U.S. Chamber of Commerce International Affairs | U.S.-Japan Business Council | JUBC Japan-U.S. Business Council

Healthcare Innovation

As the COVID-19 pandemic continues to dampen economic growth and disrupt livelihoods, and new public health threats emerge, sustainable and predictable investment in healthcare innovation is urgently needed to promote health system resilience, timely patient access to new treatments and economic competitiveness. These investments will enable the acceleration of transformative technological advances – such as genome editing and cell engineering, digital health solutions and artificial intelligence applications that promise to deliver new breakthroughs to patients at unprecedented speed. Recent geopolitical events have also highlighted the importance of collaboration to ensure resilient supply chains for medical goods, which are critical to ensuring patients are able to access needed healthcare products in a crisis. Even as the pandemic and related developments have highlighted the critical role that healthcare innovation plays in promoting global health and economic security, the Councils note with concern the proliferation of policies that risk undermining innovation and reversing major advancements in healthcare investment, compromising competitiveness for both countries. Of note, there is growing concern that significant numbers of U.S.-approved innovative medicines will not become available in Japan in a timely manner or at all, due in part to the lack of transparency and predictability in the Japanese market for innovative medicines. Similarly, the research-based biopharmaceutical industry has commented that recent U.S. policy developments will lead to fewer new treatments overall while failing to improve affordability as promised.

The U.S.-Japan Business Council and Japan-U.S. Business Council (hereafter "the Councils") therefore **reiterate their call for a bilateral private-public dialogue to improve timely access to innovative medical products through innovative, equitable, efficient, and effective healthcare systems.** Recalling the four elements of a sustainable healthcare system set forth in their 2021 statement, the Councils recommend that governments and the private sectors in both the United States and Japan dramatically strengthen their collaboration to build a sustainable global healthcare innovation ecosystem and strengthen supply chain resilience.

The Councils support ongoing discussions between the United States and Japan under the auspices of the U.S.-Japan Competitiveness and Resilience ("CoRE") Partnership, the Economic Policy Consultative Committee ("EPCC"), and other bilateral dialogues and welcome the Japan-U.S. Joint Leaders' Statement ("Strengthening the Free and Open International Order") issued by President Joe Biden and Prime Minister Fumio Kishida in May 2022. We are committed to engaging in discussions on policies that would contribute to the resilience of the global supply chain for pharmaceuticals and medical devices in collaboration with both governments.

This Joint Statement represents the collective priorities of the Councils, and we believe that the following recommendations will help both government and industry advance greater health, while strengthening innovation in the U.S. and Japan.

1. Innovation Ecosystem

Reimbursement policies must reward technological breakthroughs and improvements to encourage continued investment and meaningful access for patients. For business and private sector investors to prioritize innovation, policies must acknowledge and compensate for the risks and financial losses associated with research and development. Fair and predictable reimbursements will ensure that innovators continue to explore, develop, and refine cures and treatments for diseases and conditions to improve health.

1.1 Innovation in Healthcare

- For both: Develop and improve the R&D, regulatory environment and reimbursement system to encourage continued investment in the market.
- For both: Create new initiatives to further public-private research collaborations and use dialogue with industry, academia, medical-research institutions, investors and patient associations to identify opportunities for greater partnership and policy reform.
- For Japan: Activate strategic dialogue on a "drug discovery innovation ecosystem" as a national strategy between the public and private sectors and promote the establishment of performance indicators and monitor progress of implementation of the MHLW "Pharmaceutical Industry Vision 2021."
- 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: Reform regulatory policies to adapt to changes in the R&D landscape such as increasing biotech-led development of innovative medicines and medical devices (e.g., lower hurdles to initiate development in Japan by reducing need for Japanese data).
- For both: Prevent erosion of intellectual property protections that drive investment in biopharmaceutical research and are essential to research partnerships in Japan and the United States as well as around the world.

1.2 Evaluation of Innovation

- For Japan: Promote pricing approaches that consider the benefits derived from therapies, including clinical outcomes as well as social benefits (e.g., getting people back to work, making it easier for patients and HCP, and increasing efficiency of healthcare services) and secondary economic payoffs (i.e., increased productivity).
- For the U.S.: Advance value-based insurance design structures and improvements in patient access that mitigate financial barriers to treatment and permit graduated payment options to

allow patients to pay over time for larger expenses including those associated with advanced medicines such as oncological treatments.

