

JOINT STATEMENT 57th U.S.-JAPAN BUSINESS CONFERENCE

Redefining U.S.-Japan Business Priorities Amidst a Global Pandemic

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Members of the U.S.-Japan Business Council and the Japan-U.S. Business Council (the “Councils”) held the 57th Annual U.S.-Japan Business Conference virtually, for the first time in history, on October 26-27 EDT and October 27-28 JST, under the theme, “Redefining U.S.-Japan Business Priorities Amidst a Global Pandemic.” The COVID-19 pandemic is having an extraordinary impact on business and society, and has highlighted economic inequalities, societal divisions, and disruptions in the international order, in the midst of elevated geopolitical and economic tensions. This Conference assembled senior business leaders from the U.S. and Japan who committed to not only mitigate the risks made evident by the pandemic, but to view this crisis as an opportunity to enhance bilateral collaboration and business resiliency, promote a more open global economic environment, build more diverse and inclusive cultures and facilitate sustainable economic growth.

The Councils believe that continued U.S.-Japan cooperation remains a critical stabilizing force globally at a time of great uncertainty, in close cooperation with like-minded countries that consistently prioritize freedom, the rule of law, and other enduring principles of our democracies. We believe the following recommendations will enhance our collective abilities to contend with a complex and competitive environment.

- 1. Support government policies that encourage U.S.-Japan private sector collaboration, as well as promote business resiliency and innovation to better manage future crises.** The COVID-19 pandemic has reinforced the need for public-private cooperation in order to enhance supply chain resiliency and mitigate risks made evident by the crisis. It has also highlighted the role of innovation and the ability of digital technologies to facilitate the distribution of goods and services, improve healthcare delivery and quality of life, and sustain large segments of our workforce and therefore, our economies, despite various degrees of lockdowns. The Councils encourage both governments to prioritize measures to address the global emergency posed by COVID-19, including future-oriented initiatives that build a more resilient society and ensure long-term fiscal sustainability. In particular, the Councils recommend that the U.S. and Japan:
 - Enhance public-private dialogues to strengthen economic resiliency, addressing supply chain diversification and constraints on production and distribution;

- Refrain from imposing trade barriers that complicate efforts to secure imports and exports of goods, particularly those goods that save lives;
- Bolster policies to incentivize investment in healthcare technologies and develop innovative healthcare solutions, reducing the economic and social burdens of disease;
- Strengthen cooperation and information-sharing in the development of diagnostic products, drugs and vaccines, harmonization of healthcare standards, and the reduction of trade barriers that impede access to such innovations;
- Create an environment that supports alternative and flexible workstyles and work locations to improve productivity, as well as reinforce telework security to support these changes;
- Facilitate investment and government support in areas that promote innovation and resiliency, such as the digitalization of micro, small and medium-sized enterprises (MSMEs);
- Improve efficiency, particularly in Japan, by promoting paperless operations in close cooperation with Japan's new digital transformation agency; and,
- Promote policies that facilitate the use of data to improve business resilience, efficiency, and services to citizens, as well as pursue an appropriate balance between public interest and privacy in the deployment of data to address the global crisis.

2. Advocate for policies that promote a free, fair, and rules-based trading system and economic order, and strengthen bilateral as well as multilateral economic relationships toward those ends. While the COVID-19 pandemic has prompted governments to take protectionist measures worldwide, the Councils believe that the global rules-based trading system must be strengthened to drive economic growth. The Councils recognized that the Comprehensive and Progressive Agreement for the Trans-Pacific Partnership (CPTPP) is important for Japan and the region. As we await the second phase of the U.S.-Japan Trade Agreement negotiations, the Councils expressed optimism that a deal would build upon Phase I and result in a broad-based, high-standard, and forward-looking agreement. Furthermore, the Councils encourage both governments to closely collaborate with other like-minded countries, including those in Europe and the Indo-Pacific region, to:

- Reject trade restrictions and managed trade provisions that negatively impact the global economy, including those that unnecessarily impede the creation of geographically diverse, risk-mitigating supply chains;
- Ensure that investment review regimes and export controls on emerging and foundational technologies are narrowly tailored to balance governments' need to address legitimate national security considerations and promote economic growth;
- Eliminate tariffs based on overly broad application of national security policies, such as U.S. import restrictions based on Section 232 of the U.S. Trade Expansion Act;
- Reform and revitalize the World Trade Organization (WTO) and other international organizations that promote transparency, non-discrimination, and lower barriers to commerce, including the WTO's dispute settlement system to ensure its future effectiveness;

- Advocate for an early and successful conclusion of e-commerce WTO negotiations, as well as the resumption of plurilateral negotiations on environmental goods and information technology products;
- Address unfair industrial subsidies that undercut markets and distort competition;
- Strengthen the protection and facilitate the use of intellectual property rights, including for life sciences innovation, recognizing that intellectual property rights are a critical foundation for advances in global health and technology and pandemic preparedness;
- Facilitate the free and secure movement of data across borders, while protecting against cyberattacks and eliminating data localization requirements; and,
- Promote public-private collaboration on development solutions in third countries that encourage transparency and enhance accountability in line with the G20 Principles on Quality Infrastructure Investment.

