LGM Pharma
PARTNER SMART.

Docket No. 250414-0065
BIS-2025-0011
X-RIN 0694-XC120

PUBLIC DOCUMENT

SUBMISSION VIA FEDERAL RULEMAKING PORTAL

The Honorable Howard Lutnick
Secretary of Commerce
Attn: Bureau of Industry and Security
Office of Strategic Industries
and Economic Security
U.S. Department of Commerce
14th Street and Constitution Avenue, NW
Washington, DC 20230

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

Dear Secretary Lutnick:

LGM Pharma LLC ("LGM Pharma") welcomes this opportunity to submit comments in connection with the above-captioned Section 232 investigation.[1] Our company values and supports efforts to bolster domestic manufacturing of pharmaceuticals and related ingredients. However, LGM Pharma is concerned that the imposition of additional tariffs or other trade restrictions, particularly on Active Pharmaceutical Ingredients ("API"), would result in immediate harm to U.S. manufacturers and put Americans' ready access to affordable medicines at risk. Tackling the complex issues at stake in this investigation requires a nuanced approach. We recommend that any remedies the Department of Commerce ("the Department") pursues under Section 232 avoid disruption of critical drug supply chains, particularly as to APIs; protect and promote current public access to essential medicines; and

[1] *See Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients,* 90 Fed. Reg. 15951 (Dep't Commerce Apr. 16, 2025) ("*Sec. 232 Notice*").

encourage the development of the U.S. pharmaceutical manufacturing base through deregulation and private-public partnerships.

1. About LGM Pharma

LGM Pharma is a leading contract development and manufacturing organization ("CDMO") providing comprehensive API sourcing, drug product CDMO services, and contract analytical testing services to the pharmaceutical, biotechnology, and compounding pharmacy industries. LGM Pharma assists clients in managing all phases of the drug product development process, from API sourcing through to drug product commercialization. Our products and services are essential to the prevention and treatment of a range of diseases and illnesses, including epilepsy, pain, and peptic ulcers. For a complete list of products and indications, see Exhibit A.

LGM Pharma is headquartered in Boca Raton, Florida, with operations throughout the United States. Our Drug Manufacturing Division has plants in Colorado Springs, Colorado; Irvine, California; and Rosenberg, Texas. LGM Pharma's Supply Chain Division operates a warehouse and distribution center in Erlanger, Kentucky. LGM Pharma employs over 200 employees across its U.S. locations. Our operations generate significant economic benefits for local communities and make a major contribution to the development of a skilled U.S. workforce.

2. APIs and the Global Supply Chain

The Department has asked for views on several criteria related to its analysis of whether imports of pharmaceutical and pharmaceutical ingredients impair or threaten to impair national security, including "the extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand;" "the role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients;" "the concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks;" and "the potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over pharmaceuticals supplies."[2]

LGM Pharma imports nearly all of its API from foreign sources, including China and India. In many instances, these API are not available on the U.S. domestic market, or only on a limited or sporadic basis. LGM Pharma's customers rely on our access to these APIs for their manufacturing operations in the United States, and we have built our business model on managing the risks associated with this market reality. Our situation is not unique.

[2] *Sec. 232 Notice*, 90 Fed. Reg. at 15952.

2.1. The Current Importance and Challenge of Foreign Sourcing

The U.S. pharmaceutical industry relies heavily on foreign-produced APIs. Overall, 88 percent of all API manufacturing sites are located outside of the United States.[3] A majority of *large-scale* API facilities are located in only two countries, China and India; only 5 percent are in the United States.[4]

Generic drugs – long considered the "workhorses of the healthcare system" – account for 92 percent of all medications taken by Americans on a daily basis.[5] Manufacturers of generics are particularly reliant on imported APIs. One study estimates that 83 of the top 100 generic medicines used in the United States have no domestic source for the associated API.[6]

U.S. manufacturers often lack alternative sources in the United States in the case of the most important medicines. During the height of the COVID-19 pandemic in 2021, 75 percent of APIs used to manufacture treatments for the lethal virus had no U.S. source.[7] Only 3 percent of the APIs used to produce antivirals are available from the United States (and even then, from one U.S. source only).[8] For antibiotics, the situation is only slightly better – 8 percent of the APIs have a single domestic source, while 92 percent are only available from foreign producers.[9]

To continue manufacturing drugs in the United States, we recognize that at least for the time being, companies will continue to be reliant on foreign sourcing. If the Department were to impose trade restrictions on APIs, U.S. manufacturers would face increased costs of importing raw materials that are essential to making medicines.

