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U.S. ECONOMY

The positive news that real GDP growth in the second quarter measured 2.8% after a significant downward revision is overshadowed by other developments that will likely contribute to much slower growth going forward. While the economy should be helped by the decline in oil and commodity prices from all-time peaks in the summer, prices are still high by historical standards, and continue to put upward pressure on overall price levels, thus impacting households and corporations alike. Rising prices, coupled with weakness in the labor market, are leading to lower consumption levels. This in turn has spilled over into the corporate sector, as slower demand and higher input costs are eating into margins, thus impacting investment and production levels. Exports have been a strong point in the economy and continued growth is a critical factor in determining how well the U.S. economy holds up. In this regard, demand conditions in other markets, including Japan, are critical.

The major risk factors for the economy are the continued downward pressure brought by the ongoing slide in housing prices, sharply rising mortgage default rates, and the related credit crisis. This crisis is having a dramatic effect on virtually all U.S. banks and financial institutions, and is adversely affecting the real economy as credit to non-financial companies becomes more constricted. Private and public financial institutions in other countries, including Japan, are being affected as well. Given the wrenching and pervasive nature of this problem, the Councils urge the government to resolve this situation as quickly as possible in order to minimize further domestic and global economic instability.

JAPANESE ECONOMY

The Japanese economy has been slowing down, affected by soaring energy and raw material prices, the slowdown of overseas economies, and the turmoil in the financial and capital markets. Although the decline in production and exports has so far been more gradual compared to past recession periods, business sentiment has already deteriorated to the lowest level that had been recorded during the most recent recession period.

At present, a rise in crude oil price as well as other energy and raw material prices seems to have come to a temporary halt. On the other hand, however, the slowdown of overseas economies is becoming more severe. It is highly likely, therefore, that the Japanese economy will become weaker toward the yearend due to weakening foreign demand. In the corporate sector, profits are negatively affected by lower sales and higher variable costs associated with rising resource prices and other factors. Profit declines spread across all industries.

The environment of the household sector is also becoming increasingly severe. As real household purchasing power is declining due to accelerating prices and consumer confidence is worsening, employment conditions appear to be deteriorating as well. The number of new job offers continues to decline on a year-on-year basis, and the unemployment rate has risen to the 4 percent level. Amid the greater employment and income uncertainty and the continuous price rise, there is a strong probability that employees' real salaries will remain sluggish and consumer spending will continue to be weak.

FINANCIAL SERVICES

The Councils acknowledge that the extraordinary developments originating with the U.S. credit crisis are heavily impacting all aspects of the U.S., Japanese and global financial markets and the provision of services in those markets at the present time. Clearly, some fundamental reforms of the U.S. financial system are necessary. For now, however, the Councils can only urge the U.S. government to resolve this situation as quickly as possible in order to minimize further domestic and global economic instability. As instructed by Japan's decade-long struggle to emerge from its non-performing loan (NPL) problem which started in the early '90's, it is better to move quickly and aggressively in dealing with this situation, thus mitigating its negative impact to the broader economy.

Japan and the U.S. as Global Financial Hubs

In previous years, the Councils supported efforts underway by the governments of Japan and the United States to strengthen their markets as global hubs for financial services. This year, the Councils are encouraged by the pro-active steps taken by each government in 2008, and identify further efforts necessary, to secure that goal.

The Councils believe that Japan and U.S. should assess how treatment of skilled personnel and managers affect the attractiveness of their markets and their citizens involved in the global finance sector, 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. Both countries should improve immigration rules to attract highly skilled foreign nationals that boost talent levels and add to the tax base. The U.S. should bring its taxation of expatriates in line with global standards.

The Councils believe that Japan should carefully measure the impact of existing and future tax rules on business activity and economic growth. Japan's effective corporate tax rate should match internationally competitive standards. When it reviews the consumption tax regime, the Japanese government should ensure that the treatment of purchases of goods and services is consistent with global standards for Value Added Tax (VAT). In particular, 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. The Councils also believe that current treatment of capital gains and dividends in private income tax should be maintained even after 2010 year-end, at which point the exceptional treatment is scheduled to cease under the current plan. Meanwhile, deduction of capital losses should be allowed against interest deriving from bond investment and deposits.

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. This form of stability is undeniably in the interests of consumers. The Councils welcome the Japanese government's commitment to further enhance consumer welfare. With respect to the potential establishment of the Consumer Affairs Agency (CAA) and any transfer of laws either wholly or partially to the CAA's jurisdiction, measures should be taken to ensure that any 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 recommendation of the Working Group at the Cabinet's Council on Economic and Fiscal Policy to use cost-benefit analysis for any new related rules and regulations, including objective techniques and quantitative analysis, not only during rule-making for any CAA, but periodically after implementation to ensure that regulations are achieving their intended effects at a level that reinforces economic activity.

