

Testimony before the U.S.-China Economic and Security Review Commission

Hearing On: “A Healthy Relationship? Assessing the Risks and Opportunities of China’s Medicine and Health Development”

July 31, 2019

Benjamin A. Shobert

Author, *Blaming China: It Might Feel Good but It Won’t Fix America’s Economy*; Senior Associate, National Bureau of Asian Research; Director, Healthcare Strategy, Microsoft

Across Washington DC, the last three years have been marked by a recognition that much of what has been taken for granted in the US-China relationship specifically, and globalization more generally, needs to be re-assessed. Given the extent to which an increasingly normalized relationship between the US and China had been assumed, and taken into account during the construction of critical supply chains such as those in pharmaceuticals and medical devices, much of this re-thinking process has been jarring, and has provoked policymakers and politicians to re-think assumptions that have undergird the global economy for nearly three decades.

For industry, long standing concerns over issues such as market access and intellectual property (IP) theft in China appear to have reached a breaking point over the last two years, in particular across a variety of high technology industries, with at least one notable exception relevant to this hearing: healthcare¹. Whether the U.S-China Economic and Security Review Commission (USCC) should assume in its recommendations to Congress that healthcare will remain a durably unique high technology sector, not subject to the strains and fissures that mark other high technology industries such as telecommunications, clean-technology and semiconductors, requires a dispassionate assessment of the risks and opportunities posed both to American businesses and consumers by China’s current role in the global healthcare economy.

Healthcare has been commonly thought of as being different than other high technology industries due to several factors. First, and perhaps most critically, because healthcare remains an industry where nearly all those who contribute to its advancements believe deeply in their responsibility to better their fellow man, whether through development of new products, or in-person administration of care to the sick. Second, because healthcare is inexorably linked to those public health concerns that most governments hold front and center to their legitimacy, they make a concerted effort to balance between the needs of the public and industry in ways other sectors cannot (admittedly, not always in ways that either finds satisfying). Third, that few technological improvements cascade across the globe more quickly than those in healthcare, perhaps as best demonstrated by the increase in human longevity over the last century. Fourth, that certain research and development (R&D) heavy healthcare sectors, such as those in precision medicine, require a very special ecosystem that is not easily replicated by the brute force of industrial planning.²

¹ Note: For the purposes of this written testimony, unless otherwise explicitly stated, “healthcare” will represent healthcare services (hospitals, senior care, home healthcare, skilled nursing, etc.), as well as life science, pharmaceuticals, and medtech (durable medical equipment, disposables, surgical devices, etc.).

² Joseph Wong, *Betting on Biotech: Innovation and the Limits of Asia’s Development State* (Ithaca: Cornell University Press, 2011), 165.

For the last thirty years, these four factors have also benefited from a set of shared beliefs that, until recently, supported the narrative for why high technology companies in other sectors also wanted to be in China: the size of the Chinese market, its relative immaturity relative to the products and services available in western markets, and the Chinese government's appetite for foreign direct investment (FDI) in these sectors.³ And yet, for all of the reasons why the healthcare market in China should be seen as continuing to be full of opportunity, the last several years have begun to demonstrate that while healthcare may be unique in certain ways, it is not so different as to entirely escape the pressures that other high technology sectors have found to be problematic in China. Understanding how the risks and opportunities for the medicine and health sectors in China are changing, and their potential impact on American industry and patients, requires being grounded in several critical aspects of the Chinese healthcare sector.

China-Specific Healthcare Context

Chinese policymakers approach the healthcare sector with five concerns, only three of which should be thought of as unique to healthcare. American policymakers would do well to understand the ways in which healthcare can, and cannot, be thought of as unique from other high technology sectors from the vantage point of their Chinese counterparts.

First, that access and affordability of healthcare services across China continue to be problems of such import as to represent potential sources of instability for the government. While today China's government can accurately say that greater than 95% of the country's rural population have government provided healthcare insurance, out of pocket spending (OOP) by the average Chinese family (rural or urban) is still well above that of its industrialized neighbors.⁴ A World Health Organization (WHO) study asserted that "China ranked 188th among 191 member states in fairness of financial contribution."⁵ For all the efforts of the Chinese government to reform its domestic healthcare system, in 2015, approximately 44% of poor families in China found themselves "impoverished because of illness."⁶ Pervasive inequalities between the quality, affordability and access to healthcare via public hospitals continue to exist between urban and rural settings in China.⁷

Second, ubiquitous *hongbao* or "red envelope" practices reflect a broken funding mechanism that places additional financial strain on Chinese families and in so doing, has come to represent the Chinese government's inability to properly fund the public healthcare system. Red envelopes have long been the way in which private citizens pay to get to the front of the line at a public hospital, or pay the physician under the table in addition to any service charges they may incur, as well as the way in which companies pay physicians to prescribe certain pharmaceuticals or

³ "What Can We Expect in China in 2019?", McKinsey, <https://www.mckinsey.com/featured-insights/china/what-can-we-expect-in-china-in-2019>.

