THE NATIONAL BUREAU *of* ASIAN RESEARCH

NBR SPECIAL REPORT #71 | MARCH 2018

INNOVATIVE ASIA

Innovation Policy and the Implications for Healthcare and the Life Sciences

By Sean Connell, Shuhei Nomura, Kenji Shibuya, and Benjamin Shobert

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INTRODUCTION

Asia is the world's most economically dynamic region. Economies in the region have experienced unprecedented growth in recent years, lifting millions of people out of poverty and promoting rising standards of living. The 21 countries in the Asia-Pacific Economic Cooperation (APEC) now represent almost 60% of global GDP, while per capita incomes have risen by more than 75% over the past three decades.[1] Such gains have been enabled by several factors, with APEC, the Asian Development Bank, the World Bank, and other organizations noting in particular these countries' vital contributions to reduce barriers to market access, streamline regulatory environments, and promote positive roles for trade and investment.

Yet by a number of measures, countries across Asia are struggling to make further gains. While historically this struggle has been framed as the challenge of moving from developing to developed economy status, even the region's most successful economies are facing existential questions on the way forward. Japan and South Korea, for example, have traditionally been highlighted as the central success stories of the "Asian economic miracle"—engaging the potential of innovation and free markets to advance goals for wealth creation while also maintaining a strong commitment to improving social welfare. Yet in recent years, both countries have experienced slowing economic growth rates, challenges in stimulating job creation, and tensions in how to maintain high-quality social systems as existing frameworks face rising demand for care and services. In turn, the Organisation for Economic Co-operation and Development (OECD) has recently argued that even these traditional leaders are showing signs of strain in advancing new development. This can be seen in the struggles of small and medium-sized enterprises, stagnant productivity in the service industry, and growing calls for localization initiatives, with clear impacts on efforts to advance sustainable development.

In this context, the extent to which a country invests in innovation can be a critical indicator of its ability to bolster economic growth as well as address emerging societal and public health challenges. In some ways, the opportunities and challenges facing the innovation environment in Asia are best exemplified by efforts to harness the potential of the healthcare and life science sector. The International Monetary Fund has noted that building on domestic strengths and competitive advantages in healthcare R&D could support economic growth. And indeed, both Japan and South Korea are well-positioned to take this leap. Japan's model for providing universal healthcare has long been used as a template for the World Health Organization in its efforts to strengthen global norms, while South Korea's rapid expansion of universal healthcare to its own citizens is also well worth examining. However, both countries have struggled with how to internationalize their domestic industry and, as noted above, have faced challenges in ensuring that efforts to do so do not lead to a decline in the quality of care. Achieving such goals will require dedicated leadership and commitment to addressing ongoing, systemic challenges.

With these issues in mind, the National Bureau of Asian Research (NBR) commenced the initiative "Innovative Asia," which explores how policymaking to promote innovation can achieve the twin aims of improved public health outcomes and robust economic growth. Over the course of six months, NBR conducted dozens of interviews with leading policymakers and experts in

[1] Asia-Pacific Economic Cooperation, "Achievements and Benefits," https://www.apec.org/About-Us/About-APEC/Achievements-and-Benefits.

Japan and South Korea and held two in-region workshops and study trips. The first workshop was convened in Seoul in October 2017 and the second in Tokyo in November 2017. The essays collected in this report present important findings from the initiative about the current environment for innovation in Asia and the implications for healthcare and the life sciences.

In the first essay, Sean Connell examines the context for innovation policy in Japan and South Korea. Drawing on seminal studies by the OECD and the Information Technology and Innovation Foundation, he offers a framework for assessing the health of a country's innovation ecosystem—that is, how well-positioned domestic stakeholders are to drive new breakthroughs and to subsequently bring these ideas to market. Such measures include the extent to which governments invest in basic and applied R&D, their valuation of intangible assets, and their views on the benefits of trade and international cooperation. In applying this framework to Japan and South Korea, Connell argues that both countries are rightly seen as highly innovative economies. Both have made sustained and long-term commitments to promoting high-quality education and skill training and to reducing barriers to market access in ways that allow them to take advantage of increasingly globalized supply chains. However, both countries also have struggled with encouraging domestic entrepreneurship. Connell identifies a number of decision points on the horizon for Japan and South Korea to improve their domestic environments for innovation, as well for the United States to engage with its allies in shaping a common vision for the region.

In the second essay, Benjamin Shobert explores the unique challenges for life science innovation in Asia. As noted by participants in the Tokyo and Seoul workshops, governments across the region have rightly identified that the healthcare and life science sector is uniquely positioned to advance several objectives at the top of many national policy agendas: fostering economic growth while also enabling their populations to enjoy longer, healthier lives. Yet crafting policy frameworks that support this vision is a fundamental challenge for many countries. Shobert examines how decision-making about healthcare and the life sciences is typically framed and executed at the national level and applies this template to the efforts undertaken by Japan, South Korea, and China. Although the tension between incentivizing innovation and controlling costs is not new, it need not be an "either-or" dilemma. Shobert offers recommendations in nine key areas that could equally be applied to Japan, South Korea, the United States, and other countries across the region.

In the final essay, Shuhei Nomura and Kenji Shibuya offer an application of these ideas for improving the innovation ecosystem in Asia to Japan's efforts to strengthen its public health outcomes. Japan has earned a well-deserved reputation for having a highly successful and innovative development model, and leveraging the potential of the healthcare sector has long been at the core of this success story. Nomura and Shibuya argue that as Japan enters an era of "superaging," caring for a rapidly graying population is likely to both strain existing systems and introduce new challenges in how to provide universal healthcare without sacrificing quality or affordability. Decision-makers have sought to address these challenges by transforming traditional care systems to more specifically target the needs of individuals and communities. Nomura and Shibuya conclude by discussing recommendations for promoting population health in Japan in a sustainable manner.

NBR's Innovative Asia initiative would not have been possible without the support, guidance, and intellectual contributions of a number of individuals whose efforts deserve special

acknowledgment. First and foremost, we are grateful to Charles W. Boustany Jr., a former U.S. congressman and the chair of NBR's Center for Innovation, Trade, and Strategy. We were honored to have Dr. Boustany lead our delegation to the region, and his keen insight and experienced leadership on Capitol Hill, at the nexus of both trade and healthcare policy, added immensely to the discussions.

We are also deeply appreciative of the efforts of several senior advisers and members of NBR's Board of Directors who provided significant guidance on our exploration of these topics. In particular, Ryo Kubota, Se Hyun Ahn, and Claire Topal brought to this effort innovative and creative thinking informed by their experience with real-world applications. We are thankful for their time and leadership.

We also owe a debt of gratitude to the many panelists, specialists, and other contributors who shared their expertise on the leading challenges and opportunities facing policymakers in Asia. NBR's own Ashley Johnson was instrumental to the initiative's success, working tirelessly with the authors of this report to ensure that the final product reflects the key findings and discussions from the workshops. We are also indebted to Julia Oh, Eunhwa Shin, Sara Itagaki, and Kunihiro Shimoji, whose outreach and work behind the scenes in Japan and South Korea ensured that the dialogues and workshops were a success. At the workshop in Tokyo, Kazumi Nishikawa of Japan's Ministry of Economy, Trade and Industry offered an invaluable perspective on how governments assess, shape, and execute priorities, and we are grateful for his guidance. Finally, we were honored to co-host the South Korea workshop with the University of Seoul, whose expertise and organizational support contributed immensely to both the content and the structure of the discussions.

Overall, the essays in this report show that while there are no easy answers, improving social welfare and establishing financially sustainable systems are not mutually exclusive. Well-designed policies and forward-leaning leadership in key sectors such as healthcare and the life sciences can not only enable countries to achieve these twin goals but contribute to broader economic and strategic policy aims.

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Exploring the Context for Innovation Policy in Japan and South Korea

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NOTE: The views expressed in this essay are those of the author and do not necessarily reflect the policy or positions of any organization with which he is affiliated.

EXECUTIVE SUMMARY

This essay explores Japan's and South Korea's national innovation systems, considers potential implications for the two countries' economic policy agendas, and examines related areas for engagement with the U.S. that could enhance national and global environments for innovation.

MAIN ARGUMENT

Innovation is critical for future economic growth and job creation in Japan and South Korea. The two countries are global leaders in innovations integral to established and emerging high-tech industries. However, characteristics of their national innovation systems may be factors contributing to recent strains on their economic growth. Addressing these challenges and fostering the most conducive domestic environment for innovation requires progress on a broad set of structural reforms that have long been on the policy agenda in both Japan and South Korea. In addition, because innovation policies increasingly have global impacts as economic integration across national borders accelerates, both countries should prioritize cooperation with the U.S. in advancing trade and other policy frameworks that facilitate innovation.

POLICY RECOMMENDATIONS

- Continued progress by Japan and South Korea in advancing long-term, comprehensive structural and regulatory reforms that will enhance their domestic environments for innovation should remain an economic policy priority.
- Both countries should fully implement trade agreements to reap the benefits of provisions that will foster domestic and global environments for innovation, including strong intellectual property protections and elimination of non-tariff market barriers.
- Japan and South Korea should build on recent bilateral dialogues and frameworks with the U.S. focused around innovation-driven industry sectors to address global challenges and explore new opportunities for engagement. As part of this effort, they should explore potential approaches to increase engagement among subnational actors, including local governments, businesses, universities, and others with a role in shaping innovation ecosystems.

One of the most pressing economic challenges, as well as the greatest opportunities, that countries face is how to most effectively foster innovation that will drive future growth and prosperity. The Organisation for Economic Co-operation and Development (OECD) defines innovation as the "implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations."[1] Innovation is a dynamic and interactive process that incorporates a complex range of interconnected elements, levels of society, and public-sector, private-sector, and nongovernmental organizations and entrepreneurs.[2]

In domestic and global environments of increasing economic and societal complexity, how do countries design, develop, and implement innovation policies that will facilitate economic growth and competitiveness? The concept of a national innovation system, as described by the OECD, emphasizes the importance of flows of technology and information between people, enterprises, universities, government research institutions, and other related actors. From the vantage point of policymakers, understanding the elements of a national innovation system can help foster the development of policies that enhance networking among these actors, identify and address mismatches between institutions and policies, and support the improvement of firms' innovative capacity.[3]

In this context, scholars and policymakers increasingly recognize that one of the most important roles governments can play is to coordinate among all stakeholders, elements, and policies to shape a conducive framework in which innovations can emerge from all sources.[4] The broader set of elements and policy tools needed to develop such an environment includes science and technology R&D; education; physical, regulatory, and legal infrastructure; and trade and investment, including FDI.[5] Also important are intangible assets or knowledge-based capital, which can include intellectual property (IP), standards, organizational management, workforce training, marketing, design, brand equity, firm-specific human capital, labor mobility, networks, and tacit knowledge.

Moreover, government actions on innovation increasingly have spillover effects across national borders. Not only are policies considered successful in one country often replicated by others, but greater economic integration and the accelerating globalization of supply chains mean that policies implemented in one country can have economic consequences in others. In a 2016 assessment, the Information Technology and Innovation Foundation identified a number of positive spillover effects conducive to global innovation, including investment in basic scientific R&D; measures to facilitate technology transfers out of universities and national laboratories for commercialization by the private sector; effective education initiatives in science, technology, engineering, and mathematics; promotion of information and communications technology (ICT) deployment and

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[1] Organisation for Economic Co-operation and Development (OECD), "Ministerial Report on the OECD Innovation Strategy: Innovation to Strengthen Growth and Address Global and Social Challenges—Key Findings," May 2010, 1, https://www.oecd.org/sti/45326349.pdf.

[2] Ruud E. Smits, Stefan Kuhlman, and Morris Teubal, "A System-Evolutionary Approach for Innovation Policy," in *The Theory and Practice of Innovation Policy: An International Research Handbook*, ed. Ruud E. Smits, Stefan Kuhlmann, and Philip Shapira (Northampton: Edward Elgar, 2011), 417, 429–30.

[3] OECD, "National Innovation Systems," 1997, 7–10, http://www.oecd.org/science/inno/2101733.pdf.

[4] One example is the Obama administration's S*trategy for American Innovation*, which explicitly identified the role of government as an "innovation facilitator." U.S. National Economic Council, Council of Economic Advisers, and Office of Science and Technology Policy, *A Strategy for American Innovation: Securing Our Economic Growth and Prosperity* (Washington, D.C., February 2011), 2–6, 10, https://obamawhitehouse.archives.gov/sites/default/files/uploads/InnovationStrategy.pdf.

[5] Robert D. Atkinson, Stephen J. Ezell, and Luke A. Stewart, "The Global Innovation Policy Index," Information Technology and Innovation Foundation and Ewing Marion Kauffman Foundation, March 2012, 9–18.

adaptation; and tax policies that spur investment in R&D and create a promising environment for entrepreneurs. The study also identified those policies that can harm global innovation, including forced IP and technology transfer as a condition for market access, unfair subsidies, and currency and standards manipulation, among others.[6]

For many countries, this debate is more than just abstract; it is a critical element of their path forward. Japan and South Korea have been global models for economic growth, and a large portion of their success has been attributed to gains from innovation. Despite their status as highly innovative economies, both countries are also examples that policy environments must continually evolve in order to maintain successful ecosystems for innovation. Stories abound of how iconic Japanese companies once ahead of the technological curve were unable to find an international market, or develop new products due to internal company decisions, and lost out to competitors. Similarly, South Korean manufacturers that have nearly perfected the process of making incremental innovations—small, continuous improvements that enhance quality and reduce costs—to a vast range of products in which they are global leaders have not made the leap to introducing world-changing technologies. These struggles have drawn much attention, and how both countries adapt to the challenges they face will have a resounding impact on global innovation and economic growth.

Building on this analysis of the elements of a successful environment for innovation, the first section of this essay discusses these components in the context of Japan and South Korea. The next section then considers the implications for both countries' economic policy agendas and identifies opportunities for international engagement. The essay concludes by highlighting areas for Japan and South Korea to build on previous successes and enhance national and global environments for innovation.

Elements of a Successful Innovation Environment: A Case Study of Japan and South Korea

The remarkable and transformative economic rise of both Japan and South Korea has been powered by their dominance in innovation. Together with the United States, they lead in the generation of patents and capabilities across cutting-edge technologies considered core to emerging industries that are expected to become future growth engines. At the same time, strains have been showing in their economic systems. Japan has yet to entirely emerge from its two "lost decades" of stagnant economic growth, despite Prime Minister Shinzo Abe's aggressive agenda of fiscal stimulus, monetary easing, and structural reforms (known as Abenomics). South Korea, for its part, has seen its growth slow to the level of more mature economies before the country has reached the same income level and realized its full potential for innovation.

