

**JOINT STATEMENT**  
**46<sup>th</sup> U.S.-Japan Business Conference**  
**U.S.-Japan/Japan-U.S. Business Councils**  
**November 3, 2009**

## **U.S. ECONOMY**

Compared to where the U.S. economy was a year ago, the Councils are very pleased to see the beginnings of a gradual and modest recovery from the most severe recession in decades. The extraordinary financial rescue and stimulus measures initiated by the U.S. government in late 2008 and early 2009 deserve credit for preventing an even worse recession, and for helping turn the situation around. The economy should continue to improve as more of the stimulus measures pass through in coming months, and as business confidence gradually increases.

A slight increase in exports has been an important factor in moving the economy into a slow growth phase. As demand in overseas markets picks up, particularly in Asia, this should continue to play an important role in the recovery. Accordingly, the Councils urge the administration and Congress to pursue policy measures, including trade agreements, which support the expansion of U.S. exports as a means of supporting economic growth and job creation.

There are problem areas of significant concern. In particular, serious credit constraints remain, particularly for small and medium-sized companies. The near-term employment outlook also remains severe. With unemployment near 10%, this will continue to exert downward pressure on consumption, thus limiting growth. There have been modest increases in housing and consumer spending in recent months, propelled by temporary credits for first-time home buyers and the so-called Cash for Clunkers program. Until there are more significant and sustainable increases in commercial lending, corporate investment and consumer spending, questions about the sustainability of the recovery will remain.

Historically, the U.S. economy has proven to be resilient and dynamic, and the flexibility of capital and labor markets has been a critical factor in this. Extraordinary government efforts and spending have helped the economy weather a 50-year storm, and the Councils commend the Obama administration for bold action in a time of crisis. Going forward, economic recovery will depend primarily on private sector activities and initiatives, as the current level of public spending is unsustainable given the impact on U.S. budget deficits and national debt.

With this in mind, the Councils encourage the U.S. government to accelerate growth in this next phase of the recovery by concentrating its efforts and initiatives on stimulating private job creation through regulatory, investment and tax policies that lead to new private investment, innovation, and business development. Regulation of capital, labor and product markets is necessary, particularly in light of some of the excesses that led to the recession. However, at a time of economic weakness and growing competition in the global economy, regulation must be smart and balanced so that this does not stifle innovation and competitiveness.

## **JAPANESE ECONOMY**

The Japanese economy has been on a recovery track since the beginning of the year, but looking at sectors, those on the track have been rather limited so far. According to the BOJ's quarterly survey of business sentiment (tankan), business sentiment has shown some improvement, including small- to medium-sized companies, but it still fell short of the level achieved prior to the crisis.

One of the factors contributing to the recovery is exports. However, demand observed at the early stage of recovery for restoration of the inventory levels has already been waning, and the growth rate has been slowing down gradually. Production has also been increasing thanks to good demand from overseas and to the government measures to stimulate the economy, but here again, the growth rate has been gradually decelerating. The sentiment of excess capacity, although somewhat moderated, still remains at a level higher than the historic peak recorded during the past economic slowdown periods.

The sentiment of the household sector also is still very weak. Recently, thanks to "eco-points," subsidies for "eco-cars," and similar measures for economic stimulation, sales of household appliances and automobiles have been driving consumption. However, the employment environment is still very tough, and household income also remains sluggish. Under these circumstances, it will still take some time before consumption starts recovering in a self-sustaining manner.

In the near future, it is likely that Japan's economy will continue on its recovery track helped by recovery of overseas economies. However, there are some downside risks. In particular, the stronger yen in the foreign exchange market and suspension of public works projects under the new administration are two of the current concerns.

In the foreign exchange market, the yen remains strong against the US dollar, hitting 88 yen per dollar at one time in October 2009. In view of the fundamentals of Japan and the U.S. and interest rate trends in the two nations, yen-buying pressure could continue to build up. The Hatoyama administration is planning to review the Supplementary Budget of 14 trillion yen enacted under the previous administration. In particular, public works spending amounting to some 900 billion yen is likely to be suspended. The surplus budget thus worked out (about 3 trillion yen) will be used direct subsidies for households such as child benefits and thus help stimulate consumption. However, the change in government policies will likely delay the economic effects to materialize.

Amidst the rather weak economic recovery and remaining deflationary pressure, the BOJ remains very prudent for the exit strategy of its financial policies. Despite some market expectations, it was decided in the BOJ's October Monetary Policy Meeting to postpone the termination of CP and corporate bond purchases. Although the extreme tension in the financial market after the Lehman shock has been unwound and the real economy has bottomed out from the worst, there still remain concerns for deflation, and the BOJ remains very prudent.

## **HIGH-LEVEL ECONOMIC DIALOGUE, ECONOMIC INTEGRATION, AND AN ECONOMIC PARTNERSHIP AGREEMENT**

Given Asia's current growth and integration trends and the vital security interests that are at stake in the region, there is arguably no area of the world more important to long-term global prosperity and stability. In this context, and as the United States and Japan look for ways to promote economic recovery and increase their competitiveness amid the economic challenges of the 21st century, closer U.S.-Japan economic integration and cooperation in Asia makes sense.

The Councils accordingly call upon the governments of the United States and Japan to commit to an economic dialogue focused on facilitating economic integration of the two economies and addressing global issues of concern to both economies. This dialogue should be dedicated to achieving concrete measures that increase trade and investment, cooperation in areas such as energy and environment, and harmonization of regulations and standards -- both bilaterally and in the Asia-Pacific region. In the Councils' view, high-level engagement is an essential part of this vision in order to set priorities and provide the leadership and political weight necessary to advance an ambitious agenda at a time of growing protectionist sentiment around the world.

The successive hosting of APEC by Japan in 2010 and the United States in 2011 presents a tremendous opportunity for Japan and the United States to refocus on their common values and goals for the Asia-Pacific. The Councils urge both governments to work closely together in setting an ambitious mid and long-term vision and agenda for APEC, and to jointly drive APEC's key economic objectives and initiatives, including pursuit of free and open trade and investment in the Asia-Pacific, promotion of regional economic integration, and economic and technical cooperation in areas such as ICT, energy and environment, life sciences, etc. in order to revitalize businesses and the economies of the region.

