

May 7, 2025

Mr. Eric Longnecker
Deputy Assistant Secretary for Technology Security
Bureau of Industry and Security
U.S. Department of Commerce
Washington, DC 20230

RE: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (Docket No. 250414-0065)

Dear Deputy Assistant Secretary Longnecker,

On behalf of the National Retail Federation ("NRF") and pursuant to the Federal Register notice published by the Bureau of Industry and Security, Office of Strategic Industries and Economic Security, U.S. Department of Commerce regarding the above-referenced investigation, we are submitting the following written comments regarding the important role retail plays in ensuring consumers have adequate access to affordable medications and related products, and the likely impacts that policies that would raise the costs of these products would have on American families.

# I. <u>Introduction</u>

NRF passionately advocates for the people, brands, policies and ideas that help retail succeed. Retail is the nation's largest private-sector employer, contributing \$5.3 trillion to annual GDP and supporting one in four U.S. jobs — 55 million working Americans. NRF empowers the industry that powers the economy. For over a century, NRF has been a voice for every retailer and every retail job, educating, inspiring and communicating the powerful impact retail has on local communities.

Our members include those who provide consumers with ready access to affordable prescription and over-the-counter medications. Even before COVID, but certainly since, this segment of retailing has seen a number of changes and pressures that have challenged (for many retailers) their very ability to continue operations. We offer a summary of those pressures and describe how imperative it is to have steady and reliable supplies of pharmaceuticals to meet our customers' needs. We then discuss the certain impact that some proposed policy options would have on our customers — and on our industry.

### II. Pharmaceutical Market Dynamics

A variety of retailers sell pharmaceuticals to American families. They include chain pharmacies like CVS and Walgreens, mass retailers like Walmart and grocery chains like Giant and Safeway, independent pharmacies, and mail order and online pharmacies. Retailers sell prescription medications and generic pharmaceuticals. Census data for pharmacy and drug store NATIONAL RETAIL FEDERATION

sales show strong growth over the last five years: sales in 2024 at \$379 billion were 32.6% higher than sales in 2019. A 2023 analysis by McKinsey & Company estimates that retail chains account for the largest number of prescriptions (filling an estimated 138,000 prescriptions per location per year), followed by mass retailers and grocers (91,000 prescriptions per location per year), independent pharmacies (48,000 prescriptions per location per year), and online retailers (per location Rx data are not available). It is important to note that generic and biosimilar prescriptions account for 90% of prescriptions filled in the United States, and account for only 17.5% of the country's spending on prescription drugs. It is also noteworthy that the U.S. government through Medicare and Medicaid is a major purchaser of pharmaceuticals, with purchases accounting for 41% of total value of drug purchases in 2019.<sup>2</sup>

Even in the face of strong consumer demand for medications, the retail pharmacy sector is facing several cost pressures that have resulted in a number of store closings in recent years. A National Community Pharmacists Association found that 30.3% of independent pharmacists are considering closing their businesses in 2025 because of financial pressures. Large retail chains like CVS, Walgreens and Walmart are struggling in the face of declining margins due to reimbursement pressures, changes to pharmacy benefit manager practices, rising operational costs (including staffing shortages) and shifting market conditions; Walgreens has been forced to close a number of stores.



Source: U.S. Census Bureau

McKinsey & Co., "Meeting changing consumer needs: The US retail pharmacy of the future," March 17, 2024, <a href="https://www.mckinsey.com/industries/healthcare/our-insights/meeting-changing-consumer-needs-the-us-retail-pharmacy-of-the-future">https://www.mckinsey.com/industries/healthcare/our-insights/meeting-changing-consumer-needs-the-us-retail-pharmacy-of-the-future</a>.

U.S. Department of Health and Human Services, Office of Inspector General, "Drug Spending," December 16, 2024, https://oig.hhs.gov/reports/featured/drug-spending/.

National Community Pharmacists Association, "NCPA to CMS: A Third of Independent Pharmacies Won't Carry Drugs in the Negotiated Price Program, and 60 Percent More are Considering Dropping Out," January 27, 2025, <a href="https://ncpa.org/newsroom/news-releases/2025/01/27/ncpa-cms-third-independent-pharmacies-wont-carry-drugs-negotiated">https://ncpa.org/newsroom/news-releases/2025/01/27/ncpa-cms-third-independent-pharmacies-wont-carry-drugs-negotiated</a>.

