

**PREPARED STATEMENT OF
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**Exploring U.S. Companies' Access to Health Industries and Market Opportunities in
China**

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Introduction

The US-China Business Council (USCBC) is a private, nonpartisan, nonprofit organization of approximately 200 American companies that do business with China. From our headquarters in Washington, DC, and offices in Beijing and Shanghai, China, we represent American companies engaged in business across all industries and sectors in China, including manufacturers and marketers of pharmaceutical and medical device products.

US life sciences companies see tremendous opportunities in China, but also continue to face significant market access barriers there. These barriers include regulatory approval delays, pricing and reimbursement controls, insufficiently effective intellectual property (IP) protection and enforcement, and discriminatory localization requirements that advantage domestic companies over foreign multinationals. Efforts to strengthen Chinese industries' domestic competitiveness also contribute to the unlevel playing field for foreign companies seeking to participate in China's healthcare market.

Because China is now one of the world's largest and most dynamic markets for the health industry, it is more crucial than ever that these market access barriers be resolved. Companies that are not successful in China can no longer expect to be successful global players in the long run. If US companies in the health space are to remain trusted, innovative, global industry leaders, the challenges our companies face in China must be effectively addressed.

These issues are highly technical, unique to the health industry, and most effectively resolved by involving industry experts with deep knowledge of the sector and policy implications. A framework for regular dialogue between US and Chinese health regulators and industry representatives is necessary to effectively and sustainably address these issues. Greater engagement with Chinese regulators and industry representatives in international forums should also be a priority, and opportunities to work together on enforcement and educational efforts should be leveraged.

China health market: Overview & Opportunities

Growth in China's health market is driven by a rapidly aging population, expansion of the middle-class, and recent government reforms. China is the world's second largest market for pharmaceuticals after the United States, and fourth largest medical equipment market. China's medical device sector is among the country's fastest growing, maintaining double digit growth for over a decade.¹

¹ Export.Gov, [Healthcare Resource Guide: China](#), (17/07/2019)

US exports of pharmaceutical products and medical or surgical equipment to China have increased year-over-year for over a decade. Exports of pharmaceuticals went from just under \$400 million in 2008, to \$2.8 billion in 2018.



Source: US Census Bureau, U.S. Import and Export Merchandise trade statistics.

China's total health expenditure is around five percent of Gross Domestic Product (GDP), compared to 17 percent in the United States,² indicating the sector is still in its infancy and primed for growth. The size and growth potential of China's healthcare market makes it one of the most promising, long-term markets for US pharmaceutical and medical device manufacturers. USCBC's annual member survey consistently indicates that most American companies invest in China to access and compete for Chinese customers. Though current trade tensions will impact investment decisions, preliminary findings from USCBC's 2019 survey indicate a majority of members plan to maintain their resource commitments in China in the coming year.

The health sector is an increasingly prioritized area of strategic national interest for the Chinese government. The 13th Five Year Plan, released in 2016, prioritizes health and innovation, and President Xi Jinping's Healthy China 2030 initiative made health an explicit national priority to be included in all aspects of strategic planning.

² The World Bank, [Current health expenditure \(% of GDP\)](#), (17/07/2019)

China is currently undertaking a comprehensive set of reforms to give citizens greater access to healthcare services. US companies have substantial experience developing and operating healthcare infrastructure and solutions in global markets. Allowing broader foreign participation in China's healthcare market and in its reform process would allow Chinese consumers greater access to innovative technologies and products, international best practices, and high-quality services—accelerating the reform process.

However, the opportunities the market and these initiatives present are tempered by the challenge of competing in an environment where local or provincial government practices unfairly favor domestic players. Biopharmaceuticals and high-performance medical equipment are among the 10 strategic sectors included in Made in China 2025 (MIC 2025), a government initiative to upgrade China's domestic innovation-driven manufacturing sectors and create global leaders. While the goal of improving Chinese capabilities and patient trust in local companies is laudable, it is important to ensure such initiatives are WTO compliant and implemented transparently, to ensure they do not unfairly discriminate against foreign companies. When specific concerns are identified—such as domestic and international market share targets in strategic industries—the United States should coordinate with like-minded trading partners to ensure a coordinated response. A unilateral approach gives US negotiators less leverage and exposes the US to the double-whammy of retaliation and seeing European and Japanese competitors step into the void.