⁴ China Power Team. "Is China's health care meeting the needs of its people?" China Power. August 29, 2018. Updated May 9, 2019. <https://chinapower.csis.org/china-health-care-quality/>.

⁵ World Health Organization. "The world health report 2000 — health systems: improving performance", WHO, 2000.

⁶ Wei Fu, "Research in health policy making in China: out-of-pocket payments in Healthy China 2030", BMJ. February 5, 2018. <https://doi.org/10.1136/bmj.k234>.

⁷ Li Zhong and Li Jun, "Lessons and prospects of Universal Health Coverage in China: the importance of equity, quality and affordability," Asian Bioethics Review, March 12, 2019.

diagnostic services.⁸ As is often the case in China, these perverse incentives have led to innovations of a sort, with *huángniú* or “scalpers”, developing a business of selling their place in line at a hospital for a fee.⁹ So to, as other high technology sectors have found in China, errors of the Chinese government’s making (in this case chronically under-funded public hospitals marked by a lack of proper oversight) can result in liabilities the private sector is held accountable for. The 2013 GSK scandal, where the company was found to be widely participating in *hongbao* payments towards doctors and government officials, has been subject to a number of interpretations, one of which is that whatever legitimate Foreign Corrupt Practices Act (FCPA) violations GSK was guilty of, their actions (and those of their competitors – both foreign and domestic) had come to be accepted as part of the cost of doing business in China.¹⁰ In this way, the inconsistent application of laws in China’s healthcare economy remain an omnipresent concern as multinational corporations (MNCs) develop sales, marketing and distribution strategies for the local market.

Third, that healthcare remains one of the few parts of the Chinese political economy where Chinese families believe the government has a very specific responsibility to perform. In healthcare we see concerns over national security (does China have adequate production capacity, and/or supply of, the relevant formulary to protect itself from public health emergencies), environmental pollution (the tainted air, water and food supply representing the reason why many families must seek out care in the first place), and corruption (the previously mentioned *hongbao* practices) intersect, and much of the time all within the four walls of a government run hospital. The 2012 Pew Research Center’s analysis of China found that during the survey period, anxieties over China’s healthcare system had more than doubled, a reflection of these concerns.¹¹ The Chinese government is widely understood by the public as being accountable for the problems in the national healthcare system, and because of this, recognizes that foreign expertise and in limited capacities, foreign investment, is useful.

While the previous three factors are unique to healthcare, the next two are not. In fact, the next two share similarities with other high technology sectors that have come under pressure in China. Because of this, these next two considerations bear a deeper analysis as to how lessons from other industries may prove relevant to healthcare.

Fourth, that healthcare – in particular the development of IP in life sciences and biotech – is somehow uniquely challenging, and that China’s historical success in other high technology sectors will not apply to healthcare. As I shared in my 2017 testimony to the USCC, “China’s pursuit of a domestic biotechnology sector may well indicate the limits of its particular centralized economic planning capability. Biotechnology does not easily line up with those other high technology sectors such as clean-technology and semiconductors where China has been able

⁸ Joseph D. Tucker, Bonnie Wong, Jing-Bao Nie, Arthur Kleinman, “Rebuilding patient-physician trust in China,” *The Lancet*. Volume 388, Issue 10047, P755, August 20, 2016.

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)31362-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31362-9/fulltext).

⁹ Jia Guo, “How Does Healthcare in the U.S. Compare With China’s?” *SupChina*. March 28, 2017.

<https://supchina.com/2017/03/28/healthcare-us-compare-china/>.

¹⁰ Zhiwu Chen, “Foreign companies are easy targets in China,” *Financial Times*. July 17, 2014.

<https://www.ft.com/content/2ee46a08-0cfb-11e4-bcb2-00144feabdc0>.

¹¹ “Growing Concerns in China about Inequality, Corruption”, Pew Research Center: Global Attitudes and Trends. October 16, 2012. <https://www.pewresearch.org/global/2012/10/16/growing-concerns-in-china-about-inequality-corruption/>.

to become a globally disruptive force. A helpful way to think of high technology areas where China has been most successful is in those areas that had been already transitioned from bench science to application engineering, and in areas where process innovation (doing more manufacturing faster and at greater scale than in developed markets), has been most impactful.”¹² Healthcare incubation ecosystems – in particular life sciences and biotech – are precious and have proven difficult to re-create. Where they have developed, it has taken decades of intentional investment and cultivation of ties between academia, venture capital, research hospitals and industry to identify ways of developing, scaling and monetizing healthcare IP.¹³ While no one should doubt China’s appetite for making these investments, a degree of caution is worth striking as to whether the country will be as successful, as quickly, as it has been in other high technology sectors.

