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JOINT STATEMENT

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Members of the U.S.-Japan Business Council and the Japan-U.S. Business Council (the “Councils”) held the 60th Annual U.S.-Japan Business Conference on October 3-4 in Tokyo. The Councils jointly represent 134 companies from both the United States and Japan, with sectors including the digital economy, financial services, healthcare, energy, infrastructure, travel, tourism, and transportation.

Although the World Health Organization declared an end to the Covid-19 pandemic in March, disruptions to the global economy continue, exacerbated by Russia’s ongoing aggression against Ukraine. With these heightened security challenges, we are now at a turning point in history, where the past trend of globalization has come into question.

Under these circumstances, the Councils applaud the G7 Hiroshima Summit that was held in May this year, when the G7 nations expressed their strong will to strengthen a free and open international order based on the rule of law and agreed on the imperative of fostering economic resilience by deconcentrating and diversifying supply chains. The Councils welcome the agreement to deepen partnerships not only among the G7 countries, but also with leaders of countries in the so-called Global South. Based on the outcomes of the G7 Summit, as well as recalling that government-level cooperation between the United States and Japan has expanded and deepened in a variety of areas under frameworks such as the U.S.-Japan Economic Policy Consultative Committee and Japan-U.S. Commercial and Industrial Partnership, the Councils commit that the business communities of the United States and Japan, as strong partners, will together actively confront the challenges facing the world.

The Conference convened senior business leaders from the United States and Japan, who shared common views on challenges, such as addressing climate change and energy security with realistic and effective actions; strengthening the resiliency of semiconductor supply chains; promoting innovation and appropriate governance in AI; and fostering innovation in the healthcare sector. The Councils also believe that collaboration should be further strengthened in third country markets, including those in the Global South, to foster more resilient, sustainable, diverse, and inclusive societies and promote a more transparent and rules-based international economic order. To achieve these goals, the Councils committed to:

1. Encourage both governments to work together to ensure energy security in the Indo-Pacific region and to make realistic energy transitions toward carbon neutrality.

With the Covid-19 pandemic and heightened geopolitical risks including Russia’s aggression in Ukraine, ensuring stable energy supplies has become an urgent issue for many countries. At the same time, international cooperation to achieve carbon neutrality remains a top priority. The business communities of both countries should promote the adoption of realistic solutions to the so-called energy trilemma (ensuring energy security, equitable access to energy, and a sustainable global environment) with specific action plans. Therefore, the Councils recommend that both governments:

- Promote realistic steps to advance the energy transition and an optimal energy mix with currently available diverse measures such as renewable energy (solar, wind, geothermal), LNG, hydrogen co-firing, ammonia co-firing, and effective use of existing nuclear power plants depending on each region and industry, based on the concept of technology neutrality focusing on the objective contribution to the reduction of GHG;
- Strengthen cooperation including financial and non-monetary support for relevant industries among the U.S., Japan and other like-minded countries to promote technology innovation such as Carbon Capture, Utilization and Storage (CCUS), innovative reactors and efficient production of sustainable aviation fuel (SAF) to achieve carbon neutrality by 2050;
- Promote carbon-recycling products such as e-methane (synthetic methane) and eFuel (synthetic fuel), and bilaterally coordinate CO² counting bilaterally to promote those products.
- Enhance the development of energy infrastructure in so-called Global South countries appropriate to the situation in each country;
- Request that the adoption of new regulations, such as the Carbon Border Adjustment Mechanism (CBAM) in the EU, be transparent and consistent with WTO rules; and
- Further promote transition finance including formulating an appropriate evaluation framework that supports feasible and realistic energy transitions.

2. Support government efforts to ensure the stable supply of semiconductors.

In the midst of the Covid-19 pandemic, the semiconductor supply chain was disrupted, with tremendous consequences in diverse industries around the world. Semiconductors are an essential resource supporting the modern economy, and it is an urgent challenge for both countries to ensure a stable supply in the face of heightened security risks. It is also important for economic growth in both countries that they take the lead in semiconductor innovation, which plays a key role in promoting digital transformation. Therefore, the Councils recommend that both governments:

- Enhance cooperation to optimize secure and resilient supply chains, including diversification of procurement sources (including critical minerals), a sound science-based regulatory system to ensure access to necessary essential materials, including chemicals, and support companies' decisions to seek optimal placement of production bases;
- Continue and strengthen the support for innovation promotion and supply chain optimization, and avoid the policy of excessive preferential treatment of domestic businesses that impede optimal supply chain resilience;
- Identify future competitive technology area and formulate strategy for developing its competitiveness;
- Strengthen cooperation between the public and private sectors of the U.S. and Japan to promote innovation in next-generation technologies such as high-density integration, optoelectronic integration and SiC power devices; and
- Foster cooperation between and among countries in the development and implementation of regulations for advanced technologies.

3. Support government efforts to build optimal AI governance to maximize the social benefits of AI applications.

Technological innovation in AI, including generative AI, is advancing rapidly. It is important for both the U.S. and Japan to promote the development and utilization of AI technologies that enhance the productivity of a wide range of economic activities. There is also an urgent need to mitigate social risks such as invasion of privacy and the dissemination of misinformation and confidential information, and job displacement. Therefore, the Councils recommend that both governments:

- Strengthen bilateral and public-private collaboration on policymaking to achieve both optimal governance, including the improvement of the interoperability, and promotion of appropriate uses of AI with a human-centric perspective in order to maximize the social benefits of the technology;
- Promote the Hiroshima AI Process adopted at the G7 Summit for the development of international rules aimed for trustworthy AI as the basis for promoting safe AI usage, including industry consultation and sharing technical expertise on AI development and utilization;
- Develop the standardization necessary for the formulation of international rules and foster trust among the countries concerned as the basis for the standardization;
- Strengthen the technical and investment aspects of cybersecurity to address emerging risks associated with the advancement of AI; and

- Address and bridge the digital divide to ensure the broadest possible participation in the 21st century's digital economy.

4. Encourage government initiatives to promote innovation and ensure stable supply for healthcare goods that support health and welfare.

In both countries, which face the challenges of an aging population and widening economic disparities, the provision of accessible, advanced medical and care services is a fundamental necessity to ensure the wellbeing of the people. It is important that both countries promote cooperation in ensuring stable supplies of medical goods and access to advanced medical care, as well as improving convenience and efficiency through the utilization of digital technology. Therefore, the Councils recommend that both governments:

- Enhance closer coordination between government agencies in the U.S. and Japan to promote innovation in healthcare and nursing care;
- Collaborate to diversify supply chains, including inputs to ensure a stable and secure supply of pharmaceuticals and medical devices;
- Establish rules and infrastructure for efficient utilization of healthcare and nursing care data;
- Reform pricing schemes in Japan to enhance the predictability of investments in innovative therapies such as regenerative medicine, gene therapy, digital therapeutics, and drug discovery innovation; and
- Promote harmonization of regulations in order to promptly approve safe and effective pharmaceuticals and medical devices.

5. Pursue policies to further deepen partnerships with countries in the Indo-Pacific region.

Global markets have been increasingly fragmented in recent years. The pandemic itself, policy responses to it, and Russia's aggression in Ukraine disrupted supply chains in different ways, leading to various problems such as the global energy crisis and food shortages. Under these circumstances, promoting a Free and Open Indo-Pacific (FOIP) requires cooperation among many countries in the region. To strengthen U.S.-Japan leadership in promoting FOIP, the Councils recommend that both governments:

(1) Strengthen partnerships with the Global South

- Build partnerships for shared prosperity in the Indo-Pacific region based on the rule of law and with respect for each national and regional culture.
- Support U.S.-Japan private sector collaboration and partnerships to bring greater prosperity to the Global South.

(2) Promote quality infrastructure investment

- Promote investment through international frameworks such as the Partnership for Global Infrastructure and Investment (PGII) based on ensuring investment governance, such as the G20 Principles for Quality Infrastructure Investment; and
- Comply with international rules for sound third-country infrastructure investment based on mutual benefit.

