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U.S. Medical Devices and China's Market: Opportunities and Obstacles

Author:

Mihir P. Torsekar

Document Preparation and Design:

Monica Reed

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ADDRESS CORRESPONDENCE TO:

MIHIR TORSEKAR (202-205-3350, mihir.torsekar@usitc.gov) or
OFFICE OF INDUSTRIES
U.S. INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC 20436 USA

U.S. Medical Devices and China's Market: Opportunities and Obstacles¹

Mihir P. Torsekar

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Abstract

China's medical device market is experiencing significant growth, presenting opportunities for U.S. medical device manufacturers. The results of this analysis indicate that the United States is China's leading supplier of medical devices and that U.S. exports of both implantable and non-implantable devices to China increased 147 percent to \$2.4 billion during 2008–13. Forecasted slow growth in U.S. healthcare spending may encourage U.S. firms to work to further penetrate China's medical device market, both via exports and by continuing to establish a local presence within the country. Yet the potential for greater market access may be constrained by a number of barriers in China's market—most notably, challenging regulatory procedures, inconsistent reimbursement policies, complex tendering for purchasing medical devices, and tariffs on China's most commonly imported devices.

¹ This paper represents solely the views of the author and is not meant to represent the views of the U.S. International Trade Commission or any of its Commissioners. The invaluable assistance of Michael Anderson, - Monica Reed, Peg Hausman, and Karen Laney is gratefully acknowledged. Please direct all correspondence to Mihir Torsekar (202-205-3350, mihir.torsekar@usitc.gov), Office of Industries, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436, fax: 202-205-2018.

Contents

	<i>Page</i>
Introduction.....	1
Product coverage.....	1
U.S. industry is the world’s largest.....	2
Innovation and R&D: The lifeblood of the industry	5
The U.S. market is the world’s largest.....	7
Rate of growth of U.S. healthcare spending expected to flatten.....	7
ACA and cost containment	9
Patients are reducing healthcare spending.....	10
Reduced capital expenditures for hospitals	11
China’s growing medical device market.....	12
China’s market drivers: Demographics, economic growth, and reforms.....	12
Healthcare reforms in China	15
Chinese firms supply the rural sector	16
U.S. firms bolster local presence and target rural population.....	17
The U.S. is China’s leading medical device supplier	18
Obstacles to greater market access	21
Onerous regulations: Time lags and duplicative procedures	21
Securing a reliable distributor.....	23
Lack of time to prepare for changing standards.....	25
Provincial tendering process proves complex.....	25
Inconsistent reimbursement	26
High tariffs relative to other leading markets	26
Conclusion	27
Bibliography.....	28
 Boxes	
1 IMDs and non-IMDs.....	2
2 Classes of medical devices	5
3 Incremental nature of U.S. innovation.....	6
4 U.S. healthcare sector spending is the world’s largest	8
5 Medical device density in China is among the world’s lowest.....	14
6 China’s public healthcare system	16
7 Overview of China’s regulations of medical devices.....	24

Contents

	<i>Page</i>
Figures	
1	In 2012, the United States was the world’s largest leading single-country exporter of medical devices 4
2	The United States is considered the world leader in medical device innovation 6
3	The percentage rate of growth in healthcare spending in the United States is expected to remain flat until at least 2015 9
4	China’s elderly population is rapidly increasing as a share of the total 13
5	China’s healthcare sector spending has risen significantly since 2004, and growth is expected to continue through 2014 15
6	U.S. medical device exports to China have increased each year since 2008; in 2013, the majority of non-IMD exports were diagnostic and imaging equipment, and the leading IMD exports were cardiovascular devices..... 20
7	In 2013, China has the longest approval time—on average—for each class of medical device among leading medical device markets..... 22
Tables	
1	The United States claimed 7 of the world’s top leading medical device OEMs, by revenue, in 2012..... 3
2	U.S. medical device firms’ China strategy increasingly focused on projects establishing local manufacturing facilities in 2008–12 17

Introduction

China is one of the world's fastest-growing markets for medical devices and presents significant opportunities for U.S. firms in this field. Driven by rapid urbanization and associated lifestyle-related ailments, an aging population, and increased public investment in healthcare, China has emerged as Asia's second-largest medical device market (behind Japan) and the world's third largest.² The United States, the world's largest producer of medical devices, has increasingly supplied this market through exports, as well as by directly establishing local manufacturing facilities, headquarters, research laboratories, and the like in China. With expected curbs on the growth of U.S. healthcare spending, firms are likely to continue to pursue opportunities in China's burgeoning market. At the same time, a number of constraints within China—including complex regulations, inconsistent reimbursement policies, a complex tendering process, and extensive tariffs on commonly imported medical devices—may limit the potential for U.S. medical device manufacturers to capitalize on these opportunities.

This paper first discusses the U.S. medical device industry and market, followed by an evaluation of China's market. It then reviews U.S. exports of medical devices to China during 2008–13, discusses recent efforts by U.S. medical device firms to expand within China, and weighs the potential for future market opportunities against the barriers to market access. For the purpose of analysis, this paper defines medical devices as either implantable medical devices (IMD) or non-implantable medical devices (non-IMD).

Product Coverage

Although the medical device industry can be defined in any number of ways, this paper will focus exclusively on implantable (IMD) and non-implantable (non-IMD) medical devices.³ The former category is characterized by devices that are physically inserted into a patient, and includes cardiac, orthopedic, and dental implants (box 1). Conversely, non-IMDs are non-invasive technologies that commonly assist in the diagnosis of ailments and include devices such as x-ray equipment, for example.

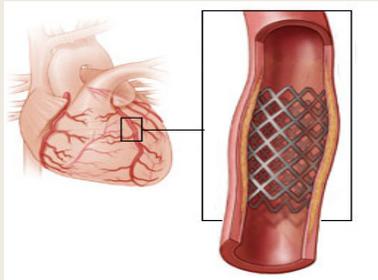
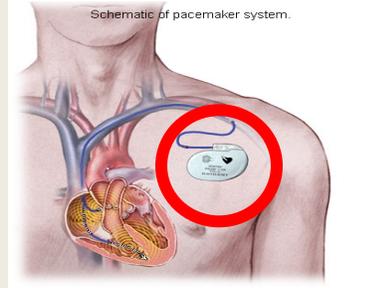
² MDMA Annual Conference, Washington, DC, April 8, 2013; Le Deu, *Healthcare in China*, July 2012, 81.

³ The relevant North America Industry Classification System (NAICS) codes include 325413, in-vitro diagnostic substances and devices; 334510 and 334517, electromedical equipment; 339112, surgical and medical instruments; 339113, orthopedic devices and hospital supplies; and 339114, dental equipment. This paper's classification of IMDs and non-IMDs covers the vast majority of medical devices that are traded and produced globally, with the exception of in vitro diagnostics (IVDs)—medical products used to diagnose diseases through the collection and analysis of body fluids. IVDs were excluded because trade in this category is limited; U.S. exports to China of these goods reached just \$332.3 million in 2012. GTIS database (accessed August 22, 2013).

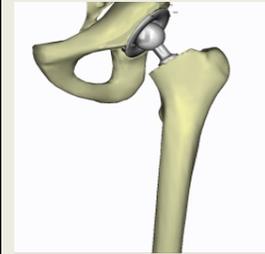
Box 1 IMDs and non-IMDs

Implantable medical devices (IMD)

Cardiovascular: Devices designed to ensure the proper functioning of the heart. For example, cardiac pacemakers are a type of implantable cardiovascular device that can help restore a regular heartbeat. Another example is a coronary stent, which are tubes that are inserted into the arterial walls during angioplasty, a procedure aimed at ensuring adequate blood flow to the heart.



Orthopedic: Devices that address dysfunctions in the musculoskeletal system. Common examples include hip and joint replacements.



Examples of IMDs (L to R): Pacemaker (circled), coronary stent, hip implant

Images courtesy of Space Weather, <http://www.solarstorms.org/SPacemakers.html>; WebMD, <http://www.webmd.com/heart-disease/coronary-stent>; and RSA Biomedical, <http://www.rsabiomedical.se/umrsa/>.

Non-Implantable medical devices (non-IMD)

Diagnostic Imaging: Devices that generate internal images of the human body, which can facilitate the diagnosis of various afflictions. Examples include x-rays, computed tomography (CT) scanners, magnetic resonance imaging (MRI), and ultrasound equipment.



Examples of non-IMDs (L to R): MRI, X-rays, and CT scanner

Images courtesy of MedlinePlus, <http://www.nlm.nih.gov/medlineplus/>.

U.S. Industry is the World's Largest

The U.S. medical device industry, which is valued at more than \$60 billion, is the world's largest and accounts for nearly 20 percent of the \$350 billion global industry, by production.⁴ Moreover, 7 of the world's 10 largest medical device original equipment manufacturers (OEMs), by revenue, are headquartered in the United States (table 1). Although large firms

⁴ Estimates of the size of the global and domestic medical device industry vary based on the products included; the industry size as defined in this context likely includes IVDs as well as IMDs and non-IMDs. American Action Forum, "Primer," June 2012.

command the greatest domestic market share,⁵ more than 80 percent of the industry’s 1,500 firms are small and medium-sized enterprises (SMEs) that employ less than 50 people.⁶ Nonetheless, it is typically the larger OEMs that commercialize most medical devices due, in large part, to their financial resources. Despite producing devices across 90 distinct categories of products, U.S. firms specialize in high-value-added technologies requiring a highly skilled workforce of engineers and technicians. The U.S. medical device industry employs more than 400,000 people throughout the country and pays wages that exceed the national average.⁷

Table 1 The United States claimed 7 of the world's top 10 leading medical device OEMs, by revenue, in 2012

Rank	Company	Country Headquarters	Revenue billion \$	Specialty
1	Johnson & Johnson	U.S.	27.4	Diagnostics, surgical care, cardiovascular, orthopedic
2	GE Healthcare	U.S.	18.3	Imaging
3	Siemens Healthcare	Germany	17.5	Diagnostics, imaging
4	Medtronic	U.S.	16.2	Cardiovascular, orthopedics
5	Baxter International	U.S.	14.2	Fluid and drug delivery
6	Philips Healthcare	Netherlands	13.2	Imaging
7	Covidien	Ireland	9.9	Surgical care
8	Abbot Laboratories	U.S.	9.8	Diagnostics, cardiovascular
9	Cardinal Health	U.S.	9.6	Surgical care
10	Stryker	U.S.	8.7	Orthopedics

Source: MPO, “The Top 30,” July/August 2013.

