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July 8, 2022

SUBMITTED ELECTRONICALLY

Mr. William Shpiece
Chair of the Trade Policy Staff Committee
Office of the U.S. Trade Representative
600 17th Street, N.W.
Washington, DC 20508

PUBLIC DOCUMENT
USTR-2022-0005

Re: Request for Comments on Proposed U.S.-Taiwan Initiative on 21st-Century Trade, 87 Fed. Reg. 34745 (June 7, 2022)[1]

Dear Mr. Shpiece:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this opportunity to provide the following comments in response to the request for comments. As a general matter, PhRMA and its members welcome the proposed U.S.-Taiwan Initiative on 21st-Century Trade to deepen trade relations between the United States and Taiwan.

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.[2] In 2020, 37 percent of U.S. biopharmaceutical industry employees were engaged in manufacturing at over 1,500 manufacturing plants across the country, nearly 35 percent were engaged in biopharmaceutical research and development (R&D), 25 percent were engaged in distribution and 3 percent were engaged in corporate administration.

Our sector also continues to be one of the most research-intensive, manufacturing-intensive and export-intensive in America, annually investing an estimated $122.2 billion in researching and developing new medicines.[3] 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.[4] The

[1] Per the subsequent notice issued on June 10, it was clarified that the deadline for comments is July 8, 2022. Request for Comments on Proposed U.S.-Taiwan Initiative on 21st-Century Trade; Correction, 87 Fed. Reg. 35591 (June 10, 2022).

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

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

[4] U.S. Census. USA Trade: Foreign Trade Data by HS Code.

biopharmaceutical sector was the largest exporter of goods among the most R&D-intensive industries in 2020 – which in addition to biopharmaceuticals included navigational equipment, semiconductors and other electronic components, medical equipment and supplies and communications equipment.[5] The U.S. biopharmaceutical industry also is among the top five employers of U.S. manufacturing jobs, with more Americans directly employed in pharmaceutical manufacturing than in manufacturing in several other manufacturing industries, including each of the following: iron and steel products, aerospace products and parts, petroleum and coal products, and electric equipment and appliances.[6]

The proposed initiative has the potential to deepen economic ties between the United States and Taiwan and to establish strong baselines from which to build in future U.S. trade initiatives. 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. To facilitate engagement on these policies, PhRMA encourages the establishment of a Medicines Working Group (MWG) that allows for regular, frequent and sustained outreach between the two governments and industry to resolve issues of importance to biopharmaceutical research, innovation and access.

With regard to some of the more specific negotiating objectives identified by the USTR in its Federal Register notice, please find below our initial perspectives on six topics: (1) general negotiating objectives for the proposed agreement; (2) customs and trade facilitation issues; (3) transparency and good regulatory practices; (4) digital economy-related matters; (5) matters related to standards, technical regulations and conformity assessment procedures; and (6) other measures or practices that undermine fair market opportunities for U.S. workers and businesses.

I. General Negotiating Objectives for the Proposed Agreements

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 USTR to negotiate an agreement with Taiwan 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.

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

[6] U.S. Bureau of Labor Statistics, Current Population Survey (CPS) Labor Force Statistics, available at https://www.bls.gov/cps/home.htm.

As the United States seeks to expand its trade agenda with Taiwan, we would first encourage USTR to ensure that Taiwan honors existing international commitments and that longstanding trade barriers – including market access and other barriers currently under discussion in the context of the U.S.-Taiwan Trade and Investment Framework Agreement (TIFA) – are prioritized for elimination. Resolving these and similar trade issues should constitute a foundation for entering into this proposed trade initiative with Taiwan.

II. Customs and Trade Facilitation

To help to ensure that lifesaving and life-enhancing biopharmaceuticals efficiently reach patients across borders, the United States and Taiwan should take actions to ensure that trade in pharmaceuticals can occur without unnecessary obstacles, including inessential customs procedures, non-modernized entry requirements and unproductive use of time or resources.

