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BIODESIGN GLOBAL SOURCEBOOK: CHINA OVERVIEW

KEY INDICATORS

Since 1978, China has evolved from a centrally planned and controlled economy to a more market-based one, adding millions of people to the middle class.[1] (See Figure 1 for a map of China.) After growing at an annual average rate of nine percent for more than two decades, its gross domestic product (GDP) reached US$7 trillion in 2011, second in the world only to the United States, at US$15 trillion.[2] The IMF predicts that China's GDP growth will exceed eight percent per year between 2011 and 2015.[3]

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China currently is the world's most populous country, with over 1.34 billion people. In 2011, its urban population surpassed its rural population for the first time, by about 34 million people.[4] Population growth in China has decreased steadily over the last two decades from about 1.2 percent to less than half a percent today[5] and is expected to continue to decline.[6] By 2030, India's population will likely surpass China's projected population of 1.4 billion by 100 million people.[7] China's median age of 35 years is relatively young compared to the median age of nearly 40 years in developed countries.[8] However, China is rapidly aging and senior citizens will account for as much as 35 percent of the population by 2050, up from some 14 percent in 2011.[9]

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China spent roughly five percent of GDP on healthcare in 2010,[10] which is comparable to other middle income countries. This percentage is slated to rise as a result of increased government spending on healthcare during the central government's Twelfth Five-Year Plan (2011-2015).[11]

Figure 1 Map of China

HEALTH SYSTEM OVERVIEW

The Chinese healthcare system has undergone three major changes in the last half century. Following the Communist Revolution in 1949, China's mostly rural population accessed basic health services via cooperative medical schemes. "Barefoot doctors" provided immunizations and basic medical care in rural areas. Workers received cradle-to-grave healthcare through state-owned enterprises and work units. Use of traditional Chinese medicine was prevalent throughout the country.

Under the economic reforms of the 1980s and 1990s, the decentralization of welfare programs and state enterprise reform led to the dissolution of those systems. Village doctors became fee-for-service private providers. In urban areas, patients had to pay user fees for access to the hospital-based healthcare system. Only some 10 percent of China's population enjoyed health care insurance coverage as of 2000.[12]

Over the last decade, the Chinese government has launched significant reforms of the country's urban and rural healthcare systems and has boosted healthcare spending. It allocated, for instance, an additional $125 billion for improvements between 2009 and 2012.[13]

Healthcare Delivery

The Ministry of Health (MOH) administers public hospitals and, along with local governments, oversees the urban healthcare system, which traditionally has been hospital based. Hospitals are classified into Tier 1, 2, or 3, each with three sub-levels: A, B, and C.[14] The most sophisticated and well-equipped hospitals are awarded the highest rating: 3A. Tier 2 hospitals are usually district level and Tier 1 hospitals are small, community-based centers.[15] Outpatient services attached to these hospitals are the first point of care for most patients for even minor ailments, creating major bottlenecks in the system. Long lines and over-crowded waiting rooms are common.[16]

To address these problems and improve healthcare delivery around the country, the Chinese government is rejuvenating the rural healthcare provider network by increasing funding for village clinics, township health centers, and the training of general physicians. A network of non-hospital-based primary care providers and urban community health centers is also being established.[17]

The private sector currently does not play a very big role in healthcare delivery in China. Private sector visits account for less than 10 percent of the patient load at urban hospitals. Private grassroots clinics treat 50 percent of patients in rural China.[18]