The Councils endorse the U.S. and Japanese government's support for APEC's efforts to accelerate Asia-Pacific economic integration and remain supportive of multilateral negotiations at the WTO. The Councils believe greater U.S.-Japan economic integration and cooperation would provide impetus for further progress on both of these fronts.

As a long-term objective, the Councils continue to strongly support a comprehensive, high-level Economic Partnership Agreement (EPA) as the most effective and enduring way to strengthen bilateral economic relations and bolster the overall competitiveness of the U.S. and Japanese economies, both regionally and globally. Such an ambitious goal would build further momentum in the U.S.-Japan economic relationship and lay the foundation for an active, forward-looking bilateral economic agenda. Working towards the goal of a comprehensive, high-standard U.S.-Japan EPA would, by enhancing economic integration between the two largest economies with similarly high standards for labor and environmental rules and technology, serve as a model and possible platform for a broader regional agreement among like-minded countries.

The Councils envision an EPA as an "FTA-Plus" agreement that would have to encompass "substantially all the trade" in goods as well as "substantial sectoral coverage" in services, as required under WTO rules, and address tariff and non-tariff measures in areas including, but not limited to, regulations and regulatory transparency, distribution, standards, commercial laws, investment rules, capital and currency markets, agriculture, cross-border data flows, trade remedies such as antidumping, competition policy, human resources and movement of natural persons, intellectual property, and secure trade.

The Councils acknowledge that the path forward for a high-standard EPA is difficult in the current political and economic environments in both countries and in light of some sensitive issues that would have to be tackled to achieve such an agreement. Nevertheless, the Councils believe the potential benefits of a comprehensive EPA to both economies far outweigh the costs

and urge the U.S. and Japanese governments to commit to this long-term goal while starting now to take incremental steps toward it. Specifically, the Councils urge the two governments to look for early opportunities to negotiate binding, interim trade-enhancing initiatives, or “building blocks,” in a few targeted areas as a means of building the trust and confidence necessary for achieving the long-term vision of a comprehensive, high-standard EPA.

For example, the Councils urge the U.S. and Japanese governments to make regulatory and standards harmonization one of their top priorities in the Regulatory Reform and Competition Policy initiative (or its successor) with a goal of reaching a broad agreement or series of agreements in key industries as determined by business-government consultation. Greater harmonization of regulations and standards would provide significant benefits to Japanese and U.S. companies in the short term by lowering production and compliance costs, while also representing a significant step toward the longer term goal of a bilateral EPA. This could also provide a critical platform and model for regulatory and standards harmonization among like-minded countries in the Asia-Pacific region through APEC.

In addition to the above, the Councils share the understanding that cooperation and harmonization between the U.S. and Japan in the area of intellectual property rights could generate benefits not only at the national level, but also globally, by enhancing the presence of predictable and balanced intellectual property systems. The Councils support the activities of the governments towards, e.g., harmonization of the national patent systems including adoption of the “first-to-file” principle, leadership for the international patent systems including the Patent Prosecution Highway, the Substantive Patent Law Treaty, and the Anti-Counterfeiting Trade Agreement, and cooperation to build respect for intellectual property rights in third countries.

The Councils acknowledge that increased trade, while bringing tremendous benefits to companies and consumers alike, often results in dislocation in certain areas due to greater competition and that concentrated efforts are required to build a strong consensus on promoting free trade moving forward. The Councils urge both governments to establish more comprehensive and robust systems to help workers, companies, and communities better adjust to rapid change in the marketplace and succeed in the increasingly global economy. Necessary measures include reforms in agriculture; trade adjustment assistance, education, labor market flexibility and security, and worker retraining systems; and portable, cost-effective pension and healthcare structures as well as effective enforcement of existing multilateral trade agreements. Most of all, it will take strong leadership and vision and sustained efforts on the part of both governments to communicate this message to key constituencies and implement these measures in ways that build support for continued engagement in the global economy.

## **Aviation**

The Councils strongly endorse the current efforts of the U.S. and Japanese Governments to negotiate an updated bilateral aviation agreement including Open Skies on the grounds that the arrangement will expand international trade and commerce and enhance convenience for passengers and shippers. By increasing the possibilities for where, when, and how often airlines can fly between the world's two largest economies, and beyond to other countries, an updated agreement will provide benefits for the U.S. and Japanese economies, and those of the Asia-Pacific region.

Open Skies agreements around the world provide substantial benefits in the form of increases in passenger and cargo traffic, lower prices for passengers, and increased jobs. With the Asia Pacific region forecast to become the world's largest aviation market over the next 20 years, encompassing more than 40 percent of the world's airline traffic, an Open Skies agreement would help facilitate the expansion of regional trade and supply networks and movement of people. The updated bilateral aviation agreement including Open Skies would help solidify Tokyo's key role as a major Asian hub for passengers and shippers, and expand efficient Asia-Pacific trade and passenger movement.

The Councils recognize the complexities involved in negotiating such an agreement but urge both governments to afford the effort to reach it the highest possible priority.

## **HEALTH CARE INNOVATION**

The current global recession is bringing further challenges to the medical device and pharmaceutical industries. The Obama administration in the United States is proposing a major overhaul of the country's health care system in the face of the large number of uninsured Americans. Japanese patients face delays in receiving the latest in medical technologies, and the healthcare system is weakened by inefficient administration of public hospitals and a physician shortage. In order to face these challenges, a thorough review is required for the countries' regulatory and reimbursement systems, R&D and clinical trial environments, and hospital infrastructure. The Councils believe that the recent changes in political leadership in both countries present a good opportunity for detailed study and launch of initiatives in the medical technology sector.

The Councils strongly believe that the goals of supporting innovation and growth in the health technology sector and ensuring high quality and efficient care are complementary. Sound fundamental policies to strengthen technology development and investment in the health technology sector bring new options for improving treatment and lessening the burden of disease. The Councils urge the U.S. and Japanese governments to (1) more strongly pursue policies in support of innovation, and (2) increase dialogue and cooperation between the governments to streamline, harmonize and pursue policies to ensure dynamic leadership of the United States and Japan in medical technology innovation.