Fifth, that China’s ability to develop a domestic healthcare sector is an essential part of its economic development strategy. As I wrote in a 2016 special report for the National Bureau of Asian Research (NBR): “Economies that have a vibrant life science community feature high-paying jobs, systems that deliberately foster innovation within academic institutions, robust protections for intellectual property (IP), and a sophisticated manufacturing infrastructure. In addition, economies that feature global champions in these high-technology fields create benefits for other industries domiciled within the same geography. The characteristics of economies that have successful life science sectors easily complement the policy agenda of the Chinese government to reframe what ‘made in China’ represents to its own people and the world.”¹⁴ While China’s ambitions in healthcare may have unique motivations versus other high technology sectors, they also share an idea and motivation; namely, that for China to continue to economically develop it will need to become a global powerhouse in higher technology industrial sectors, of which healthcare is one.

As evidenced by the growing number of domestically originated new drug submissions to China’s National Medical Products Administration (NMPA, and formerly known as the China Food and Drug Administration, or CFDA), no one should doubt China’s aspirations to successfully develop novel molecules or precision medicine capabilities, in particular with respect to efforts focused on chimeric T cell receptors (CAR-T) and Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR). In both cases, objective analysis suggests that China’s ability to make progress with respect to western R&D efforts may owe less to concerted industrial policy, and more to the lax regulatory environments within which Chinese companies operate in these two research areas in particular.¹⁵ Said differently, the lack of certain ethical oversight for CRISPR, and the regulatory approval channel CAR-T has been able to take

¹² Benjamin Shobert, Hearing On: “China’s Pursuit of Next Frontier Tech: Computing, Robotics, and Biotechnology,” March 16, 2017, U.S.-China Economic and Security Review Commission, 3.

¹³ Note: Additional context on the peculiar nature of the biotech incubation ecosystem can be found in Ajay Gautam’s book *Drugs, Politics & Innovation: An Emerging Markets Cocktail*, Partridge Singapore, March 4, 2016.

¹⁴ Benjamin Shobert, “Priming the Pump: Applying Lessons Learned from High-Tech Innovation to the Life Sciences in China”, National Bureau of Asian Research. April 2016, 27.

¹⁵ Mark Kazmierczak, Ryan Ritterson, Danielle Gardner, Rocco Casagrande, Thilo Hanemann, Daniel Rosen, “China’s Biotechnology Development: The Role of US and Other Foreign Engagement: A report prepared for the U.S. China Economic and Security Review Commission”, Gryphon Scientific and Rhodium Group, February 14, 2019, 24-25.

advantage of (a medical technology versus drug clinical trial), account for some of the velocity of Chinese efforts in these two areas, as opposed to intentional policy making.¹⁶

Yet, while we can observe an increase in the amount of domestic investment in the broader healthcare industry (in particular life science and biotech sectors), and a correlated increase in the number of domestic clinical trials, we cannot yet say that Chinese industrial policy has resulted in a thriving sector characterized by the development of new therapeutics that hold the potential to accelerate China's domestic economy by manufacturing, distributing and selling these products to the world. What we still have is a sector marked by enormous ambition and investment from both public and private sector actors in China. But, as policymakers and investors in more developed markets can attest, significant downside risks reside at the intersection of human biology, science and commercialization; China's success in this sector should not be assumed, both because past efforts to leverage industrial policy by other economies have proven unsuccessful, and because unlocking the next era of precision medicine led innovations are not scientifically nor economically assured.

These last two contextual factors both revolve around the idea of healthcare as just another high technology sector that China will be targeting. This requires special attention with respect to what the USCC has asked around risks. It is this consideration, healthcare as just another high technology vertical within which China's domestic industrial policy will be applied, that suggests caution in how risks are thought of, and designed around. Perhaps most critically, thinking of healthcare in this way allows American industry and policymakers to now reflect on and apply hard lessons learned from other, non-healthcare, high technology sectors in China. To the extent industry and policymakers outside of China now wish a more deliberate approach had been taken to how non-healthcare related high technology sectors were brought to China, we now have an opportunity to reflect on these lessons learned, and where appropriate, apply them to healthcare, to ensure the interests of both the US and China are taken into account.

Opportunities

Three opportunities continue to characterize the Chinese healthcare economy, all of which are positive for both American industry and patients.

