May 6, 2025

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

Re: ***Comments Regarding DOC's Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, Docket Number 250414-0065***

Below are comments of the American Conservative Union Foundation's (d/b/a. Conservative Political Action Coalition Foundation) (hereinafter "CPAC Foundation") Center for Regulatory Freedom (hereinafter "CRF"), and the Coalition Against Socialized Medicine, a project of the Conservative Political Action Coalition (hereinafter "CASM") on the U.S. Department of Commerce's (DOC) request for feedback regarding the Bureau of Industry and Security's Office of Strategic Industries and Economic Security's "National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, Docket Number 250414-0065, published in the Federal Register on April 16, 2025.

CRF is a project of the CPAC Foundation, a non-profit, non-partisan 501(c)(3) research and education foundation. Our mission is to inject a common-sense perspective into the regulatory process, to ensure that the risks and costs of regulations are fully based on sound scientific and economic evidence, and to ensure that the voices, interests, and freedoms of Americans, and especially of small businesses, are fully represented in the regulatory process and debates. Finally, we work to ensure that regulatory proposals address real problems, that the proposals serve to ameliorate those problems, and, perhaps most importantly, that those proposals do not, in fact, make public policy problems worse.

CASM is a project of CPAC, and represents a broad alliance of organizations dedicated to defending the free-market principles that underpin America's healthcare system. CASM stands firmly against government overreach, including efforts to implement centralized healthcare models, impose price controls, or eliminate private insurance. Instead, it champions policies that promote innovation, protect intellectual property, and increase competition by reforming anti-competitive practices. The coalition advocates for market-driven solutions that expand access to care, increase the supply of healthcare professionals, and deliver better outcomes for patients and taxpayers alike. Above all, CASM seeks to preserve the values of choice, competition, and innovation in American healthcare while exposing and opposing the creeping encroachment of socialized medicine in all its forms.

We respectfully submit the following comments in response to the Department of Commerce's Section 232 national security investigation into pharmaceutical imports. We strongly urge the Department to exempt pharmaceutical products and active pharmaceutical ingredients (APIs) from any prospective tariffs. Our comments address five core concerns with the investigation: 1) the expedited timeline and insufficient stakeholder engagement; 2) the overlap with existing trade measures; 3) the threat to global pharmaceutical supply chains; 4) the overbroad scope of the investigation; and 5) the risk of retaliatory measures and global trade disruption.

****Please note, there is an addendum at the end of these comments addressing issues related to the imperative to extend or otherwise re-open the comment period regarding this investigation, due to confusion arising from a discrepancy between the Federal Register Notice and Regulations.Gov regarding the closing date of the comment period.****

Introduction

The United States stands at a critical intersection of national security, public health, and international economic policy. In an increasingly complex and interdependent global landscape, efforts to safeguard our pharmaceutical supply chains must be pursued with precision, care, and a clear understanding of unintended consequences. As the Department of Commerce undertakes its Section 232 investigation into pharmaceutical imports, it is imperative that any resulting policy decisions are grounded in evidence, respect longstanding international partnerships, and protect the American public from harm.

These comments are being submitted to provide constructive insight into the risks posed by imposing tariffs or other trade barriers on pharmaceutical products and their components. While we share the Department's commitment to ensuring resilient and secure access to life-saving medicines, we are deeply concerned that the current Section 232 process—as applied to this

sector—may result in serious, avoidable harm to patients, healthcare providers, and the broader economy.

Our comments reflect both a principled defense of free-market healthcare and a practical understanding of pharmaceutical logistics. We believe that true national security lies not in isolating our health system from global partners, but in fostering the conditions that promote innovation, affordability, and uninterrupted access to care. We urge the Department to weigh these considerations carefully and to refrain from applying measures that would do more to destabilize than to defend.

I. Expedited Timelines and Limited Stakeholder Engagement

The current Section 232 process has been characterized by an unusually accelerated timeline that severely limits meaningful public engagement. While the statute allows for a 270-day investigation period, many stakeholders, including those in the life sciences sector, were only provided a narrow window to submit comments. Further compounding the issue, the absence of any public hearing process has prevented dialogue with the affected communities, medical professionals, and patients who rely on uninterrupted access to life-saving treatments.

