

Annual Reform Recommendations from the  
Government of the United States to the Government of Japan under the  
U.S.-Japan Regulatory Reform and Competition Policy Initiative

October 18, 2007

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The U.S.-Japan Regulatory Reform and Competition Policy Initiative (Regulatory Reform Initiative) continues to contribute to growth and opportunity for the citizens of both countries by promoting reforms that open new markets, reduce burdensome regulations, increase transparency, and stimulate competition. The Regulatory Reform Initiative, now in its seventh year, also remains a key forum for deepening and broadening our bilateral economic relationship.

The Regulatory Reform Initiative was created in 2001 under the U.S.-Japan Economic Partnership for Growth to promote a pro-growth agenda of reform through sectoral and cross-sectoral reforms. As a result, this year's recommendations by the United States focus on making continuing progress in industry sector areas such as medical devices and pharmaceuticals, communications, financial services, information technologies, and agriculture, as well as advancing progress in several cross-sectoral issue areas such as intellectual property, commercial law, competition policy, and transparency. The United States continues to look to Japan to undertake important economic reforms in these and other areas in order to achieve the aims of this Initiative.

This year's U.S. recommendations also place an emphasis on the United States' desire to continue to work closely with Japan both bilaterally and in regional and other fora to promote higher standards of intellectual property protection as well as transparency across the Asia-Pacific region and beyond.

These comprehensive U.S. recommendations serve as the basis for discussions over the coming months in the Initiative's High-Level Officials Group as well as in four different working groups covering telecommunications, information technologies, medical devices and pharmaceuticals, and cross-sectoral issues. Progress achieved by each Government in response to the other Government's recommendations is then documented and presented to the President and Prime Minister in the Regulatory Reform Initiative's annual Report to the Leaders.

The Government of the United States continues to look forward to constructive discussions on these recommendations and welcomes receiving the Government of Japan's recommendations under this Initiative.

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## RECOMMENDATION HIGHLIGHTS

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## COMMUNICATIONS

The United States continues to monitor Japan's regulatory reform efforts affecting its communications sector with a view to promoting competitive opportunities for innovative services and technologies. Key regulatory principles that enhance such opportunities include maximizing operators' choice of technology, ensuring efficient and minimally burdensome equipment approvals, transparency and impartiality of rulemaking (particularly in the wireless area).

### *RECOMMENDATION HIGHLIGHTS*

**Promoting Competition and Efficiency in the Wireless Sector:** Eliminate threat of fees for device manufacturers or users of license-exempt services (e.g. WiFi) to ensure robust usage of such services; expeditiously license new spectrum, or "re-farm" existing spectrum for wireless broadband systems on a technology-neutral basis; ensure new mobile entrants enjoy reasonable interconnection arrangements with other wireless operators to offer customers reasonable roaming arrangements as network build-out progresses.

**Promoting Streamlined Regulation of Convergent Services:** Ensure that efforts to

develop new rules for video offered over telecom networks are implemented in a transparent manner with a view to minimizing unnecessary regulation.

**Strengthening Competitive Safeguards on Dominant Carriers:** Ensure that NTT East and West offer cost-oriented interconnection rates once current regime expires; eliminate East-West subsidies and ensure interconnection offerings for their Next Generation Network are subject to sufficient transparency and consultation with affected companies; review financial conditions imposed on competing carriers.

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## INFORMATION TECHNOLOGIES

The United States' recommendations seek to promote competition and confidence in government procurement of information technologies (IT), improve mutual understanding of e-Accessibility policy, advance the adoption of information technology to improve the quality and efficiency of Japan's healthcare system, strengthen protections for intellectual property rights (IPR) focusing on infringement in the digital age, enhance IPR enforcement in the region and globally, and ensure any revisions in the implementation of the Privacy Act also enhance the business environment.

### *RECOMMENDATION HIGHLIGHTS*

**IT and e-Commerce Policymaking:** Facilitate private-sector input and transparency in policymaking; foster technology neutrality; promote compatibility with international practice.

**Government IT Procurement:** Specify plans to ensure compliance with the Basic Policy and assess progress made under the Policy; allow contractors to possess IPR created in government IT system development; promote competitive bidding.

**Health IT and e-Accessibility:** Promote adoption of Health IT through effective implementation of the Grand Design and increased incentives for use of Health IT; exchange information on e-accessibility policies and activities.

**IPR and Copyright Protection:** Strengthen protection, including through adoption of measures to defend against online piracy and increased term of protection for sound recordings and other works.

**IPR Cooperation:** Promote strong standards for IPR protection and enforcement worldwide, especially in the Asia-Pacific, through enhanced cooperation in various fora; promote information exchange on trademarks and streamline patent procedures.

**Privacy:** Ensure that any revisions of Privacy Act implementation enhance the business environment and do not restrict trans-border data flows.

## MEDICAL DEVICES AND PHARMACEUTICALS

The United States encourages Japan to implement rapidly many proposals in its August 2007 “Vision” report on its drug industry, including those on improved clinical trials, accelerated approval reviews, and fair value of innovation. Several of these proposals would also benefit the medical device market if applied in that sector. As Japan strives to provide excellent healthcare despite the challenges of an aging society, the United States also recommends that reimbursement pricing policies provide appropriate incentives for development of innovative medical devices and drugs and that regulatory policies help end the device and drug lag.

### *RECOMMENDATION HIGHLIGHTS*

**Pricing Reform:** Ensure reimbursement pricing of medical devices and pharmaceuticals appropriately values the benefits of innovative products; increase opportunities for producers of innovative devices and pharmaceuticals to explain to reimbursement pricing authorities the benefits of their products.

**Regulatory Reform:** End the lag in the introduction of innovative medical devices and drugs by streamlining reviews and approvals; improve the clinical-trial environment and encourage simultaneous global development of drugs; facilitate approvals of and reform regulatory requirements for minor changes in medical devices.

**Blood Products:** Ensure the pricing system for plasma protein therapies is based on the unique characteristics of those products; provide industry with meaningful opportunities to discuss labeling requirements and other regulatory issues.

**Nutritional Supplements:** Create a new category for foods that allow ingredient-specific claims; provide meaningful opportunities for industry input during the development of health food safety regulations; shorten approval times for new food additives.

**Cosmetics / Quasi-Drugs:** Increase transparency and efficiency in the quasi-drug approval system; allow claims based on significant and verifiable data.

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## FINANCIAL SERVICES

The United States commends the Government of Japan for committing to develop a “Plan for Enhancing the Competitiveness of Financial and Capital Markets.” The United States believes that competitive financial and capital markets are a key element contributing to sustained economic growth, efficient capital allocation, job creation, and innovation. The United States encourages Japan to adopt measures necessary to assure global financial center status. In addition to specific measures that would improve efficiency and afford more options to Japanese savers and workers, the United States calls on Japan to continue its recent progress on regulatory reform in the financial services sector notably by taking action in the following areas.

### *RECOMMENDATION HIGHLIGHTS*

**Financial Regulatory Transparency:** Expand the body of published written interpretations of financial laws, including by active use of no-action and interpretive letters; ensure all stakeholders to provide input on draft laws and regulations.

**Credit Bureaus:** In order to promote sound credit underwriting: deter excessive lending and improve consumer welfare and competitive credit markets; create a legal and regulatory framework for a credit bureau system that facilitates more accurate risk

pricing for consumers and small businesses by collecting and providing fair; open access to comprehensive full-file credit information.

**Information Sharing and Firewalls:** Identify and define the scope of required firewalls through written guidance and continue an active dialogue with foreign financial institutions regarding appropriate revisions to the current firewalls regime, including the Financial Instruments and Exchange Law and the Personal Information Protection Law.

## COMPETITION POLICY

Strong and effective Antimonopoly Act (AMA) enforcement against anticompetitive practices will provide great benefits not only to Japanese consumers, but also to the Japanese economy as a whole. At the same time, care must be given to ensure that AMA enforcement policy does not interfere with procompetitive conduct and that Japan Fair Trade Commission (JFTC) procedures are perceived to be fair and transparent. The United States welcomes the report of the Advisory Panel on Basic Issues Regarding the AMA and looks forward to the implementation of many of its recommendations. At the same time, bid rigging and its facilitation by government officials remains a continuing problem, and bold measures are needed to address this matter properly. The United States urges Japan to take measures to improve further Japan's competition environment.

### *RECOMMENDATION HIGHLIGHTS*

**Improving Antimonopoly Compliance and Deterrence:** Strengthen administrative sanctions against cartels; promote use of JFTC's leniency program; increase effectiveness of criminal enforcement; avoid surcharges on unilateral conduct; review AMA exemptions on international aviation and shipping; revise Distribution Guidelines; adopt pre-notification system for stock acquisitions; ensure competition during postal privatization; hire more outside legal professionals and economists.

**Improving Fairness and Transparency of JFTC Procedures:** Enhance credibility of hearing procedures; clarify conditions necessary to move to a pre-order hearing procedure; improve regulations on JFTC warnings.

**Addressing Bid Rigging:** Strengthen penalties against bid rigging; prevent government-assisted bid rigging and address conflicts of interest in procurement; expand administrative leniency programs; improve procurement practices.

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## COMMERCIAL LAW AND LEGAL SYSTEMS REFORM

A commercial law and legal systems regime in Japan that recognizes the realities of the global market and reflects best international practices will encourage efficient business practices and structures that will strengthen the Japanese economy. Essential aspects of a modern commercial law system include laws that will facilitate rather than impede cross-border investment and corporate governance mechanisms that promote management accountability to, and full participation by, shareholders. Japan should also ensure that international legal services can be provided in an efficient and cost-effective manner. The United States urges Japan to take measures to further improve Japan's commercial and legal environments.

### *RECOMMENDATION HIGHLIGHTS*

**Promoting Efficient Restructuring and Shareholder Value:** Review the success of introducing triangular merger techniques for cross-border acquisitions; protect shareholder interests in anti-takeover measures.

**Strengthening Good Corporate Governance:** Encourage active and appropriate proxy voting; protect shareholder interests through independent directors; ensure sufficient protection of minority shareholders.

**Protecting Foreign Firms Legitimately Doing Business in Japan:** Adopt redomestication procedures that allow a foreign company to merge or convert into a Japanese corporation; ensure that Article 821 does not have adverse effects on the legitimate operations of foreign companies.

**Achieving Legal System Reform:** Permit professional corporations and branching by foreign lawyers (*gaiben*); allow Japanese lawyers to associate freely with international legal partnerships; revise minimum qualification criteria for *gaiben*; promote arbitration and other alternative dispute resolution.

## TRANSPARENCY

Transparent regulatory and policy-making practices are a cornerstone of any good business environment. While a number of improvements have been made in Japan in recent years, such as the introduction of a more meaningful public comment procedure, actual experience clearly indicates that such improvements are not being uniformly implemented across the Japanese Government. The United States continues to urge Japan to further improve its business environment by taking new steps that ensure consistent application of high transparency standards, including by creating new rules as well as promoting best practices. The United States looks forward to cooperating with Japan to promote higher transparency standards in the Asia-Pacific region.

