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Mr. Victor Ban
Special Counsel
Office of the U.S. Trade Representative
600 17th Street, N.W.
Washington, DC 20508

**Re: Request for Comments on Promoting Supply Chain Resilience, 89 Fed. Reg. 16608 (Mar. 7, 2024)**

Dear Mr. Ban,

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 Office of the U.S. Trade Representative ("USTR"). 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. PhRMA member companies have built robust global supply chains carefully and deliberately to ensure that patients in the United States and around the world have ongoing access to safe and high-quality medicines, and our industry strongly supports and encourages efforts to further strengthen these supply chains through trade policies that value innovation, protect intellectual property (IP) and eliminate trade barriers imposed by foreign governments on imports of U.S.-manufactured medicines.

PhRMA and its member companies are committed to protecting the safety and continuity of biopharmaceutical supply chains to ensure patient access to medicines. As explained below, diverse global supply chains are key to ensuring continuity and resilience in the supply of medicines to people in the United States and countries throughout the world. 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 and effectiveness of the industry's existing global supply chains and underscores the importance of additional government policies to further support industry's already strong efforts to maintain strong ties with trusted trading partners. U.S. trade and other policies to improve supply chain resilience and security should reflect the demonstrated reality that biopharmaceutical supply chains already are highly resilient and therefore not undermine those supply chains.

USTR has requested comments on objectives and strategies that advance U.S. supply chain resilience in trade negotiations, enforcement and other initiatives. As the submission below demonstrates, trade policies that value innovation, protect IP and actively dismantle foreign trade barriers are essential to maintaining and improving the resilience of U.S. biopharmaceutical supply chains. Such policies incentivize the invention and production of lifesaving medicines, enable geographic diversification to reduce supply chain risks and reduce unnecessary costs and delays that inhibit access to medicines, ingredients and other inputs. PhRMA therefore supports trade policies, agreements and enforcement actions that prioritize strong IP protections and predictable and transparent market access, regulatory and other provisions that incentivize innovation, dismantle unfair and unnecessary trade barriers, and facilitate the manufacturing and distribution of lifesaving medicines and other health products.

Unfortunately, and as discussed in detail below, the Administration has demonstrated extremely limited ambition to further advance, or even maintain, these important policies internationally, despite multiple opportunities to do so in coordination with America's strongest allies and economic partners. Instead, the Administration has departed from these longstanding and bipartisan U.S. trade objectives, declining to pursue the very policies that are necessary to improve the resilience of biopharmaceutical supply chains. Enhancing supply chain resilience in the biopharmaceutical sector will require the United States to recommit to an ambitious, pro-innovation trade agenda.

The below submission highlights the following: (I) the U.S. innovative biopharmaceutical industry is a critical American economic sector and contributes significantly to high-standard U.S. manufacturing and employment; (II) the United States and Europe are the primary sources of active pharmaceutical ingredients used in medicines consumed in the United States; (III) U.S. innovative biopharmaceutical manufacturers have built resilient, secure and geographically diverse global supply chains with safeguards to avoid supply disruptions; (IV) current Administration trade policies fail to promote supply chain resilience in the biopharmaceutical sector; and (V) an ambitious, pro-innovation trade agenda is necessary to maintain and enhance the resilience of U.S. biopharmaceutical supply chains.

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

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. 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] 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),

[1] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2020 National and State Estimates," Mar. 2022, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/2020-Biopharma-Jobs-ImpactsMarch-2022-Release.pdf (last visited Apr. 22, 2024).

25 percent were engaged in distribution and three percent were engaged in corporate administration.[2]

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 stronger pro-innovation policies and incentives in place at home and abroad, our member companies could bring additional valuable new medicines to patients around the world. In 2023, U.S. biopharmaceutical goods exports exceeded $101 billion.[4] The 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.[5]

The U.S. biopharmaceutical industry also is among the top five employers of U.S. manufacturing jobs, with more Americans directly employed in biopharmaceutical 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]

## II. The United States and Europe are the Primary Sources of Active Pharmaceutical Ingredients Used in U.S.-Consumed Medicines

Medicines intended for U.S. patients are approved by the Food and Drug Administration (FDA) and manufactured in FDA-registered facilities in the U.S. and abroad. This includes both finished pharmaceutical products (FPP) and their active pharmaceutical ingredients (API), that is, the components of a medicine that produce the intended therapeutic effect on the body. API used in medicines consumed in the United States generally enter the supply chain in three ways: domestically manufactured API; API imported from other countries that is used domestically to produce FPP; and API produced in other countries and used to manufacture FPP in another country, which then is imported into the United States.

As detailed below, most API manufacturing facilities that supply the U.S. market are in the United States or Europe, while a high majority of API in U.S.-consumed medicines are manufactured in the United States or Europe. As the United States considers opportunities to further strengthen biopharmaceutical supply chains, PhRMA encourages USTR and other policymakers to recognize and build from the robust trade and supply chain relationships that

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[2] Id.

