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Ms. Laura Buffo
Chair of the Trade Policy Staff Committee
Office of the U.S. Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Re: Request for Comments on Americas Partnership for Economic Prosperity—Trade Track, 89 Fed. Reg. 51935 (June 20, 2024)

Dear Ms. Buffo:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this opportunity to provide the following comments in response to the request by the Office of the U.S. Trade Representative (USTR). As a general matter, PhRMA and its members welcome efforts to deepen trade relationships between the United States and countries across the Americas region.

The U.S. Innovative Biopharmaceutical Industry is a Critical American Economic Sector and Contributes Significantly to High-Standard U.S. Manufacturing and Employment

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. Pioneering work by biopharmaceutical innovators in the United States contributes significantly to economic growth and supports high-paying, high-standard and diverse jobs in all 50 states. The U.S. biopharmaceutical industry supports over 4.9 million jobs across the economy, including more than one million direct jobs, and contributes more than $1.65 trillion in economic output on an annual basis.[1]

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.[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 2023, U.S. biopharmaceutical goods exports exceeded $101 billion.[3] The

[1] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates," May 2024, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.

[2] Research!America, "U.S. Investments in Medical and Health Research and Development, 2016-2020," 2022, available at https://www.researchamerica.org/wp-content/uploads/2022/09/ResearchAmerica-InvestmentReport.Final_.January-2022-1.pdf.

[3] U.S. Bureau of Economic Analysis, International Accounts Products for Detailed Goods Trade Data, available at https://www.bea.gov/international/detailed-trade-data.

biopharmaceutical sector was the largest exporter of goods among the most R&D-intensive industries in 2023 – which in addition to biopharmaceuticals included navigational equipment, semiconductors and other electronic components, medical equipment and supplies, and communications equipment.[4]

The U.S. biopharmaceutical industry is also among the top five employers of U.S. manufacturing jobs, with more Americans directly employed in pharmaceutical manufacturing than in manufacturing in several other industries, including each of the following: iron and steel products, aerospace products and parts, petroleum and coal products, and electric equipment and appliances.[5] In 2022, 34 percent of U.S. biopharmaceutical industry employees were engaged in manufacturing at over 1,500 manufacturing plants across the country, 39 percent were engaged in biopharmaceutical R&D, 24 percent were engaged in distribution and three percent were engaged in corporate administration.[6]

USTR's Stated Priorities for the APEP Trade Track Unfortunately Continue the Administration's Misguided and Unambitious Trade Policies

USTR has requested comments to assist in the development of trade priorities for the Americas Partnership for Economic Prosperity (APEP). As the submission below explains, trade policies that value innovation, protect intellectual property (IP) and actively dismantle foreign trade barriers are essential to expanding export and economic opportunities for American workers, incentivizing the invention and production of lifesaving medicines, and reinforcing the resilience of U.S. biopharmaceutical supply chains. The APEP must prioritize these policies if it is to achieve the objectives set out in the East Room Declaration, including fostering economic integration and shared prosperity, building a transparent and predictable regulatory environment that boosts trade flows, strengthening regional competitiveness and promoting healthy communities.[7]

Unfortunately, the Administration has demonstrated limited ambition in further advancing or even maintaining these important trade policies, despite a constant chorus of concerns and constructive input from Congress, the business community and other stakeholders. Throughout the Administration's tenure, PhRMA and other stakeholders have provided extensive public comments to USTR and the Department of Commerce highlighting the need for a more ambitious and pro-innovation U.S. trade agenda, including in responses to Federal Register notices regarding: (1) negotiating objectives for the Indo-Pacific Economic Framework (IPEF) (March 10 and 11, 2022);[8] (2) opportunities to advance supply chain resilience through the U.S.-

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

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

[6] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates," May 2024, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.

[7] East Room Declaration of the Leaders of the Americas Partnership for Economic Prosperity, November 3, 2023, available at https://www.whitehouse.gov/briefing-room/statements-releases/2023/11/03/east-room-declaration-of-the-leaders-of-the-americas-partnership-for-economic-prosperity/.