3. Strengthen and promote corporate governance and commitment to diversity, inclusion, and sustainability goals. The Councils agreed on the importance of U.S. and Japanese business leadership in promoting best practices related to sustainable and environmentally conscious growth and development, as outlined by the United Nations’ Sustainable Development Goals (SDGs). The global community’s challenges cannot be addressed only through government action. Thus, we believe it is essential that both business communities:

- Make a decisive commitment to sustainable business practices for the betterment of society;
- Increase dialogue with and accountability to stakeholders;
- Promote efforts to address climate change, including business-led technological innovations, by leading international discussions among like-minded countries and encouraging the U.S., Japanese, and European governments to likewise jointly support climate change adaptation and mitigation in a coordinated, systemic and deliberate process;
- Ensure that investors are provided with relevant environmental, social, and governance (ESG) information that is material to long-term business performance;
- Increase gender, racial, and ethnic diversity in the workforce—particularly in leadership roles—based on the strong evidence that greater diversity contributes not only to better business outcomes, but to a healthier workplace and society; and,
- Improve outreach to and ensure equitable opportunities for women, as well as minority and underrepresented communities.

The COVID-19 pandemic’s impact and the trends it has accelerated will continue even after its public health risks subside. Recognizing this, our sector-specific recommendations for the digital economy, financial services, energy and infrastructure, healthcare innovation, and travel, tourism, and transportation can be found in the supplements that follow.

DIGITAL ECONOMY

The global community is facing unprecedented challenges as a result of the ongoing COVID-19 pandemic. The U.S.-Japan Business Council and the Japan-U.S. Business Council (“the Councils”) encourage the U.S. and Japanese governments to continue promoting policies and legislation to accelerate digital transformation that will facilitate not only economic recovery in the United States, Japan, and third countries, but also a better “new normal” as we continue to cope with COVID-19. We believe that these efforts should focus on:

- 1. Promoting the free flow of data and enabling data usage.** The Councils remain committed to promoting policy frameworks that facilitate data usage. In line with this, the Councils welcome the Agreement on Digital Trade between Japan and the U.S. that went into effect on January 1, 2020. We affirm its high standards as a model for the global digital economy and sincerely appreciate the efforts put forth by both governments towards fulfilling them. While steady execution of this Agreement is important, we strongly encourage the two governments to continue working closely to promote the free flow of data in multilateral fora such as the G7, G20, OECD, APEC, and the WTO.

We support efforts by both governments to promote frameworks that allow for self-regulation, utilize certifications and industry codes of conduct, and foster interoperability. We encourage the two governments to strive for greater adoption of these principles through emerging concepts, such as the Data Free Flow with Trust (DFFT) initiative agreed upon at the 2019 G20 Osaka Summit.

Moreover, we hope the WTO’s work on e-commerce rules, such as non-discriminatory treatment of digital products and services and a permanent moratorium on customs duties for electronics transmissions, will produce commercially meaningful results. While these efforts should be as inclusive as possible, a future agreement must achieve high standards. We recognize efforts made in the CPTPP, the EU-Japan EPA, and the United States-Mexico-Canada Agreement (USMCA) to advance an open global data governance architecture. We also remain supportive of ongoing efforts among Japan, the U.S., and the European Union to

cooperate more closely on resolving long-standing issues around forced technology transfers by third parties.

- 2. Strengthening privacy and data protection.** The Councils remain committed to promoting policy frameworks that facilitate the enhancement of privacy and data protection. We encourage both governments to promote high-standard privacy protection in multilateral fora as well. We urge the two governments to continue working closely to adopt these principles through established mechanisms such as the APEC Cross-Border Privacy Rules system and the OECD and to advance their adoption in third countries.

Additionally, we encourage the U.S. government to pursue federal privacy legislation that would protect consumers and eliminate a confusing patchwork of state laws, and encourage the Japanese government to work closely with the private sector when implementing updates to the Act on the Protection of Personal Information (APPI). We also urge the two governments to continue advancing interoperability between both countries' privacy regimes.

- 3. Developing and promoting secure and trusted next-generation telecommunication infrastructure.** The Councils believe that 5G technology will be both an enabler of innovation and a creator of new opportunities across all industry sectors. As the trustworthiness of 5G networks is critical for economic security, we recognize that the U.S. and Japan should collaborate closely to maintain the trustworthiness of 5G networks by accurately identifying and analyzing vulnerabilities as well as introducing advanced security technology to deploy 5G networks that citizens can use with peace of mind.