Despite these challenges, Japan and South Korea remain global leaders in many indicators closely associated with innovation. Successful environments for innovation have several common elements, as identified above, which will continue to play a major role in the development of innovative ecosystems in both economies. The following assessment examines OECD and other

[6] Stephen J. Ezell, Adams B. Nager, and Robert D. Atkinson, "Contributors and Detractors: Ranking Countries' Impact on Global Innovation," Information Technology and Innovation Foundation, January 2016, 10–13, 83–85.

indicators related to investment in basic and applied R&D, education and training, regulatory infrastructure and business environment, intangible assets, and trade and innovation.[7]

Investment in Basic and Applied R&D

R&D is a primary generator of innovation. Basic research refers to early-stage research conducted to explore hypotheses, without particular practical applications in mind, that generates scientific knowledge and breakthroughs supporting innovation. Given its high-risk nature, such research tends to be conducted primarily by the public sector rather than the private sector. Applied research builds on the findings of basic research to identify and develop technologies and practices that could have practical and commercial applications.[8] Although R&D is just one of many inputs contributing to innovation, studies have identified a correlation between investment in R&D and product and process innovations across a broad range of industries. Businesses that conduct R&D have a far greater likelihood of generating innovations than those that do not.[9]

Japan and South Korea are both at the forefront of emerging and disruptive technologies driving the creation of innovative new industries and business models (see **Figures 1** and **2**). Japan is a leading actor across a set of twenty "bursting" technologies tracked by the OECD, including greenhouse gas emissions mitigation, electric propulsion for hybrid vehicles, and stereoscopic television systems. South Korea is a key actor in eleven of these categories, including technologies relating to the human interface for digital data transfer (a set of technologies that underpin the "internet of things"), manufacture of batteries, sensitive semiconductor devices, and multiplex communication systems and mobile application services.[10]

Japan and South Korea also figure prominently in patent family shares of "disruptive technologies" that displace established technologies and lead to market entry of new firms. These include advanced materials, new generations of ICT-related technologies such as the internet of things and telecommunications innovations, and health-related technologies. Japan led OECD members in patent families for advanced materials and is second only to the United States and European Union in health-related technologies. South Korea is in the top four with Japan, the United States, and the EU in each of these categories.[11] Japan and South Korea also generate a large

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[7] As an additional reference to the indicators examined below, for charts benchmarking the comparative performance of selected elements of South Korea's and Japan's national science and innovation systems to the OECD mean, see OECD, "Korea," in *OECD Science, Technology and Innovation Outlook 2016* (Paris: OECD Publishing, 2016), 5, http://www.oecd-ilibrary.org/science-and-technology/oecd-science-technology-and-innovation-outlook-2016/korea_sti_in_outlook-2016-71-en; and OECD, "Japan," in *OECD Science, Technology and Innovation Outlook 2016*, 5, http://www.oecd-ilibrary.org/science-and-technology/oecd-science-technology-and-innovation-outlook-2016/japan_sti_in_outlook-2016-70-en.

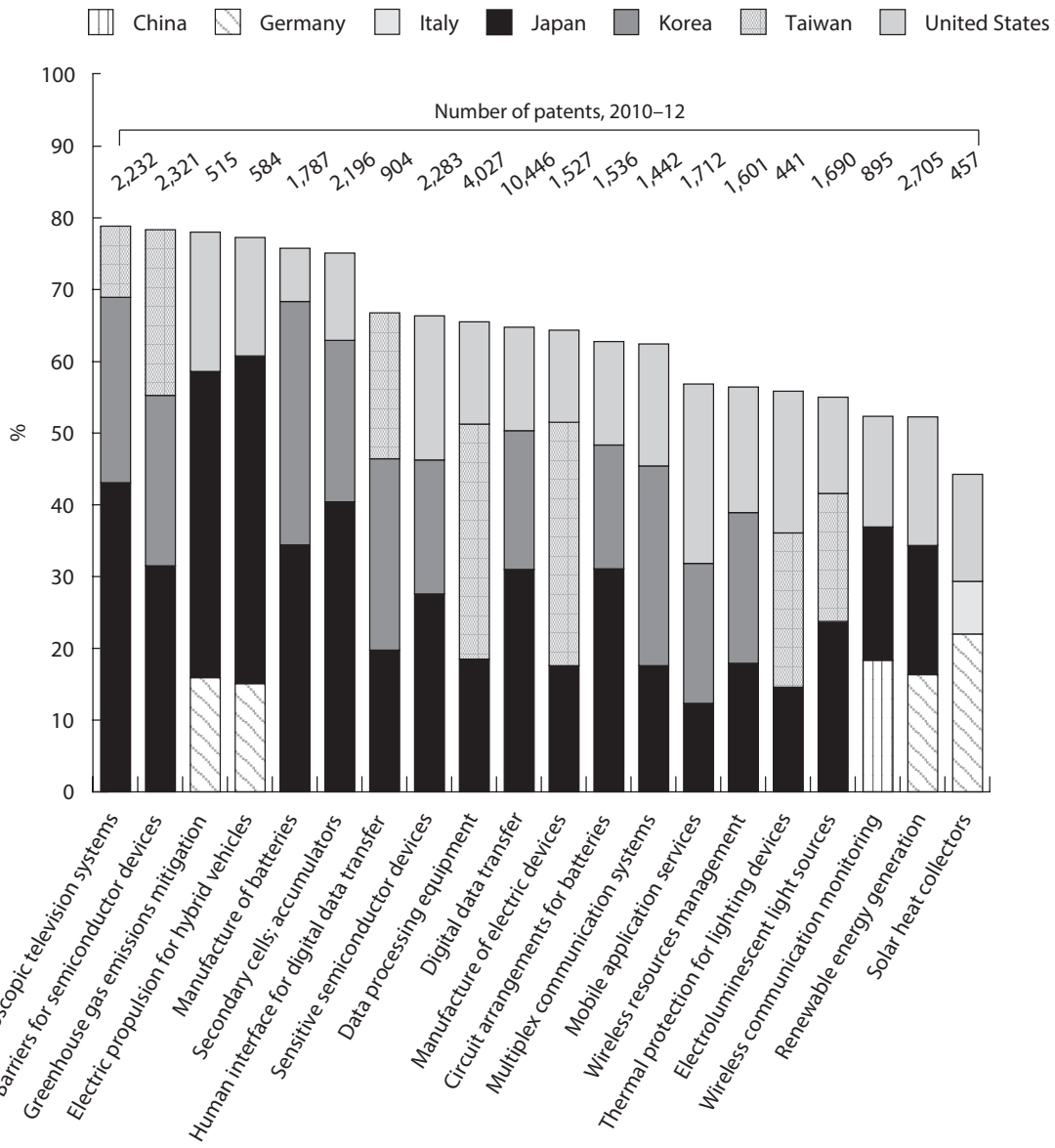
[8] Vannevar Bush's classic report *Science: The Endless Frontier* includes the following description of the importance of basic research: "Basic research is performed without thought of practical ends. It results in general knowledge and an understanding of nature and its laws. This general knowledge provides the means of answering a large number of important practical problems, though it may not give a complete specific answer to any one of them. The function of applied research is to provide such complete answers. The scientist doing basic research may not be at all interested in the practical applications of his work, yet the further progress of industrial development would eventually stagnate if basic scientific research were long neglected." Vannevar Bush, *Science: The Endless Frontier* (Washington, D.C.: U.S. Printing Office, 1945), available at https://nsf.gov/od/lpa/nsf50/vbush1945.htm#ch3.3.

[9] See, for example, National Science Board, "Research and Development, Innovation, and the Science and Engineering Workforce," National Science Foundation, 2012, 2–5, https://www.nsf.gov/nsb/publications/2012/nsb1203.pdf.

[10] OECD, *OECD* Science, *Technology and Industry Scoreboard 2015: Innovation for Growth and Society* (Paris: OECD Publishing, 2015), 76, http://www.oecd-ilibrary.org/docserver/download/9215031e.pdf. See also OECD, "OECD Science, Technology and Industry Scoreboard 2015: Korea Highlights," 2015, 4, http://www.oecd.org/sti/Korea-CN-EN-Scoreboard.pdf.

[11] Ibid., 78.

FIGURE 1 Top players in emerging technologies, 2010–12



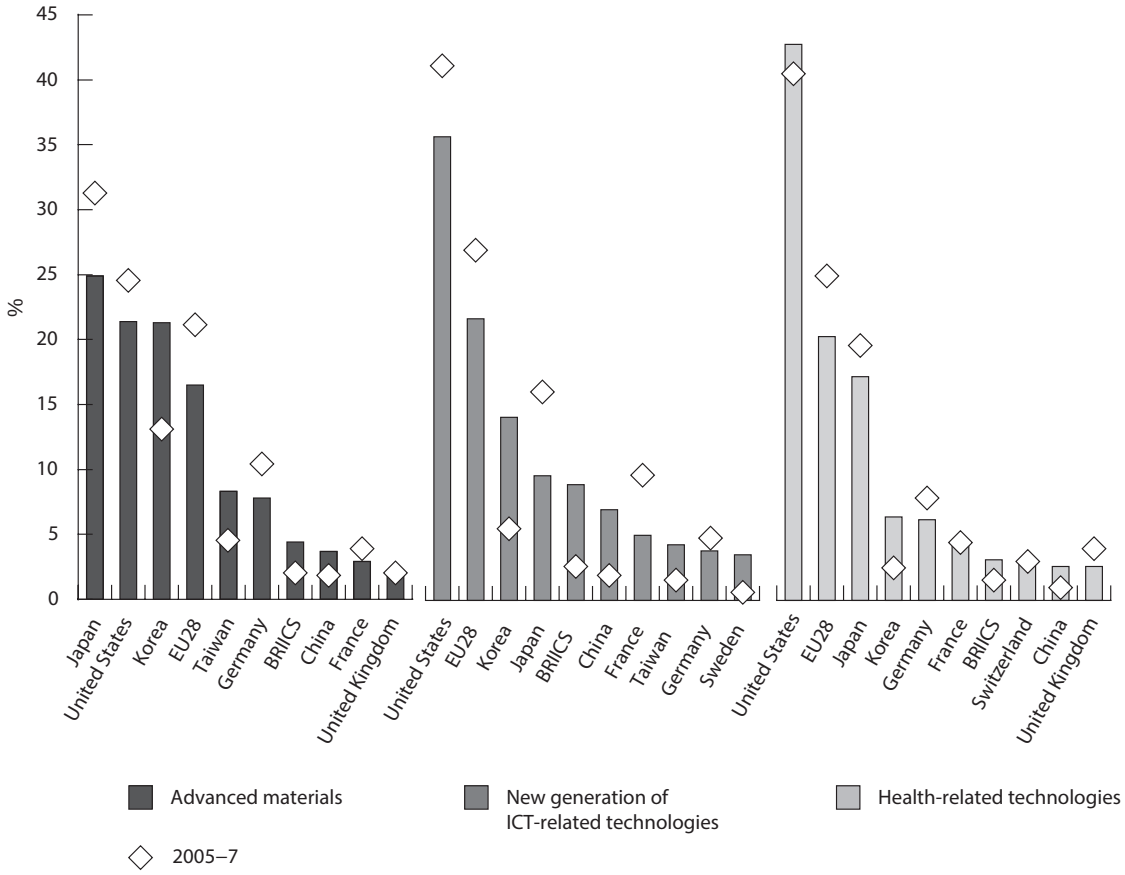
SOURCE: OECD, *OECD Science, Technology and Industry Scoreboard 2015*, http://dx.doi.org/10.1787/888933273458.

percentage of the world's innovations for ICT, health technology, biotechnology, nanotechnology, and climate change mitigation.[12]

Driving these breakthroughs are significant investments in R&D. According to the OECD, South Korea, together with Israel, ranked as the world's most R&D-intensive country in 2015,

[12] Ibid., 230–33.

FIGURE 2 Top players in selected disruptive technologies, 2005–7 and 2010–12



SOURCE: OECD, *OECD Science, Technology and Industry Scoreboard 2015*, http://dx.doi.org/10.1787/888933273474.

with gross domestic expenditure on R&D at 4.2% of GDP.[13] Its public financing of R&D was also comparatively high, at 1.0% in 2014; government investment in basic research increased to 36% of total government R&D investment in 2015.[14] Japan is the world's third most R&D-intensive country, with 3.3% of GDP dedicated to R&D in 2015.[15] It has one of the highest levels of private-sector R&D in the world and is the second-highest source of triadic patents, which are considered a key indicator of innovation capability.[16] Japan's public-sector R&D, at 0.8% of GDP in 2014, is closer to the median among OECD member economies. Applied research accounted

[13] OECD, *OECD Science, Technology and Industry Scoreboard 2017: The Digital Transformation* (Paris: OECD Publishing, 2017), 26, http://dx.doi.org/10.1787/9789264268821-en. See specifically Figure 1.14, http://dx.doi.org/10.1787/888933617111. In 2014, South Korea ranked first, followed by Israel. In 2015, Israel slightly surpassed South Korea.

[14] OECD, "Korea," 1–2. See also OECD, *OECD Science, Technology and Industry Scoreboard 2015*, 60.

[15] OECD, *OECD Science, Technology and Industry Scoreboard 2017*, 26. See specifically Figure 1.14.

[16] Triadic patents are patents that have been recognized in the United States, the EU, and Japan. Because these are generally considered to be of higher quality than inventions patented in just one of these countries, they are used by the OECD and others as an indicator of innovation.

for approximately 70% of Japan's public R&D expenditures in 2014, with the other 30% directed toward basic research.[17]

Japan and South Korea exhibit similar patterns of private-sector R&D, which is concentrated in large domestic manufacturers that conduct mostly applied R&D and commercialization activities in-house. In South Korea, the majority of these companies belong to high-tech industries, whereas in Japan they typically belong to non-resource and medium-technology manufacturing industries. Yet both countries have become primarily service-sector economies, in which small and medium-sized enterprises (SMEs) constitute the vast majority of businesses but lack the same levels of productivity as their large manufacturer counterparts. Japan and South Korea are far below the OECD average for R&D conducted both by SMEs and in the service sector (see **Figures 3** and **4**). In Japan, the share of SMEs engaged in R&D was just under 6% in 2013, while in South Korea the share was 25%.[18] R&D in service industries, as a percentage of business enterprise expenditures on R&D, totaled 12.1% in Japan and 8.1% in South Korea in 2015. The percentage of this R&D in scientific services was 6.0% and 0.7%, respectively.[19]

Collaboration between industry and universities in R&D, as well as at the international level, facilitates innovation by increasing access to new knowledge and resources and by transferring innovations and technologies out of the lab and into the private sector.[20] However, collaboration between universities, research institutions, and the private sector in Japan and South Korea is limited.