(3) Maintain and strengthen a free and open international economic order

- Focus on promoting IPEF to achieve realistic outcomes to develop trade frameworks for shared prosperity in the Indo-Pacific region at an early stage, while recognizing the importance of the return of the U.S. to the CPTPP and considerations of WTO reform;
- Enhance U.S.-Japan cooperation to address trade-distorting actions and market-distorting measures such as pervasive and harmful industrial subsidies, all forms of forced technology transfer and abuse of intellectual property rights;
- Coordinate U.S. and Japan joint efforts to ensure strong supply chain resilience with major trading partners, including the EU, by working cooperatively to ensure sound science, risk-based regulations to secure access to essential raw materials for manufacturing priority industries such as defense, semiconductors, decarbonizing technologies, health products, among others.
- Address economic coercion in cooperation between the U.S. and Japan as well as with other countries in the Indo-Pacific region; and

- Promote Data Free Flow with Trust (DFFT) in the Indo-Pacific region as a basis for strengthening economic linkages, including rule-making in frameworks such as IPEF, and promotion of practical projects to accelerate data distribution.

6. Recognize the pivotal role of the financial services sector in addressing shared challenges and strengthening the global economy.

The Councils encourage efforts by both governments to support the growth of a healthy financial system, realize a sustainable society, advance international cooperation in finance, promote digital financial innovation, and secure a brighter future. Therefore, the Councils recommend that both governments:

- Aim for regulatory coherence, a level playing field, and careful consideration in the review of financial regulation and supervision to maximize the prudential deployment of private capital.
- Encourage efforts to support financial inclusion of developing countries, such as by promoting sustainable finance, blended finance initiatives, and innovation of financial structures through multilateral development banks.
- Pay close attention to the financial needs of small and medium sized enterprises and adapt regulations to meet those needs.
- Promote digital financial innovation in areas such as data connectivity and AI.
- Pursue policies to support Japan's development as an international financial center and as a nation facilitating asset management. The Councils applaud Prime Minister Kishida's recent announcement of new initiatives to bolster Japan's asset management sector.

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 that it is essential for industries in both the U.S. and Japan to expand the digital economy by creating value through economic activity, while improving the business environment and creating business opportunities that continue to contribute to global economic growth. The Councils also believe that the U.S. and Japanese governments, as well as industries in both countries, need to pursue even closer cooperation and further demonstrate leadership to achieve a fair, just, safe, and secure society, putting an end to the digital divide and improving people’s well-being despite the increasingly diverse and complex set of global issues facing both countries. With this in mind, we present the following medium- to long-term recommendations to both governments.

1. Strengthen and promote a rules-based global trading system.

Given the need to reinforce the democratic values underpinning global trade and security amid ongoing global crises, the Councils believe that combatting protectionism is a key way to expand the global digital economy. To this end, the Councils call on the U.S. and Japanese governments to further demonstrate leadership in strengthening the rules-based global trading system.

We continue to support the United States rejoining the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (“CPTPP”), thereby establishing an expansive value chain with the participation of many Asia-Pacific countries, including those in the Global South, based on a mutual respect for diverse values and cultures, while recognizing that, politically, U.S. accession to the CPTPP is currently not achievable. We welcomed the launch of Indo-Pacific Economic Framework (“IPEF”) talks as a way to re-engage the region and believe it has the potential to promote shared prosperity in the region and uphold a free and open international economic order. To this end, we urge both governments to use the IPEF to deliver meaningful strategic and commercial outcomes that advance U.S. and Japanese interests in the region. The U.S. and Japan should demonstrate their leadership on rulemaking for the digital economy, and setting comprehensive, high-standard rules on digital trade will be critical to this effort. We therefore urge the negotiators to use the text of the U.S.-Japan Digital Trade Agreement as a floor. With respect to the strengthening of supply chains, we look forward to seeing the implementation and early introduction of systems aimed at mitigating risks and bolstering resilience among the member countries.

The Councils also encourage both governments to cooperate on efforts at the World Trade Organization (“WTO”) to reform its negotiating and dispute settlement processes and procedures to strengthen the rules-based global trading system. Accordingly, we urge the governments to reach substantial agreements at or ahead of the upcoming ministerial conference.

2. Advance digital transformation (“DX”) through closer U.S.-Japan cooperation.

The Councils believe that the acceleration of DX will be the foundation for a virtuous cycle consisting of the creation of new products and services, the promotion of green transformation (“GX”) and of economic security, the resolution of social issues, higher productivity, greater investment, improvement of healthcare, and the acceleration of innovation. Digitalization is key to resilient and efficient social and industrial infrastructures. In addition, increased utilization of data has the potential to change every aspect of economy and society. To achieve this, we believe that the U.S. and Japan should cooperate more closely, especially in the following areas:

A. Foster investment in key technologies and supply chain resilience.

The Councils believe that the U.S. and Japanese governments should promote policies that encourage greater investment, particularly in domestic and overseas R&D, to eliminate critical dependencies on certain countries while strengthening global supply chains. Deconcentration and diversification of supply chains should be the order of the day. Reinforcing the supply chain for critical technologies, such as semiconductors, is especially essential to support the digital infrastructure needed for high-volume and high-speed information processing. Further, we welcome the implementation of the Japanese Economic Security Promotion Bill and the U.S. CHIPS and Science Act. We also recognize the importance of public-private collaboration in the semiconductor field to develop strategies to identify and nurture the areas and technologies that can provide a competitive edge into the future.

B. Promote the free flow of data across borders.

We appreciate the efforts by both governments to promote policy frameworks that facilitate cross-border data flows for all services and financial services sectors, including through the Data Free Flow with Trust (“DFFT”) concept and robust digital trade disciplines, such as the U.S.-Japan Digital Trade Agreement. The Councils also welcome the G7 leaders’ endorsement of the outcome of the G7 Digital and Tech Ministers’ Meeting, i.e., “Annex on G7 Vision for Operationalizing DFFT and its Priorities” and the establishment of the Institutional Arrangement for Partnership (“IAP”) to operationalize DFFT at the G7 Hiroshima Summit. We urge the early implementation of these commitments to deliver substantive outcomes. The IAP in particular, as a principles-based, solutions-oriented, multi-stakeholder initiative, will provide a forum for international public-private collaboration with the goal of removing or reducing barriers to the cross-border transfer of data, including for financial services.

We strongly encourage the two governments to continue working closely together to promote the free flow of data in other multilateral fora, such as the G20, OECD, APEC and the WTO. We encourage both governments to embrace high-standard privacy protection and open digital markets in multilateral fora. We also urge the U.S. 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.

3. Develop and promote a safe and reliable next-generation information and communications technology (“ICT”) infrastructure.

The Councils believe that secure and trusted next-generation telecommunications infrastructure will enable innovation and new opportunities across all industries by accelerating digitalization of social infrastructure. 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, interoperable, and standards-based radio access networks (“RANs”), technologies, and solutions both domestically and internationally. We encourage the two governments to take initiative in accelerating the adoption of these technologies by implementing their commitments to invest in research, development, testing and deployment. We recognize that it is important to develop, build, and maintain a multi-layered network consisting of not only terrestrial networks, but also non-terrestrial networks and submarine cables among others, to bolster the reliability and strength of the overall information and communications network. From this viewpoint, we call on both governments to continuously strive to further collaborate with like-minded partners, including those in the Global South, to build a highly reliable and strong network by leveraging the international communications infrastructure (such as transoceanic submarine cables), thus bolstering global connectivity.

4. Accelerate the initiative to promote the use of artificial intelligence (“AI”).

The Councils anticipate that AI technology will greatly contribute to global socioeconomic development in the future and recognize that its technological advancement incurs a variety of risks. Based on this perspective, we need to ensure that the development of governance keeps up with the rapid pace of technological innovation as seen in generative AI today, in accordance with the concept of agile governance acknowledged at the G7 Digital

and Tech Ministers' Meeting in April 2023. To this end, we welcome the G7 leaders' directive to establish the Hiroshima AI Process by the end of this year, which could include the consideration of themes such as human-centric governance, the protection of copyright and other intellectual property rights, promotion of transparency, response to information manipulation by other countries (including disinformation), and the responsible use of these technologies, as described in the G7 Hiroshima Leaders' Statement, as well as the Action Plan for promoting the global interoperability of AI governance from the G7 Digital and Tech Ministerial Meeting. We encourage both governments to implement concrete policies at an early stage to achieve these objectives.

