

**Testimony before the U.S.-China Economic and Security Review Commission:
China's Evolving Healthcare Ecosystem: Challenges and Opportunities**
May 7, 2020

John Balzano, Partner, Covington & Burling, LLP¹

I. Introduction

I would like to thank the U.S.-China Economic and Security Commission for this opportunity to testify at this hearing on China's Evolving Healthcare Ecosystem: Challenges and Opportunities. I have been observing and working with China's system for regulating foods, drugs, and other medical products since 2004, both as a researcher and a practitioner. I worked with U.S. and Chinese government officials on legal reform projects and with companies around the world to understand and interface with China's regulatory system. I read, speak and write Mandarin and follow the new laws, regulations, rules and documents as they emerge daily from China's government, including the State Administration for Market Regulation, the National Medical Products Administration (NMPA), and the National Health Commission—which are some of the key regulators in the digital health area.

As an introductory point, over the last five years China's policies have encouraged development and innovation in the healthcare and drug and device regulatory areas. This development and innovation is a key pillar of the 13th Five Year Plan. For healthcare, the policies have focused on providing affordable healthcare throughout the country to all citizens through the state-run insurance plans.² This includes faster access to innovative drugs available in other countries. It also includes expansion of the regulatory framework for digital health and the ability for citizens to obtain healthcare remotely through telemedicine, e-diagnosis services, and Internet hospitals. China has strongly encouraged the use of other technology, such as artificial intelligence, in healthcare settings.

China released important regulations on digital health in 2018 that created a regulatory structure for specially licensing hospitals that provide e-services.³ And during the Coronavirus outbreak in China, the government emphasized the importance of digital health and telemedicine to ensure treatment for patients.⁴

¹ The viewpoints expressed in this document are entirely my own and do not reflect those of Covington & Burling, LLP.

² Opinion on Deepening Healthcare Security System Reform (CCP, State Council 2020), available at http://www.gov.cn/zhengce/2020-03/05/content_5487407.htm; Outline of "Healthy China 2030" (Central Committee of the CCP and State Council 2016), available at http://www.gov.cn/zhengce/2016-10/25/content_5124174.htm.

³ Notice of the National Health Commission and the Chinese Medicine Bureau Releasing Three Documents including the Interim Administrative Measures on E-Diagnosis (2018), available at http://www.gov.cn/gongbao/content/2019/content_5358684.htm.

⁴ See, e.g., National Health Insurance Commission of the National Healthcare Security Administration, Guiding Opinions on Promoting the "Internet +" Medical Insurance Service During the Prevention

These regulations permitted a variety of follow-up visits through e-diagnosis services provided by brick-and-mortar hospitals and “internet hospitals.”

In terms of regulated products that support digital healthcare solutions, such as medical device technologies, China has similarly encouraged innovation by implementing regulatory measures to more quickly register these device products. These measures include issuing guidance on how to structure applications for medical device software, and strengthening the capacity of NMPA and its Center for Medical Device Evaluation (CMDE) to review and approve products on a compressed timeline, devoting the most resources to products with a particular level of innovation (e.g., the first of their kind globally) or that fill a heightened clinical need (e.g., pediatric, orphan, or geriatric devices).⁵

Both foreign and domestic companies in China have benefitted from these policies. But as I will discuss, there are still structural features of some of these regulations or practices that either (1) restrict foreign investment or (2) tie certain additional burdens to or limit regulatory choices on the basis of the company being a foreign company or using foreign manufacturing operations. As China progresses in developing the healthcare regulatory area, the hope is that these differential burdens will be eliminated.

As requested, this testimony addresses four core legal and regulatory areas in the China life sciences industry: (1) evolving limits on foreign participation in the digital healthcare market, (2) regulatory landscape for foreign participation in the medical device and digital technology market, (3) intellectual property challenges for foreign firms, and (4) current limitations on healthcare cross-border data flow.

II. Participation by Foreign Companies in the Digital Healthcare Market

China allows foreign companies to participate in its digital health market. Companies based outside of China can, and do, invest in the provision of online medical services and the development of mobile medical applications that are registered medical devices in China. China’s laws do not prohibit participation in those markets by foreign companies.

There are, however, features of China’s healthcare regulation that restrict foreign companies in the digital health area. These features pertain to the difficulties with commercial companies generally, and sometimes in particular foreign companies,

and Control of the New Coronary Pneumonia Outbreak (Feb. 28, 2020), available at http://www.gov.cn/zhengce/zhengceku/2020-03/03/content_5486256.htm.

⁵ Opinion on Deepening Reform of the Examination and Approval System to Encourage Drug and Medical Device Innovation, (CCP Gen. Off., State Council Gen. Off. No. 42, 2017), available at http://www.gov.cn/zhengce/2017-10/08/content_5230105.htm.

entering China’s healthcare infrastructure, which is largely based on a system of licensed hospitals.