Pharmaceutical supply chains are complex and highly specialized. As such, thoughtful, well-informed commentary requires coordination across manufacturers, distributors, healthcare providers, patient advocates, and regulatory experts. A rushed process strips away the opportunity for this necessary input. Importantly, it also limits public understanding of how tariffs would ripple through our health system—especially at a time when over half of Americans already report difficulty affording their prescriptions, and 67% cite healthcare affordability as a top national concern.

In matters as consequential as national health security, policymaking must not be rushed. Hastily imposing tariffs without full vetting of downstream effects invites significant disruption to public health infrastructure, erodes trust in regulatory processes, and risks avoidable harm to American patients. We strongly urge the Department to extend the comment period, host public hearings, and engage in substantive dialogue with pharmaceutical supply chain stakeholders before issuing any report or recommendations.

II. Overlap with Other Trade Measures Leading to Complexity and Confusion

This Section 232 investigation does not occur in a vacuum. Rather, it unfolds amid a broader landscape of trade actions, including reciprocal tariffs imposed under the International Emergency Economic Powers Act (IEEPA). Certain pharmaceutical products and ingredients,

initially exempt from these IEEPA-related tariffs, are now subject to scrutiny under this new investigation.

The simultaneous application of overlapping authorities injects substantial uncertainty into pharmaceutical trade planning and investment decisions. Life sciences companies face increasing compliance burdens as they navigate an evolving and unpredictable regulatory regime, often without clarity on timelines, tariff scope, or enforcement priorities.

Adding pharmaceutical imports to the Section 232 framework—a tool traditionally reserved for steel, aluminum, and defense-related inputs—signals a dramatic shift in U.S. trade policy. It imposes additional bureaucratic and cost burdens on an industry that is already subject to rigorous regulatory oversight and international coordination. The confusion is amplified by the threat of retrospective action: companies that made long-term procurement decisions in good faith could suddenly face new import taxes on already-contracted medicines.

We urge the Department to coordinate closely with the Office of the United States Trade Representative and other relevant agencies to ensure alignment across trade policy instruments. If the Section 232 process proceeds, the Department must clarify how it intends to reconcile any tariffs imposed under this investigation with existing trade obligations and prior exemptions.

III. Potential Disruption to Critical Supply Chains of both Traditional Medicines and Biosimilars

Pharmaceutical supply chains are uniquely intricate, globalized, and inflexible. Approximately one-third of all active pharmaceutical ingredients used in U.S.-consumed medications are sourced from European Union member states. Furthermore, many high-value, low-volume specialty medicines are exclusively manufactured in EU countries with strong regulatory standards and long-standing alliances with the United States.

These medicines and ingredients cannot simply be replaced or resourced domestically. Building a pharmaceutical manufacturing facility in the U.S. can take up to ten years and cost upwards of $2 billion. Moreover, many of the EU-based compounds used in U.S. medicine production are not currently manufactured anywhere in the United States. There is no viable "onshore" substitute at any price.

The United States imported $128 billion in pharmaceutical products from Europe in 2023. Ireland alone exported $41 billion worth of drugs to the U.S., making it one of the most vital partners in American medicine supply. Disrupting this flow would delay production and distribution, compromise inventory stability, and severely harm patient access to treatments. Introducing tariffs into this system would create chaos. Medicines with tight production

schedules and storage constraints would be delayed. U.S. manufacturers relying on EU-sourced inputs would face rising costs and regulatory bottlenecks. And patients—particularly those requiring rare or biologic treatments—could face life-threatening interruptions in care.

The Department must consider that tariffs on pharmaceutical imports will not enhance national security. Instead, they will undermine the resilience and functionality of our existing pharmaceutical ecosystem. Any policy that impairs the delivery of vital medicines to American patients is a threat to public health, not a defense against foreign aggression.

In evaluating the potential effects of tariffs on pharmaceutical imports, it is crucial to recognize the distinct and increasingly vital role that biosimilars play in the U.S. healthcare system. Biosimilars offer lower-cost, highly effective alternatives to originator biologics, expanding patient access to life-saving treatments for conditions such as cancer, autoimmune disorders, and chronic diseases. Their growth has been instrumental in reducing healthcare spending while enhancing therapeutic choice. However, many biosimilars—especially those used in oncology and immunology—rely on complex international manufacturing networks and are frequently sourced from allies such as the EU, the UK, and South Korea.

Imposing tariffs on biosimilars or their components would threaten to reverse the progress made in expanding affordability and access, deterring market entry, discouraging investment, and ultimately driving up costs for payers and patients. We therefore urge the Department to specifically exempt biosimilars and their active ingredients from any Section 232-related tariffs. Doing so would safeguard a key strategy in America's effort to lower prescription drug costs and preserve competitive innovation in biologics.

