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## **U.S. ECONOMY**

The Councils are encouraged by the return of the U.S. economy to a solid 3.9% real growth rate (preliminary) in the third quarter due to stronger-than-expected personal consumption, non-residential investment, and export growth. This performance attests to the underlying resilience and strength of the economy despite serious problems in credit markets and the housing sector, which cut into the overall growth rate. There are questions about whether growth in subsequent quarters will hold at such strong levels.

The credit and housing problems persist, and will be the major risk factors to growth in the near term. Accordingly, the Councils encourage the U.S. government and Federal Reserve to continue their efforts to ensure that adequate liquidity is in the financial system, and that appropriate policy adjustments are made.

Exports will continue to play a major role in sustaining U.S. growth given the uncertainty of domestic demand over the next few quarters. It is therefore very important that the governments of Japan, the major economies of the EU, and large emerging economies implement macroeconomic and exchange rate policies that boost domestic demand-led growth, particularly consumption. It is also important that the U.S. economy and markets remain open to foreign trade and investment, and the Councils urge the U.S. government and Congress to move expeditiously to approve pending bilateral trade agreements with Peru, Colombia, Panama and Korea.

## **JAPANESE ECONOMY**

The Japanese economy remains in relatively good shape, driven by capital spending and exports. Despite a decline of real GDP in the second quarter, the economy should continue on the current moderate growth path in place since the recovery began in 2002. Corporations have made much progress in reducing debt levels, and continue to invest heavily in new plant and equipment and expand exports. There are several uncertainties about the future, however.

First, while Japanese exports continue growing at a faster pace than the previous year, strongly backed by China/Asia-bound exports, the potential negative impact of the subprime mortgage issue on U.S. growth in coming quarters could adversely affect future export growth. The weak yen, which is at almost the same level as in the mid-1980s, has been one of the factors supporting the expansion of exports.

Secondly, personal spending has been sluggish. Although employment continues growing, the retirement of high-income baby boomers from the labor market and the entry of low-income young people in turn have resulted in a decline in overall employee income. Slumping stock prices triggered by the global financial market turmoil and the pension problem have also hurt consumer sentiment, thus dampening personal spending further.

Thirdly, the construction sector has been slowing down. On the supply side, housing investment has declined significantly since June due to the revision of the Building Standard Law, and this has led to a significant year-on-year decrease in construction

starts for condominiums, etc. Demand for housing has also slowed as prices have risen in response to higher land prices and building costs.

All these factors, compounded by oil prices at \$90 per barrel, bear watching in coming months. As the government tackles problems such as regional disparity, competitive differences among corporations, and growing fiscal imbalances, it is important to continue with measures that boost productivity so that Japan's high living standards may be sustained as the population and workforce age.

## **JAPAN AND THE U.S. AS GLOBAL FINANCIAL HUBS**

Last year, the Councils recognized efforts underway by the governments of Japan and the United States to strengthen their markets as global hubs for financial services. The Councils are again encouraged by continued, proactive steps taken by each government in 2007 to identify how 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 they treat managers with responsibilities for their respective regions 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 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 financial policies. Increased use of open dialogue in policymaking, published criteria for product approvals and administrative sanctions, proper public comment procedures, no action letter systems, interpretive letters and the like significantly improve stability and the ability of companies to comply with laws. The Councils welcome FSA publication this year of revised inspection manuals, release of criteria used in issuing sanctions, and implementation of measures aimed at creating a more robust no-action letter system. Recognizing the importance of uniform comprehension of FSA regulatory interpretations by the market, the Councils urge the FSA to issue forward-looking interpretive letters on emerging issues without waiting to address those issues in response to a request from industry. The Councils believe that Japan should further clarify its guidelines for financial conglomerates and financial services supervision applicable to foreign financial institutions in order to ensure transparency in implementation of regulatory policy.

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 be lowered to international standards. If Japan reviews its consumption tax regime, the government should ensure that the treatment of such transactions is consistent with global standards for VATs (Value Added Tax) and should reconsider treatment regarding the application of consumption tax to transactions between wholly-owned affiliates. The Councils also believe that current treatment of capital gains and

dividends in private income tax should be maintained after 2008, and deduction of capital losses should be allowed against interest deriving from bond investment and deposits.

