

SECTION 3: U.S.-CHINA LINKS IN HEALTHCARE AND BIOTECHNOLOGY

Key Findings

- Longstanding problems in China's public health system, including funding shortfalls and bureaucratic weaknesses, have undermined the country's epidemiological preparedness. These vulnerabilities are compounded by a political atmosphere that silences and punishes healthcare workers who raise concerns about potential disease outbreaks because the Chinese Communist Party (CCP) fears such disclosures could undermine social stability. As a result, the risk of another epidemic in China will remain heightened even as Beijing attempts to improve its public health system in the wake of the novel coronavirus (COVID-19) pandemic.
- Chinese regulators have officially encouraged foreign participation in China's healthcare sector but maintain regulatory barriers that disadvantage foreign firms and hinder free competition. Most notably, Beijing has placed increasingly tight restrictions on foreign firms' ability to access and share healthcare-related data collected in China.
- The Chinese government has made the collection of domestic and foreign healthcare data a national priority and has sought access to U.S. healthcare data through both licit and illicit means. Chinese entities have gained access to U.S. healthcare data through investment in U.S. firms, sales of equipment and services, and partnerships with U.S. universities and hospitals, even as Beijing prevents U.S. entities from gaining reciprocal access to Chinese data. Chinese state-sponsored groups have also obtained U.S. healthcare data and targeted COVID-19 research by hacking U.S. healthcare providers and businesses.
- Through its scientific talent recruitment programs, the Chinese government has systematically targeted the U.S. research community, particularly participants in the biological and medical sciences. Although there are many benefits to research cooperation, Beijing has used financial inducements and other means to encourage foreign researchers to establish shadow laboratories in China that mirror federally funded research conducted in the United States and facilitate the transfer of commercially and medically valuable research to China.
- While China has made significant improvements to its healthcare system, substantial shortfalls remain. In particular, China lacks a long-term care infrastructure for its aging population and its healthcare system is underequipped to handle challenges posed by the rise in chronic disease.

- China’s policymakers are making major efforts to improve the quality and affordability of healthcare, prioritizing innovation in technologies and treatments to manage rising chronic disease. Prior to the outbreak of COVID-19, infectious disease monitoring and prevention have received comparatively less attention.

Recommendations

The Commission recommends:

- Congress enact legislation to require ancestry and health testing services to (1) require explicit consent from customers to sell, lease, or rent to any party individual data that are aggregated for the purposes of research; and (2) disclose to customers any parent company or subsidiary relationship.
- Congress establish a new U.S. national laboratory focusing on biotechnology or designate an existing U.S. national laboratory to focus on biotechnology.
- Congress consider establishing a “Manhattan Project”-like effort to ensure that the American public has access to safe and secure supplies of critical lifesaving and life-sustaining drugs and medical equipment, and to ensure that these supplies are available from domestic sources or, where necessary, trusted allies. Such a project would supplement the recommendation the Commission made in its 2019 Annual Report that Congress hold hearings with a view toward enacting legislation requiring the U.S. government to procure medicines only from U.S. production facilities or from facilities that have been certified compliant with U.S. standards.

Introduction

The CCP views its ability to deliver high-quality healthcare as an important pillar of its continuing legitimacy, especially as China’s population ages and chronic disease is on the rise. Developing new healthcare technology not only helps China improve its strained healthcare system but also promises significant economic gains—another crucial component of CCP legitimacy. As such, China’s government seeks to position China as a global leader in healthcare innovation. Chinese policymakers have set ambitious targets for improvements to the healthcare system and view the development of a strong domestic biotechnology (biotech) sector, a digital health ecosystem, and precision medicine capabilities as key means to achieve these goals. These priorities also align with Beijing’s industrial policy goals, and Chinese economic planning documents identify the development of biotech, artificial intelligence (AI), and precision medicine as areas where China wants to move up the value chain.

Beijing’s efforts to improve the quality of China’s healthcare system should present a range of opportunities for productive U.S.-China engagement. Instead, recent developments in China’s healthcare system typify Beijing’s asymmetric vision for economic development. Beijing has displayed only a limited willingness to allow foreign competition in its healthcare sector, collaborate on scientific research in an open and fair way, or share crucial public health information; instead, it has prioritized the development of its domestic health-

care sector at any cost. Even as it erects high barriers to foreign entry, Beijing has benefitted from the openness of the U.S. healthcare market and gained access to valuable talent, technology, and data. The CCP has also exploited vulnerabilities in the U.S. scientific research ecosystem to acquire and transfer new biomedical discoveries and innovative treatments. The Chinese government continues to prevent and even punish sharing of vital public health information under the guise of maintaining social stability. The COVID-19 pandemic, which has infected tens of millions of people and sent the global economy into a recession, has demonstrated the worldwide ramifications of Beijing's policy priorities.

This section reviews recent developments in China's domestic healthcare and public health systems, including the vulnerabilities revealed by the COVID-19 pandemic and policy challenges in delivering high-quality healthcare to an aging population. It also describes linkages between the U.S. and Chinese healthcare systems, each country's policies governing access to valuable and sensitive healthcare data, and the risks China's scientific talent recruitment programs pose to federally funded research in the biological and medical sciences. This section is based on the Commission's May 2020 hearing on "China's Evolving Healthcare Ecosystem: Challenges and Opportunities," contracted research, consultations with government officials, industry experts, and academics, and open source research and analysis.

China's Healthcare Aims Tempered by Long-Term Problems

The Chinese government's healthcare policy goals are aimed at building the capacity to meet the growing demand for high-quality healthcare services from China's large and rapidly aging population. Beijing is therefore pursuing a wide range of ambitious goals to spur the transformation of its currently underequipped healthcare system to meet this demand. Beijing is also encouraging investment in emerging-technology-based healthcare solutions such as biomedicine, telehealth, and AI in order to develop precision medicine capabilities that can mitigate the healthcare system's challenges.

Chronic Diseases and Aging Population Strain China's Healthcare System

Over the past decade, China has made significant progress in reducing the burden of diseases and disabilities caused by maternal, neonatal, and communicable conditions. For example, China's infant mortality rate fell from 13.1 percent in 2010 to 5.6 percent in 2019 and the maternal mortality rate fell from 30 deaths per 100 thousand to 18.3 deaths per 100 thousand over the same period.¹ Similarly, incidence rates of common communicable diseases such as viral hepatitis, measles, and malaria have all decreased significantly.² As people live longer, however, the burden of chronic disease has risen, becoming a significant focus of Chinese healthcare policy. As of 2018, 270 million people in China were estimated to suffer from hypertension, and 116.4 million lived with diabetes as of 2020.*³

*China now has the world's largest population of diabetics, though in percentage terms the burden of the disease is still slightly less than in the United States—10.9 percent of adults in China compared to 13.3 percent in the United States as of 2020. International Diabetes Federation, "IDF Western Pacific Members: China," May 14, 2020; International Diabetes Federation,

A variety of lifestyle and environmental factors, such as smoking and pollution, have also contributed to the rising incidence and lethality of chronic disease. As of 2017, high blood pressure, smoking, high-sodium diets, and particulate matter pollution were the four greatest health risk factors and leading causes of premature death in China.*⁴

China's healthcare system is underequipped to handle the growing burden of chronic disease. It is over-reliant on urban hospitals to provide basic care, and the primary care system, which should play a significant role in chronic disease management, is underutilized. Beijing's healthcare policies have long tried to foster preventative and primary care as the most cost-effective way to provide healthcare services to China's large population.⁵ However, primary care physicians, particularly those in rural areas, typically receive less training and are consequently less trusted by patients, who prefer to visit urban hospitals even for relatively minor conditions such as fevers and headaches. Moreover, as Karen Eggleston, Stanford University professor and authority on China's healthcare system, noted in testimony before the Commission, the expansion of healthcare coverage has enabled more patients to self-refer to facilities with a higher quality of care, leading to overcrowding at urban hospitals.⁶

A rapidly aging population poses another significant challenge to China's healthcare system. The UN forecasts 31.4 percent of China's population will be over age 60 by 2045.⁷ China's public health system is underprepared to provide long-term care to hundreds of millions of elderly people. This is partly because Chinese citizens are living longer than they used to, giving rise to new demand for long-term care services.† At the same time, the government did little to prepare the healthcare system to care for a large elderly population suffering from chronic conditions.⁸ More recently, China's healthcare system has made progress improving healthcare for its aging population. Nevertheless, meeting the healthcare needs of China's aging population remains a serious challenge. According to a national survey conducted in 2015 by China's National Committee on Aging, a government agency, approximately 80 percent of families seeking long-term care in China were unable to meet their needs.⁹

Beijing Seeks to Mitigate Healthcare Capacity Limitations with Digital Health

In order to address the growing healthcare challenges, the Chinese government has announced a series of ambitious reform goals. These measures include the Healthy China 2030 plan, a government initiative that adopts a mixture of general guidelines and quantita-

*IDF North American and Caribbean Members: United States," March 3, 2020; Hu Yiwei, "China's Diabetes Epidemic in Charts," *China Global Television Network*, November 14, 2019.