### *RECOMMENDATION HIGHLIGHTS*

**Advisory Groups:** Implement new rules to ensure transparency and access for stakeholders to provide input into government-appointed advisory groups; develop and promote transparency best practices for such groups on a government-wide basis.

**Regulatory Transparency:** Require Ministries and Agencies to make public in writing their regulations and any statements of policy or generally applicable interpretations regarding those regulations; promote use of ‘plain language’ regulations.

**Public Comment Procedures (PCP):** Ensure agencies give public comments ample consideration; take steps to lengthen the public comment period; evaluate the current effectiveness of the PCP to identify other areas to improve its implementation.

**Strengthen International Cooperation:** Intensify bilateral work to promote higher transparency standards in the Asia-Pacific, such as through ensuring active implementation of APEC Transparency Standards.

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## OTHER GOVERNMENT PRACTICES

The United States urges Japan to undertake regulatory reform in a number of other areas to help create new opportunities as well as ensure efficient competition by creating a level playing field. Full liberalization of sales of insurance products through banks, for example, will help enhance competition and consumer choice. Holding insurance cooperatives to the same regulatory supervision that private insurers must meet will also help provide for a sound, competitive insurance market for Japanese consumers. In addition, the U.S. urges Japan take a number of steps to facilitate trade in agricultural products in ways that expand consumer choice while rooted in science-based international standards to ensure a safe food supply for Japanese consumers. The business environment for foreign nationals can be improved via streamlined consular requirements.

### *RECOMMENDATION HIGHLIGHTS*

**Liberalize Bank Sales of Insurance:** Ensure the bank sales channel for insurance products is fully liberalized no later than the end of 2007.

**Insurance Cooperatives:** Build on recent progress to secure a level playing field between private companies and cooperatives (*kyosai*) that offer insurance by taking new steps to hold them to the same obligations as applied to private insurers.

**Consular Issues:** Revise the re-entry permit requirements to minimize burdens on visa holders in Japan.

**Practices Related to Agriculture:** Facilitate trade by applying science-based standards to assess substances used on organic crops; complete the review of food additives recognized as safe by relevant international organizations and used widely throughout the world; ensure measures that enforce maximum residue levels are the least trade restrictive possible; implement international standards in animal health and related measures.

**Special Zones for Regulatory Reform:** Strongly promote new approaches in Japan’s Special Zones program; apply more zone measures nation-wide.

## PRIVATIZATION

The United States continues to take great interest in Japan's effort to privatize and reform Japan Post. The United States recognizes the potential benefits for Japan's economy if these steps are taken in a fully market-oriented manner. The United States also views it essential that these reforms are undertaken transparently and bring about a level playing field between Japan Post and private sector competitors in Japan's banking, insurance, and express delivery markets. The United States continues to urge Japan to take necessary steps to ensure equivalent conditions of competition are achieved in these markets.

### **RECOMMENDATION HIGHLIGHTS**

**Level Playing Field - Savings and Insurance:**

Ensure the new postal financial institutions meet tax, legal, and regulatory obligations and are subject to the same supervisory standards as private firms; ensure these institutions do not actively leverage their Government ties to secure new advantages.

**Competitive Conditions and New Products:**

Create a level playing field in Japan's banking and insurance sectors before postal financial institutions are permitted to introduce new lending services, underwrite new or altered insurance products, and originate non-principal-guaranteed investment products.

**Level Playing Field - Express Delivery:** Apply equivalent customs clearance procedures for items handled by Japan Post Service as applied to private express carriers for similar actions, including application of the "duty declaration" system to EMS items; adequately disclose relationships and ensure cross-subsidization does not occur between competitive and non-competitive services.

**Transparency:** Ensure strong transparency in the implementation of Japan Post reforms, including providing interested parties meaningful opportunities for input and exchanges of views as the process proceeds; conduct regular reviews of the impact of the reforms on markets and invite input from all parties.

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## DISTRIBUTION

Boosting productivity, increasing efficiency, and opening new opportunities in Japan's distribution system is critically important for sustaining Japan's economic growth. The United States therefore applauds Japan's efforts to lower fees for airport use and the results of the recent U.S.-Japan Civil Aviation agreement that provide for increased access for cargo and commercial airlines. The United States requests that Japan take further steps to lower distribution costs, increase transparency, and ensure a level playing field for all industries, including retailers, airlines, and express delivery companies.

### **RECOMMENDATION HIGHLIGHTS**

**De minimis:** Streamline customs procedures by increasing the Customs Law's *de minimis* level.

**Airport Expansion and Operations:** Ensure all airport operational changes develop with appropriate public input and transparency.

**Parking Spaces:** Expand the availability of temporary parking slots in urban areas for distribution vehicles.

**Customs Procedures:** Standardize customs procedures for all packages to ensure a level playing field for all delivery agencies.



## ANNEX

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## COMMUNICATIONS

The United States has broad interests in the Japanese communications market which have been supported by the Japanese Government's efforts to foster a more competitive market, encourage new entrants, and introduce new technology. To enhance these opportunities, the United States suggests several areas where additional action would be mutually beneficial to both Japanese and U.S. suppliers and consumers.

### **I. Wireless Devices and Services**

- A. License-Exempt Use of Spectrum. Clarify that spectrum user fees will not be applied to license-exempt use of spectrum, the imposition of which could unduly constrain innovative uses of spectrum and require burdensome and inefficient collection mechanisms.
- B. Licensed Spectrum.
  - 1. Conduct broadband wireless spectrum assignment currently under consideration (two licenses proposed for 2.5 GHz spectrum) in a timely, transparent, objective and non-discriminatory manner that adheres to principles of technology neutrality; and
  - 2. Clarify procedures for ensuring competitive access to 800 MHz spectrum being vacated by carriers transitioning to 3G services in different bands.
- C. Competition in the Mobile Sector.
  - 1. Ensure new entrants' ability to roam onto existing mobile networks, particularly of the dominant NTT DoCoMo network; and
  - 2. Ensure that sufficient review is conducted to ensure that incumbents do not abuse dominant market positions as a means to unduly constrain new entrants in the market for call termination.
- D. Wireless Equipment. Finalize the procedures for "family approval" for wireless LAN antennas.

### **II. Wireline Services**

- A. Interconnection.
  - 1. Ensure that interconnection rates offered by NTT East and West continue to be set in a transparent manner, consistent with cost-oriented principles, even after transition away from long-run incremental cost (LRIC) methodology is implemented;

2. Ensure that interconnection arrangements offered by NTT East and West for their Next Generation Network (NGN) are developed in a transparent manner, where all interested parties have an opportunity to comment on economic and technical requirements NTT seeks to impose prior to implementation; and
3. Take definitive steps to eliminate cross subsidy based on transferring above-cost interconnection revenue from NTT East to West

**B. Safeguards on Dominant Carriers for New Entrants.**

1. Prior to eliminating any unbundling requirement, conduct a market review based on competition principles, incorporating public comments, to evaluate relevant instances of market power and bottleneck control;
2. Limit the amount of proprietary financial information that needs to be disclosed to NTT, ensure adequate regulatory measures are in place to protect data submitted, and ensure that appropriate levels are set with respect to amounts required by NTT for security deposits from interconnecting carriers; and
3. Ensure appropriate rates for leasing of ducts.

**III. Convergent Services.** In light of various Ministry of Internal Affairs and Communications (MIC)-sponsored study groups making recommendations on the regulatory treatment of converged services:

- A. Ensure that copy restrictions imposed on digital content distribution do not unduly burden network service providers;
- B. Institute transparent process for addressing issues relating to broadcast content provided over non-broadcast media (e.g. the Internet); and
- C. Endeavor to minimize the application of broadcast regulation on IP-based services, to ensure that new digital products and services are not encumbered with trade-distorting restrictions.

**IV. Other.** Continue to strengthen procedures and conditions for ensuring the impartiality of regulatory decision-making.

## INFORMATION TECHNOLOGIES

**I. IT and E-Commerce Policymaking.** To promote the use of information technology and e-commerce throughout Japan's economy, the United States urges Japan to ensure that its regulation of IT and e-commerce is transparent and flexible.

- A. Facilitate Private-Sector Input. Advice from the private sector is crucial to Japan's ability to formulate effective IT and e-commerce policies, plans, and regulations. The United States urges Japan to promote an active role for the private sector in the policymaking process by:
1. Ensuring the private sector has meaningful opportunities to submit views on drafts of relevant legislation, Cabinet orders, ministerial ordinances, regulations, and guidelines through public comment procedures and other means; and
  2. Ensuring the private sector can obtain information promptly about, and participate actively in, the formation and work of government-commissioned IT and e-commerce advisory and study groups.
- B. Foster Technology Neutrality. The United States urges Japan to:
1. Implement laws, regulations, and guidelines to promote choice and competitive market conditions by ensuring that technology providers and users have the flexibility to choose the technologies that best suit their needs; and
  2. Work cooperatively with the private sector on international standards development and, when appropriate, use established international standards when formulating IT and e-commerce guidelines and regulations.
- C. Promote International Compatibility. The United States urges Japan to ensure its IT and e-commerce policies and laws are compatible with international practice.

**II. Strengthening the Protection of Intellectual Property Rights.** Consistent with the goals contained in Japan's IP Policy Promotion Plan and in the mutual interest of both our countries to strengthen the bonds between our IPR regimes, the United States urges Japan to adopt the following recommendations.

- A. Enforcement System. The United States welcomes confirmation that Japan is exploring various avenues to strengthen protection of copyrighted works and will conclude studies on whether to adopt the following measures by the end of FY 2007. In this regard, the United States recommends that Japan:
1. *Statutory Damages.* Adopt a statutory damages system that will act as a deterrent against infringing activities, ensure that right holders are fairly

compensated for the losses suffered by infringement, and enhance judicial efficiency by eliminating the costly and difficult burden of having to establish and calculate actual damages or profits.

