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Via Electronic Submission

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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: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Vertex Pharmaceuticals Incorporated ("Vertex") hereby submits the following comments in response to the Department of Commerce request for input on the Section 232 national security investigation on imports of pharmaceuticals and pharmaceutical ingredients. Vertex appreciates the administration's commitment to promoting increased American manufacturing, securing U.S. supply chains, addressing predatory and unfair foreign trade practices, and strengthening the nation's biopharmaceutical industrial base. Protecting American biopharmaceutical supply chains is a national security imperative.

Vertex is a proud United States based and headquartered biopharmaceutical company with a global footprint that has a proven record of investment in American research and development to create transformative medicines for people with serious, life-threatening diseases.

Vertex has multiple approved medicines that treat the underlying cause of cystic fibrosis ("CF") – a rare, life-threatening genetic disease – and has several ongoing clinical and research programs in CF. In the last two years, Vertex received approval from the Food and Drug Administration ("FDA") for its CRISPR/Cas9 genome-edited cell therapies CASGEVY®, which treats both sickle cell disease and transfusion dependent beta thalassemia and JOURNAVX®, a new class of non-opioid medicine approved to treat moderate to severe acute pain without addiction potential. Vertex also has a robust pipeline of investigational medicines in other serious diseases including APOL1-mediated kidney diseases and IgA nephropathy (IgAN). In addition, Vertex's pipeline of cell and genetic therapies includes treatments for type 1 diabetes.

Vertex is committed to the United States. In the last two years alone, we have made over $600 million in capital expenditures in U.S. research and manufacturing, including cutting-

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edge small molecule medicine manufacturing and state of the art research and testing for cell and genetic therapies. These capital investments represent only a fraction of our overall investment in the United States, as we invest over $2 billion annually on research and development, the vast majority of that in the United States. We have plans to continue U.S. expansion – but our efforts can only materialize with strategic trade and investment policies that help, not hinder, biopharmaceutical supply chain interests.

Today, over 82% of our 6,100 global employees are based in the United States. Further, all intellectual property (IP) that supports our U.S. business, along with much of our global IP, is developed and economically owned in the United States. With most of our drug product manufactured in the United States, Vertex is a net exporter, with exports in 2024 more than double the value of our imports. Our U.S.-based manufacturing capabilities directly support the President's broader agenda to reduce the trade deficit and reindustrialize America. It is with this backdrop that we propose the following policies to help ensure President Trump's vision for putting *America First* is achieved:

Preserve U.S. Manufacturing Strength While Avoiding Unintended Harm to American Innovators

While we support targeted actions to address unfair trade practices, we urge the administration to carefully calibrate any tariffs under Section 232 to avoid unintentionally penalizing American pharmaceutical companies that are creating high-quality U.S. jobs, advancing innovation, and building resilient domestic supply chains. Broad tariffs on pharmaceutical ingredients may have the unintended effect of undermining U.S. exporters, increasing costs for American manufacturers, and even incentivizing offshoring—all of which would run counter to the national interest. Retaliatory tariffs or reduced purchases from trading partners would disproportionately harm U.S. companies like Vertex, potentially worsening the U.S. trade deficit and threatening American jobs.

For Vertex, the value of imported inputs accounts for less than 4% of total U.S. drug product sales. While 4% seems low – these inputs are essential and come from a diversified, trusted group of trading partners. These key ingredients are not viably made in the United States, and are incorporated into final U.S.-made products, which keep the high-quality jobs and manufacturing in the United States on an upward trajectory.

Support for Targeted Tariff Relief to Safeguard U.S. Innovation and Jobs

Should the Administration proceed with Section 232 tariffs, we respectfully request the following programs be maintained:

- **Import adjustment offset amount** – Pharmaceuticals which undergo drug product manufacturing in the United States should be eligible to receive an import adjustment offset amount applicable to section 232 duties on imported

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raw materials and ingredients required for U.S. manufacturing for which there is no U.S. supply.

- **Duty Drawback Programs** – Allowing recovery of tariffs on ingredients used in domestic manufacturing when the finished products are subsequently exported. This policy supports U.S. manufacturing and enhances our global competitiveness.

- **Provide tariff waiver or credit for the import of pharmaceutical manufacturing and R&D capital equipment not available in the United States** – For biopharmaceutical companies such as Vertex to continue its presence and growth in U.S. based facilities, purchasing and import of equipment must be done efficiently and at a cost point that enables rapid expansion.

Protecting American Innovation: Enforcing IP Rights

Vertex applauds the Trump Administration's focus on intellectual property (IP) protection as a critical pillar of U.S. industrial policy. As a global leader in biotechnology, Vertex relies on the strength and enforceability of U.S. IP laws to sustain investment in lifesaving innovation. We urge the Trump Administration to use this investigation to focus efforts on enforcement actions on those who have long flouted global IP norms – particularly countries on the USTR Priority Watch List – that engage in theft of U.S. intellectual property or fail to provide adequate protections.

In particular, we draw the Trump's Administration's attention to Argentina, which continues to appear on the Priority Watch List due to longstanding failures to provide timely patent examination, failure to issue pharmaceutical patents, inadequate patent enforcement, limits on subject matter eligible for patenting which is out of step with the rest of the world, and a lack of regulatory transparency. Argentina's weak IP regime poses a direct threat to American pharmaceutical innovation and undermines the integrity of the global trade system. Argentina's lack of action has allowed companies within their borders to begin manufacturing copy product not respecting the rule of law and not providing timely patent examination and issuance. With these Argentine companies freely being able to export their copy product to third-party markets, the long-term viability of our American innovation is being destroyed by the actions of the Argentine patent office.

We support decisive U.S. action to address these deficiencies through trade enforcement. Intellectual property reforms, and diplomatic pressure, including potential tariff penalties, where appropriate.

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Conclusion

Vertex stands ready to work with the administration to advance policies that restore the global integrity of U.S. intellectual property and drive American manufacturing growth. Therefore, we urge the Department of Commerce to use this investigation to recommend a strategic, targeted approach that holds those who threaten biomedical innovation accountable, while preserving the competitiveness of American innovators like Vertex. We look forward to working with you as you craft trade policy which ends unfair practices and supports the delivery of novel medical breakthroughs to patients in the U.S. and around the globe.

Amit Sachdev
Executive Vice-President, Chief Patient and External Affairs Officer