

**FIRST REPORT TO THE LEADERS ON THE  
U.S.-JAPAN REGULATORY REFORM AND COMPETITION POLICY INITIATIVE  
June 25, 2002**

On June 30, 2001, President Bush and Prime Minister Koizumi established the Regulatory Reform and Competition Policy Initiative (Regulatory Reform Initiative) which is an important component of the U.S.-Japan Economic Partnership for Growth (Partnership). Over the past year, the Governments of the United States and Japan have been working intensively to fulfill the primary objective of the Initiative – 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 2001. These recommendations provided the basis for extensive discussions between the two Governments for meetings of the High-Level Officials Group and the Working Groups. The Working Groups met throughout the year to discuss reforms in key sectors and areas, including telecommunications, information technologies, energy, medical devices and pharmaceuticals, competition policy, transparency, legal system reform, commercial law revision, and distribution. 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, including the adoption on March 29, 2002 of its revised three-year Regulatory Reform Promotion Program. The Government of the United States notes recent discussions in Japan to establish structural/regulatory reform zones and looks forward to exchanging views with the Government of Japan on this issue as developments unfold.

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.

In addition, given the immense potential for the information technologies sector to spur growth in our respective economies, the two Governments put special emphasis in this year's Report on "e-initiatives" related to e-commerce, e-government, and cyber-security. In accordance with the cooperative spirit of the Partnership, the Governments of the United States and Japan: 1) recognize and support through the multilateral framework principles and matters for liberalizing trade of digital products; 2) will demonstrate global leadership on advancing and implementing e-government services; and 3) will also work together to facilitate broader acceptance and use of the Convention on Cybercrime. (*See attached annex for specific e-Initiatives.*) These e-Initiatives will provide important momentum for our work under the Partnership and underscore our joint efforts to promote growth and boost productivity in our respective economies.

Both Governments reaffirm their determination to further promote regulatory reforms and, upon the request of either government, will meet at mutually convenient times to address the measures contained in this Report. The two Governments also share the view that measures specified in the Joint Status Reports under the U.S.-Japan Enhanced Initiative on Deregulation and Competition Policy will continue to be implemented and are consistent with the objectives of the Regulatory Reform Initiative.

**REGULATORY REFORM AND OTHER MEASURES BY**  
**THE GOVERNMENT OF JAPAN**

**I. TELECOMMUNICATIONS**

**A. Promotion of Competition**

1. The amendments to the Telecommunications Business Law, NTT Law, and related laws, which are aimed at promoting further competition in the telecommunications business field, include the introduction of new asymmetric regulations to eliminate anti-competitive behavior of major telecommunications carriers which are assumed to have market power and the establishment of the Telecommunications Business Dispute Settlement Commission. They came into effect on November 30, 2001.
2. The amended laws no longer require approval of, but only notification to, the government for formulating and changing tariffs, interconnection agreements and facilities-sharing agreements of telecommunications carriers other than those with designated regional fixed networks. After inviting public comments, MPHPT released ordinances stipulating items to be notified.
3. In addition, all Type I and Special Type II carriers are now able to offer wholesale services with increased flexibility, by notification of a contract or a tariff. After inviting public comments, MPHPT released ordinances stipulating items to be notified.
4. Furthermore, MPHPT issued a public notification in May 2002, designating telecommunications carriers which are assumed to have market power in the field of mobile communications.
5. MPHPT amended Regulations for Enforcement of the Telecommunications Business Law and other relevant regulations in April 2002 and implemented such measures as the easing of a Type I carrier's expansion of its service area, which is now in principle only subject to notification, and the easing of requirements for approval of consignment of business activities.
6. MPHPT comprehensively revised the "Manual for the Construction of Networks by Telecommunications Carriers" to reflect changes described in paragraphs 1-3 and 5 above.
7. A draft of the final report on issues such as the promotion of the opening of networks, the strengthening of administrative policies in support of consumer

activities, and the introduction of a new framework for competition policy was published by the Special Department for Desirable Pro-Competitive Policy of the Telecommunications Council on June 4, 2002. The draft of the final report includes consideration of issues such as the access to OSS for Internet-related services, the examination of the relationship between interconnection rates and user rates, and a new framework for competition resulting from, for example, possible abolition of Type I and Type II business categories. Public comments are being invited at present.

8. The Telecommunications Business Dispute Settlement Commission, established with the implementation of the amendments to the Telecommunications Business Law, NTT Law, and related laws on November 30, 2001, has resolved eight disputes through its mediation (*assen*) procedures as of the end of May 2002.
9. The Telecommunications Business Dispute Settlement Commission made public on April 19, 2002 its report on the disputes the Commission had addressed in FY2001. The mediation proposals that mediators of the Commission submitted to parties were also made public in the report within the limits agreed upon by the parties.

## **B. Fixed Interconnection**

1. In February 2001, MPHPT approved NTT East's and West's applications to phase out the interconnection rate for the I-interface subscriber module (ISM) switching function over three years from FY2000 to FY2002. As a result, the difference between ISDN interconnection and telephone interconnection has been eliminated since April 2002.
2. MPHPT approved in February 2001 the LRIC-based interconnection rates of NTT East and West from FY2000 to FY2002 for functions related to the provision of telephone and ISDN services. This has resulted in a 22.5 percent reduction for GC interconnection and a 60.1 percent reduction for ZC interconnection in April 2002, compared with FY1998.
3. Based on the recommendations in the report of the Study Group on the LRIC Model that was held from March 1997 to September 1999, and the Telecommunications Council's Report "Policy on Calculation of Interconnection Charges" of February 2000, MPHPT re-established the Study Group in September 2000 and conducted a study on the revision of the LRIC model. The Study Group issued its report in March 2002, after inviting public comments for a month in February 2002.

4. MPHPT consulted the Telecommunications Council in March 2002 about the policy on calculation of interconnection rates based on the revision of the LRIC model. The Council is presently considering such issues as the evaluation of the revised model, timing and the duration of the application of the model, and methods to calculate interconnection rates in the future. After receiving the recommendations to be issued by the Council, MPHPT will decide on the interconnection rates, in line with the Third Joint Status Report of July 2000, taking into account views on appropriate rates. The Government of Japan will exchange views with the Government of the United States no later than October 2002 on implementation of the interconnection rates for FY2002.
5. When negotiations between parties on interconnection for 110 emergency calls fail, a party may apply to MPHPT for arbitration.

### **C. Mobile Interconnection**

1. The amendments to the Telecommunications Business Law, NTT Law, and related laws which came into effect on November 30, 2001 stipulate that telecommunications carriers with Category II-designated telecommunications facilities (mobile networks) have to notify MPHPT of and publicize interconnection tariffs. In this regard, MPHPT issued a public notification in February 2002 designating Category II-designated telecommunications facilities. Article 38-3 of the Telecommunications Business Law applies to the interconnection tariff compiled by NTT DoCoMo regarding interconnection with its Category II-designated telecommunications facilities. Any carrier may submit an opinion that such interconnection tariff should be modified. When the interconnection tariff proves to surpass the sum of appropriate costs and appropriate profit under efficient management, revisions may be required by MPHPT.
2. NTT DoCoMo's interconnection rates have been significantly reduced over the last five years. The rates filed in March 2002 resulted in a reduction of approximately 14 percent compared to the previous fiscal year.

### **D. Rights of Way**

1. Revision of Guidelines: To make it easier for Type I telecommunications carriers to lay cables, MPHPT revised the "Guidelines for Use of Utility Poles, Ducts, Conduits, etc.," as stipulated in supplementary provisions to the Guidelines, after inviting public comments. The revised Guidelines have been in effect since April 1, 2002.

2. Amendment to Wireline Telecommunications Facility Order: MPHPT amended the Wireline Telecommunications Facility Order in December 2001 so that new entrants can attach communications cables to poles jointly with existing facilities if such attachments do not risk damaging the existing facilities.
3. Permission for TOKYO ELECTRIC POWER COMPANY INC. to Operate a Type I Telecommunications Business: Given the circumstances specific to TOKYO ELECTRIC POWER COMPANY INC. where its poles consist of de facto bottleneck facilities, MPHPT required, as a condition for granting permission in February 2002 for the Company to operate a Type I telecommunications business, that the Company ensure fair use of its poles among:
  - a. Its own telecommunications business division;
  - b. Its telecommunications business affiliates; and
  - c. Other telecommunications carriers.
4. Review of Regulations Related to Road Construction: To accommodate urgent construction of fiber-optic networks by telecommunications carriers that could not have been foreseen at the beginning of a fiscal year, MLIT will undertake necessary coordination approximately every 3 months and will ease the relevant restrictions on road construction in winter and around the end of a fiscal year, to the extent that road traffic is not seriously affected. This measure will be maintained until FY2005.
5. Encouragement to Lay Cable by Installing and Opening Facilities, Including Accommodation Space:
  - a. Within FY2002, MLIT will install approximately 23,000 km of accommodation space such as shared conduits to house fiber-optic cables for road management purposes and other buried cables, thus expanding nationwide networks. MLIT will promote open access to such fiber and conduit space.
  - b. MLIT will work on the development of Shared Conduits for Cables for the Next Generation (provisional title) which will be faster and less costly to install due to compact design and shallow placement. MLIT will establish model conduits within FY2002.
6. Dissemination of Sufficient Information: To enable private companies to lay fiber-optic cables on bridges MLIT will disseminate, by the end of FY2002,

information on new construction and refurbishing of bridges over directly-controlled national roads. MLIT has requested that authorities controlling other national and local roads similarly make the relevant information available.

7. Swifter Procedures: With regard to directly controlled national roads, MLIT enabled the electronic application for the use of rights-of-way nationwide in FY2001. As for the other national roads and roads controlled by local authorities, MLIT has encouraged these authorities to enable electronic application procedures, where possible within FY2003. In FY2002 MLIT will establish and publicize the basic specifications of a standard system for local authorities.

## **II. INFORMATION TECHNOLOGIES**

### **A. Legal Framework**

1. Revision of Regulations: The Government of Japan has revised various regulations that hindered e-commerce. The Government of Japan will continue to do so as necessary to further promote the growth and development of e-commerce based on policies of the Strategic Headquarters for the Promotion of an Advanced Information and Telecommunications Network Society (“IT Strategic Headquarters”) as described in the “e-Japan Priority Policy Program - 2002” issued on June 18, 2002, which is a revision of the “e-Japan Priority Policy Program” issued on March 29, 2001.
  - a. The Government of Japan submitted legislation that will regulate online auction websites in March 2002. The National Police Agency will follow the general rules of public comment procedure implemented by the Government of Japan, so that the implementing regulations will be developed in a transparent manner.
2. Private-Sector Participation: The Government of Japan has solicited private-sector opinion in the planning and implementation of its policy both through private sector participation in the IT Strategic Headquarters and through public comments to the e-Japan Priority Policy Program and the e-Japan Priority Policy Program - 2002.
  - a. The Governments of Japan and the United States will work towards including 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 on legal and regulatory difficulties that businesses face in trying to successfully establish IT-related business models.

