China's Healthcare Sector and U.S.-China Health Cooperation

Prepared statement by

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Background

Since the early 1980s, China's healthcare system has undergone profound transition. Prior to 2003, reform efforts were marked by state withdrawal from the healthcare sector and introduction of a laissez-faire approach to funding and delivering healthcare. This move yielded rapid growth in the urban health sector, especially high-tech hospital services, at the expense of rural health sector and preventive and primary care. It also converted public hospitals into a revenue generating machine, which, in conjunction with the regional maldistribution of healthcare resources, exacerbated the problems of access and affordability.

The 1990s saw the establishment of the Urban Employee Basic Medical Insurance (UEBMI) scheme, which covers formal sector employees, mostly those of state-owned enterprises. This was followed by the spread of New Cooperative Medical Scheme (NCMS) since 2002, which sought to cover the 900 million rural residents with a partial state subsidy, and the establishment of the Urban Resident Basic Medical Insurance (URBMI) scheme in 2007 to address the healthcare needs of urban residents not already covered by the UEBMI.

In April 2009, the government kicked off a new round of healthcare reform with the goal to provide safe, efficient and affordable basic health care for all Chinese citizens by 2020. The reform was anchored in five

specific targets: expanding health insurance, making public health accessible to all, improving grassroots healthcare institutions, introducing the essential drug system, and reforming the public hospitals. By 2012, significant progress had been made in achieving the first three targets. The three health insurance programs altogether cover over 95% of the population, with 15% covered by UEBMI, 70% by NCMS and 10% by URBMI. Progress has also been made in the equalization of access to public health services, and in improving the financial status of grassroots healthcare institutions (e.g., township health centers).

Despite so, introduction of the essential drug system achieved at most mixed results. While it led to the drop of the prices of drugs on the essential drug list, it has not fundamentally solved the problem of overreliance on drug sale by public hospitals in revenue generation. This is at least in part caused by the lack of significant progress in reforming public hospitals, which is widely considered the sine qua non of China's healthcare reform. Government health authorities remain the owners and general managers of public hospitals, which still provide 90% of outpatient and inpatient services, even though 43% of the hospitals nationwide are owned by non-public entities. It came as no surprise that the reform has not fundamentally solved the problem of access and affordability.

In November 2015, China issued its 13th Five-Year Plan (FYP), which highlights the need to simultaneously push for changes in areas of health care services, healthcare insurance and medications. Public hospital reform was highlighted in the plan. For the first time, the government began to talk about reforming the personnel and salary system in public hospitals. The Plan has also vowed to mobilize more medical resources to rural areas, promote training of general practitioners and family physicians and develop telemedicine to address the urban-rural gap in accessing healthcare. To address the affordability problem, the government seeks to expand catastrophic illness insurance nationwide, while in the meantime seeking to integrate basic health insurance schemes in order to construct a national basic insurance network.

Financing healthcare

Healthcare demands are hard to measure. For a country of nearly 1.4 billion people, the challenge of financing healthcare is overwhelmingly mounted. It is <u>estimated</u> that diabetes alone may consume more than half of China's annual health budget if routine, state-funded care is extended to all the diabetes sufferers. Compared to many countries, share of healthcare expenditure in total GDP remained relative low in China. In 2013, China spent 5.6% of its GDP on healthcare, which accounted for only 3% of the global healthcare spending. In other words, China addresses healthcare needs of 22% of the world's population with only 3% of the world's healthcare resources.

In the 1980s, driven by market-oriented economic reform, government spending as a percentage of total health expenditures dropped precipitously—from 40 percent in 1982 to 15 percent in 1999. China's economic take-off and the implementation of the tax-sharing reform in 1994 nevertheless carved out more fiscal space for central government to spend on healthcare. In the 2000s, two developments boosted government incentives to invest in the health sector. The first was the 2002-03 SARS crisis, which uncovered the vulnerabilities in China's healthcare system and the drawbacks in the government's single-minded pursuit of economic growth. The second was the 2008 global financial crisis, which made it imperative to construct a social safety net to encourage domestic consumption. Between 2009 and 2013, government spending on healthcare has grown 20 percent annually. Consequently, government spending in

total health expenditure increased from 15% in 1999 to 30% in 2013, and out of pocket spending dropped from 60% to 34%. Still, compared with OECD countries the share of government health spending in total fiscal expenditure remains relatively small. Even using the government adjusted figure (12.5% in 2013), China's share is still lower than that of the US (21%), UK (16%), and Japan (17%), although it might be higher than other BRICS countries.

