

# U.S. Companies' Access to Health Industries and Market Opportunities in China

Prepared statement by

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## Changing Landscape for the China's Healthcare Market

China's healthcare market has expanded continually during the past five years. The market increased from [\\$357 billion](#) in 2011 to [\\$761 billion in 2017](#). Growth is expected to continue and by 2020 it is estimated to reach [\\$1.19 trillion](#). Driven by rapid population aging, a growing burden of non-communicable diseases, emergence of a sizable middle class, and advancement in technology, the trend is expected to sustain in the coming decade. At present, however, healthcare spending in China still accounts for only [6.4 percent](#) of its GDP, which is lower than the average of OECD countries (9.0 percent). According to China's National Health Commission, the total size of China's healthcare market will reach [\\$2.39 trillion](#) by 2030. As far as pharmaceuticals are concerned, China is the second-largest market in the world, [valued](#) at \$123 billion in 2017. The pharmaceuticals market is projected to reach \$175 billion by 2022.

An equally significant development is the [growing competitiveness](#) of Chinese domestic pharmaceutical industry. Beginning in 2013, but especially after 2015, the number of Investigational New Drug (IND) applications submitted by Chinese firms has increased significantly. In 2017, 162 applications were submitted, up from 73 in 2013. In 2018, the number of new drugs developed by Chinese firms and approved by U.S. FDA has hit 430. Since 2013, major Chinese pharmaceutical firms such as Fosan, Luye, Shanghai Pharma and Humanwell Healthcare have been actively involved in cross-border mergers and acquisitions (M&As). Between 2013 and 2017, the number of cross-border M&A cases increased from 7 to 52, and the amount involved increased from \$1.2 billion to \$11 billion.

Private hospitals in China have had rapid growth in numbers. Thanks to government support of the entry of private capital in the healthcare sector, the [number of private hospitals](#) increased by 85 percent between 2013 and 2018, from 13,396 to 12,032. However, due to their inability to attract top physicians and the public's lack of trust in them, private hospitals in China tend to be small in size and provide only a limited number of services. That might explain why general hospitals (almost all of them public) continue to expand in China. In 2018, healthcare spending in those hospitals was estimated to be more than \$350 billion, an 86 percent increase over 2013. It was [estimated](#) that by 2022 general hospitals' market value will be 71 percent larger than the 2018 level.

Rapid growth of the global pharmaceutical industry has also boosted the expansion of contract manufacturing organizations (CMOs) and contract research organizations (CROs) – two forms of outsourcing services from providers – in China. Of the more than 1,100 CROs around the globe, nearly 30 percent are based in China. Propelled by the relatively low R&D cost and favorable policies and capital, Chinese [CRO industry scale](#) is expected to expand by more than 250 percent, from RMB68.7 billion in 2018 to RMB242.5 billion in 2025. Being one of the most comprehensive service platforms integrating discovery, research, and development of small-molecule chemical drugs, WuXi AppTec [claims](#) 10 percent of the world's CRO market. Driven by its complete infrastructure, adequate raw material supply, and low operating cost advantage, China is also [rapidly expanding](#) its CMO market share. Despite [problems](#) protecting human subjects and poor transparency, during 2007-2017 more than 11,000 clinical trials were launched in China, making it the [fourth largest](#) country in terms of the number of clinical trials.

Overall, there are four major drivers in China's healthcare market. First, changes in the global pharmaceutical industries provide strong incentives for multinational pharmas to outsource their R&D and manufacturing activities to China. Second, Chinese society is rapidly ageing, which is highly associated with non-communicable diseases (NCDs), including cardiovascular diseases, cancer, hypertension, and diabetes. China's population aged 65 and older is forecast to grow from 91 million in 2017 to 143 million in 2027 (US: 48.9 million in the same year). The size of elderly population presents [a huge market](#) for healthcare industry. Third, health is now high on Chinese leaders' agenda. In August 2016, China held its National Health Conference, which was the most important national meeting on health in twenty years. Following the meeting, China released the Healthy China 2030 Plan, which places public health as a policy priority. Finally, China's healthcare reform has focused on improving access and affordability. Health insurance schemes have been extended in China to cover virtually the entire population, which also stimulates demand for more and better healthcare.