*According to a 2018 survey conducted by the Chinese Center for Disease Control and Prevention, smoking rates among males remain stubbornly high. Although the overall smoking rate among adults was 26.6 percent, down slightly from 27.7 percent three years earlier, the smoking rate among male adults was 50.5 percent, down from 52.1 percent in 2015. See Chinese Center for Disease Control and Prevention, *Results of the 2018 Survey of Chinese Adult Tobacco Usage—Smoking among Chinese Ages 15+ Is Decreasing* (2018年中国成人烟草调查结果发布--我国15岁及以上人群吸烟率呈下降趋势), May 30, 2019. Translation. http://webcache.googleusercontent.com/search?q=cache:b-ev_vSkYIkJ:www.chinacdc.cn/yw_9324/201905/t20190530_202932.html+&cd=1&hl=en&ct=clnk&gl=us.

† China's life expectancy at birth has increased from 69.1 years in 1990 to 76.7 years in 2018, according to World Bank data. World Bank, "Life Expectancy at Birth, Total (Years)—China."

tive targets. Recognizing the transformative potential of emerging healthcare technologies, Beijing is also seeking to leverage advances in AI, genomics, and other fields to augment its healthcare infrastructure and deliver more efficient and cost-effective care.

Beijing's Healthy China 2030 plan was first outlined in a 2016 blueprint and subsequent 2019 action plan released by the State Council. First, the plan establishes five overarching goals: improving health levels and life expectancy, effectively controlling health risk factors, improving the healthcare system and delivery of healthcare services, building out the overall scale of the healthcare system, and improving the healthcare system's governance and oversight.¹⁰ Second, it lays out a set of specific targets to be achieved by 2030, such as raising the average life expectancy to 79 years, reducing smoking rates to less than 20 percent of adults, and reducing deaths from major chronic diseases by 30 percent from 2015 levels (see Addendum I for a list of major targets).¹¹

In line with the principles and goals established in Healthy China 2030, the government launched a number of reforms over the past five years to rationalize care and address the capacity challenges in China's healthcare system. For example, in 2015 Beijing began experimenting with mergers of primary care providers and public hospitals into medical consortiums that share resources and information. Policymakers hope these consortiums will result in a tiered care system that will reduce hospital utilization and encourage more people to use the primary care system.¹² To support the expansion of primary care capacity on which these reforms are predicated, the Chinese government is trying to nearly double its share of general practitioners from 2.6 per 10,000 people to 5 per 10,000 people by 2030.¹³

Even as China's primary care medical workforce is expanded, it continues to face capacity challenges, leading the government to also pursue a variety of technological solutions. In April 2018, the State Council announced its "Internet Plus Healthcare" initiative that builds upon both Healthy China 2030 and the government's 2015 Internet Plus plan.* The initiative calls for healthcare providers to integrate digital health technologies into their operations under the guidance of the National Health Commission and National Development and Reform Commission.¹⁴ It also promises government support for tier two and tier three hospitals to develop a variety of digital healthcare and telehealth services, including remote consultations and diagnoses for common and chronic diseases as well as AI-powered diagnostic capabilities.¹⁵

Even before the announcement of the Internet Plus Healthcare initiative, a handful of technology and financial companies began moving into digital healthcare, positioning themselves to take advantage of commercial opportunities and government policy support. Among these, Chinese tech giant Tencent is the most prolific and had investments in 40 separate healthcare companies as of October 2019.¹⁶ It has led the way in medical imaging technology applications as well as telehealth, both key components of China's digital

*The Internet Plus plan is an effort to integrate the internet, cloud computing, big data, and the internet of things into manufacturing and other traditional industries to drive future economic growth. Charles Clover, "China's Leaders Look to the Net for Growth," *Financial Times*, March 5, 2015.

healthcare industry. In the telemedicine arena, Tencent has backed WeDoctor, an online platform that lets patients receive medical advice from doctors. According to the company's website, the platform has 200 million registered users as well as 7,200 hospitals and 240,000 doctors participating.¹⁷

A variety of established and emerging competitors have increasingly moved into digital healthcare as well. For example, Good Doctor, a rival to WeDoctor backed by insurance giant Ping An, is partnering with 50 hospitals across China to develop an "internet hospital" model in line with the vision outlined in the State Council's 2018 policy.¹⁸ The company also claimed to have more than 300 million registered users of its online medical consultation platform before the outbreak of COVID-19.¹⁹ Moreover, the COVID-19 pandemic is accelerating the adoption of telemedicine services in China. Good Doctor reported a tenfold increase in the number of new users registering each day in late January and early February.²⁰ JD Health, which offers similar services to WeDoctor and Good Doctor, saw comparable growth in its userbase during the height of the lockdown in China.²¹

The application of machine learning to medical imaging technology has been a key focus for China's health technology companies. A 2019 white paper released jointly by the Shanghai Jiaotong University AI Research Institute and the Shanghai Hygiene and Health Development Research Center asserts that while foreign-developed AI healthcare applications have focused mainly on pharmaceutical research and development (R&D), in China healthcare technology companies have gained an edge in AI-enabled imaging diagnostics.²² Moreover, the use of such technologies is already widespread at top-tier hospitals. According to Chinese media reports, by the end of 2019 nearly all of the top-ranked 500 hospitals in China had adopted AI-enabled imaging diagnostic technologies in at least one care unit, while 48 percent had adopted them in three or more care units.²³

Newer AI startups are also competing for a share of China's medical imaging market. For example, Deepwise, which was established in 2017 by Baidu cofounder Lei Ming, garnered significant attention during the early months of the COVID-19 outbreak by quickly adapting its existing lung imaging diagnostic system to identify coronavirus cases. By late February 2020, the company's COVID-19 testing system had been deployed in over 100 hospitals, including in Wuhan.²⁴ Infervision, a competitor, similarly adapted its lung imaging analysis tools to spot COVID-19 cases and by April 2020 had collected 190,000 lung scans from 52 Chinese hospitals.²⁵

Beijing Bets Big on Precision Medicine

In a parallel effort that also seeks to capitalize on China's AI ecosystem, Beijing is investing heavily in precision medicine* capabilities, which it views as a means to improve healthcare delivery and help China's domestic pharmaceutical industry move up the value-added chain. In 2015, the Ministry of Science and Technology

*Precision medicine is an approach to disease treatment that considers individual genetic variation as well as the patient's environment and lifestyle, thereby allowing doctors to more thoroughly tailor treatment and prevention plans to an individual patient. The ability to analyze large data sets and predictive capabilities of AI are the foundation of modern precision medicine.

announced that China would invest \$8.5 billion (renminbi [RMB] 60 billion) into precision medicine R&D over the next 15 years.*²⁶ By comparison, the Obama Administration pledged \$215 million for a similar U.S. initiative the previous year.²⁷ According to Beijing's precision medicine plan, \$2.8 billion (RMB 20 billion) is to come from government expenditure, while corporations will supply the remaining \$5.7 billion (RMB 40 billion).²⁸

China's genomic sequencing industry already boasts several major, globally active firms. The largest is BGI, formerly Beijing Genomics Institute, founded in 1999 to contribute to the Human Genome Project.[†]²⁹ WuXi NextCODE, another sequencer that also runs an online data platform, raised \$200 million in its third round of venture capital fundraising in November 2018 and was the first sequencing facility in China to receive accreditation from the College of American Pathologists to perform molecular diagnostic and genetic testing.³⁰ Both BGI and WuXi NextCODE have benefited from acquisitions of U.S. firms and are licensed to perform testing in the United States (see "Chinese Firms Prioritize Access to U.S. Healthcare Data" later in this section).³¹

China's 13th Five-Year Plan discusses precision medicine in conjunction with other key technology areas such as semiconductors, robotics, and AI rather than in the context of healthcare policy, suggesting Beijing also views it as an industrial policy priority and potential means to help China's healthcare sector move up the value chain.³² BGI's role in supplying COVID-19 testing kits to the world is likely to reinforce Beijing's view of precision medicine as a massive commercial opportunity in addition to a healthcare priority.

COVID-19 Exposes Shortcomings in China's Epidemiological Preparedness

The worldwide COVID-19 outbreak has brought unprecedented attention to China's epidemiological preparedness. China's current system for detection and mitigation of communicable diseases dates back to 2002, when China established a Center for Disease Control and Prevention (China CDC). As Jennifer Bouey, senior policy researcher at RAND Corporation, noted in testimony before the Commission, China CDC replaced a fragmented system of Epidemic Prevention Stations across the country that lacked a mechanism for widespread data sharing, preventing China's Ministry of Health from gaining access to important information about the spread of infectious diseases.³³ Soon after the severe acute respiratory syndrome (SARS) outbreak in 2002–2003, the Chinese government restructured China CDC, eventually deciding to model it after the U.S. Centers for Disease Control and Prevention (U.S. CDC) after studying public health models in different countries.³⁴ During this time, China CDC collaborated with the U.S. CDC on issues such as HIV/AIDS prevention and influenza detection.³⁵

The Chinese government also established two separate surveillance systems to monitor outbreaks of unfamiliar diseases. The In-

*Unless noted otherwise, this section uses the following exchange rate throughout: \$1 = RMB 7.08.

