

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

December 5, 2006

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The Regulatory Reform and Competition Policy Initiative (Regulatory Reform Initiative) was launched in 2001 under the U.S.-Japan Economic Partnership for Growth to promote economic growth and open markets through sectoral and cross-sectoral reforms. The Initiative, now in its sixth year, continues to play a major role in deepening bilateral trade and economic relations.

The United States welcomes Prime Minister Abe's commitment to press forward with economic reform in Japan. Reforms that create new opportunities, stimulate competition, and foster a stronger business climate will help maintain Japan's economic growth and vitality for years to come. The United States has also been encouraged by the efforts of other reform advocates within Japan, and is hopeful these activities will intensify in the coming months and years.

This year's recommendations from the United States emphasize the importance of making continuing progress on reform in the broad areas of telecommunications, information technologies, medical devices and pharmaceuticals, financial services, competition policy, commercial law and legal services, transparency, privatization of government corporations, distribution, and agriculture.

The Regulatory Reform Initiative is also an important forum enabling the United States and Japan to intensify our cooperation in pursuit of mutual interests through promoting high standards internationally, including in areas such as intellectual property protection and transparency in regulatory practices. The United States wishes to strengthen our work under the Initiative in these and other areas.

These recommendations, in addition to recommendations from Japan, serve as the basis for discussions over the coming months in the High-Level Officials Group and in four different Working Groups covering telecommunications, information technologies, medical devices and pharmaceuticals, and cross-sectoral issues. Progress achieved by each Government under the Initiative is then presented to the President and Prime Minister in the Initiative's annual Report to the Leaders.

The periodic participation of private sector representatives in this Initiative has also greatly informed our work through their expertise, and the United States looks forward to increasing the frequency of this practice.

The Government of the United States also looks 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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## TELECOMMUNICATIONS

The United States continues to monitor Japan's regulatory reform efforts for its telecom sector in response to evolving technologies. The United States believes that increased competition would foster innovation and offer Japanese consumers greater choice at lower prices. In this regard, the Government of Japan's decision to delay until 2010 an important discussion on the reorganization of the dominant carrier Nippon Telegraph and Telephone (NTT) was disappointing. Nevertheless, the United States urges Japan to continue taking steps to ensure a competitive environment for new entrants, competitive carriers, and equipment manufacturers.

### *RECOMMENDATION HIGHLIGHTS*

#### **Ensuring Market-Based Technology Decisions:**

Improve transparency and increase stakeholder participation in policymaking and regulations; promote efficient use of spectrum to increase opportunities for new services and technologies; foster a technology-neutral licensing regime where service providers can introduce innovative technologies.

**Strengthening Competitive Safeguards on Dominant Carriers:** Prevent anticompetitive behavior by carriers with market dominance as telecom services move to IP-based networks;

ensure a competitive playing field for both wireline and mobile interconnection; promote facilities-based competition across different broadband platforms; ensure that the universal service program is administered in a competitively-neutral manner.

#### **Promoting Trade in Telecommunications**

**Equipment:** Make the Suppliers' Declaration of Conformity (SDOC) process an efficient and attractive alternative to third-party certification; adopt a "family approval" approach for radio type approval procedures.

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## INFORMATION TECHNOLOGIES

The Government of Japan has completed several major plans for IT-related policies in 2006, including the New IT Reform Strategy, Priority Policy Program 2006, and e-Government Promotion Plan. In addition, it is undertaking an extensive review of its Copyright Law and steps to achieve goals contained in the Intellectual Property Strategic Program 2006. This year's recommendations support Japan's continuing efforts to enhance protection for IPR regionally and globally, strengthen bonds between our IPR regimes, foster the development of private-sector and government IT infrastructures, and promote use of IT and e-commerce in Japan.

### *RECOMMENDATION HIGHLIGHTS*

**IT and e-Commerce Policymaking:** Foster private sector participation and transparency in policymaking; promote technology neutrality and compatibility with international practices.

**IPR and Copyright Protection:** Strengthen protection, including through adoption of a statutory damages system 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.

**Online Security:** Ensure comprehensive and transparent review of Privacy Act implementation, and that any revisions enhance business environment and do not restrict trans-border data flows; work closely with private sector on online fraud issues and continue collaboration with the United States.

**Health IT and e-Accessibility:** Provide opportunities for a wide range of vendors to participate in government health IT projects; exchange views on e-accessibility issues.

**Government IT Procurement:** Clearly define and appropriately limit liability in IT procurement contracts; allow contractors to possess ownership rights to IP created in government IT system development; reduce use of sole source contracting.

## MEDICAL DEVICES AND PHARMACEUTICALS

The United States continues to monitor Japan's efforts to change its healthcare system in response to its aging population. The United States has taken interest in Prime Minister Abe's "New Health Frontier Strategy," which would focus Government attention on disease prevention and healthy life expectancy, and the "Innovation 25" strategy, which would foster innovation in medicine and other fields. The United States urges Japan to ensure that as these efforts are undertaken Japanese patients enjoy rapid access to innovative medical devices and pharmaceuticals. Reimbursement pricing policies that reward the development of advanced devices and drugs and regulatory policies that facilitate the development of such products will help Japan meet the challenge of providing world-class healthcare to an aging society.

### *RECOMMENDATION HIGHLIGHTS*

**Pricing Reform:** Improve transparency and industry's ability to offer input on the reimbursement pricing system for drugs; implement a reimbursement pricing system for medical devices that reflects the value of advanced medical technology.

**Regulatory Reform:** Increase regulatory agency staffing; improve the environment for drug clinical trials and reviews; speed reviews of medical devices; facilitate use of medical device clinical data.

**Cosmetics/Quasi-drugs:** Reform the quasi-drug regulatory system; allow verifiable data-based claims.

**Blood Products:** Create a pricing system based on the industry's characteristics, including its regulatory and distribution systems.

**Over-the-Counter Medicines:** Clarify how Japanese regulators will implement recent legal changes related to over-the-counter medicines.

**Nutritional Supplements:** Allow informational/educational statements; expand list of allowable additives and solvents; set quantity limits based on scientific principles.

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## FINANCIAL SERVICES

The United States welcomes Japan's continued progress on financial services regulatory reforms, including removing barriers to foreign and domestic competition, and enhancing financial sector regulatory and supervisory transparency and clarity. We encourage Japan to continue its progress in establishing clear and consistent regulation and supervision of financial institutions, in line with international standards and best practice, and to continue to eliminate unnecessary regulatory barriers to competition. A more efficient and competitive financial sector can play a critical role in boosting Japan's long-term economic growth potential.

### *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:** 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.

**Defined Contribution Pensions:** Broaden and deepen pension participation and enhance labor mobility including by increasing tax deductibility of contributions and allowing employee contributions.

**Information Sharing and Firewalls:** Review legal and regulatory restrictions that unduly limit foreign financial groups' ability to manage their operations and effectively meet customer needs across legal entities; define the scope of all required firewalls and identify firewall maintenance "best practices" in detail in written guidance.

**Market Efficiencies:** Harmonize the regulatory framework governing investment advisory and investment trust management activities; allow mergers and reduce obstacles to the early termination of investment trusts; review revised institutional investor disclosure rules for shareholdings over 5 percent.

## COMPETITION POLICY

The United States believes that a strong and effective enforcement policy against Antimonopoly Act (AMA) violations will provide great benefits to Japanese consumers and the business community. Public confidence in AMA enforcement by the Japan Fair Trade Commission (JFTC) will be maximized where enforcement procedures are as fair and transparent as possible. Bid rigging remains a significant problem at all levels of government and the incentives leading officials to assist bid rigging must be addressed fully. The United States urges Japan to take measures to improve further Japan's competition regime.

### **RECOMMENDATION HIGHLIGHTS**

#### **Strengthening Antimonopoly Deterrence:**

Strengthen criminal enforcement and penalties; maintain criminal and administrative penalties against cartels; avoid imposition of surcharges on unilateral conduct; revise JFTC enforcement guidelines; review AMA exemptions; promote competition in sectors with privatization; strengthen JFTC staff and resources.

#### **Improving Fairness of JFTC Procedures:**

Establish standards for issuing stays of JFTC orders; improve confidence in the fairness of JFTC

hearings; provide procedures for AMA clearance of stock acquisitions; improve fairness of Subcontract Law procedures.

**Addressing Bid Rigging:** Prevent conflict of interests, including in the *amakudari* system, that encourage government officials to assist bid rigging; expand the range of ministries offering protections from administrative punishment for companies admitted to JFTC's leniency program; improve procurement practices to maximize competition on public procurements.

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## COMMERCIAL LAW AND LEGAL SYSTEMS REFORM

A modern commercial law regime that facilitates cross-border mergers and acquisitions and promotes good corporate governance will lead to efficiency in the business sector and the maximization of shareholder value for Japanese investors. In addition, creating a legal environment in Japan that is conducive to providing efficient international legal services to domestic and foreign companies and that facilitates the handling of legal disputes through less-costly alternative dispute resolution (ADR) mechanisms will also contribute significantly to the health of Japan's economy. The United States urges Japan to take necessary measures to improve further Japan's commercial and legal environments.