The government health spending comes from both central and local government coffers. Tax provides the most important revenue source for government revenue. Since 1995, 70% of national tax revenue has flown to the central government. The central government revenue is mainly from three sources: 1) domestic value-added taxes (VATs) and consumption tax; 2) VATs, consumption taxes and tariffs for import goods; and 3) Enterprise Income Tax. The three taxes contribute to 80% of the central government revenue. Local governments control up to 17 taxes, including income taxes of local enterprises, local business taxes, personal income taxes, real estate and land use taxes, pollution and resource fees. A key revenue source for cash-strapped local governments is land sales, which accounted for a quarter of their revenues, on average, across China. In order to avoid conflict of interest with local revenue collection, the independent State Taxation Administration (*guo shui ju*) was established which operates parallel to the existing local taxation authority (*di shui ju*). Unlike the United States, China does not have a health care tax or an itemized health insurance fee in its general tax revenue. When adjusting the share of government health spending in total fiscal spending, the government sometimes counts the health insurance premium contributions from employers as health insurance tax. But the contributions are earmarked – workers in Shanghai cannot access the fund collected in Beijing.

One of the challenges in China's health financing is the mismatch between local fiscal power and responsibilities. During 2009-14, of the \$611 trillion government spending on healthcare, the central government contributed around 183 billion or 30%, with the remaining 70% from local governments. In other words, while the local governments receive only 30% of the revenues, they shoulder 70% of the burden of healthcare financing. The power-responsibility mismatch has contributed to the debt crisis at the local level. Indeed, during 2007-2015, the sheer amount of money local governments owe doubled from less than 20% of GDP to nearly 40%. Since 2014, the property slump has dealt a serious blow to the local state revenue from land transfers. In 2015, their revenue from land transfers fell 21.6%. The situation is unlikely to improve against the recent economic downturn. In February 2015, year-on-year national public fiscal revenue only grew by 0.26 percent, while public fiscal spending was up by more than 55 percent over the same period.

Supporting the development of healthcare industries

During the 13th Five-Year Plan period (2016-2020), the government promises to deepen healthcare reform and bring higher-quality healthcare and public services to all residents in China. This would involve efforts to promote Universal Health Coverage (UHC), refine healthcare financing mechanism and coordinate governmental, corporate and individual responsibilities. The government encourages non-state actors to invest in healthcare industries, and promises to promote the not-for-profit civilian hospitals to be treated the same as public hospitals. In the meantime, the FYP emphasizes the need to create a policy environment that can foster homegrown entrepreneurship, including increased investment in research and development (R&D) for new drugs. Those originator drugs that are already marketed in China and those consistent with

the originator drugs in safety and efficacy will receive priority status in being included in the National Reimbursement Drug List (NRDL). In March 2016, China FDA formally launched a new classification system for registration of chemical drugs. Under the new classification, "new drugs" now refers only to (i) new chemical entities that have never been marketed anywhere in the world, or (ii) improved new forms of known chemical entities that have never been marketed anywhere in the world. Domestic drugs that have been marketed outside of China, even if they have not been marketed in China, are now considered generic. The new regulation is expected to provide more incentives to develop new drugs, which may receive an expedited review and a more favorable standing in post-approval tendering and reimbursement.