We also believe that open, interoperable architecture is the key technology for enhancing economic security by expanding options for selecting trusted vendors and diversifying supply chains. We urge the U.S. and Japanese governments to establish clear public policies aimed at accelerating the development and voluntary adoption and use of virtual, open, and interoperable 5G technologies and solutions both domestically and internationally, particularly with regards to the Open Radio Access Network (O-RAN) standard. Moreover, we encourage the two governments to take initiative in accelerating adoption of this technology. Doing so will enable the deployment of cost-effective, flexible 5G networks by presenting new opportunities for companies to enter the market and compete.

We also urge the two governments to continue to cooperate and play a key role in adopting similar policies for like-minded countries. This includes the adoption of open, interoperable architecture from trusted vendors and continuing to provide necessary funding through export credit agencies in order to accelerate the deployment of trusted 5G networks in other markets.

4. Striving to promote the utilization of Artificial Intelligence (AI). The Councils encourage the two governments to promote the advancement of AI technologies through the development and use of global, consensus-based, and industry-led AI standards. We encourage the two governments to build and promote governance frameworks that are flexible and driven by a transparent, voluntary, and multi-stakeholder process.

Any efforts by the two governments in this area should be mindful of existing rules and regulations, incorporate risk-based approaches to AI governance, and maintain data protection regimes that recognize the need to collect, retain, and process data for AI development, deployment, and use. We also encourage the two governments to work closely with industry and civil society to play a global leadership role focused on principles of fairness, explainability, and accountability. In this respect, we look forward to continuing close cooperation at the OECD and applaud the June 2020 launch of the Global Partnership on Artificial Intelligence (GPAI), which was established with the aim of guiding the responsible development and use of AI, and to which the U.S. and Japanese governments both belong.

5. Promoting best practices and international standards to manage increasing cyber risks.

The Councils recognize that managing cyber risk, especially with regards to critical infrastructure, is critical to the economic and national security of the U.S. and Japan and increasingly important for our nations' bilateral digital trade relationship. Given the evolving nature of cybersecurity threats, the Councils recognize that a risk-based approach is more effective to manage cyber risk than prescriptive regulation. Such an approach should at a minimum:

- Strengthen—jointly with industries—the capabilities of each government's respective national entities responsible for cybersecurity incident response;
- Consider building cyber capacity with respect to national competent authorities, legal conventions, computer emergency response teams, critical infrastructure protection, and cyber education, particularly through public-private cooperation;
- Strengthen existing collaboration mechanisms for bilateral cooperation to identify and mitigate malicious intrusions or dissemination of malicious code that affect electronic networks;
- Employ and encourage enterprises within territories to use risk-based approaches that rely on consensus-based standards and risk management best practices to identify and protect against cybersecurity risks, as well as to detect, respond to, and recover from cybersecurity events; and,
- Promote the development of cryptography communication capable of ensuring security and privacy in anticipation of the coming quantum computer age.

The Councils also support efforts by both governments to promote the NIST Cybersecurity Framework and key International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) standards around risk management and assessment, and to coordinate closely on cybersecurity capacity building programs with APEC and through the U.S. Department of State's Digital Connectivity and Cybersecurity Partnership.

- 6. Accelerating the formulation of rules for global digital taxation.** The Councils are concerned that the unilateral introduction of digital taxation in each country could lead to not only an increase in tax disputes, but also economic contraction. We urge the two governments to take the lead in accelerating the formulation of rules currently being discussed by both the G20 and the OECD as well as in ensuring the introduction of an orderly and fair taxation system.
- 7. Establishing bilaterally harmonized and interoperable frameworks in digital platforms/ICT regulations.** The Councils urge both governments to enable innovation and investment, as well as balance critical societal objectives with the benefits that digital products and services bring to the consumers. Permitting the seamless use and deployment of latest media service and technology in an open and non-discriminatory marketplace will enable consumers to leverage the best-in-class applications at competitive prices.

In turn, our economies will benefit from increased economic growth, job creation, foreign investment, and innovation. Unnecessary regulatory requirements only serve to stifle innovation and investment, dampen competition, and harm consumers. Therefore, the Councils urge the U.S. and Japan to ensure that any changes to digital platforms/ICT regulations are implemented in a transparent and predictable manner—to include prior dialogue with the private sector and key stakeholders, especially regarding measurement criteria, reasonable levels of compliance, and reporting thresholds.



ENERGY AND INFRASTRUCTURE

The U.S.-Japan Business Council and the Japan-U.S. Business Council (hereafter “the Councils”) observe that COVID-19 has reduced world energy demand, and agree that the energy and infrastructure sector needs to recover from this impact and be modernized for sustainable future development of the world’s economy. Despite the impact of COVID-19, the Councils continue to tackle climate change through the energy transition, the application of digital transformation and innovation, and the building of modern, resilient energy infrastructure. Further, the Councils note that the relationship between the economy and national security is becoming increasingly interlinked and that COVID-19 has further accelerated this relationship. In such circumstances, the Councils emphasize that United States- Japan cooperation has never been more important for the stability and prosperity of the Indo-Pacific Region.

