

**THIRD REPORT TO THE LEADERS ON THE
U.S.-JAPAN REGULATORY REFORM AND COMPETITION POLICY INITIATIVE
June 8, 2004**

The Regulatory Reform and Competition Policy Initiative (Regulatory Reform Initiative) was established by President George W. Bush and Prime Minister Junichiro Koizumi in June 2001. Now in its third year, the Initiative is intended to promote economic growth by focusing on sectoral and cross-sectoral issues related to regulatory reform and competition policy.

Consistent with the aim of achieving tangible progress and the principle of two-way dialogue, the Governments of the United States and Japan exchanged detailed regulatory reform recommendations in October 2003. These recommendations provided the basis for extensive discussions between the two Governments for meetings of the High-Level Officials Group and the Working Groups established under this Initiative. These Groups met throughout the year to discuss reforms in key sectors and areas such as telecommunications, information technologies, energy, medical devices and pharmaceuticals, competition policy, transparency and other government practices (including Special Zones for Structural Reform), legal system reform, commercial law revision, distribution, consular affairs, and trade and investment-related measures. As in previous years of this Initiative, several of the Working Groups received input from private sector representatives, who made presentations and provided their valuable expertise, observations, and recommendations on important issues taken up under this Initiative.

The Government of Japan has taken a series of regulatory reform measures over the past year, including the adoption by Cabinet Decision on March 19, 2004 of its new Three-Year Program for the Promotion of Regulatory Reform. The Government of the United States welcomes this decision and the establishment of the Council for the Promotion of Regulatory Reform in April 2004 as the successor of the Council for Regulatory Reform, which over the years has worked to effectively improve the regulatory environment in Japan. The Government of the United States also continues to welcome the opportunity to cooperate with the Headquarters for Promotion of Special Zones for Structural Reform in helping to ensure the success of the Special Zones program and looks forward to successful reform measures in the Special Zones being applied on a national basis expeditiously.

The salient regulatory reforms and other measures by both Governments that relate to the work under the Regulatory Reform Initiative are set out in this Report to the Leaders. (Financial services measures taken up in the Financial Dialogue are also included.) The two Governments welcome the measures specified in this Report and share the view that these measures will improve market access for competitive goods and services, enhance consumers' interests, increase efficiency, and promote economic activity.

Seeking to ensure this Initiative remains forward-leaning, both Governments affirm a desire to place greater focus in the coming year on areas that have assumed increased relevance to the broader economic reform agenda. This may include placing more emphasis on issues related to competition policy and privatization, which are already being taken up under this Initiative to

varying degrees. In addition, the two Governments affirm their desire to consider taking up new areas where reform would further the objectives of this important Initiative.

Both Governments reaffirm their determination to further promote regulatory reform and, upon the request of either government, will meet at mutually convenient times to address the measures contained in this Report.

REGULATORY REFORM AND OTHER MEASURES BY
THE GOVERNMENT OF JAPAN

I. TELECOMMUNICATIONS

A. Promotion of Competition

1. The Government of Japan has formulated a competition policy in the telecommunications field in line with rapid advances of technology, and has thereby facilitated the development of a telecommunications market where broadband services, affordability, and speeds are among the most advanced in the world.
2. The amended Telecommunications Business Law (TBL) came into effect on April 1, 2004, aiming at promoting further competition in the telecommunications business. The amended TBL introduces a variety of fundamental deregulatory measures, which are expected to realize a more competitive telecommunications market including the following:
 - a. Abolition of the Type I (facility-based) and Type II (others) business categories as well as the permission system for new entrants;
 - b. Abolition of obligations to file and publicize tariffs, enabling individualized contract-based services; and
 - c. Abolition of the obligation to notify agreements regarding interconnections with non-designated facilities.
3. The Government of Japan revised the relevant ministerial ordinances to bring the TBL into effect after consultation with the Telecommunication Council and solicitation of public comments for five weeks. The Ministry of Public Management, Home Affairs, Posts and Telecommunications (MPHPT) incorporated some of the opinions received through the public comment process into the revised ordinances as appropriate and articulated its views on all the comments solicited therein.
4. MPHPT is conducting a competition evaluation of the telecommunications market, beginning in FY2003, in order to evaluate the status of competition in the telecommunications market, which is becoming increasingly complex as a result of the rapid evolution of Internet Protocol (IP) and broadband technologies and services. In November 2003, MPHPT drafted the “Basic Approach Concerning the Evaluation of the Competitive Situation in the Telecommunication Business Field,” which outlined the process of this evaluation. Under the “Basic Approach,”

MPHPT plans to choose a specific market sector and evaluate its competitive situation every fiscal year, after conducting public comment procedures. With regard to FY2003, MPHPT chose “Internet access” as the scope of evaluation, and on April 27, 2004 released a draft of the evaluation results for public comment.

B. Fixed Interconnection

1. Revised charges, based on actual traffic data and revised inputs, retroactive to April 2003 will be set by fall 2004.
2. A report issued by the Telecommunication Council in March 2003 concluded that the method of calculating interconnection rates to be applied from FY2005 should be based on major changes in the market environment, including a reduction in the volume of traffic and a slowdown in new investment. Based on the report, in April 2004, a study group on the Long-run Incremental Cost Model, reestablished by MPHPT, outlined the process to be used to revise the current model after soliciting public comments for a month.
3. In April 2004, MPHPT consulted the Telecommunication Council on drafting a report on how to calculate the interconnection rates to be applied from fiscal year 2005, taking into consideration the evaluation of the new model based on factors mentioned above, and how to treat the non-traffic sensitive (NTS) cost based on the review of NTT East and West’s basic monthly charge. In addition, the Telecommunications Council will discuss whether it is appropriate to calculate and set charges separately for NTT East and West.
4. MPHPT expects the Telecommunications Council to release its final report in the fall of 2004, after conducting a public comment procedure.

C. Mobile Communications

1. A study group established by MPHPT examined the setting of user rates of calls originating from NTT East and West and terminating on mobile networks via inter-exchange carriers. The study group completed its report in June 2003 after soliciting public comments for a month. After evaluating the report, MPHPT issued the “Policy for Setting User Rates of Calls Originating from NTT East and West and Terminating on Mobile Networks Via Inter-Exchange Carriers,” and carriers other than mobile network operators have been able to set user rates since April 2004. As a result, rate reductions of up to 55 percent were realized for calls originating from NTT East and West and terminating on mobile networks.
2. NTT DoCoMo’s interconnection rates have been significantly reduced over the last three years by approximately 22 percent, to among the lowest levels in developed countries with a calling-party-pays system. The rates filed in March 2004 resulted

in a reduction of approximately 4 percent compared with rates filed the previous fiscal year. Telecommunications carriers with Category II-designated telecommunications facilities (mobile networks) continue to be required to notify MPHPT of and publicize interconnection tariffs.

D. Promotion of Advanced Technologies and Services

1. In November 2003 and March 2004, the Telecommunications Working Group of the Regulatory Reform Initiative obtained information from private sector experts on the utilization and application of radio frequency identification (RFID) in both countries. The Working Group heard their views on current trends and issues in the developing RFID market, including technology, market status, and policy.
2. In March 2004, MPHPT solicited public comment on the “Draft Final Report of the Study Group on Advanced RFID (Electronic Tag) Application in the Ubiquitous Networking Age.” Based on the report, MPHPT will continue to promote testing of both passive and active tag technology in the UHF band. Based on such testing, the Telecommunications Council will discuss technical conditions and the Radio Regulatory Council will discuss regulations.

E. Network Channel Terminating Equipment (NCTE)

1. The Governments of Japan and the United States, having exchanged views on the relevance of the 1990 Exchange of Letters on Network Channel Terminating Equipment (NCTE) (“the 1990 Letters”), share the following recognition, based upon which the two Governments propose a process for terminating the procedures established through this exchange of letters:
 - a. Significant competition among telecommunications carriers has emerged and the development process of terminal equipment has changed substantially.
 - b. Because of the shortened life-cycle of products, the shortened lead-time of product development, and the increased use of standards, timeframes described in the 1990 Letters for the disclosure of information on specifications for NCTE before the introduction of individual services may hinder prompt supply of advanced services.
2. As a transitional measure, the procedures established through the 1990 Letters will be streamlined as indicated below. Unless sufficient evidence demonstrating the continued need for these revised procedures is introduced, following solicitation of opinions from interested parties, these procedures will cease to be applied beginning in FY2006.

- a. Scope of carriers subject to revised procedures: Main carriers that determine specifications of NCTE and provide services (except those of sufficiently competitive areas), using Category I designated telecommunications facilities.
- b. Scope of information disclosure under revised procedures: Regarding NCTE where network interface information has been made generally available through a standardization process or by other means, disclosure will not be required.
- c. Term of disclosure of technical specifications: In principle, three months minimum, prior to introduction of a new service.

II. INFORMATION TECHNOLOGIES

A. Removing Regulatory and Non-Regulatory Barriers

1. Legal Framework: The Government of Japan has removed various barriers to e-commerce, electronic notifications, and transactions by introducing new rules and updating existing ones, such as the amendment of the Commercial Code and introduction of the “No-Action Letter” system. The Expert Committee on IT Strategy Evaluation (Expert Committee) under the IT Strategic Headquarters indicated in its March 2004 e-Japan Evaluation report that while IT-related regulations have been considerably improved through regulatory reforms, continuous efforts to advance regulatory reform are critical to improve the efficiency of the overall social system through IT utilization. The Expert Committee will study the causes of the slow pace of regulatory reform in some sectors and propose necessary measures to address them. More broadly, the Government of Japan will ensure that each Ministry and Agency will continue to revise existing regulations that hinder e-commerce and establish rules as necessary to further promote free and diverse e-commerce activities, and do so in a manner that promotes technology neutrality.
2. Private Sector Leadership: Under the “e-Japan Strategy II” principle that “the private sector plays a leading role with government support,” the “e-Japan Priority Policy Program 2003” articulates the necessity of facilitating smooth market operations, such as promoting free and fair competition and creating an environment where the private sector can maximize its leadership potential. Based on these perspectives, the Government of Japan will continue to promote the effective use of IT without unnecessary regulation and by removing impediments to the development of e-commerce. In addition, as the Government of Japan develops its e-commerce policies under the “e-Japan Priority Policy Program 2004,” it will promote the principle of private sector self-regulation to the extent possible.

3. Special Zones: The Government of Japan has so far approved four IT Special Zones for Structural Reform and will seriously consider applying successful regulatory exemptions in those zones on a national basis as expeditiously as possible.
4. IT Strategic Headquarters Coordinating Role and Resources: As the “e-Japan Strategy II” requires consistent and effective implementation of related measures by respective Ministries and Agencies, the Expert Committee has evaluated the status of implementation of the IT priority measures by relevant governmental organizations. The IT Strategic Headquarters will continue to produce and coordinate IT policy direction for the entire Government and will encourage related Ministries and Agencies to take further positive steps to promote development of effective IT policy. The IT Strategic Headquarters will be provided sufficient resources to fulfill its objectives. In line with this, a number of staff were added to the IT Strategic Headquarters in April 2004. In addition, the Inter-Ministerial Task Force (*renraku kaigi*), that is comprised of officials at the Director-General level, was established in February 2004 to facilitate stronger communication among Ministries and Agencies on IT policy.
5. Private Sector Input:
 - a. The Government of Japan has sought opinions from the private sector in the planning and implementation of its IT policy both through private sectors’ participation in the IT Strategic Headquarters and through the solicitation of public comments for the “e-Japan Strategy II” and the “e-Japan Priority Policy Program 2003.” Similarly, the IT Strategic Headquarters made drafts of the “e-Japan Priority Policy Program 2004 ” and other IT-related programs available for public comment, and will ensure that all comments received are seriously considered and reflected, as necessary, in the final measures and actions that are implemented.
 - b. The IT Strategic Headquarters appointed specialists from the private sector as members of the Expert Committee. In this course, the Headquarters paid attention to the maintenance of neutrality and transparency of this Committee, and chose private sector experts who could advise the Headquarters from a wide range of visions that reflect the current globalized IT society. To further expand that range of visions, the Government of Japan will actively seek input from experts, including experts from non-Japanese entities, as it undertakes subsequent evaluations of e-Japan.

B. Strengthening the Protection of Intellectual Property Rights

1. Copyright Term Extension: An amendment to the Copyright Law passed the Diet on June 18, 2003 that extended the term of protection for cinematographic works from 50 years to 70 years from their first publication. The Government of Japan will continue its deliberations on extending the terms of protection for other subject matter protected under the Copyright Law, in consideration of relevant factors including global trends and the balance between right holders' and users' benefits.
2. Statutory Damages: The aforementioned amendment to the Copyright Law also eases the burden of right holders to prove infringement in copyright cases. The Government of Japan will continue to consider further measures to decrease the burden on right holders, including statutory damages for infringement.
3. Protection of Digital Content:
 - a. The Government of Japan affirms that it has issued a decree mandating the use of only authorized software by its government ministries, which provides effective and transparent procedures to ensure that software used or procured by the government is appropriately licensed and legitimately used. The Governments of Japan and the United States will continue to exchange information on protection of digital content, including software and other intellectual property assets, on government-supported IT resources as necessary.
 - b. The Law Concerning the Liability of Internet Service Provider has had some positive results with related guidelines since its enforcement in May 2002. Under the Law and the guidelines, right-infringing information on the Internet, including digital content piracy, can be deleted upon request from a Credibility Confirmation Organization. The Government of Japan will continue to observe the status of implementation of the Law.
 - c. The Government of Japan has made efforts to render its interpretation of the scope of protection for a "temporary copy" known publicly through appropriate measures.
 - d. The Governments of Japan and the United States will continue to discuss issues related to technological protection measures.
4. Exceptions for Educational Institutions: The Government of Japan has issued guidelines and presented examples of the "educational exceptions" of the Copyright Law for educational institutions, teachers, and students to clarify the limitations of the exception under the amended Copyright Law. The Government of Japan will continue a dialogue with the Government of the United States on the status of the application of these exceptions.

5. Transmission of Broadcast Television Signals and Content over the Internet: MPHPT has been conducting tests to establish a system by which copyright holders and users can mutually and smoothly exchange information on content, including information on copyrights, in order to promote circulation of content over the broadband network, including those already televised. These tests have been technical in nature and do not include compulsory, non-voluntary or statutory licenses. In addition, these tests proceed under agreement by and based upon cooperation with broadcasting companies and right-holder organizations.
6. Digital Rights Management System: The Governments of Japan and the United States will continue to discuss issues related to digital rights management systems.
7. IP Promotion Plan and Intellectual Property Policies:
 - a. The Intellectual Property Strategy Headquarters (IPSH) discussed various policies to realize an IP-based nation and created the Intellectual Property Strategic Program (IPSP) in July 2003. To further discussion on several important issues on which IPSH did not reach final conclusions, IPSH established three task forces in October 2003: (1) Task Force on Enhancement of IP Protection; (2) Task Force on Patentability of Medical Treatment Inventions; and (3) Task Force on Content Business. The law provides that the IPSP shall be reviewed and revised at least once a year. Consistent with this, IPSH finalized and published the “IPSP for 2004” on May 27, 2004.
 - b. When reviewing the IPSP, IPSH will provide an adequate period for the solicitation of public comments, in accordance with the general rules on public comment procedure decided by the Cabinet. In doing so, IPSH will ensure that comments from the Government of the United States and other stakeholders are seriously considered and, as necessary, reflected in the final measures and actions. The Government of Japan will also ensure that the Basic Law on Intellectual Property and implementing measures for the IPSP are in compliance with international obligations, standards, and norms, and that IPSH will be provided with the necessary support and resources to implement the Basic Law and measures for the IPSP.

C. Promoting and Facilitating Public and Private Sector Use of E-Commerce

1. Privacy: On April 2, 2004, the Government of Japan adopted the Basic Policy for the Protection of Personal Information based on Article 7 of the Law for the Protection of Personal Information. Based on the Basic Policy, each Ministry and Agency is considering introduction of new implementation guidelines, and/or revision of existing ones, reflecting the current status of the individual business sectors for which they are responsible.

