U.S. Chamber of Commerce

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March 11, 2025

Ambassador Jamieson Greer
United States Trade Representative
Office of the United States Trade Representative
Executive Office of the President
600 17th Street NW
Washington, D.C. 20509

RE: "Reviewing and Identifying Unfair Trade Practices and Initiating All Necessary Actions to Investigate Harm from Non-Reciprocal Trade Arrangements," Federal Register docket number USTR– 2025–0001.

Dear Ambassador Greer:

The U.S. Chamber of Commerce ("the Chamber") appreciates the opportunity to present the following comments to the Office of the U.S. Trade Representative in response to the Federal Register notice cited above. The Chamber is the world's largest business federation, representing the interests of more than three million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations, and it is dedicated to promoting, protecting, and defending America's free enterprise system. We advocate for trade policies that help to make the United States the best place in the world to invest, build, hire, and innovate while also allowing American companies of all sizes and sectors to sell their goods and services in lucrative foreign markets. On all these fronts, the fundamental objective is to foster economic growth to make the United States more prosperous and secure.

As the FRN notes, "USTR invites comments from the public, on a country-by-country basis, to assist the U.S. Trade Representative in reviewing and identifying any unfair trade practices by other countries, and in initiating all necessary actions to investigate the harm to the United States from any non-reciprocal trade arrangements. This information will assist the U.S. Trade Representative in recommending appropriate actions to remedy such practices and reporting to the President proposed remedies in pursuit of reciprocal trade relations" as indicated in the America First Trade Policy Presidential Memorandum and the Reciprocal Trade and Tariffs Presidential Memorandum.

The NTE Report is the obvious starting point for any examination of foreign trade barriers and unfair trade practices.

The U.S. business community has often shared its views with USTR on foreign trade barriers and unfair trade practices, and many of these are included in USTR's annual National Trade Estimate on Foreign Trade Barriers (NTE Report). As USTR's professional staff are aware, this report marks an excellent starting point for the present review.

However, the 2024 NTE attracted unusual controversy as the Biden Administration deleted many foreign trade barriers that it had criticized as recently as a year earlier. Many of the deleted barriers are, in fact, violations of commitments that foreign governments have made in trade agreements with the United States. USTR appeared to claim at the time that it had free rein to ignore those commitments, but many of them have the force of law as they are addressed in congressionally approved trade agreements. It is USTR's responsibility to enforce them and to engage bilaterally to address issues that arise. The Chamber commented in more detail on this matter elsewhere, and we strongly urge USTR on this occasion to amend this error by the previous administration, enforce U.S. trade agreements, and defend U.S. companies against discriminatory treatment overseas.

The present cataloguing exercise and any subsequent policy response should prioritize U.S. economic growth and dialogue with industry.

On many policy fronts, the Chamber is urging elected officials to prioritize the goal of achieving at least 3% economic growth annually and cementing in place policies that will support faster sustained economic growth over the long term.

From 1950 to 2010, real economic growth in the United States averaged 3.4% a year, even with recessions. As a result, the 2010 economy was seven times larger than the 1950 economy. However, since 2010, growth has averaged just 2.2% a year. This slowdown in economic growth threatens Americans' standard of living. When our economy is growing at 3%, someone who is born today will see America's economy double in size by the time they are in their early 20s. But at 2% growth, it will take until they are in their mid-30s for the economy to double.

To counter this trend, elected officials need to embrace pro-growth policies across a wide range of issues—including trade. As the Office of the U.S. Trade Representative considers foreign trade barriers and possible actions to address them, it is imperative that we keep our eyes on the prize—faster economic growth. This fundamental objective undergirds our following comments. Additionally, the Chamber encourages policymakers to engage in continuous dialogue with industry on solutions

that minimize disruption to investment activities and the broader economy. In the same vein, we discourage the indiscriminate, severe, or preemptive application of tariffs, which are among the most disruptive policy choices any administration can make.

The United States should pursue "zero-for-zero" reciprocity on tariffs and other trade barriers by negotiating additional enforceable trade agreements with allies and other friendly partners.

The best pro-growth response to foreign trade barriers is to negotiate enforceable trade agreements to eliminate tariffs and other trade barriers, open foreign markets, and guarantee reciprocity. Such an approach will provide U.S. manufacturers with predictability in our supply chains to drive international exports. As the NTE Report has long noted, other governments maintain a variety of barriers that limit U.S. exports of goods and services and shut them out of lucrative foreign markets. The U.S. market is largely open to imports from around the world (with notable exceptions such as steel, sugar, and goods from China, whose exports face a U.S. trade-weighted average tariff near 30% today). However, many other countries continue to levy significant tariffs on U.S. exports, and foreign governments have erected other kinds of barriers against U.S. goods and services.

Against these barriers, America's free-trade agreements (FTAs) have a remarkably positive record. While the 20 countries with which the United States has FTAs in force represent just 6% of the world's non-U.S. population, in recent years those countries have regularly purchased nearly half of all U.S. exports. On a per capita basis, those 20 countries purchase 14 times more U.S.-made goods and services than other countries. FTAs can make big export markets even out of small economies.

Further, U.S. exports to new FTA partner countries have grown roughly three times as rapidly on average in the five-year period following the agreement's entry-into-force as the global rate of growth for U.S. exports, as Chamber research shows.

U.S. FTAs have eliminated duties on a reciprocal basis for approximately 99% of all tariff lines in almost every case (and 100% in some instances). They have also swept away non-tariff barriers with rules on technical barriers to trade, sanitary and phytosanitary standards, and other disciplines. In these ways, U.S. FTAs are often far superior to those negotiated by other countries. These binding and enforceable agreements are based on principles of fairness, openness, and reciprocity.

Other sectoral arrangements have also brought great benefit to U.S. industry and the workers it employs by eliminating trade barriers on a reciprocal basis. One

example is the zero-for-zero tariff agreement for pharmaceuticals, which could be usefully expanded to additional countries. The WTO's Information Technology Agreement is another example of zero-for-zero tariff reciprocity covering several trillion dollars' worth of global trade, thereby eliminating any "non-reciprocal" tariff concerns with countries that are members. The WTO Agreement on Government Procurement has guaranteed U.S. firms' access to foreign government spending—often a much greater share of the overall market in sectors like healthcare than is the case in the United States—and required other countries to follow the same transparent procurement procedures that the United States follows as a matter of domestic law. An approach that focuses on the sectors of most importance to U.S. workers and companies would maximize the possible economic and commercial benefits in critical sectors.

The United States needs more market-opening trade agreements that eliminate the tariffs and other trade barriers that exclude U.S. goods and services from foreign markets. More than a decade has passed since the United States added a single country to its roster of FTA partners, and the sectoral trade agenda has been listless. Meanwhile, other countries have been entering into more such pacts: According to the World Trade Organization (WTO), 373 bilateral or plurilateral FTAs are in force around the globe today—up from about 100 at the turn of the century. The EU has trade agreements in place with 78 countries, Canada with 54, Mexico 50, and China 35. Africa is hard at work making its continental free-trade zone a reality. This dynamic puts American companies at a disadvantage in global markets.

The United States should reject broad-based tariffs as a policy tool given the substantial economic harm they impose on American workers, farmers, businesses, and consumers and opt for more targeted approaches where necessary.

The Chamber acknowledges that the administration may at times impose tariffs on imports from foreign adversaries with a view toward protecting national security and in coordination with other policy tools, such as export controls, investment restrictions, and financial sanctions. Further, with regard to non-market economies where state enterprises, industrial subsidies, forced localization, and other policies at odds with the free market are commonly deployed, policymakers may seek to advance the national interest through measures that include tariffs. Our annex below details ways in which such policies are used to distort markets and disadvantage U.S. companies. Nevertheless, even when using tariffs to address legitimate concerns with foreign adversaries, the measures should ideally be targeted rather than broad-based to effectively address specific economic and national security concerns while minimizing unnecessary harm to the U.S. economy.

However, whether applied to adversaries, treaty allies, FTA partners, or countries with which the United States enjoys friendly and cooperative relations, broad-based tariffs would impose substantial and direct costs on the United States. First, a tariff is a tax on imported goods that is paid to U.S. Customs and Border Protection by the U.S. business or individual receiving those goods at the border or port of entry. Americans literally pay these import taxes.

It is also substantively true that Americans pay U.S. tariffs. The New York Federal Reserve Bank found that "the tariffs that the United States imposed in 2018 have had complete passthrough into domestic prices of imports," and other research affirms that this is usually the case. In some circumstances, dollar appreciation or other economic factors may foist some tariff costs on foreign trading partners, but even in these cases the majority of the costs fall on Americans, and dollar appreciation suppresses U.S. exports even before retaliation (see below). The bottom line is that a policy tool that lowers the real income and purchasing power of American families and businesses is ill suited for pressuring foreign governments.

The surge in inflation during the Biden administration and the resulting cost-of-living crisis was a searing experience for many Americans. Painful price increases are widely recognized as a decisive factor in the outcome of the 2024 elections. Many recent studies affirm that recent tariff plans threaten thousands of dollars in higher prices annual for the typical American household. (See American Action Forum, The Budget Lab at Yale University, Moody's Analytics, Morgan Stanley, National Retail Federation, Peterson Institute for International Economics, Tax Foundation, Tax Policy Center, UBS.)

Recent polls show the American people are following closely today's highly publicized tariff threats, signaling Americans want the administration and Congress to focus on lowering prices more than any other policy priority. Polls also affirm that Americans correctly believe broad-based tariffs will drive prices up and consequently want elected officials not to implement them.

Second, blanket tariffs would hurt U.S. manufacturers far more than they would help. More than half of all U.S. imports are raw materials, components, and other inputs used by domestic manufacturers. A large share of these imports simply is not available domestically in sufficient quantities or at reasonable cost. There is no "slack" in the U.S. economy that could be tapped to replace imports on a large scale: To illustrate, the U.S. economy continues to face labor shortages, with 113 job vacancies for every 100 Americans currently seeking work, which is a far cry from the conditions at the beginning of President Trump's first administration.

In many instances, the United States simply cannot replace imports with domestic production. Take aluminum, which has been called "congealed electricity" to convey how electricity is the chief input. With U.S. electricity prices approximately one-third higher than they were a decade ago in real terms—and rising demand poised to send prices higher—it makes sense to import aluminum from locations such as Quebec, whose abundant hydropower and low electricity prices has long made it an attractive location for aluminum smelting.

The U.S. manufacturing sector is full of world-beating, globally-competitive companies that, all told, have doubled their domestic output over the past 40 years. However, U.S. manufacturers excel in high-skill, capital-intensive sectors, not the production of labor-intensive, low-value-added products made at low wages. Tariffs that incentivize the onshoring of low-wage jobs to produce low-value-added products will serve the American worker poorly.

