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May 7th, 2025

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

Re: Section 232 Investigation on Imports of Pharmaceuticals, Pharmaceutical Ingredients, and Derivative Products (Docket No. BIS-2025-0022, XRIN 0694-XC120)

Dear Secretary Lutnick,

FUJIFILM Corporation was founded in 1934 as a Japanese photographic film manufacturer. Since its inception, FUJIFILM Corporation has been committed to developing leading-edge, proprietary technologies by leveraging its photography expertise into other products and markets. Its businesses today span a diversified range of product segments based on a portfolio of chemical, mechanical, optical, electronic, healthcare, life sciences, and imaging technologies.

FUJIFILM Corporation's primary growth area today is principally manufacturing biologics production and drug-delivery innovations that address unmet medical needs, with a current emphasis on hard-to-cure cancers, infectious diseases, and neurological diseases via its U.S. subsidiaries, FUJIFILM Diosynth Biotechnologies, FUJIFILM Irvine Scientific, FUJIFILM Pharmaceuticals, U.S.A., Inc. and FUJIFILM Cellular Dynamics.

FUJIFILM Diosynth Biotechnologies is a world-leading contract development and manufacturing organization (CDMO) for biologics, vaccines and advanced therapies. With over 30 years of experience, FUJIFILM Diosynth Biotechnologies specializes in developing and manufacturing biopharmaceuticals using microbial, mammalian, and host/virus systems. With over 4,800 employees, FUJIFILM Diosynth Biotechnologies operates a fully integrated, kojoX™ global network with major facilities in the United States, Demark, Japan and the United Kingdom (UK), with a planned new site in Holly Springs, North Carolina, USA. FUJIFILM Diosynth Biotechnologies' kojoX manufacturing network ensures supply chain agility for its customers through modular facilities

and standardized processes for seamless scaling and technology transfers. FUJIFILM Diosynth Biotechnologies offers comprehensive services, ranging from proprietary cell line development, to process and analytical development, and through to clinical and commercial manufacturing.

In the past 13 years, globally FUJIFILM Corporation has invested more than 1 trillion yen ($6.6 billion USD) on mergers and acquisitions, concentrated in the healthcare sector.
The company has invested over $4 billion in the U.S. to grow and expand its biomanufacturing capabilities targeting the production of recombinant proteins, monoclonal antibodies, viral vaccines, and gene therapies – all at the cutting edge of the current biotech medical revolution.
FUJIFILM Diosynth Biotechnologies' pharmaceutical operations span four countries, with manufacturing facilities in the United States, Denmark, Japan, and the UK, the latter three of which are longstanding U.S. allies with robust regulatory systems and strong defense partnerships.
FUJIFILM Diosynth Biotechnologies maintains no production facilities in China or India.

FUJIFILM Diosynth Biotechnologies maintains a substantial U.S. presence with over 1,900 U.S.-based employees across research, drug manufacturing, and regulatory affairs; facilities in Research Triangle Park, NC; College Station, TX; Thousand Oaks, CA, and we are currently building a new site in Holly Springs, NC. Our total U.S. economic investment exceeds $4 billion, with positive growth estimates through new investment in manufacturing capacity. FUJIFILM Diosynth Biotechnologies' project in North Carolina alone will grow the state's economy by $4.7 billion over a 12-year term. FUJIFILM Diosynth Biotechnologies maintains comprehensive business continuity planning with resilient manufacturing capabilities across multiple facilities to ensure uninterrupted supply of critical therapies to U.S. patients.

FUJIFILM Diosynth Biotechnologies' operations do not present national security risks under Section 232 criteria, as (1) FUJIFILM Diosynth Biotechnologies' manufactures exclusively in trusted allied countries with transparent regulatory frameworks; (2) FUJIFILM Diosynth Biotechnologies' operations do not engage in unfair trade practices; and (3) FUJIFILM Diosynth Biotechnologies' does not displace or impair domestic production. Instead, FUJIFILM Diosynth Biotechnologies actively strengthens the resilience of the U.S. healthcare system through domestic investment and enhancements to supply chain stability.