### **RECOMMENDATION HIGHLIGHTS**

#### **Promoting Efficient Restructuring and**

**Shareholder Value:** Allow use of foreign stock as consideration without restriction in triangular mergers and provide clear and predictable rules for tax deferral benefits that treat domestic and cross-border transactions similarly.

#### **Strengthening Good Corporate Governance:**

Encourage active proxy voting by pension and mutual funds, including by facilitating electronic voting; protect shareholders by requiring independent board directors to evaluate tender offer bids and by strengthening the executive committee and corporate auditor systems.

#### **Protecting Foreign Firms Legitimately Doing**

**Business in Japan:** Amend the Company Law so foreign firms doing business in Japan legitimately through branch offices are not subject to the restrictions of Article 821.

#### **Achieving Legal System Reform:**

Permit licensed foreign legal consultants (*gaiben*) to form professional corporations and to open branch offices; count legal experience in Japan toward the minimum qualification criteria for *gaiben*; allow Japanese lawyers to join overseas legal partnerships; promote arbitration and other alternative dispute resolution (ADR) by ensuring *gaiben* and foreign lawyers can act as neutrals and represent parties in international ADR proceedings in Japan and by implementing the new ADR Law consistently with international norms and practice.

## TRANSPARENCY

Transparency in regulatory and policy-making processes is one cornerstone of any positive business and investment climate, and the United States and Japan share a deep, mutual interest in promoting strong transparency standards and practices in the Asia-Pacific region. While we have taken important first steps in APEC to help address transparency challenges, the United States looks to Japan to intensify our cooperation in these and new ways to make more progress in this area. To advocate high standards internationally, it is also critical that Japan build on recent progress to achieve higher standard transparency practices domestically. The United States therefore urges Japan to take steps to ensure access to government-commissioned advisory councils, close loopholes and further boost the effectiveness of Japan's new public comment procedure, and ensure all government interpretations of regulations are published to provide more certainty for companies.

### *RECOMMENDATION HIGHLIGHTS*

**Advisory Groups:** Implement new rules by which government-commissioned councils operate to ensure transparency and access for interested stakeholders to provide input.

**Public Comment Procedures (PCP):** Strengthen the PCP system by lengthening public comment periods and ensuring ample time is given to consider and, where appropriate, incorporate comments.

**Strengthen International Cooperation:** Intensify bilateral work to promote implementation of APEC Transparency Standards; take new steps to promote high transparency standards in the Asia-Pacific.

**Public Input into Draft Legislation:** Provide greater opportunities for interested parties to be aware of and comment on draft legislation prepared by Ministries and Agencies in the early stages of its formation.

**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.

**No-Action Letters:** Take steps to increase the effectiveness and use of the no-action letter system to help firms clarify interpretations of regulations.

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## OTHER TRADE-RELATED GOVERNMENT PRACTICES

Regulatory reform that creates new opportunities and ensures a level playing field for all players in a market fulfills the goals of enhancing economic growth and strengthening competition to the benefit of consumers. The United States urges Japan to move forward with specific steps to achieve these goals in Japan's insurance sector, including by fully opening the bank sales channel for insurance and continuing progress to provide for a sound and secure insurance market by holding insurance cooperatives to the same regulatory supervision and standards that private insurers must meet. The United States also welcomes steps taken by Japan under this Initiative to facilitate trade in agricultural products and urges Japan to continue to make progress by taking new steps to adopt more science-based international standards that protect consumers and their food supply.

### *RECOMMENDATION HIGHLIGHTS*

**Promote 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.

**Agriculture:** Ensure measures that enforce maximum residue levels are the least trade restrictive possible; implement international standards in plant quarantine and in other measures, including biotech products; implement international standards in animal health and related measures; complete review of food additives recognized as safe by a Joint FAO/WHO Evaluation Committee.

## 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 Japan Post is required to meet tax, legal, and regulatory obligations and is subject to the same supervisory standards as private firms; ensure Japan Post does not actively leverage its 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 mail/packages handled by Japan Post as applied to private express carriers; adequately disclose relationships to 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.

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## DISTRIBUTION

Lowering costs and increasing efficiency of the distribution system can strengthen Japan's economy, benefit consumers, and create a more competitive business environment. Regarding airports, the United States remains concerned about fees, lack of transparency, and access to information about large expansion projects. The United States also is still concerned about several other areas under Distribution, including ensuring a level playing field in the express delivery market, speeding implementation of revised laws and regulations, and ensuring retailers are free to compete in the Japanese market.

### *RECOMMENDATION HIGHLIGHTS*

**Airport Landing Fee Reform:** Appoint an appropriate airport economic regulator; assure transparency in the setting of fees, and reduce fees.

**Airport Expansion and Operations:** Ensure Narita Airport's Runway B extension and other capital improvements at airports move forward in a transparent way with views of all carriers taken into account; increase transparency on proposed rule changes at Haneda Airport.

**Boost Transparency:** Ensure interested stakeholders are able to exchange views with the

Airports Discussion Group of the Aviation Subcommittee of MLIT's Transportation Policy Committee.

**Road Transport:** Speed implementation of the revised Road Transport Vehicle Law.

**Parking Spaces:** Take steps to facilitate temporary parking by distribution vehicles.

**Customs Procedures:** Set new customs regulations for express consignments; separate declaration systems.

# ANNEX

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## TELECOMMUNICATIONS

- I. Ensuring Market-based Technology Decisions.** Consumer choice in Japan's telecom market is unnecessarily limited by the regulatory environment. The Ministry of Internal Affairs and Communications (MIC) continues to act as regulator and policy promoter for this sector, fueling a perception that its decisions provide disproportionate benefits to larger companies with historical ties to the Government. The United States believes that Japan needs to move regulatory functions to a fully independent governmental organization and encourages Japan to review the need for requirements that the Government of Japan own a specified amount of NTT shares. In addition to these fundamental reforms, Japan can take immediate steps to improve transparency, promote efficient use of spectrum, and institute technology-neutral principles.
- A. To foster greater transparency in policymaking and revision of telecom regulations, the United States urges Japan to:
1. Open the selection process for Government-sponsored study groups, whereby interested stakeholders (foreign or domestic) can participate;
  2. Require Government-sponsored study groups charged with making recommendations relating to regulation (including setting any mandatory technical requirements or recommendations on spectrum allocation) to make available in a timely and accessible manner the minutes and relevant documents of each meeting;
  3. Develop procedures to enable any interested party to formally petition MIC for the development, adoption, change, or deletion of rules, and for MIC to act on a petition without requiring study group involvement.
  4. With respect to private sector-led efforts to develop standards for areas such as digital home networks or services for next-generation networks (NGNs), refrain from interfering in, seeking to influence, or coordinating such efforts, apart from ensuring that:
    - a. any such standardization activities are open to full participation by any interested company, foreign and domestic; and
    - b. any standardization effort that identifies specific bands for exclusive use of spectrum is subject to full and open notice and comment process if and when such proposals are taken up by MIC;
  5. With respect to NGNs:
    - a. Ensure any network requirements established by NTT involving interfaces necessary for interconnection with the NTT East or West networks are developed in an open and transparent fashion, with all interested parties able to fully participate in the process (i.e., not

discriminating against companies which have not been selected to participate in NTT-sponsored co-development programs);

- b. Ensure that any new design NTT East or West seeks to implement in deploying NGNs minimizes proprietary solutions that require interconnecting companies to invest in supplemental equipment, such as the proprietary “Module C” originally required for interconnecting with NTT’s circuit-switched network; and
  - c. Ensure that NTT East and West give adequate advanced notice of proposed network changes, to allow competing carriers ample time to introduce any necessary modifications into their own network.
- B. To promote efficient use of spectrum and thus increase opportunities for new services and technologies, the United States urges Japan to:
- 1. Institute a clear policy of technology-neutral licensing, separating, to the maximum extent possible, operator choice of technology from the spectrum assignment and service license process.
  - 2. With regard to access to spectrum:
    - a. Analyze incumbents’ unused spectrum, determine criteria to identify “warehousing” (hoarding), and take steps to eliminate it;
    - b. Publish draft plans for making additional spectrum available for innovative wireless technologies (including LANs, MANs) on an unlicensed consumer usage or “license-exempt” basis, including in the 5 GHz band; and
    - c. Institute a notice and comment process with a view to ensuring that licensed users of wireless broadband technologies have access to spectrum in a way that promotes multiple new entrants who are accorded maximum flexibility in their choice of technology.
  - 3. With regard to competition in the wireless sector:
    - a. Review whether there are any unreasonable impediments to access to towers and tower sites for new entrants;
    - b. Create clear guidelines for licensed operators to lease, sub-lease, and exchange spectrum with other service providers (including MVNOs); and
    - c. Ensure that new entrants are able to avail themselves of reasonable procedures to facilitate roaming onto incumbent networks, until the new entrants are able to build out their own networks.