3. The Japan Fair Trade Commission (JFTC) published the interim report of the study group on software transaction competition policy on March 20. The report provides examples of types of conduct which may be problematic under the Antimonopoly Act with respect to providing technical interface information and restrictions in software licensing agreements. JFTC solicited comments on matters studied in this report from interested parties. These comments will be used by JFTC to enhance its views and activities on promoting competition in this field.

## **B. Internet Service Provider Liability Rules**

1. The Government of Japan submitted to the Diet a bill on Restrictions on the Liability for Damages of Specified Telecommunications Service Providers and the Right to Demand Disclosure of Identity Information of the Sender in October 2001. The bill prescribes restrictions on the liability for damages of specified telecommunications service providers and the right to demand disclosure of identity information of the sender in cases where a right is infringed upon due to the distribution of information via web pages, etc. The bill passed the Diet on November 22, 2001 and was promulgated on November 30. The law came into effect on May 27, 2002.
2. The Ministry of Public Management, Home Affairs, Posts and Telecommunications (MPHPT) issued a draft ordinance and invited public comments. In response, the Government of the United States submitted comments.
3. Also, a study working group formed by private sector representatives (in which both domestic and foreign representatives for ISPs and rightholders participated) was established to draft implementing guidelines addressing right infringement under the law. The study working group invited public comments on these guidelines. Comments received included those from the Government of the United States.
4. The Government of Japan will continue to observe the implementation of the law and have a dialogue with the Government of the United States on this issue.

## **C. Intellectual Property**

1. Temporary Copies: Based on the report of the Copyright Council of December 2001, the Government of Japan understands that "temporary storage" may be "reproduction," however, some cases may be excluded by the court such as technical storage automatically taking place within a music CD player which has no economic significance.



2. WIPO Performance and Phonogram Treaty (WPPT): The Government of Japan has been enacting amendments to relevant laws in preparation for the accession to the WIPO Performances and Phonograms Treaty (WPPT). The Diet approved conclusion of the WPPT on June 12 after the passage of the relevant law on June 11. Japan will accede to the WPPT as soon as possible.
- D. **Privacy:** The Government of Japan submitted to the Diet in March 2001 the “Bill on the Protection of Personal Information” to establish a basic and common framework for the protection of information in the private sector. This framework clearly states that an appropriate balance between the “protection” and “use” of personal information must be properly maintained, and it supports self-regulatory dispute resolution mechanisms. The Governments of Japan and the United States will continue a dialogue and work together on privacy-related issues.
- E. **Consumer Protection**
1. The Governments of the United States and Japan recognize the importance of promoting consumer protection in the context of e-commerce. The Government of Japan will take measures to promote the development of private sector self-regulatory initiatives for consumer protection and the resolution of consumer disputes including Alternative Dispute Resolution (ADR) mechanisms, which is one of the policies of the e-Japan Priority Policy Program - 2002.
  2. At the IT Working Group meeting in March 2002, the United States arranged for industry leaders, ADR providers and government experts to provide information on the U.S. consumer protection legislation and organizations who handle consumer complaints. Building on this dialogue, the Governments of Japan and the United States will continue to exchange views and support private sector input on consumer protection issues.
- F. **Electronic Signatures**
1. The “Law Concerning Electronic Signatures and Certification Services” came into force in Japan on April 1, 2001. Under this law, electro-magnetic records are presumed authentic if an electronic signature attached to an electro-magnetic record satisfies the necessary conditions stipulated in article 2 and article 3 of the Law. Parties can submit electro-magnetic records with electronic signatures as proof in court, and such records will not be denied legal effect merely because they are in electronic form.
  2. The Government of Japan confirms that the Law is technology-neutral and that accreditation procedures are voluntary. Furthermore, the Law does not give accredited certification providers any legal benefits that do not extend to

unaccredited providers. As of May 2002, six applications for accreditation have been granted.

G. **Payment Systems via the Internet:** The Government of Japan, while recognizing that it should promote a competitive market for electronic payment systems in which users can have confidence, also recognizes the importance of private sector leadership in the development of electronic payment systems as mentioned in the 1998 “U.S. - Japan Joint Statement on Electronic Commerce.” The Government of Japan believes that it is important for electronic payment systems to be able to transfer money quickly, to incorporate reliable authentication and authorization technologies, and to maintain high levels of security. Therefore, the Government of Japan has been revising regulations that hinder trading and business over the Internet, in order to support an environment in which consumers can safely use e-commerce, and private-sector entities can freely engage in various economic activities.

H. **Electronic Government Procurement**

1. Open and Transparent Competition in IT Procurement: The Government of Japan has taken various measures to ensure non-discriminate, transparent and fair procurements of computer products and services in the public sector. For example, the Government of Japan established a new interagency task force (comprised of all ministries) in December 2001 to deal with crosscutting issues on government procurement of information systems. The task force issued an agreement among the ministries, “Towards Improvement of Government Procurement Systems of Information Systems,” on March 29, 2002. Based on this agreement, the Government of Japan has made efforts to prevent extreme low-priced bids and to procure high quality information systems at a reasonable price from FY2002. In order to ensure transparent government procurement, the Governments of Japan and the United States will continue to exchange information as appropriate. The Government of Japan recognizes the importance of publishing information about the results of the task force studies.
2. Online Interactivity Between Bidders and Procuring Entities
  - a. The Ministry of Land, Infrastructure and Transport (MLIT) began online bidding through the CALS/EC system in October 2001 and plans to shift all of its construction projects to this online bidding system from the beginning of FY2003, one year ahead of schedule. The Government of Japan will introduce online bidding systems for non-public works by the end of FY2003.
  - b. MLIT began operating a consolidated database of its notices for public works in FY2001.

- c. Effective November 2001, MLIT began to promote online bidding for public works in local governments by providing MLIT's online bidding software and technical know-how free of charge to local procuring entities.
  - d. Under the e-Japan Priority Policy Program - 2002 adopted in June 2002, the Government of Japan will continue to provide support for local governments' introduction of digitized administrative and application procedures including procurement.
3. Software Asset Management: In line with the Brunei Summit APEC Economic Leader's Declaration in November 2000 calling for member governments to implement the agreement to promote strong management practices for software and other intellectual property assets, the Government of Japan affirms that it has issued a decree mandating the use of only authorized software by its government ministries. The Government of Japan also affirms that this system 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 this system.

## ***COOPERATIVE EFFORTS***

### **I. E-Education**

- 1. The Governments of Japan and the United States recognize the importance of digitization of school education and will continue to discuss the benefits of e-learning in educational systems. The two governments will also continue to discuss ways they can cooperate to promote private sector technological solutions for e-education, for example, by participating in an event similar to "Global Communication 2002."
- 2. In June 2002, Japan adopted the e-Japan Priority Policy Program - 2002 which focuses on both hardware and software, and aims to improve areas such as utilization of PC-based Internet in all classes in public schools by FY2005 and the IT instructional skills of teachers.

- J. **Promotion of IT Technology**: The Governments of Japan and the United States support the use of IT and e-commerce technologies to increase the efficiency and profitability of start-ups and small firms in the global marketplace. The Government of Japan is taking various measures such as holding seminars and training programs in Japan to promote IT among these firms. To further promote this goal, the Government of the United States will provide a demonstration of the IT Management Tool, which helps start-ups and small firms to develop and use IT resources. The demonstration will be held in collaboration

with the Ministry of Economy, Trade and Industry (METI) during an IT trade mission to Japan in September 2002.

- K. **Security:** The Governments of Japan and the United States share the view that the Organization for Economic Co-operation and Development (OECD) Guidelines for the Security of Information Systems and Networks are an important basis for national approaches to information security. In support of these Guidelines, the Government of Japan hosted a workshop organized by the OECD focusing on information security in a networked world in September 2001 in Tokyo. The Governments of Japan and the United States worked together with other member countries of the OECD to expedite completion of the review of the OECD Guidelines by September 11, 2002.

### III. ENERGY

- A. **Regulatory Authorities:** The Government of Japan will continue to work to ensure that the Electricity Market Division and the Gas Market Division of METI have effective, independent and transparent regulatory authority over Japan's electricity and gas regulation. To this end, the Government of Japan recently increased the staff and budget of the Gas Market Division and the Electricity Market Division.
- B. **Competition Policy Safeguards:** The Government of Japan has taken and will take the following steps to safeguard and promote competition in the electricity market:
1. In order to promote competition in the electricity sector and to clarify further what conduct by incumbent utilities and other enterprises may contravene the Antimonopoly Act or the Electricity Utilities Industry Law, JFTC and METI will review their joint Guidelines on Fair Transaction originally formulated in 1999 as necessary.
    - a. For that purpose, on June 3, 2002, JFTC and METI published for public comment draft supplements to those guidelines that would address problematic practices in such areas as ordinary back-up, adjustment or penalty charges, changes to demand-supply adjustment contracts and surplus power purchasing contracts, refusals of partial supply and cancellation of contracts for purchasing goods or services.
    - b. After reviewing and evaluating all comments received, JFTC and METI will reconsider the draft appendix and supplements and issue new final Guidelines by the end of 2002.
  2. JFTC has actively monitored and, where appropriate, investigated potentially exclusionary practices in the electricity sector.

