Appendix to the Joint Statement Supplement of the USJBC-JUBC Healthcare Innovation Working Group

for the 60th U.S.-Japan Business Conference:

Leveraging Digital Technologies to Improve Healthcare Outcomes:

A Call to Action and Framework for U.S.-Japan Collaboration

In September 2020, the U.S.-Japan Business Council ("USJBC") called on governments to embrace and facilitate digital advancements in healthcare to propel innovation, enable pandemic response, and support improved access to care for patients around the world. The USJBC identified nine policy recommendations to support this call to action. Since that time, Japan has taken some steps to improve digitalization, such as establishing the Digital Agency and launching the Digital Garden City Nation Initiative. But much more remains to be done to deliver on the promise of digital health in Japan, including implementing a comprehensive policy to enable digitalization of health records similar to the practice in the United States (e.g., 2009 HITECH Act; HIPAA). Today, the Japan-U.S. Business Council and U.S.-Japan Business Council (hereafter "the Councils"), whose member companies include the world's most innovative technology and healthcare companies, stand together to urge the United States and Japan to seize the opportunity of the upcoming senior leaders' meetings at Asia-Pacific Economic Cooperation ("APEC").   Under the auspices of the U.S.-Japan Partnership on Trade, we urge the two nations to endorse an ambitious work plan to drive the adoption of world-class standards to facilitate the advancement of digital innovation in healthcare.

Digital innovation presents an extraordinary opportunity for Japan to reconfigure its healthcare and regulatory frameworks to better support innovation and meet the evolving needs of its society, especially as its people age. Countless studies have shown the enormous financial burden that rising social security costs will impose on the government, combined with a shrinking workforce. Digital technologies can significantly lower costs, create innovative health products, enable personalized treatments, and raise capacity for healthcare, thus helping to lighten this burden and improve the quality of life for millions in Japan.

Such innovations will ultimately bring about better patient outcomes, as well as cost savings for patients, providers, and society. For these new technologies to be implemented successfully and responsibly, however, governments must grapple with emerging policy questions that require careful consideration. Governments will also need to assess the impact these technologies are having on improving health outcomes and reducing unnecessary costs.

Proposed Framework for U.S.-Japan Cooperation on Digital Health

Given the renewed focus in both countries on digitalization and creating more resilient health systems for the future, the Councils call on the United States and Japan to launch a bilateral work program focused on facilitating digital innovation through four pillars: (1) telemedicine and remote care; (2) digital therapeutics; (3) artificial intelligence and data enabled research and development, including healthcare data utilization; and (4) cross border data flows and privacy. This work should be conducted in close consultation with the private sector in Japan and the United States, including through workshops with relevant experts in each pillar. Policy changes adopted as a result of the work program should be undertaken in a predictable and transparent public policy environment that allows stakeholders to

meaningfully participate in the development of regulations and favors efficient processes to bring new technologies to market.

Pillar 1: Telemedicine and Remote Care. Telemedicine has the ability to provide long-term, irrevocable benefits and convenience for Japanese society beyond COVID-19. This mode of care delivery will not just help address the rising demands of a rapidly aging population but also serve as a beneficial medical service for patients during future public health crises. Telemedicine usage has increased dramatically in the United States and Japan. However, a high percentage of hospitals are not taking full advantage of this modality in part due to the lack of infrastructure and potential uncertainty in reimbursement arrangements about compensating for treatment provided virtually. [1,2] Furthermore, technological linkages among hospitals lack a mechanism to provide central control or oversight. In the United States, on the other hand, trust in telemedicine has grown and its use is widespread in the wake of COVID-19, due to the statutory and regulatory framework and foundation established by the HITECH Act and HIPAA.

