SUPPLEMENT on HEALTHCARE INNOVATION
Visionary Goals & Recommendations
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Visionary Goals

R&D Process - The U.S. and Japanese markets have R&D systems that facilitate collaboration across the private, academic and public sectors and allow for efficient translational, pre-clinical and clinical development that spurs innovative R&D.

Regulatory Approvals - The U.S. and Japanese markets have regulatory systems that are transparent, predictable, and efficient that foster simultaneous global development and result in first-in-world approvals through a minimization of country-specific requirements and maximization of international standards and common practices.

Evaluation of Innovation - The U.S. and Japanese markets have pricing and reimbursement systems that fully recognize the value of innovation in transparent, predictable and efficient processes that maximize patient access and physician choice as well as encourage innovative R&D.

IPR Protection - The U.S. and Japanese markets have Intellectual Property Rights (IPR) systems that fully provide protections for inventions and data as well as transparent, predictable and effective means of enforcement and redress to ensure full protection of innovators rights and spur further innovations.

Preventive Care - The United States and Japan have an integrated educational system that promotes importance of primary, secondary and tertiary preventions among the public in order to visualize disease burden of silent chronic diseases and get self-commitment toward appropriate preventive initiatives in a timely manner.

Community-based Care - The United States and Japan have a comprehensive policy that supports and facilitates optimal utilization of healthcare goods and services within a community-based system for the treatment of chronic and terminal patients to improve patients' quality of life.

Regional Leadership Visional Goal - The United States and Japan collaborate in the Asia Pacific region to improve health and welfare as a way to lay a strong foundation for sustainable economic growth and greater international trade.

Section I:
Pharmaceuticals and Medical Devices Recommendations

1. **R&D Process:** The Councils welcome the development of the Japan Agency for Medical Research & Development (AMED) and the *Sakigake* policy, as well as Japan's greater focus on translational research, which are expected to further enhance medical research and development.

   Pharmaceuticals and Medical Devices

   - Continue to pursue and support policies that reduce the barriers between the private, academic and public sectors for collaboration globally.
   - Utilize AMED and implement the *Sakigake* policy to encourage global pharmaceutical and medical device R&D in Japan.
   - Pass the 21st Century Cures Act (HR 6) to accelerate the development and delivery of new medical products through multiple means, including increased funding for the National Institutes of Health (NIH) and the Food and Drug Administration (FDA).
   - Revamp the R&D Tax Deduction Rule so that it can maintain and promote R&D investment to enhance the international competitiveness of Japan.
   - Promote "next generation therapies" through engagement by the U.S. and Japanese governments in a dialogue to support the convergence of stem-cell and regenerative medicine research and regulation.
   - Support permanency of the U.S. R&D tax credit.

2. **Regulatory Approvals:** The Councils applaud the Pharmaceuticals and Medical Devices Agency (PDMA) for its achievements over the past several years in improving efficiencies, increasing capacity, and adopting global standards and practices to ensure expedited patient access to leading healthcare products, a number of which have now been approved in Japan before the United States. The Councils welcome Japan's decision to join the Medical Device Single Audit Program as an official member. The Councils also applaud the "International Pharmaceutical Regulatory Harmonization Strategy – Regulatory Science Initiative" formed by the Ministery of Health, Labour and Welfare (MHLW) in June 2015. This strategy aims to demonstrate Japan's proactive leadership in Asia and other regions across the global community. It includes policies such as establishing the "Asian Pharmaceuticals and Medical Devices Regulatory Training Center" within PMDA to promote understanding of pharmaceutical regulations in Japan by regulatory authority officials in Asia. Finally, the Councils recognize that FDA, on the device side, has improved the consistency, predictability and transparency of its pre-market activities. These improvements are illustrated by the agency's ability to meet or exceed all of the Medical Device User Fee Amendments (MDUFA) III submission goals to date. In addition, FDA's efforts to work with industry have led to the

successful launch of important programs, such as Case for Quality and Unique Device Identification (UDI).

Pharmaceutical & Medical Devices:

- Encourage PMDA to focus more on the clinical impact of data as well as to develop the capacity to accept newer statistical methodologies and study designs.
- Increase regulatory efficiency through active sharing of Good Clinical Practices inspection reports between FDA and PMDA, with the aim of reducing redundant on-site inspections.
- Apply the concept of the "least burdensome approach" to regulation in the United States and Japan. In particular, the Councils strongly encourage FDA to make further improvements to the regulatory environment through more risk-based assessment and better balance between pre- and post-market requirements, all of which will lead to greater investment by healthcare companies in the United States and Japan.
- Recognizing the considerable contributions of the United States and Japan toward rapidly providing medical innovation to the world, collaborate to ensure that regulatory approvals in third countries, particularly in leading emerging markets, are conducted in a transparent, fair, and expeditious manner.
- Ensure that when Japan's Compassionate Use (CU) System is implemented in JFY2015 measures are in place to ensure that CU clinical trials do not delay the introduction of new product applications for drugs and devices.