- a. For example, JFTC fully investigated complaints that Chubu Electric Power Company and Kyushu Electric Power Company were engaging in anticompetitive practices that were making it difficult for new entrants to compete successfully in the electricity wholesale and retail markets. Upon completion of its investigations into those complaints, JFTC published an explanation of its conclusions, and an Interpretation of the Antimonopoly Act in relation to Electricity Partial Supply.
  - b. JFTC will continue to make public its evaluation of business activities in this sector with the goal of seeking to clarify the range of appropriate and inappropriate conduct in these markets.
- C. **Electricity:** The Government of Japan has taken and will take the following steps to ensure fair and effective competition as Japan continues regulatory reform of its electricity market.
1. In 2001, an Electricity Industry Committee comprised of industry representatives, engineers, economists, and consumer representatives was formed to officially examine Japanese electricity market regulatory reform. The Committee developed a number of themes that are crucial to establishment of a fair and effective electric power system to efficiently deliver a secure supply of electricity that will serve as infrastructure for the economic activities and livelihood of the Japanese people.
  2. The Committee has articulated the need for a clearly delineated electricity sector reform policy that provides a stable and fair electric supply system. The Committee has articulated the following principles and objectives:
    - a. Ensuring a coordinated planning process for construction of new generation and transmission facilities to meet growing electricity demand;
    - b. Ensuring coordinated engineering operations of generation and transmission facilities to balance electricity supply and demand;
    - c. Ensuring that the electricity network serves as a common infrastructure for power providers and guarantees transparent and fair competition. (While some progress has been made toward fairness, examination is needed of whether the existing network rules and information firewalls can secure fairness and transparency for all market players.);
    - d. Examining whether the current system of dispute resolution by METI and JFTC is adequate, with a view toward ensuring fairness in transmission access; and

- e. Examining whether the existing electricity system can meet the goals of security, efficiency, fairness, and transparency.
3. With respect to improving supply system efficiency, the Committee has articulated the following principles and objectives:
- a. Examining utilization of existing transmission capacity, the system for wheeling power, and planning of interregional transmission links, with a view toward facilitating power transactions nationwide, taking account of economic rationality and reliability; and
  - b. Examining the fairness of the system for allocating the cost burden of establishing and operating the transmission network.
4. With respect to security and diversity of supply, the Committee has articulated the following principles and objectives:
- a. Examining whether a system should be established to encourage electricity transactions over wider areas and construction of facilities to support these transactions, so that power supply will be more efficiently utilized nationwide;
  - b. Establishing a mechanism to ensure that power system reforms are consistent with the development of electricity sources (such as nuclear generation), which crucially contribute to long-term security of supply;
  - c. Considering establishment of a wholesale power exchange over a broader geographic market which would create a diversified, smoothly functioning and efficient wholesale electricity supply system and would assist in the benchmarking of electricity prices. In addition, take note that such an exchange requires further study from a technical standpoint and should be carefully designed in such a way as not to distort functioning of the market; and
  - d. Reviewing whether obstacles exist to development of distributed generating assets, which would enhance consumer choice, would increase efficiency through competition with electricity supplied through the network, and would increase the efficiency of energy supply through greater use of combined heat and power systems. In addition, consider the impacts of distributed generation on the environment, how to avoid redundancy with investments in the power network, how to maintain quality of power supply, and the benefits of connecting distributed generation into the network.

5. With respect to expansion of consumer choices and securing proper supply for all customers, the Committee has articulated the following principles and objectives:
    - a. Establishing a retail market environment where consumers can choose from diverse services and prices offered by multiple suppliers through competition;
    - b. Examining consumer protection measures in the context of requirements for universal electricity service, taking account of consumers' responsibilities and negotiating power as well as electricity's vital role in everyday life;
    - c. Considering technical and practical measures needed to expand retail choice; and
    - d. Clarifying a plan and schedule for expanded retail choice as soon as possible so that businesses will have a clear understanding of the market environment that contributes to adequate supply.
  6. The Electricity Industry Committee will be drawing conclusions on the objectives and principles thus far articulated, and based on the Committee's conclusions, the Government of Japan will be conducting regulatory reform in the electricity sector. To this end:
    - a. The Electricity Industry Committee will draft a report of its findings, release this report for public comment, and make public both the comments received and responses to these comments;
    - b. The Committee will finalize the report by the end of JFY2002, taking account of the public comments that have been submitted; and
    - c. The final report will serve as the basis of legislation to be submitted to the Diet in a timely manner.
- D. **Gas:** The Government of Japan has taken and will take the following steps to ensure fair and effective competition as Japan continues regulatory reform of its gas sector.
1. METI took the important step of establishing the Study Group on Gas Market Reform in January 2001 to formally consider the direction of further regulatory reform of the gas sector. The Study Group was comprised of 29 members from academia, gas companies, new market entrants, and consumer representatives. It met thirteen times and issued a report on April 22, 2002, which provides recommendations for medium- and long-term reform of this sector.

2. The Study Group agreed reform should proceed based on several fundamental principles:
  - a. Increasing customer benefits by ensuring security of supply and decreasing gas prices;
  - b. Creating an efficient, transparent, fair, and competitive market, contributing to expansion of the usage of environmentally friendly gas energy and the sound development of the gas industry;
  - c. Moving from the current regulation of broad aspects of activities by gas utility companies to regulation that focuses primarily on the gas transportation network;
  - d. Promoting third-party usage of gas infrastructure and ensure incentives for investing in gas infrastructure;
  - e. Utilizing market mechanisms and establish a safety net;
  - f. Conforming to the customer's needs and circumstances;
  - g. Proceeding with the reform process in a gradual and predictable manner; and
  - h. Minimizing ex-ante regulation of market activities by utilizing and ensuring appropriate balance between ex-ante regulation and ex-post regulation.
3. The Study Group proposed to promote construction and interconnection of gas pipelines and to enhance third-party usage of such pipelines by:
  - a. Increasing disclosure of information on pipeline capacity;
  - b. Improving incentives for construction of new pipelines; and
  - c. Expanding third-party access regulation, including the application to transportation for wholesale purposes.
4. The Study Group proposed to promote third-party usage of Liquefied Natural Gas (LNG) terminals through negotiations between owners and users of such terminals, by means such as:



- a. Disclosing information for users to estimate spare capacity in such terminals;
  - b. Compiling by owners of documents for applicants regarding conditions and procedures for use of LNG terminals;
  - c. Writing explanations by owners to parties that are denied usage of such terminals; and
  - d. Establishing government guidelines to facilitate negotiations and prevent or resolve disputes.
5. The Study Group proposed to further the scope of retail liberalization in the gas sector, while enhancing the reliability and security of gas supply, by, for example:
- a. Gradually expanding the scope of liberalization to more customers; and
  - b. Considering efficient systems for enhancing the security of supply for customers, delineating franchised areas of gas utility companies, allowing greater flexibility in rate and tariff calculation methodology, and so forth.
6. The Study Group proposed the separation of gas transportation and gas sales activities by at least:
- a. Separating accounts for transportation and sales activities of gas companies; and
  - b. Establishing a firewall between gas transportation and gas sales activities within each gas company.
7. The report that the Study Group issued on April 22, 2002, which is available on the Internet, is considered an important and valuable reference for further regulatory reform of the gas sector in Japan. METI has invited informal public comments on the report. These comments will also be available on the Internet.
8. METI intends to establish an official Advisory Committee during 2002 to officially examine regulatory reform in the Japanese gas market. Both the report of the Study Group and the public comments mentioned in the preceding paragraph will be submitted to the Advisory Committee and become an important and valuable reference for its work. The Advisory Committee is expected to issue a report on its work in a timely manner.

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

Under the Enhanced Initiative, the Government of Japan has taken a number of important measures related to medical devices and pharmaceuticals. Follow-up on these matters continues, and Regulatory Reform Initiative measures will be treated in a manner consistent with the previous measures.

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

1. Taking into account the current circumstances in Japan, such as the aging of the population, the declining birthrate and the economic condition, the Government of Japan submitted to the Diet a bill reforming the National Health Insurance System (NHIS) that included raising patient co-payment ratios and premiums. As part of the reform, the Ministry of Health, Labour and Welfare (MHLW) revised the pricing systems for medical devices and pharmaceuticals, as stated below. These revisions, consistent with previous measures, will be applied in ways that facilitate appropriate valuations of innovative medical devices and pharmaceuticals. MHLW provided the Government of the United States and U.S. industry with opportunities to express their opinions in that stage of the reform process.
2. As stipulated in the supplementary provisions of the Law to Amend the Health Insurance Law and other related laws, in JFY2002, MHLW will assemble the Basic Plan about the Health Insurance System including the Health System for the Elderly as well as the review of the structure of the Fee Schedule and will clarify the concrete contents and the procedure. Along with the debate about the issues above, it is expected that further discussions related to the health insurance coverage of medical devices and pharmaceuticals will occur.
3. MHLW welcomes input from the Government of the United States and U.S. industry. Meaningful opportunities will continue to be equally provided to the U.S. industry as well as to the Japanese industry to actively discuss with MHLW officials at all levels and in relevant Councils industries' proposals through various stages of the process, ensuring that their views are given serious consideration, in the discussions of medical device and pharmaceutical pricing systems. Such discussions 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 products.
4. MHLW raised the pricing premium ratio for usefulness as well as for innovativeness that will be applied in order to further ensure appropriate valuation of innovative pharmaceuticals that is expected to encourage innovative drug development.

5. MHLW took the steps to allow companies to submit an application which employs any coefficients chosen by applicants for having their drug listed in the Reimbursable Drug List when the Cost Accounting Method is used for pricing.
6. MHLW adopted new Drug Classification System, which is based on pharmaceutical and clinical principles, whose results in terms of comparator selection will appropriately recognize the value of innovative pharmaceuticals.
7. Furthermore, MHLW decided that the Specified Medical Care Coverage can be applied to medical interventions with drugs that have already been approved under the Pharmaceutical Affairs Law (PAL) but have not yet been covered by the Reimbursement Drug List. Such application will not disrupt the regular listing of drugs (four times a year) which is stipulated in the “Report on Medical Equipment and Pharmaceuticals Market Oriented, Sector-Selective (MOSS) Discussions.”
8. MHLW established medical device pricing rules for new by-function categories. The rules stipulate:
  - a. A new premium pricing system that will be applied for useful and/or innovative products in order to value innovative medical devices in a more appropriate manner that is expected to encourage innovative and useful medical device development;
  - b. Application of pricing rules for C1 medical devices, which increases the frequency of granting reimbursement prices to C1 products to twice a year and maintains the provisional price mechanism for C1 products; and
  - c. Reimbursement prices are granted to C2 products coinciding with the Medical Fee Revision. However, future discussions regarding C2 timing will continue between MHLW and the Government of the United States and U.S. industry.
9. MHLW decided that the Specified Medical Care Coverage can be applied to medical interventions with medical devices being used in clinical trials.
10. Furthermore, MHLW established a standard that full payment of fees for operations using certain medical devices (e.g., PTCA, Balloon Catheters, Pacemakers, etc.) should be limited to those operations which are conducted in case-rich medical care institutions or “so called centers of excellence.” It is considered that such operations being conducted sparsely among numerous medical care institutions is one of the reasons why medical device prices are inflated in Japan.

11. Issues that are related to medical device and pharmaceutical pricing will continue to be discussed on a case-by-case basis.