In South Korea, only 5.8% of large businesses and 6.8% of SMEs collaborated on innovation with universities or research institutions, as a percentage of product and process innovation businesses in each category, during 2012–14. In Japan, these percentages were 23.6% and 12.9%, respectively.[21] Moreover, 98% of R&D financed by South Korean enterprises in 2014 was conducted in the business sector, and only 5% of company patents cite university-developed technology, compared with 9% in the United States.[22] In Japan, 99% of business-financed R&D in 2013 was carried out within businesses.[23] Greater engagement by universities and research institutions with the private sector—particularly the service sector and SMEs, which in both countries lag significantly behind large manufacturing firms in total factor productivity, as discussed above—could be beneficial to promote wider use and dissemination of public R&D.[24]

Education and Training

Education is a fundamental building block of innovation, fostering the human capital and ideas from which new innovations arise and a workforce equipped with the knowledge and capabilities

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17 OECD, "Japan," 1–2.

18 OECD, *OECD Economic Surveys: Japan 2017* (Paris: OECD Publishing, 2017), 44, http://www.oecd-ilibrary.org/economics/oecd-economic-surveys-japan_1999012x; Randall S. Jones and Jae Wan Lee, "Raising Korea's Productivity through Innovation and Structural Reform," *OECD Economic Department Working Papers*, no. 1324 (2016): 26, http://www.oecd-ilibrary.org/docserver/download/5jlr3tl19gkd-en.pdf; and OECD, "OECD Economic Surveys: Korea—Overview," May 2016, 29–34, http://www.oecd.org/eco/surveys/Korea-2016-OECD-economic-survey-overview.pdf.

19 OECD, *OECD Science, Technology and Industry Scoreboard 2017*, 171.

20 OECD, *OECD Economic Surveys: Japan 2017*, 40.

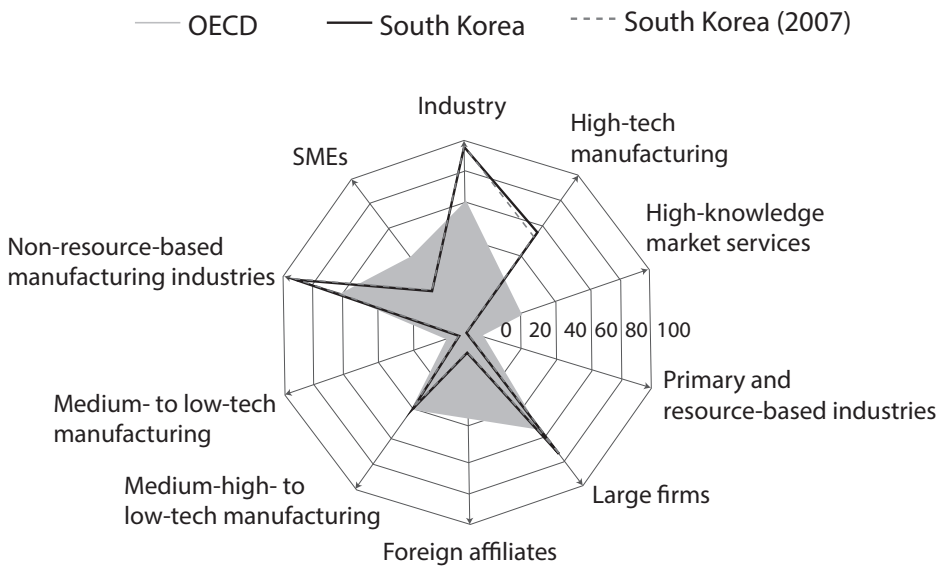
21 OECD, *OECD Science, Technology and Industry Scoreboard 2017*, 135.

22 Jones and Lee, "Raising Korea's Productivity," 29.

23 OECD, *OECD Economic Surveys: Japan 2017*, 44.

24 Jones and Lee, "Raising Korea's Productivity," 29.

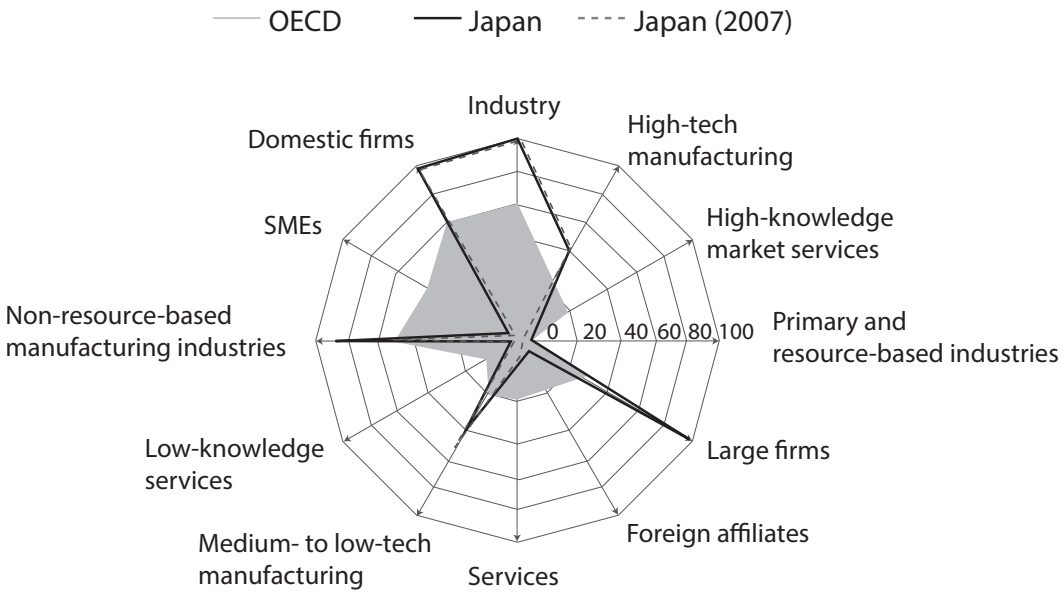
FIGURE 3 Structural composition of BERD in South Korea (as a % of total BERD or sub-parts of BERD), 2013



SOURCE: OECD, *OECD Science, Technology and Innovation Outlook 2016*, http://dx.doi.org/10.1787/888933433915.

NOTE: BERD refers to business enterprise expenditure on R&D.

FIGURE 4 Structural composition of BERD in Japan (as a % of total BERD or sub-parts of BERD), 2013



SOURCE: OECD, *OECD Science, Technology and Innovation Outlook 2016*, http://dx.doi.org/10.1787/888933433901.

NOTE: BERD refers to business enterprise expenditure on R&D.

to bring these ideas from concept into reality. In particular, universities are an important source of both basic and applied R&D that supports innovation.

Japan and South Korea rank consistently high on international assessments of education and skill sets considered essential for fostering innovation, particularly related to science and technology. Both countries rank far above the OECD average for the percentage of their adult populations at a tertiary education level, as well as in student performance on science assessments. In 2015, Japanese students were second only to their peers in Singapore in the OECD's Programme for International Student Assessment (PISA), a leading international indicator of student knowledge and skills.[25] South Korean students closely tracked their Japanese counterparts in these indicators.[26]

At the same time, aspects of the educational environments in Japan and South Korea reflect challenges for their innovation ecosystems. Both countries have tried to put greater emphasis on creative thinking and problem-solving in their educational curriculum, which has tended to prioritize rote memorization, driven in part by hypercompetitive university admission tests.[27] Notably, the percentage of top adult performers in technology problem-solving in South Korea ranked below the OECD average, while in Japan this percentage was only slightly above the OECD mean. Also important for fostering innovation is encouraging young people to consider careers in science, technology, engineering, and mathematics. In the 2015 PISA, Japan ranked below the OECD average in the number of respondents who expected to pursue careers in science (19% of boys and 18% of girls in Japan, compared with the OECD average of 25% and 24%, respectively). Japan also has one of the largest gender gaps in the enjoyment of learning science and the belief that science would be useful for a future career, with boys ranking higher than girls in both categories.[28]

In other respects, educational gaps can have significant impacts on productivity and the environment for innovation. For example, South Korea demonstrated the largest difference in the OECD between younger and older adults in terms of graduation rate and skill level, which holds back productivity in areas where a large share of older workers are employed, such as the service sector and SMEs.[29] In Japan, a considerable imbalance between skills proficiency and job descriptions—especially among women, who dominate non-regular employment in the country—is seen as a significant drag on productivity and growth.[30]

Universities play an important role in innovation ecosystems, yet the number of Japanese and South Korean universities ranked within the top 500 global institutions is comparatively low.[31] Both Japan and South Korea also lag their global peers in the number of publications in top academic journals, the international mobility of researchers, and levels of international cooperation (as measured by the percentage of articles published with international co-authors

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25 OECD, "Country Note: Japan," Programme for International Student Assessment (PISA), 2015, http://www.oecd.org/pisa/pisa-2015-Japan.pdf. The PISA 2015 focused on science, with reading, mathematics, and collaborative problem-solving as minor areas measured.

26 OECD, "Country Overview: Korea," PISA, http://www.compareyourcountry.org/pisa/country/KOR.

27 See, for example, OECD, "Policies for a Revitalisation of Japan," April 2012, 12, http://www.oecd.org/dataoecd/32/2/50190618.pdf; Linsu Kim, *Imitation to Innovation: The Dynamics of Korea's Technological Learning* (Cambridge: Harvard Business Press, 1997), 64; and Linsu Kim, "Crisis, Reform, and National Innovation in South Korea," in *Crisis and Innovation in Asian Technology*, ed. William W. Keller and Richard J. Samuels (Cambridge: Cambridge University Press, 2003), 102.

28 OECD, "Country Note: Japan."

29 Jones and Lee, "Raising Korea's Productivity," 30.

30 Randall Jones and Yosuke Jin, "Boosting Productivity for Inclusive Growth in Japan," *OECD Economic Department Working Papers*, no. 1414 (2017): 40, http://www.oecd-ilibrary.org/economics/boosting-productivity-for-inclusive-growth-in-japan_0748e0bc-en.

31 Ezell et al., "Contributors and Detractors," 41–42.

and patents filed with co-inventors).[32] Universities employ approximately 75% of PhDs in South Korea but only performed 9% of its R&D in 2014 and only 20% of basic research, compared with the average of 50%–75% in other OECD countries.[33]

Regulatory Infrastructure and Business Environment

The physical, legal, and regulatory environment of an economy shapes the framework for innovation.[34] Entrepreneurs can serve as a bellwether for the overall business environment, including how conducive it is for innovation, and thus merit particular attention for the role they can play in introducing new products, services, business models, and ideas. The Ewing Marion Kauffman Foundation, citing U.S. government data, estimates that entrepreneurial companies generated nearly all net job creation in the United States between 1980 and 2005.[35] Similarly, research by Kyoji Fukao and Kwon Hyeog-ug found that virtually all new jobs created in Japan between 1996 and 2006 were by new companies and foreign-invested businesses rather than established companies.[36]

Japan and South Korea are today largely perceived as challenging places for entrepreneurs to launch successful businesses. Administrative burdens, regulatory complexity, and protection of incumbent firms all create barriers to entrepreneurship.[37] Risk aversion and cultural attitudes are also often cited as significant impediments to entrepreneurship in Japan and South Korea in part due to strict bankruptcy laws and the stigma of failure. People in these countries speak of considerable family and societal pressures on young people to pursue traditional, stable careers in government or with large companies rather than work for small businesses or launch their own companies. Many of these pressures are enhanced in both countries by rapidly aging populations and low fertility rates.

These cultural aspects are substantiated in part by findings of the Global Entrepreneurship Monitor, which conducts the world's largest annual survey on entrepreneurship. In the most recent survey covering Japan, 31% of Japanese respondents viewed entrepreneurship as a good career choice, and 56% believed that entrepreneurs in their country received a high social status. These numbers were relatively consistent between the 2012 and 2014 surveys.[38] In South Korea, 45% of respondents in the 2016–17 survey viewed entrepreneurship as a good career choice, and 60% believed that entrepreneurs in their country received a high social status, down from 59% and 70% respectively in 2012.

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32 OECD, "Japan," 2, 5; and OECD, "Korea," 2, 5.

33 Jones and Lee, "Raising Korea's Productivity," 27.

34 This incorporates everything from access to fiber and broadband, physical infrastructure, and regulations affecting the ease of doing business to bankruptcy laws and access to finance and venture capital, among many other factors. Tax policies, such as credits and incentives, play an important role in encouraging businesses to invest in new R&D, while lower corporate tax rates can reduce burdens on businesses and enable them to increase investment in capital goods and R&D. See Ezell et al., "Contributors and Detractors," 29–37.

35 "Kauffman Foundation–Funded U.S. Census Bureau Data Highlight Importance of Business Startups to Job Creation in the U.S.," Ewing Marion Kauffman Foundation, January 14, 2009.

36 American Chamber of Commerce in Japan, "Charting a New Course for Growth: Recommendations for Japan's Leaders," 2010, 10–22, http://www.accj.or.jp/uploads/4/9/3/4/49349571/accj_charting_a_new_course_for_growth.pdf.

37 OECD, *OECD Science, Technology and Industry Scoreboard 2015*, chap. 4. Noteworthy, however, is the reduction of these barriers in South Korea during the previous decade, which will be explored later in this essay.

38 The most recent survey of Japan is found in Slavica Singer, José Ernesto Amorós, and Daniel Moska Arreola, *Global Entrepreneurship Monitor 2014 Global Report* (London: Global Entrepreneurship Research Association, 2015), 29–58. The most recent surveys of South Korea and the United States are found in Global Entrepreneurship Research Association, *Global Entrepreneurship Monitor 2016/17 Global Report* (London: Global Entrepreneurship Research Association, 2017), 105–34. Survey responses from 2012 are from Siri Roland Xavier et al., *Global Entrepreneurship Monitor 2012 Global Report* (London: Global Entrepreneurship Research Association, 2013), 20.

In Japan, 7% of respondents in 2014 perceived opportunities to start a business where they live (up slightly from 6% in 2012), while 9% felt that they had the necessary skills and knowledge to start a business (down from 12% in 2012). In contrast, 35% of South Korean respondents in 2016–17 perceived opportunities to start a business where they live (compared with only 13% in 2012), and 45% felt that they had the necessary skills and knowledge (compared with 27% in 2012). Respondents in Japan indicated a higher fear of failure (54%) than those in South Korea, where this percentage fell from 43% in 2012 to 31% in the 2016–17 survey, a level even below that of U.S. respondents.

The fact that South Korean views toward entrepreneurial opportunities and capabilities are dramatically more positive than views in Japan is noteworthy. This comparatively positive outlook may reflect the significant efforts in recent years by the South Korean government to promote entrepreneurship, including under the Creative Economy initiative launched in 2013. This initiative aimed to advance economic growth and job creation driven by science, technology, and the ICT sector and focused on fostering startups and promoting venture businesses. At the same time, the survey data also indicates a more negative outlook on economic opportunities for entrepreneurs during a prolonged period of slowing economic growth in South Korea.