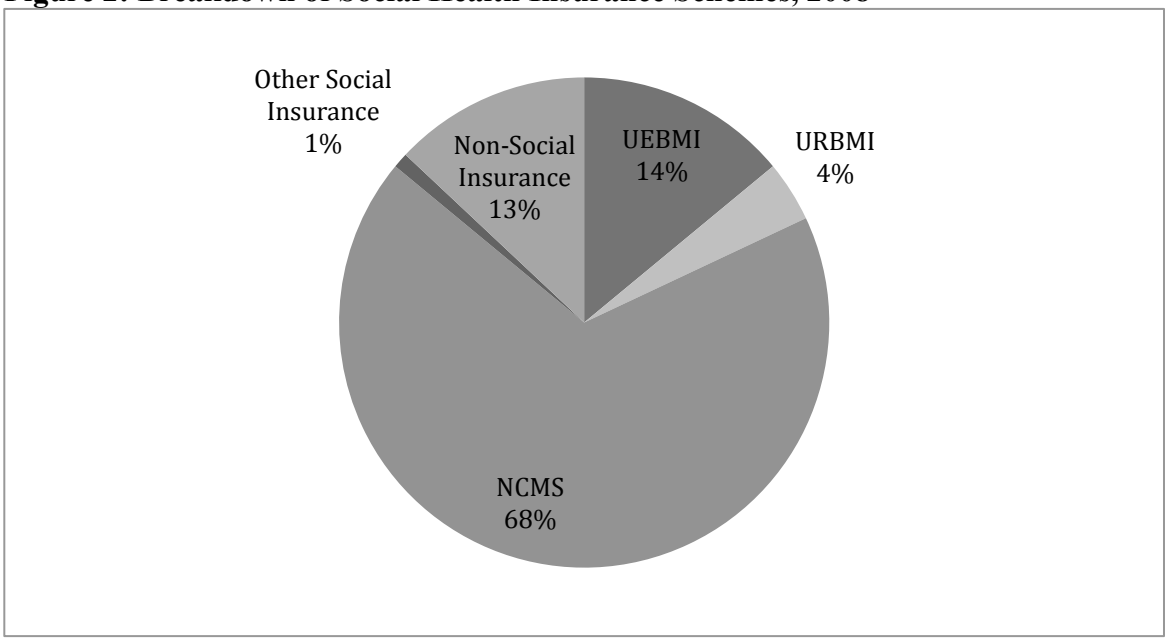
Healthcare Financing

China has made significant strides in expanding healthcare insurance programs for its citizens over the last decade. Roughly 87 percent of China's population enjoyed some kind of health insurance coverage as of 2008.[19] By 2010, the figure had grown to 90 percent, with the government aiming for 100 percent coverage by 2020.[20]

Despite these advances, patients' out-of-pocket payments are the predominant source of private healthcare financing, averaging about 78 percent per year between 2008 and 2012.[21] Insured individuals' out-of-pocket payments remain high in China because insurance plans do not adequately cover large healthcare expenditures.[22] As a result, patients are cost-conscious and have considerable say in the medical devices used in their procedures.[23]

Government health expenditures are mainly financed through social health insurance (SHI) in urban and rural areas. MOH administers the rural health insurance system, while the Ministry of Labor and Social Security oversees the urban system. Starting in the late 1990s, the Chinese government began to reform urban-based medical insurance schemes. It increased premium levels, consolidated funds of separate organizations, and established Urban Employee-Based Basic Medical Insurance (UEBMI) for employees, which is financed through payroll taxes. In 2007, the government set up a health insurance scheme for urban non-salaried residents, especially for children and seniors, known as Urban Resident-Based Basic Medical Insurance (URBMI). For rural residents, the Chinese government launched the New Cooperative Medical Scheme (NCMS) in 2003, which is a community-based rural health insurance plan mainly subsidized by the government.[24] See Figure 2 for a breakdown of social health insurance schemes in China.

Figure 2: Breakdown of Social Health Insurance Schemes, 2008[25]



MOH created NCMS to reduce rural China's illness-related financial burden and increase the affordability of medical care in rural areas. Government guidelines encourage NCMS to focus on covering inpatient care. However, both outpatient and inpatient services currently are covered to promote enrollment and prevent the worsening of minor health problems.[26] See Figure 3 for a comparison of the coverage provided under China's three main health insurance schemes.