2. *Copyright Term Extension.* Extend the terms of copyright protection for sound recordings and all other subject matter protected under the Copyright Law in alignment with the current global trend toward life of the author plus 70 years for works generally, and to 95 years from publication for works for which the term is not based on a human life.
  3. *Ex Officio.* Provide police and prosecutors broader authority to investigate and prosecute copyright crimes on their own initiative by removing the requirement of right holder consent for prosecutions.
- B. Online Piracy. Take the necessary measures to defend against infringement online, including via peer-to-peer services, by streamlining the “notice and takedown” system with a faster and more reliable method for requiring disclosure to right holders of contact information for subscribers who use networks to infringe.
- C. Protect Digital Content. Ensure the transparency of relevant rules and regulations so that right holders are not adversely affected and competition law, and protection of trade secrets are considered, including by limiting the private copy exception to copies made from a legal source and not extending this exception to activities with implications outside the home (such as downloading copies from peer-to-peer services).
- D. IP Multicasting Compulsory License. Ensure that changes to Japan’s measures concerning IP multicasting and/or rebroadcasting of television programs over the Internet both give primacy to efforts for a market-based solution and comport with international obligations.
- E. Exceptions to Copyright Protections Affecting Publishers. Ensure the education exception in Article 35 of Japan’s Copyright Law is confined to certain special cases that do not conflict with normal exploitation of copyrighted works and do not unreasonably prejudice the legitimate interests of right holders, and that any additional proposed copyright exceptions that impact scientific, technical, medical or educational publishers are carefully scrutinized on the same grounds and in a transparent manner.
- F. Technical Protection Measures. Provide effective civil and criminal remedies for unauthorized circumvention of access controls, and all forms of trafficking in devices or services to circumvent technological protection measures
- G. Patent Procedures. Streamline Patent Procedures through promotion of work share efficiencies by:

1. *12-Month Grace Period.* Provide for a 12-month grace period during which information made publicly available by the applicant or by a third party (including a patent office), which obtained the information directly or indirectly from the applicant, shall not affect the patentability of the invention.
2. *Patent Application Prosecution.* Implement procedures to avoid “piecemeal” examinations and identifying all appropriate grounds of refusal at the earliest stage in the examination process.

H. Trademarks. Exchange information on Japan’s practices regarding protection of geographical indications.

**III. Strengthening U.S.-Japan Cooperation on IPR Protection and Enforcement.** The United States and Japan have been increasing cooperation to promote increased protection and enforcement of IPR around the world, and especially in Asia. This cooperation should continue with, and in support of, work to promote a strong standard for IPR enforcement among interested trading partners.

**IV. Privacy.** Globalization necessitates accountable but efficient cross-border data flows. Undue restrictions could hinder companies from conducting business in and within Japan, impede economic efficiency, and interfere with business’ ability to meet the needs and expectations of consumers. The United States notes the June 2007 report by Japan’s Quality-of-Life Policy Council reviewing the effectiveness of the Act on the Protection of Personal Information (Privacy Act). To ensure that any revisions to the implementation of the Privacy Act bolster its effectiveness yet avoid unnecessarily impeding business services for customers, the United States urges Japan to:

- A. Develop clear, consistent, and predictable privacy guidelines across Ministries, with Ministries adding separate guideline provisions when necessary for individual business sectors; and
- B. Ensure that any recommendations regarding cross-border transfers provide effective protections for individuals’ personal information without unduly restricting the international flow of data. Further, such recommendations should include provisions recommending that the data collector implement reasonable measures to protect the privacy and security of individuals’ personal information.

**V. Health IT and e-Accessibility**

- A. Promote Adoption of Health IT. In March 2007, the Ministry of Health, Labor and Welfare (MHLW) issued a new Grand Design, an action plan for the Government of Japan’s efforts to promote adoption of Health IT. The United States encourages MHLW to implement the Grand Design so that IT is used to improve the quality and efficiency of Japan’s healthcare system. The United States urges Japan to:

1. Implement the Grand Design in a way that is open, transparent, and that promotes technology neutrality and interoperability;
2. Increase incentives for doctors and hospitals to use innovative health information technologies that facilitate information sharing, such as digital archiving systems and electronic medical records;
3. Encourage a wide range of qualified IT vendors to participate in government-sponsored projects used to develop or showcase health IT systems;
4. Provide meaningful opportunities for interested parties to present their views on health IT proposals, policies, and rules; and
5. Ensure that Japan's work on standards for health IT systems promotes harmonization with international standards.

B. Improve Understanding of e-Accessibility Policy. There is an ongoing international effort to harmonize IT accessibility policies and their underlying standards. Under this Initiative, the United States looks forward to continuing discussions with Japan aimed at facilitating a better understanding of our respective work and priorities in the area of e-accessibility. In support of this goal, the United States urges Japan to exchange information on current and future e-accessibility policies and activities between United States and Japanese Government experts.

**VI. Government IT Procurement Reform.** The United States is encouraged by Japan's efforts to stimulate competition in government IT procurement and make the process more transparent and fair.

A. Enforce the Basic Policy. Japan's "Basic Policy for the Public Procurement of Computer Systems" (Basic Policy) took effect on July 1, 2007. To improve government IT procurement practices in line with the Basic Policy, the United States urges Japan to take measures that will help ensure all procuring entities comply with the Basic Policy, such as through:

1. Specifying plans to enforce compliance with the Basic Policy, including by announcing details on the conduct and timing of follow-up surveys; and
2. Conducting follow-up surveys as soon as possible to measure progress made in implementing the Basic Policy to help determine whether improvements should be made in the policy or in compliance, and widely disseminating to the public the results of follow-up surveys.

B. Improve Communication with the Public. Effective two-way communication with interested parties about government IT procurement policy and

implementation is essential to build public trust in the system. The United States urges Japan to:

1. Provide meaningful opportunities for all interested parties, including foreign and domestic IT vendors, to provide input on the formulation of, and propose changes to government IT procurement policy;
2. Use the Government of Japan's online database for IT procurements (<http://cyoutatujirei.e-gov.go.jp>) to both obtain information from Ministries on their procurement practices, and to disseminate that information; and
3. Disclose the extent of use of non-competitive contracts.

C. Expand the Bayh-Dole System. To achieve the goal, noted in the IP Strategic Program, to expand and strengthen Japan's Bayh-Dole system by implementing that system in all government procurement, the United States urges Japan to:

1. Implement the April 2007 amendment to the Industrial Technology Enhancement Act to ensure that it is possible for contractors to possess intellectual property rights concerning software developed through government-sponsored programs; and
2. Incorporate a model clause in the Basic Policy that defines the rights and responsibilities of contractors and the government with respect to ownership of intellectual property produced through government IT procurement projects.

D. Limit Vendor Liability. The United States urges Japan to allow IT vendors to limit their liability to a level proportionate to the risks they take in government procurement transactions by:

1. Ensuring implementation of the Basic Policy's stipulation that government procuring authorities will set appropriate limits on, and clearly define, liability in IT government procurement contracts; and
2. Developing guidance, such as model contracts, that help Ministries understand how to address liability issues in IT procurement contracts.

E. Promote Competitive Bidding. Reduce the use of sole source contracting in IT procurements by taking steps such as applying rules on competitive bidding that now apply only to central government Ministries to independent administrative legal entities, government-sponsored private companies, and local governments.

F. Prohibit Backdating. Implement the Basic Policy's provisions to ensure that contracts should be swiftly concluded after winning bidders are chosen and contracts must not be backdated.



## MEDICAL DEVICES AND PHARMACEUTICALS

**I. Changes in Japan's Healthcare System.** The United States encourages the Government of Japan and its advisory bodies to fully consider input from industry, including U.S. industry, before making healthcare system changes.

**II. Medical Device and Pharmaceutical Pricing Reform and Related Issues.** The United States urges Japan to recognize the long-term benefits of reimbursement pricing that rewards development of innovative medical devices and drugs as it considers the extent of medical spending. The United States also urges Japan to take the following actions:

**A. Pharmaceuticals.**

1. Continue to allow U.S. industry participation in healthcare reform discussions with the Japanese Government, such as the Government-Private Sector Dialogue for Innovative Drug Discovery. Seek views of international experts by appointing a representative of the U.S.-research-based drug industry to the Drug Pricing Expert Subcommittee of *Chuikyo*.
2. Abolish re-pricing based on market expansion, which reduces incentives for research on additional indications and impedes access to treatments.
3. Refrain from implementing annual price revisions, which would discourage the introduction of innovative drugs and devices in Japan.
4. Provide as an alternative to the current pricing system for new drugs a flexible method that examines data submitted by manufacturers to ensure the full scope of a drug's innovative value can be evaluated and rewarded.
5. Improve and stabilize economic returns for advanced patented drugs during their patent life or exclusivity period to reflect accurately their level of innovation and the financial risks taken to develop them.
6. Ensure that comparators used in determining reimbursement prices are selected and applied in a way that accounts for an appropriate valuation of innovation. Avoid use of certain comparators that fail to value innovation appropriately.
7. Enhance transparency by allowing independent experts to lead discussions with manufacturers on their pricing applications before final discussions with the Drug Pricing Organization.
8. Reform use of the Foreign Price Adjustment (FPA) rule to reward innovation.

9. Increase the treatment period for new drugs to 30 days per prescription, in general, and work with industry to develop rules on cases in which drugs are assigned shorter treatment periods.
10. Ensure health insurance coverage for medical care and tests that are necessary for the proper use of drugs.

B. Medical Devices.

1. Work with U.S. industry to modify product category groupings for certain cardiovascular and orthopedic products to more appropriately reflect product differences, and create new functional categories for new devices that have certain improved functions over existing devices.
2. Eliminate the Foreign Average Price (FAP) rule. Until the rule is replaced, use industry-provided list prices and data only from the four current comparator countries, refrain from adding functional categories beyond those used in 2004-2006, maintain the rules on maximum price reductions, phase-in any cuts over two years, and use weighted averages.
3. Establish a voluntary process by which companies can request changes in reimbursement prices for devices that companies believe are not reimbursed appropriately due to price revisions.
4. Create a category of premiums for devices with enhanced benefits such as greater longevity and shorter recovery time. Adjust the ranges of existing premiums to match those applied to analogous drug categories.
5. Expedite the introduction of new devices by letting companies apply for reimbursement during the approval process so such applications will be discussed at the first *Chuikyo* experts meeting and the general meeting following product approval.
6. Adopt mechanisms to compensate companies for the expense and delay in market entry of having to conduct redundant or otherwise unnecessary clinical trials in Japan.
7. Provide incentives for adoption of advanced and less invasive diagnostic imaging techniques that expedite the identification and treatment of diseases and other health conditions.
8. Consult closely with industry, including U.S. industry, on reimbursement rules for in-vitro diagnostics (IVDs) so progress can be made on testing fees, “quick testing,” and the use of IVDs between clinical trial and reimbursement approval.

- C. Blood Products. Allow industry, including U.S. industry, meaningful opportunities to discuss with the Japanese Government how the current drug-based reimbursement pricing system should be reformed in recognition of the unique qualities of plasma protein therapies. Ensure the pricing system for plasma protein therapies is based on the unique characteristics of those products.

