IV. GROWING ASIAN MARKETS FOR SOURCING OR MANUFACTURING MEDICAL DEVICES

China

When discussing the sourcing of medical products in Asia, we generally think about China as being the "world's factory." Although China has in the past been associated with low-tech goods, medical device manufacturers in China have made significant improvements in medical technology and product quality. Chinese factories are more sophisticated than they were before, and some have even received certification from the US FDA as well as other international standards organizations. China's accession to the World Trade Organization (WTO) in 2002 has been a key catalyst to China's development efforts. The country now faces the constraints of being a member of an organization run by Western-style "rule of law," and must take on the responsibility of enforcing the laws. Laws regulating environmental standards are beginning to be enforced more strictly than they were previously. The WTO rules on intellectual property (TRIPS) also compel China to deal with the notorious problem of lax intellectual property right enforcement. In addition, WTO membership has prompted China to ease restrictions on foreign companies that want to market and sell medical products directly in China.

The existing presence of many multinational medical device companies has already attracted support service companies like law firms, accounting firms, and other business services providers. Furthermore, China's health care system is undergoing reforms and modernization, paving the way for further medical device market development.

The Chinese medical device industry is quickly moving up the ladder of technical sophistication and improving in quality. In particular, GMP standards are currently being implemented officially for sterile and implantable medical devices. These standards are scheduled to be extended to all medical devices in stages by 2010.

In addition to developing the manufacturing capacity and equipment to make almost any product, China has taken specific policies to attract foreign investment and development. This has been done successfully through the creation of five special economic zones (SEZs), located in Guangdong Province (Shenzhen, Zhuhai, and Shantou), Fujian Province (Xiamen), and all of Hainan Province. Foreign companies that invest in these SEZs can benefit from incentives offered by the Chinese government, such as low income tax rates or tax breaks. For instance, a firm may be exempt from paying income taxes during the first few years of a newly invested project; however, the exemption is granted once the company achieves a certain percentage of its production capacity. These zones are technically not under the jurisdiction of China's Customs authority, so they are not subject to the same customs laws that would apply in China.

SEZs have traditionally been located along the coastal and southern parts of China, but in recent years, the Chinese government has also opened up a number of cities to investment and has designated other zones in more inland regions. In addition to the SEZs, there are also economic and technological development zones (54), high-tech industrial development zones (54), free trade zones (15), and provincial-level development zones (245). For example, the Pudong New Area in Shanghai is the location of the Waigaoqiao Free Trade Zone, the Jinqiao

Export Processing Zone, the Zhangjiang Hi-Tech Park, and the Lujiazui Finance and Trade Zone.

In the Waigaoqiao free trade zone, for example, companies may be exempt from paying tariffs, customs duties, and value added taxes. They may also benefit from lower income tax rates, as well as tax exemptions or deferrals, simplified customs procedures, and waived export quotas. The technological development zones have their own industry focus as well; i.e., attracting foreign investment in high-tech industries. Medical device companies can benefit greatly from China's SEZs and free trade zones, as medical devices and equipment are one of the targeted high-tech industries.

Each economic zone has its own advantages and disadvantages since it targets different companies or types of investment. The incentives may also be different depending on the specific region, so it is important to do appropriate research. Companies should be aware that there are often conditions attached to the incentives offered in SEZs, such as export quotas, price caps, or other restrictions placed on incentives. More information can be found on China's Ministry of Commerce website (www.mofcom.gov.cn).

Finally, China's provinces and cities aggressively offer a wide variety of investment incentives of their own. This is particularly true in the parts of China further inland, compared to the coastal areas which have been industrializing for a long time. A company in a "third-tier" area may enjoy great incentives thanks to local governments eager for their business. Wages are also lower the farther one goes from the coast and the major cities. On the other hand, infrastructure and talent are at lower levels there.

