

Medical Equipment Industry Definition

The medical equipment and supplies sector (also referred to as “medical devices”-- parts of NAICS 3345 and 3391) includes surgical and medical instruments; orthopedic, prosthetic and surgical appliances and supplies; dental equipment and supplies; x-ray apparatus, tubes and related irradiation apparatus; electro-medical and electro-therapy apparatus; and ophthalmic equipment. Subsectors in this category include: electro medical and electrotherapeutic apparatus manufacturing (NAICS 334510), irradiation apparatus manufacturing (NAICS 334517), surgical and medical instrument manufacturing (NAICS 339112), surgical appliances and supplies manufacturing (NAICS 339113), dental equipment and supplies manufacturing (NAICS 339114), and ophthalmic goods manufacturing (NAICS 339115).

Demographic Change

The main demographic change influencing this industry is the rapidly growing number of elderly in the United States. The Census Bureau periodically publishes projections showing U.S. population estimates by age bracket; the latest published data (based on the 2000 Census and published in early 2004) show that the percentage of people 65 and older will increase from 12.4 percent in 2000 to an estimated 20.7 percent by 2050. According to Census estimates, there were about 35 million Americans over the age of 65 in 2000; due to the influx of “baby boomers” and an anticipated increase in overall life expectancy, by 2020 there will be more than 54 million people 65 and older, and more than 86 million by 2050.¹

The aging population is already influencing the future direction of the medical device industry due to their changing health needs and an accompanying shift in thinking on how and where seniors will be treated. Baby boomers are living longer lives than previous generations, requiring more sophisticated and longer-term healthcare. This has driven the need for advanced medical electronic devices² and raised expectations that new technologies will enhance the quality and length of patients’ lives as they get older. As the U.S. population ages, and pressures to contain costs increase, expensive hospital stays will be discouraged, and health care will be increasingly delivered in alternative settings, such as nursing homes, hospices, and, especially, the patient’s own home.

As a result, home health-care products are expected to become one of the fastest growing segments of the medical device industry. In recent years, these products have become increasingly more sophisticated and are now used in a wider variety of situations. For instance, unskilled health care workers who previously were limited to using only low technology products now have high-tech devices at their disposal for responding to critical care needs. In addition, patients will have access to an increasing array of sophisticated equipment to address their own medical care. Demographics and

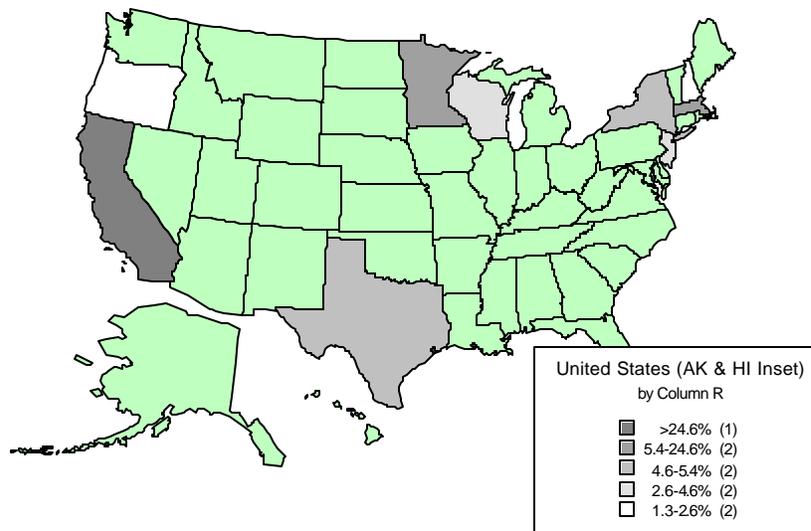
¹ U.S. Census Bureau, “U.S. Interim Projections by Age, Sex, Race and Hispanic Origin,” Summary Table 2a, “Projected Population of the United States, by Age and Sex,” 2000 to 2050.”

