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Hon. Howard W. Lutnick
Secretary of Commerce
U.S. Department of Commerce
1401 Constitution Avenue NW
Washington, DC 20230

RE: Comments on Section 232 Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (Docket XRIN 0694-XC120)

Dear Secretary Lutnick,

UCB S.A. ("UCB") respectfully submits these comments to the Department of Commerce ("Commerce") and Bureau of Industry and Security ("BIS") in response to the request for public comments on the national security investigation of imports of Pharmaceuticals and Pharmaceutical Ingredients under Section 232 of the Trade Expansion Act of 1962, as amended ("Section 232").[1] UCB is a global biopharmaceutical company with over a 90-year history of developing innovative treatments for severe diseases in neurology, immunology, and rare disorders. It serves U.S. patients with specialized medical needs and maintains a significant presence in the United States, including substantial investments in domestic research and development ("R&D"), clinical infrastructure, and patient support programs. As a long-standing contributor to the U.S. pharmaceutical industry, UCB enhances U.S. supply chain resilience and biopharmaceutical innovation.

UCB supports Commerce's goal to increase domestic production of and strengthen U.S. competitiveness in the pharmaceutical and pharmaceutical ingredients sectors. However, UCB believes that applying Section 232 measures to ally-sourced pharmaceutical imports to enhance U.S. supply chain resilience would not help Commerce achieve the President's objectives to safeguard U.S. national security. As explained further below, UCB's imports do not present a national security risk because they originate from trusted allies that do not engage in unfair trade practices and do not displace or impair U.S. production. In fact, UCB has actively contributed to strengthening the resilience of the U.S. healthcare system through domestic investment and initiatives to enhance supply chain stability. Moreover, applying Section 232 measures to UCB's imports would undermine U.S. national security goals by disrupting patient access to critical therapies, weakening allied supply chains, destabilizing specialized pharmaceutical manufacturing, discouraging domestic investment and research collaboration, and increasing

[1] *Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients*, 90 Fed. Reg. 15,951 (Apr. 16, 2025) (Docket No.BIS-2025-0022; XRIN 0694–XC120) ("April 16 Notice").

costs that erode the global competitiveness of the U.S. pharmaceutical industry. Accordingly, UCB respectfully requests Commerce to:

(1) determine that pharmaceutical and pharmaceutical ingredient imports should not be subject to Section 232 measures;

(2) should Commerce determine that a broader exemption these imports is not feasible, exclude UCB's imports under the HTSUS codes 2853909090, 2921495000, 2924296250, 2933798500, 3002140010, 3002150011, 3002150091, 3004909236, 3004909240, 3004909291, 3907290000, and 9023000000 from the scope of the Section 232 investigation of pharmaceuticals and pharmaceutical ingredients, and

(3) if exclusion from the investigation is not feasible, recommend to the President that no Section 232 measure should be applied to these imports.

I. Company Overview

UCB is a global biopharmaceutical company headquartered in Brussels, Belgium, with over a 90-year history of developing innovative treatments for serious diseases in neurology, immunology, and rare disorders. In the United States, UCB has established a substantial and growing footprint through its U.S.-incorporated affiliate, UCB, Inc., headquartered in Atlanta, Georgia. UCB contributes to U.S. innovation and biopharmaceutical research and development ("R&D") through its early-stage research and discovery facilities in Boston, Massachusetts, Seattle, Washington, and Durham, North Carolina, and a clinical development hub in Raleigh, North Carolina. It also operates a dedicated public affairs office in Washington, D.C., actively engaging with federal policy and regulatory stakeholders, as well as an administrative office in Emeryville, California. UCB employs over 1,950 U.S. workers across these locations and directly contributes to the human resource base of the U.S. pharmaceutical sector. In addition, UCB creates U.S. jobs through **[**
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UCB's U.S. operations make a significant contribution to the domestic economy. In 2024, UCB generated an economic impact of over **[** **]** through our investment in innovation and manufacturing, discounts on medicines provided to U.S. healthcare stakeholders, and the introduction of new therapies. UCB expects to **[**
], following our **[** **]** FDA approvals for new and innovative medicines in the past two years.

