

RECORD OF DISCUSSION

U.S.-JAPAN ECONOMIC HARMONIZATION INITIATIVE

January 27, 2012

OVERVIEW

The U.S.-Japan Economic Harmonization Initiative (EHI) aims to contribute to our countries' economic growth by promoting cooperation to harmonize approaches that facilitate trade, address business climate and individual issues, and advance coordination on regional issues of common interest.

The Initiative serves as a key venue for both Governments to expand cooperation in areas of common interest, deepen mutual understanding of respective regulatory and other matters to enhance greater harmonization, and address a range of issues raised by both Governments. The EHI Agenda thus covered a wide range of topics under the following four themes:

- 1) exchanging information on trade and economic-related policies of the United States and Japan;
- 2) promoting further U.S.-Japan cooperation in the economic field;
- 3) collaborating on common regional and global challenges; and
- 4) taking new steps to facilitate trade and to address business climate and other issues.

This Record of Discussion summarizes the general scope of bilateral discussions and exchanges as well as identifies key outcomes of this work that took place over the period February 2011-January 2012. Both Governments held working-level meetings during February 28 to March 4, 2011 (First Working-level Meeting), and during July 18 to 22, 2011 (Second Working-level Meeting). Both Governments also held a High-Level Officials Meeting on October 3, 2011, led by Ambassador Demetrios Marantis, Deputy U.S. Trade Representative, and Mr. Shinichi Nishimiya, Deputy Minister for Foreign Affairs of Japan. Additional *ad hoc* exchanges on individual issues also took place throughout 2011 to advance work under this Initiative.

The U.S. Government and the Japanese Government remain prepared to discuss and engage on issues of interest raised by either Government under this Initiative.

SUMMARY OF OUTCOMES

EXCHANGING INFORMATION ON TRADE AND ECONOMIC-RELATED POLICIES OF THE UNITED STATES AND JAPAN

The U.S. and Japanese Governments exchanged information and updates on an array of recent major economic and trade policy developments. This included topics such as overviews of the United States' "National Export Initiative" as well as Japan's "New Growth Strategy."

Following the Great East Japan Earthquake disaster that occurred on March 11, 2011, the Japanese Government briefed the U.S. Government on the progress and on plans for post-disaster rehabilitation and reconstruction, and provided further updates on its economic situation including supply chain recovery. The Japanese Government also took the opportunity to express sincere appreciation for all forms of assistance and continuous support extended by the United States to the nation and the people of Japan from the outset of the disaster. The U.S. Government reiterated its commitment to support Japan's reconstruction process and underlined the importance of engaging in close communication during the process of recovery of the affected areas.

Both Governments also recognized the importance of continuing to exchange information under the Initiative on new economic and trade policies and trends in light of their potential impact on U.S.-Japan economic and trade relations.

PROMOTING FURTHER U.S.-JAPAN COOPERATION IN THE ECONOMIC FIELD

Both Governments confirmed the recent and continuing cooperation undertaken in a number of bilateral fora and across a wide range of issues in the economic field. Such cooperation included the research dialogue on rare earths and other critical material. Both Governments are encouraged that such cooperation would contribute to adding a new dimension to the economic exchanges and help foster stronger economic ties between the two economies. Japan also expressed its ongoing interest in cooperating with the United States on high-speed rail.

Furthermore, under this Initiative, both Governments have been advancing an important new area of bilateral cooperation related to the information and

communications technology (ICT) sector. As a result of these exchanges, both Governments have jointly developed a set of common trade principles in the ICT services sector that reaffirm and promote our common interest in open markets in this important sector.

Both Governments also shared the view that they would continue to explore and pursue additional cooperative areas as the Economic Harmonization Initiative progresses.

COLLABORATING ON COMMON REGIONAL AND GLOBAL CHALLENGES

The U.S. and Japanese Governments discussed a broad range of regional and global trade issues and challenges, including those related to natural resources, intellectual property and technology transfer. Both Governments reaffirmed their commitment to promote further bilateral cooperation to facilitate trade, including through multilateral and regional economic fora such as the WTO and the Asia-Pacific Economic Cooperation (APEC) forum. In APEC, the U.S. and Japanese Governments continued close cooperation on privacy issues, especially on facilitating cross-border data flows.

Both Governments further highlighted the successful conclusion and the signing of the plurilateral Anti-Counterfeiting Trade Agreement (ACTA), which represents a significant achievement in the fight against the infringement of intellectual property rights (IPR) and the proliferation of counterfeiting and piracy on a global scale. The ACTA provides a new mechanism for the United States, Japan, and other Parties to the agreement to work together in a more collaborative manner to achieve the common goal of effective IPR enforcement. Both Governments underscored their close cooperation to date and expressed their commitment to continue to collaborate to realize an early entry into force of the agreement as well as to further expand participation in the agreement.

Building on these positive outcomes of cooperation, both Governments will continue to explore and pursue new areas for cooperation to address regional and global challenges through additional exchanges of information and, where necessary, take other measures.

TAKING NEW STEPS TO FACILITATE TRADE AND TO ADDRESS BUSINESS CLIMATE AND OTHER ISSUES

Positive and productive exchanges took place on a wide range of issues of interest to the business communities of both countries. Through this engagement, both Governments took various actions, such as clarifying policies or introducing new policies and approaches, with the goal of further facilitating the trade and business climate in both

countries. Both Governments furthermore affirmed the importance of this engagement as an important contribution to the overall strengthening of the U.S.-Japan economic and trade relationship, including the advancement of harmonized approaches where possible.

The following summary outlines key measures and outcomes on the broad range of individual issues of interest discussed under this Initiative.

**Summary of Outcomes and Key Measures
by the Japanese Government**

INFORMATION AND COMMUNICATION TECHNOLOGIES

Communications

Spectrum: In May 2011, a law was enacted in Japan to allow the Ministry of Internal Affairs and Communications (MIC) when assigning spectrum to ask new entrants to bear the transition costs for incumbent carriers and that these costs would be a criterion in assigning spectrum. The Japanese Government plans to use this approach in upcoming spectrum assignments in the 700 and 900 MHz spectrum.

In addition, in the context of MIC's New Broadband Superhighway policy, MIC and a related study group had been considering radio policy that would introduce the option for using spectrum auctions and issued a report in December 2011. Based on the report, MIC will take measures necessary to introduce auctions by 2015.

Dominant Carrier Regulations: In May 2011, the Japanese Diet passed legislation that strengthened the separation between facilities and other functions within NTT East and NTT West, including stricter firewalls between functions such as employees and information sharing.