- C. To foster an environment where service providers can introduce innovative technologies, the United States urges Japan to:
1. Implement the universal service fund program in a technology-neutral manner by expanding the scope of eligible operators to include other technologies capable of delivering voice services (e.g., wireless);
  2. Allow the introduction of technological solutions that reduce harmful interference and make shared use of spectrum possible, such as for Broadband Over Powerline (BPL), on both an indoor and outdoor basis;
  3. Initiate procedures to permit broader use of software-defined radios; and
  4. Ensure the least burdensome regulation and technical requirements on emerging IP-based products and services and maintain flexibility for new business models for related services.

**II. Strengthening Competitive Safeguards on Dominant Carriers.** In September 2006, MIC published its “New Competition Promotion Program 2010” to address competition concerns as telecom services migrate to IP-based networks. The United States urges Japan to continue strengthening competitive safeguards on dominant carriers in this evolving market to ensure a competitive environment for new market entrants, competitive carriers, and equipment manufacturers.

- A. Competition Policy. As regulations are developed to implement the New Competition Promotion Program 2010, the United States urges Japan to:
1. Ensure that carriers implementing Fixed-Mobile Convergence (mobile devices that “roam” onto a fixed network) do not abuse any dominance in either the fixed or mobile sector through their affiliates;
  2. Ensure that dominant carriers implementing Fiber to the Curb (FTTC) or Fiber to the Home (FTTH) do not preclude competition by unreasonably eliminating copper-based access to customers;
  3. Review licensing requirements for international Internet-based voice services and applications to distinguish between voice applications that fully substitute for traditional phone service and those that do not; and
  4. Promote facilities-based competition among different broadband platforms, aiming to encourage network operators to invest in and build competing IP-based infrastructure and minimize regulatory disincentives.
- B. Wireline Interconnection. Keeping in mind that the current LRIC model will expire in 2008, and to ensure a competitive playing field under changing market conditions, the United States urges Japan to:

1. Require NTT East and West to each set a cost-oriented interconnection rate, consistent with Japan's WTO obligations, taking into account differing costs of the respective regions; and, as necessary, permit differential interconnection rates between the regional carriers, taking into account dangers of (and ways to prevent) anti-competitive price squeezes;
  2. Eliminate the use of interconnection revenue as a source of cross-subsidization between NTT East and West; and
  3. Consider permitting interconnection (connecting with either dry copper or line-shared frequencies) at remote terminals.
- C. Mobile Interconnection. For calls terminating on mobile networks, the United States urges Japan to:
1. Institute an objective and transparent means for evaluating whether mobile wireless termination rates are set at levels that reflect the principle of cost-orientation under efficient management, consistent with Japanese law;
  2. Provide transparent means for resolving mobile interconnection issues, utilizing objective criteria as a clear basis for arbitration if commercial negotiations fail; and
  3. Analyze NTT DoCoMo's dominant position in the mobile sector, and the degree to which any existing mobile carriers exert market power in the sub market for call termination.

**III. Promoting Trade in Telecommunications Equipment.** With a view towards removing burdensome requirements that do not reflect the technological realities of the global marketplace, the United States recommends that Japan take steps to streamline its certification process for telecom equipment, to benefit both domestic and foreign equipment makers.

- A. Suppliers' Declaration of Conformity (SDOC). To make the SDOC process an efficient and attractive alternative to third-party certification, the United States urges Japan to:
1. Seek industry feedback in a transparent manner on possible reforms; and
  2. Take concrete steps to simplify and improve the process.
- B. Type Approval. The United States urges Japan to adopt a "family approval" approach for radio type approval procedures that allows modifications to radio equipment certifications without requiring a new type approval registration.

## INFORMATION TECHNOLOGIES

- I. IT and E-Commerce Policymaking.** The e-Japan Strategies and Programs have promoted the use of IT and e-commerce throughout Japan's economy. To ensure that Japan's policies continue to encourage development in these areas, the United States urges Japan to foster an open, transparent, and flexible regulatory environment.
- A. IT Policy Plans. Japan has completed several major plans for IT-related policies in 2006, including the New IT Reform Strategy, Priority Policy Program 2006, and e-Government Promotion Plan. These plans are designed to promote the further development of private-sector and government IT infrastructures and the increased use of IT and e-commerce in Japan. The United States urges Japan to implement these plans in a manner that fosters private-sector leadership, self-regulation, and active participation in policymaking processes.
- B. Private-Sector Input. Japan has acknowledged the importance of seeking input from the private sector in the development and implementation of IT and e-commerce policies. To facilitate this, the United States urges Japan to ensure that meaningful opportunities are provided for interested parties in the private sector, both domestic and foreign, to:
1. Submit their views on drafts of relevant legislation, Cabinet orders, ministerial ordinances, regulations, and guidelines through Public Comment Procedures and other means; and
  2. Obtain information in a timely manner about, and participate actively in, the formation and work of government-commissioned IT and e-commerce advisory and study groups.
- C. Technology Neutrality. To encourage maximum flexibility and innovation in the private sector, the United States urges Japan to:
1. Implement laws, regulations, and guidelines related to IT and e-commerce in a manner that does not unduly promote, mandate, or favor specific technologies (technology neutrality); and
  2. Cooperate closely with the private sector in international standards development activities and give due consideration to established international standards when formulating IT and e-commerce policies.
- D. International Compatibility. To further promote the development of cross-border e-commerce, the United States urges Japan to ensure that its policies and legal frameworks for IT and e-commerce 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. Strengthen the enforcement system against copyright infringement by taking the following measures.
1. *Statutory Damages*. Adopting 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 Japan's 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*. Providing 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.
  4. *Book Piracy*. Enforcing the Copyright Law to effectively combat illegal reproduction of books, especially on university campuses.
  5. *Movie Piracy*. Enacting effective anti-camcording legislation against the use of recording devices in movie theatres, aimed at cutting off the major source for masters used to make pirate DVDs.
- B. Protect Digital Content. Ensure the transparency of relevant rules and regulations, and effectively combat online piracy.
- C. 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.
- D. Private-Use Exception. Take further steps to strengthen the protection of digital content and preventing online piracy by narrowing the scope of the private-use exception so that activities with implications beyond the home, such as downloading copyrighted works from peer-to-peer networks, are not permitted without right holder authorization.
- E. Education Exception to Copyright Law. 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.

- F. Patent Procedures. Streamline Patent Procedures through promotion of work share efficiencies by:
1. *Deferred Examination System*. Provide for a system that ensures patent rights are clearly defined for third parties early in the application process, including by reconsidering usage of the 3-year deferred examination system.
  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.
- G. 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 be intensified in parallel with, and in support of, work to promote a strong standard for IPR enforcement among interested trading partners.

**IV. Promoting Online Security.** Public and private-sector policies that protect personal privacy, address online fraud, educate consumers, and promote secure government information systems can contribute to greater online security and the continued development of IT and e-commerce. These policies should emphasize private-sector leadership and technology neutrality, stress public/private cooperation in addressing problems, and be compatible with international practice. Such policies should also encourage cooperation between governments.

- A. Privacy. Ministries have released implementation guidelines to help companies comply with the Act on the Protection of Personal Information (Privacy Act), which took effect in April 2005. The Cabinet Office has held multiple rounds of hearings to review the effectiveness of the Privacy Act implementation and gather input from industry, non-profits and academics. The United States looks forward to the Cabinet Office’s release of a document (Report) in mid-2007, reviewing the Privacy Act’s effectiveness and potentially recommending revisions to improve implementation. To enhance understanding of, and compliance with, the Privacy Act, the United States recommends that Japan:
1. Publish information on a Cabinet Office website confirming its statement that non-compliance with voluntary guidelines will not result in penalties to firms.
  2. Ensure that reports compiled by the Cabinet Office about enforcement of the Privacy Act be thorough and detailed to better educate companies how to comply with the Act.

3. Make the Cabinet Office's review process of the implementation of the Privacy Act as effective and transparent as possible by:
    - a. Publishing a schedule, in advance, for the development and release of the Report, indicating clearly when there will be opportunities for comment, so that stakeholders can prepare effectively; and
    - b. Creating a page on the Cabinet Office website that enables stakeholders to find relevant information on the Report easily.
  4. Ensure that the Cabinet Office's Report enhances the business environment and protects personal information by:
    - a. Clearly differentiating between publicly available information and confidential or sensitive personal information, and clarify how each should be properly handled;
    - b. Standardizing implementation guidelines across Ministries as much as possible, with Ministries adding separate guideline provisions when necessary for individual business sectors; and
    - c. Making sure that any recommendations regarding cross-border transfers do not unduly restrict the international flow of data, and include provisions recommending that the data collector exercises due diligence in protecting the information.
- B. Online Nuisance, Deceptive Practices, and Fraud. Malicious, illicit and illegal activity online generates formidable and unwanted costs and can erode essential consumer confidence in online transactions. Recent U.S.-Japan collaborations to address such issues include work by the U.S. Federal Trade Commission and the Government of Japan to translate the E-consumer.gov website into Japanese, and the support of both Governments to ensure the success of the U.S.-Japan Financial Technology Seminar in April 2006. In continuing its work to address online fraud, the United States urges Japan to:
1. Work closely with the private sector in a transparent manner to encourage a balanced approach to combating online hazards featuring the use of industry-appropriate technology, best practices, and consumer education;
  2. Publish information on prosecutions under the amended Spam Law;
  3. Continue to work with the United States to help enhance understanding of Constitutional Secrecy of Communications provisions and the Telecommunications Business Law to help private sector firms comply with the law in the context of filtering and blocking spam;
  4. Collaborate with the United States to address online fraud, including

jointly supporting a seminar in Japan; and

5. Japan and the United States were among the first signatories on the Council of Europe Convention on Cybercrime (Convention). The United States ratified the Convention on September 29, 2006, and looks forward to hearing the status of Japan's plans to ratify the Convention.