First, all companies, whether foreign or domestic, face the challenge that, under China law, only licensed “medical institutions”—which is a generic term for hospitals and clinics in China—are permitted to provide medical services to individuals. Those medical institutions are licensed based on having sufficient facilities and personnel to deliver the medical services for which they are registered.⁶ Without such a license, a company cannot deliver or advertise those services.

As medical service is not defined in detail (and there are not sufficient carve-outs, for example, for health and wellness information or disease awareness), it can be difficult for any company to understand the line between providing general health and wellness knowledge and providing actual medical advice. To reduce risk, commercial companies that do not have this license may have to partner with a medical institution, whether state-owned or private, and negotiate terms with them, as opposed to having the option to provide some of these services in-house. Similar restrictions exist in the area of biobanking, which is limited to qualifying entities.⁷ Companies do not have freedom to biobank on their own absent a specific license.

A second restriction applies only to foreign companies, however. If a foreign company decides to invest in or seek to establish its own medical institution, in practice its ownership may not exceed 70 percent under current rules.⁸ In practice this has not prevented overall investment, but it is still a restriction that limits foreign investment independent of partners.

III. Medical Devices and Web Platforms

Use of technology for measuring and monitoring health indicators or assisting in disease diagnosis is another part of digital health.⁹ In China, if the instruments that conduct these functions are marketed as having a diagnostic, treatment, or disease monitoring function then they will likely need to be approved as medical devices¹⁰ by NMPA or one of the provincial medical products administrations, depending on

⁶ Medical Institution Supervision Regulations, Arts. 2, 15 (State Council No. 666, 2016), available at http://www.gov.cn/gongbao/content/2016/content_5139374.htm.

⁷ Human Genetic Resource Regulations, Art. 14-15 (State Council, No.

⁸ Special Management Measures for Foreign Investment Access (Negative List) (“Foreign Investment Negative List”), Item 33 (2019), available at

http://drc.changchun.gov.cn/zcfg/201907/t20190722_1948134.html; Interim Measures on Sino-Foreign Invested and Cooperative Medical Institutions, Art. 7 (Ministry of Foreign Trade & Econ. Collaboration, 2000), available at <http://www.satcm.gov.cn/fajiansi/gongzuodongtai/2018-03-24/2295.html>.

⁹ Medical Device Supervision and Administration Regulation, Art. 76 (State Council No., 685 2017).

¹⁰ Guiding Principles on Technical Registration Review of Mobile Medical Devices (NMPA No. 222, 2017), available at <https://www.cmde.org.cn/CL0112/7812.html>.

the class and the place of manufacture. Domestic and foreign companies can register their products as domestically made or imported devices, depending on where the products are made.

The differences between these two pathways (i.e., domestic and imported) are shrinking in many respects, but there are still disparities. For example, imported medical devices must generally be approved outside of China before they can be registered in China, whereas domestic devices may be registered with no foreign approval.¹¹ The applicant for an imported medical device registration must be the entity that holds the foreign approval in the country of origin; this restricts flexibility in structuring corporate relationships and partnerships in China. For example, foreign companies cannot transfer their marketing licenses to their China affiliates if the medical device is manufactured outside of China. To do that, they would have to transfer manufacturing to China. Also, China has maintained the requirement that foreign companies submit evidence of foreign approval despite the fact that NMPA conducts its own very rigorous review of the device marketing submission and, since 2015,¹² has established a robust inspection program for foreign medical device manufacturing facilities.¹³

China requires that all devices (including software) submit specifications that are based on China's own national and agency-level standards, which it treats as mandatory.¹⁴ This requirement restricts all companies from developing innovative designs. It can restrict any company that has designed their device abroad under more flexible medical device regulatory frameworks and that needs to conform that design to different standards in China, even if they are able to provide data to support the potentially more innovative design.

Also, certain expedited "green channel" pathways, such as the "innovative device pathway," require that intellectual property rights be held or licensed in China (even if the device is made abroad).¹⁵ A pilot marketing authorization program established in 2017 that gave more flexibility in structuring manufacturing relationships to include more than one manufacturing site was only available to entities that made their devices in China, although the China-based affiliates of foreign companies were permitted to participate.¹⁶

¹¹ Medical Device Registration Measures, Art. 13 (NMPA No. 4, 2014), available at http://www.gov.cn/gongbao/content/2014/content_2758500.htm.

¹² China Food and Drug Administration Organizes First Foreign Manufacturing Site Inspection for Medical Devices, available at <http://www.ccpie.org/cn/yjxx/ylqx/webinfo/2015/12/1481297436158390.htm>.