- a. The Government of Japan established the Inter-Ministerial Task Force (*renraku kaigi*) for the Protection of Personal Information in order to promote the protection of personal information, in a comprehensive and uniform manner, via close and consistent coordination among Ministries concerned. In the circumstances where businesses are under the jurisdiction of multiple Ministries and Agencies, sufficient liaison among themselves will be sought to lighten the burden on these businesses.
- b. The Ministry of Public Management, Home Affairs, Posts and Telecommunications (MPHPT) and the Ministry of Economy, Trade and Industry will publicize their draft implementation guidelines for approximately 30 days of public comment, and will reflect the comments in the final guidelines or otherwise respond to them.
- c. In those sectors where the proper handling of personal information is strictly required in view of the nature and the method of its use (for example, the medical sector, financial services and credit sector, and information and communications sector), the relevant Ministries and Agencies are examining additional measures, such as guidelines, regulations, or laws, based on the Basic Policy. Decisions about additional measures will be made by the date of implementation of the Law for the Protection of Personal Information (April 1, 2005). Any additional measures will be implemented giving these industries a sufficient time period to comply with them. The Government of Japan will also seek the input from the private sector in a transparent manner, utilizing appropriate means.
- d. In May 2004, the Governments of Japan and the United States held a public-private sector roundtable (*kondankai*) concerning privacy, and will continue a dialogue and work together on privacy-related issues.

2. Alternative Dispute Resolution Framework:

- a. In the 2003 Report to the Leaders, the Governments of Japan and the United States recognized that establishing a framework that allows for fair and effective Alternative Dispute Resolution (ADR) is important to the development of e-commerce. Subsequent to soliciting public comments on its August 2003 study on a possible legal framework for ADR, the Government of Japan considered stakeholder input that was received, including those comments related to e-commerce. Based on the issues raised, the Government of Japan is taking additional time to formulate legislation that will address the cross-border online aspects of ADR.

- b. As it develops legislation with the aim of creating a flexible and open legal environment for the development of ADR services, the Government of Japan will consider including measures that will promote the use of online dispute resolution, including in the cross-border context. As part of the new legislation, consideration is being given to such issues as whether non-lawyers should be allowed to act as a neutral in ADR proceedings. The Government of Japan will continue to seek input from appropriate stakeholders.
 - c. The Government of Japan will continue a dialogue and work together on ADR issues with the Government of the United States.
- 3. Network Security: Under the Japan-U.S. Joint Statement on Promoting Global Cyber Security adopted on September 9, 2003, the Governments of Japan and the United States recognized that critical infrastructure protection is a shared responsibility of the public and private sectors. The Government of Japan is working to improve and ensure the security and reliability of information systems used by local and central government entities through developing network security guidelines and standards, and affirms the importance of involving stakeholders, including the private sector, in this process. Furthermore, to promote the use of e-government, such guidelines and standards will, where appropriate, be open (non-proprietary) and consistent with standards developed by voluntary standardization bodies constituted upon consensus in industry, including the International Standards Organization (ISO).
 - a. The e-Japan Strategy II Acceleration Package calls for the adoption of security standards for central government information systems. The Governments of Japan and the United States share the view that inter-Ministerial consultation is important for realizing consistent standards applicable to all central government systems. Thus, the IT Security Office of the Cabinet Secretariat will develop standards for information security in consultation with all Ministries and Agencies. It will also seek professional advice, as necessary, from its expert research team, whose members include experts from the private sector, both vendors as well as users. The Governments of Japan and the United States also recognize that input from stakeholders representing a range of perspectives can be beneficial. Thus, the IT Security Office will examine if the use of a public comment period will enhance the effectiveness of security standards. Furthermore, the Governments of Japan and the United States will continue a dialogue and exchange ideas on security standards.
 - b. Recognizing the increasing importance for the local governments to enhance information security measures in line with the development of e-government at the local level, MPHPT developed voluntary “Guidelines

for Information Security Inspection for Local Governments” in December 2003. The guidelines are not intended to create discrimination between domestic and foreign providers.

- c. In developing these guidelines, MPHPT had discussions with representatives of the local governments and experts from the private sector to reflect a wide range of opinions and issues raised by them. The Government of Japan will consider, as necessary, opening amendments or revisions to these guidelines to a public comment process to gather input from a wider range of stakeholders.

D. Promoting Procurement Reforms for Information Systems

1. Implementation of Reforms: In December 2003, a summary of the data compiled from a follow-up survey on the implementation by 17 Ministries and Agencies of several new procedures in FY2002 for information systems procurement was published on MPHPT’s website. These procedures were adopted in accordance with the memorandum of agreement among the Ministries (Memorandum) to take steps to ensure nondiscriminatory, transparent, and fair procurements of information systems by the Government of Japan.
 - a. Recognizing the importance of consistent, government-wide implementation of procurement reforms in this area, the Government of Japan’s Chief Information Officer (CIO) Council will encourage all Ministries to implement these reforms in a timely manner; and
 - b. The Government of Japan will also continue to conduct follow-up surveys on the implementation of the Memorandum, and make the results publicly available on the Internet.
2. Strengthening of Reforms: The Ministries originally agreed upon the Memorandum on March 29, 2002, and subsequently have revised it three times, most recently on March 30, 2004.
 - a. The most recent changes included commitments to introducing Service Level Agreements, clarifying liability for losses, and resolving IPR ownership issues. In addition, to improve transparency and fairness in government procurement, all Ministries will contribute applicable information about their awarded procurements of information systems to a database launched in April 2004 that is publicly available at <http://cyoutatujirei.e-gov.go.jp/>.
 - b. As the Ministries continue to implement and review the procedures in the Memorandum, the Government of Japan recognizes the importance of

seeking input from the private sector in a transparent manner, and will ensure opportunities for interested parties to provide their views on these reforms. The Governments of Japan and United States will continue a dialogue about ways to seek public input on these reforms.

3. Adopting New Methodologies:

- a. In April 2004, the Government of Japan adopted and made publicly available on the Internet the methodology that all Ministries will use for life-cycle cost based evaluation of bids for multi-year information systems projects. All Ministries are expected to implement this methodology on projects to the extent possible.
- b. The Cabinet Secretariat issued “Japan’s Government Procurement: Policy and Achievements Annual Report (FY2003 version)” in March 2004, which lists each award in order by the procuring Ministries and Agencies. The report includes data and analysis on overall trends in Japan’s government procurements, and the results of a survey of domestic and foreign suppliers about procurement procedures. During FY2004, the Cabinet Secretariat will continue to conduct a survey of suppliers to collect their opinions concerning the threshold used by Japan for the Overall Greatest Value Method (OGVM), including the OGVM threshold for, among others, computer products and services (currently 800,000 Special Drawing Rights). The results of the survey will continue to be publicized on the website of the Prime Minister’s Office.

4. Strengthening Human Resources: As of December 2003, CIO Aides for 20 Ministries and Agencies were selected from among outside experts on the basis of their professional skills, independence, and neutrality. One of their important roles is to support and advise CIOs and other senior officials in analyzing, evaluating, and developing “optimization” plans for office systems of their respective Ministries and Agencies, so that procuring entities can obtain the best systems in the most cost-efficient and transparent manner.

- a. In order for the entire government to undertake its daily work in the most efficient manner, CIO Aides work in accordance with the “Guideline for Formulating Optimization Plan for Business Process and System” which includes the concept of enterprise architecture.
- b. CIO Aides will coordinate with each other through an Inter-Ministerial Task Force (*renraku kaigi*).

III. ENERGY

- A. **Regulatory Authorities:** The Government of Japan is undertaking significant reform of its electricity and gas sectors to develop a competitive energy market with expanded retail choice and opportunities for new market entry, all the while meeting the Basic Energy Policy Act's goals of ensuring a stable supply of energy and meeting environmental protection aims. The Government of the United States welcomes Japan's reform process. Vigilant market oversight is necessary to ensure the effectiveness of these reforms in the creation of a fair, efficient, and stable energy market. The Government of Japan thus recognizes the importance of establishing an enforcement mechanism equipped with the necessary number of staff, expertise, and independence to provide such oversight. METI is preparing its own monitoring functions in the liberalized electricity and gas market.
- B. **Public Input:** METI took steps to ensure that the development of related ministerial ordinances and guidelines to implement Japan's electricity and gas reform was an open and transparent process.
1. Electricity: In the fall of 2003, METI solicited and responded to public comments, including from the Government of the United States, on the Electricity Industry Committee's draft interim report titled "Detailed Design of the Desirable Future Electricity Industry System." In early 2004, METI also solicited public comment to the Electricity Industry Committee's draft final report.
 2. Natural Gas: In the fall of 2003, METI solicited and responded to public comments, including from the Government of the United States, on the Small Committee on System Design's draft report titled "Detailed Design of the Desirable Future Gas Industry System." In early 2004, METI also solicited public comments on its draft ministerial ordinance to partially revise the gas business accounting rules.
- C. **Electricity:** The Electricity Utilities Industry Law (the "Electricity Law") was amended in June 2003, paving the way for a new electricity industry system. METI has amended, and is preparing additional changes to, ministerial ordinances that will result in the expansion of retail choice to about 63 percent of the market (2.4 times the 2003 level) by April 2005. Also following the amendment of the Electricity Law, the Electricity Industry Committee, an expert advisory body tasked by METI to recommend reform measures, deliberated on next steps and issued its interim report titled "Detailed Design of Desirable Future Electricity Industry System." METI is now preparing necessary ministerial ordinances and other related documents based upon the amended Electricity Law and the Electricity Industry Committee's final report.
1. Fairness and Transparency in Transmission/Distribution:
 - a. *Neutral System Organization:*
 - (1) The revised Electricity Law mandated that METI designate and oversee a Neutral System Organization (NSO). In December 2003,

METI established criteria by which it will designate an entity as an NSO and issued the necessary ministerial ordinances to examine an entity's application.

- (2) METI will designate the NSO after reviewing proposed business plans, including information on its financial and technical potential.
- (3) METI will supervise the NSO in order to secure fairness and transparency, and will issue orders to the NSO if necessary to correct any inadequacies.
- (4) The NSO will issue rules that pertain to construction of facilities, network access, system operation and information disclosure, taking into account input from the Electricity Industry Committee and public comments.

b. *Behavioral Regulation:*

- (1) METI will develop necessary ministerial ordinances and other regulations, taking into account input from the Electricity Industry Committee, that establish concrete methods to separate transmission/distribution segment accounts from other segments and that provide for separation of accounts in an income statement.
- (2) METI has been working with the Japan Fair Trade Commission (JFTC) to revise the Guidelines for Fair Power Trades in order to ensure effective information firewalls and the prohibition of discriminatory treatment pertaining to wheeling services. If METI finds that a general power utility has performed an act contrary to the legal text and these guidelines, it will issue a stop or change order to the general power utility to remedy the problem.

2. System Design for a New Electricity Market:

- a. *Wholesale Electric Power Exchange:* To improve market efficiency, utilities will establish a new power exchange market beginning in April 2005 to handle forward market and day-ahead spot market transactions. JFTC will monitor trades in the power exchange under the Antimonopoly Act. METI is preparing the necessary language in the joint guidelines with JFTC in order to ensure the fairness of wholesale transactions.
- b. *Liberalization Schedule:*

- (1) As a result of the December 2003 amendment of the ministerial ordinance, the scope of retail liberalization was expanded in April 2004 to include customers using high voltage electric service at or exceeding 500kW (part of high-voltage customers).
- (2) The ministerial ordinance will be amended again to expand the scope to customers using high voltage electric service at or exceeding 50kW (all high-voltage customers) from April 2005.
- (3) Discussion on full retail liberalization, including household customers, will start around April 2007, taking into account the results of partial liberalization up to that point in time.
- (4) The Government of Japan has been publicizing expansion of retail liberalization through public advertisements in the newspaper and through leaflets.

3. Review of the Wheeling Services System:

a. *Balancing Rules:*

- (1) METI will relax the balancing rules in April 2005 so that a new entrant can choose the second fluctuation range from 3 percent to 10 percent, in addition to the primary fluctuation range of 3 percent.
- (2) A new balancing support system will be introduced toward the start of a new wheeling services system in April 2005 so that a new entrant can access customers' demand data every 30 minutes. The data is collected and owned by general power utilities, using remote metering systems or other systems.
- (3) METI will prepare ministerial ordinances and other regulatory texts in order to undertake such measures by the end of this year.

b. *Abolition of Pancaking:* To facilitate nationwide electricity transactions through fair and transparent wheeling service charges, METI will prepare, by April 2005, ministerial ordinances and other regulations in order to eliminate the "pancaking" problem.

c. *Clarification of Standards to Issue Orders to Change Rules of Wheeling Services:* METI will clarify its standards and issue necessary regulations for implementing "change orders" in order to ensure an appropriate enforcement mechanism for network regulation.

4. Review of Regulatory Reform: The Government of Japan is committed to reviewing on an ongoing basis the efficiency of the competitive market and the effectiveness of regulation. While doing so, it will take into account the need for additional steps, such as additional regulatory reforms, to ensure that an open, fair, and competitive market emerges.
- D. **Natural Gas**: The amendment of the Gas Utilities Industry Law (the “Gas Law”) was approved by the Diet in June 2003, a step that will expand the scope of retail choice to approximately 50 percent of users (1.25 times the 2003 level) by 2007. Following this amendment, the Small Committee on System Design of the Urban Heat Energy Subcommittee deliberated on a design for a new gas industry regulatory system, and in January 2004 issued its report titled “Detailed Design of Desirable Future Gas Industry System.” METI is now developing necessary implementing regulations and ordinances based on the amended Gas Law, the published report of the Small Committee on System Design, and public comments.
1. Fairness and Transparency of Third-Party Access (TPA) to Pipelines:
 - a. *TPA Rates*: METI established a ministerial ordinance for setting TPA tariffs, based on the report of the Small Committee on System Design.
 - b. *Accounting Separation*: METI will issue in June 2004 a ministerial ordinance setting out rules on the separation of accounts of the gas transportation/distribution sector from those of other sectors and also on the publication of these separated accounts in financial statements.
 - c. *Behavioral Regulation*: METI has been working with the JFTC to revise the Guidelines for Fair Gas Trades in order to ensure effective information firewalls and the prohibition of discriminatory treatment against particular TPA users as stipulated in the amended Gas Law. If METI finds that a gas utility has performed an act contrary to the legal text and this guideline, it will issue a stop or change order to remedy the problem.
 2. Development of Pipeline Network:
 - a. *Incentives for Pipeline Investment*: METI established ministerial ordinances in February 2004 to allow owners of new pipelines that fulfill certain conditions to choose to receive, for five years, either (i) a higher rate of return in setting TPA rates for their pipelines; or (ii) an exemption from their obligation to notify METI of the terms, conditions, and rates for TPA to their pipelines.
 - b. *Public Utility Privileges*: Necessary ordinances and regulations were developed and will be applied to facilitate approvals and administrative

procedures for the new pipeline owners that do not currently receive the privileges accorded to gas utility companies.

- E. **Liquefied Natural Gas:** Recognizing that liquefied natural gas (LNG) is an important fuel source for both new power and gas market suppliers, the Government of Japan has begun taking steps to encourage access to LNG facilities to third parties. The Government of Japan will issue guidelines to establish a framework relating to negotiations for third-party use of LNG terminals.

