

# Global Medical Technology

## Export Opportunities and Challenges for Device Manufacturers

by Richard Paddock

Office of Microelectronics, Medical Equipment and Instrumentation, Trade Development

These days, few topics can ignite the imagination more than the dramatic developments taking place in medical science. While advances in information technologies seemingly dominated the previous decade, biotechnology and medical science now appear to have taken over the limelight. Announcements of progress in medical technologies that allow for earlier detection of diseases and more effective treatment options are now almost daily occurrences. Recent breakthroughs in cardiac research, for example, have led to coronary stents, implantable defibrillators, and minimally invasive bypass surgery, which have together helped reduce the death rate from heart disease by 40 percent over the past 25 years. New advanced diagnostics, like gene-based testing and computer-generated assessments, are saving thousands of lives by detecting a variety of illnesses at more treatable stages.

The advances of the past few decades, however, are only a relatively modest precursor to the amazing developments that will follow in the next 10 to 30 years. Some future predictions boggle the mind—if you believe Ray Kurzweil's *Age of the Spiritual Machine*,

for example, medical science may well be rebuilding human body parts at the cellular level within the lifetime of many baby boomers. In any case, there are many reasons to believe that our children will witness remarkable events brought about by advances in biotechnology, pharmaceuticals, and medical devices. Organizations like the Advanced Medical Technology Association believe medical technology is on the “cusp of a revolution.”

Among those at the forefront of leveraging these biological miracles are medical device companies that bring innovative, life-enhancing and life-saving products to market. The U.S. medical and dental equipment and supplies industry is the most dynamic and innovative in the world, and it is considered by many to be a crown jewel of the American economy. The industry is remarkably innovative—drawing from the technologies of other industries, it incorporates and commercializes advances from sectors including microelectronics, telecommunications, advanced materials, biotechnology, pharmaceuticals, and health care services. The industry is self-sustaining—new medical discoveries create and sustain demand for new innovations to serve those new advances. Also notable is how the sector benefits the overall economy—medical

technology spurs economic growth through broad societal benefits and improved productivity.

The American medical device industry unquestionably leads the world, due largely to its commitment to investing heavily in product research and development and its close affiliation with medical and microelectronics research. The United States continues to make significant contributions to improving patient care around the world. The United States is the largest producer of medical technology in the world, as well as the world's largest exporter of medical devices. U.S. companies exported more than \$17 billion worth of medical devices in 2002. Despite past fluctuations in the domestic and world economies and future challenges from looming competition, the U.S. medical device industry remains a vibrant and progressive industry, and the United States is strategically positioned to remain a dominant player in the global market.

### INDUSTRY OVERVIEW

The U.S. medical and dental equipment industry is characterized by the production of high-quality devices through the use of advanced technology brought about by heavy investment in R&D. There are 8,000 medical device firms

in the United States, mostly small and medium-sized. More than 80 percent of medical technology companies have fewer than 50 employees, and many, most notably innovative start-ups, have little or no sales revenue. These firms are spread across the country, but they are mainly concentrated in regions known for other high-technology industries, such as microelectronics and biotechnology.

As noted, American medical device companies are renowned for their innovations. Investment in research and development more than doubled during the 1990s and is now more than four times the average for U.S. manufacturers overall. Medical device manufacturers are also benefiting from a new generation of materials and manufacturing processes.

Over the past few years, annual industry production has exceeded \$70 billion and experienced nearly 6-percent annual growth. A source of high-paying American jobs, medical technology workers earn 49 percent more than private sector employees overall and 18 percent more than general manufacturing workers. In addition, the United States holds a competitive advantage in the complementary industries on which the medical device industry relies: microelectronics, telecommunications, biotechnology, and software

development. Medical device exports have generated a consistent trade surplus: more than \$50 billion over the last 15 years, and more than \$2 billion in 2002 alone.

Surgical and medical instruments and supplies comprise the largest subsector of the medical device industry in the United States. In 2002, the United States exported surgical and medical instruments and supplies valued at over \$9 billion, a 10-percent increase over 2001. While exports of this category have continued to grow overall, imports have also increased dramatically.