## **Government Support Measures**

The Chinese government is committed to the development of China's own health, biotech, and pharmaceutical industries. An industrial policy document entitled "Made in China 2025" has identified pharmaceuticals and medical devices as one of the 10 strategic industries to receive subsidies and other government support. In 2017, China [earmarked](#) approximately \$13.2 billion to pharmaceutical R&D, which accounts for 8.9 percent of the global total in the same year. China's investment in this area is expected to reach \$29.2 billion in 2021, which will lead to the rise of its global share to 18.3 percent. It has also unveiled a number of initiatives to lure overseas Chinese scientists living abroad home. It was reported that nearly [one third](#) of the recruits of the Thousand Talents Plan – a high-profile, state-backed recruitment drive to attract overseas Chinese students and academics – have expertise in life sciences and medicine. Thanks to government support, China is quickly rising as a powerhouse in biomedical R&D. By the end of May 2017, China had nearly [300 biosimilars](#) (a biosimilar is defined as a biologic medical product that is almost an identical copy of an original product manufactured by a different company) under research and development, making it the country with the largest number of biosimilars

in research and development. The Chinese biosimilar market is expected to [hit](#) more than \$5.5 billion by 2025.

Beginning in late 2015, Chinese drug regulating agency – then China Food and Drug Administration (CFDA), now the National Medical Products Administration (NMPA) – has also kicked off reforms to accelerate the approval process for investigational new drugs (IND). Drug reviewers at the Center for Drug Evaluation (CDE) [increased](#) to more than 800 by the end of 2017, up from 70 in 2015. As a result, annual number of new drug approvals [increased](#) from 5 in 2016 to 40 in 2017. In 2018, the government agency greenlighted another 51 new drugs.

Since 2016, the government has also made efforts to consolidate its pharmaceutical industry. CFDA imposed stricter quality standards (in terms of safety and efficacy) on the production of off-patent generic drugs, which aims at [weeding out](#) over half of the nation's 2,900 or so small domestic drug makers.

In 2018, the government reduced the tax burden on pharmaceutical products to make them more available and affordable. In April, China [announced](#) it would cut the import value-added tax (VAT) on cancer drugs from 17 percent to 3 percent. From May 1, import tariffs on all common drugs and cancer drugs were reduced to [zero](#). This was followed by another [decision](#) in February 2019 to cut the VAT rate to 3 percent on medications for 21 rare diseases. Reducing VAT on these drugs will make the imported drugs cheaper in Chinese market, and increase the demand for these drugs. Meanwhile, China has [promoted](#) the research and availability of generic drugs that are in short supply, especially those used for the treatment of major infectious diseases, rare diseases, and pediatrics. As a result, Chinese pharmaceutical firms are [increasingly focused on](#) the development and production of finished pharmaceutical products (FPPs) for the domestic market (rather than concentrate only on the production and export of active pharmaceutical ingredients or APIs).

In addition, China has pursued the application of big data analytics in healthcare a national priority. Since 2014, there has been [growing investment](#) in Big Data analytics for healthcare. In 2016, there were 66 such cases. In the first quarter of 2018, there were 35, and more investment in this area is expected. China seeks to take the lead in the nascent field of precision medicine. In 2016, China launched an initiative to earmark \$9 billion to sequence and analyze genomes over the next 15 years, which [dwarfed](#) the \$215 million precision-medicine initiative launched by the Obama administration the same year. Artificial intelligence (AI) is set to play a bigger role in China's hospitals. The technologies, for example, could be used to provide initial diagnoses in a quicker, less intrusive but more accurate way. AI health market in China was [estimated](#) to be more than \$3 billion in 2018, a 53 percent increase over 2017.