As discussions for legislation of AI-related laws and regulations are progressing in various countries and regions including in the U.S., Japan and the EU, the Councils understand that it is critical to ensure interoperability of rules and standards to properly utilize and operate AI on a global scale. We urge the two governments to demonstrate leadership in achieving those goals while strengthening cooperation with relevant stakeholders, including industry, based on the spirit of the Ministerial Declaration of the 2023 G7 Digital and Tech Ministers' Meeting.

Additionally, to ensure the responsible development and use of AI, it is essential to endorse transparent, multi-stakeholder approaches to AI governance. This includes developing voluntary standards, frameworks, and codes of practice that can bridge the gap between AI principles and implementation. Multi-stakeholder initiatives have the greatest potential to identify gaps and mobilize AI actors to address them. The United States' National Institute of Standards and Technology's ("NIST") Artificial Intelligence Risk Management Framework ("AI RMF") and Japan's AI Governance Framework offer a good basis to coordinate on bilateral interoperability of AI governance, given their shared emphasis on agile governance, a risk-based approach, promoting safety, transparency, and accountability while fostering innovation, making both suitable models for broader inspiration and adoption. On the other hand, we believe that careful consideration is needed to ensure that the regulations related to misinformation/disinformation and ethics do not impede innovation.

Moreover, we believe that improvements in the energy consumption and processing capabilities of systems are important from the standpoint of green transformation, considering that massive amounts of data are utilized, and huge amounts of electricity are consumed through using AI. The mass production of advanced semiconductors, critical to achieving these goals, should also be promoted concurrently. As the importance of DX promotion grows to attain economic development and resolve social issues, the Councils encourage the U.S. and Japanese governments to assert leadership in striking a balance between the semiconductor and digital industry strategy and green growth strategy, thereby creating a virtuous cycle, a high global-level perspective, and collaboration.

5. Strengthen U.S.-Japan leadership in promoting the use of emerging technologies.

A. Deepen bilateral and multilateral cooperation on quantum technology.

We urge the two governments to accelerate the implementation of cutting-edge solutions, such as the development of quantum technology in the areas of quantum computers, quantum-safe cryptography and quantum networking, through the implementation of demonstration schemes and joint development based on the U.S.-Japan Competitiveness and Resilience ("CoRe") Partnership.

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 key standards-setting processes for emerging and critical technologies, such as in areas of quantum technology.

B. Continue public-private dialogue on immersive technologies.

The Councils support the idea agreed to at the G7 Hiroshima Summit that the governance of the digital economy, including immersive technologies, should be continually updated in line with democratic values.

Furthermore, to promote responsible innovation and implementation of technologies while upholding online safety and rights to security and privacy, discussions at relevant multistakeholder fora, including at the OECD, should continue, in close consultation and collaboration with technology companies and other relevant stakeholders.

We recognize that immersive technologies will likely give rise to many innovative opportunities across various fields and use cases, such as healthcare. In the face of structural changes, such as demographic shifts, including the aging society, and as the need to promote higher productivity and secure sufficient labor force participation increases, we call on both governments to implement robust policies designed to improve the efficacy and efficiency of healthcare and to equip individuals with capabilities such as digital reskilling and upskilling to keep pace with the digital transformation.

C. Promote an open, interoperable, and secure Internet through globally recognized cyber risk management frameworks.

The Councils recognize that securing the governance and reliability of the Internet in line with democratic values, exemplified by fairness, accountability, transparency, safety, protection from harassment, hate, and abuse, respect for privacy and human rights, fundamental freedoms, and the protection of personal data on technologies and platforms, is essential for the development of the digital society. To this end, the Councils welcome the “G7 Action Plan for Open, Free, Global, Interoperable, Reliable, and Secure Internet” from the Digital and Tech Ministers’ Meeting and urge the early implementation of concrete policies to achieve the outlined objectives.

The Councils recognize that cybersecurity risk management, especially regarding critical infrastructure, is essential to U.S. and Japanese economic and national security and is important for our bilateral partnership on digital trade. Given the evolution of cybersecurity threats and their increased frequency, use of digital technologies to bolster infrastructure resilience will be key to managing risks. Moreover, the Councils recognize that a risk-based approach is more effective for managing cyber risk than prescriptive regulation.

Approaches to cybersecurity should adhere to internationally recognized cyber risk management frameworks that are relevant across sectors that businesses can utilize to 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. A more aligned international approach to cyber policymaking also streamlines the process for SMEs that need to strengthen their cybersecurity capabilities to integrate into global supply chains.

We encourage the two governments to include the U.S.-Japan Digital Trade Agreement’s cybersecurity provisions in future trade agreements, including the WTO joint initiative on e-commerce and IPEF.



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Energy and Infrastructure



Every country sees a growing need to increase energy security in today's uncertain geopolitical environment due to recent events such as the Russian invasion of Ukraine. Furthermore, climate change represents one of the greatest challenges facing the world and requires urgent and sustained action toward carbon neutrality.

The U.S.-Japan Business Council and the Japan-U.S. Business Council (hereafter "the Councils") believe that the U.S. and Japan must be key players in navigating the world to a well-balanced future - decarbonizing the power sector and ensuring secure and stable energy supply.

To achieve carbon neutrality by 2050 and enhance energy security, international collaboration and public support from developed economies to growing economies such as legislation, regulatory reform, and incentives are essential. The world also needs to take various energy transition routes, including circular economy approaches to support decarbonization, factoring just transition considerations so that it leaves none behind as there is no one-size-fits-all approach to the energy transition.

In addition, the Councils remain committed to U.S.-Japan cooperation to realize a Free and Open Indo-Pacific (FOIP) for the prosperity and security of the region. The Councils also see Southeast Asian countries as important stakeholders to achieve FOIP.

Improving Systems Toward Upgrading Energy Security

The Councils welcome many of the energy and climate provisions of the Inflation Reduction Act (IRA) such as hydrogen and carbon capture, which supports the U.S. in achieving a carbon neutral society by 2050. We recognize that the Act needs further actions to make sure its incentives can be maximized as quickly as possible to benefit society: providing clear regulation, streamlining a cumbersome permitting system, and investing in enabling infrastructure.

The Councils also welcome the launch of the Japan-United States Energy Security Dialogue which strengthens the two countries' bilateral partnership on energy security. Recent geopolitical events and skyrocketing energy prices have reminded us that securing a stable energy supply is essential as well as pursuing decarbonization to protect daily life.

We further acknowledge the role liquefied natural gas (LNG) can play to alleviate global energy supply constraints and hence promote exports of U.S. LNG to take this role. As the Japanese government and International Energy Agency Secretariat's recently released LNG Strategy for the World report warns, "If investment into natural gas/LNG is insufficient, a supply tightness could occur before a demand decline, putting global energy security at risk...Therefore, it is important to recognize that the world may risk facing prolonged periods of supply shortages if actual demand turns out to be higher than forecasts or expectations."

Meanwhile, the lack of consistency and transparency in measurement and reporting of methane emissions creates challenges for the LNG market. We support the U.S. Department of Energy's development of the global framework for differentiated natural gas to verify emissions throughout a global supply chain. The Councils recommend the two governments to consider the following measures for the U.S. and Japan to lead efforts to enhance energy security and resilience for a stable worldwide energy supply:

- Support the development and deployment of infrastructure 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;
- Boost activities on the Coalition for LNG Emission Abatement toward Net-zero (“CLEAN”) for the initiative taken by its buyers, together with its producers, to reduce methane emissions in the value chain.
- Increase energy supply through governmental frameworks among like-minded countries and support investments in energy infrastructure to diversify supply chains and sources of energy, instead of depending on a single source;
- Utilize nuclear power and promote the new generation of safer reactors which can contribute to the enhancement of energy security as one of the important sources of safe, resilient, and green baseload power supply;
- Develop clear regulations and guidelines based on the IRA, such as domestic sourcing requirements, carbon intensity and key definitions to implement the law; and,
- Expand the IRA philosophy which includes incentives to reduce carbon emissions to other countries such as Japan to boost decarbonizing projects globally.

Securing A Realistic Transition That Works for All

The Councils are aware that the energy transition is far more complicated than simply turning off fossil fuels and switching on renewables. It requires a balancing act between decarbonizing our society and ensuring secure and stable energy supplies for each country. Every country has a different resource situation and requires a phased approach toward carbon neutrality.