Surgical appliances also include a broad array of products for outpatient use. Growing reliance on outpatient rather than inpatient procedures, have helped fuel sales of items within this category, especially those intended to reduce labor expenses, curtail hospital stays, and permit patient care in less-expensive settings. The aging populations of developed economies, including those of the United States, Western Europe, and Japan, will also place a heavier demand on home health appliances and supplies.

The American dental equipment and supplies industry covers manufacturers of equipment, instruments, and supplies used by dentists, dental hygienists, laboratories, and institutions of higher

education. The United States has historically accounted for about half of the world's market for dental equipment and supplies. U.S. manufacturers of dental equipment and supplies have clearly proven themselves to be competitive in recent years—the United States exported more than \$728 million of dental equipment and supplies in 2002, an increase of about 8.7 percent over 2001. Besides advances in technology, in which the United States has historically been a leader, a general increase in disposable income worldwide has allowed increasing numbers of people to opt for more elective dental procedures, especially cosmetic and restorative. Elective procedures are an ever-increasing source of revenue for the industry. Germany, Canada, and Japan were the top markets for American exports of dental equipment and supplies in 2002. Regionally, the European Union is still the most promising export market for the foreseeable future.

Electromedical equipment manufacturers produce a variety of powered devices, including pacemakers and patient-monitoring systems, as well as diagnostic imaging equipment. The value of U.S. exports in this category reached \$4.4 billion in 2002, a decline from \$4.8 billion in 2001, and imports totaled \$4.5 billion. Demographics and technological advances will continue to increase demand for pacemakers and defibrillators well into the 21st century. While under significant price pressure from group purchasing and heavy competition, leading manufacturers such as Medtronic and Guidant report significant growth in cardiac rhythm management products. Demand for automatic external defibrillators (AEDs) is also growing rapidly, due to technological advances and studies indicating that faster access to AEDs increases survival rates among victims of sudden cardiac arrest. The top three countries receiving U.S. exports—Japan, Germany, and Canada—represent about half of the exported pacemaker and defibrillator market.



U.S. exports of X-ray devices in 2002 totaled \$1.92 billion, a modest rise of 4.2 percent over the 2001 value of \$1.84 billion, and imports totaled approximately \$2.1 billion. The integration of radiology with information systems is the most significant trend affecting diagnostic imaging, and it will profoundly influence product development and purchasing decisions over the next five years and beyond. The initial indication of this trend is the growing popularity of picture archiving and communications systems (PACS). The United States is a world leader in PACS, which replace traditional film with digital technology that may be stored with a patient's medical history. Doctors have remote access to this information, reducing reviewing time and allowing for an increased caseload per doctor. PACS also eliminate the need for film, developing chemicals, and processing labor.

#### FUTURE OF THE INDUSTRY

Despite its current vibrancy, the U.S. medical device industry faces numerous challenges and is in the midst of radical changes. Generally, the trends, both domestic and global, that will have the most influence on the medical device industry over the next five years are cost-containment efforts, reimbursement processes, regulatory burdens and uncertainties, the availability of venture capital, technological innovations including product convergence, and e-commerce.

#### Attracting Venture Capital

Venture capital is extremely important in medical technology, especially for small and medium-sized companies with limited earnings in the early stages of development, a typical situation for many innovative firms. Companies state that venture capitalists need a predictable system in order to assess risk, and when obstacles (in the form of uncertainty) prevent access to venture capital funds, there tends to be a decline in innovative activity. Medical device company officials, who view the attraction of venture capital as a critical

#### Medical Device Manufacturing Roundtable

In July 2003, Commerce Under Secretary for International Trade Grant Aldonas chaired a roundtable in Minneapolis, Minn., that offered officials from medical device manufacturing firms a chance to discuss issues pertinent to their industry. Many of the issues raised at the event are common to other industry sectors, including concerns about the general state of the economy, tax reform efforts, looming competition from abroad, theft of intellectual property rights, excessive patent litigation, and concerns over the direction of science and math education. The issues described below, however, are fairly unique to the medical device and pharmaceutical industries.

