SUPPLEMENT on HEALTHCARE INNOVATION
Visionary Goals and Recommendations
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The R&D-based pharmaceutical and medical device industries continue to play a constructive role in improving the health and welfare of people in both countries, including by driving economic growth and job creation, as well as developing innovative healthcare solutions that support the lengthening of the average healthy lifespan and reduction of the economic burden of disease. Accordingly, the U.S.-Japan Business Council and Japan-U.S. Business Council (Councils) ask both governments to implement healthcare policies that embody the following visionary goals. The Councils recognize and welcome that progress has been made over the last several years, and offer the following specific recommendations under each visionary goal as a means to advance such progress.

Section I: Pharmaceuticals and Medical Devices

1. **R&D Process Visionary Goal** - 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.

   Pharmaceuticals and Medical Devices Recommendations

   - Pursue and support policies that reduce the barriers between the private, academic and public sectors for collaboration globally.
   - Build on Japan's new strategy for global health diplomacy such as by continuing to collaborate through public-private partnerships (PPP) that contribute to and promote R&D related to global health issues.
   - Make permanent the upper limit of 30% to Japan's R&D tax credit system, and make permanent the R&D tax credit in the U.S., both of which have led to greater investment in R&D by bio-venture, pharmaceutical, medical device and diagnostic companies.

- Continue the high-level public-private health policy dialogue, or Taiwa," that allows for comprehensive consideration of R&D promotion in Japan by multiple ministries and agencies.
- Activate clinical studies and clinical trials in Japan as outlined in the "Clinical Studies, Clinical Trial Activation Five-Year Plan 2012."
- Invigorate the FDA's dialogue with the industry under the Critical Path Initiative.
- Implement the Physician Payments Sunshine Act in the U.S. in a responsible way, so as to ensure physicians do not decide to cut off communication and drug development with opportunities with drug companies due to the risk of having a physician's Sunshine Act records misunderstood by the public.
- The Councils encourage Japan to implement plans to create a single body to oversee all government-funding for applied and translational healthcare research that will act as a bridge between academic and commercial research efforts, including by:
    - Quickly empowering the new body with a strong management team that possesses expertise in a diverse range of fields (including not only science, but also IP, law, IT, ethics and new technology assessment);
    - Continuing with long-term investment in healthcare and to consider expanding investment in such research; and
    - Boldly focusing on key research areas that can be rapidly applied to healthcare innovation.

2. **Regulatory Approvals Visionary Goal** - 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.

Pharmaceuticals and Medical Devices Recommendations

The Councils appreciate efforts by both governments to streamline drug and device approval processes, including through new goals outlined in the 2012 reauthorized drug and device user fee legislation in the U.S., as well as continued progress by PMDA toward reducing the pharmaceutical and medical device lags through productive pre-filing consultations and accelerated reviews. The Councils offer the following recommendations to build on this progress:

Pharmaceuticals

- Further improve the expertise of PMDA reviewers, including in the areas of clinical research and practice as well as in new areas of medical specialization.
- Enhance Japan's coordination capacity in the "Tripartite" exercise with China and Korea to further facilitate the use of Asian clinical trial data as the basis of approvals.
- In the U.S. and in Japan, develop benefit/risk models that do not delay patient access.
- Implement PDUFA V smoothly in the U.S.
- Continue dialogue and cooperation between regulators in the U.S., Japan and the EU.

Medical Devices

- In line with Japan's Five Year Medical Innovation Strategy and Japan's Revitalization Strategy, ensure adequate government funding to expand and enhance PMDA capabilities to reduce review times, particularly for improved and me-too devices.
- Achieve the performance goals outlined in the revised U.S. Medical Device User Fee and Modernization Act.
- Swiftly passing the proposed revisions to Japan's Pharmaceutical Affairs Law to allow for device-specific regulatory requirements.
- Ensure continued PMDA-industry dialogue to review performance and discuss issues in the post-Action Program period.
- Establish mutual recognition between the U.S. and Japan of quality management audit results.
- Support FDA efforts to implement successfully the recently finalized UDI rule, and work with Japanese and U.S. regulators to promote harmonized UDI standards globally.
- Partner with U.S. and Japanese regulators on ways to enhance quality through transparency and consistency of inspection standards processes.

3. **Evaluation of Innovation Visionary Goal** - 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.

Pharmaceuticals & Medical Devices Recommendations

- Ensure that if any new health technology assessment (HTA) or other pricing/reimbursement approach is introduced in Japan or in the U.S., it promotes innovation without restricting patient access of physician choice.

