TRADE ALLIANCE
to Promote Prosperity

Official Comments Submitted to the U.S. Department of Commerce

RE: Request for Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

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On behalf of the Trade Alliance to Promote Prosperity and our stakeholders across the U.S., I respectfully submit the following comments regarding proposed tariffs on pharmaceutical imports. We urge the Department of Commerce and relevant trade authorities to **exempt from any new tariffs the medicines and pharmaceutical ingredients that Americans rely on**, particularly those originating from European countries with long-standing trade and diplomatic ties to the United States, including Ireland, Switzerland, and the United Kingdom.

Overview

The pharmaceutical supply chain is a tightly interwoven global network that has developed over decades, enabling timely access to high-quality, safe, and effective medicines for millions of Americans. While a significant portion of U.S.-consumed pharmaceuticals are manufactured domestically, a considerable share depends on **active pharmaceutical ingredients (APIs)** and **finished products** sourced from European countries. These sources are not easily substituted, and the complexity of biotech manufacturing makes abrupt shifts in supply not only impractical but dangerous and potentially deadly.

Applying tariffs to these critical imports will **disrupt supply chains**, **increase drug prices**, **strain public health budgets**, and **limit patient access** to life-saving treatments. For these reasons, medicines and their components have long been treated as **exceptions in trade conflicts**, and we strongly urge the continuation of this precedent.

1. Tariffs Will Disrupt the Pharmaceutical Supply Chain

The United States is home to a robust pharmaceutical manufacturing sector, including nearly 1,600 domestic factories producing approximately half of all brand-name drugs used by American patients. However, these domestic operations are deeply dependent on international supply chains—particularly those in Europe—for essential raw materials, active ingredients, and in some cases, entire finished products.
For example:

- Approximately **33% of all APIs used in U.S. medicines** are sourced from Europe.
- **Ireland alone exports $41 billion worth of pharmaceutical products to the United States**, making it a cornerstone of the American drug supply.
- Some **specialized drugs**, such as advanced biologics and orphan drugs, are available only from European manufacturers due to their proprietary technology, rare ingredients, or unique regulatory status.

Pharmaceutical manufacturing is among the most capital- and time-intensive industrial sectors. Constructing a compliant facility capable of producing commercial-scale drugs can take **8–10 years** and cost upwards of **$2 billion**. These facilities must meet stringent FDA regulations and be certified for Good Manufacturing Practices (GMP), further limiting the speed with which production could be shifted domestically.

In short, **there are no short-term alternatives** to European suppliers. Attempting to re-source pharmaceutical products quickly—at any price—is not a realistic option and would almost certainly lead to shortages, delays, and compromised patient care.

2. Tariffs Will Increase Costs for Patients, Companies, and Taxpayers

According to trade data, the United States imported **$128 billion in pharmaceutical products** from Europe in 2023. A 25% tariff on these products would represent an **immediate and significant cost increase** of **more than $30 billion annually**, which would ultimately be passed along to:

- **Patients**, through higher out-of-pocket costs and reduced insurance coverage;
- **Employers**, in the form of rising premiums and benefit costs;
- **Government programs**, such as Medicare, Medicaid, and the VA, all of which are major purchasers of prescription drugs.

This tariff-induced inflation comes at a time when **more than half of Americans already report difficulty affording their medications**, and **67% believe healthcare affordability is the nation's most pressing issue**. Imposing tariffs on essential medicines will only exacerbate this crisis, disproportionately impacting vulnerable populations such as the elderly, low-income families, and those living with chronic or rare diseases.

Moreover, higher drug prices due to tariffs would **inflate federal healthcare spending**, undermining long-standing efforts to reduce costs in programs like Medicare Part D. These additional expenditures would either need to be absorbed through increased taxes, borrowing, or cuts in other areas of public health spending.

3. Medicines Are Not Consumer Luxuries—They Are Medical Necessities

It is vitally important to recognize that **prescription drugs are not discretionary consumer goods**. Unlike electronics, cars, or luxury food products, patients do not "shop around" for medicines. Drug therapies are prescribed by healthcare providers based on a patient's specific medical diagnosis, history, and biological profile. For many patients, there is **only one appropriate treatment**—and it may well be manufactured exclusively in Europe.

Medicines are also subject to rigorous FDA oversight and clinical validation, which means that even when alternatives do exist, switching from one approved drug to another can require new clinical trials, regulatory reviews, and updated treatment protocols—none of which can be achieved quickly or without cost.

For these reasons, **American and international trade policy have historically treated pharmaceuticals as exceptions to tariff regimes**. The United States has long adhered to tariff exemptions for medicines in its trade relationships with the European Union, the United Kingdom, Switzerland, and Japan, all of whom likewise reciprocate this policy. This mutual exemption ensures that patients never become **collateral damage** in geopolitical or economic disputes.

4. Exemptions Are the Responsible Path Forward

Given the stakes for patient health, national healthcare costs, and pharmaceutical innovation, we believe a **broad exemption for all pharmaceutical products and their components**—including APIs, intermediates, and finished formulations—should be included in any final tariff decisions involving European goods.

Failing to do so would:

- Disrupt access to critical therapies for millions of Americans;
- Drive up drug prices and national healthcare expenditures;
- Introduce new barriers for U.S. pharmaceutical manufacturers who depend on global ingredients;
- Set a dangerous precedent that weaponizes medical products in trade disputes.
- Conversely, a tariff exemption would:
- Ensure continuity in care for patients across the United States;
- Protect U.S. pharmaceutical jobs and manufacturing operations that rely on global imports;
- Reinforce America's commitment to humanitarian principles in international trade;
- Preserve goodwill and strategic cooperation with key European allies.

The Bottom Line

Medicines are not like other imports. They are essential goods, tied directly to the health and well-being of the American people. The United States has long held a bipartisan commitment to ensuring that patients are protected from geopolitical shocks and market disruptions in the pharmaceutical space. That commitment must be reaffirmed now.

We respectfully urge the U.S. Department of Commerce to maintain this position by explicitly **exempting all pharmaceutical products and ingredients** from any proposed tariffs. The consequences of failing to do so will be borne not by policymakers or industry actors, but by the millions of Americans who rely on timely, affordable access to life-saving medications.

Sincerely,

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