## **B. Approval Process**

1. Taking into account the rapid global development of bio/genomic technologies, diversification of the corporate behavior (e.g., outsourcing of production to allow more focus on development) as well as the need for international harmonization of regulations, the Government of Japan submitted a bill to amend the Pharmaceutical Affairs Law (PAL) with the aim to reform the measures for medical device safety, to clearly define biologics for proper treatment under PAL, to strengthen security measures for biologics considering their characteristics, to strengthen the post-marketing safety measures and to reform the approval/licensing scheme. The Government of the United States welcomes this bill. It is expected that the resulting reforms will improve the medical device and pharmaceutical regulatory systems.
2. A merger of the Organization for Pharmaceutical Safety and Research (OPSR) and the Pharmaceuticals and Medical Devices Evaluation Center (PMDEC) has been proposed and approved by the Cabinet. The Government of the United States also welcomes this plan. It is expected that this merger will improve the medical device and pharmaceutical approval processes.
3. The implementation of the revision of the PAL and the merger of OPSR and PMDEC will include an adequate transition period to ensure a smooth adjustment.
4. After passage of the bill, the Government of the United States and U.S. industry wish to make proposals for the development of concrete regulations for its implementation. MHLW will continue to provide meaningful opportunities to related parties, including U.S. and Japanese industry, on an equal basis to actively discuss with MHLW officials at appropriate levels upon request regarding their proposals through various stages of the process, ensuring that their views are given serious consideration.
5. Since 1994, the task of reviewing applications for pharmaceutical and medical device approvals has been outsourced to OPSR, the Japan Association for the Advancement of Medical Equipment and PMDEC. For those tasks that can be outsourced, MHLW is planning to consolidate and reorganize the divided tasks and outsource them to a new organization to establish a regime for faster approvals that ensures the safety and efficacy of products, while MHLW retains the tasks that the central government should assume, such as the final judgments of approval.

6. MHLW published an official document with a decision tree to clarify the categories – “me-too,” “improved” and “new” – for medical device applications on March 26, 2002 after an active dialogue with interested parties, including U.S. industry. The decision tree is expected to further clarify the demarcation between the “improved” and “me-too” categories to ensure proper classifications.
7. The issue of the treatment of thermometers and blood pressure gauges – which are subject to approval (*shonin*) under the Pharmaceutical Affairs Law as well as type test (*katashikishonin*) and individual unit verification (*kentei*) under the Measurement Law – is being reviewed by the Office of the Trade and Investment Ombudsman (OTO). Based on the OTO’s recommendations, taking necessary action will be discussed.
8. MHLW will continue the accelerated New Drug Application (NDA) approval process and the dialogue with related parties, including U.S. industry. The Government of the United States will continue to urge U.S. companies to compile and submit high-quality NDAs.
9. PMDEC and OPSR have further strengthened mutual cooperation, e.g., PMDEC staff members participate in the clinical trial consultations at OPSR. The consistency between the advice on applications provided at the clinical trial consultations by OPSR and the treatment of guidance provided in the consultations at PMDEC is expected to improve further.
10. MHLW will continue to discuss in constructive collaboration with U.S. industry on the issue of “legacy products” with the view of seeking a concrete resolution within the existing approval system. The Government of the United States will urge U.S. industry to actively cooperate with MHLW, seeking such resolution.

**C. Acceptance of Foreign Clinical Data**

1. Increased use of foreign clinical data in the approval of pharmaceuticals is a key to expediting availability of innovative drugs for patients worldwide. MHLW has been working to increase the acceptance of foreign clinical data as the primary evidence of safety and efficacy in the approval of new drugs. MHLW will continue these efforts in a manner consistent with the International Conference on Harmonization (ICH) principles and guidelines.
2. At the ICH meeting in May 2001, the members decided to address the implementation of the ICH E-5 Guideline, and the first meeting regarding this issue was held in February 2002. In moving forward with implementation of ICH E-5 Guideline, MHLW will continue working along with the members of ICH to identify the issues with the ICH E-5 Guideline including the interpretation of

racial groups as well as if and under what conditions additional data would be necessary to establish extrapolation scientifically in order to develop supplemental guidance (e.g., a Q&A) to make the guideline more easily implementable.

- D. **Blood Products:** Japan is in the process of considering new legislation for the purpose of securing a stable supply of safe blood products that includes the Demand and Supply Plan, which has the purpose of contributing to securing a stable supply of blood products. The Government of Japan, responding to concern expressed by the Government of the United States, confirms that the measures to implement the Plan will be taken in a transparent and non-discriminatory manner. MHLW confirms that it will continue to provide meaningful opportunities to related parties, including U.S. and Japanese industry, to exchange views on such provisions, and ensure that their views are given serious consideration.
- E. **Nutritional Supplements:** MHLW will add to the category of Food with Nutrient Function Claims vitamins, minerals and herbs for which labeling standards have passed necessary review by MHLW and the Pharmaceutical Affairs and Food Sanitation Council based on scientific findings regarding efficacy and safety as well as market data. During this process, MHLW will continue to provide opportunities for related parties to discuss their requests with MHLW officials with a view toward additional listings.

## V. FINANCIAL SERVICES

- A. The Government of Japan has submitted legislation for Diet approval that eliminates the requirement for physical certificates for fixed income securities and securities investment trusts, as of January 6, 2003. The legislation covers all investment trusts. The Japanese House of Representatives approved the legislation on May 21, and the House of Councilors approved it on June 5, 2002.
- B. The Investment Trusts Association has taken several steps to strengthen the regulation of money management funds (MMFs) to ensure their safety and liquidity, including tightened restrictions on eligible investment assets.
- C. Beginning in July 2000, and in line with the Government of Japan's policy of encouraging "E-government," the FSA has promoted a number of measures to allow electronic filing and reporting. The last in this series of measures is expected to be implemented in principle by the end of March 2004. The FSA's August 2001 securities market reform program effectively facilitated electronic disclosure of the prospectus of investment trusts. Simplified and enhanced procedures for the distribution of investment trust reports, including greater use of E-disclosure, took effect on June 1, 2001. The Government of Japan's March 2002 Deregulation Report stated it would conduct studies on the feasibility of electronic notification by money-lenders.

## **VI. COMPETITION POLICY**

**A. Independence and Staffing of JFTC:** In implementing the Cabinet Decision of June 26, 2001 on “Structural Reform of the Japanese Economy: Basic Policies for Macroeconomic Management,” in which the Cabinet decided that the structure and function of the Japan Fair Trade Commission (JFTC) would be strengthened:

1. The Government of Japan reaffirms “The Three-Year Program for Promoting Regulatory Reform (Revised Version),” which was adopted in the form of a Cabinet Decision on March 29, 2002. In accordance with that program, the Government of Japan will review the status of JFTC to make it more appropriate from the viewpoint of its independence and neutrality from the regulatory authorities.
2. JFTC received a net increase of 36 persons in its staff level for FY2002, resulting in a total staff level of 607 people as of March 31, 2002. JFTC’s investigative staff was increased by 25 people, bringing its total to 294.

### **B. JFTC Investigatory Capabilities**

1. The December 11, 2001 report of the Council for Regulatory Reform (CRR), adopted by the Cabinet on December 18, 2001, concluded that a comprehensive study should be undertaken of the system of enforcement measures available to JFTC under the Antimonopoly Act (AMA) and the appropriate powers that can be granted to JFTC, from the standpoint of ensuring strict enforcement of the AMA.
2. Taking into account the CRR report and Cabinet Decision, and examination and recommendations by the AMA Study Group and by the Committee Considering Competition Policy Appropriate for the 21<sup>st</sup> Century, JFTC is undertaking preparatory work for the purpose of the review of the current system of administrative and criminal measures against violations of the AMA, including the possible authorization for JFTC to exercise search and investigative powers for criminal violations and the possible introduction of a leniency program under which firms and individuals could receive more lenient treatment under the AMA if they cooperate with JFTC’s investigation.
3. JFTC is committed to applying the AMA, where possible, to cross-border anticompetitive activities, including international cartels, and is examining ways to improve its enforcement capabilities and effectiveness in this area. In this regard, on May 22, 2002 the Diet enacted legislation that provides JFTC with legal tools for effecting overseas service of process.

### **C. Effectiveness of AMA Enforcement**

1. JFTC has increased its enforcement activities against hard-core anticompetitive activities. In 2001, JFTC issued 41 formal recommendations for violations of the AMA, the most in 25 years. Thirty-five of those recommendations were against firms that engaged in unlawful bid rigging activities. JFTC reaffirms its commitment to continuing its active enforcement against AMA violations, especially with respect to cartels, bid rigging and other hard-core anticompetitive activities.
2. With the goal of strengthening deterrence of hard-core cartels and other serious anticompetitive practices, the Diet enacted legislation on May 22, 2002 that increases the maximum corporate criminal fine for violation of the AMA to ¥500 million (approximately \$3.8 million), a five-fold increase from the current maximum of ¥100 million.
3. JFTC and the Tokyo High Prosecutors Office will intensify their efforts to criminally prosecute companies and individuals that engage in anticompetitive practices that are illegal under §89 of the AMA.
4. The report of the Study Group on Reviewing the AMA, published in October 2001, recommended that JFTC consider expanding the scope of surcharge payment orders when the current system of administrative and criminal measures against violations of the AMA is to be reviewed from the viewpoint of further strengthening enforcement and deterrence against AMA violations. In response to this recommendation, JFTC is undertaking preparatory work for the review of the current system of measures, including the possible expansion of the scope of surcharge payment orders.
5. The Diet enacted legislation on May 22, 2002 that authorizes JFTC to take necessary measures against firms and trade associations, even when the unlawful activities are no longer occurring, to ensure that violations of AMA §6 (international contract prohibitions) or AMA §8 (conduct by trade associations) have ceased completely. The amendment will come into effect on June 29, 2002.

**D. Addressing Bid Rigging**

1. Recently, the ruling coalition and an opposition party have submitted separate bills to the Diet that address the issue of involvement by government procurement officials in bid rigging activities. The Government of Japan will carefully follow the process of discussions in the Diet.
2. The Government of Japan, from the standpoint of a commissioning entity of public works, believes that thorough enforcement of the “Act for Promoting Proper Tendering and Contracting for Public Works” (the “Act”), which came



into effect in April 2001, is a fundamental measure for preventing bid rigging (*dango*) and other improper bidding practices. From that standpoint, the Ministry of Land, Infrastructure and Transport (MLIT), the Ministry of Finance (MOF) and the Ministry of Public Administration, Home Affairs, Posts and Telecommunications (MPHPT) will, in June 2002 and annually thereafter, request each central government, quasi-governmental and local government commissioning entity to submit a report on the measures such commissioning entity has taken as of the end of the last fiscal year to comply with the “Guiding Principle” based on the Act. Among the items to be included in the report are (i) whether or not such commissioning entity has reported facts that raised a suspicion of *dango* to JFTC and (ii) whether such commissioning entity has prepared and published a manual for its officials regarding the handling of *dango* information.

