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Members of the U.S.-Japan Business Council and the Japan-U.S. Business Council (the “Councils”) held the 59th Annual U.S.-Japan Business Conference on October 11-12 in Washington, D.C. The Councils jointly represent 135 companies from both the United States and Japan, with sectors ranging from digital economy and financial services, to healthcare innovation and energy and infrastructure, and to travel, tourism, and transportation.

The COVID-19 pandemic continues to have a staggering impact on business and society, further exacerbating existing economic and social challenges. In addition, Russia’s aggression against Ukraine has not only shaken the international order but also had a tremendous impact on our economic activities and the lives of our citizens in ensuring our national security in the future. In line with the common intention of seeking cooperation to strengthen economic security, the governments of the United States and Japan launched a new framework called the Japan-U.S. Economic Policy Consultative Committee (the Economic “2+2”) in July 2022. The Councils welcome this effort to develop the U.S.-Japan alliance from an economic perspective.

At the same time, the global health crisis and changes in the international order resulting from security crises have presented the opportunity to reevaluate our approach to creating a healthier, more sustainable and resilient future. In this context, the Conference convened senior business leaders from the United States and Japan, who shared common views on the importance of promoting innovative technologies, particularly in healthcare; modernizing infrastructure; and tackling macroeconomic challenges facing both of our societies.

The Councils also believe that the United States and Japan should further enhance coordination and cooperation in close partnership with like-minded countries that share our basic values with respect to freedom, democracy, human rights, and the rule of law, thereby fostering more resilient, sustainable, diverse, and inclusive societies and facilitating a more transparent, rules-based international economic order. Towards these ends, the Councils committed to:

- 1. Support government policies that establish the right policy architecture and regulatory environment in promotion of innovation in healthcare, as well as the promotion of rapid and equitable access for all people and relevant entities to digital health tools, pharmaceuticals, and medical devices that are critical to public health interventions.**
Over the past two years, the COVID-19 pandemic has highlighted the challenges to healthcare systems across the globe, but it has also catalyzed innovations, accelerated the development and

deployment of new technologies, and emphasized greater cross-border collaboration. The Councils also believe that the application of new technologies to the healthcare area is an urgent challenge as we look ahead to the future aging of society in both countries. American and Japanese companies have been leaders in this transformation, and the two business communities can lead in promoting innovation and ensuring broad access to these new healthcare tools bilaterally and globally. Therefore, the Councils recommend that both governments:

- Promote more robust mechanisms for bilateral cooperation on digital health, such as working-level dialogues, to maintain regular information sharing beyond COVID-19;
- Ensure close coordination among the government agencies responsible for regulations, reimbursement, and oversight of government policy on healthcare innovation;
- Pursue fair, transparent, and predictable reimbursement reforms for pharmaceuticals, medical devices, and digital tools to reflect the value of these innovative products in the context of the overall healthcare system;
- Support cross-border data flows to allow clinicians, researchers, healthcare companies and patients to have access to comprehensive information across borders to drive decision-making, while ensuring privacy protection of health data and increasing patients' trust;
- Ensure that the respective legal and regulatory frameworks in the United States and Japan are up to date and in line with the need for developing a broad health IT infrastructure, specifically regarding cross-border data flows, privacy considerations, and AI guidelines;
- Promote data interoperability between health IT infrastructure, devices, and clinical systems to optimize patients' access to care;
- Commit to flexible, risk-based frameworks that encourage AI innovation and collaborate across borders to advance sound and interoperable practices in healthcare, while partnering with the private sector, academia, and civil society to ensure patient confidence in AI;
- Increase investments in cybersecurity to protect patients' data, ensure uninterrupted care, and secure the entire health ecosystem;
- Continue to promote paperless operations, which are essential to digital transformation in all sectors but particularly affect healthcare;
- Introduce pricing schemes dedicated for digital therapeutics such as software as a medical device ("SaMD") and for innovative therapeutics such as regenerative medicine, cell therapy, and gene therapy; and
- Enable Decentralized Clinical Trials, allowing a hybrid of in-person and remote visits to medical institutions for trial participants by making maximum use of digital tools.

2. Support governments' efforts to build smart, modern, and resilient infrastructure which will provide meaningful economic and quality of life enhancements to people in both countries and around the world. The Councils believe continued investment in infrastructure will be critical for long-term economic recovery, and welcome both governments' push to modernize domestic infrastructure, including through the implementation of the U.S.

Infrastructure Investment and Jobs Act. The Councils also recognize the role the United States and Japan can play in leading the infrastructure development in third countries through initiatives such as the G7's Partnership for Global Infrastructure and Investment. To ensure improved safety, mobility, and quality of life for decades to come, the Councils recommend that both governments:

- Recognize that infrastructure modernization should be comprehensive and complete, and should include healthcare system, energy security, clean energy, transportation, and digital connectivity;
- Promote collaboration between the two governments and the private sector to develop a realistic roadmap for innovation and implementation in the above areas;
- Formulate a flexible and realistic approach to achieve a desirable energy mix based on a technology neutral approach to reducing CO2 emissions;
- Promote domestic energy production, infrastructure development and diversification of energy supply necessary to enhance energy security, including increasing the capacity and efficiency of U.S. LNG exports to the Indo-Pacific region;
- Strengthen cooperation in clean energy technologies and infrastructure, such as LNG, sustainable aviation fuel (SAF), hydrogen, Carbon Capture, Utilization and Storage (CCUS) and nuclear;
- Promote U.S.-Japan cooperation in building next-generation infrastructure, including advanced data centers and 5G, 6G or Beyond 5G, and WiFi 6, as well as further spreading the use of online services that enables the efficient use of existing and new infrastructure and resources, and improves the quality of life in remote areas, such as e-hailing applications and short-term rental services;
- Enhance bilateral collaboration in technology development related to the protection of critical infrastructure;
- Advance infrastructure technologies and equipment supported by the U.S., Japan, and like-minded countries that are committed to the rule of law and the fundamental importance of market mechanisms in economic decision making;
- Encourage scaling up public financing and promoting investor friendly policies in emerging economies to increase investor confidence and leverage private financing to help bridge the infrastructure gap and fuel economic growth;
- Address and bridge the digital divide to ensure that everyone is equipped to participate in today's modern economy and benefit from a 21st digital economy;
- Promote the development and production of semiconductors in the United States, Japan, and other like-minded countries to strengthen the trusted supply chain of critical technologies pertinent to every aspect of infrastructure;
- Enhance collaboration among allies and like-minded countries through the Indo-Pacific Economic Framework and/or friend-shoring to deepen relationships and diversify supply chains for critical raw materials used in storage batteries, such as rare metals and battery cells; and

- Explore streamlining the CFIUS screening process for investment from trusted countries like Japan, which will facilitate investment and bilateral cooperation on building resilient supply chains and developing important advanced technologies that are critical to our mutual shared economic prosperity and national security, such as battery technology and energy storage systems.

