

**SECOND REPORT TO THE LEADERS ON THE  
U.S.-JAPAN REGULATORY REFORM AND COMPETITION POLICY INITIATIVE  
May 23, 2003**

Now in its second year, 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 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 2002. 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, including telecommunications, information technologies, energy, medical devices and pharmaceuticals, competition policy, the Special Zones for Structural Reform (raised in this Initiative for the first time this year), transparency, legal system reform, commercial law revision, and distribution. As in the first year of this Initiative, several of the Working Groups invited input from private sector representatives, who 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 in March 2003 of its re-revised three-year Regulatory Reform Promotion Program. In addition, the Government of the United States especially welcomes the establishment in Japan of the Headquarters for Promotion of Special Zones for Structural Reform and the launch of the first round of 57 Special Zones in April 2003. The Government of the United States also welcomes the opportunity to cooperate in helping to ensure the success of this innovative new approach to promoting growth through structural reform and deregulation at the local level. The Government of the United States 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.

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 submitted to the Diet in March 2003 amendments to the Telecommunications Business Law (TBL), which are aimed at promoting further competition in the telecommunications business field. The amendments to the TBL, which maintains asymmetrical regulation for dominant carriers, include the following:
  - a. Abolition of the Type I (facility-based) and Type II (others) business categories and the permission system for new entrants;
  - b. Abolition of tariff regulations on non-dominant carriers, enabling individualized contract-based services; and
  - c. Abolition of the prior notification system concerning interconnection agreements for non-dominant carriers.
2. In February 2003, after inviting public comments for a month, the Ministry of Public Management, Home Affairs, Posts and Telecommunications (MPHPT) conditionally approved NTT East's and West's applications to provide interprefectural IP-based services. Beginning in FY2003, NTT East and West will be required to file with the Minister for Public Management, Home Affairs, Posts and Telecommunications and publish reports, on a regular basis, documenting their compliance with the parameters stipulated in the guidelines for expanding the range of their businesses.
3. In order to strengthen the environment for the usage of DSL services, the Telecommunications Council's Study Group on Technology has been conducting a study regarding basic conditions for spectrum management, so that the spectrum compatibility of specifications applied to a future system, including existing specifications not yet identified, can be measured expeditiously. The draft Council report, which is open for public comments until June 2, 2003, proposes that its recommendations be reflected in the Telecommunication Technology Committee's establishment of spectrum management standards. The standards will provide an objective basis for applying NTT East's and West's interconnection tariffs.

B. **Telecommunications Business Dispute Settlement Commission:** MPHPT confirms the importance of obtaining adequate dispute settlement capabilities, funding and personnel for the Telecommunications Business Dispute Settlement Commission.

C. **Fixed Interconnection**

1. In February 2003, MPHPT consulted the Telecommunications Council about amendments to the ministerial ordinance for interconnection rates. The Council issued its report in March after holding a public hearing with relevant parties and inviting public comments. Based on the report, MPHPT revised the ministerial ordinance for interconnection rates in April.
2. In April, the Minister for Public Management, Home Affairs, Posts and Telecommunications approved the revision of interconnection tariffs NTT East and West submitted based on the revised ministerial ordinance. The new rates are in effect for two years. MPHPT will conduct a study on interconnection rates to be applicable on completion of the period, considering fundamental environmental changes, such as declining traffic volume and new investment.
3. This study will include such issues as how to recover non traffic sensitive (NTS) costs (including the scope of costs to be recovered by basic monthly user fees) and the relationship of interconnection rates to the universal service fund mechanism. In addition, the Council recommended that input data other than traffic volume, such as the unit price of equipment, also be revised when changes in traffic necessitate the recalculation of interconnection rates.
4. The Government of Japan will continue a dialogue with the Government of the United States on interconnection-related issues.

D. **Mobile Communications**

1. In order to resolve a dispute relating to the setting of user rates of fixed-to-mobile calls, a fixed network operator applied to MPHPT for arbitration under Clause 3 of Article 39 of the TBL. The Minister for Public Management, Home Affairs, Posts and Telecommunications made a decision in November 2002, after receiving a report from the Telecommunications Business Dispute Settlement Commission, that this operator should set user rates for calls to mobile networks from consumers directly linked to this operator.
2. A study group established by MPHPT is examining the setting of user rates of calls originating from NTT East and West and terminating on mobile networks via inter-exchange carriers and those originating from IP phones and terminating on mobile networks from the viewpoint of promoting competition and user benefits. Public comments have been invited on the study group's draft report released on April 25, 2003.

3. NTT DoCoMo's interconnection rates have been significantly reduced over the last several years. The rates filed in March 2003 resulted in a reduction of approximately 5 percent compared to 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.

**E. Promotion of Advanced Technologies and Services**

1. In February 2003, the Working Group held a panel discussion with experts from government and the private sector in order to hear their views on trends and issues in the developing IP telephony market.
2. The Governments of Japan and the United States will exchange views within FY2003 on the relevance of the 1990 exchange of letters on Network Channel Terminating Equipment (NCTE) in light of ongoing developments in the market, with a view toward ensuring that its provisions do not hinder the rapid deployment of advanced technologies, while maintaining the principle of the openness of network interfaces for dominant carriers.
3. The Governments of Japan and the United States will continue to exchange information on the development of advanced technologies, including wireless Local Access Networks (WLANs), and their potential role in the market.

**II. INFORMATION TECHNOLOGIES**

**A. Removing Regulatory and Non-Regulatory Barriers**

1. Legal Framework: The Government of Japan has continued to remove remaining barriers that hindered e-commerce such as amending the Commercial Code to allow the use of the Internet to send invitations for shareholders' meetings and for other purposes, implementing a "No-Action-Letter" system, and establishing new rules for e-commerce such as the "Law Prescribing Exceptions to the Civil Code Related to Electronic Contracts." The Government of Japan will ensure that each Ministry will continue to revise existing regulations that hinder e-commerce and establish rules as necessary to further promote free and diverse e-commerce activities.
2. Alternative Dispute Resolution Framework: The Governments of Japan and the United States recognize that establishing a framework that allows for fair and effective alternative dispute resolution (ADR) for online dispute settlement is important to the development of e-commerce. The Government of Japan is studying necessary measures for establishing a comprehensive institutional base for ADR, which would include allowing qualified non-lawyers to provide ADR services for profit for online dispute settlement. The study will consider allowing

exceptions to Article 72 of the Attorney Law, which is one of the possible impediments to the further growth of ADR in Japan. In the course of conducting the study, the Government of Japan will issue a report on a basic framework to promote the use of ADR that will be open for public comment during the summer of 2003. The Government of Japan will take the necessary legislative and/or regulatory measures based on the study by March 2004.

3. Private Sector Self-regulation: The Governments of Japan and the United States reaffirmed their recognition of the need for the private sector, in principle, to take the leading role for self-regulation in the area of IT and that the government's role is to promote an environment for a competitive and innovative IT sector by ensuring that new laws and guidelines do not over-regulate or hinder e-commerce.
  - a. The National Police Agency will seriously consider the principle of private sector led self-regulation in developing regulations and guidelines to implement the new law regulating online auction websites. The National Police Agency will also ensure that there will be an appropriate public comment period in accordance with Japan's Public Comment Procedure, and that the comments received are seriously considered and reflected in the final measures as necessary.
  
4. Interpretative Guidelines on Electronic Commerce: METI established the Interpretative Guidelines on Electronic Commerce in March 2002. The purpose of these Guidelines is to facilitate and promote business-to-business, business-to-consumer and other electronic transactions by providing guidance to businesses on how to address various legal problems related to e-commerce under the Civil Code and other laws. It is hoped that these Guidelines will serve as a guide to the specific interpretation of laws and will thus contribute to the establishment of new appropriate rules.
  - a. These Guidelines will remain flexible and be amended as necessary to appropriately reflect the actual market practices of e-commerce, new evolving technologies, and changes in international rules.
  - b. METI recognizes the importance of the Public Comment Procedure as an opportunity to receive comments from interested parties during the review and amendment process for these Guidelines. METI received 11 comments from interested parties during the most recent comment period in March 2003, and METI intends to incorporate some of these comments in the new Guidelines.
  - c. METI will continue to provide ongoing opportunities for review and comment on these Guidelines by interested parties through regular use of the Public Comment Procedure. In doing so, METI will provide a period of approximately 30 days for public comment, and will ensure that

comments received are seriously considered and reflected in future amendments and revisions.

5. Private Sector Input: The Government of Japan will continue to consider and implement measures to increase private sector input at all appropriate stages of the policy-making and implementation process, which will include:
  - a. Expanding utilization of information technology to make public and private sector dialogue interactive and transparent;
  - b. Ensuring an appropriate public comment period is provided in accordance with the general rules decided by the Cabinet, and seriously considering comments received, reflecting them as necessary in the measures and actions implemented;
  - c. Facilitating private sector input as appropriate in the next round of IT Working Group discussions by having representatives of Japanese and U.S. companies offer their input to the relevant Government Ministries and Departments of the two countries on legal and regulatory difficulties that businesses face in trying to successfully establish IT-related business models; and
  - d. Ensuring private sector input during the development and implementation of the “e-Japan Strategy II” and subsequent “Action Plan” scheduled to be established in 2003. The Government of Japan will continue to actively seek opinions and input from the private sector during the process of establishing the “e-Japan Strategy II” and other IT-related programs through the working committees under the IT Strategic Headquarters and regular use of the Public Comment Procedure. The IT Strategic Headquarters has made the “e-Japan Strategy II” available for public comment during May and June for a period of three weeks and will ensure that comments received are seriously considered and reflected in the final measures and actions that are implemented as necessary.

## **B. Protection of Intellectual Property Rights**

1. Copyright Term Extension: The Government of Japan submitted a bill amending the Copyright Law to the Diet on May 13, 2003 in order to extend 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 several factors including global trends.
2. Strengthening Enforcement of Copyright Protection: The Government of Japan submitted a bill amending the Copyright Law to the Diet on May 13, 2003 in

order to alleviate the burden of proof on right-holders to establish infringement and the amount of damages in copyright infringement cases. The Government of Japan will continue its deliberations on the possibility of adopting statutory damages for infringement activities.

3. Software Asset Management: 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 software and other intellectual property assets on government-supported IT resources as necessary.
4. Temporary Copy Protection: The Government of Japan will consider explaining its interpretation of the scope of protection for a “temporary copy” through appropriate measures that will be widely disseminated.
5. Internet Service Provider Liability Rules:
  - a. The Law on Restrictions on the Liability for Damages of Specified Telecommunications Service Providers and the Right to Demand Disclosure of Identity Information of the Sender came into force on May 27, 2002. This law addresses infringement not only for copyrights but also of various cross-sectoral rights on web sites and bulletin board systems, etc. This law does not impose any obligations on ISPs, but defines conditions under which ISPs are not liable with the purpose of providing a legal background for ISPs to deal with infringement of rights quickly and appropriately.
  - b. A council formed by relevant private sector representatives, both domestic and foreign, established the guidelines for proper implementation of the law.
  - c. Furthermore, the council designated several organizations as “Credibility Confirmation Organizations (CCOs)” on September 30, 2002, which examine the infringement of copyrights on behalf of ISPs. The council also established a scheme in which ISPs are able to delete infringing materials from the web site without confirming the violation of rights themselves when rights-holders ask them to delete the materials via a CCO due to infringement of their copyrights.
  - d. The law has been executed through the guidelines and CCOs, and has had some positive results; therefore, the Government of Japan does not intend to revise the law at present. The Government of Japan will continue to

observe how the law is being executed and have a dialogue with the Government of the United States on this issue.