**III. Medical Device and Pharmaceutical Regulatory Reform and Related Issues.** The United States encourages Japan to improve the regulation of medical devices and drugs so as to facilitate the introduction of such products in Japan, and to focus on preventive care by promoting access of patients to innovative devices and drugs. The United States urges Japan to:

- A. Pharmaceuticals. Make it easier for companies to develop drugs in Japan and for Japan's market by taking the following steps:
1. Work with industry, including U.S. industry, to facilitate Japan's participation in simultaneous global development of drugs.
  2. Improve the environment for clinical trials, such as implementing the new five-year plan to stimulate clinical trials and, where appropriate, expanding that plan to include additional facilities; increasing incentives for patients, hospitals, and doctors to participate in clinical trials; and improving hospital clinical trial operations.
  3. Ensure industry, including U.S. industry, can participate in the study group on ethnic factors in clinical data from Japan, South Korea, and China.
  4. Reduce the drug lag by letting industry, including U.S. industry, propose directly to the Committee on Issues Related to Use of Unapproved Pharmaceuticals certain drugs that treat serious, life-threatening diseases.
  5. Ensure the Pharmaceuticals and Medical Devices Agency (PMDA) maintains a dialogue with industry, including U.S. industry, on user fees and performance metrics, which leads to better consultations and reviews.
  6. Implement expeditiously the planned increase in PMDA drug reviewers for FY2007-2009. Allow reviewers newly hired from the drug industry to review applications pertaining to their areas of expertise.
  7. Reduce PMDA review times for post-approval manufacturing changes to levels similar to those of the United States and European Union.
  8. Reduce the processing time for new drug applications before final approval by the Ministry of Health, Labor and Welfare (MHLW).
  9. Improve regulatory reviews and promote the use of vaccines.

- B. Medical Devices. Make it easier for companies to develop medical devices in Japan and for Japan's market by taking the following steps:
1. Speed approvals and reduce requirements for "partial changes" by:
    - a. Clarifying which "minor changes" do not require regulatory approval, which may be submitted by notification only, and which may simply be recorded in an annual report.
    - b. Implementing a "real-time review" process for changes that are more significant and that require prior review and approval.
    - c. Allowing partial change submissions while previous applications for the same device are under review.
  2. Use accelerated stability test data for device approvals where accelerated testing methods are validated in scientific literature or other adequate scientific support, and accept real-time stability test data from manufacturers upon completion of the real-time testing.
  3. Ensure PMDA consults closely with industry, including U.S. industry, to develop improved performance goals for the next five-year plan and to identify measures to ensure it achieves the goals. Refrain from adjusting user fees without agreement by industry, including U.S. industry.
  4. Protect from public disclosure business confidential information contained in product approval submissions.
  5. Reduce requirements for raw material data by eliminating the requirement to specify the chemical composition of raw materials; requiring disclosure of information on device components only when information on the biological safety of the finished device is not adequate to determine the product's safety; and ensuring Japan's requirements for biocompatibility testing are fully consistent with ISO 10993.
  6. Adopt a system for simple registration of foreign manufacturing facilities in harmonization with international practices in lieu of the current accreditation system.
  7. Adopt quality management system (QMS) conformity assessments that are specific to factories rather than to products.
  8. Streamline the approval of IVDs by eliminating the pre-approval evaluation of IVDs by the National Institute of Infectious Diseases, reducing from two to one the predicate devices for which comparison is required, accepting actual product specifications, and developing simplified stability test requirements in consultation with industry.

#### **IV. Blood Products**

- A. Provide industry, including U.S. industry, with meaningful opportunities to discuss the labeling requirements of *kenketsu* and *hikenketsu*.
- B. Provide industry, including U.S. industry, with meaningful opportunities to discuss supply and demand issues, as well as other regulatory matters, such as the national assay.

#### **V. Over-the-Counter Medicines.** Provide industry, including U.S. industry, with meaningful opportunities to consult with MHLW regarding over-the-counter medicines.

#### **VI. Nutritional Supplements.** The United States urges Japan to:

##### **A. Regulatory Categories and Claims.**

- 1. Create a new regulatory category for foods that would allow ingredient-specific claims for nutritional supplements that could be used on labels, advertising, and promotional materials.
- 2. Review and revise potency limits for items in the Foods with Nutrient Function Claims (FNFC) category based on scientific risk assessment.
- 3. Liberalize the Foods for Specified Health Uses (FOSHU) category to make the framework practical for nutritional supplements products.
- 4. Work with industry to establish and implement by the end of FY2007 a system to provide information from the National Institute of Health and Nutrition's database to consumers as recommended by the Office of Trade and Investment Ombudsman.

##### **B. Health Food Safety Regulations.**

- 1. Provide meaningful opportunities for input to industry, including U.S. industry, during the development of regulations related to the safety of health foods, such as opportunities to participate as members of government-sponsored study groups or panels.
- 2. Consider developing a regulatory framework for companies to introduce new ingredients for nutritional supplements that ensures safety while being practical and timely with consideration of best practices from other industrialized nations.

##### **C. Food Additives.**

- 1. Shorten the processing time for the approval of new food additives,

particularly those evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), by taking steps such as clarifying the materials required for an application and improving efficiency in the approval process.

2. Revise in a timely manner the standards of use for food additives using scientific principles and reflecting advances in analytical techniques and technology.

D. Import Issues.

1. Continue to make the food import process more efficient by improving the system of tracking prior consultations and instructions completed by companies at quarantine stations.
2. Limit the disclosure of proprietary information on import declaration forms.
3. Address other long-standing concerns related to the import of nutritional supplement products.

**VII. Cosmetics and Quasi-Drugs.** The United States urges Japan to:

A. Quasi-Drugs. Increase the transparency and efficiency of the quasi-drug approval process by:

1. Publishing a list of active ingredients including their levels and efficacies that have been approved in previous quasi-drug applications and updating this list regularly.
2. Publishing a list of additives (inactive ingredients) including their levels that have been approved in previous quasi-drug applications and updating this list regularly.
3. Relaxing pre-approval requirements for additives (inactive ingredients) to be consistent with regulatory frameworks in other industrialized nations.

B. Advertising and Labeling. Enable Japanese consumers to make more informed decisions by:

1. Allowing additional claims for cosmetics that are within the scope of currently approved claims and that are supported by scientific data.
2. Allowing numerical claims for quasi-drugs and cosmetics based on significant and verifiable scientific data.

- C. Other Transparency and Regulatory Issues. Improve the transparency and efficiency of the quasi-drug and cosmetic regulatory systems by:
1. Working with industry, including U.S. industry, to develop a system to disclose the outcome of meetings of the Local Advertisement Controllers' Meeting (*Rokushakyo*), such as through issuing a monitoring report.
  2. Continuing to work with industry, including U.S. industry, to ensure that product standards are both safe and practical and setting specific time frames for the review process of product standard revisions so that companies can plan for changes.
  3. Streamlining import and approval paperwork and procedures for quasi-drugs and cosmetics to reduce lead time to market.
  4. Continuing to improve MHLW's web site to include more information for consumers and industry on the quasi-drugs and cosmetics regulatory systems in an easily accessible location.

## FINANCIAL SERVICES

- I. Specific Measures.** The United States commends the Government of Japan for adopting a commitment in its 2007 Basic Policies to develop, by the end of 2007, a “Plan for Enhancing the Competitiveness of Financial and Capital Markets.” The United States believes that competitive financial and capital markets are a key element contributing to sustained economic growth, efficient capital allocation, job creation, and innovation. The United States encourages Japan to adopt measures necessary to become a global financial center, including measures beyond the financial services sector such as in the areas of tax, labor, healthcare, education, and transportation infrastructure. The United States calls on Japan to continue its recent progress on regulatory reform in the financial services sector by adopting the following measures:
- A. Legal and Regulatory Framework for a Comprehensive Credit Bureau System. Building on the revision of the Money Lending Business Law, create and implement a comprehensive consumer and small business credit information system, covering all sectors of financial services. In order to promote sound credit underwriting, deter excessive lending and improve consumer welfare and competitive credit markets, it is essential to create an effective regulatory framework that enables the collection of, and provide access to, comprehensive full-file credit information.
  - B. Firewalls. The Financial Services Agency (FSA) has begun to assess the impact that current legal and regulatory provisions on firewalls have on financial services companies, including foreign financial institutions, taking into account developments in this area in other major financial markets. Foreign financial institutions are impacted significantly by various firewalls regarding the sharing of information and personnel between business units and/or legal entities and that such firewalls often render exceedingly difficult the importation of global best practices to Japan’s financial services industry. As a result, the United States recommends that the FSA identify and define the scope of required firewalls through written guidance and continue an active dialogue with foreign financial institutions regarding appropriate revisions to the current firewalls regime, including the Financial Instruments and Exchange Law and the Personal Information Protection Law.
  - C. Regulation of Financial Conglomerates. The U.S. Government welcomes the FSA’s acknowledgement in the 6th Report to the Leaders that regulation of conglomerates, including permissible management structures and the ability to share information across group companies for prudential risk management and improved customer service, are relevant to Japan’s efforts to increase its competitiveness as an international financial center. As such, the United States recommends that the FSA continue to consult with interested parties, including foreign financial firms, regarding the implementation of the Conglomerate Guidelines.



- D. Defined Contribution Pensions. In recognition of the importance of, and the value of improving, the national defined contribution pension system in terms of securing income for the elderly, labor mobility, and investment education, the United States encourages Japan to continue its efforts to improve the defined contribution pension system. Specifically, the United States recommends that Japan:
1. Increase the tax-deductible contribution limits to comparable global levels;
  2. Allow employee contributions;
  3. Allow early access to funds before the age of 60 in specific circumstances;
  4. Allow investment advice service to be made available to participants; and
  5. Introduce a defined contribution pension scheme for public sector employees.
- E. Harmonize the Regulatory Framework for Investment Advisory Services and Investment Trusts. Consistent with the basic philosophy of the Financial Instruments and Exchange Law to provide a comprehensive and consistent regulatory regime across financial products and services, the United States recommends that Japan continue to provide necessary encouragement toward the realization of true harmonization between the regulatory environment of investment advisory and investment trust management businesses level, including the integration of the self-regulatory associations governing these two businesses.
- F. Merger and Termination of Investment Trusts. The United States recommends that Japan establish standards and clear procedures for mergers and reduce obstacles to the early termination of investment trusts in order to permit investment managers to provide suitable levels of diversification within investment trust portfolios and to minimize costs to investors.
- G. Materiality Standard in Net Asset Value (NAV) Calculations. The United States recommends that Japan encourage the establishment of clear and reasonable “materiality” standards comparable to levels in leading investment management jurisdictions that define when net asset values of Japan-domiciled funds must be recalculated and when compensation may or must be paid to investors in such funds.
- H. Institutional Investor Disclosure Rules for Large Shareholdings. The United States recommends that Japan review the revisions to institutional investor disclosure rules for large shareholdings (shareholdings in excess of 5 percent) as they apply to portfolio institutional investors, particularly with regard to reducing the frequency of required reporting, easing administrative burdens (including through technological improvements) and reducing the scope for leakage of proprietary data and related speculative activity.

- I. Global Custody. The United States recommends that Japan clarify the characterization of global custody business under the Financial Instruments and Exchanges Law so as to provide consistency of the regulatory approach to this business.