### **U.S. Healthcare Firms' Access to the Chinese Market**

According to [data from WTO](#), China is one of the world's largest import market for pharmaceuticals and medical devices. In 2017, it was the 6<sup>th</sup> biggest import market for pharmaceuticals, with shipments valued at \$25.3 billion, and the 4<sup>th</sup> largest import market for medical devices, with shipments worth \$7.4 billion. This does not include pharmaceuticals and medical equipment produced and sold in China by multinational pharma. According to [a joint report](#) from McKinsey and the Chinese Pharmaceutical Association, in 2016, multinational firms claimed 35 percent market share in Level-III hospitals (i.e., urban health centers) and 27 percent market share in Level-II hospitals (e.g., county-level hospitals). They also claimed 44 percent market share in first-tier cities (Beijing, Shanghai, Guangzhou, Shenzhen) and 31 percent market share in second-tier cities (e.g., Hangzhou, Nanjing, Chongqing, and Jinan).

The lack of competitiveness of China's domestic healthcare industry and Chinese consumers' preference for high-end, imported pharmaceutical products help boost sale of products developed and manufactured by U.S. firms. About [95 percent](#) of China's registered drugs are generic ones, which are prone to low-quality problems. Despite the emergence of some large pharmaceutical firms (e.g., China Resources, SINOPHARM), China's pharmaceutical industry remains notoriously fragmented and uncompetitive. In 2016, the top 10 pharmaceutical firms accounted for only 10 percent of industry sales, compared with 48 percent in the United States. Fragmentation of Chinese pharmaceutical industry also keeps R&D investment as low as 5 percent of sales for Chinese firms, compared with 20 percent for U.S. companies. As far as medical device products are concerned, Chinese manufacturers dominate the domestic market, but they deliver mostly [low-tech and mid-range products](#). In 2014, 70 percent of the medical device products in the world were made in China, but a large number of them were probably manufactured for [Original Equipment Manufacturers \(OEM\)](#) (mostly MNCs).

Since 2017, [a raft of government measures](#) to smooth new drugs' road to approval have facilitated U.S. access to the Chinese market. In October 2017, the government [announced](#) plans to accept data of clinical trials carried out overseas. This move would [be welcomed](#) by U.S. pharmaceutical companies because until 2017 stringent clinical trial data requirements were responsible for the delay of more than 7 years for U.S. drugs to enter Chinese market. The [first licensed HPV vaccine in China](#), for example, was approved only in 2016, a decade after its US approval. As a result of fast-track approval and local study waiver, [the drug lag](#) has been reduced to 2.3 years. Merck's Gardasil 9 HPV vaccine was actually approved by the CFDA just nine days into the review process. According to [a report](#) from Deloitte LLP, the number of approvals for new drugs developed by multinational pharmaceutical companies increased from 3 in 2016 to 39 in 2017 and 40 in 2018. China further opened up its pharmaceutical market in May 2018 by exempting all cancer drugs from import tariffs. In October, the government [approved](#) 17 new cancer drugs – most of them imported drugs – to be included in its national health insurance system.

Additional pressures for opening the Chinese pharmaceutical market, especially the market for vaccines, built up in the summer of 2018, after one of China's largest domestic vaccine makers was found to have sold at least [250,000 substandard doses of vaccine for diphtheria, tetanus and whooping cough](#). The scandal seriously undermined people's confidence in the domestic vaccines. A [survey](#) of 300,000 parents suggested that 79 percent said that before the scandal, they would have given their children a Chinese-made vaccine, but only 36 percent said they would still do so now. Sixty percent of respondents said they were considering having their children inoculated outside mainland China.