UCB's pharmaceutical portfolio consists of specialized therapies for conditions with significant unmet medical needs. These include:

- leading treatments for epilepsy and other neurological disorders (covered under HTSUS **[** **]**);

- biological treatments for severe autoimmune and inflammatory conditions (including gastrointestinal disorders, dermatological disorders, and bone/metabolic disorders) (covered under HTSUS **[ ]**);

- therapies for rare diseases affecting small patient populations including pediatric patients (covered under HTSUS **[ ]**); and

- other products addressing conditions with limited or no alternative treatment options (covered under multiple HTSUS codes).

UCB operates in 36 countries around the world and maintains three manufacturing facilities, one each in Belgium, Switzerland, and Japan, all of which are longstanding U.S. allies with established regulatory systems and robust defense partnerships. UCB also manufactures its medicines through CMOs located in the United States and its allied countries (e.g., France, Germany, Italy, South Korea, and the United Kingdom ("U.K.")). In addition to **[ ]**. In contrast, UCB's manufacturing operations in China and India are limited. Final medicines and ingredients produced in these countries or those made using ingredients sourced from these countries are not imported into the United States.[2] In November 2024, UCB completed the divestiture of its manufacturing facility in China.

UCB is committed to upholding the highest standards of quality and regulatory compliance. All products are manufactured in accordance with the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA") requirements. UCB has consistently met all regulatory requirements and have successfully addressed all observations from inspections by regulatory authorities to maintain continued compliance and uninterrupted supply. UCB conducts regular audits of internal facilities and external manufacturing partners (i.e., CMOs) to ensure that they adhere to the high quality and compliance standards. All sites operate under a centralized Quality Management System. This system includes oversight of Contract Development and Manufacturing Organizations ("CDMOs"), which implements rigorous quality control and assurance practices throughout the manufacturing process. In addition, UCB fosters a strong data culture and continuously enhances its Quality Management System by integrating new digital capabilities, enhancing data quality, and strengthening reporting and decision-making processes.

[2] UCB sourced a marginal volume of its U.S. imports from China in 2024 (i.e., **[ ]** percent of its total U.S. imports). These were used exclusively for R&D activities and were not used for manufacturing pharmaceuticals or pharmaceutical ingredients.

II. UCB's Imports Do Not Impair or Threaten to Impair U.S. National Security

A. UCB's Strategic Supply Chain Minimizes National Security Risk Through Allied Sourcing and Geographical Diversification

While Commerce does not explicitly identify specific countries in the April 16 Notice, multiple U.S. government analyses have identified China and India as presenting sourcing and strategic concentration risks to pharmaceutical supply chain resilience. For example, the Department of Defense ("DoD") has categorized China as a "Very High Risk" source and India as a "High Risk" source for pharmaceutical inputs, noting that military healthcare systems face substantial supply chain vulnerabilities from this concentration.[3] In addition, a 2025 Department of Health and Human Services ("HHS") draft research plan documented that 48 percent of Active Pharmaceutical Ingredients ("API") Drug Master Files submitted to FDA in 2021 originated from Indian manufacturers, with an additional 13 percent from Chinese manufacturers, may create regulatory transparency challenges and structural vulnerabilities.[4] The 2025 Special 301 Report by the Office of the United States Trade Representative ("USTR") similarly highlighted the regulatory concerns regarding the counterfeit pharmaceuticals originating from countries including China and India.[5] These risks form the foundational concerns of the Section 232 investigation. Lastly, while focused on one aspect of upstream pharmaceutical research (i.e., gain-of-function biological research), the May 5 Executive Order, *Improving the Safety and Security of Biological Research*, underscores that inadequate oversight of such research can pose a threat to national security. The Order also identifies China as one of the "countries in concern" in this regard.[6]

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[3] *See* Off. of the Under Sec'y of Def. for Acquisition & Sustainment, *Report on the Department of Defense Pharmaceutical Supply Chain Risks* (Nov. 2023).

[4] *See* U.S. Dep't of Health & Hum. Servs., *Draft Research Plan for Addressing Shortages of Medical Products and Strengthening the Resilience of Medical Product and Critical Food Supply Chains: An Annex to the HHS Draft Action Plan* (Jan. 16, 2025) at 21.

