

JOINT STATEMENT
54th JAPAN-U.S. BUSINESS CONFERENCE
U.S.-Japan Ties at a Critical Juncture

U.S.-Japan Business Council / Japan-U.S. Business Council
Washington, D.C.
November 3, 2017

Overview and Key Themes

1. The U.S.-Japan Business Council (USJBC) and Japan-U.S. Business Council (JUBC) (hereafter, the “Councils”) held the 54th meeting of the U.S.-Japan Business Conference (hereinafter, the “Conference”) in Washington on November 2-3, 2017, under the Conference theme: “**U.S.-Japan Ties at a Critical Juncture.**” Today, a number of security and economic challenges in the Asia-Pacific require greater U.S.-Japan cooperation. North Korea’s continued pursuit of nuclear weapons and a growing number of territorial and maritime disputes are among the most prominent security concerns facing the two countries. In addition, the liberal international economic order has come under intense scrutiny in recent years. These themes remained top of mind for participants throughout the Conference.
2. This Conference assembled business leaders from the United States and Japan, who confirmed their commitment to promoting a free, open and rules-based global trading system; setting an example for sustainable economic growth; and maintaining regional stability. Throughout the conference, the Councils stressed the need for the U.S. and Japanese business communities to be in lock-step at this critical juncture, where we face growing uncertainty not only over regional security, but also regarding the shifting U.S. stance on trade – particularly in the Asia-Pacific region. The Councils underscored the importance of promoting shared values in order to preserve and build on the contributions made by U.S. and Japanese businesses to global economic growth, including through development of extensive value chains across the region.
3. The Councils agreed that a rules-based free-trading system promotes economic growth, job creation, and innovation and resilience of participating economies. The Councils duly recognize the Government of Japan’s leadership in pursuing the Trans-Pacific Partnership (TPP-11) since the US decision to withdraw from TPP. The Councils expressed their hope that discussions between the United States and Japan on a bilateral framework will be accelerated with a view to deepening their economic relations, and setting high trade and investment standards throughout the Asia-Pacific region.

4. The Councils emphasized that the U.S.-Japan Alliance is essential to stability and prosperity across the world and underscored the importance of strengthening the commercial relationship as a fundamental pillar of the U.S.-Japan relationship. The Councils encourage the governments of both countries to commit themselves to further improving market access and pursuing high standards and more comprehensive cooperation in areas such as digital commerce, competition with state-owned enterprises, regulatory practices, and intellectual property protection, among others. They applauded both governments for their renewed engagement through the U.S.-Japan Economic Dialogue, including on more effective enforcement activities against unfair trade practices by third countries. They emphasized the need for private-sector input into the dialogue and encouraged both governments to ensure concrete outcomes that create meaningful opportunities for the private sector. A priority area is enhanced collaboration on quality infrastructure, both bilaterally, and throughout the Asia-Pacific region, including closer cooperation on infrastructure projects and standards setting through APEC, in the activities of the Asian Development Bank (ADB), and in other regional fora.

Key Challenges Facing the United States and Japan

5. The Councils expressed their commitment to addressing mutually concerning protectionist trends in third countries, including those related to: government subsidies to state-owned enterprises, excess manufacturing capacity, market access restrictions, forced technology transfers, and burdensome and restrictive data policies that will have severe implications for global innovation. The Councils recognized China's growing economic influence and committed to working together to promote a level playing field for U.S. and Japanese companies. At the Conference business leaders' attention was brought to the "Made in China 2025" policy and potential concerns associated with such industrial policies.
6. The Councils expressed concern over rising protectionist sentiment on a global scale, and in particular that guided by oversimplified metrics related to trade deficits and surpluses. Metrics should take into account basic macroeconomic principles as well as the benefits that are realized from the free flow of goods, services, labor and capital. The Councils encourage both governments to avoid adopting economic policies that protect one industry, sector or market at the expense of others. To realize the benefits of a vigorous and innovative economy, both governments must take measures to ensure market competition stays healthy, robust and impartial. To that end, the Councils expressed concern over a number of U.S. proposals tabled in the North American Free Trade Agreement (NAFTA) modernization negotiations and urge U.S. negotiators to reconsider those proposals that would be harmful to U.S. businesses, such as the local content requirements in the automotive sector, as well as Japanese firms with substantial investments in the United States and across North America.
7. With both countries facing demographic challenges posed by aging populations and shrinking workforces, improving overall productivity of both countries' workforces is

critical to ensuring sustained growth and long-term competitiveness. Greater workforce productivity can be achieved through structural changes and public-private partnerships that promote diversity and incentivize individual and collective performance; optimal employment of skills, education and experience of mid-career professionals and new entrants; an enhanced focus on preventative healthcare to mitigate health risks associated with aging; and the removal of barriers to women and foreign workers entering the workforce.

Priority Challenges and Issues in the United States:

8. The Councils support development of broad consensus among Congress, the executive branch, and the American public on comprehensive policies that will enable large and small businesses to grow the economy and generate new jobs. The Councils urge the U.S. administration to prioritize domestic policies that favor economic growth, pursue a wide-ranging and rules-based approach to global trade, and ensure that transparency, predictability and a commitment to the rule of law continue to drive foreign investment into the United States.
9. The Councils applaud the focus on tax reform by the U.S. administration and Congress. Tax reform legislation should lower tax rates for all businesses to a level that will enable them to compete successfully in the global economy, attract foreign investment to the United States, increase capital for investment, and drive job creation. In addition, the Councils believe that tax reform legislation should ensure industry-specific neutrality and avoid special tax benefits or penalties targeted to one industry versus another. The Councils also appeal to both governments to review their respective taxation systems to ensure fairness for citizens of both countries working in the other to optimize the free flow of people between the two countries.
10. The United States' travel, transportation and energy infrastructure is increasingly overburdened and in disrepair from decades of underinvestment and neglect. Repair and improvement of infrastructure projects will present major foreign direct investment opportunities, and will directly enable the seamless movement of goods, services and people across state and international borders. The Councils encourage the U.S. government to prioritize improving existing U.S. infrastructure and to support investment in advanced transportation projects, such as the construction of high speed rail lines in the western and northeastern corridors and in Texas, as doing so will not only facilitate transportation, but will produce high-paying, skilled jobs for U.S. workers.
11. The U.S. faces a shrinking workforce resulting from increasing retirement of the baby-boomer generation, and will need to find ways of leveraging all of its labor potential to realize long-term economic expansion. With respect to immigration reform, the Councils encourage the U.S. government to pursue administrative reforms, along with much needed legislation that overhauls an outdated immigration system.

Priority Challenges and Issues in Japan:

12. Structural and regulatory reform will be an essential complement to current monetary and fiscal measures aimed at overcoming deflation. To do this successfully, the Japanese government must convince consumers and investors alike that national finances are sustainable and that social safety net programs will remain viable in the medium to long term.
13. Japan faces an acute demographic challenge, with over 40% of the population projected to be over age 65 by 2025. The Japanese government must develop innovative ways to increase individual and collective worker productivity to ensure that the growing costs of entitlement and social security programs are sustainable. This will necessitate the elimination of structural and cultural barriers to women entering the workforce, and consideration of enhanced participation of the elderly population and foreign workers. It is also imperative that the Japanese government implement critical labor reforms, including by developing a mechanism for legalized severance, as well as establishing an effective white-collar exemption and other measures to incentivize performance over hours worked.
14. To overcome those challenges and enable sustainable and resilient growth, the Councils recognize the concept of “Society 5.0” and urge the Government of Japan to collaborate with business to set a concrete action plan and ensure steady implementation of the strategy. In particular, the Councils believe that the greater usage of data is the key to success and it is the most important to implement a series of policies to enable it in an expeditious manner.

Sectoral Priorities:

15. Digital Economy - The Councils applaud both governments for the focus they are bringing to digital economy-related issues and also encourage them to continue to collaborate and advocate for the principles in third countries, regions and other international fora to prevent digital protectionism. The Councils support the governments’ efforts to share best practices with other countries and regions, and hope for increased dialogue between the U.S., Japan, and others. A detailed overview is provided in the digital economy supplement, and prioritizes areas related to: allowing cross-border data flows, avoiding data localization and cloud computing requirements, avoiding requirements of source code disclosure, enhancing cybersecurity cooperation, improving critical infrastructure necessary to support technological advances and connectivity, and strengthening intellectual property protection.