IV. **MEDICAL DEVICES AND PHARMACEUTICALS**

A. **Medical Device and Pharmaceutical Pricing Reform and Related Issues**

1. In Japan, the environment surrounding medical care continues to change drastically due to factors such as the aging of Japanese society and advances of medical technology. It is therefore important to maintain the universal healthcare system and to provide people with high-quality, efficient medical care both now and in the future.
2. Recent severe economic conditions have imposed financial constraints on the health system in Japan, and the Government of Japan is now tackling a fundamental reform of the medical insurance system. As part of this effort, in March 2003, the Cabinet decided to review the reimbursement prices of medical devices and pharmaceuticals with a view to reducing the price difference between domestic and foreign markets and taking current market prices into account. At the same time, it is important to ensure efficient, high-quality healthcare for Japanese patients and to encourage the development of better medical devices and pharmaceuticals.
3. In consideration of fostering an attractive environment for development of innovative medical devices and pharmaceuticals, the Ministry of Health, Labor and Welfare (MHLW) will continue to implement reforms while recognizing the value of innovation.
4. Pharmaceuticals and medical devices are important elements of medical care. It is necessary to improve the environment for providing people with prompt access to excellent medical devices and pharmaceuticals and to strengthen the international competitiveness of Japan's medical device and pharmaceutical markets and industries. To this end, MHLW published its "Vision" policy paper for the pharmaceutical industry, "Enhancing the International Competitiveness of the Pharmaceutical Industry for 'the Century of Life,'" in August 2002, and its "Vision" paper for the medical device industry, "Toward the Provision of Better and Safer Innovative Medical Devices," in March 2003. In these two Vision papers, action plans comprising a wide range of policies concerning the R&D environment, regulatory system, and insurance reimbursement were presented as "concrete

measures to be carried out in an intensive period (within five years) to promote innovation.” The Visions also recognize the role of the market and the value of innovation. Generally, in the Visions, MHLW recognized that the pricing system has important implications for encouraging investment in innovative R&D. MHLW also recognized that providing market return incentives is critical for fostering attractive and competitive pharmaceutical and medical device industries and markets. On the reimbursement system, MHLW will continue to endeavor to: 1) further promote the expeditious introduction of effective and innovative products into the insurance system through appropriate prices; and 2) conduct a medium-to-long range review of the pricing system to harmonize the achievement of global competitiveness of the industry with the public health insurance system.

5. MHLW is making steady efforts to implement the Visions. MHLW’s Headquarters for the Promotion of Policies on the Pharmaceutical and Medical Device Industries, which is led by the Vice-Minister and involves all relevant units, collects and publishes information each year on the state of progress of the two plans. MHLW will continue to make efforts in FY2004 to accelerate the implementation of the action plans, as recommended by the 2003 U.S.-Japan Private Sector/Government Commission. MHLW will also verify the results of implementation on the basis of comments made by the industries and other interested parties. The Government of the United States welcomes healthcare reform and the Visions papers as evidence that Japan is committed to promoting rapid access to the most innovative medical devices and pharmaceuticals.
6. In line with the Cabinet’s decision to review reimbursement policies, the pricing system of medical devices and pharmaceuticals was revised in FY2004. During this process, MHLW increased opportunities to communicate closely with the medical device and pharmaceutical industries including those of the United States. MHLW continues to keep the practice of having a meaningful periodical dialogue with industry, including U.S. industry. MHLW will continue to provide industry, including U.S. industry, with meaningful opportunities to provide input and with access to consultations prior to changes in pricing rules, and will give this input sincere consideration. MHLW will continue to make serious efforts to ensure that the price revision process is fully transparent.
7. As a result of the discussions of the Central Social Insurance Medical Council (*Chuikyo*), where industries had opportunities to express their opinions, MHLW did not alter the Foreign Price Adjustment rule or the Cost Calculation rule, did not introduce a repricing rule for long-listed products that lack generic competition, and did not introduce a repricing rule that uses foreign price comparisons in the pharmaceuticals pricing revision of FY2004.
8. In FY2002, MHLW substantially raised the rate of premium pricing for innovativeness and usefulness to ensure appropriate evaluation of innovative

pharmaceuticals. Since then, this system has been implemented. In FY2004, MHLW introduced a new premium pricing rule for those drugs with high medical usefulness whose prices have been calculated only based on the inter-specification adjustment. MHLW will continue to review the results of the application of premiums to ensure that premiums are being used to fully recognize and encourage innovation. The Government of the United States pointed out the importance of discussing with industry, including U.S. industry, the order in which premiums and other pricing rules are applied.

9. To better recognize the value of useful products, MHLW decided in FY2004, when repricing pharmaceuticals, to decrease the price reduction rate which would be applied to those products following market expansion, if true clinical usefulness is verified directly by the results of data collected after their market introduction. The premium that corresponds to the rate for Usefulness II is integrated into the repricing process, ensuring that the process does not unduly reduce the prices of truly useful products. MHLW will review data submitted by companies when considering whether to apply this premium.
10. MHLW evaluates a pharmaceutical product's innovativeness based on its attributes. Regarding the evaluation of innovativeness, order of introduction into the market is not considered because innovativeness is not dependent on order of market entry.
11. With respect to pricing rules for new medical devices, from April 1, 2004, MHLW took steps to foster innovation in this sector. A rule was revised in FY2004 to increase the frequency of granting reimbursement prices to C1 products from two to four times a year. In addition, the timing for granting reimbursement prices to C2 products was changed from coinciding with the Medical Fee Revision to a system where the *Chuikyo* will deliberate on such introductions when new medical technologies are introduced into the Medical Fee Schedule. MHLW continues to provide companies, including U.S. companies, with opportunities for consultations regarding the application of the criteria for C1 and C2 categories.
12. According to the rule, which is set by the *Chuikyo*, MHLW should use available prices of four countries including the U.S., the U.K., Germany and France in the medical device pricing revision process. In the process of the FY2004 medical device pricing revision, MHLW fully used price data, submitted by companies, including the U.S. list prices, in the calculation of the Foreign Price Adjustment rule, and the price data provided by U.S. companies played an important role. MHLW will continue to work with industry, including U.S. industry, on the scope of future data collection regarding medical devices. Also, MHLW is open to discussion, upon request by industry, of data collected by industry on the specific costs of bringing products to the Japanese market, while considering the *Chuikyo's* view regarding the price difference between domestic and foreign markets for medical devices.

13. MHLW will continue to ensure the transparency of the reimbursement price-setting process. The Government of the United States pointed out the importance of providing applicants with opportunities to make presentations at the first meeting of the Drug Pricing Organization (DPO) and Special Organization for Insurance-covered Medical Materials (SOIMM) during CY2004.
14. MHLW will continue to ensure transparency for the diagnostics industry (e.g., imaging devices and in-vitro diagnostics) regarding the pricing process. MHLW decided in FY2003 to include representatives of the imaging and in-vitro diagnostics industries in regular meetings with the medical device industry to hear opinions regarding the reimbursement of diagnostics.
15. MHLW will continue to provide industry, including U.S. industry, with information and meaningful opportunities to provide input and with access to consultations, upon request by industry, regarding the introduction or major revision of Diagnosis Procedure Combination (DPC) and other payment systems such as Diagnostic Related Group (DRG), Prospective Payment System (PPS), etc. MHLW recognizes the importance of innovative products regarding these systems.
16. MHLW recognizes that there is a difference in market structures between blood products and pharmaceuticals. MHLW will continue to apply pricing rules fairly and transparently.
17. The Governments of Japan and the United States will continue to discuss pharmaceutical and medical device pricing reform issues.

B. Medical Device and Pharmaceutical Regulatory Reform and Related Issues

1. On April 1, 2004, MHLW founded the Pharmaceuticals and Medical Devices Agency (PMDA), fully integrating the functions of the Organization for Pharmaceutical Safety and Research and the Pharmaceuticals and Medical Devices Evaluation Center. The establishment of PMDA has led to full consolidation of services provided in the pre-market process and application review process for approvals. This consolidation enables one team to deal with consultations on clinical trials and reviews, and hence guidance to applicants is likely to become more consistent. MHLW will ensure that PMDA uses procedures that will evaluate fairly and impartially the medical benefits and risks of pharmaceuticals and medical devices. The regulatory system will be based on accountability, efficiency, international harmonization and the latest internationally accepted science. The application review process for approvals will be based on the consideration of product safety, efficacy and quality. MHLW will ensure that PMDA seeks to both promote and protect public health, and to operate transparent, timely and sound science-based procedures. MHLW will ensure that PMDA also carries out safety

activities in the same manner. MHLW will endeavor steadily to achieve the goals of the Industry Visions by continuing efforts to ensure a more timely introduction of safer and more effective medical devices and pharmaceuticals.

2. MHLW has provided industry, including U.S. industry, with meaningful opportunities to exchange views regarding PMDA's organization, user fee system, performance measures, and other matters, as well as issues related to reform of the Pharmaceutical Affairs Law (PAL). MHLW will continue to provide industry with meaningful opportunities to exchange views regarding the user fee system, and MHLW will ensure that PMDA continues to offer such opportunities to industry regarding matters other than the user fee system. MHLW will ensure that PMDA continues to offer opportunities for timely access to useful discussions with PMDA officials involved in consultations at key stages of the development of medical devices and pharmaceuticals. MHLW will ensure that PMDA discusses with industry methods that would enhance communication between PMDA and applicants to facilitate efficient reviews.
3. On April 1, 2004, PMDA established therapeutic-area review teams with appropriate technical expertise to manage application reviews for approval and consultations. PMDA also set up a group dedicated to safety activities, which will interact with the review section including the appropriate therapeutic-area review teams. MHLW will ensure that PMDA's experts have access to continuing education, and staff rotations are conducted in view of ensuring continuity within review teams.
4. MHLW established a simple and precise user-fee system on April 1, 2004. User fees are being used to supplement PMDA's budget only for the purpose of increasing resources, including staff with relevant expertise, dedicated to the enhancement of review quality as well as faster approvals of medical devices and pharmaceuticals. MHLW will discuss any proposed fee changes with industry, including U.S. industry, and link increases in user fees to improvements in PMDA's performance measures.
5. MHLW authorized PMDA to establish transparent performance measures with baselines based on FY2003 performance. MHLW will ensure that, starting in FY2004, PMDA reports annually and publicly on its performance and describes its progress toward meeting performance goals. By law, MHLW's Evaluation Committee assesses progress in attainment of performance goals and the results are published every year. The annual reports will include administrative time. To ensure transparency, MHLW will ensure that PMDA also publishes each year information specifying the revenues received, including fees collected for new drug application (NDA) and medical device reviews and contributions for postmarketing safety, and how the revenues were expended. MHLW, in collaboration with PMDA, will continue to discuss with industry specific

quantitative and qualitative goals for improving the approval time of product applications and contents of the reports on performance goals and revenues within the confines of Japanese law.

6. For pharmaceuticals, currently about 50 percent of approved NDAs are approved within 12 months of administrative time. On April 1, 2004, PMDA established the performance targets of 70 percent of NDA approvals within 12 months of administrative time by March 31, 2008, and 80 percent of NDA approvals within 12 months of administrative time by March 31, 2009, the end of the first phase.
7. While PMDA will continue to improve the NDA review process through the medium term, the Government of the United States will strongly encourage U.S. companies that submit applications to decrease their response times during NDA reviews. MHLW will examine the possibility of using total NDA review time as a performance measure in the second term, in consideration of the outcome of the first term.
8. On April 1, 2004, PMDA implemented a priority review system with the performance goal of approving 50 percent of priority NDAs in six months of administrative time by March 31, 2009. MHLW has clarified the criteria and has expanded the scope of products considered for priority review to include products deemed to be highly necessary in medical practice. MHLW will continue to discuss the interpretation of the criteria for priority review with industry, including U.S. industry.
9. For medical devices, on April 1, 2004, PMDA established performance goals that will ensure the completion of approvals in specified times through staged improvements in the next five years. MHLW will ensure that PMDA completes the reviews of 70 percent of new device applications within 12 months of administrative time by March 31, 2005; 80 percent of new device applications within 12 months of administrative time by March 31, 2007; and 90 percent of new device applications within 12 months of administrative time by March 31, 2009. In addition, by March 31, 2005, MHLW will ensure that PMDA completes 100 percent of priority reviews in 12 months of administrative time and 95 percent of reviews of improved devices in 12 months of administrative time. Considering the implications of the April 2005 PAL reform, MHLW will ensure that PMDA improves the performance goals for me-too devices and partial change applications, and that PMDA discusses these improvements with industry, including U.S. industry.
10. MHLW will ensure that PMDA establishes in the near future performance goals for in-vitro diagnostics considering the implications of the April 2005 PAL reform. MHLW will provide industry, including U.S. industry, with meaningful

opportunities to provide input when establishing performance goals for in-vitro diagnostics.

11. To encourage medical device companies to improve the quality of their submissions, the U.S. Department of Commerce and the medical device industry plan to hold a workshop in Tokyo in CY2004. MHLW is willing to actively participate in the workshop with PMDA.
12. In the process of developing and implementing safety-related activities, MHLW will ensure that PMDA ensures transparency by providing manufacturers with meaningful opportunities to be involved in the process. Safety-related activities will be undertaken in a timely, science-based manner, taking into account guidance from international organizations, namely ICH and GHTF.
13. On April 1, 2004, PMDA implemented a two-tier system to handle appeals within the pharmaceutical and medical device approval and safety-related processes. For appeals concerning procedural matters, a hearing will be conducted between the applicant and the senior PMDA staff member with responsibility for reviews. For appeals regarding scientific details, opportunities will be given to the applicant (and its representatives) for a hearing with PMDA officials and outside experts.
14. After the enforcement of the amended PAL in April 2005, PMDA will conduct quality system audits for high-risk (class 3 or 4) medical devices. When planning whether to conduct an audit in writing or in the field, MHLW will ensure that PMDA considers risk level, which will be determined by factors including product characteristics and the nature and extent of non-conformity identified through past audits. Third-party recognized bodies will conduct audits for class 2 devices in domestic and foreign plants. In the regulatory auditing of quality systems of medical device manufacturers, MHLW and the U.S. Food and Drug Administration (FDA) will continue to draw upon such internationally harmonized guidelines as those of GHTF within the confines of Japanese and U.S. law.
15. On April 1, 2004, PMDA and its Inspectorate implemented the PAL reform that stipulates new foreign manufacturing facility inspection requirements. MHLW has stated that the time required for GMP inspections is not included in the performance measures. MHLW will discuss with FDA necessary steps for facilitating Japanese GMP inspections of U.S. manufacturing facilities. MHLW will ensure that PMDA discusses with industry, including U.S. industry, administrative procedures for such inspections.
16. On July 1, 2003, MHLW implemented full use of a common format (the CTD) for NDAs, and MHLW will ensure that PMDA continues to use this policy. MHLW will ensure that PMDA refrains from requesting summaries or documents exceeding the scope agreed at ICH.

17. MHLW will use, within the confines of Japanese law, the common format for medical devices (the STED), which is now in a pilot phase, from April 1, 2005.
18. MHLW will ensure that PMDA continues to discuss with industry as it develops guidance documents for medical devices, including imaging medical equipment, and in-vitro diagnostics.
19. As part of the postmarketing safety reform under the PAL, the In-Country Caretaker system for medical devices is scheduled to end on March 31, 2005. To inform companies of this change, the U.S. Embassy and MHLW held a seminar for In-Country Caretakers on March 25, 2004. MHLW will continue to exchange views with industry regarding the implementation of the revised PAL.

C. Blood Products

1. MHLW will continue to ensure that implementation of the Supply and Demand Plan does not discriminate against foreign products and is fully consistent with Japan's international trade obligations.
2. MHLW will work actively with interested parties, including industry, to ensure that doctors and patients receive accurate information about the risks and benefits of various therapies, including those involving blood products. In CY2004, MHLW will bring together all interested parties to discuss relevant concerns such as patient care, declining demand, and other issues.
3. In order to ensure smooth operation of the regulations on blood and blood products, MHLW will continue to hear opinions of interested parties and provide information to the United States at the meetings of the Working Group on Medical Devices and Pharmaceuticals and through other means.

D. Nutritional Supplements

1. The Japanese Market Access Ombudsman Council has recommended the liberalization of the food additive market. MHLW responded by undertaking a scientific study of 46 food additives. MHLW will consider approving additional additives that are widely used internationally and whose safety has been verified by the Joint FAO/WHO Expert Committee on Food Additives.
2. MHLW will use scientific data when making regulatory decisions on nutritional supplements.
3. By holding open discussion meetings, MHLW has provided opportunities for industry to express views on how to organize the system for health foods including

nutritional supplements. MHLW will continue to provide industry with meaningful access to consultations regarding nutritional supplement regulations.