There is no one-size-fits-all approach to achieving the energy transition with stable energy supply, but we have various solutions such as low carbon fuels such as e-methane/e-natural gas, carbon capture systems, nuclear power, and hydrogen in addition to employing natural energy resources such as solar, wind, geothermal, pumped storage hydropower, and batteries where possible.

The U.S. and Japan continue efforts to achieve a carbon neutral world with the “Japan-U.S. Energy Security Dialogue” as the center of U.S.-Japan cooperation in this area. The Councils urge the two governments to support the following for the U.S. and Japan to overcome the energy trilemma: ensuring energy security, providing energy equity – international access to affordable, clean energy - and achieving environmental sustainability:

- Maintain implementation of the U.S. Department of Energy and Japan’s Ministry of Economy, Trade and Industry Memorandum of Cooperation in the field of carbon capture, utilization and storage, conversion and recycling, and carbon dioxide removal. Continue commitment on switching to natural gas including LNG, a stable cleaner baseload power supply, and methanol from other fuels with higher emissions; and deploying cutting edge technologies such as dual-fuel gas turbines capable of combusting both natural gas and hydrogen, and eventually just hydrogen;
- Ensure a clear and sustainable rules-based approach so that each country has predictable policies toward reducing emissions or introducing a price for carbon, and develop mechanisms for emissions trading and environmental value trading, so-called Corresponding Adjustment, across countries;
- Activate incentives for carbon capture, utilization, and storage (CCUS) and other decarbonization pathways for cleaner utilization of existing infrastructure, decarbonization of hard-to-abate sectors such as the industrial and transportation sectors and production of cleaner fuels including blue hydrogen/ammonia, e-fuel, and sustainable aviation fuel;
- Coordinate on development of key regulatory and standards processes to encourage investments in decarbonization and build demand for lower-carbon products and manufacturing inputs;
- Promote cross-sectoral cooperation, such as the recent consortium announcement between U.S. and Japanese companies, to develop an entire hydrogen value chain from production to transportation, storage and utilization, and mobilization of all technologies related to hydrogen, ammonia, and e-methane/e-natural gas to quickly realize a hydrogen society.

Expanding Development and Deployment of Innovative Technologies

The Councils emphasize that disruptive innovation which supports an orderly energy transition is necessary to achieve the carbon neutrality targets set for 2050 by both the U.S. and Japanese governments. Also, no single technology can achieve this target, and an “all-of-the-above” approach is required. The Councils recommend the two governments to promote the following policies to accelerate development and utilization of innovative technologies:

- Support continued implementation of the Memorandum of Cooperation between the Ministry of Economy, Trade and Industry of Japan and the U.S. Department of Energy concerning collaboration in the field of carbon capture, utilization and storage / conversion and recycling, and carbon dioxide removal.
- Implement digital technologies in the energy and infrastructure sector, including power grids, for improvement of efficiency, utilization of limited resource, and promotion of smart, modern, and resilient infrastructure;
- Develop risk-based standards incorporating private sector consultation to enhance cyber security resilience and readiness against cyber-attacks on critical infrastructure;
- Utilize AI and IoT technologies to decarbonize value chains such as hydrogen and CO2 and optimize an energy management by power grids;
- Support private sector efforts to develop new technologies such as more efficient energy storage and carbon capture (direct air capture) technologies, innovative advanced nuclear technology, and new types of clean fuels to prepare as many technology options for the energy transition as possible and to drive cost reduction for affordability;
- Establish a CO2 value chain, which is one of the key pillars toward carbon neutrality and decarbonizing hard-to-abate sectors, by promoting development of business models utilizing captured CO2 and creating a circular economy for CO2 which has e-methane/e-natural gas as a solution;
- Set rules for CO2 accounting to facilitate the import and export of products made of captured CO2; and,
- Coordinate harmonization of standards for cross border CO2 shipping.

Cooperating With Southeast Asian Countries in Order to Achieve a Free and Open Indo-Pacific

The Councils believe the cooperation of the U.S., Japan, and Southeast Asian countries in the Indo-Pacific region is essential to realizing a Free and Open Indo-Pacific (FOIP) that brings prosperity and security to the region. Through enhancing the Japan-U.S. Clean Energy Partnership (JUCEP), the U.S. and Japan can support like-minded countries in the region to promote high quality infrastructure for energy transition and energy security with consideration of the different circumstances of each country. The Councils urge the two governments to support the following recommendations:

- Expand U.S.-Japan cooperation with Southeast Asian countries to sustainably switch coal power plants to LNG, use renewable natural gas with CCUS systems, and then convert such infrastructure to hydrogen/ammonia infrastructure with minimum modification for further emissions reduction in the long run;
- Mobilize financing to accelerate the development of low-carbon and clean energy technologies via the “Clean Energy, Decarbonization, and Infrastructure” pillar of the Indo-Pacific Economic Framework (IPEF) in the region. Simultaneously, utilize the “Supply Chain” pillar to secure the supply chain of energy infrastructure equipment and critical minerals, and freedom of navigation;
- Continue to actively engage in global development efforts including the Mineral Security Partnership that includes government partners from 12 countries including Japan and the United States to stabilize mineral supply chains;
- Utilize all existing frameworks for public-private dialogue established by the U.S. and Japanese governments to support private energy and infrastructure business projects in the region. This could take multiple forms, including by providing business matching opportunities for private companies, encouraging mobilization of private capital and reducing regulatory barriers in Southeast Asian countries;

- Encourage circular economy approaches to promote innovative sustainable business models in which products are crafted and consumed in a way that maximizes their value throughout their entire life cycle, and reduces their impact on natural resources, waste generation, and carbon emissions;
- Develop common principles and life cycle assessment (LCA) tools to evaluate circularity and environmental impact of the different alternatives, and additionally support the waste hierarchy by rethinking traditional, linear “take-make-dispose’ way of doing business to adopt new ways of working that maximize the value and use of our resources;
- Pilot increased investment in waste management through available channels such as U.S. and Japanese development funding, and others as a means to create economic value for waste plastic (as feedstock) in the developing economies in Indo Pacific region; along with new job creation – while also establishing environmental solutions;
- Encourage greater investment in recycling technology, including the deployment of advanced recycling which is a more suitable technology to address the complexity in developing economies in the region; and,
- Promote greater public awareness on new low carbon alternatives increasing public acceptance on the role of CCS, hydrogen and low emissions fuel as part of the “all-of-the above” solution to achieve a carbon neutral society by 2050.



U.S.-Japan
Business Council



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: *Maintaining a Healthy Financial System, Realizing a Sustainable Society, Advancing International Cooperation in Finance, Promoting Digital Financial Innovation, and Securing a Brighter Future.*

1. Maintaining a Healthy Financial System

Level Playing Field

The Councils embrace innovation and the healthy introduction of new financial products and services both by incumbent players and new entrants.

At the same time, the lines between traditional and new financial products — as well as between traditional financial institutions and tech-focused newer entrants — are becoming increasingly blurred. We urge supervisory authorities to be vigilant as technologies rapidly advance. For competition and innovation to thrive in finance under the principle of a level playing field, it is essential that governments and authorities evaluate a product's potential impacts on consumers and the financial system when assessing the appropriate regulations and standards to apply.

Regulatory Coherence

Regulatory fragmentation has been exacerbated by strategic, environmental, and technological developments that have motivated national governments to act before international best practices can be established. In this environment, it is critical that the U.S. and Japanese governments align on the development of appropriate regulations that are coordinated, strike the right balance between global consistency and local relevance, and move us toward financial regulatory coherence. The Councils believe an institutionalized approach should be implemented, as in the formation of other bilateral financial regulatory fora. Such a step would be a natural progression and a work product that can be produced by the ministerial Japan-U.S. Economic Policy Consultative Committee (the Economic "2+2") and the "Japan-U.S. Competitiveness and Resilience (CoRe) Partnership" created by the leaders of the two countries at their meeting in January 2022.

Careful Consideration in the Review of Financial Regulation and Supervision

The stress of regional bank failures in the U.S. in March 2023 highlighted the vulnerabilities of selected individual financial institutions, but the global financial system has shown itself to be more resilient due to the regulatory reforms implemented following the Global Financial Crisis in 2008, as reaffirmed at the recent G7 Finance Ministers and Central Bank Governors' Meeting 2023. Both Councils support the efforts of international financial regulatory agencies such as the FSB to carry out ongoing analysis of recent events to derive their causes and implications. Measures towards the improvement of future regulation and supervision should be carefully calibrated in their breadth and scope based on this analysis.

