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SUBMITTED ELECTRONICALLY

Ms. Diane Farrell
Deputy Under Secretary for International Trade
Department of Commerce
1401 Constitution Ave NW
Washington, DC 20230

PUBLIC DOCUMENT
ITA-2022-0001

Re: Request for Comments on the Indo-Pacific Economic Framework, 87 Fed. Reg. 13971 (March 11, 2022)

Dear Ms. Farrell:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this opportunity to provide the following comments in response to the request for comments by the U.S. Department of Commerce ("Commerce"). As a general matter, PhRMA and its members welcome the proposed development of an Indo-Pacific Economic Framework (IPEF) to deepen trade relations between the United States and countries throughout this region.

PhRMA member companies are devoted to inventing, manufacturing, and distributing valuable medicines that enable people to live longer, healthier, and more productive lives. The U.S. biopharmaceutical industry is the world leader in medical research – producing more than half the world's new molecules in the last decade. As a key component of America's high-tech economy, the research-based biopharmaceutical sector supports over 4.4 million jobs across the economy, including more than 900,000 direct jobs, and contributes more than $1.4 trillion in economic output on an annual basis when direct, indirect, and induced effects are considered.[1]

Our sector also continues to be one of the most research-intensive and export-intensive in America, annually investing an estimated $122.2 billion in researching and developing new medicines.[2] With the right policies and incentives in place at home and abroad, our member companies can continue to bring valuable new medicines to patients around the world. In 2021, U.S. biopharmaceutical goods exports exceeded $80 billion.[3] The biopharmaceutical sector was the largest exporter of goods among the most R&D-intensive industries in 2020 – which in

[1] TEConomy Partners for PhRMA, The Economic Impact of the U.S. Biopharmaceutical Industry: 2020 National and State Estimates, Mar. 2022.

[2] Research!America, U.S. Investments in Medical and Health Research and Development, Jan. 2022.

[3] TradeStats Express™: National Trade Data for NAICS Code 3254 Pharmaceuticals and Medicines, available at http://tse.export.gov/TSE/TSEHome.aspx.

addition to biopharmaceuticals included navigational equipment, semiconductors and other electronic components, medical equipment and supplies and communications equipment.[4]

The proposed IPEF has the potential to deepen economic and diplomatic ties between the United States and countries in this important region and serve as a catalyst for increased trade and engagement with other countries. Increased trade and investment links between the United States and the Indo-Pacific region would provide critical incentives for American innovators to research and develop new products and to make those inventions available to patients around the world.

U.S. biopharmaceutical manufacturers and their employees rely on predictable and transparent regulatory, intellectual property (IP) and pricing and reimbursement policies that support innovation ecosystems to produce valuable new medicines for patients. These policies are fundamental to innovation, providing necessary incentives for the discovery of new treatments and cures, and to sustaining continued economic growth and job creation in the United States.

With regard to some of the more specific negotiating objectives identified by Commerce in its Federal Register notice, please find below our initial perspectives on four topics: (1) general negotiating objectives for the proposed agreement; (2) digital and emerging technologies-related issues; (3) supply chain resilience; and (4) other measures or practices which undermine fair market opportunities for U.S. workers.

I. General Negotiating Objectives for the IPEF

PhRMA supports comprehensive trade agreements that open new markets, create high-paying American jobs, increase economic growth for both the United States and its trading partners, incentivize the invention and production of lifesaving medicines, and enable U.S. biopharmaceutical innovators to export those medicines to patients around the world.

PhRMA therefore encourages Commerce to negotiate an IPEF agreement that is as comprehensive and ambitious as possible and that includes strong IP protections and predictable and transparent market access, regulatory and other provisions that dismantle unfair trade barriers, incentivize innovation and facilitate the manufacturing and distribution of lifesaving medicines and other IP-intensive products.

As the United States seeks to expand its trade agenda throughout the Indo-Pacific, Commerce first must ensure that countries in that region are honoring existing international commitments and that longstanding trade barriers in those countries – including barriers identified by USTR in its Special 301 and National Trade Estimate Reports – are prioritized for elimination. Resolving these and similar trade issues should constitute a foundation for the IPEF. To this end, as potential partners under IPEF are announced, PhRMA would appreciate the opportunity to identify specific measures or practices that should be resolved in those countries before IPEF negotiations initiate.

[4] Analysis of National Science Foundation and Business Research and Development Survey (BRDIS) data by ndp | analytics.