- C. Government Information Security. Japan's New IT Reform Strategy calls for Ministries to procure new information systems and develop, and promote on a local level, evaluation structures to ensure the reliability and security of these systems. The United States urges Japan to take a balanced and uniform approach in its procurement policies and evaluation criteria to ensure predictability for IT vendors and consistency throughout Japan's central and local government entities.

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

- A. Health IT. The New IT Reform Strategy and the Priority Policy Program 2006 highlight Ministries' efforts to formulate and implement measures designed to help Japan introduce IT solutions for items such as medical records and processing of medical receipts. The United States welcomes Japan's commitment to health IT and urges it to:

1. Ensure that all relevant laws, ordinances, guidelines, and standards are, to the extent practicable, technology neutral; and
2. Provide meaningful opportunities for:
  - a. Interested parties to present their views on proposed policies and rules related to health IT through transparent, open, and inclusive policymaking processes; and
  - b. A wide range of qualified IT vendors to participate in government-sponsored projects used to develop or showcase health IT systems.

- B. e-Accessibility. Millions of people around the world have disabilities and their numbers are expected to increase as the populations of many countries age. There is an ongoing international effort to harmonize IT accessibility policies and their underlying standards. The United States encourages Japan to engage in bilateral discussions on current and future e-accessibility policies and activities aimed at facilitating a better understanding of our respective work and priorities.

- ## VI. **Government IT Procurement Reforms**. The United States supports Japan's efforts to reform its procedures for government IT procurements to accomplish goals such as discouraging anticompetitive behavior, acquiring high-quality IT systems at reasonable costs, stimulating innovation and competition, and promoting transparency and fairness.

- A. A “follow-up survey” released by the Inter-Ministerial Task Force for Information Systems Procurement (Task Force) in January 2006 indicated that many items in the Task Force’s memorandum on government IT procurement reform have not yet been implemented. With the memorandum’s five-year anniversary (March 2007) fast approaching, the United States urges the Task Force and Ministries to implement all of the memorandum’s reforms without delay by taking steps to:
1. Clearly define and set appropriate limits on liability in all IT procurement contracts. To help Ministries accomplish this, develop model contracts or other types of guidance that provide Ministries with examples of best practices and increase their understanding of how liability issues in IT procurement contracts can be addressed most effectively;
  2. Follow through on plans outlined in the IP Strategic Program 2006 to submit legislation to the Diet in FY2007 that will expand the scope of Japan’s Bayh-Dole system by making it possible for contractors to possess ownership rights to IP created through government-sponsored development of IT systems, including software; and
  3. Contribute fully to efforts to make the Government of Japan’s online database for IT procurements (<http://cyoutatujirei.e-gov.go.jp>) an effective tool to enhance transparency and fairness. To accomplish this:
    - a. Ministries, including MHLW, should provide all necessary information about their IT procurement cases to the database regularly and without delay; and
    - b. The Task Force should follow through by the end of FY2006 with plans to conduct analyses of the database to help identify trends in IT procurements. The United States recommends that the Task Force reference the suggestions for approaches to these analyses that the United States provided to Japan in March 2006.
- B. To further improve procedures for government procurements of IT systems, the United States urges Japan to ensure that:
1. Ministries and all other government procuring entities significantly reduce their use of sole source contracting in IT procurements. This action would be consistent with directives in the CIO Council’s 2006 e-Government Promotion Plan, as well as recommendations in the Board of Audit of Japan’s October 2006 report on central government computer systems, which documented the extensive use of sole source contracts in IT procurements and called on procuring entities to enhance competition and transparency in their contracting practices. To help accomplish this goal, Japan should:
    - a. Examine justifications provided for each instance of sole sourcing

to determine if they are consistent with Japan's commitments under the WTO Government Procurement Agreement;

- b. Ensure that justifications provided for sole sourcing are made public; and
  - c. Monitor and publicize progress Ministries make to increase the proportion of competitive contracts they conclude for IT procurements, in terms of both numbers of contracts and values of contracts. To help perform this task, analyses the Board of Audit of Japan performed on IT procurement data for its October 2006 report should be repeated periodically with more recent data.
2. Ministries sign IT procurement contracts as soon as possible after winning bidders are chosen, and refrain from backdating contracts; and
  3. Ministries provide meaningful opportunities, through the use of Public Comment Procedures and other measures, for interested parties to participate in the formulation of government IT procurement policies, including the Basic Guidelines for Government Procurements Related to Information Systems, which Japan is expected to issue in 2006.

## MEDICAL DEVICES AND PHARMACEUTICALS

- I. Changes in Japan's Healthcare System.** Japan faces dual challenges of limited healthcare resources and aging populations. The United States has similar concerns. Given our similar objectives and challenges, 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 Government of Japan is studying ways to limit medical spending growth, including changes to reimbursement pricing systems for medical devices and drugs. The United States urges Japan to consider the budgetary and health benefits of pricing systems that reward development of innovative products, and to take the following actions:
- A. Pharmaceuticals.
1. Improve transparency and industry's ability to offer input by:
    - a. Allowing a representative of the U.S.-research-based drug industry to be a member of *Chuikyo's* Drug Pricing Expert Subcommittee; and
    - b. Sending Ministry of Health, Labor and Welfare (MHLW) pricing recommendations to applicants well before the first Drug Pricing Organization (DPO) meetings and ensuring DPO fully explains its positions at such meetings.
  2. Implement as an alternative to the current pricing methods for new drugs a flexible pricing method by which pricing authorities evaluate data provided by applicants to assess the drugs' long-term value to Japan.
  3. Use mid-points of premium ranges as defaults when granting premiums.
  4. Abolish the re-pricing criteria for market expansion based on the sales of a product or its comparator for both a product's initial indication and for additional indications.
  5. Reverse the April 2006 revisions to the Foreign Price Adjustment rule for drugs, including the change by which the rule will no longer be applied in cases where only one foreign price is available.
  6. Refrain from implementing annual price revisions, which would discourage the introduction of innovative drugs in Japan.
  7. Allow U.S. industry to present views directly to MHLW's Council for Improvement in the Distribution of Ethical Drugs (*Ryukaikon*) on issues such as bulk-buying contracts.

8. Improve intellectual property protection in close consultation with the drug industry, including U.S. industry, as the Intellectual Property Strategy Headquarters considers proposals related to drugs.

B. Medical Devices.

1. Replace the Foreign Average Price (FAP) rule for medical devices no later than April 2008 with a system that fully reflects the value of advanced medical devices to Japan. Until the FAP rule is replaced, restrict its application to categories covered in the April 2006 FAP price changes, adopt a weighted average system for price calculations, maintain the rules on maximum price reductions, and limit the data used in price calculations to those provided by industry for the four comparator countries.
2. Work with U.S. industry to increase functional categories so as to reflect differences in technology, performance, and clinical benefits among products in the current functional categories. Adjust reimbursement for products in the modified categories to fully reflect their value.
3. Provide a provisional price for an applicant seeking C1 designation immediately after regulatory approval when that designation is requested and use the provisional price until *Chuikyo* sets the ultimate reimbursement price.
4. Continue recognizing the difference in quality between conventional and innovative diagnostic imaging equipment by granting premiums to innovative products. Recognize the value of advanced diagnostic imaging techniques by providing additional reimbursement rates, so-called *senshin gazo kasan*.
5. Establish an IVD subcommittee in *Chuikyo* to improve the reimbursement pricing system for IVDs.

- C. Blood Products. Create a pricing system for plasma protein therapies that is based on the plasma protein industry's characteristics, including the industry's regulatory and distribution systems, which differ from those of pharmaceutical products.

**III. Medical Device and Pharmaceutical Regulatory Reform and Related Issues.** Japan aims to improve its regulatory system to help patients gain faster access to medical devices and drugs. The United States urges Japan to reform regulations and practices that impede the development and introduction of devices and drugs in Japan. The United States encourages Japan to:

- A. Make it easier for companies to develop drugs in Japan and for Japan's market by:
1. Increasing substantially the staff of the Pharmaceuticals and Medical

Devices Agency (PMDA), particularly in medicines and biostatistics, so PMDA can facilitate simultaneous global development.

2. Consulting with industry, including U.S. industry, to improve understanding of simultaneous global development of drugs and facilitating Japan's participation in such programs.
3. Improving the environment for clinical trials in Japan by taking such steps as increasing incentives to participate in trials and upgrading hospital clinical trial operations.
4. Reducing the waiting time for consultations on clinical trials to 60 days and use the points system only until the 60-day waiting period is achieved.