3. Encourage governments to pursue policies that reduce rising prices and support a sustainable society: As the global economy continues to suffer under the weight of high inflation, the Councils encourage the governments to focus on policies that address root causes of the inflation and mitigate the negative impact on consumers and businesses. The Councils also recognize the importance of fair rule-based governance for a sustainable future at a time when the international economic order is faltering. Therefore, the Councils recommend that both governments:

- Allow monetary policy the room it needs to stabilize prices for as long as necessary for the price level to hit its target;
- Promote corporate governance to ensure market credibility, including transparency of corporate accounting performance, and compliance with rules;
- 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;
- Recommit to the WTO’s Trade Facilitation Agreement’s articles on express delivery shipments which include provisions on simplifying border processes and removing unnecessary or duplicative documentation or paperwork, which is time consuming and expensive for traders, particularly SMEs, without concordant benefits or impacts on safety or security;
- Agree to a robust set of rules to lower costs associated with the customs clearance process of those shipments, in alignment with the WTO’s Trade Facilitation Agreement, such as higher customs *de minimis* levels and a simplified “bucket system” for classification of goods, where a small number of categories covers a broader range of goods found in the Harmonized System;
- Advance U.S.-Japan cooperation globally to eliminate market-distorting measures, such as harmful industrial subsidies, trade-distorting actions by state-owned enterprises and unnecessary tariffs or unfair trade practices, as well as address challenges such as those related to data localization, forced technology transfer including those that are conducted on a de facto basis, and the protection of intellectual property rights; and
- Strengthen supply chain security and resilience between Japan, the United States, and other like-minded countries to curb cost-push inflation while keeping away from unilateral and discriminatory measures.

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 U.S.-Japan Business Council and the Japan-U.S. Business Council (“the Councils”) believe it is imperative to accelerate digital transformation by creating innovation and services that contribute to new value creation to realize both economic growth and job creation. The Councils will steadfastly approach these challenges and commit to playing a proactive role in tackling them, in close cooperation with the U.S. and Japanese governments. With this in mind, we present the following recommendations to both governments.

1. Strengthen and promote a rules-based global trading system. The Councils acknowledge the importance of U.S. and Japanese government leadership in promoting global economic growth, particularly given the substantial efforts made by businesses to develop extensive value chains. We call on the U.S. and Japanese governments to advance and strengthen a rules-based global trading system that promotes economic growth and integration based on the high standards of the U.S.-Japan Trade Agreement and the U.S.-Japan Digital Trade Agreement. These agreements serve as models for the expansion of the digital economy in a region that is expected to be the largest contributor to global economic growth in the coming decades.

The Councils also believe that rejoining the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (“CPTPP”) would be the straightest and best path for realizing the U.S. administration’s economic and strategic ambitions in the Indo-Pacific. We further recognize the Indo-Pacific Economic Framework (“IPEF”) can be an effective framework for the region, provided it includes enforceable commitments, in addition to high standards, that build on the U.S.-Japan Digital Trade Agreement and digital trade chapter of the United States-Mexico-Canada Agreement (“USMCA”).

The Councils also encourage both governments to cooperate on reform efforts at the WTO to improve and clarify the body’s discussion processes and procedures to strengthen the rules-based global trading system.

2. Promote the free flow of data across borders. To establish a trustworthy digital economy, we believe it is essential to promote reliable and free data flow by ensuring international interoperability in terms of rules, architecture and trust anchors, while also enabling data usage.

We appreciate the efforts by both governments to promote policy frameworks that facilitate cross-border data flow, including through Data Free Flow with Trust (“DFFT”) and robust digital trade disciplines, such as the U.S.-Japan Digital Trade Agreement. We also recognize the importance of removing the regulatory and operational barriers to data flows in parallel with the development and

implementation of trade rules. Japan's 2023 G7 presidency offers a key opportunity to expand upon the promise of DFFT and promote its implementation.

Meanwhile, digital protectionism, which restricts the free flow of data, has proliferated in some countries and regions. We strongly encourage the two governments to continue working closely to promote trust and the free flow of data in other multilateral fora such as the G20, OECD, APEC and the WTO. The Councils encourage both governments to collaborate further to achieve a high standard and commercially meaningful outcome in the WTO Joint Statement Initiative on e-commerce, including provisions, such as a prohibition of data localization and a permanent elimination of customs duties on electronic transmissions, that enable and promote the cross-border flow of data as early as possible.

3. Strengthen privacy, data protection, and innovation. The Councils are committed to policy frameworks that facilitate privacy, data protection and innovation. We encourage both governments to embrace high-standard privacy protection and open digital markets in multilateral fora. We also urge the United States and Japan to promote these principles through established mechanisms such as the APEC Cross-Border Privacy Rules ("CBPR") System, the Global CBPR Forum and the OECD's discussions on government access to personal data. We are committed to working with government leads toward a robust OECD agreement before the end of the year. As countries pursue frameworks that protect personal information and support innovation, it is also important that governments ensure any new regulation, both in design and implementation, is not discriminatory.

The Councils understand that the free flow and utilization of data, such as healthcare and financial sector information, are key to addressing pandemics and disasters and to promoting e-commerce and the digital economy respectively. We urge both governments to continue to lead discussions aimed at establishing international norms through multilateral meetings and/or fora.