See also Nick Iacovella and Jon Toomey, *Foreign Government Subsidies and FDA Regulatory Failures Are Causing Drug Shortages in the United States: Here's How to Fix It*, American Affairs (Feb. 20, 2024); Pulitzer Center, *The Massive Failures of India's Drug Regulatory System*, (Mar. 12, 2025) (Explaining that India's pharmaceutical exports present heightened reliability concerns due to documented deficiencies in regulatory framework and enforcement capabilities); Yan, Y., Guo, X., Li, Z., Shi, W., Long, M., Yue, X., Kong, F., & Zhao, Z., *New Drug Approvals in China: An International Comparative Analysis, 2019-2023*. Drug Des., Dev. & Therapy 19, 2629-2639 (2005) (Examining the regulatory shortcomings of China's pharmaceutical manufacturing sector prioritizing quantity over quality); Andrew I. Rudman, *A Bilateral Approach to Address Vulnerability in the Pharmaceutical Supply Chain* (November 18, 2024), https://www.csis.org/analysis/bilateral-approach-address-vulnerability-pharmaceutical-supply-chain (explaining that current U.S. dependency on India for 47 percent of generic medications, combined with India's reliance on China for approximately two-thirds of its API requirements, creates compounded vulnerability to supply chain disruptions stemming from geopolitical tensions, regulatory compliance issues, or manufacturing disruptions).

[5] *See* Off. of the U.S. Trade Representative, *2025 Special 301 Report* (Apr. 2025) at 18.

[6] *See Improving the Safety and Security of Biological Research*, Exec. Order No. 14292, 90 Fed. Reg. 27435 (May 8, 2025).

However, none of these concerns apply to UCB's U.S. imports, which are sourced from stable, allied, and transparent jurisdictions that support, rather than threaten, U.S. national security. UCB's finished medicine imports are exclusively manufactured in Belgium and Switzerland, and its pharmaceutical ingredient imports are sourced from Belgium, France, Germany, Italy, South Korea, Sweden, Switzerland, and the U.K., which are traditional U.S. allies and long-standing strategic partners of the United States. In other words, UCB's manufacturing and sourcing model stands in direct contrast to the concentration vulnerabilities identified in DoD and HHS analyses.

First, UCB's supply chain demonstrates only minimal geopolitical risk. UCB's strategically diversified sourcing and manufacturing rely on countries that are not only U.S. trading partners but also mutual defense partners (e.g., NATO members or countries with bilateral alliances with the United States). A significant part of UCB's sourcing takes place in Europe. Such European sourcing presents substantially lower geographical risk due to active supply chain resilience efforts, stringent regulatory standards, and allied status, reducing the likelihood of politically motivated supply disruptions.[7] In addition, a large portion of the API imports are used to manufacture finished medicine in the United States, further strengthening the resilience of U.S. supply chain.[8] Rather than contributing to the concentration vulnerabilities identified by DoD and HHS, UCB's imports strengthen U.S. pharmaceutical system resilience by offering alternative supply options for critical therapeutic treatments and manufacturing away from over-concentrated, high-risk regions.

In addition, UCB's strategic supply chain mitigates the regulatory transparency challenges and structural vulnerabilities this Administration, HHS and USTR identified. UCB's manufacturing is conducted under some of the world's most stringent regulatory oversight, which are aligned or equivalent to FDA standards. Both the FDA and EMA mandate exceptionally rigorous manufacturing criteria and conditions.[9] The FDA maintains established Mutual Recognition Agreements ("MRAs") with the EU, Switzerland, and the UK, which "allow drug inspectors to rely upon information from drug inspections conducted within each other's borders."[10] South Korea's regulatory framework is also closely aligned with these standards.[11]

Accordingly, UCB's imports do not contribute to the types of supply chain vulnerabilities identified by the U.S. government as relevant to national security concerns. Rather, UCB

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[7] Duke, Margolis Inst. for Health Policy, *Building a Resilient and Secure Pharmaceutical Supply Chain: The Role of Geographic Diversification* (Nov. 8, 2024).

[8] *See* Nat'l Acads. of Scis., Eng'g & Med., *Building Resilience into the Nation's Medical Product Supply Chains* (Nat'l Acads. Press 2022).

[9] *See* M. Ghadanian & E. Schafheutle, *Comparison between European Medicines Agency and US Food and Drug Administration in Granting Accelerated Marketing Authorizations for Covid-19 Medicines and their Utilized Regulations*, Therapeutic Innovation & Regulatory Sci. 58(1), 79, 79-113 (2024).

[10] *See* Vidya Krishnan & Arshu John, *FDA, Mutual Recognition Agreements (MRA)*, U.S. Food & Drug Admin., https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreements-mra (last visited May 7, 2025).