B. Improve drug reviews by:

1. Expanding the types of drugs the Committee on Issues Related to the Use of Unapproved Pharmaceuticals considers for approval.
2. Ensuring that PMDA continues to provide industry, including U.S. industry, with detailed performance metrics on reviews and clinical-trial consultations that contribute to a PMDA-industry dialogue on those topics.
3. Clearing the drug application backlog at PMDA as soon as possible.
4. Reducing approval times for changes in the manufacture and testing of drugs to levels similar to those of the United States and European Union.

C. Speed reviews and standardize regulatory requirements for globally approved vaccines. Ensure that the "Vision" plan for the vaccine industry promotes industry's role in safeguarding public health.

D. Improve reviews of medical devices by:

1. Doubling PMDA's staff of device reviewers to 56 by March 2008.
2. Ensuring quality management systems audits, including audits of foreign manufacturing plants, do not delay product approvals.
3. Eliminating the application backlog by March 2007.

E. Facilitate the use of medical device clinical data by:

1. Issuing new guidance clarifying when Japan accepts foreign clinical data without requiring supplemental Japanese clinical data and when Japan accepts foreign clinical data supplemented by Japanese clinical data.

2. Accepting data from clinical trials done outside Japan according to the requirements of ISO 14155 Good Clinical Practices standards and not requiring conformity with ICH guidance.
- F. Expedite the introduction of improved devices by:
1. Requiring “partial change approval” only for changes that significantly affect a device’s safety or effectiveness.
  2. Issuing guidance developed with industry that clarifies which changes require partial change approval and which require notification.
  3. Allowing partial change submissions while previous applications for the same device are under review.
- G. Reduce substantially the information required to demonstrate raw material safety and biocompatibility.
- H. Refrain from auditing third-party suppliers or requiring them to register with regulators.
- I. Establish a rule that allows the use of new diagnostic tests during the period between their regulatory approval and reimbursement approval.
- IV. Blood Products.** Take steps to facilitate the development of a market for plasma protein therapies that helps ensure clinicians and patients determine treatment levels that benefit patients the most.
- V. Over-the-Counter Medicines**
- A. Clarify to industry, including U.S. industry, how MHLW will implement recent changes in the Pharmaceutical Affairs Law (PAL) related to over-the-counter (OTC) medicines, including the circumstances under which an ingredient can change from one class to another and the rules governing the kind of information.
  - B. Consult with industry, including U.S. industry, regarding the laws and regulations that affect advertising of OTC medicines.
- VI. Nutritional Supplements.** The United States urges Japan to:
- A. Allow educational and informational statements for foods, including liberalizing the Foods for Specified Health Uses (FOSHU) and Food with Nutrient Function Claims (FNFC) categories to be consistent with the regulatory regimes for nutritional supplements in other industrialized nations.
  - B. Work with industry to establish and implement by the end of FY2006 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.

- C. Expand the list of allowable additives and solvents for foods and chemical forms of nutrients to include those commonly approved in other industrialized nations.
- D. Set or revise quantity limits for food residues and contaminants so that they are based on scientific principles and reflect advances in analytical techniques and technology. Publish testing methodologies in a timely manner.
- E. Streamline the food import process by harmonizing forms and procedures among MHLW quarantine offices and by establishing a system to keep track of prior consultations and instruction completed by companies.
- F. Reduce duties for nutritional supplements to the same level as duties for pharmaceuticals containing the same ingredient.

**VII. Cosmetics and Quasi-Drugs.** The United States urges Japan to take the following steps to increase access to safe and innovative products for Japanese consumers and to help them make informed decisions:

- A. Quasi-Drugs. Reform the quasi-drug regulatory system by replacing pre-market approval with a post-market surveillance system similar to the U.S. OTC monograph system starting with:
  - 1. Publishing a list of active ingredients with levels and efficacies that have been approved in previous quasi-drug applications.
  - 2. Eliminating registration requirements for additives that are approved for use in cosmetics and for individual excipients.
  - 3. Providing opportunities for input from industry, including U.S. industry, on revisions to the quasi-drug regulatory system.
- B. Advertising and Labeling. Revise the Pharmaceuticals Affairs Law and the Standards for Fair Advertising Practices of Drugs, Quasi-Drugs, Cosmetics, and Medical Devices to be consistent with international standards by:
  - 1. Abolishing positive lists for claims and allowing claims based on significant and verifiable data.
  - 2. Providing opportunities for input from industry, including U.S. industry, on revising advertising policy and in government-sponsored consultative bodies such as the Copy Review Board.
- C. Transparency and Regulatory Procedures. Increase transparency in the regulatory system and revise regulations that impose excessive administrative burdens or that

do not enhance safety, efficacy, or quality, by:

1. Publishing detailed information on regulations and guidance related to cosmetics and quasi-drugs in a timely manner and in a central location on MHLW's web site.
2. Working 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. Reducing lead time for importation and approval of cosmetics and quasi-drugs by streamlining procedures and paperwork.

## FINANCIAL SERVICES

- I. Specific Measures.** The United States commends Japan on its progress on financial services regulatory reforms and calls on Japan to continue such reforms, including the following measures:
- A. Create a legal and regulatory framework for a credit bureau system that will allow better risk assessment by lenders and thereby more accurate risk pricing for consumers and small businesses. Collection of and fair, open access to comprehensive full-file credit information facilitates sound credit underwriting, deters excessive lending, and improves consumer welfare.
  - B. Review the legal and regulatory restrictions, including inspection guidelines that unduly limit foreign financial groups' ability to manage their operations and meet customer needs effectively across legal entities, including branches, in Japan. Regulators should identify and define the scope of all required firewalls and identify firewall maintenance "best practices" in detail in written guidance.
  - C. Under the five year review currently being carried out, foster expanded use of corporate Defined Contribution (DC) pension programs by:
    - 1. Increasing the tax deductible contribution limit;
    - 2. Allowing employee contributions (for example, employee matching of employer contributions);
    - 3. Allowing early access to funds before the age of 60 in specified circumstances;
    - 4. Allowing investment advice to be made available to participants; and
    - 5. Ensuring transparency and broad opportunities for public comment and presentation of views to the study council during the review.
  - D. Through the regulations under the Financial Instruments and Exchange Law, harmonize the regulatory framework governing investment advisory and investment trust management activities and eliminate inconsistencies and duplications, including by merging industry associations.
  - E. Allow mergers and reduce obstacles to the early termination of investment trusts, in order to permit investment managers to combine and diversify investments, which would result in a reduction of both risk and cost to investors.
  - F. Review the revisions to the institutional investor disclosure rules for large shareholdings (shareholdings in excess of 5 percent) after a set period of time to assess their impact on market volatility and potential market-timing behavior by speculators, and the administrative burdens on portfolio institutional investors.

- G. Continue steady and substantial increases in the staff and budget of the Financial Services Agency (FSA), with a focus on strengthening both the FSA’s regulatory and supervisory capabilities.

**II. Transparency.** The United States encourages the FSA to continue its progress in enhancing financial sector regulatory and supervisory transparency and clarity, and recommends the following additional measures:

- A. The United States welcomes FSA efforts to expand the body of published written interpretations of Japan’s financial laws. Such interpretations reduce uncertainty, enhance compliance and allow for productive innovation by financial services providers. One avenue for providing such written interpretations is by enhancing the effectiveness of the no-action letter and related systems, including by:
  - 1. Drawing upon the United States’ recommendations (in the “Transparency” chapter) for enhancing the government-wide no-action letter system;
  - 2. Encouraging 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; and
  - 3. Making 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 (which is limited to “new products and services”) and may include requests for clarification of laws and regulations governing existing products and services.
- B. The United States recommends that the FSA adopt new programs and more actively use existing programs to complement the no-action letter and related systems as vehicles for expanding the body of written interpretations of Japanese financial laws and regulations. To that end, the United States recommends that the FSA take the following steps:
  - 1. Build on progress made with the FSA’s web publication of “reference cases” giving examples of FSA interpretations of Japan’s financial laws and regulations by steadily increasing the number of such cases published;
  - 2. Use the interpretive letter system to provide written interpretations on issues about which FSA officials have received informal oral inquiries and about which there may be some misinterpretation;
  - 3. Publish a “reference case” or “interpretive letter” clarifying the conditions under which regulated affiliates of foreign financial firms are allowed to

share customer information for risk management purposes with their group management and home office; and

4. 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.
- C. The FSA's active solicitation of input from private, including foreign, firms in the process of drafting the Financial Instruments and Exchanges Law has been a major step in the process of enhancing regulatory transparency in Japan's financial sector. Seeking such input also reduces the risk of adverse unintended consequences of financial laws and regulations. The United States welcomes those efforts and encourages continued dialogue in the coming months among the FSA, the Financial System Council, foreign and domestic financial firms and interested governments and industry associations as the regulations to implement the law are developed. In particular, given the huge number of regulations to be issued under the law, the United States urges that regulations be released for public comment as soon as they are completed, rather than as a package closer to implementation, to allow for thoughtful public comments to be formulated and considered, and to allow maximum time for financial firms to prepare for compliance with the new law and its regulations.
- D. A transparent and predictable inspection process is critical to sound development of financial markets and to ensure consumer 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 and inspection manuals, and encourages updates of these materials as well as outreach to the private sector to highlight inspection priorities and criteria.
- E. The United States also welcomes the Japanese financial authorities' close working relationship with private sector financial industry associations, such as the American Chamber of Commerce in Japan and the International Bankers Association, that fully represent the views and expertise of their members.