4. Develop and promote secure and trusted next-generation telecommunications infrastructure. The Councils believe that secure and trusted next-generation telecommunications infrastructure, including 5G, 6G and Beyond 5G technology will enable innovation and new opportunities across all industries. We also believe that an open, interoperable architecture is key to enhancing economic security by expanding options for selecting trusted vendors and diversifying supply chains. Based on the U.S.-Japan Global Digital Connectivity Partnership launched in May 2021, we urge both governments to continue to establish clear, secure, and trusted Information and Communications Technology ("ICT") 5G technology public policies to accelerate development and voluntary adoption, as well as the use of virtual, open and interoperable 5G technologies and solutions both domestically and internationally. Open Radio Access Networks ("Open RAN") are an important part of this strategy and are in the early stages of maturation. We encourage the two governments to take initiative in accelerating the adoption of these technologies by implementing their respective \$2.5 billion and the \$2 billion commitments to invest in research, development, testing and deployment. In the area of license-exempt spectrum, we welcome Japan's recent release of a portion of the 6 GHz band (5.925-7.125 GHz) as license-exempt spectrum and expect further releases in the future. License-exempt technologies such as Wi-Fi are important not only to Japanese

consumers and enterprise for on-premises networking and cellular offloading, but also to Japanese manufacturers of consumer goods whose Wi-Fi equipped products require global access to 6 GHz. We also believe that further research and development investments in 6G and Beyond 5G technologies by the two governments will be imperative to increasing opportunities to use those solutions in the future.

We urge the U.S. and Japanese governments to continue to cooperate and play a key role in encouraging the adoption of similar policies, such as those that promote the development and implementation of 5G, adoption of Open RAN, and investment in 6G and Beyond 5G, by like-minded countries. This includes through the Partnership for Global Infrastructure and Investment (“PGII”), a new framework announced by the G7 in June 2022 to provide support through the allocation of \$600 billion by 2027, including private funding in infrastructure investment in developing countries. With private sector cooperation, the Councils hope it will be possible to accelerate the adoption of open, interoperable architecture from trusted vendors and the deployment of trusted 5G networks in other markets.

5. Strive to promote the use of Artificial Intelligence (“AI”).

The Councils call on the two governments to play a leading role in the promotion of the development and utilization of AI technology based on the U.S.-Japan Competitiveness and Resilience (“CoRe”) Partnership to reinforce collaboration and partnerships between research institutions on science and technology through joint research and the exchange of researchers.

The Councils encourage the two governments to promote AI technologies through the development and adoption of consensus-based, industry-led, and global-based AI standards and to build and promote governance frameworks that are flexible, risk-based, and driven by a transparent, voluntary and multi-stakeholder process. We believe that both governments should encourage private companies to invest in and maximize social benefits by using innovative AI technologies.

We encourage the two governments to work closely with industry and civil society to play a global leadership role to formulate ethical standards and principles that are focused on human-centered values, fairness, explainability, transparency, security and safety, and accountability. We look forward to support from both governments for multilateral discussions at meetings such as the OECD Network of Experts on AI (“ONE AI”) and the Global Partnership on Artificial Intelligence (“GPAI”).

We hope both governments will cooperate with industry to manage and equitably classify AI systems on risk and to carefully consider the optimal balance between the costs and benefits arising from the responsibilities placed on stakeholders.

6. Promote the use of quantum information science and technology. We urge the two governments to accelerate the implementation of cutting-edge solutions, such as useful and global standard-based quantum information and computing, through the implementation of demonstration schemes and joint development based on the U.S.-Japan CoRe Partnership. We also appreciate

bilateral efforts to promote the development of cryptography communication capable of ensuring security based on quantum technology.

We support the intent of both governments to conduct joint research and development projects of these critical and emerging technologies foreseeing the potential future acquisition and utilization of such technologies, not only between the two countries but also together with like-minded countries.

In addition, it is critical that both countries identify and protect fair and rules-based standards development processes and implement approaches to bolster the participation and capacity of industry in critical standards setting processes for emerging and critical technologies, such as quantum computing.

7. Promote best practices and international standards for managing increasing cyber risks.

The Councils recognize that managing cyber risk, especially regarding critical infrastructure, is essential to the economic and national security of the U.S. and Japan and important for our bilateral partnership on digital trade. Given the evolution of cybersecurity threats, the Councils recognize that a risk-based approach is more effective for managing cyber risk than prescriptive regulation.

We are aware that a collective defense mechanism capable of sharing in real time the traces of attacks detected by companies and organizations is especially important, in light of our constant exposure to threats targeting critical infrastructure.

Approaches to cybersecurity should adhere to industry-vetted actions that businesses can take to assess and enhance their security over time. Allowing industry to combat evolving cyber threats with evolving best practices and globally recognized standards permits a more flexible, current and risk-based cybersecurity approach.

Private industry greatly benefits when governments leverage existing cybersecurity framework best practices as a starting point, such as the NIST Cybersecurity Framework or the International Organization for Standardization/International Electrotechnical Commission (“ISO/IEC”) 27103:2018 (information technology – security techniques – leverage existing standards in a cybersecurity framework) for any future policy enactments.

8. Establish “Trustworthy” principles for ICT suppliers. Given the importance of trustworthiness in ICT for businesses around the world in addressing international threats, the two Councils reaffirm the Recommended Principles for Establishing Trust in ICT Suppliers in the “Annex to the Joint Statement Supplement of the Digital Economy Working Group for the 58th U.S.-Japan Business Conference” and hope these principles will serve as a useful framework for establishing best practices across the Indo-Pacific region.