## II. Transparency

- A. The United States welcomes the FSA's efforts to expand the body of published written interpretations of Japan's financial laws, including the improvements to the no-action letter system that were implemented during the past year, and commends the outreach efforts of the FSA to explain to and engage in dialogue with the private sector regarding these changes. Written interpretations reduce uncertainty, enhance compliance and allow for productive innovation by financial services providers. The United States encourages the FSA to continue to enhance the effectiveness of written interpretation, including the no-action letter and related systems, including to:
  1. Encourage FSA staff to promote more active use of the no-action letter system, such as by indicating receptivity to no-action letter requests to firms that seek oral advice on how to interpret Japanese laws, especially on matters where the FSA's internal interpretation is settled but no public interpretation is available.
  2. Make more active use of the interpretive letter system, which allows interested parties to seek interpretations on issues beyond those covered by the no-action letter system and may include requests for clarification of laws and regulations governing existing products and services. Although non-binding, such letters would promote consistent understanding among market participants of current FSA views on existing laws, regulations and guidelines. Specifically, the United States recommends that Japan use the interpretive letter system to:
    - a. Provide written interpretations on issues about which FSA officials have received informal oral inquiries and about which there may be some misinterpretation; and
    - b. Publish negative responses to no-action letter requests.
- B. Publish "frequently asked questions" on FSA's website as was done regarding the implementation of Basel II for a wider variety of topics, including the implementation of the Financial Instruments and Exchanges Law.
- C. Establish other means to provide written interpretations of Japan's financial laws even when an interpretation has not been formally requested. Possible models include the Securities and Exchange Commission's (SEC) "telephone interpretations" web page and its "Staff Legal Bulletin" and "Staff Accounting Bulletin" systems.

- D. A transparent and predictable rule interpretation and inspection process is critical to sound development of financial markets and to the appropriate balance among consistency, innovation and consumer and investor protection. The United States welcomes measures taken by the FSA to enhance the transparency of the inspection process, including publication of the Financial Inspection Basic Policy, inspection manuals and administrative action criteria. Consistent with the FSA's efforts to promote "better regulation", the United States encourages the FSA to consult with foreign financial institutions and financial sector industry associations regarding concerns or potential improvements related to the inspection process, recognizing the sensitivities that individual companies may have regarding disclosure of company-specific inspection experiences.
- E. The United States welcomes the efforts of the FSA and encourages continued dialogue in the coming months among the FSA, the Financial System Council, foreign and domestic financial firms and other interested parties as the "Plan for Enhancing the Competitiveness of Financial and Capital Markets" is developed and implemented. Seeking early input from the private sector, including foreign firms, in the process of drafting laws and regulations and having extended public comments periods for complex changes in the regulatory framework reduces the risk of adverse unintended consequences of financial laws and regulations.

## COMPETITION POLICY

### I. Improving Antimonopoly Compliance and Deterrence

- A. Strengthen Administrative Sanctions on Hard Core Cartel Violations. In accordance with the recommendation of the Advisory Panel on Basic Issues Regarding the Antimonopoly Act (AMA Advisory Panel) that Japan ensure that administrative fines are set at a level that deprives enterprises “of a motivation to engage in a violation” of the AMA:
1. Increase the base surcharge level for cartel and bid rigging behavior to at least 15 percent of sales attributable to the unlawful practices;
  2. Provide an aggravating factor adjustment to the surcharge rate that results in a significantly higher surcharge than the base rate for firms that play a leading role in such violations; and
  3. Extend the current three-year statute of limitations for the application of cease and desist orders and surcharge payment orders to five years from the date of the last unlawful act.
- B. Promote Active Use of the Leniency Program. The Japan Fair Trade Commission’s (JFTC’s) Leniency Program has been highly successful since its implementation in 2006. In order to enhance its effectiveness:
1. Treat as a single leniency applicant all companies that are majority-owned by the leniency applicant and, where appropriate, the parent of the leniency applicant; and
  2. Ensure that any new reductions in the surcharge rate for companies that cooperate with JFTC investigations do not undermine the incentives for enterprises to participate in the Leniency Program.
- C. Increase Deterrence through Criminal Enforcement. Criminal enforcement of hard-core AMA violations is a crucial component of an effective antimonopoly deterrence system. In order to ensure effective deterrence against hard core cartels:
1. Maintain the current system of allowing the imposition of both criminal penalties and administrative sanctions against firms that engage in cartel and bid rigging activities;
  2. Extend the current three-year statute of limitations for criminal violations of the AMA for cartel activities to five years; and

3. Seek to increase significantly the number of cartel and bid rigging cases referred to the public prosecutor's office for criminal prosecution, including with respect to international cartel activities.
- D. Minimize Unintended Deterrence of Procompetitive Unilateral Conduct. The possibility of significant monetary sanctions against conduct whose lawfulness cannot easily be ascertained in advance may deter enterprises from engaging in procompetitive unilateral conduct. In order to minimize over-deterrence of procompetitive unilateral conduct:
1. Maintain the current system of remedying unfair trade practices and exclusionary practices that constitute private monopolization through the imposition solely of cease-and-desist orders; and
  2. If Japan nonetheless decides to extend surcharges to exclusionary monopolization practices and/or certain unfair trade practices, create a new discretionary surcharge system with flexible surcharge rates that takes into account, among other factors: (a) the difficulty enterprises may have in distinguishing lawful unilateral conduct from unlawful anticompetitive behavior, (b) the seriousness and extent of the violation, and (c) the degree of harm to consumer welfare.
- E. Review AMA Exemptions. Competition in Japan's markets can be enhanced by reviewing and seeking to limit or eliminate remaining AMA exemptions. To further expand the coverage of the AMA:
1. Follow the lead of the European Union, Australia and the United States in eliminating specific antimonopoly exemptions in the international aviation sector; and
  2. Complete by the end of JFY 2007 a Ministry of Land, Infrastructure and Transport (MLIT) study of the continued necessity of an antimonopoly exemption in the field of international shipping, with a view toward eliminating or limiting that exemption.
- F. Provide Guidance on AMA Compliance. Clear and transparent JFTC enforcement policies that reflect the best economic and legal understanding of sound competition law enforcement will facilitate AMA compliance and ensure that procompetitive conduct is not chilled. The United States recommends that, toward that end, JFTC in particular review and revise its 1991 Distribution and Business Practices Guidelines to reflect current economic understanding of the workings of the market, including by substantially increasing the market share safe harbors for vertical restrictions.

G. Improve Pre-Merger Notification Procedures.

1. Eliminate the post-stock acquisition notification requirements under the AMA and adopt a system in which mergers and stock acquisitions are, in principle, treated the same for purposes of pre-transaction notification obligations; and
2. Ensure that any revisions to notification thresholds applicable to foreign enterprises are consistent with International Competition Network Recommended Practices and the 2005 OECD Recommendation of the Council on Merger Review.

H. Promote Competition in Sectors Undergoing Privatization. With the October 1, 2007 establishment of the new postal corporations, it is essential that the privatization process is undertaken in a manner that promotes effective competition in the relevant markets. In order to further that objective:

1. Ensure that the Privatization Commission and relevant supervisory agencies seek and consider views, including those of the JFTC, regarding competition policy aspects of the privatization process and regarding the operations of the new postal entities; and
2. Based on careful monitoring by JFTC of the conduct of Japan Post and the new postal entities from the standpoint of ensuring competitive markets, ensure that such companies fully comply with the AMA, including through vigorous enforcement measures if such companies are found to have engaged in practices that violate the AMA.

I. Strengthen JFTC Staff and Resources. Continue steady and substantial increases in the staff and budget of JFTC, with priority given to hiring additional outside legal professionals as hearing examiners as well as staff with post-graduate economics degrees.

**II. Improving Fairness and Transparency of JFTC Administrative and Investigatory Procedures**

A. Enhancing the Credibility and Transparency of Hearing Procedures. The AMA Advisory Panel concluded that in order to maintain the current ex-post hearing procedure system, “the credibility and transparency of the administrative hearing procedures needs to be enhanced.” In order to assure the public and business community that JFTC hearing procedures are fair and impartial:

1. Lengthen significantly the minimum two-week period after JFTC’s advance notification of a draft cease and desist order or surcharge payment order to the proposed recipient during which the proposed recipient may review the evidence against it and submit its views and evidence to JFTC before the order is issued;

2. In accordance with the AMA Advisory Panel's recommendation that JFTC establish a minimum quota for hearing examiners who are outside legal professionals, increase the number of hearing examiners that are outside legal professionals with the goal of ensuring that a majority of members of multiple hearing examiner panels for any given case are outside legal professionals; and
  3. Strengthen JFTC conflict of interest rules to exclude persons with ties to the respondent or to any other person or entity affected by the proceedings, with a financial interest in the outcome of a particular case, or with any other conflict of interest, from acting as a hearing examiner in that case.
- B. Clarify Conditions Necessary to Return to Ex-Ante Hearing System. Based on the conclusions of the AMA Advisory Panel that JFTC should adopt an ex-ante administrative hearing procedure system once certain conditions are met, publicly-release a document that states the conditions that need to be met, the reasons for those conditions and the process that JFTC intends to follow to create the conditions that would allow an ex-ante administrative hearing procedure system to be implemented by JFTC.
- C. Improve Regulations Governing the Issuance of Warnings. In accordance with the recommendations of the AMA Advisory Panel, improve regulations governing the standards and procedures that JFTC will use before it issues warnings, and for publicizing the name of warning recipient, with the goal of adequately responding to due process concerns with the current procedure.
- D. Recognize Attorney-Client Privilege. Initiate a study of the treatment of attorney-client privileged materials by other major competition enforcement authorities, with the view to revising JFTC hearing and investigation procedures to be consistent with good international practice in this area.

### **III. Addressing Bid Rigging**

- A. Strengthen Penalties Against Bid Rigging. In order to deter bid rigging violations:
1. Increase the standard minimum period of suspension from bidding for all enterprises determined to have engaged in bid rigging to six months, with higher minimums for enterprises that fall within special categories (e.g. violated written oaths, are ring-leaders, etc.) and ensure that the suspensions apply on a nationwide basis; and
  2. Ban individuals who engaged in bid rigging activities from taking part in competitive bidding for up to three years.

- B. Prevent Conflicts of Interests in Procurement. In order to ensure that conflicts of interests do not facilitate bid rigging, strengthen rules against conflicts of interests by government officials, includes rules prohibiting officials for an appropriate period of time from communicating with their former agencies, or from accepting employment with companies that have received contracts from their former agencies, and increase penalties against officials and companies violating such rules.
- C. Bolster Efforts to Eliminate Government-Assisted Bid Rigging. In order to increase the awareness of the business sector, government officials and the public about measures to eliminate government-assisted bid rigging:
1. Make public any demands made by JFTC to central government agencies, public corporations or local government entities for improvement measures to prevent the recurrence of government-assisted bid rigging, as well as the specific improvement measures implemented by such entities; and
  2. Apply heavy sanctions on government officials who facilitate bid rigging, and disclose information on the number of officials from central government agencies, public corporations and local government entities who have received sanctions for facilitating bid rigging activities, and on the sanctions imposed on each such official.
- D. Expand Administrative Leniency Programs.
1. Promote adoption by all central government agencies, public corporations and local government entities of administrative leniency programs that significantly or proportionately reduce the period of suspension from bidding for companies admitted into JFTC's Leniency Program; and
  2. Publish by the end of JFY 2007 the results of the survey regarding implementation of the May 23, 2006 Cabinet decision revising "The Guiding Principles concerning Measures to Promote Proper Tendering and Contracting for Public Works," including the list of central government agencies, public corporations and local government entities that have adopted an administrative leniency program.
- E. Hinder Bid Rigging by Improving Procurement Practices.
1. Expand the use by central government agencies, public corporations and local government entities of the Overall Greatest Value Method for awarding contracts;
  2. In furtherance of the March 2007 request of MLIT and the Ministry of Internal Affairs and Communication to local governments to take measures to promote proper tendering and contracting for public works,



including by expanding the general open bidding system, installing electronic bidding systems and publishing bid contract-related information, survey local governments concerning whether these measures have been implemented, and publish the results, on a local government by local government basis, by March 2008;

3. Encourage local governments to establish “whistle blower” windows for reporting incidents of bid rigging and other improper conduct; and
4. Ensure that eligible bidders on contracts let by local governments and regional offices of central government agencies are not limited to local companies.