**Health care cost-containment efforts** have had a serious impact on device firms for several years, in many cases changing the way they do business. It is estimated that by 2007, expenditures on health care in the United States will explode to \$2 trillion, thanks in large part to the growing number of elderly who will be eligible for Medicare. Employers and workers cannot keep up the pace in premium increases expected for the private sector, and taxpayers will not be able to shoulder the growing burden of Medicare spending. Cost-containment pressures may also have a dampening effect on innovation. In order to justify paying the costs of medical devices, insurance companies are increasingly demanding that firms offer "proof" that the new technology provides clear, outcome-based benefits, before they will agree to accept any new device as a reimbursable product. Since small firms are usually the innovators in this industry, many cannot afford to bear the burden of time and expense these proofs require.

**Reimbursement rates** are values at which medical devices are reimbursed to hospitals or other purchasers under health insurance or Medicare assigned by the Center for Medicare Services (CMS) in the U.S. Department of Health and Human Services. The reimbursement amount assigned by the CMS often determines the viability of a product on the open market. Some device manufacturers perceive these rates—and the way they are calculated by the CMS—as subject to uncertainties. The result of these uncertainties, according to some industry officials, is to reduce expected returns on investment and therefore discourage investment in smaller companies working on cutting-edge products. At the recent roundtable on medical device issues in Minneapolis, one company official noted timely patient access to innovative diagnostic tests and other new technologies requires creation of streamlined, transparent, and predictable Medicare procedures. Delays in coverage, coding, and payment procedures by Medicare are all issues that the health care industry is looking to the CMS to solve.

**Government regulatory processes** are a significant issue for medical device manufacturers. Due to the life-enhancing and life-saving nature of advanced medical products, the medical device industry is regulated to a significant degree and must gain approval for devices from the U.S. Food and Drug Administration (FDA). Approval requirements for medical devices are sometimes perceived as burdensome. The Food and Drug Administration Modernization Act of 1997 is designed to greatly improve the regulatory environment, and the Medical Device User Fee and Modernization Act was passed to try to help speed the process of bringing products to market. There is a perception in the industry, however, that the system of user fees is faltering, due to a lack of funding from Congress. The industry's position is that the FDA, Congress, and industry must work together to prepare the agency for the coming revolution in medical technology.

issue, complain that investors in medical technology must face greater regulatory and policy risk than virtually any other segment of the economy.

### Product Convergence

As noted, the American medical device industry funnels a tremendous amount of money into research and development to fund innovation, which will have a significant impact on some medical equipment and supply markets. As medical and biotechnological products converge, one area that will see tremendous growth is drug delivery devices—many treatments and therapies derived from research will not necessarily be available in pill form. Medical devices will therefore act as delivery systems for new products resulting from genetic engineering and biotech research.

### Electronic Commerce

E-commerce is significantly affecting the medical device industry, and its influences are likely to grow over the next decade. Most noticeable to consumers is the proliferation of on-line sites featuring product and purchasing information. Institutional purchasers of medical equipment in the United States and abroad are integrating on-line procurement into supply chain management programs, saving time and money. Patients are also accessing treatment and product information on the Internet and are having more input in decisions affecting their health care. Medical device manufacturers realize savings by publishing device manuals on-line and through “electronic labeling,” which allows devices intended for use in health care facilities to use electronic labeling, as long as users have the option of obtaining labeling in paper form.

### Reimbursement Issues

Global reimbursement practices have also had negative impacts on the U.S. medical device industry. Many countries around the world are facing the same skyrocketing costs of health care as in the United States, and are trying to trim reimbursement rates by making

it more difficult to even have a product approved for reimbursement at all, or by establishing price caps. Germany, France, and Japan are all examples of markets where the reimbursement rate has been set lower than what American medical device firms deem appropriate, given the level of technology and quality of production.

## GLOBAL MARKET

The medical device industry has become increasingly global in scope. An ever-increasing number of multinational firms are aggressively pursuing the global market, focusing greater attention on international sales and revenue, joint ventures, and mergers and acquisitions. Many of the factors that are contributing to the growth in the domestic medical device industry are the same drivers of the global environment. As economies around the globe focus more attention on the health and well-being of their citizens, demand for hospitals and clinics, public health insurance, and general demand for a higher standard of health care will create opportunities for firms in all segments of the medical equipment industry. In order to facilitate expansion, the medical equipment industry is now, and will remain, a globalized industry.

While the United States, the European Union, Japan, and Canada are extremely large and lucrative markets for medical devices, they are mature markets with stable but low annual growth rates. Central Europe will prove to be a promising future market as integration into the European Union will improve the regulatory environment.