†The Human Genome Project was an international scientific research project from 1990 to 2003 that successfully mapped all human genes. It was funded by the National Institutes of Health and Department of Energy. Oak Ridge National Laboratory, "History of the Human Genome Project."

fluenza-Like Illness (ILI) monitoring system was created to monitor new strains of influenza.³⁶ The ILI is connected to China's hospital system and draws on case records from over 500 hospitals in 31 provinces to detect new outbreaks.³⁷ The second system, the Pneumonia of Unknown Etiology system, monitors patients with pneumonia whose cause cannot be determined. Unlike the ILI system, the Pneumonia of Unknown Etiology system is housed within China CDC and not the national hospital system, and as such does not have automatic access to hospital information systems.³⁸

Since the founding of these systems, China has mounted several successful responses to incipient outbreaks of diseases. For example, in 2013, when the H7N9 strain of the avian flu emerged in eastern China, the Chinese government reported the strain to the World Health Organization (WHO) after detecting only three cases and posted the virus's genome on a public database to facilitate research. These efforts helped keep H7N9 largely contained within mainland China, and the Chinese government's efforts received praise from international governments.³⁹

Over the past several years, however, observers of China's public health system have voiced concerns about China's ability to handle another pandemic. Harsher domestic laws in China, such as a 2017 law restricting the operation of nongovernmental organizations, made coordination with international health organizations more difficult.⁴⁰ China CDC also suffered from a lack of funding and talent recruitment. According to a 2019 report by China CDC, a political emphasis on biomedical innovation resulted in relatively low funding for public health initiatives and negatively affected talent recruitment due to low salary offerings.* The report also found that doctors and public health experts lack channels of communication, such as clinician hotlines or joint conferences between clinicians and public health experts, impeding effective information sharing.⁴¹

Nevertheless, in the months leading up to the COVID-19 outbreak, Chinese leaders expressed continued confidence in their epidemiological preparedness. In a March 2019 speech, China CDC Director Gao Fu commented on the progress China's public health system had made since the SARS outbreak of 2002–2003, saying, "Viruses like SARS may exist at any time, but incidents like SARS will not occur again."⁴² That July, more than 8,200 Chinese health officials participated in a massive online drill simulating an infectious disease scenario held by China CDC, which said the event was the largest training exercise of its kind since the SARS outbreak.⁴³ Feng Zijian, a China CDC official who helped design the exercise, said if another SARS event occurred, China "would definitely make a huge improvement over 2003."⁴⁴

*In 2010, China CDC had a staff of approximately 195,000 employees nationwide (147,000 of whom were medical workers). By 2019, this number had fallen to approximately 188,000 employees (140,000 medical workers). National Health Commission of the People's Republic of China, "2019 Statistical Bulletin of China's Health Development" (2019年我国卫生健康事业发展统计公报), June 6, 2020. Translation. <http://webcache.googleusercontent.com/search?q=cache:SDE3GW7XDy0J:www.nhc.gov.cn/guihuaxxs/s10748/202006/ebfe31f24cc145b198dd730603ec4442.shtml+&cd=1&hl=en&ct=clnk&gl=us>; National Health Commission of the People's Republic of China, "2010 Statistical Bulletin of China's Health Development" (2010年我国卫生健康事业发展统计公报), April 29, 2011. Translation. <http://webcache.googleusercontent.com/search?q=cache:KCjkd6Ph9IJ:www.nhc.gov.cn/mohwsbwstjxxzx/s7967/201104/51512.shtml+&cd=1&hl=en&ct=clnk&gl=us>.

Beijing's Internal Decision-Making Delayed Response to COVID-19 Outbreak

The COVID-19 outbreak has exposed serious deficiencies in China's epidemiological preparedness. Beijing has exacerbated these deficiencies by prioritizing politics over public health: it considers public health information politically sensitive and punishes those who share it before allowing China's political leaders to manage and shape a message. The suppression of information follows a pattern seen in other infectious disease outbreaks in China, such as SARS in 2002–2003 and, more recently, several cases of the plague in Beijing in November 2019.⁴⁵

The CCP's mismanagement of the crisis and its lack of transparency were major factors in the devastating impact of the global pandemic. These delays had potentially catastrophic consequences: one study by a team of Chinese and U.S. researchers found that by implementing containment strategies three weeks earlier, China could have reduced COVID-19 cases by 95 percent.⁴⁶

Information Control and Censorship Prevent Early Containment of Virus

CCP leaders' obstruction and active suppression of information about the outbreak of the virus occurred at both the local and national levels. Local and central officials acted against research facilities, medical facilities, and individuals attempting to alert the public and the government about the virus, particularly during the early days of the outbreak. By December 27, 2019, Vision Medicals Lab in Wuhan had obtained a partial sequence of the SARS-CoV-2 genome,* but officials from the Hubei Provincial Health Commission, representing Wuhan's provincial-level leadership, ordered the lab to cease testing, destroy all samples, and keep its information a secret.⁴⁷ By January 2, Wuhan Institute of Virology coronavirus expert Shi Zhengli had decoded the entire SARS-CoV-2 genome.⁴⁸ The following day, however, China's National Health Commission issued a notice forbidding all labs from publishing information about the virus without government authorization and ordering all samples to be destroyed or sent to a central location.⁴⁹ China CDC continued to obstruct the publication of Dr. Shi's research while multiple government labs worked to replicate her results, wasting effort that could have been focused on sharing information and arresting the spread.⁵⁰ On January 11, a research team in Shanghai preempted the government labs by publishing the genome on an unofficial site, finally releasing genetic information that was in part available on December 27 and could have been fully available by January 2.⁵¹ Still, China CDC shut down the Shanghai laboratory the following day for "rectification," a term often applied to coerced termination of activities or speech that the CCP views as politically unacceptable.⁵²

Threats and direct acts of censorship against individuals also prevented knowledge sharing among doctors and the public. Ophthalmologist Li Wenliang, who posted a warning about COVID-19 in a

*The official name of the novel coronavirus responsible for the pandemic is "severe acute respiratory syndrome coronavirus 2," which is abbreviated SARS-CoV-2. COVID-19 is the name of the disease caused by the SARS-CoV-2 virus. World Health Organization, "Naming the Coronavirus Disease (COVID-19) and the Virus That Causes It," 2020.

chat group on December 30, was summoned by the Wuhan Public Security Bureau and forced to sign a letter confessing to “making false comments” that “severely disturbed the social order.”⁵³ Dr. Li, whose death from COVID-19 in February caused an outpouring of grief and anger among the Chinese population, was one of at least eight people threatened by the police early in the outbreak.⁵⁴ In some cases, the CCP threatened harsh punishments against people who spoke out about the virus. For example, in China’s northeastern Heilongjiang Province, the People’s Supreme Court issued a notice in the first week of February that spreading rumors or “subversive” comments about the virus was punishable by 15 years in prison, with five other COVID-19-related crimes being punishable by death.*⁵⁵ Citizen journalists who attempted to reveal information about the outbreak on social media also had their posts censored.⁵⁶ Research from the University of Toronto suggested WeChat, a popular Chinese social media app, censored at least 516 key word combinations related to the COVID-19 outbreak in the critical early period between January 1 and February 15, and many citizens who reposted information related to the virus had their accounts suspended.⁵⁷ Three journalists who wrote about the COVID-19 outbreak in Wuhan disappeared in February. One of the journalists, Li Zehua, resurfaced in April with a video praising the police, leading to speculation among some observers that the video was coerced. The whereabouts of the other two journalists, Chen Qiushi and Fang Bin, remain unknown.⁵⁸

Political Paralysis and Centralized Control Hasten Spread

Local and national authorities also withheld information from the public or from authorities above them, worsening the spread of the virus within China and contributing to a critical delay in releasing news of the outbreak to the international community. By January 5, three state labs had duplicated the efforts of Dr. Shi’s lab and sequenced the genome, revealing the similarity of SARS-CoV-2 to the virus responsible for the 2003 SARS outbreak and its likely contagious nature.⁵⁹ Nevertheless, Beijing did not share this information with the WHO, which on that same day reported no evidence of significant transmission between humans.⁶⁰

Chinese health authorities did not release the genome until they were preempted by the January 11 leak from Shanghai.⁶¹ Recordings of internal WHO meetings reveal Beijing continued to withhold detailed patient data from the WHO for at least two more weeks after the January 11 publication of the genome, which severely impacted its ability to assess the threat of the new virus.⁶² According to a report by the Associated Press, WHO officials were frustrated by the slow pace of information sharing from Beijing throughout January, even as the WHO publicly praised the Chinese government for its “transparency” and response.⁶³ When China’s National Health

*The five crimes punishable by death included the following: (1) harming public safety by deliberately spreading the virus; (2) unauthorized obstruction of checkpoints or traffic; (3) deliberately causing harm through rioting, killing, or destruction of property; (4) production or sale of fake or inferior treatments; and (5) corruption or misappropriation of epidemic control funds or materials for epidemic control. Wang Yuejun and Zhang Yixin, “Maximum the Death Penalty! Heilongjiang Supreme Court Cracks Down on Crimes Related to Prevention and Control of the Epidemic Situation” 《最高死刑！黑龙江高院严打涉疫情防控相关刑事犯罪》, *Xinbei Bao*, February 3, 2020. Translation. <http://www.bjnews.com.cn/news/2020/02/03/683860.html>.