Pharmaceuticals

- Enhance the flexible use and acceptability of Phase I clinical data.
- Expand the use of pivotal studies generated in either region/country containing Caucasian and Japanese/Asian data used to establish safety and efficacy for new product approvals in both regions/countries.

Medical Devices

- Support full passage in the U.S. of the "21st Century Cures Act" that aims to 1) accelerate the discovery, development, and delivery of new medical products; 2) remove existing barriers to sharing and analyzing health data generated in research and clinical settings; and 3) ensure FDA product reviews & inspection processes are more predictable, transparent, and risk-based.
- Utilize the Medical Device Innovation Consortium (MDIC) in the U.S. in order to create forums for collaboration & dialogue between regulators, manufacturers & other stakeholders; fund key regulatory science projects (such as the Case for Quality); and provide tools to drive innovation (such as searchable databases linked to standards & test methods, educational training programs, etc.).
- Promote the Harmonization by Doing (HBD) program as a mechanism to

streamline the processes of global medical device development, reduce overall medical device development costs, and provide faster patient access to new medical technologies.

- Ensure robust and constructive Medical Device User Fee & Modernization Act reauthorization negotiations with FDA and Congress.
- Continue improvements to the efficiency of pre- and post-market (e.g. surveillance, facility inspections, etc.) regulatory processes in the United States.
- Establish mutual recognition between the United States and Japan of good clinical practices and quality management audit results.
    - The effective sharing of information, in addition to cross-training of designated auditors on the regulatory requirements in both countries, would permit a single regulatory audit of a medical device manufacturer's quality management system that will satisfy the requirements of both regulatory jurisdictions. The increased efficiency would enable greater resource allocation for new product design and development by manufacturers, as well as for the review and approval of product submissions by the regulatory agencies. These optimized efficiencies would both contribute to faster patient access to new and innovative technologies.

3. Evaluation of Innovation

Pharmaceuticals & Medical Devices

- Ensure that if any new health technology assessment (HTA) or other pricing/reimbursement approach is introduced in Japan or in the United States, it promotes innovation, using transparent, multiple-criteria decision analysis which involve various stakeholders, without restricting patient access or physician choice, and does not cause a drug or device lag.
- Ensure that the price revision process in Japan is not conducted annually, or in an ad-hoc manner.
- In the reform of Japan's consumption tax, a "reduction tax rate" should be applied to pharmaceuticals and medical devices to reduce patient burden.

Pharmaceuticals

- The Japanese pricing system pilot that provides for price stability over the life of the patent and/or exclusivity period makes the Japanese market more attractive. The current rule should be maintained on and after April 1, 2016. Combined with policies to promote greater use of generic medicines, this is a budget neutral policy that supports innovation and reduction of the drug lag.
- Abolish the anti-innovative application of the "Special Re-pricing for Market Expansion Rule," including Domino-style price reductions for all other drugs with similar pharmacological modes of action but different safety and efficacy profiles.

- We advocate the Comprehensive Strategy for Pharmaceutical Industry Reinforcement announced in September 2015, which promotes "stable supply of quality medicines," "efficient use of medical expenses," and "reinforcement of industry." This strategy helps foster innovation and advocate innovation premium while it expands the use of generic medicines up to 80 percent. It encourages R&D base pharmaceutical industry to focus on innovative medicines and promotes industry's globalization, harmonization and reinforcement.

Medical Devices

- Repeal the U.S. medical device excise tax that took effect in 2013 as part of the Affordable Care Act.
- Implement stable and predictable reimbursement policies in Japan that align with Prime Minister Abe's focus on the medical device sector as a driver of economic growth and job creation.
- Better reward innovation in Japan's reimbursement system, including through targeted improvements to the C1/C2 premium reimbursement application process, continuation of the "single room" system to reward innovative products within existing functional categories, and continuation of the device lag elimination premium.
- Reform the functional categories system to ensure that innovative products are adequately rewarded.
- Abolish Japan's Foreign Average Pricing system and replace with a market-oriented, data-driven, transparent reimbursement scheme that welcomes and rewards innovation. Until the system is abolished, maintain – and increase for certain C1 products - the current Foreign Average Price (FAP) multiplier; limit reductions to a low-end threshold of 0.75; apply the outlier rule to the lowest price; and exempt certain C1 products from reductions over at least two revision cycles.
- Refrain from implementing market-expansion repricing for medical devices.
- Ensure that Japan's Health Technology Assessment includes physician fees and welfare fees associated with the impact of innovation on overall welfare spending.

4. IPR Protection

Pharmaceutical Recommendations

- Continue to actively pursue further strengthening of IPR standards, including data exclusivity, to encourage innovation.
- Improve the U.S. Judgments on patent-eligibility (cf. Ariosa case) to avoid inhibiting innovation in health and medical field.