### Increasing Competition and a Strong Dollar

Even though total U.S. industry shipment numbers remain solid, the rate of growth has slowed somewhat in recent years. Including diagnostic products, the United States exported more than \$20 billion in medical equipment in 2002, a modest increase over the \$19.4 billion in 2001, but a diminished rate

of increase compared with the 11.2-percent rise from 2000–2001. While the dollar’s value has been dropping recently, in 2001–2002 the strong dollar made U.S. equipment more expensive overseas, dampening the level of exports. Conversely, the strong dollar has made purchasing foreign equipment cheaper, and imports have experienced double-digit growth for the past several years.

### International Regulatory Environments

The medical device industry is a highly regulated industry, and regulatory environments at home and abroad have serious implications on industry performance. An increasingly common practice among developing economies is the establishment of national regulatory requirements in addition to the usual submissions required by developed countries. Device firms are devoting tremendous amounts of time and money to determine requirements, conduct additional overseas clinical trials, and pay for the user fees.

Harmonization of medical device requirements is one way to reduce the industry’s burden and ensure maximum accessibility of safe, effective medical devices by patients. The Global Harmonization Task Force is a voluntary organization of regulators and the regulated industry from the United States, the European Union, Canada, Japan, and Australia that works on identifying feasible areas for harmonization of medical device regulation. American industry would like to see products “approved once, accepted everywhere.” Many developing countries have been invited to participate in these meetings as observers, and regional working parties for Asia and Latin America have been established.

In the developed world, the regulatory environment is much less restrictive now than it has been in the past. In 1999, the United States and the European Union entered into a mutual recognition agreement which, once

implemented, will allow U.S. device firms to use American-based, third-party organizations called conformity assessment bodies to review products based upon criteria of the EU medical device directive for sale in the EU market, and EU firms to use EU-based, third-party organizations, to recommend approval to the FDA for some products based on FDA requirements for sale in the American market.

## BEST OVERSEAS MARKETS

### European Union

The European Union has historically been the largest regional export market for U.S. medical devices and is expected to continue to be fertile ground for exports of American high-tech products due to high per capita incomes in most EU countries, a generally favorable regulatory environment, and aging populations. Steady economic growth and political and currency stability make the European Union an attractive market, which accounts for 26 percent of the global medical device market. The largest individual European markets for American exporters, in descending order, are Germany, the United Kingdom, France, Ireland, Italy, Sweden, and Spain.

The European Union maintains a uniquely open and transparent regulatory system for medical devices, based on international standards. Medical devices sold within the European Union must meet the health and safety requirements of EU medical device directive No. 93/42/EEC. This directive consolidates regulatory requirements within EU member countries under one system, meaning if a device can be sold in one country, it is approved for sale in all EU countries. In this system, product approvals are based on evaluations of safety and effectiveness of a device. If a product satisfies the requirements of the directive, the manufacturer may affix the CE mark to the product so that it may legally enter the commerce of any EU member country. Some products may fall under the jurisdiction of more than one EU directive, and must therefore meet the requirements of all the applicable directives to receive the CE mark.

Shipments of U.S. medical equipment and supplies to the 15 nations of the European Union totaled \$5 billion in 2002, representing 44 percent of medical device exports from the United States. This represents a

4-percent increase from the previous year. Surgical and medical instruments, surgical and medical supplies, and dental equipment and supplies are the best-sellers in the EU market. All three of these categories have experienced steady increases in sales, and they continue to look promising in the future.

The success of the U.S.-EU medical device mutual recognition agreement (MRA) will be an important step toward global harmonization of medical device regulatory requirements currently being addressed by the Global Harmonization Task Force. Since the FDA and the EU regulatory systems are the two primary global regulatory systems, harmonization of these two systems will have a positive influence on global harmonization. The United States does not support or seek multiple MRAs with other countries since this goes against the concept of global harmonization and because the United States is using its limited resources to ensure the success of the MRA with the European Union.