In December 2007, the FSA issued the Plan for Strengthening the Competitiveness of Japan's Financial and Capital Markets (the "Better Market Initiative"). The Councils applaud the FSA's vigorous implementation of the initiative in order to create effective, efficient, and transparent regulation under the slogan of "better regulation" and foster a close working relationship between the industry and the FSA to further enhance the competitiveness of Japan's financial and capital markets. In this context, the FSA took a considerable step forward by releasing "the Principles in the Financial Services Industry" in April, 2008, through which the Agency committed to continuously promoting efforts toward increasing dialogue with the industry. It is our expectation that expanded use of open dialogue in rulemaking, published criteria for product approvals and administrative orders, standardized public comment periods and procedures, and ex ante clarification of rules through an active no-action letter procedure and interpretive statements issued at the government's initiative significantly improve stability, predictability and compliance among market participants. The FSA should promulgate new revisions or interpretations of rules through such ex ante procedures as much as possible, including open dialogue and public comment procedures, while also allowing companies to properly prepare for implementation. Supervisory and inspection activity should be fully subject to administrative and judicial review in practice as well as in law. The FSA revised the Guidelines for Financial Conglomerates Supervision in July 2007. The Councils believe that to encourage growth among Japanese and foreign financial groups, further clarification of guidelines for financial services conglomerates and supervision of foreign financial services institutions in Japan is needed. The guidelines should be modified to reflect evolving international guidelines and best practices in group-wide supervision. Group-wide supervision must not lead to another supervisory layer, lead supervisors overseeing the worldwide group from home country jurisdictions should be accepted by supervisors in other jurisdictions, and non-lead supervisors should work together to collaborate with lead supervisors.

The Councils believe further deregulation 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 portfolio transfer for foreign insurers, will promote corporate reorganizations that promise greater business efficiency. The Japanese government should also review 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 is a key regulatory principle to 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, will have a major impact on the financial and capital markets. The Councils hope that the postal financial entities be privatized in a way that ensures equivalent conditions of competition (in accordance with Article 2 of the Privatization Law). This should benefit Japan's financial and capital markets to become globally competitive. Similarly, it is important to establish a level playing field between cooperative financial institutions and private sector financial services industries.

In the U.S., the Sarbanes-Oxley Act has helped to bolster public confidence in the securities market but has also increased significantly compliance costs for listed companies. Recent amendments to Japan's Financial Instruments and Exchange Law (FIEL) enacted in June 2008 incorporate internal controls disclosures and other reporting requirements similar to those in Sarbanes-Oxley. Both governments should continue to review these laws with a view to improving effectiveness while reducing compliance costs and time demands through dialogue with industry participants, and taking into consideration the shortcomings of the Sarbanes-Oxley Act, such as compliance with overly cumbersome procedure, Japan should carefully monitor whether the FIEL 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 is needed not only to reinforce overall pension schemes but also to reinvigorate capital markets and enhance labor market flexibility.

The Councils ask the Government of Japan to review and improve the DC Pension Plan system by: 1) increasing contribution limits substantially; 2) abolishing the special corporate tax; 3) allowing voluntary employee matching contributions; 4) expanding eligibility for participants; 5) relaxing restrictions on access to DC Pension funds; 6) enhancing portability of DC Plans; and 7) encouraging flexibility in the types of investment options available under DC plans.

Commercial Finance

In order to facilitate higher rates of capital formation and business growth, Japan's commercial finance laws need to be modified to increase competition among credit providers and lower the cost of funding available to businesses. The Councils believe that it is vital to enhance the availability of funds without reliance on real property value or personal guarantee, and to support the funding to companies that are financially weak or under bankruptcy protections. The Councils recommend the development of legal infrastructure for asset based lending and DIP (Debtor In Possession) finance. This includes the improvement of current secured transaction laws and enhancement of lender protection.

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 2008 "Seventh 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.

HEALTH CARE INNOVATION

The Councils recognize that the Government of Japan has prioritized improving the environment for investment, development, introduction and use of innovative healthcare technology to improve patients' lives through better and more cost effective diagnosis, prevention and treatment. The Councils continue to believe that innovative healthcare technology – pharmaceuticals, biologics, and medical devices – is critical to both Japan and the United States because of the benefits it provides for patient care in an aging society and because of its contributions to science, technology, economic growth and employment in both countries. The Councils recognize that slow economic growth in the U.S. and Japan negatively impacts the pharmaceutical and medical device markets in both countries. The Councils therefore urge both governments to take proactive steps when setting economic policies to ensure that the healthcare sectors in both countries have sufficient resources to support further innovation and growth.

The Councils strongly believe that certain fundamental conditions are essential for strengthening domestic technology development and foreign investment in the health technology sector. These include ensuring (1) a predictable, transparent, and efficient regulatory system; (2) a fair, adequate and predictable reimbursement environment that values innovation; (3) a sound clinical research environment supportive of clinical trials; (4) good intellectual property protection and technology transfer regimes; and (5) healthy venture finance markets.

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

Recommendations: Pharmaceuticals

1) Improve the R&D process: The Councils welcome the Japanese Government's "Five-Year Clinical Trial Activation Plan," and encourage the government to continue to expeditiously implement it with the goal of reducing the time and cost of conducting clinical trials in Japan. The Councils also encourage the Japanese Government to continue to improve administrative requirements related to conducting clinical trials in Japan, as well as PMDA to expand the number of consultations. In particular, the Councils encourage setting up the "Clinical Trial Center" besides the "Core Hospital" for clinical trial as soon as possible to help in establishing the global clinical research bases in Japan.