Energy and Infrastructure



The need to enhance energy security and resilience has been called for in the wake of events such as the COVID-19 pandemic and the recent tightening of natural gas demand and supply. But the U.S.-Japan Business Council and the Japan-U.S. Business Council (hereafter “the Councils”) recognize that Russia’s aggression against Ukraine requires a more immediate and fundamental global response. While the Councils welcome various efforts to ensure a stable supply of energy taken by the United States and Japanese governments and the international community, the United States and Japan need to lead further efforts. The Councils also emphasize that efforts to achieve carbon neutrality cannot be slowed down, and careful navigation of the balance between energy security and resilience, and energy transition is required in response to increasing extreme weather events. As such, the Councils welcome specific nuclear and gas energy activities that are recognized as environmentally sustainable economic activities by the so-called EU Taxonomy. To achieve the carbon neutral target by 2050 set by both governments, continuous development of innovative technologies and deployment of clean energy infrastructure, building on the utilization of existing baseload power supply, including highly efficient thermal and nuclear power, is necessary. In addition, the Councils continue to be committed to cooperation in the Indo-Pacific region to realize a Free and Open Indo-Pacific (FOIP).

Enhancement of Energy Security and Resilience

The Councils welcome the “Joint Statement Between the Ministry of Economy, Trade, and Industry of Japan and the United States Department of Energy on Cooperation toward Energy Security and Clean Energy Transition” dated May 4th, 2022, which aims to promote the assurance of global energy security. We further acknowledge the role liquefied natural gas (LNG) can play to alleviate global energy supply constraints and to serve as a reliable alternative to higher-emitting energy sources, and shall promote exports of U.S. LNG to take this role. The Councils recommend the two governments to consider the following measures for the United States and Japan to lead efforts to enhance energy security and resilience for stable energy supply of the world:

- Establish a multilateral task force to diversify the energy supply, which can also ensure the security and affordability of LNG supplies in the Indo-Pacific amid the rapid expansion of LNG shipments from the United States to European markets in response to Russia’s aggression against Ukraine;
- Support the development and investment in infrastructure, including gas pipelines, LNG facilities such as on the Pacific coast of Mexico and Floating Storage and Regasification Unit

- wherever deployable, to increase the capacity and efficiency of exporting U.S. LNG to the Indo-Pacific while accelerating the deployment of clean energy technologies in the region;
- Increase energy supplies through governmental frameworks among like-minded countries and bolster investments in infrastructure which can be supported by some of the permitting reforms that will provide certainty for long-term investments to diversify supply chains and energy sources; and,
 - Establish a clear pathway to expand safe utilization of nuclear power, and invest in developing the skilled workforce required to do so, to enhance energy security and serve as an important source of low-carbon baseload power supply.

Constant Efforts to Achieve Carbon Neutrality

The Councils are aware that enhancement of energy security and resilience cannot slow efforts to achieve carbon neutrality. Careful navigation of the balance between energy security and resilience, and energy transition is required. The United States and Japan continue efforts to achieve carbon neutrality under the “Japan-U.S. Climate Partnership on Ambition, Decarbonization, and Clean Energy” as the center of the U.S.-Japan cooperation. The Councils urge the two governments to support the following for the United States and Japan to demonstrate pragmatic and orderly energy transition:

- Continue commitments to deploy renewable energy including on/offshore wind, hydro, geothermal, and solar power generation, and increase capacity and modernize power grids to accommodate and efficiently utilize such power;
- Switch to natural gas, a stable cleaner baseload power supply, from other fuels with higher emissions, and deploy high-efficiency natural gas-based infrastructure such as gas turbine combined-cycle power, for orderly energy transitions with pathways such as the future conversion to hydrogen;
- Incentivize deployment of carbon capture, utilization and storage (CCUS) for cleaner utilization of existing infrastructure, decarbonization of hard-to-abate sectors such as the industrial and transportation sectors, production of cleaner fuels including blue hydrogen/ammonia, sustainable aviation fuel and synthetic methane from methanation and reduction of other greenhouse gases such as methane and fluorinated gases; and,
- Promote cross-sectoral cooperation to develop the entire hydrogen value chain from production to transportation, storage and usage, and mobilization of all technologies related to hydrogen/ammonia to quickly realize a hydrogen society.

Development and Utilization of Innovative Technologies

The Councils emphasize that disruptive innovation which supports orderly energy transition is necessary to achieve the carbon neutral target by 2050, set by both the United States and Japanese governments. Also, no single technology can achieve this target, and an “all-of-the-above” approach can mobilize all available technologies is required. The Councils urge the two

governments to promote the following to accelerate development and utilization of innovative technologies:

- Implement digital technologies in the energy and infrastructure sector including power grid and demand-response for improvement of efficiency and energy-saving on the consumer side, utilization of limited resources, and promotion of smart, modern and resilient infrastructure;
- Develop standards to enhance cyber security resilience and readiness against cyber-attacks on critical infrastructure;
- Incentivize development of new technologies such as more efficient energy storage and CO₂ capture (direct air capture) technologies, innovative advanced nuclear technology including small modular reactors, accident-tolerant nuclear fuels, disruptive nuclear materials that can improve the safety and economics of current and advanced nuclear reactors and fusion energy technologies, and new types and advanced production methods of clean fuels including different colors of hydrogen and innovative methanation in order to ensure a diversity of energy transition technology options and to drive cost reduction for affordability; and,
- Establish a value chain of CO₂ to achieve carbon neutrality, by promoting development of business model utilizing captured CO₂.

Advancing a Free and Open Indo-Pacific

The Councils believe the cooperation of two countries in the Indo-Pacific region and realizing a FOIP are critical for the prosperity and security of this region. Through the Japan-U.S. Clean Energy Partnership (JUCEP) – the core framework of the cooperation in the region for the energy and infrastructure sector – the United States and Japan can support like-minded countries in the region to promote quality infrastructure for energy transition with consideration of different circumstances in each country. The Councils urge the two governments to support the following:

- Expand long-term U.S.-Japan cooperation in third countries where step-by-step transition is required. This includes utilizing coal power plants in cleaner ways such as ammonia co-firing and CCUS – supported by the knowledge and experience of Japan with recognition of their importance from an energy security standpoint – to switch to LNG where feasible, and then to allow such LNG infrastructure to convert with minimum modifications or to shift fuels, to accommodate synthetic methane and hydrogen/ammonia for further emissions reductions;
- Materialize the “Clean Energy, Decarbonization, and Infrastructure” pillar of the Indo-Pacific Economic Framework (IPEF) to mobilize finance that will accelerate the development and deployment of low-carbon and clean energy technologies in the region and the pillar of “Supply Chains” to secure the supply chain of energy infrastructure equipment and critical minerals, and freedom of navigation; and,
- Realize private business projects related to the energy and infrastructure sectors in the region by utilizing multiple frameworks established by the United States and Japanese governments through public-private dialogue, providing business matching opportunities for private companies, encouraging mobilization of private capital and simplifying various procedures and reducing regulatory barriers in third countries.

