Strong U.S. Trade Policy Fuels American Biopharmaceutical Innovation

To maintain American leadership in biopharmaceutical innovation and manufacturing, the United States should pursue ambitious, pro-innovation trade policies.

America's innovative biopharmaceutical industry develops and manufactures medicines that transform lives and create a healthier world. The industry is a critical American economic sector that contributes significantly to U.S. manufacturing and provides high-tech, high-skilled jobs. U.S. companies and their workers lead the world in medical research, producing more than half of the world's new medicines in the last decade and exporting these American-made treatments and vaccines to patients across the globe.

U.S. biopharmaceutical innovators depend on fair access to overseas markets, as well as strong protection of American intellectual property (IP) in those markets, to undertake the substantial investments necessary to develop and manufacture new medicines in the United States.

Unfortunately, U.S. biopharmaceutical companies routinely encounter foreign trade barriers that undermine those efforts, including inadequate protection of American IP, damaging government price controls that distort markets and undervalue American innovation, high foreign tariffs and other discriminatory market access barriers.

To ensure that the United States remains the global leader in this critical sector, the U.S. government should pursue the following ambitious, pro-innovation trade policies:

- **Defend American workers and innovation through strong trade enforcement**: To provide a level playing field for America's biopharmaceutical workers, the United States must use all available tools to ensure that America's trading partners comply with their obligations in international trade and investment agreements.
- **Strengthen American supply chains by enhancing trade with trusted partners**: To further strengthen supply chains among U.S. allies and trusted partners, trade policies should facilitate the free movement of medicines and inputs, enhance regulatory cooperation and promote robust IP protection.
- **Increase American exports by negotiating ambitious trade agreements**: To expand economic opportunities for the American workers engaged in biopharmaceutical research, development and manufacturing, the United States must engage more ambitiously with trading partners to negotiate meaningful trade agreements that eliminate unfair trade barriers and protect U.S. IP abroad.
- **Protect American interests by refocusing the World Trade Organization (WTO) on its core mandate**: U.S. leadership is needed to refocus the WTO on its core mandate to promote rules-based trade, dismantle discriminatory practices and defend IP rights internationally.

The U.S. innovative biopharmaceutical industry is a critical American economic sector and contributes significantly to high-standard U.S. manufacturing and employment.

The innovative biopharmaceutical industry supports over 4.9 million jobs across the U.S. economy, including more than one million direct jobs, and supports more than $1.65 trillion in U.S. economic output annually.[1] The biopharmaceutical industry is one of the most research-, manufacturing- and export-intensive industries in America and has constructed reliable supply chains to ensure that U.S. patients have ongoing access to safe and high-quality medicines.

- **U.S. biopharmaceutical companies invested $141.0 billion in research and development** (R&D) of new medicines in 2022 – generating breakthroughs that enable people to live longer, healthier and more productive lives.[2]

- **U.S. biopharmaceutical goods exports exceeded $101 billion** in 2023.[3] The biopharmaceutical sector was the largest exporter of goods among R&D-intensive industries in 2023 – which includes biopharmaceuticals, navigational equipment, semiconductors and other electronic components, medical equipment and supplies, and communications equipment.[4]

- **34% of U.S. biopharmaceutical industry employees were engaged in or supported manufacturing** at over 1,500 plants across the country in 2022, while 39% were engaged in biopharmaceutical R&D, 24% were engaged in distribution and three percent were engaged in corporate administration.[5] In 2022, average annual compensation for U.S. biopharmaceutical workers was nearly $158,000 — more than $60,000 higher than the average U.S. manufacturing industry job.[6]

- **The U.S. biopharmaceutical industry is a top five employer of U.S. manufacturing jobs**, with more Americans directly employed in biopharmaceutical 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]

- **Most active pharmaceutical ingredients (API) used in U.S.-consumed *innovative* medicines are produced in the United States**. More broadly, 53% (by dollar value) of API used in all U.S.-consumed medicines (*i.e.*, innovative and generic) were produced in the United States in 2021, and 85% were produced in either the United States or Europe.[8]

The biopharmaceutical industry's large U.S. footprint depends on the ability to export American-made medicines to patients across the globe. U.S. trade policies that protect American IP rights internationally and eliminate foreign trade barriers are critical to the success of this vital American industry.

