



Thoughts and Progress

Medical Device Market in China

**Philip Boyer, †Bashir I. Morshed,
and ‡Tofy Mussivand*

**Department of Systems and Computer Engineering,
Carleton University; ‡Medical Devices Innovation
Institute, University of Ottawa; §Cardiovascular
Devices Division, University of Ottawa Heart
Institute, Ottawa, ON, Canada; and †Electrical and
Computer Engineering Department, The University
of Memphis, Memphis, TN, USA*

Abstract: With China's growing old-age population and economic presence on the international stage, it has become important to evaluate its domestic and foreign market contribution to medical devices. Medical devices are instruments or apparatuses used in the prevention, rehabilitation, treatment, or knowledge generation with respect to disease or other abnormal conditions. This article provides information drawn from recent publications to describe the current state of the Chinese domestic market for medical devices and to define opportunities for foreign investment potential therein. Recent healthcare reforms implemented to meet rising demand due to an aging and migrating population are having a positive effect on market growth—a global market with a projected growth of 15% per year over the next decade. **Key Words:** China—Medical device market.

China is an immense, constantly changing market with vast opportunities for expansion in the area of medical devices. Medical devices are instruments, equipment, and tools used in the prevention, rehabilitation, treatment, or knowledge generation with respect to disease or other abnormal conditions, and in maintaining and promoting positive health outcomes (1). They are used in such diverse areas as diagnostic imaging, orthopedics, implants, and many others. Past articles have provided high levels of detail on the medical device markets of Europe and North America (e.g., Pammolli et al. [2]), but there are few equivalent English language resources pertaining to the medical device market in China. Two

exceptions include a 2010 report prepared for the federal government of Israel (3), and a 2009 report prepared for the US Commercial Service (4). However, despite providing valuable information, these reports are limited in comparison with a literature review. Therefore, the objectives of this review article are: to provide a brief background on the Chinese healthcare system, challenges, and reforms; to summarize and quantify the extent of the current Chinese medical device market with regard to both domestic and foreign investment opportunities in this developing nation; and to determine the viability of investment in China's medical device market. Resources are drawn from several English-language journal databases, online publications and documents, and are limited to material released in the past 10 years relating to the state of healthcare in China and the medical devices industry/market.

SOCIOECONOMIC STRUCTURE

Population and economic trends

China is the most populous country in the world with approximately 1.3 billion people (5). As to be expected with a developing country of this size, a great number of individuals face serious health concerns, as illustrated in Fig. 1. According to the World Health Organization (WHO), more than 80% of deaths in China are attributable to chronic diseases (6,7), with an annual estimated 400 000 premature deaths linked to air pollution and 800 000 relating to injuries (8). A 2012 report suggested that 35.2% of Chinese men and 39.5% of Chinese women are overweight, compared with 14.7% averaged across both genders in 2002. In addition, 55.5% of men and 5.5% of women are currently smokers (7). To cope with such widespread health challenges, it should be apparent that China is an enormous market for the medical device industry.

This market in China is growing rapidly for three significant reasons. The first is that China's population is aging, with 8.9% of its population aged 65 or older as of 2010 (9). By 2020, this number is expected to grow to 17% (9), and by 2040 the elderly population is projected to increase to 400 million individuals (10) due to controversial legislation enacted by the Chinese government: the one-child policy.

doi:10.1111/aor.12427

Received May 2014; revised July 2014

Address correspondence and reprint requests to Dr. Tofy Mussivand, Cardiovascular Devices Division, University of Ottawa Heart Institute, 40 Ruskin Street, Ottawa, ON, K1Y 1J7, Canada. E-mail: tmussivand@ottawaheart.ca

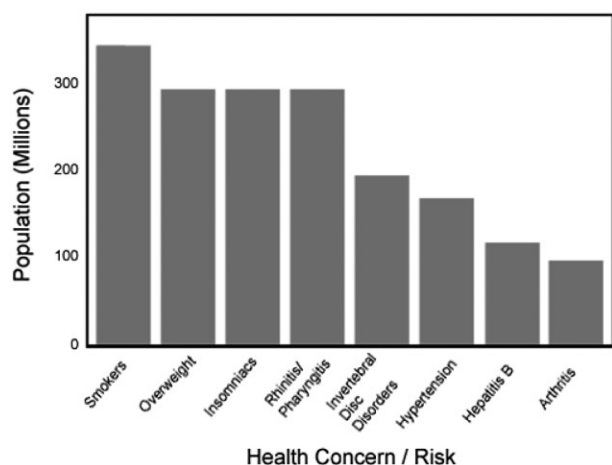


FIG. 1. Chinese with health concerns/risks by millions population (3,4).