- For both: Ensure that any Health Technology Assessment ("HTA") does not delay patient access or restrict physician choice.
- For Japan: Exclude patented new drugs from the scope of price revisions (including off-year) and market expansion repricing, similar to other G7 countries.
- For both: Ensure the regulatory, pricing and reimbursement systems recognize the innovation associated with the development of new indications for existing therapies.
- For both: Introduce financial initiatives that can reflect the value of innovation to encourage the development of innovative therapeutics such as regenerative medicine, cell therapy and gene therapy, and for digital therapeutics such as software as a medical device ("SaMD").
- For Japan: Further expand legally established combined medical care (combination of non-insurance medical treatment and insurance covered medical treatment).
- For Japan: Abolish Foreign Average Price adjustment system, which merely compares prices of medical devices without any consideration to differences in healthcare systems and business environments among countries, to ensure U.S.-approved innovative medical devices remain available in Japan.
- For Japan: When reviewing Functional Categories for medical devices, work closely with industry and ensure that any changes do not undermine rewarding innovation.

2. Digital Transformation

- For both: Promote alignment between U.S. and Japanese regulators in developing and implementing new digital health policies to reduce the cost of developing innovative therapies and improve health outcomes by collecting data and supporting physician/patient interaction.
- For both: Develop an environment in which individuals can access and use their own medical records, while healthcare providers and researchers both domestically and internationally can exchange medical data among different institutions to treat the same patient with adequate privacy protections and patient permission.
- For both: With appropriate protections and meaningful incentives, promote the development/adoption and use of interconnected/interoperable information platforms using international standards such as HL7/FHIR to support integrated care across diagnosis, treatment planning and delivery, patient follow-up, and patient data management.
- For Japan: Develop clear guidance/frameworks for healthcare institutions to store, manage and share healthcare data that improves the quality and efficiency of the healthcare system and public health, and to promote innovation.
- For both: Address Ethical, Legal, and Social Issues ("ELSI") including privacy, information protection and antidiscrimination for accelerating the sharing of de-identified healthcare data.

Conduct an education campaign to raise awareness on the advances that can be achieved with the sharing of anonymized medical data in driving evidence-based treatment solutions.

- For both: Enable Decentralized Clinical Trials, allowing a hybrid of in-person and remote visits to medical institutions for trial participants.
- For both: Promote alignment between U.S. and Japanese regulators in cybersecurity risk management approaches to protect against cyberattacks and data intrusions, ensure patient safety and minimize enterprise risk.
- For Japan: Establish a mechanism where the healthcare industry can properly deliver necessary information regarding pharmaceuticals and medical devices for patients and the public by using digital technology.
- For both: Promote the use of different treatment modalities such as telemedicine, which can be utilized in the home.
- For Japan: Further support the development of a data platform for the traceability of pharmaceuticals and medical devices.

3. Economic Security and Resilience

- For both: Promote economic security policies that enhance resilience and encourage trade with trusted partners.
- For Japan: Establish regulatory data protection for pharmaceuticals including new modalities with the highest global standard.
- For both: Reinforce investment in R&D for advanced healthcare technologies to improve the technological capabilities and industrial competitiveness of the U.S. and Japan.
- For both: Establish initiatives to enhance mutually beneficial cooperation regarding components, material and manufacturing technology between Japan and the U.S. from the viewpoint of industry development and stable supply of digital health technology.
- For both: Support countermeasures between the U.S. and Japan against infectious diseases and disasters. Establish a market incentive system for R&D for antimicrobial drugs and vaccines and promote the fight against drug resistance (AMR).
- For both: Reinforce global supply chains through alliances between the U.S. and Japan and with their allied countries for stable supply of pharmaceuticals and medical devices.
- For Japan: Ensure unexpected currency changes do not undermine the stability of the healthcare business, supply chain resilience and a stable supply of medical devices and pharmaceutical products.
- For both: Support the free and open flow of medical products across borders to ensure timely access for patients.

- For both: Establish expedited regulatory review procedures for improved supply chain such as relocation of manufacturing sites in the event of an emergency and regulatory reliance/sharing of reviews of post-approval changes related to manufacturing, and consider other initiatives to support supply chain resilience.
- For both: Establish a Mutual Recognition Agreement (MRA) on Good Manufacturing Practice (GMP) between the U.S. and Japan to improve supply chain management.
- For both: Adopt and strengthen science-based pro-vaccination policies and public information campaigns, understanding that high vaccine uptake is essential to preserving economic and social resilience vis-à-vis pandemics and seasonal and endemic disease.
- 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 and ensure the resilience of social security systems in ageing societies.