Historically, administrations from both parties have sought to address these barriers, protect American IP and challenge foreign discrimination against U.S. companies. Unfortunately, the prior U.S. Administration largely abandoned these important and bipartisan trade objectives.

To ensure that the United States continues to lead the world in biopharmaceutical innovation, the U.S. government must recommit to ambitious, pro-innovation trade policies that strengthen the American economy and enable American innovators to compete fairly in global markets.

Defend American Workers and Innovation Through Strong Trade Enforcement

To provide a level playing field for America's workers, the United States must use all available tools to ensure that America's trading partners comply with their obligations in international trade and investment agreements.

Members of the World Trade Organization (WTO) have committed to establishing functional intellectual property (IP) systems and eliminating policies that discriminate against American products and workers. These commitments include providing strong patent protection, safeguarding regulatory data against disclosure and unfair commercial use, and refraining from adopting trade restrictions and discriminatory industrial policies.[9]

U.S. regional and bilateral trade agreements affirm and build on these obligations by requiring even stronger protection of American IP, further reduction of regulatory barriers to enhance efficiencies, elimination of discriminatory market access policies against American companies, fair and transparent government pricing and reimbursement policies for medicines, and enhanced enforcement obligations.

Unfortunately, many U.S. trading partners fail to comply with these obligations. For example:

- **China** has not implemented its WTO obligation to protect clinical test and other data submitted for regulatory approval of new biopharmaceutical products. Similarly, **Argentina**, **Brazil**, **India** and several other WTO members do not provide regulatory data protection and key patent protections for innovative medicines, as required by WTO rules.
- **Mexico** has not implemented United States-Mexico-Canada Agreement (USMCA) commitments to strengthen IP protections and address regulatory approval delays for innovative medicines.
- **Korea** imposes drug pricing policies that severely devalue U.S. innovation and are inconsistent with its commitments under the U.S.-Korea Free Trade Agreement. **Japan** and several countries in **Europe** similarly maintain pricing policies that undervalue innovative American medicines.
- **Australia**, **Canada**, **Chile** and several other U.S. trading partners have not fully implemented fundamental IP obligations in U.S. free trade agreements.

The United States should pursue multiple enforcement initiatives to secure compliance with trade and investment agreement commitments. This includes the use of WTO and FTA dispute settlement procedures, which unfortunately have not prioritized IP abuses by foreign countries.

In addition, the U.S. Trade Representative should use all available tools, including the annual Special 301 report and investigations under Section 301 of the Trade Act of 1974, to identify and remedy violations. The United States also should leverage consultative mechanisms to achieve compliance, including Joint Reviews under the USMCA, and ensure that any country benefiting from U.S. tariff preferences under the Generalized System of Preferences (GSP) provides robust market access and IP protections as required by the GSP statute. Trade enforcement supports American jobs and exports, improves patient access to innovative medicines and incentivizes and protects American innovation.

Strengthen American Supply Chains by Enhancing Trade with Trusted Partners

To further strengthen supply chains among existing U.S. allies and trusted partners, trade policies should facilitate the free movement of medicines and inputs, enhance regulatory cooperation and promote robust intellectual property (IP) protection.

Over decades, the innovative biopharmaceutical industry has carefully built robust global supply chains to ensure that patients in the United States have ongoing access to safe and high-quality medicines. These supply chains have enabled U.S. biopharmaceutical manufacturers to navigate logistical challenges to avoid major disruptions to the supply of innovative medicines to patients. 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 these existing supply chains. 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.