Introduced in 1979, the one-child policy resulted in fertility rates decreasing from between 5.6 and 6.3 in the 1950s and 1960s, to 2.2 in the 1980s (11). Generally along with advanced age comes the necessity for more frequent and varied support and medical devices to maintain an individual's health, and the only reasonable response to maintain and improve the standard of healthcare of such population is to increase the number of facilities and healthcare options. The elderly are often given care as a matter of tradition in China by family members and the community (9); however, this will not cover the anticipated 500% increase in the number that will require nursing home-level care (11). Currently, only 0.8% of China's aging population receives this care, far less than international standards, and to increase that capacity to even 3%, an investment of US\$200 billion would be required (11).

The second driving force behind the burgeoning market for medical devices is the growing need to provide adequate healthcare to rural areas and migrant workers who traditionally have not been provided with it. The metropolises of Beijing and Shanghai, for example, have high doctor-to-patient ratios, but in rural areas such as Guizhou the ratio drops to a low of 0.81 doctors/1000 patients (3). Individuals living in rural areas make less than a third of those that live in the city (11), which not only means that they are less likely to be able to afford adequate healthcare, but it also encourages a huge number of workers to migrate to urban areas which places an increased expectation and demand for healthcare services and products. Between 2004 and 2012, the number of migrant workers in urban areas rose from 200 to 260 million, accounting for approximately

40% of the population in these urban areas (8,12). China's urban residents number about 500 million, where 80% of China's medical resources are located. In contrast, there are 850 million rural residents where only 20% of medical resources are located (4).

It is primarily for these reasons that China ranks 101st out of 187 countries in the 2013 Human Development Report (13), an international measure of healthcare quality. It should be noted that the opportunities for medical devices are strongly dependent on the area of the country under investigation as some provinces have extremely high capabilities whereas others lack even basic care (3).

The third major force encouraging the growth of the medical device market is the rapid increase in the wealth of the country and its people. From 1980 to 2000, average income increased fivefold in urban areas while it increased only threefold in rural areas (11). There has been a more than 10-fold increase in gross domestic product (GDP) since 1978, with China becoming the second largest economy in the world (5). China now has annual expenditure of US\$136 billion on research and development, and there are 263 medical research institutions with an estimated 926 000 researchers (5). In all of these measures, China is second only to the United States. This expansion in economy and research has primarily been due to China becoming a market-oriented economy.

The needs of the healthcare industry, including medical devices, will likely continue to grow with the age and wealth of its population (14). While as mentioned previously per capita incomes have risen, average medical costs have increased by a factor of 9 over the same period (11). This is difficult to account for without the increased use and demand for medical technologies. Increased longevity and increased affluence are simultaneously shifting the emphasis of healthcare in China, as well as medical devices, from acute to chronic healthcare (15).

Government policy and reform

One of the most glaring issues that needs to be addressed in China's current healthcare situation is the fact that these medical technologies and practices are prohibitively expensive for the majority of the population unless they receive government assistance. From 1980 to 2006, the government's share of healthcare spending dropped from 36 to 18% (16). Only 25% of the rural population is covered by health insurance. Of the total population, approximately 700 million lacked coverage as of 2006 (4). In the same year, 50% of those with serious health conditions did not take advantage of healthcare services

primarily due to financial concerns. For those who did, the vast majority paid from out-of-pocket funds on a for-service basis instead of receiving government assistance. In a nation where total health expenditure has increased 40-fold from 1985 to 2005, equivalent to 5.5% of China's GDP, out-of-pocket payments has similarly increased from 20 to 60% between 1978 and 2002 (17). In 2006, the Basic Health Insurance Scheme, the primary source of insurance in urban areas, did not cover migrant or sector workers, and as a result was accessible to only 28% of the urban population (8).

