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

Re: ***Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (XRIN 0694–XC120):*** Written Comments of Amgen Inc.

Dear Mr. Longnecker:

Amgen Inc. ("Amgen") appreciates the opportunity to submit comments to the United States Department of Commerce ("Department") regarding the Department's Section 232 National Security investigation of imports of pharmaceuticals and pharmaceutical ingredients.

Amgen is a United States-based biotechnology company founded in 1980 and headquartered in Thousand Oaks, California. We proudly conduct domestic research and development ("R&D"), manufacturing, and commercial operations in California, Florida, Illinois, Kentucky, Maryland, Massachusetts, North Carolina, Ohio, Puerto Rico, and Rhode Island. Amgen employs tens of thousands of skilled American workers across our sites and since 2018, we have increased U.S. workforce by 36%, with manufacturing and operations comprising 47% of our U.S. employee growth.

Over more than four decades, Amgen has pioneered discovery, development, and manufacturing of breakthrough medicines for grievous and other serious illness, including innovative medicines to treat cancers, cardiovascular disease, bone disorders, inflammatory, and rare diseases. We are also one of the largest manufacturers of biosimilars, which provide additional treatment options for patients.

Since our founding, Amgen has heavily invested in R&D and manufacturing in the United States. With the passage of the 2017 Tax Cuts and Jobs Act ("TCJA"), Amgen further increased direct investments in the United States, including significant resources and funds towards U.S.-based capital investment and R&D, innovation-based acquisitions, early-stage U.S biotechnology companies, and community-based philanthropy.

We currently operate six U.S.-based manufacturing facilities locate in Thousand Oaks, California; Louisville, Kentucky; Holly Springs, North Carolina; New Albany, Ohio; Juncos, Puerto Rico; and West Greenwich, Rhode Island. The majority of our medicines are produced here in the United States, and we continue to make significant investments to expand and enhance our domestic manufacturing.

Prior to (and independent of) the recently announced Section 232 investigation, Amgen increased its U.S. investments, including expending approximately $5 billion in capital since the implementation of the TCJA through 2024 to expand its domestic manufacturing operations. In February 2024, Amgen opened a state-of-the-art biomanufacturing site in Central Ohio, designed to assemble, label, and package auto-injectors, syringes, and vials for Amgen's medicines. A further $900 million expansion of our Ohio biomanufacturing facility was announced in April 2025. Our commitment to biomanufacturing in Central Ohio creates the opportunity for over 700 jobs with an overall investment of over $1.4 billion. In addition, Amgen announced in 2022 and subsequently in 2024, two new multi-product biomanufacturing facilities in Holly Springs, North Carolina, resulting in nearly $1.7 billion in announced investment creating the opportunity for over 700 high quality jobs in North Carolina.

Amgen shares in the Trump Administration's goals to strengthen the resiliency and security of America's pharmaceutical supply chain. In response to the Department's request, Amgen offers this submission informed by Amgen's role as one of America's largest biotechnology companies committed to innovation and patient care. Strengthening domestic manufacturing will require significant time and investment due to its complexity and interdependencies on the global supply chain. Accordingly, Amgen respectfully urges that any Section 232 trade measures be calibrated to focus on national security risks posed by countries of concern and supply chain continuity while avoiding unintended harm to patients and the very domestic manufacturing capacity the Government seeks to enhance. As detailed further below, Amgen believes that the Department's national security-related goals can be advanced by exempting essential pharmaceutical products from tariffs along with robust mechanisms to exclude essential drugs, inputs, and devices (especially those from trusted allies) from any import restrictions.

1. Current and Projected Demand for Pharmaceuticals and Pharmaceutical Ingredients in the United States

The United States demand for pharmaceuticals is growing at a rapid pace driven by demographics, a rise in chronic conditions, and advancements in therapies. Ensuring this demand is met safely and reliably is a matter of both public health and national security.