The U.S. global leadership in the medical device industry is also reflected in the global export market (figure 1). U.S. medical device OEMs earn between 40 and 50 percent of their revenues outside the United States, with the European Union (EU) generating an estimated 30 percent of these sales.⁸ These sales generally reflect a combination of exports and activities by foreign-based subsidiaries.⁹ Selling devices abroad offers several advantages, including the ability to mitigate currency fluctuations, for instance.¹⁰ Additionally, a U.S. manufacturer may gain market access sooner in the EU than in the United States, due to the region’s relatively fast

⁵ In 2012, GE, Medtronic, and St. Jude Medical accounted for nearly 32 percent of domestic market share. American Action Forum, “Primer,” June 2012. These three companies are the world’s 2nd-, 4th-, and 16th-largest medical device manufacturers. MPO, “The Top 30,” July/August 2013.

⁶ MDMA, “Medical Technology and Venture Capital,” June 1, 2009; USITC, *Small and Medium-Sized Enterprises*, November 2010.

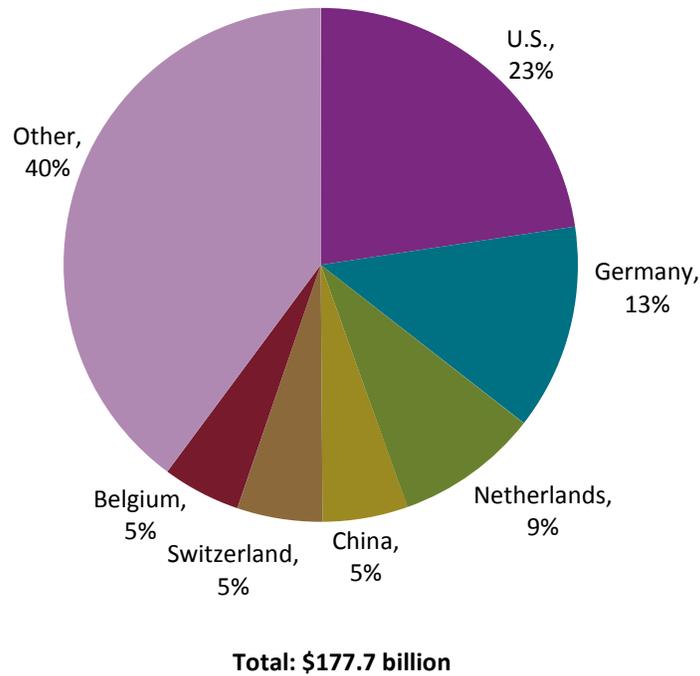
⁷ In recent years, the average medical device industry salary was about \$14,000 above the national earnings average. Lewin Group, “State Economic Impact,” June 7, 2010. This estimate likely includes IVD production and other devices not discussed in this report.

⁸ S&P, *Healthcare: Products and Supplies*, February 2014, 19. Notably, emerging markets represent a fraction of medical device sales outside the United States. For instance, Medtronic, one of the world’s leading medical device manufacturers conducts less than 10 percent of their business in these markets. *Economist*, “Left To Their Own Devices,” September 10, 2011.

⁹ S&P, *Healthcare: Products and Supplies*, February 2014, 19.

¹⁰ A strengthening U.S. dollar makes U.S. goods relatively more expensive and generally translates into reduced sales and revenues in overseas markets. Conversely, U.S. medical device OEMs benefit from a weakening U.S. dollar when entering foreign markets. During 2010–11, an estimated 40 percent of revenues garnered by the top 10 U.S. medical device OEMs stemmed from beneficial foreign exchange rates. EY, *Pulse of the Industry*, 2012, 21.

Figure 1 In 2012, the United States was the world’s leading single-country exporter of medical devices



Source: GTIS database (accessed March 6, 2014).

Note: Data were compiled at the Harmonized System (HS) 6-digit level (the HS is a system for classifying exported goods). Within the “Other” category, no single country accounted for more than 5 percent of the total export share. 2012 was the most recent year for which data were available.

approval process for medical devices.¹¹ Due in large part to the significant costs associated with overcoming regulatory barriers to market entry overseas, large OEMs typically comprise the U.S. export industry (box 2).¹²

¹¹ As noted in Figure 7 of this report, the average approval time for class I and II devices in the EU and the United States is similar. However, class III devices in the United States can take nearly three times longer to gain approval. Emergo, “The Medical Device,” 2013.

¹² S&P, *Healthcare: Products and Supplies*, February 2014, 43.

Box 2 Classes of medical devices

Medical devices range in complexity from bandages to cutting-edge capital equipment. In the United States, the Food and Drug Administration (FDA) categorizes devices into three classes, based on the relative risk they may pose to patients' health. All of the world's leading markets—including China—classify their devices on a similar basis.

- **Class one devices** present the fewest health risks to patients. Examples include tongue depressors, bandages, and examination gloves. These devices are most commonly approved if (1) the device has been registered with the FDA, (2) the agency has been notified 90 days before the device is advertised, and (3) the device has been manufactured in accordance with the good manufacturing practices (GMPs) established by the FDA to ensure high manufacturing quality.
- **Class two devices** range from relatively low-risk non-IMDs—such as x-rays, ultrasounds, and other types of diagnostic imaging devices—to moderately risky devices such as surgical lasers, ventilators, and syringes. Manufacturers of these products must gain 510(k) clearance from the FDA, which requires firms to demonstrate the safety of the device during the approval process and to conduct post-market surveillance. Further, device manufacturers are required to demonstrate that the device is “similar” to an existing product on the market; the majority of devices gain approval through this process.
- **Class three devices** are subjected to the most rigorous regulatory procedures. Examples of class three devices include many IMDs, such as cardiac pacemakers, heart valves, and implantable orthopedic devices. In particular, these devices are required to undergo a premarket application process, which requires clinical trials, detailed information about the product, and additional data to demonstrate the efficacy of the device. This process can be time consuming, taking between one and five years in some cases—a period during which a firm receives no income from this product.

Sources: S&P, *Healthcare: Products and Supplies*, February 2014; FDA, “How a Device Gets Approved,” May 25, 2013; USITC, “Medical Devices,” March 2007, 2-2.

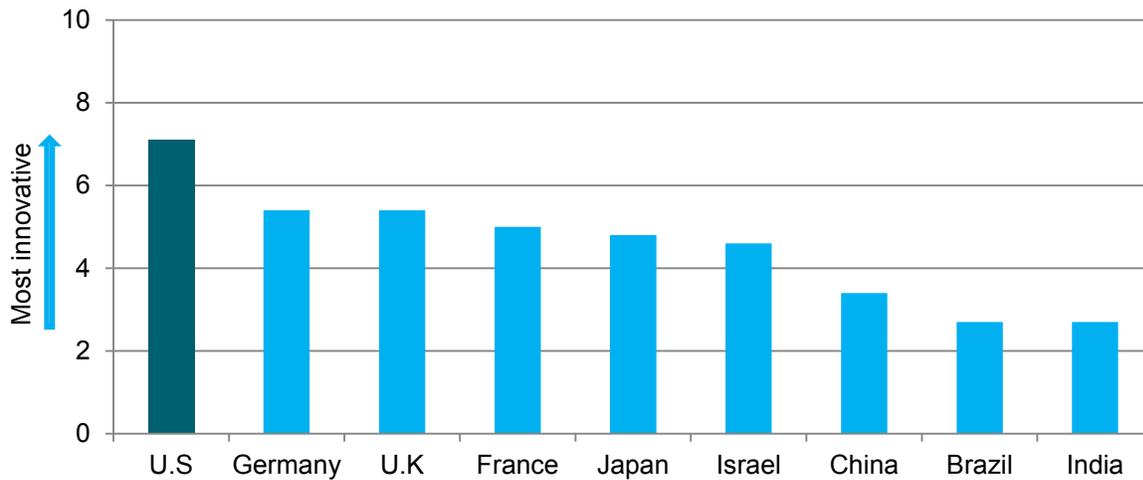
Innovation and R&D: The Lifeblood of the Industry

The U.S. medical device industry is considered the world's leader in medical device innovation, which is reflected in the resources that companies direct towards research and development (R&D) (figure 2). For instance, leading U.S. medical device manufacturers commonly devote between 9 and 10 percent of their annual revenues to R&D, in contrast to 3 to 4 percent for domestic manufacturers of other types of goods.¹³ This trend continued during the economic recession of 2007–09, during which time overall R&D investments by the U.S. medical device industry increased by 11 percent.¹⁴ Most of these resources are directed towards improving existing devices, rather than introducing novel technologies (box 3). Much of the U.S. industry's strength in medical device innovation is due to strong demand and the financial benefits associated with commercializing new technologies.

¹³ S&P, *Healthcare: Products and Supplies*, February 2014.

¹⁴ MDDI, “R&D and Investment,” January 30, 2012.

Figure 2 The United States is considered the world leader in medical device innovation



Source: PwC, Innovation Scorecard, January 2010.

Box 3 Incremental nature of U.S. innovation

Due to the relatively lengthy approval process for innovative technologies, most U.S. firms have typically concentrated their R&D on making incremental changes to existing devices.

These changes tend to involve adding new features to existing products. Cardiac pacemakers, for instance, are now in their 10th generation. In the latest iteration, these devices can be worn while under exposure to radiation therapies such as MRIs. Previous generations of pacemakers could malfunction when exposed to MRI scans due to the overheating of wires.



Pictured: Revo MRI by Medtronic, the first cardiac pacemaker that can be worn during MRI scans. Photo courtesy of Medtronic.com, <http://www.medtronic.com/for-healthcare-professionals/products-therapies/cardiac-rhythm/pacemakers/revo-mri-pacing-system/>.

Sources: PwC, *Medical Technology Innovation Scorecard*, January 2011, 7; S&P, *Healthcare: Products and Supplies*, February 2014.

The U.S. Market is the World's Largest

The United States is the world's largest medical device market, accounting for nearly 50 percent of the \$273 billion global market by sales.¹⁵ Domestically, the largest consumers of medical devices are hospitals, outpatient care facilities, and private physicians' practices. Devices are commonly acquired by administrators within these markets. To gain more power to negotiate over the costs of medical devices, many of these market participants join group purchasing organizations (GPOs);¹⁶ an estimated 98 percent of hospitals use GPO contracts in purchasing.¹⁷ Historically, hospitals have been willing to pay significant premiums in order to acquire the most novel medical technologies.¹⁸ This may reflect the preferences of physicians, who have often preferred their own brands and medical technologies regardless of the cost and have had significant influence in acquiring these devices.¹⁹ For instance, IMDs have generally been decided upon by the individual physician as opposed to the healthcare facility.²⁰

Rate of Growth of U.S. Healthcare Spending Expected to Flatten

The rate of growth in U.S. healthcare spending (box 4) is expected to flatten in the coming years, which may reduce demand for medical devices in the United States (figure 3). From 2010–13, per capita growth in U.S. healthcare spending was estimated to be 1.3 percent—the lowest recorded rate for any three-year period since 1965.²¹ The relatively slow growth rate is due partly to recent reductions in reimbursements²² for the use of certain medical devices, which have become increasingly prevalent. For instance, the Centers for Medicare and Medicaid Services (CMS) reimbursements for diagnostic imaging procedures have fallen by more than 13 percent since 2006, while declining reimbursements appear at least partly

¹⁵ Market statistics likely reflect the inclusion of IVDs and other devices not discussed in this paper. S&P, *Healthcare: Products and Supplies*, February 2014.