[11] *See* Eur. Meds. Agency, *Confidentiality Arrangement Between the EU and the Republic of Korea* (Apr. 26, 2024).

operates in alignment with U.S. norms and transparency standards and serves as a stable and reliable contributor to the U.S. pharmaceutical supply chain.[12]

B. UCB's Operations Do Not Contribute to National Security Vulnerabilities Through Unfair Trade Practices

Commerce has identified foreign government subsidies, predatory trade practices, and artificially suppressed prices as potential threats to U.S. national security and the competitiveness of the U.S. pharmaceutical industry.[13] These concerns reflect the concern that foreign producers, supported by state aid or other non-market advantages, could flood the U.S. market with underpriced products, undermining U.S. producers and supply chain resilience. UCB's imports do not present such risks.

The U.S. biopharmaceutical industry is one of the largest and most advanced in the world, serving as a key driver of national economic growth and global competitiveness. In 2024, the U.S. pharmaceutical market was valued at $639.22 billion, making it the largest globally.[14] The industry generated over $800 billion in direct output in 2022 and supported a total of over $1.65 trillion in output when accounting for broader economic effects.[15] While the United States imports significant volumes of APIs and Key Starting Materials ("KSMs"), a 2021 study found that majority (i.e., 53 percent) of APIs by dollar value used in U.S.-consumed medicines are manufactured in the United States.[16] The U.S. industry is also a major exporter of high-value, innovation-driven pharmaceuticals, with exports totaling over $80 billion in 2022 and $101 billion in 2023.[17]

UCB's pricing practices have not displaced U.S. production, suppressed domestic market entry, or distorted competitive conditions. While UCB's medicines are highly specialized and indispensable in certain disease-state markets (i.e., healthcare industry segments focused on specific illnesses or conditions), its total U.S. market share accounted for only **[ ]** percent of total U.S. pharmaceutical sales. Given this **[ ]** market share, these imports could not

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[12] *See* 15 C.F.R. § 705.4(a)(3), (a)(5); Criteria (iii), (iv), (vii) and (x) of the April 16 Notice.

[13] *See* Criteria (v) and (vi) of the April 16 Notice.

[14] *See* Nova 1 Advisor, *U.S. Pharmaceutical Market Size, Share & Trends Analysis Report by Molecule Type, by Product, by Type, by Disease, by Formulation, by Age Group, by Route of Administration, by End Market, by Country, and Segment- Industry Analysis, Share, Growth, Regional Outlook and Forecasts, 2024-2033* (Apr. 2025).

[15] *See* TEConomy Partners, *The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates* (PhRMA May 2024) at 1-2.

[16] Avalere Health, *US Makes Majority of API by Dollar Value in US-Consumed Medicines* (June 14, 2023), https://avalere.com/insights/majority-of-api-in-us-consumed-medicines-produced-in-the-us (last visited May 7, 2025).

[17] *See* National Ass'n of Mfrs., *Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing* (Oct. 2023) at 16; Niels Graham, *The US Is Relying More on China for Pharmaceuticals — and Vice Versa*, Atlantic Council (Apr. 20, 2023); Ernst & Young, *Impacts of Potential Tariffs on the US Pharmaceutical Industry* (Apr. 22, 2025) at 3.

possibly distort the price of the U.S. market and impair the world-leading competitiveness of the U.S. manufacturers.

Available data further confirm that UCB competes fairly and does not undercut U.S. manufacturers. Indeed, UCB's list prices are generally in line with, or comparable to, those of key U.S. and international competitors, reflecting that UCB's market participation is based on the quality and value of its offerings, not on pricing strategies that would undermine U.S. manufacturers.

Moreover, there is no evidence that UCB's imports were unfairly dumped into the United States or that they benefited from "unfair" subsidies. UCB's imports have never been subject to a U.S. antidumping or countervailing duty investigation, nor have they been implicated in any trade remedy proceeding under U.S. law.

C. UCB's Imports Do Not Displace or Impair Domestic Production

Rather than displacing or impairing U.S. pharmaceutical production, UCB's specialized imports fill critical gaps in domestic manufacturing. UCB's portfolio includes a range of highly specialized, differentiated treatments that serve medically vulnerable populations with significant unmet medical needs. Most of UCB's products are uniquely formulated, patent-protected or biologics-licensed therapies.