2. Extent to which Domestic Production of Pharmaceuticals and Pharmaceutical Ingredients Can Meet Domestic Demand

Amgen strongly believes in the importance of domestic pharmaceutical manufacturing. As described above, Amgen has invested significantly in domestic production and has a strong United States pharmaceutical manufacturing base in innovative and biosimilar therapies. Overall, Amgen contributes substantially to increased domestic medicine supplies by performing most of its manufacturing in the United States and its territories, ensuring that critical medicines for serious illnesses are made under U.S. oversight and quality control.

For example, Amgen's Rhode Island campus, acquired in 2002 and expanded with a $160 million next-generation biomanufacturing plant in 2018, produces biologic medicines for the U.S. and global markets. The capacity at this site has increased 150% since 2018. Our Puerto Rico site is instrumental in reliably supplying Amgen medicines worldwide and has grown over 30 years into one of the world's largest biotechnology manufacturing facilities, expanding from 30 employees and a single building to approximately 2,400 employees and over 20 buildings today. We also recently opened our new $474 million, 300,000 square foot advanced final product assembly and packaging facility in New Albany, Ohio, currently employing approximately 400 full-time staff to prepare medicines (e.g., assembly of autoinjector devices, labelling, and packing) for distribution. Amgen also recently inaugurated a 500,000 square foot state-of-the-art biologics drug substance manufacturing facility in Holly Springs, North Carolina, and broke ground on a second adjacent plant as part of a combined $1.7 billion investment expected to employ over 700 people. We also maintain a packaging and distribution center in Louisville, Kentucky, supporting efficient delivery of medicines across the country. These facilities are all in addition to our headquarters in Thousand Oaks, California, which provides extensive biologics manufacturing and process development capabilities that help accelerate Amgen's pipeline, including a 240,000 square foot facility supporting discovery research and a 50,000 square foot expansion supporting small molecule therapeutic discovery.

Although these investments are a testament to Amgen's commitment to reliable, domestic supply for lifesaving medicines, near-term domestic manufacturing alone

cannot fully satisfy U.S. demand for all medicines and ingredients. These domestic manufacturing facilities require imports of precision foreign capital equipment, active pharmaceutical ingredients, starting materials, and excipients to produce drug substances domestically. In addition, imports of delivery devices and related components such as syringes, autoinjectors, and on-body injectors are necessary for delivery and administration of essential pharmaceuticals. Accordingly, the Company notes that a careful evaluation of any new tariffs is warranted to avoid inadvertently impacting patient access and penalizing domestic manufacturing and expansion goals.

Amgen respectfully submits that the goal should be to expand U.S. production capacity in critical areas while avoiding inadvertent sudden disruption of imports essential to ongoing U.S. manufacturing that would outpace that which domestic manufacturing can absorb. For example, although Amgen manufactures a significant portion of our drug substance here in the United States from raw materials and other ingredients sourced domestically and abroad, we also rely on manufacturing facilities located both in the United States and with trusted trading partners abroad who may provide further processing or quality operations before we are able to supply product to U.S. consumers.

As detailed in Section 8, although Amgen is investing in new U.S. plants that will enhance Amgen's domestic manufacturing capabilities, these projects are complex and are challenging to complete (e.g., significant capital investments, procurement of imported materials, equipment and drug manufacturing inputs) with multi-year timelines (e.g., construction and regulatory review and approvals). Until such time that the U.S. has fully developed capabilities to supply key pharmaceutical ingredients and starting materials as well as manufacturing capacity that meets the domestic demands for pharmaceutical products, it is critical to maintain strategic imports and manufacturing operations from trusted trading partners abroad to ensure patients get the medicines they need without interruption.

3. Role of Foreign Supply Chains, Particularly of Major Exporters, in Meeting United States Demand for Pharmaceuticals and Pharmaceutical Ingredients

Amgen is proud of its domestic manufacturing operations (which are a critical component of Amgen's corporate strategy) but also recognizes that global supply chains play an integrated role in meeting U.S. pharmaceutical demand. The biotechnology industry has developed a complex, globalized network with many finished pharmaceuticals consumed in the U.S. developed and manufactured domestically using active ingredients or raw materials imported from abroad.