Regulatory Overview: Progress and Remaining Challenges

China's healthcare market has evolved significantly over the last five years. The government began a comprehensive reform of China's health sector in 2016. The former China Food and Drug Administration, now the National Medical Product Administration (NMPA), released a series of draft policies collectively known as the "innovation policies." The draft policies encourage innovation in drugs and medical devices by accelerating the review and approval for new drugs and medical devices, reforming clinical trial management, and enhancing innovator rights.

If fully implemented, these policies have the potential to streamline market access and improve the operating environment for US drug and medical device companies in China. Several of these proposed reforms also address key outcomes outlined in previous US-China trade negotiations. The 2016 US-China Joint Commission on Commerce and Trade (JCCT), for example, reaffirmed China's commitment to encouraging clinical-value-oriented innovative drugs to be registered and marketed in China, and noted that China would further improve related policies. While several revisions and guiding documents for the regulations have been released, and implementation has begun in some cases, other reforms stalled after 2017.

The March 2018 mass reorganization of government institutions, including the key regulatory agencies for life sciences and healthcare industries, is a contributing factor in slowed and stalled implementation efforts. The China Food and Drug Administration (CFDA) and National Health and Family Planning Commission (NHFPC) were dismantled, with core functions integrated into the newly created National Medical Products Administration (NMPA), National Health Commission (NHC), and the State Medical Insurance Bureau. The reorganization placed NMPA under a new giant, market regulator, the State Administration for Market Regulation (SAMR), a centralized authority overseeing regulation of intellectual property, anti-monopoly, food safety and standards, testing and certification. Following the reorganization, the former head of CFDA was appointed Party Secretary of SAMR. However, shortly thereafter a major vaccine safety

scandal at a local manufacturer forced his resignation. The leadership turnover and departure of a prominent health reformer also contributed to delays in health sector initiatives.

In the longer term, we hope the streamlining of regulatory oversight of the health industry, and potential for greater cooperation between health and IP regulators, will ultimately help improve efficiencies and enforcement. Encouragingly, at the end of 2018, health and IP related reforms began to pick up again. While progress is still necessary, reforms appear to be moving in the right direction.

Regulatory Approval System

One area directly benefiting US companies is China's reforms strengthening its framework for drug and device regulatory review and approval. This includes the launch of expedited and priority review and approval mechanisms, moves to accept overseas clinical data, as well as strengthening the capacity of reviewers to reduce China's drug lag. These efforts are expected to help streamline and significantly speed-up the market access process for US companies, and are consistent with industry's primary recommendations.³

In February and July 2018, NMPA issued technical guidance on the acceptance of overseas clinical trial data for devices and drugs, respectively. Previously, China did not accept clinical trial data developed overseas to support new medical product approval. This reform will accelerate the lengthy and costly process of conducting additional clinical trials in China. While the reform is welcome and there has been steady improvement, to date there has been no tangible implementation or confirmation of companies receiving marketing approval based on overseas clinical data. We encourage China to continue to make progress toward full acceptance of overseas clinical trial data and eliminating this market access barrier.

China has also moved forward with the implementation of expedited approval pathways for innovative and urgently needed drugs and devices. In August 2018, 48 foreign drugs already approved and marketed in the US, EU and Japan received a green light from China's Center for Drug Evaluation (CDE) for accelerated approval. This list includes several highly innovative new drugs brought to market as recently as 2017. In September 2018, NMPA issued a new "Catalogue of Medical Devices Exempted from Clinical Trials," bringing medical device clinical exemptions more in-line with internationally accepted standards.

The NMPA is continuing to undertake reforms to accelerate the drug review and approval process. November 2018 amendments to the draft Drug Administration Law (DAL) include an implicit 60-day approval timeline for clinical trials, which is expected to improve time to market for innovate new drugs, including those developed overseas. New channels to facilitate stakeholder-NMPA communications during the drug and device approval process will help reduce delays. Progress is also being made in training technical reviewers of new drug and device applications to help reduce China's drug lag.