2. Realizing a Sustainable Society

Appropriate Evaluation of the Initiatives of Financial Institutions

The importance of transition finance was reaffirmed at the G7 Hiroshima Summit, and there is a growing international understanding of its significance. Financial institutions are expected to support companies' efforts towards decarbonization through transition finance and similar initiatives. However, there is a concern that the efforts of financial institutions that are actively supporting decarbonization through transition finance are not currently evaluated under a consistent set of rules for measuring and disclosing financed emissions. Both governments should establish a framework for appropriately evaluating investments and loans aimed at achieving net zero emissions.

Promotion of Blended Finance

In order to further attract private investment towards the realization of Green Transformation, it is of utmost importance for public institutions, including multilateral development banks (MDBs), export-import banks, aid programs, and others, to establish a Blended Finance framework through measures such as assuming risks that cannot be fully covered by the private sector, including debt guarantees. Both governments should strive to create an environment and legal framework conducive to the promotion of Blended Finance.

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.

Supporting Small and Medium-Sized Enterprises

Small and medium-sized enterprises (SMEs) constitute the backbone of our economies, responsible for the vast majority of jobs, tax payments, innovation, and resiliency. But in the new era of geopolitical stress, energy transitions, digital transformation, market volatility and attendant regulatory fragmentation, SMEs are experiencing unsustainable burdens. Both governments should make it a priority to foster the diversification of SME financing instruments and channels to enable them to build resilience and undertake crucial investments, such as those in digitalization and decarbonization. This should also include non-financial support which is key to strengthen SME awareness about the steps towards net zero and provide the necessary tools that can enable them to embark and stay on the journey.

3. Advancing International Cooperation in Finance

Supporting the Global South

The Councils welcome efforts by both governments to support financial inclusion of developing countries (often called the Global South). Efforts such as the Partnership for Global Infrastructure and Investment (PGII) and the G20 Principles for Quality Infrastructure Investment are necessary to help the Global South meet its development needs. We are pleased to see the inclusion of private sector perspectives and participation in these efforts and urge the two governments to continue to integrate private sector input going forward. The Councils believe that the initiatives to promote sustainable finance and blended finance mentioned in Chapter 2 of this statement are important in supporting the Global South. In addition, aligning the global interpretation of Basel III capital rules and country regulations, sharing expertise of the development banks and financial institutions, and streamlining

documentation and standardizing contracts would remove significant barriers that currently prevent or delay banks' ability to provide capital to infrastructure investments associated with MDBs and their related organizations.

Both Councils urge their respective governments to take measures to prevent debt crises from forming in emerging economies. Such events delay the implementation of the aforementioned initiatives and introduce instability to financial markets across the world.

Economic Security

Both Councils understand that finance represents a critical infrastructure, and that it is necessary for the public and private sectors to work together to ensure cybersecurity and other measures to provide safe and sustainable services. When considering various economic security regulations, both governments should coordinate appropriately to ensure national security while taking care not to hinder free economic activity.

Furthermore, in view of the growing complexity of financial sanctions that prohibit transactions with specific targets, both governments should consider implementing close communication between the public and private sectors to enhance the effectiveness of sanctions and reduce the compliance risks of financial institutions.

4. Promoting Digital Financial Innovation

Central Bank Digital Currency (CBDC)

The Councils appreciate that both governments and central banks are deliberating CBDC policy to harness the benefits of innovation while addressing potential risks to the financial system. The Councils encourage both governments to evaluate the need for CBDCs before actually issuing them by identifying whether there is a shortcoming with other payment initiatives that a government or central-bank-issued CBDC would be able to address more effectively than private alternatives.

Data Connectivity

The Councils recommend both governments prioritize data connectivity for financial services and promote public-private collaboration to pursue high-standard rules in the digital economy. We welcome the establishment of the Institutional Arrangement for Partnership (IAP) to operationalize Data Free Flow with Trust (DFFT) and appreciate that particular attention will be paid in the IAP to areas such as data localization and regulatory cooperation in financial services.

Innovation

The Councils recognize the importance of the continued efforts by both governments to resolve regulatory and operational issues to promote digital financial innovation. Particularly, with the emergence of decentralized finance (DeFi), cryptocurrencies, non-fungible tokens (NFTs), and other digital assets, the development of legal frameworks has become crucial in balancing the utilization of digital financial innovation with the stability of the financial system and the protection of users. Therefore, the financial regulatory authorities of both countries should continue to provide timely, clear, and integrated guidance to market participants in this field.

AI/Generative AI

The use of AI in financial institutions continues to advance and global interest in generative AI is rapidly increasing. Both Councils welcome the agreement reached at the G7 Digital and Technology Ministers' Meeting to promote the mutual operation of AI governance and the adoption of trustworthy international AI technology standards through international discussions. Both national governments need to collaboratively review the various systems and guidelines related to the use of AI and the policies for dealing with associated risks to ensure that any AI-specific

regulations complement and align with existing sector-specific regulations to avoid duplicative efforts or conflicting requirements that could increase risk. We also recommend both governments focus on the development of human resources for the development and application of AI.

5. Securing a Brighter Future

Personal Financial Assets

The Councils recommend both governments adopt a policy framework, such as through tax incentives or subsidies, which supports adequate individual asset formation. We also recommend both governments to strengthen public and private collaboration in enhancing the incentives for the building of personal financial assets, 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 economic policy, which will help large personal financial assets to be more effectively invested. We recommend that the GOJ consider and implement strategies to optimize the 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 that both governments ensure that the insurance sectors are able to meet the evolving financial protection needs of consumers, to include maintaining the wide availability of long duration insurance and savings products. We encourage regulators to facilitate the insurance sectors' appropriate provision of more innovative insurance products that meet changes in customer needs while ensuring sufficient customer protection. We also recommend that both governments establish appropriate capital standards for insurers at the global, national, and jurisdictional levels.

Financial Literacy

As individuals take a more active role in managing their personal 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.

Japan's Development as an International Financial Center

The opportunity for Japan to reestablish its prominence as a global and regional financial center has never been greater. Japan possesses all the necessary attributes to become a top global financial center and attract far larger amounts of foreign investment than at present. The efforts of the Japanese government and authorities to strengthen their outreach to overseas businesses by holding promotional events, such as so-called "Japan Weeks," is highly appreciated. The Councils urge the GOJ to implement policies to establish Japan more prominently as an international financial hub for the world and Asia and as a nation facilitating asset management. This includes policies for attracting foreign financial specialists to Japan, encouraging financial firms to invest in technology, and diversifying the asset management industry to cultivate globally competitive talent. The Councils believe that the financial sectors of both countries can play a role in fostering these initiatives and contribute to the growth of financial business in Japan.

The Councils welcome progress has been made on the negotiations of the IPEF. We hope that its Pillar III (Clean Economy), if enacted, would be a catalyst for Japan becoming an International Financial Center, especially on sustainable finance.

Promoting Foreign Direct Investment (FDI) Into Japan

The Councils welcome Prime Minister Kishida's efforts to raise FDI via the Cabinet Office's "Action Plan for Attracting Human and Financial Resources from Overseas" and appreciate the GOJ's efforts to implement measures in the Plan promptly. We are pleased to support their undertakings especially in areas such as the formation of Asia's largest startup hub and improving the business environment. The Councils look forward to maintaining an open line of communication with the Cabinet Office on inbound FDI issues and stand ready to provide advice and support.



U.S.-Japan
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Healthcare Innovation



Now more than ever, sustainable and predictable investments in healthcare innovation are urgently needed to promote health system resilience, workforce productivity and stability, timely patient access to new treatments, and economic competitiveness. While the emergency responses to COVID-19 are ending, the virus and the risk of another pandemic remain, as well as the growing burden of non-communicable diseases. The continued utilization of vaccines, therapeutics, and other medical technologies is critical for individual and communities' public health and well-being. Additionally, Japan has the fastest aging population of any post-industrial nation on earth where deaths have outpaced births for over a decade. The impact of an aging and shrinking population is already visible across metrics from economic performance to public policy priorities around infrastructure and supply chain stability. Greater investment is needed to improve the distribution of and access to healthcare supplies vulnerable to geopolitical and other shocks, market uncertainty, and economic disruption. As the pandemic demonstrated, investment across life sciences is also needed to unlock breakthrough innovation that holds historic promise for patients; maximizing the benefits of digital transformation, for example can accelerate drug discovery and improve healthcare services and outcomes.