Applying Section 232 measures to biopharmaceuticals manufactured by FUJIFILM Diosynth Biotechnologies in Japan, and the UK would undermine national security goals by disrupting patient access to critical therapies, weakening trusted allied supply chains, destabilizing specialized pharmaceutical manufacturing, deterring domestic investment and research collaboration, and raising costs that erode the competitiveness of expanding U.S. pharmaceutical production.

I. Fujifilm Manufacturing Biopharmaceuticals Does Not Impair or Threaten to Impair U.S. National Security

FUJIFILM Diosynth Biotechnologies' Strategic Supply Chain Minimizes National Security Risk Through Allied and Geographical Diversification

The Department's investigation identifies three fundamental national security risks: excessive reliance on pharmaceutical and API imports from a limited number of foreign suppliers presents potential vulnerability (Criteria (iii) and (iv)); significant sourcing from nations that could "weaponize" their control over pharmaceutical supplies threatens U.S. national security (Criterion (vii)); and unreliable quality control within pharmaceutical imports could compromise public health and emergency response capabilities (Criterion (x)).[1]

While the Department does not explicitly identify specific countries in the Notice, multiple U.S. government analyses have identified China and India as presenting sourcing and strategic concentration risks to pharmaceutical supply chain resilience: 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.[2] 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

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[1] *See 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) ("Notice").

[2] Report on the Department of Defense Pharmaceutical Supply Chain Risks, Office of the Under Secretary of Defense for Acquisition and Sustainment (November 2023).

compliance issues, or manufacturing disruptions.[3] A 2024 Department of Health and Human Services ("HHS") draft research plan documented that 48 percent of API Drug Master Files submitted to FDA in 2021 originated from Indian manufacturers, with an additional 13 percent from Chinese manufacturers, creating regulatory transparency challenges and structural vulnerabilities.[4]

FUJIFILM Diosynth Biotechnologies' exclusively manufactures in the United States, Denmark, Japan and the UK. These countries outside of the United States are traditional U.S. allies and long-standing strategic partners of the United States. FUJIFILM Diosynth Biotechnologies' manufacturing and sourcing model stands in direct contrast to the concentration vulnerabilities identified in DoD and HHS analyses. FUJIFILM Diosynth Biotechnologies' supply chain demonstrates minimal geopolitical risk. Denmark, Japan, and the UK are not only U.S. trading partners but also mutual defense partners (e.g., NATO, bilateral alliances). Partnering with Denmark, Japan, and the UK 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.[5] FUJIFILM Diosynth Biotechnologies' production occurs under the world's most stringent regulatory oversight. The FDA and EMA both mandate exceptionally rigorous manufacturing criteria and conditions.[6] In addition, the FDA maintains established Mutual Recognition Agreements ("MRAs") with the EU, Switzerland, and the U.K., which "allow drug

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[3] 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.

[4] HHS, DRAFT RESEARCH PLAN FOR ADDRESSING SHORTAGES OF MEDICAL PRODUCTS AND CRITICAL FOODS AND STRENGTHENING THE RESILIENCE OF MEDICAL PRODUCT AND CRITICAL FOOD SUPPLY CHAINS: AN ANNEX TO THE HHS DRAFT ACTION PLAN (Jan 16, 2025) https://aspe.hhs.gov/sites/default/files/documents/e1956830e5587510cf92c70e53a2c8ad/supply-chain-research-plan.pdf.

[5] Building a Resilient and Secure Pharmaceutical Supply Chain: The Role of Geographic Diversification, Duke, Margolis Institute for Health Policy (Nov. 8, 2024) https://healthpolicy.duke.edu/sites/default/files/2024-11/Building%20a%20Resilient%20and%20Secure%20Pharmaceutical%20Supply%20Chain.pdf.

