

Joint Statement
55th Japan-U.S. Business Conference
- *Deepening U.S.-Japan Collaboration to Address Increasing Uncertainty -*
U.S.-Japan Business Council / Japan-U.S. Business Council
Tokyo
November 1, 2018

Overview

The U.S.-Japan Business Council (USJBC) and Japan-U.S. Business Council (JUBC) (hereafter, the “Councils”) held the 55th U.S.-Japan Business Conference in Tokyo October 31-November 1, 2018 under the theme, “Deepening U.S.-Japan Collaboration to Address Increasing Uncertainty.” Amid rising uncertainty around global trade policies, the assembled business leaders recognized the importance of strengthening U.S.-Japan ties, and expressed their determination to achieve global economic stability and sustainable growth within their two countries and beyond. Three themes from these discussions emerged—strengthening U.S.-Japan commercial and economic relations to boost trade and economic growth, promoting norms and practices that foster innovation for a sustainable society, and facing challenges in the digital world—as did a set of sector-specific recommendations from joint working groups on the digital economy, healthcare innovation, energy and infrastructure, financial services, and travel, tourism and transportation. Our joint reflections and recommendations are as follows:

I. Global Trade and Bilateral Relations

The U.S.-Japan economic relationship should be strengthened to promote bilateral trade and investment, which in turn will contribute to regional prosperity.

1. The Councils recognize that the U.S.-Japan trade and investment relationship is mutually beneficial. For many U.S. companies, Japan is the most important market outside of North America. Japanese companies also depend heavily on the U.S. market, and continue to announce major new investments in the United States. Japanese companies have become important parts of local economies across the U.S., and Japan’s cumulative investment of \$469 billion in the U.S. has resulted in direct employment of roughly 860,000 high quality jobs, paying average compensation of more than \$80,000. Evaluating this large and complex trade and investment relationship on the basis of one metric, namely the trade deficit, does not capture the breadth or depth of economic ties. In this spirit, the Councils urge the two governments to eliminate uncertainty in this important relationship by working with one another, and in consultation with the business community and other stakeholders, to build upon the strong foundation that exists today.

2. Most immediately, the Councils are committed to free trade and support measures and agreements that open markets and set high standards and strong, enforceable rules for trade and investment. In this context, the Councils are concerned over the significant economic impact on consumers, the integrated automotive industry, and the U.S. and Japanese economies if the U.S. imposes tariffs on imports of autos and auto parts from Japan, in addition to the existing tariffs on imports of steel and aluminum, which have negatively impacted some companies. The Councils also emphasize the need for a strong North American trade agreement that continues to facilitate foreign direct investment in the U.S., including from Japan, and promotes both countries' economic growth. The Councils take note of the efforts made by the negotiators from the U.S., Mexico, and Canada in reaching agreement on the U.S.-Mexico-Canada Agreement (USMCA). We will monitor closely the ratification and implementation process of the USMCA.
3. The Councils urge the two governments to focus on strengthening the commercial relationship through the U.S.-Japan Economic Dialogue and recently launched talks aimed at achieving "free, fair and reciprocal" trade under the leadership of U.S. Trade Representative Robert Lighthizer and Japan's Minister in charge of Economic Revitalization Toshimitsu Motegi. We believe these talks can give new impetus to an economic relationship that, while fundamentally sound, has considerable room for improvement and growth, provided concentrated efforts and appropriate steps are taken. The Councils also commend both governments for entering into negotiations for a U.S.-Japan Trade Agreement on goods, as well as on other key areas including services as stated in the September 26 Joint Statement between the United States and Japan. These negotiations should proceed based on mutual trust and comprehensive analysis of the economic relationship, and in accordance with World Trade Organization (WTO) rules. We expect that they will yield binding commitments that strengthen bilateral trade and investment ties, as well as promote rules-based trade and regional economic growth.

A free, fair, open and rules-based international economic order should be maintained.

4. The Councils view a free, fair, open and rules-based trading system as an essential driver of the global economy. Unfortunately, the system has come under stress in recent years due to the proliferation of trade disputes. Given our common values and shared objectives for a stable and secure Indo-Pacific, the Councils believe that finding concrete ways to enhance trade and investment rules in the Indo-Pacific region will help to chart a productive path forward. The Councils recognize the leading role of Japan in advancing the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). We also commend the approach taken by the U.S. and Japanese governments to cooperate further and invest in high-quality infrastructure development in the Indo-Pacific region, which was highlighted in the recent U.S.-Japan Summit

Meeting. The Councils further stress the need for a holistic approach that includes trade policies designed to establish and promote the highest standards and norms across a wide range of areas, including: intellectual property, electronic commerce, privacy, and cybersecurity, as well as to ensure a level-playing field among major trading countries.

5. The Councils are deeply concerned about the global proliferation of market-distorting measures and unfair trade practices. Chief among these are industrial policies that aim to encourage the growth of specific industries by providing large subsidies to state-owned enterprises, forcing technology transfers to domestic companies through joint venture requirements, and using national and cyber security as an industrial policy tool. The Councils therefore urge both governments to accelerate their efforts to secure fair, competitive conditions alongside other nations that share our basic values individually and together as well as through international forums, such as the Trilateral Meeting of Trade Ministers of Japan, the U.S. and European Union, the G7, G20, and the Organization for Economic Co-operation and Development (OECD).
6. In addition, the Councils encourage the two governments to work together to strengthen the three core functions of the WTO: rule-making, monitoring, and dispute resolution. Despite the expansion of mega FTAs, the WTO holds significant importance due to the fact it resolves trade disputes by the rule of law. We should preserve the historical achievements gained through our shared commitment to the WTO, which rejects managed trade and has reduced trade restrictions by promoting free, fair and open trade. The Councils urge both governments to take steps that enable the WTO to continue to function as an arbitrator to resolve trade disputes and consolidate rules in new fields, such as e-commerce.

II. Innovation for a Sustainable Society & Economic Growth

The two governments should work in tandem to enhance a regulatory environment that accelerates innovation across industries.