2.2. Shortages and Supply Chain Disruptions

The reliance on international supply chains for APIs, as well as finished pharmaceuticals, is one of many factors contributing to drug shortages in the United States. At each stage of manufacture and shipping, any bottlenecks, whether natural or man-made, can interfere with availability and timing of delivery. The longer and more

---

[3] *See* Michael Wall, Seethu Seetharaman & Anthony Sardella, "Revitalizing U.S. Pharma: Evaluating the Economic and Social Impacts of Advanced API Manufacturing in Missouri," Center for Analytics and Business Insights, Olin Business School at Washington University, Sept. 2024, at 4 ("Olin Paper 2024"), *available at* https://olin.wustl.edu/_assets/docs/research/APIIC-EconomicImpactReport.pdf.

[4] *See* API Innovation Center, *Building a Resilient Domestic Drug Supply Chain: The Path to National Security*, Mar. 25, 2025, at 8 ("APIIC White Paper"), *available at* https://apicenter.org/wp-content/uploads/2025/03/APIIC-White-Paper-2025-Building-a-Resilient-Domestic-Drug-Supply-Chain.pdf.

[5] APIIC White Paper at 2.

[6] *See* Olin Paper 2024 at 4.

[7] Anthony Sardella, "The US Active Pharmaceutical Ingredient Infrastructure: The Current State and Considerations to Increase US Healthcare Security," Center for Analytics and Business Insights, Olin Business School at Washington University, Aug. 1, 2021, at 4 ("Olin Paper 2021"), *available at* https://wustl.app.box.com/s/rjo1i7yews99hdr8zeo5fp0u71g47m0i.

[8] *See* Olin Paper 2024 at 4.

[9] *See* Olin Paper 2024 at 4.

complex the supply chain, the more prone is the system to disruptions.[10] In 2024, the drugs listed in short supply climbed to a record-setting 323. This year, that number had already reached 237 by March.[11]

Decisions by foreign governments can have adverse consequences on the supply chains for APIs and pharmaceuticals. At the start of the COVID-19 pandemic, the government of India restricted the export of 24 APIs and drugs.[12] Indian authorities also banned the export of the anti-malarial medicine hydroxychloroquine, which was being used in the treatment of COVID-19. The United States lost immediate access to nearly 50 percent of its source of supply for the drug.[13] Although the Indian trade restrictions were eventually lifted, the actions by the Indian government demonstrate that dependence on foreign sources can lead to sudden supply shocks.

Geopolitical tensions, such as trade wars, also threaten the stability of the global supply of medicines and APIs. The first Trump Administration invoked Section 301 of the Trade Act to impose 25 percent duties on an extensive list of Chinese imports, including many APIs, pharmaceutical chemicals, and other products used in the manufacture of drugs. The initial retaliation list was expanded in 2019, leading to additional duties on inputs into drug production. The current trade war with China has continued to increase the costs to pharmaceutical manufacturers.

3. The State of Global Manufacturing

The Department has asked for the public's views on the possible advantages enjoyed by international manufacturers of pharmaceuticals and APIs, including "the impact of foreign government subsidies and predatory trade practices on United States pharmaceuticals industry competitiveness" and "the economic impact of artificially suppressed prices of pharmaceuticals and pharmaceutical ingredients due to foreign unfair trade practices and state sponsored overproduction."[14] The Department has also inquired as to "the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance."[15]

---

[10] *See* Olin Paper 2021 at 3.
[11] *See* APIIC White Paper at 7. Due to the absence of a uniform list of shortages, numbers may vary depending on the source. For example, the U.S. Food and Drug Administration ("FDA") as of March 2025 listed 99 drugs as in short supply. Most statistics also fail to include supplies that are vulnerable to shortages. *Id.*
[12] *See* "India lifts restrictions on 24 drug exports amid coronavirus," *Times of India*, Apr. 7, 2020, *available at* https://timesofindia.indiatimes.com/business/india-business/india-lifts-restrictions-on-24-drug-exports-amid-coronavirus/articleshow/75020083.cms.
[13] *See* Lisa Du, "India Has Cut Off Half the Supply of a Potential Coronavirus Treatment Touted by Trump," *Time,* Apr. 6, 2020, *available at* https://time.com/5816105/coronavirus-treatment-cut-off-india/.
[14] *Sec. 232 Notice*, 90 Fed. Reg. at 15952.
[15] *Sec. 232 Notice*, 90 Fed. Reg. at 15952.