The time and cost of drug development also continues to be a challenge in the United States. The Councils urge the U.S. FDA to continue working with industry under the Critical Path Initiative to streamline the drug development process.

2) Eliminate the drug lag: The Councils welcome the Government of Japan's support of simultaneous global development as a means to eliminate the drug-lag as well as to expedite the availability of life saving and enhancing drugs to patients worldwide. The Councils look forward to continued exchanges between industry, MHLW and PMDA with the goal of taking concrete steps such as reducing regulatory barriers and achieving process improvements that will help facilitate Japan's participation in simultaneous global development, including product introduction.

The Councils welcome PMDA's undertaking to reduce new drug review times to 12 months by April 1, 2012 while recognizing the challenges involved in reaching this goal. However, it is critical that consistent and measurable progress take place between now and 2012. The Councils encourage PMDA to discuss with industry the development and implementation of steps to: (1) enhance the ability of the review system to consistently meet the needs of priority and standard reviews at the same time; (2) improve the question and answer process, including the management of the time-clock as well as updating of the file; and (3) secure consistency within and between review teams. Furthermore, the Councils encourage PMDA to maximize the use of global clinical data, including Asian data, as the basis for recognizing safety and efficacy.

The Councils encourage the FDA to balance the assurance of safety and expeditious approval of new drug applications by strengthening the post-marketing safety measures as provided for in PDUFA IV which as enforced in 2007.

3) Improve the pharmaceutical pricing system: The Councils in general welcome the Japanese Government's discussion about comprehensive reform of the pharmaceutical pricing system with the viewpoint of "Appropriate Assessment of Innovation." The Councils strongly encourage the Japanese Government to realize the industry's proposal of comprehensive reform that includes: (1) an appropriate price at the time of launch; (2) price stability during the life of the protected period; and (3) promotion of generics under competitive conditions. Until such reform is adopted, the Councils continue to urge that steps that would further erode the prices of patented products, such as annual price revisions and the re-pricing of highly successful innovative products, not be pursued.

The Councils urge the next president of the United States to ensure that any reforms to healthcare continue to use the market principle, and not obstruct innovation, patient and physician choice or economic growth.

4) Enhance IPR protection: The Councils continue to recommend that the U.S. government consider expanding its data exclusivity term, currently valid for five years, to keep its market exclusivity in the U.S. as long as that of Japan.

Recommendations: Medical Devices/Technology

1) Accelerate regulatory reform to achieve faster and more efficient review for all participants: The Ministry of Health, Labor and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) recently announced measures to speed up and improve the review process for medical devices. The Councils appreciate the transparent process in which the measures were developed, in particular the fact that industry representatives were given the opportunity to review and provide input into the draft measures through a series of working group meetings.

The Councils welcome the intention of the Government of Japan to eliminate the "device lag" (the delay in introducing new medical technology in Japan compared with other countries) within five years. To accomplish this goal, it is critical for MHLW/PMDA to fully implement the announced

reform measures on or ahead of schedule and to thoroughly adopt a "least burdensome approach" to all regulatory process.

In addition, it is essential for PMDA to add review staff on or ahead of schedule and ensure that they are well trained and deployed in an efficient manner. MHLW/PMDA should find ways to ensure coordination of technical expertise among reviewers in order to avoid repeated, burdensome or unnecessary requirements. The Councils welcome MHLW's willingness to increase reliance on "third party" reviewers for Class II devices, and recommends expanding the use of third party reviewers to include Class III and IV devices.

The most important measure of success of the reform measures will be achievement of the review performance goals set forth by MHLW/PMDA. The Councils look forward to carefully monitoring progress toward these targets and would support efforts to achieve the goals ahead of schedule.

Finally, the Councils remain concerned that reviewers face individual liability for their regulatory actions. Such liability should rest with the agencies and their management but not individual reviewers.

- 2) Improve environment for clinical research and new technology development: 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. In addition, the Councils urge greater dialogue among universities, government and industry regarding the conditions for clinical research in Japan and measures to improve clinical research requirements, infrastructure, and capabilities. 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.
- **3) Proposed cooperative action agenda for regulatory agencies in both countries:** The Councils continue to urge both governments to increase cooperative activities between the MHLW/PMDA and the United States Food and Drug Administration (FDA) aimed toward harmonizing requirements and developing processes to accept each other's data and reviews, including partial or incremental steps as appropriate. The Councils believe that regulatory cooperation and harmonization between the U.S. and Japan should be made a higher priority considering the fact that the two countries represent the two largest markets for medical devices in the world.
- **4)** Ensure that the reimbursement process for medical devices rewards innovation: The Government of Japan should provide incentives that reward innovation and promote the adoption of advanced medical technologies which will improve patients' lives through better and more cost effective diagnosis, prevention and treatment.