[8] Pharmaceutical Research and Manufacturers of America, Written Comments on Request for Comments on the Proposed Fair and Resilient Trade Pillar of an Indo-Pacific Economic Framework, 87 Fed. Reg. 13789 (March 10, 2022), available at https://www.regulations.gov/comment/USTR-2022-0002-1264; and Pharmaceutical Research and Manufacturers of America,

EU Trade and Technology Council (April 6, 2022);[9] (3) negotiating objectives for the U.S.-Taiwan Initiative on 21st-Century Trade (June 7, 2022);[10] (4) Advancing Inclusive, Worker-Centered Trade Policy (June 12, 2023);[11] (5) Promoting Supply Chain Resilience (March 7, 2024);[12] and (6) Supply Chain Risk Assessment and IPEF Supply Chains (June 3, 2024).[13] Members of Congress similarly have urged the Administration to implement a more ambitious trade agenda and have advanced bipartisan proposals reflecting this widely shared objective.[14] Unfortunately – and often with negative consequences for American workers and businesses facing stiff international competition – the Administration has rejected wholesale the much more serious trade strategies and objectives offered by Congress and the U.S. business community. USTR continues to pursue a trade agenda characterized by unambitious economic dialogues, inadequate enforcement of IP and other key trade commitments, and a refusal to strengthen economic and supply chain relationships through trade agreements, even with the United States' most reliable allies.

USTR's stated priorities for the APEP trade track represent a continuation of this misguided approach. Mirroring USTR's intentionally unambitious and vague strategy regarding the IPEF and similar initiatives that have failed to deliver meaningful results for American workers and businesses, USTR's initial list of priorities for the APEP excludes longstanding and bipartisan U.S. trade objectives, such as strengthening IP protection and eliminating market access barriers, that are necessary to support medical innovation, trade and supply chain resilience in the Americas.[15] Worse, the Administration appears to have downgraded its initial objectives for APEP to an even lower level of ambition. More than two years after announcing the APEP initiative, USTR has yet to clarify whether it intends to negotiate binding trade commitments with the APEP partners, raising doubts regarding the APEP's potential to facilitate trade and investment in the region. As Senator Tim Kaine (D-VA), Chairman of the Senate Foreign Relations Subcommittee on Western Hemisphere, stated in a letter last year to the Administration regarding APEP, "the Administration has changed the structure of the potential partnership. It is

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Written Comments on Request for Comments on the Indo-Pacific Economic Framework, 87 Fed. Reg. 13971 (March 11, 2022), U.S. Department of Commerce, available at https://www.regulations.gov/comment/ITA-2022-0001-0010.

[9] Pharmaceutical Research and Manufacturers of America, Written Comments on Request for Public Comments on Supply Chain Issues to Support the U.S.-EU Trade and Technology Council Secure Supply Chains Working Group, 87 Fed. Reg. 19854 (April 6, 2022), available at https://www.regulations.gov/comment/BIS-2021-0046-0017.

[10] Pharmaceutical Research and Manufacturers of America, Written Comments on Request for Comments on Proposed U.S.-Taiwan Initiative on 21st-Century Trade, 87 Fed. Reg. 34745 (June 7, 2022), available at https://www.regulations.gov/comment/USTR-2022-0005-0027.

[11] Pharmaceutical Research and Manufacturers of America, Written Comments on Request for Comments on Advancing Inclusive, Worker-Centered Trade Policy, 88 Fed. Reg. 38118 (June 12, 2023), available at https://www.regulations.gov/comment/USTR-2023-0004-1460.

[12] Pharmaceutical Research and Manufacturers of America, Written Comments on Request for Comments on Promoting Supply Chain Resilience, 89 Fed. Reg. 16608 (Mar. 7, 2024), available at https://www.regulations.gov/comment/USTR-2024-0002-0126.