The Ministry of Internal Affairs and Communications (MIC) also clarified that it will continue to apply a long-run incremental cost (LRIC) model for calculating wireline interconnection rates for dominant carriers through Japan Fiscal Year 2012.

Mobile Interconnection Rates: The Ministry of Internal Affairs and Communications (MIC) explained that it is encouraging all wireless carriers to follow the new guidelines for calculating mobile interconnection rates that currently apply starting from Japan Fiscal Year 2010 only to telecommunications carriers with Category II-designated telecommunications facilities. MIC provided information about the fact that NTT Docomo submitted a mediation request regarding Softbank Mobile's mobile interconnection rates to MIC's Telecommunications Dispute Settlement Commission in May 2011.

Converged and Internet Enabled Services: The U.S. Government and Japanese Government confirm that, at this stage, there are no regulations specific to over-the-top video services with respect to foreign equity, whether or not such services are provided on a cross border basis. This is without prejudice to other regulations that might affect such services.

International Cooperation: In January 2012, the Japanese Government and the U.S. Government have jointly developed a set of non-binding trade-related principles for information and communication technology (ICT) services. Each of these principles expresses an approach to policy and regulation in the ICT sector that is broadly shared by the U.S. Government and Japanese Government, and both governments will jointly promote the adoption of these principles by other countries.

Information Technologies

Government ICT Procurement: The Japanese Government will create a position of national Chief Information Officer (CIO) who will coordinate the work of CIOs from all of Japan's national Government agencies. The Japanese Government stated that the national CIO's mission will be to promote the use of information and communication technology (ICT) to streamline Government administration and to be more useful for citizens and industry. After studying the cost-effectiveness and usefulness of past IT-related Government investments, the national CIO will implement reforms to disseminate throughout the national Government cost-saving measures that already have succeeded in individual ministries. The national CIO will help Japan to achieve its goal of developing a universal IT infrastructure involving the use of cloud computing and other cutting-edge technologies.

Regarding Government procurement of ICT specifically, the Japanese Government will take steps to introduce greater competition, transparency, and fairness, such as by implementing national Government-wide policies that reflect international technology trends and standards and that follow principles of technology neutrality and interoperability. The Japanese Government will continue to study ways to achieve the goals and policies for Government procurement of ICT described above.

Health Information Technology: The Japanese Government explained that it will start by March 2014 the first stage of a program under the "My Hospital Everywhere" (Japan's Personal Health Record services) concept that allows people to use electronic medical and health information to receive personalized medical care anywhere in Japan and to manage their health effectively.

The Japanese Government and the U.S. Government have been discussing a proposal from the U.S. Government to hold a meeting in 2012 among their health information technology (health IT) experts to promote U.S.-Japan cooperation on health IT standards. This experts meeting is intended to move toward the goals of improving the quality and efficiency of healthcare by helping to rapidly implement health IT that is based on internationally recognized and utilized standards, that promotes technology neutrality and interoperability, and that allows patients greater access to their own health records. In addition, the U.S. Government and the Japanese Government will

continue to exchange information, with a view toward increasing bilateral cooperation on health IT.

Cloud Computing: The Japanese Government recognized the importance of cross border data flows and will continue to cooperate with the U.S. Government on this topic and on other policies that affect the development of cloud computing. The Japanese Government published the “Smart Cloud Strategy” in May 2010 and described the “Japan Cloud Consortium.” The United States Government and the Japanese Government will continue to exchange information on cloud computing.

Privacy: The Japanese and U.S. Governments continued close cooperation in the Asia-Pacific Economic Cooperation (APEC) forum on privacy issues, especially on facilitating cross-border data flows. The Japanese Government formally endorsed the APEC System of Cross Border Privacy Rules (CBPRs) at the APEC Ministerial meeting in November 2011. The Ministries and Agencies of the Japanese Government also participated in the Cross-border Privacy Enforcement Arrangement (CPEA). The Japanese and U.S. Governments are making an effort to launch the CBPR Program.

INTELLECTUAL PROPERTY RIGHTS

Technological Protection Measures: In spring 2011, the Japanese Government took three important steps to improve protection for technological protection measures. First, in March 2011, the Customs Law was amended to make the import or export of circumvention devices and programs illegal and to authorize Customs Authorities to seize and confiscate such devices *ex officio* as well as upon an application by right holders. Second, in June 2011, the Unfair Competition Prevention Act was amended to, among other items, (1) include a prohibition on “a set of parts” that can be easily assembled to make circumvention devices, (2) expand the range of devices subject to restriction by deleting a reference that limited the application to devices with a “sole function” of bypassing technological protection measures (referred to as technological restriction measures in the Unfair Competition Prevention Act), and (3) introduce criminal remedies for the provision of circumvention devices. Third, the Japanese Government is also preparing amendments to the Copyright Law that would further enhance provisions related to technological protection measures and will provide updates on developments regarding deliberations.

Term Extension: The Japanese Government explained that a previous review on term of protection of copyrights and related rights had not reached any conclusions but that it continues to review the issue as necessary, taking into account recent international developments on term extension, exchanges of views with the United States and other trading partners, and domestic discussions on this issue.

Online Piracy: The Ministry of Internal Affairs and Communications (MIC) supported an update on the work of an industry-led study group on guidelines for the Internet Service Provider (ISP) Liability Limitation Act, which includes ISPs, right holders, and academics. The Study Group has revised guidelines in several key areas and plans to publish English versions by March 2012.

Exceptions to Protection: In July 2011, the Legislative Committee of the Agency for Cultural Affairs held hearings with right holders and other interested parties regarding the private copying exception in Article 30 of the Copyright Act and will continue to review the issues raised in the hearings including the scope of the exclusion from the private copying exception contained in Article 30(1)(iii) to include other categories of copyrighted works beyond sound recordings and visual recordings. The Agency for Cultural Affairs will continue to provide meaningful opportunities for input by right holders and other interested parties.

In addition, the Agency for Cultural Affairs explained three limited exceptions to copyright protection that its Council for Cultural Affairs has been considering under general copyright reform efforts and will provide clarifications as deliberations develop.

Bilateral Cooperation: The United States and Japan continued close cooperation on strengthening intellectual property rights protection and enforcement in various bilateral and multilateral fora, including in the Asia-Pacific Economic Cooperation (APEC) forum, where the United States and Japan worked closely together to reach Leaders' agreement to implement policies that will set a non-discriminatory and market-driven innovation model in the region and Ministers' endorsement of APEC Effective Practices to Address Unauthorized Camcording. They also continued their collaborative efforts in APEC to promote the Patent Prosecution Highway, a work sharing initiative aimed at sharing work among patent offices to reduce duplication in patent examination. In addition, in October 2011, the United States, Japan, and six other countries signed the Anti-Counterfeiting Trade Agreement (ACTA), a groundbreaking initiative to strengthen the international legal framework for effectively combating global proliferation of commercial-scale counterfeiting and piracy.