LGM Pharma is committed to domestic manufacturing and product development. With well over 100,000-square-feet of GMP[16] R&D, pilot plant, and CGMP[17] manufacturing space based in the United States across three states, LGM Pharma is uniquely suited to support reshoring of pharmaceutical outsourcing initiatives. We possess state-of-the-art commercial scale-up facilities and equipment for comprehensive, cost-effective pharmaceutical development and manufacturing, including DEA Class II-V manufacturing, as well as analytical method development and validation and stability studies.

LGM Pharma's Supply Chain Division assists companies in finding low-cost ingredients for the production of pharmaceuticals in the United States. We seek to deliver quality, speed, and supply chain security to our customers. Over the course of several decades, we have acquired in-depth knowledge of the global API marketplace. We understand the forces that have driven offshoring of U.S. production, as well as the efforts that will be required to restore the U.S. supply base. Given the current market dynamics, the Department should understand that there is no "quick fix" to the issue, and that trade restrictions would only exacerbate existing concerns over drug availability and cost.

3.1. Reasons for Offshoring and Foreign Manufacturing

The offshoring of manufacturing of pharmaceuticals and APIs, particularly for generics, has grown significantly over the last 30 years. This migration overseas was matched by the rise of foreign manufacturers, who have benefitted from government subsidies and support.[18]

Countries with a low cost of doing business, like China and India, enjoy a competitive edge in the global marketplace for APIs. One of their key advantages stems from an abundance of cheap and skilled labor. Other factors contribute further to containing costs, including lax enforcement of environmental, intellectual property, and labor laws; lower utility bills and taxes; and cheaper real estate.[19]

Aside from such structural advantages, foreign governments have encouraged the growth of a home-grown pharmaceutical sector. Prime Minister Narendra Modi has

[16] GMP, or Good Manufacturing Practice, refers to FDA regulations that set minimum quality requirements for the manufacture, processing, packaging, labeling, and storage of food, drugs, cosmetics, and other products. Adherence to such regulations minimizes or eliminates the risk of contamination, mix ups, defects, and errors that could be harmful to humans or animals.
[17] CGMP, or Current Good Manufacturing Practice (CGMP). The FDA's CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength as claimed.
[18] *See* APIIC White Paper at 8-9.
[19] *See* Olin Paper 2021 at 7; *see also* "Tariffs and Geopolitics: Developing API Supply Chain Resilience in 2025," LGM Pharma Blog, Feb. 25, 2025, *available at* https://lgmpharma.com/blog/tariffs-api-supply-chain-resilience-in-2025/.

touted his efforts to make India the "pharmacy of the world."[20] Governmental programs are designed to bolster exports and lower the costs of production within India. China likewise has promoted the rise of the pharmaceutical sector through R&D support and other programs to lower input costs.[21]

3.2. The Potential Reshoring of Production Capacity for APIs

Rebuilding a strong domestic base for manufacturing APIs is going to be a rather lengthy process, requiring the mobilization of financial resources and human capital, along with the involvement of both the public and private sectors. LGM Pharma would like to see this investigation result in solutions that help stimulate the reshoring of API and drug manufacturing, provided that the Department recognizes current market realities and adopts pro-growth policies without jeopardizing U.S. businesses, jobs, and the public health. A bad outcome, including the imposition of tariffs on APIs that have no U.S. source, could exacerbate the already fragile supply system and negatively impact drug price and availability.