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. Japan's new Financial Instruments and Exchange Law (FIEL) incorporates internal controls disclosures and other reporting requirements similar to those in Sarbanes-Oxley. The Councils believe that 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.

The Councils believe that Japan should carefully monitor whether the FIEL serves its key objective of protecting investors in the most efficient fashion. More broadly, the Councils support Japan's commitment in the Economic and Fiscal Reform 2007 "Basic Policies" to develop, by the end of 2007, a "Plan for Enhancing the Competitiveness of Financial and Capital Markets." The Councils also support the recommendation of the Working Group at the Cabinet's Council on Economic and Fiscal Policy to use cost-benefit analysis, including objective techniques and quantitative analysis, not only during rule-making, but periodically after implementation to ensure that regulations are achieving their intended effects at a level that reinforces economic activity.

Finally, to encourage more people to prepare for a more secure financial future, the Councils believe that both public institutions and private companies in both countries need to enhance efforts to promote financial education among the general public.

## **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.

The Pension Protection Act of 2006 in the United States went a long way toward addressing the problem of underfunded defined benefit corporate pension systems. It also promoted broader participation by employees in defined contribution corporate pension systems by allowing automatic enrollment of employees through an opt-out system and made permanent the higher contribution limits originally passed in 2001.

## **POSTAL PRIVATIZATION**

### **Postal Savings and Life Insurance**

The new Japanese postal businesses began operations on October 1, 2007. The “Implementation Plan Regarding Succession of Japan Post’s Businesses”, which was approved in September, specifies the scope of products and services to be provided by the Postal Savings (*Yucho Bank*) and Postal Life Insurance Corporation (*Kampo Life*) and puts forward those entities’ intention to expand their business scopes quickly.

“Securing equivalent conditions of competition” is essential to ensuring that the postal savings and insurance businesses do not unfairly disadvantage the private sector. Measures to ensure equivalent conditions of competition must be effective, taking into consideration the totality of the circumstances. The Councils believe that ensuring equivalent conditions of competition are prerequisite when *Yucho Bank* and *Kampo Life* broaden the range of products underwritten/manufactured.

Accordingly, the process for approval of entry by the new postal entities into new businesses or product areas is critical. In particular, the proceedings of the Postal Privatization Committee, which oversees the progress of privatization, should be conducted in a transparent manner, such as hearing the views of relevant parties. The Councils strongly request that when the Postal Privatization Committee reviews applications concerning the expansion of the business scope, it should maintain a cautious manner so as to ensure equivalent conditions of competition with private financial institutions.

### **Express Delivery**

Japan Post Service Co., Ltd., the privatized postal delivery company, began operations on October 1, 2007.

Securing “equivalent conditions of competition” is also essential to ensuring that Japan Post Service’s express and other value-added delivery services do not unfairly disadvantage the private sector. Effective measures to ensure equivalent conditions of competition in all express and value-added delivery services – including both the domestic service, “Yu-pack,” and the international service, “Express Mail Service” (EMS) – must be undertaken to ensure the overall health of the economy and the fundamental principle of maintaining and enhancing the long- and short-term interest of both customers and taxpayers.

From this perspective, the Councils urge the Postal Privatization Committee to play a more active role in overseeing near-term progress toward establishing equivalent conditions of competition between Japan Post Service and the private sector. The Councils also urge the Committee to ensure that there is full transparency, regular communication with the private sector, and opportunities for the private sector to provide meaningful input to the Committee and to the various Ministries overseeing Japan Post Service’s businesses on these matters as privatization proceeds.

## **HEALTH CARE INNOVATION**

A fundamental part of maintaining a healthy aging population is having a health care industry that can develop innovative life-saving and life-enhancing products and therapies, shorten hospital stays, and reduce costs. The Councils believe that an innovative health care technology industry – pharmaceuticals, biologics, and medical devices – is critical to Japan and the United States, for these reasons:

- First, it is increasingly important given aging populations. Innovative drugs, biological therapies and medical devices can help ensure a higher quality of life by helping people lead longer, healthier and more productive lives.
- Second, as a science and technology-based industry, both the U.S. and Japan have a competitive advantage given their highly educated workforces and sophisticated infrastructure.
- Third, as one of the largest, fastest-growing and most innovative sectors in advanced economies, health care technology contributes significantly to overall productivity and economic growth.