7. With the competition for international leadership intensifying in the information and communications technology, life sciences, and advanced manufacturing industries, the U.S. and Japan must work together to promote innovation to maintain their industrial competitiveness and positions as global leaders. Japan, in particular, has an urgent need to increase its productivity through innovation to tackle serious social problems such as an ageing population and fiscal deterioration. The Councils believe that promoting and providing appropriate reward for innovation to tackle those issues will lead to Society 5.0 in Japan, and eventually enable to achieve sustainable development goals (SDGs).

8. The U.S. and Japan must therefore advance regulatory and policy measures that facilitate innovation. In this regard, the Councils applaud both the U.S. Administration’s regulatory reforms and the Japanese government’s “Project-Based Regulatory Sandbox,” established in June 2018, which will enable companies to test advanced technology and new business models. In consultation with the private sector, the Councils encourage both governments to accelerate efforts for further regulatory reforms to promote adoption of emerging technologies. The Councils also urge the two governments to establish fair, competitive conditions – a level playing field – for new entrants and incumbents, as well as to strengthen their engagement to harmonize international regulations through more cooperation between regulatory agencies.

Innovation ecosystems should be nurtured.

9. The Councils recognize that for the U.S. and Japan to function as global innovation hubs, it is essential that private companies actively promote innovation. The formation of supportive ecosystems is thus critical in driving innovation and should ensure strong, enforceable intellectual property rights; strengthen the supply of risk money for startups and broaden its distribution among sectors and regions; and shift human resources from mature sectors to areas of growth through labor market liquidity and improvements in social safety nets. While the Councils urge the governments to strengthen their support for establishing innovation ecosystems, we also emphasize the importance of Japanese corporations prioritizing innovation and learning from the U.S. system.
10. Investment in human capital is also necessary to keep the advantages in innovation that the U.S. and Japan currently enjoy. Educational systems in most countries are not keeping pace with the demands of a rapidly changing workforce, and technology is already placing a new premium on skills, innovation, and adaptability. Thus, the Councils encourage the two governments to strive to educate a technologically savvy workforce through investments in education and other policies. New systems must promote education that prepares students for the Fourth Industrial Revolution in a way that fuses STEM and soft skills needed for success in this new age.
11. The concept of “Health and Productivity Management (H&PM)” is also important to improve productivity and maintain the innovation advantages that the U.S. and Japan currently enjoy. H&PM can enhance corporate performance and value in capital markets by improving employees’ health, vitality and productivity, and the Councils recognize the importance of advocating for these concepts together with both governments and other business communities.

III. Challenges in the Digital World

12. The creation of innovative products, services, and business models that incorporate digital technology continues to drive the growth of the global economy. The digital economy and the “real” economy are now one and the same, creating new opportunities while also raising new issues and threats, such as cybersecurity and privacy. Finding the right balance and approach to these issues is critical, and it is important that the U.S. and Japan – both governments and private sectors – work together to provide the leadership necessary to establish high standards and good rules and practices in the Indo-Pacific region.

13. Furthermore, the Councils emphasize that the ability to move data across borders and access information is as important to an innovative economy today as the movement of capital. To realize the full benefits of the movement of data, governments should eliminate data localization policies that interrupt the transfer of data or require local process or retention of data, and work to dispel the myths that localized data increases its security. We believe the unilateral flow of data caused by some countries’ data localization initiatives can be harmful to the healthy development of the digital economy. The Councils also emphasize the importance of promoting open access to government-generated public data to enhance innovation. In both respects, we encourage the two governments to use the principles and guidelines of relevant international bodies, such as the APEC Privacy Framework and the OECD Recommendation of the Council concerning Guidelines governing the Protection of Privacy and Transborder Flows of Personal Data (2013).

For additional details, please see the attached chapter on Digital Economy.

IV. Other Sectoral Issues

14. In addition to broad discussions on the outlined principles, the two Councils held meetings of joint working groups covering the digital economy; energy and infrastructure; financial services; healthcare innovation; and travel, tourism and transportation. The working group recommendations can be found in the industry-specific chapters that follow.

IV-1 Digital Economy

Overview

The U.S.-Japan Business Council and Japan-U.S. Business Council (the Councils) share the view that digitally connected technologies will drive economic growth on a global scale for years to come. While the United States and Japan are well-positioned to realize the benefits of these new technologies and their applications, the Councils are in full agreement that our ability to do so will depend largely on the policy frameworks that are adopted and implemented—both domestically and around the world.

While we maintain our support for the high-level priorities jointly outlined last year, the Councils are observing an increase in worrisome approaches to privacy and cybersecurity in many jurisdictions. In some countries, data privacy regimes are increasingly looking to limit cross-border data flows and establish arduous localization barriers in the name of privacy and cybersecurity. Such approaches create an uneven playing field by severely hindering the ability of U.S. and Japanese companies to operate in these jurisdictions—by limiting choices, driving up costs for their customers, and ultimately reducing their competitiveness.

In addition to serving as non-tariff barriers for U.S. and Japanese firms, they stunt the growth of the economies they are designed to be helping and thwart the regulatory objectives they are put in place to achieve. Data localization and local content requirements, for example, are often implemented with the stated objective to increase security with little evidence to support that the objective is ever achieved. Rather, such measures serve as self-imposed economic sanctions that limit a country's global competitiveness and economic growth, while inhibiting the ability of companies to store data where it is most secure.

The practical implications of these policies are not the only concern that the Councils share. Policies that unreasonably focus more on *where* rather than *how* data is stored risk fragmenting the Internet along national or regional borders. This will have major economic implications in a world where every economy's digital success will depend on scalability, interoperability, and the ability for data to move freely across borders. Economies that isolate themselves from the global economy by building regulatory roadblocks to technology will undermine the ability of digitization to fully drive economic growth and create jobs.

Given these realities, the Councils encourage the U.S. and Japanese governments to work with the private sectors of both countries to:

Take proactive and coordinated leadership roles to promote a multi-stakeholder model for Internet governance, privacy, and cybersecurity globally. This includes accelerating efforts to expand the interoperability of privacy frameworks around the world.