How effective these measure will be remains to be seen. The policy rhetoric reveals inherent dilemmas and contradictions in China's healthcare reform. In absence of proper regulation, efforts to nurture robust healthcare and pharmaceutical industries in China could lead to rapid increase in the healthcare cost, further compromising government healthcare reform objectives. Indeed, between 2008 and 2012, the share of out of pocket payment dropped from 40 percent to 34 percent, but the actual healthcare cost shouldered by the patients increased by 64 percent, from 5,876 yuan to 9,655 yuan (the latter is even higher than the rural per capita net income in 2012). Similarly, an industrial policy that supports the pharmaceutical industry is out of sync with other public policy objectives. In order to incentivize original drug development, the market and the state should reward firms that create genuinely innovative products with profit margins significant higher than their generic counterparts. But this conflicts with the government's objective of ensuring affordable access to health care. The same dilemma exists in the entry of non-public hospitals. Since 2010, the government has sought to inject social capital into the healthcare sector, but thus far the public hospitals continue to enjoy monopoly status in health services provision. Yet in the absence of a competitive non-public sector, it is difficult to incentivize the public hospitals to kick off meaningful reform measures that would create a policy environment favorable to the entry of the social capital.

Opportunities and challenges for U.S. service industries

Five trends in and beyond China's health sector are going to sustain robust growth of China's healthcare market, creating opportunities for U.S. pharmaceutical companies, hospital groups, and insurance companies. The first is the rising burden of non-communicable disease (NCDs), including cancer, cardiovascular diseases, diabetes and their risk factors such as smoking. Currently more than 85% of the mortality in China is attributed to NCDs. According to a recent World Bank report, if effective measures are not adopted, the burden of NCDs in China could increase by at least 40 percent by 2030. The NCDs are expected to drive up outpatient visits, hospitalizations and overall medical spending.

In association with this epidemiological change is the demographic shift. Chinese population is aging very rapidly. In 1982, only 5% of the population is aged over 65 years old. The number increased to 9% in 2010. By the middle of the century, it is expected to reach 25% (same as the level in Japan). In order to address the population aging problem, the government abandoned its one-child policy last year. It also proposed to raise the retirement age to 65 by 2045. The relaxation of the one-child policy and the expected baby boom will create demands for consumer products such as diaper and baby formula. Population ageing has also led to the growth of a new market: senior care, including home-based, community-based and institution-based care. 23% of the elderly people are disabled, but less than 2% of the senior population uses institution-based care, even though more than 10% are willing to receive care in institutions. The number of elderly people

who are able to afford senior housing will reach 22 million by 2020. The 13th FYP promises to improve its senior care system, including comprehensively opening the senior care market. Current policy though treats institution-based care as a supplement to its multi-level senior care system, which will be predominantly residence-based, with support from the communities.

The third trend is urbanization. 25 years ago 26% of the people lived in urban areas; the rate rose to 55% by the end of 2014. By 2020, 60% of Chinese people will be living in the cities. Rapid urbanization, in combination with policy changes that allow migrant workers to reimburse healthcare costs incurred in the cities, would continue to generate more effective demand for healthcare. In the meantime, rapid social stratification also calls for healthcare to meet the country's increasingly diversified healthcare demands. Private hospitals, high-tech medical devices, patented drugs and commercial health insurance have yet to be developed to cater to the needs of the country's well-to-do population.

Fourth, the widespread use of information technology has the potential to revolutionize healthcare, drug development and distribution. A growing consensus in China is that mobile health technologies (mHealth) provides a cost-effective solution to reaching out to the population in the rural and/or remote areas. We have already seen the "Big Three" Chinese Internet and E-Commerce Companies (Baidu, Alibaba, and Tencent) compete to invest in healthcare industries. Jack Ma even predicted that the only person who could surpass his success would be from the healthcare industry.

Finally, healthcare reform in China is being deepened in a way that encourages foreign and private investment in the healthcare sector. In August 2013, Premier Li Keqiang convened a State Council meeting, signaling that China would relax restrictions on market entry and encourage private and overseas capital to invest in China's healthcare industry. It is thus no surprise that a new round of mergers and acquisitions have been under way since 2013, attracting a growing number of U.S. investors. China's 13th Five-Year Plan suggests that the government will continue to focus on developing China's biomedical industry and welcome private and foreign investment in pharmaceutical R&D. The growing medical needs and the governmental support have increasingly drawn multinational pharma players to invest in China. Since 2006, 13 of the top 20 pharma companies have established R&D centers in China.