U.S. manufacturing of APIs has not been able to keep pace with the cost advantages available to overseas producers, who have captured the API market. Of the FDA-approved facilities with the ability to produce 30 or more APIs, only four are located in the United States.[22] By contrast, India has 63 such factories.[23]

Based on our experience, the construction of a new API manufacturing facility in the United States can take, at a minimum, two to three years and cost tens of millions of dollars. Companies must also meet strict regulatory requirements, including FDA and Environmental Protection Agency approvals. The skills gap in the U.S. workforce further constrains the ability of companies to manufacture in the United States.

Innovations in manufacturing may make increased investment in the United States more attractive to investors. Advanced manufacturing technology, including the automation of production processes and 3D printing, could help to drive down costs to producers.[24] The development of continuous manufacturing, which has received FDA support, also presents an opportunity for more efficient production. According to one

[20] Mike Iacovella & 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 ("Iacovella & Toomey"), *available at* https://americanaffairsjournal.org/2024/02/foreign-government-subsidies-and-fda-regulatory-failures-are-causing-drug-shortages-in-the-united-states-heres-how-to-fix-it/#:~:text=This%20crisis%20is%20the%20result,shift%20generic%20drug%20production%20away.
[21] *See* "The Role of China in the Global Generic API Drug Market," *DrugPatentWatch*, Mar. 25, 2025, *available at* https://www.drugpatentwatch.com/blog/the-role-of-china-in-the-global-generic-drug-api-market/ ("*DrugPatentWatch*").
[22] *See* Olin Paper 2021 at 7-8.
[23] *See* Olin Paper 2021 at 8.
[24] *See* Olin Paper 2021 at 6; Olin Paper 2024 at 6.

study, this production process has led to a 30 to 50 percent reduction in the cost of goods sold ("COGS").[25]

LGM Pharma is committed to expanding U.S.-based production in the pharmaceutical sector. This March, we announced an investment of over $6 million to expand our Rosenberg, Texas manufacturing facility as part of its Phase I CDMO growth strategy.[26] The expansion will increase capacity for liquid, suspension, semi-solid, and suppository drug products, a growing market in the United States and Canada.

Aside from new construction, industry could also look to restarting idle production lines. This unused capacity could be repurposed and reactivated with modest financial expenditures.[27] Existing manufacturing facilities are also run by personnel who have years of experience in the pharmaceutical field, and offer a ready-made, highly skilled workforce. Getting existing capacity back online should be a critical component of any reshoring strategy.

4. Recommendations

The Department has asked for views on "the 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."[28] LGM Pharma appreciates the opportunity to help shape the possible outcome of this Section 232 investigation. As we have stated, the concentration of manufacturing in only a few foreign countries, and the concomitant risks to the U.S. pharmaceutical supply chain, raises some legitimate concerns about the country's ability to protect the public health, particularly during times of crisis.

This investigation offers a way for the federal government to join with the private sector, and make a valuable and long-lasting contribution to the future of the U.S. manufacturing base for APIs and drugs. LGM Pharma does not recommend new tariffs, tariff-rate quotas, or outright quantitative restrictions and bans at a time when very few, if any, domestic alternatives are available to us.[29] We and others in this industry already face the increased cost of existing tariffs, including Section 301 duties and the recent tariffs imposed under the International Economic Emergency Policy Act ("IEEPA").

---

[25] *See* Olin Paper 2021 at 6.
[26] For further information about LGM Pharma's investment, *see* "LGM Pharma Invests $6M in U.S. Drug Manufacturing Capabilities for Liquids, Suspensions, Semi-Solids, and Suppositories," LGM Pharma Press Release, Mar. 12, 2025, *available at* https://lgmpharma.com/blog/lgm-pharma-invests-6m-in-u-s-drug-manufacturing-capabilities-for-liquids-suspensions-semi-solids-and-suppositories/.
[27] APIIC White Paper at 12.
[28] *Sec. 232 Notice*, 90 Fed. Reg. at 15952.
[29] If the Department were to recommend tariffs, LGM Pharma urges the Administration to exempt APIs that are not produced, or only produced in limited quantities, in the United States.

Each new duty, when added to others already being imposed, increases costs, and constrains margins, particularly for companies operating in the low-priced generic drug space. Were the Department to adopt quantitative restrictions on APIs, or impose additional and prohibitive tariffs, the supply chain would experience immediate disruptions. U.S. manufacturers, who rely on these API to produce a range of essential and lifesaving pharmaceuticals, would face a shortage of critical ingredients, or would be forced to choose between absorbing cost increases or raising prices.[30] The ultimate loser in this scenario would be the health and well-being of Americans, who already are struggling to deal with drug shortages, the high costs of healthcare, and inflationary pressures. As the well-known adage goes, the cure would be worse than the disease.