We support China's continuing effort to accelerate and simplify the regulatory approval process for drugs and medical devices. While these initiatives represent welcome progress, the overall drug development and approval process in China remains out of alignment with international practice, as it takes much longer than is typical in other countries. Lengthy approval processes result in significant loss of effective patent terms for biopharmaceutical products. China should

³ PhRMA, Special 301 Submission 2019, "The People's Republic of China"

continue to align its regulatory framework with international standards to provide companies greater regulatory consistency.

Pricing and Reimbursement

The general lack of transparency and the unpredictability in government pricing and reimbursement decisions for new drugs and devices create significant challenges and uncertainty for US and other foreign medical product companies.

Since 2017, China has issued more regular updates of its National Reimbursement Drug List (NRDL), which designates medicines covered by state-sponsored medical insurance and has significant implications for the access and affordability of new treatments for patients in China. Prior to 2017, China had only undertaken two substantive updates to the NRDL, in 2004 and 2009. In October 2018, China added 17 oncology drugs to the NRDL, including several relatively new innovative drugs from US companies. This year, the director of the National Health Security Administration (NHSA) announced plans to add more drugs to the NRDL and establish a dynamic adjustment model that would allow new drugs to be reviewed for reimbursement on a regular or rolling basis.

New additions to the NRDL and moves toward a more regular and dynamic mechanism for drug review are positive developments. However, the lack of transparency in the negotiation process for new medicines creates uncertainty around the government's pricing and reimbursement system. The NRDL negotiation process often results in significant price cuts for new medicines, and the government's centralized volume-based tendering process puts additional price pressure on innovative and generic drugs. Such practices often lead to a *de facto* preference for domestic manufacturers over foreign companies.

Negotiations with the reimbursement regulator should be timely, transparent and predictable. Evidence-based methodologies independent of economic considerations should be adopted for clinical value assessments. A key outcome of the 2016 JCCT dialogue included an affirmation that China would implement drug pricing commitments, including that drug registration review and approval would not be linked to pricing commitments and not require specific pricing information.⁴ However, the dialogues stalled, and the US lacks a forum to discuss China's progress or hold China accountable to these commitments.

Intellectual Property (IP)

China has taken steps to strengthen its IP system, including for the health sector. In 2017, China proposed a series of policies that addressed long-standing health IP concerns around the lack of Regulatory Data Protection (RDP), loss of patent term, ineffective patent enforcement and inconsistent patent examination guidelines. Though China's IP environment as a whole has seen incremental improvements, health IP reforms have not progressed. The lack of adequate health IPR protections and enforcement undermines the ability of US companies to be successful, and threatens their continued growth here in the United States.

NMPA issued draft measures on the Implementation of Drug Clinical Trial Data Protection in April 2018, proposing six and 12 years of data protection for innovative pharmaceuticals and biologics, respectively. This protection would prevent generic product manufacturers from

⁴ USTR, "[US Fact Sheet for the 27th US-China Joint Commission on Commerce and Trade](#)," November 2016, (Last visited 18/07/2019)

proceeding to clinical trials and health authorities from evaluating generic product market authorization applications during this period. Following the State Council's October 2017 proposal of RDP, this is a strong first step toward providing better protection of originator pharmaceutical's IP.⁵ However, the proposal also includes problematic location and time-based eligibility requirements that undermine the stated goals of the proposed reforms and disadvantage global companies. This includes China's definition of a "new drug" as "new to the world," essentially requiring drugs to debut in China first in order to receive data exclusivity. This "China First" approach is inconsistent with China's international commitments under the WTO, as well as its JCCT agreements dating back to 2012, when China committed to define new chemical entities in a manner consistent with international best practices.⁶

In May 2017, NMPA also took initial steps to propose a patent linkage system, which would help resolve patent disputes involving biopharmaceutical products before follow-on products are marketed. Such an early resolution system would help promote fair competition and recognize innovator's rights and investments in R&D. However, as with RDP, progress toward implementation has been disappointingly slow.

While recent draft revisions to the Patent Law extend patent term restoration for innovative pharmaceuticals due to regulatory delays, there are no provisions in the new Patent Law requiring RDP or patent linkage. Unfortunately, RDP and patent linkage also were not included in recent draft revisions to the Drug Administration Law. Both laws are expected to be finalized by the end of the year. The Patent Law may be released for another round of public consultation, so there remain opportunities for progress on these issues in the final version.