1. The Councils encourage the U.S. and Japanese governments to work closely with the private sector to leverage their combined expertise to influence the broader international community around these areas. We encourage the governments to prioritize efforts to implement global best practices in domestic economies while institutionalizing those best practices through international cooperation and trade agreements.
2. To combat these trends, the U.S. and Japanese governments should work together in international fora such as the G7, G20, and OECD to ensure that we are actively promoting the benefits of multi-stakeholder approaches to privacy in line with the APEC Cross Border Privacy Rules (CBPR). Similarly, the governments should work with partners to promote an approach to privacy in these forums that is focused on interoperability and the cross-border movement of data rather than members adopting one entity's approach to privacy. Clear and consistent digital trade rules in the Asia-Pacific would help promote freer cross-border data flows, and could counter digital protectionism in the region, as would pursuing an interoperability mechanism between the APEC CBPR and European GDPR systems.

Explore opportunities to enhance digital trade in the Asia-Pacific through negotiated agreements.

3. We would encourage the U.S. and Japanese governments to explore opportunities to enhance digital trade in the Asia-Pacific through negotiated agreements. Any rules linked to digital trade in Asia, whether negotiated in a bilateral or multilateral context, should prohibit localization requirements across all sectors, as a baseline. We believe that steps taken by the United States and Japan to demonstrate a commitment to those rules would help create a global standard on digital trade that is able to compete with the problematic approaches to digital trade mentioned previously.

Promote U.S.-Japan cooperation to counter cyber risks.

4. Concurrently, the risk of malicious cyberattacks has dramatically increased in the IoT era, where a wide variety of products are connected to the Internet. Additionally, various kinds of systems, including core systems, are exposed to the risk of information leaks and system failures through backdoors and security holes in telecommunication equipment and software. The Councils recognize that, in order to tackle these threats, both governments have continued to engage in R&D and capacity building and have promoted the development of counter measures in the private sector by sharing the latest information and best practices. We urge both governments to play a leading role in establishing comprehensive and powerful countermeasures in cooperation with other allies.

IV.-2 Energy and Infrastructure

Overview

In order to promote the shared goal of a free and open Indo-Pacific, the governments of Japan and the U.S. are strengthening cooperation in energy and infrastructure. In addition, the energy landscape is undergoing rapid changes marked by the heightened awareness of global environmental issues, the shale gas revolution in the U.S., and Japan's reduced energy self-sufficiency due to the decommissioning of nuclear power plants. Under these circumstances, Japan and the U.S. should work towards (1) meeting the sustainable development goals (SDGs) and responding to climate change, (2) promoting the use and construction of highly efficient energy and infrastructure utilizing AI/IoT, and (3) increasing Japan-U.S. cooperation in third country infrastructure development. To that end, the U.S.-Japan Business Council / Japan-U.S. Business Council (hereafter "the Councils") propose the following recommendations to the governments of Japan and the U.S.

Contributing to the realization of the SDGs, including responding to climate change

1. The Councils urge Japan and the United States to play a leading role in the clean energy industry and promote all sources of carbon-free sources of energy.
2. Renewable energy, particularly solar and wind power, should be promoted as a mainstream source of power, with a goal toward reducing their costs and incorporating them in power systems such as the transmission and distribution network. In addition, challenges associated with output fluctuations resulting from the expanded use of renewable energy can be addressed through storage batteries, along with technological development and utilization of hydrogen. The Councils urge close cooperation and the provision of appropriate incentives in this area.
3. Nuclear power is an important baseload power source that contributes to the stabilization and decarbonization of the long-term energy supply and demand structure. Its utilization and safe operation will continue to be necessary in the future. To that end, the "Agreement for Cooperation between the Government of the United States of America and the Government of Japan Concerning Peaceful Uses of Nuclear Energy" is at the core of nuclear energy utilization. The Councils recognize that the continuous strengthening of cooperation between Japan and the U.S. based on this Agreement is extremely important. There is potential for major technological innovation in small modular and other advanced reactors, which also have good potential in respect of expansion into emerging markets. Advancing the development of these technologies requires a regulatory framework for evaluating and licensing these technologies. The Councils call upon the Japanese and U.S. governments to establish appropriate regulatory frameworks for new technologies. The Councils also urge the Japanese and U.S. governments to continue to strengthen industrial cooperation and cooperation in research and development, making use of the energy cooperation framework. In order to continue to use nuclear power, it is necessary to

safely execute decommissioning. Important projects such as decommissioning of the Fukushima Daiichi Nuclear Power Station are at the forefront of Japan-U.S. nuclear cooperation. The U.S. leads the field in this area, and its regulatory approach and results serve as guidelines for Japan. The Councils expect further expansion and progress on Japan-U.S. cooperation on this regard.

4. Global energy demand is projected to rise more than 40 percent by 2035, driven by population growth, income expansion, urbanization and transportation needs, particularly in Asia. Reducing greenhouse gas (GHG) emissions presents a formidable challenge. Achieving the necessary greenhouse gas reductions for effective global warming countermeasures will include the use of cost-effective renewable energy resources, including wind, solar and new technologies. Yet it will also require the use and development of clean energy technologies, including high-efficiency, low-carbon fossil fuel power. These technologies should include high-efficiency natural gas-fired thermal generation, which will allow Japan to leverage the expected supply of North American LNG assured by LNG export approvals, for which the US and Japanese business communities have been united in advocacy.
5. The Councils agree on the need to use coal in a more environmentally sustainable manner and invest in technologies that reduce GHG emissions. At the same time, the Councils recognize that coal will remain an affordable and reliable source of energy in emerging markets in Asia and a vital part of a diverse energy portfolio. In this context, the Councils are concerned that the growing restrictions on coal-related projects in emerging markets may bring unintended consequences of delaying the introduction of high efficiency coal-fired power plants and prolonging reliance on older and low-efficiency coal-fired power generation. For this reason, the Councils urge both governments to support the research and development, as well as the promotion and dissemination of carbon-reducing technology. In connection with using coal, CCUS (Carbon Capture, Utilization and Storage) technology is essential to ensure coal is used as a low carbon technology. The Councils urge the Japanese and U.S. governments to continue cooperation on CCUS and introduce policies designed to lower the costs of deployment and operation while encouraging more investment. Furthermore, the Councils ask for government support and incentives for joint Japan-U.S. projects to promote the widespread adoption of CCUS technology.
6. There are great expectations of improvements in energy efficiency as a means to decarbonization. The Councils recognize that in addition to using the latest technologies, such as AI and IoT, energy efficiency can be improved by promoting further use of current energy-saving technologies and equipment. The Councils hope that our governments will promote their use and the efficient use of energy, alongside new AI and IoT technologies and products, not only in Japan and the U.S. but also in third countries.