¹⁶ S&P, *Healthcare: Products and Supplies*, February 2014.

¹⁷ HSCA, "A Primer on GPOs," n.d. (accessed October 16, 2013).

¹⁸ Healthcare providers have traditionally negotiated the price of medical devices directly with the manufacturers. However, the providers' strong preference for the most innovative technologies has afforded manufacturers significant leverage in determining the price. Morgan Stanley, *The U.S. Healthcare Formula*, June 16, 2011.

¹⁹ *New York Times*, "Costs Surge for Medical Devices," November 4, 2009.

²⁰ Ibid.

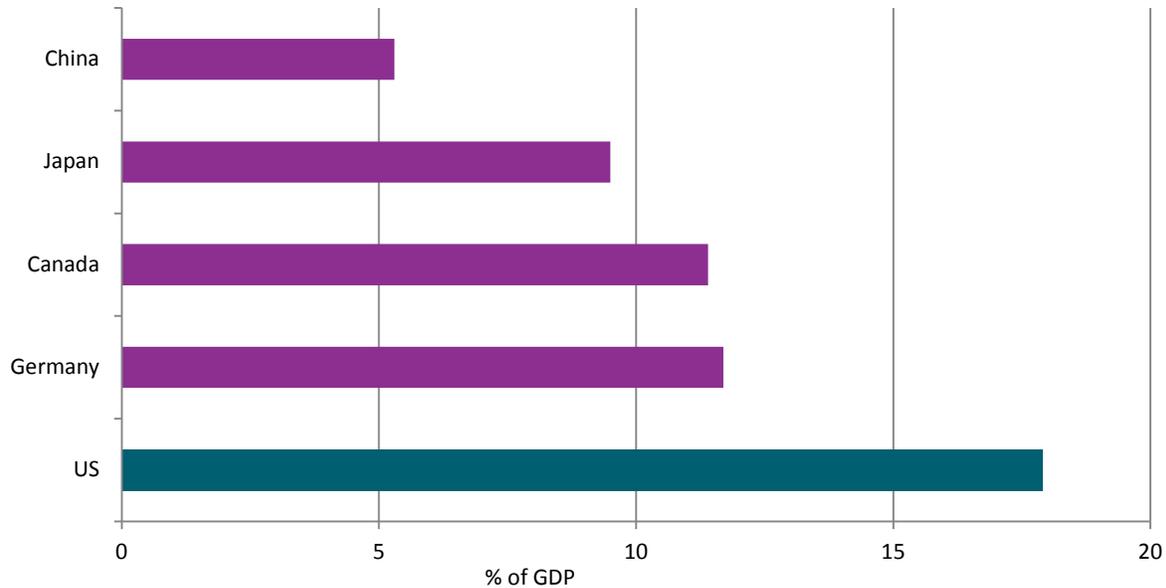
²¹ Executive Office of the President, *Trends in Health Care*, November 2013.

²² Reimbursement rates for medical procedures are a critical determinant of the type of devices an end user chooses to acquire; healthcare providers will likely refrain from using a medical device on a patient if the reimbursement is believed to be too low. Third-party insurers and the government—through the Centers for Medicare and Medicaid Services—are the principal reimbursing entities in the United States. Calvert, "How to Explain Device Reimbursement," March 29, 2006; S&P, *Healthcare: Products and Supplies*, February 2014; *New York Times*, "Costs Surge for Medical Devices," November 4, 2009.

Box 4 U.S. healthcare sector spending is the world’s highest

U.S. healthcare spending, which includes the cost of reimbursing procedures for which medical devices are used, is the world’s highest. This is true whether spending is considered in absolute terms, in per capita terms, or as a share of GDP. The U.S. industry spent an estimated 18 percent of its GDP on healthcare in 2013, with nearly \$30 billion directed towards acquiring medical devices (figure below). Further, per capita U.S. healthcare expenditures in 2012 were nearly twice those of Japan, 50 percent higher than those in the United Kingdom, Germany, and France—the leading healthcare markets in Europe—and 15 times those of China.

In 2013, the United States spent over 18 percent of its GDP on healthcare—more than any other country



Source: EIU, “U.S.: Healthcare and Pharmaceuticals Report,” December 13, 2014, and September 19, 2010.

The United States has traditionally relied on a fee-for-service model of healthcare, in which healthcare providers are compensated for the quantity of procedures conducted on patients, regardless of the impact on patient health. This model is believed to have encouraged high spending on numerous, often costly healthcare procedures:¹ the United States consistently leads the world in such procedures, including coronary artery bypass grafts, angioplasties, MRIs, and CT exams. Further, patients in the United States are believed to associate the quality of care with innovative medical technologies, which has further encouraged hospitals and clinics to acquire these devices. For example, the United States has three times as many MRI machines as the average healthcare facility in other leading markets, such as Canada and the EU.²

Sources: NRC, *The Healthcare Imperative*, 2010; EIU, “Healthcare Spending,” December 13, 2013; *Economist*, “USA Spending: Quality, Not Quantity,” June 17, 2011; EIU, “U.S. Healthcare and Pharmaceuticals Report,” June 21, 2013; PwC, “Innovation Scorecard,” January 2011; *Economist*, “USA Spending: Quality, Not Quantity,” June 17, 2011; Barnes, “Moving Away from Fee-for-Service,” May 7, 2012; Medical Mutual, “U.S. Healthcare,” April 8, 2013; Emmanuel and Fuchs, “The Perfect Storm,” June 18, 2008; OECD, “Medical Technologies,” 2009.

Notes:

¹ According to Medical Mutual, each year more than \$30 billion of U.S. healthcare spending is estimated to be directed towards unnecessary hospitalizations, redundant procedures, and the like. Medical Mutual, “U.S. Healthcare,” April 8, 2013.

² Emmanuel and Fuchs, “The Perfect Storm,” June 18, 2008.

Figure 3 The percentage rate of growth in healthcare spending in the United States is expected to remain flat until at least 2015



Source: EIU, "U.S.: Healthcare and Pharmaceuticals Report," June 21, 2013, and September 19, 2010.

responsible for a more than 10 percent drop in the use of both CT scanners and MRIs.²³ Three other significant drivers for declining healthcare expenditures include the advent of the Patient Protection and Affordable Care Act (ACA); the economic recession, which influenced consumers to reduce spending on healthcare and to increase enrollment in high-deductible insurance plans; and retrenchments in hospitals' capital expenditures, including those on medical devices.

ACA and Cost Containment

The Patient Protection and Affordable Care Act of 2010 (ACA)²⁴ has promoted reductions in healthcare spending in the United States, in part, through the introduction of accountable care organizations (ACOs). Under these voluntary programs, healthcare providers for Medicare patients are rewarded for delivering care for less money.²⁵ Further, under ACOs, hospitals and other healthcare providers are encouraged to pool their resources in an effort to coordinate

²³ An estimated two-thirds of hospital admissions in the United States are partially reimbursed by the CMS, giving the agency significant influence over the types of devices that hospitals and other end-markets acquire. The agency designates a fixed amount to distribute to hospitals for various procedures, while the hospital negotiates the price of devices with the manufacturer. S&P, *Healthcare: Products and Supplies*, February 2014, 34; *New York Times*, "Costs Surge for Medical Devices," November 4, 2009; Calvert, "How to Explain Device Reimbursement," March 29, 2006.

²⁴ As of January 1, 2013, the ACA began assessing a 2.3 percent excise tax on domestic sales of most medical devices in the United States. Because the tax does not extend to foreign sales, it is highly likely that U.S. medical device manufacturers will continue to pursue opportunities in foreign markets, especially China. As previously discussed, large OEMs already derive nearly half of their revenues from overseas sales of medical devices, and this trend is expected to continue. SMEs, however, garner the majority of their sales in the United States and thus may be impacted more heavily than the larger firms. S&P, *Healthcare: Products and Supplies*, February 2014, 3.

²⁵ *Economist*, "The Good Old Ways," September 8, 2012.

patient care, with the goal of eliminating redundancies in treatments and reducing patient readmissions.²⁶ To that end, hospitals are penalized when Medicare patients are readmitted within 30 days of receiving treatment for various conditions.²⁷ This policy is believed to have reduced hospital readmissions, which have fallen since the passage of the ACA, and to have applied downward pressure on total healthcare spending.²⁸ Because ACOs will likely result in fewer medical procedures being performed, overall demand for medical devices in the United States may decline.²⁹

Another cost-cutting element of the ACA is the implementation of healthcare exchanges, which provide a marketplace for private insurers to compete for customers. Although the exchanges are in their infancy, initial evidence suggests that nearly 60 percent of the plans listed offer “managed-care-like” features through either health maintenance organizations (HMOs) or exclusive provider organizations (EPOs).³⁰ These plans are often associated with lower healthcare costs because they offer patients a narrower network of healthcare providers. Dealing with smaller networks gives the insurer more leverage, making it possible to negotiate lower prices on various treatments and lower reimbursements for the use of medical devices.³¹ Further, “managed-care-like” plans tend to have lower premiums; the HMO and EPO plans currently listed on the exchanges are among the lowest-priced offerings, which may translate into higher enrollment.³²

Patients are Reducing Healthcare Spending

Patients in the United States have reduced their healthcare spending in recent years, due, in part, to economic uncertainties. During the economic recession, high unemployment translated into foregone healthcare treatments, as many formerly insured Americans lost coverage.³³ This reduction in medical procedures often translated into underutilized medical devices. Additionally, the recent surge in high-deductible insurance policies, in which consumers pay lower premiums but incur higher out-of-pocket costs, has also depressed patient demand for healthcare treatments.³⁴

One reason for this trend is that employers, who collectively insure an estimated 150 million Americans, have increasingly shifted the burden of financing health insurance onto their

²⁶ CMS.gov, “Accountable Care Organizations (ACO),” n.d. (accessed April 25, 2013).