While China has taken important first steps towards recognizing innovators' rights, stronger, more transparent and efficient IP enforcement mechanisms are needed. Hopefully, coordination between NMPA and China's National Intellectual Property Administration (CNIPA) will improve IP enforcement in the health sector, as both regulators are now under SAMR.

Opportunities for Engagement

International regulatory and standards setting bodies

International forums offer valuable opportunities to enhance global policy dialogue and best practice sharing that promote greater regulatory consistency globally and provide businesses more operational certainty around the world.

Encouragingly, China has been consulting more frequently with the international pharmaceutical and biotech communities, and this engagement is increasingly reflected in China's standards setting and efforts to improve regulatory capabilities. In June 2017, China joined the International Council on Harmonization (ICH), whose mission is to make standards and regulations more consistent globally. Since China became an ICH regulatory member, NMPA has pledged to adopt international technical standards and guidelines and keep abreast of the latest regulatory scientific outcomes and advanced regulatory concepts globally. China also joined the International Medical Device Regulatory Forum (IMDRF) in 2013, and is a member of the managing committee, a move that has similarly improved Chinese understanding of

⁵ Originator pharmaceutical products is a product that is first authorized worldwide for marketing, normally as a patented product, on the basis of documentation of its efficacy, safety, and quality according to the requirements at the time of authorization.

⁶ USTR, "[Fact Sheet: 23rd US-China Joint Commission on Commerce and Trade](#)," December 19, 2012 (Last visited 22/07/2019)

international medical device regulatory norms and helped influence the direction of China's policy development.

Joint education and enforcement campaigns

Public-private cooperation and engagement between industry and various arms of US and Chinese government have also helped reduce market access barriers and improve the operating environment for US companies. For example, US Trade and Development Agency (USDТА) launched the US-China Aviation Cooperation Program (ACP) with US and Chinese governments and US industry partners in 2003 to help promote technical, policy and commercial cooperation. The ACP helped improve the safety and efficiency of China's aviation infrastructure, which in turn improved the operating environment and opened new commercial and cooperation opportunities for US firms. USTDA also regularly hosts a healthcare cooperation program to facilitate public-private partnerships focused on improving healthcare delivery through training programs in both the US and China. On the IP front, the US Patent and Trademark Office frequently engages with China's IP office to discuss policy development and enforcement issues, and share best practices in support of US rights holders. Chinese government stakeholders are often eager to learn from the experience of US government regulators and industry as they work to design a system that is safe, efficient, and enables innovative economic development.

China's regulators have also remained committed to cooperating on joint special enforcement campaigns, particularly targeting counterfeited products. The manufacture and distribution of counterfeit medicines continues to be a serious challenge in China, both to public health safety as well as US companies. China's Public Security Bureau works with US companies to learn best-practices and technical standards to strengthen their ability to crack down on drug counterfeiting and improve public trust in the industry.

Bilateral cooperation is essential to the US Food and Drug Administration (FDA) mission of strengthening the safety, quality, and effectiveness of food and medical products produced in China for export to the United States. In 2008, the FDA opened its China Office with posts in Beijing, Shanghai and Guangzhou. From this platform, FDA specialists, technical experts in medicines and medical devices, and inspectors, worked with Chinese authorities to strengthen the capacity of Chinese regulatory bodies, increase FDA inspections and help the Chinese industry understand FDA standards and expectations. This work is essential to the health and safety of US consumers, and to fostering a regulatory environment aligned to US standards.

We encourage the US government to strengthen support for FDA's overseas engagement, and to continue to pursue mutually beneficial engagement with Chinese government bodies across industry sectors. Sharing US experience and best practices for developing and implementing policies will encourage China to foster a regulatory environment that is favorable for US companies.