First, the market potential. China's pharmaceutical sector is already the world's second largest, and is poised to increase in size to ~\$145 billion by 2022.¹⁷ McKinsey estimates that the Chinese healthcare economy should reach \$1 trillion by 2020.¹⁸ While the size of China's potential market is alluring regardless of industry, in healthcare China's potential plays a somewhat different role. Austerity measures driven by aging populations across western markets, alongside the transition away from fee for service to value-based care in the United States in particular, have resulted in many multinational healthcare companies aggressively seeking out new growth opportunities. The allure of the Chinese market's ability to mitigate the revenue and margin pressures faced in western markets has, in part, explained why so many

¹⁶ Ibid., 24.

¹⁷ Alex Keown, "Exponential Pharma Growth Expected in China by 2022", BioSpace, April 20, 2018. <https://www.biospace.com/article/exponential-pharma-growth-expected-in-china-by-2022/>.

¹⁸ Franck Le Deu, Rajesh Parekh, Fangning Zhang, and Gaobo Zhou, "Health care in China: Entering 'uncharted waters'", McKinsey & Company, November 2012. <https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/health-care-in-china-entering-uncharted-waters>.

multinationals (pharma and medtech in particular) have made China such a central part to their growth story.¹⁹

Second, investment. Up until the October 2018 US Department of Treasury pilot program that announced additional scrutiny would be applied to FDI (including biotech) Chinese appetite for investments in American healthcare was growing.²⁰ The Gryphon Scientific and Rhodium Group analysis of this topic from earlier this year found that “despite the recent rapid increase, the total value of outbound M&A in the pharmaceutical and biotech sectors remains relatively small at just \$7 billion in 2000-2017, which is a small fraction (two percent) of total Chinese outbound M&A in that period.”²¹ Given the American biotech venture capital sector is not currently short capital, investment monies from China are not critical.²² However, for those who have sought out Chinese capital, savvy Chinese investors have increasingly tied their willingness to deploy funds into a western biotech firm to in-licensing terms that ensure the IP in question has a route to market in China.²³ If outbound Chinese investment into American biotech companies continues to slow, so too may the market access opportunities for American biotech startups in China slow down. It is worth noting that this opportunity is quickly diminishing given the Committee on Foreign Investment in the United States (CFIUS) ruling on iCarbonX’s investment in PatientsLikeMe, a point which will be addressed later in more detail.²⁴

Third, harmonization of healthcare standards to global norms. For years, China’s pharmaceutical regulatory processes were badly out of sync with those of its developed neighbors. This resulted in treatments that could not be made available to the Chinese public. But over the last five years, Chinese regulators have turned their attention towards reforming the former CFDA (now NMPA), with striking results as measured by the velocity and number of new domestic and foreign drugs approved for use in China.²⁵ The result of these efforts to bring China’s regulatory environment up to western standards has meant that multinationals can sell their products into the Chinese market within a larger window of patent protection than had been previously afforded them. This is not only a material new source of revenue, by growing the potential total addressable market for new healthcare innovations, it is possible to spread R&D cost over more covered lives, hopefully leading to lower costs. In addition, harmonization of regulatory

¹⁹ Angus Liu, “China’s driving sales growth ahead of the U.S. for Big Pharma. But can it last?”, FiercePharma, May 28, 2019. <https://www.fiercepharma.com/pharma-asia/china-drives-growth-ahead-u-s-for-big-pharma-will-it-last>.

²⁰ Ned Pagliarulo, “US tightens scrutiny of foreign investment into biotech sector,” BioPharma Dive, October 11, 2018. <https://www.biopharmadive.com/news/us-tightens-scrutiny-of-foreign-investment-into-biotech-sector/539437/>.

²¹ Kazmierczak, et. al., 56.

²² “Another Trophy Quarter for VC-Backed Biotech Funding,” LifeSci VC, April 30, 2018. <https://lifescivc.com/2018/04/another-trophy-quarter-for-vc-backed-biotech-funding/>.

²³ “China drug in-licensing opportunities expected to swell as local pharma focus on R&D,” Pharmaceutical Technology, May 23, 2019. <https://www.pharmaceutical-technology.com/comment/china-in-licensing-deals/>.

²⁴ Christina Farr, Ari Levy, “UnitedHealth buys PatientsLikeMe, which faced Trump administration scrutiny over Chinese investor,” CNBC, June 24, 2019. <https://www.cnbc.com/2019/06/24/unitedhealth-buys-patientslikeme-after-cfius-forced-sale.html>.