The Councils recognize that in 2008, MHLW took steps to improve the environment for innovative technology through subdividing some functional categories. However, the Councils remain concerned that the process for obtaining differentiated prices for innovative products is not sufficiently accessible or available. The Councils believe that new and innovative products should be priced individually, based on their qualities and contributions to patient care.

The Councils remain concerned about the use of the "Foreign Average Pricing" (FAP) mechanism. The FAP mechanism is flawed in principle, because different costs and market structures naturally lead to varied pricing in different markets – not just for medical technology but for other industrial products as well. Use of the FAP mechanism undermines the conditions for technology development

and foreign investment in this sector. The Councils urge reducing and ultimately eliminating reliance on the FAP mechanism, and while it is utilized, the FAP process should not change referring countries or reduce limitations to price cuts. The FAP process should not be made more adverse to innovative technology or more frequent than their current use.

5) Support increased use of healthcare IT: The Councils urge greater support for use of healthcare IT to improve efficiency and patient outcomes, as further elaborated in this joint statement's discussion of ICT.

ENERGY & ENVIRONMENT

In the past year, energy and environmental policy has come to the fore, as oil prices set new records, the scientific evidence regarding climate change came into ever-clearer focus and concerns regarding energy security reach new heights. In the face of these challenges, the private sector and governments have rallied around approaches that could emphasize the development and rapid worldwide deployment of domestically available and lower-emitting energy sources.

The Hokkaido Toyako Summit was the central political event in this process. In Toyako, G8 leaders agreed on critical elements of international cooperation to combat climate change. These points included:

- setting a common goal to reduce global greenhouse gas emissions by 50% by 2050;
- agreeing that the major economies should conclude a Post-2012 climate change framework by the end of 2009;
- agreeing that sectoral approaches can be useful tools to improve energy efficiency and reduce GHG emissions through dissemination of existing and new technologies in a manner compatible with economic growth;
- calling for international environmental financial cooperation, including the creation of a Clean Technology Fund and a Strategic Climate Fund;
- promoting innovation in areas such as carbon capture and storage and taking measures to speed commercialization of new technologies; and
- supporting efforts to eliminate barriers to trade in environmental goods and services.

Consistent with our 2007 statement, the Councils support these conclusions. The Councils call on the governments of Japan and the United States to exert more leadership on climate change and energy issues, with particular attention to the following points.

Global Solutions

Energy markets and the challenges of greenhouse gas emissions are both global. Solutions to the challenges in these areas must also be global. For that reason, the Councils call for greenhouse gas reduction commitments by all major emitters as part of the post-2012 international framework. Approaches to ensure participation should include clear benefits for those

developing countries making reduction commitments – for instance providing new opportunities for Clean Development Mechanism (CDM) projects, enhancing sector-specific public/private voluntary actions and mechanisms (e.g. APP) in international technology cooperation, creating allowance trading relationships to other countries that adopt cap and trade systems, and obtaining access to the Clean Technology Fund and other international technology deployment funds.

Both governments should also accelerate their own programs to promote deployment of environmentally friendly technology to the emerging economies. Japan has announced the establishment of its "Cool Earth Partnership" initiative to help emerging countries address global warming issues. In addition, a role for the Japan Bank for International Cooperation (JBIC) will be increasingly important to help finance the dissemination of environmentally friendly technology.

Technology Neutrality

International frameworks and programs to promote cleaner, more independent and more secure energy sources should not preclude the use of any technology. As the International Energy Agency has concluded in its publication "Energy Technology Perspectives 2008," meeting the greenhouse gas emissions levels called for by political leaders will require the rapid deployment of all known cleaner technologies, including wind and solar power, nuclear energy, cleaner coal, high efficiency natural gas combined cycle, biofuels, and hydropower as well as dramatic improvements in the efficiency of energy use.

As part of creating a balanced portfolio of energy sources, it is important for both governments to expand the use of incentives for the use of renewable energy. This should include extending the U.S. federal production tax credit and increasing Renewable Portfolio Standard obligations and considering the use of commercially attractive feed-in tariffs where appropriate. Hydro, wind, solar, biomass, and other forms of renewable energy should be encouraged to the maximum extent possible. Wind energy, in particular, has become a price competitive form of renewable energy at the current technology level, and programs to encourage its use should be implemented in both countries.

In addition, the U.S. and Japanese governments should continue to encourage the construction of new nuclear plants in the U.S. and Japan, as nuclear power generation is an essential part of the energy mix in realizing energy security and GHG reduction. Thus, those legal structures necessary to develop the civilian nuclear industry should also be put in place by both countries. The civilian nuclear power industries of the United States and Japan are closely aligned through joint ventures, cooperative research and development, and customer-vendor ties. One of the requirements for the development of international business for this US-Japanese industry is the strenuous effort by both governments to create business environments that support the expansion of nuclear energy while reducing the risks of nuclear proliferation and storage, as well as liability.