The Councils offer the following specific recommendations and assessment of progress towards these goals:

### **Recommendations: Pharmaceuticals**

- **Improve the R&D Process:** The Councils continue to support Government of Japan's efforts to implement the "Five-Year Clinical Trial Activation Plan". In addition the "Clinical Trial Center" should be set up in some core hospitals. The Councils encourage PMDA to continue to efficiently meet the demand for consultations and to respond favorable to multinational clinical trial protocols. In addition to tracking the number of consultations for multinational clinical trials, we welcome PMDA metrics on the numbers of new drug applications that are approved based on multinational clinical trial data.

The Councils continue to support the FDA's dialogue with industry under the Critical Path Initiative, and look forward to concrete outcomes that will streamline the drug development process.

- **Eliminate the Drug Lag:** The Councils continue to place great importance on PMDA's undertaking to reduce new drug review times to 12 months by April 1, 2012 PMDA. To achieve concrete process improvements between now and then we look forward to industry's continued active participation in the PMDA "Expert Working Groups" on consultations and on review practices. Specifically, regarding consultations, we look forward to reviewing the experiences of the "pre-evaluation" pilot.

Regarding the approval process, the Council look forward to reaching agreement on a question and answer process that is more efficient and predictable that would include, for example, a fixed "clock-stop" when all questions would be given to the sponsor who would have a fixed time to provide answers.

The Councils strongly encourage FDA to meet the goals set out in PDUFA IV, while ensuring patient safety.

- **Improve the Pharmaceutical Pricing System:** The Councils look forward to continued meaningful discussions on industry's proposal. The ultimate purpose is the introduction of the "exceptional drug price maintenance system", under which (1) the prices of innovative new drugs are maintained until the launch of a generic, at which time (2) the prices of the innovative drugs are reduced. We strongly hope that the exceptional drug price maintenance as proposed by industry will be accepted and implemented in 2010. In the mean time Councils continue to urge against steps that would further erode the prices of patented products, such as annual price revisions and the re-pricing of highly successful innovative products, should not be pursued.

The Councils support meaningful, cost-effective healthcare reform in the U.S. that broadens access to health insurance. We continue to stress that such reform should continue to use the market principle, and not obstruct-innovation, patient and physician choice or economic growth.

- **Enhance IPR Protection:** The Councils continue to recommend that the U.S. government consider expanding its data exclusivity term which is valid for five years now, to keep its market exclusivity in the U.S. as long as that of Japan.

### **Recommendations: Medical Devices/Technology**

- **Ensure that the reimbursement process for medical devices rewards innovation:** The Councils consider it a fundamental principle that new treatments which improve outcomes and reduce the burden of disease or patient care should be valued for these contributions. A reimbursement system that fails to reward these gains will not succeed in controlling costs and ensuring high quality care across the healthcare system.

The Councils remain highly concerned about the use of the arbitrary and blunt "Foreign Average Pricing" (FAP) mechanism in Japan. The FAP is based on the flawed principle that prices for medical devices should be the same in all countries, despite movement in exchange rates and fundamentally different cost, market and reimbursement structures. Prices are not the same across countries for other complex industrial products, and there is no reason to expect them to be the same for medical devices.

The FAP mechanism is highly influenced by exchange rate fluctuations. The strong rise in the yen this year would mean a potentially dramatic price cut in Japan in the 2010 update for reimbursement prices. Without an appropriate exchange rate adjustment, such a cut would take place without any underlying improvement in the cost and market conditions in Japan, and accordingly it would be highly damaging to industry and would undermine basic conditions for medical technology innovation and investment in Japan. The 2010 update for reimbursement levels should not utilize FAP. At a minimum, the 2010 update should not include any modifications to the current list of FAP countries or to the allowable FAP differential.

The Councils also urge the creation of a more transparent and predictable process for establishing reimbursement prices and functional categories in order to support the development and introduction of innovative products, and for revising existing reimbursement prices and functional categories to support the continued availability of safe and effective existing products.

- **Strongly implement regulatory reform to achieve faster and more efficient review for all participants:** In April of 2009, the Japanese Cabinet announced a package of medical device regulation reforms and an increase in the number of medical device reviewers at PMDA. The package included publicly announced targets for reducing approval times for new devices, and a process of semi-annual public reports and consultations with industry on the review performance data and regulatory reforms.

The Councils welcome and support the reforms and the process of industry consultation. All stakeholders need to monitor implementation of the reforms to ensure that review times decrease – this is the fundamental measure of success or failure. Industry stands ready to collaborate with regulators on this project, for example through support of training programs in regulatory science and process. The principles of “least burdensome approach” and appropriate “risk/benefit” balance need to be followed.

The process of involving accredited third-party review bodies in regulatory review of low risk-category products needs to be implemented quickly, and the experience applied to expanding the program to higher risk category products.

The Councils also remain concerned that the risk of individual liability for reviewers impedes appropriate review of products. Accountability and responsibility should lie with the institutions involved in the process and not the individual regulatory personnel.

Although the PMDA's five-year plan to accelerate review times of medical devices does not include in vitro diagnostic products, the Councils believe that increased industry consultation on ways to streamline and accelerate approval process for innovative in vitro diagnostic products is necessary.

- **Strengthen U.S.-Japan Regulatory Cooperation:** The Councils strongly support the objective of convergence and harmonization of medical device regulatory requirements between the United States and Japan, with the eventual goal of mutual recognition. The U.S. FDA and Japan's PMDA/MHLW are the world's most respected and advanced medical device regulatory agencies. It will serve the goals of patient safety, regulatory efficiency as well as reducing barriers to trade if these two agencies can work cooperatively to streamline the introduction of new technology into both markets.

The Councils support the ongoing review of the “Harmonization by Doing” initiative between FDA and PMDA/MHLW. However, concrete results from the initiative are needed. Progress and results should be more closely monitored and reported on a regular basis. The scope of the initiative should be expanded beyond clinical trials. Efforts should be made to speed new product introductions in both countries, while improving patient safety.