²⁷ Surowiecki, “Controlling Health-Care Costs,” December 9, 2013.

²⁸ Ibid.

²⁹ Given the relative infancy of the ACA and associated policies such as the ACA, the actual impact on medical device demand remains uncertain.

³⁰ An HMO provides coverage chiefly through a primary care physician, who determines whether or not the patient needs to be referred to a specialist or requires other services. In most cases, these plans do not cover any treatments performed outside of the approved network. An EPO is similar to an HMO, with the chief exception being that an EPO does not require patients to receive in-network referrals from their primary care physicians. McKinsey, “Exchanges Go Live,” October, 2013.

³¹ Surowiecki, “Controlling Health-Care Costs,” December 9, 2013.

³² McKinsey, “Exchanges Go Live,” October, 2013.

³³ McCarthy, “Americans Spend Less on Healthcare,” January 9, 2012.

³⁴ The consumer typically finances the first \$1,000—\$5,000 of medical care before insurance coverage can be redeemed. Konrad, “The Many Hidden Costs,” May 29, 2009.

employees by sponsoring high-deductible plans.³⁵ Between 2006 and 2011, the share of workers enrolled in these plans increased from 3 to 13 percent.³⁶ This trend is expected to continue with the passage of ACA, which requires employers to provide health insurance to their employees; according to the annual health benefits survey, 66 percent of large firms offered these plans in 2013, while 80 percent of these firms are expected to do so in 2014. Notably, 15 percent of the companies surveyed offered only high deductible plans, up from 8 percent in 2010.³⁷ Further, nearly 25 percent of workers in small companies—firms with fewer than 200 employees—were enrolled in these policies in 2013.³⁸

Although the passage of ACA is expected to extend health insurance to more than 30 million Americans, the growing prevalence of high-deductible insurance plans may translate into reduced total healthcare sector spending.³⁹ According to one study, the adoption of high-deductible insurance policies was associated with a 25 percent reduction in healthcare spending during the first year alone, as enrollees refrained from various treatments.⁴⁰ Further, a recent survey revealed that half of the enrollees of these insurance policies did not seek medical attention for various afflictions due to the cost burden associated with their health insurance coverage.⁴¹ Moreover, surgical admissions during the first three months of 2013 fell by 4 percent, while visits to physicians declined by nearly 4 percent over the previous year. Both of these trends have been attributed, in part, to the growth of high-deductible insurance policies.⁴²

Reduced Capital Expenditures for Hospitals

U.S. hospitals have also become increasingly cost-conscious, as evidenced by their reduced capital expenditures, which are commonly directed towards medical device acquisitions.⁴³ This trend was exacerbated by the economic recession, which resulted in reduced hospital admissions and fewer resources with which to purchase new medical devices. However, this shift towards reduced spending has persisted following the recession; among the leading U.S. hospitals, capital expenditures as a percentage of revenues have ranged between 1 to 3 percent lower than pre-recession levels.⁴⁴ Further, in response to declining government reimbursements for medical procedures, hospitals have been reluctant to pay more to acquire devices that are believed to be only marginally better than the previous versions.⁴⁵ These trends stand in sharp contrast to the historical norms, in which hospitals were willing to pay

³⁵ *Economist*, “Will Obamacare Spur Firms?” January 25, 2013.

³⁶ Mercer, “Employers Accelerate Efforts,” November 2011; Konrad, “The Many Hidden Costs,” May 29, 2009.

³⁷ Andrews, “Large Companies,” March 26, 2013; *Economist*, “Will Obamacare Spur Firms?” January 25, 2013.

³⁸ Andrews, “Large Companies,” March 26, 2013.

³⁹ Fronstin and Roebuck, *Health Care Spending*, July 2013.

⁴⁰ Konrad, “The Many Hidden Costs,” May 29, 2009.

⁴¹ *Ibid.*

⁴² Berkrot, “Fewer Doctor Visits,” April 22, 2013.

⁴³ S&P, *Healthcare: Products and Supplies*, February 2014, 24.

⁴⁴ Between 2000 and 2007, capital expenditures for these entities were between 6 to 8 percent; however, between 2008 and 2012, average capital expenditures were 5.2 percent. S&P, *Healthcare: Products and Supplies*, February 2014, 24.

⁴⁵ *Economist*, “Left To Their Own Devices,” September 10, 2011.

significant premiums to acquire the most advanced and innovative medical technologies, as previously discussed.

China's Growing Medical Device Market

Given forecasted flat growth in U.S. healthcare spending, China will likely remain an extremely attractive market for U.S. medical device firms. China's medical device market, which was valued at \$13 billion in 2012, is currently the second largest in Asia and the world's third largest behind those of the United States and Japan.⁴⁶ Market growth has been driven in particular by China's urbanization, expanding economy, burgeoning middle class, and increased public investment in healthcare, as well as the aging of its population and the increasing incidence of heart disease, diabetes, and other lifestyle-related illnesses.

Although indigenous manufacturing of medical devices occurs in China, this production has traditionally been inadequate to meet the country's demand for high-technology (class two and class three) medical devices. Instead, Chinese firms have often focused on producing class one devices, such as hospital consumables and surgical gloves, or low-technology class two devices, such as black and white ultrasounds.⁴⁷

China's Market Drivers: Demographics, Economic Growth, and Reforms

As noted above, there are a number of reasons for the rapid growth of China's medical device market. Two of the most important factors are demographic: rapid urbanization and an aging population.⁴⁸ As China's economy has expanded over the past 30 years, urbanization has become increasingly widespread. Since 1980, China has witnessed the most dramatic population shift in history, as the country's urban population grew by 431 million—more than 226 percent—reaching 622 million in 2009; an additional 200 million rural migrants are expected to settle in urban areas over the next 10 years.⁴⁹ Urbanization is associated with numerous public health risks—including various non-communicable diseases such as lung cancer, cardiovascular disease, diabetes, and hypertension. The number of diabetic patients in China already exceeds that in the United States by 66 million, and more than 20 million people suffer from heart disease.⁵⁰ The higher risks are due, in large part, to the increased consumption of high-calorie, processed foods; the transition away from farming towards sedentary occupations; and increased population density, which speeds the spread of diseases.⁵¹

⁴⁶ MDMA Annual Conference, Washington, DC, April 8, 2013; Le Deu, *Healthcare in China*, July 2012, 81.

⁴⁷ S&P, *Healthcare: Asia*, March 2007; MPO, "Ultrasonic Boom," October 16, 2013.

⁴⁸ Hartford, "The Medical Device Market," June 18, 2013.

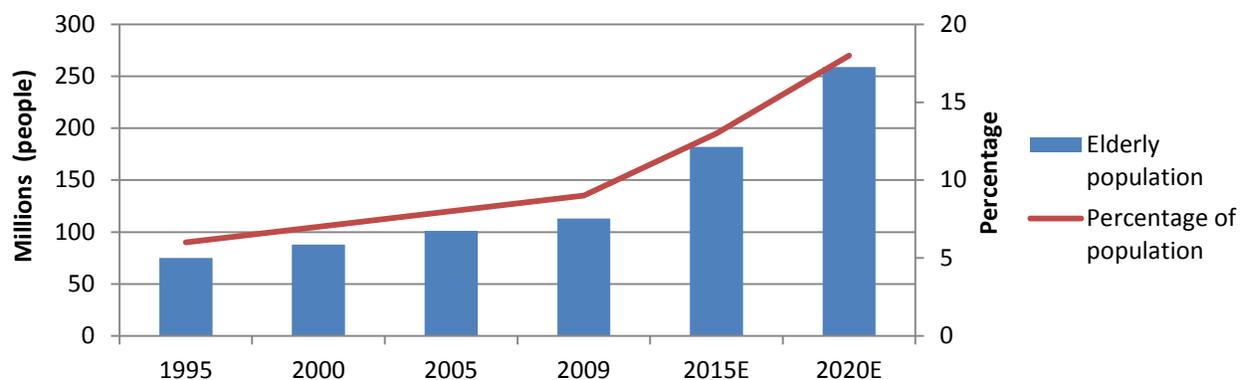
⁴⁹ Emory, "China: Disease and Health," March 7, 2012.

⁵⁰ Le Deu, *Healthcare in China*, July 2012, 4.

⁵¹ Jaffe, "In China," March 16, 2012; Van der Poel, *Urbanization*, October 2008.

The country's sizable elderly population is another demographic driver of China's medical device demand (figure 5). China has one of the world's oldest populations, with the size of its elderly population (those aged 65 and above) expected to double by 2030 to 223 million.⁵² Elderly populations are generally the largest consumers of orthopedic devices, due to the degradation of the musculoskeletal system and loss of bone strength generally associated with aging. Annual orthopedic procedures in China are therefore forecast to increase 18 percent through 2015, with many of the major segments expected to achieve double-digit growth.⁵³ For instance, joint replacements are expected to grow 17 percent annually to 454,581 procedures by 2015, while fracture management procedures are expected to expand by 25 percent, reaching 1 million procedures over the next two years.⁵⁴

Figure 4 China's elderly population (aged 65 and above) is rapidly increasing as a share of the total



Source: PwC, "Investing in China's Private Healthcare System," April 2013.

China's medical device demand has also been buoyed by significant economic growth, as reflected in the country's expanding middle class. By 2020, the middle-class urban population is expected to increase to 75 percent of the total population, from 29 percent in 2005.⁵⁵ The higher incomes associated with the growing middle class are likely to translate into broader insurance coverage and an increased ability to finance healthcare treatments.⁵⁶ Additionally, China's wealthier healthcare consumers will likely demand better healthcare treatments. However, China's healthcare system, characterized by considerable inequalities and a poor primary care system, has been unable to fulfill the growing needs of its population (box 5).⁵⁷

⁵² Seeking Alpha, "China Orthopedic," June 29, 2012.

⁵³ Ibid.

⁵⁴ Ibid.

⁵⁵ Middle-class in China can be defined as households with annual disposable income of between \$7,000 and \$27,000. Le Deu, *Healthcare in China*, July 2012, 5.