Access to financing has been a significant barrier to entrepreneurs and startups in both countries, where venture capital and angel investment remain limited. In Japan, venture capital tends to flow to more mature firms, in part reflecting limited merger and acquisition activity as an exit strategy for companies.[39] Indicators, however, show some positive trends over previous years in both countries. Venture capital in South Korea has been rising during the past decade, and angel investment nearly doubled between 2010 and 2014, in part reflecting more favorable tax policies. Increasing access to financing, including venture capital, angel investment, and crowdfunding, was a primary focus of the Creative Economy initiative. Related actions taken included the launch of a new stock exchange, the Korea New Exchange (KONEX), which aims to promote initial public offerings by SMEs through less strict listing rules and the easing of regulations on investors. The government thereby hopes to activate the market for mergers and acquisitions and increase access to loans for failed entrepreneurs.[40] At the same time, the effects of government funding and loans to SMEs are seen as detrimental, including by keeping nonviable firms alive. This can limit investment and employment in viable firms and innovative new entrants, while reducing incentives for SMEs dependent on such support to grow.[41]

Intangible Assets

Intangible assets refer to knowledge-based capital or intellectual assets. Investment in such assets offers one possible perspective on why Japan and South Korea, despite their strengths and assets, have faced challenges in introducing breakout technologies and business models. Intangible assets, as defined by the OECD, include, but are not limited to, computerized information such as software and databases; innovative property such as R&D, copyrights, designs, and trademarks; and competencies such as brand equity, marketing, firm-specific human capital, organizational

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39 Jones and Jin, "Boosting Productivity for Inclusive Growth in Japan," 21; and Jones and Lee, "Raising Korea's Productivity," 40–44.

40 OECD, "OECD Economic Surveys: Korea—Overview," 39–40.

41 Jones and Jin, "Boosting Productivity for Inclusive Growth in Japan," 11–12, 32–35. See also Robert D. Atkinson, "The Real Korean Innovation Challenge: Services and Small Businesses," *Korea's Economy* 30 (2015): 48, http://www.keia.org/sites/default/files/publications/kei_koreaseconomy_atkinson_0.pdf; and Randall Jones, "Spurring the Development of Venture Capital in Korea," *Korea's Economy* 30 (2015): 56, http://www.keia.org/sites/default/files/publications/kei_koreaseconomy_jones_0.pdf.

know-how, and networks connecting people and institutions. The OECD observes that investment in intangible assets in many member economies has matched or exceeded investment in traditional capital, including machinery and infrastructure, with significant impacts on productivity.[42] Intangible assets also incorporate several important elements of innovation ecosystems.

In Japan, the productivity gap between the manufacturing and service sectors has widened considerably, as has the gap between leading and lagging firms in both sectors.[43] Research on Japan's service sector identified significant underinvestment in intangible assets as a major source of lagging productivity. Investment in assets such as brand equity, firm-specific human capital, and organizational structure has also been significantly lower than in other advanced economies.[44]

Deployment of ICT has an important relationship with knowledge-based capital in promoting innovation and productivity. Both Japan and South Korea are leaders in revealed technology advantages for ICT patents, according to an OECD index that scores a country's competitive advantage in a field based on patent applications.[45] South Korea's ICT patent score was more than double that of the 28 EU countries in 2016.[46] At the same time, South Korea lags far behind other countries in its use and application of ICT.[47] In Japan, the growth of productivity in ICT-using sectors declined substantially after 1995, whereas in the United States productivity growth accelerated in both ICT-producing and -using sectors. The share of Japanese enterprises with a broadband connection was the second-lowest in the OECD in 2014.[48] Because investment in ICT can support innovation in production processes, this could represent one factor in the stagnation of productivity in Japan.

Additionally, underinvestment in ICT may reflect Japanese firms' reluctance to invest in technological solutions that could reduce labor.[49] In a comparison of labor productivity in information industries across 28 OECD member economies, Japan had one of the highest levels in 2001 but by 2013 had fallen to a level below the OECD average.[50] Closely linked with many structural challenges described above is Japan's labor market, including the lack of labor mobility and the widening gap between regular and non-regular workers in terms of wage levels, job training opportunities, and security.[51] South Korea's labor market shares many of the same structural issues.

Trade and Innovation

The movement and exchange of new products, services, business models, and ideas across borders and the rise in market competition and consumer demand are crucial components of trade and investment that encourage innovation. Many policies that have detrimental impacts on

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42 For a more detailed description of intangible assets, see OECD, "New Sources of Growth: Intangible Assets," 2011, 1, http://www.oecd.org/sti/inno/46349020.pdf.

43 OECD, *OECD Economic Surveys: Japan 2017*, 12, 35–37.

44 Kyoji Fukao, "Service Sector Productivity in Japan: The Key to Future Economic Growth," Research Institute of Economy, Trade and Industry, Policy Discussion Paper Series, August 2010, 9-11, http://www.rieti.go.jp/jp/publications/pdp/10p007.pdf.

45 The OECD's revealed technology advantages index indicates the relative specialization of a given country in selected technological domains and based on patent applications.

46 OECD, "Japan," 8; and OECD, "Korea," 8.

47 Atkinson, "The Real Korean Innovation Challenge," 48–50.

48 Jones and Jin, "Boosting Productivity for Inclusive Growth in Japan," 11.

49 Ibid., 41.

50 OECD, *OECD Science, Technology and Industry Scoreboard 2015*, 37 and fig. 1.24.

51 Fukao, "Service Sector Productivity in Japan," 4–6, 8–11, 14–16, 18. See also OECD, "Policies for a Revitalisation of Japan," 4, 16.

global innovation relate directly to barriers to trade and investment, including non-tariff barriers, particularly in the service sector; localization barriers; foreign equity restrictions; currency manipulation; export subsidies; IP and patent protection, including data-exclusivity protection for biologic medicines; government policies to control pharmaceutical prices; software piracy rates; and tariff rates on ICT products.[52]

In the 2016 assessment by the Information Technology and Innovation Foundation, Japan and South Korea ranked high as contributors to global innovation, particularly in terms of public R&D, tax incentives, and the level of researchers. They also ranked high on IP protections, including data exclusivity of biologic medicines. On the other hand, both countries ranked comparatively high in non-tariff barriers.[53] In addition, South Korea's subsidization of the dynamic random-access memory (DRAM) chip producer Hynix was cited by the Information Technology and Innovation Foundation as one example of an export subsidy with negative consequences for the global market. This action resulted in overcapacity of DRAM chips, causing market distortions and reducing sales and margins for Hynix's international competitors.[54] See **Table 1** for a comparison of Japan, South Korea, and the United States in this assessment.

TABLE 1 Impact on global innovation rankings: Japan, South Korea, and the United States

	Japan	South Korea	United States
Contributions	11.33	14.70	8.54
Taxes (weight: 25%)	-0.55	-0.34	-0.79
Human capital (weight: 25%)	0.14	0.27	1.25
R&D and technology (weight: 50%)	1.11	1.24	0.63
Rank	***8***	***2***	***17***
Detractions	4.30	-6.90	10.40
Balkanized production markets (weight: 40%)	-0.28	-0.79	0.25
IP protections (weight: 40%)	0.83	0.27	0.98
Balkanized consumer markets (weight: 20%)	0.42	-0.69	0.75
Rank	***27***	***42***	***6***

SOURCE: Stephen J. Ezell, Adams B. Nager, and Robert D. Atkinson, "Contributors and Detractors: Ranking Countries' Impact on Global Innovation," Information Technology and Innovation Foundation, January 2016, 28–29, 55.

[52] For an in-depth analysis of these policies, see Ezell et al., "Contributors and Detractors," 17–19, 54–83.

[53] Ibid., 33, 44, 46–47, 55, 57, 68–69, 79–81.

[54] Ibid., 15–17.

Approaches to Enhance Innovation Systems: Implications for Japan and South Korea

The strengths of and challenges for the Japanese and South Korean national innovation systems raise the question of what policies and actions would help catalyze new ideas, products, services, and systems that will contribute to economic growth. Approaches that are holistic, long-term, and anticipatory, and that incorporate the core elements of R&D, education, physical and regulatory infrastructure, intangible assets, and trade and investment, are needed for developing the most effective tools to enhance environments for innovation. Such policies would encourage the emergence and deployment of innovations and could foster new opportunities for international cooperation.

There is increasing recognition at various levels, ranging from institutions such as the OECD to national governments, of the kinds of policy approaches that can address these issues within innovation systems. Solutions include fostering and accelerating ICT use; greater investment in intangible assets and knowledge-based capital; greater labor mobility and workforce training for non-regular workers; more opportunities for women, senior citizens, and highly skilled immigrants to join the workforce; the elimination of regulatory and entry barriers to entrepreneurs and SMEs; and greater trade and inbound FDI.

The policies that Japan and South Korea adopt have significant implications not only for their domestic economies but also for the United States and other Asia-Pacific economies with which they are increasingly integrated through trade, FDI, and global supply chains. The two countries have long served as models for emerging economies, which will be watching their policy approaches closely for lessons on best practices for advancing innovation-driven growth. Additionally, Japanese and South Korean leadership is instrumental in fostering regional and global trade networks that facilitate the open flow of trade and investment essential to innovation, particularly at a time when China is pursuing a different approach to innovation, with potentially detrimental implications for other economies.

It is important for the United States, Japan, and South Korea to cooperate in ensuring that domestic and global environments are most conducive to developing, commercializing, and deploying new products, processes, services, and business models—particularly given these countries' international leadership in science and technology in some of the most innovative and rapidly growing industries. Central to this are trade and investment policy frameworks, which play a critical role in facilitating innovation. It is also important for these countries to pursue bilateral initiatives in emerging sectors that offer substantial domestic and global benefits from cooperation.

At the Domestic and National Level

Policymakers in Japan and South Korea are well aware of the above challenges to their innovation environments and have long worked to address them. The Japanese government's comprehensive growth strategies since 2013, as part of its Abenomics agenda, have included measures such as reductions to the corporate tax rate, corporate governance reform, the encouragement of more women and highly skilled foreign professionals to join the workforce, educational reform and greater focus on vocational and technical training, the creation of special economic zones offering bold regulatory reforms targeting new FDI, and participation

in the Trans-Pacific Partnership (TPP) trade agreement. Abenomics was initially successful in boosting confidence in Japan's economic outlook. At the same time, progress on structural and regulatory reforms, including those listed above, has been mixed and not as rapid as some had hoped, reflecting in part the politically challenging aspects of many of these reforms and their potentially disruptive impacts.

Successive governments in South Korea have worked to advance policy initiatives promoting science, technology, and innovation within the country's economic growth strategy, most recently the Creative Economy initiative.[55] Many related reforms, including in labor markets and education, have proved highly challenging to address and require immense political capital. The economic policies of President Moon Jae-in focus on stimulating growth through public-sector job creation and expenditures. They also include measures to advance a "fourth industrial revolution" driven by science and technology and create an environment conducive to innovation-driven growth, such as by supporting start-ups and SMEs.[56] It is important that the Moon administration not lose sight of the bigger picture of building the most conducive environment for innovation. Achieving this goal will require a long-term commitment and concerted efforts to communicate to the public the value for future prosperity.

Within the Bilateral and Multilateral Context

With the Asia-Pacific region increasingly economically integrated, Japan and South Korea have a critical role to play in setting the tone for global innovation policies. Trade is one of the most important mechanisms for promoting domestic and regional prosperity, given the role that trade and investment policies have in shaping the environment for innovation. During the last two decades, there has been significant progress made on this front. Japan and South Korea have both overcome acrimonious trade disputes with the United States to negotiate ambitious and groundbreaking trade agreements that addressed important conditions for healthy innovation ecosystems.

Korea-U.S. Free Trade Agreement (KORUS FTA). The KORUS FTA addressed many trade-related barriers to innovation in economic relations between the United States and South Korea. The agreement included some of the strongest IP protection and enforcement provisions in any U.S. trade agreement—for example, commitments by the South Korean government to fully implement the World Intellectual Property Organization Copyright Treaty and Performances and Phonograms Treaty. It also contained commitments by South Korea to make the development and implementation of technology regulations and conformity assessment procedures more transparent and predictable and to promote the use of consensus-based international standards, among other related actions. Additionally, the KORUS FTA featured provisions to ensure strong competition policy and regulatory transparency, included a binding investor-state dispute-resolution mechanism, opened economic sectors previously closed to FDI,

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[55] For a summary and midterm assessment of this initiative, see Cha Doo-won, "The Creative Economy of the Park Geun-hye Administration," *Korea's Economy* 30 (2015): 35–46, http://www.keia.org/sites/default/files/publications/kei_koreaseconomy_cha_0.pdf.

[56] An English-language version of the official press release outlining the Moon administration's five-year policy is available from Sohn JiAe, "President Moon Unveils Five-Year Policy Agenda," Korea.net, July 19, 2017, http://www.korea.net/NewsFocus/policies/view?articleId=148013. See also June Park, "Strategies, Challenges, and Considerations for Economic Growth in South Korea," interview by Ashley Johnson, National Bureau of Asian Research, November 16, 2017, http://www.nbr.org/research/activity.aspx?id=822.

and simplified customs procedures, to name a few of the non-tariff barriers it addressed.[57] The South Korean government recognized the value that the agreement would have in advancing these and other challenging domestic economic and regulatory reforms that could help foster innovation and competitiveness.

Trans-Pacific Partnership. The TPP built on many of the policies advanced in the KORUS FTA to address trade and non-tariff barriers to innovation. These included, among others, the elimination of import taxes on ICT exports between member economies; strong digital trade provisions, including free international movement of data and restrictions on the forced localization of data and services; IP protections; a pioneering chapter addressing SME-related trade barriers, including by streamlining customs procedures and increasing the transparency of exporting procedures; and some of the strongest standards for transparency in any trade agreement.[58]

The TPP has particular significance within the domestic economic context in Japan, where it offers benefits similar to those that the KORUS FTA provides to South Korea in terms of economic reforms. Beyond reducing trade barriers to Japanese goods and services overseas, the TPP is also a vehicle for advancing politically challenging structural and regulatory reforms to open Japanese markets to greater competition and spur innovation as part of the "third arrow" of Abenomics (structural reform).[59]

Following President Donald Trump's decision to withdraw the United States from the TPP in January 2017, Japan took a leading role in negotiations to continue moving forward with the agreement. This reflects the TPP's importance to Abe's agenda for economic and structural reform. Now calling the TPP the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), the remaining eleven member countries agreed in November 2017 on the core elements of an updated version of the agreement, which was signed in March 2018. The CPTPP maintains most of the original TPP, while suspending 22 provisions, including ones related to investment, IP, and pharmaceutical-related aspects, that could be reinstated at a later time.[60]

As the Trump administration pursues a new bilateral economic dialogue with Japan and discusses potential amendments to the KORUS FTA with the South Korean government, it is important not to lose sight of the accomplishments made in these agreements that enhance the domestic and international environment for innovation. In the case of the KORUS FTA, ensuring continued progress in implementation of the above-mentioned provisions and related measures will foster innovation, both within South Korea and in the country's economic relationship with the United States.

