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

Healthcare Innovation

While the emergency responses and economic adjustments implemented during the COVID-19 pandemic are diminishing, the need for continued investments in healthcare innovation to address ongoing and future health challenges remains crucial. COVID-19 demonstrated the importance of transformative technological advances and new thinking in health – from agilities in regulatory policy and digital solutions to the strengthening of healthcare infrastructure and investment in research and development for innovative vaccines and treatments. Despite their historical leadership in the life sciences, the U.S. and Japan face significant challenges. For example, pricing methods that increasingly do not reflect the value of innovation, patient experience, or long-term outcomes, frequent revisions to pricing rules, and annual price cuts to patented medicines have made the Japanese market unpredictable and less supportive of innovation. While Japan took some positive steps recently to reverse this trend, more work is needed to reverse the notable decline in biopharmaceutical R&D investment in Japan and return of a drug lag in which innovative medicines to treat unmet medical needs are not launched in a timely manner. Similarly, new price-setting policies in the U.S. are already undermining the development and availability of healthcare solutions, without fully addressing affordability concerns for patients. Furthermore, pressures persist globally to weaken intellectual property protection, making it critical that both governments continue to reinforce the importance of strong IP protection for innovation.

This April, U.S. President Joe Biden and Japanese Prime Minister Fumio Kishida agreed to expand U.S.-Japan cooperation on health and biotechnology. The U.S.-Japan Business Council and Japan-U.S. Business Council (hereafter "the Councils") commend both governments on the commitment to launch a new biotechnology innovation and healthcare dialogue with incorporation of input from the private sector aimed at addressing shared challenges and opportunities. In alignment with the Councils' previous recommendations, we welcome this new public-private dialogue and recognize it as an important opportunity to advance industrial competitiveness and address barriers to innovation.

To maximize the potential success of this new dialogue, the Councils encourage the governments to adopt a robust agenda identified through consultation with the private sector, aimed at achieving concrete outcomes and practical solutions to barriers to innovation, with frequent opportunities for private sector engagement over a five-year period. In this regard, we propose that the dialogue is structured to:

- Solicit comments (e.g., through the Federal Register process) from the private sector on specific topics prior to any government-only meetings.
- Welcome and participate in, as appropriate, private sector-organized panel discussions and side events between formal meetings.
- Measure and publicly report on progress and results from the dialogue through an annual review process.
- Support creation of a private sector advisory panel to support policy efforts.

The Councils recommend adopting a clear, objective-driven agenda which would include the following pillars:

1. **Investment in healthcare innovation.** The dialogue should include exchange of views on best practices for enabling investment that supports medical innovation. A new, holistic strategy is needed with cross-ministerial engagement to support ambition across all parts of the health innovation ecosystem. The private sector can provide regular consultation and guidance on targets and policy approaches to incorporate into the strategy, as well as lessons learned from similar endeavors in other countries.

2. **Timely patient access to innovation.** Half of innovative medicines now receive annual price cuts in Japan and the price of a medicine can be further reduced significantly and repeatedly, which represent disincentives to investment and result in significant commercial uncertainty. The public-private dialogue should seek to address the factors that contribute to reduced patient access to innovative medicine as a result of some medicines not being developed and launched in Japan and promote a meaningful exchange of views on concrete proposals for reform. For Japan, the Councils urge the government's actions to consider how the off-year price revision should be, in the light of the government's stated goals to enhance the biopharmaceutical ecosystem and promotion of innovation. The current cost-effective analysis system has some weaknesses, such as it does not consider secondary economic benefits of new health innovation, increases in productivity due to health benefits, or the impact of the health sector on the economy. Expansion of this system could significantly negatively impact timely patient access to new medicines and treatments. In the U.S., the unintended consequences of price setting are already harming the development of the next generation of treatments and cures, and the Councils recommend the government take steps to preserve the existing, market-based incentives for innovation.

3. **Supply chain resilience and economic security.** The Councils recommend that the dialogue include specific discussion of opportunities for the United States and Japan to deepen partnership to promote supply chain resilience, including through commitments to improve regulatory transparency and due process, reduce regulatory disparities and address other tariff and nontariff barriers that increase the cost of supply chain integration and otherwise make it more difficult for companies to operate in the market.

4. **Digital health partnership.** The Councils recommend leveraging the new public-private dialogue to design and launch a U.S.-Japan partnership on digital health, aimed at sharing best practices for telemedicine and remote care, digital therapeutics, artificial intelligence, and cross border data flows and privacy, as well as establishing regulatory pathways to enable patient access to these technologies.

In addition to the above pillars for the dialogue, the Councils recommend that the governments consider the following policy recommendations:

Innovation in Healthcare and Evaluation

- For both: Develop and improve the R&D, regulatory environment, and reimbursement systems to encourage continued investment in the market. Ensure that regulatory and pricing systems are keeping pace with the incredible breakthroughs in science and technology associated with new pharmaceutical and medical technology products.
- For both: Encourage adoption and implementation of high-standard IP regimes; prevent the 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.
- For both: Introduce financial initiatives that can reflect the value of innovation to encourage the development and early launch 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 both: Ensure that use of or any movement towards implementing Health Technology Assessment ("HTA") at a minimum includes consideration of the importance of patient access and physician choice.
- For both: Eliminate harmful price control policies that discourage innovation and patient access, including provisions stipulated in the Inflation Reduction Act of 2022 that disincentivize the development and stable supply of small molecule medicines, medicines for rare diseases, and R&D of new uses following a medicine's initial regulatory approval and provisions in Japan that disincentivize the development and stable supply of medical devices and innovative pharmaceuticals.
- For both: Share best practices in education, access capabilities, and adoption between the U.S. and Japan around genomic medicine and explore opportunities for collaboration.
- For Japan: Maximize the opportunity for multinational companies to engage in the new public-private forum derived from Japan's Cabinet-level working group on enhancing drug discovery capabilities and as described in the Honebuto 2024 policy paper, to identify required goals, actions, and KPIs to enable Japan to develop a comprehensive national strategy to strengthen its drug discovery capacity and play a key role in the global

biopharmaceutical innovation ecosystem.

