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Hearing on China's Healthcare Sector, Drug Safety,
and the U.S.-China Trade in Medical Products

Chairman Shea, Vice-Chairman Reinsch, and other distinguished members of the Commission, good morning. Thank you for inviting me to testify before you today. My name is Xiaoqing Lu Boynton, and I am a director at the Albright Stonebridge Group, a global strategy company, although the testimony today solely reflects my personal opinions.

I understand the Commission is interested in the latest developments in China's healthcare sector and their implications for drug safety and the U.S.-China medical trade. Healthcare sector in China today is indeed undergoing significant changes. In April 2009, the Chinese government unveiled its ambitious plan to overhaul the country's healthcare system with a goal to achieve universal healthcare by 2020. The government also announced an allocation of $125 billion between 2009 and 2011 to invest in the massive healthcare reform that has since been underway. After a successful initial three years of reform and experiment, the Chinese leadership pledged in 2012 to continue its effort to deepen the healthcare reform over the coming years. In particular, the Chinese government stated that the 12th Five Year Plan Period (2011-2015) is a critical timeframe for deepening the reform in China's healthcare sector.

The ongoing healthcare reform in China takes place in a country that has been grappling with significant health challenges in recent years, including rising infectious challenges and growing non-communicable diseases (NCDs). China is a major hotspot for influenza viruses, including the most recent outbreak of H7N9 in 2013 and the H1N1 pandemic or "swine flu" in 2009. The country also has the second highest number of tuberculosis (TB) cases in the world, accounting for 17 percent of the world's TB burden.[1] Notably, drug resistance is becoming rampant in China, where nearly 1.5 million Chinese patients have drug-resistant TB.[2] China today has approximately 780,000 people living with HIV/AIDS.[3] While the prevalence of China's HIV/AIDS epidemic remains low, there are pockets of high infection among specific sub-populations and geographic regions.[4] China also faces a large, growing burden of NCDs, such as cardiovascular diseases, diabetes, obesity, and cancer. It is estimated that there are 200 million hypertensive patients and 90 million diabetes patients in China. According to the World Health Organization (WHO), NCDs currently account for about 85 percent of China's total burden of

[1] United Nations Health Partners Group in China, *A Health Situation Assessment of the People's Republic of China* (Beijing: United Nations, 2005).
[2] "Calls for More Help in Fight against TB."
[3] *China AIDS Response Progress Report*, UNGASS, March 2012.
[4] *China 2010 UNGASS Country Progress Report (2008-2009)*, UNGASS, 2010.

diseases and its NCD mortality rate is higher than other leading G-20 countries. The WHO predicted that the number of NCD cases among Chinese people over 40 will double or even triple over the next two decades. The wide range of health challenges that China faces has propelled Chinese decision makers to look for new, efficient ways to use resources to meet the growing healthcare demand.

In 2009 before the new reform of China's healthcare system was launched, about 90 percent of rural residents and 60 percent of urban residents in China did not have health insurance.[5] Those who are covered by some sort of health insurance were frequently confronted with high premiums and limited coverage. The lack of health insurance coverage has led to the population's strong proclivity to save for the skyrocketing out-of-pocket healthcare expenses. As Beijing attempts to stimulate domestic consumption to grow the Chinese economy, establishing a robust social safety net has become critical to the government's growth strategy.

To address China's diversifying disease burden and the government's need to drive domestic consumption, reform initiatives have focused heavily on affordability and access in the healthcare sector. The healthcare reform has achieved significant outcomes over the past five years. Today, China provides 95 percent of its population with some kind of basic health insurance, making it the world's largest health insurance scheme in terms of population coverage. Most notably, the country's 833 million rural residents, the majority of whom did not have any health insurance five years ago, are now covered by the New Rural Cooperative Medical System (NCMS). The reform was also able to reduce individuals' out-of-pocket expenses. According to the latest statistics released by the Chinese government, reimbursement rate for inpatient treatment expenses for rural and urban residents increased from 50 percent in 2008 to 75 percent in 2013. Annual per capita government subsidy for the basic health insurance schemes for rural and urban residents increased substantially from $13 in 2008 to $45 in 2013.

Despite the interim achievements, China still faces significant barriers in its effort to revamp the healthcare system. In the new phase of "deepening" the healthcare reform, the Chinese government outlined three priorities in 2012 – the reform of public hospitals, expanding universal health coverage, and enhancing the national essential drug system – with the goal to control healthcare costs and improve healthcare quality at grassroots and community levels.