JAPAN POST

Japan Post: The Japanese Government explained that it continues to take measures as prescribed in the Postal Privatization Law to ensure equivalent conditions of competition between the Japan Post companies and private sector competitors. The Japanese Government also clarified that by the time that the 10-year transition period after enactment of the Postal Privatization Law is over, Japan Post Holdings will be fully regulated as a private company without any special legal exemptions, while the Japan Post Holdings Law continues to be applied.

With respect to access to the postal network for the sale of insurance products, in October 2011, Japan Post Network increased the number of post offices offering variable annuities and life insurance for companies (for management-level personnel) underwritten by private sector companies. It increased the number of post offices from 166 to 247 and from 123 to 126, respectively. This is solely the result of Japan Post Network's decision. There are no existing regulations on either the variety of insurance products offered through the postal network or the number of the post offices offering the products. The Japanese Government takes note of the private sector's interest in selling additional products through more of the postal network on commercially equivalent terms.

Regarding regulatory enforcement, an investigation released in July 2010 by the Management Organization for Postal Savings and Postal Life Insurance and Japan Post Insurance revealed the non-payment or under-payment of insurance claims from April 2003 to September 2007 by the former Japan Post Public Corporation. The Financial Services Agency (FSA) explained that, as a result, it has continued to follow up on whether Japan Post Insurance has acted in accordance with the requirements set out in the Insurance Business Law with respect to insurance claims payments and whether Japan Post Insurance has complied with the measures identified in the report that Japan Post should take to prevent the recurrence of the non-payment or under-payment of claims. The FSA stated its intention to apply the requirements under the Insurance Business Law equally to Japan Post Insurance and private companies, including by applying equivalent treatment to Japan Post Insurance when conducting investigations or taking enforcement actions targeting the entire life insurance sector.

The Japanese Government clarified that it continues to conduct market review and, based on this review, may consider competitive policies related to the treatment of Japan Post's Express Mail Service (EMS) vis-à-vis similar services offered by other international express carriers.

The Japanese Government acknowledged that equivalent conditions of competition should always be ensured in expanding the business scope of postal financial institutions.

Regarding proposed reforms, the Japanese Government provided updates on the status and its stance on the Bills for Postal Reform. The Japanese Government also explained that it intends to ensure its consistency with its WTO and other international agreements in the future operation of relevant laws and regulations. In addition, the Japanese Government provided opportunities to hear opinions from a wide range of interested parties and persons both in Japan and overseas before deciding on the Bills, and recognizes the importance of ensuring transparency continuously, including providing meaningful opportunities for input to interested parties.

INSURANCE

Insurance Cooperatives (*kyosai*): The Japanese Government explained that it will not permit the scope of insurance operations of authorized specific insurance providers to be expanded beyond the levels in 2005 and that the regulations for the “authorized specific insurance provider” system, a temporary system, will be reviewed after about five years of enactment.

Bank Sales of Insurance: In July 2011, the Financial Services Agency (FSA) announced the results of its review of the effects of the 2007 reforms of the bank sales channel. The FSA will continue to monitor the effects of liberalization in the bank sales channel with respect to market conduct rules. The FSA will consider conducting another review, as appropriate, based on data gathered on consumer responses through the monitoring process and with a view toward enhancing policyholder protection and consumer choice. With a goal of ensuring transparency, the FSA offered opportunities for stakeholders, including foreign companies, to provide their views during the review process – including through public hearings and the solicitation of public comments – and will continue to provide transparency by offering meaningful opportunities for stakeholders throughout the policymaking process as it continues to monitor this sales channel and to consider further reforms.

Life Insurance Policyholder Protection Corporation: Before March 2012, the Financial Services Agency (FSA) will conduct a review to examine whether it is necessary to continue government support for the Policyholder Protection Corporation (PPC) as well as the burden for insurers related to the PPC funding. The FSA will continue to exchange information with interested parties such as on post-funded systems, as it reviews various issues related to the PPC. The FSA also will ensure transparency throughout the deliberative process, including by offering meaningful opportunities for stakeholder input. Based on the findings of the review, FSA will consider appropriate changes to the PPC program.

TRANSPARENCY

Public Comment Procedure: The Japanese Government reported results of a December 2010 survey indicating increased compliance among Ministries and Agencies with public comment procedures. In February 2011, the Ministry of Internal Affairs and Communications (MIC) issued guidance encouraging Ministries and Agencies to adequately operate their public comment procedure including by securing a period sufficient enough to consider submitted comments. MIC will continue to monitor compliance.

TRANSPORTATION, DISTRIBUTION AND ENERGY

Technical Guidelines for Advanced Automobile Safety Features: On July 20, 2011, the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) issued an official notification clarifying that “a technical guideline issued by the MLIT is not legally binding regulation and therefore cannot be a ground for preventing or unduly delaying a motor vehicle to be placed on the market.” The notification furthermore clarified that MLIT “will not prevent or unduly delay the placing on its market on the ground that the product incorporates a new technology or a new feature which has not yet been regulated” unless the MLIT can demonstrate a risk for human health, safety, or the environment. MLIT will consult relevant stakeholders sufficiently in advance of developing technical guidelines to allow for meaningful stakeholder input before final decisions are made.

Customs Co-location: The Ministry of Finance is seriously considering the introduction of a system to enable customs officials to be located at the bonded premises of express carrier companies on a regular and ongoing basis, and is aiming to introduce such a system during Japan Fiscal Year 2012, while taking into account their status, namely as Authorized Economic Operators (AEO), and current limited human resources in Japan Customs. The Ministry of Finance met with U.S. Government officials to receive information on the co-location program used by U.S. Customs and Border Protection. The Ministry of Finance also met with U.S. companies to exchange views and to receive information on similar customs co-location practices among other countries. The Ministry of Finance will continue to solicit input from all interested stakeholders as preparations are made to introduce a system in Japan.

AGRICULTURE-RELATED ISSUES

Post-Harvest Fungicides (PHFs): The Ministry of Health, Labour and Welfare (MHLW) approved fludioxonil in September 2011 and reported that pyrimethanil is currently under review with the Food Safety Commission. Also, MHLW is to provide an update on progress of PHFs including azoxystrobin. MHLW concurred to provide clarification on its post-harvest fungicide approval process and to discuss with the United States ways to make the approval process move more quickly.