To leverage these benefits, the United States should deepen trade with allies and trusted partners, focusing on the following:

- **Facilitate the free movement of biopharmaceuticals, inputs, and related health care items** by eliminating foreign tariffs, export restrictions and other trade barriers, and improving trade facilitation and customs procedures
- **Enhance regulatory cooperation**, including through mutual recognition agreements, to increase administrative efficiencies, optimize resources and avoid unnecessarily duplicative efforts
- **Collaborate on global initiatives to protect IP rights** to foster investment and innovation and safeguard U.S. technologies against unfair exploitation by foreign actors
- **Incentivize manufacturing** to support medical research, development and production capacity as part of overall pandemic preparedness and supply chain resilience initiatives

The United States should leverage all available platforms to advance these policies, including the pursuit of new trade, supply chain and mutual recognition agreements with trusted partners, such as the European Union, Japan, Switzerland and the United Kingdom. Congress should enact legislation authorizing the President to negotiate agreements to eliminate barriers to trade in medical goods with trusted trading partners that observe high IP, regulatory and other standards.

Supply chain policies should consider that market dynamics, practices and challenges vary for innovative manufacturers and generic manufacturers. For example, American innovative manufacturers constantly combat IP threats abroad and yet are more likely to invest in comprehensive business continuity plans, including stand-by manufacturing, supply chain redundancies and robust inventory to mitigate disruptions and prevent shortages.

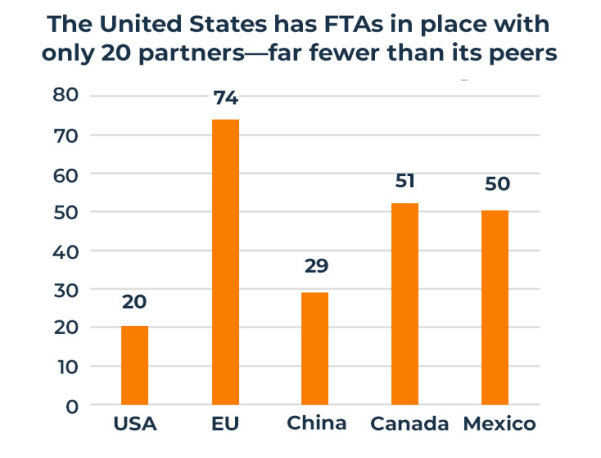
Increase American Exports by Negotiating Ambitious Trade Agreements

To expand economic opportunities for America's workers, the United States must pursue ambitious trade agreements to eliminate unfair trade barriers and protect intellectual property (IP) abroad.

Trade agreements, if commercially meaningful and properly enforced, open new markets to U.S. exports, grow our economy, enhance U.S. competitiveness and create better and higher-paying jobs. They also advance public health by providing critical incentives for medical innovation, fostering research and scientific collaboration, strengthening supply chains and improving patient access to innovative medicines. To achieve these objectives, U.S. trade agreements must:

- **Provide strong IP protections** that eliminate restrictive patentability criteria, address unreasonable patent examination and approval delays, require early and effective resolution of patent disputes and ensure robust protection of regulatory test data
- **Provide fair and equitable market access** to ensure that pricing and reimbursement policies abroad appropriately value patented medicines and are fair, reasonable and non-discriminatory
- **Eliminate foreign tariffs and customs and trade facilitation practices** that unnecessarily increase costs and delay patient access to medicines
- **Foster transparency and good regulatory practices** to ensure that stakeholders are afforded meaningful opportunities to provide input to regulators

Unfortunately, the United States has fallen far behind its peers in the pursuit of new trade agreements that reflect national interests.[10] Under the previous administration, the United States did not implement a single commercially meaningful trade agreement with a new or existing partner. This lack of engagement places America's biopharmaceutical workers at a competitive disadvantage relative to global competitors, misses critical opportunities to increase economic growth and allows foreign governments to shape global economic rules at the expense of the United States.