²⁵ Mark Terry, “30 New Drugs from Foreign Countries Approved in China in Last 21 Months”, BioSpace, November 27, 2018. <https://www.biospace.com/article/30-new-drugs-from-foreign-countries-approved-in-china-in-last-21-months/>.

standards also ensures that innovations developed in China can be exported to markets in need more quickly than they otherwise would be.²⁶

Finally, the harmonization of China's pharmaceutical sector to global standards has important quality and safety implications to American consumers. As China continues to legitimize the enforcement capability of the NMPA, and to force consolidation of its highly fragmented pharmaceutical manufacturing sector, the ability to ensure the Chinese supply chain is up to western standards increases. The USCC has expressed specific interest on this point, and it is worth reinforcing that while the NMPA's enforcement regime is relatively new, the Chinese government is very invested in ensuring they comport to global standards, both to ensure the quality, safety and efficacy for domestic consumption, as well as to ensure that Chinese novel molecules can be exported and adopted by the global market.²⁷

Risks

Five risks will need additional attention from American policymakers, in particular as they relate to lessons we should learn from the experiences of other high technology sectors in China, and those questions posed by the USCC commissioners.

First, the impact of ongoing trade tensions on bilateral investments and on supply chain uncertainties, each of which has unique characteristics within the healthcare sector: anxieties over where your new iPhone will be made is one thing. Concern over where your antibiotics or hypertensives come from is quite another. The world, not just America, has become increasingly dependent on China as its source for manufacturing pharmaceuticals. Even India, known for its unique policy and industrial environment with respect to pharmaceuticals, now has taken a dependency on Chinese manufacturing to such an extent that it is estimated 80% of India's active pharmaceutical ingredients (APIs) originate from China.²⁸

A global trade war on the basis of telecommunication equipment carries with it the risk of destabilizing the economy. A global trade war which has repercussions to medicines that are currently widely available, and at reasonable costs, would have much more deleterious effect. Whether America should have taken this dependency on foreign manufactured pharmaceuticals is not a question best directed at the US-China relationship. Rather, if American policymakers want to ensure that a certain national formulary is widely available to the public in case of crisis, policies around domestic production and inventory would be appropriate. It is worth calling attention to the point that this concern – taking a dependency on China for pharmaceutical products in particular – has historically been understood as one of the reasons the US-China relationship can and should be thought of as safe and stable. It is now interpreted through the

²⁶ Note: The export of the Ebola vaccine Ad5-EBOV, by CanSino Biologics Inc. is one early example of this. See Angus Liu, "China approves domestic Ebola vaccine developed from recent outbreak," FiercePharma, October 24, 2017. <https://www.fiercepharma.com/vaccines/china-approves-self-developed-ebola-vaccine-from-2014-outbreak-virus-type>.

²⁷ Eric Ng, "Why most small players may not survive China's pharmaceutical industry consolidation: Strategy aims to turn China's predominantly off-patent drug copying pharmaceutical industry into one that's capable of coming up with innovative patentable products," South China Morning Post, January 31, 2018. <https://www.scmp.com/business/companies/article/2131230/why-most-small-players-may-not-survive-chinas-pharmaceutical>.

²⁸ Arun Sreenivasan, "China crackdown on polluting firms leaves Indian pharma industry in quandary as API prices rise 40% in four months," PharmaBiz, July 13, 2018. <http://www.pharmabiz.com/NewsDetails.aspx?aid=109959&sid=1>.

lens of fear, and the deeper anxieties about the troubled state of relations between the two countries should not be missed by anyone. If we indeed believe America can take calculated dependencies on China for critical components to modern life – medicine being chief among these – then we are still working in good faith. However, if we no longer believe that America can do so, much of what has supported the modern era of globalization is no longer valid.

Second, CFIUS' role in evaluating Chinese FDI into the American healthcare sector. The April 2019 determination by CFIUS that the Chinese digital healthcare company iCarbonX would have to divest its \$100 million investment in the American patient healthcare platform PatientsLikeMe has drawn significant attention by both American and Chinese investors.²⁹ There are several important risks this has surfaced. CFIUS' ruling is understood to be largely a function of concerns within the American government of allowing a Chinese company to have access to a large set of American personally identifiable information (PII), including personal health information (PHI).³⁰

Trade lawyers familiar with the CFIUS process have been quick to point out that it does not appear iCarbonX pursued the appropriate CFIUS pre-approvals to ensure the deal would meet their standards.³¹ Consequently, the October 2018 interim regulation that implemented updates to the Investment Risk Review Modernization Act (FIRRMA) and which pays particular attention to “target industries” with “critical technologies” and “sensitive personal data of United States Citizens” set CFIUS and iCarbonX on a collision path.³² The specific risk CFIUS was worried about had to do with how American PHI would be exposed to a Chinese company whose business model required exposure of said PHI to artificial intelligence systems. The resulting machine learned (ML) models would have been trained on American PHI collected as part of the PatientsLikeMe platform, among other data sources (including Chinese PHI). It was unclear to American regulators whether this training activity would have taken place in computer system domiciled within the United States or China, and attempts by iCarbonX to dissuade CFIUS that the training in question could be limited to American computers was deemed inadequate.

