expanding portfolio of next generation weight loss medicines (location to be announced)
- A new manufacturing facility for continuous glucose monitoring in Indiana
- A new R&D center in Massachusetts, conducting cutting-edge artificial intelligence (AI) research and serving as hub for our new cardiovascular, renal and metabolism research and development efforts
- Significant expansion and upgrading of our existing pharmaceuticals and diagnostics R&D centers in Arizona, Indiana and California

Uncertainty in accessing supplies and materials caused by tariffs will hinder long term biopharmaceutical investments in the U.S. In making manufacturing investments, locations of facilities are highly scrutinized to ensure access to materials, skilled workers, and construction resource availability. Risk based plans for the supply chain and expansion of capacity take years to develop and evolve. The Department of Commerce should consider how to support stability, resilience, and the appropriate incentives to encourage U.S. growth over the long term to protect against unintended vulnerabilities rather than risk relocation of capacity to non-U.S. markets.

Retaliatory measures could compromise investment in U.S. production

Roche and Genentech have significant manufacturing operations in the U.S. and are actively working to become a net exporter of our medicines from the U.S. As we continue to grow, we are already currently serving patients around the world through our U.S. manufacturing capacity. A protectionist response from other nations, however, risks our ability to manufacture medicines in the U.S. for global consumption. Our ability to invest in our U.S. footprint relies not only on being able to serve a U.S. market, but to deliver U.S. made medicines globally. Accordingly, in assessing whether to impose tariffs, the Department of Commerce should consider factors beyond the existence of a trade imbalance. Specifically, to advance its policy goal of on-shoring manufacturing capacity, the Administration should consider that retaliatory measures from countries could threaten the export of biopharmaceuticals, in turn compromising funding for domestic innovation and additional investment to expand U.S. manufacturing capacity. To enhance national security, the Administration should support manufacturers' ability to rapidly deliver U.S. medicines to both U.S. and global patients without being curtailed by multilateral tariff regimes.

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Genentech appreciates the opportunity to provide comments on the 232 investigation into the pharmaceutical industry. To the extent this investigation identifies certain national security vulnerabilities, Genentech welcomes the opportunity to collaborate and provide input into how the Department of Commerce might mitigate these concerns while continuing to support a growing biopharmaceutical industry.