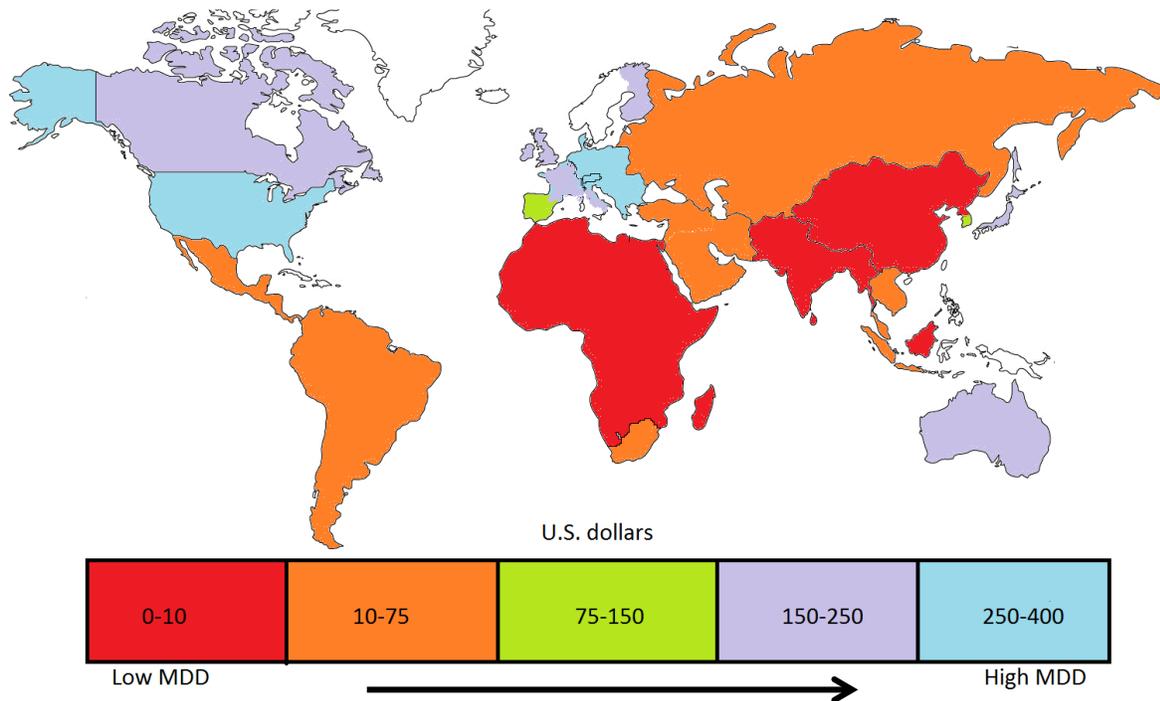
⁵⁶ Gross, "Hazards in Outsourcing," May 14, 2013.

⁵⁷ Le Deu, *Healthcare in China*, July 2012, 8.

Box 5 Medical device density in China is among the world’s lowest

Although China has the world’s third-largest medical device market, the country’s medical device density (MDD)—a measure of the relative availability of medical devices within a country—remains among the world’s lowest. MDD can be estimated by dividing a country’s medical device market size by its population to arrive at the medical device expenditure per capita.¹ A 2013 study by *Canadian Health Policy* found that of the 66 countries surveyed, China’s MDD ranked 58th, at \$6.¹ In contrast, the U.S. ranked second, behind Switzerland, with an estimated MDD of \$369. China’s low MDD likely reflects the significant inequalities that exist in the delivery of healthcare.

China’s MDD is among the world’s lowest, suggesting poor availability of medical equipment there



Sources: Compiled by Commission staff from CHP, “Medical Devices,” May 9, 2013; Hufbauer et al., Local Content Requirements, September 2013.

Notes: With the exception of Egypt and South Africa, the MDD was not available for Africa. However, according to the World Health Organization (WHO), Africa has a very low density for CT machines. This has been used to estimate Africa’s MDD in the above chart. WHO, “Baseline Country Survey,” 2010.

<http://172.16.3.33:9090/progress?pages&id=3112167621&fileName=V0hPX0hTU19FSFRfREINXzExLjAxX2VuZy5wZGY=&url=aHR0cDovL3docWxpYmRvYy53aG8uaW50L2hxLzlwMTEvV0hPX0hTU19FSFRfREINXzExLjAxX2VuZy5wZGY=&serv=3&foo=1>. Data were unavailable for the unshaded countries. Global map courtesy of <http://tertuliadofado.com/world-map-printable-blank/>.

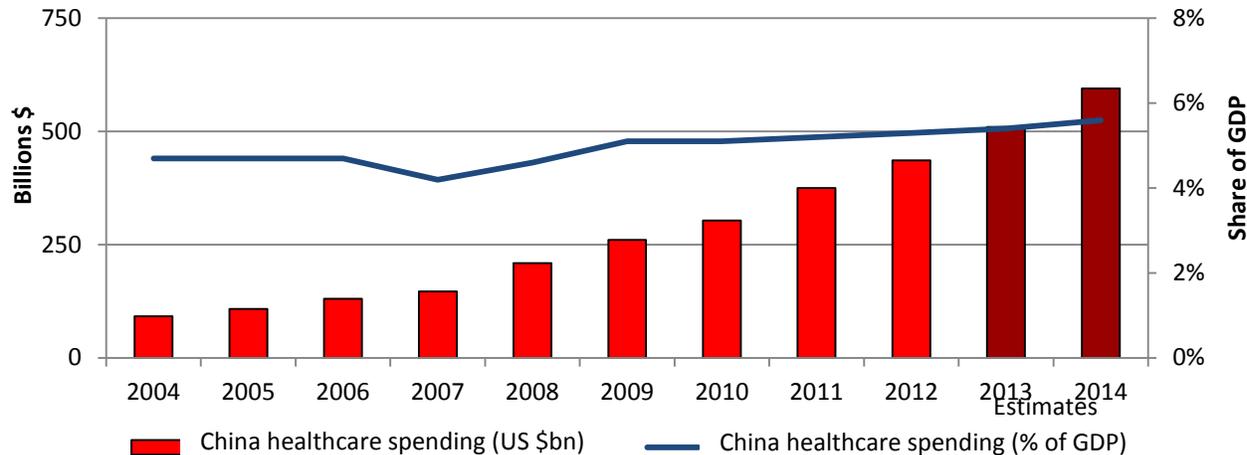
¹ The Canadian Health Policy report used per capita medical device expenditures for 2011, which have been used as a measure of MDD.

Although the country's 1,350 highest-quality hospitals tend to be outfitted with the latest medical technologies and attract the best physicians, the urban community health centers and provincial hospitals in the rural sector have been underfunded.⁵⁸ Further, the absence of a primary care system has meant that big city hospitals have been the principal providers of healthcare, leading to significant overcrowding of these facilities.⁵⁹

Healthcare Reforms in China

In an effort to resolve these challenges, the government has increased healthcare spending dramatically over the past decade and unveiled healthcare reforms in 2009 (figure 5). The stated goals of the reform included expanding basic health insurance, widening the availability of medications, developing a primary healthcare service system, increasing healthcare access for urban and rural residents, carrying out reforms of the public hospital system and pledging to spend \$125 billion through 2020 to achieve these goals.⁶⁰ During 2009–11 alone, the Chinese government directed \$2.1 billion to improve more than 30,000 rural healthcare facilities, including provincial and township hospitals and clinics.⁶¹ As of 2013, the government had already spent \$371 billion on healthcare reform since the policies were implemented, \$100 billion of which went to programs associated with increasing health insurance, reforming public hospitals, and improving community healthcare facilities.⁶²

Figure 5 China's healthcare sector spending has risen significantly since 2004, and growth is expected to continue through 2014



Source: EIU, "China Healthcare and Pharmaceuticals Report," March 4, 2013; December 2, 2011; and July 2008.
 Note: The figures above also include spending on medicines.

⁵⁸ Le Deu, *Healthcare in China*, July 2012, 8.

⁵⁹ Sussmuth-Dykerhoff, *China's Healthcare Reforms*, 2010.

⁶⁰ Ibid.

⁶¹ Le Deu, *Healthcare in China*, July 2012, 83.

⁶² Huang, "What Money Failed," March 4, 2014.

These investments are thought to have paid immediate dividends, as an estimated 95 percent of the population is believed to have some form of healthcare coverage, up from about 30 percent in 2003.⁶³ Improving primary healthcare services has spurred demand for medical devices; for example, small local hospitals (tier 1 facilities) were allotted medical device budgets of about \$720,000 in 2011 (box 6).⁶⁴

Box 6 China's public healthcare system

China's public healthcare system is divided into three tiers, with the quality of care and populations served varying considerably across the three categories:

- **Tier 1** hospitals have limited capabilities and operate in townships or villages, while mostly serving the rural populations. The devices in these facilities are generally supplied by low-cost local producers. There are an estimated 12,500 tier 1 hospitals in China.
- **Tier 2** hospitals operate in cities, counties, or districts and have 100–500 beds. There are more than 5,000 tier 2 hospitals.
- **Tier 3** hospitals are the most advanced facilities and offer comprehensive care. These hospitals generally carry the latest medical technologies (the majority of which are imported) and commonly have more than 500 beds. China has about 1,000 of these facilities.

Sources: Merritt, "Chinese Healthcare Reform," May 2011; Gross, "China's Hospital Market," January 1, 2011.

Chinese Firms Supply the Rural Sector

China has more than 4,000 indigenous medical device firms who generate over 70 percent of their revenues—which range from \$2 to \$4 million annually—from sales to hospitals in the rural sector.⁶⁵ As previously stated, much of China's indigenous production has been principally focused on class one and relatively basic class two devices. For instance, Mindray, China's largest indigenous medical device manufacturer, produces lower-end ultrasounds that are primarily used by tier one hospitals for screening; more advanced diagnosis is generally performed using imported devices.⁶⁶

Local Chinese medical device companies have achieved recent success either by providing simplified versions of the devices that U.S. firms typically provide or offering lower-priced alternatives. For instance, for use in primary care facilities, Chinese manufacturers have unveiled affordable patient monitors that lack the features that make these devices attractive to high-tiered hospitals. In another example, indigenous Chinese producers of coronary stents have been able to claim market share from U.S. medical device OEMs by commercializing stents

⁶³ Huang, "What Money Failed," March 4, 2014; EIU, "China: Healthcare," March 4, 2013; Jaffe, "In China," March 16, 2012.

⁶⁴ Le Deu, *Healthcare in China*, July 2012, 83.

⁶⁵ Le Deu, *Healthcare in China*, July 2012, 91; Sussmuth-Dykerhoff, *China's Healthcare Reforms*, *Health International*, 2010, no. 10; Medtech Switzerland, *People's Republic*, 2012. This production supplies half the market while the U.S. and other foreign multinationals supply the remainder of the market via exports or through affiliates manufacturing in China. Embassy of Canada, *Life Sciences Sector*, 2013; Deu, *Healthcare in China*, July 2012, 92.