As explained in Section I, UCB's imports include medicines for severe autoimmune and inflammatory conditions, neuromuscular disorders, neurological disorders including epilepsy, and rare and ultra-rare diseases affecting small patient populations, including pediatric patients, as well as other conditions with limited or no alternative options.[18] These therapies are differentiated by their distinct formulations or mechanisms of action, many of which are not shared by other U.S. manufactured drugs. To illustrate, UCB manufactures **[**

]. When access to these therapies is disrupted, patients may experience severe adverse reactions, disease progression, or loss of therapeutic effect due to their inability to tolerate or respond to alternatives.

[18] In the United States, a rare disease is defined as a condition that affects fewer than 200,000 people. An ultra-rare disease is a condition affecting fewer than 1 in 50,000 people. This means that in the United States, for any ultra-rare disease, less than 7,000 individuals are living with that condition.

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Additionally, UCB's imports often serve small patient populations with chronic, high-severity diseases. These niche therapeutic areas generally lack sufficient commercial incentives to support large-scale domestic manufacturing investment. As a result, U.S. producers have not developed, and are unlikely to develop, alternatives in the short or medium term. Even if U.S. manufacturers attempted to produce some of these highly specialized therapies, the complexity of manufacturing these biologics, coupled with regulatory exclusivity protections and technical barriers, would prevent effective substitution or rapid domestic production. In fact, most of UCB's products are protected by patents or approved under biologics license applications, preventing duplication by domestic firms. For products not under patent, even when the requisite technology is domestically available in a U.S.-based CMO, technology transfer typically takes three to five years, including FDA inspection and approval. When such technology is not available, building a new manufacturing facility and obtaining regulatory clearance can take six to eight years, depending on scale and complexity of each product.

UCB's imports do not compete with or displace existing U.S. pharmaceutical production. Instead, they complement it by filling important areas of unmet medical needs. Any disruption in access to these medicines would not lead to a revival of domestic production but rather would leave patients without effective or safe treatment options.

III. UCB Actively Strengthens U.S. Supply Chain Resilience Through U.S.-Based R&D, Investments, and Economic and Therapeutic Support for American Patients

The Administration has expressed concerns that meeting the healthcare needs of American patients is a national security matter. This concern includes the potential erosion of domestic manufacturing capacity due to high levels of pharmaceutical imports, which could undermine the ability to respond to supply disruptions or emergencies.[19] However, rather than contributing to these risks, UCB actively supports U.S. pharmaceutical supply chain resilience through its extensive U.S. operational footprint, substantial R&D investments and venture funding for expanding biopharmaceutical infrastructure, and significant economic and therapeutic support for American patients.

As explained in Section I, UCB maintains a broad operational footprint in the United States, employing over 1,950 U.S. workers across multiple locations. In 2024, UCB's total U.S. economic footprint exceeded [ ], including spending on clinical operations, research infrastructure, employee compensation, and external partnerships. These activities create broad-

[19] *See* criteria (ii), (iii), (viii), and (x) of the April 16 Notice.

ranging opportunities for the American workforce, spanning manufacturing, operations, research, development, and management and enhance U.S. capabilities in research and development.

UCB's manufacturing model incorporates domestic production through CMOs, which produces a range of medicines **[ ]**. Notably, some of these U.S.-manufactured medicines are subsequently exported, contributing to U.S. export growth. Additionally, UCB sources various supplies from U.S. manufacturers, such as autoinjectors and materials used in manufacturing and research, further supporting the domestic economy.

UCB, a member of Pharmaceutical Research Manufacturers Association ("PhRMA"), is also an integrated part of the U.S. biopharmaceutical innovation and manufacturing ecosystem. It makes significant investments in R&D and venture funding, through collaborations with various U.S. entities to expand the U.S. biopharmaceutical R&D infrastructure and develop innovative solutions for patients. In 2024 alone, UCB conducted over 75 active clinical R&D studies in the United States, covering core therapeutic areas of immunology, neurology, and rare diseases.[20] These trials were executed in partnership with U.S. academic institutions, hospitals, and clinical research organizations, facilitating knowledge transfer and supporting the long-term innovation capacity in the U.S. healthcare system.