II. Digital and Emerging Technologies

Issues concerning the digital economy play a critical role in biopharmaceutical innovation. Digital trade, data, data usage and international data flows are essential components of biopharmaceutical research, development, manufacturing and delivery. For example, digital health technology tools, such as mobile devices, wearables and sensors, enable decentralized clinical trials that can offer flexibility in how data are collected from clinical trial participants, allow sponsors to design more patient-centric drug development studies, improve research efficiency, reduce barriers to trial participation and support more diversity in clinical trials. These components also enable digital therapeutics and patient adherence technologies. In particular, a vibrant digital economy and open digital trade are essential to the following key stages of biopharmaceutical innovation:

- **Research and development (R&D)**: Digital trade enables biopharmaceutical manufacturers to access large, multi-country health data sets and genomic data to make timely, rapid and informed R&D decisions; optimize clinical trial design and enrollment and conduct multiregional clinical trials; and secure regulatory approvals in multiple countries.

- **Manufacturing**: Digital trade facilitates the manufacturing of finished biopharmaceuticals, including compliance across borders with good manufacturing practices (GMP) and other regulatory requirements.

- **Delivery**: Digital trade promotes the development and use of innovative cross-border payments systems, digital therapeutics operations and patient adherence technologies.

- **Pharmacovigilance**: Digital trade is essential to monitoring, identifying and responding across borders to any health-related impacts from biopharmaceuticals.

Sound public policies that encourage open digital trade practices related to the above stages of biopharmaceutical innovation increase digitally enabled trade in life-enhancing biopharmaceuticals and improve global public health. Conversely, government measures that discourage or restrict digital trade adversely impact biopharmaceutical innovation and, as a result, impede domestic and global advancements in patient care and economic growth.

The innovative biopharmaceutical industry therefore encourages the United States and its IPEF partners to negotiate a high-standard agreement that eliminates digital trade barriers that discourage innovative biopharmaceutical R&D, manufacturing, delivery and pharmacovigilance. **Specific policy recommendations to eliminate digital trade barriers include the following:**

- **Prohibit unnecessary data localization requirements and other restrictions on cross-border data flows**. Barriers to the cross-border movement of data and digital health services and products often take the form of provisions that (i) directly or indirectly prohibit a company from exporting any or certain types of data beyond a country's geographic border; (ii) require a company to store within a national territory data that the company stores or intends to store abroad, resulting in duplicative practices and

significant resource diversions; and/or (iii) other conditional restrictions that prohibit or impede a company's ability to transfer data beyond a geographic border (e.g., sending data to a regional data center for storage or to a third-party vendor for processing). Restrictions, if any, on data flows should be transparent, implemented clearly, developed based on input from all stakeholders, and only as restrictive as necessary.

- **Prohibit forced technology transfers**. The practice of requiring foreign companies to share sensitive technologies or proprietary data with domestic companies as a condition of doing business in a local market is a considerable barrier to trade that can have a significant negative impact on companies engaged in digital commerce. Any transfer of technology related to biopharmaceutical research, development, manufacturing or delivery should be voluntary and occur on market-based terms. Requirements to disclose source code, algorithms, trade secrets or other intellectual property assets to a government or local entity should be prohibited.

- **Prohibit and, where necessary, eliminate digital tariffs**. As the global digital economy flourishes, many governments are assessing how to impose customs duties on electronic transmissions. Given the increasing digitalization of the biopharmaceutical industry, such duties could significantly impede trade of digitally enabled products such as digital therapeutics and 3D printing. IPEF partners should reaffirm the World Trade Organization moratorium on customs duties on electronic transmissions and commit to seek to build on that moratorium in bilateral and global fora.

- **Establish appropriate legal and governance frameworks** to address access to and exchange of health data regarding health care research, delivery, policymaking and regulatory activities.

III. Supply Chain Resilience

PhRMA and its member companies are committed to protecting the safety and continuity of biopharmaceutical supply chains to ensure patient access to medicines, therapeutics, and vaccines. Diverse global supply chains are key to ensuring continuity and resilience in the supply of medicines to the American people. Diversity across biopharmaceutical supply chains reduces the potential impact of disruptions that result from natural disasters or other public health emergencies. Indeed, despite unprecedented logistical challenges and demand surges, the United States has not experienced significant supply shortages for innovative biopharmaceuticals during the COVID-19 pandemic. This is a testament to the resilience, diversity and effectiveness of the industry's existing global supply chains, and underscores the importance of maintaining strong ties with trusted trading partners.