Energy efficiency measures should also be considered as an integral part of an overall energy technology program. In particular, increased research into and deployment of information technology (IT) is fundamental to solving today's environmental challenges and enabling long-term sustainability. An analyst firm calculated that the IT sector uses two percent of global energy consumption. Green IT approaches that promote both further energy-saving in IT

equipment and through IT solutions that can reduce the other 98 percent of global energy use are vital to contribute to a sustainable society.

Innovation of work styles, lifestyles and social infrastructure with low environmental loads can be achieved through IT solutions. For example, updating existing software and PC hardware can save millions of pounds of greenhouse gas emissions annually, and IT solutions, such as webbased communication and collaboration systems can sharply cut back on the carbon footprint of the morning commute and business travel (by one estimate as much as 500 million tons of CO2 by 2020). In the area of electricity infrastructure, "smart grid" technology can improve the efficiency of electricity transmission and distribution.

The "Green IT Initiative" was established by the Japanese government to promote Green IT and under this initiative the Green IT Promotion Council was established in February 2008 as an industry-government-university partnership for implementing Green IT. Government support for the IT industry should be a key part of an overall energy technology strategy. We ask for the U.S. and Japanese governments to establish an evaluation method for measuring companies' contribution for reducing CO2 emissions. Also, the dissemination of environmental and energyefficient IT technologies developed by U.S. and Japanese companies to developing countries can contribute substantially to the reduction of CO2 globally. We ask for both governments to take the lead together in promoting Green IT to contribute to addressing global warming.

Innovation

While promoting the deployment of existing technologies, the Japanese and United States governments and the private sector should continue research and development in the energy field, aimed at improving existing technologies and achieving breakthroughs to new technologies. Government should set policy and legal frameworks to provide incentives for innovation. Within those frameworks, the private sector must make the investments and develop the business models that allow for a successful transformation to low carbon economies. The result can be public-private partnerships appropriate to the challenge, through which the private sector will drive to develop and implement innovative solutions.

The cornerstone of innovation policy in Japan and the United States is the system of intellectual property protection, which encourages both innovation and the availability of information to the public. Far from promoting solutions to the challenges we face, such action outside of normal commercial activity such as the forced transfer of cleaner energy technologies would stall the engine of innovation just when it is most needed. In fact, intellectual property right protection encourages commercial deployment of existing technologies as well as investment in the development of new technologies. Rigorous intellectual property rights protection should be a condition of eligibility for participation in funding or other programs to promote cleaner technology deployment in emerging economies.

<u>Flexibility</u>

Developing policy solutions to high energy prices, climate change, and energy security is a monumental challenge and international systems should be flexible enough to allow for locally appropriate solutions, so long as those solutions are effective. The United States and Japan, for instance, have dramatically different domestic energy resources. While taking into account the different situations, and recognizing that such measures could be combined with cap and trade, baseline and credits systems, benchmark and performance standards, and tax incentives, the Councils support use of "sectoral" approaches that could enable developed economies such as Japan and the United States to set fair and achievable targets as well as to provide incentives to emerging economies to deploy more efficient and cleaner technologies. Sectoral approaches may be applied through technology-based international partnerships that share best available technologies (BAT) and best practices, and set common benchmarks.

The global nature of greenhouse gas emissions also argues for flexibility in the location of greenhouse gas emission cuts. If greater and less costly emission reductions can be achieved in a developing country rather than in a developed country those emission cuts should be encouraged. The existing CDM is one way of achieving this result. The CDM, however, should be simplified and modified to speed approval of legitimate projects and drive greater emission reductions. Furthermore, appropriate investment infrastructure including institutional stability and intellectual property rights protection should be ensured so that private financial flows in clean technology in developing countries can be further expanded. The Councils also believe that CDM scheme should include nuclear generation, large-scale hydro, and DSM programs.

Reduce Costs

The Councils believe that governments should take all available measures to reduce costs associated with the application of cleaner energy and environmental technologies.

- Trade Barriers Although there are many agreements related to global environmental issues, one action governments can take quickly is to eliminate customs duties (tariffs) and other trade barriers to environmentally friendly goods and services. The Councils support efforts to eliminate tariff and non-tariff barriers to environmentally friendly goods and services in the WTO, whether achieved in a revival of the Doha Round or independently along the lines of the Information Technology Agreement or other agreements. Tariffs and trade barriers represent an additional cost that governments impose on the types of projects they are simultaneously offering incentives to support. Eliminating such barriers will help to cut project costs and improve the rate of technology deployment.
- Industrial Standards As another cost reducing measure, the Councils believe it is important for the governments of Japan and the United States to encourage the use of products that are compliant with International Safety Standards while taking account of endemic safety issues in particular countries. Both governments should take appropriate measures to foster international trade in all environmentally friendly products, for example by reviewing recently amended Japanese Safety Standards related to wind power equipment, as the recently amended standards may have had the unintended effect of reducing the rate of construction of renewable energy facilities.

LABOR POLICY REFORM

The Councils continue to emphasize the importance of labor policy reform in Japan as one of the most important ways to increase productivity and grow the economy. Reforms are needed in response to several broad forces:

- declining birthrates and an aging population are resulting in a shrinking workforce and lower economic vitality;
- demand for more diverse lifestyles is leading workers to put more value on work-life balance;
- information and communications technology (ICT) allows new ways of working; and
- greater integration into the world economy requires workers to have more mobility.