Third, U.S. moves to impose broad-based tariffs would swiftly bring painful retaliation against American exports, which topped $3 trillion last year. In the past, foreign governments have responded to U.S. tariffs by raising their own duties on Iowa pork, Michigan autos, Pennsylvania apples, South Carolina washing machines, and Wisconsin cheese. The American workers and farmers who make these products are likely the first to feel the pain of that retaliation.

The risk is also rising that foreign retaliation will target other key sectors of the U.S. economy in novel ways. In a dispute more than a decade ago, Brazil threatened to suspend U.S. patents on pharmaceuticals, chemicals, and biotechnology in response to U.S. cotton subsidies (a negotiated agreement settled the dispute.) Speculation has arisen that some governments are considering such retaliatory moves today. Similarly, foreign governments may be considering "cross-retaliation" against U.S. services industries, whose exports last year topped $1 trillion. Other foreign officials have vowed their governments will respond to U.S. tariffs by no longer procuring U.S. products or from U.S. companies. Broad-based tariffs against multiple major trading partners and covering potentially trillions of dollars of imports may be expected to elicit a commensurate response.

The United States should disavow tariffs as a response to the U.S. trade deficit, which arises principally from the large U.S. fiscal deficit and is not the result of foreign trade barriers.

The overall U.S. trade deficit is not the result of foreign trade barriers. Indeed, the U.S. trade deficit is not an appropriate gauge of whether a particular set of trade policies or trade agreements is delivering benefits to the American people more broadly.

The Chamber agrees with the vast majority of economists who argue that "foreign import barriers and exports subsidies are not the reason for the US trade deficit," as Martin Feldstein, who chaired President Ronald Reagan's Council of Economic Advisers, has written:

> The real reason is that Americans are spending more than they produce. The overall trade deficit is the result of the saving and investment decisions of US households and businesses. The policies of foreign governments affect only how that deficit is divided among America's trading partners.

In balance of payments accounting, a country with a current account deficit (of which a trade deficit is typically the largest component) must by definition have a capital account surplus of identical value. The current account records trade in goods and services and net earnings on foreign investments. The capital account records international investments themselves (as opposed to earnings on them), both inbound and outbound, and a capital account surplus means the United States is a net importer of savings from abroad.

At present, the U.S. capital account surplus is overwhelmingly due to the large U.S. fiscal deficit, which today surpasses 6% of GDP. The federal government finances this deficit through the issuance of Treasury securities, some of which are purchased by foreign governments and private enterprises. In this manner, the United States is able to finance ongoing consumption and capital spending in excess of its current savings.

A current account deficit is often a sign of economic good health, signaling that purchasing power is strong and consumers are optimistic enough to spend. Historically, the U.S. trade deficit has expanded when the U.S. economy has grown faster than those of our major trading partners, as in the expansions of the 1980s and 1990s. By contrast, the U.S. current account has moved in the direction of a surplus in recessions, as happened in the Great Depression and the 2007-2009 recession. (The U.S. trade deficit was 3.1% of GDP in 2024, down from 5.5% in 2006.)

In fact, higher tariffs lead to higher trade deficits, not surpluses. According to a Chamber review of data from the Geneva-based International Trade Center and UNCTAD, 25 of the 30 countries with the world's highest tariffs have trade deficits. The overwhelming majority of these high-tariff countries have very low incomes, and the few high-tariff countries with trade surpluses—such as Algeria, Chad, and Congo—serve as poor models for U.S. economic policy.

The economist Joseph E. Gagnon of the Peterson Institute for International Economics recently summarized the matter well: "Although tariffs do not reduce trade deficits, they do reduce imports and exports, as well as total income."

The United States should disavow tariffs as a response to foreign value-added taxes, which do not constitute a trade barrier.

Both value-added tax (VAT) systems, such as those employed in Europe and well over 100 other countries (including Canada's Goods and Services Tax or GST), and U.S. state and local sales taxes are consumption taxes. VATs are imposed incrementally throughout the supply chain on the value added at each stage of production. Sales taxes are generally imposed on final consumption. The economic result is the same.

A German consumer buying a car pays Germany's 19% VAT regardless of whether the car is made domestically or abroad. Similarly, an American consumer in Tennessee will pay the state's 7% auto sales tax regardless of whether the car is made domestically or abroad.

Both European VATs and U.S. sales taxes are destination-based, meaning they are not levied on cars that are exported and sold abroad. However, European governments rebate the portion of the VAT that has already been paid in earlier stages of production when cars are exported. Such rebates are not necessary under a U.S. sales tax because none is generally imposed until final sale. None of this suggests that European VAT refunds are a subsidy.

Because such VATs are thus "border adjusted," there is no impact on trade flows. Nor do VATs play a role affecting business investment or sourcing decisions, as a subsidy might. VATs are not a barrier to trade, nor are they discriminatory: That is, goods are treated exactly the same, regardless of where they are manufactured. Imposing "reciprocal tariffs" in response to their use would be harmful and inappropriate. (See more from The Tax Foundation.)

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This document includes annexes offering detailed commentary on foreign trade barriers and trade practices. To reiterate the points above, these are not intended to justify the application of broad-based tariffs but should help U.S. negotiators to focus on specific issues of importance to American businesses of all sizes.

The Chamber appreciates the opportunity to share these comments and looks forward to further discussion to address these important issues, including those outlined in our non-exhaustive annexes.

Sincerely,

John Murphy
Senior Vice President and Head of International
U.S. Chamber of Commerce

ANNEX A
Country-Specific Comments

Argentina

Issue: *Restrictive patentability criteria*
Impact: Through Resolutions 118/12, 546/12 and 107/17, the Ministries of Health, Production, and El Instituto Nacional de la Propiedad Industrial (INPI—Institute that manages National IP policy) defined a series of evaluation and patentability criteria for chemical and pharmaceutical inventions. These administrative rules and guidelines exclude most products that constitute a new entity from patent protection, limiting the patentability of inventions in the pharmaceutical industry far beyond the standards of most patent offices in the world. These regulations have created significant space for domestic pharmaceutical companies to develop alternatives to innovative products based on original research from others, thereby considerably discouraging innovation by restricting patentability across various groundbreaking areas.
Recommendation: Argentina should work to repeal its restrictive patentability criteria and extend the IPR protections it affords to all types of chemical and pharmaceutical innovations, thereby bringing these protections up to the level of international practices. This reform would improve market access for U.S. innovative pharmaceutical firms.

Issue*: Live matter patentability*
Impact: INPI Resolution 283/15 introduced a more restrictive interpretation of Article 6 of the Patent Act that restricts live matter or gene patentability. As a result, the patentability of nucleotides or amino acids is limited compared to other countries such as the U.S. Like the patentability guidelines for synthetic pharmaceutical products, this regulation limits the return on investment in R&D in genetic engineering. Argentina's considerable potential in genetic engineering was drastically reduced by this measure, as innovation in key areas like seeds (similar to the transgenic HB4 wheat developed domestically), animals, and functional foods lags behinds other markets due to the absence of patentability requirements. This is compounded by the fact that Argentina maintains the UPOV 1978 standard, whereby seed patents and breeders' rights cannot coexist.
Recommendation: Recognizing the patentability of live matter would allow Argentina to develop groundbreaking inventions in an area in which it has shown considerable comparative advantages already with the development of HB4 wheat. This could be combined with the adoption of UPOV 91 standards to ensure the protection of plant varieties to encourage innovation and level the playing field for U.S. companies.

Issue: *Low standards for test data protection and exclusivity*
Impact: Ongoing challenges to the innovative agricultural chemical and pharmaceutical sectors are inadequate protection against unfair commercial use, as well as the unauthorized disclosure of undisclosed test or other data generated to obtain marketing approval for products in those sectors. The Argentine IP system permits regulatory approval based on bioequivalence and bioavailability standards, which allows domestic companies to take advantage of—practically at no cost—clinical trial data published by foreign pharmaceutical companies disclosed before the regulatory authorities of other countries. This allows domestic companies to act as free riders and benefit from R&D efforts made by competitors. Compounded with strict patentability standards, the low level of protection of test data considerably discourages investment in clinical trials by foreign pharmaceutical companies in Argentina. Argentina does not protect regulatory test data as required under TRIPS. Existing laws and decrees allow officials to rely on originator-submitted data to approve competitors' products, undermining intellectual property rights.
Recommendation: Argentina should consider extending protection to test data and recognizing its exclusivity, a necessary requirement for innovation in applied chemistry and pharmaceuticals in today's world. This would bring Argentina in line with most other countries that have recognized this increased protection of intellectual property rights and open up the market for U.S. companies to conduct clinical trials.

Issue: *Patent extensions*
Impact: The protection afforded by an Argentine patent lasts for 20 years. However, this term is counted from the filing date as opposed to the moment the patented product receives regulatory approval or is put on the market. The period between the filing date and the moment the patent is approved or rejected usually lasts from 5 to 7 years. Additionally, even if the patent receives approval, the product must receive regulatory authorization by a regulatory authority (ANMAT in Argentina's case) to be marketed. This additional period reduces the effective protection of a patent in most countries from 20 years to 7 to 10 years. In most countries, this is resolved by granting patent holders an additional period after expiration to compensate the delay caused by the approval of the regulatory authority. This is not the case in Argentina where no extensions are given despite the long periods before a patent is approved.
Recommendation: Extending the term of patents in a context of considerable delays for patent review would ensure that the intended level of protection granted by patents is effective in practice. Argentina should follow established international practice and consider extending patent terms by up to 5 years where applicable to foster an innovative environment that takes into consideration a delay that is not attributable to innovators.

Australia

Issue: *Delays in Australia's regulatory system for approval and reimbursement of new medicines*
Impact: Australia utilizes a health technology assessment mechanism for all new product listings, which has resulted in lengthy reimbursement times and delayed patient access. On average, it takes 47 months from regulatory approval of a product to reimbursement listing in Australia. Similarly, there is a high rate of rejections with few new products appraised as being cost effective. Compared with other OECD peers, many innovative products are not launched or listed on the pharmaceutical benefits scheme (PBS) and, in effect, never made available to Australian patients. For example, of the 460 new medicines launched between 2012-2021, Australian patients only had access to 32% of those medicines, while patients in the U.S. had access to 85%.
Recommendation: These issues are being addressed in an ongoing Health Technology Assessment Review (HTA), and we urge the administration to promptly implement the recommendations that meet the shared goals of the review under the Strategic Agreement to accelerate patient access and ensure that Australia is a wave 1 launch country.