Enhance energy and infrastructure efficiency by utilizing AI and IoT

7. The Councils recognize that the introduction and promotion of AI and IoT technologies will drive solutions to various problems in the energy field. IoT technology makes it possible to collect a wide range of information and data in real time, and that data can be used to create value. In fact, AI technology can create value from enormous data sources that are usually very difficult to analyze. For example, applying IoT to power generation equipment makes it possible to monitor its status in real-time, and makes it possible to operate the equipment with greater flexibility, along with efficient inspection and repair cycles based on its actual condition. AI can also be used in demand forecasting to improve the accuracy of consumption prediction.

Expanding the use of AI and IoT will promote the collection and use of diverse data, and for this reason the importance of protecting data privacy and ensuring security will become only more important in the future. In order for their benefits to be fully realized, the Councils urge the two governments to work together to build a policy framework that allows the data generated by AI and IoT technologies to be used effectively in the energy field.

In both Japan and the U.S., aging transmission and distribution networks, and the danger of cyber-attacks on power infrastructure are important issues. Dealing with them requires a transition to high-efficiency, secure, next-generation transmission and distribution networks that deploy AI, IoT and other technologies. While the increase of renewable energy resources is making smooth progress, the Councils believe this will also make its problems with continuity and completeness as a power source more apparent. In response, in addition to advanced supply and demand adjustment technologies, we will in the future increasingly require technologies like VPP (Virtual Power Plants) and Demand Response to efficiently manage resources on both the demand and supply sides. The Councils request that the Japanese and U.S. governments provide support in the form of incentives for investment, development, and promotion of appropriate system designs in areas such as secure next-generation transmission and distribution networks, as well as new technologies such as VPP and demand response.

Japan-U.S. cooperation in third country infrastructure development

8. Last November, the Japanese and U.S. governments signed a Memorandum of Understanding on energy cooperation to encourage high-quality infrastructure in the Indo-Pacific region. Since then, a number of public and private sessions have been held. The Councils welcome the various support measures for Japan-U.S. cooperation projects, including advocacy and capacity building initiatives for third country governments. The Councils look forward to further democratically guided cooperative projects in a wide range of fields. At the same time, the Councils recognize that large-scale cooperation projects in third countries are directly linked to Japanese and U.S. security and long-term national policies and urge the governments of Japan and the U.S. to

continue policy dialogues with third party governments, so as to improve regulatory cooperation, operational efficiency of infrastructure maintenance, and administrative transparency.

9. The Councils recognize the mutual benefit that U.S. LNG exports to Japan brings: For Japan, U.S. LNG is a new supply source that helps diversify suppliers, enhance Japan's energy security, and contributes to the expansion of the LNG market. For the U.S., LNG exports present an opportunity to boost its companies' presence in the Asia region. In order to expand exports of U.S. LNG, the Councils urge the U.S. government to ensure a stable budget to develop and maintain access channels of crude oil and LNG export bases. The U.S. has many ports on rivers, and annual dredging is essential to maintain channels deep enough for large vessels to use them. It is also important to deploy enough dredgers to quickly remove sediment inflows from disasters like hurricanes. In addition, studies are underway to deepen ports and channels to improve the economic efficiency of crude oil transportation, and we urge the U.S. government's support not only in crude oil but LNG. A further consideration is that ships sailing from the ports on the eastern seaboard must pass through the Panama Canal, which imposes cost and time constraints. The Councils would like to see the earliest possible development of infrastructure (e.g., pipelines, storage, export bases) on the U.S. west coast. Both Councils appreciate the efforts made by the U.S. government to simplify and streamline licenses for LNG infrastructure, and hope to see a continuation of similar moves. Japanese and U.S. companies have begun to cooperate in exports of U.S. LNG to the Indo-Pacific region, but in order to expand exports, governments in this region should formulate comprehensive introduction plans, and port infrastructure should be improved to include LNG terminals for unloading LNG. Because long-term cash flows remain an obstacle, the Councils hope the Japanese and U.S. governments will continue policy dialogues with Asian counterparts, capacity building, and seek support from government financial institutions and similar entities.

IV-3 Financial Services

Overview

Financial institutions are critical to the healthy functioning of the global economy. The industry drives economic activity by providing credit and liquidity and protects households and businesses through risk management solutions. The Councils support the majority of post-crisis regulatory reforms adopted by most of the major economies, including the United States and Japan. The reforms generally have effectively and efficiently strengthened the global financial system and promoted more sustainable economic growth. At this juncture, 10 years after the financial crisis, we are encouraged by recent initiatives to assess post-crisis reforms against their intended objectives, and urge a continued active process by governments to reexamine reforms that have produced unintended effects on growth and to be alert to new and emerging risks. At a time of increasingly rapid technology-driven change in the production and delivery of financial products and services, a growing shared interest in achieving sustainable development globally, and demographic shifts with far-reaching implications, the Councils believe it is more vital than ever for industry and governments to collaborate in creating an environment that encourages innovation, growth and appropriate consumer protections while ensuring systemic soundness.

Responding to a New Era of Innovation

1. Innovation has brought the latest technologies to market and a new vitality to the global economy. At the same time, it has presented new risks. The challenge is to ensure that regulatory policies and financial institution behavior maximize the opportunities while containing excessive risk taking. The Councils urge both governments to pursue policies that address this important challenge.
2. **Establishing a Framework for Effective Financial Supervision and Regulation in the New Era:** The Councils believe it is essential to maintain a level playing field between new entrants, including FinTech/BigTech, and conventional financial services companies. An appropriate balance should be struck between regulations that support innovation and economic growth and enhance customer convenience, while maintaining robust customer protections. The Councils endorse, and regard as a key priority, the principle of “same activity/same risk/same rules/same supervision.” The U.S. and Japan should collaborate to take the lead in proposing rules at the global level by entities such as the Financial Stability Board (FSB). U.S. and Japanese financial institutions stand ready to work constructively with our respective governments to achieve this objective.
 - The Councils believe it is critical to conduct a fundamental review of “business scope” banking regulations in Japan and the U.S. to create the foundation for free and fair competition.
 - Considering the cross-border nature of digitalization, the U.S. and Japanese governments should jointly lead the establishment of a globally harmonized regulatory framework and

encourage coordination and dialogue among new market entrants, existing companies and regulators — for example via initiation of a formal dialogue between the U.S. and Japan and coordination on a bilateral “regulatory sandbox”.