IV. Broad Scope of Investigations Raising Concerns

The scope of this Section 232 investigation is expansive and ill-defined. It captures not only finished pharmaceutical products, but also precursor compounds, APIs, and potentially medical devices. The breadth of the inquiry exceeds any reasonable interpretation of what constitutes a direct national security concern.

This overreach creates a chilling effect across industries that depend on pharmaceutical inputs or operate within the broader healthcare ecosystem. It also raises the specter of cascading trade restrictions affecting countless downstream users—ranging from hospitals and pharmacies to clinical researchers and contract manufacturers.

Such a vast and vague investigation increases the risk of regulatory overreach and miscalculation. We recommend that the Department narrowly tailor its investigation to actual

national security threats and exclude from consideration any products that are not directly relevant to national defense or emergency preparedness.

V. Risk of Retaliation and Trade Disputes

Finally, we caution that unilateral tariffs on pharmaceutical imports from close allies, including EU member states, risk provoking retaliation and escalating trade tensions. The EU, Switzerland, the United Kingdom, and Japan—key pharmaceutical exporters to the U.S.—are longstanding partners in global health cooperation and innovation.

For decades, the U.S. and these partners have agreed not to impose tariffs on most pharmaceutical products, precisely to avoid turning patients into collateral damage in trade disputes. Disrupting this consensus undermines trust, violates longstanding norms, and signals to adversaries that even medicine is fair game in geopolitical disputes.

Tariff impositions under Section 232 would likely be challenged at the World Trade Organization (WTO), and could prompt retaliatory duties on U.S. exports. Such actions would not only harm U.S. pharmaceutical companies with global operations but also erode the spirit of international collaboration that underpins our shared health security.

These trade disputes could destabilize pharmaceutical R&D networks, slow clinical trial cooperation, and limit cross-border regulatory harmonization—each of which is essential to responding to global health threats. In a post-pandemic world, where pandemic preparedness and medical coordination are paramount, erecting barriers to pharmaceutical trade is dangerously shortsighted.

Conclusion

The imposition of tariffs on pharmaceutical imports under the Section 232 framework would represent a profound and misguided intervention in the American healthcare system. The investigation's accelerated timeline, redundant overlap with other trade tools, potential to disrupt supply chains, excessive scope, and likelihood of retaliation all point to a policy path that would do far more harm than good.

Pharmaceuticals are not luxury goods. They are essential elements of public health and national well-being. Patients cannot "buy American" when their lives depend on medicines manufactured in Ireland, Switzerland, or Germany. Trade policy must recognize that pharmaceuticals are not interchangeable commodities but complex, highly regulated therapies developed and delivered through years of collaboration, innovation, and trust.

We therefore respectfully urge the Department of Commerce to exempt all pharmaceutical products and ingredients from any Section 232 tariffs. To do otherwise would endanger American lives, burden our health system, and isolate the United States from its allies at a time when solidarity is most needed.

Please do not hesitate to reach out if you have any questions. My email is ALanger@mail.conservative.org.
Sincerely,

Andrew Langer
Director
Center for Regulatory Freedom

Executive Director
Coalition Against Socialized Medicine

****ADDENDUM****

After the final draft of this comment was completed, it came to the attention of CRF and CASM that there is a discrepancy between the Federal Register Notice regarding this investigation and the corresponding portal on Regulations.gov. In the Federal Register, the listed due date was Wednesday, May 7, 2025, while according to Regulations.Gov, the comments were due today, Tuesday, May 6, 2025. At some point on the afternoon of May 6, this discrepancy was initially corrected – with the deadline on Regulations.gov moved to the afternoon/evening of May 7. Then, later on in the afternoon of May 7, the dead was moved *yet again*, this time to 1:59AM EDT on 5/7/25.

This is unacceptable, especially within the context of an already-compressed time frame. Given the serious repercussions throughout the economy and the impact on public health arising from the possibility of tariff impositions in this economic sector, further short-changing of the opportunity for the regulated community and the public at large to offer their comments on such an important matter stands four-square against the entire "notice and comment" structure that undergirds the regulatory process in the United States.

Given the mistake on the part of the Federal Government (and regardless of whose fault it is), this alone should justify pausing this proceeding and re-opening it for public comment.

Thank you.