Specific policy recommendations to facilitate trade include the following:

- **Permanently eliminate tariffs**. The imposition of tariffs on pharmaceutical products and the various inputs used to invent, manufacture and deploy those products negatively impacts the ability of patients across the globe to access lifesaving medicines. Tariffs impose a direct cost on trade in pharmaceuticals and their inputs and, in so doing, reduce patients' access to treatments and cures. Resources directed to tariff payments instead could be channeled into other elements of the health sector, including the research, development, clinical and manufacturing processes necessary to produce both new and existing treatments. The innovative biopharmaceutical industry therefore urges the United States and Taiwan to pursue tariff elimination on health products, including finished therapeutics, diagnostics and vaccines, as well as the active pharmaceutical ingredients, raw materials, chemicals, other inputs and intermediaries, and specialty equipment used to invent, manufacture and deploy these products.

- **Eliminate existing, and commit to refrain from imposing future, export restrictions**. Export restrictions impede patient access to pharmaceutical products, including immediate access to lifesaving medicines and vaccines. By imposing barriers on companies and other actors that are coordinating complex global pharmaceutical supply chains, such restrictions severely disrupt international collaborative efforts to invent, manufacture and deploy pharmaceutical products across borders. The innovative biopharmaceutical industry therefore urges the United States and Taiwan to review and promptly eliminate export restrictions on health products and commit to refrain from imposing new restrictions, in accordance with World Trade Organization (WTO) rules.

- **Improve customs practices and related trade facilitation policies**. Pharmaceutical products, when traded, are subject to both general customs procedures and additional monitoring and control requirements designed to ensure product safety and efficacy. However, overly complex and inefficient border procedures can cause unnecessary costs, delays and even loss of product. Streamlined and digitized customs procedures reduce these risks, helping to strengthen global supply chains and ensure that medicines and other pharmaceutical products reach patients without disruption or delay. To ensure that

customs and other border procedures facilitate trade in pharmaceuticals and do not unnecessarily impede patient access to medicines, the innovative biopharmaceutical industry urges the United States and Taiwan to improve trade facilitation measures for pharmaceutical products through a variety of actions. These include sharing best practices, enhancing customs clearance procedures, developing and publishing national trade facilitation plans, and prioritizing full and immediate implementation of and building on the WTO Trade Facilitation Agreement.

III. Transparency and Good Regulatory Practices

Too often, foreign governments impose burdensome and nontransparent regulations on the biopharmaceutical sector and employ price controls and reimbursement policies that discriminate against American products. Such practices and policies are unique to the biopharmaceutical industry, given the dominant position of such foreign governments as the sole or primary purchasers of health care. As a result, market access for innovative medicines depends not only on U.S. innovators meeting strict regulatory approval standards and obtaining necessary IP protections, but also on obtaining positive government pricing and reimbursement determinations. This is particularly true in Taiwan, where access to the market is largely contingent on successful listing and reimbursement under the Pharmaceutical Benefit and Reimbursement Scheme. Unfortunately, that process lacks transparency and entails significant due process concerns. For example:

- Despite the lengthy pricing and reimbursement process, applicants are provided limited opportunities to engage meaningfully with relevant government bodies;

- No independent mechanism exists to appeal negative pricing and reimbursement determinations;

- Coercive negotiating tactics, including threats to disclose confidential commercial information when negotiating and renewing managed entry agreements, are engaged to force American manufacturers to accept pricing agreements on unreasonable commercial terms and conditions; and

- Consultations with industry on proposed reforms to the government's pricing and reimbursement policies are perfunctory at best.

Regulatory procedures and decisions regarding the approval and reimbursement of medicines must be governed by fair, transparent and verifiable rules guided by science-based decision making. There should be meaningful opportunities for input from manufacturers and other stakeholders to health authorities and other regulatory agencies and a right to appeal government pricing and reimbursement decisions to an independent and objective court or administrative body.

