HEALTHCARE INNOVATION

Healthcare systems must constantly evolve to meet the changing needs of society and to incorporate new technologies that offer improved health outcomes and greater efficiency. The COVID-19 crisis has made clear the link between health and the economy, underscoring the need to make strategic investments in healthcare and the importance of collaboration and coordination between government and industry. The future sustainability of our healthcare systems, including rapid response to pandemic threats, requires on-going dialogue and partnership between stakeholders. **In consideration of these factors, the U.S.-Japan Business Council and Japan-U.S. Business Council (hereafter "the Councils") propose a bilateral private-public dialogue focused on elements of an innovative, equitable, efficient, and effective healthcare system that provides patients with timely access to best available medical innovations**.

In our view, a sustainable healthcare system integrates the following four elements:

1. ***Innovation Ecosystem:*** Continuous creation of breakthrough innovation in healthcare technologies, medicines and vaccines, healthcare delivery systems, and healthcare provider capability, which are supported by medical mechanisms to support the assessment of the benefits of these innovations.
2. ***Patient and healthcare provider access to the best possible care:*** Optimal patient and provider experience and access allowing the use of innovations to produce the greatest return on health system investment to patients, their families, and the broader economy.
3. ***Budget Optimization:*** Efficient and flexible resource allocation driven by evidence that maximizes outcomes, minimizes unnecessary expenditures, and maintains capacity to respond to emerging challenges.
4. ***Data and digitalization:*** Effective data collection and analysis, with appropriate privacy protections, to inform individual patient and health system level decision-making based on actionable insights.

To achieve these priorities, the Councils recommend a formal dialogue where policymakers and industry collaborate regarding technologies and innovative contributions to advance healthcare sustainability.

This Joint Statement represents the collective opinions of the Councils and reflects the shared interests of Japanese and U.S. industry. Our objective has always been to support patient-centered healthcare while fostering the competitiveness and resilience of the industry and of the Japanese and U.S. economies. Therefore, we support the "CoRE" partnership formed by former Prime Minister Suga and President Biden. The dialogue we propose is consistent with the partnership's goals to support the competitiveness and resilience of our nations. The following policy recommendations address issues currently impacting the sustainability, efficiency and effectiveness of our health systems and the ecosystems that enable innovations in various sectors.

Healthcare System Sustainability

- For both: Enhance collaboration between governments to improve emergency preparedness through a variety of avenues including: research and development, supply chain management, therapy and diagnostic production and monitoring, and rapid evaluation of medical value.
- For both: Improve regulatory review processes with staff expertise and adequate resources.
- For both: Ensure reimbursement schemes are aligned with the innovation in pharmaceutical, medical device, diagnostics, sensors and patient support aids.

Data and Digitalization

- For both: With appropriate privacy protections in place, accelerate the collection and use of life-course data including genome data by both the public and the private sector. Enhance trust in processes that govern collection (including tools), use and reuse of data. The use of real-world data and big data in the evaluation of medical technology, such as cost-effectiveness, will support progress of value-based healthcare.
- For both: Allow private industry to utilize real-world data to develop and gain approval of innovative medical devices and innovative medicines, such as genomic medicine for cancer, implantable and wearable medical devices with physiologic closed control system, and medical imaging diagnostics assisted by AI.
- For both: Promote alignment between U.S. and Japanese regulators in developing and implementing new digital health policies, which accelerate, and reduce the cost of, developing innovative therapies and improve health outcomes by using technology to collect data and support physician/patient interaction.
- For Japan: Accelerate clinical trials by utilizing real-world data to replace placebo groups where appropriate, and developing Decentralized Clinical Trials platforms.
- For both: Permit industry, academia, government and medical institutions to collaborate in the development of real-world databases of sufficient quantity and quality in order to improve data utilization, including disease registries. This would support the innovation ecosystem allowing for more local research and development.
- For both: Encourage the adoption of an interoperable IT platform that is used to support integrated care across diagnosis, treatment planning and delivery, patient follow-up, and patient data management, making IT platforms available to manufactures and healthcare professionals.

- For both: Address ethical, legal and social issues on utilizing medical records and personal health data.
- For both: Promote the use of remote practices such as telemedicine, which can be utilized in home care.
- For Japan: Develop the environment in which individuals can access and utilize their own medical records in medical institutions and personal health records.
- For Japan: Enhance an early introduction of a special law to promote protection and utilization of privacy information specific to healthcare that will contribute to the promotion of R&D.
- For Japan: Further support the development of a data platform for the traceability of pharmaceuticals and medical devices.