- a. The three ministries will publish a summary of the reports by Fall 2002 and annually thereafter.
  - b. If the report from a commissioning entity indicates that it is especially necessary, the three ministries may ask the commissioning entity to take measures for improvement.
3. MLIT will, by June 2003, prepare a booklet containing materials related to countermeasures for *dango* and make it available on the MLIT website. MLIT will publicize and introduce the booklet to other commissioning entities for their reference and use. The booklet will include, among other materials: (i) procedures for reporting facts that point to the likelihood of *dango* activities to JFTC, (ii) measures for implementing “suspension of designation” of firms that commit *dango* and other illegal activities and (iii) excerpts from the Guiding Principle concerning the collection of compensation for damages incurred as a result of *dango* when it is possible to confirm the amount of damages.
  4. In light of the fact that, recently, illegal activities have been frequently found with regard to contracting for public works, in February 2002 MLIT established the “Committee for Thoroughly Ensuring Proper Tendering and Contracting of Public Works,” which is led by the Vice-Minister of MLIT. On March 27, 2002, the Committee established administrative measures for the purpose of ensuring thorough enforcement and implementation of the Act and further prevention and deterrence of illegal activities, including *dango*. These measures include:
    - a. Publication of concrete standards for the imposition of administrative penalties based on the Construction Business Act, including an increase in the administrative penalty on firms that repeat the same kind of illegal activities. For example, firms that are finally determined by JFTC to have

engaged in a *dango* violation within three years after the previous penalty shall now have their business license suspended for a minimum of 30 days (up from 15 days previously); and

- b. A policy to publish on the Internet the name of each firm subjected to administrative penalties, as well as a description of the illegal activities and the administrative penalty imposed.

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

1. JFTC will continue to play an active role in promoting competition in industries undergoing deregulation.
2. JFTC will devote a large portion of its staff to monitoring the markets where government regulations have been eased or more vigorous competition is expected.
3. In April 2001, JFTC established the Information Technologies and Public Utilities Task Force within its Investigation Bureau, strengthening its efforts to investigate and take necessary measures against violations of the AMA in industries undergoing deregulation, such as the telecommunications, electricity and gas sectors. The IT and Public Utilities Task Force has already undertaken a number of actions to promote competition in sectors undergoing deregulation, including warnings in December 2001 against two major telecommunications companies for suspicion of discriminatory treatment of competing telecommunications carriers that would violate the AMA.
4. JFTC has recruited outside experts from economics and intellectual property rights fields and has assigned them to those sections that are key to regulatory reform. JFTC has also been allocating personnel on a priority basis. JFTC will continue to recruit outside experts and to allocate personnel on a priority basis in order to enhance the capabilities of such sections, including the IT and Public Utilities Task Force.
5. On November 30, 2001, JFTC and MPHPT issued joint Guidelines for the Promotion of Competition Policy in the Telecommunications Business Field. The Commission and the Ministry will conduct a review of the Guidelines in 2002 and will continue to do so as necessary in the years ahead. Both agencies will continue to cooperate in promoting competition in the telecommunications sector.
6. JFTC addressed for the first time competition issues raised by the convergence of the telecommunications and broadcasting sectors when it published the report prepared by the Study Group on Government Regulation and Competition Policy

on that topic. The Report included recommendations on promoting competition and new entry in this area.

7. JFTC and the Ministry of Economy, Trade and Industry (METI) continue to work together in promoting and preserving competition in the electricity and gas sectors. In particular,
  - a. JFTC continues to attend the Electricity Industry Committee, which is examining such issues as the expansion of consumer choices and ways to ensure fairness in transmission access, and is providing its opinion from the viewpoint of promoting competition.
  - b. JFTC attended METI's Study Group on Gas Market Regulatory Reform, which studied such issues as the expansion of the liberalization range, and access and transparency for pipelines and LNG terminals, and provided its opinion from the viewpoint of promoting competition. The study group published its report in April 2002.
8. In order to ensure that the restructuring and privatization of public corporations is accomplished in a manner that enhances competition, the Cabinet in March 2002 adopted a plan by the Administrative Reform Promotion Headquarters to enable the private sector to do business operations currently carried out by public-service corporations, and thereby prevent dominant control by public corporations.
9. JFTC will conduct surveys of one or more sectors in FY2002 for the purpose of evaluating the competitive situation in such sector(s). Such survey(s) may include sectors characterized by a highly oligopolistic market structure.

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

### **A. Public Comment Procedures**

1. Ministries and agencies will make efforts to take into consideration the comments and information submitted by the public when formulating, amending or repealing a regulation based on "Public Comment Procedure for Formulating, Amending or Repealing a Regulation" decided by the Cabinet in March 1999.
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 Public Comment Procedure, the Ministry of Public Management, Home Affairs, Posts and Telecommunications (MPHPT) conducts a survey on how public comment procedures are implemented and makes the results public. MPHPT will continue its efforts so that the Public Comment Procedure will be effectively

utilized through such measures as conducting a survey on the implementation of the Procedure by each ministry and agency.

**B. “No Action Letter” System**

1. By the end of March 2002, twelve ministries and agencies of the Government of Japan had adopted detailed rules related to the implementation of Prior Clearance Procedures for Application of Laws and Ordinances by Administrative Organs (*Gyousei kikan ni yoru horei tekiyou jizen kakunin tetsuzuki*), the so-called “No Action Letter” system with respect to fields such as information technology and finance where active creation of new industries as well as innovative products and services is taking place. Under this system, businesses may submit inquiries to ministries and agencies with regard to the interpretation and application of laws and ordinances to specific factual situations. The ministries and agencies respond in writing to inquiries within 30 days, in principle, and make their responses public.
2. In order to ensure proper implementation of the above-referenced procedure, MPHPT is currently conducting a survey of the implementation of the procedure and will make its findings public as soon as the survey is completed via media such as its website. The results of the survey that will be made available include the introduction and implementation status of the procedure for each ministry and agency, a list of the laws and ordinances of each ministry and agency that may be subject to inquiries and information on each of the responses that have been issued, including the inquiries.

**C. Access to Information:** On December 5, 2001, the "Law Concerning Access to Information Held by Independent Administrative Institutions, etc." (tentative translation, Law No. 140 of 2001) was promulgated. The Law provides the right to request the disclosure of information held by Independent Administrative Institutions (*dokuritsu gyosei hojin*), Public Corporations (*tokushu hojin*), etc. and stipulates an obligation that the corporations inform the public of their activities. The Law will become effective on October 1, 2002.

**D. Administrative Guidance:** The Government of Japan continues to observe the Administrative Procedure Law and ensure transparency and clarity of administrative decisions, such as granting permissions, and administrative guidance. MPHPT will continue to be open to opinions from the public concerning the Administrative Procedure Law and administrative guidance.

**E. Policy Evaluation System**

1. On April 1, 2002, the Government of Japan implemented the Government Policy Evaluation Act (GPEA) (*Gyousei Kikan ga Okonau Seisaku no Hyouka ni Kansuru Horitsu*).
2. On December 28, 2001, the Cabinet adopted, as a Cabinet Decision, the "Basic Guidelines for Policy Evaluation" in accordance with Article 5 of the GPEA to ensure that policy evaluations are conducted in accordance with the Law. The Basic Guidelines identify items required in the basic plan for policy evaluation, which is developed by the head of each administrative organization, and prescribe the measures for policy evaluations by the Government.
3. Based on the GPEA and the Guidelines, each administrative organization had prepared a mid-term basic plan and an annual implementation plan, and is now conducting its own policy evaluations.

F. **Public Corporations:** On December 19, 2001, the Cabinet adopted a "Program for Readjustment and Rationalization of the Public Corporations." In implementing this Program, the Government of Japan will:

1. Conduct the restructuring and privatization based on this Program in a transparent manner; and
2. Establish an advisory committee consisting of well-informed persons from the private sector to monitor and evaluate the implementation of the Program.

G. **Postal Financial Institutions**

1. With regard to the transfer of the postal services from the Postal Services Agency to the New Public Corporation in 2003, the Minister of Public Management, Home Affairs, Posts and Telecommunications (MPHPT) established the Study Group on Public-Corporatization of Postal Services. This Study Group compiled an "Interim Report" on December 20, 2001. In this process, the Study Group ensured transparency by such efforts as conducting public hearings in Tokyo, Sendai, Kumamoto, and Nagoya at which interested parties expressed their views, implementing the public comment procedure by inviting public comments on the Study Group's draft interim report and posting detailed minutes of the meetings of the Study Group, as well as reference materials for the public, on the Internet.
2. Based on the above-mentioned "Interim Report," MPHPT drew up the "Japan Postal Services Public Corporation (JPSPC) Bill" on April 26, 2002 and the "Japan Postal Services Public Corporation Enforcement Bill" on May 7, 2002, both of which are under deliberation in the current Diet session. (\*The English translation for the names of these bills is provisional.)

3. With regard to the regulations related to the establishment of the JPSPC, MPHPT will provide opportunities for private sector interested parties, upon request, to exchange views with MPHPT officials.
4. The draft postal legislation provides that: (a) after JPSPC is formed, the insurance products and riders underwritten or sold on consignment by JPSPC will continue to be offered pursuant to law; and (b) approval from the Diet will be required to expand or change the products or riders offered by JPSPC, except for limited alterations within the scope of the products or riders authorized by law. JPSPC cannot originate any non-principal-guaranteed investment products, as the draft postal legislation does not include any provisions describing these products.
5. The draft postal legislation intends to make *kampo* and *yucho* subject to inspection and taxation requirements similar to those to which private sector financial companies are subject.

## VIII. LEGAL SYSTEM AND INFRASTRUCTURE

### A. Legal Services (*Gaikokuho-Jimu-Bengoshi*)

1. To promote cooperation and collaboration between *bengoshi* and *gaikokuho-jimu-bengoshi* (*gaiben*), the Office for Promotion of Justice System Reform plans to submit legislation to the ordinary session of the Diet, which is expected to commence in mid-January 2003, to deregulate the requirements for specified joint enterprises (*tokutei kyodo jigyo*). The Government of Japan is providing opportunities for *gaiben* and other interested parties to provide input into that process.
2. The Government of Japan takes note of the U.S. Government's proposal related to the establishment of professional corporations by *gaiben* and the recognition in Japan of limited liability entities established in the home jurisdictions of *gaiben*.
3. Concerning the review of the regulation that prohibits a *gaiben* from employing a *bengoshi*, the Government of Japan will carefully study how to handle the matter, based upon the Recommendation of the Justice System Reform Council, which states that "(c)ontinued consideration should be given to abolishing the prohibition on the employment of Japanese lawyers by GJB (*gaiben*), as a matter for the future, paying heed to the international discussion."
4. Concerning the review of the regulation that provides that *gaiben* may handle legal business regarding third country law under a certain condition, and the deregulation of the requirements of legal practice experience for registration as a *gaiben*, the Government of Japan will carefully study how to handle these matters,

based upon the Recommendation of the Justice System Reform Council, which states that “(a)s for the review of the GJB (*gaiben*) system and the management thereof, prompt and thorough consideration should be given from the users’ point of view, bearing in mind international discussion.”