MRLs: The Ministry of Health, Labour and Welfare (MHLW) concurred to work together in 2012 with the United States on a priority list prepared by the U.S. Government for maximum residue level tolerances (MRLs). MHLW also concurred to continue increasing the level of cooperation and consultation with the United States to ensure compliance with relevant MRLs.

Food Additives: The Ministry of Health, Labour and Welfare (MHLW) and the U.S. Government will continue to work together to finalize the approval of the remaining commonly used food additives as soon as possible.

Gelatin: The United States supplied information regarding gelatin, including on gel-bone sourcing practices in the United States, to the Ministry of Health, Labour and Welfare (MHLW) for its review and consideration. For example, after numerous discussions between relevant government authorities, one U.S. manufacturer exchanged information with the MHLW in November 2011 regarding the manufacturing processes of gelatin for human consumption.

COMPETITION POLICY

Enforcement Effectiveness:

- Review of the Business Combination Regulation: In July 2011, the Japan Fair Trade Commission (JFTC) revised the business combination regulations (investigation procedures and criteria) to further improve the speed, transparency, and predictability of business combination investigations. Specifically, the JFTC abolished the prior consultation system, and improved communication channels between notifying companies and the JFTC, bringing the JFTC's merger review process more in line with that of other major competition law enforcement jurisdictions.
- Early Termination of Merger Reviews: As part of the revisions to the JFTC's business combination regulations, the JFTC eased the requirements for shortening the 30-day waiting period for merger transactions subject to pre-merger notification obligations. The JFTC will now shorten the waiting period when it receives a written request and it is evident that the transaction creates no problems under the Antimonopoly Act (AMA), and the JFTC will no longer require justification for the request.
- Specialized Antimonopoly Knowledge for Judges: In anticipation of possible amendments to the AMA that would provide for direct appeals of JFTC decisions to the Tokyo District Court, the Tokyo District Court has been working on ways to provide judges with the specialized AMA knowledge necessary for handling such appeals. In March 2011, a judge from the Tokyo District Court traveled to the United States on business, met with several other judges and conducted a study for that purpose.

- Voluntary AMA Compliance: The JFTC clarified that, in determining appropriate measures under the AMA, it may take several factors into consideration. One of them is whether the respondent voluntarily remedied its unlawful conduct before the JFTC investigation has commenced. In such circumstances, where the JFTC finds it particularly necessary, it may decide to order the enterprise concerned to take measures to make public that the conduct has been discontinued and any other measures necessary to ensure elimination of the conduct.

Procedural Fairness:

- Procedural Fairness in JFTC Enforcement Decisions: The Japanese Government introduced an Antimonopoly Act (AMA) amendment bill to the Diet in March 2010 that would improve Japan Fair Trade Commission (JFTC) enforcement decision procedures from the standpoint of enhanced procedural fairness, including by providing proposed recipients of JFTC orders with an explanation of the content of the anticipated order, an opportunity to inspect and copy evidence relied upon by the JFTC, an opportunity to question JFTC staff about its evidence, legal theories and other matters, and an opportunity to present evidence and make arguments to the JFTC in their defense prior to the JFTC's final decision. The bill would also abolish the JFTC's hearing procedure and provide that appeals of JFTC decisions would be filed with the Tokyo District Court. The AMA amendment bill continues to await enactment by the Diet.
- Procedural Fairness in JFTC Investigation Procedures: A supplemental provision of the AMA amendment bill would require the Japanese Government to review JFTC investigation procedures from the point of view of securing procedural fairness and consistency with other administrative procedures in Japan. The supplemental provision requires that the review reach a conclusion approximately one year after the day of promulgation of the AMA amendment legislation.
- Procedural Fairness – Standards for On-site Inspections: The JFTC clarified that its policy continues to be to conduct on-site inspections when it determines that such inspections are necessary after considering various factors from a comprehensive standpoint, such as whether there is a reasonable belief that the alleged conduct constitutes a violation of either section 3 or 19 of the AMA, whether additional evidence is necessary to establish the infringement, and whether there is a reasonable concern that the evidence might be destroyed or otherwise lost.

BUSINESS LEGAL ENVIRONMENT

Corporate Governance (Strengthening the Corporate Governance System and Protection of Minority Shareholders): Since March 2010, when the Japanese

Government introduced disclosure obligations on listed companies, including with respect to the structure of their corporate governance systems, and the Tokyo Stock Exchange (TSE) revised its listing rules to require listed companies to have at least one independent director or auditor for the purpose of protecting general shareholders, the Japanese Government and the TSE have continued to consider ways to improve the corporate governance systems of Japanese companies. In October 2011 the TSE announced that it is working to take effective measures to strengthen the corporate governance system for listed companies. And in December, the Corporate Law System Subcommittee of the Ministry of Justice's Legislative Council issued an interim proposal on revision of the Companies Act with respect to, among other things, corporate governance of Japanese companies and measures to enhance protection of minority shareholders. The Ministry of Justice has solicited public comments on this interim proposal, and welcomes comments from all interested persons.

Legal Services (Professional Corporations for Foreign Legal Consultants): The Japanese Government indicated that it aims to submit legislation to the Diet as soon as possible that would permit foreign legal consultants (*gaiben*) to form professional corporations (*hojin*). Such a professional corporation would be permitted to establish branch offices in any part of Japan.

MEDICAL DEVICES AND PHARMACEUTICALS

Pharmaceuticals and Other Issues

New Premium Pricing: Throughout 2011, the Japanese Government exchanged views with industry on the perpetuation of the pilot premium for drug development. The new pilot premium pricing rule has made a considerable contribution to the development of both new drugs and additional indications for existing drugs in need. Of the development requests submitted to companies in 2010, 44 applications have been approved, applications have been filed for 30 drugs and/or indications, and clinical trial notices have been submitted for 50 products (as of August 23, 2011). The Japanese Government is in the process of validating that over the long term, the premium will further lead to the reduction of the drug lag, encouragement of simultaneous global development of drugs, and increased access by Japanese patients to the world's newest and most innovative drugs. The Central Social Insurance Medical Council (Chuikyo) has been deliberating on the pilot premium rule throughout 2011 and will determine whether to make the rule permanent.

Repricing for Market Expansion: In 2011, the Japanese and U.S. Governments exchanged information on several aspects of Japan's Repricing for Market Expansion rule. These included not applying the rule to comparator priced products and changing the formula to calculate price reductions for cost-up method products if the rule cannot

be eliminated. Since the market expansion repricing rule is considered by the Japanese Government to be an essential component of a sustainable Public Health Insurance System, the Japanese Government will continue to consider means to eliminate the irrational impact of the market expansion repricing rule on the ability of pharmaceutical companies to continue bringing innovative products to the Japanese market, including by receiving information from the U.S. Government and from industry stakeholders.