[3] 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-Investment-Report.Final_.January-2022-1.pdf (last visited Apr. 22, 2024).

[4] U.S. Bureau of Economic Analysis, International Accounts Products for Detailed Goods Trade Data at https://www.bea.gov/international/detailed-trade-data (last visited April 18, 2024).

[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 (last visited Apr. 22, 2024).

currently exist, in terms of both finished products and their API, with key partners such as the European Union.

### A. Most API manufacturing facilities that supply the U.S. market are in the United States or Europe

The FDA publishes data regarding API manufacturing facilities that supply the U.S. market. According to recent FDA data, about 28 percent of API manufacturing facilities supplying the U.S. market are in the United States – more than any other single country – while 26 percent are in the European Union, 18 percent are in India, 13 percent are in China, two percent are in Canada and 13 percent are elsewhere in the world.[7]

The FDA also tracks the location of facilities used to make API for the 370 medicines designated by the World Health Organization as "essential medicines." As of 2019, the United States had 221 facilities producing API for these essential medicines – more than any other single country – while 166 facilities (15 percent) were in China and 687 facilities (64 percent) were elsewhere in the world.[8]

### B. Most API in U.S.-consumed medicines are manufactured in the United States or Europe

While the CARES Act signed in March 2020 created additional reporting requirements on drug volume and is designed in part to provide greater insight into supply chains, the best data currently available that provides a measure of drug volume by country (rather than simply the location of the facilities registered to produce medicines) is international trade data showing imports and exports of API (in dollars).

A study performed by Avalere Health found that in 2021 more than half (53 percent) of the $85.6 billion of API used in medicines consumed in the United States was manufactured in the United States; 29 percent was manufactured in European Union Member States, three percent was manufactured in Switzerland, and one percent was manufactured in the United Kingdom. In total, approximately 85 percent of the API used in medicines consumed in the United States in 2021 was manufactured in either the United States or these European countries. The remainder was manufactured in China (seven percent), Singapore (four percent), India (two percent) and other countries (two percent).

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[7] Testimony of Janet Woodcock, M.D. Center for Drug Evaluation and Research, FDA, "Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program" (Dec. 10, 2019), available at https://www.fda.gov/news-events/congressional-testimony/securing-us-drug-supply-chain-oversight-fdas-foreign-inspection-program-12102019 (last visited Apr. 22, 2024).

[8] See Testimony of Janet Woodcock, M.D. Center for Drug Evaluation and Research, FDA, "Safeguarding Pharmaceutical Supply Chains in a Global Economy" (Oct. 30, 2019), available at https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019 (last visited Apr. 22, 2024).

Avalere's estimates account for all three ways in which API enters the U.S. supply chain, rather than focusing solely on U.S. imports of API that are used to manufacture FPP in the United States.[9]

## III. U.S. Innovative Biopharmaceutical Manufacturers Have Built Resilient, Secure and Geographically Diverse Global Supply Chains with Safeguards to Avoid Supply Disruptions

Research-based biopharmaceutical manufacturers are committed to ensuring safe, stable and secure supply chains, which requires significant investment in time and resources to ensure that patients receive safe and effective medicines when needed.

### A. Existing biopharmaceutical supply chains have been carefully established to promote resilience

In developing biopharmaceutical supply chains, manufacturers consider the locations of each source facility and have extensive measures in place to manage the various elements of production processes, including ensuring sufficient access to the skilled workers and materials needed. Biopharmaceutical manufacturers must begin setting up the manufacturing supply chain for a medicine years before that medicine is even approved for use by patients. Changes made to any supply chain component, material or design require careful consideration and planning, as well as substantial engagement with the FDA to obtain regulatory review and approval. Building a new biopharmaceutical manufacturing facility can take an average of five years, and as many as 10 years, before it is globally operational and can cost as much as $1 to 2 billion. As the R&D process progresses and researchers get closer to a potential successful treatment, companies must build the capacity to manufacture sufficient quantities of that medicine safely and efficiently for the number of patients needing treatment, as well as develop plans for getting those medicines to patients. This includes, for example, contracting with various suppliers to ensure high-quality, reliable sourcing of certain materials used in the manufacturing process, ensuring the availability of a highly skilled labor force with the ability to manufacture the medicine and maintaining the critical quality control and testing systems needed to protect patients.

Over decades, biopharmaceutical manufacturers have built these robust global supply chains carefully and deliberately to ensure that patients in the United States and around the world have access to safe and high-quality medicines. Biopharmaceutical companies invest significantly in the design and ongoing maintenance and modernization of manufacturing facilities and their quality systems. These efforts were successful in avoiding any major disruptions in the supply of brand or innovative prescription medicines during the COVID-19 pandemic. It is important to recognize that market dynamics vary for brand or innovative manufacturing companies and generic manufacturing companies, with brand medicine manufacturers more likely to have robust business continuity plans that may include stand-by manufacturing and robust inventory to mitigate against potential disruptions including shortages. Conversely, generic manufacturers

[9] 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 (last visited Apr. 22, 2024).

driven primarily by cost considerations are less likely to have supply chain redundancies and, therefore, more likely to experience drug shortages. As a result, appropriate attention should be given to increasing resilience concerning critical generic medicines necessary to support acute care during a public health emergency.