- **Improve environment for clinical research and new technology development:** The Councils continue to believe that a sound environment for clinical research is a basic condition for medical technology innovation. The Councils urge a thorough review of Japan's medical device R&D environment. This would include regulatory systems, patient protection mechanisms, and reimbursement and health insurance systems for patients in clinical research. There is need for renewed dialogue among government, universities, industry and patient associations about patient needs and the benefits of new technology. The Councils renew their recommendation to establish a regulatory environment with transparent rules whereby manufacturers can provide prototypes for use in clinical research, with appropriate protection for participating patients. The Councils also renew their recommendations to set “visions” for therapies and technologies needed to address important patient needs, and to establish structured critical path processes to realize efficient patient access to those therapies and technologies.
- **Support increased use of healthcare IT:** The Councils urge greater support for use of healthcare IT to improve efficiency of healthcare resource use and generate better outcomes or reduce burdens for patients, including technologies for remote patient monitoring and disease management. Reimbursement coverage should be extended for those technologies.

### **Consumer Health Care**

Consumer health product manufacturers produce a wide variety of over the counter (OTC) and quasi drugs that help consumers improve their quality of life. However, manufacturers face challenges in bringing these products to Japanese consumers in an efficient manner due to insufficient regulatory transparency and slow product reviews. Increasing transparency and reducing the average review times in Japan could be done in a manner that results in greater choice for consumers without reducing safety, quality, or efficacy.

### **Recommendations:**

- **Reduce review times for over-the-counter and quasi-drugs:** The Councils recommend a streamlined and expedited product approval and partial change process in Japan for over-the-counter and quasi-drugs, especially for products that use active ingredients that have been previously approved for use in similar products. This would allow reviewers to spend more time on products that present higher risk.
- **Increase quasi drug transparency:** The Councils appreciate the MHLW for working with industry to publish a list of previously approved active ingredients for quasi drugs in December 2008. The Councils recommend the Japanese government to further increase transparency by establishing a clear process and schedule for regularly updating and expanding the list.

## FINANCIAL SERVICES

### Overview

The Councils believe that a robust financial sector based on market principles, effective regulation, transparency, and strong global institutions is vital to achieving sustained economic growth and recovery. The Councils are encouraged by steps taken in the United States and Japan to restore confidence in the integrity of the financial system and put the economies on track for a sustainable recovery. As the United States and Japan continue working to recover from the global financial and economic crisis, the Councils welcome measures designed to protect customers and investors, promote market discipline, support competition and innovation, and avoid protectionism.

The Councils welcome Japan's continued commitment to strengthening the competitiveness of its financial markets and improving the quality of financial regulation through steps to enhance its effectiveness, efficiency, consistency and transparency through its Better Regulation and Better Market Initiative programs.

The Councils also welcome the United States' commitment to improving financial regulation and supervision, which should help to restore confidence in the financial markets, provide protection for consumers and investors, reward innovation, and enable adaption and evolution with changes in the financial markets.

Today global bodies and financial regulators around the world are focused on strengthening financial regulation. The Councils hope that both the United States and Japanese governments will assess the effectiveness of tightening their national regulations to avoid over-regulating while also attempting to minimize pro-cyclicality in the financial system. Where appropriate, financial regulation should respect country and regional differences, which may not be possible under a single global standard. The Councils will continuously encourage both governments to be thoughtful and moderate in order to form effective, stable financial markets for the long term.

### Specific Recommendations

The Councils urge the governments of the United States and Japan to adopt the following measures, which the Councils believe will contribute to achieving robust, well-regulated financial sectors in the United States and Japan.

- **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 commercial entities have in making investment decisions. Moreover, this form of stability is undeniably in the interests of consumers as well.
- **Consumer welfare and regulation by the CAA:** The Councils welcome the Japanese government's commitment to further enhance consumer welfare. With respect to the establishment of the Consumer Affairs Agency (CAA) and the transfer of laws either wholly or partially to the CAA's jurisdiction, measures should be taken to ensure that the CAA is adequately staffed with appropriate experts and that any concurrent jurisdiction should be transparent and not result in double regulation, duplicative investigations, and penalties to regulated entities. In a similar fashion, the Councils support the use of cost-benefit analysis for any new related rules and regulations, including objective techniques and quantitative analysis, not only during rule-making for the CAA, but periodically after implementation to ensure that regulations are achieving their intended effects at a level that reinforces economic activity.
- **Corporate reorganization:** The Councils believe further measures to allow smooth and flexible tax-deferred corporate reorganizations should be implemented to accelerate the development of

Japanese and foreign financial groups in Japan. Greater ease of foreign branch domestication procedures, including elimination of the sales blackout in portfolio transfer for foreign insurers and introduction of a new quasi company split system allowing a foreign branch to incorporate a stock company by transferring its business to such stock company in accordance with procedures comparable to the company split, would promote corporate reorganizations that promise greater business efficiency. The Japanese government should also consider the simplification of the reporting requirements for investors holding equity asset that surpass 5% of outstanding shares in a company in recognition of the distinction between portfolio investors and those investors seeking effective management or ownership of an entity.