6. Technological Protection Measures: The Governments of Japan and the United States will continue to discuss issues related to technological protection measures.
7. Intellectual Property Policy: The Intellectual Property Policy Outline was published in July 2002 by the Intellectual Property Policy Council established in the Cabinet. The Basic Law on Intellectual Property to implement the Intellectual Property Policy Outline was approved by the Diet in November 2002 and entered into force in March 2003. The Intellectual Property Strategy Headquarters and Secretariat of Intellectual Property Strategy Headquarters were simultaneously established in the Cabinet on March 1, 2003.
  - a. The Intellectual Property Strategy Headquarters will be developing the Intellectual Property Promotion Program based on the Basic Law on Intellectual Property. When planning the Intellectual Property Promotion Program, the Intellectual Property Strategy Headquarters will set an adequate period for public comments, in accordance with the general rules decided by the Cabinet. The Intellectual Property Strategy Headquarters will ensure that comments received are seriously considered and reflected in the final measures and actions that are implemented as necessary. In addition, the Government of Japan will ensure that implementing measures for the Intellectual Property Promotion Program and the Basic Law on Intellectual Property are in compliance with international obligations, standards and norms.

### C. **Promoting and Facilitating Use of E-Commerce**

1. Privacy: On May 23, 2003, the Diet passed the “Law on the Protection of Personal Information” to establish a basic and common framework for the protection of personal information in the private sector. This law clearly states that an appropriate balance between the “protection” of and “use” (e.g. for legitimate interests of business) of personal information must be properly maintained, and it supports self-regulatory approaches to privacy, such as dispute resolution mechanisms. The Government of Japan will open the relevant implementing ordinances to public comment. Recognizing the importance of working to maintain cross-border flows of information, the Governments of Japan and the United States will continue a dialogue and work together on privacy-related issues, including consideration of ways to discuss with the private sector the importance of privacy protection.
2. Promotion of Alternative Dispute Resolution: The Government of Japan will issue a report on a basic framework to promote the use of ADR, including the possible contents of legal measures, and will make the report available for public



comment during the summer of 2003. This framework will encourage the use of ADR for e-commerce disputes. The Government of Japan will put in place necessary measures for establishing a comprehensive institutional base for ADR by March 2004 to create a supportive, flexible and open legal environment that promotes the development of ADR services, including private-sector led ADR services, that meet the demands of the online marketplace.

3. Electronic Signatures:

- a. The Government of Japan confirms that an electromagnetic record, with or without electronic signature, is admissible as evidence; and shall not be denied its competency as evidence for the simple reason that the record is in an electromagnetic form. In addition, under the “Law Concerning Electronic Signatures and Certification Services,” it is provided that electronic signatures shall maintain technological neutrality to avoid over-dependence upon any specific technology.
- b. Upon revision of the Regulations for Enforcement of the “Law Concerning Electronic Signatures and Certification Services,” the relevant ministries invited public comments thereon in April and June of 2002. Based on receipt of public comments, these ministries in November 2002 amended certain provisions and at present are working on additional revisions to the implementing regulations. The Government of Japan confirms that these and all future revisions will maintain technological neutrality and will not give accredited certification providers any legal benefits that do not extend to unaccredited providers.
- c. The Law on the Electronic Signature Authentication by the Local Governments was passed by the Diet in December 2002. The law’s implementing ordinances will be drafted based on a transparent process by seeking the opinions of specialists including the private sector, and announced in 2003. Although the law names PKI as the technology to be used, the Government of Japan recognizes that other authentication technologies may be more appropriate for certain government-to-citizen (G2C) online transactions. Therefore, the Government of Japan states that the ordinances will not restrict or prohibit the local governments’ use of other types of technologies for e-government services. The Government of Japan will review the law in the future and, if necessary, revise it to expand the scope of technologies allowed. The Government of Japan will encourage local governments adopting this system to use fair and open processes in procuring the supporting technologies and solutions.

4. Network Security:

- a. The Governments of Japan and the United States recognize the importance of ensuring the security and reliability of information systems and networks, including those used by governments, the private sector, and individual users, as both countries strive to create a “culture of security.” In this area, METI has developed information security guidelines and standards for information security inspectors that will be mandatory only within its own Ministry. METI developed these in a transparent manner, incorporating many of the comments received from 35 interested parties during the 30-day public comment period. METI confirms that its guidelines for a registration system for network security inspectors will be implemented in a transparent and consistent manner and be nondiscriminatory, allowing for registration by both domestic and foreign network security inspection service providers.
- b. The Governments of Japan and the United States will continue to share information and perspectives regarding the challenge of securing government, private sector, and individual users’ information systems. To this end, the Governments of Japan and the United States will cooperate to hold a network security event in late 2003 with all interested parties to raise awareness of the issue and highlight best practices and the potential of public-private partnerships in promoting network security.

**D. Expanding Procurement Opportunities for IT-related Goods and Services**

1. The Government of Japan confirms that, in accordance with the March 29, 2002 memorandum of agreement among the ministries (revised on April 22, 2002 and March 19, 2003), all ministries have agreed to adopt measures to ensure non-discriminatory, transparent and fair procurements of information systems (both products and services) by the Government of Japan. Key measures include:
  - a. Overall Greatest Value Method (OGVM, or *kasan hoshiki*) for information systems related to e-government that are expected to exceed 800,000 SDRs;
  - b. Publication on ministry web sites of additional information on bidding results;
  - c. Use of “life-cycle cost”-based evaluations for multiple-year projects; and
  - d. Consideration of Software Process Improvement such as the Capability Maturity Model as a technical factor for software products depending on its widespread use by the private sector.
2. The Government of Japan will conduct a follow-up survey of all ministries regarding the implementation of this memorandum by the end of FY2003 to

promote achievement of the original goals of the memorandum, including prevention of extreme low-priced bids. The Governments of Japan and the United States will continue to exchange information through the IT Working Group.

3. In September 2002, the Government of Japan established a “CIO Council” consisting of high-ranking officials from each ministry who are in charge of IT management. The CIO Council will propose and implement comprehensive measures to improve the development of e-government services, including procurement of information systems based on the memorandum of agreement, in order to optimize the use of IT by the central government.
4. Online Bidding:
  - a. In October 2002, MPHPT launched an online bidding system for non-public works procurement that enables companies to submit bids via the Internet. Other ministries will launch similar online bidding systems by the end of FY2003; and
  - b. MPHPT is also striving to operate the system in order to allow bids to be accepted 24 hours a day as soon as is technically feasible. Other ministries will work toward the realization of 24 hours operation of their online bidding systems based on the “E-Government Construction Project (tentative name)” designed by the CIO Council.
5. E-Education: In March 2003, the Government of Japan supported two international education symposiums, organized by the Government of the United States, which were held in Tokyo and Kyoto. The participants of these symposiums included educators from local school districts, government policymakers from both countries, and industry representatives. Through exchanging views on PC-based Internet use in public schools and IT training for teachers in these symposiums, the Governments of Japan and the United States reaffirmed the importance of promoting private sector technological solutions for e-education, which can lead to economic opportunities in this area.

### III. ENERGY

- A. **Regulatory Authorities:** The Government of Japan has undertaken a process to develop energy reform, while ensuring a stable supply of energy and its consistency with environmental protection, as designated by the Basic Energy Policy Act. The reform would expand liberalization of Japan’s retail electricity market to about 63 percent (2.4 times the current level) by 2005 and Japan’s retail gas market to about 50 percent (1.25 times the current level) by 2007. This process is welcomed by the Government of the United States. The effectiveness of these important pieces of legislation in ensuring a fair, efficient and stable energy market depends on vigilant market oversight. The

Government of Japan recognizes the importance of an enforcement mechanism equipped with the number of staff, expertise, and independence necessary to perform this task.

- B. **Electricity:** The Diet is currently deliberating electricity reform legislation that, if adopted, would amend the Electricity Utility Industry Law and come into full force in April 2005.
1. In the course of developing electricity reform legislation, the Ministry of Economy, Trade, and Industry (METI) took several key steps to ensure the process was open and transparent:
    - a. Tasked with developing reform recommendations, the Electricity Industry Committee made all of its 14 sessions, held from November 2001 to February 2003, open to the public. METI disclosed all of the minutes and reference materials from those meetings on its website; and
    - b. METI made available for public comment a draft of the Electricity Industry Committee's final report on electricity reform and publicly responded to the comments that were filed. The final version of the Electricity Industry Committee's report (Framework of the Desirable Future Electricity Industry System) was adopted in February 2003 and served as the basis for the electricity reform legislation which was submitted to the Diet in March 2003.
  2. The electricity reform legislation is designed to foster market participants' confidence in fairness and transparency in the transmission/distribution sector and facilitate a coordinating function that is essential for electricity system reliability through the following regulatory measures, while maintaining the general electric utilities system:
    - a. Prohibiting information obtained through wheeling services from being used for purposes other than providing such services;
    - b. Separating the accounts of the transmission/distribution sector from those of other electricity sectors in order to prevent cross-subsidization, and publishing the details of the separated accounts; and
    - c. Prohibiting unjust discriminatory treatment by the transmission/distribution operations of the utilities against specific electricity industry firms.
  3. The electricity reform legislation would establish a neutral transmission system organization (NSO) made up of private sector participants with government oversight, responsible for:

- a. Establishing rules concerning the transmission/distribution sector by using fair and transparent procedures; and
  - b. Supervising participants' compliance with these rules.
4. In order to use power plant supply capacity effectively on a nationwide scale, the electricity reform legislation proposes a review of the present wheeling services system, with a view of making changes, such as abolition of the system of collecting charges each time a transaction crosses from one service area to another.
5. The electricity reform legislation enables market participants to supply electricity through their own power lines from distributed generation to "Specified-Scale Electricity Demand" users within the portion of the market being liberalized, except where duplicative investment in transmission and distribution facilities may have profound harmful social effects to the extent of damaging the benefits to general consumers. The legislation recognizes the need to consider development of such efficient, diverse power supply options such as distributed generation.
6. The electricity reform legislation includes a provision for repealing the Electric Power Development Promotion Law in conjunction with complete privatization of the Electric Power Development Company (EPDC), in order to accomplish the aim of administrative reform. The privatized EPDC is expected to play an important role within the new framework such as the wholesale power market.
7. The Government of Japan recognizes the importance of the following measures to the electricity reform legislation's effectiveness in creating a fair, efficient and stable electricity market:
  - a. Strict enforcing of regulations through establishment and strengthening of a mechanism that would conduct vigilant ex-post market oversight and settle regulatory disputes in a neutral and fair manner;
  - b. Ensuring that any such mechanism within METI possesses the number of staff, expertise, and independence necessary to effectively perform the above tasks;
  - c. Strongly and consistently enforcing the Anti-Monopoly Law, where appropriate, as a necessary complement to the liberalization of the electricity market;
  - d. Ensuring that the regulatory authority establishes guidelines concerning the proposed prohibition of using information obtained through wheeling services for purposes other than providing such services, as well as

guidelines concerning the proposed prohibition of unjust discriminatory treatment for specific electricity industry firms;

- e. Deciding through a fair, just, and transparent process cost allocation for transmission facility expansion, taking into account the market participants' benefits and cost burden;
  - f. Taking concrete steps to promote prompt and smooth implementation of the proposed NSO, including:
    - (1) Establishing enforceable standards for designation of the NSO, comprised of diverse membership, including not only power utilities, but also new entrants, distributed generators with connections to networks and wholesale power companies, and scholars with expert knowledge;
    - (2) Ensuring that the NSO establishes rules to promote efficient and stable operation and construction of transmission facilities through a fair and transparent process and that the created rules are published;
    - (3) Requiring that the NSO operate an information disclosure system on power transmission networks, which would include the available capacity of transmission lines; and
    - (4) Taking timely steps to define the concrete details of the above disclosure system.
  - g. In April 2007, the Government of Japan will start examining whether to decide to go forward with full liberalization of the electricity industry, based on weighing issues of securing system reliability, the concurrent achievement of policy goals such as energy security and environmental protection, the securing of last resort service and universal services, and other practical and technical problems; and
  - h. EPDC would be privatized in a manner consistent with the Anti-Monopoly Law, with sufficient consideration given to the market impact of the privatization of the EPDC.
8. The Electricity Industry Committee submitted to the METI Minister in its final report the following recommendations, which will be taken into consideration as the legislation, if adopted, is implemented:
- a. Promote a fair, efficient and stable electricity market by:

- (1) Creating a private-sector, nationwide, voluntary wholesale power exchange to handle forward market and day-ahead market transactions, for the purposes of improving market participants' ability to make sound investment decisions on electric power development and minimizing market participants' exposure to unnecessary supply-demand imbalance risks; and
      - (2) Revising transmission access rules, providing for measures such as relaxation of the existing balancing rule from 30-minute/3 percent to a range of 3 percent to 10 percent of demand, and abolition of the accidental back-up charge for imbalances that exceed the fluctuation range.
    - b. Expand electricity customers' choice of suppliers by:
      - (1) Expanding the scope of retail electricity liberalization to approximately 40 percent of the market by April 2004, by including customers using high voltage electric service at 500 kW or more; and
      - (2) Expanding the scope of retail electricity liberalization to approximately 63 percent of the market by April 2005, by including all customers using high voltage electric service at 50 kW or more.
  - 9. If the Diet adopts the electricity reform legislation, the Government of Japan would continue to develop transparently implementing regulations and other measures to enforce the expanded liberalization of the electricity sector to occur in April 2005. In this process, the Government of Japan will ensure that such measures prepared to implement the electricity sector reform legislation are subject to the Public Comment Procedure.
- C. **Gas:** The Diet is currently deliberating gas reform legislation that, if adopted, would amend the Gas Utility Industry Law and come into force in April 2004.
- 1. In the course of developing gas reform legislation, METI took several key steps to ensure the process was open and transparent:
    - a. Tasked with developing reform recommendations, the Urban Heat Energy Subcommittee made all of its four sessions, held from September 2002 to February 2003, open to the public. METI disclosed all of the minutes and reference materials from those meetings on its website; and
    - b. METI made available for public comment a draft of the Urban Heat Energy Subcommittee's final report on gas reform and publicly responded

to the comments that were filed. The final version of the Urban Heat Subcommittee's report (Framework of the Desirable Future Gas Industry System) was adopted in February 2003 and served as the basis for the gas reform legislation which was submitted to the Diet in March 2003.

2. The gas reform legislation is designed to foster efficient infrastructure for gas supply and effective usage of such infrastructure through the following regulatory measures:
  - a. Promoting construction and improvement of pipelines for gas supply use by parties other than the general gas utilities by giving third parties that construct gas supply pipelines the public utility privilege (such as eminent domain), which is afforded only to general gas utilities under the current system;
  - b. Applying third-party access obligation, which is applied only to the four major domestic utilities under the current system, to all parties that own or operate pipelines for gas supply;
  - c. Obligating all pipeline owners and operators for gas supply in principle to draft, file, and disclose standard terms, conditions, and rates for third party access; and
  - d. Increasing transparency and neutrality of third-party access by ensuring that the regulatory authority establishes implementing regulations or other measures to provide for separation of accounts, information firewalls, and prohibition of discriminatory treatment against particular third-party access users.
3. The gas reform legislation expands gas customers' choice of suppliers by:
  - a. Changing the current prior permission system for large-scale retail supply to a notification system, with the regulatory authority maintaining the authority to give change orders or termination orders;
  - b. Bolstering the wholesale market by expanding the application of the obligation to draft standard terms, conditions, and rates – currently only required for large-scale retail gas supply – to third-party access for wholesale purposes; and
  - c. Terminating the current notification system for wholesale gas supply.
4. The Government of Japan recognizes the importance of the following measures to the gas reform legislation's effectiveness in creating a competitive, stable gas market: Guaranteeing verification of fair, transparent gas business operation by



establishing and strengthening a mechanism that would conduct stricter rate approval examinations and audits, settle disputes that occur as a result of free competition in the market, and conduct neutral and fair ex-post facto monitoring and dispute settlement, with a high degree of expertise and independence, and ensuring that any such mechanism within METI possesses the number of staff, expertise, and independence necessary to effectively perform these tasks.

5. The Urban Heat Energy Subcommittee submitted to the METI Minister in its final report the following recommendations, which will be taken into consideration as the legislation, if adopted, is implemented:
  - a. Foster efficient infrastructure for gas supply and effective usage of such infrastructure by:
    - (1) Offering incentives for a limited time period for investment in new pipeline construction in regions where the pipeline network is not fully established and regions where natural gas is not widely used, as well as trunk pipelines that connect several demand regions; and
    - (2) Considering specific contents, which pipeline projects are to be the object of the incentives, and period for the incentives in the procedures related to the development of implementing regulations and other measures, including feasible measures presented by the Subcommittee, such as:
      - i. Not subjecting some pipeline owners and operators of such pipelines to the obligation to draft, file, or disclose standard terms, conditions, and rates for third-party access; and
      - ii. Allowing owners and operators of such pipelines to adopt a higher rate of return in setting rates for third-party access.
    - (3) Promoting non-discriminatory negotiations between LNG terminal owners (or operators) and third-party users of LNG terminals by publishing joint METI/Japan Fair Trade Commission guidelines including feasible measures presented by the Subcommittee.
  - b. Expand gas customers' choice of suppliers by:
    - (1) Expanding the scope of retail liberalization to approximately 44 percent of the market by including users with an annual demand of 500 thousand cubic meters and higher by 2004;

- (2) Expanding the scope of retail liberalization to approximately 50 percent of the market by including users with an annual demand of 100 thousand cubic meters and higher by 2007; and
  - (3) Determining in a timely manner whether and how to liberalize gas retail for household and small commercial users with an annual demand of less than 100 thousand cubic meters, while evaluating and examining the results and problems of previous liberalization, and taking into account the changes in the gas procurement structure and the experiences of liberalization in other countries.
6. If the Diet adopts the gas reform legislation, the Government of Japan would continue to develop transparently implementing regulations and other measures to enforce the expanded liberalization of the gas sector to occur in April 2004. In this process, the Government of Japan will ensure that such measures prepared to implement the gas sector reform legislation are subject to the Public Comment Procedure.

#### **IV. MEDICAL DEVICES AND PHARMACEUTICALS**

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

1. The Government of Japan is undertaking comprehensive healthcare reform. The Government of Japan has assembled the “Basic Plan” on the review of the Health Insurance System and the Fee Schedule in line with the supplementary provisions of the Law to Amend the Health Insurance Law and other related laws. Further discussions related to the review of the Fee Schedule will take place.
2. As part of the above process, further discussion related to the medical device and pharmaceutical pricing systems will take place, and the Ministry of Health, Labour and Welfare (MHLW) will continue to provide meaningful opportunities for industry, including U.S. industry, to express their opinions.
3. Such opportunities can be used to address the enhancement of the systems’ full recognition of the value of innovation in order to encourage faster introduction and broader availability of innovative medical devices and pharmaceuticals.
4. On December 17, 2002, MHLW released a draft comprehensive healthcare reform proposal entitled “Future Form of the Health Insurance System and Review of the Medical Fees System.” This proposal was significant to the Government of the United States because:
  - a. MHLW presented the proposal as a starting point for wide-ranging discussions on comprehensive healthcare reform, including health

insurance coverage of medical devices and pharmaceuticals with each stakeholder, including U.S. industry; and

- b. MHLW recognized the need for comprehensive fee schedule reform, in view of improving the quality and efficiency of health services, as well as reform of the healthcare delivery system, such as the fact that the current medical fee structure contributes to lengthy average hospital stays as well as lack of hospital specialization.
5. On August 30, 2002, MHLW released a major policy paper for the pharmaceutical industry, titled “Towards Reinforcing the Global Competitiveness of the Pharmaceutical Industry, Mainstay of the ‘Century of Life’ - Vision of the Pharmaceutical Industry.” On March 31, 2003, MHLW released a similar paper for the medical device industry, titled “Vision of the Medical Device Industry -- Aiming to Provide ‘Better,’ ‘Safer,’ and More Innovative Medical Devices.” Taking into account the mechanism of “progressive” development of industry through a “favorable cycle of demand and innovation,” these Visions clearly state the view that industry develops through free corporate competition based on the market principle, and that this should remain the basic concept. Based on this concept are the action plans that are integral parts of these Visions. Subtitled as “Specific Measures for ‘Period of Intensive Promotion of Innovation’ (Up to 5 Years),” the action plans contain a wide range of measures such as the following:
  - a. Research and Development: 1) expansion of basic research; 2) promotion of technology transfers and industry/university/government coordination; 3) reinforcement of the infrastructure for clinical trials, including the establishment of “Large-Scale Clinical Trial Network”; and 4) promotion of medical/engineering/pharmaceutical R&D collaboration.
  - b. Regulatory System: 1) improvement and consolidation of the regulatory system through revisions of review criteria, etc.; and 2) further acceleration and qualitative improvement of the approval process by integration of review bodies into the new Incorporated Administrative Agency called the Pharmaceuticals and Medical Devices Organization (new agency) that will start its activities in April 2004, and by qualitative and quantitative reinforcement of its review staff.
  - c. Reimbursement System: 1) further promotion of expeditious introduction of effective and innovative products into the insurance system through appropriate prices; and 2) 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.
6. While keeping the practice of having a meaningful dialogue with both domestic and foreign industry, MHLW will continue to endeavor to create an attractive

environment that encourages innovation by steadily implementing the measures expressed in the action plans so that better pharmaceuticals and medical devices are made available to people in a faster manner.

7. In FY2002, MHLW significantly raised the pricing premium ratio for innovativeness and usefulness for the purpose of further ensuring appropriate valuation of innovative pharmaceuticals that is expected to encourage innovative pharmaceutical development. MHLW will continue to review the results of the application of the new and expanded premiums for medical devices and pharmaceuticals to ensure that premiums are being used to fully recognize and encourage innovation.
8. The transparency of the medical device and pharmaceutical pricing processes remains an important topic. MHLW has been ensuring the efficiency and transparency of the pricing processes of medical devices and pharmaceuticals by guaranteeing related industries, including U.S. industry, opportunities for direct access to discuss individual product characterizations and pricing recommendations with officials from the Economic Affairs Division.
9. MHLW increased the transparency of the medical device and pharmaceutical pricing processes by clarifying that the data used to characterize medical devices and pharmaceuticals for pricing are those contained in the Review Reports from the Pharmaceutical and Medical Device Evaluation Center.
10. MHLW will continue to provide companies with opportunities to clarify questions regarding the product coverage in the new Diagnosis Procedure Combination system.
11. MHLW will discuss with industry, including U.S. industry, the actual cost structures that are associated with the special regulatory requirements of biologic products to explore how those characteristics can impact the cost of such products.
12. MHLW is open to discussion, upon request by industry, including U.S. industry, regarding the recognition of innovative diagnostic equipment, e.g. imaging devices and in-vitro diagnostics.
13. The Government of the United States continues to urge MHLW to reassess the pharmaceutical repricing rule from the perspective of recognizing the value of innovation. The door remains open to address this point.
14. Issues that are related to medical device and pharmaceutical pricing will continue to be discussed on a case-by-case basis.