[13] Pharmaceutical Research and Manufacturers of America, Written Comments on Request for Comments on Commerce Supply Chain Risk Assessment and IPEF Supply Chains, 89 Fed. Reg. 47536 (Jun. 3, 2024), available at https://www.regulations.gov/comment/ITA-2024-0004-0036.

[14] *See, e.g.*, Medical Supply Chain Resiliency Act, S.2115 and H.R.4307, 118th Congress (2023), available at https://www.congress.gov/bill/118th-congress/senate-bill/2115 and https://www.congress.gov/bill/118th-congress/house-bill/4307; and US Trade Leadership in the Indo-Pacific Act, H.R.7962, available at https://www.congress.gov/bill/118th-congress/house-bill/7962.

[15] Request for Comments on Americas Partnership for Economic Prosperity—Trade Track, 89 Fed. Reg. 51935 (June 3, 2024), Office of the U.S. Trade Representative.

shifting from pursuing text-based agreements with binding commitments and is instead developing a "forum" intended to bring leaders together to broadly discuss areas of mutual interest and shared goals."[16] USTR's Federal Register notice provides no clarity in this regard, as it omits any reference to negotiating objectives or an eventual trade agreement with the APEP partners and instead seeks input with respect to "priorities and lines of effort consistent with the . . . collaborative nature of the Partnership." As discussed below, PhRMA urges USTR and its APEP partners to negotiate binding and ambitious trade commitments that reinforce and build on existing free trade agreements (FTAs) in the region, in order to further the objectives established in the East Room Declaration.

With regard to the list of priorities identified by USTR in its Federal Register notice, please find below our initial perspectives on the following topics: (1) general negotiating objectives for the APEP trade track, including compliance with existing trade commitments and strong IP protections; (2) regulatory barriers, including transparency, good regulatory practices and discriminatory pricing and reimbursement policies; (3) customs and trade facilitation issues; (4) reinforcing the resilience of medical supply chains in the Americas; (5) digital economy; and (6) opportunities for further collaboration to address trade barriers.

I. General Negotiating Objectives for the APEP Trade Track, Including Compliance with Existing Trade Commitments and Strong IP Protections

PhRMA supports comprehensive trade agreements that open new or expand existing markets to U.S. exports, grow our economy, enhance U.S. competitiveness and create better and higher-paying jobs by eliminating foreign trade barriers and protecting U.S. IP abroad. Such agreements advance public health by providing critical incentives for medical innovation, fostering research and scientific collaboration, strengthening medical supply chains and improving patient access to innovative medicines.

As the United States seeks to deepen its trade relationships with the APEP partners, USTR first must ensure that those countries are honoring their existing international commitments under the World Trade Organization (WTO) Agreements and bilateral and regional FTAs. USTR must also ensure that longstanding trade barriers in those countries – including barriers identified by USTR in its Special 301 and National Trade Estimate (NTE) Reports – are prioritized for elimination. Resolving these and similar trade issues should constitute a foundation for the APEP. To this end, PhRMA, through its submissions to USTR to inform the Special 301 and NTE Reports, has identified specific measures or practices that should be resolved in those countries. PhRMA and its members would appreciate the opportunity to discuss those measures and practices further with USTR.

USTR and its APEP partners should also negotiate new, high-standard trade and IP commitments that build on existing FTAs in the region and reflect international best practices. Recent U.S. FTAs such as the United States-Mexico-Canada Agreement (USMCA) incorporate important advances in areas such as IP protection and regulatory practices, including sectoral commitments to ensure transparency and fairness in regulatory procedures and decisions regarding the

[16] Letter from Senator Kaine to Secretary Blinken, Ambassador Tai and Mr. Sullivan regarding the Americas Partnership for Economic Prosperity, Oct. 5, 2023, available at https://www.kaine.senate.gov/imo/media/doc/10523apepletter.pdf.

approval and reimbursement of medicines. USTR should ensure that all APEP parties adopt and implement these and other high-standard commitments described below, which are essential to incentivize the discovery of new treatments and cures and to sustain economic growth and job creation in the United States.