¹³ Regulations on Foreign Inspections for Drugs and Medical Devices (NMPA No. 101, 2018), available at <http://www.nmpa.gov.cn/WS04/CL2138/334163.html>.

¹⁴ Medical Device Supervision and Administration Regulation, Art. 6.

¹⁵ Innovative Medical Device Special Approval Examination Procedures, Art. 2 (NMPA No. 83, 2018), available at <http://www.nmpa.gov.cn/WS04/CL2093/331560.html>.

¹⁶ Notice on the Expansion of the Medical Device Registrant System Pilot Work (NMPA Device Reg. Div., No. 33 2019), available at <http://www.nmpa.gov.cn/WS04/CL2197/339662.html> (program in 21 provinces named therein).

Deployment of digital health technology via the Internet can also be limited. While this is not my area of expertise, China's Internet regulations place restrictions on ownership of servers in China by foreign companies. If the websites on those servers are conducting for-profit activities, they must receive telecommunication licenses—which are difficult generally to obtain—and even then the foreign invested company may only own 50% of the telecommunications venture.¹⁷ To deploy technology online, foreign companies must often partner with Chinese technology or Internet companies to release the applications on websites in China.

Content that is released online is subject to stringent content and advertising restrictions under special rules for drugs, medical device, and medical service advertisements,¹⁸ rules governing drug and medical device informational websites, and rules governing Internet advertisements generally.¹⁹ These restrictions apply to all online content, regardless of whether it comes from a foreign or domestic company.

IV. Intellectual Property Restrictions

Restrictions on intellectual property gathered from research depend on the context. For example, there is a set of laws and regulations that govern when research is funded by the Chinese government. In general, those laws require that there be an agreement between the government and the Chinese party on the allocation of intellectual property obtained from the research.

If a Chinese company takes a grant from the government and later decides to transfer its rights to foreign parties, the law may call for the Chinese company to first obtain permission from the government department supervising the research.²⁰ In practice, however, it is not clear that these provisions have played a serious and limiting role. My understanding is that these restrictions can be navigated, and I am not aware that the government regularly restricts these transfers.

¹⁷ Special Management Measures for Foreign Investment Access (Negative List) ("Foreign Investment Negative List"), Item 20 (2019), available at http://drc.changchun.gov.cn/zcfg/201907/t20190722_1948134.html.

¹⁸ Advertisement Law, Art. 16 (Nat'l People's Cong. Standing Comm. 2018); Medical Device Advertisement Examination Standards (SAMR, NMPA No. 40, 2009), available at <https://www.cmde.org.cn/CL0094/2237.html>; Medical Service Advertisement Rules (NHC No. 26, 2006), available at http://www.gov.cn/ziliao/flfg/2006-11/28/content_455183.htm.

¹⁹ Tentative Measures on Internet Advertisements (SAMR No. 86 2016), available at http://www.cac.gov.cn/2016-07/08/c_1119187555.htm.

²⁰ Law on the Scientific and Technological Progress, Art. 21 (Nat'l People's Cong. Standing Comm. 2007); Law on Promoting the Transformation of Scientific and Technological Achievements, Art. 6 (Nat'l People's Cong. Standing Comm. 2015).

The more serious impediment for foreign companies or foreign invested companies (i.e., companies based in China that have some level of foreign investment) is China's Human Genetic Resources (HGR) Regulations. Those regulations were first issued in 1998, but were largely unenforced or narrowly interpreted until 2015. The HGR Regulations protect biological samples containing the genetic code of Chinese citizens and the information associated with those samples as a national resource.²¹ The HGR Regulations tie the protection of this natural resource not only to public health but also to the national security of China.

Under the HGR Regulations, foreign companies or any company controlled (in some measure) by a foreign company may not independently collect, store, use, transfer, or export human biospecimens obtained in China. These companies may only take some of these actions as part of a collaboration with a Chinese party, and that collaboration must be approved by the Office of Human Genetic Resources Administration (OHGRA), which is an agency under the Ministry of Science and Technology.

This means that for every foreign-sponsored clinical trial in China in which, for example, a blood sample is taken there must be an approval by OHGRA. This approval is in addition to the approval by the drug regulator, NMPA, to conduct the trial and the approval by the local ethics committee(s) in the relevant hospitals. HGR approval occurs at the end of the process and adds several months to the preparation time for a trial.