- E. **Special Zones for Structural Reform:** The Government of the United States supports the Special Zones for Structural Reform initiative. MHLW will study the feasibility of special zones for structural reform proposals regarding medical devices and pharmaceuticals, if such proposals are made, on the premise that health and hygiene standards will not be jeopardized.

V. FINANCIAL SERVICES

- A. In a step toward global best practice, members of the Investment Trusts Association came into compliance over FY2003 with new guidelines for disclosure of investment performance. These guidelines include clarification of the relevant benchmark, comparison with the benchmark in graphs, and explanation for deviations from the benchmark. The guidelines also cover the use of clear, simple language and the provision of contact information for investor inquiries.
- B. With a view to supplementing the public pension system, so as to secure sufficient income for the aging population, the Government of Japan decided to raise contribution limits of Defined Contribution (DC) Pension Plans in FY2004 from 432,000 yen to 552,000 yen per year for employees benefited by only a DC pension system, and from 216,000 yen to 276,000 yen per year for employees benefited by other company pensions. The contribution limit for private DC pension plans for employees for whom the companies do not provide any company pensions will also be raised from 180,000 yen to 216,000 yen per year.
- C. The Government of Japan understands the Government of the United States request to remove barriers to electronic commerce. The Government of Japan will continue careful deliberations on whether or not to allow e-notification under the Money Lending Business Law.
- D. The Financial Services Agency (FSA) has made more active use of its No-Action Letter (NAL) system over the past year. Moreover, it has taken a number of steps and is considering additional measures designed to enhance the usefulness of the NAL system. These actions represent continued progress in enhancing the transparency of Japan's financial regulatory regime.
 - 1. The number of FSA no-action letters issued has increased recently, with nine NALs issued since April 2003, compared to just four issued during the first two years in which the FSA's NAL system was in place.
 - 2. The FSA has also undertaken a review of its NAL system, following the March 2004 Cabinet Decision. The FSA will take the following steps to enhance the

effectiveness of its NAL system and increase the number of NAL requests, including:

- a. Continuing to make efforts to inform financial market participants that they can seek clarification of Japan's financial laws and regulations via the FSA's NAL system.
 - b. Announcing that groups of firms and/or industry associations – including international groups such as the American Chamber of Commerce in Japan and IBA, as well as domestic industry associations such as the JSDA or JBA – can submit NAL requests on behalf of specific firms.
 - c. Amending the bylaws of its NAL system: (i) to clarify that the FSA will not issue a NAL finding if the individual or firm withdraws its NAL request and asks the FSA not to issue a NAL; and (ii) to require future NALs to include language clarifying the legal or regulatory basis of the finding expressed in the NAL.
3. The FSA remains open to suggestions from the Government of the United States and members of the financial community as to how best to enhance its NAL system and other efforts to increase the transparency of financial regulation in Japan.

VI. COMPETITION POLICY

A. Deterrence of AMA Violations and Strengthened JFTC Enforcement Powers

1. The Study Group on Reviewing the Antimonopoly Act, held by the Japan Fair Trade Commission (JFTC) since October 2002, issued a report in October 2003 on the results of its review of the Antimonopoly Act (AMA). The JFTC published the "Outline of Amendment to the AMA" in December 2003 based on the Study Group report and the public comments that were filed thereon. After further consideration, the JFTC, on May 19, 2004, completed the proposal to amend the AMA. The Government of Japan will make every effort to submit the bill to the Diet this year. The proposed amendments include:
 - a. Approximately doubling the surcharge rates applicable to enterprises that engage in certain violations of AMA Section 3 from the current rate of e.g. 6 percent for large firms;
 - b. Further increasing the surcharge rate by another 50 percent for firms that were assessed another surcharge payment order within the last ten years;
 - c. Lengthening the cap on the maximum period of sales on which surcharges will be assessed to four years, from the current maximum of three years;

- d. Enlarging the scope of conduct subject to surcharge orders to include (i) private monopolization or restraints of trade concerning the price, volume of supply, market share or customers of particular goods or services, and (ii) purchasing cartels;
 - e. Introducing a leniency program whereby, before the commencement of the investigation conducted by the JFTC, the first qualifying company would be immune from assessment of surcharge and the second qualifying company would receive a 50 percent reduction in the surcharge amount. After the commencement of the investigation, the first or second qualifying company would receive a 30 percent reduction in the surcharge amount. The total number of companies eligible to apply for the leniency program is limited to two.
 - f. Introducing compulsory measures by the JFTC for criminal investigations;
 - g. Extending the statute of limitations for the JFTC to issue cease and desist orders to three years after the termination of the violating conduct; and
 - h. Raising the maximum criminal fine for violating cease and desist orders of the JFTC from 3 million yen to 300 million yen.
2. In addition, the JFTC will announce that under the new leniency program the first qualifying company before the commencement of the JFTC's investigation will not be the subject of a criminal accusation by the JFTC.
3. The Government of Japan is committed to strengthening criminal enforcement of the AMA through further enhancement of close cooperation between the Public Prosecutors Office and the JFTC for effective implementation of the criminal provisions of the AMA. In this regard:
- a. In July 2003, JFTC filed a criminal accusation against four companies and five individuals for bid rigging on water meter procurement contracts by the Tokyo Metropolitan Government. All companies and individuals were found guilty by the court. The companies were sentenced to pay criminal fines of 20-30 million yen (approximately \$175,000-\$260,000). The prosecutors recommended sentences on the individuals of 12-14 months of jail time. The court imposed jail sentences on the individuals of 12-14 months, but suspended the execution of the sentences, with three years probation.
 - b. The JFTC will enhance its efforts to gather information on and to investigate alleged AMA violations, and will actively implement the criminal provisions of the AMA when the JFTC finds concrete facts of

violations. In this course, the JFTC will also exchange information and views with the Public Prosecutors Office in a manner adequate to facilitate the filing of criminal accusations.

4. With respect to merger review, the JFTC aims at further improving its economic analysis ability by making use of post-graduate level economists, and published and will continue to publish the results of individual cases in which it has conducted a detailed examination.
5. The JFTC established the “Competition Policy Research Center” in the General Secretariat in June 2003 and has been making efforts to enhance the economic analysis ability of its officials through joint studies with outside experts. The Center released four reports based on such joint studies with visiting researchers in FY2003.

B. Eliminating Bid Rigging: The Government of Japan is committed to dismantling the bid rigging system in Japan and eliminating bid rigging on all central government, government-related entity and local government contracts. To this end, and with the purpose of deterring and penalizing companies that engage in bid rigging:

1. In September 2003, Ministry of Land, Infrastructure and Transport (MLIT) strengthened its measures on suspension of designation of contractors that engage in illegal activities, including bid rigging. Under those strengthened measures:
 - a. Companies that engage in bid rigging will be subject to nationwide suspension of designation by MLIT and all of its Regional Development Bureaus if top executives or members of the board of directors of the company were complicit in the bid rigging activities, regardless of whether the bid rigging was on projects let by MLIT, other central government agencies, public corporations or local governments;
 - b. The maximum term of suspension of designation for a company that engages in bid rigging in violation of the Antimonopoly Act was extended from 9 months to 12 months.
 - c. Within the term mentioned in subparagraph b above, the term of suspension of designation that is actually imposed on a company that engages in bid rigging will be made more severe in cases where (i) the bid rigging involved “government-led bid rigging” (*kansei dango*), and the company tried to induce public procuring entities to be complicit in the bid rigging in violation of the Bid Rigging Involvement Prevention Act, or (ii) the bid rigging was the subject of whistleblowing, and the company clearly denied the allegations of bid rigging by the whistleblower, although it, in fact, had committed the bid rigging.

2. In June 2003, MLIT introduced a new contract clause to be used in all MLIT construction and design/consultation services contracts. It specifies pre-established damages equal to 10 percent of the contract price that must be paid by its contractors that commit bid rigging in order to compensate MLIT for the damages caused by the bid rigging.
3. In June 2003, MLIT published the measures that it took to prevent the Economic Research Association and the Construction Research Institute from engaging in or repeating bid rigging. MLIT has taken measures mentioned above to prevent recurrence of bid rigging by those organizations.

C. Promoting Competition in Industries Undergoing Deregulation

1. With respect to the importance of promoting regulatory reform and competition policy in an integrated manner, the Three-Year Program for Promoting Regulatory Reform provides that:
 - a. In order to introduce competition in regulated sectors in which new entry has been limited, the JFTC will continue to conduct surveys on the status of competition in these sectors from the viewpoint of promoting competition when policy recommendations are necessary, and will actively make proposals when there is room for improvement. For these regulated sectors, the regulatory agencies and the JFTC will consider a mechanism under which they can work together on the establishment and review of systems concerning competition, and will make related guidelines as necessary.
 - b. A system will be introduced to convey to the Council for Promotion of Regulatory Reform the reports and recommendations by the JFTC to relevant Ministries concerning the promotion of competition in regulated sectors. The Council will follow-up on the status of consideration of such recommendations.
 - c. In view of the indivisibility of regulatory reform and the promotion of fair competition, the Council for Promotion of Regulatory Reform and the JFTC will continue to maintain close cooperation.
2. The JFTC endeavors to have the perspectives of competition policy fully reflected in the design of new regulatory systems by participating in study groups convened by the Ministry of Economy, Trade and Industry (METI) and the Ministry of Public Management, Home Affairs, Posts and Telecommunications (MPHPT) and by explaining its viewpoint on competition in relevant sectors. In particular, in the past year, the JFTC attended study groups on the electricity and gas sectors.

3. The JFTC has been active in preparing guidelines to clearly identify the conduct that may violate the AMA in regulated sectors.
 - a. In April 2004, the JFTC and MPHPT published draft revisions to the Guidelines Concerning the Promotion of Competition Policy in the Telecommunications Business Field, and requested public comments. The final revised guidelines are expected to be published this summer;
 - b. In light of the amendments to the Electric Utilities Industry Law that will take effect on April 1, 2005, the JFTC and METI have been working to revise the “Guidelines Concerning Appropriate Electric Power Dealings;” and
 - c. In addition, the JFTC and METI have been working to revise the “Guidelines Concerning Appropriate Dealings in the Natural Gas Sector.” JFTC and METI will publish the draft revisions for public comment.
4. For the promotion of regulatory reform, the JFTC has been holding the “Study Group on Government Regulations and Competition Policy” and conducting surveys and reviews on regulatory problems and directions of improvement of regulations from the viewpoint of competition policy.

D. JFTC Resources

1. The JFTC received an increase of 35 persons in its staff for FY2004, resulting in a total staff of 672 as of March 31, 2005.
2. The JFTC has aimed to enhance the professional knowledge and ability of its staff through training and on-the-job experience, and has been endeavoring to recruit experts from various fields, such as law, economics and telecommunications.

VII. TRANSPARENCY AND OTHER GOVERNMENT PRACTICES

A. Furthering the Promotion of Regulatory Reform

1. The Government of Japan adopted a Cabinet Decision on March 19, 2004 entitled “The Three-Year Program for the Promotion of Regulatory Reform” (new Three-Year Program) comprising 762 regulatory reform measures. In addition, on April 1, 2004, the Government of Japan established The Council for the Promotion of Regulatory Reform (CPRR) to replace the Council for Regulatory Reform (CRR), whose mandate expired on March 31, 2004. Both steps demonstrate the Government of Japan’s continued strong commitment to structural reform, including regulatory reform.

2. The Government of Japan has implemented approximately 5,000 regulatory reform measures in a wide range of fields by establishing and promoting three successive reform programs prior to the new Three-Year Program. Building on past achievements, the new Three-Year Program is a compilation of measures to further accelerate structural reform of the Japanese economy and society and details specific regulatory reform steps that have been identified as the issues to be addressed from FY2004 to FY2006. The new Three-Year Program includes measures that will contribute to the following:
 - a. Significantly reduce the Central Government's involvement in sectors of the economy that can function more effectively without government involvement;
 - b. Revitalize the Japanese economy by spurring new business, increasing demand, and expanding employment; and
 - c. Create new opportunities for domestic and foreign businesses to build markets in Japan that will increase consumer welfare.
3. On April 12, Prime Minister Koizumi expressed his high expectation that the CPRR will be a central body that promotes regulatory reform, including the opening of governmental sectors for the participation by the private sector, for improved consumer welfare and revitalization of the economy. In this new structure, four of the CPRR's members will attend meetings of the Headquarters for the Promotion of Regulatory Reform and will have enhanced opportunities to directly interact with the Cabinet to discuss the CPRR's reform recommendations. The CPRR will also closely coordinate with the Council on Economic and Fiscal Policy, which submitted the Basic Policy on Economic and Fiscal Management and Structural Reform to the Prime Minister on June 3, 2004 (the Basic Policy was adopted by Cabinet Decision on June 4, 2004), as well as with the Headquarters for the Promotion of the Special Zones for Structural Reform. The CPRR will also monitor the implementation of the new Three-Year Program and has the mandate to require, when it deems necessary, the heads of relevant governmental organizations to submit materials, provide explanations, and extend cooperation to the CPRR.
4. On May 25, the Cabinet decided to establish the Headquarters for the Promotion of Regulatory Reform, which decided on the "Basic Policy for the Promotion of Regulatory Reform" on the same day. The Headquarters, headed by the Prime Minister and composed by all Ministers, will endeavor to ensure the implementation of the new Three-Year Program, and revise it in March 2005 based upon the reports to be made by the CPRR. The Headquarters also provides the CPRR with sufficient opportunities to work together closely, including those of

attending meetings of the Headquarters, as mentioned above, as well as of having discussions focused on specific topics with relevant Ministers.

B. Public Comment Procedures

1. As reaffirmed by the new Three-Year Program for the Promotion of Regulatory Reform, Japanese Ministries and Agencies continue to use the Public Comment Procedure (PCP) in order to improve transparency and to ensure fairness in the decision making process in the establishment, revision, and abolition of regulations. The Three-Year Program decided by the Cabinet on March 19, 2004, also provides for numerous reform measures to improve the PCP in FY2004, including:
 - a. The PCP period should be 30 days in principle, and in exceptional cases where less than 30 days are provided, Ministries and Agencies must make public the reason for this determination to shorten the period;
 - b. In cases where public comments are not incorporated, Ministries and Agencies should make public detailed explanations for these decisions;
 - c. Regulatory proposals subject to the PCP should include Regulatory Impact Analyses (RIAs) as often as possible;
 - d. The Government of Japan is studying the incorporation of the PCP into the Administrative Procedure Law;
 - e. Ministries and Agencies should make public, as much as possible, on their websites the entire texts of comments and information submitted by the public; and
 - f. The Ministry of Public Management, Home Affairs, Posts and Telecommunications (MPHPT), will undertake improved reviews of the implementation and effectiveness of the PCP to, for example, ensure comments are fully taken into account, and as appropriate, incorporated into final regulations.
2. MPHPT continues to conduct and publish an annual survey on the implementation of the PCP, and will maintain close communications with relevant Ministries and Agencies in this regard.
3. In January 2004, MPHPT improved the web portal of the Government of Japan (www.e-gov.go.jp/) so as to allow the public to more easily find PCP solicitations for draft rules and regulations.

C. **Special Zones for Structural Reform:** Prime Minister Koizumi and his Administration continue to make the Special Zones for Structural Reform a priority component of Japan's economic revitalization plan. Since the approval of the first 57 Special Zones in April 2003, the total number of zones has grown to 324. The Government of Japan is taking necessary steps to ensure that successful zones have the largest economic impact on the greater Japanese economy. To this end, the Government of Japan is:

1. Operating the entire application and regulatory exemption process for the Special Zones in a transparent manner;
2. Working to expand market-entry opportunities in the Special Zones;
3. Ensuring domestic and foreign companies alike have non-discriminatory access to operate in the zones;
4. Applying successful regulatory exemptions in the Special Zones on a national basis as expeditiously as possible;
5. Ensuring opportunities for U.S. and other foreign companies to submit proposals for regulatory exemptions for Special Zones and to make proposals to local municipalities to establish Special Zones; and
6. Ensuring the Evaluation Committee for the Special Zones undertakes the following in determining which regulatory exemptions in the Special Zones should be applied nationwide.
 - a. Ensure transparent decision-making process through open meetings and publicly available information to determine nationwide regulatory exemptions; and
 - b. Publication of the decisions and supporting information on evaluations after the decisions are made so that all interested parties can fully understand the evaluation process.