Financial Services



The Financial Services Working Group of the Japan-U.S. Business Council and the U.S.-Japan Business Council endorse collective actions in five areas: *Building a Healthy Financial System, Realizing a Sustainable and Carbon Neutral Society, Developing Japan as a Global Financial Center, Promoting Digital Financial Innovation, and Securing the Future for an Aging Population.*

1. Building a Healthy Financial System

Financial regulations are the foundation for building a healthy financial system to encourage sustainable economic growth. As an essential element of a healthy financial system, regulations should be reviewed regularly to ensure a level playing field, be harmonized across jurisdictions, take into account technological developments, consider structural changes in societies and international regulatory discussions. The Councils' recommendations pertain to the following areas:

Level Playing Field. A level playing field is an important regulatory principle for strengthening financial and capital markets and avoiding market inefficiencies and distortions. Digital innovation introduces various actors, including technology companies, into the financial services value chain. Applying the same set of regulations on the same activities regardless of the actor by assessing risks for the financial system will promote competition and innovation while ensuring financial stability and consumer protection.

Regulatory Harmonization. The Councils encourage U.S. and Japanese regulators to continue working together on building a globally harmonized regulatory framework. In particular, financial regulations on climate change are rightfully being developed globally, and international harmonization of financial regulations in major jurisdictions, including the United States and Japan, is vital. We believe it is important to implement a process for consistent bilateral cooperation, as well as to discuss broader multilateral cooperation on climate change and other issues, and urge the U.S. and Japanese governments to formalize the process, such as by establishing a financial regulatory forum to discuss regulatory cooperation in these areas.

Stable Inflation and Economic Growth. In view of surging inflation and its negative effects on the global economy, the U.S. and Japanese governments and monetary authorities should implement policies to strike a balance between stable inflation and economic growth, paying careful attention to the particular circumstances of each country. The Councils request that the U.S. and Japanese

governments and monetary authorities consider providing support to those severely affected by inflation, examining and addressing the side effects of monetary policies, and maintain communication with public to avoid excessive market volatility.

2. Realizing a Sustainable and Carbon Neutral Society

Russia's aggression against Ukraine has resulted in a sharp increase in global energy prices, considerably affecting near-term momentum toward energy sustainability and carbon neutrality globally. Given these challenges, the Councils appreciate the U.S. and Japanese governments maintaining their commitments to carbon neutrality by 2050. The financial services sector can play a key role in this effort, through initiatives such as supporting transition activities, in addition to promoting sustainable finance and assessing climate change risk.

Review of Timeframe. Achieving carbon neutrality by 2050 requires considerable efforts by both governments and private companies. Given the ongoing energy crisis, the Councils recommend both governments review the timeline and milestones in the process and respond flexibly, while maintaining the target of carbon neutrality by 2050.

Transition Finance. The Councils support the transitional activities needed to achieve a sustainable and carbon neutral society in an efficient, sufficient, and orderly manner. The Councils support strengthening public-private collaboration to promote sustainable finance and transition finance and to provide greater flexible financial assistance for attaining the target.

Reporting and Disclosure. Both countries' financial regulatory agencies should engage in a public-private dialogue to consider disclosure and reporting standards related to sustainable financing activities, and climate-related risks and opportunities. The goal should be to establish a globally harmonized framework for reporting and disclosure that balances investor needs for transparency and informed decision-making with the need for financial institutions and reporting entities to have flexibility within the framework. Such flexibility is critical in view of the uncertainties and subjective interpretation inherent in any analysis of the assessment and impact of climate change and sustainable financing activities.

3. Developing Japan as a Global Financial Center

The Councils support a multifaceted effort to strengthen Japan's position as a global financial center and laud the continued work to update and improve the quality and coverage of the Corporate Governance Code and Stewardship Code, alongside other important measures to enhance Japan's business environment and overall competitiveness. To this end, the Councils encourage the Government of Japan (GOJ), particularly the Ministry of Finance and the Financial Services Agency, to continue these efforts, which should include policy measures to enhance the

growth of Japan's financial markets and better serve the needs of Japan's individual investors. We urge greater cross-ministerial collaboration, which is vital for achieving these goals. In particular, the Councils recommend focusing on four key areas:

Corporate Governance and Transparency: Further progress on areas such as board independence, diversity, and accountability in accordance with revised Corporate Governance Code, coupled with measures to enhance the availability of diverse talent to fill demand for independent directors is needed.

Finance Professional Ecosystem: Far greater numbers and specializations are needed, as well as general modernization of employment practices, including hiring, promotions, performance appraisal and termination.

Individual Investment Market Participation: Greater attention should be paid to financial planning and fiduciary standards, as well as reforms in the individual investor markets, including in advisor quality, sales practices, asset allocation.

Institutional Markets: Institutional markets should be broadened and resources allocated to create a more nimble clearing and market infrastructure, expanded product range, and adoption of more sophisticated Information Technology.

4. Promoting Digital Financial Innovation

The COVID-19 pandemic has increased the need for digital innovation across every industry. In the financial services sector, it is necessary to address the enhancement of financial products and services and improve customer convenience by promoting digitalization at a faster rate than ever before. At the same time, it is important that governments support regulations and policies that ensure strong consumer protections. The Councils urge the U.S. and Japanese governments to strengthen collaboration in the following ways to harness the benefits of innovation while managing any potential risks:

Central Bank Digital Currency (CBDC). While central bank digital currencies are being researched globally, the Councils appreciate that the United States and Japan are carefully assessing the security risks and their impact on the financial system. The Councils encourage the U.S. and Japan to strengthen collaboration and to lead international efforts in cooperation with third countries, such as aligning a set of shared technical standards that would enable interoperability to integrate CBDC with existing systems and infrastructure, and ensuring fair competition by avoiding differential treatment between domestic and foreign companies in CBDC schemes.

