US-JAPAN BUSINESS COUNCIL | JUBC Japan-U.S. Business Council

# HEALTHCARE INNOVATION

Much has changed since the last joint statement of the U.S.-Japan Business Council and the Japan U.S. Business Council ("the Councils"). In September 2019, no one contemplated the worldwide economic fallout that would result from a viral pandemic. Yet one year later global economies are reeling, while healthcare providers are putting themselves at risk to care for patients and the world's top scientists are relentlessly pursuing treatments and vaccines.

The COVID-19 crisis spotlights the interdependent relationship of government and industry, both domestically and abroad. The long-standing collaborative structure of medical innovators and health system administration has allowed for an unprecedented rapid response to the pandemic, which could not have been achieved without considerable resources. The bio-medical industry was able redirect its scientists, maintain its supply chain, increase manufacturing and distribution capacity and launch clinical trials in record time because countries like Japan and the U.S. reward innovation. The revenue derived in the normal course of business from innovative medical equipment, cancer therapies, auto-immune drugs, anti-inflammatory treatments and diabetes medications (among many others) enables the industry to tackle unmet medical needs and respond in times of crisis. This model must be preserved and enhanced to ensure sustainability and preserve innovation, and it is important that medical expenditures be recognized as investments rather than merely costs.

The following recommendations by the Councils to the U.S. and Japanese governments are intended to strengthen both of our economies and advance medical innovation. Citizens of both countries should have access to the latest innovative medical technology and biopharmaceutical therapies. Japan and the U.S. are world leaders in medical innovation. The Councils underscore the importance of preserving and enhancing the systems that built these industries to maintain our competitive advantages.

**COVID-19 Response and Access to Therapy**

- For both: Pursue policies that facilitate partnerships among private parties in the development, production, and distribution of COVID-19 technologies to meet the challenge of rapidly scaling up manufacturing of COVID-19 vaccines and therapies. This includes maintaining policies that allow for efficient and expeditious licensing of intellectual property among private parties.

- For both: Commit to work closely with businesses to identify and remove obstacles to the swift approval and distribution of COVID-19 technologies, including unnecessary regulatory requirements, approval delays, and any other trade-related barriers, while adhering to necessary safety regulations.
- For both: Continue the strong collaboration with the International Coalition of Medicine Regulatory Authorities (ICMRA) and explore tools for regulatory cooperation, including exceptional use of regulatory reliance and recognition.
- For both: Enhance collaboration between the U.S. and Japanese governments to improve emergency preparedness, to include a framework for rapid regulatory approval with guidelines for evaluating new technologies for infectious diseases and a collaborative procurement process for public health supplies in emergency circumstances.
- For both: Commit to developing a joint response to emerging supply chain challenges and reject export bans and bilateral trade restrictions, which cause serious damage to patient access and industries in both countries. Recognize that responses to emerging global health crises, such as COVID-19, have an important international dimension and recommit to sustaining the interoperability of global supply chains. Overreliance on one country can be mitigated by working within a trusted trade network.
- For both: Conduct a national public information campaign to educate the public about the facts and safety of the COVID-19 vaccine and dispel anti-vaccination misinformation in conjunction with the approval and deployment of a COVID-19 vaccine.
- For Japan: Establish an Office of Infectious Disease Control to oversee both normal and emergency infectious disease control.
- For Japan: Consult closely with industry and support its efforts to devise context-specific strategies that avoid resource duplication and create timely access to key medical products.

**Value of Innovation**

- For both: Urge continued evaluation of Japan's C1/C2 premium pricing process and U.S. Medicare's coverage, coding, and payment processes for new medical advances that improve the diagnosis of and treatments for patients.
- For both: Reinforce the role of a global rules-based trading system including intellectual property rights as provided under the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and other accords. Finalize a broad-based, high-standard, and forward-looking bilateral trade agreement that recognizes the importance of fair value for innovation and jointly promotes high-standard intellectual property rights among other trade partners.
- For Japan: Given the impact of COVID-19, the drug price revision scheduled for April 2021 should not be implemented.
- For Japan: Revise the drug pricing system to ensure that developers and innovators are appropriately rewarded and that pharmaceutical companies are able to invest in the development of new drugs.
- For Japan: Maintain stability in the price revision mechanism for medical devices, including revision timing and formula, while finding ways to inject greater transparency and consultation into the revision process including functional category consolidation.

