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Mr. Bryant Trick
Assistant U.S. Trade Representative for Europe and the Middle East
Office of the U.S. Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Re: Request for Comments on the U.S.-EU Trade and Technology Council (TTC) Global Trade Challenges Working Group (September 5, 2024)

Dear Mr. Trick:

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 and support the United States-European Union Trade and Technology Council (TTC) and view it as an important opportunity to deepen existing strong trade and investment relations between the United States and the European Union.

Unfortunately, three years after the launch of the TTC, the Biden Administration has yet to leverage the initiative to strengthen the transatlantic trade relationship in the biopharmaceutical sector. Indeed, the USTR's September 5, 2024 request for comments from the U.S. business community and other stakeholders concerning the TTC comes nearly three years and three months *after* the United States and the European Union announced the TTC on June 15, 2021.[1] Failure to prioritize this important sector in the TTC misses critical opportunities to strengthen the resilience of medical supply chains with a trusted partner and to support jobs, innovation and economic growth in both regions. PhRMA urges USTR to engage more ambitiously with the European Union, which is similarly seeking to strengthen its supply chains through trade with like-minded partners, is increasingly showing interest in sectoral trade initiatives and is supportive of addressing biopharmaceutical issues through the TTC.[2]

The submission below provides information regarding the innovative biopharmaceutical sector's robust U.S. economic footprint and the strength of U.S.-EU supply chains. The submission also

[1] The White House, "U.S.-EU Summit Statement," (June 15, 2021), available at https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/15/u-s-eu-summit-statement/).
[2] European Commission, "Strategic dependencies and capacities," (May 2021) at p. 43, available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021SC0352&from=EN; European Commission, Fact Sheet on the Critical Medicines Alliance (January 2024) at p. 2, available at https://health.ec.europa.eu/system/files/2024-01/hera_cma_factsheet_en.pdf; European Commission, "Political guidelines for the next European Commission 2024-2029" (July 18, 2024), available at https://commission.europa.eu/document/download/e6cd4328-673c-4e7a-8683-f63ffb2cf648_en?filename=Political%20Guidelines%202024-2029_EN.pdf; European Commission, President Ursula von der Leyen's mission letter to Maroš Šefčovič – Commissioner Designate for Trade and Economic Security and Inter-institutional Relations and Transparency, available at https://commission.europa.eu/document/4047c277-f608-48d1-8800-dcf0405d76e8_en.

details PhRMA's perspectives on overall objectives for the TTC, including specific opportunities to strengthen the transatlantic trade and investment relationship in the biopharmaceutical sector.

The U.S. Innovative Biopharmaceutical Industry is a Major 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.[3]

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.[4] 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.[5] 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.[6]

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.[7] 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.[8]

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[3] 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.

[4] 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.

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

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

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

[8] 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.

Open Trade Policies and Strong Intellectual Property Protections Have Enabled Innovative Biopharmaceutical Companies in the United States and the European Union to Build Resilient Supply Chains

Supply chains in the innovative biopharmaceutical industry showed remarkable resilience and agility during the COVID-19 pandemic. Despite unprecedented logistical challenges and demand surges, biopharmaceutical manufacturers in the United States and the European Union avoided major disruptions to the supply of innovative medicines and rapidly increased production of new vaccines and treatments. These successes are a testament to the resilience and effectiveness of the *innovative* industry's existing global supply chains and underscore the need for the United States and the European Union to maintain strong trade ties and robust intellectual property (IP) protections. These policies play a key role in enabling investment in biopharmaceutical manufacturing in both economies, ensuring reliable supplies of innovative medicines for patients in both the United States and the European Union.

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.

A high majority of API in U.S.-consumed medicines are manufactured in the United States or Europe. 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.[9] The remainder was manufactured in China (seven percent), Singapore (four percent), India (two percent) and other countries (two percent). The TTC presents an opportunity to further strengthen biopharmaceutical supply chains between the United States and the European Union.

The United States and the European Union Should Leverage the TTC to Further Strengthen the Biopharmaceutical Sector in Both Economies

USTR has requested comments to inform future work under the TTC Trade Working Group, including on opportunities to enhance bilateral trade in a manner that is mutually beneficial to U.S. and EU stakeholders. As close allies and world-leading hubs for safe and effective biopharmaceutical manufacturing, the United States and the European Union enjoy a robust and mutually beneficial trade and investment relationship in the biopharmaceutical sector. High levels of medical innovation in the United States and the European Union, enabled by generally

[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.

high levels of IP protection, yield enormous health benefits for patients in both economies. Patients also benefit from rigorous manufacturing standards in both jurisdictions, which ensure reliable supplies of safe and high-quality medicines for U.S. and European patients. At the same time, the export opportunities created through transatlantic trade support economic growth and jobs for biopharmaceutical and numerous other workers in both economies.