[6] *See* Ghadanian, M., & Schafheutle, E. (2024). 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 science, 58(1), 79–113. https://doi.org/10.1007/s43441-023-00574-6.

inspectors to rely upon information from drug inspections conducted within each other's borders."[7]

In contrast, both Chinese and Indian manufacturers have demonstrated a pattern of repeatedly violating FDA regulations.[8] India's pharmaceutical exports present heightened reliability concerns due to documented deficiencies in regulatory framework and enforcement capabilities.[9] China's pharmaceutical manufacturing sector also exhibits regulatory shortcomings that prioritizes quantity over quality, and proliferation of "me-too" drugs and weak basic research.[10] In addition to issues with overall quality and enforcement concerns from those regions, the rise of counterfeit pharmaceuticals threatens public health, national security, and the economy. These products, illicit copies of branded, generic, or over-the-counter drugs, may have the wrong amount of an active ingredient or even harmful impurities.[11] Many of the counterfeit pills brought into the United States are produced in Mexico, with chemicals to make the fentanyl supplied by China.[12]

Counterfeit products affect the operations of legitimate pharmaceutical companies, including costs to prevent the sale of fake products, a decrease in revenue that goes to the counterfeit market,

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[7] *See* Vidya Krishnan, Arshu John, FDA, Mutual Recognition Agreements (MRA), https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreements mra#:~:text=The%20FDA%20has%20Mutual%20Recognition,Switzerland.

[8] 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.

[9] The Massive Failures of India's Drug Regulatory System, Pulitzer Center (Mar. 12, 2025) https://pulitzercenter.org/stories/massive-failures-indias-drug-regulatory-system#:~:text=In%202022%2C%20a%20minister%20of,%E2%80%94%20263%20drugs%20%E2%80%94%20were%20spurious.

[10] Yan, Y., Guo, X., Li, Z., Shi, W., Long, M., Yue, X., Kong, F., & Zhao, Z. (2025). New Drug Approvals in China: An International Comparative Analysis, 2019-2023. Drug design, development and therapy, 19, 2629–2639. https://doi.org/10.2147/DDDT.S514132.

[11] "About PSI." Pharmaceutical Security Institute.

[12] "DEA Issues Public Safety Alert on Sharp Increase in Fake Prescription Pills Containing Fentanyl and Meth." Drug Enforcement Administration.

and notably, the potential loss of trust in a legitimate, life-impacting drug. As the United States looks for solutions to address supply chain challenges, medication accessibility, and onshoring domestic manufacturing, understanding and preventing the distribution of counterfeit pharmaceutical products from those countries should be a priority.

Rather than contributing to the concentration vulnerabilities identified by DoD and HHS, FUJIFILM Diosynth Biotechnologies' manufacturing capabilities strengthen U.S. pharmaceutical system resilience by diversifying sourcing away from over-concentrated, high-risk countries and regions; providing alternative supply options for critical therapeutic treatments; and enhancing supply chain transparency and regulatory predictability.

Accordingly, FUJIFILM Diosynth Biotechnologies' operations do not increase supply chain risk described in 15 C.F.R. § 705.4(a)(3), (a)(5) or Notice Criteria (iii), (iv), (vii) and (x). Instead, FUJIFILM Diosynth Biotechnologies is a responsible and trusted market participant whose conduct is fully aligned with U.S. norms and market transparency standards.

FUJIFILM Diosynth Biotechnologies' Operations Do Not Contribute to National Security Vulnerabilities Through Unfair Trade Practices

The Department identifies 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 (Criteria (v) and (vi)). These concerns are grounded in the possibility that foreign producers could flood the U.S. market with underpriced products, supported by state aid or other non-market advantages, undermining U.S. producers and supply resilience. The U.S. pharmaceutical industry makes substantial contributions to the national economy, public health, and global competitiveness.

In 2021, the U.S. pharmaceutical industry contributed approximately $355 billion to GDP, generated $655 billion in total economic output, and supported about 1.5 million U.S. jobs across the supply chain.[13] The R&D intensity was 16.1 percent, which is more than three times the national

[13] National Association of Manufacturers, Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing (Oct. 2023) at 23; PhRMA, Economic Impact (last visited Apr. 25, 2025).