In addition, there are growing discussions on the widening disparity in Japanese society, especially a gap between regular workers and non-regular/contingent workers. The increasing share of non-regular employment accounted for 33.5% of the total employment in 2007, up from 25.9 percent in 2000. In response to criticism against growing social disparity, the Japanese government has led an intensive debate on labor policy to create more regulations to protect such "vulnerable" workers who, despite their best efforts to secure regular employment, have been situated in the lower class of society due to a tight job market since the 1990's.

The Councils are concerned that this approach will threaten business vitality and worsen economic conditions, particularly for small and medium-sized business. Broadly speaking, the best way to protect employment and improve working conditions is to put in place policies that boost overall economic growth and productivity, including labor policies and regulations that reflect a balanced approach to deregulation and re-regulation. Overly rigid or restrictive labor regulations will hinder Japan's competitiveness in an increasingly globalized international community, and diminish the appeal of Japan as an attractive investment location for Japanese and foreign business. Labor policy reform is also necessary to achieve Japan's international strategy to take leadership role as an economic hub in Asia.

Over the past few years, the Councils have issued joint statements and made recommendations for labor reform policies reflecting the changing environment. We strongly believe that our recommendations would help the Government of Japan achieve its national strategic goals to improve Work-life Balance, increase and better utilize Diversified Talented People, and promote Tele-working. However, the Councils' recommendations have been hindered primarily by the political climate as opposed to disagreement between parties representing adverse interests, or a lack of social understanding. The Councils therefore hope that the new administration is able to review and find constructive solutions for labor policy issues soon.

The Councils recommend that the Government of Japan organize a new core Labor Policy Reform Team drawn from business, academia, government policy makers, and opinion leaders as soon as possible. This team should take a leading role in conducting an intensive and ambitious discussion of labor policy reform such as making new working rules and promoting deregulation of the labor market.

The Councils hereby request once again the implementation of our recommendations including the following:

1. <u>New working rules</u>

Promote constructive dialogue to enhance job performance and diversified working conditions

- (1) <u>Introduce a self-control working management system for high value-added, creative jobs</u>: Japan should promote performance-based and merit-based employment and consider introducing optional new rules for high value-added and creative jobs to allow such workers to be more independent and have more control over their way of working, instead of measuring their performance by the number of hours worked.
- (2) <u>Introduce pecuniary settlement:</u> Introduction of a monetary settlement in the event of employee dismissals is necessary to prevent the risk of unnecessary, costly court actions and increase predictability for both employers and employees.

2. <u>Review existing rules</u>

- (1) <u>Discretionary work system:</u> As a related rules to the above 1 (1), the existing discretionary work system should be reviewed for its necessity, including its continued relevance.
- (2) <u>Establish freedom of contract in the employment relationship</u>: The Ministry of Health Labor and Welfare (MHLW) should more precisely define and limit the scope of what is considered an unjustified dismissal in the Labor Contract Law to encourage greater respect for the contractual employment relationship and also to provide the flexibility required by Japanese businesses.
- (3) <u>Improve the Worker Dispatch Law:</u> Specifically, further improvement and easing of regulation is required on the restriction on dispatch term, the obligation to make an offer for direct employment and 26 professional work types that are exempt from restriction of dispatch term because there are needs from both labor and management to allow diverse and flexible work styles. In this regard, the Notice entitled the "Standards regarding classification of worker dispatching business and outsourced business" (April 17, 1986; Ministry of Labor Notice No. 37) should be reviewed to allow companies to accept a diversified workforce.

3. <u>Improve Defined-Contribution (DC) pension plans</u>

The Government of Japan should improve the Defined-Contribution pension plan system by: 1) allowing voluntary employee contributions; 2) increasing contribution limits substantially; 3) expanding eligibility for participants; 4) relaxing restrictions on access to DC pension funds before retirement; 5) enhancing portability of DC plans, including by making rollover easier; and 6) encouraging the provision of advice by plan administrators and increasing flexibility in the types of investment options available under DC plans.

4. Streamline visa processes for skilled employees and technology exchange programs:

The Councils encourage both governments to enhance cooperation with a view to improving their respective immigration laws and systems. The following measures would help Japan to achieve its goal of making it a gateway to Asia and an international economic hub.

• <u>Pre-screened pools of approved specialists</u>. Both Governments should consider introducing into economic cooperation agreements a provision that would allow the designation of a pool of

specified experts who could be pre-screened for security purposes and who could then receive visas on short notice.

- <u>"H"-type visa:</u> Japan should adopt the equivalent of the U.S. "H"-type training visa to promote Tokyo as a regional and global training center.
- <u>Business Visitor visas</u>: A system for fast-tracking short term visitor visas for employees should be implemented; and
- <u>Long-term technical exchange:</u> A system for both Japan-bound and U.S.-bound technical expert visas should be fully implemented.