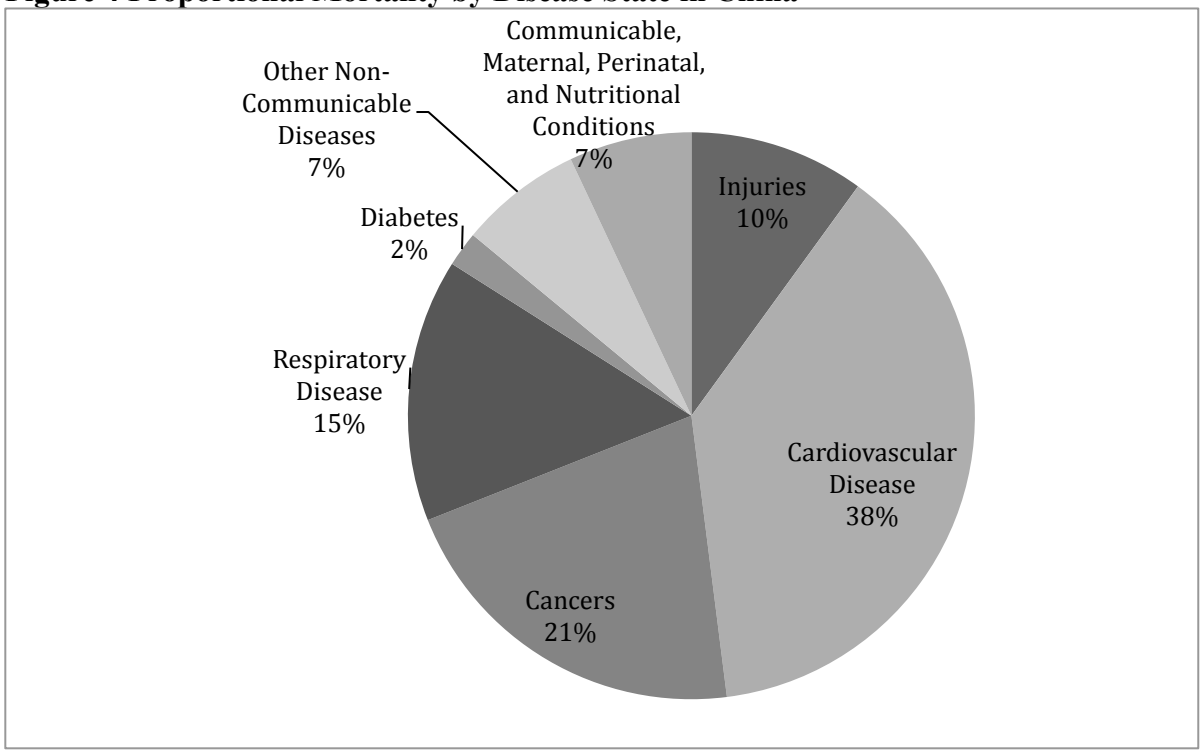
Figure 3: Coverage Under China's Three Main Health Insurance Schemes[27]

UEBMI Urban Employee-Based Basic Medical Insurance	URBMI Urban Resident-Based Basic Medical Insurance	NCMS New Rural Cooperative Medical Scheme
Outpatient and inpatient health services	In principle, inpatient care only	Outpatient and inpatient care in about 70 percent NCMS counties, with the other 30 percent for inpatient care only
Reimbursed drug list	Reimbursed drug list	Reimbursed drug list
More generous because of sound financing base (employer/employee contributions)	Relies heavily on government subsidies	Relies heavily on government subsidies

DISEASE BURDEN

Over the last two decades, China's disease profile has shifted from infectious diseases to chronic non-communicable diseases, which now account for 70 percent of the country's disease burden.[28] Although tuberculosis and some other infectious diseases are still prevalent, the top causes of death in both urban and rural areas are cancer and cardiovascular disease (see Figure 4).[29] The increase in chronic non-communicable conditions largely reflects growing obesity, urbanization, and sedentary lifestyles in China. The Chinese health system will have to change its current focus on acute care to preventative strategies to manage these chronic conditions.