Additional bilateral dialogues. Beyond trade policy discussions, the outlook for strengthening international cooperation between the United States, Japan, and South Korea related to innovative economic sectors is positive. During the past two decades, a range of bilateral

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57 For the full text of the KORUS FTA and information on its provisions, see Office of the U.S. Trade Representative, "U.S.-Korea Free Trade Agreement," https://ustr.gov/trade-agreements/free-trade-agreements/korus-fta. See also U.S.-Korea Business Council, "The U.S.-Korea Free Trade Agreement: Economic Opportunity, Strategic Imperative," 17–20.

58 The full text of the TPP is available at Office of the U.S. Trade Representative, "TPP," https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text. A summary of key provisions is available in "How the Trans-Pacific Partnership Boosts Made in America Exports, Supports Higher-Paying American Jobs, and Protects American Workers," White House, Office of the Press Secretary, Fact Sheet, October 5, 2015, https://obamawhitehouse.archives.gov/the-press-office/2015/10/05/fact-sheet-how-trans-pacific-partnership-tpp-boosts-made-america-exports.

59 When Japan joined the TPP negotiations, some in the country commented that the third arrow could be the TPP. This observation came up during the author's conversations with businesses in Tokyo in November 2013.

60 The full text of the CPTPP and related information about the agreement is available from Government of Canada, "Comprehensive and Progressive Agreement for Trans-Pacific Partnership," https://international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cptpp-ptpgp/index.aspx?lang=eng&utm_campaign=cptpp&utm_source=gac&utm_medium=slideshow-en.

dialogues focused on emerging high-tech sectors have been initiated between the United States and Japan to explore potential areas for engagement. These include the Internet Economy Dialogue; the Dialogue to Promote Innovation, Entrepreneurship and Job Creation; and the Clean Energy Policy Dialogue.

Between the United States and South Korea, the "new frontiers of cooperation" first advanced by then presidents Barack Obama and Park Geun-hye in 2015 prioritized cybersecurity, space, global health, environmental sustainability and climate change, and broader science and technology collaboration. These areas factored prominently in the larger category of "global issues" in the joint statement issued following the summit meetings between Presidents Trump and Moon in June 2017 and November 2017, underscoring their importance as areas for bilateral engagement. More broadly, other science and technology fields in which all three countries have significant expertise and capabilities are increasingly at the fore, such as nuclear energy and security, and offer positive benefits to building further collaboration.

At the Subnational Level

In addition to national-level dialogues such as trade and investment negotiations, it is also important to explore ways in which activities at the subnational level can facilitate engagement around innovation and economic growth. In the United States, state and city governments often pioneer policy solutions and best practices that can serve as national models. Regional innovation clusters in the United States, such as Silicon Valley, have long attracted attention from Japan and South Korea and could serve as a nexus for bilateral economic engagement. Activities already taking place are entrepreneurship prize competitions connecting Japanese and South Korean tech startups with U.S. venture capital and mentors and a week-long immersion program called Jannovation that introduces Japanese entrepreneurs to the Silicon Valley ecosystem.

Additionally, a wide range of joint R&D activities and demonstration projects at the subnational, state, and local levels aim to commercialize and deploy innovative technologies. Examples include the International Institute for Carbon-Neutral Energy Research at Kyushu National University in Japan, which is a joint initiative with the University of Illinois at Urbana-Champaign; collaboration on hydrogen fuel-cell research between the University of South Carolina and South Korea's Woosuk University; and projects to develop smart-grid and clean-energy technology by bringing together public- and private-sector partners in Hawaii and Okinawa.[61]

Conclusion

Fostering innovation that will catalyze new economic growth and prosperity is increasingly at the center of the economic agendas in Japan and South Korea, as well as being integral to both countries' relationships with the United States. With their immense technological assets and capabilities, Japan and South Korea are well-positioned to lead the development of emerging industries and sectors. Achieving the full economic and societal benefits requires

[61] More details on these and other examples are described in Sean Connell, "New Frontiers of Cooperation in U.S.-Korea Relations: Opportunities for Economic Engagement," Korea Economic Institute of America, Academic Paper Series, May 17, 2017, http://www.keia.org/sites/default/files/publications/kei_aps_connell_170522.pdf; and Sean Connell, "Exploring New Partnerships and Opportunities in U.S.-Japan State and Local Economic Collaboration," Sasakawa Peace Foundation USA, December 5, 2017, 4–8, https://spfusa.org/wp-content/uploads/2017/12/Exploring-New-Partnership-final.pdf.

that both countries prioritize addressing imbalances in their innovation ecosystems, including structural, regulatory, and cultural barriers that prevent them from reaching their potential. Full implementation of bilateral and multilateral trade agreements will contribute positively to domestic and global environments for innovation. Additionally, Japan and South Korea should continue to build on momentum in bilateral economic and security dialogues with the United States focused on innovation-driven sectors and explore new initiatives that will support opportunities at both the national and subnational levels, including between local governments, businesses, universities, and other actors.

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The Unique Challenges for Life Science Innovation in Asia

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EXECUTIVE SUMMARY

This essay examines several short-term challenges to life science innovation in Asia and offers recommendations for balancing domestic political needs and innovation in a way that maximizes access to healthcare while controlling expenditures.

MAIN ARGUMENT

In early stages of economic development, a country's healthcare and life science industry typically only focuses on addressing basic public health concerns. As nations achieve higher levels of development, the focus shifts toward providing best-in-class therapeutics and healthcare innovations while leveraging these advancements to promote economic growth, as has been the case for countries like Japan and South Korea. When handled properly, the healthcare delivery, life science, medical device, and healthcare information technology industries have the potential to both foster economic growth and address a country's unique public health challenges. However, when policies for these industries are improperly managed, countries can suffer from a lack of access to the latest therapeutic drugs and healthcare delivery platforms and impede the growth of and investment in viable ecosystems for innovation. These considerations call for governments to carefully craft policies that balance the need for promoting innovative solutions to public health challenges while also controlling healthcare expenditures.

POLICY IMPLICATIONS

- National governments should ensure that domestic healthcare and life science industry standards are harmonized with global regulatory standards. Doing so increases market access and product competitiveness, which accelerates innovation and lowers costs. It can also reduce consumer risk by ensuring that local manufacturers are held to the latest international safety standards.
- Domestic regulatory and pricing policies need to be transparent and predictable because unanticipated changes may disincentivize industry from pursuing necessary future innovations.
- In order to achieve advancements in the life science sector, governments need to foster ecosystems that incentivize innovation by encouraging collaboration between academic institutions, government-led incubator hubs, private venture-capital firms, and commercial enterprises.
- As the fields of precision medicine and big data mature, governments will need to ensure that policies enable researchers across the world to access, learn from, and leverage various types of personal health information.

Many national governments around the world wrestle with how best to incentivize innovation in healthcare, while also keeping an eye on containing costs. Asia's developed economies are no exception, and in some cases face even more acute challenges related to demographics than their Western peers. With the possible exception of national defense policy, few issues are as politically sensitive as is healthcare. As evidenced by the Japanese government's reaction to a series of scandals in its pharmaceutical sector in late 2014, the public has an expectation for how the government will build policies that ensure access to safe and innovative medicines.[1] Yet in many cases efforts to do this run contrary to basic questions of affordability, regulatory approval, and market access with which government officials must also wrestle. Especially as costs rise and access to innovative therapeutics suffers, political pressure can result in heavy-handed reactions to private-sector healthcare and life science (HLS) players, in particular pharmaceutical manufacturers. This is more because of political expediency and other considerations unrelated to health or innovation than because of a careful reassessment of industrial or public health policy.[2]

Handled properly, healthcare delivery, life science, medical technology, and healthcare information technology industries hold the potential to become both a source of economic growth and a solution for many of a country's unique public health challenges. Japan has been widely considered one of the success stories in this regard. Several decades ago, Japan took aggressive steps to reform its pharmaceutical protocols to become one of the privileged countries where market access, clinical trial regulations, intellectual property (IP) laws, and investment all accrued meaningful economic value. When these issues are handled improperly, as China has only recently begun to acknowledge through a series of accelerated reforms to its Food and Drug Administration (FDA), countries can suffer from a lack of access to innovative therapeutics and healthcare delivery platforms, while also never successfully seeding domestic innovation despite massive, multiyear investments.[3]

This essay explores several short-term challenges that Asian countries face in finding an appropriate balance between innovation and public policies that maximize access while controlling healthcare expenditures. The first section provides context on how technocrats think about the task of managing competing interests. The next section then offers nine recommendations identifying the most effective levers to achieve the interests of industry and public health. The essay ultimately argues that national economies can successfully manage policies that encourage innovation while also both ensuring improvements in healthcare outcomes and controlling costs.

High-Level Decision-making

Most policymakers decide how to structure industrial policy for a domestic HLS space around three concerns: public health, economic development, and national security (i.e., a nation's ability to manufacture basic medicines). The interplay among these three factors is dynamic and changes over time as a country's economy matures. This essay focuses on the first two (public health and

[1] "Drug Scandals Impact Industry in Japan," Pharmtech.com, December 2, 2014, http://www.pharmtech.com/drug-scandals-impact-industry-japan.

[2] Daniel C.K. Chow, "How China's Crackdown on Corruption Has Led to Less Transparency in the Enforcement of China's Anti-bribery Laws," *UC Davis Law Review* 49, no. 2 (2015): 685–702.

[3] "China to Reform Oversight of Drug Prices, GMP Compliance," FDAnews, March 31, 2017, https://www.fdanews.com/articles/181143-china-to-reform-oversight-of-drug-prices-gmp-compliance.

economic development), given that they have played the most critical role in shaping industrial policies in Asia. National security concerns in the HLS sector can be narrowly defined and rarely play a major role in shaping industrial policy. A good example is the Japanese government's $18 million investment in an earthquake-proof facility to store vaccines: this policy was important to national security but not economically determinative to the broader biotech community.[4]

Promoting Basic Public Health

Early in the economic development of many Asian countries, HLS policy was guided by the need to address basic public health problems. These tended to include building primary or community care infrastructure, ensuring the availability of the basic medicines captured in the World Health Organization's recommended hospital formulary, and rolling out a framework for public healthcare financing that offers some sort of universal coverage, even if the services and consumables covered are minimal.

These policies meant that countries needed to pay special attention to the "iron triangle," or mechanisms that would ensure that quality standards were upheld, therapeutics were affordable, and healthcare delivery was broadly accessible. Achieving all three goals—concurrently or sequentially—is of course not a foregone conclusion, as is evidenced by China and much of Southeast Asia's struggles to this very day.[5] The tension between cost and public health never goes away; rather, what does change is the level of care to which patients expect access, as well as the additional goals such as economic development that policymakers fold into a broader agenda.

Advancing Economic Development

In the early days of the development of a country's HLS sector, economic development is a lower policy goal than is the improvement of healthcare outcomes. Yet for those countries that become economically successful and develop a meaningful middle class, the conversation often shifts from ensuring basic access toward ensuring that best-in-class therapeutics and healthcare interventions are available. As the cases of Japan and South Korea illustrate, as countries determine that the HLS sector can represent a meaningful source of potential economic development, they also often begin to craft industrial policy, guided by significant government investment, in pursuit of a domestic HLS ecosystem that can serve as an engine for economic growth and improved healthcare outcomes. In many cases, this policy focus can increase FDI, improve pricing and reimbursement (P&R) schemes, and lower barriers to market access. Indeed, this is the reason that South Korea has more than doubled its R&D investment in the HLS space over the last decade and Japan has made similar investments during the same period. Accelerating efforts in 2008 as part of its New Drug Creation and Development Program, China has announced a national biotech plan that clearly seeks to establish the Chinese economy as one of the world's leaders in life sciences.[6]

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[4] Rick Fonte, Patrick Flochel, and Sriram Shrinivasan, "EY Life Sciences Report: Asia," EY, March 2017, 7, http://www.ey.com/Publication/vwLUAssets/ey-life-sciences-report-asia-march-2017/$FILE/ey-life-sciences-report-asia-march-2017.pdf.

[5] Yanzhong Huang, "The Sick Man of Asia," *Foreign Affairs*, November/December 2011, https://www.foreignaffairs.com/articles/china/2011-11-01/sick-man-asia.

[6] Overviews of China's national economic development strategy as it relates to the life science sector can be accessed via written testimony submitted for two hearings of the U.S.-China Economic and Security Review Commission. See Benjamin Shobert, "Market Access for U.S. Medical Goods and Services in China," hearing before U.S.-China Economic and Security Review Commission, April 3, 2014, https://www.uscc.gov/sites/default/files/Shobert_testimony.pdf; and Benjamin Shobert, "Biotechnology," hearing before U.S.-China Economic and Security Review Commission, March 16, 2017, https://www.uscc.gov/sites/default/files/Benjamin%20Shobert_Written%20Testimony_FINAL.pdf.

Balancing the Twin Goals of Economic Development and Public Health

The transition that a country makes from the prioritization of basic needs, which can be largely framed through a public health prism, to a focus on economic development and innovation is important to understand. Overall, the life cycle for the HLS sector begins with a country's recognition that a particular set of public health problems require it to open its borders to foreign products. Given the global nature of the pharmaceutical supply chain—in particular, the concentration of active pharmaceutical ingredient manufacturing in China and India—total self-sufficiency is impractical for nearly any national economy. Once markets open to foreign investment and distribution, multinational corporations (MNCs) become eager to identify opportunities in these new markets. Companies also recognize that unless these countries' regulatory regimes match global standards, they run any number of risks as businesses that could limit long-term revenue growth and profitability.

For example, numerous countries across Asia have long struggled with "drug lag," a phenomenon where a new therapeutic drug is not approved by the government of a specific export economy at the same time that governments in the rest of the world issue their respective approvals.[7] Several decades ago, Japan and South Korea both had this problem, and until recently China's FDA was notorious for its inefficient regulatory schemes that consistently led to pervasive drug lag.[8] Pharmaceutical MNCs did not begin to see a way to incorporate China into their early-launch plans until the 2000s, when Bristol-Myers Squibb introduced Baraclude, a new treatment for hepatitis B. Endemic problems around drug lag lead to situations where the export economy does not approve a new therapeutic drug until the patents are close to expiration. Because of this phenomenon, many MNCs have historically avoided launching new products in markets like China, Japan, and South Korea where the lack of harmonization with global regulatory standards represents an unnecessary IP and market-access risk. Companies are also aware that as national governments think through their respective policies on these issues, the potential for compulsory licensing remains a key concern, as has proved to be the case in India.[9]

However, if a country's broader economic development goals are achieved, it often begins looking for higher-technology industries where policy can be set around key investments, such as those in genomics, healthcare information technology, and biotech, as has been common across Asia. At this stage in most Asian countries' development, there are two goals: pursuing even better healthcare outcomes and accelerating innovation to achieve domestic economic growth. The importance of the latter goal is critical. Many states across Asia believe that the HLS industry, particularly where personalized medicine and big data intersect, is one of the key areas in which they must compete globally in the 21st century.