Pharmaceuticals

- The new 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. It should be made standard policy on April 1, 2014.
- Abolish the anti-innovative application of the "Special Re-pricing for Market Expansion Rule," such as Domino-style price reductions for all other drugs with similar pharmacological modes of action but different safety and efficacy profiles.
- Ensure that the Foreign Price Adjustment rule continues to take into consideration the cost of global R&D and rewarding innovation.

Medical Devices

The Councils appreciate changes made during Japan's 2012 price revisions to address the medical device lag and to encourage faster introduction of new and improved devices. Moving forward, the Councils offer the following recommendations to spur innovation in Japan and the U.S.:

- Eliminate Japan's FAP rule and transition to a product-based, market-oriented pricing system that allows for the full evaluation of innovative medical technologies and enables Japan to effectively execute its Five Year Medical Innovation Strategy.
- Reform the functional categories system to allow for multiple reimbursement prices within each functional category that would better reflect differences in innovation and service levels.
- In line with Japan's Five Year Medical Innovation Strategy, ensure, at a minimum, that reimbursement policies implemented for the 2014 – 2016 period facilitate a stable and predictable environment that encourages investment in the medical device sector.
- Repeal the U.S. "Medical Device Excise Tax" that took effect in 2013 as part of the Affordable Care Act (ObamaCare), so that it will not undermine the industry's efforts to develop innovative products and therapies.

4. **IPR Protection Visionary Goal** - 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. From March 16, 2013, the U.S. will implement a first-to-file system which will result in better harmonization of the U.S. and Japanese patent systems.

Pharmaceutical Recommendations

- Adopt a 12-year period of data protection for biologics in Japan.
- Extend the data exclusivity period in the U.S to 8 years (and 10 years for orphan drugs) for small molecules.
- Implement 12-years of data protection for biologics in the U.S.

5. **U.S.-Japan Regulatory Cooperation Visionary Goal:** The U.S. and Japanese regulatory authorities further collaborate on joint projects, including by engaging in candid and positive discussions on the basic principles and framework for health care regulations.

Pharmaceuticals and Medical Devices Recommendations

- Cooperate to promote IPR, including data protection periods, and greater transparency in medical product pricing regimes in other markets though high standard trade agreements, such as TPP.

- Collaborate in APEC to improve the environment for US and Japan medical product exports to Asia Pacific countries by promoting regulatory convergence; strengthening medical sector codes of conduct; promoting collaboration to reduce the economic burden of disease; combating counterfeit medical products; and improving the investment environments for life sciences.
- Cooperate in the World Trade Organization to eliminate tariffs on all medical devices and drugs.

Section II: Preventative Medicine and Diagnostics

1. **Vaccine Policy Visionary Goal:** The U.S. and Japanese government officials should have clear, insightful and aspirational national vaccine plans for Japan to

reduce "Vaccine Gap" in Japan and accelerate access to innovative and global standard vaccines for Japanese.

Recommendations:

With this vision in mind, the Councils respectfully recommend that the Government of Japan take the following steps: (1) Develop a holistic National Vaccine Plan and promote vaccination based on the plan; (2) Establish a clear process and criteria for National Immunization Program; (3) Support a Vaccine and Immunization Sub Council in order to accelerate implementation and execution of planned vaccine policy in a timely manner; (4) Establish a financing system for recommended vaccines that designates the federal government as a funding body of vaccination costs in order to promptly achieve uniform vaccination to those wishing to receive vaccines nationwide; (5) Establish adequate communication channels and/or systems to provide accurate, understandable and transparent information about value, efficacy and safety of vaccines to the public to enhance and secure informed vaccine decision-making; and (6) Implement a simplified national testing system to realize flexible vaccine supply.

2. **Diagnostics Visionary Goal:** The U.S. and Japan recognize the innovative medical diagnostic industry as an important driver of job and export growth, and support the use of innovative diagnostics for early diagnosis and treatment to improve patient Quality of Life and help extend the healthy lifespan of the population, and use pricing incentives for diagnostics to improve efficiency in health spending.

Recommendations

1) In line with this vision, the Councils urge the Government of Japan to take the following steps:

(A) Adopt an action program to increase the number of reviewers and accelerate reviews of innovative new IVD (in-vitro diagnostic) products by the PMDA (currently only 36% of products are reviewed within the target time of 6 months);

(B) Construct a streamlined and harmonized regulatory system for IVD as part of the planned Pharmaceutical Affairs Law revision;

(C) Continue efforts to create a robust regulatory pathway and reimbursement policy suitable for companion diagnostics; and
(D) Provide pricing incentives for innovation by differentiating among reimbursement prices of various IVD products based on their relative value and quality, including potential for faster and more accurate diagnosis at point of care.

2) The governments of the U.S. and Japan 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.