### Asia

Although buffeted by the financial crisis in the late 1990s, and the recent

## Top 10 Markets for U.S. Exports of Medical Devices

Country	1998	1999	2000	2001	2002	Percent Change 2001–2002
Japan	2,002,246	2,134,340	2,356,082	2,537,144	2,395,576	-5.6%
Germany	1,192,376	1,377,041	1,445,568	1,655,764	1,679,968	1.5%
Canada	1,282,051	1,414,021	1,411,291	1,512,893	1,487,074	-1.7%
The Netherlands	1,032,649	995,826	1,109,472	1,112,628	1,353,840	21.7%
United Kingdom	760,163	782,543	893,391	1,051,560	952,030	-9.5%
France	893,649	957,075	856,947	1,012,213	948,892	-6.3%
Mexico	555,981	605,950	773,369	814,688	946,289	16.2%
Ireland	212,700	227,904	346,898	723,510	879,437	21.6%
Australia	454,456	441,724	457,751	461,614	523,153	13.3%
Italy	357,183	429,588	471,780	491,683	518,304	5.4%
Belgium	421,704	498,586	518,632	642,326	514,741	-19.9%

Sources: U.S. Department of Commerce, U.S. Department of the Treasury, and the U.S. International Trade Commission. Data includes NAICS 334510, 334517, and 33911 except 339115.

SARS epidemic, U.S. exports of medical devices to Asia are on track to make significant gains in the near future. Relatively strong figures suggest that the governments and citizens of Asian nations greatly value health care and are willing to make sacrifices in other areas to preserve it. American manufactured medical devices, although more expensive than comparable equipment manufactured in Japan or the European Union, enjoy a reputation for quality and innovation throughout Asia. The recent SARS epidemic, while making

surgery equipment, and MRI systems. In addition, the Advanced Medical Technology Association, working in conjunction with the Office of the U.S. Trade Representative and the U.S. Department of Commerce, has aggressively advanced the economic benefits of innovative products and lobbied against price-control policies. As a result of bilateral negotiations on medical equipment and pharmaceuticals, local governments in Japan are authorized to base medical device purchases on the best overall value

for medical equipment and supplies was estimated at \$2.1 billion in 2002. With more than 1.2 billion people and steady economic growth for two decades, China is increasingly a target market for American exporters of high-technology medical equipment.

#### Latin America

Despite problems associated with some markets in Latin America in recent years—most notably economic downturns in Mexico, Argentina, and Brazil—Latin America continues to



a temporary dent in regional growth rates, has also reinforced the need for improved health care infrastructure in many countries.

The Japanese market for U.S. medical and surgical instruments amounted to \$917 million in 2002. The main forces driving Japan's demand for medical devices are its rapidly aging population and the escalating rise of health care costs. Thus far, American-manufactured devices have resisted government cost-cutting measures by appealing to the Japanese preference for high quality and innovation, particularly in such areas as CT systems, pacemakers, laser

for performance and specification requirements, not simply on the initial cost of the devices.

China, including Hong Kong, is the second-largest market for U.S. medical device exports in Asia. U.S. exports to China will increase 5 to 10 percent annually for the foreseeable future. American medical device exports to China totaled \$350 million in 2002, an increase of 3.2 percent over 2001. When Hong Kong is included, however, total U.S. exports reach \$624 million. Many in the industry believe these figures actually understate the actual size of China's market. China's overall market

be a promising market for U.S. medical device manufacturers. As one of the most highly dependent regions on imported medical products, Latin America currently provides significant opportunities to U.S. exporters. In 2002, sales to Latin American markets exceeded \$1.9 billion, roughly equivalent to sales for 2001.