16. Financial Services – The Councils support regulatory and supervisory efforts that achieve an appropriate balance between strengthening financial stability, benefiting the wider public interest, and preserving the ability of financial institutions to drive economic growth. In that regard, the Councils highlight the extensive employment, credit, liquidity, and risk management financial institutions provide, which are critical to the functioning of the economy and financial systems around the globe. The Councils support government efforts to promote regulations and international standards that: allow appropriate risk-taking necessary to finance growth; maintain a level playing field; are proportionate to the issue they aim to address; achieve consistency across jurisdictions where appropriate; and avoid unintended consequences. These areas, and other priorities, are further discussed in the Financial Services Sector supplement.

17. Energy - The Councils recognize that energy security is paramount to national security, and that diversified energy mix which incorporates renewable and non-renewable energy sources will ensure reliable, resilient and environmentally sustainable economic growth. The Councils applaud both governments for their continued collaboration on innovative nuclear energy generation technologies as a means of producing emissions-free energy and welcome the Statement of Intent signed by both governments which desires to strengthen the special bond between two nations through greater industrial cooperation. We recognize that there are abundant collaboration opportunities to ensure nuclear power generation facilities are safe and survivable when natural disasters strike. The Councils also recognize that the U.S. shale revolution, especially in the production of natural gas and Liquefied Natural Gas (LNG), holds great potential for increased energy trade, cooperation and security between the U.S., Japan and the broader Asia-Pacific region, and the Councils urge both government promote cooperation in this area.

18. Healthcare - The Councils note their ongoing commitment to public-private collaboration toward addressing pressing healthcare challenges, improving health outcomes and raising economic productivity worldwide. They advise both governments to further improve the healthcare environment in both countries in a way that allows for greater efficiency and fully acknowledges the value of innovation. In that regard, the Councils underscore the importance of ensuring that pricing and reimbursement systems fully recognize real-world patient and caregiver value and are efficient, transparent, and consistent. In addition, the Councils note the importance of ensuring regulatory practices that encourage global development and result in first-in-world approvals. The Councils also note the importance of collaboration across the public, private, and academic sectors and encourage both

governments to provide platforms for efficient translational, pre-clinical, and clinical development that will spur innovative R&D.

19. Travel, Tourism and Transportation – Travel between the United States and Japan helps forge close ties and common values between our peoples and secure the foundation for the strong partnership between our two countries. The Councils recognize that international travel and tourism have been an important recent driver of economic growth in both countries. Just over the past four years, the number of inbound international travelers to Japan has tripled, and the Councils commend the Government of Japan for its focus on improvements aimed at enhancing transportation infrastructure and in providing convenience for foreign visitors to Japan, and encourage the US government to explore ways to improve the environment around international travel and tourism to the United States. The Councils believe that the 2020 Tokyo and 2028 Los Angeles Olympic and Paralympic Games can spur further economic growth, and also provide significant opportunities for public-private sector collaboration to help make the Games a success. The Councils believe that the recent authorization of integrated resorts (IR) by the Diet of Japan will enhance growth in this sector and, as Japan considers appropriate regulations, the Councils encourage the Japanese government to address public concerns while maintaining the positive potential IR has for tourism and investment for the Japanese economy.

**Supplement to the JOINT STATEMENT
54th JAPAN-U.S. BUSINESS CONFERENCE
*Financial Services Sector***

Striking the Right Balance Between Regulation and Economic Growth

■ **Critical Role of Financial Institutions:** Financial institutions are critical to the functioning of the economy and financial systems around the globe. The sector serves society by providing credit to drive economic activity, liquidity to facilitate the need for cash, and risk management to shield households and businesses. In a rapidly-changing world, financial institutions continue to evolve and innovate to benefit consumers and society. Further, the financial industry is an important component of trade in services around the globe and, in particular, between Japan and the U.S.. Investments by U.S. financial firms in Japan, and by Japanese financial firms in the U.S., provide extensive employment and promote economic growth in both countries.

Since the financial crisis of 2008, countries have sought to coordinate at an international level to develop a global regulatory framework to strengthen financial stability and lower the likelihood and severity of a future financial crisis. At the same time, the United States and Japan have pursued far-reaching reforms to prevent another crisis and sustain their economies over the long term. The Councils fully support reasonable reforms designed to strengthen the global financial system, and ultimately promote sustainable economic growth.

In this new global regulatory environment, the Councils believe that any regulatory and supervisory measures undertaken by the regulators should be appropriate and proportionate to attain clear supervisory objectives for the benefit of the wider public interest, and not go beyond those objectives, to avoid unintended consequences on the real economy and distortion in market competition. As work continues to develop and implement a new regime of international financial standards, the Councils see key opportunities for the United States and Japan, as the largest and third-largest economies in the world, respectively, to cooperate and speak with one voice on areas of common interest. The Councils strongly urge U.S. and Japanese financial regulators to continue working in close collaboration with each other and the industry to complete the reform process, while striking an appropriate balance between financial stability and economic growth. The Councils believe a coherent regulatory framework and level playing field can be achieved through continued commitment to international cooperation and coordination. At the same time, the Councils request that both the US and Japan pursue a leadership role in formulating international financial standards.

In this context, the Councils urge both governments to adopt the following measures and principles, which will contribute to the sound regulation of financial services in both countries and help ensure robust and effective outcomes in the development of international financial standards.

The Councils believe transparency contributes to policy effectiveness by reducing uncertainty in the decision-making of market participants, and promotes financial and systemic stability by enabling better understanding of government policies. Transparency is critical for commercial entities to confidently make management and investment decisions and, as a result, improve the quality of financial services for customers. In this regard, the Councils urge regulators in both countries to continue to expand dialogue with the financial industry and consider views of market participants when crafting and implementing new regulations.

In responding to the imperatives of aging societies globally, for example, the implications for financial markets, macroeconomic growth, and financial stability are significant. With financial institutions playing an increasingly important role in the management of shifting demographics, the Councils encourage governments to provide a policy environment that supports financial markets and institutions in addressing these challenges.

As the demands for infrastructure investment expand in Asia and around the globe¹, financial institutions will continue to play a vital role in financing the economy and supporting growth. Given their scale, global reach and strong fundamentals, financial institutions in the U.S. and Japan are especially well prepared and eager to support these agendas.

Finally, as cybercrime has now become the second-most reported economic crime, financial institutions are a prime target. The Councils affirm their obligation to protect consumers from cyber threats and to seek continued collaboration with relevant policy-making institutions to prevent them.

■ **Cross-sectoral guiding principles:** Efforts toward international financial regulatory reform have delivered substantial progress nearly ten years after the global financial crisis. With implementation of the immediate post-crisis reform agenda now largely complete, the timing is appropriate for a thorough assessment of the output and effects of the new rules and consideration of necessary revisions. The Councils believe in the need for

¹ Asian Development Bank estimates that investment of USD 1.7 trillion per year is needed in developing Asia until 2030 to maintain growth momentum. Additionally, according to the Organization for Economic Co-operation and Development, total global infrastructure investment requirements from 2007 to 2030 will come to USD 71 trillion.

<https://www.adb.org/publications/asia-infrastructure-needs>

<http://www.oecd.org/daf/inv/investment-policy/Fostering-Investment-in-Infrastructure.pdf>

certain guiding principles in designing the optimal regulatory framework based on an ongoing cross-sectoral discussion. These guiding principles include the following:

- Regulatory reform must not place excessive emphasis on eliminating risk to the detriment of the appropriate risk-taking necessary to finance growth, as the ultimate goal of regulation is to contribute to sound economic growth and sustainable economic development
- While consistency among different jurisdictions is an important consideration, regulators and global standard setting bodies must recognize that application of uniform, one-size-fits-all regulations may not be appropriate in certain cases
- Regulation should be proportionate to relevant risks, and the necessity for a given regulation should be supported by a clear demonstration of the link between intent and substance
- Counter-cyclical macro-prudential regulation should be encouraged and pro-cyclical regulation should be avoided

■ **Insurance Regulations:** Insurance companies pool and transfer risks on behalf of society, thereby serving as a source of financial strength and stability during times of distress, including the 2008 financial crisis. However, regulatory changes since the financial crisis threaten to undermine insurer's ability to continue to fulfil that role and to serve their customers. The Councils call on the U.S. and Japanese Governments to ensure that the International Association of Insurance Supervisors' (IAIS) global insurance capital standard (ICS), and all other recommendations for policy measures, promote, rather than inhibit, the ability for insurers to fulfil their vital role. With respect to global insurance capital standards, any standard should: achieve comparable levels of capital and a level playing field among all market participants; be appropriate for the variety of insurance business models; and be capable of easy implementation in each jurisdiction. Development of such IAIS policy measures must be done in a deliberate and transparent manner and not beholden to arbitrary G20, Financial Stability Board (FSB), or IAIS imposed deadlines that could increase the likelihood of standards that produce unintended consequences.

With regard to the ICS of the 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 stable, long-term nature of most life insurance liabilities. Such unwarranted volatility could force companies to exit long-term guaranteed businesses that are prudently managed with sophisticated risk management techniques and essential to consumers in our markets. In addition, fundamental issues, such as the balance between simplicity and risk sensitivity, and between the need to account for the diversity of insurance markets around the world and comparability, must be appropriately recognized to avoid adversely impacting the role the sector plays in capital markets and for consumers. Sensible approaches to valuing insurance liabilities, qualifying capital resources, and calibrating stresses are essential for avoiding unintended consequences.

The Councils agree potential sources of systemic risk should be addressed to preserve financial stability. As with capital standards and other policy measures for the insurance sector, the approach to assessing systemic risk must account for inherent differences between insurance and other financial service sectors. Further foundational elements for an appropriate approach include: a comprehensive cross sectoral analysis; recognition of both micro and macro-prudential regulatory reforms successfully implemented since the global financial crisis; and a focus on activities that may give rise to systemic risk across the sector rather than individual entities. The Councils urge both governments to explore an activities based approach to assessing systemic risk in the insurance sector, which is still an early stage concept, at the IAIS and FSB and within their respective jurisdictions, while paying due consideration to the need for this new approach to not create additional undue regulatory burdens or unintended consequences.

The U.S. state-based regulatory system for insurance has been responsive to the needs of the local marketplace for over 150 years. The Councils welcome continued efforts to further modernize U.S. state-based insurance regulation, including the recently announced NAIC Macro-Prudential Initiative (MPI).

■ **Banking Regulations:** The Councils welcome the series of regulatory reforms successfully implemented in the aftermath of the global financial crisis. Overall these reforms have resulted in a more stable, better capitalized and more liquid global banking industry far better positioned to withstand even the most challenging market and economic conditions. However, the Councils believe that any further regulatory reforms need to be considered carefully in the context of their impact on economic growth and job creation.

New proposals should not result in an increase in overall capital requirements for the banking sector, consistent with the commitment made by the Basel Committee on Banking Supervision (BCBS) and supported by the Group of Central Bank Governors and Heads of Supervision and the G-20.

Moreover, in view of the significant amount of complex new rulemaking in recent years, existing rules should be subject to ongoing assessment to determine their effectiveness in striking the appropriate balance between ensuring financial system stability on the one hand, and not creating an unnecessary drag on economic growth and innovation, on the other. As Commissioner Mori of the Financial Services Agency (FSA) stated at the Thomson Reuters Pan Asian Regulatory Summit in 2015, "If dozens of specialized doctors surround a patient and inject different strong medicines for every symptom, what would be the combined effects on the patient?". It is important that this assessment and adjustment process also take in to account the specific characteristics of banking models in different jurisdictions to avoid unnecessarily adverse outcomes.

To this end, the Councils welcome recent actions by the Trump administration in the U.S. to assess existing financial industry regulations and consider prudent modifications to those rules that constrain economic activity and innovation without delivering commensurate stability benefits. While the Councils do not endorse a broad rollback of the basic framework global regulators have worked hard to implement since the crisis, they do believe that incremental rulemaking would not yield further benefits and that selected areas, such as the current highly complex rules on bank trading activity, could be clarified or simplified in ways that would eliminate unnecessary constraints on banks' ability to facilitate end-user needs, without increasing risks to stability. In addition, the Councils are hopeful that the post-crisis tendency of U.S. supervisors to "gold plate" Basel regulations will be reconsidered in favor of more global consistency.

The Councils also want to express support for efforts by international bodies to conduct similar assessments on the effectiveness of post-crisis rule making. The FSB's framework for evaluating the effects of the G20 financial regulatory reforms, published in July, will, the Councils hope, help guide regulators in remediating rules that are not achieving their intended outcomes or that are producing unintended detrimental consequences for the proper functioning of capital markets and growth.

More specifically, the Councils urge the BCBS to ensure that requirements be designed and calibrated appropriately, especially regarding capital floors and maintenance of the Basel III leverage ratio as a supplement to the risk-based capital framework. Finally, the Councils reiterate support for the commitment by the BCBS to finalize regulatory reforms at the earliest possible date, thus enabling markets and the banking industry to stabilize around a common global framework.

■ **Cross-border Data Flows:** As the digital economy creates vast new business opportunities, promoting the flow of data and information across borders allows businesses to freely operate and innovate anywhere in the world. However, the Councils are concerned about a trend in many jurisdictions to force localization of data processing and storage as well as restrict the transfer of certain data offshore. Although it is argued that the aim is to protect consumers, in fact placing servers in each country weakens data security and increases operating costs, ultimately increasing costs to consumers. Furthermore, placing limitations on the transfer of data offshore between companies often prevents them from transferring data internally to home offices or an affiliate offshore, and inhibits financial service providers from performing fundamental activities such as managing: employee information; financial and management information; information for fraud prevention, anti-money laundering, and tax planning; disaster recovery; reinsurance; and more.

Given the economic significance of cross-border data flows, the Councils strongly oppose requirements to locally host data processing and storage facilities as a condition of doing business in a particular country. Likewise, the Councils are of the view that any restriction on the transfer of data offshore should not inhibit reasonable business operations or management.

In this context, the Councils support efforts for the Governments of the U.S. and Japan to work together for more open data architecture in markets in Asia and beyond.

■ **International Coordination and Regulatory Consistency:** The Councils support a healthy, vibrant financial system based on sound regulation, and fully support the letter and spirit of the agreements reached at the 2009 Pittsburgh Summit of the G-20. There remains concern, however, that the cumulative impact of new regulation – new liquidity, funding, leverage and risk-based capital requirements, as well as overlapping and complex methodologies – impose severe burdens and limitations on financial institutions, which raise costs and impair market access for end users. The Councils remain concerned that the cumulative effect of this extensive rulemaking will be to constrict credit availability and constrain capital markets, impacting both economic growth and the ability of end users to hedge risk.

In light of the number of new and globally significant regulations implemented following the global financial crisis, it is critical to give full consideration to whether there are possible unforeseen negative effects on financial markets or the financial system, and whether such effects could set the stage for a new type of financial crisis. The Councils appreciate that some work has begun by international regulators to examine this potential, but considerably more analysis remains to be done.

In addition, it is crucial to take further steps to enhance the consistency of regulations between jurisdictions in order to avoid fragmentation and rising costs to end users of financial services, thereby impeding economic growth. However, while consistency among different jurisdictions is an important consideration, regulators and global standard setting bodies must recognize that application of uniform, one-size-fits-all regulations may not be appropriate in certain cases. When local conditions in different jurisdictions necessitate separate paths, regulators in any given jurisdiction should avoid applying rules on an extraterritorial basis. In this context, the Councils see considerable potential for US-Japan cooperation in the regulatory space. For example, as global standard-setting bodies continue the rapid development of international insurance regulations, the United States and Japan have a common interest in communicating closely to share best practices and advocate on areas of common ground.

■ **Level Playing Field:** Like-regulation for like-products and service providers, i.e., a level playing field, is a key regulatory principle for strengthening financial and capital markets and avoiding market inefficiencies and distortions. The Councils urge both governments to avoid distortions that arise when one market participant enjoys favorable treatment over another. It is important to establish a level playing field between mutual aid cooperatives (*kyosai*) and FSA-regulated private sector financial service providers. The Councils also look forward to the Japanese government's further steady progress 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 the postal financial institutions and the private sector.

■ **Neutrality in the Consumption Tax:** The Government of Japan should ensure that its consumption tax regime is consistent with global best practices for value-added taxes (VAT). In particular, the consumption tax law and related regulations should be revised to ensure neutrality in the treatment of sales of financial services offered through sales agents.

■ **Support for Measures to Increase Economic Growth by Enhancing Tokyo's Role as a Global Financial Center:** The Councils support efforts at both the national and local levels to spur economic growth in Japan by taking measures to promote healthy growth of the financial industry and expand the role of Tokyo as an international financial hub.

For example, in line with its commitment to further develop Tokyo as a financial center, the FSA launched a consultation desk in April to give advice on Japan's financial regulations to foreign financial businesses seeking to establish Japan operations. More broadly, the initiative led by the Tokyo Metropolitan Government (TMG), in collaboration with the national government and the private sector, to expand financial activity in Tokyo has the potential to implement a range of constructive policy measures that could lead to a more diverse, steadily growing and sustainable financial industry, contributing meaningfully to economic growth.

The Councils support such efforts to pursue a robust agenda that focuses on identifying barriers to innovation and healthy growth of the financial industry. The Councils will spare no efforts to help realize the measures that would most effectively make Tokyo a more vibrant, innovative and internationally relevant financial center.

SUPPLEMENT on HEALTHCARE INNOVATION

54th U.S.-Japan Business Conference
The U.S.-Japan Business Council / Japan-U.S. Business Council
November 3, 2017

Executive Summary

Section I: Creating a more Transparent and Predictable Environment for Innovation to Continue Improving People's Health Worldwide

R&D Environment: Pursue R&D paradigms that foster collaboration among industry, government, academia, patients and non-profit organizations to accelerate the translation of innovative biopharmaceutical science into impactful health products.

Regulatory Approvals: Further develop regulatory systems to be more transparent, predictable, and efficient. Such systems, for example, should help foster simultaneous global clinical development of experimental therapies, leading to first-in-world approvals by minimizing country-specific requirements and optimizing international standards and common practices.

Evaluation of Innovative Therapies: Ensure that pricing and reimbursement schemes and their reforms are designed and implemented to fully recognize the value of innovation in a transparent, predictable and efficient manner. Such schemes should equally optimize patient outcomes and physician choices, encourage innovative R&D, and allow full and equitable access to innovative products and services by those who need them within existing healthcare systems.

IPR Protection: Strengthen Intellectual Property Rights (IPR) systems to fully protect inventions and related data. By ensuring full protection of innovators' rights through transparent, predictable and effective means of enforcement and redress, such systems will contribute to spur further innovations.

Section II: Maintaining Workforce Health and Productivity, Reducing Economic Burdens of Diseases, and Extending Healthy Life Expectancy

Preventive Care and Health and Productive Management: Create incentives to promote wellness through preventive care measures, such as use of vaccines and health and productivity management initiatives inside public and private organizations through systematic process management and behavioral modification.

Healthcare System Efficiency: Pursue more efficient healthcare systems through appropriate adoption of outcome oriented healthcare management and digitalization combined with a community-based approach.

Global Leadership: Collaborate globally to improve people's health and welfare, including in the U.S., Japan and the Asia Pacific region, laying a stronger foundation for more sustainable economic growth and greater international trade.

**SECTION I: Creating a more Transparent and Predictable
Environment for Innovation to Continue Improving People’s Health
Worldwide**

1. R&D Environment

Innovation is at the center of the healthcare industry in the United States and Japan. In the U.S., the Councils welcome the passage of the 21st Century Cures Act (HR 6) that is expected to accelerate the development and delivery of new medical devices and biopharmaceuticals. The Councils applaud the opening of the Japan Agency for Medical Research & Development’s (AMED) overseas offices.

Biopharmaceuticals and Medical Devices

- To further promote innovation in both countries, increase regular discussion between industry and governments throughout the discovery, development and delivery of innovations.
- Ensure sufficient government funding is secured and managed independently by AMED. The Councils are encouraged by the progress of AMED’s use of English as the primary business language to facilitate cross-border collaboration, and hope to see its further development.
- The Councils welcome initiatives aimed at promoting healthcare ventures in Japan. Such measures could include setting up clear regulatory guidelines/requirements and tax incentives to attract foreign investments into healthcare.
- Maintain and expand the Japanese R&D Tax Credit permanent while deregulating the Open Innovation Tax Credit in order to promote R&D investments and enhance the international competitiveness of Japan.
- Make the current two-year suspension of the U.S. Medical Device Excise Tax permanent.
- Continue to foster development of “next generation” innovative therapies through engagement by U.S. and Japanese government agencies to support convergence of stem-cell and regenerative medicine policies and legislation.
- As the Clinical Research Law is implemented, the Councils urge the Government of Japan to fully take into account the characteristics of medical devices, including its procedure-driven nature; short product life cycle; more frequent minor and major modifications; and longer service life that make it difficult to conduct large scale studies.
 - Continue to promote “seamless innovation”, or what is referred to as “open innovation” in Japan by reducing regulatory barriers and creating incentives for collaboration between industry, government, academic and non-profit sectors.

2. Regulatory Approvals

The Councils welcome implementation of the *Sakigake* strategy with the inclusion of regenerative medicines and medical devices, as well as the introduction of the Act on the Safety of Regenerative Medicine. The Councils applaud continued timely reviews of pharmaceuticals in Japan as well as its adoption of new “fast track” pathways.

Biopharmaceutical and Medical Devices:

- Encourage PMDA to increase its focus on clinical relevance of data, as well as to improve internal capacity to evaluate newer statistical methodologies and study designs,

including the flexible acceptance of Phase I clinical and pivotal study data from outside of Japan.

- Ensure that user fees are reasonable and that any increases in them are linked to agency performance.
- Increase the active sharing of Good Clinical Practices (GCP) inspection reports between FDA and PMDA to reduce redundant on-site inspections and increase regulatory efficiency.
- Apply the concept of the “least burdensome approach” to regulation in the U.S. and Japan. In particular, the Councils strongly encourage FDA to: (1) make further improvements to the regulatory environment through more risk-based assessment and better balance between pre- and post-market requirements; and (2) make sure that the introduction of new approaches, such as “estimand” and associated “missing data collections,” do not add significant burdens or delays to the development timeline of clinical trials. The Councils believe these approaches will lead to greater investment by healthcare companies in the United States and Japan.
- Ensure that sufficient budget and human resources are allocated to the PMDA to support the "priority review designation system" based on the *Sakigake* strategy.
- Building on the progress of the U.S. and EU’s mutual recognition of good manufacturing practices (GMP) for pharmaceuticals, pursue such GMP mutual recognition between the U.S. and Japan.
- Promote alignment between US and Japan regulators in developing and implementing new “digital health” policies that can accelerate and reduce cost of development of innovative therapies

Biopharmaceuticals

- Harmonize the regulatory and legal requirements of the electronic record/electronic signature for electronic regulatory submissions.
- Make sure that the legal requirements for the sharing of genomic data are harmonized to global standards to accelerate pharmacogenomics (PGx) research and development.
- Define clear and harmonized regulatory guidelines and policies on preclinical data requirements prior to clinical investigation for biotechnology products.
- Fully utilize Real World Data (RWD) such as medical information database and/or patients disease registry for post marketing surveillance (PMS).

Medical Devices

- Utilize the Medical Device Innovation Consortium (MDIC) in the U.S. to create forums for collaboration and dialogue between regulators, manufacturers & other stakeholders; fund key regulatory science projects (such as the Case for Quality); and provide tools to drive innovation (such as searchable databases linked to standards & test methods, educational training programs, etc.).
- Promote the Harmonization by Doing (HBD) program as a mechanism to streamline the processes of global medical device development, reduce overall medical device development costs, and provide faster patient access to new medical technologies.
- PMDA significantly raised the review fee and the contribution of safety measures from April 2017. The councils expect PMDA to improve their performance of review process and strengthen its organizational governance.

- Continue improvements to the efficiency and consistency of pre- and post-market (e.g. surveillance, facility inspections, etc.) regulatory processes in the United States.
- Establish mutual recognition between the United States and Japan of good clinical practices and quality management audit results.
- The Council welcomes the Japanese government’s commitment to promote medical device R&D, as communicated through the Basic Plan. Industry looks forward to working with the government and other stakeholders to support implementation of the Basic Plan.
- Promote a harmonized approach to Unique Device Identification with the aim of ensuring quality, logistical efficiency, and traceability for medical safety.

Diagnostics

- Continue efforts to create clear, transparent, and predictable regulatory path and reimbursement policies for companion diagnostics. As part of this process the Councils welcome MHLW’s decision to provide the IVD industry a meaningful opportunity to provide the industry’s views at Chuikyo.
- The governments of the U.S. and Japan should collaborate in global efforts to streamline and harmonize the regulatory pathway for the development of companion diagnostics for use in the growing area of personalized medicine.

3. Evaluation of Innovative Therapies

Innovation in the biopharmaceutical and medical device sectors benefits millions of people worldwide by helping them living healthier, longer and more productive lives. Such innovation is also critical to drive economic growth and development. It is therefore critical for the U.S. and Japan to build sustainable systems that fairly evaluate and reward innovation, including exploring possible new healthcare financing measures to further spur innovation.

Biopharmaceuticals and Medical Devices

- Recognize that innovation delivers improved clinical value and outcomes over conventional or existing clinical interventions. Innovative products leading to improved clinical outcomes should be fully rewarded and accessible under the existing universal health coverage systems in Japan.
- Abolish the anti-innovative application of the “Special Re-pricing for Market Expansion Rule”
- Ensure that the current clinical trial-based health technology assessment (HTA) system and procedures in Japan aim at promoting innovation, including taking into account physician fees and welfare fees as well as the impact of innovation on overall welfare spending. It should also, be inclusive of all the various impacted stakeholders. Ensure that HTA recommendations do not restrict patient access and outcomes or physician choice, and do not delay drug or device regulatory approval and/or access.

Biopharmaceuticals

- Make the Japanese “Price Maintenance Premium” permanent while ensuring that its scope of application is not diminished to provide price stability over the patent life and/or exclusivity period of innovative biopharmaceutical products, which would continue to make the Japanese market more attractive. Combined with policies to

promote greater use of generic medicines, this is a budget neutral policy that supports innovation.

- Ensure the price revision process in Japan is conducted every two years with off-years price revisions limited to generic and long-listed biopharmaceutical products (LLPs) that have a significant discrepancy between the National Health Insurance price and the actual market price.
- Ensure drugs are not repriced based on indication extrapolation alone, which will discourage investment in additional clinical trials to meet unmet medical need.
- Preserves recognition of the value of innovative pharmaceutical R&D by not excluding or diminishing the U.S. price in the “Foreign Price Adjustment.”
- Expand incentives for the development of innovative stem-cell and regenerative therapies through adequate reimbursement policies.

Medical Devices

- Repeal the currently suspended U.S. Medical Device Excise Tax that took effect in 2013 as part of the Affordable Care Act.
- Implement stable and predictable reimbursement policies in Japan that align with Prime Minister Abe’s focus on the medical device sector as a driver of economic growth and job creation.
- Ensure that the medical devices prices revision in Japan is not conducted every year.
- Careful introduction of health technology assessment (HTA) system in consideration of the characteristics of medical devices.
- Ensure that, new functional classification can be reapplied in case additional clinical experiences are shown even after the first reimbursement in consideration of the characteristics of medical devices.
- Better reward innovation in Japan’s reimbursement system by reconsidering the FAP revision formula (see below); making targeted improvements to the C1/C2 premium reimbursement application process; continuing the “single room” system to reward innovative products within existing functional categories including, if appropriate, establishing functional category subdivisions for innovative products; and continuing the device lag elimination premium.
- Reimbursement for special treatment materials is utilized by functional category system but not by brand as pharmaceuticals. For that reason, there might be a case where products with a large difference such as actual usage status, structure, or market price would be mixed in the same functional category. It is expected to accelerate the innovation by further expanding the subdivision of the functional category.
- Abolish Japan’s Foreign Average Pricing system and replace with a market-oriented, data-driven, transparent reimbursement scheme that welcomes and rewards innovation. Until the system is abolished, maintain – and increase for certain C1 products - the current Foreign Average Price (FAP) multiplier; adjust the reimbursement upward for products with FAP ratio lower than 0.75; apply the outlier rule to the lowest price; and exempt certain C1 products from reductions over at least two revision cycles.

Diagnostics

- Develop pricing incentives for companion diagnostics that can improve efficiency in healthcare spending.

4. IPR Protection

Biopharmaceuticals and Medical Devices

- Strengthen the IP transfer bridge between academic institutes and companies with manufacturing and sales capabilities for both biopharmaceuticals and medical devices.

Biopharmaceuticals

- Continue to further strengthen IPR standards in the U.S. Japan and globally, including data protection to continue fostering innovation.
- Increased collaborative efforts between the U.S. and Japan to minimize the use of compulsory licenses in other regions, which by World Trade Organization design should be used only in specified circumstances (i.e., to meet a health crisis or emergency) rather than being applied as tools for price control.
- Ensure that IPR systems in Japan and the U.S. fully recognize and offer robust, comprehensive protection for next generation innovative therapies, such as gene , stem-cell, , and regenerative therapies.
- Maintain early resolution mechanisms to ensure that generic products do not enter the market when the originator product has still valid IP protection.
- Extend patent term restoration to address untimely pricing and reimbursement approvals in third country markets.
- Consider the introduce Patent Box system in US and Japan to further promote innovation.
- In TPP 11, remaining member countries are inclined to agree on the suspension of the data protection discussion until the return of US. The Councils urge Japan to pursue the highest standard of data protection for biologics to promote innovation.

Medical Devices

- Establish a harmonized patent term extension system to ensure the same scope of patented inventions subject to the extension.
- Restrict patent right enforcement by non-practicing entities.
- Ensure that IPR systems in Japan and the U.S. fully recognize and offer robust, comprehensive protection for next generation medical devices associated with innovative therapies, such as gene, stem-cell, regenerative therapies, etc.

Section II: Maintaining Workforce Health and Productivity, Reducing Economic Burdens of Diseases, and Extending Healthy Life Expectancy

2. Promote Preventive Care and Health and Productivity Management

The Councils recommend that both governments advance ongoing health policy reform discussions of on preventive care and wellbeing promotion. Such policies, once properly developed and implemented, could help mitigate healthcare-related economic challenges in both countries.

Specifically, the Councils offer the following suggestions to Japan and U.S. government policy makers:

- Collaborate with healthcare professionals to develop public education programs on preventive health measures, including programs to improve awareness on vaccinations, early diagnosis of disease, and slowing disease progression. Such programs should also include education on possible treatment options when relevant.
- Accelerate Japan's vaccine policy reform efforts through increased collaboration between government, industry, academia, medical societies and patient advocacy organization to promote sustainable vaccination programs.
- Speed efforts to recognize the health benefits of functional foods, such as health foods and dietary supplements.
- A systematic Process Management and encouraging behavioral change of employees for improving their quality of life is needed for the organizations to strengthen Health and Productivity Management. The Councils thus recommend both governments to set up a strategic planning committee or taskforce of Healthcare Society, and encourage international standardization and possible disclosure system.

3. Healthcare System Efficiency

- Health Management should be based on clinical value and clinical outcome, not solely on frequency or numbers of clinical measures in Japan.. To make an effective universal coverage healthcare system like Japan's sustainable, able to account for various innovative products and services to be provided within the system, evaluation standards for healthcare expenditures should be evolved from volume-based to value- and outcome-based calculations. The Councils support the initiatives proposed by the "Next Generation Healthcare Information and Communication and Technologies(ICT)" Infrastructure Council in Japan, which promotes the use of real-world data (RWD) through ICT databases for disease prevention, evaluation of health technologies, and to foster research & development.
- Incentive models should be built to facilitate ICT investment through medical and long-term care funding and reimbursement. Advanced medical technologies and innovative approaches, such as remote healthcare service (Tele-Health), should be utilized to reduce the physical and economic burdens created by chronic and terminal illness. A community-based approach should be adopted that educates patients and their families on resources available from both private and public providers. Well defined and transparent insurance models should be promoted that enables patients to receive

consistent, high-quality care as they transition from hospitals and other skilled nursing facilities to their homes.

- Regulatory evaluation criteria and reimbursement rules specific to medical devices used at home should be developed.
- It should be acknowledged that the foreign caregivers are an essential component of sustainable community-based care system, providing training and certification programs to accelerate recruitment of foreign caregivers.

4. Global Leadership

The Councils recommend the U.S. and Japanese governments continue to collaborate on improving health and welfare globally (and in particular in the Asia Pacific Region) to lay a strong foundation for sustainable economic growth and greater international trade. This continued collaboration allows both countries to lead healthcare promotion and reform initiatives not only in APEC markets, but also in other emerging regions and countries.

- Recognizing the leading contributions by the U.S. and Japan to providing biomedical innovation to the rest of the world, they should collaborate to ensure that regulatory review and approvals in other countries, particularly in leading emerging markets, are conducted in a transparent, fair, and expeditious manner.
- Collaborate on the adoption of codes of ethics based on APEC Kuala Lumpur Principles for medical devices Declaration of Helsinki as well as the Mexico City Principles for biopharmaceutical industry. The Councils support collaborative global health initiatives such as “U.S.-Japan Cooperation for a More Prosperous and Stable World,” “G7 Ise-Shima Vision for Global Health” as well as APEC “Healthy Asia Pacific 2020” vision. The Councils welcome the positive trend of strengthening collaboration among industry, governments, academia and global organizations to effectively prevent and control global crisis and develop sustainable and high performing health systems. The Councils will contribute by actively investing in R&D and voluntarily supply necessary medicines during pandemic outbreaks.
- Request Japan and U.S. to take leadership in accelerating the research, and development of and access to innovative therapies for rare, pediatric and infectious diseases in APEC markets, by creating an incentive mechanism for the creation of cross-border, seamless-innovation platforms, consisting of a seed database and patient registry using real world data, where industry, academia and government can collaborate closely for drug discovery and development.
- Request that US and Japan partner effectively to advance Digital Health, recognize their leading role in the development of cutting-edge medical and digital technologies
- Health and social care policy reforms in Japan to address the challenges of and support a super-aging society (with the smaller birth rate) could provide the global standard to drive healthcare system reforms in other countries in the world. Collaboration between the Japanese and U.S. governments to implement ideal measures to challenge these issues should become best practices in other Asia Pacific regions, which will eventually face similar situations in the future.

Supplement on Energy
54th Japan-U.S. Business Conference
The U.S.-Japan Business Council / Japan-U.S. Business Council
November 3, 2017

Current Situation and Common Challenges Related to Energy

1. The U.S.-Japan Business Council and the Japan-U.S. Business Council (hereafter referred to as “the Councils”) agree that recent cooperation and dialogue between Japan and the U.S. has made significant progress. Not only has cooperation intensified in oil and natural gas, power-generation systems and nuclear policies, it has converged in the areas of cyber security, basic research in energy and the environment, energy efficiency and micro-grids. This cooperation lays the foundation for facing challenges such as global warming while contributing to a prosperous, peaceful and safe Asia-Pacific region.
2. The Councils aim to discover new opportunities for business cooperation between Japan and the U.S. by understanding and assessing the potential direction of both countries’ energy policies through Private-Private and Public-Private dialogue. The Councils applaud the meeting between Mr. Rick Perry, United States Secretary of Energy and the Japan-U.S. Business Council in June as a successful example of this Public-Private dialogue and fully agree with his remarks emphasizing the importance of the U.S. - Japan cooperation in the energy field. Furthermore, the Councils believe that energy and environmental challenges are closely linked to the national security of both nations, and that identifying resolutions to these problems now will enhance the economic relationship between Japan and the U.S.
3. A revolution in U.S. shale and Liquefied Natural Gas (LNG) production is a recent, significant change to the global energy environment and has transformed the U.S. from a net-importer of energy resources to a net-exporter. This revolution has the potential to yield important opportunities for Japan, which does not have enough energy resources to meet domestic demand, by providing access to additional energy sources and diversifying its energy mix. There are also important opportunities for the U.S. as well, such as the jobs created from continued investment by Japanese companies in industrial infrastructure including LNG liquefaction and storage facilities, and LNG carriers. The Councils agree that further cooperation in developing the Asian LNG market by both countries will lead to expanded business activities and contribute to strengthening energy security in the region.
4. The Councils recognize that there is a growing awareness and desire among both countries’ populations for a sustainable society capable of growth and consumption that minimizes harm to the environment. The historical leap in economic productivity

and growth that accompanied the Industrial Revolution was powered by an accelerating cycle of fossil fuel production and consumption, especially in oil and coal. However, more efficient consumption of these fossil resources, as well as further innovation in renewable energy technologies, will be required to mitigate the economic impacts of future price fluctuations, resource depletion and global warming.

5. Both countries' Governments and private sectors recognized early on the need for economically and environmentally sustainable energy sources, and enthusiastically promoted nuclear power as a low emitter of green-house gases, as well as carbon-reduction technologies for the use of coal and oil. Both countries have cooperated in research of renewable energy sources and energy conservation, and led technological innovation of high efficiency power systems utilizing natural gas, the cleanest of the fossil fuels. The U.S. continues to lead innovation in shale gas and oil drilling technologies, which provides an important opportunity to diversify Japan's energy sources which remain largely dependent on Middle Eastern exports. It also provides an opportunity to provide cheaper gas to emerging Asian countries, and reduce resource volatility.

Mutual Cooperation for Energy Diversification

6. The Councils agree that a balanced energy allocation (energy mix) is an important component of both Japanese and the U.S. energy security, and encourages both governments to promote policies aimed at achieving a sustainable, stable and reliable energy portfolio.
7. For Japan, imported energy choices, diversification of sources, technological innovation and security of maritime transportation routes are important factors for achieving economic goals. These goals, as articulated in Abenomics, keep growth strategies on track and are essential for contributing to international countermeasures against global warming.
8. The Councils agree that natural gas will remain an important energy resource for Japan and the U.S., but for different domestic reasons. Investment by both countries in large infrastructure projects for natural gas production, storage and shipping will create additional employment opportunities in the U.S. while providing valuable experience to the professional workforces of both countries as this field is pioneered.
9. As a result of continued shale gas development in the U.S., Japanese companies are investing heavily in the infrastructure required to transport LNG to Japan and the Asia region, including construction of production-bases, transportation and storage facilities. These investments have made remarkable contributions to the U.S. economy in terms of growth and employment, and have further promoted the benefits of Japan-U.S. cooperation in energy infrastructure development.

Mutual Cooperation in Nuclear Energy

10. The Councils acknowledge that the Great East Japan earthquake in March, 2011 was a historical turning point for Japanese energy policy as it brought to the national consciousness the need to mitigate future vulnerabilities in power generation infrastructure.
11. The Councils observed that shale gas development in the U.S. and the falling costs of renewable energy sources have resulted in a current decline in demand for new nuclear power generation plant construction. With fewer nuclear power generation facilities coming on-line, there is a lower demand for highly skilled, competent technicians, engineers and other professionals entering the workforce. Fewer professionals entering the field of nuclear energy technology risks loss of institutional knowledge, decline of the nuclear energy industry writ large, and the ultimate loss of an economically viable source of low-emission energy.
12. The Councils agree that the governments and private-sectors of the U.S. and Japan must engage in regular dialogue to ensure mutual understanding of each other's security and economic environments. The Councils are in agreement that a mutual cooperation system would facilitate the development and exchange of nuclear energy generation technology and contribute to both countries' energy security. The Councils also agree that commercialization and research of advanced nuclear reactors (including small modular reactors or SMRs) is worth noting as a potentially safer and lower-cost nuclear reactor.
13. The Councils agree that the Japan-United States Agreement for Peaceful Nuclear Cooperation is the bedrock for continued cooperation and technological exchange between the U.S. and Japan in the nuclear energy industry. The Councils welcome the Statement of Intent signed by both governments which desire to strengthen the special bond between two nations through greater industrial cooperation. The Councils encourage both governments to continue to cooperate in important projects such as decommissioning work in Fukushima Daiichi.

Challenges to U.S.-Japan Energy Cooperation

14. **Oil.** Although the U.S. energy industry has benefited from public-private cooperation and innovation in oil shale, there is concern on the Councils that the consequent reduction in oil prices will discourage future investment in U.S. energy development.
15. **Coal.** The U.S. government has recently supported attempts to revive the declining coal industry by promoting it as an abundant, cheap energy source that has lower environmental impacts than in the past due to clean-coal technologies such as Carbon

Capture and Storage (CCS).

16. In the states of Alabama and Texas, Japanese and U.S. companies are cooperating on ventures to store carbon harvested from CCS deep underground rather than the atmosphere. However, the cheap cost of coal as an energy source is offset by the high capital costs associated with CCS, making large-scale use of clean-coal technology currently viable in the U.S. market. Despite these high barrier costs to using CCS for coal-fired energy, the Councils believe the U.S. and Japan should continue development of this technology to make it more cost-effective and practical for large-scale use in Asia and beyond.
17. **Renewable Energy.** The Councils have identified several barriers to more widespread adoption of renewable energy technologies and techniques: (1) wide variance in types of renewable power sources; (2) cost competitiveness of development and use as compared to cheaper (fossil) sources; (3) geographical and social conditions of different nations/ societies. The Councils emphasize the importance of government's role in crafting appropriate legislation and educating consumers on the benefits of clean energy to encourage its acceptance.
18. Japan is readily adopting more renewable energy technologies and policies to achieve internationally recognized CO₂ emission goals. The Council encourages further cooperation between the public and private sectors on energy transportation, storage, smart-grid technologies and management of energy demand/response to reduce investment risks for banks and developers.

Benefits and Challenges of Innovative Technologies

19. The Councils agree that Artificial Intelligence (AI) and the Internet of Things (IoT) pose both significant opportunities and security challenges for energy collaboration between the U.S. and Japan. These technologies have spurred innovation in environmental friendly technologies while also reducing their implementation costs, making them more practical than ever for wide-spread, common use.
20. The Councils agree that anticipated leaps in innovation of AI and IoT technology, enabled by the digital economy, will make global warming countermeasures such as the Paris Agreement practical and achievable in the near future. The IoT, which networks physical devices to people and programs, will play an especially important role in eliminating excess CO₂ emissions and wasteful power consumption by vastly improving the efficient management of equipment use, electricity demand-supply functions and transportation.
21. Before 2014, use of fossil fuel in global and personal transportation remained one of the most difficult challenges in reducing global warming CO₂ emissions. The Councils agree that zero-emission vehicles such as electric cars, driverless vehicle technologies and an emergent sharing-economy (such as car sharing) hold great

potential for dramatically reducing environmental waste.

22. The Councils acknowledge that public-private collaboration for the achievement of a “hydrogen society”, which primarily focuses on fuel cell technology, has accelerated in Japan as a result of the approaching 2020 Tokyo Olympics. The Councils agree that successful cooperation between Japan and the U.S. is important to promote further innovation and investment in hydrogen energy so as to rapidly realize the economic benefits of this technology.
23. The Councils encourage the governments of both countries to support continued investment, research, development and integration of these technologies, to include required infrastructure, so that they can be leveraged in high-end manufacturing, robotics, big-data, energy network security and the efficient management of electrical grids and energy consumption.

Mutual Cooperation in Energy Conservation

24. The Councils acknowledge that energy conservation policies, and the degree to which they are implemented in our two countries, depends on the unique national character, social circumstances, cultural background and resources of each. Because Japan has managed a shortage of energy sources for decades, the Japanese society, government and economy place a high value on Conservation practices, technologies and innovation. The Councils agree that there are opportunities for the U.S.-Japan public and private sectors to exchange best-practices in Conservation standards, public relations and implementation, and thus encourage the U.S. and Japanese governments to support continued dialogue promoting Energy Conservation policies that support sustainable economic growth.
25. The Councils agree that energy efficiency standards should be an integral part of new commercial and residential building and appliance design to ensure resources are used in a sustainable way. Improved standards for commercial and residential structures will not only promote a high quality of life, but will reduce overall energy consumption in absolute terms, reduce the environmental impact of fossil consumption from CO2 emissions, and improve the energy security for both countries. The Councils also agree that policies must balance the medium and long-term operational costs of higher efficiency standards with appropriate investment incentives to make them practical and scalable.

Supplement on Travel, Tourism and Transportation
54th Japan-U.S. Business Conference
The U.S.-Japan Business Council/ Japan-U.S. Business Council
November 3, 2017

The U.S.-Japan Business Council and Japan-U.S. Business Council (hereinafter “the Councils”) have long believed that travel between the United States and Japan facilitates cultural understanding and the exchange of ideas, and thus underpins the strength of the U.S.-Japan relationship. The Councils established a Travel and Tourism Committee (“the Committee”) in 2014 with the twin objectives of expanding and deepening U.S.-Japan exchanges, and supporting measures to enhance the economic benefits from travel and tourism.

Since the Committee’s creation, there has been growing discussion about the importance of transportation infrastructure in increasing travel and tourism, including in providing better access to airports and in enhancing the experience of international travelers. In order to more accurately reflect the Committee’s interest in these areas, and to facilitate discussion on opportunities for growth associated with a robust transportation system, infrastructure, and new technologies, the Councils this year have decided to update the Committee name to “Committee on Travel, Tourism and Transportation.”

Measures to boost growth in the travel, tourism and transportation industries

Travel and tourism have long been key drivers of the U.S. economy, and recognition in Japan of the industry as an important engine of growth is steadily increasing. Prime Minister Shinzo Abe has set a GDP target of 600 trillion yen by 2020, and has identified success in the travel and tourism sector as key to achieving that goal. At the end of 2015, Prime Minister Abe set forth a comprehensive policy intended to increase tourism, and the Committee has received helpful updates from the Government of Japan on implementation of these initiatives.

Japan has seen extraordinary growth in travel and tourism in recent years. In 2011, eight million people visited Japan; by 2016 that figure had grown to 24 million; and 2017 is on track to surpass even that. The Japanese government is aiming for 40 million foreign visitors by 2020—the year of the Tokyo Olympic and Paralympic Games—which it hopes will generate 8 trillion yen. The Abe government has set an even more ambitious target for 2030: 60 million tourists contributing 15 trillion yen to the Japanese economy.

The Committee commends the positive steps taken by the Japanese government that have facilitated this remarkable growth, but notes that additional progress needs to be made. Easing visa regulations and expanding the network of airline routes have made travel easier and more attractive to visitors to Japan. However, issues such as limited landing slots at airports, congestion in immigration processing areas, inconvenient airport

access, limited availability of MICE (Meeting, Incentives, Conference and Exhibition) facilities, and limited multi-language services still need to be addressed. Similarly, a shortage of hotels have encouraged a flood of informal guest houses, which has on occasion resulted in frustrated visitors. The Committee thus welcomes the Government of Japan's continued focus on implementing the "Tourism Strategy to Invigorate the Japanese Economy" which it announced in 2015, and encourages particular attention to these areas where improvements are needed as the Games approach. The Committee recognizes that similar challenges—congestion in immigration processing areas, and road and airport infrastructure in need of repair—exist in the United States and advocates further discussion on those issues, as well. Public-private sector cooperation could provide additional momentum to this effort, and the Committee encourages further discussion on this possibility.

Looking beyond tourism, growth in international cargo transportation provides another opportunity to positively contribute to the U.S. and Japanese economies. A strong system for ensuring the efficient international transportation of goods will be critical to ensure secure and efficient supply chains, and in turn support the manufacturing aspirations of both countries. The Councils encourage both governments to continue to take leading roles in setting international rules and standards that would achieve these security and efficiency goals. Amid an increase in tourism and cargo traffic, the Councils also strongly encourage the Japanese and U.S. governments to support policies designed to jumpstart and sustain technological innovations that would enable growth in these important sectors. Innovative ideas such as connected cars or autonomous vehicles, drone delivery systems, the effective use of big data analytics to increase efficiencies in transportation systems, multi-language translation tools, and face authentication security systems hold promise, and could help mitigate existing impediments to international tourism or cargo transportation.

From the 2020 Tokyo Olympics/Paralympics to the 2028 Olympics/Paralympics in Los Angeles

The Councils believe that the 2020 Tokyo and 2028 Los Angeles Olympic/Paralympic Games can spur further economic growth, and the Committee held good discussions on how to capitalize on the opportunities the Games provide. The Councils see promising ways in which private companies in Japan and the United States can support the Games to make them a success. In light of the overall objective of the Committee to stimulate exchange between our two countries, the Councils seek to promote the values of the Olympics and Paralympics, namely diversity and respect for other peoples. The Games provide an opportunity to make infrastructure improvements that increase accessibility to all people. The Councils believe that a more "barrier-free" environment—that is inclusive of physical disabilities, and diverse languages and cultures—will showcase Tokyo as a true global and metropolitan city and serve to fuel tourism. We are confident that the Games will be a great success for Japan and will serve to demonstrate the warm hospitality that Japan has to offer, and hope that the positive legacy created in Tokyo will be passed on to Paris in 2024 and to Los Angeles in 2028.

The potential of IR for sustainable economic growth

Last year, the Committee asked the British think tank Oxford Economics to assess the economic effects of an expansion of Integrated Resorts (IR) that incorporate MICE facilities. The Oxford Economics report projected that authorizing IR in Japan would increase the number of foreign visitors by 4.9 million per year, and would boost Japan's overall economic growth. Specifically, the report projected that if an IR facility were to be built in both Tokyo and Osaka, it would result in raising Japan's GDP by 0.46 percent, creating 180,000 direct and indirect jobs and generating consumption worth 3.8 trillion yen.

In December 2016, Japan enacted the Act on Promoting Development of Areas for Specified Integrated Resort Facilities. In March 2017, the government set up an implementation team under the supervision of Prime Minister Abe to begin preparation for the creation of IR facilities. Both Councils recognize the importance of addressing public concern about IR resorts, and of continued efforts to enhance public understanding. As Japan considers appropriate regulations, the Councils encourage the Japanese government to address public concerns about gambling addiction and other issues, while maintaining the positive potential IR has for tourism and investment for the Japanese economy. Toward this end, the Councils hosted two very productive workshops this year for Japanese stakeholders. Both Councils will continue to work closely with the Japanese government so as to share global lessons learned from the experiences of integrated resorts in other countries.

Supplement on Digital Economy
Enabling the Potential of the Digital Economy
54th Japan-U.S. Business Conference
The U.S.-Japan Business Council / Japan-U.S. Business Council
November 3, 2017

The U.S.-Japan Business Council and Japan-U.S. Business Council (the Councils) see tremendous opportunity surrounding the digital economy, and hope to see the United States and Japan continue to lead the international community in its development. We applaud both governments for the focus they are bringing to digital economy-related issues, support the governments' efforts to share best practices with other countries and regions, and hope for increased dialogues between the U.S., Japan, and others.

To this end, we urge the governments to prioritize the following forward looking public policies related to data and personal information, intellectual property, and the promotion of international standards and best practices related to privacy, cybersecurity, and technical interoperability.