⁶⁶ Zakreski, "Adapting," January 1, 2010.

that were priced nearly 30 percent lower than those sold by U.S. firms;⁶⁷ imported stents can cost twice as much as domestically produced versions.⁶⁸ As a result, U.S. market share for these devices has fallen from 80 percent during 2000–10 to 15 percent in 2011; Chinese producers now claim an estimated three-quarters of the stent market.⁶⁹

U.S. Firms Bolster Local Presence and Target Rural Population

In an effort to capitalize on China’s burgeoning medical device market, U.S. firms have expanded their local presence in China while also targeting the country’s rural population. For instance, during 2008–12, U.S. multinationals invested in more than 20 new projects, such as building local manufacturing facilities and erecting laboratories for research and development (R&D) (table 2). Moreover, within the past two years, leading U.S. medical device manufacturers have acquired local Chinese firms: in 2013, the world’s largest orthopedic device manufacturer, Stryker Corporation, acquired China’s leading producer of spinal products for \$764 million; Medtronic acquired a Chinese orthopedic implant manufacturer for \$816 million in 2012; and Johnson & Johnson bought its first Chinese medical device manufacturer, Guangzhou Bioseal Biotech, during 2012 as well.⁷⁰

Table 2 U.S. medical device firms’ China strategy increasingly focused on projects establishing local manufacturing facilities in 2008–12

Company	2008	2009	2010	2011	2012	
3M		x				
Abbot Vascular				☀		x Manufacturing
Baxter		x				
Boston Scientific				☀ x □		☀ Education and training center □ Sales, marketing, and support
Cook Medical	○					○ Shared services center
Corning			x			
DePuy ¹			x			
GE Healthcare	x			x ♦ □		♦ Headquarters
Johnson & Johnson		♦			#	# Design, development, and testing
Medtronic	□			♦ #		
Spacelabs Healthcare	x					
St. Jude Medical				☀		
Stryker		x				☀ Research and development
Thermo Fisher				x		
Zimmer				☀		

Source: Compiled from Financial Times, fDi Intelligence, 2013 (accessed June 2013).

Notes: The years shown in the table reflect the dates that the listed projects were announced, not their completion dates.

¹ DePuy is a subsidiary of Johnson & Johnson.

Currently, China heavily relies on U.S. producers to supply the mid-to-high end of the country’s medical device market;⁷¹ U.S. firms garner nearly three-quarters of their local revenues from the tier 3 hospitals and the remainder from the tier 2 hospitals.⁷² Further, U.S. medical device

⁶⁷ *Economist*, “Frugal Healing,” January 20, 2011; Le Deu, *Healthcare in China*, July 2012, 92.

⁶⁸ Deng, “Tales of Three,” November 2012.

⁶⁹ Crawford, “Asia’s Continued Manufacturing Evolution,” May 2012; Le Deu, *Healthcare in China*, July 2012, 92.

⁷⁰ USITC, “U.S. Firms,” August 2013; MPO, “The Top 30,” July/August 2013, 44.

⁷¹ Medtech Switzerland, *People’s Republic*, 2012.

⁷² Le Deu, *Healthcare in China*, July 2012, 93.

firms alone account for more than 70 percent of China's orthopedic implants market.⁷³ However, many of these companies are now competing directly with Chinese firms within the rural market segment. Price and practicality are the principal interests for these consumers, and many of the local solutions that U.S. firms have developed emphasize portability through miniaturized designs and product servicing through remote diagnostics at affordable prices.⁷⁴

For example, GE, the world's leading producer of medical imaging devices, has developed an exclusive line of affordable and portable medical technologies to fulfill the needs of rural communities that may otherwise not have access to these technologies, through their "Brivo" line of diagnostic imaging products.⁷⁵ Further, the company relocated its X-ray production from Wisconsin to Beijing in 2011, with the intention of creating products for the lower-end, primary-care segment of the Chinese market.⁷⁶ GE is expected to unveil 40 new products that are intended for this market segment in particular.⁷⁷ The company's new production center in China is expected to directly compete with Mindray Medical, China's largest local company.⁷⁸

Another example is the way U.S.-based Medtronic has been using its partnership with Weigao, a Chinese firm with a significant rural market presence. Medtronic has introduced several products for the local market and is distributing Weigao's spinal and orthopedic products to the rural sector.⁷⁹ Similarly, Boston Scientific has announced plans to increase annual sales in China by 30 percent over the next five years, creating devices exclusively for the local market.⁸⁰

The U.S. is China's Leading Medical Device Supplier

The United States is China's leading supplier of medical devices, representing nearly one-third of China's imports of these goods.⁸¹ Further, during 2008–13, U.S. medical device exports to China increased by 147 percent to \$2.4 billion (figure 5). Moreover, in 2013, China was the United States' sixth-largest export market for medical devices, accounting for nearly 7 percent of total U.S. exports of these goods.⁸² China's demand for diagnostic imaging devices has been especially strong; these goods represent nearly half of the country's total medical device demand, with future growth likely driven by a consumer-wide shift in preventative healthcare,

⁷³ Ibid., 92.

⁷⁴ Immelt, *How GE Is Disrupting Itself*, October 2009; GE Healthcare News. "First-time CT Users," June 2011.

⁷⁵ GE's Brivo compact ultrasound devices can sell for \$15,000 in China versus \$100,000 for a high-end model. Immelt, *How GE Is Disrupting Itself*, October 2009; GE Reports, "Tackling Access," October 20, 2009.

⁷⁶ Layne, "GE Moves," July 25, 2011.

⁷⁷ Hollmer, "GE Healthcare," October 23, 2012.

⁷⁸ Layne, "GE Moves," July 25, 2011.

⁷⁹ Medtronic, "Form 10-K," April 27, 2012; Liu, "Medtronic Opens," September 15, 2011; *Economist*, "Frugal Healing," January 20, 2011.

⁸⁰ Burkitt, "Boston Scientific," December 24, 2013.

⁸¹ DOC, *Healthcare Technologies*, 2012-13, 19; GTIS, Global Trade Atlas database (accessed July 11, 2013).

⁸² The value of total U.S. exports of medical devices in 2013 was \$41.0 billion, of which China represented \$2.7 billion, according to the Global Trade Atlas database. The estimate of U.S. medical device exports to China differs from the \$2.4 billion cited throughout this paper due to differences in categorization of the medical device industry. GTIS, Global Trade Atlas database (accessed March 6, 2014).

for which these devices are commonly used.⁸³ During 2008–12, U.S. exports to China of diagnostic imaging devices accounted for approximately two-thirds of total U.S. medical device exports to China.⁸⁴

Additionally, China's demand for IMDs is strong and currently accounts for 20 percent of the country's medical device market.⁸⁵ In particular, high-end interventional cardiovascular devices, such as coronary stents, are in high demand within China. Official estimates suggest the country performs the world's second-highest number of heart stent surgeries behind the United States, as these treatments are preferred to more invasive therapies such as open-heart surgery.⁸⁶ Although Chinese firms now claim 75 percent of the domestic coronary stent market, U.S. exports of these devices are believed to have increased considerably since 2008, attesting to the continued popularity of U.S.-produced stents in China.⁸⁷

⁸³ Within this category, ultrasound and magnetic resonance imaging (MRI) technologies have achieved significant growth. Gross, "Updates on China's Medical Device Market," November/December 2010.

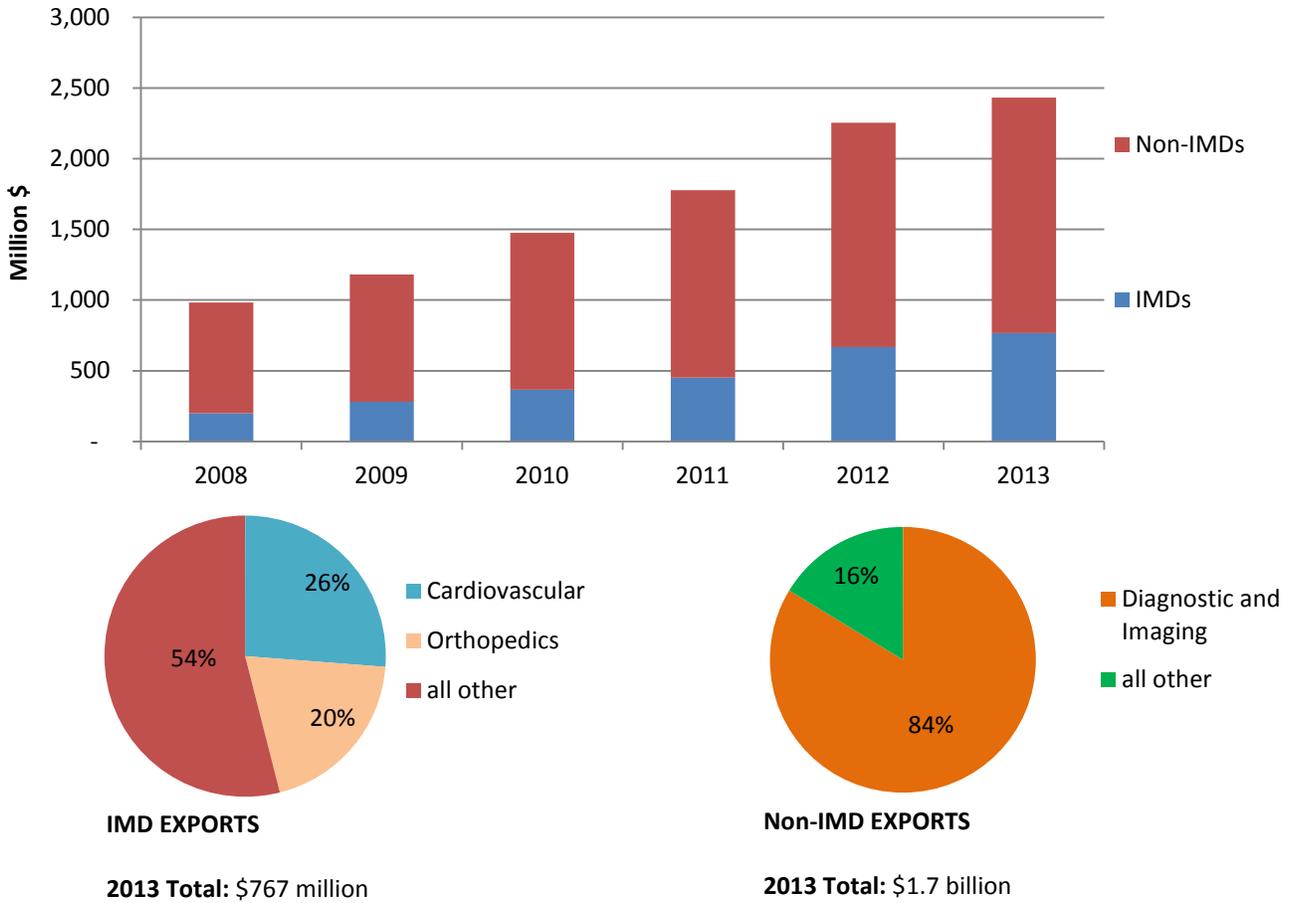
⁸⁴ Official Statistics of the U.S. Department of Commerce.