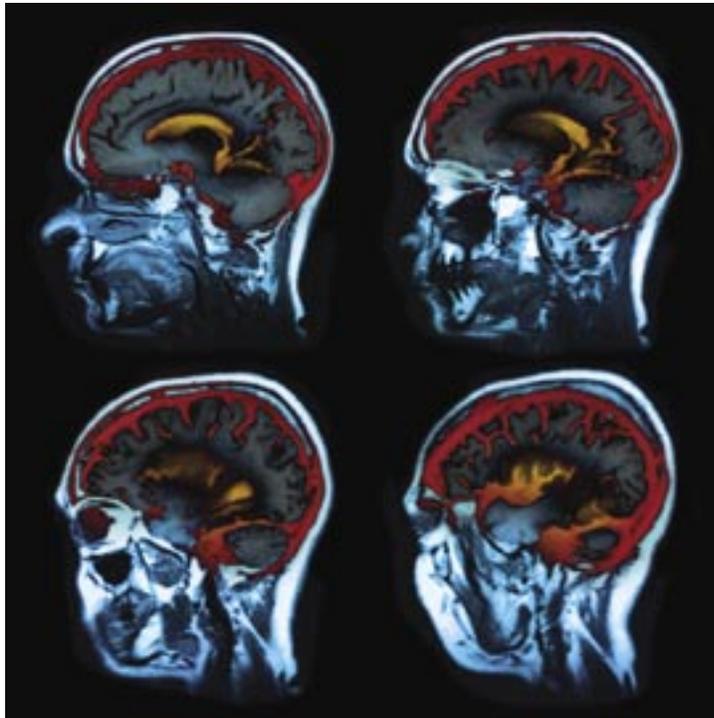
Several positive trends have emerged in the Latin American health care sector. For example, many countries in the region embarked on health care reform programs as early as the mid-1990s, and results are slowly emerging. In many developing countries, health

authorities are reforming insurance regulation to ensure availability of comprehensive insurance coverage, both private and public, for citizens even of limited economic means. Mexico's National Development Program, created in 1995, has seen results through an increase in health care spending, an expansion of coverage under the government's social security program, and a decentralization of management. Chile's 1994–2000 Health Sector Reform Project has doubled the health budget since 1990 and increased construction of therapeutic diagnostic centers and hospitals to enhance primary care and improve emergency and ambulatory care services. In many developing countries, health authorities are reforming insurance regulation to ensure availability of comprehensive insurance coverage, both private and public, for citizens of even limited economic means.

Mexico remains the top market for U.S. medical equipment exports in Latin America, accounting for more than half of exports to the region. More than 50 percent of the medical device import market in Mexico belongs to U.S. firms. While other countries showed diminishing numbers, total U.S. exports of medical devices and supplies to Mexico grew by about 18 percent from 2001 to 2002. Under the North American Free Trade Agreement, tariffs have been eliminated on almost all medical devices, providing an added incentive for interest in the market. Final elimination of tariffs on remaining medical devices will occur by the end of 2003.

Despite currency devaluation in recent years, which caused sales values to decline, Brazil remains a major

market and the second leading importer of American-manufactured medical devices in Latin America. In 2002, Brazil imported American medical and ophthalmic equipment valued at \$328 million. Brazil's economic slowdown affected government investment plans for public hospitals, and the challenge for Brazil will be finding means to improve public health care facilities with less government funding. Brazil has taken significant steps to improve its regulatory environment including the creation of Agencia Nacional de



Vigilancia Sanitaria, but more needs to be done.

U.S. medical equipment is not only seen as desirable in the larger economies, but also in smaller economies such as the Dominican Republic, Costa Rica, Honduras, and Panama. High quality, reliability, durability, favorable prices, good maintenance service, and timely delivery are the main factors for increasing sales in the medical sector. In Central America, the aftermath of Hurricane Mitch brought funds for rebuilding the infrastructure of these nations, and a major emphasis is being placed on the health

of citizens. New hospitals and health clinics are being built, which provide numerous opportunities for American firms to supply the region with medical devices.

The U.S. medical device industry has a clear understanding of the future challenges it faces in the global marketplace and is taking steps to address them. Despite these challenges, the American medical device industry will likely remain dominant in the years ahead. The International

Trade Administration of the U.S. Department of Commerce stands ready to help the industry in global markets through a variety of trade-facilitating programs. The International Trade Administration has a number of market research products to help companies interested in selected markets. The Office of Microelectronics, Medical Equipment and Instrumentation (OMMI) maintains a Web site that offers profiles of regulatory environments in several countries, and the office will be releasing a study on Brazil's medical device marketplace in the fall of 2003. The Department of Commerce also has a

number of trade missions and other trade promotion events scheduled for the coming year, as well as an active project advocacy program. U.S. companies seeking assistance can contact OMMI at (202) 482-3360, or visit [www.trade.gov/td/mdequip](http://www.trade.gov/td/mdequip). ■

Thank you to Gerry Zapiain and Jay Biggs, in the Office of Microelectronics, Medical Equipment and Instrumentation, for their contributions to this article.