## III. The Pharmaceutical Supply Chain

The U.S. pharmaceutical supply chain is global, and this is actually a good thing. A fully or even largely domestic supply chain for pharmaceuticals is no less vulnerable to disruptions than a global chain. U.S. production disruptions can arise due to breakdowns in machinery or natural disasters, to name just a few recent examples.

- After Hurricane Maria devastated Puerto Rico in 2017, a global hub for insulin production, the U.S. faced widespread shortages. Millions of diabetics were affected until the FDA expedited approvals for alternative manufacturing facilities.
- The 2023 shortage of Cisplatin, a vital chemotherapy agent, was fueled by manufacturing delays stemming from equipment malfunctions at key production sites, including manufacturing facilities in North Carolina. The impact was significant, with many oncology centers facing delays in treatment schedules, forcing some patients to switch to alternative therapies.
- Hurricane Helene in 2024 shut down Baxter International's facility in Marion, N.C., due to severe flood damage. The facility supplies 60% of intravenous (IV) solutions to U.S. hospitals. This resulted in a nationwide shortage of IV fluids, forcing hospitals to delay surgeries and ration supplies.

Having multiple options, including international options for obtaining APIs and finished drugs, ensures not just more reliable supplies of pharmaceuticals but competition which helps to limit price increases. While increasing domestic supply around the United States, but not limiting import supply, would be helpful to alleviating local domestic production disruptions, such increases are highly capital-intensive (including building up a trained labor pool) and will take time to complete. Moreover, changing API sources is a lengthy process requiring finished dose manufacturers to test the new API and confirm that it is safe and compliant for their processes. Typically introducing a new API supplier takes 12-15 months, not including time for regulatory approval. It is also a costly process, and, as a result, most price-sensitive generic medicines have only 1 to 2 qualified API sources. Access to imported pharmaceutical products at affordable costs should be assured during this process.

### IV. U.S. Trade Policy Options: Potential Impacts

There are a number of policy options available to support reshoring of API and domestic pharmaceutical production short of tariffs, which would be very harmful to American consumers who depend on life-saving therapies — and even to the U.S. government, a huge buyer of pharmaceuticals through Medicare and Medicaid as noted above. These options include speeding the process for FDA approval of new drugs and new sources of API, reform of the reimbursement policy, and easing of regulatory complexities.

Efforts should also include incentives and investments that encourage diversification of the supply chain and partnering with geographically diverse manufacturers, not just within the United States but including suppliers in other countries. Congress should also appropriate

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adequate funding to support the efforts of the Administration for Strategic Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA), and other relevant agencies. While the government has focused on increasing supply chain resilience for pharmaceuticals deemed critical for the acute care of patients, including sterile injectable medications, there also must be a commitment to foster a resilient, robust supply of pharmaceuticals dispensed by retail pharmacies. As noted above, retail pharmacies dispense billions of prescriptions and over-the-counter medications. These drugs are essential for the treatment of common illnesses, severe illnesses and chronic conditions, such as diabetes mellitus and chronic obstructive pulmonary disease (COPD).

Tariffs would only increase costs and therefore prices. This would not be wise policy given the already-razor thin margins pharmacies face, which would force them to pass all cost increases on to customers. Moreover, if the cost of pharmaceuticals increases above the level that reimbursement will cover, many pharmacies will have to make choices not to carry some items or close their doors. Patients will no longer have access to certain medications. Should the administration insist that tariffs are necessary, policymakers should set up a process to consider exclusions, especially where domestic production is non-existent today.

## V. Conclusion

Imposing tariffs on pharmaceuticals without any exclusions will increase costs for generic and brand drug importers, which is likely to increase the price of drugs for pharmacies and their patients. This can have a disastrous impact on public health. Pharmacies, already operating on razor thin margins, will feel an immediate impact.

Pharmacies will be impacted with initial carrying costs of purchasing drugs at a higher price and likely will have to lower safety stock for product on hand that could cause filling delays and pharmacy closures, negatively impacting patients. If the cost of some pharmaceuticals increases above the level that reimbursement will cover the drug, many pharmacies will have to make choices not to carry some items or close their doors. This will be exacerbated by the existing low reimbursement environment from PBMs already putting pressure on pharmacies and creating closures. Patients will no longer have access to certain medications. This will result in increased patient visits to the emergency department, increasing costs for the health care system.

If you have any questions, please contact me or Jonathan Gold, NRF's Vice President for Supply Chain and Customs Policy (goldj@nrf.com).

Sincerely,

David French

Executive Vice President, Government Relations