In particular, continuing the reform of Chinese public hospitals remains a top priority. Due to an outdated personnel compensation system for Chinese doctors and the lack of healthcare resources over the past decades, Chinese public hospitals have been widely criticized for their heavy reliance on drug sales and diagnostic tests for profits. High mark-ups of drug prices in public hospitals have led to rising healthcare costs. To solve this problem, China's top health regulator – the National Health and Family Planning Commission – has launched pilot reforms to separate drug prescribing and dispensing and eliminate drug mark-ups in public hospitals in urban areas and at county levels. In order to meet the growing and diversifying healthcare demand and to alleviate the burden of public hospitals, the Chinese government also encourages private investment in the healthcare sector. The NHFPC has set a target that private hospitals

[5] Vanessa Wong, "Health and Wealth," *Insight Magazine*, April 3, 2007.

should handle 20 percent of China's inpatient and outpatient volume by 2015, which is now estimated at about 11 percent and 8 percent respectively.

To address the skyrocketing drug costs, the Chinese government has also focused on developing a national essential drug list, or the EDL, which is a catalogue of 520 types of cost effective drugs issued in March 2013. (A prior version of the EDL was issued in 2009, which consisted of 307 drug types.) EDL drugs are permitted to participate in centralized tenders organized by provincial government. With the ultimate goal of reducing drug costs, the EDL tenders are highly price driven and pay little attention to drug quality. According to the Chinese statistics, EDL drug prices have declined by 25 percent on average since the establishment of the national essential drug system in 2009. However, in some provinces, the EDL tenders have led to a shortage of certain commonly used, low-priced drugs. The Chinese government has vowed to improve the price-driven system to ensure drug supply and quality in 2014.

China's healthcare reform is unfolding at a time when the top Chinese leadership has launched a nationwide anti-corruption campaign, an important initiative that the Xi Jinping/Li Keqiang administration has used to consolidate central power. Since taking office a year ago, the Xi/Li administration has used its anti-corruption drive to oust dozens of high-profile businessmen and government officials. As the healthcare reform attempts to cut down costs and expand access to affordable care, the Chinese government has heightened its scrutiny of the healthcare sector to crack down on commercial corruption, especially in public hospitals, that has largely contributed to the rising cost of healthcare. In June 2013, U.K.-based pharmaceutical company GlaxoSmithKline (GSK) was involved in a bribery scandal in China over criminal activities, including Chinese police allegation that the company paid up to $490 million to travel agencies to facilitate bribes to doctors, hospitals, and Chinese officials. A handful of other multinational pharmaceutical companies were also investigated following the GSK scandal. While the investigations in China have put many foreign pharmaceutical companies in the spotlight, they are not exclusively anti-foreign. A number of domestic pharmaceutical companies were also targeted in the corruption probes, most prominently Sinopharm – China's largest, state-owned drug distributor. However, foreign pharmaceutical companies could be easy targets due to the public belief that foreign drugs benefit from the government's pricing policies and their prices are too high. The anti-corruption investigations in the healthcare sector well serves the reform goal to rein in costs of drugs and healthcare products, which are believed to critical to stimulate domestic consumption. For instance, following the highly public scandal, GSK announced last year that it would lower the prices of its products in the China market. Given the Chinese government's commitment to cracking down on corruption, companies in sensitive industries – including pharmaceutical and medical device industries – will continue to face a heightened scrutiny of their operation and pricing practices in the near to medium term.

The ongoing healthcare reform in China presents several key opportunities and challenges to U.S. companies. The U.S. government and U.S. companies should pay attention to the following issues.

- Public hospital reform – Pilot reforms to separate drug prescribing and dispensing are expected to significantly reduce drug mark-ups. This could potentially benefit the U.S.

innovative healthcare companies as the old system favors low-cost drugs which the public hospitals could have large mark-ups. However, hospitals may still prefer lower-end products in order to control costs during the reform process. Yet, the growth of private hospitals in China could also open space for the increased sales of high-end medical devices to meet growing demand of high-quality care especially among the rising Chinese middle class.

- Expanded healthcare coverage in rural areas – The Chinese government's focus on expanding the scope and level of its basic healthcare coverage in rural areas means potentially new vast market for pharmaceutical and medical device companies. For U.S. pharmaceutical and medical device companies, expanded healthcare coverage could prove to be an opportunity to increase exports to China.

- Price-focused approach – While the Chinese market of essential drugs is substantial, it remains challenging for U.S. drug makers due to the heavily price-driven process of the EDL tenders. The government's price-focused approach could mean potential risks for multinational companies.

- Anti-corruption investigations – The heightened scrutiny of the healthcare sector, which is expected to continue in the coming months, will make the China market more complex. It is important for foreign companies to focus on its compliance efforts to minimize potential risks.