Issue: *Patent notification*
Impact: Australia does not notify medicine patent holders of an application by a competitor to supply a generic version of the same product. The registration process instead relies on a declaration by the generic company that the patent is no longer valid. However, such declarations are often contested due to the complexity of multiple patents on a single product. The first opportunity for the innovator to learn of the generic entry is when it is advised by the Government that it will be forced to accept a 25% reduction in the reimbursed price due to a competitor product becoming registered and available. This often leads to the patent holder needing to take emergency injunctive action in the court to block the competitor's launch while it assesses its patent validity.
Recommendation: A previous legislative proposal would create a patent notification framework under which first follow-on applicants would be required to notify the rightsholder when an application has been submitted to the TGA but before the agency begins its review process. This would provide the patent holder with 12 months to review their patent validity ahead of the approval. The Chamber would support the adoption of this framework, which would bring Australia in line with its obligations under Article 17.10(4) of the Australia-United States Free Trade Agreement. This process stalled through the onset of the COVID-19 pandemic and change of Government.

Issue: *Differential treatment for local vaccine manufactures*
Impact: In October 2024, the Australian government tabled the Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024, which activated a range of new and advantageous procurement processes for one local vaccine manufacturer not available to other competitors. This included alternative methods of HTA approval and exemption from standard procurement rules, independent of merits review and transparency of decision making (such as publishing public summary documents). Accordingly, this created an uneven playing field for U.S. companies. Such a measure may also act as a disincentive to local financial investment due to the uncertainty of the application of rules for vaccine funding approval and procurement. This unfavorable treatment of imported goods appears to be in conflict with Australia's international obligations under Article III:4 of the WTO General Agreement on Trade and Tariffs, Articles 5.1.1 and 5.1.12 of the WTO Technical Barriers to Trade Agreement, Articles 4.1, 4.4, 4.6, 10.1 and 15.4 of the WTO Government Procurement Agreement, Articles 2.2, 8.7, 15.2 and 15.3 of the US-Australia Free Trade Agreement.
Recommendation: U.S.-manufactured products should be allowed to compete on an equal basis with Australian produced goods, consistent with the WTO and U.S.-Australia Free Trade Agreement articles cited above.

Brazil

Issue: *Ethanol tariffs*
Impact: In February 2023, the Brazilian Foreign Trade Chamber (Camex) reinstated a 16% tariff on U.S. ethanol imports, later increasing it to 18% in 2024. Previously, ethanol imports benefited from 0% tariffs under a tariff-rate quota program. The U.S. imposes a 2.5% tariff on Brazilian ethanol, highlighting an imbalance which has become a significant trade irritant in the bilateral relationship. Moreover, Brazilian producers benefit from access to U.S. programs like the Renewable Fuels Standard and California's Low Carbon Fuel Standard, while U.S. ethanol lacks access to Brazil's RenovaBio program.
Recommendation: Brazil should lower ethanol tariffs to ensure reciprocity and allow fair market access for U.S. producers. The imbalance in tariffs coupled with challenges in accessing RenovaBio not only puts U.S. producers at a competitive disadvantage but also impacts price stability and hinders energy cooperation between the two largest ethanol-producing nations.

Issue: *Healthcare market access*
Impact: Brazil's Health Regulatory Agency (ANVISA) faces workforce shortages and regulatory delays that disrupt supply chains and limit access to essential health products. The outdated RDC 81/2008 governs the import of health products to Brazil and creates delays and extra costs for U.S. companies, which also face lengthy approval processes as Brazil does not recognize U.S. FDA approvals. While ANVISA aligns regulations with Mercosur, U.S. companies do not benefit from expedited approvals, leading to longer wait times and higher compliance burdens compared to competitors from other markets.
Recommendation: The regulatory bottlenecks and staffing shortages at ANVISA pose significant challenges for U.S. companies operating in Brazil's healthcare sector. Brazil should increase workforce capacity at ANVISA, accelerate the RDC 81/2008 reforms, and establish mutual recognition agreements with the U.S. FDA in order to overcome regulatory hurdles and improve market access for U.S. companies.

Issue: *Tax reform implementation*
Impact: Brazil has one of the most complex tax systems globally. In December 2023, the Brazilian government approved a long-awaited tax reform that aims to modernize the tax system by consolidating taxes at the federal, state, and municipal, levels. Currently, in some sectors such as ICT, Brazil provides tax incentives for digital goods developed locally while imported telecom products can reach cumulative taxation rates as high as 40% in some states. While the reform is expected to reduce the tax burden –making U.S. exports more competitive and simplifying compliance for business – full implementation will not occur until 2033.

Recommendation: It is imperative that the transition period is managed effectively to reduce administrative burdens on companies as the tax reform is implemented. The Chamber urges Brazil to ensure fair treatment of U.S. companies across industries.

Issue: *IP standards*
Impact: Brazil's IP standards do not align with global best practices, failing to provide the same treatment as Brazilian companies receive under U.S. law and unfairly excluding the pharmaceutical industry. The average patent examination time by Brazil's National Institute of Industrial Property (INPI) for the biopharmaceutical sector is approximately 9 years, significantly longer than the global average of 3 years. Brazilian law also lacks Regulatory Data Protection (RDP) for pharmaceuticals, though it provides protections for veterinary and agricultural chemical products. Legislative efforts to expand compulsory licensing beyond Trade-Related Aspects of Intellectual Property Rights (TRIPS) standards create uncertainty for U.S. innovators, deterring investment in new products.
Recommendation: Amendments to Brazil's IP law are crucial to reduce examination delays and allow proportional adjustments to patent terms in cases of excessive delays not caused by applicants. Brazil should also implement legal mechanisms for pharmaceutical RDPs and align IP standards with international best practices, ensuring compulsory licensing rules are compatible with WTO obligations.

Issue: *Polyethylene tariffs*
Impact: In 2024, the U.S. accounted for approximately 70% of all Polyethylene (PE) imports to the Brazilian market, making it the largest supplier of PE to Brazil after the domestic producer. In October 2024, Brazil increased tariffs on chemical imports from 11.5% to 20%, including PE. Brazil is also in the midst of an anti-dumping investigation into U.S. and Canadia PE, which if successful, would impose an additional 21.4% tariffs, bringing the total to 41.4%. Currently there is no anti-dumping duty applied, but a provisional measure is expected between April and June 2025.
Recommendation: Protectionist tariff policies implemented by Brazil would not only harm U.S. chemical exporters but also lead to higher prices for domestic consumers. Brazil should carefully assess domestic industry needs to determine if anti-dumping measures are necessary and engage in dialogue with the U.S. to find a mutually beneficial solution that avoids the imposition of additional tariffs.

Issue: *Telecom testing requirements*
Impact: Brazil imposes numerous burdensome regulatory requirements on companies operating in the ICT sector. Brazil's National Telecommunications Agency (Anatel) does not accept test data generated outside of Brazil, except in limited cases where equipment is physically too large or costly to transport. This requires almost all IT/telecom equipment testing – including mobile phones and optical cables – to be conducted in Brazil, leading to increased costs and delays.

Recommendation: These regulatory barriers create unnecessary obstacles to market entry, delay time-to-market for U.S. products, and increase costs for companies exporting to Brazil. Brazil's requirements should align with its WTO commitments, including the WTO Technical Barriers to Trade (TBT) Agreement, Article 2, Section 2.2, which requires that technical regulations do not create unnecessary obstacles to international trade.

Canada

Issue: *Pharmaceutical intellectual property issues*
Impact: Given Canada's model of healthcare and health spending, biopharmaceutical rightsholders face significant challenges in exercising their IP rights due to the growing focus on rigid cost control and minimizing overall biopharmaceutical spending. Over the past several years, Canadian authorities reformed how patented medicines are evaluated and priced through the Patented Medicine Prices Review Board's (PMPRB) evaluation methodology. These reform efforts have focused almost exclusively on cost and expenditure reduction. Using powers vested in the PMPRB, Canada utilizes international price comparisons, which has expanded the size of the basket and removed the United States and Switzerland as comparator economies. In addition, Canada has not properly implemented the patent terms adjustment (PTA) system required under USMCA. The adopted regulations impose limitations that prevent innovators from receiving full compensation for patent office delays, failing to meet Canada's trade obligations. Canada's patent term restoration system (PTR) does not effectively compensate for marketing approval delays, adopting only the minimum CETA-required term while also including an "export" exception that further weakens protections. Restrictive eligibility criteria further limit its effectiveness, diverging from international standards.
Recommendation: Canada should fully implement its IP obligations under USMCA, including the provision for the PTA system. Canada should also provide for patent term restoration (PTR), which provides additional patent life to compensate for the time lost during clinical trials and the regulatory approval process. Health Canada should put in place adequate safeguards to limit and control the release of confidential business information (CBI) to ensure the regulations are consistent with Canada's international treaty obligations.

Issue: *Procurement practices not aligned with trade obligations*
Impact: Canada's recent procurement practices raise concerns of unfair treatment to U.S. companies in several areas including potential preferences for locally produced vaccines, provincial preferences not considered in federal processes, price outweighing recognized value, "winner take all" tenders and lack of transparency.
Recommendation: Ensure that Canada upholds its Government Procurement Agreement (GPA) trade obligations.

China

The Chamber has long pointed out the structural challenges to U.S. companies doing business in China, most recently in response to the USTR's annual request for comments concerning China's compliance with WTO commitments (see here). While that document offers a more detailed discussion of China's trade barriers, we reiterate our major concerns below:

Issue: *New security-focused laws and policies that impede information gathering necessary for business decisions*
Impact: China's *Counter Espionage Law* has been revised to broadly include "other documents, data, materials, and items related to national security together" with state secrets and intelligence in its definition of espionage activity. Recent revisions to the *State Secrets Law* also introduced "work secrets," which are broadly defined as secrets "that are not state secrets but would cause a definite adverse impact after leaking." Such broadly scoped legislation, combined with Chinese authorities' track record of high-profile raids on foreign consulting firms, impede standard due diligence practices and complicate the corporate governance of multinational firms.

Issue: *Procurement policies that focus on indigenization and self-sufficiency in a manner that undermines opportunities for U.S. companies in China, including via barriers to government and state-directed procurement, especially in targeted sectors such as IT and medical devices*
Impact: China's continuing failure to fulfill its 2001 commitment to join "as soon as possible" the WTO Agreement on Government Procurement has become even more problematic as China has in recent years taken aggressive steps to restrict access to its government-linked purchases—a huge share of the overall Chinese market—in order to favor "indigenous" producers sectors over established U.S. companies in targeted technology sectors. U.S. companies continue to raise concerns over purported initiatives by China's State-owned Asset Supervision Administration Commission requiring, inter alia, state-owned enterprises to have their IT stacks completely localized by 2027. China has since 2021 required that government funded hospitals (the majority of the Chinese healthcare market) only purchase medical equipment that has been made in China and has since then overlaid additional content and technology requirements that are very difficult for a non-Chinese company to meet. Most recently, China has announced plans for domestic content and domestic technology requirements in all government procurement that go far beyond comparable requirements that Chinese companies face in the U.S. private or public sector market.