II. Regulatory Barriers

A. Transparency and Good Regulatory Practices

Foreign governments, including several in the Americas, often impose burdensome and nontransparent regulations on the biopharmaceutical sector that delay access to medicines and create substantial trade barriers. Such regulations often are inconsistent with international best practices and with trade agreement obligations that require regulatory practices and decisions to be timely, fair and transparent. For example, Mexico has severely delayed the marketing authorization process for pharmaceutical products since early 2019, despite its USMCA commitment to issue determinations regarding marketing authorizations "within a reasonable period of time."[17] Colombia's regulation on biologic medicines includes an unprecedented "abbreviated" pathway for the registration of non-comparable products, which is inconsistent with WHO guidelines and accepted standards in the United States and other countries, and which could result in the approval of medicines that are not safe and/or effective.[18] These and similar practices throughout the region impede market access for U.S. products and undermine public health objectives.

PhRMA strongly urges the Administration to work with the APEP partners to eliminate unnecessary regulatory barriers s and foster global best practices related to assessing the safety and efficacy of new medicines, including developing new pathways for approval of medicines and increasing capacity within regulatory agencies. The APEP 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. In addition, all APEP partners should adopt and uphold high-standard commitments on transparency and good regulatory practices, such as those found in the USMCA, to ensure that procedures and decisions regarding the approval and reimbursement of medicines are 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. Addressing these important issues can help to optimize deployment of limited regulatory agency resources and expedite patient access to innovative and lifesaving or life-enhancing medicines.

B. Discriminatory Pricing and Reimbursement Policies

Foreign governments, including several in the Americas, often employ price controls and reimbursement policies that discriminate against American medicines. Such practices and policies are unique to the biopharmaceutical industry, given the dominant position of such

[17] USMCA Article 12.F.6.

[18] Decree 1782 of September 18, 2014.

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. Some countries, including in the Americas region, have resorted to using national compulsory licensing provisions improperly or threatening disclosure of confidential commercial information to coerce American manufacturers to accept pricing agreements on unreasonable commercial terms and conditions.

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 to ensure that pricing and reimbursement policies abroad are fair, reasonable and non-discriminatory, and appropriately value patented biopharmaceuticals. PhRMA urges USTR and to seek and promote the full implementation of such commitments as part of the APEP.

In particular, proposed laws, regulations and procedures concerning how medicines are approved, priced and reimbursed should 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.

Specific regulatory determinations or pricing and reimbursement decisions should 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. In some countries, deadlines for making decisions on whether to approve new medicines do not exist. In other countries, such deadlines exist but regularly are not met. These delays impede market access, deplete important 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 that includes a right to appeal government pricing and reimbursement decisions to an independent and objective court or administrative body.

Implementation of these bedrock principles would preserve the individual autonomy of each country to regulate the approval and reimbursement of new medicines, but establish 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 countries throughout the Americas region.

III. Customs and Trade Facilitation

To help ensure that lifesaving and life-enhancing biopharmaceuticals efficiently reach patients across borders, USTR and its APEP partners 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:

- **Eliminate tariffs on medicines and inputs.** 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 its APEP partners to eliminate tariffs on medicines, inputs and equipment used to produce these products, where they have not already done so through existing regional and bilateral FTAs and other trade agreements.[19] APEP partners should also 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 tariffs and other trade barriers.

- **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 USTR, as part of the APEP negotiations, to ensure that all parties to the agreement review and promptly eliminate export restrictions on health products and commit to refrain from imposing new restrictions, in accordance with WTO rules.

[19] Such commitments should extend to 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.

- **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 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 USTR to ensure that parties to the APEP 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.