CFIUS undoubtedly has an important job to do with respect to guarding America's national security, including the privacy of American citizens. The unique “claw-back” or “disturbance” rights CFIUS possesses means that any foreign investment deemed to cross a national security or privacy line can be deemed illegitimate and mitigation by the foreign company required. This, coupled to the current US-China trade war, has resulted in a dramatic decrease of Chinese

²⁹ Christine Farr, Ari Levy, “The Trump administration is forcing this health start-up that took Chinese money into a fire sale,” CNBC, April 4, 2019, <https://www.cnbc.com/2019/04/04/cfius-forces-patientslikeme-into-fire-sale-booting-chinese-investor.html>.

³⁰ Harry Clar, Betty L. Louie, Jeff Zhang, and Xiang Wang, “Grind and PatientsLikeMe Outcomes Show Non-Cleared Transactions’ Exposure to CFIUS Scrutiny, Especially When PII Is Involved,” Orrick, April 23, 2019. <https://www.orrick.com/Insights/2019/04/Grindr-and-PatientsLikeMe-Outcomes-Show-Non-Cleared-Transactions-Exposure-to-CFIUS-Scrutiny#>.

³¹ “CFIUS Developments: Notable Cases and Key Trends,” Gibson Dunn, April 24, 2019. <https://www.gibsondunn.com/cfius-developments-notable-cases-and-key-trends/>.

³² Michael E. Leiter, Ivan A. Schlager, Donald L. Vieira, Daniel J. Gerkin, Michelle A. Weinbaum, “CFIUS Pilot Program Expands Jurisdiction to Certain Noncontrolling Investments, Requires Mandatory Declarations for Some Critical Technology Investments,” Skadden, Arps, Slate, Meagher & Flom LLP, October 11, 2018. <https://www.skadden.com/insights/publications/2018/10/cfius-pilot-program-expands-jurisdiction>.

investment in American biotech: the first half of 2019 has seen a 60% reduction in American biotech firms by Chinese venture capital.³³

Third, differences in the appetites for investment and risk by the American and Chinese political systems. Across the globe, national governments are standing up large biobank initiatives. In 2016, the United States launched the 21st Century Care Act, with \$6.3 billion in funding, to include a variety of population health data.³⁴ In 2013, the United Kingdom established Genomics England, a program designed to sequence 100,000 genomes.³⁵ Similar efforts are in motion in Canada, Japan, Thailand, Qatar and Latvia. China meanwhile has been even more ambitious, with a variety of national and provincial efforts ranging in scope and budget, but all designed to create datasets that include genetic information. One of the more widely referenced examples in China is the China National GeneBank, which aims to have genetic material from 10 million different bio-samples.³⁶ The range of activities vary across each of these efforts, but they typically include a fully sequenced human genome, tied to a longitudinal health record (the electronic capture of an individual's healthcare, including lab data).

What these initiatives share in common is not just the advancement of human knowledge: these curated data sets serve as the foundation to the 21st century's biotech industry. The greater diversity, quality and quantity of data available to researchers should in turn result in accelerated precision medicine development, which should result in companies being able to spin out new therapeutics and diagnostics predicated on access to these privileged data sets. Justifying government led investments in these data sets has become increasingly difficult, in the US in particular.

If American policymakers do not incentivize the development of equally large and technically rich data sets in the United States as are available in China, we are foregoing a significant opportunity both economically, and from a public health point of view. To the extent the USCC is particularly invested in preventing the United States from falling behind China, or to taking an even greater dependency on Chinese healthcare products, strategies to deepen American investment in the development of these curated data assets will be required.

Fourth, asymmetric data access standards and policies between the US and China, and their impact on economic competitiveness and consumer privacy. The previously mentioned data assets are the result not only of a citizen's PHI, they also exist as a result of public sector financing of these biobank initiatives. The public anticipates a return on its investment in the form of advanced therapeutics, as well as the development of new companies who successfully commercialize their offerings, enriching the economy as a result. However, as currently

³³ Tom Hancock and Hannah Kuchler, "Chinese VC spending on US biotech hit by security reviews," Financial Times, July 8, 2019. <https://www.ft.com/content/6d647f7e-a13a-11e9-974c-ad1c6ab5efd1>.

³⁴ Trudy Lieberman, "With media watchdogs on the sidelines, pharm-funded advocacy groups pushed Cures Act to the finish line," HealthNewsReview.org, December 6, 2016. <http://www.healthnewsreview.org/2016/12/with-media-watchdogs-sidelined-pharma-funded-advocacy-groups-pushed-cures-act-to-the-finish-line/>.