PhRMA urges the United States and the European Union to leverage the TTC to further strengthen this important relationship by better aligning regulatory approaches in the biopharmaceutical sector, producing concrete deliverables that remove barriers to trade in biopharmaceuticals and related health care items, and ensuring that the IP of biopharmaceutical innovators in the United States and the European Union is protected globally. This approach will further the stated objectives of the TTC to grow the bilateral trade and investment relationship, promote innovation and leadership by U.S. and European firms, strengthen cooperation on supply chains, support collaborative research and facilitate regulatory cooperation.[10]

In rhetoric, the Biden Administration has rightly recognized that trade relationships with trusted partners such as the European Union are essential to improve the resilience of supply chains, including in the medical sector.[11] Consistent with this principle, USTR's 2024 Trade Policy Agenda sets out objectives to "facilitate trade in safe and effective medicines and minimize drug shortages;" "facilitat[e] the movement of supply chains to trusted partners through friendshoring and near-shoring;" and "secure smoother and more efficient movement of essential goods during a pandemic[.]"[12] Members of Congress have similarly recognized that strengthening medical supply chains requires expanding trade with trusted partners that maintain high regulatory, IP and other standards. The Medical Supply Chain Resiliency Act, which enjoys bipartisan support in both houses of Congress, would further this objective by expressly authorizing USTR to negotiate trade agreements with trusted trading partners, such as the European Union, to eliminate tariffs and other trade barriers in the medical sector and promote strong IP, regulatory and other standards.[13]

In practice – and as noted in our introductory comments above – the Biden Administration unfortunately has declined to use the TTC to strengthen U.S.-EU biopharmaceutical supply chains or, more broadly, prioritize stronger U.S.-EU trade and investment relationships in the medical sector. PhRMA and its member companies encourage USTR and the Biden Administration generally to support the Medical Supply Chain Resiliency Act and commit to using the TTC to advance the important objectives outlines below.

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[10] The White House, "U.S.-EU Summit Statement," June 15, 2021, available at https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/15/u-s-eu-summit-statement/.
[11] 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.
[12] 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.
[13] 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.

I. General Negotiating Objectives for the TTC

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

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

PhRMA encourages the United States Government to pursue concrete and meaningful deliverables through the TTC that are as ambitious as possible. Such deliverables include strong IP protections and predictable and transparent market access, regulatory and other provisions that dismantle unfair and unnecessary trade barriers, incentivize innovation and facilitate the manufacturing and distribution of lifesaving medicines and other products and the ingredients and other inputs necessary to produce those medicines and products. While PhRMA continues to encourage the United States and the European Union to pursue as comprehensive of an agreement as possible, PhRMA also recognizes the complementary role of targeted agreements to reduce trade barriers, promote IP and strengthen supply chains and regulatory cooperation.

The submission below therefore highlights specific opportunities to leverage the TTC to enhance bilateral trade and investment in the biopharmaceutical sector, including by: (1) affirming the importance of strong IP protections and working jointly to promote IP protection globally; (2) enhancing regulatory cooperation and reducing regulatory barriers that discriminate against American medicines; (3) identifying and aligning on policies to foster supply chain diversification among trusted trading partners, including the elimination of tariffs and export restrictions on biopharmaceuticals; and (4) eliminating digital trade barriers that inhibit innovative biopharmaceutical R&D, manufacturing, delivery and pharmacovigilance.

II. Affirm the Importance of Strong IP Protections and Commit to Working Jointly to Promote the Protection and Enforcement of IP Rights Globally

Strong IP protections are a critical enabler of biopharmaceutical innovation and investment and therefore are integral to maintaining transatlantic leadership and robust transatlantic supply chains in this sector. Through the TTC, the United States and the European Union should jointly affirm these important benefits as well as the need for both parties to preserve strong existing IP rights in their own economies and to strengthen IP rights internationally. In this regard, the European Union should reconsider recent legislative proposals, which risk compromising regulatory data protection in the region, create a counterproductive regional framework for compulsory licensing and negatively impact trade secret protection.

In particular, the United States and the European Union should commit to prioritize the inclusion of strong IP provisions in their respective trade agreements and to work jointly at the World

Trade Organization (WTO) and in other international fora with likeminded partners to promote the protection and enforcement of IP rights globally. Within the WTO, the United States and the European Union should work to ensure that WTO members recognize and embrace the vital role of robust and predictable IP protections in enabling innovation and investment, including in any review or discussion regarding the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

The United States and the European Union should also continue to insist that any international agreements referencing transfers of technology by private rights holders indicate that such transfers must be voluntary and on mutually agreed terms, and consistent with existing WTO rules. Similarly, any WTO discussions concerning technology transfer (including in the Working Group on Trade and Transfer of Technology) should reflect and respect these policies. Together, these rules and policies concerning IP, innovation and technology transfer play a critical role in facilitating medical innovation and safeguarding the technologies of U.S. and European innovators against unfair exploitation by foreign actors.

