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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 Endo USA, Inc.

Dear Secretary Lutnick:

I. Introduction and Executive Summary

Endo, Inc. and its U.S. operating company Endo USA, Inc. (collectively "Endo") appreciates the opportunity to submit comments in connection with the above-captioned Section 232 investigation regarding imports of pharmaceuticals and pharmaceutical ingredients.[1]

- Endo, a U.S. domiciled corporation, employs approximately 1,300 skilled professionals in the U.S., including approximately 600 employees in Michigan, Pennsylvania, New Jersey and New York in the manufacture of branded, sterile injectable and generic medications, including biologic XIAFLEX® (collagenase clostridium histolyticum), and life-saving hospital products ADRENALIN® (epinephrine injection, USP) and VASOSTRICT® (vasopressin injection, USP).

[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*").

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- The U.S. Departments of Defense and Health and Human Services have partnered with Endo in an over $120 million project at the company's Rochester, Michigan facility to expand the product inspection, bulking, filling and packaging capacities as well as sterile fill-finish manufacturing services in support of the U.S. Government's national defense efforts to produce critical medicines for pandemic preparation.

- Endo's Rochester, Michigan operations in particular, employing approximately 500 workers, depend on reliable access to active pharmaceutical ingredients, excipients and components (collectively "API") which are overwhelmingly sourced outside of the U.S. The domestic supply of API is far from adequate to meet the demand of Endo's U.S. facilities, let alone all pharmaceutical manufacturers in the U.S. Tariff barriers limiting access to API would lead to drug shortages and would present a viability risk for U.S. manufacturers.

- Access to API imports is critical for the national security of the U.S. and the health of its citizens. The government should not inhibit its own investments in the national defense by restricting access to essential import supplies of API.

If the Department of Commerce were to recommend trade restrictions on pharmaceuticals as a result of this Section 232 investigation, it should:

- Exclude imports of API at least temporarily, if not indefinitely, to allow for the multi-year investments in domestic manufacturing capacity to take place. At a minimum, it should exempt government contract partners and Veterans Administration hospital suppliers from tariffs on imports of API for products manufactured in the U.S.

- More importantly, the Department should recommend deregulation and tax incentives to promote domestic sourcing of Key Starting Materials ("KSM") and API manufacturing over the course of the next four to five years.

II. About Endo

Endo is a diversified pharmaceutical company focusing on developing and delivering medical therapeutics, specifically in the areas of urology, orthopedics, and endocrinology, and sterile injectables for hospitals and health systems, along with generics. These products are complex in nature and require unique expertise, skilled labor, technology, and equipment.

Endo employs approximately 1,300 skilled workers in the U.S. including approximately 600 involved in manufacturing across multiple sites: Cranbury, New Jersey; Horsham, Pennsylvania; Rye, New York, and Rochester, Michigan. Endo has corporate offices in Woodcliff Lake, New Jersey, and its global headquarters in Malvern, Pennsylvania.

As a U.S.-based manufacturing organization with expertise in life-saving sterile injectables, Endo produces products efficiently with cutting-edge equipment (much of it manufactured outside the U.S.) and essential highly trained employees, all in compliance with quality standards and regulatory requirements. Additionally, Endo's biologic product XIAFLEX is made almost entirely in the U.S., with bulk drug substance produced in Horsham, Pennsylvania.

III. Endo's National Defense Partnership with the U.S. Government

For over 100 years, Endo's Rochester, Michigan facility has produced medicines for people suffering from tetanus, gangrene, diphtheria, rabies, and smallpox, among other diseases. This facility was one of just three to produce and distribute the life-saving polio vaccine in the 1950s, then stepped up again in 2020 to make products treating critical COVID-19 patients and provide fill-finish manufacturing services for one of the vaccine candidates. In 2021, the U.S. Department of Defense signed a fill-finish manufacturing agreement with Endo to support national defense efforts in the production of critical medicines for future pandemic preparedness. This was the first contract awarded in the Department's concerted effort to reinforce domestic essential medicine production, to secure and strengthen the U.S. supply chain for critical medicines as a proactive step in future pandemic preparedness. Under the terms of the agreement, the U.S. Government provided funding to establish a new sterile fill-finish manufacturing asset at Endo's Rochester facility, and to provide expanded product inspection, processing and packaging capacity. Administration of the agreement was transferred to the Department of Health and Human Services in 2023.

IV. APIs and the Global Supply Chain

Endo's Rochester facility, in particular, being dedicated to sterile fill-finish manufacturing services, depends on API, excipient and component imports that are not readily available in the U.S. 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 U.S. demand for pharmaceuticals and pharmaceutical ingredients;" and "the concentration of U.S. imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks."[2]

Endo imports nearly all of its API from foreign sources. In many instances, these API are not available on the U.S. domestic market, or only on a limited or sporadic basis. Endo's customers rely on our access to these API. Our situation is not unique.

The U.S. pharmaceutical industry relies heavily on foreign-produced APIs. Overall, 88 percent of all API manufacturing sites are located outside of the U.S.[3] A

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

[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

majority of large-scale API facilities are located in only two countries, China and India, where KSM are available. Only 5 percent of API manufacturing facilities are in the U.S.[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] Like other manufacturers of generics, Endo by necessity relies on imported APIs. One study estimates that 83 of the top 100 generic medicines used in the U.S. have no domestic source for their API.[6]

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

Pharmaceutical excipients, which are critical components in drug formulations, are predominantly sourced from countries like India, China, and the European Union. U.S. producers are struggling to keep up with the demand for excipients. Global pharmaceutical excipients market is expected to reach USD 9.78 Billion by 2025, at a compound annual growth rate of 5.93% from 2018 to 2025. At that rate of growth, it is not feasible domestic producers to be the exclusive producers of the ingredients required for the formulation and delivery mechanism of the medication.