Recovery of the Energy and Infrastructure Sector from COVID-19

The Councils agree that recovery of the energy and infrastructure sector from COVID-19 is essential to sustain the future development of the world economy. While world energy demand has been temporarily reduced by COVID-19, future energy demand is expected to increase as the world economy develops. In order to keep abreast of anticipated future economic development and growth, the global energy and infrastructure sector needs to recover from the impact of COVID-19. Thus, the Councils urge the two governments to consider the following measures to support this recovery:

- Continue the policy of economic reopening coupled with maximum consideration of safety, to promote recovery of energy demand;
- Ensure that economic measures do not decelerate energy transition but rather accelerate it, not only in the United States and Japan, but also in third countries;
- Provide incentives to stimulate investments in the energy and infrastructure sector and offset the impact of COVID-19, including in oil & gas, and power generation and grid, in order to facilitate energy transition over the coming 5-10 years; and,
- Continue to provide open markets and competitive opportunities to each other’s energy resources, equipment and services providers, and refrain from any new measures that would discriminate on the basis of national origin or local production.

Energy Mix in Response to Climate Change

The Councils remain committed to tackling climate change and to realizing a low-carbon society through the development and implementation of diversified clean energy technologies, building on international cooperation, including with third countries, while considering the unique circumstances of each country and advancing practical approaches. We urge the two governments to promote U.S.-Japan cooperation in the following ways:

- Establish a business environment that leads to further expansion of renewable energy in the United States and Japan by promoting the entire industry, including the supply chain, energy storage and carriers, on/offshore wind power generation, solar power generation, and further innovation, while enhancing the flexibility and resiliency of the grid and ensuring fair access to it;
- Promote stable cleaner power, such as highly efficient natural gas-based combined cycle as a baseload power supply to support growth in renewable energy;
- Continue efforts to promote and develop nuclear power, an important source of low-carbon baseload energy, such as advanced reactors which include small modular reactors, and to cooperate for decommissioning;
- Continue R&D and financial support for economical implementation of carbon capture and usage/recycle technologies such as CO₂-EOR and methanation; and,
- Develop a safer and more affordable supply chain of both green and blue hydrogen to realize a ‘hydrogen society,’ with a policy framework which stimulates supply in the United States and Japan to balance demand for purposes of hydrogen gas turbines, fuel cells, transports and industries.

Digital Transformation and Innovation

The Councils acknowledge the increasing needs of digital transformation and innovation in the energy and infrastructure sector, in order to enhance efficiency, resilience and value addition. We further note that ever-faster digitalization is required in order to meet the needs of post-COVID-19 society. The Councils also recognize growing concerns regarding the criticality of security associated with implementation of digital and innovative technologies. The Councils recommend the two governments adopt measures both individually and through United States- Japan cooperative initiatives to achieve the following important goals:

- Accelerate development of innovative technologies in the energy and infrastructure sector such as more cost-effective and efficient energy storage, including batteries and direct air capture solutions;
- Realize low-carbon smart cities that are economically and environmentally well-balanced;
- Interconnect energy and infrastructure projects by utilizing digital technologies that effectively control and operate multiple energy generation and storage facilities distributed across a region;

- Promote investments to advance the stability, resilience, safety, and modernization of the grid and other smart energy solutions;
- Develop and implement innovative digital technologies in the energy and infrastructure sector such as remote facility management and maintenance systems for post-COVID-19 society that limit physical contacts; and,
- Enhance cyber security readiness of critical infrastructure by multiplying strengths of both the United States and Japan.

Stability and Prosperity of the Indo-Pacific Region

The Councils continue to support U.S.-Japan contributions to the realization of stability and prosperity in the international community, and especially in the Indo-Pacific region. The stability and prosperity of this region is also important for the national and energy security of the United States and Japan, and should be promoted in tandem with other friends and like-minded countries. We urge the two governments to support the following:

- Promote U.S. liquefied natural gas (LNG) exports by cooperating to secure sea lanes and establishing a transparent LNG market in the Indo-Pacific region and an LNG supply chain in the region, including floating storage and regasification units and power generation related facilities with small LNG distribution networks;
- Further materialize and organize relationships of government-led programs and initiatives such as the Free and Open Indo-Pacific (FOIP) Strategy, Economic Prosperity Network, Blue Dot Network and Japan-United States Strategic Energy Partnership (JUSEP), and enhance public-private cooperation and engagement related to these programs and initiatives for promotion of quality infrastructure;
- Deepen U.S.-Japan cooperation on those economic security policies where the COVID-19 experience has revealed necessity of enhancement. Also, consider the potential impacts of these policies, such as the Executive Order on Securing the United States Bulk-Power System, on cooperation between the United States, Japan and like-minded countries; and,
- Expand the resources and authorities of U.S. and Japanese government financial institutions, such as the U.S. International Development Finance Corporation (DFC) and the Japan Bank for International Cooperation (JBIC), to promote private sector participation in government-led economic security programs and initiatives of the United States, Japan and like-minded countries in the region.