INTELLECTUAL PROPERTY RIGHTS

The Councils are acutely aware that intellectual property is playing an increasingly important role in corporate activities amid rapid changes in the business environment, such as increased globalization and rising resource and energy prices. The Councils share the understanding that the United States and Japanese economies could derive greater benefits from the presence of strong and balanced intellectual property systems not only at the national level but also internationally, and urge the governments of the two countries to demonstrate leadership in the following areas.

1. The Councils are convinced that strong and balanced intellectual property system and transparently enforced competition laws and systems are not in conflict and together contribute importantly to stimulate innovation and enhance benefits to consumers. The Councils recognize the need to promote policy approaches in each area that permits market forces to deliver innovative technologies, products, and services of high quality to consumers at appropriate prices. In an increasingly globalized economy, the trend toward "open innovation," is growing fastest in certain technology areas where innovation is occurring rapidly, and product life cycles are shorter. "Open innovation" can be accomplished through a range of uses of intellectual property, including through dedicating rights to the public, agreeing not to assert rights under certain circumstances as well as the licensing of intellectual property. With this situation in mind, the Councils call for continuing efforts to support "open innovation" so as to enable technologies to be widely spread and used in those areas, and to enable individual companies to realize the economic value of their innovations to the fullest extent.

2. The Councils call on the governments of the two countries to monitor and take appropriate actions to address new issues associated with content and the shift to digital media, given increasing broadband access and increased globalization. Specifically, governments should encourage voluntary discussions and solutions among market participants, particularly where these are likely to result in balanced approaches regarding the use and protection of content, while allowing users and other parties to enjoy the benefits of technological innovations. It is also necessary to clarify the calculation methods of transfer pricing concerning IP and to operate mutually agreed procedures and advanced pricing agreements and other measures in a swift and effective manner.

3. The Councils are concerned about excessive damage awards, especially to entities that do not utilize patented inventions. The Councils urge that this issue continue to be monitored in U.S.

and Japan, based on the understanding of The Councils' request that the patent systems should be improved through the revision of the two nations' patent laws or other means, and their strong need to make legal damages more rational.

4. The Councils believe that US patent system can be improved by continuing attention to the quality of patent examinations, and enhancing the expertise of district court judges. The Councils also encourage the Japanese government to ensure further consistency in the criteria for determining patentability between the Japan Patent Office and the courts. The Councils also encourage that both governments shorten the patent examination period. These measures should further improve stability and predictability in the determination of patentability.

5. The Councils recommend that the governments of the United States and Japan take the lead on critical initiatives for the international patent systems, including the Patent Prosecution Highway, and the Substantive Patent Law Treaty (including the proposals by the Group B+ countries on a possible agreement on a limited basket of patent harmonization provisions). In particular, we call on the new U.S. Congress when it convenes in January 2009 to make the reform and streamlining of the US patent system an important priority, including adoption of the "first-to-file" principle, in order to better harmonize the operation of the national patent system with international rules. The Councils also urge the two governments to explore the implementation on a trial basis the mutual recognition of patent examinations, restricting participation initially to companies filing over 100 patents annually in each jurisdiction. A step of this nature is urgently need to reduce the workload and improve the quality and timeliness of patent application adjudication by the US and Japan patent offices and will represent tangible and visible progress toward achieving the goal of international patent harmonization.

6. The Councils enjoin the governments of the United States and Japan to work together, and through partnerships between the public and private sectors of the two nations, to eliminate infringement of intellectual property rights in a third country by urging the government of that country to take necessary actions for solving the problem. In particular, the Councils support the two governments in their efforts to continue cooperation against counterfeit and pirated goods. This includes efforts to create an international legal framework to prevent counterfeit and pirated goods, such as the Anti-Counterfeiting Trade Agreement (ACTA) initiative, which the G8 summit set the goal of concluding negotiations by the end of this year. The business communities of the United States and Japan request the two governments to exercise active leadership to promptly realize the ACTA, and will provide as much cooperation as possible to that end.

SECURE TRADE

The Councils once again urge both governments to achieve a more effective secure trade system with the objective of modifying or eliminating measures that add to lead times and costs without providing a clear security benefit. In particular, as noted in a recent letter to the Commissioner of the U.S. Customs and Border Protection Agency from the Councils, the Councils remain concerned that new advanced data collection requirements for ocean-bound freight, or so-called 10+2 regulations, and the requirement that 100% of containers entering U.S. ports be scanned starting in 2012 will make trade between the U.S. and Japan (and other markets) more costly and complicated. In that most experts consider the threat-based risk management approach the most effective way to deploy limited security resources rather than trying to have a 100% solution at single supply chain points, the Councils urge reconsideration of this requirement.

The Councils also urge both governments to enhance their respective Authorized Economic Operator (AEO) programs so that they provide more tangible benefits to traders, as well as establish mutual recognition of these programs. Compatible secure trader programs, and mutual recognition, would facilitate bilateral trade by establishing uniform procedures for companies to follow. Similarly, the Councils encourage both governments to implement robust national single window systems to further streamline and harmonize requirements for traders.