5. In undertaking the study referred to in paragraphs 3 and 4, 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.
6. The Government of Japan continues to support *Nichibenren* and local bar associations providing *gaiben* with effective opportunities to participate in the proceedings of the bar associations, including attending general meetings concerning the rules and regulations that apply to *gaiben*, expressing their opinions in those meetings, and participating in the making of decisions with regard to the development and enforcement of all rules and regulations that may apply to them.
7. The Minister of Justice, unless exceptional circumstances exist, endeavors to make a decision on an application to be recognized as a *gaiben* in approximately two months.

## **B. The Justice System Reform**

1. The Justice System Reform Council submitted its final Recommendation to the Cabinet on June 12, 2001. The Government of Japan, on June 15, 2001, adopted a Cabinet Decision to specify measures necessary to realize justice system reform, and to take such necessary measures as aiming to enact relevant laws within three years.
2. The Justice System Reform Promotion Law was enacted in November 2001, and the Office for Promotion of Justice System Reform was established under the Cabinet on December 1, 2001. Based on the Law, the Cabinet adopted the Program for Promoting Justice System Reform on March 19, 2002. The Office for Promotion of Justice System Reform (Reform Office) is playing a central role in preparing necessary legislation according to the Program. The Program provides for the following:
  - a. To reform the arbitration law, the Reform Office plans to submit legislation to the ordinary session of the Diet, which is expected to commence in mid-January 2003, which will include a major revision of the existing Arbitration Law and improvement of the legal framework for arbitration, including international commercial arbitration;

- b. To increase the speed and efficiency of civil litigation, the Reform Office and Ministry of Justice plan to submit legislation to the ordinary session of the Diet, which is expected to commence in mid-January 2003, to reduce by half the length of time required to complete court trials through measures to promote efficient scheduling of hearings, and facilitate litigants' collection of evidence at early stages of litigation; and
- c. To reinforce the review function of the judicial system vis-à-vis the administration, the Reform Office is undertaking a comprehensive study, including review of the Administrative Case Litigation Law and consideration of the most appropriate manner for conducting judicial review of administrative actions, and will take necessary measures by November 30, 2004.

## **IX. COMMERCIAL LAW**

**A. Flexibility in Capital Structure:** In order to increase the flexibility of a company's capital structure and to improve the methods through which companies may obtain financing and services or provide incentives to managers and employees, the Commercial Code was amended to:

- 1. Relax restrictions on the size of units of stocks, including abolishment of the ¥50,000 per share minimum issue price and restrictions on the minimum net assets per share at the time of stock splits;
- 2. Authorize the issuance of tracking stock;
- 3. Allow a company to issue shares with limited voting rights, the total number of which may not exceed more than one-half of the total issued and outstanding shares. (Before the amendment, a company could not issue those types of shares, except for non-voting shares, and the total number was limited to one-third of total outstanding shares.);
- 4. Liberalize substantially the restrictions on issuance of stock options, including:
  - a. Abolition of the restriction on the range of persons to whom a Japanese company may render stock options, which had been limited to directors or employees of that company;
  - b. Abolition of the present restriction on the quantity of stock options that can be issued by a company; and
  - c. Allowing transfers of stock options.



5. Permit closely-held corporations to issue new classes of shares with rights to appoint and dismiss a specified number of directors or statutory auditors (*Kansayaku*); and
6. Allow a company to use certifications issued by professionals such as lawyers, accountants or tax accountants as an alternative to an inspection by court appointed inspectors for valuation of in-kind capital contributions. Such professionals will not be subject to strict liability.

## **B. Improvements in Corporate Governance**

1. With the goal of improving the ability of companies to manage and govern themselves in an efficient manner, the Commercial Code was amended to:
  - a. Introduce a new system of corporate governance, consisting of the board of directors, executive or corporate officers, and three committees (the audit committee, nominating committee, and compensation committee) composed of at least a majority of outside directors, for large corporations. If a corporation chooses the new system, there is no requirement to have statutory auditors (*Kansayaku*). This new system enables the board of directors to properly delegate substantial management authority to officers.
  - b. Permit companies to use the Internet or other electronic means to provide notices of shareholders' meetings and other similar communications to shareholders upon individual consent, and permit shareholders to exercise their voting rights through the use of electronic devices. In addition, companies will be permitted to meet their mandatory disclosure requirements for balance sheets (and profit and loss statements) by making the full text available for 5 years in an electronic format.
2. The Government of Japan will continue to implement high quality, internationally acceptable accounting standards. In that regard, on April 19, 2002, the Business Accounting Council issued an exposure draft on accounting standards impairment of fixed assets for public comments. In the draft, the standard becomes operative for financial statements covering periods beginning on and after April 1, 2005, and earlier adoption for financial statements covering periods ending on and after March 31, 2004 is not prohibited. The Government of Japan will supplement recent progress in adopting internationally acceptable accounting standards with strict enforcement of the implementation of those standards (through outside audits and other means) in order to ensure that a financial statement accurately represents the financial condition of a company.

C. **Branches and Statutory Agents for Foreign Companies:** The Commercial Code was amended to abolish the requirement that foreign companies conducting continuous business activities in Japan must set up a branch office in Japan. In the amendment, no strict liability is imposed on the statutory agents of foreign companies.

D. **Flexibility in Procedures of Mergers**

1. In order to facilitate merger and acquisition activity, the Government of Japan will initiate within FY2002 a study regarding introduction of such techniques as triangular mergers and cash mergers – including short form (squeeze out) mergers – in commercial law.
2. During the course of such study, the Ministry of Justice will provide the international business and legal communities opportunities to give input into such study and will make every effort to take into account such input in reaching its conclusions.

E. **Public Input into Commercial Law Revision Process**

1. On April 18, 2001, the Corporate Law Division of the Legislative Council issued its Tentative Summary Draft Legislation proposing the broad revision of the Commercial Code with a view to inviting comments from the public on the Draft Legislation. The Legislative Council took into account as much as possible the various opinions it received and issued the Final Summary Draft Legislation on February 13, 2002.
2. The Legislative Council will continue to make every effort to take into account comments and opinions from various sectors of society, including the international business and legal communities, in preparing its summary draft legislation in the future, as it did in the past.

X. **DISTRIBUTION**

A. **Nippon Automated Cargo Clearance System (NACCS)**

1. Before introducing the new user fee structure at the renewal of the Air-NACCS System in October 2001, the Nippon Automated Cargo Clearance System Operations Organization (NACCS Center) established a useful dialogue with users of the Air-NACCS System and used the public comment procedure. This dialogue with users led to the introduction of the current three-year arrangement. The Center also used the public comment procedure in April 2002. The Center will continue to seek users' opinions through various measures, including public comment procedures, whenever its user fee structure is revised in the future.

2. The Government of Japan expects that the Center will continue to communicate with all users before introducing a new fee structure and furthermore to provide administrative information to the public about its operations in a timely fashion when requested to do so in accordance with relevant laws and statutes.

**B. Simplification of Customs Procedures**

1. The Government of Japan has taken a number of measures to expedite customs clearance of cargoes. These include the Pre-arrival Examination System for import cargoes, the System of Instant Import Permit upon arrival for air cargoes, the Simplified Declaration Procedure (in March 2001), the advanced examination system for export air cargoes before bringing into the *hozei* area, and the manifest declaration system for express consignment whose declared value meets certain conditions (both in October 2001).
2. The time-release survey of March 2001 showed that as a result of these efforts to expedite customs clearance, the required time for cargo release has been shortened considerably. According to the findings of the survey, the average time from import declaration to import permission of air cargoes has been reduced to 0.6 hours and the average time from arrival of a vessel into port to import permission has been reduced to 25.7 hours (about a 19% reduction in comparison with the equivalent data collected in March 1999).
3. The Government of Japan will continue to promote simplification of its customs procedures.

**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. 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 consider the requests of the Government of Japan to shift to a first-to-file system, to ease requirements for the unity of invention, and to modify the system which is based on the Hilmer Doctrine.
  - b. The Government of the United States will continue to consider the requests of the Government of Japan regarding abolition of the exceptions to the publication of patent applications within 18 months from the filing date.
  - c. The Government of the United States will continue to consider the requests of the Government of Japan regarding further improvements of the re-examination system and support the adoption of bills on the re-examination system which are now under discussion in the 107th Congress.
3. Exon-Florio Provision: The Government of the United States recognizes the Government of Japan's concerns on the "Exon-Florio" clause regarding, inter-alia, predictability of regulations, legal stability of completed transactions, and ensuring due process. In operating the clause, the Government of the United States is mindful of the Government of Japan's concerns, and will ensure the clause's consistency with WTO rules.
4. 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 the federal and local government level. In the meantime, the Government of the United States has taken the following interim measures:

- a. The National Institute of Standards and Technology (NIST) at the Department of Commerce and the National Conference on Weights and Measures (NCWM) coordinated regarding full implementation of the revised Uniform Packaging and Labeling Regulations (UPLR), which permit metric-only labeling on U.S. consumer products as of January 1, 2000.
- b. A legislative proposal has been prepared for submission to Congress to update the Fair Packaging and Labeling Act (FPLA) to permit the option of metric-only labeling on products covered by the Act.

**B. Sanctions Acts**

1. The Government of the United States understands the concerns of the Government of Japan regarding legislation enacted in August 2001, extending the Iran Libya Sanctions Act until 2006.
2. The Government of the United States understands the concerns of the Government of Japan regarding the Cuban Liberty and Solidarity Act of 1996.
3. The Government of the United States will continue its efforts to ensure that sanctions initiatives at the state and local level are consistent with U.S. foreign policy. Such efforts will include working with the governors, attorney generals and government procurement officials of relevant states to ensure the consistency of their sanctions acts with the U.S. constitutional standards.

**C. Distribution**

1. Customs Clearance: After the 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 World Customs Organization (WCO).
2. 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 Government 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.

3. 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).
4. 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.
5. 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**: The Government of the United States' antitrust agencies are currently reviewing the appropriate scope and reach of various limitations on and exemptions to the applicability of the federal antitrust laws. The Government of the United States' antitrust agencies are also examining certain court doctrines and decisions to determine whether the Government of the United States should file amicus curiae briefs in an effort to ensure that those doctrines and decisions are not imposing inappropriate constraints on the reach of the antitrust laws.