FINANCIAL SERVICES

The Financial Services Working Group of the Japan-U.S. Business Council and the U.S.-Japan Business Council endorsed collective actions in three areas: *Realization of a Sustainable Society*, *Promotion of Digital Financial Innovation*, and *Securing the Future for an Aging Population*.

1. **Realization of a Sustainable Society.** In order to achieve a sustainable society and meet the United Nations Sustainable Development Goals (SDGs), business leaders should consider the impact of their decisionmaking on society and the environment. The financial services sector plays a key role in this effort by encouraging and engaging in sustainable finance, incorporating climate-related risk assessment in decisionmaking, and investing in infrastructure. The Councils' recommendations include:

Sustainable Finance. Businesses are increasingly reevaluating their financial decisions with environmental, social, and governance (ESG) considerations in mind. The Councils recommend that both countries' financial regulatory agencies engage in a public-private dialogue to establish a framework to facilitate fair and informed decision-making with regard to financing of innovation and other efforts to catalyze the transition toward sustainable societies.

Climate Change. Climate change and increasingly devastating natural disasters could pose a threat to economic and financial stability. Therefore, it is critical that the financial services industry build its resilience by including climate-related risk assessments in business and investment decisions. The Councils support the Task Force on Climate-related Finance Disclosure (TCFD)'s Final Report of 2017, which calls for the assessment and disclosure of decision-useful information of risks and opportunities associated with climate change, and urge the governments of Japan and the United States to work together and lead international efforts to create and implement a global standard to help investors make informed decisions.

Infrastructure Financing. Infrastructure is a driving force for growth and prosperity and an important component of economic recovery and resilience. The Councils urge the governments of the United States and Japan to share and implement best practices to foster and encourage

infrastructure investment, such as through incentivization, public-private cofinancing, and other policy measures.

- Promotion of Digital Financial Innovation.** Digital innovation is a catalyst for change in the financial services industry, allowing for the efficient provision of financial products and services as well as broader consumer outreach. Due to the evolving nature of digital innovation and its applications to the financial services sector, cooperation between the public and private sectors is critical to fully harness the benefits of this innovation while sufficiently mitigating the risks that emerge in tandem with it. The Councils recommend the following three areas of Japan-U.S. cooperation in the public-private sphere:

Level Playing Field. Digital and business innovation introduces various actors in the financial services value chain. Effective financial regulatory frameworks should apply the same regulations and supervision to the same activities regardless of the actor. This activity-based supervision promotes competition and innovation, while ensuring financial stability and consumer protection. The Councils urge, and regard as a key priority, financial regulatory agencies in Japan and the United States to implement activity-based supervision.

Digital Currency. The Councils appreciate that the governments of Japan and the U.S. are actively conducting research related to central bank digital currencies, while carefully considering the associated security risks and effects on the existing financial system. The Councils support cooperation between these issuers of two globally traded currencies and encourage both governments to lead related international efforts among other like-minded countries.

Financial Center Tokyo. The Councils support a multifaceted effort to establish Tokyo's position as a global financial center, and believe it will contribute meaningfully to diversifying risk amidst an uncertain geopolitical environment. The Councils applaud the Tokyo Metropolitan Government (TMG)'s efforts to encourage financial innovation and invite foreign financial technology firms to establish operations in Tokyo, as well as the Japanese Financial Services Agency (FSA)'s commitment to take measures to improve domestic financial and capital markets. The Councils encourage the TMG and FSA to engage in and advocate for policy measures to enhance Tokyo's attractiveness, including through competitive corporate and individual tax rates.

- Securing the Future for an Aging Population.** In the Indo-Pacific and around the world, population aging poses a threat to financial sustainability on both an individual and a fiscal level. The Councils urge both governments to collaborate with industry to formulate and implement policy recommendations in the following priority areas:

Long-term saving. With societal aging and increased pension fund liabilities, the risk of pension shortfall for current and future retirees continues to rise, particularly in terms of fiscal

sustainability and retirees' financial security. The Councils recommend public and private cooperation in raising awareness of and incentivizing private retirement saving, financial planning, and long-term savings, including through insurance and private pension funds, along with other financial products designed for asset accumulation.

Aging and Financial Inclusion. Thanks to business innovation and digitization, financial products and services are becoming more accessible and affordable. Without technological and financial literacy, however, consumers cannot enjoy these benefits and are excluded from the financial system. The Councils encourage public-private cooperation to increase technology and financial literacy particularly for vulnerable populations, as it will continue to be critical to increasing financial inclusion in the coming decades.