**B. Medical Device and Pharmaceutical Regulatory Reform and Related Issues**

1. MHLW is undertaking major regulatory reform based on the revised Pharmaceutical Affairs Law (PAL) under which it is establishing the new agency to conduct reviews of medical devices and pharmaceuticals. It is expected that these measures will speed up the process within the Japanese pharmaceutical and medical device administration system, ensure higher quality of administration services, and enable the system to adapt to the new challenges of the bio-genomic age. MHLW is developing an administration system that embraces the ideas of performance of administration (efficiency, technical quality and credibility), international harmonization and the latest internationally accepted science. MHLW has been actively discussing with each stakeholder, including U.S. industry, and adopting constructive proposals from industry in order to cope with issues regarding PAL reform and the new agency. Such meaningful opportunities will continue to be provided.
2. MHLW will discuss actively with each stakeholder, including U.S. industry, in the process of developing and utilizing a user-fee system for the new agency through cooperative and transparent procedures. MHLW will ensure that each stakeholder, including U.S. industry, has meaningful opportunities to present its opinions about the user-fee system regarding, for example, the transparency, predictability, equitability and intended use as well as methods for assessing the efficiency of the new agency.
3. From the perspective of preventing health damage caused by adverse reactions of pharmaceuticals and other products covered by PAL, MHLW carries out post-marketing safety measures promptly as well as appropriately, and this implementation will be continued in close cooperation with the new agency. MHLW pays close attention to ensure the transparency of the process not only to manufacturers, but also to the public. For example, through direct access to MHLW safety officials, MHLW will continue to exchange opinions about the treatment of adverse reaction data with Japanese and foreign manufacturers in a non-discriminatory manner. Taking the vital importance of post-marketing safety measures for the people's health into account, MHLW will continue to give scientifically sound consideration to foreign adverse reaction data as well as domestic data in evaluating adverse reactions.
4. Discussions about harmonizing regulation of medical devices are underway at the Global Harmonization Task Force (GHTF), in which both Japan and the U.S. participate. Based on the discussions, for example, at GHTF, MHLW has incorporated, for example, risk-based classification of medical devices into the amendment of PAL. While continuing to cooperate with other GHTF members, MHLW will continue medical device regulatory harmonization efforts in areas such as classifications, data requirements, testing standards and Quality System regulations.

5. In February 2003, MHLW abolished the guideline on biocompatibility tests of medical devices, and established new internationally harmonized guidance on biocompatibility evaluations.

C. **Blood Products**

1. On July 31, 2002, the Government of Japan promulgated the Law to Secure the Stable Supply of Safe Blood Products together with amendments to PAL. During that Diet session, supplementary resolutions regarding the regulation of blood and plasma products were adopted. This legal framework stipulates that such regulations are to be implemented by July 30, 2003.
2. MHLW will, for example, continue to provide meaningful opportunities to the Government of the United States and U.S. industry to address their concerns, including those regarding the new “kenketsu” and “hikenketsu” labeling requirement. Implementation of any such regulations will be fully consistent with common international trade obligations.
3. MHLW will conduct public outreach to clearly convey to the Japanese public that “kenketsu” and “hikenketsu” do not have any safety connotations.

D. **“Large-Scale Clinical Trial Network:”** MHLW promotes the creation of the “Large-Scale Clinical Trial Network” to make the Japanese clinical trial system internationally attractive and competitive. MHLW welcomes the constructive cooperation of both domestic and foreign industry for the success of the network. This network will build up domestic infrastructure for clinical trials and will provide pharmaceutical and medical device manufacturers with incentives to develop products in Japan. The Government of the United States welcomes such steps by the Government of Japan. MHLW will continue to exchange information with industry, including U.S. industry, regarding the features of the network. For example, questions of product and study design control, as well as associated intellectual property rights protection, can be addressed through the use of contracts between sponsors and investigators.

E. **Nutritional Supplements:** With regard to “food for specified health uses,” which can bring beneficial effects to the diet of the Japanese people, MHLW welcomes an increase in the number of applications from manufacturers, including U.S. companies, in the Japanese market. A “kentokai” is being formed to discuss the overall issues concerning so-called *kenkoshokuhin* (health food) including nutritional supplements. U.S. industry, on an equal basis with Japanese industry, will be provided with meaningful access to consultations regarding nutritional supplement regulations. MHLW has asked the industry concerned to choose members from the industry for this group.

V. **FINANCIAL SERVICES**

- A. The Government of Japan submitted legislation for Diet approval that will permit the postal financial institutions (*Yucho* and *Kampo*) to employ the asset management services of investment advisory companies. The Diet's House of Councillors ("upper house") approved the legislation and forwarded it to the House of Representatives ("lower house") on April 18, 2003.
- B. On May 14, the Government of Japan announced that it will consider increasing defined contribution pension plan contribution limits in FY2003.
- C. In the spring of 2003, the Financial Services Agency (FSA) sought comment from scholars, lawyers, money lenders and other concerned parties, on potential revisions of the Money Lending Business Law. One of the issues on which the FSA sought comment was the appropriateness of allowing the use of electronic notification to satisfy written disclosure requirements.

## VI. COMPETITION POLICY

- A. **Independence and Neutrality of the JFTC:** The Government of Japan, in accordance with the Three-Year Program for Promoting Regulatory Reform (Re-revised Version) ("Three-Year Program"), which was adopted in the form of a Cabinet Decision on March 28, 2003, submitted a bill to the 156<sup>th</sup> session of the Diet to change the organizational status of the Japan Fair Trade Commission (JFTC) to that under the Cabinet Office in order to make its status more appropriate, considering that the Cabinet Office is responsible for promoting regulatory reform and ensuring consumer interests. The bill passed the Diet on April 2 and came into effect on April 9, 2003.
- B. **JFTC Resources**
  - 1. The JFTC received a net increase of 36 persons in its staff level for FY2003, resulting in a total staff level of 643 people as of March 31, 2004. The JFTC's investigative staff was increased by 24 officials, bringing its total to 318.
  - 2. The JFTC has been recruiting post-graduate-level economists and has already employed 3 such persons since FY2001. The JFTC will make efforts to employ additional post-graduate-level economists in order to introduce more sophisticated techniques for economic analysis in merger investigations and economic research.
  - 3. The JFTC will assign such economists to sections in need of them including an existing section for economic research, and aims at further enhancement of its economic analysis system by substantially strengthening cooperation with outside experts including academic economists.
- C. **Effectiveness of JFTC Enforcement**

1. The Three-Year Program, which was adopted in the form of a Cabinet Decision, provides for the reviewing and strengthening of enforcement of the Antimonopoly Act (AMA) and for measures to be taken to that purpose by the end of FY2003. The Three-Year Program includes:
  - a. Review of criminal accusation procedures;
  - b. Review of the surcharge system;
  - c. Introduction of a leniency program;
  - d. Expansion of the scope of surcharge application; and
  - e. Review of the statute of limitations period for issuing cease-and-desist orders.
  
2. The JFTC, recognizing the necessity of sufficient enforcement and deterrence against violations of the AMA, is reviewing the current system of administrative and criminal measures, and established the Study Group on Reviewing the Antimonopoly Act in October 2002 for that purpose. The JFTC Study Group, which will issue a report including its recommendation by autumn 2003, is reviewing:
  - a. The surcharge system in terms of ensuring its effectiveness;
  - b. The necessity and feasibility of a leniency policy;
  - c. The necessity and feasibility of providing the JFTC with search and investigative powers appropriate for criminal violations;
  - d. Criminal accusation procedures;
  - e. Penalties for non-compliance with JFTC investigations; and
  - f. The limitations period for issuance of cease-and-desist orders.
  
3. With respect to the private remedy system under the AMA, the Three-Year Program provides that: “The Government of Japan will monitor the actual implementation of the injunction system. If it is considered necessary, after reviewing the results of relevant cases, the Government of Japan will initiate a study on methods for enhancing the private remedy system for AMA violations, including the possible expansion of the scope of acts that may be the target of a private action seeking injunctive remedies.”



4. The Public Prosecutors Office (PPO) and the JFTC have been working closely together at an early stage of investigations to exchange information and views on the legal and factual basis for the JFTC to file criminal accusations for AMA violations in particular cases. The Government of Japan will further enhance close cooperation between the PPO and the JFTC for effective implementation of the criminal provisions of the AMA.

**D. Measures to Address Bid Rigging**

1. The Act concerning Elimination and Prevention of Involvement in Bid Rigging etc. (Bid Rigging Involvement Prevention Act) came into effect on January 6, 2003. That Act authorizes the JFTC to demand central and local government commissioning agencies to take corrective measures to prevent continued complicity of its officials in bid rigging activities, and to report such measures to the JFTC. The Act also contains provisions concerning disciplinary action against officials who have participated in *dango* (bid rigging) and compensation for overcharges when the officials caused damage to the government due to willful or grave negligence.
2. The JFTC has been actively implementing the Bid Rigging Involvement Prevention Act, and will continue to do so.
  - a. On January 30, 2003, pursuant to the Act, the JFTC demanded the Mayor of Iwamizawa City to implement measures to prevent a recurrence of bid rigging on public works projects commissioned by the city.
  - b. In that case, the JFTC developed procedures for determining the participation of government officials in the bid rigging activities, and will use those procedures in future cases where participation by government officials in bid rigging is suspected.
  - c. In order to ensure effective implementation of the Act, when the JFTC demands Heads of Ministries and Agencies, including heads of local governments or specified corporations, to take corrective measures to ensure that participation by government officials in bid rigging is eliminated and does not recur, the JFTC will demand the Head of Ministry or Agency to report back to the JFTC in a timely manner on the corrective measures it has implemented.
  - d. The JFTC is committed to assisting commissioning entities, upon request, in investigating suspected participation of commissioning officials in *dango* activities, and in calculating overcharges resulting from such activities.

3. For the purpose of full implementation of the Bid Rigging Involvement Prevention Act and the Guiding Principle based on the Proper Tendering Act:
  - a. MLIT will prepare and publish on its website by June 2003 a booklet related to countermeasures for *dango* that can be used as a roadmap by central government and local government procurement officials in reporting suspected bid rigging to the JFTC and implementing suspension of designation of firms found to have engaged in bid rigging. The booklet will include:
    - (1) A manual for commissioning agencies and officials on procedures for dealing with *dango*-related information;
    - (2) Documents regarding standards for implementation of “suspension of designation” of firms that commit bid rigging and other illegal activities;
    - (3) Information, including excerpts from the Guiding Principle of the Act for Promoting Proper Tendering and Contracting for Public Works, concerning the collection of compensation for damages incurred as a result of *dango*; and
    - (4) The text of the Bid Rigging Involvement Prevention Act.
  - b. MLIT is also preparing for a new contract clause, by early summer 2003, which shall be applicable to construction and design/consulting services contracts of MLIT. It will specify pre-established damages equal to a set percentage of contract price that must be paid by its contractors that commit bid rigging.
4. In the case of damage action suits filed by local governments, including those which were filed in the context of citizen suits filed pursuant to Section 242-2 of the Local Autonomy Act, the JFTC is committed to assisting local governments seeking recovery of overcharges for bid rigging or other activities that are prohibited by the AMA. Such assistance will include providing relevant information and materials in the JFTC’s possession, considering restrictions concerning confidential information such as trade secrets of entrepreneurs, and offering the JFTC’s expertise pursuant to Section 84 of the AMA that is useful for calculating overcharges that should be recovered by such local governments.

#### E. **Competition and Regulatory Reform**

1. The JFTC participates as an observer in the Basic Policy Directions Subcommittee under the Electricity Industry Committee of the Advisory Committee for Natural Resources and Energy of the Ministry of Economy, Trade

and Industry (METI). The JFTC submitted its opinion in a November 2002 committee meeting that it is necessary to secure fairness and transparency in the transmission sector and that a fair and procompetitive framework is indispensable for an effective wholesale power exchange system, etc. The JFTC coordinated closely with METI on the bill to amend the Electricity Utility Law, which was submitted to the current session of the Diet, and will coordinate with METI in the future on designing a new regulatory system from the viewpoint of promoting competition in the electricity sector.