## COMMERCIAL LAW AND LEGAL SYSTEMS REFORM

### I. Promoting Efficient Restructuring and Shareholder Value

- A. Review the Use of Modern Merger Techniques. Despite the introduction in May 2007 of provisions in the Company Law allowing foreign companies to acquire the shares of Japanese companies through a triangular merger technique, the conditions for deferring the recognition of capital gains on such transactions for tax purposes may be too onerous to permit the effective use of this technique. In order to determine whether the tax deferral rules unduly impede the ability of foreign investors to use triangular mergers, the United States recommends that Japan issue a report by August 2008 detailing the frequency with which triangular merger techniques have been used by foreign companies to merge with Japanese companies since May 2007 and, if rarely, measures that Japan will take to address that problem.
- B. Protect Shareholder Interests in Anti-Takeover Measures.
1. Conduct and publish by April 2008 a survey on the adoption of defensive measures by Japanese corporations to determine whether they are protecting the interests of shareholders, rather than of management, and are otherwise consistent with the goals and rules of the Tokyo Stock Exchange (TSE) as well as with the 2005 Takeover Defense Guidelines issued by the Ministry of Economy, Trade and Industry. Include recommendations on what additional measures are necessary to ensure that anti-takeover measures do not harm shareholder interests; and
  2. Require that all publicly-traded companies establish a committee composed of truly independent directors to review and provide their views and recommendations on any take-over bid (TOB) received by the company. Require that the board of directors include in its “position statement report” the views and recommendations of the committee of independent directors and, where applicable, the reasons why those views and recommendations were not adopted by the board.

### II. Strengthening Good Corporate Governance

- A. Encourage Active and Appropriate Proxy Voting.
1. Require that at least large publicly-traded companies provide proxy materials to shareholders a minimum of four weeks before the shareholders meeting;
  2. Clarify the fiduciary duty on pension fund managers to exercise proxy voting rights solely in the interest of beneficiaries by revising the Ministry of Health, Labor and Welfare’s 1997 and 2002 guidelines on the roles and duties of pension fund managers, and by other means; and

3. Establish a clear fiduciary duty on mutual fund and investment trust managers to evaluate and vote proxies for the benefit of investors in the fund or trust.

B. Foster Protection of Shareholder Interests through Independent Directors.

1. Take measures to increase the number of independent directors in publicly-traded companies by requiring that, by the beginning of JFY 2009, at least all large publicly-traded companies and all publicly-traded companies with one controlling shareholder have at least two independent outside directors on their boards;
2. Ensure that outside directors are truly independent by:
  - a. Revising the definition of “outside director” in the Company Law to also exclude, at a minimum, persons who (i) have had significant transactions with the company or are employees of other companies that have a significant business relationship with the company, or (ii) have an immediate family member who has had significant transactions with the company or is an executive officer in a company that has a significant business relationship with the company; and
  - b. Encouraging the TSE and the other major Japanese stock exchanges to adopt listing rules or guidelines that define outside directors in a manner generally consistent with the listing standards of the New York Stock Exchange or NASDAQ for determining director independence.

C. Ensure Sufficient Protection of Minority Shareholders. Reconvene the Corporate Value Study Group (CVSG) to evaluate and make recommendations aimed at ensuring that minority shareholder interests are sufficiently protected. In that regard, direct the CVSG to:

1. Examine the protection of minority rights in the context of management buy-outs and take-over bids, as well as the usefulness of requiring bidders to disclose third party fairness and valuation opinions to the public in order to assure objective valuation and support of the offered price;
2. Determine the adequacy of existing rules and procedures that serve to protect investment value before it has been lost;
3. Evaluate the adequacy of fiduciary and other legal duties on controlling shareholders, particularly with regard to related party transactions between a controlling shareholder and the company, and to ensuring a fair price and fair dealing in minority squeeze-out situations; and

4. Include both foreign and domestic investors as members, and provide an active role for Company Law experts at the Ministry of Justice.

### III. Protecting Foreign Firms Legitimately Doing Business in Japan

- A. Adopt Redomestication Procedures. Amend the Company Law to create a simple procedure for a foreign company to merge or convert into a Japanese corporation, and ensure that the Japanese tax consequences of such redomestications do not unduly impede the ability of foreign companies to use these procedures.
- B. Monitor Effects of Article 821. Continue to watch closely the effects on foreign companies of Article 821 of the Company Law and amend that provision if necessary to prevent adverse effects on the legitimate operation of foreign companies in Japan.

### IV. Achieving Legal System Reform

- A. Permit Professional Corporations and Branching.
  1. Permit registered foreign lawyers in Japan (*gaiben*) to form professional corporations on the same basis and with the same benefits, including the ability to establish branch offices, as professional corporations for Japanese lawyers (*bengoshi*); and
  2. Allow all law firms, including foreign law firms and their *bengoshi* and *gaiben* partners in Japan, to establish multiple branch offices in Japan without regard to whether they have formed a professional corporation.
- B. Allow Bengoshi to Associate Freely with International Legal Partnerships. Ensure that there are no legal or bar association rule impediments to Japanese lawyers, whether in solo practice, in partnership with other *bengoshi* or in partnership with *gaiben*, becoming members of an international partnership of lawyers outside of Japan.
- C. Revise Minimum Qualification Criteria for Gaiben. Amend the *Gaiben* Law so that all experience practicing the law of the home jurisdiction, wherever that experience was obtained, will be counted toward the three-year experience requirement for qualification as a *gaiben*.
- D. Promote Alternative Dispute Resolution (ADR). Amend the *Gaiben* Law to explicitly permit *gaiben* to act as neutrals and to represent parties in all international ADR proceedings taking place in Japan.

## TRANSPARENCY

- I. Public Input into Policy Development – Advisory Groups.** The United States believes that the Japanese Government's assurance of the openness and transparency of all advisory councils (*shingikai*) and other government-commissioned study groups that are commenting or making recommendations on policy and regulatory matters is necessary to ensure that the views of interested parties are reflected in their deliberations. The United States continues to urge Japan to supplement the general guidance for advisory groups outlined in an April 1999 Cabinet Decision with specific requirements that would ensure basic transparency standards in the creation and management of all advisory councils and study groups. Specifically, the United States recommends that Japan:
- A. Enhance publicly accessible information about advisory groups by requiring related Ministries and Agencies to:
    - 1. Make public a notice of intent to form such groups and information about the process for their establishment;
    - 2. Continue to develop a centralized, publicly accessible electronic list of advisory groups and their members; and
    - 3. Make detailed minutes of advisory group meetings and meeting materials publicly available in principle.
  - B. Issue guidelines that require related Ministries and Agencies to provide interested parties the opportunity to provide input into the deliberations and recommendations of advisory groups, including by:
    - 1. Ensuring that all interested parties have the opportunity to participate in such groups to the maximum appropriate extent;
    - 2. Providing ample and meaningful opportunities for all interested parties to provide input into policy formulation throughout the deliberations by such groups; and
    - 3. Providing ample advance public notice prior to council and group meetings to enable interested parties to prepare for and attend discussions.
  - C. In addition to improving the specific requirements and responsibilities governing the operation of government-appointed advisory groups as outlined above, the United States recommends that Japan, on a centralized basis, develop before the end of 2008 a guide of best practices on ensuring advisory group transparency and actively promote their use in all Japanese Government ministries and agencies.
- II. Public Comments.** As Japan implements its Public Comment Procedure (PCP), the United States strongly encourages Japan to monitor the impact of the Administrative Procedure Law and take new steps to enhance the effectiveness of the system.

- A. In order to improve the current PCP system, the United States recommends that Japan:
1. Provide adequate public comment periods (30 days minimum, 60 days in principle). In cases where an urgent need for a shorter period exists, clear written explanations should be provided;
  2. Make proposed regulations public at the earliest possible time to allow interested parties sufficient time to analyze issues and prepare meaningful public comments;
  3. Ensure Ministries and Agencies fully consider public comments and allow sufficient time to incorporate them, where appropriate, into final regulations; and
  4. Respond to submitted comments in a timely, meaningful manner.
- B. The United States recommends that the Japanese Government continue to conduct surveys of the implementation of the PCP and issue guidance on its implementation. The United States also recommends that Japan undertake a thorough evaluation of the effectiveness of changes in the Administrative Procedure Law related to the PCP, publicly report the findings of that evaluation, and provide opportunities for public input on these findings.
- C. The United States recommends that Japan's Ministries and Agencies, although not required under Japan's Administrative Procedure Law, provide greater opportunities for interested parties to be aware of and comment on draft legislation in the early stages of its formation.

**III. Transparency in Regulation and Regulatory Enforcement.** To ensure the private sector has sufficient information about regulations as well as information necessary to stay in compliance with regulations, including Government interpretations of such, the United States recommends that Japan require Ministries and Agencies to make public their regulations and any statements of policy or generally applicable interpretations of those regulations. The United States also urges Japan to promote the use of plain language when drafting regulations to prevent arbitrary and inconsistent interpretation.

**IV. Strengthen U.S.-Japan Cooperation to Promote High Standard Transparency Practices.** The United States recommends that our Governments continue to intensify our cooperation to raise transparency standards in the Asia-Pacific to improve investment and business environments throughout the region, including by jointly promoting the implementation of the APEC Transparency Standards and the use of APEC transparency model measures as reference for future trade agreements.

- V. Foreign Translations of Japanese Laws.** The United States encourages Japan to continue with its program of translating into English its laws of greatest interest and, as it does so, continue to closely consult with the foreign business community.
- VI. Implementation of Rulemaking.** The United States recommends that Japan ensure that its Ministries and Agencies ensure the implementation of a reasonable delay in effectiveness of regulations (at least 30 days) to allow regulated entities a fair opportunity to come into compliance with the new regulation. The United States also recommends that any clarifying documents, such as implementing guidelines or regulations, be made available as soon as possible after the publication of regulations.