Data Connectivity. The Councils' financial services firms view data connectivity as a means to connect to their customers, manage risks, and provide critical services globally and as one of the

key factors to economic growth and financial stability. To that end, the Councils recommend both governments recognize the importance of financial services data connectivity and promote public-private collaboration to pursue high-standard rules in the digital economy. We sincerely appreciate the efforts put forth by both governments to promote policy frameworks that facilitate Data Free Flow with Trust (DFFT) through robust digital trade disciplines.

Innovation. We recognize the importance of both governments' continued efforts to eliminate regulatory and operational issues for promoting digital financial innovation. With the advent of decentralized finance (DeFi), cryptocurrency, non-fungible tokens (NFTs), and other digital assets, both countries' financial regulatory agencies should provide market participants with timely, clear, and integrated guidance in this evolving area as legal certainty will be key to harness innovation.

5. Securing the Future for an Aging Population

With developed countries including the United States and Japan facing an aging population, both countries need to tackle the common challenge of ensuring financial sustainability. The Councils urge both governments to collaborate with industry to formulate and implement policy recommendations in the following areas:

Private Saving. The Councils recommend both governments to strengthen public and private collaboration in incentivizing private saving, including through insurance, private pension funds, and financial planning. The Councils support the GOJ's "Doubling Asset-based Incomes Plan" under Prime Minister Kishida's new economic policy, which will help the public's large personal financial assets to be more effectively invested. We recommend the GOJ to address the obstacles in order to optimize allocation of financial assets across the investment spectrum in Japan, from corporate and public pensions to defined contribution plans and individual savings.

Insurance. The Councils recommend both governments adopt a policy framework, such as through tax incentives or subsidies, that supports adequate individual asset formation. We also recommend the governments establish appropriate capital standards for insurers at the global, national, and jurisdictional levels, as well as ensure that long duration insurance and savings products remain widely available to consumers.

Financial Literacy. As individuals activate private investments, increasing financial literacy becomes even more important. The Councils recommend public-private collaboration on increasing technology and financial literacy, particularly for vulnerable populations, as well as on financial education for youth.



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Healthcare Innovation



As the COVID-19 pandemic continues to dampen economic growth and disrupt livelihoods, and new public health threats emerge, sustainable and predictable investment in healthcare innovation is urgently needed to promote health system resilience, timely patient access to new treatments and economic competitiveness. These investments will enable the acceleration of transformative technological advances – such as genome editing and cell engineering, digital health solutions and artificial intelligence applications that promise to deliver new breakthroughs to patients at unprecedented speed. Recent geopolitical events have also highlighted the importance of collaboration to ensure resilient supply chains for medical goods, which are critical to ensuring patients are able to access needed healthcare products in a crisis. Even as the pandemic and related developments have highlighted the critical role that healthcare innovation plays in promoting global health and economic security, the Councils note with concern the proliferation of policies that risk undermining innovation and reversing major advancements in healthcare investment, compromising competitiveness for both countries. Of note, there is growing concern that significant numbers of U.S.-approved innovative medicines will not become available in Japan in a timely manner or at all, due in part to the lack of transparency and predictability in the Japanese market for innovative medicines. Similarly, the research-based biopharmaceutical industry has commented that recent U.S. policy developments will lead to fewer new treatments overall while failing to improve affordability as promised.

The U.S.-Japan Business Council and Japan-U.S. Business Council (hereafter “the Councils”) therefore **reiterate their call for a bilateral private-public dialogue to improve timely access to innovative medical products through innovative, equitable, efficient, and effective healthcare systems.** Recalling the four elements of a sustainable healthcare system set forth in their 2021 statement, the Councils recommend that governments and the private sectors in both the United States and Japan dramatically strengthen their collaboration to build a sustainable global healthcare innovation ecosystem and strengthen supply chain resilience.

The Councils support ongoing discussions between the United States and Japan under the auspices of the U.S.-Japan Competitiveness and Resilience (“CoRE”) Partnership, the Economic Policy Consultative Committee (“EPCC”), and other bilateral dialogues and welcome the Japan-U.S. Joint Leaders’ Statement (“Strengthening the Free and Open International Order”) issued by President Joe Biden and Prime Minister Fumio Kishida in May 2022. We are committed to engaging in discussions on policies that would contribute to the resilience of the global supply chain for pharmaceuticals and medical devices in collaboration with both governments.

This Joint Statement represents the collective priorities of the Councils, and we believe that the following recommendations will help both government and industry advance greater health, while strengthening innovation in the U.S. and Japan.

1. Innovation Ecosystem

Reimbursement policies must reward technological breakthroughs and improvements to encourage continued investment and meaningful access for patients. For business and private sector investors to prioritize innovation, policies must acknowledge and compensate for the risks and financial losses associated with research and development. Fair and predictable reimbursements will ensure that innovators continue to explore, develop, and refine cures and treatments for diseases and conditions to improve health.

1.1 Innovation in Healthcare

- For both: Develop and improve the R&D, regulatory environment and reimbursement system to encourage continued investment in the market.
- For both: Create new initiatives to further public-private research collaborations and use dialogue with industry, academia, medical-research institutions, investors and patient associations to identify opportunities for greater partnership and policy reform.
- For Japan: Activate strategic dialogue on a “drug discovery innovation ecosystem” as a national strategy between the public and private sectors and promote the establishment of performance indicators and monitor progress of implementation of the MHLW “Pharmaceutical Industry Vision 2021.”
- For Japan: Maximize the utilization of Sakigake and conditional approval to expedite the availability of innovative medical treatments where significant unmet medical need exists.
- For Japan: Reform regulatory policies to adapt to changes in the R&D landscape such as increasing biotech-led development of innovative medicines and medical devices (e.g., lower hurdles to initiate development in Japan by reducing need for Japanese data).
- For both: Prevent erosion of intellectual property protections that drive investment in biopharmaceutical research and are essential to research partnerships in Japan and the United States as well as around the world.