Additionally, UCB continues to strengthen U.S. healthcare capabilities and delivers innovative solutions to American patients through partnerships with numerous U.S. companies and venture investments. It has collaborated extensively with U.S. companies to develop and manufacture medicines in the United States, expanding domestic manufacturing capacity and ultimately contributing to the resilience of U.S. supply chains. Additionally, through its corporate venture arm, UCB Ventures, UCB invests in early-stage U.S. companies developing breakthrough therapies in advanced medical fields, such as next-generation cell and gene therapy, regenerative medicine, cell and tissue homeostasis, and RNA modulation. As a committed long-term investor, UCB works closely with these U.S. companies to facilitate knowledge transfer and support their development.

UCB provides substantial economic and therapeutic support to U.S. patients. UCB offers significant discounts or price concessions to the U.S. healthcare system, helping to reduce the overall cost burden on the U.S. distribution system and private and public payers. In addition, UCB provides copay assistance and free drug programs for uninsured or underinsured patients and delivers patient support programs to help patients obtain access and stay on their therapies when medically appropriate. These programs are particularly relevant to patients with limited treatment alternatives, whose health depends on consistent, uninterrupted access to specialized therapies.

Beyond financial support, UCB's specialized medicines address critical unmet medical needs for vulnerable U.S. patient populations. UCB has developed a portfolio of differentiated treatments that serve as lifelines for Americans with severe, chronic, or rare conditions who often

[20] *See* UCB, *Integrated Annual Report 2024* at 311.

have limited or no alternative therapeutic options. Uninterrupted access to these medicines is fundamental to patient survival and quality of life. Historically, recognizing the critical role they play in sustaining life and health, medicines have been excluded from tariffs to prevent dangerous supply chain disruptions. For the patients relying on these life-changing therapies, maintaining uninterrupted access is not merely a policy preference but a matter of patient survival or safeguarding their quality of life. This is particularly true for patients dependent on therapies that cannot be easily substituted or interrupted without severe, potentially irreversible consequences.

IV. Applying Section 232 Measures to UCB's Imports Would Undermine National Security Goals

Imposing trade measures on UCB's imports would undermine the policy goals of supply chain resilience, innovation, and patient access to treatments. Such measures would disrupt the intricate, multistage manufacturing processes that define the pharmaceutical industry, particularly for complex products such as those developed and manufactured by UCB.

The pharmaceutical supply chain flows hierarchically from KSMs to APIs, from APIs to Drug Products and then from Drug Products to finished drug products. This system relies on decades of investment in specialized facilities, equipment, and expertise at each stage.[21] As a result, certain inputs and intermediates may need to cross the U.S. border multiple times throughout the manufacturing process, as some production steps are only feasible in particular locations. This cross-border movement exposes the production of complex, innovative medicine to compounded tariff burdens. Recovery from such disruptions is constrained by regulatory and logistical obstacles, and reestablishing production capacity typically requires significant time and resources.[22]

These risks are particularly crucial for UCB's medicines, which treat rare and severe conditions and often involve highly specialized facilities and processes. Disruptions to UCB's supply chain cannot be quickly addressed through alternative sourcing or manufacturing adjustments. Transferring technology and obtaining regulatory approvals to relocate production is necessarily a lengthy and complex process. However, any delays in manufacturing or distribution may result in serious treatment interruptions for patients dependent on these therapies.

As previously explained, restrictions on UCB's imports would harm U.S. patients by limiting access to critical, specialty therapies. The U.S. patients depending on these highly specialized medicines, particularly those with few or no alternative options, would face significant delays or loss of access to clinically essential medicines. In addition, the clinical areas UCB serves (e.g., autoimmune diseases, myasthenia gravis, and epilepsy) often involve

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[21] Nat'l Acads. of Scis., Eng'g & Med., *Building Resilience into the Nation's Medical Product Supply Chains* (Nat'l Acads. Press 2022) at 3.

[22] *Id.* at 113-14.

high-acuity, high-dependency care, where continuity of treatment is medically essential. Interruptions to access could result in disease progression or other serious adverse outcomes.

For these reasons, U.S. Policymakers have long recognized that tariffs on pharmaceuticals and ingredients can impede patients' access by increasing costs and contributing to shortages. In fact, the first Trump Administration acknowledged that tariffs could interfere with the government efforts to expand access to healthcare products and that the additional costs are ultimately borne by healthcare providers and patients.[23] These barriers to access can ultimately endanger the patients' health. Recognizing these risks, the United States and other developed economies including Canada, the European Union, Japan, Singapore, Switzerland, and the United Kingdom generally refrained from imposing tariffs on pharmaceuticals for several decades.