2. In order to promote competition in the electricity sector and to clarify the conduct by incumbent utilities and other enterprises that may violate the AMA, the JFTC and METI revised their joint Guidelines Concerning Appropriate Electric Power Dealings in July 2002.
3. The JFTC participates as an observer in the Gas Policy Working Group of the Urban Heat Energy Subcommittee of METI's Advisory Committee for Natural Resources and Energy. In a December 2002 working group meeting, the JFTC conveyed its view on how to ensure fair and free competition in the gas sector. The JFTC coordinated closely with METI on the bill to amend the Gas Utility Law, which was submitted to the current session of the Diet, and will coordinate with METI in the future on designing a new regulatory system from the viewpoint of promoting competition in the gas sector.
4. With a view to promoting competitive conditions in the telecommunications sector, the JFTC and MPHPT revised the Guidelines for the Promotion of Competition in the Telecommunications Business Field on December 25, 2002. The JFTC and MPHPT will continue to conduct a review of the Guidelines as necessary. Both agencies will continue to cooperate in promoting competition in the telecommunications sector.
5. For appropriate operation of Section 8-4 (measures against a monopolistic situation) and 18-2 (reporting requirement of parallel price increases) of the AMA, the JFTC will continue to monitor relevant firms by defining sectors and items to be monitored and to conduct surveys on prices and margins of such firms.

## **VII. SPECIAL ZONES FOR STRUCTURAL REFORM**

- A. **Special Zones as a Pillar of Regulatory Reform:** Prime Minister Koizumi established the Headquarters for Special Zones for Structural Reform in July 2002, declaring that the zones would be a central pillar of his regulatory reform agenda. Since July 26, 2002, the Headquarters has been working in an open and transparent manner to facilitate structural and regulatory reform based on zone proposals submitted by Japan's prefectures, municipalities, other local public bodies, and private sector entities. On April 21, 2003, the Prime Minister approved establishment of the first 57 zones, which fall into several

broad categories, including International Logistics/Distribution, Industry/Academic Cooperation, Industry Promotion, and IT Promotion.

**B. Special Zones Transparency:** The Headquarters has taken significant steps to ensure transparency in the development of the Special Zones initiative, in the zone application process, and in establishing procedures to implement the zones. Several of the steps taken to ensure transparency include:

1. Publishing important zone-related information on the Internet, including:
  - a. The entire zone application and approval process;
  - b. Notification of solicitation for zone proposals;
  - c. All responses of ministries and agencies to zone proposals, for instance their rationale for their opposition to revising/abolishing regulations relevant to the zone proposals; and
  - d. Summaries of consultations by Headquarters officials with ministries and agencies, and with prefectures, municipalities, other local public bodies, and private sector entities regarding their proposals.
2. Establishing points of contact (i.e. through e-mail at: [toc@cas.go.jp](mailto:toc@cas.go.jp)) so that interested parties can readily seek information, lodge complaints, or raise other zone-related issues;
3. Headquarters officials actively and openly meeting with interested parties, including foreign government officials, in an effort to understand all sides of relevant issues before making a decision;
4. Using the No Action Letter system to address specific issues in the Special Zones process, including:
  - a. Special Zone submitting bodies can request interpretations of relevant laws, ordinances, and other relevant administrative interpretations from the competent administrative organization prior to submitting a draft zone plan; and
  - b. Provision of interpretation(s) of laws and ordinances, and other relevant administrative interpretations for local public bodies within 30 days in writing or by electronic means.
5. Establishing a complaint desk at the Office for the Promotion of Special Zones for Structural Reform to resolve problems related to the zones at the local and national level.

- C. **Implementing the Special Zones Equally:** The Government of Japan will ensure that domestic and foreign companies alike have equal opportunity to submit zone proposals, to have those proposals approved, and to operate in the zones.
- D. **Evaluating and Expanding the Special Zones:** The Headquarters will form a council, comprised of a diverse group of individuals from the private sector and academia, etc., to recommend to the Prime Minister which of the zones are succeeding and should be expanded nationally, which are unsuccessful, and which require more time before a definitive “pass or fail” decision can be made. In this process, the Headquarters will ensure that:
1. The council will be operated in a transparent manner; and
  2. Successful measures used in the zones will be applied on a national basis expeditiously.
- E. **Future Special Zones**
1. Following the April 21, 2003 approval of the first 57 zones, there will be a second series of zones launched in the middle of May 2003. This will be followed by additional rounds including July 1-14 and October 1-14.
  2. The Headquarters will continue to solicit and receive zone proposals on a regular basis (about twice a year) from prefectures, municipalities, and the private sector. Round 3 for submitting proposal applications will run from June 1 to 30 and Round 4 will run from November 1 to 30.
  3. The regulations stipulated in these and future proposals that are suspended will be added to the current list of regulations suspended under the zones initiative, thereby expanding that list in an ongoing process.
- F. **Enhanced Focus on Special Zones:** Recognizing that the Special Zones can deliver significant reform and growth benefits to the Japanese economy and that foreign firms can play an important role in the establishment and success of the zones initiative, the Governments of Japan and the United States will place a greater focus on the zones, including:
1. Generally encouraging foreign firms, including U.S. companies, to submit zone ideas to the Headquarters and actively participate in zones where they determine a business opportunity exists;
  2. Through the Headquarters, assisting industry, foreign as well as domestic, to develop zone proposals, including in the sectors and areas covered by the Regulatory Reform Initiative; and

3. Continuing to actively exchange information at the Cross-Sectoral Working Group and explore ways to help ensure the success of the zones initiative.

## **VIII. TRANSPARENCY AND OTHER GOVERNMENT PRACTICES**

### **A. Public Comment Procedure**

1. To improve the application of the Public Comment Procedure (PCP) and promote its effective and widespread use, the Ministry of Public Management, Home Affairs, Posts and Telecommunications (MPHPT) has requested that all ministries and agencies make efforts to gather a broader range of opinions and information through the PCP when formulating, amending or repealing a regulation by:
  - a. Allowing for appropriate comment periods, depending on the nature of cases; and
  - b. Using more effective means of soliciting public comments.
2. In an effort to further promote the fairness and transparency of the decision-making process of ministries and agencies, and to increase the effectiveness of the PCP, MPHPT conducts a survey on how public comment procedures are implemented and makes the results public.
3. MPHPT will continue its efforts so that the PCP will be effectively utilized through such measures as conducting a survey on the implementation of the PCP by each ministry and agency.
4. MPHPT is planning to enhance the Japanese e-government portal ([www.e-gov.go.jp/](http://www.e-gov.go.jp/)) in a systematic and integrated way through greater provision of information on PCP as well as summaries of organizations, policies and administrative procedures of all the government ministries and agencies.

### **B. Public Input into the Development of Legislation**

1. Deliberations in the Diet are a formal opportunity for the public to put their ideas and opinions into bills.
2. Recently, some ministries or agencies, at their discretion, have opted for public input into draft legislation during its development, before it is submitted to the Diet, as follows:
  - a. In the fall of 2002, the Cabinet Secretariat sought public comment on the “Summary of the Proposed Basic Law on Intellectual Property” before it was finalized and submitted to the Diet.

- b. In early 2003, METI solicited public comments on draft reports for electricity and gas reform recommendations that served as the basis for energy sector reform legislation submitted to the Diet in March 2003.
3. With specific regard to the Life Insurance Policyholder Protection Corporation (Life PPC) and the Non-Life Insurance Policyholder Protection Corporation (Non-Life PPC), 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 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 FY2005, on reforming the Life PPC, including contributing to groups or components of those groups which might be convened by the Government of Japan.

#### **C. Public Corporations**

1. On December 19, 2001, the Cabinet adopted a “Program for Readjustment and Rationalization of the Public Corporations.” In implementing this Program, by the end of 2002, the Government of Japan conducted necessary measures (amendment of relevant laws, etc.) to organizationally reform 118 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, the advisory committee consisting of well-informed experts from the private sector to monitor and evaluate the implementation of the Program has met 11 times since its launch in July 2002. The summaries of the minutes of those meetings and discussion papers have been made public.

#### **D. Postal Financial Institutions**

1. On April 1, 2003, the new public corporation Japan Post was established by the “Japan Post Bill” and “Japan Post Enforcement Bill,” which passed the Diet on July 24, 2002. In the process of drafting these bills, the Ministry of Public Management, Home Affairs, Posts and Telecommunications (MPHPT) provided for transparency and opportunities for public comment: MPHPT established a study group that conducted public hearings, invited public comment on its draft interim report, and posted detailed minutes of meetings and reference materials on the Internet. 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 opportunities for private sector interested parties upon request to exchange views with MPHPT officials.

2. The insurance products or riders underwritten or sold on consignment by Japan Post are to be 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. Procedures to be followed when making such limited alterations are stipulated by law, which provides for the same or higher degree of transparency than comparable procedures applied in the private sector. Japan Post cannot originate any non-principal-guaranteed investment products, as the Japan Post Law does not include any provisions describing these products.
3. The Japan Post Law and Japan Post Enforcement Law bring *Kampo* and *Yucho* inspection and taxation requirements closer to those of private sector financial institutions than they were in the past. The Government of Japan believes that those differences that remain in inspection and taxation requirements do not result in unfair competition between *Kampo* and *Yucho* and private sector financial institutions. MPHPT will continue to provide opportunities for these private sector financial institutions upon request to exchange views with MPHPT officials on these issues.

## IX. LEGAL SYSTEM AND INFRASTRUCTURE

### A. Legal Services

1. Based on the Program for Promoting Justice System Reform endorsed by the Cabinet in March 2002, the Government of Japan submitted legislation in March 2003 to the ordinary Diet session to promote cooperation and collaboration between Japanese lawyers (*bengoshi*) and foreign lawyers qualified under Japanese law (*gaiben*). The legislation included the “Bill to Amend the Special Measures Law Concerning the Handling of Legal Business by Foreign Lawyers” that provides for the following amendments (which will come into effect within two years of promulgation of the law based on the Cabinet order):
  - a. The elimination of the prohibition on the employment of *bengoshi* by *gaiben*;
  - b. The elimination of the regulations on joint enterprises between *gaiben* and *bengoshi*; and
  - c. The abolition of legal provisions for specified joint enterprises (*tokutei kyodo jigyo*) and the establishment of joint enterprises between *bengoshi*



or bengoshi professional corporations (*bengoshi hojin*) and *gaiben* (*gaikokuho kyodo jigyo*.)

2. Enactment of the bill will have the following results:
  - a. A *gaikokuho kyodo jigyo* organized as a single law firm or as separate firms will be able to provide integrated legal advice and legal services on any and all matters within the competence of its members;
  - b. *Gaiben* and *bengoshi* or *bengoshi hojin* in *gaikokuho kyodo jigyo* will be able to adopt a single law firm name of their choice, under the following conditions:
    - (1) The *gaiben* share an office with their *bengoshi* partners;
    - (2) There is no limitation on the scope of practice of the *gaikokuho kyodo jigyo*; and
    - (3) The name of the firm includes the phrase “*gaikokuho kyodo jigyo*.”
  - c. *Gaiben* and *bengoshi* in *gaikokuho kyodo jigyo* will be free to determine the profit allocation among them freely and without restriction;
  - d. *Gaiben* will be permitted to hire *bengoshi* to work with them directly or in a *gaikokuho kyodo jigyo* or in a *gaikokuho-jimu-bengoshi jimusho* composed of multiple *gaiben*; and
  - e. *Gaiben* and *bengoshi* will continue to be permitted to enter into relationships on an ad hoc basis that involve the sharing of profits and expenses.
3. Concerning the establishment of *gaiben* professional corporations, the Government of Japan will conduct a preliminary study of how to handle the matter. In undertaking the study, the Government of Japan will exchange views with the Japan Federation of Bar Associations (*Nichibenren*), the Foreign Lawyers Association of Japan (*Gaikokuho-Jimu-Bengoshi Kyokai*) and the American Chamber of Commerce in Japan.
4. *Gaiben* are entitled to attend the proceedings, including general meetings, of *Nichibenren* and the local bar associations of which they are a member, in which the rules and regulations governing *gaiben* are deliberated, and to state their opinions and participate in the decision making with regard to the development and enforcement of all rules and regulations that may apply to them. The Government of Japan actively supports the provision by *Nichibenren* and the

local bar associations of effective opportunities to participate in such proceedings in accordance with the above principles.