D. **Public Input Into the Development of Legislation:** Some Ministries and Agencies, at their discretion, have been opting for public input into draft legislation during its development, before it is submitted to the Diet.

1. A law revising the Insurance Business Law to introduce the new Life Insurance Policyholder Protection Corporation (PPC) went into effect on June 8, 2003. The Insurance Working Group of the Financial Systems Council in May 2004 began discussions on the review of the Life Insurance PPC and the Non-Life Insurance PPC systems.

2. The Government of Japan will continue to provide interested parties with meaningful opportunities to be informed of, comment on, and exchange views with officials on proposed amendments to the Insurance Business Law and/or other existing laws and regulations related to the Life and Non-Life PPCs. These opportunities would include actively contributing to the deliberations, to be finalized by the end of FY 2005, on reforming the Life PPC, including conveying opinions as appropriate for future deliberations of the Financial Systems Council and its working groups, which will continue to act as the focus of discussions on PPC review.

E. Privatization of Public Corporations

1. On December 19, 2001, the Cabinet adopted the “Reorganization and Rationalization Plan for Public Corporations.” In implementing this Program, by the end of 2003, the Government of Japan conducted necessary measures (amendment of relevant laws, etc.) to organizationally reform 127 of the 163 public corporations subject to the Program.
2. The Government of Japan remains committed to the continued restructuring and privatization of Japan’s public corporations and will continue to undertake this process in a transparent manner.
3. Established by the Government of Japan, an advisory committee consisting of well-informed experts from the private sector to monitor and evaluate the implementation of the Program has met 27 times since its launch in July 2002. The summaries of the minutes of those meetings and discussion papers have been made public.

F. Postal Financial Institutions

1. The Government of Japan is aware that the Government of the United States has expressed its strong concern to the Government of Japan regarding the differences between *Kampo* and private insurance companies, and has stressed the importance of establishing a level playing field in which all participants are subject to the same regulatory, legal, and tax requirements. The Japan Post Law and Japan Post Law Enforcement Law bring *Kampo* inspection and taxation requirements closer to those of private life insurance companies than they were in the past. The Ministry of Public Management, Home Affairs, Posts and Telecommunications (MPHPT) will continue to provide opportunities for private life insurance and other financial companies, upon request, to exchange views with MPHPT officials on *Kampo* and *Yucho* inspection and taxation requirements. Discussions on topics relating to the differences between *Kampo* and the private sector will be conducted in the Council on Economic and Fiscal Policy within the context of the privatization of Japan Post. The Government of Japan furthermore is aware that the Government of the United

States has requested that no new or altered *Kampo* products should be introduced until a level playing field is established between *Kampo* and private sector companies. The Government of Japan confirms that Japan Post now has no plans to introduce any new or altered *Kampo* products or riders.

2. With regard to the formulation of proposals to seek from the Diet amendments to law related to *Kampo* products and distribution or origination by Japan Post of non-principal-guaranteed investment products, MPHPT recognizes the importance of informing the general public of such formulation of proposals and will provide meaningful opportunities for private sector interested parties upon request to exchange views with MPHPT officials. Japan Post cannot originate any non-principal-guaranteed investment products, nor introduce new lending services not offered at present, as the Japan Post Law does not include any provisions describing these products or services.
3. In response to the strong concern raised by the Government of the United States over the introduction of a new *Kampo* product in January 2004, the Government of Japan has regularly provided the Government of the United States with data related to sales of this product, and will continue to provide information on the sales of this product upon request. The Governments of Japan and the United States will also continue to maintain communication on this subject.
4. The insurance products or riders underwritten or sold on consignment by Japan Post are offered pursuant to law. Approval from the Diet is required to expand or change the products or riders offered by Japan Post, except for limited alterations within the scope of the products or riders authorized by law.
5. Concerning the privatization of postal services, the Council on Economic and Fiscal Policy on April 26, 2004, issued a paper listing issues it considers necessary to discuss, and will continue discussions to complete its final report around the fall of this year. On the same day, Prime Minister Koizumi established the Office for Privatization of Japan Post in the Cabinet Secretariat. The Office will work on drafting legislation on postal privatization for submission to the Diet in 2005.
6. Steps have been taken to ensure transparency in the discussions on privatization by the Council on Economic and Fiscal Policy. The Minister of State in charge of Economic and Fiscal Policy holds a press conference on the outline of discussions of each meeting of the Council. In addition, the handouts and minutes of Council meetings are publicized on the website of the Cabinet Office. Moreover, to hear the circumstances of various districts and the views of the people there, Postal Privatization Local Meetings have been held. With regards to the discussions on and decisions relating to the privatization of Japan Post, the Government of Japan recognizes the importance of informing the general public of such information. In the process of privatization, MPHPT and the newly created Office for Privatization

of Japan Post will also provide in a timely manner meaningful opportunities for private sector interested parties upon request to exchange views with relevant officials, including on the potential impact of the Government of Japan's decisions on private sector companies in the market.

- G. **Insurance Cooperatives:** On April 15, 2004, the Insurance Working Group of the Financial Systems Council started discussions regarding unregulated *kyosai* which are currently operating without the benefit of regulatory oversight. The Government of Japan will seek opinions broadly in the process of the discussions.
- H. **No-Action Letter:** In a March 2004 Cabinet Decision, the Government of Japan broadened the scope of its No-Action Letter (NAL) Procedures. The Cabinet Decision clarified that firms in all industries subject to government regulation may seek written clarification of those regulations, not merely firms in "new industries such as IT, finance, etc."

VIII. LEGAL SERVICES AND JUDICIAL SYSTEM REFORM

A. Legal Services

1. Freedom of Association

- a. In July 2003, the Diet enacted an amendment to the Special Measures Law Concerning the Handling of Legal Business by Foreign Lawyers (*Gaiben Law*) that introduced completely new mechanisms regarding the association between Japanese lawyers (*bengoshi*) and registered foreign lawyers (*gaiben*), including lifting the ban on employment of *bengoshi* by *gaiben*, abolishing the specified joint enterprises (*tokutei kyodo jigyo*) system and establishing joint enterprises between *bengoshi* and *gaiben* (*gaikokuho kyodo jigyo*) (GKJ), through drastic deregulation based upon a fundamental revision of the existing systems.
- b. The amended *Gaiben Law* provides that the Law shall come into force on the day designated by government ordinance within two years from the promulgation of the Law (July 25, 2003), to enable completion of necessary preparatory measures, including the adoption of necessary new rules and regulations by the Japan Federation of Bar Associations (*Nichibenren*). The Government of Japan will decide the actual effective date of the amended Law after consulting with *Nichibenren* about the need for new rules and regulations and the time it will take to complete necessary work.
- c. *Nichibenren* has begun the process of drafting rules and regulations for the implementation of the new amendments, including regulations concerning the employment of *bengoshi* by *gaiben* and concerning GKJ. The

Government of Japan actively supports the provision to *gaiben* by *Nichibenren* and the local bar associations of full and effective opportunities to participate in the formulation of such proposed rules and regulations, including by permitting them to attend all relevant meetings and proceedings of *Nichibenren* and the local bar associations and to express their views on the proposed rules and regulations.

- d. The Ministry of Justice (MOJ) has been making efforts to seek *Nichibenren's* correct understanding of the amended law and the appropriate handling of related procedures in bar associations through consultations with *Nichibenren* so that *Nichibenren* will make its rules and regulations consistent with the fundamental idea and interpretation of the amended *Gaiben* Law.

2. Professional Corporations and Branches: Concerning the establishment of *gaiben* professional corporations which are able to establish branch offices, MOJ has conducted a preliminary study of the issue and has decided to study whether *gaiben* should be permitted to form professional corporations from the standpoint of trends in the needs for international legal services in Japan and for the actual operation of GKJ, the experience of the *bengoshi* professional corporation system and principles of non-discrimination.

B. **Judicial System Reform**

1. The Government of Japan submitted a bill to amend the Administrative Case Litigation Law to the ordinary session of the Diet in March 2004. This bill addresses the following broad points with regard to judicial review of administrative actions:
 - a. Enlarging the scope of remedy, including the expansion of standing for third parties;
 - b. Consolidating and speeding up of administrative litigation;
 - c. Making administrative litigation easier to use and to understand; and
 - d. Providing relief pending review in advance of judgment on the merits.
2. The bill sets out considerations that the court must use in determining whether third parties other than the person at whom the administrative disposition was aimed have the requisite legal interest for standing. This provision requires the court to consider not only the wording of laws and regulations on which an administrative disposition is based, but also the intention and purpose of the laws and the content and nature of the interest which should be considered in the administrative

disposition. In these considerations, the courts are also directed to consider the intention and purpose of other related legislation with common purposes, the content and nature of the interest which would be harmed if the administrative disposition is in breach of authorizing law, how the interest will be harmed and the severity of the injury, in determining whether standing requirements are satisfied. The Government of Japan expects that, through these provisions, standing will be in substance broadly construed.

IX. COMMERCIAL LAW

A. Adoption of Modern Merger Techniques

1. The Corporate Law Committee of the Ministry of Justice's Legislative Council is currently discussing the modernization of Japanese corporate law. A preliminary outline of the bill to modernize Japan's corporate law, which included the introduction of modern merger techniques, was published for public comment on October 29, 2003. In particular, the preliminary outline included provisions that would introduce flexibility in merger currency so as to allow for the use of triangular mergers, cash mergers and share exchanges using foreign shares, and also included provisions to permit short form (squeeze out) mergers. Based on the results of the discussions of the Corporate Law Committee, and taking into account the comments received on the preliminary outline, the Government of Japan intends to submit legislation to modernize Japan's corporate law, including with respect to the introduction of modern merger techniques, during the next regular session of the Diet in 2005.
2. The Government of Japan is studying ways to facilitate corporate restructuring and investment in Japan, including tax treatment of modern merger techniques in line with the decision made by Japan Investment Council in March 2003.
3. In the past year, two foreign companies, through their Japanese subsidiaries, were able to take advantage of the exceptions to the Commercial Code allowed by the Revised Special Measures Law for Industrial Revitalization (IRL) to effect a take-over of a Japanese company using an equity-swap/merger mechanisms with cash consideration. METI will continue to review corporate restructuring techniques and the trend of mergers conducted under the IRL, and will study impediments to using modern merger techniques in Japan.

B. Promoting Shareholder Value through Active Proxy Voting

1. Pension Funds: The Government of Japan recognizes the important role of active shareholder voting in strengthening corporate governance and shareholder value to the benefit of the beneficiaries of pension funds. In this light, the Government of Japan supports the promotion of proxy voting by managers of public and private

pension funds as a mechanism for increasing investment returns to pension funds, and has taken the following actions in this regard:

- a. In 2001 the Minister for Health, Labour and Welfare (MHLW) issued the Basic Policy for pension fund managers of the Government Pension Insurance Fund (GPIF). That Basic Policy encourages GPIF outside pension fund managers to exercise their voting rights to improve shareholder value.
- b. GPIF has issued general guidelines applicable to all of its pension fund managers requiring them to exercise proxy voting rights to maximize shareholder value and to report to GPIF annually on their actual record of proxy votes. GPIF makes public the record of proxy voting reported by each of its fund managers. Each fund manager, in turn, has prepared their own internal policies regarding how proxy voting rights will be exercised, and these policies are reported to MHLW. MHLW will study whether to make public the proxy voting policies of each fund manager.
- c. In 2003, the Pension Fund Association, a government-related organization (*ninka hojin*) established under the Employee Benefit Law that manages 8 trillion yen in pension fund assets, issued detailed proxy voting guidelines for its internal and outside fund managers and is working to integrate the individual proxy voting guidelines adopted by each fund manager. In addition, the Local Government Official Pension Fund (*chikyoren*) recently issued proxy voting guidelines that its fund managers must follow, and the Central Government Official Pension Fund (*kokkyosai*) is considering whether to adopt such guidelines as well.
- d. With regard to private pension funds, the scope of the fiduciary duties of fund managers under the Employees Pension Insurance Law is developing under the law. The Government of Japan supports the continued development of fiduciary duties for pension fund managers with respect to the exercise of proxy voting rights.

2. Mutual Funds:

- a. The Government of Japan supports the promotion of proxy voting by mutual fund and investment trust managers as a mechanism for increasing corporate value. In 2003, the Investment Trust Association, a self-regulatory association established under the Investment Trust Law and under the jurisdiction of the Financial Supervisory Agency (FSA) and composed of virtually all mutual fund companies in Japan, has promulgated rules on proxy voting which must be followed by member mutual fund and investment trust managers. Those rules require member companies to

disclose their proxy voting policies, including the objectives and basic stance of the company with regard to proxy voting, the decision making process on exercising proxy voting rights and the screening criteria used in determining how the proxy voting rights will be exercised.

- b. FSA will encourage the Investment Trust Association to amend their rules on proxy voting to also require members to publicly disclose their actual proxy voting record.

C. Promoting Good Corporate Governance through Protection of Whistleblowers:

Based on the report released by the Consumer Policy Committee of the Quality-of-Life Policy Council, the Government of Japan submitted the Whistleblower Protection Bill to the Diet on March 9, 2004. The bill provides civil remedies to protect employees who blow the whistle for public interests from dismissal or mistreatment, provided that certain requirements are met. The bill covers whistleblowing on crimes or violations concerning laws and ordinances related to human life, health, and property, which include violations of the Securities and Exchange Law. As a result, employees who blow the whistle on fraudulent misrepresentations to shareholders or other unlawful practices under securities laws that may interfere with corporate governance or shareholder oversight will be protected against termination or other retaliation by their employers.

D. Alternative Dispute Resolution

1. The Government of Japan recognizes that alternative dispute resolution (ADR) mechanisms can play an important role in helping individuals and businesses resolve disputes in an efficient and economical manner. The Government of Japan will continue to study, through the Consultative Group of Experts for the Study of ADR under the Office for Promotion of Justice System Reform, ways to strengthen and revitalize ADR in Japan so that it will become an attractive alternative to court litigation as a measure of dispute settlement. The Government of Japan has as its goal the creation of a flexible and open legal environment that facilitates the development of ADR services including those operated by the private sector and will take steps to provide the necessary infrastructure for ADR in that regard as soon as possible.
2. The Government of Japan noted the recommendations of the Government of the United States regarding ADR, including allowing non-lawyers to act as neutrals in ADR proceedings and not adopting any mandatory certification system for organizations or individuals offering ADR services. The Government of Japan indicated that consideration is being given to such matters.

X. DISTRIBUTION

A. Landing and Airport Fees

1. The Government of Japan expressed its views on the concerns held by the Government of the United States regarding reduction of landing fees at Narita and Kansai International Airports.
 2. In accordance with the bill passed by the Diet in July 2003, the New Tokyo International Airport Authority was transformed in April 2004 into the Narita International Airport Corporation, a special company currently wholly owned by the Government of Japan, as a means to achieve full-privatization in the future.
 3. During discussions with the Government of the United States, the Government of Japan outlined the mid-term management plan made by the Narita International Airport Corporation, which aims to reduce landing fees as soon as possible, following a thorough assessment of the Corporation's business conditions.
- B. **Airfares:** The Government of Japan expressed its views on the concerns of the Government of the United States regarding airlines sales distribution and double disapproval pricing.
- C. **Further Reduce Overtime Charges in International Physical Distribution Special Zones:** The 50 percent reduction in overtime charges within the International Physical Distribution Special Zones in April 2003 increased the competitiveness of Japan's international ports. The Government of Japan subsequently decided to reduce overtime charges nationwide by 50 percent as of April 1, 2004. Japanese consumers and businesses now benefit from an overtime rate in the International Physical Distribution Special Zones that is only 25 percent of the rate charged before April 2003. These decisions are a positive signal to international markets that Japan continues to operate as an important trans-shipment hub for air and sea distribution. The Government of the United States highly appreciates this progress.
- D. **Nippon Automated Cargo Clearance System (Air-NACCS):** A third party panel, comprised of domestic and foreign interests, is reviewing Air-NACCS pricing and is drafting a report on NACCS user fee reforms, on which the Government of the United States noted its appreciation. The NACCS Operating Center intends to post the panel's recommendations on its web site (www.naccs.go.jp) in June or July of this year, and intends to invite public comment for a user fee reform draft reflecting the recommendations. The report is expected to improve the Air-NACCS fee system for all users, further advancing Japan's air customs clearance process.
- E. **Interline Contracts:** In the course of the third year of the Regulatory Reform Initiative, the Government of Japan explained to the Government of the United States that door-to-door air transport service is available by interline contracts between Japanese and foreign carriers, and that there are no governmental regulations on this business activity.