- To facilitate innovation and growth, regulations designed for legacy industry practices should be reviewed and updated, including cloud services and data sharing by financial institutions through application programming interfaces.
3. **Level Playing Field:** Maintaining a level playing field – that is, like regulation for like products and service providers – has been a key regulatory principle for strengthening financial and capital markets and avoiding market inefficiencies and distortions since the pre-digitalization era. In the spirit of this principle, the Councils urge both governments to avoid market distortions such as, in the case of Japan, mutual aid cooperatives (*kyosai*), non-Financial Services Agency (FSA)-regulated private sector financial service providers, and between Japan Post Holdings and the private sector. The Councils look forward to further steady progress by the Japanese government on postal privatization and stand ready to play a constructive role as the Government continues to take steps to create a level playing field between postal financial institutions and the private sector.
4. **Free Flow of Cross-Border Data:** The free flow of data generates innovation and contributes to job creation and economic growth. The Councils strongly oppose the trend in some jurisdictions to force localization of data processing and storage and to monopolize de facto standards of data utilization. The two governments must work toward more open data architectures in Asia and other markets.

The U.S., Japan, and Global Social Challenges

5. The Councils recognize the significant impact that the financial services industry has on virtually every aspect of society. In this spirit, the U.S. and Japanese financial industries embrace their responsibility to contribute innovation and leadership regarding the future role of finance in supporting prosperity. In Japan, this effort has the potential for especially potent results in the government’s “Society5.0” initiative.
6. **Aging Population:** As the nation confronts significant challenges related to an aging and declining population, Japan is well-positioned to serve as a global role model on the development of innovative financial services to address rapidly shifting demographics and the emergence of artificial intelligence (AI). In the U.S., the success of defined contribution plans as a wealth creator similarly can provide Japanese policy makers with a highly useful framework for further initiatives to reduce the burden on an increasingly stretched public pension system. The Councils therefore urge regulators and elected officials of both countries to engage with industry to establish policy priorities, and requisite regulatory frameworks, to drive innovation and product

development geared to the needs of the elderly, and to cultivate conditions to promote wealth formation among younger generations.

7. **Infrastructure Investment and Support from a Financial Perspective:** Financing infrastructure is a priority of the G20 and U.S. and Japanese financial institutions stand ready to advance this agenda. The Councils support U.S.-Japan cooperation for developing national infrastructure projects. The Councils seek a supportive environment that includes: a suitable regulatory framework (see below), an appropriate level of public-private risk sharing, and a reliable pipeline of bankable projects.
8. **Cost/Growth Balance and Financial Standards for the SDGs and ESG:** Consideration for sustainable development goals (SDGs) and Environmental, Social and Governance (ESG) is important for social infrastructure financing. The Councils discourage a “negative list” approach in the evaluation of specific projects, as it can inappropriately reject suitable technologies, for example super-high efficiency coal-fired power generation.
 - The governments of the U.S. and Japan are encouraged to take the lead in pursuing a balance between economic growth and sustainability goals. The Councils urge the establishment of financial market standards conducive to this end.

10 Years Later - Addressing the Next Possible Crisis, Striking a Balance, and Avoiding Fragmentation

9. The U.S. and Japanese financial industries recognize that many pre-crisis business practices were contributing factors to the crisis itself as well as to the Interbank Offered Rate (IBOR) issue and others. In response, the industry has taken far-reaching steps to realign business practices, embed cultures that prioritize ethical conduct and anchor businesses in sustainable, customer-first practices. In Japan, for example, the 2017 “Principles for Customer-Oriented Business Conduct” released by the FSA created a model of long-term investment asset formation and produced a major new focus on appropriate fiduciary duties. Strong incentives to make fiduciary duty standards public practice in turn has led to an increase in public trust of financial institutions. Additionally, fraud prevention structures have been further strengthened through the conduct risk and compensation management principles provided by the Basel Committee on Banking Supervision.
10. **Examining Crisis Risk and Response:** The Councils believe that post-crisis financial regulatory reforms have been highly effective in fostering a far more sound and resilient global financial industry. However, 10 years after the last crisis, we also believe it is essential for industry and regulators to engage in an ongoing process of evaluation to assess whether the existing regulations are functioning effectively against emerging risks, and to identify regulations that may be inhibiting economic growth without enhancing safety and soundness.

- New global risks have emerged, including increased external liabilities of developing economies and associated currency volatility; rising leverage at many companies with relatively weak credit ratings, and; rising global asset price volatility as monetary policy normalizes in several developed economies. While the Councils believe existing regulations provide adequate safeguards against these risks, we also believe vigilance is key to early detection of excessive risk-taking.
- In Japan, the protracted low interest rate environment places significant pressure on the business models of financial institutions and could impede the financial intermediation function. This in turn could trigger excessive risk-taking, for example at regional financial institutions. The Councils urge policymakers to consider the multi-dimensional effects of continued ultra-low interest rates.
- Additionally, digitalization has introduced new types of risks not covered by conventional prudential regulations, including cyber risk, crypto assets, and growth of non-traditional financial intermediaries. The Councils strongly recommend that, along with appropriately monitoring and responding to these issues, the Japanese and U.S. governments collaborate to drive the global agenda in establishing an appropriate regulatory framework.

11. Setting Appropriate Regulations: Post-crisis efforts toward international financial regulatory reform have delivered substantial progress. However, the Councils have concerns regarding the increasing costs accrued by financial institutions to conform to certain post-crisis regulations, as well as possible unintended effects on the real economy. With implementation of the immediate post-crisis reform agenda now largely complete, the Councils support continued evaluation of the impact of the reforms and revisions to regulations determined to be overly restrictive or causing unintended negative consequences. The two governments should provide their full support for this effort and seek to collaborate with private sector financial institutions to ensure appropriate outcomes are achieved.