Each Amgen medicine relies on a supply chain of components (including drug substance and active pharmaceutical ingredients, chemical starting materials, specialized biologic growth media, and drug delivery devices) and we will continue to require a mix of domestic production and imports to source these inputs at the scale needed. Resilient, diversified, and secure import sources (especially of inputs not made domestically) and supply chains are necessary for the pharmaceutical industry even as we work to boost domestic manufacturing. Geographic diversification of supply chains is critical to our supply strategy and supports patients' access to essential medicines as well as enables us to navigate supply demand variabilities. Abruptly curtailing import supply without ready alternatives would risk creating shortages given the scale of U.S. patient need for such medicines.

As discussed in Section 7 below, where supply is currently concentrated in a country of concern, U.S. policy can be a critical enabler for the U.S. pharmaceutical industry by supporting diversification of import sources from American allies or incentivizing domestic capacity for backup. In short, the global supply chains remain an important part of a healthy and diversified supply chain that ensures a consistent domestic supply of finished pharmaceuticals, pharmaceutical ingredients, and medical devices.

4. Concentration of United States Imports of Pharmaceuticals and Pharmaceutical Ingredients from a Small Number of Suppliers and the Associated Risks

Please see response in Section 3.

5. Impact of Foreign Government Subsidies and Predatory Trade Practices on United States Pharmaceuticals Industry Competitiveness

Certain countries have provided subsidies, tax incentives, and other support to their own domestic manufacturing. Even facing such headwinds, Amgen remains globally competitive. The enactment of the Tax Cuts and Jobs Act ("TCJA") in 2017 significantly leveled the playing field between the United States and foreign jurisdictions, enabling Amgen and our biopharmaceutical peer companies to invest in U.S. manufacturing. As noted above, Amgen has invested almost $5 billion in direct capital expenditures in the United States since 2018. This includes significant new investments in U.S. manufacturing in Ohio and North Carolina.

Amgen firmly supports the extension of the tax rates and policies in the TCJA. Extending the TCJA will help ensure that the U.S. remains a competitive location in which to invest in manufacturing capabilities and capacity in the biopharmaceutical industry. The TCJA is an important policy to promote domestic manufacturing, incentivize onshoring

of domestic manufacturing, foster growth, and mitigate against national security risk. An assessment under Section 232 of opportunities to adopt additional U.S. policies that promote domestic manufacturing may help incentivize onshoring of domestic manufacturing, foster growth, and mitigate against national security risk.

6. Economic Impact of Artificially Suppressed Prices of Pharmaceuticals and Pharmaceutical Ingredients Due to Foreign Unfair Trade Practices and State-Sponsored Overproduction

In addition to the response in Section 5 above, we note that many foreign countries undervalue American innovation through a variety of policies that reduce the financial return to American innovators and serve to undermine the value of American intellectual property. We urge the Government to use this investigation to understand more fully the impact that the use of price controls and weak intellectual property protection by foreign governments have on the ability of U.S. companies to continue to lead the world in the development of new medicines. Examples of some of the challenges U.S. firms face overseas can be found in the 2025 National Trade Estimate of Foreign Trade Barriers ("NTE") at ustr.gov and in the comments submitted by the Pharmaceutical Research and Manufacturers of America ("PhRMA") for both the 2025 NTE and the 2025 Special 301 Trade Report at phrma.org. Fairer treatment by foreign governments would directly support national security by providing additional resources to invest in the United States and support additional American innovation.

7. Potential for Export Restrictions by Foreign Nations, Including the Ability of Foreign Nations to Weaponize Their Control Over Pharmaceuticals Supplies

Amgen appreciates the concern that certain countries of concern may restrict exports to control supply chain. Amgen respectfully encourages the Department to consider focusing its investigation on countries of concern, rather than on imports of pharmaceuticals, active pharmaceutical ingredients, other derivative materials, and drug delivery devices and related components from reliable trading partners. A broad application of tariffs to safeguard against foreign nations' ability to increase tariffs on key components of pharmaceutical products may impact patient access and pricing of products critical to treating serious illness and serving U.S. patients. A more targeted investigation into pharmaceutical imports from countries of concern could mitigate against potential cost increases and supply chain constraints that may negatively impact U.S. patients.