5. The Government of Japan will continue to clarify the fundamental idea and interpretation of the Special Measures Law Concerning the Handling of Legal Business by Foreign Lawyers in a timely and appropriate manner so that *Nichibenren* establishes rules which reflect such an idea and interpretation. The Government of Japan will continue to have discussions with *Nichibenren* with respect to implementation of the Law.

## **B. Judicial System Reform**

1. In order to increase the speed and efficiency of civil litigation, the Government of Japan submitted the bill to amend the Code of Civil Procedure to the ordinary session of the Diet in 2003. The bill includes the following provisions in order to reduce by half the length of time required to complete court trials:
  - a. Requiring the court, for complicated cases, to establish a trial plan, in order to promote efficient scheduling of hearings; and
  - b. Giving a party the ability to make an inquiry for information from the other party, and empowering the court to request a holder of a document to transmit it to the court, in order to facilitate litigants' collection of evidence before the institution of a suit.
2. Based on the Program for Promoting Justice System Reform endorsed by the Cabinet on March 19, 2002, the Office for Promotion of Justice System Reform is continuing a comprehensive study on the review of the administration litigation system, through discussions of the Consultation Group of Experts for the Study of Administrative Litigation among the Secretariat of the Reform Office, and will take necessary measures by November 30, 2004. The Consultation Group of Experts has held hearings with experts and other interested persons and has studied the administrative litigation systems in foreign countries. Since October 2002, the Consultation Group of Experts has been debating concrete and wide-ranging issues related to the review of the administrative litigation system. The Reform Office, from July 1, 2002 to August 23, 2002, sought public comment on the review of judicial oversight of administrative agencies and is ready to receive opinions at any time on any aspects of the Justice System Reform.

## **X. COMMERCIAL LAW**

### **A. Flexibility in Merger Procedures**

1. The Revised Industrial Revitalization Law, which includes Commercial Code exemptions for "flexible treatment of considerations for mergers, etc.," went into

effect on April 9, 2003. According to the revised law, a business enterprise whose business plan is authorized by the government will be able to implement a merger, absorption/splitting or share exchanges, using shares of parent companies including foreign enterprises, and/or cash, as consideration. As a result of the introduction of these flexible procedures, it has become easier for foreign companies to participate in M&A activities through their subsidiaries in Japan.

2. The modernization of Japanese corporate law is now under discussion at the Committee of the Corporate Law of the Legislative Council of the Ministry of Justice (MOJ). In the context of modernization of Japanese corporate law, the MOJ is studying the introduction into the Commercial Code of modern merger techniques, including the introduction of flexibility in merger currency (such as triangular mergers and cash mergers) and the introduction of short form (squeeze out) mergers. The tentative outline of the bill including proposals relating to merger techniques will be made public in 2003 and public comments from the international business and legal communities will be welcomed.

## **B. Improved Corporate Governance**

1. Since June 1, 2002, it has been possible to file electronically most securities law-related reports and filings, and such filings have been available for public review at the Financial Services Agency web site. Beginning mid-2004, in principle most of the mandatory securities law-related reports and filings must be filed electronically and will be available for public review in electronic form at [www.fsa.go.jp/edinet/edinet.html](http://www.fsa.go.jp/edinet/edinet.html).
2. Pursuant to the revision of the Law for Special Exceptions to the Commercial Code concerning Audit, etc. of Stock Corporations, which came into effect on April 1, 2003, companies that adopt the committees system are required to register the name of each member of each committee and whether or not he/she is an outside director. All directors, including the members of the committees of the companies, are appointed at the shareholders meeting. The number of shares they hold, their career summary and the nature of their relationship with the company are required to be set forth in the materials accompanying the notice of the shareholders meeting for appointment of directors. The shareholders who hold voting rights at the meeting are able to get information in such materials on whether each member is independent and if not, the nature of the relationship with the company that makes the member not independent.
3. The Government of Japan expressed its views on the assertions of the Government of the United States regarding proxy voting.

## **XI. DISTRIBUTION**

- A. **Landing and Airport Fees:** The Government of Japan expressed its views on the concern of the Government of the United States regarding reduction of landing fees at Narita and Kansai Airports. The Government of Japan submitted the bill to the Diet to transform the Narita Airport Authority into a fully government-invested special company towards full-privatization.
- B. **Reduction in Overtime Charges in International Physical Distribution Special Zones:** For the purpose of promoting structural reform and revitalizing Japan's regional economies through the implementation and facilitation of business enterprises managed by local municipalities, Prime Minister Koizumi's Cabinet established the programs for the promotion of Special Zones for Structural Reform (Special Zones) last summer. On April 21, 2003, the Prime Minister certified 12 regions as international physical distribution special zones, in which overtime charges are reduced and the customs framework for overtime clearance is improved. These Special Zones include major Japanese seaports and airports (Narita and Kansai International Airports, and the major seaports of Tokyo, Yokohama, Nagoya, Osaka, Kobe and Kita-Kyushu). In the zones, the Ministry of Finance's Customs and Tariff Bureau (CTB) implemented measures to reduce overtime charges by 50 percent. These charges are collected from companies that desire to have goods processed through Customs outside regular operating hours (8:30 am - 5:00 pm on weekdays). Through the measures, CTB provided local municipalities with an environment to support their efforts to heighten the competitiveness of Japan's international ports.
- C. **Improvement of Customs Framework for Overtime Clearance**
1. CTB has positively responded to requests for overtime clearance through measures such as stationing Customs officers on a 24/7, 365 days a year basis at Customs offices that handle a substantial number of overtime operations.
  2. In the recent trend of rapid progress in the full-time operation of ports, there have been requests to further promote cooperation between government and the business sector. In order to respond to the requests and for the purpose of grasping the problems regarding the full-time operation of ports, CTB has implemented the "Trial Customs Framework for Overtime Clearance." In the trial, Customs officers are stationed for a certain period of time outside regular office hours at Customs offices that handle a substantial number of container-related declarations. Needless to say, in the Customs offices not covered by the trial but receiving frequent requests for overtime clearance, CTB realizes the necessity of responding to such requests by positioning Customs officers accordingly. In the international physical distribution Special Zones, CTB has implemented measures to station Customs officers at ports during times when declarations for overtime service are anticipated.

3. Based on these measures and requests, CTB has decided to put in place a full-scale framework for overtime clearance at Customs offices in major ports starting in July 2003.

**D. Easing of U-Clearance**

1. To facilitate expeditious Customs clearance, CTB has already implemented a pre-arrival examination system that enables importers to receive document inspection by Customs prior to the arrival of aircraft. Cargo that Customs determines does not require physical examination and is in need of immediate release can utilize the U-Clearance system, which was introduced in April 1996 for air cargo and has the same effect as the immediate delivery procedure in the United States.
2. Additionally, CTB will be examining the feasibility of implementing the U-Clearance system for cargo that is transported by bonded transportation to Hozei warehouses other than TACT (Tokyo Air Cargo Terminal) in Baraki. (TACT is a Hozei area designed to complement the function of Narita Airport.)

- E. For Further Facilitation of Customs Procedures:** Responding to the request for the facilitation of international physical distribution, since April 1, 2003, CTB has launched a system that enables non-residents to file import duty declarations, etc., and control inventory.

- F. Prior Approval:** CTB took note of the request from the Government of the United States that pre-clearance be granted at the time of the final approach of an aircraft.

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

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

**A. Trade/Investment Related Measures**

1. Anti-Dumping Measures: The Government of the United States will ensure that its anti-dumping laws conform to its WTO obligations.
2. 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.
3. The U.S. Patent System: 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, and there continues to be limited domestic support for the adoption of a first-to-file system. The Government of the United States will continue to discuss with the Government of Japan its requests to modify the system which is based on the Hilmer Doctrine. The United States would like to note that this issue is under discussion in the ongoing substantive patent law harmonization talks, and will be discussed at the next meeting in May 2003.
  - 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.
  - 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. While 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, in the current political climate, it is unlikely that an attempt to narrow or eliminate the exceptions will be successful.

- 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, and has, in general, favored the basic concept. The U.S. Congress recently passed legislation that would provide for third party appeals to the Federal Circuit in inter parties reexamination.
4. 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 7, 2002, the National Institute of Standards and Technology (NIST) at the Department of Commerce hosted a forum in Washington, D.C. to develop industry and public support for the update to the Fair Packaging and Labeling Act (FPLA). A working group was established to implement the initiative to update FPLA.
    - 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.
  5. Re-Export Controls: The Government of the United States understands the concerns of the Government of Japan regarding the operation of the re-export system. In response to Japanese concerns, in April 2003, the Department of Commerce posted updated “Guidance on Reexports and other Offshore Transactions Involving U.S.-Origin Items” in English at: <http://www.bis.doc.gov/Licensing/ReExportGuidance.htm>. The Department of Commerce is in the final stages of adding a Japanese language version of this guidance to its website. Regarding the Government of Japan's proposal requesting the United States to station experts on export control regulation at the U.S. Embassy and Consulates in Japan, the Department of Commerce has personnel available in Tokyo to assist with inquiries regarding export control regulations. The Government of the United States will make every effort to fully respond to these inquiries. The Government of the United States will continue discussions with the Government of Japan regarding the Japanese request to require U.S. exporters to provide Japanese importers (re-exporters) with sufficient information on the products (e.g. ECCN number).
  6. 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.

**B. Sanctions Acts**

1. The Government of the United States understands the concerns of the Government of Japan regarding the Iran and Libya Sanctions Act.
2. 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. The Government of the United States will strive to continue its efforts to ensure that any proposals for sanctions initiatives at the state and local level are consistent with U.S. foreign policy. Should any new sanctions be proposed, the Government of the United States will make every reasonable effort to work with the governors, attorney generals and government procurement officials of relevant jurisdictions to ensure the consistency of such sanctions with the U.S. constitutional standards.

**C. Distribution**

1. Counterterrorism Measures in Maritime and Other Sectors: The Government of the United States understands the concerns of the Government of Japan regarding the implementation of the provisions of the Maritime Transport Security Act of 2002 and the 24 hour advance vessel manifest rules, and regarding proposed rules of advance manifest submission for air transportation under the Trade Act of 2002. The Government of the United States offers the following comments:
  - a. In introducing and implementing security measures including advance manifest submission and C-TPAT, the Government of the United States will continue to work closely with relevant Japanese authorities to balance the two objectives of security and trade facilitation while taking into consideration views of the business sector.
  - b. The United States Bureau of Customs and Border Protection will work closely with the Japanese Customs and Tariff Bureau, and all interested parties, on the implementation of the Container Security Initiative.
2. Import Cargo Time Release Survey: After successful introduction of the Automated Commercial Environment (ACE), the Government of the United States will immediately conduct a Time Release Survey based on the Time Release Study Guide developed by the WCO.



3. Merchant Marine Act of 1920: The Government of the United States took note of the concern of the Government of Japan regarding the Merchant Marine Act of 1920. The Government of the United States took note of the assertions by the Government of Japan of the significant improvement of the situation of the Japanese ports. 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 progress achieved on these issues.
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 (MSP).
5. Cargo Preference Measures: The Government of the United States took note of the request of the Government of Japan to abolish the Cargo Preference Measures, including the law requiring that the transport of Alaskan North Slope crude oil be done on U.S.-flag ships.
6. Ocean Shipping Reform Act of 1998: The Government of the United States took note of the assertion by the Government of Japan that the Ocean Shipping Reform Act of 1998 allows the FMC to impose unilateral regulations on the commercial shipping activities of Japanese and other foreign shipping firms.