- Like regulation for like products and service providers: Like regulation for like products and service providers is a key regulatory principle for strengthening Japan's financial and capital markets and avoiding market inefficiencies and distortions that arise when one market segment or participant is given favorable treatment over another. On October 1, 2007, the new Japanese postal financial entities began operations which, given the scale of these businesses, have a major impact on the financial and capital markets. The Councils believe that ensuring equivalent conditions of competition is essential in determining whether the postal financial entities broaden the range of products underwritten/manufactured. In addition, it is indispensable to establish appropriate systems to ensure better customer protection. Similarly, it is important to establish a level playing field between cooperative financial institutions and private sector financial services industries.
- Compliance costs: As a result of the global financial crisis, both countries are actively considering wide-ranging and significant changes to their financial regulatory systems. Any such legal and regulatory changes will undoubtedly require companies in both countries to incorporate changes to their systems and processes in order to comply, and it is possible that significant and unnecessary costs could be incurred. As an example of a prior response to financial crisis, while the Sarbanes-Oxley Act helped to bolster public confidence in the securities market, the Act itself increased significantly compliance costs for listed companies in the United States. Japan's Amendment of Financial Instruments and Exchange Act (FIEA), promulgated in June 2008, incorporates internal controls disclosures and other reporting requirements similar to those in Sarbanes-Oxley. Both governments should take into consideration the development of new laws and regulations with a view to improving effectiveness while reducing compliance costs and time demands through dialogue with industry participants, consider the shortcomings of the Sarbanes-Oxley Act, such as compliance with overly cumbersome procedures, and, in the case of the FIEA, carefully monitor whether the FIEA serves its key objective of protecting investors in the most efficient fashion.
- Pension Reform: The Councils continue to believe that the reinforcement of corporate pension schemes to supplement national pension schemes in Japan is increasingly important in light of rapid demographic and social changes. In particular, the expansion of the Defined Contribution (DC) Pension Plan system would have the dual benefits of creating a better retirement outcome for Japanese workers and supporting the laudable goal of moving from a savings to an investing society. The Councils ask the Government of Japan to review and improve the DC Pension Plan system by: 1) further increasing the limits on tax deductible contributions; 2) allowing employee matching of employer contributions, with the only applicable limit on employee contributions being the level of employer contributions; 3) allowing withdrawals prior to age 60 (under certain conditions); and 4) introducing a DC pension plan for public workers.
- Commercial Finance: In order to facilitate business growth and to enhance needed liquidity to a broad cross-section of commercial entities, Japan's commercial finance laws need to be modified to encourage lenders to provide credit to businesses. The Councils believe that it is vital to enhance the availability of funds supported by a broad range of collateral, without excessive reliance on real property values or personal guarantees. The Councils recommend the improvement of current secured transaction laws, including the legal infrastructure for asset based lending and Debtor In

Possession (“DIP”) finance so as to achieve (1) a more uniform and exclusive system for registration and perfection of security interests in various classes of collateral, (2) stronger lender protection in DIP financing, and (3) a uniform set of commercial lending regulations that would enhance clarity and regulatory parity among lenders.

- Reform and Modernization of U.S. Insurance Regulation: Over the past 150 years, the U.S. state-based regulatory system for insurance has served consumer interests, protected consumers, and been responsive to the needs of the local marketplace. However, there are challenges to companies doing business across multiple states. Amid changing market conditions both in the United States and globally, it is clear that further progress can be made to modernize and reform the U.S. state-based system of insurance regulation. U.S. reinsurance collateral requirements are an issue of specific concern to many non-U.S. insurers. The Councils urge legislators and regulators to work together to ensure that U.S. reinsurance regulation is consistent with global best practices. Modernization and reform of U.S. insurance regulation was discussed in the July 2009 “Eighth Report to the Leaders on the U.S.-Japan Regulatory Reform and Competition Policy Initiative.” The Councils recognize the progress that has been made in recent years and urge relevant policymakers and regulators to continue to make further progress towards practical solutions beneficial to both U.S. domestic and Japan-based market players.

### **Investment and Tax Rules for Enhanced Competitiveness**

The Councils strongly believe that the Japanese and the U.S. governments should carefully measure the impact of existing and future investment and tax rules on business activity and economic growth. Broadly speaking, one critical objective of investment and tax policy should be to move towards global standards/treatment as a means of helping ensure that both economies remain globally competitive as destinations/locations for both domestic and foreign portfolio and direct investment.

- Corporate Tax Rates: The OECD’s weighted average for corporate tax rates in all member economies fell below 30% for the first time in 2009 as Canada, Sweden and Korea, among others, enacted significant cuts. In contrast, on a combined (national, state and local) basis, corporate tax rates in Japan and the United States, at 39.5% (40.7% for large corporations based on the “inhabitants tax” rate) and 39.1% respectively, remain the highest in the OECD. According to OECD studies, corporate taxes “are the most harmful for economic growth” because of negative effects on capital accumulation and productivity. The Councils thus urge both governments to undertake corporate tax reforms with a goal of simplifying and aligning the U.S. and Japanese corporate tax systems with OECD/global trends and practices by: (1) lowering statutory corporate tax rates closer to the OECD weighted average of 30% to provide a foundation for a balanced, globally competitive corporate tax regime that encourages investment by domestic and foreign companies; and/or (2) adopting a “territorial” system in which profits earned by U.S. and Japanese companies in foreign markets are not taxed, thus enabling them to compete globally against companies from countries with comparable tax regimes. Meanwhile, the Councils welcome the Japanese Government's introduction, in the 2009 tax reform, of a measure to treat the dividends received from overseas subsidiaries as non-taxable income.
- Tax Treatment of Net Operating Losses: The Councils believe that Japan’s 7-year carry-forward period for Net Operating Losses (“NOLs”) should be significantly extended to be in line with other major developed economies – if not an unlimited period as in major economies such as the UK, France, and Germany, Japan’s carry-forward period should at least be extended to 20 years to match with the current NOL carry forward period of the U.S. and Canada. The carry back has been revised for small and medium enterprises in the 2009 tax reform but it should intrinsically be allowed to all corporations. A large number of corporations, large and small, have incurred significant losses during the financial downturn of the last few years; extension of the NOL carry forward period,

particularly if done retroactively for losses incurred during the current economic downturn of 2007-2009, will provide immediate stimulus to these companies. An extension will spur future capital investment in new technologies, and economic growth.

- Consumption Tax: The Councils urge the Japanese government to ensure that the treatment of purchases of goods and services is consistent with global best practices for Value Added Tax (VAT). For example, Japan's consumption tax law and related regulations should be revised to ensure neutrality in the treatment of the sales of financial services offered through third-party sales agents and to allow VAT grouping for financial service providers that are wholly-owned affiliates.
- Capital Gains and Dividends: The Councils also believe that current treatment in private income tax of capital gains and dividends on shares of listed companies in Japan should be maintained even after 2011 year-end, at which point the temporary treatment is scheduled to cease under the current law. Meanwhile, deduction of capital losses should be allowed against interest deriving from bond investment and deposits.