IV. Reinforcing the Resilience of Medical Supply Chains

PhRMA and its member companies are committed to protecting the safety and continuity of biopharmaceutical supply chains to ensure patient access to medicines. Over decades, the innovative biopharmaceutical industry has carefully built robust and diverse global supply chains to ensure that patients in the United States and around the world have ongoing access to safe and high-quality medicines. During the COVID-19 pandemic, these supply chains enabled biopharmaceutical manufacturers in the United States to avoid major disruptions to the supply of innovative medicines while rapidly increasing production of new vaccines and treatments, despite unprecedented logistical challenges and demand surges. This is a testament to the resilience, diversity and effectiveness of the *innovative* industry's existing global supply chains and underscores the importance of maintaining strong ties with trusted trading partners.
Any new policies to improve supply chain resilience must not undermine existing supply chains, which – for *innovative* medicines – already are highly resilient. The supply chain for innovative medicines consumed in the United States is comprised largely of domestic and allied production, with 53 percent (by dollar value) of active pharmaceutical ingredients (API) used in U.S.-consumed medicines produced in the United States and 85 percent produced in the United States or Europe as of 2021.[20]

A fundamental strategy for maintaining a stable, operational supply chain is geographic diversity, which mitigates the risk of supply chain disruptions and allows manufacturers to access key raw materials that are not readily available in every country. The Administration's own supply chain strategy therefore recognizes that diversification of critical supply chains through cooperation with allies and partners is essential to improve resilience.[21] The APEP presents an opportunity to further this objective by facilitating trade in medicines and inputs among trusted partners in the Americas, consistent with USTR's stated aims to "facilitat[e] the movement of supply chains to

[20] Avalere Health, "US Makes Majority of API by Dollar Value in US-Consumed Medicines," (June 14, 2023), available at https://avalere.com/insights/majority-of-api-in-us-consumed-medicines-produced-in-the-us.

[21] The White House, Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth (June 2021) at p. 17, available at https://www.whitehouse.gov/wp-content/uploads/2021/06/100-daysupply-chain-review-report.pdf.

trusted partners through friend-shoring and near-shoring;" "facilitate trade in safe and effective medicines and minimize drug shortages;" and "secure smoother and more efficient movement of essential goods during a pandemic[.]"[22]

PhRMA has provided detailed recommendations to USTR outlining the specific trade policies that would be most effective in strengthening biopharmaceutical supply chains, most recently in response to USTR's April 3, 2024, Request for Comments on Promoting Supply Chain Resilience.[23] PhRMA requests that USTR consider those recommendations as it develops policies to enhance supply chain resilience among the APEP parties, and urges USTR to focus on the following opportunities:

- **Facilitate the free movement of biopharmaceuticals, inputs, related health care items and key personnel among the APEP partners – including through the elimination of tariffs, export restrictions and other trade barriers, and improving trade facilitation and customs procedures, as recommended above.** By imposing barriers on companies and other actors that are coordinating complex global biopharmaceutical supply chains, such restrictions severely disrupt international collaborative efforts to invent, manufacture and deploy biopharmaceutical products around the world, as the WTO and other organizations documented during the COVID-19 pandemic.[24]

- **Enhance regulatory cooperation with APEP partners to increase administrative efficiencies, optimize resources and avoid unnecessarily duplicative procedures that inhibit the flow of life-saving medicines.** The United States should also support capacity building in the region, including by sharing best practices, leveraging existing regulatory harmonization efforts and designing and implementing capacity building programs, as appropriate. Further, the United States and APEP partners should agree to prioritize, particularly during global public health emergencies, transport of biopharmaceuticals and their inputs; designate biopharmaceutical employees, vendors and suppliers as essential workers; and facilitate necessary travel of key industry employees to support research, development, quality control, production and distribution.