Issue: *Entrenchment of policies that focus on indigenization and self-sufficiency in a manner that undermines claims of openness and market opportunities for U.S. companies in China, including via government and state-directed procurement*
Impact: China's continuing failure to fulfill its 2001 commitment to join "as soon as possible" the Agreement on Government Procurement has become even more problematic as U.S. companies continue to raise concerns over the purported existence of a secret document from China's State-owned Asset Supervision Administration Commission requiring, inter alia, state-owned enterprises to have their IT stacks completely localized by 2027. Most recently, China has announced plans for domestic product standards in government procurement that seeks to impose content level / sourcing requirements that go beyond the substantial transformation test Chinese companies face in the U.S. market.

Issue: *Divergence from global best practices in antitrust, licensing / certification, and patent invalidation and failure to implement "Phase One" Agreement obligations in IP*
Impact: China's apparent willingness to be a global outlier exacerbates longstanding issues with regulatory transparency and consistency. There is a growing list of merger and acquisition reviews—particularly in tech-related deals—in which the review time and required remedies exceeds those in other jurisdictions, which has led to the effective cancellation of several major deals. Examples from other sectors include requiring pharmaceuticals to be marketed in China first to meet the definition of "new drug", the refusal to allow data supplementation in patent invalidation cases, deliberate delays in approving imported agricultural products, and inconsistent / incomplete approval of electronic payment system providers. Moreover, the failure to permit supplemental data to demonstrate patentability and the failure to provide meaningful patent term extension are in direct contravention of China's obligations under the "Phase One" Agreement. China also still does not provide meaningful regulatory data protection despite agreeing to do so in its WTO Accession agreements decades ago.

Colombia

Issue: *Use of compulsory licenses*
Impact: The issuance of compulsory licenses in Colombia, particularly the recent decision to grant a license on an innovative medicine, and the public announcements of additional actions, pose significant challenges to the intellectual property (IP) landscape. Such actions undermine U.S. investments in Colombia as well as the U.S. Colombia Trade Promotion Agreement (TPA). This approach, which deviates from international norms and legal requirements as established in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, will undermine the protection of IP rights of U.S. companies. This will. Disrupt U.S. companies' existing business models and partnerships, increasing risks and uncertainties, which could hinder their ability to expand market presence and capitalize on opportunities in Colombia, ultimately affecting their growth and profitability.
Recommendation: Colombia should strengthen IP protection frameworks, using compulsory licenses only in exceptional circumstances and aligning with international standards. Such an approach could bolster transparency and predictability for businesses and investors. Additionally, the Chamber encourages the U.S. government to work closely with the Colombian government to enable access to innovative treatments by promoting competition in the marketplace, rather than undermining IP protection.

European Union

Issue: *General Pharmaceutical Legislation (GPL) and patent package*
Impact: The EU's proposed General Pharmaceutical Legislation (GPL) weakens intellectual property protections, reducing incentives for U.S. pharmaceutical companies to invest in the European market. The weakening of regulatory data protection (RDP) and reduced market exclusivity erode legal certainty and impose lower standards than in the U.S. The U.S. exports $36 billion in pharmaceuticals to the EU, and these changes could lead to billions in lost sales and reduced R&D investment, particularly in innovative medicines.
Recommendation: The EU should maintain or strengthen its current framework for regulatory data protection to ensure continued investment in pharmaceutical innovation. Market exclusivity provisions should not be contingent on external factors like market access. Defining "unmet medical need" more broadly and introducing stronger incentives for innovative medicines are also important priorities. Any adoption of a pan-EU compulsory licensing mechanism should at least be compliant with the EU's WTO obligations.

Issue: *Medical Device Regulations (MDR/IVDR)*
Impact: The EU's Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) have created significant bottlenecks, delaying approvals for U.S. medical device manufacturers. The increased cost and complexity of compliance, including stricter certification and documentation requirements, have raised total industry costs by over $1 billion. These regulatory burdens discourage innovation, slow patient access to life-saving technologies, and limit the ability of U.S. firms to compete in the EU market.
Recommendation: The EU should revise the MDR/IVDR to streamline approval processes, enhance governance, and introduce an accelerated pathway for innovative products. In the short term, targeted measures such as guidance documents, implementing acts, and amendments should address immediate regulatory barriers and improve market access for U.S. medical device manufacturers.

Issue: *Clawback policies*
Impact: Several EU member states impose clawback mechanisms on pharmaceutical and medical device companies, requiring firms to return revenue if healthcare spending exceeds often underfunded healthcare budget limits. These unpredictable financial penalties disproportionately impact U.S. firms, creating uncertainty, undervaluing innovation and discouraging long-term investment. If expanded, these policies could result in essentially a tax of billions of dollars on U.S. life sciences companies, potentially leading to market exits or reduced product availability in the EU.

Recommendation: Brussels should assess whether national clawback mechanisms conflict with EU procurement rules. Member state governments should balance fiscal policies with the need for medical innovation, ensuring that clawback schemes do no create excessive burdens on industry.

Issue: *Corporate Sustainability Due Diligence Directive (CS3D)*
Impact: CS3D, set to be phased in starting in 2027, requires companies to identify, prevent, and mitigate human rights and environmental abuses in their supply chains. The Directive applies to global operations of in-scope companies. Failure to comply with these obligations carries the risk of fines of up to 5% of companies' net worldwide turnover. The Commission has proposed changes to CS3D that should be rapidly adopted by co-legislators, including a one-year delay.
Recommendation: In addition to the amendments laid out by the Omnibus legislation, the EU should take into consideration that the U.S. has robust corporate governance, environmental, and human rights laws. The EU should clarify that actions taken lawfully in jurisdictions with robust laws should not be the target of EU Member State enforcement or stakeholder litigation under CS3D. If an EU operation of a U.S.-parented company is determined to be out of scope of the CS3D, the parent company should likewise be exempt.

Issue: *EU deforestation regulation (EUDR)*
Impact: The EU approved a 12-month delay to the start of EUDR but has not indicated how it approach further negotiations. The EUDR requires companies selling cocoa, palm oil, coffee, and other products on the EU market to prove that their supply chains are not contributing to global deforestation. U.S. government concerns about the feasibility of EUDR have not been addressed.
Recommendation: The EU should adopt a zero-risk category of countries with strong governance and environmental standards, including the United States. The U.S. should be recognized as a deforestation-free jurisdiction, which would mitigate the risk of trade barriers.

Issue: *PFAS / chemical strategy*
Impact: The EU's Chemical Strategy for Sustainability aims to curb the use of perf- and polyfluoroalkyl (PFAS) chemicals in countless products. According to a 2023 U.S. Chamber of Commerce study, the total economic and fiscal impacts of goods exported from the U.S. to the EU that contain PFAS in 2022 and are at-risk represent 502,000 domestic jobs, $168 billion in sales output, and $81 billion in U.S. GDP.
Recommendation: The EU should carry out risk based PFAS recommendations that include a comprehensive breakdown of costs, impacts, and potential unintended consequences. Restrictions should be limited to substances used in broad consumer applications with high potential for exposure to proven dangerous or hazardous materials.

Issue: *Methane regulation*
Impact: The EU Methane Regulation sets emissions limits for all fossil fuels placed on the EU market and mandates that companies measure, monitor, report, and verify methane emissions. Due to the aggregation of gas at liquefication terminals, multiple processing steps, and the structure of supply contracts, among other factors, U.S. exporters may not be able to track the original source of natural gas and crude oil. This could prevent them from accessing the EU market, acutely damaging the EU's energy security.
Recommendation: Article 28 of the Methane Regulation allows for the possibility of equivalency of MMRV regimes. The EU and the U.S. should urgently open a formal process of determining equivalence to ensure availability of U.S. LNG exports to the EU.

Issue: *Carbon Border Adjustment Mechanism (CBAM)*
Impact: Companies have faced significant difficulties during the transitional phase of the CBAM, including technical issues, high administrative burdens, challenges with calculating data and embedded emissions, and trade frictions. Although U.S. production is carbon-efficient, the lack of a domestic carbon price means that U.S. goods must pay CBAM fees and face the full administrative burden of CBAM. Similar issues apply to the United Kingdom's CBAM measure.
Recommendation: Engage in further dialogue with industries and trading partners to: ensure compatibility with international obligations, address ongoing complications with CBAM compliance, and avoid trade disruptions and inefficiencies. Pause CBAM implementation pending these adjustments.

India

Issue: *Intellectual property protection*
Impact: American companies face continued IP violations in India. While the 2024 Patent (Amendment) Rules address some IP obstacles, systemic barriers remain due to India's complex legal and regulatory framework. Section 3(d) of the Patents Act imposes restrictive patentability criteria, and a new framework for digital sequence information could further limit IP rights globally. India's regulatory system lacks transparency and coordination between the Central Drugs Standard Control Organization (CDSCO) and state agencies. After four years of initial approval, state regulators can issue manufacturing licenses without verifying patent status, leading to patent infringements and market uncertainty. India does not provide regulatory data protection (RDP) as required under Article 39.3 of the WTO TRIPS Agreement. Regulatory authorities rely on originator-submitted test data to approve follow-on products, discouraging pharmaceutical innovation and investment.
Recommendation: Substantial reform is needed in India's IP policy frameworks to meet trade obligations (i.e., those outlined in TRIPS) and ensure American IP is treated the same as Indian in the United States. We encourage continued dialogue between U.S. and Indian stakeholders to enhance IP frameworks in a way that supports India's innovation ecosystem while ensuring fair treatment of American IP.

Issue: *Market access and regulatory standards*
Impact: India's evolving regulatory landscape presents an opportunity to align its standards with international best practices. The recent guidance under Rule 101, allowing expedited drug approvals for U.S. FDA-approved therapies subject to post-launch trials in India, is a positive step. Ensuring consistent implementation of this policy would facilitate greater access to life-saving therapies for Indian patients.
Recommendation: We encourage collaborative efforts to streamline regulatory approvals, enabling faster access to safe and effective therapies for Indian consumers while facilitating trade.

Issue: *Government pricing policies*
Impact: Price controls, including those applied to patented medicines in the National List of Essential Medicines (NLEM), fail to account for research and development costs. Trade Margin Rationalization (TMR) policies and inconsistent implementation of price control exemptions create uncertainty and deter pharmaceutical investment.
Recommendation: We encourage structured industry consultations before policy implementation to create a more predictable environment for investment in India's healthcare sector.

Issue: *Discriminatory government procurement policies*

Impact: "Make in India" regulations disadvantage foreign suppliers by restricting their ability to participate in government tenders. Strict local content requirements and exemptions favor domestic manufacturers, including those producing potentially patent-infringing medicines, creating an uneven competitive landscape.
Recommendation: "Make in India" regulations need to be amended to include U.S. suppliers in the government procurement process. Urge the governments to sign a public procurement agreement (bilaterally or via the WTO PPA) that allows mutual access to each other's public sector. This will drive trade, investment, and innovation in both countries.