Tariffs would also undermine trusted, allied supply chains. UCB's imports are sourced from the countries with which the United States maintains strategic partnerships, mutual defense treaties, and shared regulatory values. Penalizing these trusted trade flows would send a counterproductive signal to the market and discourage the companies from further investing in diversified supply models. It could also risk pushing procurement toward lower-cost but higher-risk suppliers, including those in jurisdictions the Administration is more concerned about.

Further, tariffs would disincentivize foreign direct investment and collaborative research efforts that support U.S. biopharmaceutical sector. From 2017 to 2022, the biopharmaceutical industry attracted more new foreign direct investment into the United States than any other sector, totaling over $148 billion and more than 550 new U.S. manufacturing facilities between 2018 and 2023.[24] Trade restrictions could also deter foreign R&D collaboration with U.S. academic institutions and biotech firms, weakening long-term innovation capacity.

A 25 percent tariff on pharmaceutical imports could increase the annual cost of imported medicines by approximately $50.8 billion.[25] It may also increase domestic production costs by $15.1 billion, undermining the competitiveness of the U.S. manufacturers.[26] In such circumstances, it is clear that tariffs are not the answer for promoting greater domestic production of these products. In fact, every dollar collected in tariffs would be one less dollar available for reinvestment in U.S. research, manufacturing, and infrastructure. Rather than imposing broad-based tariffs, policymakers should focus on targeted incentives and practical measures to strengthen domestic resilience and ensure the United States' continued supply chain security.

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[23] *See* Off. of the U.S. Trade Representative, *2025 Special 301 Report* (Apr. 2025) at 30-31.

[24] *See* NDP Analytics, *Analysis of U.S. FDA Drug Establishments Current Registration Site* (Apr. 2023, Apr. 2022, Feb. 2021, Jan. 2020, Apr. 2019, Apr. 2018); Tim McLung, *Biopharmaceutical Manufacturing Companies Continue to Expand Their Economic Footprint Across the United States*, PhRMA (May 2023).

[25] Ernst & Young, *Impacts of Potential Tariffs on the US Pharmaceutical Industry* (Apr. 22, 2025) at 6-8.

[26] *Id.*

V. Conclusion

UCB appreciates Commerce's consideration of its comments, which demonstrate that UCB's imports do not impair or threaten to impair U.S. national security. These imports are sourced from allies with rigorous regulatory standards and are not associated with unfair trade practices that could create U.S. supply chain vulnerabilities in the pharmaceutical industry. UCB's operations also make a meaningful contribution to the economic strength and industrial resilience of the United States through domestic employment, sourcing, and investment in R&D. Imposing Section 232 tariffs on UCB's imports would disrupt critical supply chains, restrict patient access to essential therapies, discourage allied cooperation, and undermine the very investment and innovation that U.S. policymakers seek to promote.

Given the essential nature of pharmaceutical products and the wide-ranging consequences that tariffs would have on supply stability and patient access, UCB respectfully urges Commerce to avoid imposing Section 232 measures on pharmaceutical and pharmaceutical ingredient imports. Should Commerce determine that a broader exemption of these imports is not feasible, UCB respectfully urges Commerce to consider excluding UCB's imports from the scope of the investigation, specifically the products classified under HTS codes 2853909090, 2921495000, 2924296250, 2933798500, 3002140010, 3002150011, 3002150091, 3004909236, 3004909240, 3004909291, 3907290000, and 9023000000, which cover the types of pharmaceutical products and medical training materials used for R&D that UCB imports. If such an exclusion is not feasible, Commerce should recommend that no Section 232 measures be applied to these products.

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Please be advised that this letter contains sensitive information about UCB and its business and commercial activities, as indicated in brackets ("**[ ]**"). This information is confidential, and not customarily released publicly and is, therefore, exempt from the public access provisions of the Freedom of Information Act, 5 U.S.C. § 552(b)(4). Such information, if disclosed, could adversely affect the financial and competitive positions of UCB and the normal conduct of their business operations. Accordingly, UCB respectfully requests business confidential treatment for the bracketed information in this submission, pursuant to 15 C.F.R. § 705.6.

UCB welcomes the opportunity to engage with Commerce to discuss its submission. Should you have any questions about this submission, please contact Patty Fritz (Vice-President, U.S. Corporate Affairs) at **[ ]**.

Best regards,

/s/Taco van Tiel
Taco van Tiel

President
UCB, Inc.