**D. Competition Policy**

1. The Government of the United States' antitrust agencies continue to review, and where appropriate, 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 December 2002, the United States filed an *amicus curiae* brief with the Court of Appeals for the District of Columbia Circuit in Covad Communications Co. v. Bell Atlantic Corp., arguing, among other things, that the 1996 Telecommunications Act should not be read to have created an implied exemption to the antitrust laws.

**E. Legal Services and Other Legal Affairs**

1. Legal Services:
  - a. In August 2002, the American Bar Association (ABA) officially adopted the recommendations of its Commission on Multijurisdictional Practice to encourage every State to permit the local establishment of foreign legal consultants (FLCs) by adopting a rule consistent with the 1993 ABA Model Rule for the Licensing of [Foreign] Legal Consultants (ABA Model Rule). The recommendation also urges each State with an existing

FLC Rule to review it for consistency with the ABA Model Rule. The ABA also adopted the recommendation of the Commission urging every State to adopt a rule allowing foreign lawyers to enter the State “temporarily” to provide legal services related to their practice where they are admitted (a so-called “fly in/fly out” or “FIFO” rule).

- (1) For the purpose of implementing these resolutions, the ABA directed its standing Joint Committee on Lawyer Regulation, currently chaired by Delaware Supreme Court Justice Randall Holland, to encourage and assist local bar associations in securing adoption of these rules by the State Supreme Courts that exercise such rights and obligations in most of the States.
- (2) The ABA Joint Committee has, since August 2002, sent letters to the Chief Justices of all of the States, requesting that they consider adopting the two ABA Model Rules or amend their existing rules to be in conformity with the ABA Model Rules.
- (3) As a result, as of April 15, 2003, the Bar Associations of Georgia, Oregon and Louisiana have recommended that the state Supreme Courts in those States modify their existing rules to conform to the ABA Model Rule and to permit FIFO access by foreign lawyers.

- b. The Government of the United States continues to support the adoption of such rules by all of its States, and continues discussions of legal services issues with the ABA to that end. The Government of the United States will 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 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 Law:

- a. The President, in his State of the Union Address and in other speeches, expressed concern about the undue burden that is placed on the business community from inappropriate tort litigation and unreasonable awards and strongly supported medical malpractice suit reform.

- b. The U.S. Supreme Court has also recently reaffirmed constitutional limits on punitive damage awards. In April 2003, the Supreme Court, in its decision in State Farm v. Campbell, found that a punitive damages award of \$145 million on a \$1 million compensatory judgment violated constitutional due process. It held that in awarding punitive damages, courts must ensure that they are both reasonable and proportionate to the amount of harm to the plaintiff and to the general damages recovered.
  
- F. **Consular Affairs:** The Government of the United States will continue discussions with the Government of Japan regarding measures that could address issues of concern held by the Government of Japan in relation to consular affairs.
  - 1. Social Security Numbers and Driver's Licenses:
    - a. On March 26, 2003, the Social Security Administration (SSA) published a Notice of Proposed Rule Making regarding assignment of Social Security Numbers (SSNs). Through the public comment process, the Government of Japan submitted a comment to the SSA on May 13, requesting the SSA to work with the remaining states, especially Illinois, which have not yet introduced an alternative identifier system, and to suspend the implementation of new rules until the remaining states complete introduction of such a system. The Government of the United States will take full consideration of the comment.
    - b. The Social Security Administration will continue to work with state governments that require SSNs for driver licensing to find alternative identifier systems to accommodate persons not authorized to work in the United States.
  - 2. Arrival-Departure Records, or 'I-94s': The Bureau for Citizenship and Immigration Services (BCIS) within the Department of Homeland Security will continue to make efforts to reduce the processing period for applications to extend the period of permission to stay of non-immigrant visa holders. As part of its ongoing Immigration Benefits Re-engineering Program, the BCIS is also making efforts to streamline the processing of applications for extensions of stay. The Government of the United States took note of the Government of Japan's request that the BCIS continue to consider the establishment of a standard period for processing extension of stay applications to be applied uniformly in all appropriate BCIS offices. The BCIS is currently in the process of prioritizing work at its service centers. The center managers, with guidance and support from the headquarters' Service Center Operations Division, are putting together a plan to dedicate appropriate resources across all types of application forms. While it is impossible to have an exact matching processing time for a particular form across all centers, BCIS endeavors to maintain some parity by sharing processing time information and best practices with all center directors, and the United States will

provide Japan with updated information on the result of such efforts as appropriate. The BCIS notes that it has standardized procedures for processing Form I-539 across all the centers. That was a positive step towards BCIS's effort of streamlining and standardizing the adjudicative process for change of status and extension of stay applications.

- G. **Facilitation of the Resolution of Disputes in the Construction Business:** The Government of the United States took note of the view expressed by the Government of Japan that dispute resolution for some U.S. public works projects may be time-consuming for the companies involved and that dispute resolution should be facilitated. Disputes related to U.S. federal public works projects can be resolved fairly and expeditiously through the Alternative Dispute Resolution (ADR) mechanism as stipulated in the Federal Acquisition Regulations (Section 33). The Government of the United States will continue to exchange information with the Government of Japan on this issue, including developments at state and local levels.

## II. TELECOMMUNICATIONS

- A. **Participation in the U.S. Wireless Market:** The Government of the United States will continue a dialogue with the Government of Japan on restrictions on direct investment in the U.S. wireless market. 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, many 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 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 2002 Biennial Review. In March 2003, the FCC issued its Biennial

Regulatory Review Report for year 2002. The Commission also concurrently released the 2002 Biennial Regulatory Review Staff Reports (Staff Reports). The Telecommunications Act of 1996 requires the Commission 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 Commission's 2002 Biennial Regulatory Review Report and the accompanying Staff Reports fulfill its statutory responsibility and identify current rules that should be modified or repealed.

3. The Commission 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. The Government of the United States acknowledges Japan's interest in clarification of procedures regarding Section 310 (b) (4) of the Communications Act and current reporting requirements on carriers regarding traffic and revenue data, issues also identified in FCC Staff Reports. The statements from Chairman Powell and the Commissioners, as well as the Staff Reports, including the International Bureau's report, are all available at <http://www.fcc.gov/biennial>.

#### **C. State-Level Regulations**

1. The Government of the United States will continue a dialogue with the Government of Japan regarding state-level regulation, including licensing procedures and the Government of Japan's interest in regulatory harmonization among states. Taking account of Japan's concern 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 Japan and other countries to work with the National Association of Regulatory Utility Commissioners (NARUC) on items relating to state-level regulation, and has communicated to NARUC Japan's interests.
2. The FCC continues to consider whether to adopt harmonized nationwide reporting requirements (known as performance standards) it proposed regarding aspects of incumbent local exchange carrier compliance with the Telecommunications Act of 1996.

#### **D. Access Charges and Interconnection**

1. In the *Notice of Proposed Rulemaking, Developing a Unified Intercarrier Compensation Regime* (NPRM), the FCC begins a fundamental re-examination of all currently regulated forms of intercarrier 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 intercarrier compensation regimes. In sum, the FCC seeks to move forward from the transitional intercarrier compensation regimes to a more permanent regime that consummates the pro-competitive vision of the Telecommunications Act of 1996.

2. Upon the release by the FCC of the Triennial Review order adopted February 2003 (FCC 03-36), the Government of the United States will continue a dialogue with the Government of Japan to further clarify TELRIC pricing rules and other issues.

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

1. The Government of the United States recognizes the Government of Japan's concerns regarding the processing period for export licenses and Technical Assistance Agreement (TAA) approval of commercial communications satellites.
2. The Government of the United States has taken the following measures to improve policies and procedures for export licensing and TAA approval for commercial communications satellites:
  - a. The Department of State's Directorate of Defense Trade Controls, which licenses defense trade, underwent a significant reorganization in January 2003 with the goal of improving export licensing policies and procedures;
  - b. In addition, the Directorate is developing an electronic "paperless" licensing system. This will facilitate applications and accelerate processing times; and
  - c. Effective September 2002, the dollar value of export licenses, including those for commercial communications satellites, above which congressional notification is required has been raised from \$50 million to \$100 million when the exports are to U.S. allies, including Japan. As a result, the range of satellites which do not require congressional notification has been expanded.
3. The Government of the United States will continue its efforts to minimize delays in export licensing and TAA approval for commercial communications satellites in accordance with U.S. law while safeguarding national security.

**F. Promotion of Advanced Technologies and Services**

1. In February 2003, the Working Group held a panel discussion with experts from government and the private sector in order to hear their views on trends and issues in the developing IP telephony market.
2. The Governments of Japan and the United States will exchange views within FY2003 on the relevance of the 1990 Exchange of Letters on Network Channel Terminating Equipment (NCTE) in light of ongoing developments in the market, with a view toward ensuring that its provisions do not hinder the rapid deployment of advanced technologies, while maintaining the principle of the openness of network interfaces for dominant carriers.
3. The Governments of Japan and the United States will continue to exchange information on the development of advanced technologies, including wireless Local Access Networks (WLANs), and their potential role in the market.

### **III. INFORMATION TECHNOLOGY**

#### **A. Copyright Protection**

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. In response to the Government of Japan's requests for clarification about several aspects of United States Copyright Law with regard to these rights, our two Governments have had a series of productive discussions among copyright experts. The Government of the United States provided extensive information on the statutory and case law basis for the protection of the right of making available, as well as information on the protection of live performances, moral rights and unfixed works under the U.S. legal system. The Government of the United States and the Government of Japan will continue the discussion on these issues.
2. The Government of the United States and the Government of Japan will continue the discussions on the protection of the right of rental for computer programs with special emphasis on video game programs.
3. The Government of the United States and the Government of Japan recognize the importance of ensuring the protection of the rights of broadcasting organizations. To that end, the two Governments will continue to work on a new treaty in this area in the World Intellectual Property Organization (WIPO). The Government of the United States has submitted a comprehensive new proposal for a treaty, which gives protection for broadcasting, cablecasting and webcasting organizations, to be considered at the next meeting of the WIPO Standing Committee on Copyright and Related Rights in June of this year.

4. The Government of the United States will work with Japan through the IT Working Group to explore and consider cooperative measures to combat piracy of digital content 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. Federal and State Authority**

1. 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.”
2. Various versions of the Energy Policy Act of 2003 currently under consideration by the U.S. Congress would acknowledge Federal Energy Regulatory Commission’s (FERC) authority to establish and supervise RTOs, as well as to enforce mandatory reliability standards for the interstate transmission grid; police market transparency and manipulation and direct unregulated utilities to open access to their transmission; assess penalties for violations commensurate with the harm resulting from anti-competitive behavior; and review electric and natural gas mergers, which will reinforce the agency’s ability to maintain competition.
3. 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.
4. To ensure that standards of reliability continue to be maintained as electricity markets become more competitive, the Energy Policy Act of 2003 would make all owners and operators of the bulk power system subject to enforceable reliability standards. FERC would have authority under the Act over an Electric Reliability



Organization (ERO), as well as to order compliance with the ERO's standards and to enforce this compliance.