Commission sent its second team of experts to Wuhan on January 8, Wuhan officials withheld evidence of human transmission by failing to inform the visiting experts of the infection of healthcare workers.⁶⁴

Tightly centralized control from Beijing and the CCP's reflexive suppression of potentially destabilizing news added to the bureaucratic paralysis and further prevented an effective public health response. Notably, Chinese government officials refused offers from the U.S. CDC to visit China and assist with the COVID-19 outbreak. In early February, the *New York Times* reported that for more than a month the U.S. CDC had been offering to send experts to China but had not received a response. According to the report, many U.S. healthcare workers believed the reluctance to accept U.S. assistance came from China's central government.⁶⁵ It was only when General Secretary of the CCP Xi Jinping convened a January 25 Politburo Standing Committee meeting on the virus that the Party-state began to mobilize.*⁶⁶ The mayor of Wuhan spoke out about the impact of China's top-down leadership structure in late January, claiming he had been powerless to release sensitive information about the virus without authorization from Beijing.⁶⁷ A recent weakening of the authority of China CDC also left it unable to issue public warnings or even report directly to the central government,⁶⁸ so its decision to raise its emergency level to the second highest on January 6 remained a secret from the public and even from some of its own staff.⁶⁹

Local political considerations took precedence over the public health response, significantly worsening the outbreak as officials' motivation to prevent the spread of bad news during important political meetings pulled the focus away from the outbreak at a crucial moment.⁷⁰ The Wuhan Health Commission ceased reporting on the outbreak entirely between January 6 and January 10 in the leadup to Wuhan's two largest political meetings of the year, known as the "two sessions."⁷¹ Wuhan held the first of its "two sessions" between January 12 and January 17, during which time the Wuhan Health Commission's daily briefings reported no new cases.⁷² On January 18, the Wuhan Health Commission announced four new cases,⁷³ but Wuhan officials nonetheless went ahead with a 40,000-family public banquet on January 25 in preparation for the Spring Festival.⁷⁴ On the date of the banquet, official statistics reported a total of 45 cases, but an independent estimate by the Imperial College in London suggests that by this point about 1,723 people had already experienced onset symptoms.⁷⁵

Proposed Public Health Reforms Raise Whistleblowing Concerns

In the aftermath of the COVID-19 outbreak, the Chinese government has announced the overhaul of some of its existing public health legislation. In February, China's National People's Congress

* General Secretary Xi failed to mention the virus in his New Year speech on January 23. The Politburo and Politburo Standing Committee also made no mention of the outbreak during their meetings on January 7 and 16. It was not until January 20, when the State Council's Executive Committee met to discuss the return of an inspection team from Wuhan, that General Secretary Xi—who was not even in Beijing at the time—issued emergency guidance. For more, see Minxin Pei, "How Has the Coronavirus Crisis Affected Xi's Power: A Preliminary Assessment," *China Leadership Monitor*, June 1, 2020.

Standing Committee (NPCSC), the government's top legislative body, announced a ban on the consumption of most types of wild animals, which public health experts have identified as a likely source of SARS-CoV-2.⁷⁶ While this decision is meant to be temporary, the NPCSC also said it will amend its existing Wild Animal Protection Law and Animal Epidemic Prevention Law.⁷⁷ Finally, the NPCSC said it will expedite review of the draft biosecurity law, first reviewed by the body last October.⁷⁸ The current draft legislation includes a provision requiring healthcare workers to promptly report cases of infectious diseases.⁷⁹ However, Chinese legal and public health experts have voiced concern over the law's provision that reports may not contain "false" information—grounds for punishing Dr. Li for his reports of early COVID-19 cases.⁸⁰ These experts said the law should be amended to protect healthcare workers reporting suspected cases of an infectious disease, even if the information later turned out to be inaccurate.⁸¹

U.S. Firms Face Challenges in China's Healthcare System

As China's healthcare system has grown, U.S. participation in the Chinese healthcare market has increased as well, both in absolute terms and as a proportion of total U.S. healthcare exports. In 2019, U.S. exports of medical devices and equipment to China totaled \$3.1 billion, 8.3 percent of total U.S. medical device exports and nearly double the share in 2012.⁸² Pharmaceutical products—particularly immunological products such as vaccines—are also a significant U.S. export to China, totaling \$5.5 billion in 2019, 8.3 percent of global U.S. pharmaceutical exports.*⁸³ U.S. foreign direct investment (FDI) in Chinese healthcare has also increased. According to the U.S.-China Investment Hub, a joint research initiative by Rhodium Group and the National Committee on U.S.-China Relations, cumulative U.S. FDI in Chinese healthcare since 2010 is \$12.7 billion, 9.7 percent of total U.S. FDI in China.⁸⁴ Investment has focused on medical devices and pharmaceuticals, while healthcare services remain a small part of overall investment, accounting for just 7 percent of U.S. healthcare FDI in China since 1990.⁸⁵

Foreign participation in China's healthcare market is, in theory, encouraged by China's government. In 2019, the National Development Reform Commission and the Ministry of Commerce jointly released an updated "national encouragement catalogue" of over 400 industries where foreign investment was officially encouraged, including several medical sectors such as pharmaceutical manufacturing, certain types of medical equipment manufacturing, eldercare facilities, and biomedicine R&D and manufacturing.⁸⁶ Industries on the "national encouragement catalogue" receive incentives such as favorable tax treatments, streamlined approval processes, and discounted land prices.⁸⁷

*Although the United States exports pharmaceutical products to China, U.S. imports from China of key pharmaceutical products show a high dependency. For example, China, the world's largest producer of active pharmaceutical ingredients, manufactures the majority of the world's penicillin. The U.S. generic drug industry no longer produces certain critical medicines such as penicillin and doxycycline, and sources the advanced pharmaceutical ingredients for such products from China. For more on U.S. dependence on Chinese pharmaceutical exports and U.S. participation in China's pharmaceutical market, see U.S.-China Economic and Security Review Commission, Chapter 3, Section 3, "Growing U.S. Reliance on China's Biotech and Pharmaceutical Products," in *2019 Annual Report to Congress*, November 2019.

Overall, however, foreign participation in China's healthcare system remains subject to several important restrictions. According to China's 2019 negative list, which outlines sectors in China's economy where foreign investment is prohibited or restricted, foreign investment in healthcare organizations is limited to joint ventures with Chinese entities, with the Chinese entity having at least a 30 percent ownership stake.*⁸⁸ Additionally, foreign firms exporting pharmaceutical products or medical devices to China are subject to a lengthy and costly approval process. Foreign firms are also subject to increasingly stringent regulations governing healthcare-related data in China. These restrictions make it more difficult for U.S. firms to compete in China's healthcare industry.⁸⁹

U.S. Medical Devices Face Obstacles in China's Market

The sale of medical devices is one of the most significant avenues for U.S. participation in China's healthcare market.⁹⁰ In many respects, the Chinese government has narrowed the regulatory gap between foreign and domestic products over the past few years. For instance, after negotiations with the U.S. Department of Commerce in 2014, the Chinese government agreed to allow foreign companies to receive clinical trial waivers in China if the companies have already conducted multiregion clinical trials that include data from China. This has reduced the necessity of a foreign company to conduct duplicative clinical trials, although subsequent changes to China's regulations have made conducting any clinical trials involving Chinese data a significantly more burdensome process (see "Human Genetic Resource Regulations" below).⁹¹

Despite progress in narrowing the regulatory gap with Chinese firms, U.S. companies still face a series of obstacles that prevent them from being able to compete in China's healthcare market on an equal footing. China's approval process for foreign medical devices is often the first obstacle to overcome. While most countries have a process for reviewing foreign medical devices, China's process includes particularly burdensome requirements.⁹² For instance, imported medical devices must generally be approved in another country before the manufacturer can apply to sell them in China. This is despite the fact that China's National Medical Products Association, the regulatory body responsible for approving devices for sale in the country, conducts a separate review of the medical device application and since 2015 has had a program to inspect foreign medical device manufacturing facilities.⁹³ According to a March 2020 report by the Office of the U.S. Trade Representative (USTR), China's approval requirements for foreign medical devices can delay market entry up to five years—a significant setback in an industry characterized by a high pace of innovation.⁹⁴