## OTHER GOVERNMENT PRACTICES

### I. Bank Sales of Insurance

- A. After monitoring the effectiveness of these safeguards until December 2007, the Financial Services Agency (FSA) in September 2007 found no significant problems with bank's insurance sales practices and plans to fully deregulate the bank sales channel as scheduled in December 2007. The United States welcomes this finding and urges Japan to fully liberalize the bank sales channel for the full range of insurance products without delay as scheduled in December 2007, consistent with the Financial System Council's recommendation.
- B. The United States welcomes Japan's commitment that it will review, and if necessary revise, the 10 million yen ceiling on third sector insurance products that smaller banks may sell to related companies prior to full liberalization in December 2007. The United States requests that Japan eliminate the 10 million yen ceiling on first and third sector insurance products in order to eliminate an unfair disadvantage to first and third sector insurance service suppliers.
- C. The United States also recommends that Japan review and revise, as necessary, restrictions on the use of certain "non-public financial information" of bank customers such as customer deposits and loan balances to enable bank agents to review these in advance, consistent with their sales of other financial services products, to help ensure among other things that insurance products offered are suitable to customers.
- D. The United States welcomes confirmation from Japan that related rules preventing inappropriate sales tactics to enhance consumer protection are to be developed and implemented in a manner that does not favor one product, sales method or services supplier over another. The United States requests that Japan continue to ensure that timely opportunities are made available to interested parties to provide views and input relating to the development and implementation of such rules.

### II. Insurance Cooperatives. Insurance cooperatives (*kyosai*) provide insurance products that compete directly with the private sector and occupy substantial market share in Japan's insurance market. The lack of a uniform regulatory regime for *kyosai* undermines the ability of Japan to provide companies and policyholders with a sound, transparent regulatory environment, and affords *kyosai* significant advantages over their private competitors. Some *kyosai* continue to take advantage of this situation to expand their market presence and product offerings. The United States therefore recommends:

- A. With specific regard to *kyosai* regulated by various ministries, create a level playing field between *kyosai* and their private sector competitors by subjecting *kyosai* to the same laws, requirements, standards, and oversight by the same regulator as their private sector counterparts. As a first step toward achieving equal conditions of competition, undertake a thorough review of the rules and regulations governing the supervision and inspection of these *kyosai* to determine



their conformity with Financial Services Agency (FSA) standards of supervision for private insurance service suppliers.

- B. With respect to *kyosai* regulated by the Financial Services Agency under the “Small Amount, Short-term Insurance Provider” system, undertake a thorough review of this system in a transparent manner within the period provided for under the Insurance Business Law (IBL). Such *kyosai*, to the extent they directly compete with FSA-licensed insurance companies, should be regulated as insurance companies under the Insurance Business Law and treated consistently with private companies. Remaining unregulated *kyosai* should be monitored by the FSA to determine if they legitimately should be subject to the IBL.

**III. Policyholder Protection Corporation (PPC).** The amended Insurance Business Law, which came into effect on April 1, 2006, stipulates that the system regarding PPC’s financial resources will be reviewed within three years. As Japan begins preparations to review the Life and Non-Life Policyholder Protection Corporations, the United States recommends Japan adopt measures, including a shift to a post-funded system, to help ensure that a more efficient, sustainable safety net system is created before the current system expires. The United States welcomes confirmation from Japan that the Financial Services Agency and relevant advisory groups will provide meaningful opportunities for input as the review process moves forward. The United States urges that Japan:

- A. Prepare related draft legislation and other measures in a transparent manner, including via access to deliberations by advisory groups and via public comment procedures.
- B. Adopt measures to ensure that the PPC is used as a last resort, including through a shift to a post-funding system, to help ensure that a more efficient, sustainable safety net system is created before the current system expires.

**IV. Domestication of Foreign Insurance Operations.** The United States requests Japan to take the necessary measures so that foreign incorporated insurance companies operating branches in Japan who wish to transfer their businesses to a Japan-incorporated entity, have a procedure whereby transfer of their businesses can be made in a seamless way that protects policyholders and other creditors and maintains the continuity of the business. Specifically, the United States request that Japan:

- A. Revise the Insurance Business Law’s portfolio and business transfer provisions to:
  - 1. Create a system to permit “overnight” reorganization by eliminating or creating exceptions to the sales blackout rule, and ensure that any revisions to the Company Law to permit redomestications are recognized by the Insurance Business Law;
  - 2. Establish statutory disclosure, notice and deemed approval procedure with all creditors analogous to procedures permitted in merger and spin-off by Japanese insurers;

3. Allow the transferee entity to assume all assets and liabilities of the transferring entity in transactions approved by FSA and creditors; and
  4. Permit a “deemed license” (*minashi menkyo*) assumption of regulatory licenses and approvals on condition that the transferee entity can demonstrate in the FSA review of the transaction that it will satisfy the same conditions and business methods after the transfer’s completion.
- B. Ensure that the tax treatment of de-mutualization, domestication, consolidation, or transfer of a foreign insurance company’s business within Japan is roughly equivalent and does not unduly impede the ability of foreign insurance companies to use these procedures.

## V. Consular Issues

- A. Re-entry Permits. Japanese law requires all foreign residents to obtain "re-entry permits" prior to traveling outside of Japan, regardless of the length of time the traveler intends to spend abroad. Failure to obtain the permit can cause visa-holders to lose their status as residents once they depart Japan. Obtaining a re-entry permit is a burdensome requirement in terms of cost and convenience, particularly in the event of last-minute travel obligations for foreign business persons and other residents in Japan. The United States therefore encourages Japan to take steps to change immigration regulations so as to require re-entry permits only for trips outside Japan that are of particularly long duration, such as those lasting a year or longer.
- B. Domestic Employee Visas. American citizens living in Japan complain that there are unreasonable restrictions on the visa issuances of business executives' personal/domestic employees. The United States requests that Japan give due consideration to such concerns within the foreign resident community and work wherever possible to find solutions to improve the situation.

**VI. Special Zones for Regulatory Reform.** The United States recommends that Japan further expand the Special Zones for Structural Reform program, including by allowing for-profit healthcare companies to operate in Special Zones providing full-service medical offerings. The United States furthermore urges Japan to continue transparent administration of the system and seek greater application of Zone measures nation-wide.

**VII. Government Practices Relating to Agriculture.** The United States welcomes steps taken by Japan under this Initiative to facilitate trade in agricultural products through adoption of more science-based international standards that protect consumers and their food supply. Such steps have enhanced the efficiency of the trading environment and the transparency of relevant rules and regulations. The United States therefore urges Japan to continue to make this progress by taking the following additional measures:

- A. Apply science-based standards to assess the safety of production substances used on organic crops and to modify the current pesticide residue policy with the goal of enhancing organic trade.
- B. Implement a Maximum Residue Limits regime that ensures that any mitigating measures are the least trade restrictive possible, provide national treatment to imports, and are in accordance with international practices.
- C. Complete the review of 20 food additives that are recognized as safe by Joint FAO/WHO Evaluation Committee on Food Additives and used throughout the world. Twenty-six additives were approved in the past year, but a number of food additives remain.
- D. Apply science-based standards in accordance with World Organization for Animal Health protocols to promote enhanced trade in animal products.
- E. Accelerate bilateral work already underway to implement a plant quarantine system that harmonizes the classification of plant pests and diseases based on the International Plant Protection Convention standards for official control and risk analysis.

## PRIVATIZATION

- I. **Privatization of Public Corporations.** As Japan implements the restructuring and privatization of public corporations, the United States urges Japan to create a level playing field for all market participants. The United States also recommends that such steps be undertaken in a transparent manner, including by ensuring domestic and foreign private sector entities are given meaningful opportunities to provide input and express views on matters affecting the market.
- II. **Japan Post Reforms.** The United States recognizes the potential benefits for the Japanese economy of a market-oriented reform of Japan Post which, if implemented vigorously, should stimulate competition and lead to a more productive use of resources. The implementation of a fully market-oriented reform is also necessary to eliminate long-standing advantages that the postal institutions have been accorded over U.S., Japanese, and other private companies and to ensure that new advantages are not created. As the implementation of these reforms progresses, it is important that all necessary measures are taken to ensure the legislation's principle of establishing equivalent conditions of competition between the new Japan Post entities and the private sector.
  - A. Level Playing Field for Postal Savings and Insurance and Financial System Stability. The United States welcomes confirmation by Japan that Japan Post Bank and Japan Post Insurance, from the outset of the privatization process in October 2007, will cease offering products that carry government guarantees and will be required to meet the same tax, legal, and regulatory obligations and, along with Japan Post Holdings, be subject to the same supervision and disclosure standards as private sector companies. The United States is also encouraged by Japan's commitment that measures shall be implemented to ensure that the privatized postal financial institutions, in practice, objectively meet the same licensing, disclosing and supervisory requirements as private sector financial institutions. The United States also welcomes confirmation that relationships among the new postal companies with capital relationships will be ensured on an arms-length basis and that no schemes exist to allow for cross-subsidization (and thus also transfer of risks) between and among the new entities created under related laws. As the sole authority over the supervision and inspection of Japan Post Bank and Japan Post Insurance under the Banking Law and Insurance Business Law, the Financial Services Agency (FSA) will play a critical role in assuring they develop and exercise effective risk management so as not to jeopardize financial system stability. In addition to fully implementing the above-mentioned measures, the United States urges Japan to also take the following steps to help meet the Japan Post Privatization Law's aim to achieve equal conditions of competition between the new Japan Post entities and private firms:
    1. *Product Distribution and Sales Channels.* Ensure private firms are given equal and transparent access to compete for distribution of financial products through Japan Post Network consistent with industry best practices and, consistent with the arms-length rule, ensure that the Japan Post Holding's relationships with Japan Post Bank and Japan Post

Insurance are undertaken on a truly market basis. Furthermore, ensure that Japan Post Network, including its employees, is and will be subject to FSA supervision when acting as an agent or intermediary for any financial transactions such as taking deposits, lending, exchange transaction and selling insurance products.

2. *Deposit and Reinsurance Relationships.* With respect to deposit and reinsurance contracts the Incorporated Administrative Agency Management Organization for Postal Savings Postal Life Insurance (Public Successor Corporation) enters with Japan Post Bank and Japan Post Insurance, respectively, contain all necessary measures to:
  - a. Ensure full and complete separation of pre-existing accounts and contracts (those held prior to October 2007) from accounts and contracts concluded beginning October 2007 so as to ensure a full separation of risk, and ensure that the Deposit Insurance Corporation and insurance Policyholder Protection Corporations will not be liable for pre-existing accounts and contracts;
  - b. Ensure deposit and reinsurance contracts are on a fully arm's length basis and, as such, will not allow for cross-subsidization of the new postal financial institutions through such arrangements. With respect to transparency, make public the method used for determining the reinsurance fees; and
  - c. Ensure the Public Successor Corporation's financial condition, including surpluses and/or deficits, and reinsurance transactions are publicly disclosed and accounted for in a manner that meets generally accepted corporate accounting rules/standards in Japan.
3. *Implicit Government Guarantee.* Including until such time that Japan Post Holdings is fully divested from its shares of the postal financial institutions, take meaningful steps to ensure that consumers and the marketplace are aware that products issued from October 2007 will not be backed by the Government. In addition, prior to expanding the scope of Japan Post Bank and Japan Post Insurance businesses and on a periodic basis thereafter, carefully monitor actual sales practices and enforce related laws to ensure accounts and contracts from October 2007 are not misrepresented as having a Government guarantee, as well as to ensure the postal financial institutions do not leverage their relationship with the Government to provide them an advantage over their competitors in the marketplace.
4. *Antimonopoly Act Enforcement.* Ensure through appropriate Japan Fair Trade Commission studies and other steps that the privatization and reform of Japan Post is undertaken in a manner that promotes free

competition, transparency and arms-length business practices, effective enforcement of competition policy and regulatory reform.