The Councils commend the Government of Japan for making the healthcare industry a priority under the “Innovation 25” initiative, and strongly urge that forward movement toward the initiative’s goals continue. In addition, we encourage the improvement of people’s quality of life and the realization of economic growth through the implementation of the “Five-year Strategy for the Creation of Innovative Pharmaceuticals and Medical Devices” as well as the continuation of the “Government-Industry Policy Dialogue.” In the U.S., the FDA has launched the Critical Path Initiative, a national effort to stimulate and facilitate modernization of the scientific process through which potential human drugs, biological products, and medical devices are transformed from discoveries into actual products.

The Councils believe that there are the following similarities in the regulatory and market conditions needed to support innovative pharmaceutical and medical device industries:

- The best way for governments to encourage innovation is to establish the most supportive conditions possible so that researchers, scientists, entrepreneurs, investors and manufacturers may pursue the best ideas rather than trying to promote specific technologies or companies.
- These include:
  - (1) a predictable, transparent, and efficient regulatory system that leads to timely and reasonable decisions, before and after marketing;
  - (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

There are some key differences that need to be recognized, as outlined below:

### **Recommendations: Pharmaceuticals**

1. **Improve the R&D Process:** It is more expensive and time consuming to conduct clinical trials in Japan than in any other major market. The Councils agree that further practical steps, such as building greater capacity and introducing more competition into this segment of the market, are critical. In addition, attention needs to be given to the administrative requirements that pull Japan out of sync with other major markets.

The time and cost of drug development is recognized by the US FDA as an issue as well. To attempt to make the R&D process more efficient the FDA has introduced the Critical Path Initiative. The Councils endorse this effort.

2. **Eliminate the “drug lag”:** Japan has a problem in that Japanese patients cannot access the newest drugs that can be used in other countries. There is a difference of 2.5 years between the launch time in the U.S. and Japan. There are various factors that cause the drug lag such as the longer time and higher cost of the clinical trial in Japan, and the longer time of the examination by the Pharmaceuticals and Medical Devices Agency (PMDA). MHLW and PMDA have set the goals of reaching median approval times for standard new drug applications, including biologics, of 12-months total time by April 1, 2012, and by reducing development time by 1.5 years, which are most welcome. To facilitate this PMDA will be significantly increasing its staff size through increased user-fees. It is critical that measurable, steady progress takes place in approval times from April 1, 2007 through April 1, 2012. In addition, the Councils encourage the Japanese Government to take steps to further expedite the availability of products that today are approved overseas, but not in Japan.

Faster approval of new drugs is also desirable in the U.S. The Councils strongly supports the implementation of the reauthorization of the Prescription Drug User Fee Act (PDUFA).

3. **Reform the pharmaceutical pricing system:** It is one of the factors of the ‘Drug-lag’ in Japan that the prices of new drugs are inadequate and unattractive and they are subject to downward price revisions. Comprehensive pricing system reform should be realized to recognize the value of innovative new drug more adequately. PhRMA and JPMA announced pharmaceutical drug pricing system reform proposals in July. The Government of Japan should earnestly consider these proposals from the viewpoint of encouraging innovation and eliminating the drug-lag, and try to realize them as soon as possible. In the interim, 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.

On the other hand, there is a growing concern with controlling medical expenditure by the government in the U.S. Any steps that the U.S. Government takes must continue to use the market principle, and not obstruct innovation, patient and physician choice or economic growth.

4. **Enhance IPR protection:** The MHLW has decided to expand the term of data exclusivity from six to eight years. The Councils 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. In addition, the Councils affirm that innovation and strong intellectual property protection play critical roles in developing new

and effective life science and pharmaceutical products. Patient access to these medicines and therapies is and always will remain a primary focus of both countries and our innovator companies. The Councils urge both governments to stand against the weakening of IP rights in these vital industries, including by combating the counterfeiting of patented medicines and preventing unfair reliance upon proprietary innovator data by non-innovators.