## COMPETITION POLICY

### I. Improving Antimonopoly Compliance and Deterrence

#### A. Strengthen Criminal Enforcement.

1. Make use of the Japan Fair Trade Commission's (JFTC's) expanded investigatory powers and new leniency program to increase significantly the number of cartel and bid rigging cases that are referred to the public prosecutor's offices for criminal prosecution.
2. In light of the new jurisdiction of district courts and district public prosecutors' offices to handle criminal Antimonopoly Act (AMA) prosecutions, consider the usefulness of implementing programs to educate prosecutors and judges about the goals and operation of the AMA.
3. Strengthen criminal penalties against individuals who engage in unlawful cartel activities by lengthening the maximum sentence of incarceration to five years imprisonment.

#### B. Maintain Criminal and Administrative Sanctions on Cartels. Maintain the current system of allowing the imposition of both criminal penalties and administrative sanctions against cartel activities by enterprises.

#### C. Avoid Over-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. The United States recommends that Japan 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.

#### D. Review and Revise Existing Antimonopoly Enforcement Guidelines. In order to ensure that JFTC enforcement policies reflect the best economic and legal understanding of sound competition law enforcement, review and revise, as appropriate, existing JFTC enforcement guidelines. In particular:

1. Revise the 1999 Patent and Know-How Licensing Guidelines to clarify that JFTC fully recognizes the procompetitive benefits of intellectual property rights and that it will apply a rule-of-reason analysis to virtually all IPR licensing practices;
2. Raise substantially the market share safe harbors for vertical non-price behavior in the 1991 Distribution and Business Practices Guidelines and review other aspects of those Guidelines to ensure that they reflect current economic understanding of the operation of markets;

3. Review the 2004 Guidelines to Application of Antimonopoly Law to Reviewing Business Combinations with a view to ensure they reflect the state of the art in economic thinking on delineating the relevant product and geographic markets and on determining the likely competitive effects of a transaction, while ensuring that consumer welfare considerations continue to be the paramount goal; and
  4. Ensure that any proposed revisions to JFTC Guidelines are published for public comment before they are finalized.
- E. Review AMA Exemptions. Follow the lead of the European Union, Australia and the United States in examining the possible elimination of antimonopoly exemptions in the international aviation and other sectors.
- F. Improve the Accessibility of Relief in Private Antimonopoly Litigation. Review possible ways to increase the ability of persons injured by Antimonopoly violations to recover their damages and obtain other relief from the courts.
- G. Promote Competition in Sectors Undergoing Privatization. Ensure, through appropriate JFTC studies and other steps, that privatization and reform of Japan Post is undertaken in a manner that promotes effective competition in the relevant markets. Carefully monitor the practices of newly privatized entities, including new Japan Post entities, to ensure they do not engage in anticompetitive behavior.
- H. Strengthen Staff and Resources. Continue steady and substantial increases in the staff and budget of JFTC, with an emphasis on strengthening the criminal investigation and economic analysis capabilities of JFTC.

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

Reviewing JFTC procedures to ensure they are as fair and transparent as possible will increase the confidence of the public and the business community in JFTC enforcement of the AMA. With that goal in mind, the United States recommends that Japan:

- A. Improve Transparency in Decisions to Stay Enforcement of Elimination Orders. In order to ensure that elimination orders for AMA violations do not unnecessarily cause serious harm to the recipients of such orders before they have had an opportunity to respond fully to a JFTC determination of an AMA violation, establish and publicize clear standards that JFTC will use in determining whether to grant a request to stay the enforcement of an elimination order pending review of such order in a hearing procedure or by a court.
- B. Improve Public Confidence in Hearings. Consider steps to improve confidence in the fairness of JFTC hearing procedures, such as ensuring at least a majority of hearing examiners in each particular hearing procedure are not JFTC career employees.

- C. Ensure Fairness in Actions under the Subcontract Law. Ensure that proposed recipients of recommendations and public warnings and cautions under the Act Against Delay in Payment of Subcontract Proceeds, etc. to Subcontractors are provided an adequate opportunity to submit evidence and arguments in their defense prior to the issuance of those measures.
- D. Increase Certainty in Stock Acquisition Transactions. Introduce transparent and timely procedures that will allow parties that intend to acquire or hold stock in other companies to obtain a formal and binding decision from JFTC on the consistency with the AMA of such stock acquisition or stock holding.
- E. Continue Transparency of AMA Basic Issues Study Group. Provide an opportunity for interested persons, including foreign parties and organizations, to orally provide views on the Study Group's work before its final report is issued. Also, publish the final report and recommendations of the Study Group for public comment before any measures are taken to implement those recommendations.

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

- A. Prevent Conflicts of Interest – *Amakudari*. Strengthen measures to ensure that central and local government officials, and officials of public corporations, that participate in or supervise the procurement of goods and services are not faced with conflicts of interest, including those created by the *amakudari* system, that may cause them to assist in bid rigging activities. In particular:
  - 1. Revise laws and National Personnel Agency rules against conflicts of interests by government officials, including rules prohibiting officials from taking jobs in companies that have received contracts from their agencies, to ensure conflicts of interests do not facilitate bid rigging, and increase penalties against officials and companies violating such rules.
  - 2. Improve the effectiveness of Ministry of Land, Transport and Infrastructure (MLIT) rules designed to prevent conflicts of interest by its officials engaged in or supervising procurement activities.
  - 3. Prohibit personnel offices of government agencies from seeking to place retiring officials in jobs that violate conflict of interest rules and policies.
- B. Expand Administrative Leniency. Expand the administrative leniency program adopted by MLIT in February 2006, which reduces by half the period of suspension from bidding for companies admitted into JFTC's leniency program, to other government agencies and public corporations.
- C. Improve Procurement Practices. Review procurement practices to ensure competition is maximized, including by ensuring 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 through Modern Merger Techniques**

- A. Facilitate Use of Foreign Shares as Consideration. Take necessary measures to ensure that the new provisions of the Corporate Code that, as of May 1, 2007, will permit the use of shares of foreign companies as consideration in triangular and other types of merger transactions are implemented in a manner that permits use of virtually all foreign stock without significant restriction or procedural hurdles.
- B. Implement Clear and Non-Discriminatory Tax Deferral Rules. Revise the Tax Code before May 1, 2007, to provide clear and predictable rules regarding the availability of tax deferral benefits for triangular merger transactions that use foreign shares as consideration, and ensure that, unless necessary to avoid specific tax avoidance concerns, those rules provide the same tax deferral benefits under similar basic conditions to all triangular merger transactions, regardless of whether they involve the use of shares of domestic or foreign companies.

### **II. Strengthening Good Corporate Governance**

- A. Facilitate and Encourage Active Proxy Voting.
  - 1. Promulgate Financial Services Agency regulations or encourage adoption of rules by the Tokyo Stock Exchange (TSE) and other major stock exchanges in Japan that require each publicly-traded company above an appropriate size threshold to provide proxy materials to its shareholders at least four weeks in advance of its annual meeting.
  - 2. Encourage and facilitate the ability of publicly-traded companies, directly or through the major Japanese stock exchanges, to make available to shareholders mechanisms for electronic voting of proxies.
  - 3. Strongly encourage the Investment Trust Association of Japan to adopt rules requiring mutual fund and investment trust managers to publicly disclose their actual proxy voting records.
  - 4. Adopt legislation, or promulgate regulations or guidelines by the Ministry of Health, Labor and Welfare or other appropriate ministries, that will require or at least strongly encourage private pension fund managers, including insurance companies that manage pension funds, to exercise proxy votes for the benefit of their ultimate beneficiaries.
- B. Protect Shareholder Interests.
  - 1. Eliminate potential conflicts of interest of Boards of Directors in responding to tender offer bids (TOB) by requiring that the statement of

the position of the Board of Directors on the offer that is conveyed to FSA pursuant to the Securities and Exchange Law and the adoption or invocation of any anti-takeover measures in response to a TOB be authorized by a committee of the Board of Directors that is composed of a majority of outside directors or auditors.

2. Encourage the TSE and other major Japanese stock exchanges to have listing rules or guidelines that encourage best practices in the protection of shareholder interests, including by requiring or encouraging companies to have a certain number or percentage of outside directors and by revising the definition of outside directors and outside auditors to ensure that they are truly independent.
3. Encourage the MOTHERS, JASDAQ and Hercules stock exchanges to adopt listing and delisting rules that restrict companies from introducing anti-takeover measures that seriously harm the interests of shareholders.

- C. Strengthen the Executive Committee System. Empower the Board of Directors of a company that has opted to have executive committees to legally delegate to such committees relevant decision-making and other powers of the Board including, for example, delegating to the audit committee the power to hire the outside auditing firm.
- D. Improve the *Kansayaku* System. Establish a formal study group to examine whether the current *kansayaku* (corporate auditor) system can be improved to more effectively prevent corporate malfeasance.

