To whom it may concern,

BioPhorum and offer of support

My organization, BioPhorum (www.biophorum.com), is offering its support. As the largest collaboration space for biopharmaceutical manufacturing, we have over 150 members, including ~75 major biopharma companies (like Pfizer, GSK, Amgen, AstraZeneca, Merck) and ~75 key suppliers (like Thermo Fisher Scientific, Merck Millipore, Cytiva, Sartorius), all with global and US manufacturing and commercial presence.

Given that many of these companies have manufacturing facilities in the USA, we can offer valuable insights for the 232 investigation into global biopharmaceutical manufacturing and US capabilities. It's important to understand that biopharmaceutical production differs significantly from traditional pharmaceutical manufacturing processes involving small molecules or chemical synthesis.

Context for the relevance of the 'Bio' - part of the Pharmaceutical Manufacturing Industry

In 2024, approximately 1.8 billion units of biologic drugs were manufactured in the USA, including monoclonal antibodies, vaccines, and biosimilars. The economic contribution of these biologics to the USA was around $450 billion. This reflects their importance in healthcare and advancements in biomanufacturing technologies.

Raw materials for biologics often originate from agriculture (animal and vegetable) and minerals, sourced globally. Plastics and plastic components used in production also come from global supply chains.

Areas of support to the scope of the 232 investigation

I have conducted a preliminary assessment of the scope of the 232 investigation and have identified in the attached file the sections where BioPhorum could contribute to the investigation and subsequent report, based on the document as notified.

Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

https://www.federalregister.gov/documents/2025/04/16/2025-06587/notice-of-request-for-public-comments-on-section-232-national-security-investigation-of-imports-of

It is advised that if you wish to receive public comment on the following areas:

The Department is particularly interested in comments and information directed at the criteria listed in § 705.4 of the regulations as they affect national security, including the following:

(i) the current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States;

(ii) the extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand;

(iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients;

(iv) the concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks;

(v) the impact of foreign government subsidies and predatory trade practices on United States pharmaceuticals industry competitiveness;

(vi) the economic impact of artificially suppressed prices of pharmaceuticals and pharmaceutical ingredients due to foreign unfair trade practices and state-sponsored overproduction;

(vii) the potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over pharmaceuticals supplies;

(viii) the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance;

(ix) the impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security; and

(x) any other relevant factors.

The areas highlighted in the attached file are the primary areas where BioPhorum members could collaborate as an industry to provide data and insights to support the investigation. Additional areas may be identified. There are likely other relevant factors (point 'x' in the scope) that should be considered.

BioPhorum track record for reference

BioPhorum has supported public consultations by the US FDA and EPA, provided educational support to Senators and Congress representatives on regulatory impacts, and shared socio-economic insights related to biopharmaceuticals. We've done similar work with the European Commission and Chemicals Agency and have collaborated with BARDA on industry resilience and diversification during COVID. We are interested in supporting the 232 investigation.

Opportunity to support the 232 investigation beyond the 7th May 2025

We believe that BioPhorum has relevant insights to offer when the 232 investigation is ready to engage with the biopharmaceutical industry. However, the deadline of May 7th for providing information related to areas of interest to the US Department of Commerce is too short for meaningful contributions from our members. We propose additional opportunities to provide such support over the extended duration of the 232 investigation (subject to confirmation of the 270-day timeline starting April 1, 2025 - or clarification of the actual closing date).

We request your agreement that BioPhorum would be an appropriate organization to support the needs of the 232 investigation, or at least play a role in contributing informed perspectives from both US and global viewpoints. This will help ensure that post-investigation decisions are beneficial for both US citizens and the global community.

We invite representatives involved in the 232 investigation to discuss this offer further with myself and my colleague Tori Crawford, our Regulatory and External Partnership Manager, along with representation from our members if necessary. Please let us know if this is of interest so we can coordinate arrangements with the investigation team.

Yours sincerely,

Bob Brooks, PhD

Phorum Director

BioPhorum Supply Resilience