1.2 Evaluation of Innovation

- For Japan: Promote pricing approaches that consider the benefits derived from therapies, including clinical outcomes as well as social benefits (e.g., getting people back to work, making it easier for patients and HCP, and increasing efficiency of healthcare services) and secondary economic payoffs (i.e., increased productivity).
- For the U.S.: Advance value-based insurance design structures and improvements in patient access that mitigate financial barriers to treatment and permit graduated payment options to

allow patients to pay over time for larger expenses including those associated with advanced medicines such as oncological treatments.

- For both: Ensure that any Health Technology Assessment (“HTA”) does not delay patient access or restrict physician choice.
- For Japan: Exclude patented new drugs from the scope of price revisions (including off-year) and market expansion repricing, similar to other G7 countries.
- For both: Ensure the regulatory, pricing and reimbursement systems recognize the innovation associated with the development of new indications for existing therapies.
- For both: Introduce financial initiatives that can reflect the value of innovation to encourage the development of innovative therapeutics such as regenerative medicine, cell therapy and gene therapy, and for digital therapeutics such as software as a medical device (“SaMD”).
- For Japan: Further expand legally established combined medical care (combination of non-insurance medical treatment and insurance covered medical treatment).
- For Japan: Abolish Foreign Average Price adjustment system, which merely compares prices of medical devices without any consideration to differences in healthcare systems and business environments among countries, to ensure U.S.-approved innovative medical devices remain available in Japan.
- For Japan: When reviewing Functional Categories for medical devices, work closely with industry and ensure that any changes do not undermine rewarding innovation.

2. Digital Transformation

- For both: Promote alignment between U.S. and Japanese regulators in developing and implementing new digital health policies to reduce the cost of developing innovative therapies and improve health outcomes by collecting data and supporting physician/patient interaction.
- For both: Develop an environment in which individuals can access and use their own medical records, while healthcare providers and researchers both domestically and internationally can exchange medical data among different institutions to treat the same patient with adequate privacy protections and patient permission.
- For both: With appropriate protections and meaningful incentives, promote the development/adoption and use of interconnected/interoperable information platforms using international standards such as HL7/FHIR to support integrated care across diagnosis, treatment planning and delivery, patient follow-up, and patient data management.
- For Japan: Develop clear guidance/frameworks for healthcare institutions to store, manage and share healthcare data that improves the quality and efficiency of the healthcare system and public health, and to promote innovation.
- For both: Address Ethical, Legal, and Social Issues (“ELSI”) including privacy, information protection and antidiscrimination for accelerating the sharing of de-identified healthcare data.

Conduct an education campaign to raise awareness on the advances that can be achieved with the sharing of anonymized medical data in driving evidence-based treatment solutions.

- For both: Enable Decentralized Clinical Trials, allowing a hybrid of in-person and remote visits to medical institutions for trial participants.
- For both: Promote alignment between U.S. and Japanese regulators in cybersecurity risk management approaches to protect against cyberattacks and data intrusions, ensure patient safety and minimize enterprise risk.
- For Japan: Establish a mechanism where the healthcare industry can properly deliver necessary information regarding pharmaceuticals and medical devices for patients and the public by using digital technology.
- For both: Promote the use of different treatment modalities such as telemedicine, which can be utilized in the home.
- For Japan: Further support the development of a data platform for the traceability of pharmaceuticals and medical devices.

3. Economic Security and Resilience

- For both: Promote economic security policies that enhance resilience and encourage trade with trusted partners.
- For Japan: Establish regulatory data protection for pharmaceuticals including new modalities with the highest global standard.
- For both: Reinforce investment in R&D for advanced healthcare technologies to improve the technological capabilities and industrial competitiveness of the U.S. and Japan.
- For both: Establish initiatives to enhance mutually beneficial cooperation regarding components, material and manufacturing technology between Japan and the U.S. from the viewpoint of industry development and stable supply of digital health technology.
- For both: Support countermeasures between the U.S. and Japan against infectious diseases and disasters. Establish a market incentive system for R&D for antimicrobial drugs and vaccines and promote the fight against drug resistance (AMR).
- For both: Reinforce global supply chains through alliances between the U.S. and Japan and with their allied countries for stable supply of pharmaceuticals and medical devices.
- For Japan: Ensure unexpected currency changes do not undermine the stability of the healthcare business, supply chain resilience and a stable supply of medical devices and pharmaceutical products.
- For both: Support the free and open flow of medical products across borders to ensure timely access for patients.

- For both: Establish expedited regulatory review procedures for improved supply chain such as relocation of manufacturing sites in the event of an emergency and regulatory reliance/sharing of reviews of post-approval changes related to manufacturing, and consider other initiatives to support supply chain resilience.
- For both: Establish a Mutual Recognition Agreement (MRA) on Good Manufacturing Practice (GMP) between the U.S. and Japan to improve supply chain management.
- For both: Adopt and strengthen science-based pro-vaccination policies and public information campaigns, understanding that high vaccine uptake is essential to preserving economic and social resilience vis-à-vis pandemics and seasonal and endemic disease.
- 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 and ensure the resilience of social security systems in ageing societies.



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Travel, Tourism and Transportation



Amid the tension in the international community caused by Russia's aggression against of Ukraine, it is essential for Japan and the United States to strengthen their collaborative efforts while looking outward towards their friends in the Indo-Pacific region and beyond. The travel, tourism, and transportation (“TTT”) industries are key platforms to promote dialogue, peace, tolerance, and sustainable development. The COVID-19 pandemic has taken its toll on the TTT industries over the last two and a half years. Although its long-term impact on the industries remains to be seen, increasing vaccination rates and changes in the composition of the virus suggest that the sectors may be turning a corner.