### B. Existing biopharmaceutical supply chains include important safeguards to ensure safety

The FDA regulates virtually every stage in the life cycle of a prescription medicine sold in the United States, including API for medicines available to U.S. patients. Biopharmaceutical manufacturers are required by law to report substantial information to the FDA relating to API and sourcing of API, and FPP and API manufacturers are required to register and provide certain information on each registered manufacturing facility with the FDA. The FDA's Current Good Manufacturing Practice (CGMP) requirements apply to FPP as well as API manufacturers to ensure quality regardless of where their facilities are located. In addition, biopharmaceutical manufacturers have their own robust quality control systems in place to help ensure the quality of the product throughout the entire manufacturing process. This includes the establishment of robust supplier qualification programs to vet potential vendors to help ensure that they meet CGMP requirements.

Manufacturers have complex systems in place as a matter of course to avoid major disruptions in their supply chains. This includes robust inventory management systems that track anticipated demand by looking at historical demand and supply data. These systems allow manufacturers to continuously monitor their supply and distribution lines to ensure sufficient supply, anticipate risk and avert potential disruption. Companies put in place risk management plans that include alternate manufacturing sites, inventory reserves and/or a range of global external suppliers and logistics planning to ensure continuity in shipping of supplies. Manufacturers also have systems in place to monitor demand and work closely with the FDA to prevent and mitigate shortages, including by reporting substantial data to the FDA regarding certain potential shortages.
As the United States considers opportunities to enhance cooperation, transparency and visibility concerning critical supply chains with key trading partners, we encourage governments to focus on appropriately sharing existing data reported to their respective regulators to identify potential supply chain risks in a secure manner, while protecting the confidentiality of proprietary data, and subsequently working in lock-step with relevant manufacturers to address risks.

### C. Existing biopharmaceutical supply chains are geographically diverse

One of the most fundamental strategies for maintaining a stable, operational supply chain that can respond rapidly to public health emergencies is geographic diversity. Geographic diversification of the supply chain is beneficial, especially in the time of pandemics or other emergencies, because of the flexibility it gives companies when they need it most. If an entire biopharmaceutical supply chain is dependent upon one geographic area and that area experiences a natural or national disaster or pandemic, there could be significant infrastructure and supply disruptions with global implications. Hurricane Maria in 2017 is a case in point. Approximately 50 biopharmaceutical manufacturing facilities were in Puerto Rico at the time of the hurricane, and their capacity was impacted by the disaster. Because of robust supply chains and close

coordination with the FDA, the industry was quickly able to shift manufacturing to facilities in other areas and prevent long-term drug shortages.

Biopharmaceutical companies need to be able to adjust their supply chains in the case of an emergency that may result in disruptions, like Hurricane Maria. Building a new facility takes significant time and resources, so it is not a feasible solution in an emergency. Instead, innovative biopharmaceutical companies typically rely on a globally diverse supply chain that includes a range of redundancies and business continuity plans to prevent and mitigate potential disruptions. Companies consider the locations of each facility and have extensive measures in place to manage the various elements of the manufacturing process, including, as appropriate, maintaining inventories of certain materials and ensuring sufficient access to the skilled workers, specialized equipment and materials needed.

Global supply chains also allow manufacturers to access key raw materials that are not readily available in every country. Coordinated global production ensures that all countries have access to the ingredients needed to produce a wide range of medicines. Manufacturers consider many factors for where raw materials, API and medicines should be sourced and produced. Some countries do not have the proximity to, or capacity to develop, the ingredients essential to the production of certain drugs. Other countries, including the U.S., cannot source certain ingredients, such as rare earth minerals, either because of a lack of minable concentrations or commercial viability, and often restrictive environmental or other regulations governing mining. The Biden Administration's supply chain strategy rightly recognizes that diversification of critical supply chains through cooperation with allies and partners is essential to improve resilience.[10] Consistent with this principle, USTR's 2024 Trade Policy Agenda similarly sets out objectives to "facilitat[e] the movement of supply chains to 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[.]"[11] However, as highlighted below, the Administration has shown extremely limited ambition in advancing or even maintaining the very trade policies that would best promote these objectives, including in bilateral and regional trade initiatives that purport to prioritize supply chain resilience.

## IV. Current Administration Trade Policies Fail to Promote Supply Chain Resilience in the Biopharmaceutical Sector

PhRMA and its member companies are committed to protecting the safety and continuity of biopharmaceutical supply chains to ensure patient access to medicines. As noted above, despite unprecedented logistical challenges and demand surges, the United States did not experience significant supply shortages for innovative biopharmaceuticals during the COVID-19 pandemic. Nevertheless, the COVID-19 pandemic underscored that more can be done to promote resilient

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[10] 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-day-supply-chain-review-report.pdf (last visited Apr. 22, 2024).