Drug Lag: The review period has been reduced as a result of a series of measures taken by the Japanese Government to reduce the drug lag. On June 28, 2011, Japan's Pharmaceuticals and Medical Devices Agency (PMDA) reported that it exceeded its goal of reducing standard and priority drug review times in Japan Fiscal Year 2010. Compared with Japan Fiscal Year 2009, drug review periods decreased by 4.5 months to 14.7 months for standard products and by 2.7 months to 9.2 months for priority products in Japan Fiscal Year 2010. In addition, the Japanese Government welcomed encouraging statements from the U.S. Government and industry about the number of consultations regarding multinational clinical trials and concurred to continue to utilize such data in accordance with ICH guideline for approvals in Japan.

Administrative Review Period: In April 2011, Japan's Ministry of Health, Labour and Welfare (MHLW) implemented new procedures to accelerate new drug approval procedures by streamlining the two-step review process by the Committee on Drugs and the Pharmaceutical Affairs Council. Under the previous system, new drugs approved by the Committee on Drugs were then reviewed in the Pharmaceutical Affairs Council and approved one month later. Under the new system, only the Committee on Drugs is required to recommend approval of new drugs, thus shortening total drug approval times by approximately one month.

Blood Products: In February, 2011, the Plasma Protein Therapeutics Association (PPTA), the industry association representing producers of plasma protein therapies, was invited to present its views to an expert panel convened by Ministry of Health, Labour and Welfare (MHLW). MHLW will continue to provide opportunities for PPTA to provide input into studies conducted by the expert panel as necessary, as well as in closed meetings with MHLW.

Vaccines

Vaccine Access: As the Japanese Government moves forward with revisions to its immunization system, the Ministry of Health, Labour and Welfare (MHLW) will build on the temporary measures, implemented in 2010, that improved access to the Haemophilus Influenzae Type b (Hib), heptavalent pneumococcal conjugate vaccine, and Human Papillomavirus (HPV) vaccines by giving adequate consideration to making these vaccines part of routine vaccinations.

Vaccine Exchanges: On July 26, 2011, the Japanese and U.S. Governments held the second annual U.S. – Japan Vaccine Policy Exchange, during which the two Governments engaged in a dialogue to develop a better understanding of short and long term goals for U.S. and Japanese vaccine policy. Topics of discussion included the U.S. Advisory Committee on Immunization Practices (ACIP) and vaccine safety issues in the U.S. and Japan. Japanese and U.S. officials shared their interest to continue these exchanges on vaccine policy.

Medical Devices

Foreign Average Price (FAP) Rule: In 2011, the Japanese and U.S. Governments exchanged information on several aspects of the FAP rule. These included issues relevant to ensuring stability in the rules and practices used to calculate FAP, including by mitigating the impact of foreign exchange fluctuations and refraining from adding an additional country to the basket of comparator countries, while ensuring appropriate pricing for medical devices in the public medical insurance system, in case the rule cannot be eliminated. Both Governments will continue exchanging information on the operation of the FAP rule as part of the entire set of rules for medical device pricing in Japan considering the impact of the FAP rule on the timely introduction and stable supply of medical devices in Japan.

Device Lag: On July 27, 2011, Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) reported that it met its target review goals by reducing approval times to 15.1 months for new devices in the priority category, 16.5 months for new devices in the regular category, and 15.5 months for improved devices for which clinical data is required. As for me-too devices and improved devices that do not require clinical data, where the target review times have not been met, PMDA will continue to make efforts with cooperation of industry to meet its goals moving forward. Also, recognizing the existence of a device lag, where innovative medical devices are not introduced in a timely manner or do not become available in Japan, the Japanese Government will continue taking measures to facilitate the introduction of innovative medical devices into the Japanese market.

Reducing Regulatory Burden for Companies: The U.S. Government and industry welcome the change that allows utilizing of audit results by different audit bodies and the packaging of audit units to reduce the frequency of Quality Management Systems audits. The Japanese Government will continue to discuss, including with industry, measures to lessen the burden on the medical devices industry.

Related Discussion about Medical Devices (Revision of PAL): As the Japanese Government moves forward with changes to its Pharmaceutical Affairs Law (PAL), the U.S. Government expects that it will enhance the regulatory environment for medical devices and IVDs. Stakeholder groups such as industry, including U.S. industry,

academia, health care professionals, and consumer and patient groups have submitted proposals on revision on the PAL, which advocate strengthening safety measures and supervision of medical products as well as accelerating approval of indispensable medical products. U.S. industry has submitted proposals on revision on the PAL, including the request that consideration be given to the unique characteristics of medical devices compared with drugs, quasi drugs, and cosmetics. The Japanese Government will consider views from stakeholder groups as it makes revisions to the PAL.

Cosmetics

Advertising and Labeling: On July 21, 2011, the Japanese Government authorized the addition of cosmetic efficacy claim 56 to its list of preapproved efficacy claims. Companies that claim that their products minimize the appearance of fine lines due to dryness will now be able to provide this information to consumers. The U.S. Government welcomes that this addition will allow for consumers to make more informed decisions.

Import of Cosmetics and Quasi-drugs: On July 22, 2011, the Japanese Government recognized the necessity to clarify the import process by supporting industry's quasi-drug guideline creation process and beginning discussions with Regional Bureaus of Health and Welfare in regard to accepting electronic copies of import forms as supplementary documents for notification of change of import forms. The Japanese Government will provide timely updates on ongoing measures being taken to improve the import process.

Nutritional Supplements

Regulatory Categories and Claims: On June 16, 2011, the Consumer Affairs Agency (CAA) commissioned a pilot project for the functional assessment of eleven health and nutritional ingredients. The CAA will provide updates on the progress of this project and potential plans for modifying the Food for Specified Health Uses (FOSHU) and Food with Nutrient Function Claims (FNFC) regulations.

Food Additives: In April 2011, based on a Cabinet decision, the Ministry of Health, Labour and Welfare (MHLW) requested that the Food Safety Commission of Japan (FSCJ) carry out a risk assessment for the possible use of isopropanol as a solvent for extraction. After receiving the results from FSCJ, MHLW will proceed with legal formalities for the expansion of its use unless the results raise any safety concerns. MHLW will continue to accept requests for consultation regarding applications for substances classified in Japan as food additives, including organic solvents, from industry.