F. **Credit/Debit Cards**

1. The Government of Japan took note of the request from the Government of the United States to promote the use of credit and debit cards as means of payment for government services. The Government of Japan also noted that, for instance, approximately 100 hospitals belonging to the National Hospital Organization have declared their intention to accept credit/debit card payments, some of which have already started to accept them and others are now under preparation.
2. The Government of Japan recognizes the importance of maintaining a sufficient level of security standards in ATM networks for banks in Japan. The Government of Japan also noted that hosts of banks' ATMs decide encryption standards for their networks, including complying with international PIN security and encryption standards.
3. The Credit Authorization Terminal (CAT) system, which is promoted by the initiative of the Japan Credit Card Association (JCCA) to be placed at member stores, is specified to accept credit cards issued overseas. The total number of installed CATs is increasing steadily, and there are approximately 950,000 units throughout Japan. The installation of these terminals is a step toward improving the environment for the use of foreign credit cards.
4. The National Police Agency (NPA) is tightening regulations related to credit/debit card fraud in Japan. NPA is reinforcing cooperation with customs and immigration authorities and credit and debit card issuers and merchants to prevent smuggling and use of "raw" cards into Japan, which do not carry any personal information and could be used as materials for false cards, as well as illegal entry of criminal groups.

**REGULATORY REFORM AND OTHER MEASURES BY
THE GOVERNMENT OF THE UNITED STATES**

I. CROSS-SECTORAL ISSUES CONCERNING REGULATORY REFORM AND COMPETITION POLICY

A. Consular Affairs

1. Biometric Identifiers on Passports:

- a. The Department of Homeland Security (DHS) and Department of State have asked Congress to pass legislation that would extend until November 30, 2006 the deadline for Visa Waiver Program (VWP) countries to have machine readable passports that include biometric identifiers, and also for DHS to have readers for these biometric passports at all ports of entry.
- b. Concurrently with this request, DHS announced that it will begin processing visitors traveling under the VWP in US-VISIT beginning by September 30, 2004 at air and sea ports of entry. US-VISIT requires that most foreign visitors traveling to the United States on a visa and arriving at an air or sea port have their two index fingers scanned and a digital photograph taken to verify their identity at the port of entry. By September 30, 2004, this process will also apply to visitors traveling under the VWP at all air and sea ports of entry and will be expanded to land border ports of entry as US-VISIT is deployed to those locations. Since January 5, 2004, the Government of the United States has been making efforts to ensure Japanese citizens traveling to the United States with visas, who are subject to US-VISIT requirements, could enter the United States without significant delays or difficulties and will continue to do so.
- c. The National Institutes of Standards and Technology (NIST) recommended, and the Secretary of Homeland Security and the Secretary of State have approved, the use of fingerscans in addition to digital facial image as the biometrics that will be used in the US-VISIT system for U.S.-issued travel documents. The biometric requirements for US-VISIT differ from the International Civil Aviation Organization (ICAO) recommendations in that US-VISIT will utilize both digital facial image and fingerscans to verify identity and conduct appropriate checks. U.S. border security policy is under constant review and will be subject to continued review to ensure both the safety and security of the United States and the facilitation of international travel. In this regard, the Government of the United States will make further efforts to provide Japanese travelers with sufficient information in advance.

- d. The Government of the United States is working with and will continue to work with the Government of Japan to ensure that the Government of Japan's program for production of ICAO-compliant biometric passports will meet the requirements to remain in the VWP. The Government of the United States will work with the Government of Japan to test various technologies that will be used to produce and read these documents.
- e. The Government of the United States will continue to inform the Government of Japan on the status of legislation to extend the deadline for VWP countries to issue machine-readable passports that include biometric identifiers.

2. Collection of Biometric Information at Ports of Entry:

- a. The Government of the United States understands the Government of Japan's concerns about protecting the information of Japanese citizens obtained through the new biometric requirements. That information will be stored in databases maintained by DHS and the State Department as part of an individual's travel record. The system will be available to U.S. Customs and Border Protection Officers at ports of entry, special agents in U.S. Immigration and Customs Enforcement, adjudications staff at U.S. Citizens Immigration Services offices, and United States consular offices - and appropriate federal, state, and local law enforcement personnel. The program will be implemented in compliance with US-VISIT established privacy policies and our privacy impact assessment. Authorized officials will have access to the data for official business on a need-to-know basis. Safeguards have been implemented to ensure that the data is not used or accessed improperly. While the Government of the United States plans to retain this data for security purposes and to improve the efficiency of ports of entry, it fully understands the position of the Government of Japan that the data of an individual traveler should be erased upon his/her departure from the United States. In addition, the DHS privacy officer will review pertinent aspects of the program to ensure that proper safeguards are in place.
- b. The US-VISIT program's budget is \$330 million for FY2004, \$380 million for FY2003. These funds are primarily intended to cover technology acquisition and improvements. DHS has established processes to enable officers to obtain and process this information in an expeditious manner. While it has no plans for significant additional staff at this time, DHS will continue to monitor the situation at ports of entry to ensure that it has adequate human and physical resources to fully and efficiently implement US-VISIT as the program expands at the end of September 2004 to include

visitors traveling under the Visa Waiver Program (VWP), which will result in a substantial increase in the number of travelers going through US-VISIT.

3. Visa Process: The Government of the United States has taken a number of steps to improve visa processing in Japan and North America.
 - a. The Visa Branches at the U.S. Embassy in Tokyo and Consulate General in Osaka, the two largest U.S. visa-issuing offices in Japan, have adopted an improved, web-based appointment system, and allow applicants to apply at the visa branch of their choice. These measures have significantly reduced the visa processing backlog in Tokyo and Osaka.
 - b. The Department of State has added two new visa officers at the U.S. Embassy in Tokyo and three more will be added over the next several months. Osaka has added one visa officer and will add one more.
 - c. The Department of State currently exempts certain Japanese nationals in the H and L categories from personal interview requirements.
 - d. The new appointment system allowing appointments to be made up to three months in advance at the U.S. missions in Japan eases the difficulties of scheduling trips to Japan to renew visas. The Government of the United States reiterated to the Government of Japan that the applicant's legal status in the U.S. does not expire with the visa; therefore the applicant need only apply for a new visa when planning on traveling abroad. The U.S. Embassy has also upgraded its web site with more detailed information for visa applicants.
 - e. In order to allow applicants to plan their travel, the Department of State publicizes visa revalidation processing times on its website (www.travel.state.gov). This information is also available through the American Immigration Lawyers Association.
 - f. As an alternative, for efficient processing, Japanese citizens can also apply to renew their visas at U.S. embassies and consulates in Canada or Mexico. These embassies and consulates offer an appointment system through their websites, accessible at <http://www.nvars.com>.
4. Social Security Numbers:
 - a. The Social Security Administration (SSA) continues its dialogue with States concerning driver's license requirements. At this time it is the SSA's understanding that the State of Illinois is the only State that will not

substitute an alternative identifier for a Social Security Number (SSN) for driver licensing purposes. The SSA has informed the State of Illinois of its concern for the ability of some lawfully admitted non-citizens to obtain driver's licenses in Illinois.

- b. The Illinois General Assembly has passed HB 5320, which would enable Japanese citizens lawfully admitted to the U.S., and other lawfully admitted non-citizens, without work authorization, to get Illinois driver's licenses. Once implemented, the amended Illinois Vehicle Code Sec. 6-105.1 will provide as follows:
 - (1) The Secretary of State may issue a temporary visitor's driver's license to a foreign national who (i) resides in this State, (ii) is ineligible to obtain a social security number, and (iii) presents to the Secretary documentation, issued by United States Citizenship and Immigration Services, authorizing the person's presence in this country.
 - (2) A temporary visitor's driver's license is valid for three years, or for the period of time the individual is authorized to remain in this country, whichever ends sooner.
 - (3) The Secretary shall adopt rules for implementing this Section, including rules regarding the design and content of the temporary visitor's driver's license.
 - c. The SSA and the Department of Homeland Security (DHS) continue to work to improve the verification process for immigration status, which is required to issue SSNs to non-citizens. SSA and DHS are working to verify all cases electronically in place of paper verification.
 - d. The SSA is working to expand enumeration at entry (EAE) to include some nonimmigrant classes. Expanded EAE will alleviate many problems for nonimmigrants needing to work immediately upon arrival in the United States.
5. Permission to Stay: The Citizenship and Immigration Services Office of the Ombudsman (OCIS) within the Department of Homeland Security is exploring ways to improve the process of applying for extension of permission to stay. OCIS will continue to make efforts so that the processing period for applications to extend the period of permission to stay will be reduced for non-immigrant visa holders.

6. Driver's Licenses: According to an April 2004 report by the National Immigration Law center, 14 states now link visa and driver's license expiration dates. The Government of the United States will seriously consider the requests of the Government of Japan when formulating its position on this issue.

B. Distribution

1. Counterterrorism Measures in Maritime and Other Sectors:
 - a. The United States is working closely with numerous international organizations, including the World Customs Organization (WCO), in developing and refining guidelines, benchmarks, and best practices surrounding supply-chain security in order to ensure that robust internationally common and unified systems come to fruition.
 - b. The United States strives to be consistent with existing international practices where they exist. In cases where no internationally recognized practices exist, the United States works to develop, with international cooperation, new best practices.
 - c. The Government of the United States appreciates the Government of Japan's comments concerning requirements for advance electronic presentation of cargo information. The United States Bureau of Customs and Border Protection (CBP) is considering providing a grace period to allow companies to adjust after the advance manifest rules for air cargo are implemented in late summer or early fall 2004.
 - d. The CBP is currently developing the mechanism and strategy to enroll additional domestic and foreign supply chain sectors into C-TPAT. The intent is to construct a supply chain characterized by active C-TPAT links at each point in the logistics process.
 - e. The CBP will continue to work to ensure that C-TPAT members realize the benefits of the program.
 - f. The CBP appreciates the close cooperation of the Japanese Customs and Tariff Bureau, and all interested parties, on the implementation of the Container Security Initiative (CSI), and will continue to consult with those parties regarding CSI.
 - g. In 2004, the Automated Commercial Environment (ACE) program will experience the greatest amount of growth to date, providing significant capabilities to government and the trade community. In addition, coordination with other government agencies on ACE will intensify and

participation will grow. The current ACE development focus is on Periodic Payment and e-Manifest, which are scheduled for release in summer 2004 and winter 2005 for truck capabilities. Periodic Payment features provide centralized payment processing by account to allow for monthly periodic statement and payment capabilities. The e-Manifest feature will enable quicker entry for pre-filed and pre-approved cargo for trucks and will be delivered first to the seven busiest land border ports. The ACE will ultimately be delivered to all port, locations, and transportation modes.

2. Customs Liquidation: The Bureau of Customs and Border Protection will continue to discuss with the Government of Japan its concerns regarding the 314 day customs liquidation cycle.
3. Merchant Marine Act of 1920: The Government of the United States and the Government of Japan exchanged views regarding the Merchant Marine Act of 1920. The executive agencies of the United States will continue to consult and exchange information with the Government of Japan and will keep the Federal Maritime Commission (FMC) informed of the situation of Japanese ports.
4. Maritime Security Program: The Government of the United States took note of the request of the Government of Japan to abolish the Maritime Security Program.
 - a. The Maritime Security Program (MSP) is intended to ensure that an active U.S. merchant fleet and the trained personnel needed to operate both active and reserve vessels will be available to meet U.S. national and global security requirements for sealift capacity. On November 24, 2003, the President signed the National Defense Authorization Act for Fiscal Year 2004, which includes authorization of the Maritime Security Act of 2003 (MSA 2003), and a \$1.734 billion reauthorization of the MSP for 60 ships for fiscal years 2006 through 2015.
 - b. The Government of the United States will ensure that the Government of Japan be kept informed of the list of the dedicated vessels and any changes in the MSP. The Government of the United States believes the MSP is important to meet global security needs at this time.
5. Cargo Preference Measures: The Government of the United States and the Government of Japan exchanged views on Cargo Preference Measures, including the law requiring that the transport of Alaskan North Slope crude oil be done on U.S.-flag ships. The Government of the United States took note of the opinion of the Government of Japan that measures such as cargo preferences may distort conditions for free and fair competition in the international maritime market. With respect to these issues, the Government of the United States explained the following:

- a. United States Government-owned cargoes covered by cargo preference laws, including the transport of U.S. military cargo, represent less than one percent of the United States' total ocean borne foreign trades; and
 - b. The last Alaskan crude oil to be exported was in April 2000. Since that time all Alaskan crude oil production has moved to the U.S. West Coast market for refining and domestic consumption.
6. Ocean Shipping Reform Act of 1998: The Government of the United States and the Government of Japan exchanged views on the Ocean Shipping Reform Act of 1998. The Government of the United States took note of the concern of the Government of Japan.

C. Trade/Investment-Related Issues

1. The Federal Buy-American Act and Other Related Rules
 - a. The Government of the United States recognizes that the issue of Buy-American is important to the Government of Japan.
 - b. The bill referred to in the Government of Japan's submission was enacted as Public Law 108-136 on November 24, 2003. As passed, this law does not impose additional "buy national" requirements on the Department of Defense, and does not require application of any provision determined to be inconsistent with international agreements.
 - c. The Government of the United States emphasizes that the implementing regulations of the Federal Buy America Act provide that public interest and non-availability waivers may be granted for a component of rolling stock, and in such cases, the component would be treated as domestic when calculating the overall component content of the vehicle.
2. Anti-Dumping and Safeguard Measures:
 - a. The Government of the United States will ensure that its anti-dumping laws conform to its WTO obligations. In that regard, the Administration supports legislation that would repeal the Anti-Dumping Act of 1916 and bring relevant provisions of the Continued Dumping and Subsidy Offset Act into compliance with WTO recommendations and rulings. In addition, the Administration will continue to work closely with Congress on legislation to implement the WTO recommendations and rulings in the Hot-Rolled Steel dispute.

- b. The Government of the United States withdrew its steel safeguard measures on December 4, 2003.
3. Exon-Florio Provision: The Government of the United States recognizes the Government of Japan's concerns on the "Exon-Florio" clause regarding, inter alia, predictability of regulations, legal stability of completed transactions, and ensuring due process. In operating the clause, the Government of the United States is mindful of the Government of Japan's concerns, and will ensure the clause's consistency with WTO rules.
4. The Patent System of the United States: The Government of the United States and the Government of Japan reaffirm mutual support for effective substantive patent law harmonization efforts, and at the same time:
 - a. The Government of the United States will continue to discuss with the Government of Japan its concerns with the United States' first-to-invent patent system. The United States acknowledges that its first-to-invent system is unique, but despite its shortcomings the United States believes that the system has worked well in and for the United States. While there is some growing interest in first-to-file, this remains a controversial issue in the United States. The Government of the United States will continue to discuss with the Government of Japan its requests to modify the Hilmer Doctrine. The United States would like to note that this issue has been discussed in the ongoing substantive patent law harmonization talks at WIPO and was discussed in detail at the Trilateral Working Group on Patent Law Harmonization, which met at the United States Patent and Trademark Office in February 2004.
 - b. The Government of the United States will continue to consider the requests of the Government of Japan to ease requirements for the unity of invention. It should be noted that the United States is currently studying adoption of a Unity of Invention standard.
 - c. The Government of the United States will continue to discuss with the Government of Japan its requests regarding abolition of the exceptions to the publication of patent applications within 18 months from the filing date found in the U.S. early publication system. The United States hopes that its experience with the early publication system will reveal that the need for exceptions will be proven to be unwarranted. The Government of the United States, however, explained that, in the current political climate, any attempt to narrow or eliminate the exceptions would be unlikely to succeed.