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 Anti-Monopoly Act (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:

- <u>Appeals process</u>: 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. 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 new one established within the judicial system, in accordance with general principles of administrative lawsuits.
- <u>Investigations</u>: JFTC investigations should adhere to fundamental, international standards of due process and transparency, including the following procedures and protections:
 - (1) Disclosure of all 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; and
- (4) Preservation of confidentiality of information provided to the JFTC.

Merger Notification

In addition, to promote the efficient and effective review of international merger transactions, the JFTC should incorporate higher threshold levels for merger notifications into the AMA to ensure that Japan will assert jurisdiction over only those transactions that have a significant relationship to Japan.

To avoid unproductive activity for both the JFTC and the parties to international merger transactions, the AMA should be amended so that mergers involving any parties, regardless of nationality or location of the headquarters/major business premises, are covered by Japan's notification requirements only when those transactions have material nexus with Japan based on each of the parties having a material level of sales within the jurisdiction. A comparatively low level of assets or sales of the target company would be required to meet the current AMA notification thresholds as well as the JFTC's proposed new thresholds for notification. These thresholds would be over-inclusive by requiring notification of transactions that have no material impact on competitive conditions in Japan. Raising the new proposed thresholds to a substantially higher level that is material to an economy the size of Japan's would minimize unproductive activity by the JFTC and the parties, while still encompassing mergers with possible material competitive effects in Japan. The JFTC should focus on compatibility with the International Competition Network's (ICN's) "Nexus to Reviewing Jurisdiction" Recommended Practice, which states that merger notification thresholds should incorporate appropriate standards of materiality as to the level of "local nexus" required for merger notification, based on the parties' activity within the jurisdiction. In order to meet the "materiality" standard of the ICN's Recommended Practices, Japan, as the second largest economy in the world, should have a local nexus requirement that is substantially higher than the current or proposed thresholds in the AMA.

<u>Surcharges</u>

Finally, the Councils urge that the JFTC reconsider the proposal to impose surcharges on unfair trade practices. Because it is difficult to correctly distinguish an unfair trade practice (for example, abuse of superior bargaining position, unjust low price sales, or discriminating conduct against small and medium-sized enterprises) from legitimate competition, surcharges may be wrongly imposed on conduct without any substantial negative effect on competition. In addition, the resultant confusion on the part of companies attempting to comply with the law may have a chilling effect on procompetitive conduct. These potentially negative effects would be compounded by the fact that there is no requirement of dominance or market power to be held liable for unfair trade practices. In case the surcharge is going to be imposed, the meaning of "substantial restriction of competition" in the context of private monopolization must be clarified in the Antimonopoly Act in order to ensure legal stability and predictability, and to observe the principle that penalties must be clearly defined by law. Likewise, as for unfair trading practice, the specific description of conduct that newly comes under the scope of surcharges must be

specified in the Antimonopoly Act taking into account the relevant precedents to date, and for this purpose we suggest the current approach itself to regulate certain conducts individually be reviewed.

ECONOMIC PARTNERSHIP AGREEMENT

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 strengthen the overall competitiveness of the U.S. and Japanese economies amid rapid Asian economic growth and integration. 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 as the new U.S. administration takes office early next year.

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, trade remedies such as antidumping, competition policy, human resources and movement of natural persons, intellectual property, and secure trade.

The Councils endorse the U.S. and Japanese government support for APEC's efforts to accelerate trans-Pacific economic integration, including the ambitious long-term goal of a Free Trade Area of the Asia-Pacific (FTAAP), and believe that a U.S.-Japan EPA could provide a starting point and model for such integration going forward. Indeed, such an agreement could boost both countries' competitiveness in Asia and globally by enabling the United States and Japan to take the lead in establishing the regulatory framework that will serve as a key element of the emerging trade and economic architecture in the dynamic Asia-Pacific region. The Councils remain supportive of multilateral negotiations at the WTO and believe that negotiation of a comprehensive, high-standard U.S.-Japan EPA would provide impetus for further progress in multilateral negotiations.

The Councils acknowledge that the path forward for a high-standard agreement is difficult in the current political environments in both countries and in light of the many tough issues that would have to be tackled to achieve a comprehensive, high-standard EPA. Nevertheless, in light of the tremendous potential benefits to both countries, the Councils call upon the governments of the United States and Japan to commit to the medium-term goal of achieving a comprehensive, high-standard U.S.-Japan EPA.

The Councils also acknowledge that increased trade, while bringing tremendous benefits to companies and consumers alike, often results in dislocation in certain areas due to greater competition. The Councils recognize the need to establish robust systems in both countries 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, and worker retraining systems; and portable, cost-

effective pension and healthcare structures. Such efforts are required to build a strong consensus on promoting free trade moving forward.

Against this backdrop, the Councils believe that, as work is being done toward building a consensus for the establishment of a comprehensive, high-standard EPA, the two governments should negotiate binding, interim trade-enhancing initiatives that would allow the two countries to work together immediately to solve business environment problems that impede trade and investment between the two countries and impede their competitiveness with respect to the rest of the world.