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

#### **1. Improve environment for clinical research and new technology development:**

- Recognizing that innovation for medical devices requires close collaboration between manufacturers and physicians, establish the regulatory environment where manufacturers can provide prototypes for use in clinical research, with appropriate protection for participating patients.
- Create a vision by identifying disease areas and milestones for therapy and technology development; allowing patients to see their future opportunities through the promotion and advancement of medical technology investments.
- Establish a structured critical path process that enables early applications of innovative technology through efficient industry research and efficient regulatory review processes.

#### **2. Accelerate regulatory reform to achieve faster and more efficient review for all participants:**

- Promote regulatory science activities among industry, academia and governments to further develop regulatory expertise, especially regarding risk management and the science and technology of medical devices.
- Establish firm streamlined criteria that are consistent with international practices and transparent standard process for improving review times and increasing review performance, and manage review practices according to those processes.
- Recognizing the varied nature of medical devices and technology, increase the number of experts from sources such as the private sector, academic institutions, national research institutions, third party reviewing bodies, and physicians from both home and abroad.
- Facilitate employing third party organizations to outsource selected parts or full portions of reviewing process to reduce the burden of the increasing workload.
- Also consider lifting individual liability of reviewers for product performance and clarifying that such responsibility lies with the institutions and their management.

#### **3. Ensure that the reimbursement process for medical devices rewards innovation:**

- Enhance the transparency of the re-pricing process, without utilizing the Foreign Average Pricing (FAP); while it is utilized, the FAP process should employ appropriate weighting for averaging methodology and should not change referring countries and limitations to price cuts.
- Recognizing that improvements in medical devices often come in incremental steps that may nevertheless represent or add up to significantly better therapy, provide reasonable and effective mechanisms for evaluating and awarding higher reimbursement rates for innovative products including those products with incremental improvements.
- Subdivide functional categories grouping old generation products with advanced, innovative products, and create new categories for new and innovative technology, in order to provide adequate reimbursement versus inclusion into existing categories.
- Recognize the value of innovative technology for prevention, early detection and intervention in order to achieve the best quality of life and most cost-effective care.



#### **4. Proposed cooperative action agenda for regulatory agencies in both countries**

- Continue and enhance activities for achieving harmonized regulatory environment and promote exchanges of personnel among relevant agencies.
- Engage in U.S.-Japan government-to-government dialogue for development of appropriate systems and processes to accept each other's data and reviews, including partial or incremental steps as appropriate.
- Explore the concept of establishing or recognizing a third-party organization, such as a notified body, whose reviews would be valid in both markets.

### **ENERGY AND ENVIRONMENT/CLIMATE CHANGE**

Based on improved understanding of climate change and the contribution of human activities, the Councils agree that the U.S. and Japanese governments must take more rapid and aggressive steps toward mitigation. Delay in curbing greenhouse gas (GHG) emissions is poor risk management, as this will likely force our countries to take more drastic and costly action in the future. Given Japan's role as host of the 2008 G-8 Summit and the U.S. role as host of the Major Economies Meeting on Energy Security and Climate Change, the U.S. and Japan are well positioned to exert leadership in structuring an effective, practicable and flexible international framework for reducing GHG emissions in the post-Kyoto Protocol period after 2012. To create the greatest certainty of future market conditions, it is essential to reach agreement on a post-Kyoto international framework by 2010.

The Councils believe such a framework should adhere to these essential principles:

- 1) Predictability: Definite but realistic, scientifically-based medium- and long-term targets and commitments for reducing GHG emissions should be set so that businesses may plan and adjust accordingly. Predictable market signals indicating the relative costs/benefits of CO<sub>2</sub> emissions are necessary for companies to justify investment in more efficient and expensive capital equipment and, longer term, to develop and adopt new technologies. In the U.S., it is particularly important to develop a national program to avoid the confusion and compliance difficulties inherent in multiple state emission-reduction targets or programs.
- 2) Comprehensiveness: Any viable national or international program must include all major GHG producing sectors and nations, including the U.S., China and India.
- 3) Sector neutrality and equitability: Any targets should not impose excessive burdens on any one industrial sector or emission source, but should be spread proportionally across sectors/sources. Obligations should take into consideration the relative capabilities of each sector and country to meet them.
- 4) Market flexibility and efficiency: To increase viability, any program, including a mandatory framework, must be flexible in order to minimize the impact of emission-reduction measures on economic growth. This will require that a range of instruments such as cap and trade systems, baseline and credits systems, benchmark and performance standards, and tax incentives be available for use according to national circumstances. Any program should be structured to ensure adequate returns to investors and an orderly replacement of capital assets as the markets stimulate new technologies for reducing emissions.