³⁵ James Gallagher, "DNA project 'to make UK world genetic research leader,'" BBC, August 1, 2014. <https://www.bbc.com/news/health-28488313>.

³⁶ Zhuang Pinghui, "China opens first national gene bank, aiming to house hundreds of millions of samples," South China Morning Post, September 22, 2016. <https://www.scmp.com/news/china/article/2021623/chinas-noahs-ark-first-national-gene-bank-opens-shenzhen>.

embodied in both law and practice, American researchers do not have equal ability to work with Chinese PHI, as do Chinese researchers with American PHI.

De-identified PHI from Americans may be shared across borders, provided the de-identification process meets the Health Insurance Portability and Accountability Act (HIPAA).³⁷ However, as the Gryphon-Rhodium report from February 2019 makes clear: “Only a Chinese entity may apply for such a permit; therefore, the only lawful way for international entities to access Chinese genetic data is through collaboration with a Chinese institution. All collaborations involving genetic data must be approved by the participating institutions and by the China Administration of Human Genetic Resources. Chinese entities partner with a foreign institution must state the purpose of the collaboration, the duration of the collaboration, and any plans for sharing and ownership of IP.”³⁸ Such a regulatory approach by the Chinese government may in fact be perfectly reasonable, but it must be symmetric with the same approach to how PHI is shared across borders by the US government. A more elastic posture on the part of the American government, who is now revisiting the consequences of taking more liberal approaches to asymmetric policies between the US and China in other non-healthcare arenas, may not be appropriate, in particular with respect to something as sensitive as PHI.

On this point, it is important to not get ahead of the facts. It has been suggested that Chinese access to American PHI could result in their ability to design the perfect bioweapon, targeted only at Americans.³⁹ This makes for good science fiction, but thus far quite bad science; and, in being bad science, it runs the risk of being both inflammatory and counter-productive. What American policymakers should care about is not disincentivizing the development of large Chinese biobanks with vast quantities of PHI. What American policymakers should care about is that we are making similar investments, and that America and China have agreed upon protocols specific to de-identification and bilateral cross-border data sharing, so as to ensure the pace of progress in healthcare continues to accelerate.

Fifth, the trade-off between high volume and low profit, as embodied by the Chinese government’s tendering process. This concern is nothing new, but continues to be a risk that will require attention, and possibly discussion as part of the U.S.-China Comprehensive Economic Dialogue (CED), as it has been in prior administrations. Specifically, the ongoing pricing pressure that American multinationals are under in the pharma sector in particular, as it relates to their ability to access broader portions of the Chinese healthcare system (the public hospital formulary, and its reimbursement system in particular) will need ongoing attention.⁴⁰

The Intersection Between Artificial Intelligence and Healthcare

In many important ways, the USCC’s questions lay the groundwork for one of the more critical matters that needs Congress’ attention: the intersection between artificial intelligence (AI) and

³⁷ “Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule”, Health and Human Services, <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html>.

³⁸ Kazmierczak, et. al., 129.

³⁹ Davd J. Lynch, “Biotechnology: the US-China dispute over genetic data,” Financial Times, July 31, 2017. <https://www.ft.com/content/245a7c60-6880-11e7-9a66-93fb352ba1fe>.

⁴⁰ David Shen, “China announces pilot scheme for pharmaceutical tendering with minimum procurement quantities,” Allen & Overy LLP, December 5, 2018. <https://www.lexology.com/library/detail.aspx?g=8cdd2be6-8e6f-4b81-8582-e3ea87cbca43>.

healthcare in China. Currently, several city-specific AI initiatives in China represent significantly larger investments in AI than the US government is planning to make in total.⁴¹ This represents a very real challenge to the ability of AI dependent healthcare companies in the US building out their technology stacks, identifying use cases, and ensuring insights can be derived and applied to the benefit of American patients.

Large biobanks are not the only healthcare data asset national governments care about, and are investing in. China's Ministry of Science and Technology has established a number of programs designed to collect and centralize other types of data, including not only the previously mentioned genomic and longitudinal health record data, but also imaging records such as those from magnetic resonance imaging (MRI) and computed tomography (CT) scans.⁴²

AI's ability to develop new use cases hinges on access to large quantities of training data, and no country in the world is as serious about funding this aggregation of data across a number of disparate verticals, than is China. As American policymakers wrestle with questions around asymmetric data access policies between the US and China, it would be wise to keep in mind that American healthcare and technology companies stand to benefit if promulgated policies in both countries were to exist that allowed training on both countries' data sets. At current investment levels, China will amass a much larger and more diverse healthcare specific set of data upon which to train AI than will the United States. This point must be reinforced: it is in the interests of American industry and patient care to ensure that our companies and research institutions can train on these data sets, and if they cannot, to diligently work to build up equivalent resources upon which American AI companies can train.⁴³

As with the analysis of China's progress in CAR-T and CRISPR, some of these advancements are the result of differences in regulatory standards between the two countries. In the case of how Chinese researchers train on large healthcare data sets, China does not have the same oversight as American researchers are obligated to under an Institutional Review Board (IRB).⁴⁴ What this means in practice is that Chinese researchers and entrepreneurs not only have access to differentiated data sets, they can also work with them more easily than their American counterparts can work with data assets that reside within their home country.