- d. The Government of the United States will continue to consider the requests of the Government of Japan regarding further improvements of the reexamination system.
5. Metric System: The Government of the United States will continue measures to expand and increase the use of the metric system in the private sector and at the federal and local government level. In the meantime, the Government of the United States has taken the following interim measures:
- a. On November 6, 2003, the National Institute of Standards and Technology (NIST) at the Department of Commerce hosted a forum in Washington, D.C. to develop industry support for the update to the Fair Packaging and Labeling Act (FPLA). The industry support for the amendment for permissible metric only labeling now includes trade associations representing more than 500 U.S. businesses. NIST reports that it will continue to work with other industry groups to expand support for this initiative. The latest report on NIST's activities is available at: <http://ts.nist.gov/ts/htdocs/200/202/forum/forumdir.htm>.
 - b. This initiative includes working with state weights and measures directors, in those states that have not implemented the Uniform Packaging and Labeling Regulation (UPLR) to promote adoption of regulations for permissive metric only labeling. NIST reports that 45 states now accept goods labeled with metric only in retail stores. NIST will continue working with the remaining states over the next year to gain acceptance for metric only labeling at the local level.
6. Re-Export Control: The Government of the United States recognizes the concerns of the Government of Japan regarding the operation of the re-export system.
- a. In response to Japanese concerns, in 2003, the Department of Commerce posted updated "Guidance on Reexports and other Offshore Transactions Involving U.S.-Origin items" in English at: www.bis.doc.gov/Licensing/ReExportGuidance.htm and in Japanese at www.bis.doc.gov/InternationalPrograms/Foreign_Language/Welcome_Japanese.htm
 - b. The Department of Commerce has personnel who are specifically trained in U.S. export control regulations available in Tokyo to assist with inquiries regarding export control regulations. The Government of the United States takes note of the Government of Japan's continuing request to have the United States station experts with more experience on export control regulation at the U.S. Embassy and Consulates in Japan to meet the needs of Japanese re-exporters more fully.

- c. Requiring U.S. exporters to provide export control classification numbers (ECCNs) of U.S.-origin items to Japanese importers would pose a significant burden, and potential liability, on U.S. exporters who would need to ensure that the item remains as classified under the exported ECCN. The Government of the United States will continue to discuss this issue with the Government of Japan.
 - d. The Department of Commerce may seek to increase its international industry outreach program on U.S. export and re-export controls in Asia, including new seminars in Japan, in the near future. The Department of Commerce will continue to work with its counterparts in the Government of Japan on this issue.
7. Import Tariff Calculation Method and Labeling Requirements of Origin for Clocks and Watches: The Government of the United States recognizes the concerns of the Government of Japan regarding tariffs and labeling requirements for clocks and watches. The Government of the United States will continue to discuss with the Government of Japan regarding these issues, taking full account of the position held by the Government of Japan concerning a review of the U.S. tariff schedule and labeling requirements as well as discussions underway at the WTO.

D. **Sanctions Acts**

- 1. Iran and Libya Sanctions Act:
 - a. The Government of the United States appreciates having the views of all its trading partners in this matter, including those of the Government of Japan. In response to the issues raised by the Government of Japan, the Government of the United States explained that by its terms, the Iran and Libya Sanctions Act (ILSA) applies to those who engage in activities covered by the statute, without distinction by nationality. It was explained that the legislative history of the Act indicates a concern by Congress that the law be applied in a manner consistent with the international obligations of the United States. The Government of the United States will continue to have a dialogue with the Government of Japan on these issues.
 - b. The United States notes that the scope of the law was significantly changed in April 2004, when its application to Libya was terminated in response to Libya's progress in dismantling its weapons of mass destruction and the missiles capable of delivering them.

2. Cuban Liberty and Solidarity Act of 1996: The Government of the United States understands the concerns of the Government of Japan regarding the Cuban Liberty and Democratic Solidarity Act of 1996.
3. Burmese Freedom and Democracy Act of 2003: The Government of the United States understands that the Government of Japan has concerns regarding the Burmese Freedom and Democracy Act of 2003 and Executive Order 13310. The Office of Foreign Assets Control (OFAC) has made available on its website comprehensive information on the Burma sanctions program. There is also a contact number there for those with questions on the sanctions program. OFAC has a Compliance office which deals with questions specifically on whether certain transactions are compliant or not. The ban on the exportation of financial services is as written a very broad one. Listed on the OFAC site are the general licenses already issued and to what they apply.
4. Sanctions Acts Instituted by Local Governments:
 - a. Over the years, the United States has made considerable effort to reach out to state and local authorities – in Massachusetts, California and elsewhere – to help ensure that sanctions initiatives at the state or local level support U.S. foreign policy and are consistent with U.S. international obligations. The United States will continue those efforts when needed.
 - b. According to the City Purchasing Office in Berkeley, California, the City has not enforced its Selective Purchasing Ordinance targeting Burma since the Supreme Court struck down the Massachusetts’ Burma Law in June 2000.
 - c. The Town Council of the City of Chapel Hill, North Carolina, rescinded its policy barring service contracts with businesses doing business in Burma on June 26, 2000.
 - d. A listing of state and local sanctions, and their status, is available at the website of the NGO USA*Engage.

E. Competition Policy

1. The Government of the United States’ antitrust agencies continue to look for opportunities to express their views on the appropriate scope and reach of limitations on and exemptions to the applicability of federal antitrust laws.
2. In that regard, in May 2003, the United States filed an *amicus curiae* brief with the United States Supreme Court in Verizon Communications v. Trinko arguing that an implied antitrust immunity should not be found by the Court.

F. Legal Services and Other Legal Affairs

1. Legal Services:

- a. In August 2002, the American Bar Association (ABA) adopted a resolution to encourage all states to adopt foreign legal consultant systems based on the ABA's Model Rule. Since that time, the ABA has been working diligently to gain acceptance of its resolution in this regard. In January 2004, the ABA distributed its resolution to the Chief Justice of each state Supreme Court and to the President of each state's bar association and requested that the states report back on the status of their implementation of the ABA's resolution.
- b. In response to the ABA's efforts, the bar associations of the States of Georgia, Pennsylvania and Idaho, among others, have recommended to their Supreme Courts that they adopt the ABA's model Foreign Legal Consultant rule.
- c. The Government of the United States supports the adoption of foreign legal consultant rules consistent with the ABA Model Rule in all States and will, in that regard, continue to work closely with the ABA in the ABA's efforts to achieve full implementation of its resolution. The Government of the United States will continue to convey to the ABA the request of the Government of Japan that States that already have adopted foreign legal consultant systems consider reducing the period of practicing experience required for acceptance of foreign lawyers as foreign legal consultants and abolishing any rule that only practicing experience in the period immediately preceding the date of application can be considered as practicing experience, and will continue to encourage the ABA to inform the appropriate State authorities of that request. At the next meeting of the U.S.-Japan Regulatory Reform and Competition Policy Initiative, the Government of the United States will inform the Government of Japan whether it has received from the ABA any formal response by State authorities to the Japanese request, and the content of any such response.

2. Product Liability: The Administration is firmly committed to alleviating the undue burden on the business community from inappropriate tort litigation and unreasonable awards. President Bush has expressed his strong support for tort reform at the federal level in various speeches. The Administration is supporting a number of bills that have been introduced in Congress to further tort reform, including bills in the areas of medical liability, class action lawsuits, asbestos-related litigation and gun manufacturer liability. The Administration will continue to work for their passage in both houses of Congress.

- G. **Public Construction Works – Facilitation of the Settlement of Disputes in the Construction Business:** The United States continues to recommend that firms seek to negotiate provisions for an ADR process directly with state and municipal authorities, or to suggest ADR as a mechanism to resolve problems that arise in procurement contracts in which they are involved. In addition, firms are encouraged to raise their concerns regarding dispute resolution directly with the local or state governments that have issued the procurement. The Government of the United States has established a contact point for Japanese firms that experienced problems related to dispute resolution at the state or local level and encourages Japanese firms having problems to use this contact point. The contact point will listen to the firms' concerns regarding the problems they are experiencing related to public works procurement, and will take additional steps as appropriate.

II. TELECOMMUNICATIONS

A. Participation in the U.S. Wireless Market

1. The Government of the United States acknowledges the Government of Japan's interest in the restrictions on the ratio of foreign direct investment in the U.S. wireless market, and will continue a dialogue with the Government of Japan on this issue.
2. Taking account of Japan's concern in this area, the Government of the United States clarifies that U.S. law does not prohibit private foreign entities from holding up to 100 percent direct or indirect investment in non-broadcast, non-common-carrier or non-aeronautical en route or non-aeronautical fixed radio station licenses. In addition, such entities may directly own up to 20 percent and may indirectly own up to 25 percent in broadcast, common carrier and aeronautical en route or aeronautical fixed radio station licenses without special Federal Communications Commission (FCC) approval; up to 100 percent indirect ownership is also possible in principle, if it is found that this would be in the public interest. With respect to indirect investment relating to common carriers, the FCC makes a rebuttable presumption in favor of entry if the foreign investor is from a WTO member country. Under the above framework, several foreign companies have entered the U.S. market. The Government of the United States will continue to provide information to the Government of Japan on the classification between common carriers and non-common-carriers in the United States.

B. Certification and Licensing Criteria for Foreign Carriers' Entry into the U.S. Telecommunications Market

1. The Government of the United States will continue a dialogue, based on consultations involving relevant agencies, with the Government of Japan on issues relating to the transparency of U.S. certification and licensing criteria, and the

application of foreign policy, trade policy, and competition concerns to licensing decisions.

2. A review of regulations relating to international services is underway as a part of the 2004 Biennial Review. The Telecommunications Act of 1996 requires the FCC to review the rules issued under the Communications Act that apply to telecommunications service providers to determine whether any regulations are no longer necessary in the public interest due to meaningful economic competition and whether such regulations should be repealed or modified. The comment period for the 2004 is now open, and the Government of the United States welcomes Japan to enter its recommendations on the record.
3. The FCC will decide whether to act on staff recommendations by issuing Notices of Proposed Rulemaking as appropriate to effectuate the recommendations in the Staff Reports. Any Notice of Proposed Rulemaking would invite comments from interested parties, including from the Government of Japan.
4. The Government of the United States acknowledges Japan's interest in clarification of procedures regarding Section 214 and Section 310 (b) (4) of the Communications Act and current reporting requirements on carriers regarding traffic and revenue data.

C. State-Level Regulations

1. The Government of the United States will continue a dialogue with the Government of Japan regarding state-level regulations, including licensing procedures, the Government of Japan's interest in regulatory harmonization among states, and adoption of unified reporting requirements.
2. Taking account of concerns raised by the Government of Japan in this area, the Government of the United States notes that all carriers - domestic as well as foreign - are required to file forms unique to each state in which they operate. The Government of the United States welcomes efforts by the Governments of Japan and other countries to work with the National Association of Regulatory Utility Commissioners (NARUC) on items relating to state-level regulations, and has communicated to NARUC Japan's interests. The Government of the United States will provide the Government of Japan with information on NARUC's work.
3. The FCC's newly established the Office of Intergovernmental Affairs will foster a better understanding of FCC programs, policies, rules and decisions, facilitate a two-way exchange of information and communications on telecommunications issues between FCC, state, local, and other federal agencies, and promote cooperation and coordination in areas of overlapping jurisdiction.

D. Access Charges and Interconnection

1. In the *Notice of Proposed Rulemaking, Developing a Unified Inter-carrier Compensation Regime* (NPRM), the FCC begins a fundamental re-examination of all currently regulated forms of inter-carrier compensation. The FCC will test the concept of a unified regime for the flows of payments among telecommunications carriers that result from the interconnection of telecommunications networks under current systems of regulation. Specifically, the NPRM seeks comment on the feasibility of a bill-and-keep approach for such a unified regime, as well as modifications to existing inter-carrier compensation regimes, taking into account the CALLS Agreement, which is in force until superceded by new rules. In sum, the FCC seeks to move forward from the transitional inter-carrier compensation regimes to a more permanent regime that consummates the pro-competitive vision of the Telecommunications Act of 1996.
2. The Government of the United States will continue a dialogue with the Government of Japan to further clarify rules for TELRIC pricing, UNEs, and other related issues, based upon the final decision to be made by the court concerning the Triennial Review as well as with a view to promoting competition and investment.

E. Procedures for Processing Export Licenses and TAA Approval of Commercial

Satellites: In 1998 the United States Congress directed the United States Government to treat all satellite exports as munitions exports, subject to munitions licensing procedures, including case-by-case review. The Directorate of Defense Trade Controls of the Department of State considers each application for the export of a satellite, satellite components, or technical data on its merits, including whether or not security considerations will allow the release of technical data. Detailed information about the Arms Export Control Act and ITAR (International Traffic in Arms Regulations), including information on the licensing process, is also available on the web at <http://pmdtc.org/reference.htm>.

1. The electronic licensing system has been active since January 15, 2004, and was formally inaugurated by Secretary Powell on February 18, 2004. Additional information is available on the web at <http://www.pmdtc.org>. This system will make the licensing process more streamlined and efficient. The Governments of the United States will respond to the extent possible to requests for information from the Government of Japan regarding improvements resulting from this new system.
2. The Government of the United States will continue its efforts to minimize delays and maximize transparency of procedures in export licensing and TAA approval for commercial communications satellites in accordance with U.S. laws, regulations, and policies. The United States Government and the Government of Japan have conducted an informative dialogue on export licensing for commercial

satellites. Recognizing the importance of U.S.-Japan relations, the Department of State is prepared to discuss specific cases with the Government of Japan if necessary.

F. **Promotion of Advanced Technologies and Services:** In November 2003 and March 2004, the Telecommunications Working Group of the Regulatory Reform Initiative obtained information from private sector experts on the utilization and application of radio frequency identification (RFID) in both countries. The Working Group heard their views on current trends and issues in the developing RFID market, including technology, market status, and policy.

G. **Network Channel Terminating Equipment (NCTE):**

1. The Governments of Japan and the United States, having exchanged views on the relevance of the 1990 Exchange of Letters on Network Channel Terminating Equipment (NCTE) (“the 1990 Letters”), share the following recognition, based upon which the two Governments propose a process for terminating the procedures established through this exchange of letters:
 - a. Significant competition among telecommunications carriers has emerged and the development process of terminal equipment has changed substantially.
 - b. Because of the shortened life-cycle of products, the shortened lead-time of product development, and the increased use of standards, timeframes described in the 1990 Letters for the disclosure of information on specifications for NCTE before the introduction of individual services may hinder prompt supply of advanced services.
2. As a transitional measure, the procedures established through the 1990 Letters will be streamlined as indicated below. Unless sufficient evidence demonstrating the continued need for these revised procedures is introduced, following solicitation of opinions from interested parties, these procedures will cease to be applied beginning in FY2006.
 - a. Scope of carriers subject to revised procedures: Main carriers that determine specifications of NCTE and provide services (except those of sufficiently competitive areas), using Category I designated telecommunications facilities.
 - b. Scope of information disclosure under revised procedures: Regarding NCTE where network interface information has been made generally available through a standardization process or by other means, disclosure will not be required.

- c. Term of disclosure of technical specifications: In principle, three months minimum, prior to introduction of a new service.