- For Japan: Maintain and strengthen research and development incentives for pharmaceuticals, vaccines, and Active Pharmaceutical Ingredients (API) manufacturing sites.
- For Japan: Ensure that any health technology assessment (HTA) or cost effectiveness assessment (CEA) in Japan does not delay patient access or restrict physician choice. Consider conducting analysis post-launch to evaluate the real-world effectiveness of the product compared to clinical trial efficacy.
- For the U.S.: Abandon international reference pricing proposals as they do not appropriately reflect the value of innovation and would undermine sustained research and development (R&D) investment in the next generation of therapies and vaccines.

**Enhance Clinical, Regulatory and Legal Systems**

- For both: Policy proposals should be based on a predictable and transparent public policy environment that allows stakeholders to meaningfully participate in the development of rules or regulations and favor efficient processes to bring new technologies to market such as expanded resources for cell and gene therapy regulatory reviews, and creation of cloud-based submission platforms.
- For both: Promote infrastructure development for virtual clinical trials, such as recruiting patients online and using virtual medical examinations if feasible.
- For Japan: Ensure the regulatory, pricing and reimbursement systems recognize innovation associated with the development of new indications for existing therapies.
- For Japan: Move toward an online registration process for new medical device licenses and license renewals.
- For Japan: Establish a regulatory data protection regime for new indications of existing therapies to incentivize research in areas of high unmet need.

**Increase the Efficiency and Effectiveness of Healthcare Expenditures**

- For both: Recognize that pharmaceuticals and medical device expenditures can help reduce long-term cost of care.
- For both: Pursue medical device and pharmaceutical pricing schemes that better align prices to value, including patient outcomes and convenience, as well as to the cost-offsets within the healthcare system and the wider society.
- For Japan: Innovative high-priced medicines should be covered by public insurance to ensure access to the latest medicines. In addition, in order to ensure the sustainability of the social security system, prioritize prescription drug benefits.
- For Japan: Optimize medical and nursing care costs by promoting the use of generic drugs and rationalizing drug use.
- For the U.S: Encourage the use of value-based agreements that more appropriately reimburse providers for advanced therapies like cell and gene therapy.

**Encourage Preventive Measures**

- 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 both: Support and encourage businesses' voluntary initiatives to promote health and productivity management in both countries.
- For Japan: Adopt pro-vaccination policies and give greater recognition to the societal value of innovation relating to prevention.
- For Japan: Promote innovation and policies for new screening methods from a preventive viewpoint, for example, to improve the rate of breast cancer screening.

**Promote Use of Digital Health**

- For both: Embrace and promote digital therapeutics and digitalization in healthcare to provide additional value for patients, healthcare providers, and the healthcare system. Create policies and a regulatory environment conducive to the monetization and reimbursement of digital solutions; accelerate the development and widespread adoption of digital therapeutics.
- For both: Launch public education campaigns to build understanding and trust in the utilization of health and medical information for research purposes.
- For both: Establish an environment for collecting and utilizing life course data including genomic information and develop a framework that enables sharing of this data with the private sector in a manner that protects privacy.
- For Japan: To promote individual-based health management and prevention, create an environment where individuals can access and utilize their own life course data through the development of personal health records of a private company.
- For Japan: Under the initiative of the government, develop and introduce conversion technology to ensure data compatibility and promote the standardization of medical data.
- For the U.S.: Prescription Drug User Fee Act (PDUFA) reauthorization preparations should explore how to incorporate the use of digital technologies in clinical trials for more efficacious monitoring of participants.
- For the U.S.: U.S. policy should promote interoperability and encourage greater utilization of consumer digital health products particularly in rural and underserved settings.