Regular, industry-specific bilateral engagement

American companies value the high-level engagement that bi-lateral meetings like the US-China Joint Commission on Commerce and Trade (JCCT) provide. Established in 1983, the JCCT was a mechanism for consistent, year-round engagement between US and Chinese government leaders, and was one of the principle vehicles for addressing specific commercial issues in the bilateral trade relationship. The JCCT medical device and pharmaceutical working group was particularly successful. Launched over a decade ago, the Med-Pharm working group was one of the longest standing JCCT subgroups. It also was the only working group to include industry

representatives in the negotiations – a reflection of the highly complicated, technical issues in the sector.

In 2014, I served as the US Medical Device Working Group Co-Chair. Since then, China has made progress on several of the outcomes we reached that year, including efforts to reduce the drug lag and accelerate the medical device and pharmaceutical regulatory review and approval system, as well as accelerating the adjustment of medical device clinical trial exemption catalogues. US industry representatives participating in the 2014 discussions also shared best practices, including the development and implementation of America's Unique Device Identification system, and China has since made progress in developing its own device and drug traceability system. That system has been developed with reference to international standards and has incorporated industry feedback received during public consultation periods.

Real structural change takes time and requires precise negotiations. Critical to the progress achieved during the JCCT era were the release of Joint Fact Sheets and agreements to continue the dialogue the following year. The Joint Fact Sheets outlined specific outcomes by industry sector and cross-cutting issues. They also helped reduce misunderstandings or misinterpretations as to what was agreed. In 2014, agreeing to further dialogue was also specifically included in the Med-Pharm outcomes: "China and the United States agree to engage in enhanced dialogue with expert and high-level officials of relevant Chinese and US agencies in 2015 to promote efficient pharmaceutical and medical device regulation and market access."⁷ This joint commitment to future rounds of dialogue and engagement helped to create accountability, and allowed us to track China's progress, however slow, toward implementing the prior years' commitments.

Most importantly, the JCCT platform enabled us as negotiators to build trust with our Chinese counterparts. Trust is crucial to finding mutually beneficial solutions across industry sectors and issues. Regular dialogue offered important opportunities to build an understanding of each other's policymaking considerations and processes. With more nuanced mutual understanding, we were able to develop mutually agreeable policy proposals and implementation timelines, and ultimately achieve more sustainable results.

USCBC Recommendations

China is and will remain an important market for US health sector companies. While there are challenges that impact the ability of US health companies to equally compete in the China market, China's general direction of reform is pointing in the right direction. China has made improvements in accelerating time to market for innovative drugs and devices, and has proposed policies that would more adequately recognize innovators rights. However, much needs to be done to enhance transparency and enforcement, particularly in pricing and procurement and in protecting IP rights. Holding China accountable to WTO commitments would be a good start.

The long-term growth and global leadership of innovative US life sciences companies will depend on our ability to effectively address the issues US companies face in China. However, the issues of the health sector are highly technical, nuanced and often unique to individual companies. It is essential that these issues are systematically addressed through targeted policy discussions between our two governments, and regular government consultation with

⁷ USTR, "[US-China Joint Fact Sheet on the 25th US-China Joint Commission on Commerce and Trade](#)," December 2014, (last accessed 07/22/2019)

industry and technical experts. Re-launching a platform like the JCCT to facilitate regular dialogue on industry specific topics is necessary to address the specific commercial issues of US health companies. Strengthening congressional support for the US FDA's overseas efforts to improve Chinese regulatory standards and product quality and safety is also critical. Cooperative initiatives such as these would also help produce mutually beneficial results for the broader US-China relationship.

The opportunity for public-private engagement provided by organizations such as the US Trade and Development Agency is also invaluable as a mechanism to help build and inform Chinese capacities around US norms and practices. Chinese government stakeholders are more willing to engage in this process when the platform has the explicit support of the US government. We encourage US policy makers not to overlook such platforms, and to strongly support the engagement initiatives of various government agencies.

Finally, it is important that the growth and development of the US health and life sciences industry is not unintentionally restricted by overly broad policies. As the Department of Commerce Bureau of Industry and Security considers new export control measures, Congress should ensure that "emerging and foundational technologies" are defined as narrowly as possible so as not to hamper continued US job growth and collaboration in the sector.

The US-China bilateral commercial relationship is at a critical juncture. Trust is at an all-time low. USCBC encourages the US government to leverage all available tools to pursue enhanced engagement and cooperation with China to help build trust across the relationship.