- B. **PUHCA Review:** The National Energy Policy issued in May 2001 recommends repeal of the Public Utility Holding Company Act (PUHCA) in order to enhance competitive market entry. A number of reform bills over the past several years have proposed repeal of PUHCA, in whole or in part, most recently the Energy Policy Act of 2003, introduced in April 2003. This bill remains under consideration by the U.S. Congress.
- C. **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. The Energy Policy Act of 2003 would provide that federal Power Marketing Authorities, municipalities, and the Tennessee Valley Authority must open access to their transmission.
- D. **Standard Market Design:** The Government of the United States recognized the abundance of new generation planned in regions with RTOs organized in a manner similar to the proposed Standard Market Design (SMD). The Government of the United States further clarified that SMD inherently aims to ensure coordinated development of generation and transmission facilities. SMD proposes to eliminate pancaking problems that take place in inter-RTO transactions. As part of its transparent policy process, the Government of the United States will continue to ensure opportunities for public comment, as is the case in the SMD process.
- E. **Incentives for Investment in Transmission Facilities:** FERC is committed to achieving the goal of a robust infrastructure for the future and bringing all customers into the winner's circle of lower prices and enormous cost savings. For this reason, it has proposed incentives that will help encourage needed investment in transmission infrastructure and improve grid performance.
  - 1. FERC has proposed a new transmission pricing policy that would create rate incentives that reward transmission investment as well as formation of RTOs and independent transmission companies, because independent regional grid operation and coordination will improve grid performance, reduce wholesale transmission and transaction costs, improve electric reliability, and make wholesale electricity competition more effective.
  - 2. Specifically, the new policy would give a generic rate of return on equity incentive equal to 100 basis points for investment in new transmission facilities. In order to assure that the resulting rate is reasonable, these incentives would be subject to a cap equal to the top of a range of reasonable rates of return on equity for a proxy group consisting of the transmission owners participating in the local Regional Transmission Organization.
- F. **Clarification of the Market Regulation Policy**

1. U.S. energy regulatory statutes, the Natural Gas Act and the Federal Power Act, provide that all rates are based on a clear, transparent standard implemented in 1935. The Federal Power Act states that all rates must be just and reasonable, and prices are based on this standard in cases when competition fails. The just and reasonable standard provides for a reasonable profit margin to be earned on utility investments.
2. The Government of the United States will continue to take the initiative to improve market design to foster wholesale competition that is critical for the successful expansion of retail electricity liberalization to more people in the United States.

**G. Price Cap Regulation in the Wholesale Market**

1. Unlike the states, FERC does have the ability to impose price caps or bid caps on wholesale electricity. It will trigger such caps only 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.
2. The existence of a transparent reporting system, RTOs, and Independent System Operators (ISOs) in the United States enables the designation of must-run plants in an objective and integrated manner. RTOs and ISOs provide objective dispatch operators to designate must-run plants. These operators have no commercial ties and can therefore make unbiased decisions.

**H. Normalization of the Electricity Transaction Market:** The Government of the United States took concrete measures to improve oversight and prevent market manipulation in the energy sector. The President has created the Corporate Fraud Task Force. Member agencies have been selected based on their missions and their competencies. The Department of Justice's U.S. Attorneys serving on the Task Force come from major business centers: New York, Chicago, Los Angeles, Houston, San Francisco and Philadelphia. In addition to investigators from the Federal Bureau of Investigation (FBI), the Department of the Treasury's Internal Revenue Service (IRS), and the Postal Inspection Service, members include the regulators from the Securities and Exchange Commission (SEC), Commodities Futures Trading Commission (CFTC), Federal Communications Commission (FCC) and FERC, as well as the Department of Labor.

**I. Improvement of the Credibility of the Method of Settling Accounts Related to Energy Derivatives:** The Government of the United States took the following measures to address deceptive accounting practices and market manipulation and exploitation:

1. The SEC is undertaking greater scrutiny of accounting practices.

2. FERC has issued a final rule establishing accounting standards for derivatives.
3. In regard to preventing cross-subsidization of unregulated energy activities by affiliated regulated energy enterprises, FERC has initiated a Regulation of Cash Management Practices rulemaking to prevent the siphoning off of cash from the regulated utilities to support unregulated energy endeavors. FERC has also announced a policy that bases its approval of debt securities backed by regulated utility assets on the condition that utilities use such issuances only for regulated utility purposes.
4. By changing the nature of energy markets' price volatility and limiting the risks associated with physical delivery, SMD would encourage development of a viable electricity futures market.

## **V. MEDICAL DEVICES AND PHARMACEUTICALS**

### **A. Good Manufacturing Practices**

1. The U.S. Food and Drug Administration (FDA) and the Japanese Ministry of Health, Labour and Welfare (MHLW) have actively worked toward a cooperative arrangement similar to a mutual recognition agreement regarding Good Manufacturing Practices (GMPs) for pharmaceuticals based on the Exchange of Letters (EOLs) in December 2000. FDA will continue to engage MHLW on cooperative activities and will work to ensure the smooth implementation and maintenance of the EOLs. FDA continues to work with MHLW through exchanges of information and other cooperative activities regarding GMPs for medical devices. FDA and MHLW recognize the importance of these activities.
2. For a number of years, GMPs mutual recognition has been one of the important issues that has been addressed in the MOSS meetings, but it remains outstanding. With the goal of achieving GMPs mutual recognition, or a similar cooperative arrangement, MHLW wrote FDA a letter on February 24, 2003 to advance GMPs cooperation between the United States and Japan on medical devices and pharmaceuticals in a positive manner. On GMPs for pharmaceuticals, MHLW's requests contained, for example, reviewing the current cooperation described in the EOLs, and ideas to strengthen the cooperation towards the next step in developing mutual recognition or an alternative cooperation arrangement. With regard to GMPs for medical devices, MHLW's requests focused on agreeing on initial steps for future development of mutual recognition or an alternative cooperation arrangement. The FDA is seriously considering these proposals and is conducting an internal review with the aim of responding to MHLW as soon as possible.
3. The FDA fully appreciates the points made by MHLW aimed at solving these outstanding issues.

## B. Good Clinical Practices

1. FDA and MHLW continue cooperative activities on Good Clinical Practices (GCPs), especially in the ICH fora. In addition, FDA recognizes the importance of these activities, and FDA will continue to respond appropriately to foreign regulatory bodies' requests, including MHLW's, for information regarding GCPs.
2. On February 24, 2003, MHLW wrote to FDA outlining proposals to advance GCPs cooperation on pharmaceuticals. The FDA is seriously considering this proposal and is conducting an internal review with the aim of responding to MHLW as soon as possible.
3. The FDA fully appreciates the points made by MHLW aimed at solving this outstanding issue.

## VI. FINANCIAL SERVICES

### A. Banking

1. Federal Reserve FR Y-7 – Annual Reporting System: The FR Y-7 is an annual report on financial and organizational information filed by all foreign banking organizations (FBOs) that engage in banking in the United States. The Federal Reserve uses information to assess an FBO's ability to be a continuing source of strength to its U.S. banking operations and to determine compliance with U.S. laws and regulations. The FR Y-7 was recently revised to conform to changes in regulations, facilitate the use of the data collected, and reduce the burden on FBOs. The revisions are expected to reduce the estimated annual aggregate reporting burden by approximately one-third.
2. Assets Pledge Requirement in New York: The asset pledge requirement for foreign banks' operating branches or agencies in the state of New York was recently amended by the New York State Banking Department to reduce the amount of the pledge for the majority of foreign banking organizations. New York law currently requires a foreign bank with branches or agencies licensed in the state to maintain a pledge of one percent of third-party liabilities. There is a minimum pledge requirement of \$2 million, and the pledge is capped at \$400 million for well-rated institutions.
3. Deductible Interest of U.S. Branches of Foreign Banks -- Payable Interest to Head Office: The United States has specific rules regarding the interest deductions claimed by U.S. branches and U.S. subsidiaries of foreign corporations; both sets of rules are intended to ensure that such interest deductions are limited to an appropriate amount. In the case of branch operations, the United States and Japan are participating in an ongoing project at the Organization for Economic Cooperation and Development (OECD) Committee on Fiscal Affairs that is

considering methods for determining the appropriate amount of interest deduction for the branch operations of a foreign corporation.

## B. Others

1. Registration Requirements for Foreign Issuers in Case of Mergers, Consolidations, Reclassification of Securities, etc.: Under the U.S. federal securities laws, all public offerings of securities in the United States, including share exchange offers in acquisition transactions, must be registered with the U.S. Securities and Exchange Commission (SEC). In 1999, the SEC adopted a new 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 percent of the shares of the target company. In addition, even above the 10 percent level of U.S. ownership, more tailored relief has been adopted that addresses conflicting regulatory mandates and offering practices.
2. Regulations on Sales and Offer 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 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. Further, as described below, non-U.S. investment advisers may easily register in the United States as investment advisers and offer their services to U.S. funds or establish funds that are organized in the United States.
3. Registration Requirements for Foreign Investment Advisory Companies:
  - a. The Investment Advisers Act of 1940 (Advisers Act) generally requires the registration of any investment adviser, whether domestic or foreign, that uses U.S. jurisdictional means in connection with its business as an investment adviser, unless the adviser is exempted or prohibited from registration. All investment advisers that serve as investment advisers to registered funds must register under the Advisers Act.

- b. The SEC staff has administered the Advisers Act to provide non-U.S. investment advisers with increased flexibility in offering their services to U.S. investors. Non-U.S. investment advisers may structure their advisory businesses in a way that provides their U.S. clients with the protections of the Advisers Act, but does not subject their dealings with their non-U.S. clients to the Advisers Act. As a result, non-U.S. investment advisers may easily register in the United States as investment advisers and offer their services to U.S. funds or establish funds that are organized in the United States.
4. Regulations on Sales to U.S. Investors of Foreign Derivative Products in Foreign Stock Exchanges:
- a. *Limited exemption from licensing requirements for foreign intermediaries who sell foreign futures and options products to U.S. investors:*
    - (1) Part 30 of the Commodity Futures Trading Commission's (CFTC) rules govern the offer or sale of any foreign futures or options contracts to persons located in the United States. In general, these rules require the registration of any person, foreign or domestic, who solicits or accepts orders from a U.S. customer for a foreign futures contract, or option thereon. (Note that options on securities are regulated by the Securities and Exchange Commission.)
    - (2) Commission Rule 30.10 allows persons located and doing business outside the United States, who are subject to a comparable regulatory framework in the country in which they are located, to seek a limited exemption from CFTC registration. When the Commission grants a 30.10 exemption, persons located and doing business outside the United States may solicit or accept orders directly from U.S. customers for foreign futures or options transactions without registering with the CFTC. A petitioner who seeks an exemption pursuant to Rule 30.10 must set forth the comparable rules applicable in the jurisdiction in which that person is located and present a factual basis for a finding of comparability. Appendix A to Part 30 articulates standards to be used by staff in assessing the 30.10 comparability requirement. The CFTC granted 30.10 relief to the Tokyo Grain Exchange in 1993.
  - b. *Approval of foreign instruments for sale to U.S. investors:*
    - (1) In general, the Commodity Exchange Act (CEA) and CFTC regulations do not restrict the offer or sale of foreign exchange-traded futures and commodity option products in the United States, but special procedures and prohibitions apply in certain cases.

With respect to foreign broad-based stock index futures, the Commission staff must first issue a no-action letter to allow the offer or sale in the United States of a foreign exchange-traded stock index futures contract, or option thereon. In this regard, we note that the following broad-based Japanese stock index futures contracts have been approved:

- i. FTSE Japan Index futures contract (Osaka Securities Exchange);
  - ii. MSCI Japan Index futures contract (Osaka Securities Exchange);
  - iii. Nikkei Stock Index 300 futures contract (Nikkei 300) (Osaka Securities Exchange);
  - iv. Nikkei Stock Average Index futures contract (Nikkei 225) (Osaka Securities Exchange);
  - v. Tokyo Stock Price Index (TOPIX) futures contract (Tokyo Stock Exchange); and
  - vi. S&P/TOPIX 150 Index futures contract (Tokyo Stock Exchange).
- (2) Foreign exchange-traded security futures products (futures or options on narrow-based security indices or single securities), generally may *not* be offered or sold in the United States until the CFTC and SEC adopt rules governing such products.
- (3) Debt obligations of a foreign government must be designated as an exempted security by the SEC under SEC rule 3a12-8 before a futures contract or option thereon can be offered or sold in the United States. Because the SEC has approved Japanese debt securities for sale in the United States, futures and options on futures based on Japanese debt securities may be offered for sale to U.S. investors without CFTC approval.