The United States and Japan share a history as global leaders in life sciences. Yet dozens of changes in pricing rules and annual/biannual price cuts, including to patented medicines and medical technologies in Japan, have put pharmaceutical and medical technology (“medtech”) innovation ecosystems in Japan at risk. On the medtech side, changes made to functional categories and to price reductions calculated against the Foreign Average Price have also put the innovation ecosystem in Japan at risk. These changes have decreased Japan's share of the early-stage pipeline, precipitated stagnation in new clinical trials, and exacerbated the drug/device lag and drug/device loss, in which innovative medicines and technologies to treat unmet medical needs are increasingly not launched in Japan in a timely manner – or not launched at all. Likewise, recently adopted U.S. price-setting policies will hinder the development of new treatments overall while failing to fully address affordability issues in the health care system. Furthermore, labor shortages, increases in materials and transportation costs, and devaluation of the Japanese Yen, have made it difficult for both U.S. and Japanese companies to supply existing products and necessary ingredients to Japan.

The U.S.-Japan Business Council and Japan-U.S. Business Council (hereafter “the Councils”) encourage both governments to take the following three steps to maintain competitiveness as healthcare innovation leaders:

1. **Restore market-based incentives for investment in life sciences and medtech innovation.** Reimbursement policies must reward technological breakthroughs and improvements, to encourage continued investment and permit access for patients. For Japan, the Councils urge adoption of the recommendations reflected in the April 2023 PhRMA, EFPIA and JPMA Joint Statement on Proposals for the 2024 Drug Pricing Reform.
2. **Establish a bilateral public-private dialogue to improve timely access to innovative medical products.** The Councils welcome recent efforts to cooperate on pharmaceutical supply chains and biotechnology start-ups under the Japan-U.S. Commercial and Industrial Partnership. We call for the governments to formally incorporate public-private dialogue into the new initiative, with a renewed focus on the full range of issues that affect the competitiveness of the life sciences industry in both countries. In addition, we urge the governments to consider expanding the scope of the dialogue to address other challenges facing the health sector.
3. **Launch a new U.S.-Japan partnership to share best practices on digital health.** New policies are needed to promote access and integrate digital therapeutics and health solutions, such as telemedicine digitalization and utilization of healthcare data. Enabling the deployment of digital tools, including AI, will accelerate R&D and

facilitate patient access to medical technologies that improve patient outcomes. Therefore, the Councils encourage the governments to launch a new partnership guided by the Framework for U.S.-Japan Cooperation on Digital Health contained in the Appendix.

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

1. Innovation Ecosystem

Reimbursement policies must reward technological improvements and breakthroughs to encourage investments in health and permit access to treatments for patients. For business and private sector investors to prioritize innovation, policies must acknowledge and compensate for the risks sustained and financial losses associated with R&D. 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 systems to encourage continued investment in the market. Ensure that regulatory and pricing systems are keeping pace with the incredible breakthroughs in science and technology associated with new pharmaceutical and medtech products.
- For both: Create new initiatives to further public-private research collaborations and facilitate dialogue with industry, academia, medical-research institutions, health providers, and investors to identify opportunities for greater partnership and policy reform.
- For Japan: Establish the command tower function to develop a comprehensive strategy as expeditiously as possible, per this year's *Honebuto*, to would promote more effective and substantive dialogue moving forward between MHLW and the industry, enabling productive implementation of identified measures.
- For Japan: Reform policies and regulations to resolve the lag and loss in bringing treatments to market by reviewing and implementing the recommendations of the MHLW Expert Panel on Comprehensive Pharmaceutical Policies which were issued in June 2023.
- For Japan: Promote MHLW's "Whole Genome Analysis Action Plan" with a broader continuum of disease areas and accelerated implementation plans, with the timely establishment of an implementation organization. Such efforts could be enable enhanced innovative drug discovery capabilities and further collaboration between the two countries.
- For Japan: Reform regulatory policies to promote the development of innovative medicines and medical devices in Japan by reducing the need for Japanese specific data and allow the consideration of other real-world evidence.
- For both: Encourage adoption and implementation of high-standard IP regimes; prevent the 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, population and economic benefits, including those that will affect the health system generally and frontline healthcare workers in particular.
- For the U.S.: Eliminate harmful price control policies that discourage innovation and patient access, including provisions that disincentivize the development of small molecule medicines and R&D of new uses following a medicine's initial regulatory approval.

- For both: Ensure that any movement towards implementing Health Technology Assessment (“HTA”) at a minimum include consideration of socioeconomic value and the importance of patient access and physician choice. Also, make healthcare, nursing care, and other data available for assessment.
- For Japan: Exclude patented new drugs from the scope of price revisions (including off-year) and market expansion and spillover repricing, similar to other G7 countries.
- For Japan: Address the current challenges of low business predictability due to numerous changes to pricing rules and little room for negotiation by the industry in the pricing process.
- 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: With respect to medical devices, abolish the Foreign Average Price adjustment system, which bluntly compares medical devices pricing without any consideration to differences in healthcare systems and business and reimbursement environments among countries, to ensure U.S.-approved innovative medical devices remain available in Japan.
- For Japan: When reviewing Functional Categories for medical technologies, work closely with industry to ensure that any changes do not undermine rewarding innovation.
- For Japan: When conducting cost effectiveness evaluations for breakthrough medical technologies, ensure that available published evidence and internationally accepted cost-effectiveness modeling are considered; avoid the mechanistic use of benefit thresholds when determining value to avoid creating barriers to the entry of innovations.

2. Digital Transformation

- For both: Redouble an overarching commitment to swift and effective digitalization in healthcare with strong leadership and adequate support from the government.
- 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 their own health data, particularly as healthcare providers and researchers both domestically and internationally can exchange health data among different institutions to treat the same patient with adequate privacy protections.
- For Japan: Implement a comprehensive health data policy that promotes building data infrastructure by the government and includes legal frameworks that enable utilization of health data by the private sector while appropriately protecting patient privacy.
- For both: With appropriate protections and meaningful incentives, promote the development, adoption, and use of interconnected/interoperable health data 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 both: Address Ethical, Legal, and Social Issues (“ELSI”) including privacy, information protection, and antidiscrimination to accelerate the sharing of de-identified health data. Conduct an education campaign to raise awareness of the advances that can be achieved with the voluntary sharing of anonymized medical data in driving evidence-based treatment solutions and evidence-based policy making.
- 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 to protect against cyberattacks and data intrusions, ensure patient safety, and minimize enterprise risk.
- For Japan: Establish a mechanism by which 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 diverse 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 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: Define drugs with high medical needs, especially for long-time established therapies, and build a system to support their drug prices to secure stable supplies.
- For Japan: Establish regulatory data protection period 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 between the U.S. and Japan regarding components, material, and manufacturing technology from the viewpoint of industry development and stable supply of medical products and technologies.
- For both: Support joint U.S. and Japan countermeasures 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: Support removal of unjustified trade barriers to medical products to ensure timely access for patients.
- For both: Establish expedited regulatory review procedures for improved supply chains such as the 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 diseases.
- For both: Recognize the evidence-based health benefits of functional foods, so that the benefits can be communicated to promote wellness.

Healthcare Innovation



Appendix to the Joint Statement Supplement of the USJBC-JUBC Healthcare Innovation Working Group
for the 60th U.S.-Japan Business Conference:

Leveraging Digital Technologies to Improve Healthcare Outcomes: A Call to Action and Framework for U.S.-Japan Collaboration

In September 2020, the U.S.-Japan Business Council ("USJBC") called on governments to embrace and facilitate digital advancements in healthcare to propel innovation, enable pandemic response, and support improved access to care for patients around the world. The USJBC identified nine policy recommendations to support this call to action. Since that time, Japan has taken some steps to improve digitalization, such as establishing the Digital Agency and launching the Digital Garden City Nation Initiative. But much more remains to be done to deliver on the promise of digital health in Japan, including implementing a comprehensive policy to enable digitalization of health records similar to the practice in the United States (e.g., 2009 HITECH Act; HIPAA). Today, the Japan-U.S. Business Council and U.S.-Japan Business Council (hereafter "the Councils"), whose member companies include the world's most innovative technology and healthcare companies, stand together to urge the United States and Japan to seize the opportunity of the upcoming senior leaders' meetings at Asia-Pacific Economic Cooperation ("APEC"). Under the auspices of the U.S.-Japan Partnership on Trade, we urge the two nations to endorse an ambitious work plan to drive the adoption of world-class standards to facilitate the advancement of digital innovation in healthcare.