average of 4.6 percent.[14] In the broader biopharmaceutical ecosystem, including development-stage firms, R&D intensities may reach as high as 34 percent.[15] The U.S. pharmaceutical market was valued at $634.34 billion in 2024 and is projected to grow to $1,107.4 billion by 2034, with a compound annual growth rate (CAGR) of 5.73 percent.[16] The United States accounts for 30 to 40 percent of the global pharmaceutical market, including 45 percent of global pharmaceutical sales and 22 percent of global pharmaceutical production.[17] In 2023, U.S. biopharmaceutical goods exports exceeded $101 billion. Also, while approximately 70 to 80 percent of APIs by volume were imported from India and China in 2021,[18] 53 percent of APIs by value used in U.S.-consumed medicines are manufactured domestically and an additional 33 percent of APIs are sourced from European allies.[19]

FUJIFILM Diosynth Biotechnologies cannot reasonably be viewed as exerting downward pressure on overall U.S. pharmaceutical pricing or production dynamics. There is also no evidence that FUJIFILM Diosynth Biotechnologies' pricing practices displace U.S. production, suppress domestic market entry, or distort competitive conditions. Accordingly, FUJIFILM Diosynth Biotechnologies' operations do not raise the types of trade distortion concerns described in 15 C.F.R. § 705.4(a)(4), (b)(4) or Notice Criteria (v) and (vi). Instead, Fujifilm is a responsible market participant who does not engage in unfair trade practices.

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[14] National Center for Science and Engineering Statistics, Business R&D Performance in the United States Tops $600 Billion in 2021 (Sept., 28, 2023) (Official government data from the 2021 Business Enterprise Research and Development ("BERD") Survey).

[15] Amitabh Chandra et al., Comprehensive Measurement of Biopharmaceutical R&D Investment, 23 Nature Rev. Drug Discovery 652 (2024).

[16] https://www.biospace.com/press-releases/u-s-pharmaceutical-market-size-to-hit-usd-1-107-4-billion-by-2034.

[17] Cameron Santoro, The Future of Pharmacy: Trends, Threats, Transformations, AJMC (February 11, 2025) https://www.centerforbiosimilars.com/view/the-future-of-pharmacy-trends-threats-transformations.

[18] *See* Andrew I. Rudman & Jerry Haar, Strengthening US-Mexico Quality Pharmaceutical Supply Chains, Wilson Center (June 11, 2024).

[19] PhRMA comments.

FUJIFILM Diosynth Biotechnologies' Operations Do Not Displace or Impair Domestic Production

The Department determines whether pharmaceutical imports displace or impair domestic production, and whether the United States could feasibly increase domestic manufacturing to meet demand (Criteria (i), (ii), and (x)). As a contract pharmaceutical manufacturer, the therapies FUJIFILM Diosynth Biotechnologies manufactures in the U.S. on behalf of pharmaceutical companies serve patient populations living with chronic, severe disease. FUJIFILM Diosynth Biotechnologies does not compete with U.S.-produced pharmaceutical products. In fact, FUJIFILM Diosynth Biotechnologies directly supports the development and manufacturing of U.S. produced pharmaceutical products. Further, due to their complexity and regulatory exclusivity, U.S. manufacturers cannot substitute for most of these treatments in the short or medium term. By meeting otherwise unmet medical needs, FUJIFILM Diosynth Biotechnologies' manufacturing capabilities complement U.S. production capacity and directly support the availability of life-sustaining treatments to U.S. patients.

Accordingly, FUJIFILM Diosynth Biotechnologies' imports do not raise displacement concerns under 15 C.F.R. § 705.4(b)(1)-(b)(3) or Notice Criteria (i), (ii), or (x). Instead, they serve a vital function in ensuring continuity of care and strengthening the overall security and capacity of the U.S. health system.

II. Fujifilm Actively Strengthens U.S. Supply Chain Resilience Through U.S.-Based R&D, Manufacturing, and Investments

The Department raises concerns that high levels of pharmaceutical imports may erode the capacity of domestic industry to meet long-term national security needs, particularly in the event of supply disruptions or emergencies (Criteria (ii), (viii), and (x)). Contrary to these concerns, FUJIFILM Diosynth Biotechnologies actively strengthens U.S. supply chain resilience through substantial domestic investments, integrated U.S. operations, extensive manufacturing capabilities, and responsible pricing practices that collectively enhance rather than diminish domestic pharmaceutical capacity and healthcare system sustainability.