Issue: *Tariffs on pharmaceuticals*
Impact: Reducing tariffs on pharmaceuticals would not only enhance access to affordable medicines for Indian consumers but also promote greater trade and investment in the healthcare sector. Rationalizing duties can help strengthen India's role as a global pharmaceutical hub while ensuring reciprocal trade benefits.
Recommendation: A review of import duties could support India's healthcare affordability goals while fostering a robust pharmaceutical trade relationship. Additionally, the Chamber has called a potential trade agreement to include provisions to allow for dual-location of pharmaceutical manufacturing, thereby strengthening the global supply chain. This would be a win for the U.S. and India.

Issue: *Strengthening anti-counterfeit measures*
Impact: India remains a major source of counterfeit pharmaceuticals, posing serious health risks. Despite global efforts to combat counterfeit drugs, illicit trade continues to grow, underscoring the need for stronger enforcement measures.
Recommendation: We support collaborative efforts to enhance anti-counterfeiting measures and border enforcement, particularly in high-risk trade corridors.

Issue: *Soybean exports to India*
Impact: India currently applies tariffs of more than 50% on soybeans. Additionally, India currently retains an import ban on genetically modified organisms (GMOs) (despite India using GMOs in dairy feed, Argentine soybean oil, and elsewhere). India also mandates companies possess a zero-dockage certificate (which is not obtainable), proof of devitalization (which is not commercially feasible), or produce a declaration of a weed-free crop/area at source, presenting yet another set of hurdles to American soybean producers.
Recommendation: We encourage establishing a dialogue aimed at reducing soybean tariffs and other trade barriers to allow GMO soybeans into the country so as to reduce prices for Indian farmers and consumers and enhance food and nutrition security objectives.

Issue: *Taxation on beverages*

Impact: Non-alcoholic aerated beverages attract the highest Goods & Services Tax (GST) rate in India at 28%, while chips/biscuits/confectionary/other similar products face 12%-18% GST. The Indian government labels the carbonated beverages industry as a "sin/demerit" product, which prompts an additional 12% penalty cess on aerated beverages (40% tax rate of GST + cess). As a result, the industry pays an estimated $750 million annually in additional taxes compared to other related food sectors. These taxes also disincentivize the formalization of the carbonated beverages sector, leading to issues of counterfeit products and revenue leakage. Currently, an estimated 80% of India's non-alcoholic/aerated beverage market is unorganized and part of the revenue leakage.
Recommendation: A review of tax classifications for non-alcoholic beverages could encourage investment, innovation, and revenue generation while maintaining public health objectives.

Issue: *Medical device pricing policies*
Impact: There is uncertainty about bringing additional medical devices under price controls without a suitable mechanism separate from drugs and appropriate to medical devices. In 2017, the Indian government introduced price controls on cardiac stents and knee Implants, which were ultimately capped after being added to the National List of Essential Medicines (NLEM). American companies in this space now need to consistently navigate a lengthy and cumbersome price review process as part of the NLEM, creating significant uncertainty in the market. Since 2017, industry has been plagued with multiple challenges, including supply chain disruptions caused by pandemic, rupee depreciation, increased labor and freight costs, and inflation, among others.
Recommendation: Trade Margin Rationalization is recommended for Medical Devices. Treat knee implants at par with other non-scheduled devices and retain them under Paragraph 20 of DPCO (providing an ability to take a 10% price increase per provisions of Paragraph 20 of DPCO) without an annual revision clause.

Issue: *Import of refurbished/reused medical equipment*
Impact: A licensing change in April 2024 has also meant that American medical device companies are now unable to import refurbished/reused medical equipment into India, despite the use of these products globally, including CT scanners and other advanced surgical systems, and despite India's healthcare system already having adopted some of these products in Tier 2 and 3 cities. The change has prevented American companies from importing products for nearly a year despite its product being widely used across India and worldwide. Meanwhile, Indian and non-U.S. OEMs increase their market share.
Recommendation: A new policy for refurbished medical equipment could be developed to allow for American companies to import their certified products, passing savings to Indian consumers and enhancing their choice options.

Issue: *India's large state-owned enterprise (SOE) sector*
Impact: India's public sector plays a crucial role in economic development. Ensuring competitive neutrality in key sectors would encourage greater private sector participation and foreign investment, fostering economic dynamism.
Recommendation: As part of any trade deal, India should commit to liberalize additional SOE segments, and in the meanwhile, the Competition Commission of India should undertake a market study (and act if needed) to ensure equal treatment for American investors and enterprises.

Indonesia

Issue: *Import licensing regulations*
Impact: In 2023, the Indonesian government imposed stringent import requirements on approximately 4,000 HTS codes, covering 70% of the $9.3 billion in annual U.S. exports to Indonesia. Significant delays in issuing import licenses followed, resulting in 1) the effective restriction of imports on goods such as electronics, traditional medicines, cosmetics, and footwear; 2) increased compliance costs for traders and operators; and, 3) reduced availability of products due to disruption in the supply chain. Following the business outcry, the regulation was amended multiple times.
Recommendation: Encourage the Indonesian government to design legally binding commitments to promulgating regulations in accordance with good governance best practices, including transparency and a reasonable consultative process, which will also be key to Indonesia's aspirations for Organization for Economic Cooperation and Development (OECD) accession.

Issue: *Local content requirements*
Impact: U.S. companies continue to identify Local Content Requirements (LCR) in Indonesian as one of the most significant challenges they face. According to Indonesian officials, LCR is intended to stimulate domestic industries, but goods and services supplied by companies without a majority Indonesian shareholding cannot qualify as local content, and opportunities for U.S. business in the ICT, pharmaceutical, medical device, renewable energy, and aerospace sectors are held back by overly stringent local content requirements.
Recommendation: The administration should urge Indonesia to not discriminate against American-provided goods and services.

Issue: *Natural resource export proceeds retention*
Impact: Indonesia has recently revised increased its policy requiring certain natural resource-related international firms to retain export proceeds in-country, increasing the percentage from 30% to 100%, along with an extension of the retention period from three months to twelve months. This applies to the mining, forestry, plantation, and fisheries sectors, while the oil and gas sector will continue to follow the previous 30% / three-month provision**.** The policy's stated goal is to maximize the use of foreign exchange proceeds from export activities in Indonesia to support the domestic economy, though the government states it is seeking a balance between repatriating foreign exchange proceeds and providing flexibility for exporters' cash flow.
Recommendation: Indonesia's retention policies negatively impact international firms' cash flows and should be reduced and ultimately removed.

Issue: *Patent law*
Impact: Indonesia is a significant destination for U.S. pharmaceutical exports, which totaled $216 million in 2023. However, Indonesia's 2024 Patent Law has allowed for government use of patents for imported pharmaceutical products, including those from the U.S. The law has overly broad criteria for the implementation of compulsory licenses, which undermines the legal certainty IP provides and weakens the framework needed to sustain U.S. pharmaceutical exports.
Recommendation: The administration should work with Indonesian counterparts to ensure their IP framework aligns with international patent standards.

Japan

Issue: *Pharmaceutical and medical device pricing and reimbursement*
Impact: The lack of transparency, predictability, and due process in Japan's reimbursement system for health products, including pharmaceuticals and medical devices, hampers healthcare innovation and has led to Japan experiencing major drug lag and drug loss in recent years. Current U.S.-Japan trade and commercial dialogues are not structured to address these issues. Most recently, Japan announced in December 2024 its decision to continue with the off-year price revision impacting American-made medicines, including innovative, long-listed products as well as generics, effective April 1, 2025. The Ministry of Health, Labour and Welfare (MHLW) also plans to consider expanding cost-effectiveness evaluations (Japanese HTA) in the FY2026 system reform and implementing market expansion re-pricing in the FY2027 off-year drug price revision. These latest proposals contradict Japan's efforts to address its drug lag and drug loss and could significantly discourage biopharmaceutical R&D investment and hinder the timely market presence or launch of innovative medicines in Japan, as well as the continued availability of medicines already in the market.
Recommendation: Japanese policymakers should restore market-based incentives for investment in life sciences and medical technology innovation. Reimbursement policies must reward technological breakthroughs and improvements to encourage continued investment and permit access for patients. Additionally, the U.S. and Japanese governments should establish a bilateral public-private dialogue to improve timely access to innovative medical products. The Japanese government should also engage in meaningful, transparent, and inclusive stakeholder consultation, including with the most heavily impacted American companies, on the latest drug repricing proposals.

Issue: *Non-Tariff Barriers (NTBs) in Japan's regulatory process*
Impact: The Government of Japan often forms advisory groups or expert panels to review policy and make recommendations on regulatory issues. These groups hold significant influence over the formation of Japanese regulation. The Government of Japan forms these groups behind closed doors without an open call for applicants or a public comment opportunity, leading to very few foreign firms being appointed to serve on them. The group, once formed, also controls whom it invites to present opinions and issues to the group. These groups frequently exclude foreign firms while making regulation that will directly impact foreign firms' operations in Japan. While some agencies make an effort towards transparency by televising or livestreaming advisory group meetings, this is not consistently applied across the government, and opportunities to get onto the agenda of the expert groups to make formal comments are minimal to non-existent.

Recommendation: The Government of Japan should adhere to good regulatory practices and ensure transparency in the creation of these advisory groups by declaring their intent to create one and setting aside seats for foreign firms with significant economic investments in Japan to participate. There should also be a more transparent process to gain an audience with the advisory group as it formulates and implements policy. We also encourage the Government of Japan to provide documents and materials in English in order to increase transparency.

Korea

Issue: *Pharmaceutical and medical devices pricing and reimbursement and intellectual property policies*
Impact: Korea's pharmaceutical and medical device pricing and reimbursement policies continue to undervalue U.S. intellectual property (IP) and innovation and fail to "appropriately recognize the value of the patented pharmaceutical product" in violation of Article 5.2(b) of the U.S.-Korea Free Trade Agreement (KORUS). Korea's pricing and reimbursement scheme for pharmaceuticals is extremely complex and maintains a strict focus on cost-containment measures that remain uncoordinated. More recently, there has been recent legislation restricting the availability of patent term extensions, which is the most significant concern in the IP area. Both policies undermine and hinder Korea's goal to become a biotech hub and constitute a barrier to American companies' ability to supply health products in the Korean market.
Recommendation: Korea must implement KORUS FTA commitments and both governments should restart discussions under the Medicines and Medical Devices Committee established under KORUS Article 5.7 on reforms to regulatory and reimbursement systems aimed to appropriately recognize the value of innovative technologies; improve transparency, predictability and due process; sustain a sound science regulatory approach; and overall, incentivize investment in innovation. These discussions must also involve relevant Korean government ministries, including the Ministry of Health and Welfare, to ensure a successful dialogue aimed at achieving concrete outcomes and practical solutions to barriers to innovation.

