Alliance for Pharmacy Compounding

Compounding the Joy of Living®

April 30, 2025

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

Re: XRIN 0694-XC120, on Section 232 National Security Investigation of Pharmaceutical Imports

Dear Secretary Lutnick,

On behalf of the Alliance for Pharmacy Compounding, I appreciate the opportunity to provide input on the Department of Commerce's Section 232 investigation into the national security implications of pharmaceutical imports. As the voice of over 5,000 compounding professionals representing independent pharmacies and outsourcing facilities nationwide, APC is committed to ensuring that patients have access to safe, effective, and affordable medications.

Compounded medications play a vital role in our domestic healthcare system by addressing gaps in the drug supply chain that traditional manufacturers do not fill. These medications are prepared by state-licensed pharmacies to meet the specific needs of individual patients, particularly when FDA-approved drugs are unavailable or when, in the judgement of a prescriber, there is no commercially available drug appropriate for a particular patient's needs. This personalized approach is not a loophole in law and FDA guidance; it is intentional policy that ensures continuation of care and that patients receive the most appropriate treatment for their unique medical conditions.

While much of the active pharmaceutical ingredient (API) used in compounded medications is manufactured offshore by FDA-registered manufacturers, compounding pharmacies rely on these imported APIs to serve their patients effectively. U.S.-based compounding pharmacies and outsourcing facilities are locally owned, independent businesses that play an essential economic role by providing jobs and supporting the local tax base. Tariffs on APIs will increase costs for domestic compounding pharmacies. These cost increases will, in many instances, raise the prices American patients must pay for their compounded medications. Compounding pharmacies are integral to the communities they serve, offering personalized healthcare and ensuring that patients have access to critical medications that may not be available through traditional commercial

channels. These businesses are not only vital to patient care but also contribute significantly to economic stability and growth in their regions, reinforcing the local economy and the wellbeing of their communities.

Furthermore, outsourcing facilities operating under Section 503B of the Federal Food, Drug, and Cosmetic Act are subject to stringent FDA oversight, including compliance with current good manufacturing practices (CGMP). These facilities are integral to the U.S. drug supply chain, providing larger-scale compounded medications to hospitals and clinics when commercial products are in short supply.

Given the essential role of compounded medications in patient care and the domestic nature of the compounding pharmacy industry, APC urges the Department of Commerce to consider the unique contributions of this sector when evaluating the national security implications of pharmaceutical imports. According to a recent U.S. Pharmacopeia report, 85% of APIs used in prescription medicines come from foreign sources. Many of these APIs cannot be sourced domestically and imposing tariffs or other restrictive measures on pharmaceutical imports could inadvertently disrupt the supply of critical medications and undermine the capacity of compounding pharmacies to meet patient needs.

We appreciate the Department's efforts to ensure a secure and resilient pharmaceutical supply chain and stand ready to collaborate in any way that supports these objectives while safeguarding patient access to essential compounded medications.

Thank you for considering our comments.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer