

**Joint Statement**  
**50<sup>th</sup> US-Japan Business Conference**  
**U.S.-Japan Business Council/Japan-U.S. Business Council**  
**November 14-15, 2013**  
**Washington DC**

The U.S.-Japan Business Council and Japan-U.S. Business Council (hereinafter, "the Councils") marked an important milestone with the 50<sup>th</sup> U.S.-Japan Business Conference held November 14-15, 2013. Meeting this year under the theme "Pacific Partners: Opportunities for Collaboration and Growth in the 21<sup>st</sup> Century," the 50<sup>th</sup> conference allowed members to reflect on the changes in the U.S.-Japan economic relationship over this time, and to envision the next 50 years.

The Councils acknowledged the improvement in the tone and substance of the conference and our economic relationship over the years: from serious tensions over market access and trade deficits throughout the 1970s, 1980s and 1990s, to the much more positive tone and constructive approach in recent conferences. Indeed, the Councils come away from the 50<sup>th</sup> Conference assured of the increasingly close and cooperative economic ties between our countries and the many opportunities to expand the commercial dimensions of our bilateral relationship in ways that will strengthen the overall U.S.-Japan alliance and contribute to sustained growth in both countries.

The Councils look forward to working closely with each other, and our respective governments, in the areas outlined below for the mutual benefit of our respective member companies and the U.S. and Japanese economies. Given the changes in the global business environment and corporate dynamics, the Councils also pledge to work together to refine and enhance our bilateral activities in order to maximize our ability to fulfill this mission.

**U.S. and Japanese Economic Growth and Key Issues**

With emerging economies in a decelerating trend and the Eurozone emerging slowly and unevenly from recession, there are heightened expectations for the U.S. and Japan to become the leading force in the world economy. The U.S. and Japanese economies have recovered moderately and the most extreme risks seem to have passed, but the Councils recognize there are vulnerabilities in each country and, by extension, the global economy.

## Fiscal and Monetary Policy Challenges

In particular, the Councils have concerns with fiscal and monetary policy challenges of the United States and Japan, which pose some downside risks to the world economic outlook.

- First, understanding that the balance between fiscal consolidation and growth policy is important and delicate, the Councils urge both governments to establish credible medium- and long-term fiscal plans that are implemented gradually in ways that will stabilize the global financial system. The Councils strongly urge the U.S. Congress and administration to take into account the unsettling effect the recent debt ceiling extension had on global markets and confidence in the United States as an investment destination and avoid similar situations in the future.
- Second, the process of scaling back quantitative easing (QE), or “Tapering”, could lead to a sharp increase in long-term interest rates and excess volatility in the global financial and capital markets. The Councils urge both central banks, especially the Federal Reserve Board, to ensure effective communication on the exit strategy and a careful calibration of its timing and pace. The Bank of Japan’s quantitative easing policy is proving effective in reversing deflationary trends and stimulating domestic demand, as intended, and should be continued for the near term. It is the Councils’ view that this policy does not constitute currency manipulation, but is similar to what the Federal Reserve and other central banks have done to support domestic recovery and price stability, a position taken repeatedly by the G-7.

In addition to careful macroeconomic management, both countries need to move forward with bold and aggressive micro policies that will stimulate greater investment and business expansion that leads to job creation and higher household incomes.

## United States

The Councils urge the Obama administration and U.S. Congress to move forward on the following measures:

- Market-based measures to support domestic energy production, particularly by taking full advantage of new discoveries of shale oil and gas.
- Regulatory reforms that reduce administrative and cost burdens and provide regulatory certainty for businesses.

- Tax reforms that lower the statutory U.S. corporate tax rate to OECD norms over time.

#### Japan: Launching the Third Arrow

The Councils commend and support the Abe government's broad economic policy framework, dubbed Abenomics, encompassing bold monetary easing policy, flexible fiscal policy, and "Third Arrow" growth measures. In light of macro constraints, the Councils agree that the critical element for achieving sustainable long-term growth is bold regulatory and structural reforms to spur private investment and private sector-led growth, including in critical sectors such as agriculture, health care, ICT, and travel and tourism. To this end, the Councils urge the Abe government to initiate and implement Third Arrow measures including agricultural reforms, labor market reforms, tax reforms that lower the corporate tax rate to the OECD average and, especially, regulatory reforms that reduce administrative and cost burdens and provide regulatory certainty for businesses.

#### Foreign Direct Investment

The Councils stress the importance of foreign direct investment (FDI) as a critical source of economic growth and employment in both countries. The USJBC has emphasized to Congress and other stakeholders the strong and positive contribution Japanese investment makes to the U.S. economy in terms of output, employment, tax revenue and trade, and encourages more investment by Japanese companies in the United States through both Greenfield investment and Mergers & Acquisitions. The Councils welcome the new initiative by the Obama administration and Select USA to encourage and facilitate more FDI in the United States, but suggest that greater regulatory and policy certainty are essential for investment decisions.

The Councils continue to be concerned by the relatively low level of FDI in Japan (less than 4% of GDP), but are encouraged by the Abe government's recognition that Japan needs more of it to help stimulate economic growth and new employment. As the government formulates policies and measures to promote more FDI, it is important to note that sustained economic growth and bold regulatory and other economic reforms that create a truly business friendly environment are the most important factor to attract FDI in either country. Accordingly, the Councils urge the Government of Japan to move forward with bold reforms to improve the business environment, including through regulatory and legislative changes that create new investment opportunities for domestic and foreign companies and level the playing field for foreign investors. The Councils urge the Government of Japan to work closely with the private sector in identifying such opportunities and to move boldly to take advantage of them, particularly with the 2020 Tokyo Olympics in mind.

## **U.S.-Japan Trade and Economic Cooperation: TPP and other Initiatives**

There are many opportunities for the United States and Japan to support global and regional growth and prosperity by supporting expansion of trade and investment and establishment of high standards and rules for commerce. The Councils agree that the United States and Japan should play the leading roles in moving the world system to greater trade liberalization, cooperation and expansion as a means of boosting economic growth in both countries, and globally, and pledge to accelerate efforts to support this objective.

In particular, in the Councils' view, the United States and Japan can and should play leading roles in helping establish a rules-based, high-standard economic architecture for the Asia-Pacific region, with the establishment of a Free Trade Area of the Asia-Pacific (FTAAP) as the long-term goal.

### TPP

The Councils commend the Obama administration and the Abe government for moving boldly to bring Japan into the Trans-Pacific Partnership negotiations despite domestic industry and political opposition in both countries. Japan's entry into the negotiations is truly a game changing development that makes TPP more commercially significant for all parties, and provides a historic opportunity to strengthen the U.S.-Japan economic relationship and alliance.

As the largest and most sophisticated economies in the TPP negotiations, the U.S. and Japan have many common interests. The Councils therefore urge both governments to work closely to secure a comprehensive, high-standard agreement that will eliminate tariff and non-tariff barriers to trade in all manufactured and agricultural goods, services and investment while establishing new rules and disciplines in critical "21<sup>st</sup> Century" areas such as intellectual property, investment, competition/State-Owned Enterprises (SOEs), cross-border data movement, regulatory coherence and transparency, and supply chain and trade facilitation measures. TPP's impact will go far beyond the TPP itself. In light of other major multilateral and plurilateral trade negotiations also underway, it is particularly important that TPP establish high standards and strong rules that will serve as a template for these other initiatives so that trade in goods and services, as well as investment, will continue to grow in the coming decades.

Given the substantial immediate and longer term benefits to be achieved, the Councils urge the U. S. and Japanese governments to lead the TPP negotiations to a successful conclusion as soon as possible. The Councils support the objective to conclude negotiations by the end of 2013,

but agree that the timetable should not drive an outcome that does not meet the ambition and high standards envisioned and committed to by the leaders of the TPP partners in 2011. As the negotiations enter the final stages, it is particularly important that the United States and Japan demonstrate leadership by finding practicable solutions that establish high standard rules in 21<sup>st</sup> Century areas and, consistent with the commitment to a comprehensive agreement, improve market access through the elimination of tariffs on all goods, with flexibilities on timing as needed for a few products.

The parallel bilateral negotiations between Japan and the United States are an essential element of a strong overall TPP agreement that, in combination with the broader TPP negotiations, should produce significant and mutually beneficial improvements in the bilateral trade and investment relationship. Accordingly, it is important that these negotiations result in additional firm commitments and concrete measures to eliminate tariff and, especially, non-tariff measures in all areas outlined in the agreements between the U.S. and Japanese governments on April 12, 2013.

In line with the points above, the Councils pledge to work closely with each other and both governments to promote wider understanding of the importance of TPP to the U.S. and Japanese economies among legislators and other stakeholders in both countries.

#### Other Agreements

The United States and Japan should take strong leadership positions in driving various other multilateral or plurilateral negotiations such as the Information Technology Agreement II (ITA-2), APEC Environmental Goods and Services, Trade in Services Agreement (TISA), and Trade Facilitation agreement currently underway to successful conclusion in a timely manner. The overriding objective in all should be to eliminate tariff and non-tariff barriers to trade on as many products or services as possible, including through expansion of product coverage under the ITA-2 and APEC Environmental Goods & Services negotiations; eliminate chokeholds that drive up costs and create inefficiencies in moving goods; and establish new rules that facilitate 21<sup>st</sup> Century trade and investment.

#### **Global Energy and U.S.-Japan Cooperation**

The energy profiles of the United States and Japan have changed dramatically over the past few years. The United States has emerged as a leading producer of carbon fuels due to new discoveries and recovery methods for shale oil and gas. The shale revolution provides a significant competitive advantage to the U.S. economy that could, under the right policy

framework, contribute significantly to domestic growth and trade expansion. Combined with further development of renewable technologies and improvements in efficiency, the United States can potentially become a net exporter of energy in the years ahead.

Japan has been affected by the shutdown in nuclear electricity generation in the aftermath of the Tohoku disaster. Among other things, this has led to higher energy costs for corporate and household users and sharp increases in carbon fuel imports for thermal electric power generation. As Japan is at a critical point in determining its energy roadmap for the future, the Councils urge the government to work closely with the user groups including business and the energy industry in outlining an energy policy mix that will support economic growth, provide stable and affordable electricity for industrial and household users, and encourage development and use of new energy technologies. In the Councils' view, a stable, predictable and affordable electricity supply is an essential element for economic growth in the short and longer terms. To this end, it is important for Japan to continue its use of nuclear power as a source of electricity.

While there are many challenges posed by these developments, the Councils believe the United States and Japan have a historic opportunity to increase government and private sector cooperation in ways that will help meet them while ensuring sustainable and secure energy supplies for our economies and reducing adverse environmental impacts.

To maximize this opportunity, the Councils strongly urge the U.S. and Japanese governments to establish and institutionalize a comprehensive, high-level U.S.-Japan Strategic Energy Dialogue that would facilitate regular engagement between senior U.S. and Japanese government officials and business executives on a comprehensive range of energy issues. This dialogue should encompass policy, technological development and commercial application and opportunities in the major sectors of energy production, use and related technologies, including: carbon (oil, LNG, clean coal); renewables (solar, wind, geothermal, biomass, alternative fuels, batteries); demand management/efficiency (smart grid/meter, efficient building materials); and nuclear power with enhanced safety.

The Councils look forward to working with both governments to develop a timetable and agenda for the Strategic Energy Dialogue in the coming months, with a goal of holding the first Strategic Energy Dialogue in 2014.

## **Healthcare Innovation**

The pharmaceutical and medical device industries note the remarkable progress made over the past decade in developing a shared industry vision toward adoption of healthcare policies in both countries that support innovation and rapid adoption of leading pharmaceuticals and medical devices in the U.S. and Japan.

The Councils also emphasize that strong, globally competitive, innovation-based pharmaceutical, medical device and diagnostic industries are critical components of strong domestic economies in both countries, contributing significantly to R&D, employment, trade and tax revenue. Accordingly, the Councils applaud the both governments for recognizing the important role the health care sector plays in overall economic growth, and look forward to engaging with officials from relevant ministries on ways to support industry growth and development while improving overall patient care.

To this end, the Councils encourage the regulatory authorities in the U.S. and Japan to continue promoting fundamental policies that support industry innovation – such as R&D measures that facilitate and protect innovation, as well as expeditious regulatory review and approval process, transparent and predictable pricing and reimbursement procedures that take into account the high costs of innovation. The Councils welcome plans in the Japan Revitalization Strategy to establish a “control tower” function (Japanese version of NIH) in medical R&D to accelerate practical application of innovative medical technologies of potential benefit to patients worldwide.

The Councils also note the increasing importance of international trade to industry success. Given the sophistication of the U.S. and Japanese industries and relative transparency of the regulatory processes, the U.S. and Japan should work closely together in developing rules and practices in other countries that will support sound medical treatment. In particular, the Councils urge the U.S. and Japan to collaborate closely in the TPP negotiations to ensure the TPP agreement includes the strongest possible pharmaceutical IPR standards, as well as to ensure transparency and procedural fairness in other participating countries related to medical device and pharmaceutical reimbursement.

## **Financial Services**

The Councils stress that strong and transparent financial systems, capital markets and financial services sectors are essential to U.S., Japanese and global economic growth. Accordingly, the

Councils fully support regulatory reform to strengthen the global financial system, and our respective domestic systems.

However, the Councils remain concerned about the potential for unintended consequences of the current domestic and global regulatory reforms on financial and capital markets, which threaten to harm the sector's ability to fuel growth. In this new regulatory environment, the Councils believe that supervisory measures should be appropriate to attain appropriate supervisory objectives and not go beyond what is necessary to achieve those objectives. In this regard, it is especially important for regulators to take into account the fundamental differences between banking and insurance when setting regulatory structures and capital standards.

The Councils also worry about "the balkanization of regulation" - regulatory fragmentation across national jurisdictions, which will lead to greater ring-fencing of capital and liquidity, and reduce efficiencies and systemic resilience of the global financial system. In this context, the Councils call on both governments to continue working through the G20, the Financial Stability Board or other global standards-setting bodies, while ensuring transparency and accountability of duly elected leaders, to strengthen the current framework of global economic governance for pursuing the strong, sustainable and balanced expansion of the global economy. Furthermore, the Councils urge both governments to cautiously monitor the cumulative impact of regulation and to enhance cross-border cooperation and coordination among global regulators, in order to promote greater international regulatory consistency avoiding extraterritorial application.



SUPPLEMENT on HEALTHCARE INNOVATION  
Visionary Goals and Recommendations  
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The R&D-based pharmaceutical and medical device industries continue to play a constructive role in improving the health and welfare of people in both countries, including by driving economic growth and job creation, as well as developing innovative healthcare solutions that support the lengthening of the average healthy lifespan and reduction of the economic burden of disease. Accordingly, the U.S.-Japan Business Council and Japan-U.S. Business Council (Councils) ask both governments to implement healthcare policies that embody the following visionary goals. The Councils recognize and welcome that progress has been made over the last several years, and offer the following specific recommendations under each visionary goal as a means to advance such progress.

Section I: Pharmaceuticals and Medical Devices

1. R&D Process Visionary Goal - The U.S. and Japanese markets have R&D systems that facilitate collaboration across the private, academic and public sectors and allow for efficient translational, pre-clinical, and clinical development that spurs innovative R&D.

Pharmaceuticals and Medical Devices Recommendations

- Pursue and support policies that reduce the barriers between the private, academic and public sectors for collaboration globally.
- Build on Japan's new strategy for global health diplomacy such as by continuing to collaborate through public-private partnerships (PPP) that contribute to and promote R&D related to global health issues.
- Make permanent the upper limit of 30% to Japan's R&D tax credit system, and make permanent the R&D tax credit in the U.S., both of which have led to greater investment in R&D by bio-venture, pharmaceutical, medical device and diagnostic companies.

- Continue the high-level public-private health policy dialogue, or Taiwa," that allows for comprehensive consideration of R&D promotion in Japan by multiple ministries and agencies.
  - Activate clinical studies and clinical trials in Japan as outlined in the "Clinical Studies, Clinical Trial Activation Five-Year Plan 2012."
  - Invigorate the FDA's dialogue with the industry under the Critical Path Initiative.
  - Implement the Physician Payments Sunshine Act in the U.S. in a responsible way, so as to ensure physicians do not decide to cut off communication and drug development with opportunities with drug companies due to the risk of having a physician's Sunshine Act records misunderstood by the public.
  - The Councils encourage Japan to implement plans to create a single body to oversee all government-funding for applied and translational healthcare research that will act as a bridge between academic and commercial research efforts, including by:
    - Quickly empowering the new body with a strong management team that possesses expertise in a diverse range of fields (including not only science, but also IP, law, IT, ethics and new technology assessment);
    - Continuing with long-term investment in healthcare and to consider expanding investment in such research; and
    - Boldly focusing on key research areas that can be rapidly applied to healthcare innovation.
2. Regulatory Approvals Visionary Goal - The U.S. and Japanese markets have regulatory systems that are transparent, predictable, and efficient that foster simultaneous global development and result in first-in-world approvals through a minimization of country-specific requirements and maximization of international standards and common practices.

#### Pharmaceuticals and Medical Devices Recommendations

The Councils appreciate efforts by both governments to streamline drug and device approval processes, including through new goals outlined in the 2012 reauthorized drug and device user fee legislation in the U.S., as well as continued progress by PMDA toward reducing the pharmaceutical and medical device lags through productive pre-filing consultations and accelerated reviews. The Councils offer the following recommendations to build on this progress:

## Pharmaceuticals

- Further improve the expertise of PMDA reviewers, including in the areas of clinical research and practice as well as in new areas of medical specialization.
- Enhance Japan's coordination capacity in the "Tripartite" exercise with China and Korea to further facilitate the use of Asian clinical trial data as the basis of approvals.
- In the U.S. and in Japan, develop benefit/risk models that do not delay patient access.
- Implement PDUFA V smoothly in the U.S.
- Continue dialogue and cooperation between regulators in the U.S., Japan and the EU.

## Medical Devices

- In line with Japan's Five Year Medical Innovation Strategy and Japan's Revitalization Strategy, ensure adequate government funding to expand and enhance PMDA capabilities to reduce review times, particularly for improved and me-too devices.
  - Achieve the performance goals outlined in the revised U.S. Medical Device User Fee and Modernization Act.
  - Swiftly passing the proposed revisions to Japan's Pharmaceutical Affairs Law to allow for device-specific regulatory requirements.
  - Ensure continued PMDA-industry dialogue to review performance and discuss issues in the post-Action Program period.
  - Establish mutual recognition between the U.S. and Japan of quality management audit results.
  - Support FDA efforts to implement successfully the recently finalized UDI rule, and work with Japanese and U.S. regulators to promote harmonized UDI standards globally.
  - Partner with U.S. and Japanese regulators on ways to enhance quality through transparency and consistency of inspection standards processes.
3. Evaluation of Innovation Visionary Goal - The U.S. and Japanese markets have pricing and reimbursement systems that fully recognize the value of innovation in transparent, predictable and efficient processes that maximize patient access and physician choice as well as encourage innovative R&D.

#### Pharmaceuticals & Medical Devices Recommendations

- Ensure that if any new health technology assessment (HTA) or other pricing/reimbursement approach is introduced in Japan or in the U.S., it promotes innovation without restricting patient access of physician choice.

#### Pharmaceuticals

- The new Japanese pricing system pilot that provides for price stability over the life of the patent and/or exclusivity period makes the Japanese market more attractive. It should be made standard policy on April 1, 2014.
- Abolish the anti-innovative application of the “Special Re-pricing for Market Expansion Rule,” such as Domino-style price reductions for all other drugs with similar pharmacological modes of action but different safety and efficacy profiles.
- Ensure that the Foreign Price Adjustment rule continues to take into consideration the cost of global R&D and rewarding innovation.

#### Medical Devices

The Councils appreciate changes made during Japan’s 2012 price revisions to address the medical device lag and to encourage faster introduction of new and improved devices. Moving forward, the Councils offer the following recommendations to spur innovation in Japan and the U.S.:

- Eliminate Japan’s FAP rule and transition to a product-based, market-oriented pricing system that allows for the full evaluation of innovative medical technologies and enables Japan to effectively execute its Five Year Medical Innovation Strategy.
- Reform the functional categories system to allow for multiple reimbursement prices within each functional category that would better reflect differences in innovation and service levels.
- In line with Japan’s Five Year Medical Innovation Strategy, ensure, at a minimum, that reimbursement policies implemented for the 2014 – 2016 period facilitate a stable and predictable environment that encourages investment in the medical device sector.
- Repeal the U.S. “Medical Device Excise Tax” that took effect in 2013 as part of the Affordable Care Act (ObamaCare), so that it will not undermine the industry’s efforts to develop innovative products and therapies.

4. IPR Protection Visionary Goal - The U.S. and Japanese markets have Intellectual Property Rights (IPR) systems that fully provide protections for inventions and data as well as transparent, predictable and effective means of enforcement and redress to ensure full protection of innovators rights and spur further innovations. From March 16, 2013, the U.S. will implement a first-to-file system which will result in better harmonization of the U.S. and Japanese patent systems.

#### Pharmaceutical Recommendations

- Adopt a 12-year period of data protection for biologics in Japan.
  - Extend the data exclusivity period in the U.S to 8 years (and 10 years for orphan drugs) for small molecules.
  - Implement 12-years of data protection for biologics in the U.S.
5. U.S.-Japan Regulatory Cooperation Visionary Goal: The U.S. and Japanese regulatory authorities further collaborate on joint projects, including by engaging in candid and positive discussions on the basic principles and framework for health care regulations.

#### **Pharmaceuticals and Medical Devices Recommendations**

- Cooperate to promote IPR, including data protection periods, and greater transparency in medical product pricing regimes in other markets through high standard trade agreements, such as TPP.
- Collaborate in APEC to improve the environment for US and Japan medical product exports to Asia Pacific countries by promoting regulatory convergence; strengthening medical sector codes of conduct; promoting collaboration to reduce the economic burden of disease; combating counterfeit medical products; and improving the investment environments for life sciences.
- Cooperate in the World Trade Organization to eliminate tariffs on all medical devices and drugs.

#### Section II: Preventative Medicine and Diagnostics

1. Vaccine Policy Visionary Goal: The U.S. and Japanese government officials should have clear, insightful and aspirational national vaccine plans for Japan to

reduce "Vaccine Gap" in Japan and accelerate access to innovative and global standard vaccines for Japanese.

Recommendations:

With this vision in mind, the Councils respectfully recommend that the Government of Japan take the following steps: (1) Develop a holistic National Vaccine Plan and promote vaccination based on the plan; (2) Establish a clear process and criteria for National Immunization Program; (3) Support a Vaccine and Immunization Sub Council in order to accelerate implementation and execution of planned vaccine policy in a timely manner; (4) Establish a financing system for recommended vaccines that designates the federal government as a funding body of vaccination costs in order to promptly achieve uniform vaccination to those wishing to receive vaccines nationwide; (5) Establish adequate communication channels and/or systems to provide accurate, understandable and transparent information about value, efficacy and safety of vaccines to the public to enhance and secure informed vaccine decision-making; and (6) Implement a simplified national testing system to realize flexible vaccine supply.

2. Diagnostics Visionary Goal: The U.S. and Japan recognize the innovative medical diagnostic industry as an important driver of job and export growth, and support the use of innovative diagnostics for early diagnosis and treatment to improve patient Quality of Life and help extend the healthy lifespan of the population, and use pricing incentives for diagnostics to improve efficiency in health spending.

Recommendations

- 1) In line with this vision, the Councils urge the Government of Japan to take the following steps:
  - (A) Adopt an action program to increase the number of reviewers and accelerate reviews of innovative new IVD (in-vitro diagnostic) products by the PMDA (currently only 36% of products are reviewed within the target time of 6 months);
  - (B) Construct a streamlined and harmonized regulatory system for IVD as part of the planned Pharmaceutical Affairs Law revision;

(C) Continue efforts to create a robust regulatory pathway and reimbursement policy suitable for companion diagnostics; and  
(D) Provide pricing incentives for innovation by differentiating among reimbursement prices of various IVD products based on their relative value and quality, including potential for faster and more accurate diagnosis at point of care.

- 2) The governments of the U.S. and Japan 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.

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The Councils believe that a robust financial services sector, based on market principles, effective regulation, transparency, and strong global institutions is vital to achieving sustainable growth in both Japan and the U.S., as well as in the global economy. The financial system promotes sustainable economic growth not only through the development and strengthening of the financial services industry itself and the creation of jobs, but also through the industry's support of businesses and consumers. The Councils therefore urge both governments to adopt the following measures and principles, which the Councils believe will contribute to achieving a sound, robust, and well-regulated financial services sector in both countries that will serve the global economy well. These principles are all the more important now that both governments are part of a large, prolonged restructuring of the global financial regulatory regime through various international standards setting bodies.

■**Transparency:** 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 to the confidence that commercial entities require to make management and investment decisions, and is undeniably in the interests of consumers as well. In this regard, the Councils urge regulators in both countries to continue to expand the dialogue with the financial industry and consider views of market participants when crafting and implementing new regulations.

■**International Coordination and Regulatory Consistency:** The Councils are of the view that, as regulatory bodies implement a large array of new and globally significant regulations, it is crucial to harmonize this activity between jurisdictions in order to avoid fragmentation and higher costs to end users of financial services, which will slow economic growth.

When local conditions in any two jurisdictions call for variation in approaches to managing systemic risk, but regulators of those same jurisdictions seek to achieve similar outcomes, regulators of one jurisdiction should avoid applying rules on an extraterritorial basis. The Councils welcome the increased awareness and use among, notably, U.S. regulators of "substituted compliance" over the past year, particularly in the area of derivatives, an example of reaching similar regulatory goals without lowering standards, at least where Japan and the U.S. are concerned. The Councils encourage the continued use of this important tool with careful attention to timing of regulatory implementation. Moreover, the Councils urge regulators to streamline the rule making process between agencies within each jurisdiction, as well as with other jurisdictions, so as to achieve consistency of outcomes, which in turn will enhance the smooth functioning of a global financial marketplace.

Moreover, measures to ring fence the capital and liquidity of local entities (e.g. U.S. regulation on foreign banking organizations) lead to regulatory fragmentation across national jurisdictions



and thus pose the risk of decreasing the efficiency of the global financial system and reducing systemic resilience globally. Accordingly, the Councils urge regulators to promote greater international regulatory consistency through the development of effective resolution regimes based on strong mutual trust, so as to rebuild a resilient international financial system that benefits the global economy.

■**Assuring Liquid Financial Markets:** The Councils welcome the continued efforts by regulatory authorities, in the wake of the 2008 crisis, to shore up the global financial system through the overhaul of the regulatory system currently underway. There is a concern, however, that the cumulative impact of all these new reforms will constrain liquidity and thereby hinder market making functions. In the years ahead, the financial industry will have to grapple with: i) Basel III's introduction of higher capital charges, liquidity and leverage ratios; ii) restrictions on proprietary trading and market making by such regulations as the Volcker rule; iii) shadow-banking regulations; and iv) new margin requirements on a variety of derivative transactions.

All of these rules encourage institutions to restrain liquidity. Investors, by turn, will invest less in illiquid markets, hampering the ability of corporations or consumers to borrow or raise capital. The drag on growth will be considerable. The Councils specifically warn against any more regulations that might further constrain liquidity, such the introduction of restrictive leverage ratios that fail to allow for the netting of offsetting positions when calculating the denominator.

■**Volcker Rule:** The Councils understand U.S. regulatory agencies are making a concerted effort to finalize the Volcker rule limiting proprietary trading by year end. The Councils support the rule's worthy goals of systemic stability, as well as consumer and investor protection while not imposing undue impact on credit availability, liquidity and the convenience of end users. The Councils urge the U.S. to expand the range of exempted securities substantially, to include, at a minimum, Japanese government bonds, interests in joint ventures and subsidiaries, and other investments where the costs of the rule might outweigh the benefits.

■**Accounting for Differences between Banking and Insurance:** The Councils call on the U.S. and Japanese Governments to ensure that the International Association of Insurance Supervisors, as it develops a global insurance capital standard as well as a backstop capital requirement for global systemically important insurers, take fully into account the difference between insurers and banks. The Councils urge the two Governments and IAIS to consider an alternative capital framework that is tailored to insurance companies, ensures sufficient capital to protect solvency, comprehensively covers risks, provides a basis for comparison among banking and insurance and other financial institutions and can be implemented easily.

■**Ensuring Inclusive Growth:** The Councils encourage the United States and Japan to exert their leadership within the G-20 and the Basel processes so that policies do not impede prudent financial intermediation and jeopardize growth among small- and medium-sized enterprises ("SMEs").

■**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 welcome the Abe administration's clear vision regarding postal reform 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.

■**U.S. Insurance regulation:** Over the past 150 years, the U.S. state-based regulatory system for insurance has been responsive to the needs of the local marketplace. The Councils welcome continued efforts to further modernize U.S. state-based insurance regulation. In addition, the Councils are encouraged by the recent developments in the field of U.S. reinsurance regulation and will continue to monitor the further progress closely.

■**Commercial Finance:** Japan's commercial finance laws should be updated to promote a competitive and transparent asset based lending market. The Councils recommend modernization of the Civil Code and relevant lending laws so as to achieve (1) a more uniform and exclusive system for registration and perfection of security interests, eliminating risks of "hidden liens"; (2) broad coverage by such system of various classes of collateral, encompassing movable and immovable property as well as intangibles such as receivables; (3) a clear legal infrastructure for DIP financing with adequate lender protections; and (4) a uniform set of commercial lending regulations that would enhance clarity and regulatory parity among lenders. Such measures would encourage liquidity for business and ultimately business growth.

■**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.

■**Promote Ease of Cross-Border Funding for Multinational Affiliates:** Promotion of cross-border investment requires allowing multinationals to flexibly fund operations in other countries. Unlike in other developed markets, though, Japan's Money Lending Business (MLB) Law subjects such affiliate lending to impractical registration requirements. This makes it harder and more expensive for companies to bring funding into Japan, thus discouraging FDI at a time when it should be encouraged. Other major markets (U.S., UK, Germany, Hong Kong, Singapore) do not restrict or require money lending registration merely for affiliate funding. Exceptions are already recognized for parent/subsidiary lending pursuant to FSA No-Action letters, yet sister company lending does not benefit from this exemption, even where they are each 100 percent under common ultimate ownership. Such sister company lending should be made exempt from MLB registration.

SUPPLEMENT ON ENERGY and U.S.-JAPAN COOPERATION  
50th U.S.-Japan Business Conference  
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### Energy Policy at a Crossroads

Both the United States and Japan are in the midst of historic changes in the energy sector, driven by developments as varied as new technologies, the discovery of new reserves of energy, the continuing effects of restrictions in power generation capacity, most notably from the disasters of March 11, 2011 in Japan, and the overhaul of long-standing regulatory regimes with a view to promoting competition and innovation. While many challenges are posed by these developments, the Councils believe that these challenges can be squarely met through U.S.-Japan energy cooperation that can help unleash the potential of existing and new energy sources and their development and distribution. Such cooperation is also vital to ensure sustainable and secure energy supplies for our economies, while making good on commitments to reduce adverse environmental impacts.

### Benefits of Enhanced Cooperation

The broad benefits of enhanced energy cooperation include:

- Enhanced energy security for Japan by achieving an optimal energy mix, including through continued use of nuclear power with enhanced safety;
- Expanded commercial opportunities in LNG, shale gas/oil development due to the discovery and recovery of new fields in the United State;
- Accelerated development and deployment of commercially competitive renewable energy sources and fuels;
- Improvements in energy efficiency and demand management from technology exchange and sharing of best practices.

### Establish a Comprehensive, High-Level Strategic Energy Dialogue

To accelerate enhanced cooperation in the interests of both countries, the Councils strongly urge both governments to establish a comprehensive, high-level U.S.-Japan Strategic Energy Dialogue. The Councils appreciate that there are existing, productive dialogues on specific energy sectors, such as the bilateral nuclear dialogue and the upcoming METI-DOE conference on Renewables. However, the Councils believe there would be significant value to a more

comprehensive cross-sectoral dialogue that would include both government-to-government and government-to-private sector dimensions, and encompassing carbon energy (oil, LNG, clean coal), renewable technology development and deployment (solar, wind, geothermal, biomass, alternative fuels, batteries), energy efficiency and better demand management (smart grid/meter, efficient building materials), and safe and sustainable nuclear energy production and usage.

In the Councils' view, it is important to have interaction between government and business representatives that will enable practitioners from major U.S. and Japanese companies engaged in various phases of energy production and technology development to exchange ideas and recommendations on regulatory, pricing, technological feasibility, and other issues with an objective of developing energy policy in both countries that supports continued industry expansion and economic growth.

#### Continuing Critical Role for Nuclear Power

In the Councils' view, nuclear power generation will continue to be an important component of the energy mix going forward. Accordingly, the Councils recommend that the Government of Japan, in cooperation with the U.S. and other governments, establish rigorous, consistent and transparent nuclear safety and regulatory procedures that embrace or surpass the highest standards and best practices from around the world. The Councils welcome the Government of Japan's establishment of an independent Nuclear Regulation Authority (NRA) to pursue this goal.

At the same time, the Government of Japan, drawing on expertise from all sources, both Japanese and overseas, should move expeditiously to complete resolution of the situation at the Fukushima Daichi nuclear power plant, and should move forward with the restart of nuclear facilities in line with the rigorous safety standards recommended above. Likewise, U.S. public and private sector players should move actively to assist with this process, and the Japanese government and industry should encourage and accept such assistance, noting the mutual interest of both countries in Japan quickly rebuilding a sustainable, safe and economic power production capacity.

With the prospect that future electricity demand from nuclear power plants will grow, especially in emerging countries, the Councils also agree that the U.S. and Japan should cooperate in promoting the export of nuclear power plants with the leading-edge safety technology based on the experience of the Fukushima Daichi nuclear accident. Global

cooperation in nuclear energy development will be advanced by adoption of the clear and predictable framework for nuclear related liability represented in the *Convention on Supplementary Compensation for Nuclear Damage* (CSC). The Councils applaud the recent announcement by the Government of Japan that it intends to join the CSC, and urge it to move expeditiously to sign and ratify this important convention, and the Governments of both the United States and Japan to work actively with other governments to hasten additional ratifications.

#### Seizing the Shale Gas and the LNG Opportunity

With the discovery of vast amounts of shale gas, and enhanced technological capacity to recover it, the United States has the potential to become a major exporter of LNG over the next several years if certain technical, financial, transportation and political aspects of this complicated process are aligned properly. On the other hand, the demand for LNG in Japan has increased dramatically. This situation creates a tremendous opportunity for the United States and Japan to expand energy cooperation through the export of U.S.-produced LNG to Japan if the relevant factors are aligned.

Licenses have been granted to some LNG projects to export U.S.-produced LNG to several countries that have free trade agreements (FTAs) with the U.S. The Councils applaud the US Department of Energy's approval over the past several months of several applications for U.S. LNG exports to Japan, a non-FTA country. The Councils further applaud Japan joining the ongoing Trans-Pacific Partnership negotiations and look forward to Japan having the option to receive LNG from any U.S. export facility once this agreement is in place. In the meantime, though, we encourage the Department of Energy to continue expeditiously approving applications for LNG exports to Japan. Japan is a critical ally and economic partner of the United States, and on this basis, its receipt of U.S. LNG is a win-win for both countries. Such cooperation enhances Japan's energy security and expands U.S. exports to Japan, providing another economic bond and investment opportunity that strengthens bilateral economic integration and overall relations.

Furthermore, the U.S. "shale gas revolution" creates many opportunities for U.S.-Japan cooperation in the U.S. market. Japanese firms should be encouraged to play an active role in U.S.-based projects to exploit shale gas, including through investment in specific projects in partnership with U.S. companies, and co-development of technologies that can be used in each others' markets and around the world.

## Accelerating Development of Renewable Energy

The development and dissemination of renewable energy can play an important role towards enhancing energy security and addressing climate change. Renewable energy technologies are not without challenges, such as their intermittent supply. They have a higher cost, are typically in earlier stages of technology development, and are not available at the scale needed when compared to conventional energy options. To overcome these challenges and accelerate the development of economically viable renewable technologies, the Councils recommend that our respective governments support and encourage R&D and private investment in energy technology companies. Wind, solar, geothermal and biomass should all be considered part of an integrated and diverse menu of energy options.

Deregulation has an important role to play. Japan should speed up its environmental assessment process, taking about a year, rather than the three to four years that can be required in Japan. Both countries should cooperate on standards for smart grid and other renewable technologies. Standards should be scientifically based and adopt global standards as much as possible, since local standards that are different can discourage cross-border investment in energy projects and potentially tilt the playing field against new entrants. These reforms will encourage domestic and foreign companies to launch private projects on a more timely and cost-effective basis.

It is important that government policies to support renewable energy development not impose significant rate increases on industrial and household energy users, as this will have a negative impact on economic growth. Care must be taken to avoid distorting markets by offering large-scale subsidies or setting artificially high prices for electricity generated through renewable technologies.

## Striking a Good Balance between Energy Security, Economic Growth and the Environment

Some voices see energy security, economic growth and environmental protection as conflicting goals. The Councils view this as a false trade-off. A proper energy mix policy can promote these goals in harmony. The Councils thus call for Japan, in updating its Energy Basic Plan by the end of this year, to provide for the best mix of energy sources and technologies that will further these goals and allow for a regulatory regime that provides maximum predictability for companies operating in Japan, as well as investors. This would involve a continuing critical role for nuclear, which produces secure energy without GHG emission, expanded investment in renewables of all types, and development of new types of fossil fuel technologies.

New fossil fuel solutions include not only LNG as noted above, but also new highly efficient coal or gas fired thermal plants, coal gasification, ultra super-critical coal thermal power and combined cycle technologies that can significantly increase the efficiency of fossil fuel power generation. For example, updating older gas turbines with new technology to increase efficiency – combined with the lower cost of shale gas from the US – could significantly reduce the cost for LNG energy production at upgraded units in a relatively short period of time.

Japan should also speed up the environmental assessment processes when power plants are constructed and replaced. Increased use of distributed power solutions, with highly efficient power generation capacity at or close to the sites of use, can reduce burdens on the electricity grid, and enhance security and reliability.

All reasonable efforts should be made to prioritize energy sources that are low or non-emitters of GHG's and other particulate pollution. One of the strengths and attractions of Japan as a business center in Asia is its high level of environmental standards and air quality. This should not be compromised, and indeed, with Tokyo's selection as host city of the 2020 Summer Olympics and Paralympic Games, Japan has the chance to showcase a world class model for environmentally sustainable energy development for megacities.

Finally, environmentally responsible energy policy will be enhanced by the expanded use of energy efficiency and energy management technologies including latest generation smart meters and other measures. The Councils recommend that the U.S. and Japan take a strong leadership role to promote free trade in and wider usage of environment-related goods and services around the world through trade liberalization efforts such as the APEC Environmental Goods and Services negotiations.