[11] 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 (last visited Apr. 22, 2024).

and diverse supply chains. Indeed, it is well-documented that trade barriers imposed before and during the pandemic disrupted biopharmaceutical supply chains, including for COVID-19 vaccines and treatments. For example, the World Bank and the World Trade Organization (WTO) jointly recognized that "[d]uring the first two years of the pandemic, suppliers stepped up global shipments of therapeutics, vaccines, diagnostic gear, and personal protective equipment. Barriers to the movement of goods, people, and technology, however, hampered that effort."[12] 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.[13] 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. To improve the resilience of U.S. biopharmaceutical supply chains, the United States must work with allies and trading partners to eliminate these unnecessary barriers.

In addition, the rapid research, development and production of COVID-19 vaccines and treatments made especially clear that IP protections play a critical role in ensuring resilient biopharmaceutical supply chains. Industry's success in combatting COVID-19 was founded on IP protections, without which U.S. companies would have been unable to justify the significant investments needed to research, develop and manufacture safe and effective – but economically speculative – vaccines and treatments. As a result of the unprecedented collaboration and hundreds of partnerships among the private sector, researchers, academia, governments and other organizations – all of which were enabled and facilitated by robust IP frameworks – biopharmaceutical manufacturers were able to develop and scale-up supply of COVID-19 treatments and vaccines in record time.

These experiences underscore that U.S. trade policies that value innovation, protect IP and champion open trade are necessary to maintain and enhance the resilience of biopharmaceutical supply chains. Such policies incentivize the invention and production of lifesaving medicines, enable geographic diversification to reduce supply chain risks and reduce unnecessary costs and barriers that inhibit access to medicines, ingredients and other inputs. Unfortunately, the Administration has demonstrated limited ambition in further advancing, or even maintaining, these important policies internationally. Instead, USTR has departed from these longstanding and bipartisan U.S. trade objectives by deprioritizing, and in certain instances proactively opposing, the very trade policies that best promote resilient biopharmaceutical supply chains. The following USTR trade policies are especially concerning:

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[12] World Trade Organization and World Bank Group, Trade Therapy: Deepening Cooperation to Strengthen Pandemic Defenses (June 2022) at p. 9, available at https://www.wto.org/english/res_e/booksp_e/tradetherapy2022_e.pdf (last visited Apr. 22, 2024).

[13] 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 (last visited Apr. 22, 2024).

### A. Refusal to negotiate new and meaningful trade agreements

The Administration has declined to negotiate new comprehensive and high-standard trade agreements with well-positioned and willing partners. Remarkably, USTR has elected not to pursue a world-leading and precedent-setting agreement even with the United Kingdom – a like-minded partner, one of America's greatest allies and a country with very high labor, environmental and other standards. This decision is a major and incomprehensible error that imposes great costs on the U.S. economy and misses critical opportunities to bolster biopharmaceutical supply chains by enhancing U.S.-UK scientific, economic and regulatory cooperation through an ambitious bilateral trade agreement.

### B. Unambitious economic dialogues

Those dialogues in which the Administration has engaged are unambitious, limited by design and disappointing. These include the U.S.-EU Trade and Technology Council (TTC), the Indo-Pacific Economic Framework (IPEF) and multiple bilateral dialogues. These dialogues exclude ambitions to deliver strong market access, IP and regulatory commitments that would facilitate trade and investment among trusted partners and improve the resilience of biopharmaceutical supply chains. In other words, the Administration's trade aspirations exclude achieving the very trade commitments that would be most effective in advancing its stated objectives "to secure trusted supply chains through strategic arrangements with trusted partners (friend-shoring) and with regional partners (near-shoring)."[14] Despite the constant chorus of concerns expressed by Congress, the business community and other stakeholders, the Administration has not corrected its trade policies to meaningfully advance those objectives, even as the United States' major economic competitors are actively pursuing trade agreements to expand their own roles in critical supply chains.

Even where IPEF and other U.S. dialogues purport to prioritize supply chain cooperation, their effectiveness in this regard is severely limited by the Administration's decision to exclude fundamental trade policies that are necessary to improve resilience. For example, meaningfully strengthening biopharmaceutical supply chains with trusted trading partners necessarily *requires* that those partners increase the level of IP protection that they provide. Unfortunately, the Administration does not appear to appreciate this fact. The Administration recently announced a "first-of-its-kind" IPEF Supply Chain Agreement, and yet IP is not even included among the negotiating objectives of the initiative's trade pillar.[15]

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[14] Federal Register notice at p. 16608.

[15] U.S. Department of Commerce, Press Statement on the Substantial Conclusion of IPEF Supply Chain Agreement Negotiations, available at https://www.commerce.gov/news/press-releases/2023/05/press-statement-substantial-conclusion-ipef-supply-chain-agreement (last visited Apr. 22, 2024); Office of the United States Trade Representative, United States and Indo-Pacific Economic Framework Partners Announce Negotiation Objectives, available at https://ustr.gov/about-us/policy-offices/press-office/press-releases/2022/september/united-states-and-indo-pacific-economic-framework-partners-announce-negotiation-objectives (last visited Apr. 22, 2024).