Issue: *Non-Tariff Barriers (NTBs) in Korea's regulatory environment*
Impact: In Korea, U.S. companies face an opaque regulatory framework that at times fails to measure up to internationally recognized good regulatory practices. New rules and regulations are often introduced on short notice, and they are frequently crafted behind the scenes and consequently more likely to benefit domestic interests at the expense of foreign competitors. Policies are often framed with insufficient analysis, impact assessment, consultation with the industry, or coordination between Korea's ministries and regulatory agencies. Public consultations often only serve as after-the-fact formalities with little prospect for meaningful change. This lack of stakeholder consultation is most likely to happen when rule-making processes are driven by National Assembly members. Other challenges include the Korean government's intervention in business affairs and the Korea Fair Trade Commission's arbitrary investigations, rulings, and actions, which often disproportionately target U.S. companies.
Recommendation: Korea should engage in regular public-private dialogue, good-faith consultation periods, and appropriate time for industry to provide comments on business-related policies during the planning, formulation, and implementation

phases of the policies, which frequently disproportionately impact U.S. businesses operating in the country.

Issue: *Criminal prosecution of U.S. business executives*
Impact: Chief executives of U.S. companies have often been subjected by Korean authorities to criminal prosecution, exit bans, and the threat of prison or deportation for regulatory infractions that range from employment law violations to misfiling of customs declarations. In other advanced economies, these violations would be exclusively civil in nature and target the corporation rather than an individual. These legal actions are often driven by political motives and severely damage Korea's image as an attractive destination for FDI and hinder U.S. companies' ability to attract top global talent to take leadership positions in Korea.
Recommendation: Korea should refrain from excessive or unfair criminal punishment, including arbitrary exit bans of executives for remote administrative transgressions, and allow sufficient time for full deliberation with stakeholders, including the U.S. business community.

Mexico

Issue: *Energy policies that unfairly favor Mexico's state-owned energy companies*
Impact: The Mexican government's efforts to reverse the 2013 liberalization of the energy sector and tilt the playing field toward state-owned Pemex (petroleum company) and the Federal Electricity Commission (CFE - electric utility) disadvantage U.S. companies and U.S.-sourced energy supplies. President Sheinbaum has continued the constitutional reforms of the energy sector initiated by her predecessor. Reforms were enacted in October 2024 to alter the legal status of CFE and PEMEX, making them public companies and no longer productive state companies. CFE now has dispatch precedence over private sector companies in the electricity sector. Only the state is allowed to supply transmission and distribution services. In addition, reforms were passed to dissolve the autonomous energy regulatory agencies (among other independent regulatory bodies) and incorporate them into the Secretariat of Energy. President Sheinbaum presented a draft energy reform to Congress at the end of January 2025 that will allow new partnerships with the private sector but only when the state holds the majority stake. In addition, Mexico hinders U.S. private sector access to the energy sector by delaying, rejecting, or failing to respond to requests for new permits or permit modifications for energy projects, examples include renewable energy projects and the transshipment and storage of fuels, among others.
Recommendation: The U.S. should request a formal dispute settlement panel under USMCA to address Mexico's lack of compliance with its USMCA obligations.

Issue: *Failure to Comply with USMCA Intellectual Property Commitments*
Impact: More than four years after the entry into force of USMCA, many of the critical IP obligations have yet to be comprehensively implemented. Mexico enacted the Federal Law for Protection of Industrial Property in 2020, but it has yet to issue the necessary implementing regulations. Mexico lacks adequate patent enforcement, regulatory data protection, especially for biologics, and a patent term restoration system. These provisions face a "transition deadline," some of which passed in January 2025, and others due by July 2025. Mexico's failure to implement these provisions disadvantages American innovators seeking to export IP-intensive products to Mexico.
Recommendation: The U.S. government should work with the Mexican government to ensure the full implementation and application of the USMCA requirements in Mexican law. For example, we appreciate the close collaboration between USG and the Federal Commission for the Protection Against Health Risks (COFEPRIS) as Mexico seeks to improve its patent enforcement framework, which should be continued.

Issue: *Market Access for pharmaceuticals and medical devices*
Impact: U.S. companies continue to face unfair market access due to lengthy delays in regulatory approvals and opaque and unpredictable procurement practices. Under Mexican law, FDA-approved products should receive an expedited review by COFEPRIS within 90 days. COFEPRIS has not been using this review pathway, resulting in long delays in approvals that prevent market access and which are inconsistent with Mexico's USMCA commitments (Annex 12-F). U.S. suppliers of medical devices face similar challenges regarding market access due to lengthy delays for marketing authorizations, which should be approved within a reasonable period of time according to USMCA commitments (Annex 12-E). Since 2018, Mexico has frequently changed its procurement system, creating uncertainty and inefficiency. The latest change gave state-owned company BIRMEX's control over public procurement and its 2025-2025 consolidated procurement process for medicines and medical equipment raised a number concerns regarding the process and market access.
Recommendation: Mexico should leverage the expedited review pathway for FDA-approved products and continue to implement other measures to address the approval backlog. COFEPRIS should also strengthen its compliance with USMCA Chapter 28 Good Regulatory Practices and provide greater transparency and predictability in its procurement processes.

Issue: *Unfair tax enforcement*
Impact: U.S. companies increasingly are subject to practices by Mexico's tax authority (SAT) that are not consistent with Mexican law or international best practices. These actions create a significant level of uncertainty, risk of unfair penalties, and additional costs for U.S. companies. Although the specifics of each case may vary, common practices by SAT include unreasonable timeframes for responding to audits, differing or opposing views or criteria for the same issue, and unreasonable levels of documentary proof. For example, in cases pertaining to intercompany transactions involving Mexico, the U.S. and other countries, SAT's formal approach has been to deny the deduction of all intercompany payments from Mexico to the U.S. (and other countries), under domestic law, citing that the expenses were not strictly necessary and requesting an exaggerated level of documentary proof regarding how intangibles were transferred by the U.S. and received in Mexico. Companies may face multiple audits spanning several years that remain unresolved, resulting in increased exposure to penalty, interest, and surcharge impact of the tax assessments.
Recommendation: USG should hold SAT accountable to observing OECD/internationally recognized best practices for tax administration, improve public guidance regarding the most common tax compliance matters, and increase the staffing.

Issue: *Barriers to competition in the telecommunications sector*
Impact: The government assesses a fixed fee for spectrum regardless of use, which distorts the market and results in an advantage to the preponderant agent. This affects the ability of smaller scale operators to compete and places the current U.S. player in the market at a disadvantage. Mexico's high spectrum fees, which exceed the international median by 60%, also hinder competition, as documented in a 2023 study by Mexico's Federal Telecommunications Institute (IFT). In November 2024, the Mexican Congress maintained the annual spectrum fees for 2025 at the same elevated levels as in 2024. In addition, the state-owned operator ALTAN has preferential terms and state-owned enterprise CFE, originally allowed to provide service to social beneficiaries, is now allowed to compete with private operators. The competitive landscape was further weakened by constitutional reforms passed in December 2024 that eliminated the autonomous regulatory agency IFT and other autonomous agencies. The government plans to create a new single economic competition authority that would absorb the functions of the IFT and the former Federal Economic Competition Commission (COFECE).
Recommendation: The Mexican government should ensure that the secondary laws on competition, telecommunications and broadcasting provide a fair and competitive market environment and are consistent with Mexico's international obligations, including USMCA.

Issue: *Market access for electronic payment services providers*
Impact: Under USMCA, Mexico adopted new high-standard financial services commitments related to cross-border trade, including application of the national treatment and market access obligations for electronic payment services (EPS). Nearly five years after the entry into force of USMCA, Mexico continues to maintain significant barriers for U.S. EPS suppliers that effectively prevent the suppliers from processing domestic payment card transactions in Mexico using their proprietary standards and protocols and deploy value-added services.
Recommendation: Mexico should take all necessary steps to finalize, publish, and implement regulations that enable U.S. EPS suppliers to compete on a level playing field as soon as possible and in advance of the formal USMCA review. These necessary steps should include prompt public consultations in accordance with Mexican law and USMCA rules.

Saudi Arabia

Issue: *Localization tax, officially known as the Economic Participation Policy (EPP), affecting U.S. companies in the healthcare sector*
Impact: The EPP was announced by the Local Content and Government Procurement Authority (LCGPA) in November 2022 as a broader version of the Off-Set Program that was introduced to military contracts in 1983. It targets all civil contracts, and mandates that companies participating in local tenders at a value above 100 million SAR must show a plan to deliver economic contribution to the Kingdom equivalent to 35% of the tender value of imported products. The goal of the EPP, in effect, is to increase investments in local manufacturing, and this is hitting U.S. healthcare companies (both in the biopharmaceutical and MedTech sectors) especially hard. For the healthcare sector this policy means requiring more local manufacturing of medicines and health devices and products in order to participate in public tenders. This mandated re-investment is the equivalent of a localization tax. Furthermore, the 35% reinvestment figure is not sustainable and unrealistic for companies in the healthcare sector to meet. If the existing policy mandate is not changed, the Saudis stand to lose the huge investments that U.S. healthcare companies have made into the Kingdom, which over the last ten years is valued at over $13.6 billion, and Saudi citizens will lose access to vital and innovative medicines and technologies.
Recommendation: All mandates requiring local reinvestment by healthcare companies participating in public tenders should be removed, and the policy should be shifted to focus on incentives that attract investment.

Türkiye

Issue: *Pharmaceutical exchange rates*
Impact: Türkiye's pharmaceutical products are subject to an artificial exchange rate that is currently 43 percent lower than the actual exchange rate (see graph below). The United States comprises approximately 10 percent of the Turkish pharmaceutical market and was the leading importer by growth ($175 million) in 2023. In 2023, U.S. industry exported $522 million in pharmaceutical products, however lost approximately $261 million because of this system, a year when the artificial pharmaceutical exchange rate was approximately 52 percent lower than the real exchange rate during the course of the year.
Recommendation: Türkiye's pharmaceutical exchange rate should reflect the real exchange rate. This system negatively impacts Türkiye's healthcare system, both patients in Türkiye and the viability of health tourism in the country, given more innovative medicines and therapeutics are harder to access.

Issue: *Agricultural tariffs*
Impact: In June 2018, Türkiye imposed tariffs on U.S. agricultural goods imported to Türkiye, perhaps most impactfully on U.S. nuts. These tariffs have a $500 million yearly estimated impact. There are also a raft of other major trade barriers our agricultural exports face including additional taxes and GMO restrictions.
Recommendation: Encourage Türkiye to drop these tariffs in exchange for relief on Section 232 steel and aluminum tariffs, which will help ease food inflation and be popular with consumers in Türkiye. Currently, U.S. nuts are cheaper than those in Türkiye due to high inflation.