Manufacturers of innovative medicines have implemented robust practices and processes to avoid major disruptions in their supply chains. These include inventory management systems that track, assess, and estimate supply and demand and allow manufacturers to continuously monitor their supply and distribution lines to ensure sufficient supply, anticipate risk and avert significant disruptions. Companies also as standard practice put in place risk management plans

that may include alternate manufacturing sites, inventory reserves and/or a range of global external suppliers and logistics planning to ensure continuity of supply.

Nevertheless, the COVID-19 pandemic has underscored the need for resilient and diverse supply chains. In its May 2021 "Rome Declaration", the G20 highlighted "the importance of open, resilient, diversified, secure, efficient and reliable global supply chains across the whole value chain related to health emergencies."[5] The September 2021 G20 Health Declaration similarly noted the need to "enhance resilience and rapid scalability of the supply chain at a global level in a coordinated manner, and support expanding local and regional health goods manufacturing capacities."[6] The proposed IPEF offers an important opportunity to build on the lessons learned from the ongoing pandemic to further strengthen supply chain resilience and better prepare for future challenges. This includes developing a framework of areas in which the United States and its partners in the Indo-Pacific region could bolster biopharmaceutical supply chains to prepare for future global health challenges, as well as strengthen trade and investment. Parties to the agreement must avoid policies that could weaken supply chain resilience or disrupt supply chains through overburdensome requirements. Specific proposals include:

- **Leverage regional manufacturing infrastructure to support expanding vaccine and therapeutics research and development (R&D) and production capacity as part of overall pandemic preparedness and supply chain resilience initiatives**. Countries within IPEF should align on shared priorities and government programs or policies aimed at enhancing capabilities to prevent, detect and respond to future infectious disease and other threats.

- **Facilitate the free movement of pharmaceuticals and inputs and other health care items, as well as key personnel, particularly during global public health emergencies.** IPEF partners should identify and align on global policies to facilitate trade in biopharmaceuticals, including through pursuing and supporting initiatives at the World Trade Organization designed to eliminate trade barriers. Such policies should include:

    - Eliminating tariffs, export restrictions and other trade barriers on biopharmaceuticals, their inputs and related supplies, and improving trade facilitation and customs procedures.
    - Establishing policies and mechanisms to identify and address health care supply constraints, e.g., designating a single point of contact within each government to share information and act concerning supply chain constraints and related issues.
    - Strengthening regulatory cooperation and capacity building, including by sharing best practices, leveraging existing regulatory harmonization efforts, and designing and implementing capacity building programs, as appropriate.

[5] Global Health Summit: The Rome Declaration (May 21, 2021), available at https://www.governo.it/sites/governo.it/files/documenti/documenti/Approfondimenti/GlobalHealthSummit/GlobalHealthSummit_RomeDeclaration.pdf.
[6] Declaration of the G20 Health Ministers, Rome (Sep. 6, 2021), available at http://www.g20.utoronto.ca/2021/210906-health.html.

- Agreeing to prioritize, during global public health emergencies, transport of biopharmaceuticals and their inputs; designate biopharmaceutical employees, vendors and suppliers as essential workers; facilitate necessary travel of key industry employees to facilitate R&D and production.

- **Strengthen cybersecurity capabilities and infrastructure and use of existing collaborative mechanisms to address cyberthreats to health systems and supply chains.** IPEF countries increase and strengthen collaboration regarding combatting cyberattacks, facilitating cybercrimes enforcement and sharing relevant intelligence and best practices.

IV. Other Measures or Practices Which Undermine Fair Market Opportunities for U.S. Workers

U.S. biopharmaceutical workers face a variety of trade barriers in multiple Indo-Pacific countries that significantly impede the invention, manufacturing and distribution in those countries of medicines. To address these issues, and to ensure that IPEF meets its long-term potential, PhRMA encourages the establishment of a Medicines Working Group (MWG) that commits IPEF governments to regular, frequent and sustained engagement on issues of importance to biopharmaceutical research, innovation and distribution – including implementation of IPEF commitments. The MWG should include both regular dialogues among IPEF governments, as well as regular dialogues among IPEF governments, industry and other stakeholders. Through such engagement, IPEF partners could strengthen biopharmaceutical trade initiatives and deepen biopharmaceutical regulatory cooperation, thereby advancing economic growth, spurring further biopharmaceutical innovation and improving global health outcomes.

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In summary, PhRMA and its members strongly support the promise of ambitious IPEF negotiations to address meaningful global economic challenges. We thank you for the opportunity to provide these comments and look forward to being an active stakeholder throughout the negotiations.

Sincerely,

/s/

Douglas Petersen
Deputy Vice President, International Advocacy