Summary of Outcomes and Key Measures
by the U.S. Government

TRADE FACILITATION

Customs and Distribution: The U.S. Government and the Japanese Government recognize the importance of strengthening counter-terrorism measures. The Department of Homeland Security (DHS) continues to consult closely with relevant Japanese government agencies on related issues.

- **24-Hour Rule/10+2 Security Filing Requirement:** The bilateral Authorized Economic Operator (AEO) and C-TPAT programs have been successful; however, other U.S. rules and regulations related to the provision of advance information preclude a relaxation of the 24-Hour Rule and the 10+2 Filing Requirement. DHS officials intend to remain in close contact with their Japanese counterparts, including by continuing to explore possible ways to further expand mutually shared benefits to participants in AEO programs in both countries.
- **100 Percent Screening of Maritime Cargo:** Section 232 of the SAFE Port Act (as amended by the 2007 Implementing Recommendations of the 9/11 Commission Act) requires that by July 2012, 100 percent of maritime inbound cargo destined for the United States be scanned prior to loading in a foreign port, unless certain statutory conditions exist that allow DHS to seek extension of the deadline. Secretary of Homeland Security Janet Napolitano has noted on several public occasions that 100 percent scanning of maritime cargo, required by Section 232 of the SAFE Port Act, poses significant operational, diplomatic, financial, and technical challenges. Secretary Napolitano indicated that DHS is likely to seek a waiver of this mandate. However, the Department has not yet done so and may wait until closer to the June 30, 2012, deadline to exercise this option. DHS has engaged in close consultation domestically and with Japan and other foreign trading partners and is continuing research and development work to address some of the limitations inherent in available technology and to explore innovative next-generation capabilities.
- **100 Percent Screening of Air Cargo:** The Transportation Security Administration (TSA) is required by the 9/11 Act to achieve 100 percent screening of air cargo uplifted domestically and inbound to the United States, commensurate with the level of screening required for passenger checked baggage. Japan has concerns about the impact of this new requirement on its industry. TSA has engaged in extensive outreach to interested stakeholders, including inviting public comments in January 2011, to review appropriate measures to fulfill the requirement. The proposed strategy of these changes was to enable industry to achieve the 100 percent screening of international inbound passenger air cargo by December 31, 2011. Based

on responses from stakeholders, TSA has reconsidered this deadline. TSA will continue to work with industry partners to leverage and enhance ongoing programs including the collection of pre-departure data for internationally bound cargo, and certify foreign aviation security programs that are commensurate with TSA standards through TSA's National Cargo Security Program recognition process. The U.S. Government and the Japanese Government will continue to share information and work through the program to improve air cargo screening.

Transportation of Lithium Batteries: The U.S. Government is carefully reviewing comments, including from trading partners and industry, to a Notice of Proposed Rulemaking issued in January 2010 by the Department of Transportation on ensuring the safe transportation of lithium cells and batteries, and will continue to update the Japanese Government on the status of the rulemaking. The U.S. Government will also continue to make the Japanese Government aware of any additional opportunities for public input in the rulemaking process.

Re-export Controls: The Bureau of Industry and Security (BIS) has added a new license exception, STA (Strategic Trade Authorization), to the Export Administration Regulations as a part of BIS' export control reform initiative. Among the conditions for using STA is a requirement for the U.S. exporter to furnish the consignee with the ECCN (Export Control Classification Number) of each item. Separately, BIS has also established a webpage where sources of publicly available information on Commodity Classifications can be found. The U.S. Government will continue to discuss any outstanding issues raised by the Japanese Government.

Port of Los Angeles Clean-truck Program: The U.S. Government shared with the Japanese Government information about a ruling by the U.S. Court of Appeals for the Ninth Circuit on September 26, 2011, pertaining to the Port of Los Angeles Clean Truck Program and the treatment of independent truck operators under that Program. The U.S. Government further explained that the Port has terminated the employee-driver mandate in the Clean-truck Program.

Importation of Radio Frequency Devices into the United States: The U.S. Government confirmed that the Federal Communications Commission (FCC) will accept the manufacturer that conducts the final inspection of a product to be the "manufacturer" as listed on FCC Form 740. The FCC plans to include this clarification in the next update of FCC Form 740. Absent special circumstances, the FCC conducts rulemakings in a manner that provides sufficient time for industry to prepare in case related procedures are to be changed in the future.

Export License Process: Under ongoing export control reform, the U.S. Government is in the process of rewriting the United States Munitions List (USML). One of the benefits of this process is the moving of parts and components for many munitions items that

the President determined no longer warrant USML control to the Commerce Control List (CCL). This will bring licensing issues on those items under Department of Commerce regulations. Many of these parts and components being moved from the USML to the CCL will be eligible to go license free to Japan under License Exception Strategic Trade Authorization (STA), thereby streamlining the process for exporters to fulfill their compliance responsibilities. On July 15, 2011, the Department of Commerce published in the Federal Register a proposed rule on the structure for moving items from the USML to the CCL. The U.S. Government will continue to revise and align the USML and the CCL, with a view to eventually combining the two lists into a single list that may be controlled by a single agency.

Anti-Dumping Measures: The U.S. Government ensures that its anti-dumping laws, regulations and other measures conform to its WTO obligations. The U.S. Government explained its positions regarding the outstanding items at the WTO Dispute Settlement Body, i.e., the Zeroing dispute and the Hot-Rolled Steel case. The U.S. Government and the Japanese Government also discussed issues of the disbursement of duties set by the U.S. Continued Dumping and Subsidies Offset Act of 2000 (Byrd Amendment).

Model Matching and Sunset Reviews: The Department of Commerce met with officials from the Japanese Government as well as Japanese industry representatives and exchanged information and views on model matching with respect to the anti-dumping duty order on ball bearings and parts thereof from Japan, as well as clarified procedures related to sunset reviews regarding the anti-dumping duty orders on the fifteen Japanese products concerned. Interested parties continue to have the opportunity to request and participate in administrative reviews and sunset reviews conducted by the Department of Commerce on existing orders.

Regulations in the States of California and New York Regarding On-sale Licenses for *Shochu*: The U.S. Government brought this issue raised by the Japanese Government to the attention of relevant officials of the State of California and the State of New York. The U.S. Government conveyed a report by New York officials that related legislation (A.160-A/S.0424-B) passed by the New York legislature during mid-2011 was subsequently vetoed (Veto Message No.49). State officials from California and New York confirmed that the issue remains under the jurisdiction of their respective State legislatures. The U.S. Government will continue, as appropriate, to bring the issue raised by Japan to the attention of relevant State officials.