Although private and wholly-foreign-owned hospitals account for almost half of China's total number of facilities, they account for only about 10% of total in-patients and out-patients served, far below the projected goal (20%). For U.S. investors who want to establish and operate hospitals in China, there are several hurdles to cross. One of the major concerns is talent recruitment. Under current rules, foreign physicians who aspire to practice in China must pass the Chinese medical test to get a practicing certificate. This hurdle forces many foreign hospitals to hire Chinese physicians to fill the gap, but most of the Chinese doctors are moonlighting because they are also full-time employees in the public hospital sector. Multi-sited licensing reform, which allows doctors to practice in more than one primary healthcare institution, did not make much progress in many places in part because of resistance from the managers of the public hospitals. Foreign hospitals seeking to import high-end medical services need first to obtain government approval, which can be a tedious process. In addition, services provided by foreign hospitals are not covered by China's health insurance schemes, which limits the demand for their services.

Compared to hospitals owned by foreigners, foreign medical device firms fare better. Many U.S. companies have hired local Chinese talent to expand their medical device business. And as long as they have better products and provide good after-sale services, these firms can remain competitive in the Chinese market. However, they are advised to adopt "bullet-proof safeguards" (e.g., keeping critical IP components in the home office). Uncertainties also arise with the increasingly stringent product-registration processes, changes in the tendering process, the fragmentation of reimbursement, and increased scrutiny of pricing. Public tendering has recently been moved to the provincial level, leading to price for several categories of medical device products.

Overall, access to China's growing market is becoming more complex for foreign investors. Access conditions vary at the provincial, the city, and even the hospital level. For pharmaceutical companies, the increasing complexity and uncertainty stem from growth in the number of reimbursement categories and continued government pressure to reduce prices and ease the burden on patients. The 2014 GSK scandal suggests that in a country where rule of law is still good only in theory, multinationals too can be victims of the capricious and arbitrary Chinese politics. The anti-corruption campaign in China, which seemingly targets only foreign companies in the healthcare sector, further increased the cost of relying on giving bribes and other illicit tactics to increase product sales in China. Successful business operation in the country requires lower expectations and improved management, but it is equally important for top pharmaceutical executives to have the political acumen to swim with the political tide, not against it.

Public-private partnership in pharmaceutical R&D

Pharmaceutical Public-private partnership can be defined as any informal or formal arrangement between one or more public sector entities and one or more private sector entities created in order to develop new medicines for the public good. It offers an integrated and systematic approach to the development and purchase of needed vaccines, drugs and therapies to address public health challenges. To be specific, it enables companies to realize shared value while furthering public health goals by sharing risk, mobilizing significant resources for diseases where private entities have no incentive to invest in new drug development and bringing together data or expertise that resides with different parties. PPPs become particularly relevant in dealing with public health emergencies, when there is an urgent need for pooling of resources not only to accelerate the development of medical countermeasures but also to make large scale manufacturing feasible.

While PPP is increasingly becoming a buzz word in the Chinese economy, pharmaceutical PPPs remain largely alien in China's new drug development. On the one hand, there are excessive government restrictions on foreign entities intending to get involved in government-funded projects. On the other hand, local researchers remain predominantly government funded and, despite growing state funding, their ability to innovate has been seriously constrained by <u>institutional</u>, <u>policy and capacity-related challenges</u>. In contrast to the market failure in the development of drugs for rare or neglected diseases, what we have seen in China is a government failure behind <u>the unsuccessful efforts to incentivize original drug development</u>.

Despite these problems, some nascent, informal PPPs are emerging in China that enables Chinese firms and research entities to participate in global R&D. With growing state support, many overseas Chinese scholars have returned and established their own technology firms in China. Tapping into China's relatively low price for skilled labor, for example, contract research organizations (CROs) built by these scholars have

become increasingly important, if not essential, for global drug discovery and innovation. Currently, there are more than 400 CROs in China providing preclinical and clinical research services, mostly to MNCs and research organizations overseas. Among these CROs the most well-known is WuXi PharmaTech (Charles River Laboratories wanted to buy for \$1.6 billion). By 2010, it had already had more chemists than any other CROs in the world.