Amgen, as a United States-based biotechnology company exports finished pharmaceuticals and drug substances to many of these reliable trading partners in addition to importing raw materials, active pharmaceutical ingredients, and medical devices from these countries. These trading partners are integral to the

pharmaceutical supply chain. Therefore, to maintain U.S. competitive advantage and supply continuity, we must maintain our engagement with such partners while taking appropriate measures (e.g., stockpiling, and redundant sourcing) to mitigate against ability of foreign nations to control pharmaceutical supplies.

8. Feasibility of Increasing Domestic Capacity for Pharmaceuticals and Pharmaceutical Ingredients to Reduce Import Reliance

Amgen's expansive and sophisticated domestic manufacturing network demonstrates that it is feasible to increase and strengthen America's pharmaceutical manufacturing base. But increasing domestic capacity for pharmaceuticals requires significant time, investments, and involves operational and regulatory complexities. Additionally, certain materials, ingredients, and components other than finished pharmaceuticals may be more difficult to source domestically. For example, devices such as syringes, autoinjectors, and on-body injectors will take significant time to transition to domestic manufacturers, build facilities, and receive approval by U.S. regulators.

Below please find examples of the complexities and hurdles to expanding domestic capacity for pharmaceutical manufacturing.

- **Significant Capital Investment:** Building state-of-the-art pharmaceutical manufacturing sites require significant investments and a stable, predictable environment as well as the opportunity to recoup such investments. Sudden tariff impositions or market instability may impact investment decisions. A supportive ecosystem, including extension of the TCJA, will improve feasibility of increased domestic manufacturing.
- **Significant Lead Time and Regulatory Process:** Constructing a new pharmaceutical manufacturing facility is a multi-year endeavor. This timeline includes design, construction, equipment installation, validation, and regulatory approvals and qualification of the site for production. Even after construction, facilities must be validated and approved by the FDA for each product. For example, our Ohio facility (for assembly/packaging) took over two years from groundbreaking to FDA operational approval, which is considered rapid. Our North Carolina drug substance plant similarly was announced in mid-2021, and the first phase opened in early 2025, nearly three and a half years from announcement to operation. Transitioning from a foreign manufacturer to U.S. manufacturing also requires additional regulatory steps. Thus, increasing domestic manufacturing capacity is time-intensive and policies should account for this inherent lag.
- **Supply of Inputs:** Manufacturing pharmaceuticals requires raw materials, reagents, equipment, and packaging procured from multiple suppliers. Some of these inputs currently have limited or no U.S. production (for instance, certain drug starting

materials or specialized production equipment). Increasing domestic manufacturing does not necessarily eliminate all import needs.

Increasing domestic capacity requires partnership and sustained commitment from both industry and government to reshape the manufacturing base over the coming decade. Abrupt measures that outpace increases in domestic pharmaceutical manufacturing capacity can significantly impact patient access for essential treatments. Accordingly, Amgen suggests that a trade policy aligned with U.S. national security interests should (i) incentivize and facilitate domestic manufacturing growth (e.g., extension of the TCJA, tax credits, grants, public-private partnerships, regulatory flexibility to accelerate facility deployments without compromising quality), while (ii) exempting tariffs for critical imports to maintain access to supply in the interim.

9. Impact of Current Trade Policies on Domestic Production of Pharmaceuticals and Pharmaceutical Ingredients, and Whether Additional Measures, Including Tariffs or Quotas, Are Necessary to Protect National Security

Amgen strives to secure a resilient supply chain through redundancy and geographic diversification as well as robust business continuity plans. In addition, Amgen has increased its investment in the U.S. irrespective of trade policies and respectfully encourages the Department to focus its investigation on imports from countries of concern. To the extent imports are necessary, Amgen primarily sources them from trusted trade partners.