As these economic development goals come into focus, most countries begin to struggle with basic questions about the financial sustainability of their healthcare model. People begin to live longer with morbidities that, while manageable, come at a significant cost to the publicly funded healthcare system. Consequently, at such moments a paradigm tends to emerge that suggests that innovation and cost containment are incompatible goals and that government policy needs to focus on the latter. However, cost controls, if excessive, have the potential to suppress innovation

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[7] Benjamin Shobert, "A Decade Old Drug Launch in China with Important Insights Today," *Forbes*, March 18, 2015, https://www.forbes.com/sites/benjaminshobert/2015/03/18/a-decade-old-drug-launch-in-china-with-important-insights-today/#76126e644a80.

[8] Ibid.

[9] "India Grants First Compulsory License to Generic Drug Producer," International Centre for Trade and Sustainable Investment, March 14, 2012, https://www.ictsd.org/bridges-news/bridges/news/india-grants-first-compulsory-license-to-generic-drug-producer.

both by MNCs seeking to invest in and gain access to the local economy and by local domestic champions with similar needs for improved government P&R strategies. The next section explores in greater depth the challenge of building national policies that can balance these goals.

Balancing Cost Control and Innovation: Nine Key Policies

Given the concerns over public healthcare expenditures to treat aging populations in Asia and much of the developed West, how can policymakers strike the right balance between cost control and innovation? How can policies to balance cost and innovation be framed in both-and rather than either-or terms? Nine policies are key to achieving this goal.

Ensuring That Domestic Standards Are Harmonized to Global Regulatory Standards

National governments should work to ensure that domestic standards for their HLS industry are harmonized with global regulatory standards. Other high-tech industries beyond biotech have benefited by ensuring that international manufacturers hold themselves to a set of agreed-on technical standards. In fact, global regulatory harmonization has had a key accelerator effect on various technologies such as mobile phones, personal computers, and the "internet of things" by expanding their international market opportunities.[10] Global harmonization should be framed as an opportunity for companies to sell across different global markets at the same time, a move that should not only accelerate innovation but also lower costs. Handled properly, these regulatory standards will also significantly reduce consumer risk by holding local manufacturers to international quality-control and good-practice standards.

In addition, global harmonization creates protections against IP theft. This is a concern not only for MNCs but also for domestic innovators who aspire to sell their products in global markets and require IP protections in order to do so. Similarly, ensuring compliance with global standards for multiregional clinical trials benefits MNCs not only by eliminating inconsistencies between various national clinical trial regimes but also by addressing problems specific to drug lag that prevent the most innovative therapies from being brought to the global commons at the same time.[11] However, not every required set of global standards is in place today. Work remains to be done on the establishment of global diagnostic standards that are key to the future of personalized medicine and genomics, as well as on the issue of access to personal health information across national borders.

Building Big Data Policies That Accelerate Bilateral Innovations

In the world of big data, the importance of standards for global diagnostics and access to personal health information for accelerating innovation in the HLS sector in Asia and around the world cannot be overstated. This sector will not be exempt from what has been characterized as an arms race for data in the 21st century. Many of the most important health insights are difficult, if not impossible, for non-domestic players to provide because foreign companies' access to personal

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[10] Tonya Villafana, "Medicines Regulation, Regulatory Harmonization, Global Initiatives," World Bank, slideshow, September 13, 2012, http://www.worldbank.org/content/dam/Worldbank/document/HDN/Health/Regulatory%20Harmonzation_China-Harvard%20Meeting_October%202012.pdf.

[11] H.M. James Hung, "Values and Challenges of MRCT: A Regulatory Perspective" (presentation at APEC workshop, June 15–18, 2009), http://www.nifds.go.kr/apec/upload/old/tp200901/Plenary_1_2_Jim_Hung.pdf.

health information is either forbidden or limited.[12] Beyond the HLS sector, basic data sovereignty issues already have regulators chasing technology disruptors in the United States and the European Union in an attempt to ensure that foreign actors cannot access personal information without adequate safeguards. The unique privacy concerns of individual healthcare data are even more challenging. Access to personal health information will be absolutely critical for innovators to be successful in fields such as digital health, population health management, and gene therapy. Because of this, global standards, specifically those ensuring data quality, the frequency of updates, opt-in and opt-out rights for consumers, and clarity on how government and industry monetize personal health information will need to be developed. Already the fragmentation of global regulatory standards outside healthcare poses a risk to the free-flowing data schemes that will be required for the future of medicine.

Japan has recently begun to evaluate what would be required to establish its national healthcare system as the best place for the next generation of innovation in healthcare information technology. Led by the Ministry of Economy, Trade and Industry, the country is currently touring global innovation centers in order to better understand what policies other economies have put in place around data sharing and interoperability, the role of key technologies such as Fast Healthcare Interoperability Resources and blockchain, and how to ensure that the highest-veracity, most relevant personal health information is available to researchers and entrepreneurs within Japan. This approach has an analog in the life science sector, where modeling successful global endeavors and then localizing them for the Japanese economy were effective. For Japan, or any economy with similar aspirations, to be successful, particular attention will need to be paid to ensuring that personal health information standards are harmonized globally and that data can flow across borders as freely as do traditionally manufactured HLS products such as therapeutic drugs and medical devices.

The promise of big data in healthcare is limited if policies are not put in place that ensure access to personal health information by innovators outside a country. Given that restrictions on data access already limit how such information can be used within the country where it originates, the question of access for outside actors is even more challenging. This issue is further complicated by the deep dysfunction in how global trade accords are being crafted to deal with the unique problems and opportunities of the 21st century.

Ensuring That New Standards Are Developed in a Transparent, Scientifically Sound Manner

Where domestic regulatory processes do need to be differentiated from global standards, the processes used to establish indigenous standards should be constructed in a transparent and scientifically sound manner. Countries with unique demographic, economic, or public health problems may need carveouts that address these challenges. For example, India's approach to compulsory licensing has long reflected the unique problems it faces related to healthcare access and affordability—at least from the point of view of Indian policymakers. These carveouts are to be expected, as even the most mature Western economies have areas where their requirements do not fully map onto global standards. However, the mechanism by which these spinoff companies are established needs to be transparent and scientifically supported. A positive example is how

[12] "Rebalancing Health System—Innovation and Sustainability," Center for Strategic and International Studies and Health and Global Policy Institute, April 14, 2017, https://www.csis.org/analysis/rebalancing-national-health-systems-innovation-and-sustainability.

most countries have used compulsory licenses focused on treatments for HIV/AIDS and other communicable diseases.[13] In addition, when national economies successfully lobby for such a carveout, industry can and should be expected to have a petitioning process in place that allows companies to push back and argue for improved P&R once the economy in question has matured.

Investing in Technocratic Capacity

Because the HLS sector is an area where scientific talent is required to monitor, manage, and regulate the industry, governments must invest in technocratic capacity well in advance of their establishing an increased regulatory burden. In a market such as China today, or Japan fifteen years ago, where multiple access issues had unintentionally complicated and delayed the ability to bring innovations to the country, one of the key reforms that accelerated the growth of the HLS sector was a deliberate investment in the scientists and other data specialists required to harmonize the country's domestic regulatory regime with global standards. This can be a particularly challenging step because the advent of a more scientifically rigorous regulatory scheme incentivizes MNCs to similarly expand their base of domestic scientific talent, which can disadvantage government regulators who compete with the private sector for talent.

Protecting IP Rights

Special attention needs to be given to IP rights. While this is not a new issue in the biotech sector, several Asian governments have adopted policies that limit the period of time during which companies can challenge IP issues. The South Korean Ministry of Food and Drug Safety, for example, has created a narrow window for companies—most of which have turned out to be foreign—to challenge potential cases of patent infringement.[14] As the technical complexity and data disclosure expectations for companies accessing foreign markets increase, so too must the amount of time that they have to respond to potential IP issues. To give one example, in South Korea potential IP infringement needs to be addressed in nine months.[15] This period of time is rarely sufficient for an industry stakeholder to identify a case of infringement, let alone prepare and prosecute a case as an outsider.

Managing Pricing and Reimbursement Changes

P&R changes need to be predictable. Beyond the previously mentioned arguments for overall transparency and predictability, P&R issues are key given the higher cost of most next-generation HLS interventions. Fundamental changes that are not anticipated run the risk of disincentivizing companies from making necessary investments in innovation in the first place. A number of next-generation life science interventions are extremely expensive on a per-dose basis, yet overall are less expensive when measured against either the lack of any existing curative therapies or the total cost of longer-term (even life-long) treatment regimes. Japan's efforts between 2016 and 2017 to begin reforming its reimbursement for a variety of novel molecules, best evidenced by Ono Pharmaceutical's near 50% price reduction for its Opdivo oncology treatment, illustrate how

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[13] Yanzhong Huang, "The Compulsory Licensing of Pharmaceuticals: Will China Follow in India's Footsteps?" Council on Foreign Relations, Asia Unbound, October 1, 2012, https://www.cfr.org/blog/compulsory-licensing-pharmaceuticals-will-china-follow-indias-footsteps.

[14] Hee-Eun Kim, "Drug Patent Protection in Korea under the EU-Korea Free Trade Agreement," Covington, Inside EU Life Sciences, June 10, 2013, https://www.insideeulifesciences.com/2013/06/10/drug-patent-protection-in-korea-under-the-eu-korea-free-trade-agreement.

[15] "Patent and Drug Marketing Approval (MA) Linkage in Korea," Kasan, Korea IP Law Blog, March 6, 2015, http://koreaniplaw.blogspot.com/search/label/Green%20List.

policymakers are attempting to make real-time offsets between innovation, market access, and reimbursement. Similarly, in South Korea a process that began in earnest in 2012 has led to price cuts of up to 25% for branded drugs and over 30% for generic drugs. Cumulatively, over half of all drugs on the country's established P&R list have been affected.[16] A national strategy that focuses purely on the per-dose cost runs the risk of limiting specific types of pharmaceutical innovation that may have higher upfront costs, even when the overall expenditure is lower than the entire treatment regime or the cost of treatment in cases where the regime is curative.

Given the unique political calculus that revolves around healthcare costs, strategies that can be politically expedient (such as focusing public displeasure on a large initial cost) can lead industry to put its R&D efforts elsewhere. The challenge for government technocrats is not trivial here: they must advocate for the public to accept higher upfront costs on the basis of lower long-term expenses. This is not an easy position to hold, especially as P&R strategies evolve and begin to shift the out-of-pocket spending required for individuals to access the most innovative treatments. One such example is the effort to treat hepatitis. The next wave of treatments will have high upfront costs but be actually curative, whereas existing treatments with lower upfront costs entail life-long spending. In such therapeutic areas, an unpredictable P&R policy could fundamentally set R&D back a generation if this total cost is not understood, internalized, and formalized by local governments and consequently entrepreneurs regard the market as too volatile for undertaking a long-term development push.

Meanwhile, while health technology assessments and other pharmaco-econometric tools have to be used to discern whether an innovative therapy is worth its expense, industry rarely trusts assessments that are developed without its input for the same reason that it rarely trusts government-led analysis of innovative therapies absent industry input. A good example of the unintended negative downstream consequences of such an approach is what has transpired in South Korea, where the P&R strategy requires that a weighted average from approved generics is set as the price ceiling for future reimbursement, including for innovative therapies. This means that the price of a generic drug is capped at 59.5% of the original drug's price after the expiration of a patent and is lowered again to 53.6% in one year. Yet as noted by the U.S. International Trade Administration, "because new drugs are originally priced against a weighted average in a therapeutic category that includes generics, the patent-expiry price cuts cause a downward spiral in prices across the board."[17] Even when policymakers have the best intentions, greater dialogue between industry and technocrats would likely support more market-oriented policies that can achieve both goals. This serves as a good reminder that the development and use of health technology assessments needs to be handled in a transparent way that allows both the government and industry the opportunity to argue for their respective points of view.

Fostering an Ecosystem That Incentivizes Innovation

National governments need to be open to incentivizing innovation, while admitting that P&R policies that reward innovators may not immediately follow. Historically, the ability to pay for innovation—which is a function of economic development—has come before national governments

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[16] Catarina Féria Walsh, "Country Report: The Healthcare Market in South Korea," PMLiVE, May 2012, http://www.pmlive.com/pharma_intelligence/country_report_the_healthcare_market_in_south_korea_404120.

[17] "South Korea: Country Case Study," International Trade Administration, 2016 ITA Pharmaceuticals Top Markets Report, 2016, https://www.trade.gov/topmarkets/pdf/Pharmaceuticals_Korea.pdf.

could pursue an industrial strategy for the HLS sector. Access to academic centers where state-of-the-art bench science is being conducted requires meaningful investment by government. Once these R&D activities begin to generate useful scientific findings, venture capitalists and MNCs in the biotech sector will look for ways to extract research assets and incubate them.

Here it is helpful to revert to the economic development model that supports investing in high-tech industries in general and the life sciences in particular. The life science and healthcare information technology sectors require a peculiar industry ecosystem with complex interdependencies between academic institutions where bench science and hard research are being conducted, government-led incubator and accelerator hubs where science begins to transition to applied engineering, a viable private capital market that knows how to graduate applied engineering assets to commercial products, specially designed IP regimes that address the high risk and long runway of life science R&D, and a local P&R environment that pays for innovation. Because of this special ecosystem, life sciences tend to become a national priority only after other lower-threshold industries have been pursued.

However, China is challenging this model. While the country's middle class continues to grow from a purchasing-power vantage point, the national healthcare reimbursement system remains well behind anything that could be thought of as incentivizing innovation. Consequently, if China were to follow the traditional path of waiting until it could incentivize innovation through its P&R policies, much of its current investment in biotech would need to wait. Many observers believe that China would actually be better off reallocating funding it has directed toward incentivizing investment in the domestic life science sector to a more sustainable national P&R plan. Instead, the country is attempting to accelerate its own biotech innovation efforts to meet those of economic competitors in the West, while at the same time acknowledging that its P&R policies are not yet on par with those of the United States, Japan, South Korea, and the EU. This stands in stark contrast with South Korea and Japan, whose moderate success in the life science sector has drafted off of a willingness to let P&R policies encourage market access for domestic and foreign innovators.