Additionally, Chinese regulators require all medical devices, including software, to conform to China's mandatory national and industry-level standards for medical devices.⁹⁵ If a firm has designed its medical product according to a different country's standards, it must redesign its device to conform to Chinese standards, even if

* From 2013 to 2015, pilot programs allowed full foreign ownership of hospitals in certain cities. These laws have been superseded for most foreign investors, although investors from Taiwan, Hong Kong, and Macau may still fully own hospitals. Greg Harris, "Foreign Investment in Chinese ElderCare and Healthcare: Overview," *Winston & Strawn*, June 15, 2018.

the firm can prove the original design is more effective.*⁹⁶ According to John Balzano, an attorney whose practice focuses on legal and regulatory issues in China, this restricts the ability of foreign firms to submit more innovative designs to China's medical product market.⁹⁷ Moreover, the USTR has found that unlike U.S. standards-setting processes, which are open to foreign input, China's Standardization Law has failed "to establish that standards-setting processes are open to domestic and foreign participants on a non-discriminatory basis."⁹⁸

Under certain circumstances, foreign firms may sell medical devices in China under an expedited approval route. In 2014, Chinese regulators began a program for innovative foreign medical devices, known as the "Green Channel." Under the "Green Channel," foreign firms are given priority in an approval process. However, this process requires that intellectual property rights for the device be registered in China or be licensed to a Chinese partner, even if the product is manufactured abroad.⁹⁹ As such, firms using the "Green Channel" must either register the intellectual property in China, a delay that undercuts the usefulness of the "Green Channel," or risk the potential of an unfair licensing agreement that diminishes the long-term value of the firm's intellectual property.¹⁰⁰

Finally, even when foreign medical devices are approved for sale in China, foreign firms still face an uneven regulatory playing field that favors domestic products. A March 2020 USTR report found that many of China's provincial governments continue to implement medical device procurement plans that include provisions requiring manufacturers to disclose sensitive data, provide subsidies for domestically produced products, and explicitly limit certain types of procurements to domestically produced devices.¹⁰¹

Human Genetic Resource Regulations

Some of the most significant restrictions on international firms selling medical devices in China come from China's human genetic resource (HGR) regulations, which state that foreign parties cannot independently collect, store, use, transfer, or export human biospecimens obtained in China.[†]¹⁰² Instead, the foreign parties must enter into a collaboration with a Chinese partner, and the collaboration must be approved by the Office of Human Genetic Resources Administration (OHGRA), which is part of the Ministry of Science and Technology.¹⁰³ The HGR regulations are not specific to medical device or pharmaceutical device approval, but rather apply to all research conducted in China.¹⁰⁴ Clinical trials constitute a large portion of the projects approved under the HGR, however: according to statistics released by the OHGRA, of the 2,385 projects approved in 2018, over 90 percent

*While the United States requires foreign medical devices to conform to domestic standards, applicants may also demonstrate that a proposed medical device is "substantially equivalent" to an approved device in the United States, even if it contains different technical specifications. 21 C.F.R. Section 807.81 (2019).

†The HGR regulations define "human genetic resource" as "genetic material from organs, tissues, and cells, and other genetic material containing human genome and genes." Regulations of the People's Republic of China on the Management of Human Genetic Resources (中华人民共和国人类遗传资源管理条例), Article 2, 2019. Translation. http://webcache.googleusercontent.com/search?q=cache:7AmTk7LOQuAJ:www.gov.cn/zhengce/content/2019-06/10/content_5398829.htm+&cd=1&hl=en&ct=clnk&gl=us.

were clinical trials to help gain approval for the marketing of pharmaceuticals and medical devices.¹⁰⁵

While many countries regulate access to citizens' medical data and genetic information, the HGR regulations are significantly more stringent and involve substantially greater procedural hurdles.¹⁰⁶ Foreign scientists have reported that complying with these regulations has led to delays and incomplete data sharing, creating a risk of a slower pace of progress in scientific research.¹⁰⁷ For foreign companies seeking to complete studies in order to sell devices in China, these obstacles have commercial implications as well. According to Mr. Balzano, complying with these regulations adds months to preparations for trials.¹⁰⁸ These trials are necessary for the approval of certain foreign medical devices for sale in China.¹⁰⁹

The HGR regulations also include a provision governing how the foreign firm and its Chinese counterpart can divide the intellectual property associated with the studies. If any "exploratory research" conducted by the U.S. and Chinese parties under their collaboration leads to any patentable inventions, the patent rights must be shared jointly by the U.S. and Chinese parties.¹¹⁰ This rule cannot be altered by mutual agreement of the U.S. and Chinese parties, as the OHGRA will not approve research collaborations unless they include this provision. Moreover, the HGR regulations do not define the term "exploratory research," leading to significant ambiguity as to what research falls under the "joint-patent" rule.¹¹¹ According to Mr. Balzano, these obstacles hinder negotiations with Chinese partners and the OHGRA as parties attempt to reach an agreement on the types of research subject to the rule. The regulatory hurdles can lead to additional delays of three to four months for research studies in China.¹¹²

Chinese Firms Prioritize Access to U.S. Healthcare Data

China's government has made collecting healthcare-related data a national priority.¹¹³ In June 2016, the State Council issued the Guiding Opinions on Promoting and Regulating the Development of the Application of Healthcare Big Data, which stated that healthcare big data is a "fundamental, strategic national resource" and formulated plans to develop healthcare data.* While data from individual medical records are unlikely to lead to the development of new medical treatments, aggregating healthcare data across large populations can lead to medical breakthroughs with significant commercial value.¹¹⁴ Due to the ethnic diversity of the U.S. population, U.S. healthcare data are particularly valuable in this regard.¹¹⁵ As such, Chinese firms have invested significantly in U.S. healthcare firms, driven in part by government incentives such as government investment funds that target biotech firms.¹¹⁶

In some cases, Chinese entities have gained access to U.S. healthcare data by taking equity stakes in U.S. healthcare firms. For instance, in 2013 BGI acquired the U.S. company Complete Genomics, giving BGI access to proprietary sequencing technology in the United

*The State Council publication does not define "big data"; however, in healthcare the term generally refers to the "aggregation of multiple aspects of healthcare-related information covering the full life-cycle of a large constituency of people, covering personal health, medical services, disease control and prevention, food safety, health preservation, among other things." Hogan Lovells, "China to Grow Big on E-Healthcare Data," August 2016.

States.¹¹⁷ In 2015, WuXi Healthcare Ventures invested in 23andMe, a U.S. company offering genetic tests to consumers. WuXi's interest in 23andMe was driven in large part by 23andMe's proprietary genomic database.¹¹⁸

More recently, Chinese FDI in U.S. healthcare has slowed down. According to the U.S.-China Investment Project, a research initiative led by Rhodium Group and the National Committee on U.S.-China Relations, Chinese FDI in U.S. health, pharmaceuticals, and biotech was \$443.7 million in 2019, the lowest amount since 2013 and a decrease of more than 80 percent from 2017.¹¹⁹ Additionally, after the passage of the Foreign Investment Risk Review Modernization Act of 2018, Chinese investment in U.S. healthcare has received greater scrutiny. In 2019, the Committee on Foreign Investment in the United States ordered the Chinese tech firm iCarbonX, which is backed by Tencent, to divest from its 2017 stake in PatientsLikeMe, a U.S. health firm that helps patients identify other patients with similar conditions.¹²⁰ Chinese venture capital (VC) investment in U.S. healthcare firms, however, remains robust.¹²¹ The U.S.-China Investment Project reported that Chinese VC investment in U.S. life sciences firms increased 13 percent between 2014–2015 and 2018–2019, more than any other category of VC investment.¹²²

Beijing Pursues Biotech Leadership amid a “Biorevolution”

Rapid advances in different sectors of biotech, including DNA sequencing, DNA synthesis, CRISPR (gene editing), synthetic biology, and AI, have led to a “biorevolution” that will play a pivotal role in the economy of the 21st century.¹²³ According to a 2020 report by McKinsey, over the next ten to 20 years, foreseeable uses of biotech could have an economic impact of up to \$4 trillion a year.¹²⁴ These advances in biotech not only have significant economic potential but also could solve pressing issues in healthcare, agriculture, materials, and energy. They also carry significant national security implications, including the possible development of more virulent bioweapons.¹²⁵ Recognizing the transformational potential of biotech, China's government has aggressively pursued leadership in the sector. In 2010, the Chinese government designated biotech a “strategic emerging industry” and has prioritized state support for the industry in plans such as Made in China 2025.¹²⁶ As Tara O'Toole, senior fellow and executive vice president at In-Q-Tel, noted in her testimony before the Commission, while the United States remains the “innovation engine” of biotech, China is making rapid advances, particularly in “translational” research (which converts basic research into products), an area of particular weakness in the U.S. biotech ecosystem.¹²⁷