Policy Framework. Finally, the Councils urge the adoption of a policy and regulatory framework that does not hinder insurers and other financial institutions from supporting the long-term protection, investment, and retirement needs of society. This includes establishing appropriate capital standards for insurers at the global, national, and jurisdictional levels that strike the right balance between financial stability and transparency, as well as ensuring that long duration insurance and savings products remain widely available to consumers.



HEALTHCARE INNOVATION

Much has changed since the last joint statement of the U.S.-Japan Business Council and the Japan U.S. Business Council (“the Councils”). In September 2019, no one contemplated the worldwide economic fallout that would result from a viral pandemic. Yet one year later global economies are reeling, while healthcare providers are putting themselves at risk to care for patients and the world’s top scientists are relentlessly pursuing treatments and vaccines.

The COVID-19 crisis spotlights the interdependent relationship of government and industry, both domestically and abroad. The long-standing collaborative structure of medical innovators and health system administration has allowed for an unprecedented rapid response to the pandemic, which could not have been achieved without considerable resources. The bio-medical industry was able to redirect its scientists, maintain its supply chain, increase manufacturing and distribution capacity and launch clinical trials in record time because countries like Japan and the U.S. reward innovation. The revenue derived in the normal course of business from innovative medical equipment, cancer therapies, auto-immune drugs, anti-inflammatory treatments and diabetes medications (among many others) enables the industry to tackle unmet medical needs and respond in times of crisis. This model must be preserved and enhanced to ensure sustainability and preserve innovation, and it is important that medical expenditures be recognized as investments rather than merely costs.

The following recommendations by the Councils to the U.S. and Japanese governments are intended to strengthen both of our economies and advance medical innovation. Citizens of both countries should have access to the latest innovative medical technology and biopharmaceutical therapies. Japan and the U.S. are world leaders in medical innovation. The Councils underscore the importance of preserving and enhancing the systems that built these industries to maintain our competitive advantages.

COVID-19 Response and Access to Therapy

- For both: Pursue policies that facilitate partnerships among private parties in the development, production, and distribution of COVID-19 technologies to meet the challenge of rapidly scaling up manufacturing of COVID-19 vaccines and therapies. This includes maintaining policies that allow for efficient and expeditious licensing of intellectual property among private parties.

- For both: Commit to work closely with businesses to identify and remove obstacles to the swift approval and distribution of COVID-19 technologies, including unnecessary regulatory requirements, approval delays, and any other trade-related barriers, while adhering to necessary safety regulations.
- For both: Continue the strong collaboration with the International Coalition of Medicine Regulatory Authorities (ICMRA) and explore tools for regulatory cooperation, including exceptional use of regulatory reliance and recognition.
- For both: Enhance collaboration between the U.S. and Japanese governments to improve emergency preparedness, to include a framework for rapid regulatory approval with guidelines for evaluating new technologies for infectious diseases and a collaborative procurement process for public health supplies in emergency circumstances.
- For both: Commit to developing a joint response to emerging supply chain challenges and reject export bans and bilateral trade restrictions, which cause serious damage to patient access and industries in both countries. Recognize that responses to emerging global health crises, such as COVID-19, have an important international dimension and recommit to sustaining the interoperability of global supply chains. Overreliance on one country can be mitigated by working within a trusted trade network.
- For both: Conduct a national public information campaign to educate the public about the facts and safety of the COVID-19 vaccine and dispel anti-vaccination misinformation in conjunction with the approval and deployment of a COVID-19 vaccine.
- For Japan: Establish an Office of Infectious Disease Control to oversee both normal and emergency infectious disease control.
- For Japan: Consult closely with industry and support its efforts to devise context-specific strategies that avoid resource duplication and create timely access to key medical products.

Value of Innovation

- For both: Urge continued evaluation of Japan's C1/C2 premium pricing process and U.S. Medicare's coverage, coding, and payment processes for new medical advances that improve the diagnosis of and treatments for patients.
- For both: Reinforce the role of a global rules-based trading system including intellectual property rights as provided under the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and other accords. Finalize a broad-based, high-standard, and forward-looking bilateral trade agreement that recognizes the importance of fair value for innovation and jointly promotes high-standard intellectual property rights among other trade partners.
- For Japan: Given the impact of COVID-19, the drug price revision scheduled for April 2021 should not be implemented.
- For Japan: Revise the drug pricing system to ensure that developers and innovators are appropriately rewarded and that pharmaceutical companies are able to invest in the development of new drugs.