### C. Unwillingness to engage meaningfully at the WTO to dismantle trade barriers

The Administration has exhibited a clear and disappointing lack of commitment to WTO discussions concerning trade and health. Throughout the COVID-19 pandemic, our industry encouraged the United States and other WTO members to formalize and pursue a robust trade and health agenda to address and resolve the multiple trade barriers that impeded access to COVID-19 medicines, including tariffs, export restrictions and customs barriers.[16] Multiple WTO members, including geographically diverse countries at various levels of economic development, advanced constructive proposals along these lines, including proposals to eliminate tariffs, discipline export restrictions, enhance regulatory cooperation and improve trade facilitation measures.[17] Additional support for such initiatives was voiced in other international fora – including the G7 and the G20 – well in advance of the WTO's decision to waive certain commitments to protect IP on COVID-19 vaccines under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.[18]

Unfortunately, the U.S. Administration failed to meaningfully support these initiatives, despite substantial agreement among health and supply chain experts that the elimination of trade barriers would enhance medical supply chain resilience. For example, at the direction of Congress in the CARES Act of 2020, the National Academies of Sciences, Engineering, and Medicine evaluated and developed recommendations to improve the resilience of U.S. medical supply chains, and concluded in a March 2022 report that "[m]ajor exporters of medical products, including the United States, should negotiate a plurilateral treaty under the World Trade Organization that prohibits export bans and restrictions on key components of global medical product supply chains."[19] Despite this, the U.S. Administration took no action to advance such an initiative.

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[16] See, e.g., ABPI, EFPIA, IFPMA, PhRMA, WTO Twelfth Ministerial Conference: A Critical Opportunity to Strengthen the Global Trade and Health Agenda, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/V-Z/WTO-Twelfth-Ministerial-Conference---A-Critical-Opportunity-to-Strengthen-the-Global-Trade-and-Health-Agenda.pdf (last visited Apr. 22, 2024).

[17] This includes proposals from the European Union concerning trade facilitation, regulatory cooperation and disciplining export restrictions, and proposals from the "Ottawa Group" to limit export restrictions on medical goods, reduce tariffs and improve trade facilitation, among other proposals. See General Council, Urgent Trade Policy Responses to the COVID-19 Crisis, Communication from the European Union, WT/GC/231 (Jun. 4, 2021) and General Council, COVID-19 and Beyond: Trade and Health, Communication from Australia, Brazil, Canada, Chile, the European Union, Japan, Kenya, Republic of Korea, Mexico, New Zealand, Norway, Singapore and Switzerland, WT/GC/223 (Nov. 24, 2020).

[18] This includes the May 2021 G20 "Rome Declaration," which acknowledged "the central role of the WTO, and the importance of open, resilient, diversified, secure, efficient and reliable global supply chains across the whole value chain related to health emergencies." Similarly, the September 2021 "Declaration of the G20 Health Ministers" recognized the urgent need "to eliminate WTO-inconsistent barriers that jeopardize the effective operation of the supply chains for essential medical goods." See 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 (last visited Apr. 22, 2024); and Declaration of the G20 Health Ministers (5-6 Sep. 2021), available at https://reliefweb.int/sites/reliefweb.int/files/resources/G20_Italia_2021_Health_Declaration_final_05092021_OFFICIAL.pdf (last visited Apr. 22, 2024).

[19] National Academies of Sciences, Engineering, and Medicine. 2022. Building resilience into the nation's medical product supply chains. Washington, DC: The National Academies Press. https://doi.org/10.17226/26420.

Absent U.S. leadership, the WTO's Twelfth Ministerial Conference produced no concrete commitments to reduce or eliminate trade barriers in the health sector, while adopting a harmful and unnecessary TRIPS waiver on COVID-19 vaccines. For example, the Twelfth Ministerial Conference's most topical deliverable, the Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics, includes a variety of recognitions, recollections and reiterations but does not require any new meaningful actions or commitments by WTO Members.[20] Rather than seek to resolve longstanding and serious trade barriers that disrupt biopharmaceutical supply chains, the Administration aligned itself at the Twelfth Ministerial Conference with foreign governments that purported to seek a TRIPS waiver based on concerns about access to medicines but that themselves are prolific users of trade restrictions that limit such access.

Remarkably – and to the great disappointment of many U.S. allies and key trading partners – the United States similarly declined to champion a meaningful trade and health agenda at the WTO's Thirteenth Ministerial Conference, which likewise concluded without any concrete requirements that countries reduce or eliminate discriminatory trade policies that impede trade in medicines. Due to this failure of U.S. leadership, the WTO has made no meaningful progress toward addressing unnecessary trade barriers that continue to disrupt biopharmaceutical supply chains.