Figure 4 Proportional Mortality by Disease State in China[30]



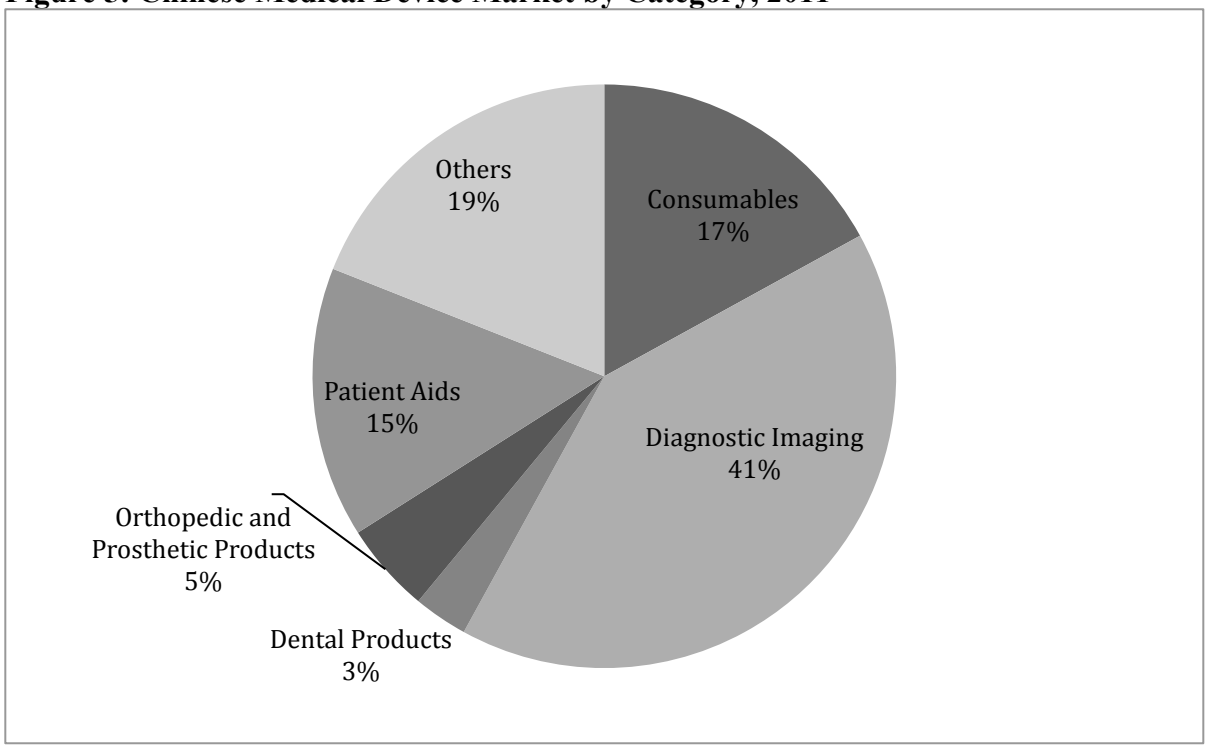
MEDICAL DEVICE INDUSTRY

The Chinese medical device market took off during the last decade, growing roughly 22 percent per annum.[31] Estimated to be worth as much as US$13 billion in 2012,[32] it is the fourth largest device market in the world, after the United States, Japan, and Germany.[33] Given how small China's device market is on a per capita basis, worth only US$10 per person in 2010 compared to US$348 in the United States, its growth potential is great, with some forecasters pegging its value at US$25 billion by 2016.[34] Imported medical devices, primarily advanced technologies such as imaging equipment and implantable devices, account for over 60 percent of the market (see Figure 5).[35] China primarily exports consumables, such as syringes and wound-care supplies.

Foreign companies dominate the high-tech devices sector, selling primarily to Tier 3 hospitals in urban settings. Among the top 10 medical technology manufacturers in China, seven are foreign firms or joint ventures. Domestic players tend to function on a small scale, often regionally, and sell low-tech devices in markets outside the major cities. There are notable exceptions, however, in the coronary stent industry. Moreover, local companies are increasingly consolidating their operations and making inroads in mid-tech device sectors.[36]

Multinational medical device firms traditionally have not had much of a physical presence in China, conducting business through sales affiliates. They are now expanding their China operations into fully integrated businesses with local product development, global product planning, and scaled-up distribution. Domestic companies, meanwhile, are populating their product pipelines with new and acquired products and are increasing sales.