- In connection with supporting infrastructure finance, highly restrictive regulations applied to project finance under the Basel Accords should be reviewed and modified to produce a more appropriate balance between the risk-related concerns of regulatory authorities and actual risk posed.
- With regard to the Insurance Capital Standard (ICS) of the International Association of Insurance Supervisors (IAIS), the Councils urge the two governments to ensure the standard — and its market-based approach in particular — does not cause unwarranted volatility that is at odds with the characteristics of stable, long-term life insurance liabilities. Such unwarranted volatility could force companies to exit long-term insurance businesses that are essential to customers and result in negative effects on long-term funding necessary for infrastructure investment. The Councils urge both governments and their regulatory bodies to promote approaches to an ICS that would avoid such unintended consequences. Further, the Councils encourage both governments and their regulatory bodies to carefully assess the

impacts implementing an ICS like framework in their respective market would have on the ability to address public policy objectives (e.g., aging societies, infrastructure needs, etc.) and competition (e.g., level playing field) before moving to do so.

- As JFSA modernizes its solvency requirements for insurance companies, the Councils urge JFSA to avoid valuation methodologies that result in non-economic volatility which could deteriorate long-term business. The long-term, illiquid liabilities of life insurers are ideally matched with long-term, illiquid assets such as infrastructure investments; solvency regulations should avoid the same negative effect on long-term funding as noted above.
- The Councils support IAIS' and FSB's efforts to develop an activities-based approach to address systemic risk. From a macro-prudential viewpoint, it is important for both governments to focus on the potential contributions to systemic risk from business activities of insurance companies and analyzing whether existing regulatory measures can sufficiently address potential risks. The Councils urge both governments to exercise sufficient care and avoid adopting unneeded regulations or those that may cause unintended effects. Additionally, due to the existence of issues that certain sectors cannot fully respond to independently, cross-sectoral discussions are necessary to establish appropriate regulatory frameworks for addressing systemic risk.
- The Councils also encourage proactive utilization of RegTech, SupTech and other advanced technologies to further accelerate the efficiency of regulatory compliance.

12. Avoiding Market and Regulatory Fragmentation: Market fragmentation should be avoided, as it impedes efficient and seamless global financial system. When regulators impose cross-border requirements on an extraterritorial basis that deviates widely from international norms, it contributes to an un-level playing field and to market fragmentation. The Councils urge the governments of the U.S. and Japan to set an example of appropriate regulatory deference, both in banking and insurance, and make proactive efforts toward equivalency assessments across jurisdictions. This will enhance liquidity and efficiency in markets and limit fragmentation, while maintaining robust cross-border risk mitigation.

- **Reference: Cross-sectoral guiding principles:** In seeking to build a more effective regulatory framework, the Councils believe in the need for certain cross-sectoral guiding principles, including:
 - Regulatory reform must not place excessive emphasis on eliminating risk to the detriment of the appropriate risk-taking necessary to finance growth.
 - While consistency among different jurisdictions is an important consideration, regulators and global standard setting bodies must recognize that the application of uniform, one-size-fits-all regulations may not be appropriate in certain markets.
 - Regulation should be proportionate to relevant risks and effective and efficient in meeting their objectives.
 - Counter-cyclical macro-prudential regulation should be encouraged and pro-cyclical regulation avoided.

IV.-4 Healthcare Innovation

Overview

The National Health Insurance (NHI) system is a backbone of the longevity of the Japanese. Its sustainability is the challenge facing the government in a stagnating economy with a declining working-age population, and increasing healthcare spending in a rapidly ageing society. Meanwhile, the life science industry, an economic growth driver, is facing increasing global competition. To date, the government's focus on controlling social security expenses has been achieved primarily through price reduction of medicines and medical supplies. However, to maintain the NHI system, the government should secure fiscal savings in other areas of the healthcare system.

In addition to the sustainability of the NHI system, the government should also promote innovation from viewpoint of establishing a social security system for all generations as well as promoting a '100-year life era.' New industry platforms are being developed along with diverse healthcare modalities (e.g. small molecules, middle molecules, and large molecules). The advancements of new digital technologies like AI, big data, and telemedicine have set off a new wave of innovation in the health care industry. The application of such technologies will enable us to increase the precision of diagnosis and treatments that can significantly contribute to the sustainability of the NHI.

To maintain the sustainability of the NHI, it is necessary to promote healthy life expectancy, reform incentive and reimbursement systems, secure alternative or supplementary finance sources, and incorporate the latest healthcare technologies, including biopharmaceuticals, biomarkers, gene therapy, regenerative medicines, medical devices, advanced radiation therapy and proton therapy techniques, real world data, etc., in our medical practice. It is also necessary to improve the regulatory and reimbursement environments for advanced healthcare technologies to ensure that patients get timely access to innovation with appropriate prices. Toward these goals the Councils make the following recommendations.

Build a Sustainable Healthcare System and Enhance Innovation

Delivering innovations that contribute to an extension of healthy lifespans and that help people to remain active throughout their lives under comprehensive NHI reform.

1. It is necessary that the government and stakeholders recognize the value of innovation as a key investment in achieving a healthy and productive society. In order to achieve this goal, the US-Japan Business Council and the Japan-US Business Council (hereafter, the 'Councils') recommend that all stakeholders should work to build a social health care system that properly values innovative medicines, medical devices and preventive care.
 - The Councils believe pro-innovation policies that are transparent and predictable need to be restored, including meaningful consultation with industry in advance of future policy changes and fair and predictable rules that appropriately reward innovation. These include repeal of

the revised Price Maintenance Premium company and product criteria, as well as the implementation of any annual repricing mechanism. For medical devices, annual price revision must be avoided. Maintaining the overall stability in the current rules governing the biennial revision process (because of the large number and complexity of medical devices that are often used with other products and services) is important, with an openness to consider targeted improvements in support of existing and new medical devices that deliver value to the health care system.