Pillar 2: Digital Therapeutics ("DTx"). Digital therapeutics, a new category of digital medicine, have the potential to revolutionize healthcare by incorporating new technology and promoting the practice of personalized, evidence-based healthcare. DTx enable HCPs to provide individualized, simplified, and optimal care for patients. Countries with regulatory policies and reimbursement schemes that enable DTx will attract more investment, lead global biomedical innovation, and foster a healthier, more productive population. Japan has taken several steps to promote early commercialization of stand-alone medical software, or Software as a Medical Device ("SaMD"), yet at present the United States approves five times more SaMD products than Japan – including those medical devices that use artificial intelligence ("AI") and machine learning.[3] While the United States leads Japan on digital therapeutic approvals, it does not have a reimbursement mechanism to compensate for the offering of SaMD at this time. This is an issue which should be further reviewed to maximize the successes that DTx may provide in both countries,

Pillar 3: Data Utilization, AI, and Data Enabled Research & Development ("R&D"). Increased utilization of health data has the potential to substantially enhance patient care. By evaluating data, providers and innovators have the opportunity to not only discover new therapies, but also identify more effective opportunities to deliver care, and assess evidence to support the development and assessment of treatment outcomes. Research in healthcare AI has been growing rapidly, even before the COVID-19 pandemic outbreak. In its most recent policy framework, Japan has embraced "Medical Dx" as a pathway to enabling health data platform integration, which could accelerate utilization of real-world evidence and drug discovery. Yet launching real-world applications based on AI and real-world data ("RWD") has proven challenging. Regulators have been leery of granting approvals for these newly developed technologies due to concerns about generalizability and bias, while concerns about compliance with data protection laws have made it difficult to collect health data for training algorithms. Future discussion is needed in order to advance scientific research and improve access to innovative digitally enabled treatment. . It is increasingly critical to address these challenges and build the necessary trust with patients to support data-enabled R&D. Embracing data-driven solutions to healthcare challenges through evidence-based policy that supports data utilization will also help make Japan a more attractive destination for healthcare innovation.

Pillar 4: Cross-Border Data Flows and Privacy. The COVID-19 pandemic has demonstrated the importance of rapidly sharing information across borders as companies work with governments to quickly identify and investigate potential treatments and vaccines. At the same time, policies enacted in other nations that are intended to protect citizens' privacy may impede cross-border research, the effective deployment of technology, including AI tools, and the monitoring of health products. Some privacy regimes, for instance, unduly restrict the transfer of health and genetic information across borders, greatly limiting innovation and cooperation.

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1 See Eisaku Nitta and Yusuke Konishi, "Japan greenlights online doctor visits as outbreak hits hospitals," Nikkei Asian Review. https://asia.nikkei.com/Business/Health-Care/Japan-greenlights-online-doctor-visits-as-outbreak-hits-hospitals
2 2 "Survey results regarding telephone and online medical care," Japan's Ministry of Health, Labour and Welfare. https://www.mhlw.go.jp/content/10803000/000657038.pdf
3 Japan - Medical Devices (trade.gov)

Key Action Items for a Recommended U.S.-Japan Work Plan on Digital Health

1. **Reimbursement.** Review existing reimbursement methods with the potential of identifying new options for payment policies that could promote the alternative delivery of treatments including via digital therapeutics and telemedicine.
2. **Responsible AI.** Review policies on responsible AI for healthcare R&D and explore harmonizing definitions and frameworks for responsible AI.
3. **Data collection and interoperability.** Exchange best practices on responsible data collection, enhancing interoperability, and leveraging private sector technologies and capacity.
4. **Enhancing trust.** Develop recommendations for engagement with the public in the United States and Japan to promote trust and understanding about the value of collecting, storing, and using data to evaluate and/or create new medicines/technologies, and support pandemic detection and response.
5. **Paperless operations.** Develop best practices to promote paperless operations for healthcare, including:
   - removing the requirement to create/submit physical documents;
   - amending the regulations under the Electronic Signature Act to clarify the legal status of cloud-based digital signatures;
   - ending the use of hanko personal seals;
   - relaxing the scanner storage requirement specified by the Electronic Books Maintenance Act;
   - promoting digital government; and
   - moving toward a national certification system for administrative time stamps.