While there will be significant adjustment costs, the Councils believe that the climate change challenge can also create new economic opportunities for both the U.S. and Japan if the following policies and approaches are adopted:

- **Emphasize energy efficiency:** Improvements in energy efficiency should be the foundation of any climate change strategy, as it is half as expensive to conserve energy as to add new capacity. According to the International Energy Agency, buildings and appliances account for approximately 24% of total CO<sub>2</sub> emission reductions that would be required in a long-term plan.<sup>1</sup> The Councils urge their governments to work together to develop stronger codes and standards for commercial buildings, houses, and household appliances, and on measures to ensure compliance with such codes and standard. Significant improvements in vehicle fuel-efficiency are also essential, but these should be economically and technologically feasible and phased in over a reasonable time frame.
- **Focus on sectors:** To encourage major emitting economies such as China, India, and Brazil to participate in an international emission reduction framework, the Councils support use of “sectoral” approaches that could enable developed economies such as Japan and the United States 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.
- **Accelerate development and use of renewables:** Increasing the use of renewable energy technologies such as hydro, wind, solar, geothermal, and biomass will promote energy security, diversification, and conservation while reducing GHG emissions. Both governments should explore all possible short- and long-term measures and incentives to encourage further research, development, deployment and usage of these technologies.
- **Increase nuclear cooperation:** Nuclear power generation is gaining widespread recognition as one of the most important potential contributors to energy security and GHG reduction. Accordingly, the U.S. and Japanese governments should continue to encourage the construction of new nuclear plants in the U.S. and Japan. Both government and private sectors should enhance cooperation on the following initiatives to support further development of the industry: the Global Nuclear Energy Partnership; government financing of new nuclear plants; development of advanced nuclear technology such as “GenIII/IV”; and policies and best practices regarding plant safety, waste disposal, proliferation and the establishment of an international nuclear fuel supply assurance mechanism.
- **Develop clean coal technologies:** There is a need for an effective regulatory framework and incentives, and national/international public/private cooperation, to encourage the development and appropriate application of clean coal technologies, including IGCC (Integrated Gasification Combined Cycle) and carbon capture and sequestration. The ability to offer this technology at affordable prices depends to a large extent on the ability to develop a number of commercial-scale projects that will, over time, drive cost reductions.
- **Enhance Asia-Pacific Partnership for Clean Development and Climate (APP):** The APP offers significant potential to become one of the best models for sectorally based public/private cooperative actions such as (a) sharing best practices in reducing greenhouse

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<sup>1</sup> Energy Technology Perspective 2006, International Energy Agency

gas emissions; (b) developing innovative cleaner energy projects; and (c) identifying barriers to and creating effective incentives for the deployment of advanced technologies. To maximize this potential, both governments need to commit the resources and political influence required to make this a more effective mechanism.

- **Promote transfer of “clean” technology:** As major producers of “clean” technology such as wind turbines, solar panels, and heat pump systems, the U.S. and Japan should accelerate its transfer, particularly to the larger emitting countries among emerging economies. Cooperative, multilateral programs such as the APP can facilitate this process. The U.S. and Japanese governments should also devise programs to help finance the purchase of clean technology -- bilaterally, through the U.S. Ex-Im Bank and Japan Bank for International Cooperation, and multilaterally, through the World Bank and Asian Development Bank. Aggressive efforts should also be made through the WTO and APEC to eliminate tariff and non-tariff measures affecting the export of clean technology.
- **Improve the Clean Development Mechanism (CDM):** The CDM, a project-based flexible mechanism, has the potential to allow the transfer of substantial financial flows from developed countries to emerging economies via technology transfers, if appropriate modifications are made. This could reduce CO2 emissions by a significant amount. Accordingly, this mechanism must be continuously improved and expanded.

#### **LABOR MARKET FLEXIBILITY**

The Councils continue to emphasize labor market flexibility as one of the most important ways to increase productivity, a critical component of economic growth in both countries, but particularly in Japan because of the dwindling birthrate and aging society. Last year, the Councils recommended that both governments emphasize Japanese labor policy more in bilateral discussions of economic issues, and urged approval of certain reform measures. The political situation prevented any action from being taken in 2007, however.