III. Enhance Regulatory Cooperation and Eliminate Regulatory Barriers

A. Regulatory Cooperation

The United States and the European Union should collaborate on R&D priorities (e.g., to combat antimicrobial resistance) and enhance regulatory cooperation to increase administrative efficiencies, optimize resources and avoid unnecessarily duplicative procedures that inhibit the flow of life-saving medicines. The U.S.-EU Mutual Recognition Agreement (MRA) between the U.S. Food and Drug Administration and the European Medicines Agency, which entered into force in 2017, is an important policy tool for this purpose. As USTR has recognized, mutual recognition agreements can reduce unnecessary costs and duplicative efforts, enabling regulators to better exercise their respective regulatory discretion to re-allocate resources to where they are most needed, helping ensure that imported medicines are as safe as possible.[14] To fully realize and expand the benefits of the U.S.-EU MRA, the United States and the European Union should:

- Ensure the full implementation of the MRA, including by prioritizing implementation 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; (ii) advanced therapy medicinal products that are based on genes, tissues or cells; and (iii) Good Clinical Practice inspections to decrease unnecessary duplication of resource-intensive inspections and minimize risks of error or uncertainty.

[14] Office of the US Trade Representative, 2023 Trade Policy Agenda and 2022 Annual Report (Feb. 2023) at p. 150, available at https://ustr.gov/sites/default/files/202305/2023%20Trade%20Policy%20Agenda%20and%202022%20Annual%20Report%20FINAL.pdf.

In addition, the United States and the European Union should:

- Foster information exchange between the EMA, FDA and sponsors through cloud-based submissions, with appropriate confidentiality protections. While enabling technologies are being developed and both agencies are developing their respective internal digital transformation plans, ensuring U.S.-EU alignment at early stages will foster interoperable, international cloud infrastructure.
- 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.

B. Discriminatory Pricing and Reimbursement Policies

Foreign governments, including several EU Member States, often employ price controls and reimbursement policies that undervalue American innovative medicines. Such practices and policies are unique to the biopharmaceutical industry, given the dominant position of such foreign governments as the sole or primary purchasers of health care products and services. 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.

PhRMA members appreciate steps that previous Administrations 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 the adoption and promote the full implementation of such commitments in EU Member States as part of the TTC.

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 the EU.

IV. Strengthen Supply Chains and Facilitate Trade

The United States and the European Union should use the TTC to identify and align on policies to facilitate trade among trusted partners in biopharmaceuticals, including through robust U.S.-EU bilateral engagement and pursuing and supporting initiatives at the WTO designed to eliminate trade and regulatory barriers. Such policies should include:

- **Eliminating 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.
- **Eliminating existing export restrictions and committing to refrain from imposing such restrictions in the future.** 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.
- **Prohibit forced technology transfers and mandatory localization.** 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, including by impeding their abilities to research, manufacture and distribute medicines to patients globally. Any localization measure should be transparent and non-discriminatory, including in public procurement. Any transfer of technology related to biopharmaceutical

research, development, manufacturing or delivery should be voluntary and occur on mutually agreed terms. Requirements to disclose source code, algorithms, trade secrets or other IP assets to a government or local entity should be prohibited. The TTC should establish a strong platform to advance an aligned U.S.-EU position on these issues.

Among other approaches, the United States and the European Union should work together to formalize and pursue a robust WTO trade and health agenda focused on these and other relevant objectives, such as improving trade facilitation measures and enhancing the quality and effectiveness of WTO members' regulatory policies and procedures. 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.[15] As part of these efforts, the United States and the European Union should seek to restart discussions to improve and expand the WTO Agreement on Trade in Pharmaceutical Products, both by encouraging new members to accede to the Agreement and by beginning negotiations to expand the product scope of the Agreement, with the aim of achieving comprehensive coverage.

In addition, to facilitate their efforts to diversify medical supply chains, the United States and the European Union should work domestically to enact policy proposals that promote the reduction of trade barriers in the biopharmaceutical and related health sectors among trusted partners, such as the Medical Supply Chain Resiliency Act proposed in the U.S. Congress and certain policies under consideration by the Critical Medicines Alliance established by the European Union.

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 the European Union to negotiate high-standard commitments that eliminate digital trade barriers that discourage innovative biopharmaceutical R&D, manufacturing, delivery and pharmacovigilance.

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

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 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. The United States and the European Union should reaffirm the WTO 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.

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In summary, biopharmaceutical innovators in the United States and the European Union strongly support efforts to enhance transatlantic trade and investment in our sector. The achievement of these objectives would mutually benefit the patients, health systems and innovative economies of both the United States and Europe and deepen the already robust trade and investment relationships between these important partners and allies. These outcomes are consistent with the "major goals" of the TTC, as established by the leaders of the United States and the European Union at the June 2021 U.S.-EU Summit. The TTC is an important opportunity for the parties to achieve these goals, as they relate to the two economies' world-leading biopharmaceutical industries, through reducing trade barriers, increasing regulatory cooperation and promoting IP protection. These approaches will foster innovation, improve preparedness for future pandemics and health crises, and expand economic opportunities for workers in the United States and the European Union.

Sincerely,

/s/ Douglas Petersen

Douglas Petersen
Deputy Vice President, International