In addition to investment interests, Chinese companies have been able to gain access to U.S. healthcare data in the course of business with U.S. healthcare entities. For instance, BGI has formed partnerships with a number of U.S. universities, hospital systems, and other organizations to provide them with genomic sequencing services. In many cases, Chinese firms are able to provide services much more affordably than domestic actors, often due to government subsi-

dies.¹²⁸ According to a 2019 report prepared for the Commission by Gryphon Scientific, 23 companies associated with China are certified to perform genetic testing in the United States.¹²⁹

In the wake of the COVID-19 outbreak, the United States has further opened up its market to Chinese medical devices that collect U.S. healthcare data. On March 27, 2020, the U.S. Food and Drug Administration (FDA) granted emergency use authorization to BGI Americas, the U.S. subsidiary of BGI, for its test device to detect COVID-19.* This marks the first time the FDA has approved a device manufactured in China.¹³⁰ In June 2020, Genetron Health, a Chinese precision medicine company, announced it had also received emergency use authorization from the FDA for its COVID-19 detection kits.¹³¹ By August 2020, BGI had sold more than 35 million COVID-19 test kits to 180 countries, including the United States.¹³² Complementing market access for testing devices, Chinese companies are gaining access to global health data by establishing laboratories ostensibly intended to support COVID-19 testing. BGI, for example, has established 58 such laboratories in 18 countries.¹³³ These labs are providing Chinese researchers with heterogeneous genetic data to serve Chinese ambitions to dominate the biotech market.

In many cases, China's access to U.S. healthcare data is only lightly regulated. Unlike many countries, the United States does not have overarching federal regulations on data protection, and instead has a framework of various state-level data protection laws as well as federal regulations that address the use of data in certain sectors of the U.S. economy.¹³⁴ For the healthcare industry, the Health Insurance Portability and Accountability Act (HIPAA) provides legal protection of healthcare data. HIPAA defines protected health information and establishes permitted disclosure of such information. However, HIPAA does not protect healthcare-related information in all cases. Notably, HIPAA does not apply in cases when data are collected purely for research or for nonhealthcare purposes (such as ancestry tests or fitness trackers). It also does not apply in cases where patient data have been anonymized.¹³⁵

Chinese State-Sponsored Hacking Targets U.S. Healthcare Data and Research

In addition to obtaining U.S. healthcare data through legal means, Chinese entities and individuals have been implicated in intellectual property theft, hacking of U.S. companies, and other illicit activities. In May 2019, the U.S. Department of Justice (DOJ) charged Chinese national Wang Fujie and an unnamed accomplice with hacking Anthem and three other unnamed U.S. businesses in 2014 and 2015.†¹³⁶ The information breached included social secu-

*BGI Americas received a loan worth between \$350,000 and \$1 million through the Paycheck Protection Program administered by the Small Business Administration, which is designed to help keep small businesses affected by the COVID-19 pandemic keep employees on their payroll. The extension of a Paycheck Protection Program loan came under scrutiny, particularly because BGI has worked on building a gene bank in Xinjiang. On July 17, BGI Americas announced it had returned the loan, citing U.S. Department of the Treasury guidance stating that the loans were not intended for companies with access to the equity market. Bethany Allen-Ebrahimian, "Chinese Biotech Giant's U.S. Subsidiary Returns PPP Loan after Axios Story," *Axios*, July 20, 2020.

†In April 2015, Premera Blue Cross, a U.S. health insurance company, announced that in 2014 hackers had accessed the company's records dating back to 2002. The information obtained by hackers included longitudinal data, which track health information from individual patients over a period of time and are especially valuable in medical research. Two other large companies affli-

rity numbers, bank account information, clinical information, and insurance claims of 11 million people.¹³⁷ The indictment alleged the defendants were members of an “extremely sophisticated hacking group operating in China,” though it did not specify whether the group was state affiliated.¹³⁸

Alleged Chinese state-sponsored hacking attempts have also targeted U.S. healthcare research, including the development of COVID-19 treatment. In July 2020, DOJ indicted two Chinese nationals, Li Xiaoyu and Dong Jiazhi, for hacking into computer systems since 2009 and stealing hundreds of millions of dollars from hundreds of victims around the world, including technology and pharmaceutical firms. The indictment alleged the individuals hacked not only for personal profit, but also with the cooperation of China’s Ministry of State Security.¹³⁹ According to U.S. government officials, earlier in 2020 Li and Dong shifted their focus to firms conducting COVID-19 research.¹⁴⁰ DOJ alleged the individuals most recently attempted to hack several U.S. biotech firms conducting research on COVID-19 vaccines and treatments.¹⁴¹ The indictment did not specify whether these efforts were successful.

Risks of U.S.-China Biomedical Research Collaboration

The Chinese government views a shortage of top-tier scientific talent as a key bottleneck for its ambitions to become a leader in a variety of industrial technologies, including biotech. To address this gap, Beijing has created a large number of nationally and locally administered talent recruitment programs aimed at attracting both foreign-educated Chinese researchers and leading foreign researchers themselves. The Thousand Talents Program (TTP) and Hundred Talents Program are the most well-known of such talent recruitment programs, but there are many others.¹⁴² China’s talent recruitment programs have targeted a broad set of scientific disciplines that align with Beijing’s industrial policy priorities. In recent years, these programs have increasingly included biotech, as the sector has come to occupy a more prominent place in China’s industrial and healthcare policies. For example, as of mid-2018, 44 percent of TTP recruits specialized in life sciences or medicine.¹⁴³

Through the TTP and other scientific talent recruitment programs, the Chinese government has orchestrated the illicit transfer of data generated through federally funded biomedical healthcare research conducted at U.S. universities. It has also mobilized large numbers of “nontraditional collectors of information” (i.e., graduate students and postdoctoral research fellows) to exploit legal gray zones to bring research discoveries with potential commercial, medical, or military value back to China.¹⁴⁴

ated with Blue Cross, Anthem and CareFirst, also announced hacks of their systems in 2015 that exposed the nonmedical data of 79 million and 1.1 million customers, respectively. The attacks on all three companies shared similar characteristics, and U.S. Federal Bureau of Investigation investigators reportedly considered Chinese state-sponsored hackers to be the most likely culprit behind the attacks. Edward You and Keith G. Kozminski, “Biosecurity in the Age of Big Data: A Conversation with the FBI,” *Molecular Biology of the Cell* 26:22 (2015): 3894–3897; Matthew Goldstein and Reed Abelson, “Up to 1.1 Million Customers Could Be Affected in Data Breach at Insurer CareFirst,” *New York Times*, May 20, 2015.

Chinese Government Influence in Federally Funded Biomedical Research Grants

Chinese talent recruitment programs have targeted grant recipients and individuals involved in the grantmaking process at the U.S. National Institutes of Health (NIH), which is the largest funder of biomedical research in the world.¹⁴⁵ In 2016, the U.S. Federal Bureau of Investigation notified the NIH it was concerned about breaches of confidentiality in its peer review process.¹⁴⁶ Subsequent internal NIH reviews revealed additional concerns, including failure to disclose foreign funding on grant applications and the diversion of NIH-supported research to foreign countries.¹⁴⁷ As of June 2020, the NIH had identified 399 scientists “of possible concern” working in 189 institutions.¹⁴⁸ In 93 percent of cases where the NIH contacted an affiliated institution, China was the source of undisclosed foreign funding.¹⁴⁹ As of June 2020, 54 scientists investigated in the NIH reviews have resigned or lost their jobs as a result of these investigations, which remain ongoing.¹⁵⁰

In addition to investigating individuals of possible concern, the NIH has used outreach and educational efforts to respond to the challenge posed by Chinese influence. In August 2018, NIH Director Francis Collins sent a letter to grantee organizations highlighting the threat of foreign influence and in June 2019 published a reminder notice about the institute’s policies regarding financial conflicts of interest.¹⁵¹ A special NIH Working Group for Foreign Influences on Research Integrity also recommended in a December 2018 report that the NIH work with other federal agencies to “implement a broad education campaign” about the need to disclose potential financial conflicts of interest.¹⁵² Despite these efforts, the NIH is underequipped to deal with Chinese influence and generally relies either on tipoffs from law enforcement or on grantee institutions themselves to report potential problems.¹⁵³ A September 2019 review of NIH policies conducted by the U.S. Office of the Inspector General of the Department of Health and Human Services discovered that the NIH Division of Grants Compliance and Oversight conducted only three reviews of institutions’ compliance programs in 2018, compared with 27 reviews in 2013.¹⁵⁴

The NIH is not the only federal grantmaking agency in the biomedical research domain targeted by Chinese talent recruitment programs. The National Science Foundation faces similar oversight challenges as the NIH in vetting its grantees, and there are a number of public case examples of talent recruitment plan members misappropriating the foundation’s research.¹⁵⁵ With both agencies, it is difficult to assess the scope of the problem, as much of what is known about cases of foreign influence remains part of active investigations and therefore is not publicly accessible. However, NIH Director of Extramural Research Michael Lauer has described “a tapestry of incidents” coming to light and expressed concern that the scale of the problem might be “much worse than what we are seeing.”¹⁵⁶ Indeed, a growing volume of public case examples has shed light on China’s talent recruitment plans and how they operate.