## **ENERGY and ENVIRONMENT**

With the global debate on climate change moving to a new stage as nations prepare for COP 15 in Copenhagen this December, and with both the U.S. and Japanese governments debating ambitious policies to reduce domestic emissions while creating new jobs related to environmental goods and services, this is an opportune and critical time for the United States and Japan to cooperate on this important global issue. As major industrialized nations Japan and, especially, the United States are major consumers of energy and emitters of CO<sub>2</sub> and other greenhouse gases (GHG). Japan and the United States are also among the most important developers of the low carbon and energy efficient technologies required to achieve any large scale reduction in GHG emissions on a global basis. Accordingly, the Councils call on the United States and Japan to cooperate in three areas:

- Negotiation of a Post-Kyoto climate change agreement and related agreements
- Diffusion of effective baseload technologies including Nuclear Power Generation
- Development and application of policies to promote greater efficiency and the rapid deployment of renewable energy technologies

### **International Agreement**

The Councils urge the governments of the United States and Japan to support a Post-Kyoto system that creates a realistic and sustainable long-term policy environment to encourage investment in the development and deployment of zero or low GHG emission technologies. Attaching a long term, predictable cost to carbon emissions is an important piece of that policy framework, along with measures that achieve deployment of zero and low-emissions technologies in the short term.

To achieve the required GHG emission reductions and create the political balance needed for significant emission cuts in developed countries, the Post-Kyoto agreement should include substantial and meaningful commitments from all major emitting countries, including China and India.

The Post-Kyoto international framework and national policies implementing commitments under that framework should achieve both a low carbon society and economic prosperity, as these are not mutually exclusive. It is therefore vitally important that this new international climate change regime include commitments to fundamental market principles and proven pro-growth policies. In particular, Japan and the United States should take the lead to ensure that a new agreement not justify or encourage either: (1) the application of trade barriers; or (2) reductions in intellectual property right protection.

Accordingly, in parallel with the Copenhagen process, the Councils urge the U.S. and Japanese governments to take the lead in driving a Global and/or Plurilateral Environmental Agreement aimed at reducing costs for cleaner and lower emitting technologies through the elimination of tariff and non-tariff barriers to trade in environmental goods and services. Such a new agreement would promote the international exchange of advanced products and services under a higher level of global harmonized rules, and make for a better investment environment. It could also ensure proper IP protection for environmental goods and services so that these may be traded and transferred across borders.

The Councils also urge the U.S. and Japanese governments to exert greater leadership in harmonizing environmental regulations and standards, including the emerging area of carbon footprint labeling. As various environmental labels and standards proliferate from governments, retailers and standardization agencies around the world, consumers often find it difficult to understand the differences among them, while businesses increasingly face challenges in complying with them. For example, in April 2009, the Government of Japan began a new process for certifying methodologies for the voluntary calculation and numerical display on

product labels of the quantity of GHGs (in kilograms or tons) emitted during the production, distribution, use and disposal of products and services. Proposals for similar programs are being considered in the U.S. Congress.

Although the Councils support the principle of encouraging reductions of GHG emissions, they are concerned that the lack of sufficient validated datasets for many products makes it difficult to generate accurate numerical labels that can be easily understood by consumers. Moreover, the Councils are concerned that the resulting country-specific methodologies could become a trade barrier, and that the narrow focus on product carbon emissions could shift attention away from other ways of reducing GHG emissions or promoting environmental sustainability. Rather than focusing on the display of numerical carbon footprints based on country-specific methodologies, the U.S. and Japanese governments should promote a broader framework of environmental sustainability that is based on technically valid and globally harmonized standards.

### **Diffusion of Effective Technologies**

A Post-Kyoto agreement that attaches a cost to the emission of GHGs is unlikely to set meaningful GHG emission price signals for many years. Yet the cost of most low carbon baseload energy technologies is higher than the cost of higher-emission alternatives. Action must be taken today to create volume manufacturing and deployment of these technologies to speed learning and bring costs down. This calls for specific national measures to promote a range of technologies. The Councils specifically recommend the following:

- *Nuclear Generation:* To have any reasonable hope of achieving the kinds of GHG reduction targets being considered by both governments, both countries will have to rely much more on nuclear electricity generation than at present. The peaceful use of nuclear energy can generate baseload power with virtually zero GHG emissions. This is an area in which U.S. and Japanese companies are already closely aligned and therefore presents a unique opportunity for bilateral cooperation in establishing market conditions for a revival of new plant construction around the world. Specifically, the U.S. and Japan should continue to collaborate in the following areas: (1) Promotion of Safeguards/non-proliferation measures; (2) Safety and Security in civilian nuclear regulatory systems and policies in their own countries and around the world; (3) Creating conditions for growth in civilian nuclear power plant construction through an effective nuclear liability regime.
- *Clean Coal:* Coal is another widely available fuel for large scale baseload power generation. However, in order to permit the use of coal while cutting GHG emissions, the International Energy Agency has called for the construction of over 100 full scale carbon capture and storage (CCS) plants by 2020.<sup>1</sup> The United States and Japan are world leaders in coal gasification systems and the use of the resulting synthetic gas in combined cycle power plants. This technology (Integrated Gasification Combined Cycle, or IGCC) is proven, efficient and able to reduce CO<sub>2</sub> emissions today.<sup>2</sup> Government engagement is required to put in place legal frameworks for the storage of CO<sub>2</sub> and to either provide incentives for storing carbon or to provide financial support for the incremental cost associated with capturing and storing carbon. The Councils thus urge the United States and Japan to serve as leaders in applying IGCC technology with CCS around the world through grants and other incentives for carbon capture demonstration. Japan and the United States should also encourage best practice sharing through public-private programs such as the Asia-Pacific Partnership for Clean Development and Climate as part of an effort to decrease emissions from large coal-consuming countries such as China and India.

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<sup>1</sup> International Energy Agency, "Technology Roadmap: Carbon Capture and Storage," 2009, p. 4.

<sup>2</sup> A commercial scale IGCC is under construction in Edwardsport, Indiana and the owner has begun plans for adding CCS capability to that facility.

## **Efficiency and Renewable Energy Technologies**

Through further energy efficiency gains and deployment of renewable energy technologies, the U.S. and Japan can substantially reduce carbon-based energy consumption and GHG emissions.