China is a key location for establishing a manufacturing base, as well as a huge market for Western companies. Large multinational medical companies such as General Electric, Siemens, Johnson & Johnson, Philips, and Toshiba have all invested in China through joint ventures or wholly foreign-owned enterprises (WFOEs). These large companies dominate the Chinese high-end medical device market.

While there are local device manufacturers all over China, two areas in particular have a high density of manufacturers. These are the Shenzhen area (Guangdong province) and the Shanghai-Nanjing corridor (Shanghai and Jiangsu provinces). Each area has companies making a wide range of devices, but the Shenzhen area is more oriented around electrical devices, whereas the Shanghai-Nanjing corridor makes a greater proportion of disposable products.

On May 6, 2009, the Chinese State Council endorsed a proposal to extend more economic privileges to the Shenzhen SEZ as it seeks to transform the zone into an international metropolis. The State Council is currently reviewing Shenzhen's formal proposal (submitted in October 2009). It seeks to expand the SEZ fivefold from 400 sq km to 1,950 sq km, nearly twice the size of Hong Kong. The area will include suburb districts, such as Baoan, Longgang and Guangming, to lessen the inequality between the area inside and outside the SEZ. The cheap land will attract hi-tech industries and relieve the shortage of land the SEZ currently faces.

While China is generally thought of as the leading location in Asia for sourcing low to medium-tech medical products, other countries have also become attractive (i.e., Vietnam). In fact, as China's capabilities and competencies have improved and developed, the cost of doing business in China has also increased. These changes in the business environment are particularly harmful to low-cost, labor-intensive industries. In late 2008, with the global economic slowdown, many local Chinese manufacturers of toys, plastics, etc. have been forced to shut their doors. However, by contrast, Chinese medical device manufacturers are well positioned in this environment, since China's response will be to develop its expertise and move up the value chain to more sophisticated, high-tech products.

From the perspective of foreign-invested companies in China, some incentives are being lowered. Starting from January 1, 2008, the corporate income tax rate was unified. Previously, most foreign-invested companies paid 15% tax, whereas domestic companies paid 33% (not counting various exemptions). These rates are to be unified gradually to 25% for all companies. However, this is partly symbolic, as most domestic companies do not pay the official tax rate in practice.

In 2009, China expanded and improved its trade relations with multiple Asian countries. The much-anticipated China-ASEAN Free Trade Area (CAFTA) will soon be the largest free trade zone in the world by population, with 2 billion people. By grouping China with the ten ASEAN nations, the area integrates a market with a trade volume of over $4 trillion and a combined GDP of $6 trillion.

Tariffs will be eliminated for 90% of goods traded between China and the more developed ASEAN-6 (Singapore, Brunei, Indonesia, Malaysia, Philippines and Thailand). Tariff reductions for the remaining four ASEAN countries (Cambodia, Laos, Myanmar and Vietnam) will be implemented by 2015. The Pan-Beibu economic zone and the Nanning-Singapore economic corridor, both South China-ASEAN areas, are two examples of emerging economic zones after CAFTA enters formal operation on January 1, 2010.

In May 2009, the Chinese State Council approved plans to construct a Haixi Economic Zone (HEZ) on the western side of the Taiwan Strait. The idea was first proposed by Fujian authorities in 2004. The Haixi region encompasses 23 cities from four provinces (Fujian, Zhejiang, Guangdong and Jiangxi), with the largest city being Quanzhou. Its location is not only crucial to improving cross-strait relations, but it also links two major economic areas – the Yangtze and Pearl River deltas.

The investment area between Fujian and Taiwan has shifted somewhat from manufacturing to scientific research and technical services recently. In 2008, the trade volume between the two regions reached $7.5 billion, up 55% from the previous year. The city of Xiamen contributed $4.0 billion, a little over half of Fujian's total trade volume. Xiamen is currently constructing new advanced industrial facilities and upgrading others. In September 2009, Fujian authorities also announced that Pingtan Island will become a SEZ.