United Kingdom

Issue*: Drug pricing*
Impact: The UK's Voluntary Scheme for Branded Medicines Pricing and Access (VPAG) imposes price caps on pharmaceutical products, limiting revenue potential for U.S. drug manufacturers. These controls reduce profitability, discourage investment, and delay the introduction of innovative medicines. The UK pharmaceutical market, valued at over $30 billion, sees billions in lost revenue due to restrictive pricing measures. Reduced industry engagement risks limiting patient access to cutting-edge treatments.
Recommendation: The UK should refine its pricing scheme under VPAG to create a stable and predictable environment for pharmaceutical investment. Ensuring that the NHS can purchase high-quality, innovative medicines will enhance patient care while maintaining industry incentives for drug development.

Issue: *Sustainability disclosure requirements*
Impact: The UK's Sustainability Disclosure Requirements (SDR) introduce extensive reporting obligations, increasing compliance costs and regulatory uncertainty for U.S. businesses operating in the UK. These new requirements will require firms to allocate additional resources to sustainability reporting, impacting profitability and competitiveness. Companies with complex supply chains face particularly high burdens. While precise cost estimates remain unclear, compliance costs could reach hundreds of millions annually, similar to EU sustainability regulations.
Recommendation: The UK government should work closely with industry stakeholders to ensure SDR implementation is proportionate, implementable, and aligned with international best practices. A phased approach with reasonable timelines and flexibility for businesses will minimize unnecessary costs while maintaining transparency objectives. Reducing regulatory fragmentation between the UK, EU, and U.S. frameworks will also help prevent undue compliance burdens on U.S. businesses.

Vietnam

Issue: *Access barriers for innovative medicines*
Impact: A 2022 report from PhRMA revealed that only 42 out of the 460 new medicines launched globally between 2012 and 2021 were available in Vietnam. Of these 42 new medicines, only 27% are accessible in the public hospital channel through National Reimbursement Drug List (NRDL). Marketing Authorization (MA) reviews can take 3-4 years, on top of an additional 3-4 years for listing in the NRDL. These delays significantly limit the access of U.S. medicines into the market. In addition, the delay in reviewing dossiers for renewing MA every 5 years creates drug supply shortages. These challenges are worsened by weaknesses in Vietnam's IP protection system.
Recommendations: We recommend that Vietnam speed up the availability of new medicines by reducing the Marketing Authorization approval timeline; that it allow its regulators to use the work of other trusted regulatory authorities when making their own decisions, to prioritize resources while still ensuring the quality, safety and efficacy of medicines; and, make Marketing Authorization renewals automatic.

Issue: *Barriers to foreign companies in distributing pharmaceutical products*
Impact: In Vietnam, Foreign-Invested Enterprises (FIEs) have the right to import but are not entitled to distribute drugs and drug ingredients in Vietnam except for drugs and drug ingredients produced directly by their own entities in Vietnam. This includes transportation and storage, and other aspects of distribution planning and strategy development. This is at odds with practice in other Southeast Asian countries.
Recommendation. We recommend that the government eliminate these restrictions.

Issue: *Bancassurance (bank regulation)*
Impact: Vietnamese regulation bans banks from selling investment-linked products via bank networks/bancassurance. The restrictions reduce opportunities for VN consumers to obtain life insurance coverage, in turn preventing the government from achieving its goal of 15% of the population having life coverage by 2030 and 18% by 2040 (the current level is 11%).
Recommendation. The U.S. Chamber recommends that Vietnam loosen its regulations to allow bancassurance, which will in turn help the government reach its life insurance penetration goals.

Issue: *VAT on exported services*
Impact: Vietnam's Law on VAT defines exports of services subject to the 0% VAT rate as "Services provided directly to organizations and individuals abroad and consumed outside of Vietnam." However, without clear and specific guidance on the criteria for determining whether an intangible service is "consumed outside of Vietnam", there is substantial legal uncertainty. This lack of clarity has resulted in inconsistent

interpretations among provincial tax authorities and Vietnamese taxpayers, resulting in inconsistent application of the law. For U.S. businesses, this inconsistency in VAT treatment on services procured from Vietnamese suppliers creates uncertainty in expense planning and leads to irrecoverable VAT costs when the 10% rate is applied, ultimately increasing the overall cost of doing business in Vietnam.
Recommendation: We recommend that the Vietnamese government follow international best practices to provide clear guidance on the criteria for zero-rating exported services in the forthcoming Decree detailing the implementation of the VAT Law. Services that are provided to overseas entities and have their economic benefit realized outside of Vietnam should be recognized as qualifying for 0% VAT. This would bring Vietnam in line with most other countries in the region.

ANNEX B
Digital Practices

The digital economy has become a ripe target for foreign governments intent on enacting policies that explicitly or implicitly target American firms or serve as non-tariff barriers.

American companies are easy targets because of our leadership in innovation, high visibility in foreign markets, and significant market share in critical sectors like digital services, e-commerce, and cloud computing. Compounding the problem, actions and inaction by the prior administration provided an opening for foreign governments to exploit their understanding that the U.S. government no longer prioritized defending U.S. companies against discriminatory digital trade practices. The Chamber, joined by numerous other stakeholders, was clear in our criticism of the prior administration's downplaying and outright elimination of critical digital trade concerns from USTR's 2024 National Trade Estimate Report on Foreign Trade Barriers.

The impact of these discriminatory practices, which frequently violate international trade agreements, can be profound. U.S. companies are forced to navigate a patchwork of burdensome regulations that domestic competitors can avoid, pay punitive taxes or fines, and compete against foreign firms that benefit from government subsidies and preferential treatment. It erodes the competitiveness of our businesses, undermines the principles of free trade, and threatens the economic leadership of the United States.

Examples of such barriers include:

1. Cross Border Data Flows and Localization Issues

Data localization requirements and restrictions on cross-border data flows are increasingly being used by foreign governments in ways that discriminate against U.S. companies and undermine the global digital economy. These policies often mandate that companies store data within a country's borders, with governments justifying them under the pretext of protecting national security or privacy. In practice, they often serve as tools of digital protectionism, favoring domestic firms and limiting the ability of U.S. companies to compete. These restrictions fragment the global digital economy, increase costs for businesses, undermine cybersecurity efforts, and hinder innovation by preventing companies from leveraging global data networks.

Vietnam's Personal Data Protection Law (PDPL) has an overly broad scope of application, open-ended definitions, excessive consent requirements, vague language

regarding prohibited acts and the right of action to claim compensation for damages, impractical/unfeasible timelines for compliance with data requests from authorities, among other concerns. This is set to be enacted in May 2025 and take effect on January 1, 2026. **India** also espouses uneven data localization requirements, most evidently via its emerging Digital Personal Data Protection (DPDP) Act, which permits regulators to require data localization despite generally supporting cross-border data flows.

Additionally, **Vietnam's** cybersecurity law requires companies to store data locally and establish physical offices within the country, creating significant barriers for U.S. firms operating in the region. Similarly, **Indonesia** has implemented regulations mandating local data storage for certain sectors, such as financial services.

China's Cybersecurity Law and related regulations impose some of the most restrictive data localization requirements globally, forcing companies to store data within China and subjecting them to extensive government oversight. Data localization, prescriptive security requirements, and preferences for domestic technologies in sectors lacking any reasonable connection to legitimate national security concerns restrict the free flow of commercial data across borders and limit access to a burgeoning market for American digital products and services. While new rules issued by the Cyberspace Administration of China on cross-border data flows have eased some requirements that burdened multinational businesses, there remains a complete lack of definitions for "important data" in many sectors. Moreover, recent efforts to liberalize cross-border data flows have been largely limited to China's free trade zones. Different approaches between zones has created uncertainty, and it is unclear whether companies with established data infrastructure in other parts of the country must physically move to one of the free trade zones to enjoy the liberalized restrictions or will instead be allowed to first conduct an intra-country transfer to a data handler in the free trade zone that best meets their needs.

Both **Pakistan and Bangladesh** are considering data privacy laws that could restrict data flow in ways that target U.S. companies and undermine their in-country operations and investments.

Brazil's General Data Protection Law (LGPD) includes provisions that can restrict cross-border data flows, while **Nigeria's** data protection regulations have introduced localization requirements for certain types of data. Additionally, **Türkiye** mandates that 45% of the hardware used in 4G networks must originate from the country. Similar localization requirements will likely be applied to 5G networks, which are planned to go out for tender in 2025. In 2023, Türkiye's Informatics Industry Association (TUBISAD) valued the country's ICT hardware market at roughly $12.2

billion, suggesting data localization requirements in this sector could shut U.S. industry out of a nearly **$5.5 billion** market.

These policies not only discriminate against U.S. companies but also harm the broader digital ecosystem by limiting access to global markets and reducing the efficiency of digital services. For example, data localization requirements can prevent U.S. cloud service providers from offering competitive solutions, as they are forced to duplicate infrastructure in multiple countries. Additionally, these measures often expose companies to increased cybersecurity risks, as localized data storage can create vulnerabilities and reduce the ability to implement global security standards. By forcing U.S. companies to comply with fragmented and protectionist data policies, these governments are undermining the principles of an open and interconnected digital economy.

2. E-Commerce

The U.S. Chamber strongly advocates for policies that support the growth and development of e-commerce, emphasizing the importance of avoiding taxes that could stifle this sector. Imposing additional taxes on e-commerce transactions not only burdens consumers and businesses, but also hinder innovation and economic growth. By keeping e-commerce free from excessive taxation, businesses, including SMEs, can continue to thrive, invest in new technologies, and create jobs.

Türkiye's new regulation (late summer 2024) targeting e-commerce companies has doubled taxes on items arriving from non-EU countries from 30% to 60%. Further, the measure reduced the *de minimis* (duty-free) threshold from EUR 150 to EUR 30, including the shipping cost. The law imposes additional requirements (notarization and stamping, etc.), which effectively require any company aiming to ship items valued above EUR 30 to utilize the services of a customs broker.

Additionally, **Türkiye's** proposed amendment Article 25 requires foreign e-commerce merchants to enter into a "card acceptance agreement" with at least one financial institution in Türkiye facilitating payments, namely, Troy. This provision is concerning, as it seems inconsistent with banking laws in many countries that require financial institutions facilitating card acceptance and e-commerce transactions to operate within their jurisdiction. One U.S. company has suggested individual losses as a result of Article 25 could reach **$100 million**.

Lastly, efforts to undermine the World Trade Organization's E-Commerce Moratorium on Customs Duties on Electronic Transmissions should not go unnoticed. This includes opposition to the measure from **India, South Africa and Indonesia**. Research has clearly documented the net benefits of the e-commerce moratorium,

which the Chamber believes should be made permanent. Among other benefits, such a policy would contribute to supply chain resilience for manufacturing and services industries, which rely on the constant flow of data to enable production flows for critical products. A failure to renew the moratorium would be a critical mistake.

3. Digital Services Taxes

Digital Services Taxes (DSTs) represent another discriminatory effort by foreign governments to unfairly target U.S. technology companies while shielding domestic competitors. We welcomed the first Trump administration's successful efforts to challenge these unfair taxes on U.S. companies, as well as early indications that you will continue to push back as DSTs crop up.