Grant Fraud, Shadow Labs, and Research Theft

A recent string of well-publicized cases has generated significant attention to the issue of foreign influence in federally funded scientific research both within the academic community and among the public more generally. These cases encompass a broad range of potentially problematic activities, some of which are more harmful to the integrity of U.S. research than others. Among the most problematic activities are the outright theft of U.S. research discoveries and the Chinese government's practice of recruiting and compensating foreign researchers to establish shadow laboratories in China that duplicate or otherwise build upon federally funded grant research conducted in the United States. However, participation in Chinese talent recruitment programs is not illegal, and prosecution of those involved typically only occurs when they do not disclose their foreign funding on federal grant applications. This exposes a clear gap in the United States' ability to protect its innovation ecosystem.

The most notable case in the academic community was that of Charles Lieber, a Harvard University chemistry professor and nanoscience researcher who was arrested in January 2020 and later federally indicted on charges of lying to the government about his participation in the TTP and his ties to Wuhan University of Technology.¹⁵⁷ According to the charging documents, Dr. Lieber's Harvard-based research group was the recipient of \$15 million in grant money from the NIH and U.S. Department of Defense. Dr. Lieber allegedly failed to disclose either his participation in the TTP as a "One Thousand Talent high level foreign expert" or his appointment as a strategic scientist at Wuhan University of Technology, despite receiving a salary of \$50,000 per month and more than \$1.5 million in research grants and living expenses related to these positions.¹⁵⁸

Dr. Lieber's case may illustrate a larger pattern of efforts by the Chinese government to recruit U.S. researchers. The purpose of Dr. Lieber's recruitment by Wuhan University of Technology was likely to duplicate portions of the research he was already conducting with federal money in the field of nanoscience. In other cases, however, no technology has apparently been transferred as a result of U.S. researchers' participation in a talent recruitment program, and the wrongdoing appears confined to grant fraud. In December 2019, the Tampa-based Moffit Cancer Center (Moffit) announced it had accepted the resignation of six cancer researchers, including the center's CEO Alan List and director Thomas Sellers, for conflict-of-interest violations related to their participation in the TTP.¹⁵⁹ Moffit subsequently released a summary of its compliance investigation, which detailed an extensive web of personal relationships that connected the six researchers to the TTP through the center's partnership with a cancer institute and hospital at Tianjin Medical University.¹⁶⁰ The report acknowledges that none of the six researchers' participation in the TTP was against NIH or Moffit rules and says there is no evidence that intellectual property or patient data were compromised. However, the researchers failed to properly and fully disclose their participation in the TTP and their financial interests in China prior to the opening of the investigation.¹⁶¹

In some instances, institutions have themselves become liable for failing to disclose their researchers' participation in Chinese tal-

ent recruitment programs. For example, in December 2019 Grand Rapids-based biomedical research and educational organization Van Andel Research Institute (Van Andel) agreed to pay a \$5.5 million settlement to resolve DOJ allegations that it made false claims on grant applications for NIH funding.¹⁶² Although Van Andel did not admit to any wrongdoing as part of the settlement, the U.S. government alleged the institute should have been aware of Chinese funding received by two of its researchers, Eric Xu and Jiyan Ma, between 2012 and 2018.¹⁶³ It failed to disclose this information on grant applications it submitted to the NIH between 2012 and 2019.¹⁶⁴ Indeed, Van Andel operates a strategic partnership with the Shanghai Institute of Materia Medica, whose website lists Professor Xu as a director of its Key Laboratory for Receptor Research.¹⁶⁵ Moreover, the Chinese version of Professor Xu's bio on the website states that he has been a TTP recruit since 2009, a fact the government alleged Van Andel received a letter about.¹⁶⁶ An April 2019 press release on Van Andel's website also lists several Chinese funding sources alongside three NIH grants as providing support for Professor Xu's successful mapping of a parathyroid hormone receptor that could lead to the development of new osteoporosis and cancer medications.¹⁶⁷

Although diversion of research by talent recruitment program participants is the primary challenge for federal agencies, there are also cases of outright theft. In December 2019, Zaosong Zheng, a cancer pathology researcher at Beth Israel Deaconess Medical Center, was detained at Boston Logan International Airport after authorities discovered 21 vials containing biological specimens hidden inside a sock in his checked luggage. Dr. Zheng initially lied to federal agents about the contents of his luggage but in a subsequent interview admitted to stealing the specimens from Beth Israel Deaconess Medical Center with the intent of bringing them back to China to conduct further research and publish the results under his own name. Dr. Zheng's grand jury indictment does not allege that he was a TPP participant, but he did receive a stipend of approximately \$2,000 per month from the Chinese Scholarship Council, a nonprofit institution affiliated with the People's Republic of China's Ministry of Education that provides scholarships and funding for undergraduate students, graduate students, and postdoctoral fellows studying abroad.¹⁶⁸

It is notable that in none of these cases were the individuals involved accused of violations based on the fact of their participation in Chinese talent recruitment programs. Instead, the accusations primarily related to their failure to disclose such participation on federal grant applications. It is legal for U.S. researchers—even those who have received federal grant money—to obtain foreign funding, have foreign affiliations, or participate in China's talent recruitment programs.¹⁶⁹ This is intentional, as the ecosystem of federally funded basic scientific research is designed to be open and transparent.¹⁷⁰ However, there is a qualitative difference between Chinese nationals participating in a collaborative investigative process, the results of which are eventually publicized in a transparent manner, and illicitly duplicating that research in China so that its applications can be commercialized and patented by Chinese compa-

nies. Federal investigations have revealed that participation in Chinese talent programs tends to encourage illicit transfer of research data.¹⁷¹ Because Chinese talent recruitment programs exploit the open and transparent characteristics of federal research grants, regarding Chinese influence as a matter for law enforcement alone severely limits the United States' ability to respond to the transfer and diversion of taxpayer-funded research discoveries.

Implications for the United States

For the Chinese government, meeting the healthcare needs and improving living standards of China's rapidly aging population is a vital part of maintaining its legitimacy. Consequently, it seeks to rapidly improve China's healthcare system, build hospital capacity, improve doctor training, invest in cutting-edge technology, and collect vast troves of medical data. Although improvements in China's healthcare would benefit the global health ecosystem, Beijing has pursued its healthcare ambitions in a way that raises serious concerns for U.S. national security, economics, and public health.

In the immediate term, China's collection of healthcare data through both licit and illicit means presents risks to the privacy of U.S. citizens, millions of whom have already had personal healthcare data exposed in hacking attacks by groups likely associated with the CCP. These privacy risks could also pose challenges to U.S. national security if the Chinese government gains access to sensitive medical information about U.S. policymakers, military personnel, and others, including researchers.¹⁷² While the strategic applications of individuals' healthcare data remain poorly understood, a report prepared in January for the U.S. Office of the Director of National Intelligence stated such information could be used to determine targets for surveillance, manipulation, or extortion.¹⁷³

China's data collection efforts also threaten the future competitiveness of U.S. firms. The lack of reciprocity in data-sharing and the asymmetric nature of China's restrictions on healthcare data provides it with a greater opportunity to develop new medical treatments than the United States, with a less centralized set of data, cannot. These challenges to U.S. innovative capacity are compounded by Chinese policies that often incentivize U.S. firms to turn over R&D discoveries to Chinese partners, thus trading their long-term competitive prospects for market access. Beijing's targeting of U.S. healthcare research, through both legal and illicit means, also gives it an advantage by reducing the costs of R&D conducted in China. Though new innovative medicines and therapies coming out of China could benefit U.S. patients, in the long run U.S. healthcare firms could forfeit their position as global leaders, and the United States could become even more dependent on Chinese firms for new medical treatments.

As the ongoing COVID-19 pandemic demonstrates, Beijing's imposition of strict political controls on its healthcare system can have devastating public health and economic consequences for both the United States and the global community. Had the Chinese government been more willing to share critical information in the early stages of the outbreak, precious time to contain the virus would not have been lost. Instead, Chinese policymakers' preoccupation with

maintaining control resulted in costly delays. In the future, Beijing's impulse to repress public health information could result in disruptions even more severe than COVID-19.¹⁷⁴

If conducted on an open and reciprocal basis, U.S.-China health-care exchanges could yield positive results for both countries, leading to the creation and delivery of new treatments and prevention of global health crises. Beijing's current approach suggests, however, it is more interested in dominating the next generation of healthcare technologies and manipulating them for its own narrow benefit.