PhRMA members appreciate steps that USTR and other federal agencies have taken to ensure fair and equitable market access for innovative medicines in overseas markets, including seeking and securing commitments in trade agreements and other dialogues to ensure that pricing and

reimbursement policies abroad are fair, reasonable and non-discriminatory, and appropriately value patented biopharmaceuticals. In this context, we would encourage the United States and Taiwan to build on the approach taken in the U.S.-Korea Free Trade Agreement by including in the U.S.-Taiwan Initiative on 21st-Century Trade a specific chapter and side letters, as necessary and appropriate, to address the lack of transparency and due process in Taiwan's pricing and reimbursement system. To the greatest extent possible, the commitments contained in this chapter and addressed in any side letters should be legally binding and enforceable.

In particular, the United States should seek to ensure that Taiwan commits that proposed laws, regulations and procedures concerning how medicines are approved, priced and reimbursed will be:

- Promptly published or otherwise made available to enable interested parties to become acquainted with them.
- Published prior to adoption in a single official journal of national circulation and with an explanation of the underlying purpose of the proposed regulation. Interested parties, including trading partners and domestic and foreign industry, should be provided a reasonable opportunity to comment on the proposed measures. Those comments and any revisions to the proposed regulation should be addressed in writing at the time that the agency adopts its final regulations. Finally, there should be reasonable time between publication of the final measures and their effective date so that the affected parties can adjust their systems to reflect the new regulatory environment.

Further, the United States should seek to ensure that Taiwan commits that any specific regulatory determinations or pricing and reimbursement decisions will be:

- Based on fair, reasonable, consistent and non-discriminatory procedures, rules and criteria that are fully disclosed to applicants.
- Completed within a reasonable and specified timeframe. Delays to timelines for regulatory determinations or pricing and reimbursement decisions can impede market access, deplete patent terms and negatively impact patients waiting for life-saving medicines.
- Conducted in a manner that affords applicants timely and meaningful opportunities to provide comments at relevant points in decision-making processes.
- Supported by written reports which explain the rationale for the decision and include citations to any expert opinions or academic studies relied upon in making the determination.
- Subject to an independent review process.

Implementation of these bedrock principles would preserve the individual autonomy of the United States and Taiwan to regulate the approval and reimbursement of new medicines, while also establishing fair and transparent procedures that provide the business certainty needed for U.S. biopharmaceutical companies to invest in innovative R&D and export American products to Taiwan.

IV. Digital Economy

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:

- **R&D**: Digital trade enables biopharmaceutical manufacturers to access large, multi-regional 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 jurisdictions.

- **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 Taiwan to negotiate a high-standard agreement that establishes international best practices to eliminate 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; (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, only as restrictive as necessary and developed based on legitimate policy objectives and input from all stakeholders.

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

V. Standards, Technical Regulations and Conformity Assessment Procedures

PhRMA strongly supports efforts to foster global best practices related to assessing the safety and efficacy of new medicines, including developing new pathways for approval of medicines, increasing capacity within regulatory agencies and eliminating unnecessary regulatory barriers. The proposed initiative should seek to build on existing global and regional initiatives, such as those under the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, to harmonize regulatory standards to ensure that regulatory approval processes do not impede effective and efficient global drug development, review and evaluation. Such efforts can help to optimize deployment of limited regulatory agency resources and expedite patient access to innovative and lifesaving or life-enhancing medicines.

VI. Other Measures or Practices that Undermine Fair Market Opportunities for U.S. Workers and Businesses

In order to address most thoroughly, effectively and efficiently the trade barriers faced by the U.S. biopharmaceutical industry in Taiwan – including those identified in the context of the TIFA negotiations – PhRMA encourages the establishment of an MWG that commits the United States and Taiwan to regular, frequent and sustained engagement on issues of importance to

biopharmaceutical research, innovation and distribution – including implementation of commitments made under the TIFA and the U.S.-Taiwan Initiative on 21st-Century Trade. The MWG should include both regular dialogues between the two governments, as well as regular engagement among the governments, industry and other stakeholders. Through such engagement, the MWG will provide a critical forum for determining how the two governments can 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 an ambitious trade agreement between the United States and Taiwan. 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