Fostering an Ecosystem That Encourages Entrepreneurs to Take Risks

Asian economies such as Japan and South Korea need to focus on policies that encourage individual entrepreneurs, as well as small and medium-sized enterprises, to take risks. In both countries, the oversized role that large industrial conglomerates play in the national economy reflects an aversion to risk that is incompatible with the type of disruption required to become a global leader in HLS. Domestic reforms like those undertaken in the United States with the Bayh-Dole Act, which allowed academics to financially benefit from developing IP, are key to unlocking scientific innovation within academic institutions. Of the various challenges confronting Asian economies, none may be more problematic than this one. In late 2015, South Korea announced a 500 billion won government-led investment plan for biologics that will emphasize investments that ensure that domestic academic centers and local innovators are connected and incentivized. The government hopes the program will add 120,000 new jobs by 2025.[18]

[18] Simon Mundy and Andrew Ward, "South Korea Pushes to Be New Force in Pharmaceuticals," *Financial Times*, June 9, 2015.

Clarifying and Evaluating Priorities

National governments need to carefully weigh whether biotech in particular is the right sector to build an industrial policy around. Biotech requires a very unique ecosystem connecting government, academia, venture capital, P&R, and industry that can take several decades to develop. Thus far, the returns on capital from other countries, both within Asia and across the world, that have set up biotech as a key pillar of their industrial policy are mixed at best. As Joseph Wong states in his seminal book *Betting on Biotech*, "from the perspective of the economic planner, scientist, or bio-industrial stakeholder in Asia, what had once been a sense of considerable optimism at the beginning of the first decade of the 2000s about the prospects of commercial biotech has now become a dreaded feeling of impending failure."[19] Unlike other high-tech manufacturing industries, biotech does not benefit from being a fast follower. The existing knowledge base for life science innovation—the special ecosystem that brings together academic R&D, venture capital, government policies, and the government as a source of reimbursement—cannot address what Wong has referred to as the "pronounced temporal uncertainties" unique to this sector. Biotech's risk-to-reward premium is enormous, which is why success has continued to require some level of intentional government support in the form of R&D investments and P&R policies that reward innovation. Because of this uncertainty, national governments that want to emphasize life science innovation must have clarity on why this sector is preferred over others and then create a political and policy roadmap that will optimize investments for success.

The HLS industries are fundamentally more complex technically and politically than those of nearly any other sector in the modern era of globalization. This particular moment in globalization, when the world is talking less about steel and ships and more about biotech, clean technology, and IT services, is poorly suited for much of what animates the contemporary discussion about free trade. The convergence of healthcare information technology, genomics, big data, and life sciences will require trade protocols, IP standards, and regulatory regimes to be updated precisely at a time when the ability of national governments to deal with complex issues that relate to globalization has dramatically decreased. Over the next 30 years, as the world struggles with how best to manage demographic changes and provide financially sustainable public healthcare for large populations with multiple long-term chronic diseases, policies that encourage the right balance between innovation and affordability will need additional attention.

Conclusion

The current era of globalization will require nations to balance domestic political concerns with the need to embrace new policies to foster innovators. Innovation will take place within increasingly technically sophisticated industries like the life sciences, biotech, and healthcare information technology with very high risk premiums. As such, the political will to embrace greater risk should not be assumed. In fact, one can envision any number of large economies determining that their political fortunes are better served by de-emphasizing policies that encourage innovation and focusing instead on more politically advantageous ways of engaging industry—namely, aggressive moves and public posturing on prices—to the detriment of industry. The effects of such an approach can already be seen in the inconsistent mechanisms supported

[19] Joseph Wong, *Betting on Biotech* (Ithaca: Cornell University Press, 2011), ix.

by the P&R policies in China, Japan, and South Korea. While these moves may be politically astute, they are likely shortsighted and may foundationally push industry away from viewing these markets as either growth opportunities for existing technologies or places where investment in R&D is likely to be rewarded based on how domestic P&R is managed.

Globally, no country has achieved the perfect balance between innovation and affordability. Even the most developed Western economies are today wrestling with how to fulfill the political commitments they have made to provide access to cost-effective and innovative therapies without breaking the bank. In order for everyone involved—technocrats, politicians, the average citizen, and industry—to benefit, we cannot assume what trade-offs must be made between access, affordability, innovation, and care. These need to be identified in ways that allow stakeholders to weigh in on how they believe the balance should be struck and consensus be built. Absent such an approach, global healthcare outcomes—as measured by increased longevity and the ability to generate new interventions that address the burdens of aging and chronic disease—could well hit a wall where further innovation is not possible because a balance between the needs of government, the individual, and industry could not be achieved. Barriers to innovation no doubt exist, but the world is best served if these are found to be technological rather than technocratic.

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Improving Population Health in the Era of Superaging: Japan's Challenges and Opportunities

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EXECUTIVE SUMMARY

This essay examines the changing characteristics of the burden of disease in Japan and provides recommendations for national and local policymakers to improve public health in a rapidly aging population.

MAIN ARGUMENT

Japan established universal health coverage in 1961. Since then, it has achieved excellent population health at a relatively low cost, while offering universal access to healthcare across regions. Today, Japan is at the forefront of research and policymaking on population aging, confounded by a slowdown in the progress in improving population health, an increase in the burden of age-related morbidity, and growing health inequalities across prefectures. The development of Japan's policies on aging can add perspective to debates that many countries are currently having or are likely to conduct. Now is an opportune time to take steps to ensure the sustainability and equity of Japan's health accomplishments over the past 50 years.

POLICY IMPLICATIONS

- Further progress in improving public health in Japan primarily depends on the prevention of major modifiable risk factors for noncommunicable diseases, such as tobacco smoking, dietary risks, and metabolic risks.
- Promoting local and regional stewardship for integrated healthcare services will help more efficiently allocate resources and ensure that funding is sustainable in different local contexts.
- Enhancing the performance of health systems by using health information and communications technology can help identify current and potential bottlenecks and thereby improve the delivery of services and promote the efficient use of resources.

Japan established universal health coverage in 1961, which has been instrumental in providing the latest breakthroughs in medicine and treatment to the population. Its premier accomplishment in the past 50 years has been the achievement of excellent population health at a low cost and increased equity between different socioeconomic groups.[1] Through a rapid reduction in the mortality rates of communicable diseases among children in the early 1960s, Japan's life expectancy has become world-leading (83.7 years in 2015).[2] Simultaneously, coupled with a low fertility rate (1.4 births per woman in 2016), Japan is at the forefront of the debate over "superaging." The number of individuals aged 65 and over has nearly quadrupled in the last 40 years, rising to 27% in 2016 as a percentage of the total population. This figure is expected to grow to 40% by 2060.[3]

Japan is therefore well-positioned to take the lead in exploring the implications of population aging. Its experience can add perspective to the policy debates that are currently underway in many countries confronted with an aging population. As our recent research in the *Lancet* has shown, while Japan has been successful overall in reducing the rates of mortality and disability from most major diseases, progress has slowed and variations in public health between prefectures are growing.[4] However, substantial opportunities exist to craft more robust policies to support a healthier population in Japan.

This essay examines the changing characteristics of the burden of disease in Japan and provides recommendations for national and local policymakers to improve the health of the country's rapidly aging population. The essay begins by analyzing the key challenges regarding disease burden in Japan. The next section provides an overview of the major policy options the government has developed to address some of these issues. The third section then highlights three specific recommendations that will help guide policy agendas to address Japan's healthcare challenges in an efficient and sustainable manner. The essay concludes with a brief summary of the findings and implications.

The Disease Burden Profile of Japan: Key Issues and Challenges

Japan can claim great success in introducing universal health coverage, which has led to excellent population health for all socioeconomic groups at a low cost. In the era of superaging, however, the country now faces significant challenges that must be addressed in order to ensure the sustainability and equity of Japan's health accomplishments of the past 50-plus years.[5]

First, the progress in population health has slowed down. This is largely a result of the leveling off of mortality reduction since around 2005 (see **Table 1**), primarily from cardiovascular disease

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1 Nayu Ikeda et al., "What Has Made the Population of Japan Healthy?" *Lancet* 378, no. 9796 (2011): 1094–105.

2 World Health Organization (WHO), *World Health Statistics 2017: Monitoring Health for the SDGs* (Geneva: WHO, 2017), http://apps.who.int/iris/bitstream/10665/255336/1/9789241565486-eng.pdf.

3 Ministry of Health, Labour and Welfare (Japan), "Jinkoudoutaitoukei no gaikyou" [Overview of Vital Statistics in 2015], 2016, http://www.mhlw.go.jp/toukei/saikin/hw/jinkou/kakutei15/index.html; Ministry of Internal Affairs and Communications (Japan), Statistics Bureau, "Population Estimates by Age (5-Year Age Group) and Sex," 2016, http://www.stat.go.jp/english/data/jinsui/tsuki/index.htm; and Ministry of Internal Affairs and Communications (Japan), Statistics Bureau, "Population and Households," in *Japan Statistical Yearbook 2017* (Tokyo, 2017), chap. 2, http://www.stat.go.jp/english/data/nenkan/66nenkan/1431-02.htm.

4 Shuhei Nomura et al., "Population Health and Regional Variations of Disease Burden in Japan, 1990–2015: A Systematic Subnational Analysis for the Global Burden of Disease Study 2015," *Lancet* 390, no. 10101 (2017): 1521–38.

5 Ibid.

TABLE 1 Five-year reduction rates of age-standardized mortality (%, measured in five-year periods)

Year	Both sexes	Male	Female
1995	6.9	4.5	9.4
2000	9.7	8.3	11.6
2005	7.1	7.3	7.7
2010	6.2	7.7	5.4
2015	3.1	5.4	1.0

SOURCE: Institute for Health Metrics and Evaluation, "Global Burden of Disease Study 2015," 2016.

and cancer. The increasing burden from degenerative disorders such as Alzheimer's disease also hampers Japan's progress in improving population health (as will be further elaborated below).[6]

Second, as a consequence of the growing phenomenon of survivorship, the Japanese population suffers from more chronic and age-related morbidity. **Table 2** shows the 2015 ranking of causes of disability-adjusted life years (DALYs)—an indicator that combines mortality and morbidity. Alzheimer's disease (including other forms of dementia) was a distinctive cause of DALYs, increasing almost 50% from 2005 to 2015. Another key metric for monitoring the shift of the burden of disease is age-standardized DALYs, which assess the impact of a disease by comparing populations with different age structures to minimize over- or under-representation of the impact of certain diseases on different age groups. While the age-standardized rates of DALYs from many leading causes have declined since 2005, the rates due to musculoskeletal disorders (e.g., lower back and neck pain) and sense organ diseases (e.g., hearing loss and vision loss) have remained static. More importantly, Alzheimer's disease was the only one of the ten leading causes that increased age-standardized DALY rates significantly over the same period (by 3.3%). The increasing burden from Alzheimer's disease may lead to higher demand for long-term and special care, putting constraints on healthcare expenditure and resource utilization and thus threatening the sustainability of the Japanese health system.[7]

Third, Japan is experiencing rising prefectural variations in the burden of disease.[8] For example, our study from 2017 found that Shiga Prefecture, located in the western region of Japan's main island of Honshu, had the highest number of diseases with mortality and DALY rates that are significantly lower than the national mean (sixteen for mortality and twelve for DALYs out of the

[6] Nomura et al., "Population Health and Regional Variations of Disease Burden in Japan."

[7] Naoki Ikegami et al., "Japanese Universal Health Coverage: Evolution, Achievements, and Challenges," *Lancet* 378, no. 9796 (2011): 1106–15.

[8] Nomura et al., "Population Health and Regional Variations of Disease Burden in Japan"; and Yoshiharu Fukuda, Hiroyuki Nakao, Yuichiro Yahata, and Hirohisa Imai, "Are Health Inequalities Increasing in Japan? The Trends of 1955 to 2000," *BioScience Trends* 1, no. 1 (2007): 38–42.

TABLE 2 Top ten causes of DALYs in Japan

Rank in 2015	Cause	Type of cause	Change in number of DALYs from 2005 (%)	Change in age-standardized DALY rate from 2005 (%)
1	Ischemic heart disease	Chronic disease	7.6	-14.5
2	Lower-back and neck pain	Chronic disease	6.7	-0.1
3	Sense organ diseases	Chronic disease	22.7	0.8
4	Cerebrovascular disease	Chronic disease	-0.7	-21.4
5	Alzheimer's disease	Chronic disease	49.6	3.3
6	Lower-respiratory infections	Infectious disease	22.4	-10.8
7	Lung cancer	Chronic disease	8	-11.1
8	Self-harm (mostly suicide)	Injury	-8.8	-5.3
9	Stomach cancer	Chronic disease	-4.5	-20.6
10	Colorectal cancer	Chronic disease	11.4	-6.4

SOURCE: Institute for Health Metrics and Evaluation, "Global Burden of Disease Study 2015."

NOTE: DALYs represent disability-adjusted life years; ranking is based on the number of DALYs from each cause.

twenty leading causes).[9] Hence, Shiga had the highest life expectancy at birth in 2015 (84.7 years). By contrast, Aomori Prefecture in the northernmost part of Honshu recorded the lowest life expectancy at birth in 2015 (81.6 years) and had the highest number of diseases. At the same time, Aomori had mortality and DALY rates that were significantly higher than the national mean (thirteen for mortality and eleven for DALYs out of the twenty leading causes).

The reason for the health inequalities across prefectures is still little understood. In our article for the *Lancet*, we found no significant correlations between the age-standardized mortality or DALY rate in 2015 and health expenditure per capita in 2015 and health workforce density in 2014.[10] Known risk factors (behavioral, metabolic, and environmental and occupational risks) were also homogeneously distributed across prefectures. However, variations in lifestyle, socioeconomic status, and poverty trends in each prefecture have not been fully analyzed. Here, health system performance, which varies across the country, is often a greater contributor than other factors in addressing health inequalities.[11]

[9] Nomura et al., "Population Health and Regional Variations of Disease Burden in Japan."

[10] Ibid.

[11] The WHO defines a health system to include all the activities whose primary purpose is to promote, restore, or maintain health. The assessment goals of health system performance should be expressed in terms of outputs (readiness/quality of program activities), outcomes (program results), and impacts (program effects), which will likely relate to health status, rather than inputs and processes (program infrastructure). See WHO, *World Health Report 2020—Health Systems: Improving Performance* (Geneva: WHO, 2000).

Visions for Japan's Healthcare Policy

Efforts to reform Japan's health system are guided by several underlying values and principles. Yasuhisa Shiozaki, the former minister of health, labour and welfare, established the Health Care 2035 Advisory Panel in June 2015, which brought together young leaders on health policy from within and outside the ministry to develop a long-term strategy for the next twenty years.