Current U.S. trade policy for pharmaceuticals has generally favored access, recognizing that patients benefit from an uninterrupted supply of medicine across borders. Notably, many pharmaceuticals are exempted from tariffs under the World Trade Organization Pharmaceutical Agreement among major nations, recognizing the importance of patient access to pharmaceutical therapeutics. Imposing new broad tariffs or quotas under Section 232 would mark a significant departure from established policies and may have an inadvertent impact on U.S. patients and healthcare. Furthermore, any tariffs against trusted trade partners may disrupt our cooperative efforts to secure supply chains.

A. Focus on Countries of Concern vs. Broad Tariffs

As discussed in Section 7 above, Amgen recommends that if the investigation finds national security risks, the response should be targeted toward countries of concern or specific problem areas, rather than blanket measures affecting all imports. A "one-size-fits-all" tariff on every imported pharmaceutical or ingredient, regardless of source, would punish domestic production as well as the U.S. allies that are reliable contributors to our essential pharmaceuticals.

B. Targeted Exemptions and Carve-Outs

If any import measures are deemed necessary, we urge the Department to include exemptions and carve-outs for critical categories. This would align with the principle of "do no harm" to patients. For example, critical inputs, starting materials, and chemical precursors used in manufacture of Drug Substance (DS) and Active Pharmaceutical Ingredients (APIs) can be exempted because these materials are not currently produced in sufficient volumes domestically. Imposing tariffs on critical drug ingredients that U.S. manufacturers must import to produce pharmaceuticals would raise manufacturing costs and potentially curtail manufacturing domestically, impact patient access, and undermine supply security. Until domestic production of starting materials and chemical precursors are established and scaled, imports should remain tariff-free to encourage U.S. drug production. The Department may consider tariff exemptions for critical inputs used in domestic manufacturing of DS or API that is similar to the exemption from reciprocal tariffs for Canada and Mexico for parts and components which will be substantially finished in the United States.

C. Leveraging Section 484(f) to Refine Biologics-Related HTS Categories for Security and Innovation

Currently, many biologic and small molecule pharmaceuticals and components are grouped in broad Harmonized Tariff Schedule (HTS) headings. Additionally, drug delivery devices, raw materials, inputs, and intermediates critical to pharmaceutical manufacturing, delivery and administration are scattered across various chapters of the HTS. To strengthen the Section 232 exemption framework, we recommend the Department coordinate use of *Section 484(f) of the Tariff Act of 1930* – via the Committee for the Statistical Annotation of Tariff Schedules – to create new HTS subcategories focused on biologic and small molecules pharmaceuticals and their components and inputs used in domestic manufacturing.

Specifically, through the Section 484(f) process, the Department may consider adding granular 10-digit statistical breakouts which would enable application of specific tariff exemptions for certain biologics, small molecules, devices, and related manufacturing materials and inputs. Such refinements will advance national security goals through targeted trade measures and exclusions as well as support U.S. patient access and investments in domestic manufacturing.

D. Incentivize Reshoring

As discussed in Section 5 above, the TCJA has had a significant favorable impact on Amgen's ability to invest in U.S. manufacturing; an extension of the TCJA is critical to

ensuring that the U.S. remains a competitive jurisdiction in which to continue to invest. The Department may also consider the beneficial impact of incentives and similar measures to encourage companies to produce key drugs and ingredients in the U.S.

10. Amgen's Commitment to United States Biotechnology Supply Chain Security

Amgen appreciates the Department's consideration of these complex issues. Amgen is proud to be a leading U.S. biotechnology manufacturer that contributes directly to U.S. national security through our domestic R&D, manufacturing, and commercial operations. National security in health care means having dependable, diversified sources for critical essential medicines. We are committed to working with the Administration to achieve this goal. However, we urge the Department to craft solutions to avoid unintentional disruption of the complex supply networks that currently supply essential medicines to American patients.

Thank you for the opportunity to provide input. Please do not hesitate to contact the undersigned should you have any questions regarding this submission or require any further information that may assist the Department with its investigation.

Sincerely,

Lisa Gruber
Vice President, Tax