ADDRESSING THE BUSINESS CLIMATE

Section 310(b)(4) Restrictions on the Foreign Investment in the Licensing of Broadcast and Common Carrier Radio Stations: The U.S. Government clarified that foreign indirect investment in the U.S.-organized parent of a licensee over 25 percent is

possible by petitioning the Federal Communications Commission (FCC) for a public interest finding, which is customarily granted for companies from WTO Members.

Competition in the Retail Devices Market: In April 2010, the Federal Communications Commission (FCC) issued (i) a Notice of Proposed Rulemaking to improve the current approach to compatibility between cable service and consumer electronics (“CableCARD”) and (ii) a Notice of Inquiry on Video Device Competition and other related matters, which requested comments from all interested parties. In October 2010, the FCC adopted CableCARD rules to improve the regime. In addition, in April 2011, the FCC issued a Further Notice of Inquiry on video competition more generally, which also requested comments from all interested parties. In July 2011, Ministry of Internal Affairs and Communications officials met and exchanged information with the FCC on approaches to address policy concerns regarding competition in the retail market for set top boxes and gateway devices in both countries.

Universal Service and Access Charges: In July 2011, the Ministry of Internal Affairs and Communications met and exchanged information with the Federal Communications Commission (FCC) on approaches to address policy concerns regarding the provision of universal service and the system of access charges in both countries. In October 2011, the FCC adopted an Order and Further Notice of Proposed Rulemaking that issues rules for reforming the Universal Service Fund and developing a unified intercarrier compensation regime. Among other things, these reforms create a new Connect America Fund with an annual budget of no more than \$4.5 billion which will extend broadband infrastructure to the millions of Americans who currently have no access to broadband.

International Cooperation: In January 2012, the Japanese Government and the U.S. Government have jointly developed a set of non-binding trade-related principles for information and communication technology (ICT) services. Each of these principles expresses an approach to policy and regulation in the ICT sector that is broadly shared by the U.S. Government and Japanese Government, and both Governments will jointly promote the adoption of these principles by other countries.

Overseas Military Construction: The U.S. Government responded to the Japanese Government’s request by providing clarifications relating to overseas military construction projects by joint ventures, including cases where a joint venture between an American company and a foreign corporation might be qualified as a United States firm. For companies interested in future tendering opportunities, the Department of Defense will take additional steps to provide information on its website at <http://www.acq.osd.mil/dpap> regarding Federal Acquisition Regulations with respect to joint ventures.

Acceptance and Status of Foreign Lawyers as Foreign Legal Consultants: The U.S. Government reported that the Supreme Court of Iowa adopted a rule providing for the licensing of foreign legal consultants in that state, bringing to 31 the number of U.S. jurisdictions that have adopted a foreign legal consultant system. Those 31 jurisdictions account for approximately 90 percent of the total legal services business in the United States. In addition, the U.S. Government clarified state rules regarding the handling of third country law by foreign legal consultants, as requested by the Japanese Government.

Jones Act: The Department of Homeland Security (DHS) clarified for the Japanese Government that the Jones Act does not prohibit all maritime transportation, subject to the Act's requirements for U.S. shipbuilding, and provided specific examples of permissible activities. DHS provided website links to its rulings database and its informed compliance publication and is prepared to respond to further inquiries to the extent possible. In addition, DHS clarified that a vessel owner, operator, charterer, or other interested party to a transportation activity may, prior to engaging in that activity, submit a request with supporting evidence for a prospective ruling to determine whether the proposed activity violates the Jones Act.

Merchant Marine Act of 1920: On January 26, 2011, the Federal Maritime Commission (FMC) terminated its proceeding initiated in 1996 and subsequent semi-annual reporting requirements, while encouraging the industry and the shipping public to report any new restrictions or disputes affecting shipping in U.S.-Japan trade as they arise. The Japanese Government and the U.S. Government will continue to exchange views regarding the Merchant Marine Act of 1920.

Unshu Oranges: In an effort to advance Japan's request for harmonization of the import requirements for Japanese-origin unshu oranges, the U.S. Department of Agriculture (USDA) and the Ministry of Agriculture, Forestry and Fisheries (MAFF) concurred to a list of pests of concern in September 2011 and USDA provided MAFF with proposed risk mitigation measures in November 2011. Once officials in both countries are able to concur to this proposal and U.S. regulatory requirements have been met, unshu oranges should be able to be exported to the United States without a USDA field inspection.

Buy American Act: The Federal Acquisition Regulation addresses the use of Buy American clauses in procurements of construction materials. In response to the Japanese Government's request for clarification of Buy American Act procedures, the U.S. Government explained the various bases and means for waiving the Buy American Act, including the Contracting Officer's determination needed for certain waivers of the Buy American Act. The U.S. Government clarified for the Japanese Government how a determination is made to waive Buy American restrictions for acquisitions that are not covered by the WTO Government Procurement Agreement (GPA) or another trade

agreement. The U.S. Government also reaffirmed that the Buy American Act does not apply to acquisitions that are covered by the WTO GPA or another trade agreement.

Congo Conflict Minerals: The Securities and Exchange Commission (SEC) has not completed drafting its final regulations under Section 1502 of the Dodd-Frank Act (Dodd-Frank Wall Street Reform and Consumer Protection Act). The SEC continues to carefully evaluate a number of the draft regulations needed for implementation, taking into consideration the numerous public comments and feedback on earlier versions. In October 2011, the SEC held a public roundtable to discuss the rulemaking and to enhance understanding between the Government and interested stakeholders. The SEC indicated that issuance of the final regulations has been postponed to between January and June of 2012.

The U.S. Government is in the process of establishing a Public-Private Alliance for Responsible Minerals Trade (PPA) and is continuing to work with the private sector and non-governmental organizations to support supply chain solutions to conflict minerals challenges in the Democratic Republic of the Congo and the Great Lake Region of Central Africa.

The U.S. Government will continue to provide updates to the Japanese Government on this issue.

Medical Loss Ratio Requirement: The U.S. Government will continue to provide updates and clarifications to the Japanese Government regarding the goals and status of implementation of the medical loss ratio under the Affordable Care Act.

Reinsurance Collateral Requirement: During 2011, the States of New York, New Jersey, and Indiana enacted new regulations that reduce the amount of collateral required for reinsurance companies that, together with their regulatory regime, meet certain criteria.

In November 2011, the National Association of Insurance Commissioners (NAIC) adopted revisions to the Credit for Reinsurance Model Law and Regulation which, if adopted by the States, would modernize U.S. state-based regulation of insurance by reducing reinsurance collateral requirements for non-U.S. insurers.