China has a few private hospitals, and public hospitals are expected to cover 70–90% of their expenses due to the government providing very low funding, declining from 36% in 1980 to 17% in 2004 (7). With a healthcare expenditure of 350 billion RMB (US\$56 billion) in 2004 (stated as US\$110 billion in another source [3]) and government allocation of only 50 billion RMB (US\$8 billion), hospitals have been forced to turn to user fees and drug markups as major sources of revenue (16). The result has been “over-prescription of medicines and unnecessary and expensive medical testing” with evidence “that C/T scans are being performed at a rate 100 times higher than in comparable U.S. hospitals” (16).

To address these problems, the Chinese central government has initiated several health insurance plans since 1988 (16). Since its inception in 2003, the new cooperative medical scheme (NCMS), one of China's three main health insurance schemes, has vastly improved access and health insurance to rural residents (18). The initiative “Health China 2020” began in 2009, with funding of US\$125 billion over the following 3 years, with the goal of providing healthcare insurance coverage for all of China's citizens by 2020 (19,20). Comparatively, in 2007 only US\$2 billion was allocated toward reforms. The result of these reforms is that by 2011/2012, insurance coverage (combined urban and rural) achieved between 92 and 95.7% of the population (20,21), which very nearly meets the government's goal of universal coverage by that time (17). Furthermore, reforms have been shown to have significantly reduced individual copayments for both outpatient and inpatient healthcare (22). The 11th and 12th 5-year plans (2006–2010 and 2011–2015) have been enacted with the intention not only to provide further healthcare reform, primarily by vastly increasing the number of care centers (23) and providing subsidies to rural residents (4), but also to increase government promotion of industries such as biotech (23). A third of this funding will come from government at the national level, and the remaining two-thirds will

come from local governments, in comparison with 91 and 9%, respectively, in 2003 (20). Lastly, 15% of the medical devices currently in use have been deemed obsolete and marked for replacement (3), and according to the reforms, US\$250 million has been allocated by the Chinese government to subsidize new purchases. This may provide an opportunity for foreign manufacturers and investors.

STATE OF CHINA'S MEDICAL DEVICE MARKET AND INDUSTRY

Domestic market for medical devices

China's healthcare expenditure has risen from US\$110 billion (2004) to US\$256 billion (2009), and is expected to reach US\$600 billion by 2015 (3). The numbers of domestic medical device manufacturers vary according to sources, perhaps depending on categorization, with a low of 3000 (3) to a high of approximately 11 000 (4). Sales of medical devices was greater than US\$14 billion in 2009, making it the third largest medical device market in the world after the United States and Japan, and is predicted to eclipse Japan in the latter half of the decade (3) with a projected increase of 15% annually (6). In general, more than 70% of medical devices can be categorized in four types: diagnostic imaging devices, medical supplies, orthopedics and implanted medical devices, and dentals (3).

In the past decade, China experienced an extremely rapid growth in medical device imports and exports with an average annual increase of 30% (4). Noting that estimates of value vary between sources, import rates have been stated to range from a growth of US\$1.64 billion in 2001 to US\$5.22 billion in 2008 (4), to US\$2.657 billion in the first quarter of 2012 alone, of which diagnostic equipment accounted for US\$2.03 billion (14). Exports have been estimated at US\$8.4 billion in 2007 and US\$3.6 billion in the first quarter of 2012 (14). Although the growth rate of China's trade in medical devices is significantly higher than other economic powers, this has slowed in recent years, mainly because of such factors as weak global demand due to recession and rising domestic labor costs (diminishing China's competitive advantage) which have risen by 33% in the 3 years leading up to the first quarter of 2012 (14). The result is a more modest increase of 14.54% for imports and exports in the first quarter of 2012 (14).

Research and development (R&D) is another measure of the strength of China's medical device market. China ranked 13th in total publication of biotechnology articles with 2.1% in 2008, but its

contribution has been growing at a rate of 48% per year (24).

Quality and concerns

As there are many unique issues affecting China's population, there is a great opportunity for domestic industry to provide products to address them. Chinese companies often have different requirements and standards for revenue, and they are often able to operate in domestic markets that are not ideal for larger foreign firms, such as poor rural communities (23). The majority of the products developed target the illnesses that afflict these individuals, with focus on low cost and low technology.