**III. Protecting Foreign Firms Legitimately Doing Business in Japan.** Amend Article 821 of the Commercial Code to make clear that foreign firms doing business in Japan through branch offices that are duly registered under the Commercial Law and complying with applicable regulatory and tax laws are not subject to the prohibition of engaging in transactions on a continuous basis in Japan or to the liabilities of their directors and officers set out in that article.

#### **IV. Achieving Legal System Reform**

- A. Permit Professional Corporations and Branching. Permit *gaiben* to form professional corporations on the same basis and with the same benefits as *bengoshi* professional corporations. Also, allow 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. Revise Minimum Qualification Criteria for *Gaiben*. Amend the Foreign Lawyers Law so that all experience practicing the law of the home jurisdiction, wherever that experience is obtained, is counted toward the three-year experience requirement for qualification as a *gaiben*.

- C. Allow *Bengoshi* to Associate Freely with International Legal Partnerships Outside Japan. Publicly confirm that Japanese lawyers, whether in solo practice, in partnership with other Japanese lawyers or in partnership with *gaiben*, may become members of an international partnership of lawyers outside Japan without limitation or restriction.
- D. Promote Arbitration and Other Alternative Dispute Resolution
1. Ensure that *gaiben*, foreign lawyers and non-lawyers are permitted to act as neutrals in any international arbitration or other international alternative dispute resolution (ADR) proceedings that take place in Japan, in whole or in part, regardless of the governing law or matter in dispute.
  2. Amend the Foreign Lawyers Law to make clear that *gaiben* may represent parties in any international ADR proceeding taking place in Japan.
  3. Ensure that the Law for the Promotion of the Use of Alternative Dispute Resolution (ADR Law) is implemented in a manner that is consistent with international norms and practices, and promotes rather than hinders the goal of establishing Japan as a center for international dispute resolution. In furtherance of this goal:
    - a. Apply the Public Comment Procedure to all government proposed ordinances, regulations and guidelines related to the implementation of the ADR Law; and
    - b. Ensure that Japan Association of Arbitrators publishes for public comments its proposed rules related to implementation of the ADR Law and allows at least 60 days for the submission of comments before the rules are finalized.

## TRANSPARENCY

**I. Public Input into Policy Development – Advisory Groups.** Advisory councils (*shingikai*) and other government-commissioned study groups are often accorded a significant role in Japan’s policy development. The Government of Japan’s active assurance of the openness and transparency of such groups is necessary to ensure the views of interested parties are reflected in their deliberations and enrich the policies that result. While general guidance for advisory groups is outlined in an April 1999 Cabinet Decision, specific requirements are lacking. The United States therefore urges Japan to standardize and improve the transparency of and access to these advisory councils and other working 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. Create 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.
- B. Ensure interested parties have full opportunities to provide input into advisory group deliberations and conclusions by requiring Ministries and Agencies to:
  - 1. Conduct open nominations for group membership when possible and permit all interested parties to participate in such groups to the extent possible;
  - 2. Provide meaningful opportunities for interested parties to provide input into deliberations by such groups; and
  - 3. Provide ample advance public notice prior to group meetings to enable interested parties to prepare for and contribute to discussions.

**II. Public Comment Procedures (PCP).** As Japan implements its revised PCP, the United States strongly encourages Japan to review the amended Administrative Procedure Law and proactively take new steps to boost the system’s effectiveness. Some deficiencies have already been identified in Japan’s latest annual survey of PCP implementation, such as frequent solicitation of public comments for periods shorter than 30 days.

- A. To improve upon deficiencies in the current PCP system, the United States urges Japan to take the following measures:

1. Provide adequate public comment periods (30 days minimum, 60 days in principle), barring a genuinely urgent need to do otherwise (in which case clear written explanations should be provided);
  2. Make draft regulations public as early as possible to allow interested parties sufficient time to prepare meaningful public comments;
  3. Ensure Ministries and Agencies fully consider public comments and allow ample time to incorporate them, as appropriate, into final regulations; and
  4. Respond to submitted comments in a timely manner, prior to release of final regulations whenever possible.
- B. The United States also recommends that Japan thoroughly evaluate the effectiveness of recent changes to the PCP, publicly report evaluation findings, and provide opportunities for public input on these findings.
- 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 encourages Japan to require Ministries and Agencies to make public in writing their regulations and any statements of policy or generally applicable interpretations regarding those regulations.
- IV. Public Input into the Development of Legislation.** The United States recommends that Japan's Ministries and Agencies provide greater opportunities for interested parties to be aware of and comment on draft legislation in the early stages of its formation.
- V. Strengthen U.S.-Japan Cooperation to Promote High Standard Transparency Practices.** The United States recommends that our Governments intensify cooperation to raise transparency standards in the Asia-Pacific to improve investment and business environments throughout the region. Steps should include jointly promoting the implementation of the APEC Transparency Standards and the use of APEC transparency model measures as a reference for future trade agreements.
- VI. Foreign Translations of Japanese Laws.** To enhance the effectiveness of Japan's initiative to translate laws into foreign languages, the United States recommends that Japan continue to closely consult with the foreign businesses on this initiative and ensure timely completion of translations of laws selected under the foreign translations initiative as well as laws already in effect prior to the implementation of the initiative.
- VII. Implementation of Rulemaking.** The United States recommends that Japan ensure that its Ministries and Agencies ensure reasonable periods (at least 30 days) between the publication of final regulations and their effective date (except for clearly-defined, extraordinary circumstances) to give parties required to comply with such regulations a fair opportunity to comply by the initial date of enforcement.

**VIII. Special Zones for Structural Reform.** The United States recommends that Japan continue transparent administration of the Special Zones for Structural Reform and seeks greater application of Zone measures nation-wide.

**IX. No Action Letters.** The United States urges Japan to take further steps to enhance the effectiveness and increase the usage of Japan's no-action letter system, which allows regulated firms to seek clarification of an administrative agency's interpretation of laws and regulations. Specifically, the United States recommends:

- A. Giving Japan's no-action letter system the force of law by incorporating its requirements into the Administrative Procedures Law.
- B. As an interim step, providing by Cabinet Decision more detailed government-wide guidelines to administrative agencies as to the requirements governing the agencies' individual no-action letter systems, and setting a timetable for those agencies to set up their no-action letter systems. Specific steps should include:
  - 1. Establishing one “window” per agency to receive no-action letter requests.
  - 2. Promoting more active use of the no-action letter system, including by:
    - a. Outreach efforts by administrative agencies to inform firms in regulated industries that they can seek clarification of Japan's laws and regulations via the agency's no-action letter system;
    - b. Announcing that groups of firms and/or industry associations can submit NAL requests on behalf of specific firms; and
    - c. Establishing internal systems to encourage agency staff to actively solicit no-action letters from individual firms and other interested parties that seek informal oral interpretations of laws and regulations on issues that are matters of settled policy.
- C. Establishing both government-wide and agency-specific fora for seeking private sector input as to how to improve the no-action letter systems of the various government administrative agencies.

## OTHER TRADE-RELATED GOVERNMENT PRACTICES

### I. Bank Sales of Insurance

- A. The United States urges Japan to fully liberalize the bank sales channel for insurance products without delay, no later than before the end of 2007.
- B. Prior to full bank sales liberalization, the United States furthermore urges Japan to eliminate the 10 million yen ceiling on third sector insurance products that smaller banks may sell to related companies in order to eliminate an unfair disadvantage to third sector insurance service suppliers.
- C. 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 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). 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 the preparation of related draft legislation and other measures is undertaken in a transparent manner.

**IV. 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. 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 by:
  - 1. Ensuring that the Ministry of Agriculture, Forestry and Fisheries expeditiously finalizes its review of the status of four cosmopolitan pests of lettuce to determine whether they should be subject to quarantine measures; and
  - 2. Undertaking joint pest risk assessments on other pests/commodities of priority interest to the United States.
- 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. Apply science-based standards in accordance with World Organization for Animal Health protocols to promote enhanced trade in animal products.
- D. Update relevant rules and regulations to reflect international safety standards as applied to biotech products.
- E. Complete the review of the 46 food additives that are recognized as safe by Joint FAO/WHO Evaluation Committee on Food Additives and used throughout the world. While this review commenced on an expedited basis in 2003, so far only 15 additives have been approved.