Addendum I: Healthy China 2030 Plan Major Targets

Campaign	2015 Baseline (if available)	2030 Target
Achieving longer average life expectancy	76.4 years	79.0 years
Popularizing health knowledge	Health literacy level is 10 percent.	Raise Chinese citizens' health literacy level to at least 30 percent.
Improving the healthcare system	<ol style="list-style-type: none"> 1. 2.2 (assistant) doctors per 1,000 people. 2. Personal health expenditure accounts for 29.3 percent of total health expenditure. 	<ol style="list-style-type: none"> 1. 4.7 registered nurses per 1,000 people. 2. 3.0 (assistant) doctors per 1,000 people. 3. Personal health expenditure should account for about 25 percent of total health expenditure.
Implementing an innovative medical and health service supply model	N/A	Establish a "three-in-one" model for prevention and control that integrates professional health institutions, specialized hospitals, and primary-level medical and health institutions.
Expanding the healthcare industry	N/A	The size of the healthcare industry should reach \$2.3 trillion (RMB 16 trillion).
Strengthening innovation in medical technology	N/A	Bring quality standards for medicine and medical devices completely in line with international standards.
Promoting a healthy environment	<ol style="list-style-type: none"> 1. 76.7 percent of days have acceptable air quality in cities at prefecture level and above. 2. 66 percent of surface water quality is at or better than Class III standards. 	<ol style="list-style-type: none"> 1. Continued improvement in the number of acceptable air quality days. 2. Continue to improve drinking water quality and consumer product safety.
Strengthening comprehensive urban and rural health	N/A	<ol style="list-style-type: none"> 1. All rural people will use sanitary toilets. 2. Increase the number of healthy/sanitary cities to 50 percent, with full coverage of provinces and autonomous regions.

Addendum I: Healthy China 2030 Plan Major Targets—Continued

Campaign	2015 Baseline (if available)	2030 Target
Improving nutrition and diets	<ol style="list-style-type: none"> 1. Incidence of adult obesity stunting among children five years old or under is 8.1 percent. 2. Average daily salt intake is 10.5 grams. 3. Adult daily fat and oil intake is 42.1 grams. 4. Average daily intake of added sugar is 30 grams. 5. Average daily intake of fruits and vegetables is 296 grams. 	<ol style="list-style-type: none"> 1. Reduce the incidence of adult obesity stunting among children five years old or under to less than 5 percent. 2. Reduce average daily salt intake to less than 5 grams. 3. Reduce adult daily fat and oil intake to between 25 and 30 grams. 4. Reduce average daily intake of added sugar to less than 25 grams. 5. Increase average daily intake of fruits and vegetables to more than 500 grams.
Implementing nationwide fitness programs	<ol style="list-style-type: none"> 1. 89.6 percent of the population meet national fitness standards. 2. The proportion of people who engage in regular exercise is 33.9 percent. 3. 360 million people regularly participate in physical exercise. 	<ol style="list-style-type: none"> 1. Increase the proportion of the population that meets national fitness standards to 92.17 percent. 2. Increase the proportion of people who engage in regular exercise to at least 40 percent. 3. 530 million people will regularly participate in physical exercise.
Strengthening training for healthy skills	<ol style="list-style-type: none"> 1. 1.6 sports instructors for every 1,000 people. 2. 88 percent of rural villages have sports facilities. 	<ol style="list-style-type: none"> 1. Have 2.3 sports instructors for every 1,000 people. 2. Build sports facilities in all remaining rural villages.
Improving the public fitness system	N/A	Build a three-tier system of public sports facilities with 2.3 square meters per capita and a 15-minute fitness circle in urban communities.
Implementing tobacco control	<ol style="list-style-type: none"> 1. The proportion of the population protected by smoke-free regulations is about 10 percent. 2. Percentage of the population over age 15 that smokes is 27.7 percent. 	<ol style="list-style-type: none"> 1. Increase the proportion of the population protected by smoke-free regulations to 80 percent. 2. Gradually realize a ban on smoking in public places. 3. Reduce the percentage of smokers over age 15 to 20 percent.
Promoting mental health	<ol style="list-style-type: none"> 1. Chinese citizens' mental health literacy rate is 12 percent. 2. Chinese citizens sleep an average of 6.5 hours per day. 3. China has 2.6 psychiatrists per 100,000 people. 	<ol style="list-style-type: none"> 1. Raise Chinese citizens' mental health literacy to 30 percent. 2. Increase the average hours Chinese citizens sleep per day to between 7 and 8. 3. Increase the number of psychiatrists to 4.5 per 100,000 people.

Addendum I: Healthy China 2030 Plan Major Targets—Continued

Campaign	2015 Baseline (if available)	2030 Target
Improving women's and children's health	<ol style="list-style-type: none"> 1. Infant mortality rate of 8.1 percent. 2. Maternal mortality rate of 20.1/100,000. 3. Anemia incidence among pregnant women is 17.2 percent. 4. The national prenatal screening rate is 61.1 percent. 	<ol style="list-style-type: none"> 1. Reduce the infant mortality rate to 5 percent or lower. 2. Reduce the maternal mortality rate to 12/100,000 or lower. 3. Provide pregnant women with free basic health services. 4. Reduce anemia incidence among pregnant women to under 10 percent. 5. Increase the national prenatal screening rate to more than 80 percent.
Improving family planning service management	Birth gender ratio of 113.5 males for every 100 females.	Achieve naturally balanced gender ratio at birth.
Reducing mortality of children under 5	Child mortality rate of 10.7 percent.	Achieve child mortality rate of 6.0 percent.
Improving health at elementary and middle schools	Proportion of students that meet national student health standards is 31.8 percent.	<ol style="list-style-type: none"> 1. Increase the proportion of students that meet national student health standards to at least 60 percent. 2. More than 25 percent of students nationally are rated "excellent" by national student health standards. 3. Significantly reduce the incidence of new myopia. 4. Students should have at least one hour of sports activity daily. 5. Young people should master more than one sports skill. 6. Complete compliance of school sports facilities. 7. Students participate in sports activities at least three times a week.
Improving dental health	N/A	Fewer than 25 percent of 12-year-old children have cavities.
Improving elderly health	N/A	<ol style="list-style-type: none"> 1. Reduce the incidence of dementia in those aged 65 and older. 2. Increase the percentage of tier 2 hospitals with elderly medicine units to more than 90 percent. 3. Increase the percentage of tier 3 hospitals with convalescence units to more than 90 percent.

Addendum I: Healthy China 2030 Plan Major Targets—Continued

Campaign	2015 Baseline (if available)	2030 Target
Preventing early death from major chronic diseases	Major chronic diseases accounted for 19.1 percent of deaths in 2013.	Early deaths from major chronic diseases should be 30 percent below 2015 numbers.
Preventing cardiovascular disease	<ol style="list-style-type: none"> 1. Mortality rate from cardiovascular and cerebrovascular disease of 238.4 per 100,000 people. 2. Blood lipid testing rate for people over 35 years old is 19.4 percent. 3. Knowledge of high blood pressure among those over 30 is 47 percent. 	<ol style="list-style-type: none"> 1. Reduce the mortality rate from cardiovascular and cerebrovascular disease to 190.7 per 100,000 or below. 2. Increase the standard management rate for people with high blood pressure to more than 70 percent. 3. Increase blood lipid testing rate for people over 35 to more than 35 percent. 4. Increase knowledge of high blood pressure among those over 30 to at least 65 percent.
Preventing and treating cancer	Overall five-year survival rate for cancer patients is 40.5 percent.	Increase the overall five-year survival rate for cancer patients to at least 46.6 percent.
Preventing chronic respiratory disease	Mortality rate from chronic respiratory diseases in those aged 70 and younger is 10.2 per 100,000.	Reduce the mortality rate from chronic respiratory diseases in those aged 70 and younger to 8.1 per 100,000.
Treating diabetes	<ol style="list-style-type: none"> 1. Standard management rate for diabetes patients is 50 percent. 2. Diabetes knowledge among those over 18 is 36.1 percent. 	<ol style="list-style-type: none"> 1. Increase the standard management rate for diabetes patients to at least 70 percent. 2. Increase diabetes knowledge among those over 18 to more than 60 percent.
Preventing infectious disease	36,700 annual schistosomiasis cases.	<ol style="list-style-type: none"> 1. Reduce incidence of hepatitis B among children under age 5 to 0.5 percent. 2. Completely eliminate schistosomiasis.
Promoting road traffic safety	N/A	Reduce road-related deaths per 10,000 vehicles by 30 percent.

Note: Where baseline figures for 2015 are not available, they have been substituted with baseline data from the closest available year.

Source: Various.¹⁷⁵

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