⁸⁵ Gross, "Updates on China's Medical Device Market," November/December 2010.

⁸⁶ MPO, "Cardiologist Say Stents are Overused in China," October 17, 2012.

⁸⁷ Stents are classified in the Harmonized Tariff Schedule of the United States (HTS) under 9021.39.00: "Artificial parts of the body (other than artificial joints) and parts and accessories thereof." Total U.S. exports to China under HTS 9021.39.00 were \$161 million in 2012, an increase of more than 500 percent since 2008.

Figure 6 U.S. medical device exports to China have increased each year since 2008; in 2013, the majority of non-IMD exports were diagnostic and imaging equipment, and the leading IMD exports were cardiovascular devices



Source: Official statistics of the U.S. Department of Commerce.

Obstacles to Greater Market Access

Despite the significant increases in U.S. exports of medical devices to China and the growing local presence of U.S. firms, a number of potential constraints to further expansion exist. These include onerous regulations for foreign-made devices, inconsistent reimbursement policies, complexities in the provincial tendering process, and extensive tariffs on the majority of imported medical devices.

Onerous Regulations: Time Lags and Duplicative Procedures

China's approval process for foreign-made devices is characterized by significant time lags and duplicative procedures. According to the *Wall Street Journal*, navigating this process can take twice as long in China as it does in the United States or the EU for most class I and II devices (figure 7).⁸⁸ Although the framework used by the China Food and Drug Administration (CFDA) to categorize these goods is similar to the one used by the U.S. Food and Drug Administration, the countries can differ widely in how they rate the relative risks associated with specific devices.⁸⁹ For instance, while most countries identify the majority of imaging and diagnostic equipment as class II goods, China classifies these as class III devices, for which local clinical trials are required.⁹⁰ In addition, nearly all imported IMDs—and all IMDs that are implanted for more than 30 days—must undergo clinical trials in China, regardless of whether such trials have already been conducted in other markets.⁹¹ Further, the country often requires duplicative inspections of manufacturing facilities; testing of class II and III devices that may have already been conducted in other markets according to internationally accredited standards;⁹² and redundant border inspections for IMDs such as pacemakers.⁹³

⁸⁸ Burkitt, "Boston Scientific," December 24, 2013; Emurgo, "The Medical Device," 2013.

⁸⁹ As previously discussed, China and the U.S. both classify devices into three categories based on relative risks. In addition, China requires that manufacturers comply with an internationally accredited quality management system called "ISO 13485," or receive a favorable inspection report from the FDA in the United States. Emurgo Group, "Country Regulatory Practices," 2010.

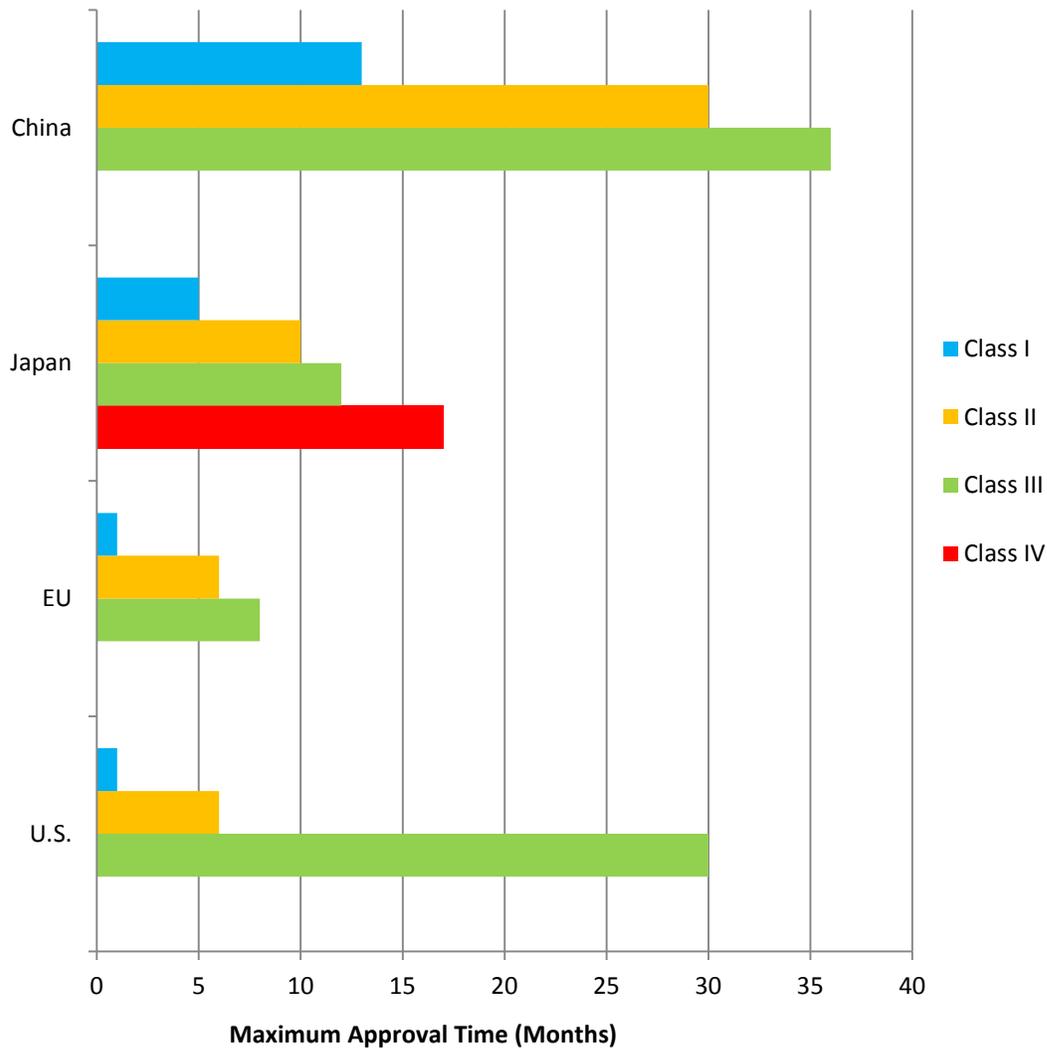
⁹⁰ In June 2012, the CFDA agreed to list four sub-categories of diagnostic equipment as lower risk goods that would be exempted from clinical trials. Among the devices identified were medical x-ray equipment and some medical ultrasound equipment. USTR, *2013 Report on Technical Barriers*, April 2013, 57; Emurgo, "The Medical Device," 2012.

⁹¹ USTR, *2013 Report on Technical Barriers to Trade*, April 2013, 57.

⁹² China applies a safety marking regulation to most class II and III devices called the China Compulsory Certification (CCC), which requires in-country testing. Emurgo, "The Medical Device," PowerPoint presentation, March 6, 2013.

⁹³ USTR, *2013 Report to Congress on China's WTO Compliance*, December 2013, 66.

Figure 7 In 2013, China had the longest approval time—on average—for each class of medical device among leading medical device markets



Sources: Compiled by USITC staff from Emergo, "The Medical Device Regulatory Approval Process, China; Japan; Europe; and USA," 2013.

Note: The EU divides class II devices into two subgroups, "a" and "b." On average, class IIa devices are approved between 1-3 months, while class IIb devices are approved between 2-6 months. Japan is the only leading medical device market that identifies a fourth class of devices, which refers to IMDs that pose a potentially fatal risk to patients. Class III devices in Japan are also IMDs, but are not believed to cause fatalities if the device were to malfunction. Class III devices in the United States can take between 18–30 months to gain approval, while the typical approval time for the same class of device in China ranges from 17–36 months.

Further, any foreign device proposed for sale in China must be approved for use by the country of origin before the manufacturer can initiate the application to sell it in China, regardless of whether the manufacturer intends to sell the device in the country of origin.⁹⁴ Additionally, applicants must provide documentation in Mandarin Chinese on the uses of the device, apply for an Import Medical Device Registration Certificate (IMDRC) from the CFDA, and appoint both a legal agent and an after-sales agent to coordinate the submission of the device and liaise between the manufacturer and the CFDA.⁹⁵ In addition to the significant time lags previously discussed, complying with these procedures imposes additional costs. For instance, the cost of approving class II devices is estimated at \$13,000, which includes the fees associated with CFDA testing and translating documents into Chinese.⁹⁶ Similarly, class III devices can cost nearly \$225,000 to gain approval, with about 90 percent of these expenses stemming from the costs to conduct in-country clinical trials.⁹⁷ Once approved, moreover, nearly every foreign-made device must reapply for a renewal registration no less than two years before the IMDRC certificate expires, a process which mimics the original registration process in time and cost (box 7).⁹⁸

Securing a Reliable Distributor

Once approved, foreign-made medical devices face additional barriers, including the need to rely on local distributors to deliver the devices to end users. There are more than 15,000 medical device distributors in China, each of whom may have different product specialties or provincial familiarities, which can prove challenging to exporters.⁹⁹ Large firms may deal with hundreds of different distributors, for example.¹⁰⁰ In some instances, OEMs who have an established presence in China—such as Zimmer—have been able to manage this challenge by hiring a network of local dealers, agents, and sales associates who can facilitate the sale of the OEMs' products in hospitals and clinics.¹⁰¹ However, new market entrants and SMEs in the United States attempting to export into China are unlikely to have these resources.¹⁰²

⁹⁴ This restriction may prove especially onerous to firms who specifically design devices for China's market or manufacture in another market for export. USTR, *2013 Report to Congress*, December 2013.

⁹⁵ Emergo, "The Medical Device," 2012; Emergo, "Overview of Medical Device Approval," January 2011.

⁹⁶ Emergo, "The Medical Device," March 6, 2013. As of June 1, 2014, the CFDA plans to expand clinical trial requirements to include all class II and III devices, while allowing for certain exceptions. For instance, devices that have well-reputed manufacturing processes, designs, and are similar—in terms of function and safety—to devices that have already been approved for sale in China may be exempted from this requirement. This new policy will likely introduce further challenges to manufacturers of these classes of devices; establishing in-country clinical trials can impose significant burdens and include the costs to recruit participants, secure facilities to conduct the tests, and design the study. Eisenhart, "Medical Device Regulatory Changes," April 28, 2014.

⁹⁷ Emergo, "The Medical Device," March 6, 2013.