First, FUJIFILM Diosynth Biotechnologies maintains a broad, embedded operational footprint in the United States, including over 1,900 employees and four sites across the U.S. The

strategic U.S. investment and expansion supports a key pillar of FUJIFILM Diosynth Biotechnologies' Partners for Life strategy, which is to build capacity in large-scale production in locations across the U.S. to support biopharma customers' end-to-end needs and provide supply chain resiliency.

As the United States is the largest market for biopharmaceuticals, FUJIFILM Corporation has made significant investments here, exceeding $4 billion in building world-class biopharmaceutical manufacturing sites, life sciences capabilities, and growing its technical talent. By increasing investments in domestic biopharmaceutical manufacturing, we can protect patients during pandemics, strengthen national security, support job growth, and bolster local economies. Our U.S. based employees, with expertise in drug manufacturing, clinical science, regulatory affairs, supply chain, and program management contributing directly to the human resource base of the U.S. pharmaceutical sector.

In addition, FUJIFILM Diosynth Biotechnologies is currently in the final phase of planning to establish additional domestic manufacturing facilities in the United States as part of a long-term strategic commitment to the U.S. market and to enhance supply chain resilience. In April 2024, FUJIFILM Corporation announced an additional investment of $1.2 billion in its Large-Scale Cell Culture CDMO Business to further expand the planned FUJIFILM Diosynth Biotechnologies end-to-end bio-manufacturing facility in Holly Springs, North Carolina, bringing the total investment in the facility to over $3.2 billion. The expansion adds significant large-scale production capacity to FUJIFILM Diosynth Biotechnologies' global network through its United States, Denmark, Japan and UK manufacturing hubs. The investment will generate an additional 680 jobs by 2031, also bringing the total number of new, highly skilled local jobs to 1400 in Holly Springs. As of April 2025, the site already hired 500 people to fill those positions.

The new facility will offer large-scale cell culture manufacturing of bulk drug substance production with 8 x 20,000L bioreactors with the potential to expand and add a further 24 x 20,000L bioreactors based on market demand. In addition, the facility will also provide commercial scale, automated fill-finish and assembly, packaging, and labelling services. This project is estimated to grow the North Carolina economy by $4.7 billion. The facility is set to open in late 2025 and will be one of the largest biopharmaceutical manufacturing facilities in North America.

Pharmaceutical companies must find the biomanufacturing strategy that can best accommodate uncertain and evolving demand forecasts in order to deliver innovative biologics that address blockbuster indications, rare diseases, or global pandemic threats. There are three major biologic manufacturing strategies, each with specific advantages: scale up, scale out, and continuous. FUJIFILM Diosynth Biotechnologies' capabilities provide its customers all three to seamlessly pivot as demand evolves throughout different clinical phases, affording a dynamic, cost-effective plan for the life cycle of drug manufacturing.

Scale up, or traditional large-scale manufacturing, is the strategy for producing large volumes of biologic medicines. It is an ideal solution for customers in late-stage clinical development planning to begin commercial manufacturing. Though scale up is widely considered the most conventional strategy for meeting high demand, it requires up-front investments in time and money. FUJIFILM Diosynth Biotechnologies, with manufacturing capabilities for all three strategies, uses its large-scale, stainless-steel manufacturing platform leveraging multiple 20,000-Liter bioreactors that offer high efficiency and a lower cost of goods. FUJIFILM Diosynth Biotechnologies invested in network capacity localized in the US, Denmark, Japan, and UK with sustainable modular-designed facilities that enable process transfers with unprecedented speed for maximum agility.