- **Preserve, strengthen and enforce IP rights.** Strong IP protections are a critical enabler of biopharmaceutical innovation and investment and therefore are integral to maintaining U.S. leadership and robust supply chains in this sector. The United States should leverage the APEP to promote strong IP protections abroad, including by ensuring that all APEP

[22] USTR, 2024 Trade Policy Agenda and 2023 Annual Report (March 2024) at p. 11, available at https://ustr.gov/sites/default/files/The%20Presidents%202024%20Trade%20Policy%20Agenda%20and%202023%20Annual%20Report.pdf.

[23] *See* Pharmaceutical Research and Manufacturers of America, Written Comments on Request for Comments on Promoting Supply Chain Resilience, 89 Fed. Reg. 16608 (Mar. 7, 2024), Office of the U.S. Trade Representative, available at https://www.regulations.gov/comment/USTR-2024-0002-0126.

[24] For example, The WTO documented more than 60 types of "trade-related bottlenecks" that affected critical medical products and inputs during the pandemic, including high tariffs and taxes, export restrictions, burdensome and duplicative requirements related to inspections and release of goods, divergent regulatory requirements and lack of coordination among border agencies. World Trade Organization, Indicative List of Trade-Related Bottlenecks and Trade-Facilitating Measures on Critical Products to Combat COVID-19 (October 2021), available at https://www.wto.org/english/tratop_e/covid19_e/bottlenecks_update_oct21_e.pdf.

parties fully implement their IP obligations in existing U.S. trade agreements, and should negotiate ambitious new commitments to strengthen IP protections across the region. Strengthening IP protection and enforcement in the Americas will improve supply chain resilience by incentivizing investment in research and manufacturing and safeguarding U.S. technologies against unfair exploitation by foreign actors.

- **Leverage and expand regional manufacturing infrastructure to support vaccine and therapeutics research, development and production capacity as part of supply chain resilience initiatives.** The United States should align with like-minded APEP partners on shared priorities and government policies and programs to enhance prevention of, detection of and response to future infectious diseases and other threats. Further, the United States should explore with key partners (i) mechanisms to increase resilience in the supply of active pharmaceutical ingredients for critical generic medicines necessary to support acute care; and (ii) the role of incentives and other investments to support the development of further innovations, e.g., innovations concerning platform technologies, environmental manufacturing processes, digitalization of supply chains and continued geographic diversity in the supply of consumables and other biopharmaceutical items.

- **Strengthen cybersecurity capabilities and infrastructure and use of existing collaborative mechanisms to address cyberthreats to health systems and supply chains.** During the COVID-19 pandemic, biopharmaceutical manufacturers and regulators faced a growing number of cyberattacks. The United States should increase and strengthen collaboration with like-minded partners regarding combatting cyberattacks, facilitating cybercrimes enforcement, sharing relevant intelligence in a timely manner and protecting proprietary data.

V. 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.

A vibrant digital economy and open digital trade are essential to the key stages of biopharmaceutical innovation, including research and development, manufacturing, delivery and pharmacovigilance. Sound public policies that encourage open digital trade practices related to these 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 APEP 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 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. APEP 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.

VI. Opportunities for Further Collaboration to Address Trade Barriers

U.S. biopharmaceutical workers face a variety of trade barriers that significantly impede the invention, manufacturing and distribution of medicines in the Americas region. To address these issues, and to ensure that APEP meets its long-term potential, PhRMA encourages the establishment of a Medicines Working Group (MWG) that commits APEP governments to regular, frequent and sustained engagement on issues of importance to biopharmaceutical research, innovation and distribution – including implementation of APEP commitments. The MWG should include both regular dialogues among APEP governments, as well as regular dialogues among APEP governments, industry and other stakeholders. Through such engagement, APEP 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 urges USTR to pursue an ambitious APEP agreement that expands export and economic opportunities for American workers, incentivizes the invention and production of lifesaving medicines and reinforces the resilience of innovative biopharmaceutical supply chains. We appreciate the opportunity to provide these comments and look forward to being an active stakeholder throughout the APEP process.

Sincerely,

/s/ Douglas Petersen

Douglas Petersen
Deputy Vice President, International