Tariff barriers restricting access to APIs and excipients would lead to drug shortages and present viability risks for U.S. manufacturers. The costs of these tariffs, especially if they were in the range of 25% as automobile, aluminum and steel Section 232 tariffs have been, would increase the costs of some drugs beyond what could be passed on to patients. U.S. drug manufacturers would have to make very difficult choices about which product lines to offer and may have to rationalize or reduce the products they can afford to produce. This cost compression for U.S. manufacturers would inhibit their ability to reinvest in their companies, which is critical for research, for developing new drugs, new formulations of existing drugs and for improving patient

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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.

outcomes. Rising costs, limitations on product lines, stagnation in reinvestment and R&D would be a disastrous combination of factors for the viability of U.S. manufacturing.

These risks would present a grave concern for the handful of domestic manufacturers of sterile, injectable products. There are very few U.S. manufacturers like Endo who make life-saving sterile, injectable products in the U.S. Intensive care units during the COVID crisis absolutely depended on the ability of these manufacturers to meet massive, surging demand for products like VASOSTRICT® and ADRENALIN®. Medicines like these are too important to be put at risk.

V. The Potential Onshoring of Production Capacity for APIs

With respect to "the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance,"[10] Endo supports policies to grow domestic manufacturing and product development as they presumably would diversify the company's supply chain sources. However, Endo does not believe that the solution for essential inputs in short supply is to further limit that supply until the demand side of the market collapses or new supply emerges. 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. These concerns would inhibit the U.S. Government's interest in ensuring there is enough capacity for sterile fill-finish manufacturing to meet the challenges of another pandemic.

Building a strong domestic base for manufacturing API will be a lengthy process, requiring the mobilization of financial resources and human capital, along with the involvement of both the public and private sectors. The U.S. Government needs to adopt pro-growth policies without jeopardizing the public health in the short and medium term.

The construction of a new API manufacturing facility in the U.S. can take, at a minimum, two to three years and cost tens of millions of dollars. Companies also must meet strict regulatory requirements, including FDA and Environmental Protection Agency approvals.

Government support for innovations in manufacturing may make increased investment in the U.S. more attractive to investors. Advanced manufacturing technology, including the automation of production processes and 3D printing, could help to drive down costs to producers.[11] The development of continuous manufacturing, which has received FDA support, also presents an opportunity for more efficient production. According to one study, this production process has led to a 30 to 50 percent reduction in the cost of goods sold ("COGS").[12]

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[10] *Sec. 232 Notice*, 90 Fed. Reg. at 15952.
[11] *See* Olin Paper 2021 at 6; Olin Paper 2024 at 6.
[12] *See* Olin Paper 2021 at 6.

VI. Department of Commerce 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."[13] The API concern (as it is for excipients and components) is a limitation of options for supply. Tariffs and quotas on pharmaceuticals can only limit further options for supply. The ultimate losers in that scenario would be the health and well-being of Americans, who already are struggling to deal with drug shortages (over 120 sterile injectables are already experiencing shortage),[14] the high costs of healthcare, inflationary pressures, and of critical importance to Endo, the hundreds of U.S. manufacturing jobs that we have in Michigan, Pennsylvania and elsewhere that depend on imports to fill the gap in U.S. supply.

The Department should not impose tariffs on pharmaceuticals. U.S. manufacturers like Endo will need to access imports of pharmaceuticals for a minimum of four to five years to allow for the multi-year investments in domestic manufacturing capacity to take place. Moreover, the Department should not impose tariffs on imports by government contract partners or on imported products supplied to Veterans Administration hospitals as such tariffs would be an inefficient and counterproductive tax on government purchases.

The federal government should join with the private sector to make a valuable and long-lasting contribution to the future of the U.S. manufacturing base for life-saving drugs.

- **Public-private partnerships**: The objective of growing domestic supply 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.[15] Endo encourages the U.S. government to pass legislation and adopt 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 growth of U.S. production is hindered by onerous U.S. regulations. Streamlining FDA, EPA, and other approval processes; cutting taxes; and other similar measures could lower the cost of producing APIs, excipients and components in the U.S. The FDA could also prioritize review of

[13] *Sec. 232 Notice*, 90 Fed. Reg. at 15952.
[14] ASHP active drug shortage report as of April 2025
[15] 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.

submissions from U.S.-based applicants seeking to produce in the U.S. Endo welcomes the issuance of the recent Executive Order ("EO") on regulatory relief to promote domestic manufacturing of critical medicines.[16] This EO represents an important step towards implementing regulatory reforms hindering production in the U.S.

- **Critical shortages list**: The U.S. government should produce a uniform system of tracking shortages of drugs, API, excipients and components, particularly for essential medicines. A common list would assist industry and policymakers to 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.

Endo appreciates the Administration's interest in resolving the problems associated with limitations on domestic pharmaceutical production. Thank you for consideration of our views and recommendations.

Sincerely,

Alexander A. Nikas

Vice-President and Asst. General Counsel, Global Commercial Operations and R&D

Endo USA, Inc.

[16] *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/