Their report—*The Japan Vision: Health Care 2035*—proposes a paradigm shift that would transform Japan's current health system into a multidisciplinary system in the era of superaging.[12] The core principles would shift from the provision of identical services uniformly across whole populations toward services that target individual needs and continuously value equality and solidarity. The focus of this new system would shift from hospital-centered care toward patient-centered long-term care within communities as well as proactive interventions to improve patients' lifestyles and behavior, workplace environment, and housing conditions, among other factors. The report also recommends that the principles of Japan's health system shift from curative care toward care that improves quality of life, including mental and social well-being, especially for those living with long-term or chronic illness.[13] The pillars of this vision include healthcare professionals, information sharing, and sustainable financing.

Healthcare professionals. In the next twenty years, Japan will likely face healthcare workforce shortages. In an aging society, people are expected to experience more chronic diseases and multimorbidity, which often require care by professionals from both the healthcare and social care sectors. Thus, Japan must promote educating and training its workforce to be capable of performing multiple functions in both service sectors. Other endeavors include shifting and sharing tasks among health workers, which increases service delivery capacity by delegating some tasks from higher-level to less-specialized workers. These will concurrently support the growth of an integrated community care system (ICCS).

Information sharing. With regard to healthcare governance at lower levels, it is necessary to help prefectures better use comparative health data to analyze and understand population needs and appropriately allocate resources through cutting-edge information and communications technology (ICT). These efforts will lead to improved quality of healthcare and support further reorganization of the healthcare system through adjustments to key elements, including hospital functions and the number of inpatient beds.

Sustainable financing. Progressive population aging also could put the future of the Japanese healthcare system in a dire financial situation. It is therefore critical that Japan adopt measures to make the system financially sustainable. To ensure the sustainability of public funding, various strategies should be considered, including increasing existing taxes and imposing new taxes on products that are known to adversely affect health, such as tobacco, alcohol, and sugar. Implementing policies that tax pollution and other actions that are harmful to the environment could also play a positive role.

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[12] Ministry of Health, Labour and Welfare (Japan), *The Japan Vision: Health Care 2035* (Tokyo, 2015). See also Hiroaki Miyata et al., "Japan's Vision for Health Care in 2035," *Lancet* 385, no. 9987 (2015): 2549–50; and Michael R. Reich and Kenji Shibuya, "The Future of Japan's Health System—Sustaining Good Health with Equity at Low Cost," *New England Journal of Medicine* 373, no. 19 (2015): 1793–97.

[13] Miyata et al., "Japan's Vision for Health Care in 2035."

Recommendations

Despite the challenges discussed above (e.g., morbidity expansion due to health transitions and growing health variations between prefectures), Japan—a front runner in the era of superaging—has great potential to improve the health of its population. We propose the following three major recommendations to help guide policy agendas, including *The Japan Vision: Health Care 2035*, and prioritize policies for promoting population health in Japan in a sustainable manner.

Strengthen the Prevention of Risk Factors

Further progress in improving public health primarily depends on the prevention of major risk factors for noncommunicable diseases, such as smoking, dietary risks, and metabolic risks—the leading risks of death and DALYs in the Japanese population in 2015 (see **Table 3**). A comprehensive package of preventative measures should be encouraged in order to lower the effect of risk factors of metabolic syndrome, including by improving unhealthy lifestyles and diet (mostly due to high sodium levels) and increasing the coverage of antihypertensive drugs. This package would be

TABLE 3 Top five risk factors for deaths and DALYs in Japan with proportion of total deaths/DALYs attributable to each risk factor

	Rank in 2015	Risk factor for deaths (%)	Risk factor for DALYs	Type of risk factor
Men	1	Smoking (18.9)	Dietary risks (13.8)	Behavioral
	2	Dietary risks (18.8)	Smoking (12.5)	Behavioral
	3	High systolic blood pressure (15.0)	High systolic blood pressure (10.1)	Metabolic
	4	High fasting plasma glucose (7.1)	High fasting plasma glucose (6.7)	Metabolic
	5	Alcohol and drug use (5.5)	Alcohol and drug use (6.1)	Behavioral
Women	1	Dietary risks (18.0)	Dietary risks (9.5)	Behavioral
	2	High systolic blood pressure (17.4)	High systolic blood pressure (7.9)	Metabolic
	3	High fasting plasma glucose (7.6)	High fasting plasma glucose (5.5)	Metabolic
	4	High total cholesterol (6.6)	Impaired kidney function (3.2)	Metabolic
	5	Impaired kidney function (5.8)	Smoking (2.8)	Behavioral

SOURCE: Institute for Health Metrics and Evaluation, "Global Burden of Disease Study 2015."

NOTE: DALYs represents disability-adjusted life years; ranking is based on the proportion of total deaths or DALYs attributable to each risk factor.

particularly relevant given evidence suggesting that Japanese might be genetically susceptible to being overweight or to developing diabetes mellitus.[14] In April 2008 the government commenced a screening and intervention program specifically targeting metabolic syndrome. People aged 40–74 years are eligible to have an annual health checkup and a health education intervention, although the program's effectiveness is not yet well-evaluated.[15]

Importantly, tobacco smoking has a striking effect on population health. Despite its well-known harmful effects, smoking is still commonplace in Japan, where 30% of men and 10% of women smoke today.[16] The country should adopt more drastic measures to discourage the consumption of tobacco products. In 2017 the Ministry of Health, Labour and Welfare attempted to introduce its strictest smoking policy to date. The law would have banned smoking on the premises of public facilities, such as restaurants and bars, hospitals, and municipal offices, with the long-term goal of making the 2020 Tokyo Olympics smoke-free. The policy was strongly supported by the general public, patient groups, researchers, and practicing health professionals, including the Japan Medical Association.[17] However, it was fiercely opposed by pro-tobacco policymakers, the tobacco industry (led by Japan Tobacco Inc.), and bar and restaurant owners concerned about the effect the ban would have on revenue.[18]

One of the prevailing arguments in opposition to a ban is the assertion that prohibiting smoking in public places may harm restaurants and other businesses. However, this assertion has been disproved by a number of studies. In New York City, for example, one year after the 2003 Smoke Free Air Act banning smoking in all workplaces went into effect, restaurant and bar tax receipts increased by 8.7%, and employment subsequently grew by 10,600 jobs.[19] In response to the Ministry of Health, Labour and Welfare's proposed smoking ban, pro-tobacco lawmakers suggested that Japan should instead focus on policies that segregate smoking and nonsmoking areas in public places (i.e., the creation of designated smoking rooms).[20] However, such an unrestrictive ban is likely to be ineffective in preventing "passive smoking" among children and nonsmoking adults through the inhalation of secondhand smoke.

Promote Local Governments' Stewardship of Integrated Services

As an aging society, Japan experiences higher rates of chronic disease and multimorbidity. To allocate healthcare resources more efficiently and ensure that funding is sustainable in different

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14 Naoki Sakane et al., "Beta 3-Adrenergic-Receptor Polymorphism: A Genetic Marker for Visceral Fat Obesity and the Insulin Resistance Syndrome," *Diabetologia* 40, no. 2 (1997): 200–204; and Toshihide Yoshida et al., "Mutation of Beta 3-Adrenergic-Receptor Gene and Response to Treatment of Obesity," *Lancet* 346, no. 8987 (1995): 1433–34.

15 Ministry of Health, Labour and Welfare (Japan), "Tokuteikenshin Tokuteihokenshidou ni tsuite" [Standard Health Examination and Guidance Program], 2008, http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000161103.html.

16 Japan Tobacco Inc., "Kitsuensharitsu" [Smoking Rates], 2016, https://www.jti.co.jp/corporate/enterprise/tobacco/data/smokers/index.html.

17 Yusuke Tsugawa, Ken Hashimoto, Takahiro Tabuchi, and Kenji Shibuya, "What Can Japan Learn from Tobacco Control in the UK?" *Lancet* 390, no. 10098 (2017): 933–34; and Japan Medical Association, "Jyudoukitsuen wo kyouka jitsugen surutameno shomeikatsudou shuuryou no gohoukoku to orei" [Petition to Support a Policy That Prevents Secondhand Smoke], 2017, http://www.med.or.jp/people/info/people_info/005096.html.

18 Justin McCurry, "Japan Urged to Go Smoke-Free by 2020 Tokyo Olympics," *Guardian*, January 31, 2017, https://www.theguardian.com/world/2017/jan/31/japan-urged-to-go-smoke-free-by-2020-tokyo-olympics; and Marissa Payne, "'How Would I Live If Smoking Is Banned?' Japanese Politicians Decry Calls for Smoke-Free Olympics," *Washington Post*, May 2, 2017, https://www.washingtonpost.com/news/early-lead/wp/2017/05/02/how-would-i-live-if-smoking-is-banned-japanese-politicians-decry-calls-for-smoke-free-olympics.

19 "The State of Smoke-Free New York City: A One-Year Review," New York City, 2004, https://www.tobaccofreekids.org/assets/content/pressoffice/NYCReport.pdf.

20 "Japan's Tobacco Lobby Fires Up as Government Pushes Ahead with Tougher Smoking Laws," *Japan Times*, March 13, 2017, http://www.japantimes.co.jp/news/2017/03/13/national/social-issues/japans-tobacco-lobby-fires-government-pushes-ahead-tougher-smoking-laws/#.WQbzgVOGPUI.

local contexts, the authority and responsibility of local governments in creating and implementing health policy should be clearly defined and strengthened.

As proposed in *The Japan Vision: Health Care 2035*, Japan is striving to establish an ICCS by 2025.[21] This would be a comprehensive system that provides communities with appropriate living arrangements, healthcare, and social services, such as daily life support that supplements end-of-life care in long-term-care settings. The system would be funded through the long-term-care insurance system.[22]

Nurses would play an important role in the ICCS by working on a team alongside social workers and care managers, as well as community volunteers working under the supervision of nurses. The establishment of an ICCS will require strong stewardship by local governments, given that the contexts for healthcare and other social care are locally differentiated. For example, each prefectural government is required under the Medical Service Act (amended in 2014) to develop its own community health vision. Local leaders are expected to present models for ideal healthcare service for their communities.[23] In doing so, the data and information needed to implement this vision will be gathered, analyzed, and shared; healthcare demand will be estimated; and interested bodies and stakeholders in the prefecture will discuss healthcare service provisions.

Because the evaluation of these reforms to establish an ICCS is still in the early stages, more attention and caution should be paid to measuring performance. Also, in order to ensure the successful performance of the ICCS, Japan needs to empower local planning entities that can expand regional autonomy. This should facilitate dialogue and decision-making among groups that have not previously collaborated, including local governments, local medical associations, private industries, and civil society groups.

Enhance Health System Performance and Assessment

Prefectural governments face the challenge of improving the performance of their health systems amid aging demographics, increasing multimorbidity, and growing concerns about financial stability. One of the key measures required to improve health system performance is insurance reform, such as the consolidation of social health insurance plans at the prefectural level.[24] This would not only improve the fairness of premium contributions and copayment settings but also boost the authority of the prefectural governments.[25] They would then have a mandate to exert tighter supervision and control over the provision of healthcare to more efficiently allocate resources in the prefecture.

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21 Ministry of Health, Labour and Welfare (Japan), "Chiikihoukatsu kea sisutemu" [Integrated Community Care System], http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/hukushi_kaigo/kaigo_koureisha/chiiki-houkatsu.

22 The long-term-care insurance system was introduced in 2000 to meet the challenges of Japan's aging society and to contain health expenditures. Its beneficiaries are those requiring long-term care or support services, including nursing care and day service. The insured must be certified as being in the condition requiring such services due to having dementia or being bedridden. This system is primarily funded through compulsory contributions by those over 40, general taxation, and copayments by the insured of 10% of the cost of services. The managing entities (insurers) of the long-term-care insurance system are the municipalities.

23 Yohsuke Takasaki et al., "Health Care Reform through Demographic Transition—The Case of Japan: Integrated Community Care System for Sustainable UHC and Society," Japan Center for International Exchange, 2016.

24 Kenji Shibuya et al., "Future of Japan's System of Good Health at Low Cost with Equity: Beyond Universal Coverage," *Lancet* 378, no. 9798 (2011): 1265–73. In addition to long-term-care insurance, there are three main types of health insurance in Japan: employee's health insurance (EHI), national health insurance (NHI), and late elders' health insurance (LEHI). EHI is provided to employed workers (company employees) and their dependents and is insured by several insurers, mostly depending on the size of the company. Meanwhile, NHI is designed for people who are not employed and are under 75, and it is insured by municipal governments. The people who are not eligible for either EHI or NHI, including self-employed persons over 75, are enrolled in LEHI, which is insured by prefectures.

25 Ikegami et al., "Japanese Universal Health Coverage."

This option recently became more realistic after the Ministry of Health, Labour and Welfare announced its intention to consolidate citizens' health insurance (for the unemployed, self-employed, and retirees) within all prefectures. Under this reform, prefectural governments will assume fiscal responsibility from municipal governments for citizens' health insurance by 2018 in order to stabilize management and equalize services and premium contributions among different municipalities within a prefecture.[26]

The performance of the health system must be monitored and assessed to ensure accountability and to enhance quality through peer competition. As emphasized in *The Japan Vision: Health Care 2035*, national and prefectural governments should invest in health ICT to exploit the potential for big data to assist in identifying the bottlenecks of the current health system, improve the delivery of health services, and promote efficient use of health resources. For example, a new platform called the Person-centered Open PLatform for wellbeing (PeOPLe) is an endeavor to make the best use of data on population health and health system performance. This initiative was proposed by the Ministry of Health, Labour and Welfare in October 2016 and is expected to be implemented by 2020.[27] This is an open-data platform that integrates personal data from electronic medical records, including on insurance claims, immunizations, and checkups.

Conclusion

Japan is at the forefront of developing policy solutions to deal with the challenges of population aging. The country faces an increase in the burden of age-related morbidity and growing health inequalities across prefectures, among other public health issues. Moving forward, it will be important for Japanese policymakers to strengthen the prevention of key risk factors, promote local and regional stewardship for integrated services, and enhance health system performance and assessment in order to further improve population health and reduce inequity. Given the position of Japan as a global leader that has previously achieved excellent population health at a relatively low cost, its development of policies on population aging will likely add perspective to debates in other countries. With these factors in mind, now is an opportune time for Japan to work to ensure the sustainability of its public health achievements over the past 50-plus years.

[26] Takasaki et al., "Health Care Reform through Demographic Transition."

[27] Ministry of Health, Labour and Welfare (Japan), "ICT wo katsuyou shita jisedaigata hokeniryou sisutemu no kouchiku ni mukete" [Toward the Construction of a Next Generation Health Care System Utilizing ICT], 2016.

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