According to the United Nations World Tourism Organization, global destinations welcomed almost three times as many international arrivals in the first quarter of 2022 as in the same period of 2021. Asia and the Pacific recorded a 64% increase over 2021, however levels were 93% below 2019 numbers as several destinations including Japan remained closed to non-essential travel. While the number of inbound travelers to the United States and United Kingdom has recovered to about 70% of 2019 levels, Japan’s inbound tourism numbers remain below 10% of the industry’s peak in 2019.

The U.S.-Japan Business Council and the Japan-U.S. Business Council (“the Councils”) look to continue to partner with the public sector and offer the following recommendations, recognizing the pandemic’s continuing effects on the TTT industries while keeping an eye towards the future recovery of the industries. We believe our collective efforts will contribute not only to the recovery of the industry, but also to growth in demand spurred by the creation of new business models, innovation, the Osaka-Kansai EXPO in 2025 and a broad recovery in the two countries.

1. Revitalization of the economy through implementation of lessons learned from the pandemic

The Councils commend the Kishida administration’s efforts to introduce measures to promote the return of business travel to Japan, including the resumption of visa-free independent travel to Japan and the elimination of post-arrival PCR testing, in line with the G7 members. At the same time, we recommend the government take several additional steps to further ease border control measures to facilitate an environment where people, goods, money and digital technologies can move freely, thus advancing Japan's economic growth.

Implementing lessons learned from the pandemic

The Councils welcome the strengthening partnership between the two countries in the area of public health, such as the Japanese version of the CDC recently announced by the Government of Japan. Additionally, the Councils recommend the consideration of new crisis management systems based on lessons learned from the COVID-19 pandemic. It is essential to see the roadmaps for these systems early in the development process to improve the ability to react to similar crises in the future. Additionally, it is important to take advantage of the current JPY/USD exchange rate, currently at its lowest level in the last 24 years and attract inbound tourists to stimulate the recovery and revitalize the Japanese economy. Restarting active cross-border travel between the U.S. and Japan will not only stimulate business between the two countries, it will also revive tourism, study abroad, cultural exchange, and serve as the cornerstone for medium- to long-term economic growth between the two countries.

Japan has made a strong push to promote the country as a tourism nation since the late Prime Minister Abe returned to power in 2012. This policy led to TTT stakeholders to make significant investments in their respective industries over the years. These stakeholders have since had difficulty planning and strategizing for the return of leisure travel given the unpredictable effects of the pandemic. Going forward, the Councils recommended more transparent, clear, and frequent communication on the government's intentions to TTT stakeholders as the industries recover.

To the best of both countries' abilities during the pandemic, Japan and the United States should continue to hold close dialogue, share best practices to achieve a healthy balance between socioeconomic activities and implementing systems for preventing infectious disease in addition to promoting the provision of healthcare. Effective communication with the private sector and public is key.

2. Continue to promote the development and establishment of digital products and services related to TTT

The COVID-19 pandemic has accelerated Japan's promotion of digital transformation ("DX") which has led to new ways of doing things, making life easier both from a professional and private perspective. For example, working from home and "workcations," where location and time zones are less relevant, have led to new forms of efficiencies in the workplace. The Councils look forward to both governments supporting these types of new digital initiatives going forward. The Councils also look forward to seeing these types of technologies showcased at the 2025 Osaka-Kansai EXPO as well as the 2028 Los Angeles Olympic Games.

Promotion of new types of tourism

As a response to new work and lifestyle changes arising from the effects of the COVID-19 pandemic, the Councils recommend the promotion of less known nature and culture tourism assets, local customs, and extended stays through less-traveled prefectures, in addition to tourism promotion via digital platforms. Recruitment of new talent is also a key issue in the tourism industry warranting the consideration of a hard look at current policies in place and enlisting the support of both governments for the development of tourism human resources going forward.

Promotion of new transportation technologies and MaaS services

The Councils recommend Japan to continue to promote Mobility-as-a-Service (“MaaS”) initiatives in the TTT sector. Innovative technologies such as driverless automobiles, delivery systems utilizing robot and drone technology, and transportation systems utilizing big data are expected to contribute not only to the development of smart cities, but also to issues facing both Japan and the United States in the areas of traffic congestion, labor shortages and carbon neutrality.

Promotion of usage of mobility and travel apps

The promotion of the availability and use of mobility and travel apps widely used globally would lead to many benefits including the elimination of language barriers for travelers to Japan, increased usage of local travel providers, promotion of visitation to destinations off the beaten path, increasing worker efficiency and productivity, etc. Current domestically developed apps are difficult to use for international travelers given the lack of user-friendly English interfaces and inability to use international credit cards or payment methods. Increased usage of digital methods will also allow for efficient methods to collect user data allowing TTT stakeholders to better understand trends and plan for future growth.

3. Sustainability in Travel, Tourism, and Transportation

The Councils recognize that the pandemic should be viewed as an opportunity to initiate a better future for the TTT industries, where digitalization and low carbon initiatives enable sustainable growth.

Ensuring inclusive development

The Councils encourage both governments to support inclusive development in the TTT sectors, such as developing attractive tourism resources and new ventures that provide business opportunities for small and medium enterprises in rural areas while ensuring equal access to technologies, services, and opportunities for work to all people regardless of race, ethnicity, gender, age or any other status.

Encouraging government support for low carbon initiatives

The Councils are collectively committed to achieving ambitious carbon neutral emissions goals and encourage both governments to support collaborative initiatives between the U.S. and Japanese

industries, including research and development efforts of technology for the mobility sector and next-generation aircraft. For example, in the automotive industry, it is important to pursue diverse technology options according to local needs without limiting existing technology options. It is essential for the Japanese and US governments and private sector to contribute to the realization of these sustainable efforts by sharing technology widely to third countries. The promotion of non-fossil fuels is also crucial for the decarbonization of the entire energy value chain. In the airline industry, Sustainable Aviation Fuels (SAF) have been identified as one of the key elements to help achieve these goals, and the Councils encourage both governments to remove barriers to the realization of a cost competitive SAF market, while providing incentives to foster investment and supporting the establishment of a resilient supply chain and deployment of SAF.