### **Challenges Faced by U.S. Health Firms In Selling into the China Market**

Despite conditions that facilitate market access, U.S. health firms face new challenges in selling into the China market. The government industrial policy clearly targets Chinese domestic healthcare industry to improve its competitiveness against foreign firms. Released in 2015, Made-in-China 2025 seeks to [increase](#) the share of domestic content of core components and materials of medical devices to 40 percent by 2020 and 70 percent by 2025. The government has also put in place measures to encourage the development and production of generic drugs by domestic Chinese pharmaceutical firms. Large Chinese pharma such as Sino Biopharmaceutical are beefing up their innovative capabilities. As of January 2018, China (tied with Canada and trailing U.S. and U.K.) has the [third largest](#) number of pharmaceutical firms developing new drugs. It was [reported](#) that executives from some multinational pharmaceutical firms are leaving for new positions in Chinese pharmaceutical firms.

With the deepening of China's healthcare reform, foreign pharma are also facing increasing pressures to ["be cooperative"](#) by making their drugs more affordable. Since 2016, Chinese government has organized a

nationwide drug price and reimbursement list negotiation, which determines what new and innovative drugs to be included in the government reimbursement list. Under the single-payer system, the newly created National Healthcare Security Administration (NHSA) possess much more leverage than its predecessors in negotiating with foreign pharmas for price cuts. The negotiations resulted in [an average price cut](#) of 44 percent across 36 products in 2017, and 57 percent across 17 products in 2018.

It is worth noting that despite significant price reductions, foreign pharmaceutical manufacturers have not seen drops in their sales for these drugs. Because of the increasing volume of sales that comes from government reimbursement, sales of the 36 drugs included in the government negotiations actually [increased](#) by an average of 40 percent. For this reason, many foreign companies seem to be [willing](#) to compromise on the price in order to gain access to the market in China.

In April 2018, the Chinese government unveiled measures that included authorizing the granting of [compulsory licenses](#) to enhance the availability of innovative drugs. Beginning in July, public outcry also has prompted the government to [tame prices of cancer drugs](#) sold by foreign pharmaceutical companies. This was followed by a new procurement scheme introduced in late 2018 which aims to dramatically cut the amount of payment for generic drugs covered by health insurance. The new policy listed 31 drugs for procurement in a program that covers all public hospitals in 11 cities (which combined represent a third of China's pharmaceutical market). Pharmaceutical firms are invited to submit competing offers in the bidding process, with the one that can offer the lowest tender price automatically chosen as the winner and collects the entire guaranteed purchase amount from all 11 cities. Under the [cut-throat, winner-takes-all bidding process](#), multinational pharmas stand to lose major market share for their high-cost, off-patent pharmaceuticals because quality assurances for their medicines are no longer the guarantee to win hospital tenders.

In June 2019, NHSA launched a pilot program of diagnosis-related groups (DRGs) that classifies hospital cases into different groups, in 30 cities. It is expected to take [five to ten years](#) for the measure to be fully implemented nationwide. The new provider payment reform measure aims to lower the cost of pharmaceutical products (which now count as costs in DRG payment). This [poses new challenges](#) for foreign pharmas marketing their products: not only will they have to ensure their products are included in the treatment protocols of different patient groups, but the new provider payment method might discourage doctors from prescribing new and innovative drugs in order to lower drug costs.

The ongoing trade war also threatens US pharmaceutical firms' efforts to access the Chinese market. While the tariffs on approximately \$300 billion worth of Chinese products proposed by the United States Trade Representative (USTR) in May 2019 [excludes](#) "pharmaceuticals, certain pharmaceutical inputs, and select medical goods," the list [unveiled](#) by the Chinese government to impose punitive tariffs on imported U.S. goods included commonly used drugs and medical devices. A leading Chinese economist also [implied](#) early this year that Beijing curb its exports of APIs as a countermeasure in the trade war with the United States. As Washington tightens scrutiny of investment from overseas, [Chinese venture capital investment](#) in the U.S. biotech firms fell by more than half in the first half of this year, raising fears that U.S. pharmaceutical start-ups will encounter difficulties to raise funds and access the Chinese market.