Scale out is used to increase capacity while staying within the 2,000-Liter range often used for clinical batches. It is ideal for manufacturing targeted therapeutics for niche indications, where the patient population and overall need are much smaller. Scale out allows customers to rapidly increase and ramp up output without having to perform additional studies required for large-scale manufacturing. Furthermore, it offers greater flexibility, lower upfront costs, and shorter lead times thanks to smaller, modular, single-use facilities. On the downside, it does not allow the efficiency of scale provided by a scale-up approach. At FUJIFILM Diosynth Biotechnologies, the scale-out approach is conducted in high-throughput ballroom facilities with multiple 2,000-L bioreactors. By remaining at the same scale throughout, drug companies have the advantage of collecting more data about their manufacturing process. If demand shifts, customers can move to scale up rapidly and easily due to the alignment between the fed-batch manufacturing platforms.

Continuous is an innovative manufacturing solution that leverages small, agile facilities that adapt easily to forecast fluctuations while providing the cost efficiency of large-scale systems.

According to the FDA, continuous manufacturing has, "the potential to improve product quality and reliability, lower manufacturing costs, reduce waste, decrease inventory, and increase manufacturing flexibility in response to product demand."[20]

Second, FUJIFILM Diosynth Biotechnologies directly strengthens U.S. healthcare capacity through collaborating with U.S. biotech firms, research institutes, and other pharmaceutical companies. Building clinical infrastructure across domestic institutions that creates long-term value for the U.S. healthcare system by collaborating with U.S. companies as well as international companies based in allied countries. As recently as April 22, 2025, FUJIFILM Diosynth Biotechnologies announced a 10-year manufacturing supply agreement, valued at over $3 billion, with Regeneron Pharmaceuticals, Inc. to provide U.S.-based production of its industry-leading biologic medicines, which treat millions of patients worldwide. The deal nearly doubles Regeneron's U.S. manufacturing capacity and is just one example of how FUJIFILM Diosynth Biotechnologies is proving to be a trusted partner in brining domestic manufacturing back to the United States, transferring advanced knowledge and technologies to domestic partners.

FUJIFILM Diosynth Biotechnologies' total U.S. investment exceeded nearly $4 billion in 2024, including spending on domestic manufacturing operations, research infrastructure, employee compensation, and external partnerships. These investments: support high-value domestic jobs in research and healthcare; promote public-private collaboration within the U.S. pharmaceutical innovation ecosystem; build and sustain U.S. capacity to address future public health threats. FUJIFILM Diosynth Biotechnologies' policies also support system-wide resilience, reducing the likelihood that supply challenges or pricing volatility will restrict patient access to necessary treatments.

Through FUJIFILM Diosynth Biotechnologies' modular production model, kojoX™, the expansion enables the construction of identical large-scale production facilities in U.S. and Denmark to ensure that customers can seamlessly integrate drug manufacturing production regardless of location. FUJIFILM Diosynth Biotechnologies' kojoX manufacturing network ensures supply chain

[20] Center for Drug Evaluation and Research. (2022, June 28). An FDA self-audit of continuous manufacturing for Drug Products. U.S. Food and Drug Administration

agility for its customers through modular facilities and standardized processes for seamless scaling and technology transfers. FUJIFILM Diosynth Biotechnologies offers comprehensive services, ranging from proprietary cell line development, to process and analytical development, and through to clinical and commercial manufacturing. This harmonized design enables validated drug substance API processes to transfer to new, equivalent production lines within networks.

FUJIFILM Diosynth Biotechnologies understands the critical challenges of manufacturing supply and capacity constraints, regulatory complexity, and geopolitical risks that lead to inefficiencies in the supply chain, inhibiting rapid clinical development and patient access to new medicines. FUJIFILM Diosynth Biotechnologies' policy of building a resilient supply chain to mitigate geopolitical risks translates into procuring 95% of our raw materials from the United States, Denmark, Japan and the UK, keeping it as close as possible to customers' markets and their patients. FUJIFILM Diosynth Biotechnologies remains dedicated to putting people first, transforming the industry through innovation and expertise, and ensuring that our global network supports the production of life-changing medicines that improve patients' lives.

In contrast to importers that act as external market participants, FUJIFILM Diosynth Biotechnologies' strategy integrates U.S. capacity-building into its global operations, directly advancing the Administration's goals of supply chain resilience, scientific leadership, and allied engagement**.** As such, FUJIFILM Diosynth Biotechnologies' approach to pricing and patient access contributes positively to the national security objectives articulated in 15 C.F.R. § 705.4(a)(7), (b)(4) and Notice Criteria (vi) and (x).