- *Smart use of energy:* Both the United States and Japan have opportunities to further reduce their GHG emissions through the internal application of existing technologies and the accelerated development and deployment of new technologies. Indeed, given that energy conservation is the most effective way to decrease CO<sub>2</sub> emissions for all sectors, including manufacturing and business, the Councils urge the U.S. and Japanese governments to make further substantial efficiency gains a national priority. The Councils urge the two governments to expand upon their cooperative efforts to develop and promote new technologies to achieve more energy-efficient buildings. Both governments should encourage production of more energy-efficient industrial motors, industrial systems and appliances/household goods through the application of rigorous energy efficiency and performance standards. Green IT approaches that promote further energy saving through both IT equipment and IT solutions are also vital. In addition, the Councils urge both governments to continue their support for promising technologies such as plug-in hybrid vehicle, electric vehicle, and heat pump systems for households, buildings and production processes.

Government policy should also promote supply side efficiency. In particular, each country should deploy smarter and more efficient electrical grid systems to reduce system-wide losses and facilitate energy saving decisions by businesses and consumers. Here, too, regulations and standards that promote interoperability are essential, and the Councils urge both governments to work closely with the private sectors in developing and properly harmonizing such standards. Government policy should promote grid security. As new communications, sensors, and command and control capabilities are adopted to form the smart electrical grid, it must also operate securely in an increasingly hostile cyber-security threat environment. Government policy should establish appropriate cyber-security standards and incentivize its adoption by the electrical industry.

- *Renewable Energy Development and Deployment:* Government policy in the United States and Japan should contribute to the accelerated growth of renewable energy sources. This should include Wind, Solar, Geothermal, Biomass, Hydro and ocean power. In addition to the appropriate economic incentives such as a predictable price on carbon, it is essential to have strong, consistent and harmonized regulations and standards, as well as strong intellectual property protection, to facilitate the development and deployment of these technologies on the needed domestic and global scales. To stimulate domestic use, the United States and Japan should adopt appropriate legislation, such as Renewable Portfolio Standards and long-term tax incentives, to similarly increase the levels of renewable penetration on their grids.

Through cooperation in the above areas, the United States and Japan can accelerate innovation, investment and job creation in new products, services and technologies that will be in high demand to meet future environmental needs in the U.S and Japan, and around the world.

## COMPETITION POLICY

### Due Process of the Japan Fair Trade Commission

The Councils urge the Government of Japan to revise the Anti-Monopoly Act (AMA) to better comply with global fair standards of “due process” in the investigative and appeals processes of the Japan Fair Trade Commission (JFTC) in the enforcement of Japan’s AMA. This policy would increase respect for Japanese law and encourage greater cooperation in AMA enforcement, while ensuring fairness and justice.

Specifically, the Councils urge the following changes:

- Appeals process: Under the current appeals process, the JFTC first issues cease-and-desist orders or surcharge payment orders and then reviews its own orders in an administrative appeals process (*Shinpan*). In practical terms, this means the JFTC acts as “prosecutor, judge and jury,” which is especially problematic where, as in the Japanese system, there are inadequate safeguards to ensure the independence of the initial hearing officers. As a result, the system lacks credibility and fairness and does not meet with the legal standard of due process applied in the United States and major European countries. Therefore, the Councils urge the Government of Japan to abolish this appeals process and replace it with a procedure within the judicial system in which a named corporation can appeal to a district court in accordance with general principles of administrative lawsuits.
- Investigations: JFTC investigations should adhere to fundamental, international standards of due process and transparency, including the following procedures and protections:
  - (1) Disclosure of evidence held by the JFTC to the party under investigation;
  - (2) Respect for the attorney-client privilege and the right to have counsel present during all stages of an investigation to protect the defense rights of parties that are subject to investigations and interviews;
  - (3) Respect for the right against self-incrimination as embodied in the Japanese Constitution;
  - (4) Preservation of confidentiality of information provided to the JFTC; and
  - (5) Hearing procedure in advance of issuance of administrative orders and the presentation of the reason and the evidence to the party at the time of the issuance of the order.
- Exclusionary Conduct: Recent amendments to the Antimonopoly Act expand the scope of conduct subject to punitive surcharges to include “exclusionary monopolization” and certain unfair trade practices. In connection with these amendments, the JFTC recently publicized draft guidelines on exclusionary monopolization. The Councils urge that the JFTC take into consideration comments submitted on the guidelines. Such guidelines should seek to avoid chilling conduct that is typically not considered to be inherently anticompetitive. Specifically, the Guidelines should incorporate the following considerations:
  - (1) A company should have monopoly power or dominant market power before it can be held liable for exclusionary monopolization.
  - (2) The guidelines should focus on the conduct’s effect on competition as a whole, not merely the effect on any individual competitor. Accordingly, there should be substantive guidance on what type and degree of competitive effect will be considered a “substantial restraint of trade.”
  - (3) The Guidelines should set forth clear standards and safe harbors for drawing the line between illegal below-cost pricing and low prices that benefit consumers.

- (4) The Guidelines should set forth clear standards consistent with international norms with respect to exclusive dealing, tying, refusal to supply, and discriminatory treatment. The JFTC should further clarify the distinction between exclusionary monopolization and unfair trade practices.

## **COMPETITIVENESS: LABOR POLICY**

Faced with extraordinarily difficult economic conditions over the past year, U.S. and Japanese companies alike have had to take many difficult steps to reduce operating costs, reallocate resources and streamline labor forces in order to maintain competitiveness in the global market. The Councils acknowledge the social, political and economic concerns over the high unemployment rates in Japan and the United States that have resulted in part from such measures. Both governments are to be commended for taking extraordinary steps to mitigate the impact on workers through the extension of unemployment benefits in the United States, support for work-sharing and relocation, and investment in areas such as energy and transport infrastructure, environment, and advanced ICT applications in healthcare and other areas to create short and longer-term jobs. While short-term crisis mitigation is essential, governments need to maintain focus on the mid-term measures required for both economies to exit from the crisis in a stronger and more sustainable competitive position.