The Department should therefore steer clear of blunt and heavy-handed trade actions, and consider instead smart and tailored remedies to address any impairment of national security from imports of pharmaceuticals and APIs. Any solutions should account for the substantial lag time in expanding or building new capacity. LGM Pharma proposes that the Department consider the following recommendations when reaching a final decision in this investigation:

- **Public-private partnerships**: The task of reinvigorating the U.S. supply base for the pharmaceutical and API sector presents many challenges. The objective of reducing dependency on foreign sources, and reversing years of offshoring, will take the combined efforts and resources of government and the private sector. Universities and research institutes should be included as part of any comprehensive strategy.[31] LGM Pharma encourages the U.S. government to take the lead in passing legislation and adopting programs to stimulate investment and government-private sector cooperation. Federal, state, and local governments, in consultation with industry, should help to fund important R&D to spur innovation, improve productivity and competitiveness, and lower costs of production in U.S. plants. The government could likewise provide matching funds for the expansion of existing capacity or the construction of new, state-of-the-art facilities. The government should also foster training programs to improve workers' skills and boost productivity, including apprenticeship and internship placement.

- **Deregulation**: The costs of reshoring U.S. production is hindered by comparatively more onerous regulations than those faced in other countries. Streamlining FDA, EPA, and other approval processes; cutting taxes; and other

[30] President Trump recently issued an Executive Order intended to foster policies that would lower drug prices for Americans. *See* Executive Order 14273 of April 15, 2025, "Lowering Drug Prices by Once Again Putting Americans First," 90 Fed. Reg. 16441 (Apr. 18, 2025). A Section 232 remedy that would increase the price of pharmaceuticals and APIs, particularly generics, would be directly contrary to the goal that the President has set of making medicines more affordable.

[31] One such successful endeavor is the Missouri ICP ("Invest-Contract-Partner") public-private partnership and operating model created by the St. Louis-based API Innovation Center. *See* Olin Paper 2024 at 8.

LGM Pharma
PARTNER SMART.

similar deregulatory measures could lower the cost producing APIs and drugs in the United States. The FDA could also prioritize review of submissions from U.S.-based applicants seeking to produce in the United States. LGM Pharma welcomes the issuance of the recent Executive Order ("EO") on regulatory relief to promote domestic manufacturing of critical medicines.[32] This EO represents an important step towards implementing regulatory reforms hindering production in the United States.

- **Critical shortages list**: The U.S. government should produce a uniform and centralized system for tracking shortages of drugs, particularly for essential medicines. A common list would assist industry and policymakers understand where U.S. vulnerabilities lie, and help to focus resources on the most critical needs first. Such a list is vital for ensuring that resources go to the right places on the proper timeline.

LGM Pharma appreciates this Administration's dedication to resolving the problems associated with overreliance on imported APIs. We remind the Department that while we support the goal of reshoring production, an outcome focused more on stopping imports first, before making the necessary adjustments to the U.S. market, would do harm to public health by increasing costs, limiting availability, and hurting U.S. producers reliant on foreign API.

Thank you again for consideration of our views and recommendations. We look forward to working with the Department, and the rest of the Trump Administration, to find workable and durable solutions to the nation's dependency on imported APIs and other pharmaceutical products.

Sincerely,

Hamilton J. Lenox
Electronically signed by: Hamilton J. Lenox Reason: Author Date: May 7, 2025 12:29 EDT

Hamilton J. Lenox
Chief Commercial Officer

Shailesh Vengurlekar
Electronically signed by: Shailesh Vengurlekar Reason: Author Date: May 7, 2025 12:22 EDT

Shailesh Vengurlekar
Senior V.P. - Quality & Regulatory Affairs

[32] *See* Executive Order on Regulatory Relief to Promote Domestic Production of Critical Medicines, May 5, 2025, *available at* https://www.whitehouse.gov/presidential-actions/2025/05/regulatory-relief-to-promote-domestic-production-of-critical-medicines/.