- For Japan: Maintain stability in the price revision mechanism for medical devices, including revision timing and formula, while finding ways to inject greater transparency and consultation into the revision process including functional category consolidation.
- For Japan: Maintain and strengthen research and development incentives for pharmaceuticals, vaccines, and Active Pharmaceutical Ingredients (API) manufacturing sites.
- For Japan: Ensure that any health technology assessment (HTA) or cost effectiveness assessment (CEA) in Japan does not delay patient access or restrict physician choice. Consider conducting analysis post-launch to evaluate the real-world effectiveness of the product compared to clinical trial efficacy.
- For the U.S.: Abandon international reference pricing proposals as they do not appropriately reflect the value of innovation and would undermine sustained research and development (R&D) investment in the next generation of therapies and vaccines.

Enhance Clinical, Regulatory and Legal Systems

- For both: Policy proposals should be based on a predictable and transparent public policy environment that allows stakeholders to meaningfully participate in the development of rules or regulations and favor efficient processes to bring new technologies to market such as expanded resources for cell and gene therapy regulatory reviews, and creation of cloud-based submission platforms.
- For both: Promote infrastructure development for virtual clinical trials, such as recruiting patients online and using virtual medical examinations if feasible.
- For Japan: Ensure the regulatory, pricing and reimbursement systems recognize innovation associated with the development of new indications for existing therapies.
- For Japan: Move toward an online registration process for new medical device licenses and license renewals.
- For Japan: Establish a regulatory data protection regime for new indications of existing therapies to incentivize research in areas of high unmet need.

Increase the Efficiency and Effectiveness of Healthcare Expenditures

- For both: Recognize that pharmaceuticals and medical device expenditures can help reduce long-term cost of care.
- For both: Pursue medical device and pharmaceutical pricing schemes that better align prices to value, including patient outcomes and convenience, as well as to the cost-offsets within the healthcare system and the wider society.
- For Japan: Innovative high-priced medicines should be covered by public insurance to ensure access to the latest medicines. In addition, in order to ensure the sustainability of the social security system, prioritize prescription drug benefits.
- For Japan: Optimize medical and nursing care costs by promoting the use of generic drugs and rationalizing drug use.
- For the U.S: Encourage the use of value based agreements that more appropriately reimburse providers for advanced therapies like cell and gene therapy.

Encourage Preventive Measures

- For both: Recognize the evidence-based health benefits of functional foods, such as health foods and dietary supplements, so that the benefits can be communicated to promote public health.
- For both: Support and encourage businesses' voluntary initiatives to promote health and productivity management in both countries.
- For Japan: Adopt pro-vaccination policies and give greater recognition to the societal value of innovation relating to prevention.
- For Japan: Promote innovation and policies for new screening methods from a preventive viewpoint, for example, to improve the rate of breast cancer screening.

Promote Use of Digital Health

- For both: Embrace and promote digital therapeutics and digitalization in healthcare to provide additional value for patients, healthcare providers, and the healthcare system. Create policies and a regulatory environment conducive to the monetization and reimbursement of digital solutions; accelerate the development and widespread adoption of digital therapeutics.
- For both: Launch public education campaigns to build understanding and trust in the utilization of health and medical information for research purposes.
- For both: Establish an environment for collecting and utilizing life course data including genomic information and develop a framework that enables sharing of this data with the private sector in a manner that protects privacy.
- For Japan: To promote individual-based health management and prevention, create an environment where individuals can access and utilize their own life course data through the development of personal health records of a private company.
- For Japan: Under the initiative of the government, develop and introduce conversion technology to ensure data compatibility and promote the standardization of medical data.
- For the U.S.: Prescription Drug User Fee Act (PDUFA) reauthorization preparations should explore how to incorporate the use of digital technologies in clinical trials for more efficacious monitoring of participants.
- For the U.S.: U.S. policy should promote interoperability and encourage greater utilization of consumer digital health products particularly in rural and underserved settings.



TRAVEL, TOURISM AND TRANSPORTATION

Travel, tourism, and transportation have been key drivers of economic growth for the United States and Japan in recent years. Since January 2020, however, the COVID-19 pandemic has sent shockwaves through societies and economies, and consumer demand in these sectors has declined significantly. According to the United Nations World Tourism Organization, the pandemic could lead to an annual international tourism decline of 60% to 80% from 2019 figures, threatening local economies and putting millions of jobs at risk. The number of foreign visitors to Japan and the United States is likewise sharply declining, while lockdowns and stay-at-home orders have even deflated domestic tourism demand.

The U.S.-Japan Business Council and the Japan-U.S. Business Council (“the Councils”) recognize the importance of cooperation between government and industry and offer the following recommendations to ensure the sustainability of these industries during and post-pandemic recovery. We believe these actions will not only support the efforts underway for the 2020 Tokyo Olympic and Paralympic Games and World Expo 2025 Osaka Kansai, but will also help address the long-term changes that may emerge in travel behavior as a result of the pandemic.

1. **Protect the value chain of travel, tourism, and transportation**

The travel, tourism, and transportation sectors are highly diverse and include a significant number of small and micro-businesses. These sectors are often interdependent and a crisis in one sector can have disastrous follow-on effects for the entire value chain. Therefore, it is necessary to align these interlinked parts of the value chain, as well as to provide direct and indirect support to protect the value chain.