### D. Failure to adequately protect American IP abroad

U.S. biopharmaceutical innovators face serious IP challenges in foreign markets. As documented in PhRMA's annual Special 301 and National Trade Estimate submissions to USTR, many foreign governments fail to provide the IP protections necessary to support biopharmaceutical innovation and supply chains, despite their commitments under the WTO TRIPS Agreement and U.S. free trade agreements. Unfortunately, the Administration has not adequately enforced our trading partners' commitments to protect American innovation, allowing harmful policies and practices in key jurisdictions to go unaddressed. For example, and as discussed in greater detail below, Mexico has yet to implement key IP obligations under the United States-Mexico-Canada Agreement (USMCA).

Worse, the Administration undermined American innovation at the WTO's Twelfth Ministerial Conference by agreeing to eliminate certain obligations of foreign governments to protect IP on COVID-19 vaccines through the TRIPS waiver. This harmful and deeply unnecessary decision runs directly counter to the goal of promoting secure and resilient supply chains for innovative medicines, as it weakens the very incentives that enable the invention and production of such medicines. In addition, by eliminating the ability of original innovator companies to exercise oversight over production of COVID-19 vaccines, the TRIPS waiver could enable unqualified or malicious actors to supply adulterated, substandard or counterfeit vaccines, threatening the safety of the supply chain for these products. Furthermore, the Administration's decision to effectively hand over American innovations to countries looking to undermine U.S. leadership in biomedical

[20] WTO Ministerial Conference, Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics, WTO Doc. WT/MIN(22)/31 (Jun. 22, 2022), available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/31.pdf&Open=True (last visited Apr. 22, 2024).

discovery runs counter to the Administration's stated objectives to bolster supply chain resilience by growing American biotechnology infrastructure, innovation and employment.[21]

Having produced more than enough doses to vaccinate the world, the innovative biopharmaceutical industry encouraged the Administration to demonstrate leadership at the WTO by opposing the TRIPS waiver and refocusing global attention to resolving international challenges to distributing and administering that global vaccine surplus. Instead, the U.S. Government joined foreign governments in championing the TRIPS waiver for COVID-19 vaccines, to the detriment of American innovation, supply chains, and global public health.

### E. Refusal to eliminate tariff barriers that impede biopharmaceutical supply chains

The Administration has refused to pursue binding trade agreements that include the reduction or elimination of tariffs on health goods or other products. This refusal has had profoundly negative effects, including precluding U.S. engagement in negotiations for comprehensive trade agreements and other bilateral, plurilateral and multilateral agreements that could meaningfully enhance supply chain resilience.

Many countries maintain substantial tariffs on medicines and other health goods – especially large developing countries, where average applied most-favored nation (MFN) tariffs on medicines can be as high as 10 percent.[22] Such tariffs impede the functioning of biopharmaceutical supply chains by imposing direct costs on biopharmaceutical products and the various inputs used to invent, manufacture and deploy those products. This inhibits the diversification of supply chains, impedes patient access to medicines and diverts resources that could instead be directed to the research, development, clinical and manufacturing processes necessary to produce both new and existing medicines.

Furthermore, the Administration's refusal to pursue tariff reductions on health goods or other products represents a significant and unilateral departure from the negotiating objectives reflected in every iteration of trade promotion authority enacted by Congress since 1974, and in numerous predecessor statutes dating back to 1934. Over this 90-year period, Congress has enacted at least 19 such laws authorizing the President to negotiate trade agreements (or extending the duration of such authorities) for the purpose of reducing or eliminating tariffs among the United States and its trading partners.[23] Over the same time period, Congress on at

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[21] See, e.g., Exec. Order No. 14081, Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy (Sep. 12. 2022), available at https://www.whitehouse.gov/briefing-room/presidential-actions/2022/09/12/executive-order-on-advancing-biotechnology-and-biomanufacturing-innovation-for-a-sustainable-safe-and-secure-american-bioeconomy/ (last visited Apr. 22, 2024).

[22] The WTO reported in 2020 that Members' average applied most-favored nation (MFN) tariff on medicines was 2.1 percent, but many Members maintained higher tariffs on medicines, including Argentina (7.7 percent); Brazil (7.8 percent), Colombia (5.7 percent), Congo (5.0 percent), India (10.0 percent), Indonesia (3.8 percent), Korea (6.9 percent) and Thailand (7.6) percent. See World Trade Organization Secretariat, Trade in Medical Goods in the Context of Tackling COVID-19 (Apr. 2020), available at https://www.wto.org/english/news_e/news20_e/rese_03apr20_e.pdf (last visited Apr. 22, 2024).