Industrial design of more advanced products is discouraged due to the high risk involved in innovative research because such projects will likely not achieve profitability for many years (23). China's venture capital sector is restricted by financial issues and is not accustomed to the business models required to support R&D in its initial stages (24,25). This is not helped by the current price regulations in China which ensure that even after a patent expires, a biotechnology product will likely not drop significantly in price, effectively discouraging consumption in the domestic market (24). The result has been firms that sell low-risk products that are often direct copies of foreign-made products. This has kept the industry knowledge base at a relatively low level. The Chinese scientific elite have tended to seek education in western nations and not return to their country of origin as they would be less likely to be on the cutting edge of technological innovation, with recent statistics stating that of the US doctorates awarded to foreign nationals, 26.4% were of Chinese origin (15).

However, the Chinese government is gaining awareness of the fact that an insular industry is unlikely to be successful and only domestic firms with the capacity to innovate are likely to thrive in the global marketplace (24), and now seeks to create an environment that is more conducive to local businesses producing devices that can compete internationally (26).

FOREIGN INVESTMENT AND DEVICE MANUFACTURING IN CHINA

Foreign industry: trends and opportunities

Traditionally, foreign companies investing in high-technology areas such as medical devices would approach the Chinese market with reservation (25), but in the past few years there has been a reduction on tariff rates on foreign medical products (3). This and other improvements to the desirability of the

Chinese market system are primarily the result of China's entrance into the World Trade Organization (WTO), and the restrictions and requirements placed upon them as a result (3). In 2005, 18% of the foreign investment in developing countries (US\$622.43 billion) (27) went to China, and based upon the growth of the domestic market since then, it is a safe assumption that this number has grown.

Foreign companies are attracted to the Chinese market due to the low cost of labor (27). High-technology firms will develop their production lines in China where expenses can be minimized before exporting their products to the international community where they can take advantage of competitive pricing (28). This is one of the main reasons for low patenting productivity in China because companies will conduct R&D in more developed nations with more patent protection and use their Chinese counterparts for the manufacturing portion of their business (28). The Chinese government has been implementing reforms in this area to make research and development within China a more attractive enterprise (3).

The focus of foreign companies in China has been the high-technology, high-cost market (3), with these firms accounting for 37% of high-tech companies as of 2005 (28) (Fig. 2). The contrast is even more apparent in the high-end medical device market as foreign firms have come to dominate with an 80% share; seven out of the top 10 largest firms are foreign companies or are joint ventures with domestic

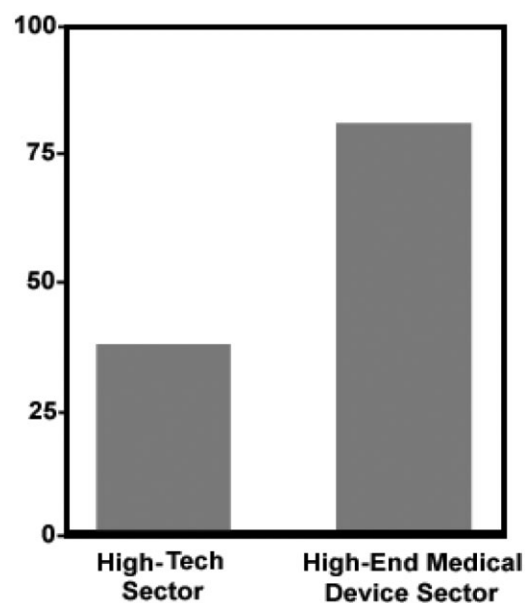


FIG. 2. Percentage market share of foreign companies in the Chinese high-tech sector and specifically the high-end medical device sector (3,28).

companies (3). These companies are catering primarily to the best hospitals in China where the clientele is generally of the wealthier upper class and government officials, who have created demand and are willing to pay for the highest quality of care. However, there are growing opportunities in rural areas for foreign firms to develop a market base as the current series of government reforms are allowing for the construction of new hospitals and upgrading old ones, encouraging them to invest in new and better-quality equipment, primarily in medical diagnostics (3). The strongest areas of foreign investment in medical devices in the Chinese market include medical imaging (computed tomography [CT], X-ray, magnetic resonance imaging [MRI], ultrasound, etc.), products related to more advanced surgical procedures, and equipment for treatment of chronic disease (4). This equipment should ideally be competitively priced with domestic companies for those firms interested in catering to the rural and urban poor, and it is recommended that foreign companies provide the training and maintenance of these devices to increase market reliance and to ensure lasting profitability (3).