1) Design public policies that will enable new and transformative technologies to benefit society broadly:

The Councils recognize the potential of new technologies, including those linked to Artificial Intelligence (AI) and the sharing economy. We encourage the two governments to continue to welcome these new technologies for their potential economic benefits, and discourage burdensome regulations that might kill new technologies in their infancy. With that said, the Councils recognize that the economic benefits of such technologies may not necessarily be distributed evenly across society, and that certain technologies may affect the labor market in unintended ways.

However, as history has shown us, technological developments have often improved the livelihoods of people. The Councils believe well-designed economic incentives and appropriate public policy can help shape a positive direction for technological change, helping to improve productivity, create higher levels of employment, promote and inclusive growth. To this end, the Councils encourage the two governments to 1) invest in and develop new technologies; 2) educate and train citizens for the jobs of the future; and 3) carefully consider how to best empower workers during the transition to a more automated, digital economy.

2) Establish a safe and secure environment for the use of data and its free movement across borders and avoid data localization mandates:

Given the growing importance of cloud computing and cross border data flows, the U.S. and Japan should work to establish a safe and secure environment for the use of data that serves as a basis for corporate activity without restrictions on locality. The seamless exchange of data across borders and internationally harmonized rules on the protection of personal information will facilitate growth of the digital economy on a global scale. As the two governments consider approaches to address critical privacy and security challenges, it is essential that any such requirements are not made overly prescriptive or one-size-fits-all, do not create barriers to cross-border data flows, and avoid data localization mandates. The Councils ask that the governments be proactive in reinforcing the idea that privacy protection is in no way linked to the physical location of servers or stored data.

To this end, the Councils applaud the leadership demonstrated by the U.S. and Japan with regards to cloud computing. We encourage the two governments to advocate that governments avoid requiring network or data separation for all public institutions utilizing cloud services, thus requiring companies to create separate intranets for these institutions. This approach not only undermines the efficiencies of cloud computing, but makes it prohibitively expensive for companies to build the required physical servers in jurisdictions that cannot leverage the economies of scale of an international infrastructure. This will ultimately deter cloud computing technologies from becoming ubiquitous, and prevent the benefits of the technology from being leveraged on a global scale.

Further, the Councils emphasize the need for a harmonized regulatory framework across all levels of government in both countries, and encourage frequent regulator-to-regulator dialogues between the U.S. and Japanese governments to help achieve this objective. The Councils believe that contradictory and scattered regulations decrease business efficiencies, increase compliance costs, and ultimately impede the development and adoption of new technologies and the growth of the digital economy at large. The need for harmonization is particularly acute in the digital economy, where business models and data flows often fall under the mandates of multiple regulators.

3) Promote internationally harmonized rules and best practices for the protection of personal information:

The Councils applaud the U.S. and Japan for their continued leadership in the promotion of internationally harmonized rules and best practices for the protection of personal information, and in particular in their continued promotion of these ideals

through the APEC Cross Border Privacy Rules system (APEC CBPR). In the absence of the cutting edge rules for digital trade, privacy, and cross-border data flows agreed upon under the Trans Pacific Partnership, the APEC CBPR has become one of the few multilateral tools that U.S. and Japanese companies have to ensure competitiveness in Asia's dynamic marketplace.

We welcome the recent discussions between APEC members and the European Union on interoperability between CBPR and the EU's General Data Protection Regulation (GDPR). We urge the U.S. and Japan to continue to lead in creating a future work plan, particularly as Japan and the EU work towards mutual adequacy decisions on international data transfers. There is great room for U.S.-Japan collaboration in spreading such rules and practices throughout the Asia-Pacific through trade agreements, APEC processes, and other platforms. We urge the governments to identify such opportunities in concert with the private sector.

Similarly, The Councils are encouraged by Japan's continued efforts to pursue the cutting edge rules for digital trade, privacy, and cross-border data flows agreed upon under the Trans Pacific Partnership, and hopeful that Japan will continue to promote these high-standards on a regional and global scale.

4) Prioritize connectivity and the further development of digital infrastructure:

The Councils urge the two governments to continue to prioritize the development of digital infrastructure that will be required for future growth, and the realization of the benefits associated with "the 4th Industrial Revolution" or "Society 5.0". We encourage the two governments to continue efforts to facilitate international payments and transactions and make the Internet a truly seamless commercial platform, and importantly to prioritize connectivity. The Councils believe the deployment of ultrahigh-speed Internet Protocol networks will be a critical component to the development of the digital economy, and importantly serve as a "backbone" to some of the most promising technologies of the future.

5) Protect Intellectual Property:

Protection and enforcement of intellectual property rights remain the foundation of innovation and are key to the realization of the potential of the digital economy. The Councils encourage regular consultation between the two governments and the private sectors to ensure that intellectual property protection laws and regulations adequately support and protect existing rights, as well as the new ideas and business models that will emerge from ICT technologies.

Further, the Councils consider proper and legal usage of intellectual property essential for economic growth, and urge both governments to promote balanced policies of protection and usage of IP. The Councils believe that security requirements should not mandate forced technology transfer or review of IP such as source code. Such IP is business proprietary information that is essential to a company's ability to innovate and remain economically competitive. These requirements are problematic for ICT firms that (i) are already struggling to protect their intellectual property, and (ii) may have licensing obligations that preclude the disclosure of such code to customers in other countries who would be deeply concerned about possible security issues if a foreign government is given access to the code. Trade-inhibiting security reviews for ICT products and services may not only weaken security and constitute technical barriers to trade as defined by the WTO, but also reduce incentives to innovate.

6) Avoid country-specific regulations or requirements and develop voluntary, industry-led, and consensus-driven standards:

The Councils are concerned with the increase in country-specific government mandates relating to the digital economy – including privacy and cybersecurity requirements, technical standards, and interoperability. We believe such policies hinder U.S. and Japanese firms' ability to operate in external markets, limit the positive effects of competition, and are a substantial obstacle to the full realization of the digital economy's transformative potential. In contrast, technologies built on global standards combined with globally consistent regulations can boost innovation and competition, and will ultimately improve the lives of consumers across the globe.

The Councils also emphasize the importance of voluntary, industry-led, and consensus-driven standards developed through transparent and impartial processes, and focused on market-driven outcomes. A competitive environment that uses technology neutral frameworks will allow the digital economy to be leveraged in the most efficient manner, and will help prevent competition policy from being used to achieve industrial policy goals.

The Councils believe that the role of government should be to 1) encourage the development and adoption of standards related to the digital economy and emerging connected technologies, 2) foster interoperability in an open and transparent manner, and 3) participate in the standards setting process as a convener, trusted expert, and major purchaser and implementer of standards, but avoid "picking winners".

7) Increase U.S.-Japan collaboration on cybersecurity in international fora:

Given the nature of cyber threats, the Councils reaffirm their support for globally-aligned approaches to cybersecurity that advance cybersecurity and keep pace with the constant evolution of cyber threats. In international fora, the Councils encourage the U.S. and Japanese governments to:

- 1) Promote a flexible, innovation-enabling approach to cybersecurity;
- 2) Harness the convening power of government to increase public-private collaboration;
- 3) Prioritize risk management as the basis for enhancing cybersecurity;
- 4) Utilize international standards to enable the deployment of best-in-class approaches to cybersecurity across borders; and
- 5) Embrace opportunities for international cooperation and coordination.

7.2) Encourage cyber threat information sharing to increase cyber resilience:

The Councils recognize the potential for cyber threat information sharing to increase cyber resilience in the U.S. and Japan, by providing advanced warning of potential threats and their characteristics. Given that critical infrastructure is often operated by private entities, it is critical that they be incorporated into information sharing initiatives. The Councils encourage the U.S. and Japanese governments to:

- 1) Employ international information sharing standards and protocols;
- 2) Implement sufficient liability protections for companies who share threat information;
- 3) Provide incentives for companies to expand engagement in information sharing entities; and
- 4) Be transparent and conservative about how information shared with government entities can be used by law enforcement agencies.

7.3) Promote cybersecurity in the Internet of Things (IoT):

With 20 billion connected devices estimated to be in use by 2020, the Councils recognize the importance of cybersecurity of such devices in preventing large scale attacks. Regulators should be cognizant, however, of the limitations of top-down regulation of IoT security and the need to avoid prescriptive solutions that hamper innovation. The Councils have adopted the following principles, which they encourage regulators to embrace:

- 1) Promote technical compatibility and interoperability, to ensure that political boundaries do not become obstacles to the movement of devices, data, or IoT-related services;

- 2) Leverage international standards to promote common approaches and solutions;
and
- 3) Encourage the development of richer interactions between devices and the network so that machine learning and automation can be leveraged to manage at the endpoints more effectively.