Creating better working opportunities to meet various interests and needs of society is one of the most critical policy agendas for the Government of Japan. Specifically, the Councils urge the Government of Japan to implement earlier labor policy proposals, including the following:

- (1) establish more precisely the definition and scope of what is considered an unjustified dismissal;
- (2) introduce monetary settlements in alternative dispute resolution procedures;
- (3) expand and define more clearly the category of “overtime exempt” employees; and;
- (4) improve the Defined Contribution (DC) pension plans.

The Councils acknowledge that labor issues are challenging given the need to balance competing interests. In Japan, these include work-life balance, diversity management, and addressing the changes associated with an older and declining workforce. As the Japanese economy becomes more global, however, maintaining antiquated labor laws will not only hurt the competitiveness of Japanese companies, but will affect Japan’s attractiveness as a place for global companies to invest.

The U.S. labor market is more dynamic due to flexible employment rules, merit-based compensation and portable retirement (defined contribution) plans. This flexibility has been a key to strong U.S. economic performance in recent years. The U.S. also faces various challenges. In particular, as the need for more highly skilled workers in knowledge-based, high value-added industries such as information technology, health care, and finance increases, significant improvements in K-12 and higher education, are essential.

Improved social safety nets and retraining programs to help workers in transition are necessary in both countries.

## **INTELLECTUAL PROPERTY**

The Councils understand that recent changes in the business environment, characterized by progress in globalization and the rapid spread of information technology, are making intellectual property increasingly important as a source of corporate value and driver of innovation. The Councils believe that the U.S. and Japan share a common interest in strengthening intellectual property rights both domestically and globally. Accordingly, the Councils urge the two governments to show leadership in the following areas:

First, the Councils encourage both governments to consider initiatives such as the Patent Prosecution Highway and the Substantive Patent Law Treaty as key measures for an international patent system. Vital to this will be U.S. adoption of a first-to-file system, in order to bring U.S. practice into conformity with international rules and procedures. The Councils are pleased to note that legislation addressing this important matter recently was passed in the U. S. House of Representatives, and hope to see further progress on this issue.

Second, the Councils urge the U.S. government to improve its patent system by ensuring the quality of patent examinations, the expertise of district court judges and the reasonableness of court proceedings and damage awards. The Councils also urge the Government of Japan to shorten the patent examination period and establish uniform criteria for determining inventiveness and patentability so as to avoid conflicting standards between the Japan Patent Office and courts.

Third, the Councils urge both governments to work jointly, as well as through public-private partnerships, to eliminate intellectual property infringement in third countries by encouraging the governments of these nations to take independent measures to address these problems. In particular, the Councils support continued collaboration in combating piracy and counterfeiting, including efforts toward the possible international legal framework on preventing the proliferation of counterfeit and pirated goods.

Fourth, the Councils affirm that IP and competition laws share the same basis of enhancing consumer welfare and promoting innovation – and that policy approaches in these area need to work in tandem to bring new and better technologies, products and services to consumers at lower prices. Moreover, given the increasingly global nature of

commerce – particularly in information technology and other innovation-intensive sectors – it is vital that a country's IP and competition law regimes not be in tension with those of its key trading partners.

Fifth, the Councils underscore that, while interoperability is clearly an important objective in today's networked society, software developers are meeting the market's demand for products that work together seamlessly within heterogeneous networks without government intervention such as compulsory licenses. Patents are, in fact, a critical component of the industry's interoperability strategy, allowing firms to share proprietary technologies without jeopardizing the commercial value of their innovations.

Sixth, the Councils request both governments to take steps to address new issues brought about by globalization and the advent of digitization. These include achieving a balance between the protection and utilization of media content. It is necessary to clarify the assessment method for the allocation of profit among entities and implement promptly and efficiently transfer pricing and tax measures such as Advanced Pricing Agreements and the Mutual Agreement Procedures.