There are other rate limiting factors for the adoption of AI in healthcare, and it may well be that China could develop AI faster not only because of those previously mentioned advantages, but also because the healthcare delivery vehicles in China are so different, and already so manpower constrained, as to make the patient, physician and payer willing to turn certain parts of the workflow and patient experience over to technology, where an equivalent patient journey in the United States would be actively resisted. Regardless of these considerations, the USCC would

⁴¹ Luiza Ch. Savage and Nancy Scola, "'We are being outspent. We are being outpaced': Is America ceding the future of AI to China?" POLITICO, July 18, 2019, <https://www.politico.com/story/2019/07/18/global-translations-ai-china-1598442>.

⁴² Luxia Zhang, "Big data and medical research in China," *BMJ* 2018; 360:j5910. <http://dx.doi.org/10.1136/bmj.j5910>.

⁴³ Sui-Lee Wee and Paul Mozur, "Amazon Wants to Disrupt Health Care in America. In China, Tech Giants Already Have," *New York Times*, January 31, 2018. <https://www.nytimes.com/2018/01/31/technology/amazon-china-health-care-ai.html?partner=IFTTT>.

⁴⁴ Tom Simonite, "How Health Care Data and Lax Rules Help China Prosper in AI", *Wired*, January 8, 2019.

do well to pay attention to how the era of healthcare-specific AI is informed and governed by, asymmetric data access and privacy policies between the United States and China.

Recommendations for Congress

Given the current challenges in the US-China relationship, and the lessons that should be taken from other high technology sectors and applied to healthcare, let me propose the following five recommendations for Congress:

1. **Deliberately gate Chinese FDI into American healthcare sectors based on the ability of American healthcare companies and institutional investors to make equivalent investments in China.** If American companies cannot invest within a specific healthcare sector in China, their Chinese competitors should not be able to make associated investments in the United States. Healthcare services (hospitals in particular) require attention on this front and have been part of the US Trade Representative's negotiation with Beijing over the last year.
2. **Review America's national formulary and determine how best to ensure supply chain resiliency for specific likely public health crises.** To the extent America has taken a supply chain dependency on supply of pharmaceuticals manufactured in China, American policymakers should revisit subsidies designed to encourage domestic production of specific products organized around, and prioritize by, the most likely public health crises.
3. **Pursue harmonized standards around sharing of PHI.** The first step should be a bilateral agreement on the de-identification of PHI, and the mechanisms by which de-identified PHI can be shared across borders. Ideally, this discussion should include more than just the United States and China, as how PHI will be normalized serves as a foundational element to how large data assets will be developed, curated and shared globally. As with the first recommendation, if China is not willing to agree to bilateral standards on this point, Congress should act to negate Chinese access to American PHI, even if de-identified, by Chinese researchers. CFIUS already anticipates some of this given its ability to deny proposed, or negate past, investments by foreign firms where exposure of American PII might occur. Few things are more sensitive than an individual's personal health information, and as such, this matter will require significant thought; however, the extent to which large data assets involving PHI constitute the future of economic competitiveness and development of new medicines, both countries would do well to begin thinking about how to ensure data sharing policies that address their citizen's privacy concerns.
4. **Update trade policy to reflect the era of big data, cloud computing and AI to ensure symmetric data access rights between American and Chinese companies and academic research centers.** Current trade protocols were built to address the needs of a manufacturing economy. They have struggled to accommodate the era of cloud computing, big data and AI. Congress should establish a specific review of current USTR policy with a specific view on how to modernize trade protocols with the needs of big data driven industries in mind.

5. Increase government led investment in the collection of large data sets for the purposes of AI. Estimates vary as to China's overall investment plans in AI, but as one example, the Chinese city of Tianjin plans to spend \$16 billion on a variety of AI investments over the next several years. This is larger than the total amount the US government plans to spend on the same. China has certain natural advantages in this sector, not least of which is the large amount of available labor to label training data (a key part of how machine learning systems develop new capabilities). To counteract these unique capabilities, the US government must develop an AI strategy that includes new investments spread across research institutions, government and industry. While healthcare is the focus of today's testimony, there are critical national security issues involved in ceding the era of AI to China.