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

1. Legal Services:
  - a. In the United States, 23 States and the District of Columbia have foreign legal consultant rules. From the viewpoint of facilitating international business, the Government of the United States continues to support the adoption of such rules by the other States.
  - b. In August 2002, the American Bar Association's (ABA) Commission on Multijurisdictional Practice will submit a Report to the ABA House of Delegates in which the Commission will recommend that with regard to lawyers admitted to practice only in non-U.S. jurisdictions, the ABA encourage U.S. jurisdictions to adopt the ABA *Model Rule for the Licensing of Legal Consultants* or to conform their already existing rule to the Model Rule. The Government of the United States supports the adoption of this Rule by states.
  - c. The Government of the United States will continue the discussion of legal services issues with the ABA. The Government of the United States has

informed the ABA of the requests of the Government of Japan with respect to foreign legal consultant rules.

2. Product Liability Reform: The Government of the United States recognizes that U.S. and foreign companies have concerns regarding the product liability system. The Government of the United States confirms that it has no intention of treating foreign companies unfavorably in any product liability reform process.

**F. Consular Affairs**

1. 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.
2. Regarding Arrival-Departure Records, or “I-94s,” the INS 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 INS 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 INS continue to consider the establishment of a standard period for processing extension of stay applications to be applied uniformly in all INS offices.
3. Social Security Numbers:
  - a. Regarding Social Security Numbers (SSNs), the Government of the United States has provided the Government of Japan with contacts points at the Social Security Administration to register and respond to complaints as they arise.
  - b. Many U.S. agencies and private businesses ask individuals for SSNs for many purposes, even from persons to whom SSA is not permitted by law to assign SSNs, and even when that information is not required to provide a requested service. For this reason, the SSA advises any Japanese citizen (who is not eligible for an SSN) asked for an SSN, to inform the agency or business that he/she does not have an SSN, and ask them to use another means of identification, for purposes of whatever service he/she requires.
  - c. The Social Security Administration will continue to inform private businesses of the amended rule of 1996 limiting the issuance of SSNs, and will continue to instruct relevant administrative agencies and businesses to accept alternative means of identification.

- d. The Government of the United States took note of the Government of Japan's request that the SSA consider amending the relevant rules so that legal residents can obtain SSNs.
4. Regarding international driver's licenses, the Government of the United States will confirm the official policies of individual states regarding the use of international driver's licenses and will, as necessary, request that individual states share this information with all relevant law enforcement authorities.

## 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 concerns in this area, the Government of the United States clarified that United States law does not prohibit private foreign entities from holding up to one hundred percent direct investment in non-broadcast, non-common-carrier or non-aeronautical en route or non-aeronautical fixed radio station licenses.

### 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 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 (including the application of dominant carrier regulations to international carriers).
2. As part of the 2000 Biennial Regulatory Review of regulations relating to international services, the FCC eliminated the obligation that U.S. international carriers classified as dominant for the provision of particular international communications services solely because of foreign carrier affiliation file international service tariffs. The FCC will provide relevant information on the 2002 Biennial Regulatory Review to the Government of Japan.

C. **State-Level Regulations:** 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. Regarding aspects of incumbent local exchange carrier compliance with the 1996 Telecom Act, the FCC has proposed simplified and harmonized nation-wide reporting requirements (known as performance standards).

### D. **Access to Incumbent Carriers' Networks**



1. In May 2002 the United States Supreme Court upheld the FCC's decision to use a forward-looking costing methodology, namely the Total Element Long-Run Incremental Cost (TELRIC) methodology, as the standard for setting rates for access to the networks of incumbent local exchange carriers. The Government of the United States will continue to provide information to the Government of Japan on implementation of this methodology throughout the United States.
2. The FCC is exploring the feasibility of instituting a unified inter-carrier compensation regime covering inter-state, commercial wireless, and local services.

E. **Procedures for Processing Export Licenses and TAA Approval of Commercial Satellites:** The Government of the United States explained that the export process for commercial communications satellite components and technical data for NATO and non-NATO allies, including Japan, had been simplified under the Defense Trade Security Initiative (DTSI) announced in May 2000. Taking into account Japan's concerns with regard to the procurement of commercial satellites in a timely fashion, the Government of the United States will continue its efforts to shorten the processing period for export licenses and TAA approval for commercial communications satellites.

### III. INFORMATION TECHNOLOGY

A. **Copyright Protection:** The Government of the United States will continue a dialogue with the Government of Japan on issues of concern related to copyright protection and will promptly provide relevant information upon request from the Government of Japan to the extent reasonable.

#### *COOPERATIVE EFFORTS*

##### B. **E-Education**

1. The Governments of the United States and Japan recognize the importance of digitization of school education and will continue to discuss the benefits of e-learning in educational systems. The two governments will also continue to discuss ways they can cooperate to promote private sector technological solutions for e-education, for example, by participating in an event similar to "Global Communication 2002."
2. In June 2002, Japan adopted the e-Japan Priority Policy Program – 2002 which focuses on both hardware and software, and aims to improve areas such as utilization of PC-based Internet in all classes in public schools by FY2005 and the IT instructional skills of teachers.

- C. **Promotion of IT Technology:** The Governments of the United States and Japan support the use of IT and e-commerce technologies to increase the efficiency and profitability of start-ups and small firms in the global marketplace. The Government of Japan is taking various measures such as holding seminars and training programs in Japan to promote IT among these firms. To further promote this goal, the Government of the United States will provide a demonstration of the IT Management Tool, which helps start-ups and small firms to develop and use IT resources. The demonstration will be held, in collaboration with METI, during an IT trade mission to Japan in September 2002.
- D. **Security:** The Governments of the United States and Japan share the view that the Organization for Economic Co-operation and Development (OECD) Guidelines for the Security of Information Systems and Networks are an important basis for national approaches to information security. In support of these Guidelines, the Government of Japan hosted a workshop organized by the OECD focusing on information security in a networked world in September 2001 in Tokyo. The Governments of the United States and Japan worked together with other member countries of the OECD to expedite completion of the review of the OECD Guidelines by September 11, 2002.

#### IV. ENERGY

- A. **Federal and State Authority:** In response to the Government of Japan's inquiries, the Government of the United States confirmed the following improvements already underway or planned to address the overlapping structure of federal and state regulations and different regulations:
1. The Supreme Court, in the case of *New York vs. Federal Energy Regulatory Commission*, confirmed FERC's jurisdiction over electric transmission lines throughout the country, consistent with federal authority over interstate commerce in the U.S. Constitution. The Supreme Court ruled that FERC's authority extends even to transmission lines involved in retail sales, and even when rates for transmission are bundled with those for generation or distribution.
  2. The Energy Policy Act of 2002 currently under consideration by the U.S. Congress would further reinforce FERC's authority to establish and supervise Regional Transmission Organizations (RTOs), as well as to enforce mandatory reliability standards for RTOs; police unjust or discriminatory rates and to 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 Regional Transmission Organizations (RTOs) with both operational and planning responsibilities for wide geographical regions. It is anticipated that the larger markets created by

RTOs will enhance competition. Further, it has issued a Notice of Proposed Rulemaking for a Standard Market Design rule expected to be issued around the end of 2002. The standard market design rule would assure that any supplier of electric power could be given consistent treatment nationwide, rather than adapting its strategy to differing markets in different regions.

4. Traditionally, reliability of electric service in the United States has been maintained through voluntary regional reliability organizations under the aegis of the North American Electric Reliability Council (NERC). To ensure that standards of reliability continue to be maintained as electricity markets become more competitive, the Energy Policy Act of 2002 would make participation in such reliability organizations mandatory for all users, owners, and operators of the bulk power system. The FERC would have authority under the Act to order compliance with reliability standards and to enforce such compliance by the power to impose penalties on entities that are found, after public hearing, to have violated a reliability standard approved by the Commission.
5. The National Energy Policy (NEP), released in May 2001, voices a national interest in maintaining a robust transmission infrastructure. The NEP notes that transmission constraints can reduce system reliability, increase market manipulation, restrict competition, and result in higher prices to consumers and industry. To minimize transmission constraints in the context of competitive markets, the NEP advocates efficient transmission system investment with accelerated siting and permitting of needed transmission facilities, as well as regional transmission organizations, improved energy efficiency, increased voluntary load response to grid constraints, and compliance with reliability rules. The National Energy Policy recommends that existing laws be used to encourage investment in transmission facilities and also recommends new legislation to grant the federal government authority to obtain rights of way for new electric transmission lines as it already has for gas pipelines.

**B. Liberalization Schedule:** The Government of the United States reported to the Government of Japan on the extent of and time frame for liberalization:

1. With respect to liberalization of wholesale markets (which have been open to competition for over twenty years and were brought to full market pricing by the Energy Policy Act of 1992 and Orders 888 and 889 – issued by the FERC in 1996 to ensure fair and non-discriminatory access to the transmission grid for all electricity suppliers):
  - a. About one-third of all electric power in the United States is now provided by non-utility generators (NUGs), whose share of electricity generated grew steadily from 12 percent in 1998 to 29 percent in 2001.

- b. Almost all new powerplants which are planned or under construction are being built by competing NUGs, not by traditional utilities.
  - 2. With respect to liberalization of retail markets, which received its major impetus from states with high-cost electricity that wished to obtain power at lower cost:
    - a. Seventeen states and the District of Columbia, with nearly half of the total population of the United States, have provided for retail choice of suppliers by electricity customers.
    - b. Several other states have official studies underway to examine the possibility of providing retail choice in the future. According to the National Regulatory Research Institute, ten additional states continue to study restructuring. In addition, two states have limited retail access, and four states which have delayed retail access are likely to ultimately provide it as well.
    - c. The federal government is actively monitoring the scope and timetable of liberalization in remaining states and considers that widening competition in wholesale markets, with the promise of lower prices, will help encourage additional states to open up their retail markets to competition.
  - 3. The Congress of the United States requested a report on retail electric power regulatory reform from the Federal Trade Commission (FTC) which the FTC issued in September 2001, with several key conclusions:
    - a. Competitive wholesale markets are important to achieving effective competition in retail markets;
    - b. Policies are needed to make demand for power in both wholesale and retail markets more responsive to price;
    - c. If consumers who do not switch retail suppliers are guaranteed a rate that does not reflect the market costs of providing power, both entry by new retail power suppliers and incentives for customers to choose a new supplier will be inhibited; and
    - d. Effective consumer protection policies will encourage retail choice and competition by providing accurate, timely and comparable information about retail suppliers.
- C. **PUHCA Review:** Recognizing that the Public Utility Holding Company Act of 1935 (PUHCA) restricts competition in electric power markets by attaching conditions to

participation in the marketplace by certain firms, the National Energy Policy (NEP), issued in May 2001, recommends repeal of PUHCA in order to enhance competitive market entry. Repeal of PUHCA is contemplated in the Energy Policy Act of 2002, which is under consideration by the U.S. Congress.