## PRIVATIZATION

- I. Privatization of Public Corporations.** As Japan moves forward with 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 ensuring domestic and foreign private sector entities are given meaningful opportunities to provide input and express views on matters affecting the market. Such steps should include, but not be limited to, full use of the Public Comment Procedures and meaningful opportunities to participate in related advisory councils that deliberate and make recommendations on reforms.
- II. Japan Post.** The United States welcomes a market-oriented reform of Japan Post. If implemented vigorously, the United States recognizes the potential benefits for the Japanese economy of these reforms by stimulating competition and leading to a more productive use of resources. The implementation of a fully market-oriented reform is also necessary to eliminate long-standing advantages that Japan Post has 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 fully realize the legislation's principle of establishing equivalent conditions of competition between Japan Post 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 the Postal Savings Bank and Postal Insurance Corporation, from the outset of the privatization process in October 2007, will no longer be allowed to offer products that carry government guarantees and will be required to meet the same tax, legal, and regulatory obligations and, along with the Post Office Corporation, be subject to the same supervision and disclosure standards as private sector companies. The United States also welcomes confirmation that relationships among the new postal companies must be on an arms-length basis and that no schemes exist that allow for cross-subsidization (and thus also transfer of risks) between and among the new entities created under related laws. 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 Japan Post 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 the Post Office network and, consistent with the arms-length rule, ensure that the Post Office Corporation's relationships with the Postal Savings Bank and Postal Insurance Corporation are undertaken on a truly market basis.
  2. *Deposit and Reinsurance Relationships.* With respect to deposit and reinsurance contracts between the Incorporated Administrative Agency

Management Organization for Postal Savings and Postal Life Insurance (Public Successor Corporation) and the Postal Savings Bank and the Postal Insurance Corporation, respectively, take 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 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 arms-length basis and, as such, will not allow for cross-subsidization of the new postal financial institutions through such arrangements; 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.* Until such time that the Government of Japan is fully divested from its shares of the postal financial institutions, take meaningful steps to ensure consumers and the marketplace are aware that products issued from October 2007 will not be backed by the Government. In addition, 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 effective competition in the relevant markets. In addition, carefully monitor the practices of Japan Post entities to ensure they do not engage in anticompetitive behavior.
5. *Regional Social Contribution Fund.* Ensure 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, prior to October 2007, 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.
- B. Conditions of Competition and the Introduction of Products. The United States urges Japan to ensure a level playing field is actually created between the postal financial institutions (both existing institutions and, from October 2007, the new institutions) and private financial institutions before the postal financial institutions are permitted to introduce new lending services, new or altered insurance products underwritten by the postal insurance business, and the origination of non-principal-guaranteed investment products by the postal savings business. Relevant measures should include those that ensure the postal financial institutions, in practice, meet the same licensing and supervisory requirements as private sector financial institutions, including requisite risk management and internal controls requirements and full FSA supervision. Achieving a level playing field also includes requiring the postal entities to meet the same obligations and standards that other companies must meet when introducing new products or riders. Moreover, prior to engaging in any new product sales or transactions, sales agents and representatives of the Post Office Corporation, Postal Savings Bank, and Postal Insurance Corporation would have to fully meet the same requirements and standards that licensed private sector providers must meet to engage in such sales and transactions. Such requirements should include the development of systems and management skills to effectively evaluate and manage the risks associated with those products.
- C. Level Playing Field for Express Carrier Services. The United States welcomes confirmation by Japan that the logistics and postal services operations of the Postal Services Company will be subject to the same taxes as private companies and, furthermore, will be subject to the same aviation safety and security regulations. The United States also welcomes confirmation that the Minister of Land, Infrastructure and Transport will supervise Japan Post's international physical distribution services under transportation laws and, with respect to postal services, supervise related operations according to freight transportation laws and ordinances. In order to fully achieve a level playing field in the express carrier services sector, the United States recommends the above measures are fully implemented and that the following additional steps are taken:
1. Ensure that supervision by the Ministry of Land, Infrastructure and Transport of Japan Post operations is undertaken according to the same standards as those applied to private companies.
  2. Apply customs clearance procedures for mail and packages handled by Japan Post equivalent to those applied to private express carriers for similar actions. Specifically, the United States urges Japan to ensure that mail delivered under EMS follows the "duty declaration" system and not

the “duty assessment” system that Japanese regulations currently apply to EMS mail.

3. Require Japan Post to pay equal costs for customs clearance for similar actions, including NACCS charges and the costs for application document preparation. Furthermore, Japan should ensure it applies all safety and security laws and regulations to Japan Post letters in the same manner as to documents carried by private express carriers.
4. Take all necessary measures to make public disclosures of the Postal Service Company’s business and transactions sufficient to ensure 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.

D. Transparency. The United States welcomes measures being taken to ensure the preparatory process and implementation of the reforms of Japan Post progress in a transparent manner. The United States recommends that steps continue to be taken to make the preparation and implementation of these reforms fully transparent and inclusive of the views of interested parties, including by:

1. Ensuring 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. Providing 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;
3. Seeking 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, and also ensure that input is fully considered and, where appropriate, incorporated into draft measures before they are finalized; and
4. Ensuring 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 consumers and boost the economy by:
- A. Immediately further reduce landing and user fees, which in combination remain the highest in the world, for Japan's three major international airports: Narita, Kansai, and Centrair;
  - B. Appointing an independent economic regulator for "corporatized" airports such as Narita Airport to ensure fees are set transparently and fairly;
  - C. Ensuring the landing fee calculation at all airports is transparent both for domestic and international flights, and includes only those costs associated with the use of airport runways and facilities, as prescribed by IATA; and
  - D. Inviting and considering the comments of all interested stakeholders, including U.S. and other foreign airlines, for the deliberations of the Airports Discussion Group of the Aviation Subcommittee of MLIT's Transportation Policy Committee.
- II. Airport Expansion and Operation.** Narita Airport has started an ambitious set of construction projects to extend its Runway B to allow for use by larger aircraft. Many carriers, not only those from the United States, are concerned this project has increased in scope and may be inefficient and unprofitable. While the United States applauds NAA's recent profit of 14.77 billion yen in FY2005 as evidence that the corporatization/ privatization of Narita Airport is on track, there is widespread concern that fees will be raised again in the future to fund this expansion and that the expansion may not be carried out in the most economical way. There are similar concerns with construction at other airports. The United States urges Japan to make the process for planning and financing of Narita and other airports' expansion fully transparent, and to provide a detailed breakdown of the necessary budgets in a timely fashion.
- III. Haneda Airport Operations.** The project to construct a fourth runway at Haneda Airport, to be completed by 2009, will provide needed new slots to the Tokyo area. The planned internationalization of Haneda, however, has moved forward without adequate transparency. In particular, the lack of transparency has created concern over two issues: 1) a perimeter for allowable regular international flights has been proposed, but it seems to be an artificial and arbitrary limit as some international charter flights will operate beyond the perimeter; and 2) changes in operating hours that may affect U.S. carriers in the future may be made without adequate input from all parties concerned. Thus, the United States urges Japan to create a transparent mechanism by which carriers and other interested private-sector parties can be informed of proposed rule changes, expansion plans, curfews, and other changes at Haneda, with a full explanation of the justification for an action, and provide such information in a timely manner to allow for comment on any proposal during the decision-making process, before it has been finalized.

#### **IV. Improving Efficiency in Customs Processing**

- A. Separate Customs Treatment for Express Consignments. In order to enable more efficient and faster handling of express shipments and to bring Japan in line with growing international practice, the United States recommends that Japan establish separate customs regulations for express consignments and operate a separate section to handle such consignments, distinct from the current system that was designed for traditional air cargo and ocean freight. Any such regulations should be developed in a transparent manner, including by seeking domestic and international industry input.
- B. Customs Declarations. To further improve customs processing procedures and efficiency of operations, the United States recommends that Japan:
  - 1. Introduce a system for customs declaration whereby the declaration of shipment acceptance is separate from the declaration of tax 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; and
  - 2. Allow Nippon Automated Cargo Clearance System (NACCS) users to declare express items at any convenient Customs office, rather than limiting them to the office where the cargo is physically stored, in order to allow shipments to more quickly reach their destinations in Japan.

- V. **Customs *de Minimis*.** The United States recommends that Japan significantly increase the Customs Law *de minimis* limit from its current 10,000 yen level to higher level (such as 30,000 yen) to help reduce customs workloads and customs clearance time.

- VI. **Parking Spaces for Distribution Vehicles.** To ensure smooth and timely distribution of packages and other items following strict enforcement actions being taken under the recently revised Road Traffic Law, it is important for Japan to take new measures to ensure sufficient parking spaces are available for distribution vehicles in urban centers. Specifically, the United States recommends that Japan take the following measures:

- A. Create New Parking Zones for Delivery Vehicles. Increase the number of parking spaces available for distribution vehicles as well as the number of short-duration loading and unloading zones available on major streets.
- B. Introduce Long-Term Solutions. Examine other measures that help provide a long-term solution, such as revising building codes to require property owners to provide distribution vehicle parking spaces in commercial buildings.
- C. Introduce Temporary Mitigation Measures. Until more permanent solutions are introduced, examine the feasibility of introducing an “observation rule,” by which parking officers will first observe whether the vehicle is attended by a driver and whether loading or unloading activities are taking place before issuing a ticket.

- VII. Speed Implementation of the Revised Road Transport Vehicle Law (RTVL).** The United States welcomes changes made to the RTVL in May 2006 that will create a one-stop omnibus registration system for automobiles. However, the new system is not due to be fully introduced until late 2011. The United States encourages Japan to take steps to develop and introduce the new omnibus registration system well before late 2011.
- VIII. 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. The United States urges Japan to ensure that its initiatives to revitalize urban areas do not impede the ability of developers and operators of large-scale stores to open locations in urban, suburban or rural areas and that national regulations are applied consistently throughout the country. The United States furthermore requests that Japan undertake a thorough and fully transparent review of its new measures, including regularly soliciting input from interested parties, and publishing the results of its reviews in a timely fashion.