In January 2011, the U.S. Department of Health and Human Services (HHS) and other federal agencies announced a new public-private healthcare partnership between the U.S. and China. The initiative is aimed at fostering cooperation in research, training and regulation. The initial U.S. participants include Pfizer, Medtronic, Abbott Laboratories and Johnson & Johnson, as well as trade groups AdvaMed, which represents medical device makers, and the Pharmaceutical Research and Manufacturers of America, which represents drug makers. In the meantime, we have seen private foundations and international NGOs forge partnerships with Chinese state-owned enterprises in R&D. Through a generous grant from the Bill & Melinda Gates Foundation, for example, an international non-nonprofit organization called PATH in 2009 signed a collaboration agreement with the government-owned Chengdu Institute of Biological Products (CDIBP) to develop a vaccine for Japan Encephalitis (JE). PATH provided technical and financial support so that CDIBP could meet the strict standards required for prequalification by the World Health Organization. Three years later, the vaccine became the first single-dose JE vaccine that the WHO has approved for use on children. By 2017, the JE vaccine is anticipated to reach nearly 290 million people in Asia.

PPPs have also been used in China's development of anti-Ebola drugs. During the outbreak. When a limited supply of ZMapp was quickly exhausted in the fall of 2014, a small private Chinese company, Beijing Mabworks, <u>produced</u> about 100 doses of experimental drug (MIL77) within three months, making more potentially lifesaving treatments available for desperate patients. The drug was <u>reported</u> to have successfully treated a British military nurse who contracted Ebola while serving in Sierra Leone. Even though the Chinese drug was similar to ZMapp in the antibodies it used, Mabworks had a more efficient manufacturing process developed prior the outbreak: supported by Chinese government grants, it was able to use mammalian cells to quickly produce antibodies targeted against viral diseases in humans.

Relying on PPPs to deal with global health security threats has its own drawbacks. As Stefan Elbe <u>noted</u>, partnership in the private sector is often confined to smaller companies, which usually do not have the capabilities and expertise to cross the so-called "valley of death," or the transition from laboratory success to human clinical trials. There are also intellectual property roadblocks. Indeed, the use of information by Mabworks on the ZMapp patents raised concerns of potential IP infringements by the Chinese company. Still, PPPs offer an important means to engage China to contribute to global health security in an efficient and effective manner.

U.S-China cooperation in addressing other health challenges

U.S.-China cooperation, of course, is not confined in R&D for new drugs, vaccines and therapies. They have cooperated in other areas of global health security. The U.S. and China were two of the first countries to respond to the Ebola outbreak in Western Africa. Unlike the United States, China has not publically framed the Ebola outbreak as an international security threat or deployed a large number of military personnel to the affected countries. Its dispatch of elite PLA units to the affected countries nevertheless suggests that it

did view the outbreak as an existential security threat that required a response out of the normal political boundaries. Beijing's willingness to implicitly securitize trans-border disease outbreaks has opened a new area for future collaboration between China and other countries (e.g., the U.S.) under the Global Health Security Agenda. Indeed, during the crisis Chinese military personnel trained a Liberian engineering company so that the latter could play an instrumental role in helping the U. S. Army to construct its treatment center in the country. Similarly, the U.S. Air Force provided large forklifts to help unload the supplies that China brought to Liberia. On June 24th, 2015, US Secretary of Health and Human Services Sylvia Mathews Burwell, Chinese Vice Premier Liu Yandong and Minister Li Bin of China's National Health and Family Planning Commission, met to recommit to that partnership in addressing public health emergencies by renewing a Memorandum of Understanding for the next five years on cooperation to address emerging and re-emerging infectious diseases.

In addition, both governments have established partnerships over basic medical research. In 2008, National Cancer Institute (NCI) launched a research partnership with China and established NCI Office of China Cancer Programs. This is followed by the launch of US-China Program for Biomedical Research Cooperation in 2011, by NIH and National Science Foundation of China.