### **Regulatory Burdens for Foreign Pharmaceutical Firms**

Despite China's efforts to improve its regulatory process, its volatile, obscure, and byzantine regulatory system continues to present significant burdens to foreign pharmaceutical firms seeking to operate in China. The onerous requirements also makes the market out of reach for small for start-up companies with limited investment capital. Foreign firms are still [required](#) to renew their drug import license every



five years. Since the renewal is not guaranteed, the uncertainty has negative impacts on the long-term stability of their operations in China. Foreign companies also face tough disclosure requirements in filing new applications for their products. According to guidelines of China's National Intellectual Property Administration (CNIPA), all the relevant experimental data demonstrating the efficacy of the product [must be included](#) at the time of application, and post-filing data cannot be used to defend against invalidation. Such data requirements [make it difficult](#) for applicants to file new applications in a timely manner.

It is also difficult for foreign pharmaceutical firms to get their products included in the National Reimbursement Drug List (NRDL), aka the China National Formulary (CNF). The list covers basic drugs, but it includes mostly common and inexpensive drugs and is not updated very frequently. Companies [complain](#) that pharmaceutical tendering is too frequent, involving too many government agencies and they have to be on the go across the country to participate in a tender. Centralized tendering and procurement system for pharmaceuticals contributes to additional regulatory burden for foreign firms. In addition, hospitals may refuse to use the drugs that won the bid.

Foreign pharmaceutical firms are also increasingly subject to tougher enforcement of China's anti-bribery laws. China's revised Anti-Unfair Competition Law (AUCL), which came into effect in January 2018, [prohibits](#) individuals and entities from bribing a business counterpart or public official, or using other means to obtain a business opportunity or competitive advantage. It also prohibits bribery via a third party (an individual or entity), and employers will be held liable for their employee's bribery acts. In May, the newly created State Administration for Market Regulation (SAMR) kicked off a campaign to crack down on unfair competition and commercial bribery with a focus on activities in the pharmaceutical and medical device sector, a sector which is traditionally prone to high bribery risks. Because product prices of foreign firms are typically higher than those of domestic ones, it is [not uncommon](#) for foreign firms to use agents to host academic conferences to entertain hospital managers or doctors in order to have their products sold in Chinese hospitals. Such "hidden practices" are now the target of the crackdown as China gears up its enforcement of anti-corruption law.

### **Enforcing Pharmaceutical Intellectual Property Rights**

Although a large percentage of U.S. companies in China [identified](#) lack of protection of intellectual property (IP) rights as a major regulatory challenge, disputes over pharmaceutical-related IP have not been a prominent concern in U.S.-China economic relations. Driven by the need to join the World Trade Organization (WTO), China not only extended all patent coverage to twenty years, but also capitulated to U.S. demands on issues such as data exclusivity and patent linkage. Upon its WTO entry, China agreed to adhere to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which sets standards for IP protection. Unlike India, China has not used the flexibility offered in the WTO TRIPS regime and the Doha Declaration on the TRIPS Agreement and Public Health (2001) to take an aggressive approach toward patent-related issues, despite an AIDS epidemic, an unprecedented crisis of non-communicable diseases, and a pharmaceutical industry capable of producing generic versions of most patented drugs sold in China. Thus far, there have been no successful applications for compulsory licensing of any patented drugs in China. Since 2014, IP courts have been established in approximately 20 Chinese cities. In January 2019, the Supreme People's Court [launched](#) the appellate tribunal for IP disputes. Starting May 2018, China has also [lengthened](#) patent protection on pharmaceuticals from 20 to 25 years. Thus far, concerns about China's enforcement of IP rules appear [not to have had a significant impact](#) on the flow of pharmaceutical-related investment into China.