Medical Devices

- Establish a harmonized patent term extension system to ensure the same scope of patented inventions subject to the extension.
- Strengthen the IP transfer bridge between academic institutes and companies with manufacturing and sales capabilities.
- Restrict patent right enforcement by non-practicing entities.

5. **Global Health Security:** The Councils support Prime Minister Abe and President Obama's joint statement on "U.S.-Japan Cooperation for a More Prosperous and Stable World" and its focus on cooperating and leading on global health issues.

Section II:
Sustaining Healthy and Productive Workforces, Reducing Economic Burdens of Diseases, and Extending Healthy Life Expectancy

1. **Preventive Care:** To realize the Preventative Care Visionary Goals, the Councils recommend both governments upgrade ongoing health policy reform discussions, with a focus on primary, secondary and tertiary preventions among the public. Investment in such preventative measures has potential to help mitigate the healthcare related economic challenges in both countries. Specifically, the Councils offer the following suggestions:
   - Develop a comprehensive preventive care educational program that utilizes transparent and evidence-based data to promote wellness.
   - Collaborate with healthcare professionals to educate the public on preventative health measures that focus on vaccine awareness, early diagnosis, and share best practices in slowing disease progression. The program should also strive to educate the public on possible treatment options.
   - Accelerate Japan's vaccine policy reform efforts to bring the country to vaccination levels comparable to those of other developed economies. The U.S. and Japanese governments should collaborate on this initiative as well as strengthen the collaboration between government, industry, academia, and civil society to promote sustainable vaccination programs.

2. **Diagnostics:** The Councils welcome the adoption by the PMDA of a new action program in April 2014 to increase the number of reviewers and accelerate reviews of innovative new IVD (in-vitro diagnostic) products. The Councils urge the Government of Japan to take the following steps:
   - Continue efforts to create a robust regulatory pathway and reimbursement policy suitable for companion diagnostics.

- Apply the evaluative treatments scheme to IVDs so that reagents can be used in insured care as soon as regulatory approval is obtained, which is especially important for diagnoses of emerging infectious disease.
- Develop pricing incentives for diagnostics to improve efficiency in health spending.
- The governments of the U.S. and Japan should collaborate in global efforts to streamline and harmonize the regulatory pathway for the development of companion diagnostics for use in the growing area of personalized medicine.

3. **Community-based Care Recommendations**
   - The Councils recommend the U.S. and Japanese governments develop and implement comprehensive policies that support and facilitate appropriate treatment and palliative measures for chronically and terminally ill patients. Such programs should focus on improving the patient's quality of life and leverage advanced technologies to address realities of cost of care and physician shortages as the population ages.
   - Utilize advanced medical technologies and innovative approaches to reduce the physical and economic burdens created by chronic and terminal illness. A community-based approach should be adopted that educates patients and their families on the resources available from both private and public providers.
   - A clear and transparent insurance model should be promoted that enables patients to receive consistent, high-quality care as they transition from hospitals and other skilled nursing facilities to their homes.

4. **Healthcare Digitalization**
   - The Councils support the Next Generation Healthcare ICT Infrastructure Task Force, a joint project initiated between Headquarters for Healthcare Policy and IT Strategic Headquarters in Japan. The project promotes introduction of the My Number System in healthcare services, data digitalization, utilization of real-world data (RWD) to improve healthcare service to the elderly, including cost optimization, and to foster research & development as well as utilization of RWD by private healthcare business.
   - Promote a harmonized approach to Unique Device Identification with the aim of ensuring quality, logistical efficiency, and traceability for medical safety.

5. **Regional Leadership:** The Councils recommend the U.S. and Japanese governments collaborate in the Asia Pacific region on improving health and welfare as a way to lay a strong foundation for sustainable economic growth and greater international trade. This collaboration allows both countries to lead healthcare promotion and reform initiatives not only in APEC but also in other emerging regions and countries to increase healthy work forces and expand healthier longevities.

- Continue collaboration between the FDA and PMDA in the APEC Regulatory Harmonization Steering committee to promote regulatory convergence through 2020 based on capacity building and best practice sharing in the area of biopharmaceuticals and medical devices.
- Strengthen collaboration between the MHLW and the U.S. Department of Health and Human Services to support the creation of a robust "roadmap" for the implementation of the APEC "Healthy Asia Pacific 2020" vision statement that was endorsed by APEC ministers in 2014.
- Leverage the G7 Kobe Healthcare Summit to discuss innovative measures for neglected and drug resistant infectious diseases, as well as Non-Communicable diseases, as part of the global healthcare agenda. Find ways to incentivize the healthcare industries to develop innovative products and services that address given healthcare challenges.
- Continue collaboration on the adoption of codes of ethics by industry associations based on the APEC Kuala Lumpur Principles for the medical device industry and Mexico City Principles for biopharmaceutical industry.