

Aaron Broadwell, MD
President

May 5, 2025

Gary Feldman, MD
Immediate Past President

Eric Longnecker
Deputy Assistant Secretary, Technology Security
Bureau of Industry and Security
Department of Commerce
1401 Constitution Avenue NW
Washington, D.C. 20230

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1401 Constitution Avenue NW
Washington, D.C. 20230

Erin Arnold, MD
Director

Leyka Barbosa, MD
Director

Kostas Botsoglou, MD
Director

Re: Public Comments on Section 232 National Security Investigation of Imports on Pharmaceuticals and Pharmaceutical Ingredients (BIS-2025-0022/XRIN 0694-XC120)

Mark Box, MD
Director

Michael Brooks, MD
Director

Dear Deputy Assistant Secretary Longnecker and Director Astle:

Amish Dave, MD, MPH
Director

The Coalition of State Rheumatology Organizations (CSRO) would like to express concerns regarding the Department's consideration of potential tariffs on imported pharmaceutical products and pharmaceutical ingredients. CSRO serves the practicing rheumatologist and is comprised of over 40 state rheumatology societies nationwide with a mission of advocating for excellence in the field of rheumatology and ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease.

Harry Gewanter, MD, MACR
Director

Adrienne Hollander, MD
Director

Robert Levin, MD
Director

Rheumatologic diseases, such as rheumatoid arthritis, psoriatic arthritis and lupus, are systemic and incurable, but innovations in medicine over the last several decades have enabled rheumatologists to better manage these conditions. With access to the right treatment early in the disease, patients can generally delay or even avoid damage to their bones and joints, as well as reduce reliance on pain medications and other ancillary services, thus improving their quality of life.

Amar Majjhoo, MD
Director

Gregory Niemer, MD
Director

Tariffs Increase Patient Out-of-Pocket Costs

Joshua Stalow, MD
Director

CSRO shares the administration's concerns over the out-of-pocket costs imposed on patients with chronic conditions and has been a vocal advocate in advancing policies that help alleviate that financial burden. Many rheumatologic patients are prescribed specialty drugs for chronic conditions after trying and failing all available lower cost alternatives. Because our patients have comorbid conditions, they often take other medications for their non-rheumatologic conditions as well. We are deeply concerned that imposing tariffs, leading to increased cost of prescription drugs in the United States (U.S.), will decrease adherence, resulting in loss of control of our patients' rheumatologic diseases and their comorbid conditions, as well. Patients may spend months or years of trial and error, working with their physician to find a treatment regimen that properly manages their condition.

EXECUTIVE OFFICE

Leslie Del Ponte
Executive Director

When faced with higher out-of-pocket costs, patients often abandon their treatment plan, which can lead to disease progression, flare ups, increased steroid use, and even loss of effectiveness of their original therapy if eventually restarted. Managing the results of non-adherence to their medication requires the use of substantially more resources than allowing for continuity of care from the start.

We are deeply concerned that imposing tariffs may exacerbate challenges to maintaining continuity of care by increasing the cost of prescription drugs in the United States. Approximately forty percent of prescription drugs are manufactured outside of the United States.ⁱ We are skeptical that tariffs on these prescription drugs will be absorbed by others within the pharmaceutical supply chain and will instead be passed on directly to patients. This will be particularly burdensome for patients prescribed complex and expensive specialty medications as well as those patients who pay cost-sharing, instead of a fixed copay, for their prescription medications.

Furthermore, rheumatologists cannot simply choose to place a patient on a U.S. made medication instead of one that is imported from another country. Regardless of what a rheumatologist deems appropriate based on the patient's clinical factors and relevant clinical guidelines, patients are restricted to therapies available on pharmacy benefit formularies, which control access and prefer certain medications over others. PBMs have historically selected higher priced drugs for their formularies when there are manufacturer rebates and fees that they can profit from. These tariffs are unlikely to deter PBMs from preferring higher priced medications, causing premiums to increase as health plans spend more on prescription medications and cost-sharing for patients to go up based on higher list-prices.

Tariffs May Worsen Provider Reimbursement for Office-Administered Drugs

Many rheumatologists directly administer biologic products to patients at their in office infusion suits. These practices are typically engaged in “buy and bill,” whereby the practice pre-purchases drugs and bills the health plan for reimbursement once the medication is administered to a patient. Margins for practices engaged in buy and bill are thin. To maintain the viability of administering drugs in outpatient settings – which are often more cost-effective settings for the payer and safer for immunocompromised patients – reimbursement must account for acquisition costs, such as intake and storage, equipment and preparation, staff, facilities, and spoilage insurance.

Currently, most health plans reimburse providers for the cost of the medication plus an add-on payment at a bundled rate. This reimbursement methodology for Medicare Part B drugs is typically calculated based on the Average Sales Price (ASP) plus six percent, with some exceptions, to account for acquisition costs. The ASP is a market-based price that considers the weighted average of all manufacturer sales prices for the drug, including rebates and discounts.

Tariffs would commensurately increase the ASP for medications manufactured abroad as well as those that rely on ingredients from other countries, compounding this problem. There is a two-quarter lag between the time the ASP calculation takes place and the effective date of the ASP provider payment limits.ⁱⁱ This means that provider reimbursement would not be adjusted for six months after price increases caused by tariffs on Part B drugs go into effect, resulting in under-reimbursement for the higher acquisition costs of provider administered medications.

Reimbursement rates that do not sufficiently compensate for Part B drugs put rheumatology practices – arguably the safest and most cost-effective setting for administration of physician-administered drugs – at risk. CSRO urges the administration to hold healthcare providers harmless from any tariffs on drugs and medical supplies or equipment. If tariffs are imposed, the administration must ensure that those additional costs are factored in the associated payment methodologies, as physician practices have no means in the current fiscal climate to absorb additional costs. This is particularly critical as physicians have taken financial hits in Medicare payment of 33% over the last 20 years,ⁱⁱⁱ and Medicare’s physician fee schedule

remains untethered to any measure of inflation, such as the Medicare Economic Index (MEI), which also does not consider the tariffs that have been enacted since the rate setting or those added throughout the year. We urge the administration to thoughtfully address these disparities in provider reimbursement if tariffs are enacted.

Rheumatologists and our practice partners are on the front lines and manage complications when a patient is unable to afford their medication, which is why patient drug affordability is a top priority for CSRO. However, we are highly concerned that tariffs on pharmaceutical products and their ingredients may exacerbate patient out-of-pocket costs and financially cripple provider reimbursement for administered medications. We respectfully urge the administration to maintain the current tariff-free trade of pharmaceutical products and their ingredients to protect patient access to essential medications. We thank you for your consideration and are happy to further detail our comments to upon request.

Respectfully,



Aaron Broadwell, MD, FACR
President
Board of Directors



Madelaine A. Feldman, MD, FACR
VP, Advocacy & Government Affairs
Board of Directors

ⁱ The Petrie-Flom Center – Health Law Policy, Biotechnology and Bioethics at Harvard Law School. “[Who’s Gonna Pay? The Impact of Tariffs on Pharmaceutical Products](#),” April 2025.

ⁱⁱ Centers for Medicare & Medicaid Services. “[Average Sales Price \(ASP\) Quarterly Publication Process Frequently Asked Questions](#),” January 2025.

ⁱⁱⁱ American Medical Association. “[Medicare physician payment continues to fall further behind practice cost inflation](#),” January 2025.