From a national economic and employment perspective, both countries face growing competition from lower-wage economies in many manufacturing and service industries. It is critical that U.S. and Japanese policymakers not respond to this challenge through trade protection or limits on overseas investment by domestic companies, as this will stifle growth and job creation in the United States and Japan even more. Moreover, the Councils caution that the imposition of rigid and restrictive labor rules and social mandates on companies, large or small, in response to rising unemployment ultimately will be counterproductive, as this will discourage investment and business expansion – the critical engines of sustainable job creation.

Instead, the Councils urge both governments to focus on measures that increase the competitiveness of the U.S. and Japanese economies and their attractiveness as investment locations for foreign and domestic companies.

Labor policies and labor market conditions are a critical part of competitiveness. As high-cost, knowledge and innovation-based economies, the United States and Japan cannot compete on the basis of wage costs, and thus have immediate and long-term needs to increase the number of high-value, high-wage jobs in manufacturing and service sectors. The reality is that in today's global economy, labor markets, rules, and practices must evolve constantly, as things that worked a decade ago may not work now. In the 21<sup>st</sup> Century, the U.S. and Japanese labor markets will have to be more dynamic and flexible in order to adjust quickly to changes in cyclical and structural economic conditions, global competition, social and demographic trends, and technology and business models.

To survive and thrive, companies must adjust work force location and size and salary and benefit practices in response to economic conditions, global competition, specific market demands, social and demographic trends, strategic imperatives, and technological innovation. Workers must adjust as well: job changing, active career development and diversified working style are more common practices now, so workers must upgrade skills and knowledge, be willing to relocate, or change careers. In short, for sustainable new job creation, which is key for improvement of the labor environment, companies need to have the flexibility – and workers the support and encouragement – to adapt.

In Japan, to address the current labor problems characterized by a high ratio of non-traditional workers and growing unemployment, particularly among younger and non-traditional workers, more regulatory and policy changes that enable greater employer flexibility in managing the workforce in response to demand conditions are critical. Given the high structural costs and rigid rules of the traditional employment system, domestic and foreign companies utilizing traditional employees only are not able to cope effectively with any dynamic change in the business environment, for example, when they are scaling up production in response to higher demand for goods and services. In this context, it makes a certain economic sense to hire non-traditional

workers. Given these conditions, measures that seek to limit or eliminate the use of non-traditional workers merely address the symptoms, not the cause of the problem, and ultimately would be counterproductive.

The U.S. labor system is more flexible and dynamic, but rising health care costs have led to stagnant wage levels and growing burdens on U.S. companies, thus making job creation more difficult. There are also criticisms that worker rights and protection have been downplayed in recent years, thus prompting legislative and/or regulatory initiatives to facilitate recruitment of union membership and improve workplace conditions in certain industries. Clearly, U.S. labor laws must be upheld, but there is a risk that some initiatives such as the Employee Free Choice Act, or EFCA, could be counterproductive in terms of improving the competitiveness of the U.S. labor market.

### **Recommendations**

With this as background, and with the goal of promoting a sustainable and common solution, the Councils urge both governments to take a comprehensive approach and work with U.S. and Japanese companies and labor organizations to develop smart and competitive labor policies and rules that balance worker protection and social needs with employer flexibility and productivity needs. The overarching theme should be to protect and enable the worker, not protect the job.

From the viewpoint of stabilized economic growth policy, it is important to pursue a dynamic and appropriate policy mix that creates jobs through innovation and investment in leading manufacturing and service industries, including through the advanced application of ICT. In addition, it is essential to create a social system that gives people hope and confidence for the future and gives them access to better social services as they age and leave the workforce.

More specifically, the Councils urge both governments to join with the private sectors, including the Councils, in launching a new, collaborative model of dialogue and partnership on these critical issues. In particular, the Councils look forward to having a dialogue with the new government of Japan on the need for, and elements of, a balanced and collaborative approach.

Some key elements needed to enhance worker protection and social needs include:

- **Upgrade training programs:** Improved business-government-labor partnerships to develop educational and worker training/re-training systems and institutions that enable workers to adjust more rapidly to these changes. More generous allowances such as tax credits or low interest loans should be made available to workers who want to upgrade skills and educational levels.
- **Improve social safety nets:** Expanded and improved social safety nets that provide unemployment benefits (income assurance) and health insurance for longer employment transition periods are needed in the U.S. In Japan, finding ways to create domestic jobs in the global economy while reforming social security and improving other parts of the social safety net should be a priority.
- **Increase portability and flexibility of health insurance and pensions:** In the U.S. more portable health insurance and pension benefits would enable workers to move more easily between jobs. In Japan, restrictions on access to pension benefits before retirement in certain cases of financial hardship should be relaxed. Also, substantial increases to contribution limits on defined-contribution retirement plans should be implemented as a priority. As indicated in the Financial Services recommendations, these include allowing matching contributions by employees in defined-contribution pension plans.

From the employer perspective, key elements include the following:

- Recognition of today's more diversified workforce: Proposals to treat all non-traditional regular employees (such as fixed term contract employees, dispatched workers and other contingent workers) the same as regular employees should be considered carefully. Ideas such as converting contingent workers to regular employees or uniform treatment might look attractive in the short-term, but will remove flexibility and choice for both workers and employers, and will burden the economy in the long term. Today's diverse employment models respond to both lifestyle choices of workers and to market needs of employers
- Changes in pension and health care plans: Both Japan and the U.S. should encourage employers to provide pension and health care benefits to their employees through more flexibility in the regulatory environment. As indicated in the Financial Services recommendations, in Japan, these include raising the limits on contributions and allowing matching contributions by employees in defined-contribution pension plans.
- Allow skilled workers to move more freely: Both countries should set as priorities the need to attract highly skilled foreign nationals that boost talent levels and add to the tax base. Specific measures include changes in immigration rules and/or certain types of visa quotas to allow skilled workers to move more freely across borders for short-term (six months or less) work or training assignments, longer term assignments, or fixed-term positions.
- Treatment of expatriate workers: The Councils believe that Japan and the United States should assess how treatment of skilled personnel and managers affect the attractiveness of their markets and their citizens involved in global finance and other sectors characterized by high mobility, including how regulatory and tax rules treat managers with responsibilities for a company operating within the country or region and how their expatriate citizens are taxed. The U.S. should bring its taxation of expatriates in line with global standards.