- For Japan: Continue to reform regulatory policies to resolve the lag and loss in bringing treatments and vaccines to market by harmonizing regulations to global standards and allowing the consideration of real-world evidence. Policies should eliminate requirements unique to Japan and be verified on a regular basis to ensure they are implemented as intended.
- For Japan: Promote pricing approaches that consider the wide range of benefits derived from therapies, including clinical outcomes as well as social, population and economic benefits, including those that will affect the health system.
- For Japan: Exclude patented new drugs from the scope of price revisions (including off-year) and market expansion and spillover repricing, similar to other G7 countries.
- For Japan: Create a new pricing mechanism for innovative products with no comparator to ensure fair and adequate value is given to novel drugs without a subjective and onerous transparency penalty.
- For Japan: Provide more regular and meaningful opportunities for stakeholders including the industry to provide input regarding the development of rules impacting the health care sector and otherwise address the current challenges of low business predictability due to numerous changes to pricing rules and little room for negotiation by the industry in the pricing process.
- For Japan: With respect to medical devices, abolish the Foreign Average Price adjustment system, which bluntly compares medical devices pricing without any consideration to differences in healthcare systems and business and reimbursement environments among countries, to ensure innovative medical devices remain available to patients in Japan.
- For Japan: When reviewing Functional Categories for medical technologies, work closely with industry to ensure that any changes do not undermine rewarding innovation.
- For Japan: When conducting cost effectiveness evaluations for innovative drugs and medical technologies, ensure that available published evidence, value-based healthcare/procurement guidelines, and internationally accepted cost-effectiveness modeling are considered; avoid the mechanistic use of cost-effectiveness thresholds when determining value to avoid creating barriers to the entry of innovations. Cost effectiveness evaluations should also consider secondary benefits provided by new health innovation, increases in productivity due to health benefits, and the impact of the health sector on the economy.
- For Japan: Provide early access to diagnostics and screening assays for diseases like cancer and rare diseases, given screening, prevention, and better targeted therapies lead to lower healthcare costs in the long term.
- For the U.S.: Address the unintended consequences of pricing reforms on provider reimbursement, so that all physicians can afford to administer the most appropriate medicines for their patients.

Digital Transformation

- For both: Redouble an overarching commitment to swift and effective digitalization in healthcare with strong leadership and adequate support from the government.
- 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. Health data platforms should be designed with consideration of the secondary use of health data collected, which may be used for medical research and development.
- For both: With appropriate protections and meaningful incentives, promote the development, adoption, and use of interconnected/interoperable health data platforms – whereby individuals can access their own health data – 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 both: Address Ethical, Legal, and Social Issues ("ELSI") including privacy, information protection, and antidiscrimination to accelerate the sharing of de-identified health data. Conduct an education campaign to raise awareness of the advances that can be achieved with the voluntary sharing of anonymized medical data in driving evidence-based treatment solutions and evidence-based policy making.
- For both: Address barriers to data sharing mechanisms, while maintaining appropriate privacy protections, to allow for the discovery of novel targets and therapies and facilitate the integration of genomic/multiomic data into the healthcare system through cooperation with researchers and clinicians and a sharing of best

practices between the two countries.
- For both: Further promote the application of Decentralized Clinical Trials, allowing a hybrid of in-person and remote visits to medical institutions for the benefit of trial participants.
- For both: Promote alignment between U.S. and Japanese regulators in cybersecurity risk management to protect against cyberattacks and data intrusions, ensure patient safety, and minimize enterprise risk.
- For both: Promote the use of diverse treatment modalities such as telemedicine, which can be utilized in the home.
- For Japan: Implement a comprehensive health data policy that promotes building data infrastructure by the government and includes legal frameworks that enable utilization of health data by the private sector while appropriately protecting patient privacy.
- For Japan: Establish a digital mechanism by which the healthcare industry can properly deliver necessary information regarding pharmaceuticals and medical devices to patients and the public.
- For Japan: Further support the development of a data platform for the traceability of pharmaceuticals and medical devices.

Economic Security and Resilience

- For both: Promote economic security policies that enhance diverse and resilient supply chains and encourage trade with trusted partners.
- For both: Reinforce global supply chains through alliances between the U.S. and Japan and support removal of unjustified trade barriers to medical products to ensure timely and equitable access for patients and stable supply of health products including therapeutics and medical devices.
- 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 between the U.S. and Japan regarding components, material, and manufacturing technology from the viewpoint of industry development and stable supply of medical products and technologies.
- For both: Support joint U.S. and Japan countermeasures against infectious diseases and health emergencies. Establish a market incentive system for R&D for antimicrobial drugs and vaccines and promote the fight against drug resistance ("AMR").
- For both: Establish expedited regulatory review procedures for improved supply chains such as the 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-a-vis pandemics and seasonal and endemic diseases.
- For both: Recognize the evidence-based benefits of fundamental health solutions, such as a well-balanced diet, exercise, and adequate sleep, so that the benefits can be communicated to promote public health and wellness and enhance primary disease prevention for healthy longevity in aging societies.