Figure 5: Chinese Medical Device Market by Category, 2011[37]



CHINA'S REGULATORY ENVIRONMENT

Since 2003, the State Food and Drug Administration (SFDA) has been the single regulatory body in charge of overseeing the safety of food, drugs, cosmetics, and medical devices in China.[38] Modeled after the Food and Drug Administration (FDA) in the United States, SFDA classifies devices as Class I, II, or III. Some devices, however, may fall under a different device classification than in the United States. SFDA requires domestic and foreign companies that manufacture higher risk devices, such as stents and other long-term implantables, to conduct clinical testing in China. Manufacturers of other devices can use clinical data generated in other countries to support approval processes, such as FDA approval or CE Mark. Imported medical

devices require the submission of a specific Registration Standard document to SFDA, with product samples for testing. SFDA takes into consideration a company's compliance with global quality management requirements, such as ISO 13485:2003 certification.[39]

Local players have an advantage steering their medical devices through China's regulatory pathways. For stents and other high-risk devices, the regulatory process has become increasingly onerous. It currently can take higher risk devices up to three years to obtain regulatory approval from the start of clinical trials, which adds to manufacturers' development costs.[40]

REIMBURSEMENT ISSUES

MOH is responsible for the bidding and tendering system used in public hospitals to purchase new medical equipment, such as large-scale devices and certain implantables. Tenders set prices, which are subject to a ceiling in most parts of China, as well as identify medical device manufacturers for hospital procurement departments.

Since 1999, China has required a formal tendering process, which served to increase transparency of purchases and reduce end-user prices. However, the initiative raised costs for device makers (through tendering fees and bid bonds), lengthened purchase cycle times, and increased bureaucratic red tape. Authorities subsequently introduced several different reforms, such as those by the Shanghai Pricing Bureau in 2003 and the Central Tendering System in 2006. This has led to a patchwork of tendering rules across different provincial governments.[41]

The tender process favors domestic manufacturers, which benefit from wide distribution networks, cultural affinity with government officials, and highly competitive prices.[42] For instance, Shanghai authorities in recent years fixed the ceiling price for procedures using coronary stents at a level below the price of imported stents. As a result, only patients who could afford to pay the price difference normally chose an imported stent over a locally made one.[43] Similarly, reimbursement rates for imported devices, which vary by locale, may be less than the rates fixed for domestic devices.[44]

INTELLECTUAL PROPERTY PRACTICES

China's current patent law system is relatively new. In 2008, the Chinese government launched a national intellectual property (IP) strategy to demonstrate its determination to encourage innovation and create a knowledge-based economy. China joined the World Intellectual Property Organization (WIPO) in 1980 and ratified the World Trade Organization (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 2001. There are three types of intellectual property rights in China, including patent, trademark, and copyright. Patents include "patents for invention," "patents for utility model," and "patents for design."[45]

The duration of a Chinese patent for invention is 20 years, and the duration of patents for utility model and design is 10 years starting from the application date in China.[46] Inventor remuneration is mandatory in China and any entity that is granted patent rights over an invention must compensate the inventor. China follows a "first to file" rule. If two or more applicants apply for a patent for the same invention separately, the first applicant will be granted the patent right.[47] China also recognizes the right of priority for a patent application filed in one of the Paris

Convention foreign countries within 12 months (or six months for design patents) of filing in China.

The theft of IP and trade secrets in China by Chinese competitors and partners poses perennial concern for foreign and domestic manufacturers. According to the U.S. Embassy in Beijing, China has one of the world's highest piracy rates, with counterfeit goods accounting for over 20 percent of products sold in the country.[48] China accounted for more than 75 percent off counterfeit products seized at U.S. borders between 2004 and 2009.[49]

Inadequate enforcement of international laws governing IP rights and a protectionist instinct hinder efforts to reduce IP infringement in the country.[50] Foreign companies traditionally have not had much success seeking redress for infringement in Chinese courts. That said, enforcement and reparations are starting to improve as Chinese companies increasingly find themselves IP theft victims. Struggling to build national brands, they are demanding better IP protection.[51]

Endnotes

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