Digital innovation presents an extraordinary opportunity for Japan to reconfigure its healthcare and regulatory frameworks to better support innovation and meet the evolving needs of its society, especially as its people age. Countless studies have shown the enormous financial burden that rising social security costs will impose on the government, combined with a shrinking workforce. Digital technologies can significantly lower costs, create innovative health products, enable personalized treatments, and raise capacity for healthcare, thus helping to lighten this burden and improve the quality of life for millions in Japan.

Such innovations will ultimately bring about better patient outcomes, as well as cost savings for patients, providers, and society. For these new technologies to be implemented successfully and responsibly, however, governments must grapple with emerging policy questions that require careful consideration. Governments will also need to assess the impact these technologies are having on improving health outcomes and reducing unnecessary costs.

Proposed Framework for U.S.-Japan Cooperation on Digital Health

Given the renewed focus in both countries on digitalization and creating more resilient health systems for the future, the Councils call on the United States and Japan to launch a bilateral work program focused on facilitating digital innovation through four pillars: (1) telemedicine and remote care; (2) digital therapeutics; (3) artificial intelligence and data enabled research and development, including healthcare data utilization; and (4) cross border data flows and privacy. This work should be conducted in close consultation with the private sector in Japan and the United States, including through workshops with relevant experts in each pillar. Policy changes adopted as a result of the work program should be undertaken in a predictable and transparent public policy environment that allows stakeholders to

meaningfully participate in the development of regulations and favors efficient processes to bring new technologies to market.

Pillar 1: Telemedicine and Remote Care. Telemedicine has the ability to provide long-term, irrevocable benefits and convenience for Japanese society beyond COVID-19. This mode of care delivery will not just help address the rising demands of a rapidly aging population but also serve as a beneficial medical service for patients during future public health crises. Telemedicine usage has increased dramatically in the United States and Japan. However, a high percentage of hospitals are not taking full advantage of this modality in part due to the lack of infrastructure and potential uncertainty in reimbursement arrangements about compensating for treatment provided virtually.^{1,2} Furthermore, technological linkages among hospitals lack a mechanism to provide central control or oversight. In the United States, on the other hand, trust in telemedicine has grown and its use is widespread in the wake of COVID-19, due to the statutory and regulatory framework and foundation established by the HITECH Act and HIPAA.

Pillar 2: Digital Therapeutics (“DTx”). Digital therapeutics, a new category of digital medicine, have the potential to revolutionize healthcare by incorporating new technology and promoting the practice of personalized, evidence-based healthcare. DTx enable HCPs to provide individualized, simplified, and optimal care for patients. Countries with regulatory policies and reimbursement schemes that enable DTx will attract more investment, lead global biomedical innovation, and foster a healthier, more productive population. Japan has taken several steps to promote early commercialization of stand-alone medical software, or Software as a Medical Device (“SaMD”), yet at present the United States approves five times more SaMD products than Japan – including those medical devices that use artificial intelligence (“AI”) and machine learning.³ While the United States leads Japan on digital therapeutic approvals, it does not have a reimbursement mechanism to compensate for the offering of SaMD at this time. This is an issue which should be further reviewed to maximize the successes that DTx may provide in both countries,

Pillar 3: Data Utilization, AI, and Data Enabled Research & Development (“R&D”). Increased utilization of health data has the potential to substantially enhance patient care. By evaluating data, providers and innovators have the opportunity to not only discover new therapies, but also identify more effective opportunities to deliver care, and assess evidence to support the development and assessment of treatment outcomes. Research in healthcare AI has been growing rapidly, even before the COVID-19 pandemic outbreak. In its most recent policy framework, Japan has embraced “Medical Dx” as a pathway to enabling health data platform integration, which could accelerate utilization of real-world evidence and drug discovery. Yet launching real-world applications based on AI and real-world data (“RWD”) has proven challenging. Regulators have been leery of granting approvals for these newly developed technologies due to concerns about generalizability and bias, while concerns about compliance with data protection laws have made it difficult to collect health data for training algorithms. Future discussion is needed in order to advance scientific research and improve access to innovative digitally enabled treatment. . It is increasingly critical to address these challenges and build the necessary trust with patients to support data-enabled R&D. Embracing data-driven solutions to healthcare challenges through evidence-based policy that supports data utilization will also help make Japan a more attractive destination for healthcare innovation.

Pillar 4: Cross-Border Data Flows and Privacy. The COVID-19 pandemic has demonstrated the importance of rapidly sharing information across borders as companies work with governments to quickly identify and investigate potential treatments and vaccines. At the same time, policies enacted in other nations that are intended to protect citizens’ privacy may impede cross-border research, the effective deployment of technology, including AI tools, and the monitoring of health products. Some privacy regimes, for instance, unduly restrict the transfer of health and genetic information across borders, greatly limiting innovation and cooperation.

1 See Eisaku Nitta and Yusuke Konishi, “Japan greenlights online doctor visits as outbreak hits hospitals,” Nikkei Asian Review. <https://asia.nikkei.com/Business/Health-Care/Japan-greenlights-online-doctor-visits-as-outbreak-hits-hospitals>

2 “Survey results regarding telephone and online medical care,” Japan’s Ministry of Health, Labour and Welfare. <https://www.mhlw.go.jp/content/10803000/000657038.pdf>

3 Japan - Medical Devices (trade.gov)

Key Action Items for a Recommended U.S.-Japan Work Plan on Digital Health

1. **Reimbursement.** Review existing reimbursement methods with the potential of identifying new options for payment policies that could promote the alternative delivery of treatments including via digital therapeutics and telemedicine.
2. **Responsible AI.** Review policies on responsible AI for healthcare R&D and explore harmonizing definitions and frameworks for responsible AI.
3. **Data collection and interoperability.** Exchange best practices on responsible data collection, enhancing interoperability, and leveraging private sector technologies and capacity.
4. **Enhancing trust.** Develop recommendations for engagement with the public in the United States and Japan to promote trust and understanding about the value of collecting, storing, and using data to evaluate and/or create new medicines/technologies, and support pandemic detection and response.
5. **Paperless operations.** Develop best practices to promote paperless operations for healthcare, including:
 - removing the requirement to create/submit physical documents;
 - amending the regulations under the Electronic Signature Act to clarify the legal status of cloud-based digital signatures;
 - ending the use of hanko personal seals;
 - relaxing the scanner storage requirement specified by the Electronic Books Maintenance Act;
 - promoting digital government; and
 - moving toward a national certification system for administrative time stamps.

Travel, Tourism and Transportation



Given the global instability driven in part by Russia's invasion of Ukraine and the ongoing U.S.-China tensions, it is crucial that the U.S. and Japan continue to strengthen and expand their partnership with the Indo-Pacific region and the rest of the world. The travel, tourism, and transportation industries ("TTT industries") play a significant role in deepening mutual understanding between nations and are a key element in promoting peaceful relations between nations. The TTT Working Group reaffirms the importance of dialogue, peace, tolerance, and sustainable development.

The COVID-19 pandemic severely impacted the travel, tourism, and transportation industries beginning in 2020. However, according to the United Nations World Tourism Organization (UNWTO), by the first quarter of 2023 the number of tourists worldwide has recovered to 80% of pre-COVID-19 levels. Amid the rapid recovery of tourism and travel, there is renewed momentum to revitalize these industries prior to upcoming major international events, including the Osaka-Kansai Expo in 2025. In order to continue this recovery and further promote tourism, there is also an urgent need to address issues such as the shortage of human resources, which has worsened as a result of the COVID-19 pandemic.

The Japan-U.S. Business Council and the U.S.-Japan Business Council (referred as "the Councils" below) recognize the need for both nations to join hands with the global industries as they make the following recommendations to the governments of the U.S. and Japan to ensure continued sustainable growth. We believe that our efforts will contribute not only to the recovery of the industry, but also to the social and economic growth of both countries, creating new business models, promoting innovation and digital technology, and confronting human resource shortage issues.