5. *Regional Social Contribution Fund.* Ensure that the Fund is administered transparently (including sufficient and periodic public disclosure of the cost allocation methodology, cost and revenue data used to make such calculations, and the distributions of funds) and include measures such as internal controls and transparent, precise disbursement criteria to prevent benefits from unfairly accruing to the postal financial service suppliers but not to other domestic and foreign service suppliers.
6. *Asset Valuation.* Ensure that independent auditors undertake a full valuation of the assets, liabilities, and reserves of the Incorporated Administrative Agency Management Organization for Postal Savings and Postal Life Insurance (Public Successor Corporation), and that this valuation is fully disclosed to the public.
7. *Cross-subsidization.* To ensure transparency in the independent operations of Japan Post Holding's subsidiaries, request that independent auditors of the subsidiaries report an opinion on the measures put in place to eliminate cross-subsidization, as well as those measures' effectiveness.
8. *Ensuring FSA Resources.* The United States welcomes news the FSA has reserved personnel to review the new Japan Post entities' compliance with relevant financial laws and regulations and urges Japan to ensure that sufficient personnel and other resources from among FSA's regular supervisory staff are provided so that the FSA can properly regulate the postal financial entities under all regulations applicable to private sector firms on a national treatment basis with other market participants.

- B. Conditions of Competition and the Introduction of Products. The United States urges Japan to ensure that a level playing field is actually created between the postal financial institutions and private financial institutions before the postal financial institutions are permitted to introduce new lending services, new or altered insurance products underwritten by Japan Post Insurance, and the origination of non-principal-guaranteed investment products by Japan Post Bank. The United States welcomes confirmation that the FSA will apply the same standards as private sector financial institutions to Japan Post Bank and Japan Post Insurance under the Banking Law and Insurance Business Law when engaging in sales and distribution of their financial services or insurance products. The United States also welcomes Postal Services Privatization Commission (PSPC) review of new product applications to ensure that new or altered products do not create market distortions. Achieving a level playing field also includes requiring the postal entities to meet objectively on a national treatment basis the same obligations that other companies must meet, including when introducing new products or riders. Thus, the United States urges Japan to ensure effective monitoring and compliance of the postal financial institutions with laws and

regulations in the same manner as its private sector peers, and that the reform process and its implementation are consistent with Japan's WTO obligations, particularly the national treatment principle of GATS.

C. Level Playing Field for Express Carrier Services. The United States continues to urge Japan to take all necessary steps to fully ensure that 'equivalent conditions of competition,' as called for under Article 2 of the Japan Post Privatization Law, are established between the new Japan Post companies and private express carrier companies. In this regard, the United States urges Japan to take the following steps to help create a fully level playing field:

1. Apply customs clearance procedures for mail and packages handled by Japan Post Service Company equivalent to those applied to private express carriers for similar actions. In particular, the United States urges Japan to ensure that mail delivered under express mail service (EMS) follows the "duty declaration" system and not the "duty assessment" system that Japanese regulations currently apply to EMS.
2. Require Japan Post Service to pay equal costs for customs clearance for similar processes, including NACCS charges and the costs for application document preparation.
3. Apply all safety and security laws and regulations to Japan Post items in the same manner as to those carried by private express carriers.
4. Take all necessary measures to make public disclosures of the Japan Post Service Company's business, including transactions involving Japan Post Holdings and its subsidiaries, sufficient to demonstrate that cross-subsidization among the Company's businesses and with other Japan Post entities does not occur, including requiring disclosures of separate business areas to the same standards required of other private companies.
5. Ensure that supervision by the Ministry of Land, Infrastructure and Transport (MLIT) of the new Japan Post entities and their related operations is undertaken according to the same standards as those applied to private companies.
6. Make draft regulations available for public review and implement in a timely fashion final regulations that subject the logistics and postal services operation of Japan Post Service to the same taxes as private corporations and make such subject to the same aviation safety and security regulations; and ensure EMS services are governed by MLIT under the same transportation laws and regulations and, with respect to postal services, supervise related operations according to freight transportation laws and ordinances.

D. Transparency. The United States urges that all necessary measures are taken by Japan to ensure the implementation of these reforms is fully transparent, including providing ample opportunity for the views of interested parties to be considered before final decisions are made. This is particularly important during decision-making processes where the final decision may impact the competitive environment and thus the businesses of Japan Post's private sector competitors in both the financial services and express delivery sectors. Specifically, the United States urges the following measures be taken by Japan:

1. Ensure meaningful opportunities are provided to interested private sector parties, including U.S. and other foreign companies, to actively contribute to deliberations by committees or components of such convened by the Government of Japan, including the Postal Services Privatization Committee, on issues that may impact the private sector;
2. Conduct regular (i.e. annual) public reviews of the implementation of the Japan Post reforms, including by providing meaningful opportunities for all interested parties to express their views on the impact of the reforms on markets and on the degree of equivalence of competitive conditions of competition between the new Japan Post entities and the private sector, and also provide for transparent verification of the compliance of these entities with the same laws and regulations that currently apply to the private sector.
3. Provide meaningful and timely opportunities for private sector interested parties to exchange views with relevant Government of Japan officials on matters pertaining to Japan Post reforms that may affect the private sector;
4. Seek public input through the use of Public Comment Procedures and other methods with respect to implementing regulations, guidelines, Cabinet and other orders, implementation plans, and other measures established for matters pertaining to Japan Post reforms, and also ensure that input is fully considered and, where appropriate, incorporated into draft measures before they are finalized; and
5. Ensure that information relating to the planning and implementation of Japan Post reforms, including the discussion materials and minutes of related government-convened advisory groups, is made public in a timely way by continued use of web postings, press conferences, and other tools.



## DISTRIBUTION

- I. **Airport Landing and User Fees.** The United States urges Japan to improve the business and tourism climate in Japan and help boost the economy by further reducing landing and user fees at Narita, Kansai, and Chubu International Airports, which would benefit both Japanese consumers and industry. Landing fees and other user charges should be transparent both for domestic and international flights and directly related to the costs associated with the use of airport runways and facilities, consistent with International Civil Aviation Organization and other relevant guidance.
- II. **Airport Expansion and Operation.** Both Narita Airport and Haneda Airport are in the process of an ambitious set of projects that will expand capacity beginning in 2010. Japanese and U.S. civil aviation negotiators have agreed to resume talks by the summer of 2008 that will consider, among other issues, market access issues related to this expansion of capacity. The process for planning and, at least in the case of Narita, financing this work has not been fully transparent, and there are concerns that foreign airlines, including U.S. carriers, have not been given an adequate opportunity to comment meaningfully in the setting of plans for utilization of the airports once new slots are available in 2010. These concerns include the manner in which slots at the two Narita runways will be managed and the various perimeter and other rules that the Ministry of Land, Infrastructure and Transport (MLIT) envisages to restrict the use of slots at Haneda. Although these issues will be addressed in U.S.-Japan Civil Aviation Talks set to resume by the summer of 2008, the United States urges Japan to:
  - A. Ensure that, through a timely and transparent consultative process, non-Japanese carriers have meaningful opportunities to comment throughout the establishment of new rules and procedures at both airports; and
  - B. Support rules and procedures that offer flexibility to carriers and ensure use of the airports at the highest levels of efficiency, as such decisions will significantly affect for years to come the options of the traveling public and the movement of cargo in the Tokyo Metropolitan Area.
- III. **Improving Efficiency in Customs Processing.** The United States welcomes the Government of Japan efforts to formulate an Authorized Economic Operator (AEO) system in Japan. In this regard, the United States recommends that Japan apply the following measures to customs brokers with good compliance records.
  - A. Two-staged Declaration of Import. Introduce a system for customs declaration whereby the declaration of shipment acceptance is separate from the declaration of tax and duty payment to allow customs officers to work during daytime business hours only while enabling express carriers to release import items in a timely way outside regular business hours.

- B. Postmortem Declaration of Exports. Introduce a system to allow customs brokers to make export declaration after export. The declaration process is available in the United States and is effective for the necessary speedy process of export due to the curfew hours of Narita Airport.
  - C. Freedom of Selecting Customs Office for Declaration. Customs brokers using Nippon Automated Cargo Clearance System (NACCS) should be able to declare express items at any convenient Customs Office beyond a territory of the Customs Office, in order to allow shipments to more quickly reach their destination.
  - D. Reduction of Overcharge Costs and NACCS Charges. In order to facilitate smooth and speedy customs declaration processes, the overcharge costs and NACCS charges should be lowered.
- IV. ***De Minimis.*** To follow a global trend toward reducing customs workloads while maximizing efficiency, the United States recommends that Japan increase the Customs Law *de minimis* limit from its current 10,000 yen to a level comparable to the US \$200 *de minimis*, which would equate to a rounded yen amount of 25,000.
- V. **Parking for Distribution Vehicles.** The United States welcomes assurances that distribution vehicles, including those carrying *Yu-pack* and Express Mail Service (EMS) items, will be treated equally with regard to the enforcement of parking laws and traffic regulations. In light of the impact of the revised Road Traffic Law (effective June 1, 2006), the United States continues to urge Japan, particularly MLIT and the National Policy Agency (NPA), to take measures that help provide additional parking spaces for distribution vehicles in urban centers where shortages have appeared through the Law's enforcement. The United States therefore recommends that Japan:
- A. Increase the number of parking spaces and short-duration loading, unloading and delivery zones on major streets;
  - B. Coordinate policies among concerned ministries and local autonomies in order to facilitate the introduction of local measures to help facilitate distribution activities in crowded areas; and.
  - C. Ensure equitable application of parking laws for all distribution vehicles in the dense congestion of Tokyo streets.
- VI. **Laws Affecting Large Scale Retail Stores.** Revisions made to the Central City Invigoration Law and the City Planning Law in May 2006 have the potential to significantly erode retailers' ability to open larger stores that meet customers' needs. To measure the actual impact of these new nationwide measures, the United States requests that Japan undertake fully transparent reviews of the new regulations a timely fashion, including ensuring that meaningful opportunities to provide input are made available to interested parties and that the results of these reviews are made public.