Non-governmental organizations are also involved in establishing partnership with China. In August 2014, Massachusetts General Hospital was <u>reported</u> to be in early discussions with two partners to build a full-service hospital with 500 to 1,000 beds in China. Mass. General also signed a "framework agreement" with a Chinese hospital specializing in traditional medicine and a Chinese investment firm, allowing the three parties to exchange financial information and work on developing a definitive agreement to open a facility in an island city close to Hong Kong.

In late November 2015, the U.S.-China Joint Commission on Commerce and Trade (JCCT) was held in Guangzhou, China. Secretary of Commerce Penny Pritzker and U.S. Trade Representative Michael Froman co-led a high-level U.S. government delegation to the high-level dialogue. The Chinese delegation was led by Vice Premier Wang Yang. For the first time in JCCT's 26 years of history, the dialogue featured a one-day healthcare event attended by senior government officials and business leaders from the healthcare industry in both countries.

Policy recommendations

Unlike security-related issue areas, the dynamic of U.S.-China health cooperation is largely insulated from the fluctuations of domestic politics and strategic foundations. Indeed, even in the post-Cold War era, U.S.-China health cooperation continues to grow in breadth and depth. In part, this is because health is a politically less sensitive area where each side feels strongly about. Shared health concerns challenge the two countries to promote jointly the welfare of their people. Already, we have seen effective bilateral cooperation under way in HIV/AIDS prevention and control, in food and drugs safety, and in addressing international public health emergencies.

Transformation in both countries' healthcare sectors are generating extra business opportunities. In the JCCT healthcare event, Dr. Michael Lu of U.S. Department of Health and Human Services identified five changes in the U.S. healthcare system: improved access through the Affordable Care Act, payment reforms,

delivery systems transformation, health information technologies, and quality improvement and innovation. Similar dynamics can be found in China. With the government targeting healthcare as a social and strategic priority, the healthcare market is rapidly expanding. China now trails the United States as the second largest market of health industry in the world. It is estimated that five years from now the size of China's health service industry—which covers medical care, pharmaceutical products, healthcare products, medical devices, and health management—would reach \$1.3 trillion, up from less than 1.7 trillion RMB in 2012. This would mean an annual growth rate of 21 percent between 2012 and 2020.

But U.S.-China cooperation in healthcare is not just about market opportunities. It is also about how to improve health and well-being of the people in both countries. The two objectives are not necessarily mutually exclusive, but without proper regulation and balance of interests, single-minded pursuit of business opportunities may exacerbate the problem of affordability, thereby defeating the very purpose of the healthcare reform. Already, demographic and epidemiological transitions against the background of moving toward universal health coverage have raised concerns regarding financing and cost control in both countries. The growing cost of healthcare highlights the importance of cooperation in preventive care. Over the past years, both countries have been collaborating over tobacco control research and tobacco surveillance. But the areas of cooperation can be further expanded to include health management, environmental health, healthy life style promotion, and encouraging the private sector and social forces in health education and risk reduction.

Meanwhile, in seeking cooperation with China we have to keep in mind the inherent dilemmas and contraditions in China's health policy processes. While the 13th Five Year Plan suggests that China is willing to allow the market to play a more decive role, it continues to rely on heavy-handed industrial policy in pursuit of the growth of its healthcare and pharmaceutical industires. While the government welcomes the entry of foreign business and nvestment, it has increased information and ideological control while sustaining its devotion to bolstering domestic industrial competiveness. Against this background, the U.S. Congress is advised to work more deligently and closely with the executive branch to pressure Beijing to improve the operating environment of U.S. businesses in China.

Cooperation by definition is not a one-way street. As Chinese Vice Premier Wang Yang noted, in order to ensure effective Sino-U.S. cooperation over healthcare, China would ease the market access and strengthen the efforts in IP protection, but it also hoped the U.S. side to consider favorably China's concerns in patent protection duration and corporate social responsibilities. I would suggest that a working group be created to address these concerns and explore how the two sides can cooperate with each other for a win-win. Policymakers and business leaders of both sides are challenged to seize the new opportunities and promote the bilateral cooperation to a new high, as this is good for not only the health of the bilateral relationship, but also the health and well-being of people in the two great nations.