Subject: MC2 Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients
Docket No. BIS–2025–0022 | XRIN 0694–XC120

To the Bureau of Industry and Security:

On behalf of the **Medical Countermeasures Coalition (MC2)**, we appreciate the opportunity to provide comments on the Department of Commerce's Section 232 investigation into the national security implications of pharmaceutical and pharmaceutical ingredient imports.

MC2 represents a broad and mission-driven coalition of twenty biopharmaceutical companies, academic institutions, and nonprofit organizations dedicated to strengthening the nation's preparedness and response capabilities through the development and deployment of **medical countermeasures (MCMs)**—products used to prevent, diagnose, or treat diseases related to chemical, biological, radiological, or nuclear (CBRN) threats. As such, our comments focus exclusively on issues relevant to national security and public health preparedness, distinct from broader market access or pricing concerns traditionally associated with the commercial pharmaceutical sector.

Strategic Context

Over the past two decades, repeated biological incidents—from the anthrax attacks post-9/11 to the COVID-19 pandemic and the ongoing risk of mpox and avian influenza—have underscored the **centrality of medical countermeasures to national security**. These products often have a **limited commercial market**, often rely on sustained public-private partnerships, and require government engagement to support advanced development, procurement, and surge manufacturing.

A resilient and secure supply chain for MCMs—including domestic availability of active pharmaceutical ingredients (APIs), key starting materials (KSMs), and fill-finish capabilities—as well as a stockpile of finished products ready for rapid deployment, is not merely an economic concern; it is a **matter of strategic defense**. The U.S. cannot afford to rely on adversarial nations or fragile global supply chains for the production and supply of life-saving countermeasures in the event of deliberate attack or emerging infectious disease.

Unlike many commercial pharmaceuticals, for MCMs the choice is often not between imported or domestic pharmaceuticals, but between domestically developed and produced medical countermeasures or no countermeasures at all.

However, the nature of MCMs demand a more activist, industrial policy to truly protect America. Because MCMs are most needed in public health crises, like pandemics, MCMs are especially susceptible to export controls from foreign suppliers. But because

the quantity of MCMs needed to safeguard the country is small relative to the entire commercial market for medical products, achieving a secure MCM supply chain is unusually important and feasible.

Key Recommendations

1. **Differentiate Strategic Medical Countermeasures from Commercial Pharmaceuticals**
   We urge BIS to consider the unique characteristics and national security relevance of MCMs in any findings or recommendations. Many MCMs are **developed, stockpiled, and deployed under government-led programs** like BARDA, Project BioShield, and the Strategic National Stockpile (SNS). They must be treated differently than general drug imports in the formulation of trade remedies or industrial base policies

2. **Support Domestic Industrial Base Expansion for MCMs**
   The United States must invest in a **distributed and sustainable domestic manufacturing base** for countermeasures. This includes API and KSM production capacity, as well as advanced fill-finish and cold chain logistics for biologics. MC2 supports efforts by ASPR, BARDA, and the Office of Industrial Base Expansion (OIBX) to increase domestic capacity and reduce reliance on foreign sources. With consistent support for these central programs, new strategically important manufacturing lines could be ready within 24-36 months. Implementation of trade barriers, if any, should be phased in to allow American manufacturers to procure essential materials.

   American industry and manufacturers have always benefited from the import of critical supplies and components from our closest allies and trading partners. We recommend that our North American and European partners be exempted from any new pharmaceutical tariffs or trade restrictions.

3. **Ensure Coordination with Public Health Preparedness Agencies**
   Any policies stemming from the Section 232 process should be developed in coordination with HHS/ASPR, BARDA, and CDC to avoid disruption of government-led preparedness programs. A Section 232 finding should **strengthen—not fragment—the public-private ecosystem** that has enabled the rapid development of 70+ FDA-approved MCMs.

4. **Prioritize Platform Technologies and Stockpile Readiness**
   Investments should support platform technologies that enable rapid manufacturing of vaccines, therapeutics, and diagnostics. Any reshoring strategies should be linked to **strategic stockpile planning and 100-day MCM readiness goals**, ensuring production is surge-ready in the face of a public health emergency. This means aligning domestic manufacturing

capacity with surge production needs and ensuring that materials, fill-finish capabilities, and workforce pipelines are in place before the next public health emergency strikes. Supply chain resilience is not just an economic imperative—it is a core component of national security.

Conclusion

The Medical Countermeasures Coalition supports the Administration's efforts to examine the vulnerabilities in the pharmaceutical supply chain through the lens of national security. We urge the Department to recognize that medical countermeasures occupy a **unique, security-focused space within the broader pharmaceutical landscape**.MCMs are not commercial commodities—they are mission-driven assets developed to protect the nation from chemical, biological, radiological, and nuclear threats. Any policies or remedies resulting from this investigation must be designed to strengthen, not disrupt, the specialized public-private partnerships and procurement frameworks that underpin our biodefense infrastructure. Applying blanket trade remedies without this distinction risks undermining U.S. preparedness and weakening our ability to respond to future national emergencies.

Policies developed as a result of this investigation should support our nation's biodefense infrastructure, rather than disrupt it through overly broad remedies that fail to distinguish MCMs from the rest of the pharmaceutical market. We look forward to collaborating with the administration on our shared goal of securing U.S. biosecurity and MCM independence. Thank you for the opportunity to support the administration and its work to rebuild American manufacturing.

Thank you for your consideration.

Sincerely,
Taylor B. Sexton
Executive Director
Medical Countermeasures Coalition
www.medicalcountermeasures.org