III. Applying Section 232 Measures to Biopharmaceuticals Manufactured by FUJIFILM Diosynth Biotechnologies in Denmark, Japan, and the United Kingdom Would Undermine National Security Goals

The Notice invites comment on whether new trade measures, including tariffs, quotas, or other import restrictions, are warranted to protect U.S. national security, and what their potential impact would be on domestic resilience and capacity (Criterion (ix)). Imposing trade remedies on FUJIFILM Diosynth Biotechnologies' manufactured products would undermine the stated policy goals. It would disrupt U.S. patient access to critical, non-commodity therapies. Any restriction on

these products could delay or block access to life-saving therapies, with disproportionate effects on vulnerable patients. It would undermine trusted, allied supply chains that enhance resilience.

Outside of the United States, FUJIFILM Diosynth Biotechnologies exclusively manufactures in Japan, Denmark and the UK, the countries with which the United States maintains strategic partnerships, mutual defense treaties, and shared regulatory values. Undermining imports from these allies would send a counterproductive signal to trusted partners and discourage further investment in diversified, transparent, and ethical supply models. It would also risk pushing procurement toward lower-cost but higher-risk suppliers, including those in jurisdictions the Administration is more concerned about. It would disrupt intricate, specialized pharmaceutical manufacturing processes. The pharmaceutical supply chain flows hierarchically from KSMs to APIs, and then to finished drug products. This complex, multistage process involves specialized facilities, equipment, and expertise developed over decades at each step.[21] Disruptions, whether caused by tariffs or other barriers, can trigger cascading effects throughout this highly interdependent system. Adjusting the supply chain after a disruption can be challenging due to logistical and regulatory hurdles, and re-establishing production capacity often entails substantial time delays.[22]

It would discourage foreign direct investment and domestic collaboration. FUJIFILM Diosynth Biotechnologies is currently planning to establish domestic manufacturing facilities in the United States as part of a long-term strategic commitment to the U.S. market and to enhance supply chain resilience. However, the imposition of Section 232 tariffs would impede this domestic manufacturing investment, by diverting substantial financial resources away from this capital-intensive project, as the company would face immediate increased costs. The economic burden of tariffs, specifically on pharmaceuticals manufactured in Denmark would require the reallocation of capital expenditure budgets away from planned U.S. manufacturing investments toward managing the unplanned tariff expenses on existing product flows.

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[21] National Academies of Sciences, Engineering, and Medicine. 2022. *Building Resilience into the Nation's Medical Product Supply Chains*. Washington, DC: The National Academies Press at 3.

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

IV. Conclusion

FUJIFILM Diosynth Biotechnologies manufacturing biopharmaceuticals in Japan, Denmark and the UK do not impair or threaten to impair U.S. national security. Instead, they strengthen U.S. healthcare supply chains resilience and invest in U.S. research, development, and manufacturing. Imposing Section 232 measures on FUJIFILM Diosynth Biotechnologies' manufactured products would disrupt patient access to critical therapies, undermine trusted supply chains, deter investment, and increase costs for U.S. manufacturers.

The Department should consider excluding FUJIFILM Diosynth Biotechnologies' facilities in Denmark, Japan, and the UK from the scope of the investigation. Applying Section 232 measures to FUJIFILM Diosynth Biotechnologies' manufactured biopharmaceuticals, both API and finished goods, would undermine national security goals by disrupting patient access to critical therapies, weakening trusted allied supply chains, destabilizing specialized pharmaceutical manufacturing, deterring domestic investment and research collaboration, and raising costs that erode the competitiveness of expanding U.S. pharmaceutical production. FUJIFILM Diosynth Biotechnologies' strategy integrates U.S. capacity-building into its global operations, directly advancing the Administration's goals of supply chain resilience, scientific leadership, and allied engagement. FUJIFILM Diosynth Biotechnologies remains a trusted and transparent partner and are fully committed to creating jobs and expanding critical supply chain manufacturing in the United States.