- The Councils believe that careful deliberation with stakeholders and rigorous testing are necessary for the implementation of value assessment tools such as Health Technology Assessment (HTA). Such value assessments should be based on rigorous post-launch evidence from the entire healthcare system, including the impacts on various stakeholders, the overall healthcare system and the economy. It is necessary to ensure that any HTA assessment and recommendation do not restrict patient access and treatment outcomes or physician choice, and do not delay drug or medical device regulatory approval and/or patient access.
 - Progress is needed on the Council on Economic and Fiscal Policy (CEFP) reforms for rebuilding better social security system that do not deal with drug pricing system. The government should carry out reforms to other parts of healthcare system, such as optimization of medical service allocation and co-payment reform, by developing more concrete goals and action plans.
2. It is necessary to adopt a longer-term strategy to ensure both the stability of the healthcare system and promotion of innovation in coordination with key stakeholders. There have been several vision papers put out by the government and by industry that have very constructive suggestions on how Japan can move forward with a pro-innovation policy agenda that helps address key concerns. These include *Japan Healthcare Policy*. For the next revision of the Healthcare Policy, the Councils recommend that the government should take into consideration the *JPMA Industry Vision 2025*, the *PhRMA Vision Report of the Innovative Biopharmaceutical Industry*, the *JFMDA Industry Vision Report 2018*, and the Economist Intelligence Unit's *Medtech and a Vibrant Japan Study*.

Promoting cutting-edge technology and investment to achieve sustainable promotion of innovation and timely patient access.

3. Strengthening translational research: Overcoming the ongoing issues in the area of Japanese translational research so that Japan can capitalize on its strengths to become a world leader in medicines discovery and global provision. The Councils recommend the further establishment of a public-private collaboration between AMED, academia, bio-ventures and the pharmaceutical industries in Japan to tackle barriers to translational research in Japan and to accelerate research and development of new medicines to address Japan's specific health needs as well as to improve

global health.

4. Improving the competitiveness of Japan by leveraging advanced regulatory science, like expedited approval pathways, as a regional and global leader:
 - The Councils would like to ensure that multi regional clinical trials are conducted under common international practices and guidelines, especially ICH E-17.
 - The Councils would like to ensure that patients have early access to innovative medical products through the *Sakigake* system, or through the conditional approval which are being scrutinized for legislation. These measures should be implemented as soon as possible. Product eligibility criteria should be equivalent to the U.S. and EU systems to ensure global competitiveness. All innovative products that meet the requirements or eligibility should be designated to reduce costly and time-consuming clinical trials.
5. Establishment of a data protection system in Japan: Examine introducing a new rule that would achieve the highest global standard of protection of clinical data for biologic medicines to enhance Japan's global competitiveness, which will be a main source of future medical innovations.

Optimizing expenditure through an increase in efficiency

6. The Japanese Government should comprehensively examine overall healthcare spending with the aim of optimizing expenditures, and consolidate the vast number of dispersed medical centers.
7. A sustainable pro-innovation environment could be achieved through re-investing some of the savings available through off-patent reforms. Further reforms of the off-patent sector, including policies to encourage and promote the use of generics/biosimilars, could release savings to support the broader health care budget, cover pro-innovation policies and remove the need for additional cost-cutting measures.

Encouraging preventive measures/preemptive medicines that contribute to an extension of healthy lifespan - Developing new policies that encourage and reward primary and secondary prevention measures that contribute to an extension of healthy lifespan.

8. To realize a goal of achieving healthier lifespans through prevention, the Councils believe that the government should adopt pro-vaccination policies and give greater recognition to the value of innovation relating to prevention. Of particular importance would be policies that incentivize innovations where their acquisition cost is less than cost-savings for the total health system and to the broader economy.
9. The government should set a goal and policies for infectious disease control, taking into consideration potential threat of infectious diseases coming from inside/outside of the country

and burden of the diseases. Laying out the basic principle that many diseases are preventable by immunization and vaccination, the government should prepare for immunization and vaccination program as well as treatment program.

10. Sustainability should be the most important forces driving industrial innovation on vaccine development with a sense of urgent against global health threats caused by pandemic influenza and imported infectious disease with emerging & re-emerging infectious diseases. It is important to initiate governmental initiatives for increasing public funding and promoting public-private partnership, which includes the preparedness of emergency use from practical and legal perspective, and the promotion of universal health coverages across different countries and regions through delivery of vaccines.
11. Regular use of dietary supplements can have substantial health benefits, thus reducing healthcare expenditures. The Councils suggest that the governments recognize the evidence-based health benefits of functional foods, such as health foods and dietary supplements, so that the benefits can be communicated to promote public health.

Promote the use of Digital Health

Enact new public policies that support the delivery of health care through promising new digital health technologies, e.g., AI, Big Data and practical use of Real World Data, as soon as possible

12. Encourage investment in, and development of, digital health products; establish coverage and payment policies that encourage technology innovation and patient access; and ensure regulatory paradigms for digital health products are transparent, predictable, consistent, timely, and science-based.
13. The early approval review system for the next generation of medical devices should not review the content of the algorithm but consider the evaluation of performance and safety by real world data after marketing. Similarly, the Councils encourage the two governments to work together to prevent such preconditions in other markets.
14. Allow private industry to utilize real world data in order to create innovative medical devices and innovative medicines, such as cancer genomic medicine, medical imaging diagnostics assisted by AI. Therefore, the Councils recommend that industry, academia, government and medical institutions collaborate to develop real world data bases of sufficient quantity and quality to assist industry in the development of innovative and medical devices and pharmaceuticals.
15. Create networked specialty centers: Facilitate remote care and improved efficiencies through creation of networked specialty centers (i.e., cancer) that utilize a common IT platform to support

integrated care across diagnosis, treatment planning & delivery, patient follow-up, and management of patient data.

Utilizing Information and Communication Technology (ICT) data infrastructure to streamline the drug development and pharmacovigilance processes

16. The Councils consider that introducing a unique Medical ID number, the government should promote ICT data infrastructure to streamline the drug development and pharmacovigilance processes. The government should improve the existing system which has been uniquely developed in Japan, to align to the global standards, and if necessary conduct necessary change of related regulations. The Councils recommend Japan maintain the highest safety standards, by integrating similar large-scale medical information databases which link data of diagnosis, medical checkup, nursing, and genomic information through ICT usage.