1. Lessons Learned from the Pandemic and Preparing for the Next Crisis

As we look past the effects of the COVID-19 pandemic, it is crucial that we make use of the lessons and experience gained to strengthen management systems during future crises and build a society that is more resilient against any future infectious disease outbreaks.

It is undeniable that the decision-making process of easing border restrictions in Japan lagged far behind its G7 counterparts during the pandemic. Going forward, it is essential to evaluate and apply disease prevention measures based on science, as well as to carefully consider the timing of implementing those measures. The economic effect of measures taken in Japan during the past three years should be closely examined so that countermeasures against future outbreaks are less disruptive and better aligned with those of economic partners.

The Government of Japan must also urgently analyze the collaboration among ministries, as well as between the government and experts who provide data-driven advice on countermeasures. We welcome the launch of the Cabinet Office's pandemic response agency on September 1, 2023, and hope that its implementation will improve the predictability of business in future crises. Lastly, it is critical to seek out and encourage valuable public-private partnerships to solve critical infrastructure needs during a pandemic or state of emergency, such as temporary private lodging and accommodation.

Initiatives to Revitalize Mutual Interaction

As rising inflation continues to have a profound impact on society, it is essential that we promote international travel to stimulate consumption and facilitate economic recovery in Japan. Active air travel between Japan and the U.S. will invigorate business in both countries and support medium to long-term economic growth in Japan and the U.S. by promoting leisure tourism, study abroad programs, and cultural exchange. In both countries, it is essential to stimulate both inbound and outbound exchanges. Strategic initiatives by both governments are essential for growth, such as the easing of visa requirements for visitors to Japan, innovating on digital nomad visas, and efforts to increase the percentage of Japanese citizens holding passports.

2. Increasing Quality Tourism and Addressing the Shortage of Human Resources

To further expand the travel, tourism, and transportation industries, it is essential that we focus on improving the quality of tourism, including by increasing tourist consumption versus pure arrival numbers and attracting visitors to regional areas. The Councils support local government marketing campaigns and digital promotion efforts, and industry exhibitions to raise awareness of less recognized destinations and activities.

Developing a Balanced Tourism Industry

The concentration of demand in specific regions and seasons affects not only the quality of service and traveler satisfaction, but also productivity and the working environment for the industry. The Councils recommend policies to promote off-peak tourism in addition to measures to encourage flexible vacation options for international travelers. Consumer preferences are shifting, with an increased desire to visit new and emerging destinations, and the TTT industries can help drive greater dispersal of tourism throughout Japan in partnership with local governments. Additionally, while countermeasures against the negative aspects of tourism are necessary, it is important to raise awareness and educate people about the economic benefits of tourism and the benefits of values-based connections between local people and tourists.

Strengthening Support for Human Resource Recovery and Development

While tourism demand is recovering rapidly, the lack of human resources in the industry has been exacerbated during the pandemic following an employee exodus from travel-related industries, including surrounding fields such as transportation. This situation is hindering a full business recovery.

Key drivers to secure and maintain a stable workforce include flexibility in work hours and location, the ability to respond in real time to fluctuations in labor demand, diversified sources of talent which include foreign national workers in both nations, and innovation through digital transformation and other means. There is an urgent need to analyze how national and local governments can provide support and regulatory reform to improve productivity, working conditions, and access to workers. Strategic policies could help remove barriers to operate, encourage innovation and the shift to digitalization, provide access to desperately needed workers to fill long-unfilled job openings, and incentivize sustainability measures by reducing associated financial burdens.

Urgent action is required for hotels, including ryokans and private lodgings, airports, and logistics sites, where personnel shortages are limiting operations of facilities that are critical for economic recovery. Furthermore, a shortage of drivers in public transportation, with taxis being the primary example, is causing concerns about smooth mobility, and it is presumed that this is resulting in significant economic losses. We welcome the recent initiation of government discussions to solve the issues of truck and taxi driver shortages and we urge both governments to pursue expanded legal pathways to help alleviate chronic workforce challenges in these industries.

Promoting the Use of Transportation and Travel Apps

Apps and other digital tools related to transportation and tourism have great potential for eliminating language barriers for travelers, attracting visitors to new destinations, and improving worker productivity. The Councils encourage the adoption and utilization of end-to-end digital ecosystems, such as robotics, automation, AI, and

virtual reality technology. Increased usage of digital technology can also cast light on consumption trends and other factors that will hopefully lead to further business development in the future.

The installment of cashless payment at tourist attractions and transportation systems will boost convenience for overseas travelers and reduce the burden on human resources. It will also promote tourism to less-traveled domestic destinations and help revitalize local economies.

However, some applications used in Japan are not user-friendly for foreign travelers because they do not support English, or do not accept international credit cards or electronic payment methods of any kind. The Government of Japan can help by promoting the importance of considering an international audience in modern technology development. Additional consideration should also be given to introducing or improving ride-sharing and new mobility systems for secondary transportation issues.

Data utilization and collaboration are expanding, including the spread of next-generation transportation using automated driving, Mobility as a Service (MaaS), as well as efforts toward the practical application of flying cars. It is important to promote collaboration with different transportation systems and other industries to expand the scope of where mobility can contribute, and to create new value beyond the boundaries of mobility. It is also important to create systems through collaboration between the government and the private sector to contribute to solving a wider range of issues.

3. Sustainability in Travel, Tourism, and Transportation

The Councils believe that it is important to use the lessons from the COVID-19 pandemic to catalyze sustainable growth in the travel, tourism, and transportation sectors. Digitalization, reducing the carbon footprint of operations, and promoting low-carbon technology development should continue to be prioritized.

Support for Low-Carbon Initiatives

The Councils look forward to continued support from the governments of the U.S. and Japan for the business community's efforts to achieve carbon neutrality, including the development of energy-saving technologies and processes in the mobility sector, the commercialization of sustainable fuels, and the development and introduction of next-generation aircraft using advanced technologies.

In the automotive industry, it is important to pursue a variety of technology options that meet the conditions of each region to achieve global carbon neutrality. Additionally, by exporting U.S.- and Japan-developed technologies to third countries, the U.S. and Japanese governments, along with the private sector, will contribute to sustainability initiatives around the world. Rebuilding and creating resilient supply chains, including securing critical minerals, is also important for sustainable efforts. Through multilateral channels such as the Indo-Pacific Economic Framework for Prosperity ("IPEF") and bilateral agreements between the U.S. and Japan, concerted efforts are being made to strengthen supply chains. We look forward to continued leadership and effective support from the U.S. and Japanese governments to ensure the expansion of the utilization of diverse low-carbon technologies.

The promotion of clean, sustainable fuels is also necessary to promote a low carbon value chain and sustainable economic growth. In the aviation industry, Sustainable Aviation Fuels (SAF) are considered to be the key to reduce carbon emissions in the near-term as well as long-term for long-haul international flights.

In the U.S., states like California are accelerating efforts to encourage investment in SAF development by providing state-specific incentives in addition to federal incentives. The Councils encourage the U.S. to extend the SAF blenders tax credit beyond two years, promote research of lifecycle carbon intensity of feedstocks, and expand state efforts on SAF. The Councils also encourage similar efforts in Japan to maximize the development and use of SAF in country.

Policy mechanisms that lower operational costs for the SAF industry in addition to capital investment assistance are necessary for Japan to build an internationally competitive SAF market. Incentives that apply to consumers, such as

airlines, and to other supply chain elements beyond manufacturing are essential to lower prices and spawn a successful SAF market in Japan. Such policies coupled with capital investment assistance would help Japan establish leadership in the global SAF market and thus stay on the leading edge of sustainable travel, tourism, and transportation in support of economic growth.

Promoting Inclusive Development

We hope that the U.S. and Japanese governments will continue to redesign systems so that all stakeholders involved in the travel, tourism, and transportation sectors can enjoy the benefits of the technologies and services described in this proposal. We believe it is increasingly critical to build inclusive policies that support employment opportunities regardless of nationality, race, religion, gender, age, disability, or any other status. In addition, we hope that both governments will support the development of tourism resources that will provide business opportunities for micro-entrepreneurs as well as local, small- and medium-sized enterprises.