Vaccines, Prevention, Functional Foods

- For both: Adopt and strengthen science-based vaccination policies and public information campaigns and give greater recognition to the societal value of prevention.
- For both: Recognize the evidence-based health benefits of functional foods, such as health foods and dietary supplements, so that the benefits can be communicated to promote public health.
- For Japan: Promote innovation and policies for new preventative screening services, for example, to improve the rate of breast cancer screening, detect atrial fibrillation, consistently monitor glucose levels with continuous glucose monitoring systems, and diagnose cognitive impairment at earlier stages.

Innovation Ecosystem

- For both: Recognize the importance of innovation and pursue pharmaceutical and medical device pricing and reimbursement reforms to reflect the value of these treatments in the context of the overall healthcare system. Recognize that pharmaceutical and medical device price reductions have a minimal impact on the Total Cost of Healthcare while having a significant impact on the amount of funds available for R&D slowing the pace of needed innovation.
- For both: Ensure the regulatory, pricing and reimbursement systems recognize the innovation associated with the development of new indications for existing therapies.
- For both: Ensure that any Health Technology Assessment (HTA) or Cost Effectiveness Assessment (CEA) in the U.S. or in Japan does not delay patient access or restrict physician choice.
- For both: Pursue medical device and pharmaceutical evaluation schemes that link pricing to both the patient outcomes and preference, as well as to the cost-offsets within the healthcare system and the wider society.
- For both: Maintain and provide new incentives for public-private research collaborations and use dialogue with industry, academia, and medical-research institutions to identify opportunities for greater partnership and policy reform to enhance coordination.

- For both: Safeguard intellectual property protections that sustain risk-taking investment and long-term research into new medical technologies and tools.
- For Japan: Further expand legally established combined medical care (combination of non-insurance medical treatment and insurance covered medical treatment).
- For Japan: Introduce pricing schemes suitable for innovative therapeutics such as cell and gene therapies and software as a medical device.

Pharmaceuticals

- For both: Explore opportunities to create additional benefit and plan design structures to reduce potential barriers to medicines and devices that out-of-pocket copayments may pose.
- For both: Consider a Mutual Recognition Agreement (MRA) on Good Manufacturing Practice (GMP) between the U.S. and Japan to improve supply chain management.
- For Japan: Encourage innovation by applying cost-savings from the expanded use of generics after the patent/exclusivity period of originators to pay for new therapies and/or contribute to research funds.
- For Japan: Simplify pricing and reimbursement rules to create a more transparent and predictable operating environment.
- For Japan: With regard to value-based pricing, consider the full range of benefits derived from therapies, including reduction of nursing-care expenses and improved labor productivity.
- For Japan: Improve the Price Maintenance Premium Policy by expanding the product criteria for medicines.
- For Japan: Limit off-year price revisions to products where the margin of discount between the National Health Insurance (NHI) reimbursement price and the medical institution purchase price is larger than the market average.
- For Japan: Maximize the utilization of *Sakigake* and conditional approval to expedite the availability of innovative medical treatments where significant unmet medical need exists.
- For Japan: Establish regulatory data protection for pharmaceuticals including new modalities with the highest global standard.
- For the U.S.: Abandon international reference pricing proposals, which do not reflect the value of the innovation or allow for sustained investment in future therapies to address unmet medical needs.

Medical Devices

- For Japan: Maintain current price revision formula and frequency (e.g., once every two years). More specifically, we recommend the following:
  - Undertake functional category consolidation only with specific data-driven reasons for doing so, including sufficient time for consultation with relevant companies and clinical experts within the affected categories and exclusion of newly established functional categories for a certain amount of time to allow for stabilization of categories and data collection.

  - To the extent the Foreign Average Price (FAP) price revision rule must remain, maintain the current FAP ratio, FAP comparator countries and R-zone level, eliminate the off-cycle FAP survey, and reduce the impact of short-term exchange rates on the FAP calculations.
  - Adopt a FAP floor to add fairness to a system that currently has an upper limit but no lower limit.
  - Provide further clarification of Market Expansion Repricing rules and suspend implementation until all outstanding issues are addressed in consultation with industry.
  - Consider premium reimbursement opportunities for new "pioneer medical devices."
- For Japan: Establish a new infection control management fee specialized for operating rooms to accelerate the use of medical devices related to infection control in addition to STM (special treatment material), corresponding the COVID-19 situation and the increasing risk of new infectious diseases.
- For the U.S.: Urge continued reforms to the Medicare program's coverage, coding and payment processes for new medical devices that improve the treatment and diagnosis of Medicare beneficiaries.
- For the U.S.: Work with the FDA and Congress to reauthorize the FDA's Medical Device User Fee Program before it expires next year, and partner with FDA to ensure a more efficient and transparent medical device facility inspection process, per the 2017 FDA User Fee Reauthorization Act.