Safety of medical institutions as social infrastructure in the digital age

17. Medical devices are changing the way we manage chronic health conditions, improve quality of life and health care, and save lives. Governments and industry stakeholders should enhance public and private collaboration to advance innovation and smart risk management policies to realize the promise these connected devices have for public health. Cyber Security is not only the medical device manufacturers' responsibility, but medical institutions also share such responsibilities as clearly stated and defined under the "Safety Management Guidelines" written in the "Guidance on Securing Cyber Security of Medical Device (July 24, 2018)". The guidance also reviews the importance of conducting maintenance contracts. In response to this, medical institutions and medical device manufacturers cooperate to promote cyber security compliance. The Councils recommend enacting the following three things in order to enhance cooperation between device manufacturers and medical institutions to strengthen the security of connected medical devices:

- Enact a new regulation having medical institutions comply with the "Safety Management Guidelines" and conclude a mandatory maintenance contract with the medical device manufacturers.
- Make an exemption clause in the modification application in the case of changes regarding the compliance of the cybersecurity section of the already certified equipment's to provide quick and prompt application and approval.
- Define the roles and responsibilities of the medical device manufactures and the medical institution regarding on how to provide information safely and in security to users of implantable medical devices.

IV-5 Travel, Tourism and Transportation

Overview

The U.S.-Japan Business Council/Japan-U.S. Business Council launched a travel-tourism subcommittee in 2014, reflecting the increasing importance of inbound international travel to Japan's economy, and with the aim of deepening and expanding the level of U.S.-Japan business and cultural exchanges. Last year, to reflect the growing importance of transportation infrastructure and logistics to economic growth, the Councils updated the Committee name to "Committee on Travel, Tourism, and Transportation." The Councils have discussed ways to maximize the benefits to both economies of the travel, tourism, and transportation industries.

Ways to further develop and expand the travel, tourism, and transportation industries

1. The travel, tourism, and transportation sectors have tremendous economic benefits. Travel and tourism have been key growth drivers for the U.S. and Japanese economies. Prime Minister Shinzo Abe has set ambitious national targets for the travel and tourism sector, as part of Japan's broader goal of growing GDP to 600 trillion yen by 2020. In June 2016, he announced an initiative called "A Tourism Vision to Support Japan's Tomorrow", which aims to attract 40 million foreign tourists (and an associated 8 trillion yen) by 2020. In 2030, Japan hopes to grow that number to 60 million foreign tourists who will contribute 15 trillion yen to the Japanese economy.
2. The Councils have welcomed briefings by Japanese government officials on action plans to meet such goals, and commend Japan on the progress already achieved. Relaxing visa regulations, expanding airlines' networks, and a relatively weaker Japanese yen have made travel to Japan more attractive and convenient. In 2018, the number of Japan-bound foreign tourists is expected to exceed 30 million, and the average duration of those visits has increased, as well.
3. While recognizing that Japan's tourism initiatives that have resulted in rapid growth, the Councils also note a few areas for improvement. The Councils believe that increasing the number of landing slots at airports, faster immigration processes, improving access to airports, increasing the number of MICE (Meeting, Incentives, Conference, Exhibitions) facilities, and increasing the availability of multi-language services would help enable the growth in travel and tourism sought by Japan. The Councils recognize that the United States also has challenges in the areas of immigration processing and aging transportation infrastructure including airports, and recommend further talks to accelerate cooperation between private and public sectors.
4. The increasing number of inbound tourists is also causing concern over a shortage of accommodations in Japan. The Councils hope that the use of private lodgings will complement the growth in hotel accommodations to help ease the shortage. Recognizing that the law enacted

by the Japanese government in June will help regulate unregistered private lodgings, the Councils also note that the process to register a private home for public accommodation is confusing and could limit the number of private lodgings available for public accommodation. In the run-up to the 2020 Tokyo Olympic/Paralympic Games, the Councils urge the Japanese government to address this issue, and to find other ways to increase accommodation capacity and convenience.

5. As for the transportation sector, the Councils recognize the importance of creating transportation options that are convenient and accessible to all, including for those who cannot drive. Some taxi companies in Japan, for example, have introduced new models that offer more comfort and functionality for foreign tourists, and the United States has developed policies for innovative demand-responsive, app-based transportation services which have improved productivity for the transportation industry and convenience for both residents and tourists. Japan and the United States are also researching self-driving cars and both governments are trying to implement appropriate safety regulations. The Councils encourage further discussions to support the freedom of transportation, and encourage the U.S. and Japan to implement measures that will stimulate technological innovation in this important industry. For example, delivery systems via unmanned aerial vehicles, efficient transport systems using big data, multi-language translation tools, and facial recognition security software are promising R&D areas that could facilitate international tourism, logistics, and transportation.

The 2020 Tokyo Olympic/Paralympic Games to the 2028 Los Angeles Olympic/Paralympic Games

6. With the Tokyo Olympic/Paralympic Games less than two years away, the Tokyo Organising Committee of the Olympic and Paralympic Games has briefed the councils on the status of games schedules, facility construction, traffic regulation and volunteer training. The Councils are trying to identify ways to maximize the economic and social opportunities generated by the Games. The Councils believe the 2020 Tokyo Olympic/Paralympic Games as well as the 2028 Los Angeles Olympic/Paralympic Games will drive further economic growth, and will be a great opportunity to emphasize diversity and social harmony. The Councils believe that the Games will showcase Tokyo as a true global city that embraces cultural and linguistic diversity, as well as a barrier-free society that includes persons with disabilities. Such an image of Tokyo will help generate greater tourism demand. The upcoming Games will bring success to Japan, and help Japan show its famed “Omotenashi (hospitality)” to the world. The Councils hope that Tokyo will be able to pass on this positive legacy to the 2028 Games in Los Angeles.

Potential of Integrated Resorts toward sustainable economic growth

7. Both Councils recognize that Integrated Resorts (IR) will help grow Japan’s travel and tourism industries, contribute to regional revitalization, and boost related industries as well as local

suppliers and businesses. The Councils applaud the July enactment of a bill authorizing the opening of IR, which followed the IR promotion law of December 2016. Further legal steps are to be taken, and the selection process of IRs locations will begin. The Councils recognize the need to address public concerns about gambling addiction and money laundering, and recommend strong public-private partnership to ensure that the IR projects positively contribute to the Japanese economy. The requirement to get local authority approval every five years is a cause for concern. It is likely to give investors pause, and is not conducive to long-term, stable business success.