#### **INFORMATION & COMMUNICATIONS TECHNOLOGY (ICT)**

Recognizing that innovation is at the heart of a successful ICT strategy, the Councils note that both governments can best contribute to it by sustaining an environment that allows companies and individuals to compete in the marketplace to bring new ideas and technologies to the consumer. Governments should not micro-manage the development of ICT equipment and applications by trying to pick winners or by favoring one technology over the other, as this distorts the competitive discipline of the market and ultimately slows innovation. The Government of Japan's promotion of broadband diffusion is a successful example of how government policy can appropriately support the growth of the ICT sector.

A comprehensive response to online privacy concerns in the ever-changing Internet environment requires close cooperation between the private and public sectors. The Councils urge that this cooperative effort should seek to promote market-driven technological solutions, recognize the privacy principles around which there already exists broad consensus, and develop legal frameworks that support such technological solutions and principles. Working together, industry and government can provide the technologies and structures that effectively address the privacy concerns of online consumers, while ensuring that the Internet achieves its full potential. Both governments also need to work together closely across borders to address privacy concerns to ensure businesses are subject to consistent obligations and to provide consumers with confidence about interacting online.

ICT is a driving force in the world economy, leading to cutting-edge developments in e-commerce, global communication, education, entertainment, and many other areas. ICT will continue to change our lives and to offer new and exciting opportunities, particularly for the generation of people growing up in an increasingly connected and interdependent world. The Councils call for policies that ensure a more secure and dependable network

as social infrastructure and that exclude unlawful and harmful information - including support for effective cybercrime laws, adequate enforcement capacity, and enhanced public awareness - which are essential to our societal and economic future, to public safety, and to global security. Both Governments can also help build public-private partnerships based on information sharing and strategies for critical infrastructure protection.

The Councils also believe that harmonizing the legal framework for telecommunications and broadcasting is necessary. The new framework should give preference to market-driven solutions to promote new entrants and business models with the goal of providing consumers with the full benefits of the ongoing convergence of technologies and services in the digital media area and affording a firm basis for the global development of the content industry. The Councils believe that a wider range of content available through the Internet, broadcasting, and new services over next generation networks is necessary to achieve the full benefits of this new technology for delivering content. The Councils anticipate that new business models for the distribution of digital content will be established. An appropriate revenue sharing arrangement among stakeholders is needed to facilitate new business opportunities in the media space.

The Councils share the Government of Japan's goals of improving the productivity of the healthcare system, meeting the needs of Japan's aging population, and finding innovative solutions to address the doctor shortage. The Councils believe that ICT is vital to effective sharing of patient data and that for this reason more work needs to be done on standardization of healthcare nomenclature and documents and the development of industry-wide privacy and security standards (Healthcare Public Key Infrastructure - HPKI) to ensure the protection of personal data. The Councils believe that market driven solutions will ultimately provide maximum benefits for the consumer and encourage the adoption of widely shared approaches rather than customized solutions.

## **SECURE TRADE**

In an era of global supply chains, logistics and transportation is an increasingly critical and strategic component of business. Ensuring security in the post-9/11 environment while maintaining the essential open and free-flowing trading system requires close cooperation between governments and industry in the development and implementation of new security programs. Cooperation and adoption of harmonized requirements among countries can provide opportunities to improve trade efficiency as trade flows increase and governments seek to enhance their ability to assess risk of cargo.

In some cases, particularly ocean-bound freight, the Councils are concerned about new requirements being discussed, such as the new advanced data collection requirements (the so-called 10+2 regulations) and 100% container scanning legislation, that could make trade between the U.S. and Japan (and other markets) more costly and complicated. Accordingly, the Councils urge both governments to continue their dialogue on secure trade with the objective of modifying or eliminating measures that add to lead times and costs without providing a clear security benefit.

It is important to note that secure trade issues are not bilateral in nature, so any effective measure must be applied in a multilateral context. The Councils thus support multilateral efforts to globally harmonize trade security requirements through organizations such as the World Customs Organization (WCO), which is promoting common rules and programs to be adopted globally to facilitate trade in the new security environment. To date, 149 countries, including the U.S. and Japan, have agreed to implement the WCO “SAFE” Framework. APEC is also pushing harmonization through the APEC Framework of Standards to Secure and Facilitate Trade.