Canada's DST is a particularly egregious example of this discriminatory practice. The tax, with first payment due on June 30, 2025, imposes a 3% levy on revenues generated from digital services provided to Canadian users. It was deliberately structured to target large U.S. companies while leaving Canadian firms largely exempt. Even more troubling, Canada's DST violates its commitments under the United States-Mexico-Canada Agreement (USMCA) and WTO rules, disregarding its trade obligations.
Canada is not alone in pursuing such measures. In Europe, **France, Italy, and Spain** have already implemented DSTs that explicitly target U.S. companies, creating a fragmented and hostile tax environment. By singling out U.S. companies, these countries are engaging in protectionist behavior that harms American businesses, distorts global markets, and risks escalating trade tensions. Moreover, they set a dangerous precedent for other nations to follow, further emboldening discriminatory practices and financial extraction from American firms.

Accordingly, digital services companies operating in **Türkiye** are required to a 7.5% digital services tax. This rate is substantially higher than the average of 3.0% charged in EU member states. Particularly for intermediary companies, such as travel bookings facilitators where margins are low, the 7.5% DST is detrimental to their continued existence in the Türkiye market. The annual cost to U.S. companies is estimated to exceed **$100 million**, with some projections reaching as high as **$160 million** per year.

4. Cybersecurity and Cloud Policies

Cybersecurity and cloud policies are increasingly being used by foreign governments to discriminate against U.S. companies. These policies often require companies to meet burdensome and discriminatory standards, such as mandatory technology transfers, local partnerships, or compliance with restrictive certification processes.

While these measures are framed as efforts to enhance national security or protect critical infrastructure, they frequently target foreign companies, particularly U.S. firms, while favoring domestic providers.

The **EU** has introduced cybersecurity and cloud policies that raise significant concerns for U.S. companies. The EUCS Cloud Services Scheme would block U.S. cloud providers from key parts of the European market unless they enter into joint ventures with European providers. Similarly, the AI Act draft Code of Practice would impose more aggressive restrictions on U.S. AI models than EU and Chinese rivals and compel disclosure of U.S. trade secrets and data to foreign authorities and competitors. The EU should align AI definitions with multilateral approaches like the OECD and G7 Hiroshima Principles, focus on AI systems posing unique risks, and avoid classifying General-Purpose AI as high-risk. The bloc should emphasize applications causing significant irreversible damage, pursue a balanced, risk-based approach for high-risk use cases, and protect data privacy and IP while emphasizing AI system results.

South Korea has also implemented cybersecurity and cloud policies that disproportionately impact U.S. companies. For instance, in order to serve public sector clients, South Korea's Cloud Security Assurance Program (CSAP) requires cloud providers to meet strict certification standards that have been tailored to favor domestic providers, effectively excluding U.S. companies from competing for government contracts. Similarly, South Korea's cybersecurity regulations impose requirements for data storage and processing that create additional compliance burdens for foreign firms.

Other markets, such as **China and Vietnam**, have implemented even more restrictive policies, including mandatory source code reviews and requirements for local data centers, further disadvantaging U.S. companies and exposing them to risks such as intellectual property theft and forced technology transfers. These measures, which were enacted without opportunities for U.S. input, collectively create a challenging and discriminatory environment for U.S. businesses in the global digital economy.

With respect to encryption, **Vietnamese** regulations do not make sufficient distinctions between the primary function versus the important functions of products with encryption capabilities and how those products are classified. Moreover, import licensing is limited to IT vendors. However, when importing items such as spare parts for warranty, replacement parts, etc., U.S. companies rely on express services. These are not IT vendors that the government traditionally licenses. The U.S. Chamber recommends that Vietnam provide clarity on the status of these encryption regulations and make the appropriate distinctions between products with encryption as the primary function versus those with encryption capabilities.

5. Platform Regulation

Platform regulation has emerged as a significant challenge for U.S. companies operating in the global digital economy. Many foreign governments are implementing or considering regulatory frameworks that disproportionately target large U.S. digital platforms, often under the guise of promoting competition or protecting consumers. While the Chamber supports fair and transparent rules that foster competition and innovation, we are deeply concerned about the discriminatory nature of these regulations, which frequently exempt domestic companies or impose burdens that disproportionately affect U.S. firms.

The **EU** has been at the forefront of enacting platform regulations that cause significant harm to U.S. companies. The Digital Markets Act (DMA) and Digital Services Act (DSA) impose sweeping obligations on so-called "gatekeeper" platforms, a designation that disproportionately applies to U.S. firms and, despite Europe's assurances that European companies would be captured, applies to *zero* European firms. These regulations mandate changes to business models, data-sharing requirements, and interoperability obligations that undermine intellectual property and innovation.

In addition, the **United Kingdom's** Digital Markets, Competition, and Consumer Act created regulations that have only identified U.S. tech firms as designated companies having strategic market status and have imposed strict "conduct requirements," with potential fines of up to 10% of global revenue. **Germany's** German Competition Act was recently amended to include broad limitations disproportionately imposed on U.S. companies, including mandatory sharing of proprietary data with rivals. This has already resulted in proceedings and findings targeting U.S. firms. More specifically, Article 19a of the German Competition Act is being applied on an extraterritorial basis solely against US companies. Article 19a imposes sweeping restrictions on the conduct of U.S. companies far beyond standard antitrust rules, with fewer substantive and procedural safeguards for impacted companies.

Equally concerning are the EU's efforts to export its regulatory model to other markets, encouraging other countries to adopt similar frameworks. This extraterritorial influence amplifies the harm caused by the EU's policies, as it risks further balkanization of the regulations U.S. companies must navigate, increasing compliance costs and operational complexity. **South Korea,** for example, has proposed measures that would impose significant restrictions on large digital platforms, including requirements for algorithm transparency and limits on self-preferencing. Its National Assembly could soon pass legislation that would target American companies in ways very similar to the DMA. **India** has also signaled interest in adopting similar policies, with its draft Digital India Act raising concerns about

potential discrimination against foreign platforms, as has **Australia**. **Brazil** and other markets in Latin America are exploring comparable regulatory frameworks, which could further fragment the global digital economy and create additional barriers for U.S. companies. In **Türkiye**, proposed amendments to the Law No. 4054 on the Protection of Competition, which is already actively enforcing the activities of U.S. companies, would go beyond the scope of the current EU-style restrictions in terms of how it seeks to regulate self-preferencing and data sharing. In **Japan**, The Act on Promotion of Competition for Specified Smartphone Software (SSCPA) and proposed implementing regulations would impose significant limitations on U.S. providers of mobile services, and mandatory sharing of technology, while sparing rivals in Japan and China from the rules.

6. Excessive Fines

Excessive and disproportionate fining of U.S. companies by foreign governments is a significant and growing concern for the U.S. business community. As with platform regulation, the **EU** has aggressively targeted U.S. firms with massive fines under competition law and data protection regulations like the General Data Protection Regulation (GDPR). The DMA, DSA, and the AI Act all grant the EU broad powers to fine U.S. companies. These fines disproportionately affect U.S. companies, as enforcement actions are overwhelmingly directed at American firms while domestic European competitors escape similar scrutiny. This selective enforcement creates an uneven playing field, raising serious concerns about the discriminatory intent behind these actions and broader implications for U.S. businesses operating in Europe.

The Chamber is particularly alarmed by the pattern of enforcement that appears to single out U.S. companies for practices that are common across the global digital economy. In addition to fines under GDPR that have disproportionately targeted U.S. firms, antitrust fines under EU competition law have been levied almost exclusively against U.S. firms. This discriminatory approach not only undermines the competitiveness of U.S. businesses but also suggests that these fines are being used as to protect domestic industries and extract revenue from successful American companies.

Similarly, the **United Kingdom's** Data Protection and Digital Information Bill introduces stricter compliance measures for businesses handling personal data, revising data handling obligations and increasing legal risks for U.S. firms. Potential restrictions on cross-border data transfers and additional administrative requirements could create regulatory fragmentation between the UK and other markets. The UK should align its data protection framework with international best practices to reduce unnecessary compliance burdens.

7. Network Fees and Streaming Content Requirements

The **European Union, South Korea, Colombia, Indonesia** and others have considered network fees that would unfairly target U.S. companies, as they primarily focus on large American content and application providers (CAPs) to subsidize broadband infrastructure. The proposals that have been put forward ignore the substantial investments these companies already make in digital infrastructure, such as undersea cables, data centers, and content delivery networks, which reduce costs for internet service providers and improve global connectivity. Beyond their discriminatory application, these fees, if implemented, would increase costs for consumers, stifle innovation, and undermine the quality of digital services offered.

Similarly, local content requirements for over-the-top (OTT) and streaming services are of great concern to U.S. companies, as these policies unfairly target foreign platforms. These requirements often mandate that streaming platforms include a certain percentage of locally produced content in their catalogs or contribute financially to local content production funds. While these measures are often justified as efforts to promote cultural preservation or support domestic creative industries, they disproportionately burden U.S. streaming services, which already invest heavily in global content production and distribution. Such policies create additional costs and compliance challenges, limiting the ability of U.S. companies to compete fairly in international markets.

As with other regulatory measures, the **EU** has been at the forefront of imposing these requirements, with its Audiovisual Media Services Directive (AVMSD) mandating that streaming platforms ensure at least 30% of their content is European. This policy forces U.S. companies to adjust their business models and absorb additional costs to comply with the quota. Similarly, **Canada**'s Online Streaming Act (Bill C-11) requires foreign streaming services to contribute to Canadian content production, further increasing the financial burden on U.S. platforms. These policies not only create barriers to market access but also raise concerns about their consistency with international trade obligations.

Other markets are pursuing similar measures. **Brazil**'s Video on Demand (VOD) Bill disproportionately targets U.S. video platforms while favoring Brazilian broadcasters and imposes platform-wide tax to fund Brazilian content development. **Australia** pushed a policy requiring financial contributions from foreign streaming services to support its domestic film and television industries. These policies collectively create a fragmented and protectionist regulatory environment that increases costs for U.S. companies. Local content requirements represent a growing form of digital protectionism that undermines the principles of free trade and open markets, disproportionately harming U.S. businesses in the digital economy.

8. Mandatory Payments to Benefit Domestic Competitors

Countries have begun to force select market participants to make mandatory payments to news publishers. Some key examples are **Australia**, where the News Media Bargaining Code requires certain designated online service providers to pay Australian news publishers for links and snippets. Only two companies, both American, have been deemed in scope. **South Africa's** Competition Commission released its provisional report on the Media and Digital Platforms Market Inquiry, with recommendations that target U.S. companies to pay the country's publishers an undetermined sum annually as a value exchange for hosting news on search or social media websites. In addition, **Canada's** Online News Act singled out U.S. technology companies to pay hundreds of millions of dollars annually to Canadian news publishers.