[23] See Reciprocal Trade Agreements Act of 1934 (P.L. 73-316, extended by Congress in 1937, 1940, 1943, and 1945); Trade Agreements Extension Act of 1948 (P.L. 80-792, extended by Congress in 1949 and 1951); Trade

least 18 separate occasions has enacted legislation approving and implementing the resulting trade agreements negotiated by the President.[24]

It is unclear how tariff reductions negotiated in accordance with decades-old objectives and authorities established by the United States' democratically elected Congress, and implemented pursuant to trade agreements approved by that same Congress, "undermin[e] support for democracy itself," as USTR's Federal Register notice asserts.[25] In contrast, Congress has enacted no legislation that endorses USTR's unilateral decision to abandon this longstanding and bipartisan U.S. trade objective. Further, USTR's assertion that tariff liberalization "has contributed to the hollowing out of the American industrial base" is contradicted by significant evidence, including the U.S. International Trade Commission's 2021 finding that U.S. trade agreements have had net positive effects on U.S. output, income, employment among both men and women (whether college- or high school educated), and wages.[26]

## V. An Ambitious, Pro-Innovation Trade Agenda Is Necessary to Maintain and Enhance the Resilience of U.S. Biopharmaceutical Supply Chains

Multiple opportunities exist for the Administration to leverage trade policy to maintain and enhance the resilience of U.S. biopharmaceutical supply chains. Most importantly, the U.S. Government should engage more ambitiously with U.S. trading partners to negotiate, conclude and enforce comprehensive trade agreements that eliminate and address trade barriers and support medical innovation. Current opportunities include, but are not limited to, initiating negotiations with the United Kingdom and other well-positioned trading partners and increasing the ambitions of ongoing initiatives, including the TTC, the IPEF, bilateral dialogues and WTO discussions concerning trade and health. Specific proposals include:

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Agreements Extension Act of 1953 (P.L. 83-215, extended by Congress in 1954, 1955, and 1958); Trade Expansion Act of 1962 (P.L. 87-794); Trade Act of 1974 (P.L. 93-618); Trade and Tariff Act of 1984 (P.L. 98-573); Omnibus Trade and Competitiveness Act of 1988 (P.L. 100-418, extended by Congress in 1993); Trade Act of 2002 (P.L. 107-210); Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (P.L. 114-26).

[24] See the Trade Agreements Act of 1979 (P.L. 96-39, implementing the Tokyo Round agreements); United States-Israel Free Trade Area Implementation Act of 1985 (P.L.99-47); United States-Canada Free-Trade Agreement Implementation Act of 1988 (P.L. 100-449); Uruguay Round Agreements Act (P.L. 103-465); North American Free Trade Agreement Implementation Act (P.L. 103-182); United States-Jordan Free Trade Area Implementation Act (P.L. 107-43); United States-Singapore Free Trade Agreement Implementation Act (P.L. 108-78); United States-Chile Free Trade Agreement Implementation Act (P.L. 108-77); United States-Australia Free Trade Agreement Implementation Act (P.L. 108-286); United States-Morocco Free Trade Agreement Implementation Act (P.L. 108-302); Dominican Republic-Central America-United States Free Trade Agreement Implementation Act (P.L. 109-53); United States-Bahrain Free Trade Agreement Implementation Act (P.L. 109-169); United States-Oman Free Trade Agreement Implementation Act (P.L. 109-283); United States-Peru Trade Promotion Agreement Implementation Act (P.L. 110-38); United States–Panama Trade Promotion Agreement Implementation Act (P.L. 112-43); United States–Korea Free Trade Agreement Implementation Act (P.L. 112-41); United States–Colombia Trade Promotion Agreement Implementation Act (P.L. 112-42); United States-Mexico-Canada Agreement Implementation Act (P.L. 116-113).

[25] Federal Register notice at p. 16609.

[26] U.S. International Trade Commission, Economic Impact of Trade Agreements Implemented Under Trade Authorities Procedures, 2021 Report (Pub. 5199) at p. 90, available at https://www.usitc.gov/publications/332/pub5199.pdf (last visited Apr. 22, 2024).

### A. Facilitate the free movement of biopharmaceuticals, inputs, related health care items and key personnel

The United States should pursue policies and agreements that facilitate trade in biopharmaceuticals, including through robust engagement in bilateral, plurilateral and multilateral initiatives designed to eliminate trade and regulatory barriers. Such policies should include:

- Eliminating tariffs, export restrictions and other trade barriers on biopharmaceuticals, their inputs and related health care items and improving trade facilitation and customs procedures. Among other approaches, the United States should lead efforts at the WTO to formalize and pursue a robust trade and health agenda focused on these objectives. Existing proposals that have received broad support, such as the "Ottawa Group" proposal for a WTO Trade in Health Initiative, provide a valuable starting point for these efforts.[27]

- Enacting domestic policy proposals that promote the reduction of trade barriers in the biopharmaceutical and related health sectors among trusted trading partners. For example, the Medical Supply Chain Resiliency Act, which enjoys bipartisan support in Congress, would authorize USTR to negotiate trade agreements with trusted trading partners to eliminate tariffs and other trade barriers in the medical sector and promote strong IP, regulatory and other standards.[28] This approach would increase supply chain diversification through expanded trade with allied nations that maintain high standards and have demonstrated a commitment to maintaining open trade with the United States, especially during health emergencies.

- Working with like-minded foreign governments to establishing policies and mechanisms to identify and address potential health care supply constraints in a timely manner, e.g., designating a single point of contact within each government to share information and act quickly to address major supply chain constraints and related issues in times of a public health emergency.