Reducing Information Disclosure Statement Requirements for Prior Art Documents: An internal U.S. Patent and Trademark Office (PTO) working group continues to review these requirements in PTO's effort to improve and streamline efficiencies. PTO is taking into consideration views from stakeholders in relation to the balance between imposing obligations on patent applicants on the one hand, and promoting a higher quality, more effective and efficient examination process on the other.

Ethanol: In accordance with Clean Air Act requirements, the U.S. Environmental Protection Agency (EPA) provided notice and an opportunity for public comment from all interested stakeholders on the E15 waiver request to the Clean Air Act, and issued decisions in October 2010 and January 2011 that conditionally allows E15 to be introduced into commerce for use in 2001 model year or newer passenger cars and light trucks. These waivers are conditioned on the fuel manufacturers' ability to satisfy fuel quality conditions and conditions that mitigate the misfueling of vehicles and engines not covered under the waiver decisions. In July 2011, EPA issued regulations to help fuel providers to more easily provide the fuel for retail sale and to avoid misfueling vehicles not covered by the waiver. The EPA is committed to working with industry to inform public and interested stakeholders of the changes and has engaged in a public outreach and education campaign with relevant parties, including automobile manufacturers, to ensure that a smooth introduction of E15 takes place.

Visa Issues: The Department of State intends to continue to work with the Japanese Government on issues related to visa issuance and revalidation procedures. The Department of State clarified its policies on visa fee issues raised by the Japanese Government.

Department of Homeland Security officials acknowledged concerns raised by the Japanese Government regarding the calculation of I-94 validity periods at the ports of entry. Customs and Border Protection (CBP) has been working with the American Immigration Lawyers Association (AILA) to provide additional field guidance and training to CBP officers.

Restriction Requirement Due to Non-Fulfillment of Unity: The U.S. Government clarified that applicants filing with the U.S. Patent and Trademark Office (PTO) have a choice to file either a national application or an international application through the Patent Cooperation Treaty (PCT) in order to receive treatment according to either U.S. restriction practice or PCT unity of invention practice. In addition, PTO established an internal working group tasked with exploring efficiencies in restriction practice to reduce rework, reduce pendency, and simplify examination, as part of a multi-step approach to addressing patent stakeholder concerns with restriction practice.

"Attorney-Client Privilege" for Patent Attorneys: The U.S. Government supported discussion of this issue at May 2011 meeting the World Intellectual Property Organization Standing Committee on the Law of Patents (WIPO/SCP). The U.S. Government continues to support discussion of this issue at the WIPO/SCP and continues to consider views from all interested parties.

Expeditious Issuance of Social Security Numbers: In response to concerns raised by the Japanese Government, the Social Security Administration explained the required procedures for acquiring a social security number, the average processing time, and

their efforts to expedite the process. The U.S. Government will continue to work with the Japanese Government with respect to social security number-related issues.

State-based Insurance Regulation and Supervision: In October 2011, the Federal Insurance Office (FIO) of the Department of the Treasury published a notice in the Federal Register requesting public comment as it prepares its report to Congress titled “How to Modernize and Improve the System of Insurance Regulation in the United States.” FIO’s report is due to Congress in January 2012.

In December 2010, the National Association of Insurance Commissioners’ (NAIC’s) Group Solvency Issues Working Group adopted amendments to its model holding company act and regulation that, once adopted by state legislatures, will lead to improvements in group supervision by state insurance regulators.

During 2011, New Jersey, Nevada, Alabama, and Oregon joined the Interstate Insurance Product Regulation Commission, bringing the number of jurisdictions in the Interstate Insurance Compact to forty-one. The 41 states represent 70 percent of the asset-based premium volume.

Ballast Water Management: The U.S. Government continues to follow a diligent process that is transparent and open to public comment as it develops the most appropriate standards for ballast water management. The Environmental Protection Agency (EPA) consulted with two respected advisory boards, the Science Advisory Board and the National Academy of Sciences, when developing the new draft standards. It then presented its findings to individual States. The EPA will continue to work with the States and the Coast Guard as it moves forward with its standard, and will continue to keep the Japanese Government apprised of developments.

State-based Environmental Regulations: The Environmental Protection Agency (EPA) and the Department of Transportation (DOT) issued on July 29, 2011, a Supplemental Notice of Intent (NOI) announcing plans to propose stringent federal greenhouse gas and fuel economy standards for model year (MY) 2017-2025 light-duty vehicles as part of a coordinated National Program. The Notice outlines the key elements of a National Program that EPA and DOT (National Highway Traffic Safety Administration) jointly signed on November 16, 2011. The Notice was published in the Federal Register on December 1, 2011. The State of California, 13 major automakers, and other stakeholders expressed support for the next phase in the Administration’s National Program for increasing fuel economy and reducing greenhouse gases for light-duty vehicles. This effort to develop a National Program for clean vehicles will allow manufacturers to continue building a single, light-duty fleet that satisfies all Federal standards, as well as those of California and other states. The July 29 Notice of Intent is a further initial step in the rulemaking process, and the agencies will provide ample time for public comment on the proposal before the action is finalized.

REGULATORY HARMONIZATION

Driver's Licenses Issues: U.S. states have sole authority to manage procedures related to the issuance of state drivers' licenses. In response to the concerns raised by the Japanese Government about the issuance of state drivers' licenses, such as different state requirements for term of validation, the Department of State contacted the American Association of Motor Vehicle Administrators (AAMVA). The AAMVA, an independent non-government organization, has advised it would be willing to help facilitate communications between the Japanese Government and U.S. state motor vehicle agencies for a potential settlement of the issues.

Patent Reform: In September 2011, President Obama signed the America Invents Act into law. This patent reform law brings the U.S. patent system in line with other patent systems and enhances the U.S. patent system by offering greater certainty about patent rights and alternatives to expensive litigation when patent rights are disputed. Among other things, the Act addresses concerns that the Japanese Government has raised regarding the first-to-invent system, reexamination system, and Hilmer Doctrine. The U.S. Government will continue to provide updates on developments regarding these and other patent issues.

Metric System: The National Institute of Standards and Technology (NIST) actively promotes the use and benefits of the International System of Units (metric system) in trade and commerce both domestically and internationally. Metric units are permitted in 96 percent of all U.S. states, and NIST is continuing to work with the two remaining states (Alabama and New York) to eliminate legal prohibitions against metric labeling. NIST has published a proposal to amend labeling laws to allow metric labeling on consumer packages. NIST is also developing a unit pricing best practice guide for developing retail shelf labels that help consumers make value comparisons in metric units. NIST will continue to exchange views and information with the Japanese Government and, as appropriate and where possible, work with the Japanese Government on individual issues.