III. INFORMATION TECHNOLOGY

A. Protection of Intellectual Property Rights

1. The Government of the United States recognizes the importance of ensuring the protection of the right of making available, rights concerning live performances, and moral rights, and the Government of the United States also recognizes the importance the Government of Japan places on the protection of unfixed works. Concerning the Government of Japan's requests for clear and reliable protection of these items under the U.S. Copyright Law, the Government of the United States has had a series of productive discussions with the Government of Japan. The Governments of the United States and Japan will continue discussions on these issues.
2. To ensure adequate continuing protection, the Government of the United States will continue to monitor the development of case law concerning the protection of moral rights.
3. The Government of the United States will continue discussions with the Government of Japan on the protection of the right of rental for computer programs with special emphasis on video game programs.
4. The Government of the United States shares with the Government of Japan an understanding on the importance of the protection of intellectual property in Asia. Under this recognition, the Government of the United States will work with Japan at the IT Working Group to explore and consider cooperative measures to combat piracy of digital contents and strengthen protection of other IT-related intellectual property rights in Asia.

IV. ENERGY

The Government of the United States has taken market reform measures to improve and normalize the U.S. energy market. This process is welcomed by the Government of Japan.

A. Power Outage in the Northeast of North America and the Improvement of Network Reliability

1. Following the August 14, 2003, blackout that affected 50 million people in the United States and Canada, the two leaders created a task force to investigate its cause and recommend corrective measures. The task force released its final report

on April 5, 2004, which specifically identified the causes of the blackout and why it spread. It also recommended steps to minimize the probability of future blackouts, including the need to establish mandatory reliability standards for electric utilities. The task force's recommendations included the following:

- a. Mandatory and enforceable electricity reliability standards should be implemented with penalties for noncompliance, backed by appropriate government oversight.
 - b. The institutional framework of the North American Electric Reliability Council (NERC) and its initiatives on compliance should be strengthened.
 - c. A funding mechanism approved by regulators for NERC and the regional reliability councils should be developed in order to ensure their independence from the parties they oversee.
 - d. Deficiencies identified in one local utility and some reliability organizations in the United States should be addressed.
 - e. A range of technical recommendations made by NERC on February 10, 2004, should be supported and strengthened.
 - f. Near-term and long-term training and certification requirements for operators, reliability coordinators and operator support staff should be improved.
 - g. The physical and cyber security of the network should be increased.
2. The Government of the United States is strongly supportive of measures to improve reliability in electricity supply and supports the recommendations outlined in the final report. Most of the 46 recommendations listed in the final report have already been assigned specific time frames for implementation.

B. Improving the Two-Layer Structure of Federal and State Regulations and Disparity Among States

1. While our system of government provides for separate federal and state responsibility over energy regulation, Congress and the Federal Energy Regulatory Commission (FERC) continue to take steps to limit any adverse impact of multiple state systems.
2. The most recent version of the Energy Policy Act of 2003 pending in the Congress states: "It is the sense of Congress that, in order to promote fair, open access to electric transmission service, benefit retail consumers, facilitate wholesale

competition, improve efficiencies in transmission grid management, promote grid reliability, remove opportunities for unduly discriminatory or preferential transmission practices, and provide for the efficient development of transmission infrastructure needed to meet the growing demands of competitive wholesale power markets, all transmitting utilities in interstate commerce should voluntarily become members of independently administered Regional Transmission Organizations (RTO) that have operational or functional control of facilities used for the transmission of electric energy in interstate commerce and do not own or control generation facilities used to supply electric energy for sale at wholesale.”

3. Various versions of the Energy Policy Act of 2003 currently under consideration by the U.S. Congress would acknowledge FERC’s authority to establish and supervise RTOs, including enforcement of mandatory reliability standards for the interstate transmission grid; to police market transparency and manipulation and direct unregulated utilities to open access to their transmission; to assess penalties for violations commensurate with the harm resulting from anti-competitive behavior; and to review electric and natural gas mergers in order to reinforce FERC’s ability to maintain competition.
4. FERC is vigorously pursuing the establishment of RTOs with both operational and planning responsibilities for wide geographical regions. The standard market design rule would harmonize RTOs’ wholesale electric markets in the different regions.
5. To ensure that standards of reliability continue to be maintained as electricity markets become more competitive, the Energy Policy Act of 2003 legislation would make all owners and operators of the bulk power system subject to enforceable reliability standards. Under the legislation, FERC would have authority over an Electric Reliability Organization (ERO), including the ability to order compliance with the ERO’s standards and to enforce this compliance.

C. The Comprehensive Energy Bill

1. The Energy Policy Act of 2003 (the Comprehensive Energy Bill), intended to modernize our energy production and distribution systems, is currently being deliberated in Congress. The proposed Act includes provisions in the following areas.
 - a. Modernization of the electricity grid by reforming outdated laws, promoting open access to the transmission grid, promoting regional planning and coordination, protecting consumers, and developing and deploying new technology.

- b. Establishment of mandatory and enforceable reliability standards for electric utilities to lessen the likelihood of transmission grid failures and blackouts.
 - c. Expansion of investment in transmission and generation facilities by providing increased rates of return on new transmission investments.
 - d. Elimination of transmission bottlenecks by providing for last-resort federal siting authority for high-priority transmission lines and expedited transmission permitting activities on federal land.
 - e. Establishment of regulatory certainty to attract needed investment in new and expanded Liquefied Natural Gas (LNG) facilities.
2. Both President Bush and Secretary of Energy Abraham have issued recent statements calling for U.S. Congress to pass comprehensive energy legislation. Provisions for mandatory standards for the electric transmission system have bipartisan support and are an important aspect of the legislation.
- D. **PUHCA Repeal:** The Energy Policy Act of 2003 legislation would help encourage expanded investment in transmission and generation facilities by repealing the Public Utility Holding Company Act (PUHCA), to be carried out within one year after it is enacted.
- E. **Publicly Owned Entities:** The Government of the United States continues to assess the impact of Publicly Owned Entities (POEs) on fair competition in a liberalized market. Many POEs have already submitted to FERC policies on rates and tariffs. The Energy Policy Act of 2003 would provide that federal Power Marketing Authorities, municipalities, and the Tennessee Valley Authority open access to their transmission, thus making them subject to competition in the same way as private companies in their region.
- F. **Standard Market Design:** The Government of the United States recognized the abundance of new generation planned in regions with RTOs, with electricity markets organized in a manner similar to FERC's proposed Standard Market Design (SMD). The Government of the United States further clarified that SMD facilitates more coordinated development of generation and transmission facilities. SMD proposes to eliminate pancaking problems that take place in inter-RTO transactions. To ensure full transparency, the Government of the United States will continue to ensure opportunities for public comment, as is the case in the SMD process.
- G. **Clarification of Market Regulation Policies and Measures of the Federal Energy Regulatory Commission**

1. Once a Notice of Proposed Rulemaking (NOPR) is issued, it is open to a regular public comment period, frequently followed with an additional 30 day period for rebuttal comments. This is mandated by law and consistently applied, and guarantees that the rule is subject to inquiry and reflects input from those most affected by the rule. Since the regulatory authority carefully takes the comments into account, the final rule may differ significantly from the proposed rule. FERC issues two to three NOPRs every year.
2. As part of FERC's comprehensive outreach to the states and other stakeholders, FERC regularly continues to hold open conferences in which all parties have an opportunity to address policy decisions. For example, there are frequent and open regional technical conferences announced regarding the White Paper on Bulk Power Market Design. FERC uses these opportunities to discuss with states, market participants, and interested parties reasonable timetables for RTO development activities to benefit customers within the region.
3. FERC recently modified the indicative market power screens it uses in assessing generation market power. The screens will apply on an interim basis to all initial market-based rate applications and triennial reviews. The policy was adopted after substantial public comments and is a response to requests by the public for a rehearing of an earlier order. The policy provides applicants procedural options, several types of generation dominance tests and the option of proposing mitigation tailored to the particular circumstances of the applicant.

H. **Price Cap Regulation in the Wholesale Market:** FERC can impose price caps or bid caps on wholesale electricity when necessary to prevent the abusive exercise of market power. Since FERC does not make arbitrary changes in prices, but uses transparent mitigation measures, market participants are able to assess the market and make sound business decisions even when wholesale bid caps are implemented. After careful examination of the costs and benefits of price cap regulation, this can be the most effective and efficient measure to prevent abusive exercise of market power.

V. **MEDICAL DEVICES AND PHARMACEUTICALS**

A. **Participation of the U.S. Food and Drug Administration (FDA) in the Meeting of the Working Group on Medical Devices and Pharmaceuticals:** MHLW had informed FDA of its wish to hold beneficial and productive discussions on MHLW's requests, by attending the sessions held in Tokyo and Washington, D.C. of the Working Group on Medical Devices and Pharmaceuticals. MHLW appreciates FDA for the participation of its officials in discussions at the session of the Working Group meeting in March 2004. FDA and MHLW recognize the importance of cooperative relationships, and FDA will henceforth delegate staffs who are familiar with MHLW's requests as appropriate. The U.S. Department of Commerce and FDA will work collaboratively to advance the discussions with MHLW in the Working Group on Medical Devices and Pharmaceuticals.

- B. **FDA's Regular Meeting with Foreign Industry:** MHLW has continuously offered meaningful opportunities for directly exchanging views with U.S. and other foreign medical device and pharmaceutical industries operating in Japan. FDA, too, will provide continuous and meaningful opportunities for discussions concerning its regulations on medical devices and pharmaceuticals with Japanese and other foreign pharmaceutical and medical device companies who have submitted an application with FDA and provide opportunities for regulatory discussions with Japanese and other foreign industry associations. FDA will also seek to provide the Japanese pharmaceutical industry with similar opportunities when the latter's representatives visit the United States.
- C. **Mutual Recognition Agreement (MRA) on Good Manufacturing Practices (GMP) of Medical Devices and Pharmaceuticals:** As the revised Pharmaceutical Affairs Law will be put in force in April 2005 in Japan, which will require GMP certification for medical device and pharmaceutical approval, an MRA on GMP or establishment of a similar cooperative relationship will enable innovative medical devices and pharmaceuticals to be brought to market more quickly. With the goal of achieving GMP mutual recognition, or a similar cooperative arrangement, MHLW has urged FDA to advance GMP cooperation between the United States and Japan on medical devices and pharmaceuticals in a positive manner. FDA acknowledges that closer cooperation between FDA and MHLW could lead to improved patients' access to medical devices and pharmaceuticals developed by U.S. companies and that it will be beneficial for the relevant industries of both the United States and Japan. FDA and MHLW are pursuing and are close to achieving an agreement to share confidential information. As a means to pursue enhanced cooperation, FDA has promised to give MHLW access to the FACTS database, a computerized inventory of regulated firms, which contains the results of inspections into medical device and pharmaceutical manufacturers, and to promptly respond when MHLW requests further details. FDA and MHLW will continue to discuss procedures for sharing medical device information and GMP inspection reports on pharmaceuticals.
- D. **MRA on Good Clinical Practices (GCP):** In view of Japan's growing accumulation of experiences following the introduction of ICH Good Clinical Practice standards, FDA is willing to provide training to personnel of MHLW and PMDA in order to promote the exchange of information on GCP between Japan and the United States within its resource constraints. MHLW and FDA will study how to carry out personnel exchanges and mutual inspections.
- E. **Compliance with Guideline of the International Conference on Harmonization (ICH):**
1. Based on the intention of the timely implementation of internationally harmonized guidelines, FDA and MHLW are discussing the incorporation of and compliance with such guidelines at meetings of ICH.

2. As has been discussed at ICH, FDA continues to fully support the use of MedDRA terminology in the international setting for which it was designed.
3. With regard to the test duration of chronic toxicity testing of new drugs in non-rodents, FDA would be willing to provide updated information about the number of cases requiring longer duration than that according to the ICH guideline in response to a request from MHLW through the ICH steering committee.

F. **Early Implementation of Matters Agreed Upon by the Global Harmonization Task Force (GHTF):** In recognition of the importance of the global convergence of regulatory systems, FDA is striving within the confines of U.S. law toward implementation of “Essential Principles of Safety & Performance of Medical Devices” and other matters that have not been fully implemented in the United States.

G. **Acceptance of Test Data Obtained by Means of Harmonized Pharmacopoeial Test:** FDA is considering handling data obtained by harmonized test methods at ICH as those handled according to the U.S. Pharmacopoeia (USP).

H. **Simplification of Data Requirements for Investigational New Drugs (IND) Applications:** At ICH, FDA is willing to discuss what data on manufacturing and control should be required in the investigational stage for new drug applications.

VI. FINANCIAL SERVICES

A. **Registration Requirements for Foreign Issuers in Case of Mergers, Consolidation, or Reclassification of Securities:** Under the U.S. federal securities laws, all public offerings of securities in the United States are required to be registered with the U.S. Securities and Exchange Commission. A public offering of securities includes share exchange offers, such as when an acquiring company makes a bid to acquire a target company by issuing its shares in exchange for target's shares. In 1999, the SEC adopted a rule that exempts from registration offers where the acquiring company and the target company are foreign companies, and where U.S. residents hold less than 10% of the shares of the target company. SEC staff is aware of Japan’s interest in raising this level. However, at the time of adopting this rule, the SEC carefully considered the level of U.S. ownership that was desirable and appropriate for purposes of this exemption and in the interest of investor protection. The SEC believes that, at the 10% level, U.S. holders' interest are best served by being able to participate in, rather than be excluded from, the acquisition offer, even though they do not receive the full protections of the U.S. federal securities laws.

In addition, even above the 10% level of U.S. ownership, more tailored relief has been adopted that addresses conflicting regulatory mandates and offering practices. Accordingly, Japanese companies engaged in merger and acquisition or other transactions that fail to meet the 10% threshold are encouraged to raise specific concerns with SEC staff.

- B. **Qualification of Financial Holding Companies:** Pursuant to the Gramm-Leach-Bliley Act, a foreign bank with U.S. banking operations may become a financial holding company (“FHC”) if the bank meets certain prudential criteria. These criteria are comparable to the prudential standards applied to the U.S. bank subsidiaries of U.S. bank holding companies that are FHCs, giving due regard to the principle of national treatment and equality of competitive opportunity. The standards are applied to all foreign banks on a nondiscriminatory basis. More than thirty foreign banks are FHCs. The Government of the United States welcomes applications for FHC status by any foreign financial institutions that meet these prudential criteria.
- C. **Regulation on Sales and Offers of Foreign Investment Trusts/Companies:** All funds that seek to sell their shares publicly in the United States generally must register with the SEC as investment companies under the Investment Company Act of 1940 (“Company Act”). Section 7(d) of the Company Act requires that any non-U.S. fund that wishes to register as an investment company and publicly offer its securities in the United States must first obtain an order from the SEC. To issue such an order, the SEC must find that “by reason of special circumstances or arrangements, it is both legally and practically feasible effectively to enforce the provisions of the Act against the non-U.S. fund, and that the issuance of the order is otherwise consistent with the public interest and the protection of investors.” Section 7(d) represents a prudential standard that generally ensures that U.S. investors receive the same essential investor protections, whether they acquire shares in a non-U.S. fund or in a U.S. fund. The section provides non-discriminatory, national treatment for non-U.S. funds; that is, any non-U.S. fund that can provide the investor protections required by the Company Act may legally access the U.S. market to the same extent as any U.S. fund upon receiving a Section 7(d) order from the SEC. The SEC recognizes that non-U.S. investment companies, such as those in Japan, may have difficulties meeting the prudential standards of Section 7(d). However, staff interpretations and innovations in the mutual fund industry have significantly increased the ability of foreign advisers to offer their services to U.S. investors and to establish funds that are organized in the United States.
- D. **Participation of US Investors to Foreign Exchange Traded Funds (ETFs).** The regulation of foreign ETFs under the U.S. federal securities laws will depend on the particular structure and characteristics of the ETF. In general, however, the SEC would treat the offer and sale of non-U.S. ETF securities to U.S. investors in the same manner that it treats the offer and sale of any non-U.S. fund securities to U.S. investors, which is on a national treatment basis. As described above, all non-U.S. funds that seek to sell their shares publicly in the United States must obtain 7(d) orders from the SEC and then register as investment companies under the Company Act. In addition, because ETFs operate differently from traditional investment companies, U.S. ETFs have had to seek exemptive relief from certain provisions of the Company Act. Non-U.S. ETFs likely would also have to seek exemptive relief to register under the Company Act.