Many governments instituted travel bans and other restrictive measures, which led to reductions of more than 80% in global passenger flights in the spring of 2020. These measures also limited the ability of transportation and cargo carriers to effectively deliver critical goods, including medical devices, personal protective equipment (PPE), medicine, and perishable items, which are necessary for combatting a pandemic and for the subsequent recovery. Further, the reduction in passenger flights limited the ability of cargo carriers to position pilots to support critical operations. The Councils request that the U.S. and Japanese governments maintain support to the airline industry, including relaxation of slot rules, and landing fee and aviation fuel tax

exemptions. The Councils encourage the governments to support the Public Health Corridor concept, introduced by ICAO, that seeks to ensure continued flight operations with minimal restrictions on aircraft operations, prevent the spread of COVID-19 through air travel, and protect the health and safety of crew through actions that aim to operate as much as possible a “COVID-19 free” environment. The governments should work together to ensure carriers are not subject to conflicting entry screening requirements. The National Air Transportation Facilitation Committee (required by ICAO Annex 9) should also seek to promulgate such rules and guidance material where possible in a manner broadly applicable to all sectors affected by the health emergency, including other transportation sectors.

In addition, the Councils recommend that both governments extend support to a wide range of industries, including the accommodation industry, which have been severely impacted by the sudden halt of inbound tourism flow. Small and micro-businesses not only need financial support for business continuity, for example, but also need health-related guidance to be in an easy-to-understand format.

Given the challenges posed by COVID-19, the Councils believe it is important to utilize not only hotels, but private residences to accommodate mild cases, returnees from overseas, health care workers, and those individuals in quarantine. In Japan, the use of private residences for lodging continues to increase since the implementation of the new private lodging law in 2018. Japanese authorities should therefore recognize private lodging services as part of a new social infrastructure that can contribute to COVID-19 response.

2. Protect the safety and security of travel, tourism, and transportation for all stakeholders

While the Councils recognize ongoing government efforts to re-open international travel, there are still many issues to be addressed to fully ensure the safety and security of travelers. The Councils recommend that both governments, together with public health officials, continue to work closely with the private sector to promote best practices and guidance for the safety and security of travellers, as well as to facilitate the digitalization of travel.

For example, digital signs can provide information on the local infection rate, on mask and handwashing requirements, and can be used in conjunction with surveillance cameras in crowd management. As tourism increases, we encourage governments to establish and expand systems for health status documentation and effective contact tracing, ranging from traditional techniques to digital solutions, to limit the spread and prevent further resurgence of COVID-19, as well as facilitate the protection of both health and privacy. Such information is also useful for tourist resorts to manage reputational risk. The Councils stress the importance of bilateral government cooperation in order to establish an information infrastructure that ensures the safety and security of both tourists and those in the hospitality industry.

3. Reform the industries and implement the new normal

The crisis is expected to have a permanent impact on consumer behavior, accelerating the move to contactless payments and fostering a greater emphasis on hygiene. The Councils encourage both governments to facilitate economic growth by minimizing trade disruptions and expediting in-bound and out-bound trade through smooth and coordinated reform initiatives.

With respect to Japan's stated goal of increasing cashless payments to 40% of all consumer transactions by 2025, the Councils also recommend that Japan implement Near Field Communication (NFC) Type A/B standards. These standards are already well-established in metropolitan areas like New York, London, and Sydney, and the Councils urge the Japanese government to lead practical solutions through continued dialogue with private sector stakeholders.

Given recent dramatic changes in daily life and business as a result of COVID-19, e-commerce has proven to be a lifeline, particularly for millions of small businesses hard hit by the pandemic. This trend will continue well beyond the current pandemic, and therefore governments should facilitate e-commerce, including cross-border e-commerce through pro-competitive laws and regulations that encourage investment. Governments should also ensure equal treatment between public and private delivery services. The Councils encourage both governments to recommit to the World Trade Organization's Trade Facilitation Agreement articles on express delivery shipments that often include critical medical supplies and other time-sensitive shipments, to expedite the simplification of customs clearance processes especially for low value goods, and to avoid the imposition of new import barriers, export restrictions, or other trade barriers.

The Councils also recognize the importance of creating new transportation methods in the post-COVID 19 era. For example, innovative technologies, such as automated driving, delivery systems that utilize drones and robots, and efficient transportation systems using big data, will contribute to developing smart cities and solving common social problems in both countries, including traffic congestion, manpower shortages, and environmental problems. For example, in both the U.S. and Japan, new taxi rates, such as pre-defined fees and variable pick-up fees, are tested by using big data. The Councils endorse these practices and request both governments to promote digital transformation across numerous industries. In addition, given the critical importance of safety and social acceptability in implementing new technologies, the Councils encourage governments to communicate their initiatives to the local communities.