The HGR Regulations also include an intellectual property restriction that is enforced.²² In order to obtain HGR approval, the Chinese party and the foreign party must agree on how to divide intellectual property associated with the study. The OHGRA has explained that it does not interpret this requirement as applying to the background drug or device itself, or the data generated to assess the endpoints in the protocol.²³ But, the HGR Regulations require that if any patentable inventions arise out of "exploratory research" associated with the collaboration, the Chinese and foreign parties must jointly share the patent rights.²⁴

This joint-patent rule is not a default rule that the parties can contract around. Rather, this sharing is required and OHGRA approval will not occur without an acceptable intellectual property provision in the clinical trial agreement and HGR application. Therefore, the joint-patent rule results in difficult negotiations with the hospital and the OHGRA, sometimes with uncertain conclusions surrounding rights

²¹ Human Genetic Resource ("HGR") Regulations, Art. 8 (State Council No. 717, 2019).

²² HGR Regulations, Art. 24.

²³ The OHGRA has not issued a great deal of explicit guidance but has made these statements in response to inquiries. It may be inferred from their forms, *Compare* application forms for a notification pathway for research to support marketing ([here](#)) with the forms that support approval for broader research ([here](#)). The latter have an intellectual property section, while the former do not.

²⁴ HGR Regulations, Art. 24.

to the data and intellectual property coming from the study centered around an undefined principle of “exploratory research.”

V. Cross-Border Data Flows

The HGR Regulations also have a data flow restriction, meaning they cover not only the biospecimens (or the human genetic materials) of Chinese citizens but also the data associated with those biospecimens (human genetic information). Any time this clinical trial data is transferred to a foreign party, the OHGRA must be notified in some way.²⁵

OHGRA is notified through a two-step process. In the first step, the data must be uploaded to a government website (and kept on file). In the second step, the parties to the collaboration work together with the hospital that hosted the clinical trial to upload a form that describes where the data is going. Once OHGRA accepts both submissions the data may be transferred. Before accepting the application, OHGRA has the option to conduct a national security review to determine if the data is sensitive.²⁶

The implication of this data restriction is that any scientific data that comes from tests on human samples in China requires a potentially cumbersome process to transmit the data from Chinese to foreign parties.

Enforcement in the HGR area is a concern. In 2018, while OHGRA originally focused on cases in which samples were received without permission, recent regulatory changes indicate it can expand to data.²⁷ Penalties could include fines and orders to destroy the samples, as well as disqualification of a company from applying for future studies for several years. Due to the recent amendment to HGR Regulations in 2019, the penalties are more substantial and possibly include hundreds of thousands of dollars in fines and, in serious cases, life time disqualification.²⁸ This includes penalties for a foreign company that exports samples or data abroad in violation of the regulations.

China has other data restrictions. For example, China has a Cybersecurity Law, which it has been slowly implementing and can potentially restrict cross-border data transfers for operators of “critical information infrastructure” (a term that is still being defined). China also has Scientific Data Management Regulations that regulate the flow of scientific data funded by the government, and various

²⁵ HGR Regulations, Art. 28. Collaborators in the approved project are not subject to this restriction, but they are limited to a defined universe of entities, including the sponsor of the study, *Id.*

²⁶ The process is described in Scope and Procedures for Filings of Provision of HGR Information Abroad or Release for Use, available at <https://fuwu.most.gov.cn/r/cms/zwpt/web/assets/pdf/8.rlyczyxxdwtghkfsybafwhcx.pdf>.

²⁷ Penalties from 2018 are listed, [here](#).

²⁸ See, e.g., HGR Regulations, Arts. 41, 43.

provisions in other regulations that prevent healthcare data from being stored outside of China. For example, the Internet hospital regulations prevent healthcare data storage outside China. My understanding, however, is that the HGR restriction has been the most difficult in practice to date.

VI. Conclusions

I would like to thank the Commission again for the opportunity to offer this perspective. China has made considerable progress in building the legal and regulatory infrastructure for its healthcare and life sciences industries, including in particular digital health. There is more to be done, however, to remove problematic restrictions and limitations. For example:

- Restrictions on certain areas of foreign investment and mandates that require Chinese-foreign joint ownership in certain percentages, including in the areas of internet platforms and medical institutions, should be lifted or eased.
- The gap between the imported and domestic pathways for medical devices should be closed to promote innovation and create opportunities to structure valuable partnerships. For example, no evidence of foreign approval should be required regardless of the approval status abroad, if the device can meet the standard for approval.
- Chinese standards and testing laboratories should not be mandatory if the necessary data can be generated in other reliable ways.
- There should be additional flexibility and legal support (i.e., it should be legally permissible) for use of the Internet to offer and promote health and general wellness platforms.
- Parties to scientific and clinical research projects should have the freedom to freely enter into collaborations and contract with respect to intellectual property associated with those endeavors.
- There should be realistic mechanisms and channels to permit and facilitate the transmission of biospecimens and pure scientific and research data out of China, and to allow institutions and companies that generate that data to store it in China and abroad.