- D. **Publicly Owned Entities:** Over the past several years, the Government of the United States has been assessing the impact of Publicly Owned Entities (POEs) on fair competition in a liberalized market. The Energy Policy Act of 2002 would provide that federal Power Marketing Authorities and the Tennessee Valley Authority are treated as electric utilities for regulatory purposes. They would thus be required to provide access to government-owned transmission facilities to all competing generators on a non-discriminatory basis.
- E. **Wholesale Price Caps:** In response to an inquiry from the Government of Japan regarding price caps in wholesale markets, the Government of the United States noted:
1. As a general matter, price caps for wholesale power transactions run contrary to the effective functioning of competitive markets, in which prices should signal supply scarcity and a sustained period of high prices helps encourage the construction of needed new supply.
  2. However, short-run demand response is limited because many consumers lack the metering devices and real-time price information that would allow them to limit their demand in response to higher prices. Hence, short-run demand curves may become nearly vertical, with very sharp price spikes which far exceed marginal costs. In the short run, construction of new generating plants cannot be counted on to limit price spikes. In addition, flawed state regulatory policies, no longer in force, barred customers from signing long-term hedging contracts that would have protected them from price spikes. Under such conditions, the market cannot reach equilibrium as it would in a fully functioning competitive market situation.
  3. With this in mind, and in the face of sustained price spikes to which residential and small commercial customers had little ability to respond, the FERC established a variable benchmark wholesale power price for the Western Area Power Administration on a temporary basis which is equal to the cost of power from the highest-cost generating unit in service in the West.
    - a. All generators bidding at or below the benchmark price receive that price. Generators exceeding the benchmark must justify their prices or face possible refunds.
    - b. Since the benchmark is set at the short-run incremental cost of generation from the unit which has the highest marginal cost of operation, there

remains a substantial market incentive to provide new supply from more efficient plants which will have lower operating costs.

- c. Further, by requiring justification for prices above the benchmark, the risk of market manipulation in the face of weak demand response is reduced.
- d. The benchmark power price, in short, aims to simulate the equilibrium price that would obtain in a properly functioning competitive market and thus avoids the shortcomings of a fixed, inflexible wholesale price cap.

## V. MEDICAL DEVICES AND PHARMACEUTICALS

Under the Enhanced Initiative, which was based on the principle of two-way dialogue, the Government of the United States has taken a number of important measures related to medical devices and pharmaceuticals. Follow-up on these matters continues, and Regulatory Reform Initiative measures will be treated in a manner consistent with the previous measures. Through this Initiative and other processes, the Food and Drug Administration (FDA) is pleased to continue working closely with MHLW on matters that affect the public health of our citizens.

- A. **Good Manufacturing Practices:** FDA and MHLW have actively worked toward a cooperative arrangement similar to a mutual recognition agreement (MRA) regarding Good Manufacturing Practices (GMPs). In December 2000, FDA and MHLW exchanged letters regarding cooperation on pharmaceutical GMPs to exchange inspection reports and other pharmaceutical surveillance information. FDA will continue to engage MHLW on cooperative activities and will work to ensure the smooth implementation and maintenance of the exchange of letters. FDA continues to work with MHLW through exchanges of information and other cooperative activities regarding GMPs for medical devices. The cooperative process will be pursued and further technical discussions will be continued. The Government of the United States understands that MHLW wishes to pursue medical device GMP cooperation in a manner similar to the pharmaceutical GMP cooperation arrangement, which is similar to an MRA, and will continue to discuss this with MHLW in the Medical Devices and Pharmaceuticals Working Group. FDA and MHLW recognize the importance of these activities.
- B. **Good Clinical Practices:** FDA will continue cooperative activities, including with MHLW regarding Good Clinical Practices (GCPs) especially in the ICH fora. In addition, FDA recognizes the importance of these cooperative activities, and FDA will continue to respond appropriately to foreign regulatory bodies' requests, including MHLW's, for information regarding GCPs. When MHLW staff come to the United States, FDA may discuss these activities, including exchanging information. The Government of the United States understands that MHLW wishes to pursue this issue, and will continue to discuss this with MHLW in the Medical Devices and Pharmaceuticals Working Group.

- C. **Export Certification for Anabolic Steroids:** The Drug Enforcement Agency (DEA) and MHLW will continue to discuss – including the required format of an authorized letter from the competent authority of Japan – the one-year exemption of the requirement for a certificate issued by MHLW for each export of anabolic steroids from the United States to Japan.
- D. **Cosmetic Color Regulation:** A cosmetic company is exempted from submitting the color additive to FDA for certification provided that the company uses a color additive batch that has been certified by FDA. The Government of the United States takes note of MHLW’s request regarding the possible use of self-certification, and will continue to discuss this issue with MHLW in the Medical Devices and Pharmaceuticals Working Group.

## VI. FINANCIAL SERVICES

- A. **Market Access by Bank-Affiliated Securities Firms:** The Gramm-Leach-Bliley (“GLB”) Act provides capital and management standards for a foreign bank that are comparable to the standards applied to a U.S. bank owned by a financial holding company (“FHC”), giving due regard to the principle of national treatment and equality of competitive opportunity. The standards are applied to all foreign banks on a nondiscriminatory basis. Foreign banks may also conduct securities activities in the United States on a more limited basis without obtaining FHC status, including through so-called “section 20” companies, provided capital and other prudential considerations are satisfied.
- B. **Deposit Requirement for Foreign Banks:** The Capital Equivalency Deposit (CED) requirements for foreign banks operating as branches in the United States differ depending on whether the foreign branch is licensed by the Office of the Comptroller of the Currency (OCC) or by one of the U.S. states. By statute, OCC-supervised banks (i.e., federal branches) must maintain a minimum CED of 5% of third-party branch liabilities. Subject to this statute, the OCC is making changes to the CED requirement to allow OCC-supervised foreign bank branches more flexibility in meeting the 5% requirement. For example, the liability base over which the CED is calculated has been redefined, to exclude certain liabilities previously included. A proposed amendment to the statute would further modernize the CED requirement and permit the OCC to tailor the amount and composition of the CED as necessary for the protection of depositors and other creditors.
- C. **Disclosure for U.S. Shareholders:** Under the U.S federal securities laws, all public offerings of securities in the United States must be registered with the U.S. Securities and Exchange Commission. A public offering of securities includes share exchange offers, such as when an acquiring company makes a bid to acquire a target company by issuing its shares in exchange for target’s shares. In 1999, the SEC adopted a 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% of the shares of the target company. At the time of adopting this rule, the SEC carefully considered the level of U.S. ownership that was desirable for purposes of this exemption from U.S. registration requirements. The SEC believes that U.S. holders' interests are best served by being able to participate in, rather than be excluded from, the acquisition offer, even though they do not receive the full protections of the U.S. federal securities laws. In addition, even above the 10% level of U.S. ownership, more tailored relief has been adopted that address conflicting regulatory mandates and offering practices.



## ANNEX FOR E-INITIATIVES

### I. Advancing E-commerce Through Liberalized Trade of Digital Products

Given the growing importance that e-commerce has in revitalizing economies and spurring future growth, the Governments of the United States and Japan will work together to ensure the liberalized treatment of digital products and the expanded global use of e-commerce by cooperating in the multilateral framework on the following matters and basic principles: 1) affirming the ability to deliver WTO-scheduled services electronically; 2) according digital products associated with each country non-discriminatory treatment; 3) publishing or otherwise make available to the public its laws, regulations, and measures of general application which pertain to electronic commerce; 4) acknowledging the importance of avoiding unnecessary measures to the use and development of e-commerce; in addition: 5) Both the Governments of the United States and Japan currently do not impose customs duties on digital products transmitted electronically. Our Governments will work toward a global understanding that this duty free environment should remain; 6) In the spirit of trade liberalization, the Governments of the United States and Japan will work together to form a multilateral consensus on the determination of customs valuation for digital products on the carrier media; and 7) the Governments of the United States and Japan will also work together to encourage non-ITA members to join the ITA.

### II. Advancing E-Government

Both Governments share the view that realizing E-Government will enable citizens and businesses to utilize wide-ranging services provided by the government without any constraint of time or location. Implementing E-Government systems creates business opportunities, facilitates global trade and has a positive multiplier effect throughout our economies.

As a basic premise to realizing an E-Government, our two Governments have focused on principles, as reflected in our respective policy guidelines and legislation on E-Government -- namely, the United States' "E-Government Strategy" and Japan's "Basic Law on the Formation of an Advanced Information and Telecommunications Network Society." The United States and Japan are determined to demonstrate global leadership on advancing and implementing E-Government services worldwide and, our two Governments recognize the importance of the following concepts:

- **TRANSPARENCY:** E-Government should promote a digitized administration, which must be transparent and substantially accessible at all times, making all online interactions and transactions convenient for its citizens.
- **EFFICIENCY:** E-Government should simplify and improve the efficiency of government administration, and lessen the burden on citizens and businesses. It should not be bureaucracy-centric.

- **SECURITY:** E-Government must strive to offer a secure, reliable and private environment for transactions to take place in, so that people may use information systems and networks with a sense of security.
- **PRIVATE SECTOR LEADERSHIP:** E-Government procedures should be agile, innovative and market-based. The private sector should take the leading role in principle in the area of IT, while the Government should create an environment to ensure fair competition and promote, rather than stifle innovation.

Both the Governments of Japan and the United States are putting these E-Government concepts into practice by creating interactive web sites that assist consumers, businesses, governments and citizens. To illustrate this point, Japan is currently emphasizing areas such as electronic filing, electronic procurement, electronic procedures for revenues and expenditures, and the provision of administrative information which are exemplified by the U.S. EZ Tax Filing, Federal Asset Sales, One-Stop Business Compliance Information, and Recreation One-Stop programs respectively.

### **III. Cooperation on COE Convention on Cybercrime**

In view of the significance of the Convention, both Governments will work together to facilitate broader acceptance and use of the Convention through the following steps:

- Encouraging the remaining Council of Europe (COE) members to sign the Convention;
- Encouraging eligible states to become parties to the Convention to secure its entry into force;
- Generally supporting efforts by the COE to promote third-party accession for the Convention for its broader application; and
- Consistent with UNGA Res. 56/121, encouraging states to take into account the Convention when developing their national law, policy and practice.