The U.S. Government should engage more ambitiously with trading partners to negotiate commercially meaningful trade agreements. Immediate opportunities include resuming negotiations on a precedent-setting bilateral trade agreement with the United Kingdom, initiating targeted negotiations with the European Union, Japan and Switzerland, and leveraging the Joint Review of the United States-Mexico-Canada Agreement (USMCA) to align the Agreement's IP chapter more closely with the United States' existing high standards and thereby incentivize additional North American manufacturing and stronger supply chains.

Protect American Interests by Refocusing the World Trade Organization (WTO) on its Core Mandate

U.S. leadership is needed to refocus the WTO on its core mandate to promote rules-based trade, dismantle discriminatory practices and defend intellectual property (IP) rights internationally.

The U.S. biopharmaceutical industry has long supported a strong international trading system rooted in the WTO's core principles of openness, fairness and predictability. WTO rules, including the baseline global IP protections enshrined in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), play an essential role in enabling American workers to develop and manufacture innovative medicines and export them to health systems and patients around the world.[11]

Regrettably, the WTO has strayed from these core principles and rules and often has served as a venue for certain foreign governments to attack intellectual property rights. The prior U.S. administration exacerbated this problem when it agreed in 2022 to waive certain TRIPS protections for COVID-19 vaccines. This harmful and unnecessary decision predictably failed to increase access to vaccines and emboldened foreign governments that seek to undermine IP rights internationally and impose other discriminatory policies.

Strong U.S. leadership is needed to enforce U.S. rights at the WTO and ensure that WTO members do not take further steps to undermine American innovation. The United States should pursue enforcement actions to address widespread violations of the TRIPS Agreement and ensure that any reviews or discussions concerning the TRIPS Agreement focus on full compliance with its obligations. The United States also should continue to insist that any international agreements referencing transfers of technology by private rights holders indicate that such transfers must be voluntary, on mutually agreed terms and consistent with existing WTO rules.

The United States also should work with like-minded countries to eliminate foreign trade barriers that inhibit the development, production and distribution of medicines. Eliminating foreign tariffs on American-made medicines, disciplining export restrictions and improving the trade facilitation and regulatory practices of foreign governments will support U.S. manufacturing, protect American biopharmaceutical workers and strengthen medical supply chains.

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[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] Id.
[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.
[4] Analysis of National Science Foundation and Business Research and Development Survey (BRDIS) data by ndp | analytics.
[5] 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.
[6] Id.
[7] U.S. Bureau of Labor Statistics, Current Population Survey (CPS) Labor Force Statistics, available at https://www.bls.gov/cps/home.htm.
[8] 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.
[9] Regulatory test data refers to the comprehensive package of information biopharmaceutical innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine for marketing approval.
[10] United States Trade Representative, Free Trade Agreements, available at https://ustr.gov/trade-agreements/free-trade-agreements; European Commission, Press release: European Commission proposes to strengthen EU trade agreement enforcement, (Dec. 21, 2023), available at https://ec.europa.eu/commission/presscorner/detail/en/IP_23_5742; U.S. Department of Commerce, China – Trade Agreements, available at https://www.trade.gov/country-commercial-guides/china-trade-agreements; Ministry of Commerce of the People's Republic of China, Free Trade Agreements, available at http://fta.mofcom.gov.cn/english/fta_qianshu.shtml; Global Affairs Canada. Free Trade Agreements and Agreements Canada has Signed by Country, available at https://www.tradecommissioner.gc.ca/fta-ale-canada.aspx?lang=eng; U.S. Department of Commerce. Mexico – Trade Agreements, available at https://www.trade.gov/country-commercial-guides/mexico-trade-agreements.
[11] The WTO TRIPS Agreement, which entered into force in 1994, strengthened the worldwide protection and enforcement of intellectual property rights by creating an international minimum standard of protection for intellectual property rights.