### B. Enhance regulatory cooperation with like-minded partners

The United States should enhance regulatory cooperation with like-minded partners to increase administrative efficiencies, optimize resources and avoid unnecessarily duplicative procedures that inhibit the flow of life-saving medicines. For example, mutual recognition agreements (MRAs) are an important policy tool to leverage cooperation with likeminded and experienced regulatory authorities abroad. As USTR has recognized, mutual recognition of good manufacturing practices (GMP) inspections of biopharmaceutical manufacturing facilities can reduce unnecessary costs and duplicative efforts, enabling regulators to better exercise their

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[27] Draft General Council Declaration, COVID-19 and Beyond: Trade and Health, JOB/GC/251/Rev.3 (30 June 2021).

[28] 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 (last visited Apr. 22, 2024) and https://www.congress.gov/bill/118th-congress/house-bill/4307 (last visited Apr. 22, 2024).

respective regulatory discretion to re-allocate resources to where they are most needed, helping ensure that imported medicines are as safe as possible.[29]

Governments such as the European Union, Japan, Switzerland and the United Kingdom are natural candidates for new or expanded U.S. biopharmaceutical MRAs or other regulatory cooperation initiatives. For example, the Secure Supply Chains Working Group convened by the U.S.-EU Trade and Technology Council is an important, near-term opportunity to promote more efficient and secure biopharmaceutical supply chains with the European Union. To do so, the United States and the EU should:

- Ensure the full implementation of the U.S.-EU Mutual Recognition Agreement between the U.S. Food and Drug Administration and the European Medicines Agency, which entered into force in 2017. Opportunities include prioritizing implementation of the MRA regarding (i) pre-approval inspections; (ii) recognition of inspections of manufacturing sites in third countries; and (iii) biological products registered by the Center for Biologics Evaluation and Research.

- Extend the scope of the MRA to include (i) inspections of manufacturing facilities for human vaccines and plasma-derived pharmaceuticals, as envisioned by the MRA; and (ii) Good Clinical Practice (GCP) inspections to decrease unnecessary duplication of resource-intensive inspections and minimize risks of error or uncertainty.

In addition, the United States and like-minded 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.

### C. Prioritize strong IP protections

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 therefore should use all available trade policy tools to promote strong IP protections abroad, including (i) prioritizing the enforcement of IP obligations in existing U.S. trade agreements; (ii) ensuring that any future U.S. trade agreements include strong IP provisions; and (iii) promoting the protection and enforcement of IP rights through U.S. engagement at the WTO and in other international fora. Preserving and strengthening the global IP system will improve supply chain resilience by incentivizing investment in domestic research and manufacturing and safeguarding U.S. technologies against unfair exploitation by foreign actors.

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[29] Office of the US Trade Representative, 2023 Trade Policy Agenda and 2022 Annual Report (February 2023) at p. 150, available at https://ustr.gov/sites/default/files/2023-05/2023%20Trade%20Policy%20Agenda%20and%202022%20Annual%20Report%20FINAL.pdf (last visited Apr. 22, 2024).

### D. Ensure full implementation of USMCA biopharmaceutical commitments

As an immediate step to promote more resilient supply chains within North America, the United States should work to ensure that Mexico fully implements its IP and regulatory commitments under the USMCA. To date, Mexico has yet to implement certain IP obligations in the USMCA regarding patent enforcement mechanisms, regulatory data protection for biologic and small molecule products, patent term restoration and appropriate application of the Bolar Exemption to patent rights. Mexico also continues to severely delay the marketing authorization process for biopharmaceutical products, contrary to its commitments in the USMCA Sectoral Annex on Pharmaceuticals. Furthermore, although Mexico committed to open, fair and transparent government procurement procedures under Chapter 13 of the USMCA, it continues to make frequent and nontransparent changes to its public procurement system, resulting in supply chain challenges and product shortages.

These IP and regulatory obstacles have created significant challenges for biopharmaceutical companies seeking to operate in Mexico. Full compliance with IP and regulatory commitments under the USMCA would improve the business climate in Mexico and incentivize the development of more robust biopharmaceutical supply chains within North America.

### E. 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 partners, such as the European Union, 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.

### F. 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.

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In summary, PhRMA and its members believe that the U.S. government can and should leverage trade policies to bolster the resilience of U.S. biopharmaceutical supply chains. Unfortunately,

USTR's current approach fails to prioritize the very trade policies that are necessary to achieve this objective. To improve supply chain resilience, the United States must pursue an ambitious, pro-innovation trade agenda that incentivizes the development of life-saving medicines and eliminates trade barriers that disrupt efforts to invent, manufacture and deploy such products in the United States and around the world. This includes negotiating and enforcing trade agreements that incentivize innovation, provide strong IP protections, enhance regulatory cooperation and eliminate tariffs, export restrictions and other trade barriers on innovative medicines and inputs. PhRMA urges USTR to refocus attention on these critical priorities.

Sincerely,

/s/ Douglas Petersen

Douglas Petersen
Deputy Vice President, International