Compared with pharmaceutical companies, U.S. medical devices manufacturers may be more concerned about IP enforcement when selling their products in China. They may soon find their competitors in China offering a similar product at much lower price (and very likely lower performance level as well). To some extent, the OEM practice encourages product copycat in China. It is also relatively easy to challenge an established patent in China. Anyone can challenge a patent's validity in China without having to show up at a hearing in person. This presents a potential blackmailing or money-making opportunity. According to a report, since 2015 nearly 75 percent of the challenges to pharma patents have resulted in at least one claim being [invalidated](#).

## Policy Recommendations

In October 1982, Bristol-Myers Squibb founded Sino-American Shanghai Squibb Pharmaceutical Ltd, the first China-U.S. joint venture pharmaceutical firm. By the end of the 1990s, almost all the major U.S. pharmaceutical and medical device firms had set up shops in China. A look at U.S. companies' engagement in China's healthcare market reveals self-sustaining dynamics that until recently enabled them to expand and thrive despite the fluctuation in U.S.-China relations. Today, the booming Chinese healthcare market has created both opportunities and challenges for U.S. firms. If history can teach us anything, it is that both sides should avoid putting the healthcare industry at risk of collateral damage as a result of a deteriorating bilateral relations. USTR did the right thing by [excluding](#) pharmaceuticals, certain APIs, and select medical goods from the proposed tariffs in May, but the on-and-off of key products used by U.S. drug makers from the trade tariff list is creating [uncertainties](#) for U.S. biopharmaceutical companies. Tightening scrutiny of Chinese investment in the U.S. biotech firms also may cripple US pharmaceutical start-ups' ability to raise funds and access the Chinese market. It is important to urge China to enforce pharmaceutical-related IP. As pharmaceutical industry's value chain becomes globalized, and international collaboration over health-related research becomes the norm, however, we should avoid looking at the entire US-China health-related exchange and investment through the prism of national security. In a nutshell, do no harm. This principle applies to both U.S. and China. We should deliver an explicit message to the Chinese side that healthcare products should not be used as a weapon in the U.S.-China trade war.

However, the U.S. government can still do more. It should significantly step up investment in healthcare-related R&D, especially in areas such as AI health and precision medicine. It should continue supporting U.S. companies' access to the Chinese healthcare market. In the trade negotiations with China, the USG should urge the adoption of effective measures to level the playing field and ensure fair treatment of U.S. companies, which involves eliminating unnecessary or unreasonable regulatory burdens shouldered by foreign companies operating in China. In urging China to open its healthcare market to foreign competition, we should let China know that doing so would not only improve Chinese people's access to safer, affordable, and effective pharmaceutical products, but also – given the strong public outcry over substandard drug products made by Chinese domestic firms – contributes to social and political stability. It is worth noting that none of China's vaccine scandals have involved foreign manufacturers. It should also support the expansion of private hospitals so that they become truly competitive actors in China's healthcare market. The U.S. can also help China beef up its regulatory capacities in the healthcare sector. This involves encouraging NMPA to further improve its review process, helping improve oversight when conducting clinical trials and supporting the creating of an independent IP court system. The U.S.-China Social and Cultural Dialogue, the only high-level forum to discuss U.S.-China cooperation after 2017, should be reopened as an institutional venue to discuss these issues.

U.S. companies, meanwhile, should seize upon the opportunities provided by China's regulatory reforms to sustain its competitive edge in the Chinese market. Rather than view China as a "second-wave" market,

U.S. pharmaceutical firms should prepare to have their innovative new drugs included in the National Reimbursement Drug List once they are approved by FDA. They need to ensure maximum protection of their products by making use of the full IP framework that exists in China. They may also want to take a more proactive role in China's healthcare reform by making the most effective drugs more affordable in China. As negotiations that led to the inclusion of pharmaceuticals made by foreign pharma in the NRDL showed, a win-win outcome is indeed possible. The Chinese market is sufficiently large and diverse that there is always something for everyone.