⁹⁸ IMDRC certificates currently last for four years, however the CFDA has announced that as of June 1, 2014, these certificates will be valid for five years. Emergo, "The Medical Device," 2013;

⁹⁹ Burkitt, "Boston Scientific," December 24, 2013.

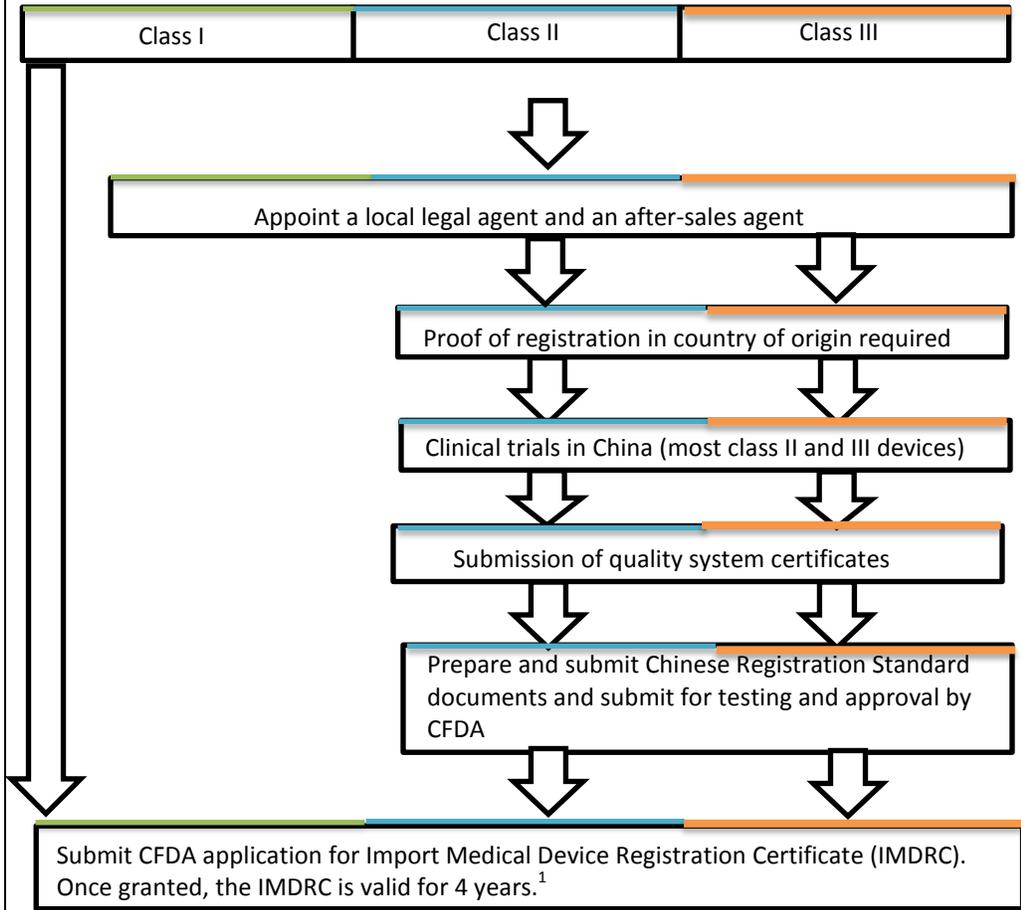
¹⁰⁰ Le Deu, *Healthcare in China*, July 2012, 84.

¹⁰¹ Zimmer, "10-K," December 31, 2012.

¹⁰² Industry representative interview with author, Washington, D.C., March 25, 2014.

Box 7 Overview of China’s regulations of medical devices

Although the CFDA’s classification of medical devices is similar to the one used by the U.S. FDA, the approval process in China can take much longer than in United States due to redundant testing on equipment that may have already been tested by an internationally accredited quality management system; duplicative in-country clinical trials on most class II and III devices; and a product re-registration process that mimics the original registration process.



Sources: Adapted from Emergo Group, “China’s Regulatory Process for Medical Devices,” 2013 ; USTR, 2013 Report on Technical Barriers to Trade, April 2013.

Note:

¹ As of June 1, 2014, these certificates will be valid for five years.

Lack of Time to Prepare for Changing Standards

An additional regulatory challenge is the lack of transition time afforded foreign manufacturers to adjust to changing regulatory standards in China, such as testing requirements, for example.¹⁰³ Unlike in the United States and the EU, where manufacturers receive a transition time to adjust to new regulations, once a national standard for a medical device has been approved in China, that standard must be adhered to immediately.¹⁰⁴ Thus devices that were compliant with one regulation may not be compliant under a new set of regulations and will not be approved for sale in China. This challenge can be compounded by the fact that China is relatively slow to adopt standards that have been approved in other markets, such as the United States and EU. For instance, IEC 60601, a series of testing standards intended to ensure the safety of medical devices, has undergone three revisions in the United States and the EU, while China is expected to maintain the second version of this standard until 2014 and will not accept the third version.¹⁰⁵ This can prove problematic for manufacturers seeking to sell a device in each of these markets, as a device that is compatible with the latest version of a standard may no longer comply with a previous version.

Provincial Tendering Process Proves Complex

China's provincial tendering process for medical devices, which determines the price at which a good may be sold, is characterized by complexity. Since 2007, the procurement of medical devices has been facilitated through a distinct centralized tendering process for each of the country's 34 provinces and provincial-level cities.¹⁰⁶ Due to the various administrative requirements—applicants are required to write detailed specifications of the device—imposed on the hundreds of firms competing to gain tenders, a firm can wait years before a price for a device is established for sale in a particular province.¹⁰⁷ This process may disadvantage manufacturers of high-technology products in particular, as manufacturers must enter lengthy negotiations to justify the relatively higher prices these goods command and are required to provide more detailed specifications of these products, due to the technological complexity of these goods.¹⁰⁸ Further, tenders are only valid for one to two years, after which time the application process must be repeated.¹⁰⁹ Moreover, firms who have already been approved are not necessarily assured of being approved again.

Another point of concern for firms is that the process for awarding tenders often results in prices lower than the manufacture's asking price.¹¹⁰ In an effort to lower medical device costs, the tendering process often imposes price ceilings, which may not adequately reflect the cost of

¹⁰³ USTR, *2013 USTR Report to Congress on China's WTO Compliance*, December 2013. This can prove uniquely burdensome to foreign manufacturers, the majority of whom design devices to be sold in multiple markets.

¹⁰⁴ Industry official, email message to author, June 28, 2013.

¹⁰⁵ Industry official, email message to author, June 28, 2013; Emergo, "The Medical Device," March 6, 2013.

¹⁰⁶ USTR, *2013 USTR Report*, December, 2013; Burkitt, "Boston Scientific," December 24, 2013.

¹⁰⁷ Zakreski, "Adapting to China's Changing Medical Device Market," January 1, 2010.

¹⁰⁸ Ibid.

¹⁰⁹ Medtech Switzerland, *People's Republic*, 2012.

¹¹⁰ Ibid.

R&D, shipping, and other variables that may influence the asking price of an imported device.¹¹¹ Although firms are often willing to accept lower prices in exchange for the potential of securing high-volume sales, these sales may never materialize, forcing a firm to accept potentially significant losses.¹¹²

Inconsistent Reimbursement

The level of reimbursement for medical devices can vary across provinces, cities, and hospitals; this inconsistency is one of the leading post-approval obstacles.¹¹³ For example, a given procedure may garner ¥30–¥200 (\$5–\$33) or may not receive reimbursements at all, depending on the province in which the treatment is administered.¹¹⁴ Further, reimbursements are heavily weighted towards local products; imported orthopedic implants receive 10–35 percent of the reimbursement rates that local producers are given, for example.¹¹⁵ In Beijing, domestically produced coronary stents can be reimbursed at 70 percent of the selling price, while imported stents may only be reimbursed at 50 percent.¹¹⁶ Additionally, recent revisions to pricing rates for various devices, which are imposed at the provincial level, have translated into price reductions of 20–30 percent in Guangdong and Henan provinces, which lowers the expected reimbursements rates. Other provinces have discussed similar reductions for highly demanded IMDs, such as drug-eluting stents.¹¹⁷ As previously discussed, reimbursement rates are a significant driver of medical device demand; lower reimbursement rates for imported devices create incentives to acquire a locally produced device.

High Tariffs Relative to Other Leading Markets

In contrast to the United States, the EU, and Japan, who offer duty-free treatment to medical devices, China imposes tariffs ranging from 4 to 9.5 percent on these goods.¹¹⁸ Further, China's most commonly imported medical devices from the United States, including ultrasounds, MRIs, and various orthopedic implantable devices, are assessed duties of between 4 and 5.7 percent.¹¹⁹ These tariffs can discourage imports in favor of local production and, as Chinese production of these goods continues to expand, U.S. medical device exports may be undermined, given the high cost of commonly exported medical devices to China. For example, the retail price of an MRI can exceed \$100,000. In contrast, the United States' other leading

¹¹¹ In 2012, the Chinese government proposed price controls for six classes of IMDs, a suggestion which could adversely impact U.S. and other foreign medical device manufacturers. USTR, *2013 USTR Report on China's WTO Compliance*, December, 2013, 53.

¹¹² Zakreski, "Adapting to China's Changing Medical Device Market," January 1, 2010.

¹¹³ Sussmuth-Dykerhoff, *China's Healthcare Reforms*, 2010.

¹¹⁴ Le Deu, *Healthcare in China*, July 2012, 7.

¹¹⁵ *Ibid.*, 93.

¹¹⁶ Further, in Shanghai, the stent procedures have been capped at such a rate that imported stents are effectively discouraged, generally being affordable only to patients wealthy enough to pay out of pocket. Deng, "Tales of Three," November 2012.

¹¹⁷ Le Deu, *Healthcare in China*, July 2012, 93.

¹¹⁸ WTO, Integrated Database (IDB) (accessed December 22, 2012).

¹¹⁹ *Ibid.*

U.S. export markets, such as the EU and Japan, do not apply duties to imported medical devices.

Conclusion

Despite numerous challenges, China's burgeoning medical device market is translating into significant opportunities for U.S. medical device manufacturers. U.S. exports have increased significantly in each of the past five years, amid increased public sector investments in China and the country's growing incidence of non-communicable diseases. At the same time, forecasted flattening of U.S. healthcare spending as the country transitions away from a fee-for-service model may encourage more firms to continue to expand into China's medical device market. However, despite the potentially significant opportunity for these firms, China's regulatory barriers, complex price tendering process, inconsistent reimbursement policies, and high tariffs may frustrate efforts to achieve greater market share within the country.

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