### **Recommendations**

- **Promote harmonized requirements and ensure that security benefits of new rules are worth costs:** Through its work in the WCO on the SAFE Framework, the U.S. and other governments developed a consolidated list of data elements that governments could collect in advance from traders for risk targeting. However, with its “10+2” proposal, the U.S. appears ready to implement new, unilateral data requirements outside of the scope of what was agreed to in the WCO SAFE Framework. This sets a bad precedent and is precisely the type of unilateral action that will unnecessarily impose unmanageable costs on traders. The Councils urge the U.S. to work any such changes that are necessary through the mechanisms established within the SAFE Framework prior to implementation in order to continue to support and promote harmonized requirements. Further, the Councils, like other business groups, have other concerns about the proposed “10+2” rule such as protection against possible data security/proprietary information leaks to unauthorized parties, and the fact that some of the data points are beyond the ability of some players in global supply chains to obtain. In the Councils’ view, a full cost-benefit analysis of this program is necessary to determine if security would be enhanced enough to offset the additional costs to business. In addition to this 10+2 rule, the so-called 24-hour rule is still problematic, although it was agreed to as part of the core elements of the SAFE Framework. Further efforts should be made to solve problems created by the security requirement of presenting trade data ‘before loading aboard.’
- **Establish mutual recognition of Authorized Economic Operator (AEO) programs:** The Councils urge both governments to continue their joint work towards achieving mutual recognition of their respective AEO 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 continue work towards implementing robust national single window systems to further streamline and harmonize requirements for traders.
- **Reconsider 100% container screening requirement:** The Councils are concerned about the requirement that, starting no later than 2012, 100% of all containers entering U.S. ports be scanned at ports of origin before entry. This requirement has the potential to disrupt the smooth flow of international trade given the enormous number of containers (12 million in 2006) entering U.S. ports from around the world. This requirement conflicts with the principles of the current U.S. threat-based risk management approach that deploys multiple layers of security at various points in the supply chain. In that most experts consider the threat-based risk management approach the most effective way to deploy limited security resources than trying to have a 100% solution at single supply chain points, the Councils urge reconsideration of this requirement.

## **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 at a time when U.S. and Japanese economic ties with Asian countries are expanding much more rapidly than with each other, and the number of bilateral or regional trade agreements in the Asia-Pacific region – including those initiated by the U.S. and Japan – proliferates.

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.

The Councils are encouraged that leading business groups in Japan and the U.S., such as *Nippon Keidanren*, the Business Roundtable and the American Chamber of Commerce in Japan (ACCJ), have also endorsed a U.S.-Japan EPA over the past year. The Councils are also encouraged that the two governments have begun the process of “information exchange” with regard to details of U.S. Free Trade Agreements (FTAs) and Japanese EPAs with third countries. These are very positive developments, but more action is needed by the private sector and both governments to move this forward.

Despite the political and other challenges in both countries affecting a potential launch of EPA negotiations, the Councils believe it is important to act now to lay the groundwork so that negotiations could proceed in 2009. In particular, the Councils recommend that the period between late-2007 and late-2008 be used for extensive analysis and information exchange regarding the potential economic impact, priority and sensitive areas for negotiation, and implications of a comprehensive U.S.-Japan EPA. The Councils recognize that while negotiations on such an agreement would be complex and difficult in some areas, the potential political and economic benefits to both countries are substantial. The Councils believe it is essential to consider a U.S.-Japan EPA in this broader context while carefully considering how to resolve sensitive areas.

The Councils believe the private sector should play a leading role in this phase, and pledge to work together, and with other business organizations, in sponsoring or directly conducting this analysis and dialogue. However, the Councils also believe that it is critical for both governments to participate in or endorse such activity in order to give it credibility and help generate wider support and sustain momentum for a possible U.S.-Japan EPA.



For Japan, the most important task now is to promote structural reform of the agriculture sector with the objective of strengthening its international competitiveness and transforming it into a vibrant industry. Another urgent task that should be tackled parallel with this is to make measures required to meet the challenges of globalization compatible with the construction of a healthy domestic agricultural sector. The Japanese business community will continue to support the on-going structural reform of the agricultural sector.

In short, the strategic, political and economic case for an EPA between the United States and Japan is more compelling than ever. Such concrete steps will enhance the prospects for a U.S.-Japan EPA, and the Councils urge both governments to move accordingly to get this process underway.