Challenges and barriers

Other than catering to the wealthy elite, foreign firms are most heavily invested in high-tech because it is more difficult for local firms to reproduce these devices. In developed countries, the prohibition of so-called "copying" of an intellectual property is rigidly enforced, whereas in China and in other developing nations the patent laws are weakly enforced so that foreign firms must resort to other measures for protection, including design secrets and focusing on more complex products that require a significantly greater knowledge base than is typically available to domestic companies (28). Protection has improved since China joined the WTO; however, there is still a view common among developing countries that increasing protection of intellectual property (IP) rights would stifle industries that are based upon imitations and fakes, and thereby stifle economic growth (23). As previously mentioned, that view is gradually being replaced by the realization that to maintain competitiveness in the global marketplace, domestic firms must be capable of innovation, and that innovation must be protected by stronger patent laws. Fortunately, it has been stated that the recent trend appears to be in favor of stronger IP protection (29). One positive aspect of this culture of imitation is that in copying foreign-made products, domestic knowledge does increase to a certain limited degree (28).

Another difficulty often faced by foreign companies entering the Chinese market is lack of local knowledge (27). This may include such considerations as social factors, intermediate suppliers, and policy changes. One way that these difficulties have been addressed is to locate companies in industrial clusters where strong local business linkages are already established, which can have the added benefit of shared supply lines and lowered production costs (27). Several such clusters for medical devices are located in the metropolis of Shanghai (3), which also happens to be one of the largest markets for premium medical devices, along with Beijing, Shenzhen, Guangzhou, and Hong Kong (29). Partnering with local distributors, in particular, appears to be a viable method of entry into the Chinese market, but it should be noted that there are over 10 000 distributors of medical devices in China, most of which are extremely small outfits, which necessitates the employment of a large sales force by the marketing or development firm (29). It is also advisable to be open to partnerships with various levels of government, hospitals, and even the Chinese army (29).

One major consideration (which is likely a consideration when entering into any foreign market) is regulatory procedures governing medical devices. There are significant regulatory procedures for foreign-made medical devices, which are governed by the State Food and Drug Administration (SFDA) (15). Like in the United States, medical devices are classed into three different types: Class I, where safety and effectiveness can be ensured through routine administration; Class II, where further control is needed; Class III, where they are implanted in the human body, used for life support or sustenance, or pose potential risk to a person and must be strictly controlled (26). Oversight of Class I and II devices is assigned to provincial governments, whereas the SFDA is in charge of Class III (3). According to SFDA regulations, approval of registration of medical devices takes between 60 and 90 days for a US\$500 fee; however, it has been stated that a majority of companies wait for up to a year to receive approval to move to clinical trials (26). This lengthy approval time discourages both foreign and domestic businesses in medical device development. This is thought to be partially owed to the execution of the head of the SFDA in 2007 due to corruption charges, leading to a more thorough and lengthy evaluation process with the intention of being "more careful" (29). However, regulatory restrictions for devices undergoing clinical trials are extremely relaxed, possibly due to the long approval process

and pressure to generate revenue or lack of expertise in regulatory staff (26). The Chinese central government has recently taken steps to mitigate these problems, in particular, implementation of new registration requirements intended to make it easier for foreign companies to export medical devices to the Chinese market, as well as price caps and reduction of tariffs (7).

CONCLUSIONS

China is an immense market with many opportunities in the field of medical devices as indicated by its rapid growth in the medical device sector both for domestic and foreign firms. The current series of government reforms that are to be completed in 2020 and the rapid pace of economic growth are making the country more attractive to foreign investment. Presently, the best opportunities for foreign company investment are in high-technology, high-cost diagnostic devices, but this is gradually changing due to the rising demand by the rural and urban poor for better healthcare, and as enforcement of intellectual property rights improve, with similar market increases anticipated in the area of chronic healthcare as China's society ages. Despite improvements by the Chinese government, there still remain substantial social and economic concerns, but if correctly implemented the benefits and opportunities for profits and expansion in locating a medical device company in China outweigh the inherent risks.

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