² “Baby Boomers Driving Growth of Medical Electronics,” Electronic News/Reed Business Information, June 4, 2004.

technological advances will continue to increase demand for pacemakers and defibrillators well into the 21st century.

Economic and Geographic Concentrations

Medical device manufacturers are located throughout the country, but are mainly concentrated in certain states known for other high-technology industries including microelectronics and biotechnology. The states with the highest concentration of medical device companies include California, New York, Florida, Massachusetts, Illinois, New York, Minnesota and Georgia.



2004 Employment for NAICS 3345 - Navigational, Measuring, Electro Medical, and Control Instruments Manufacturing - by State

(Note: NAICS 334510, electro medical and electrotherapeutic apparatus manufacturing, and NAICS 334517, irradiation apparatus manufacturing, are the only segments within NAICS 3345 that are classified as part of the medical device sector. NAICS 334510 and 334517 account for about 15 percent of total activity within NAICS 3345.

In addition, note that data disclosure limitations may not allow all states with substantial employment in this industry to be presented on this map.

According to a state economic development communications manager, Florida has the second-highest number of FDA-registered medical device companies, ranking only behind California.³

Merger and Consolidation Trends

The mid- to late-nineties saw a tremendous number of mergers and acquisitions within the medical device industry, and this trend is expected to continue in the 21st century. The long-term effects are not yet fully known, but the consolidation of the medical device industry is already changing the structure of firms and the delivery of medical technology to patients.

| Mergers and Acquisitions Transaction Volume, 1997-2003 | | |
|--|---------------------------|-----------------|
| Year | Total Value (\$ Billions) | Number of Deals |
| 1997 | 24.0 | 62 |
| 1998 | 32.6 | 82 |
| 1999 | 6.7 | 71 |
| 2000 | 13.3 | 77 |
| 2001 | 8.8 | 61 |
| 2002 | 5.3 | 56 |
| 2003 | 9.2 | 71 |

Source: Windhover’s Strategic Transaction Database (as published in AdvaMed’s “The Medical Technology Industry at a Glance: 2004)

There are a number of dynamics driving this trend. Small firms that find it too expensive to devote significant resources to providing “proof data” for their new innovations are merging with larger firms that have the financial resources necessary to bring new products to market. Larger firms receive the benefit of the new technology and, therefore, maintain market share, while small firms can afford to continue to produce and get the benefit of the large firm devoting resources to continued incremental improvements crucial to the industry. The rate of consolidation has been further augmented by two other trends in recent years:

- 1) Larger firms generally have a greater capability for exporting products globally than do small stand-alone firms.
- 2) Larger firms are better positioned to negotiate favorable deals with group purchasing organizations (GPOs), such as HMOs and health care companies with a nationwide reach.

³ Bell, Stacey. “United in Growth,” *Medical Product Outsourcing Magazine*, July/August 2005, p. 44.

Economic Overview

U.S. Domestic Industry Overview

Since 2002, annual industry production in this sector has exceeded \$70 billion and experienced approximately 6 percent annual growth. In 2004, the production value of the six NAICS codes that comprise the medical device industry totaled \$82.4 billion.⁴ The U.S. holds a competitive advantage in the complementary industries on which the medical device industry relies, namely microelectronics, telecommunications, instrumentation, biotechnology, software development, etc.

The medical device industry is highly regulated, and the regulatory environment at home and abroad has serious implications on industry performance. Domestically, medical device firms devote considerable resources toward product approval processes, clinical trials, user fees and plant audits. The U.S. FDA is conscious of the need to streamline regulatory processes and procedures, and is proactively trying to address the concerns of U.S. firms.

Issues related to reimbursement rates for medical devices are a primary concern for U.S. medical device companies, as an adequate reimbursement rate usually determines whether a product will be viable in a given market. In the U.S. there are several players involved in establishing reimbursement rates. The Department of Health and Human Services' Center for Medical and Medicaid Services (HHS/CMS) is the central agent of control and change in the area of cost containment and reimbursement for Medicare and Medicaid. Other players in the U.S. market include HMO's, private health insurance companies and the Veterans' Administration.

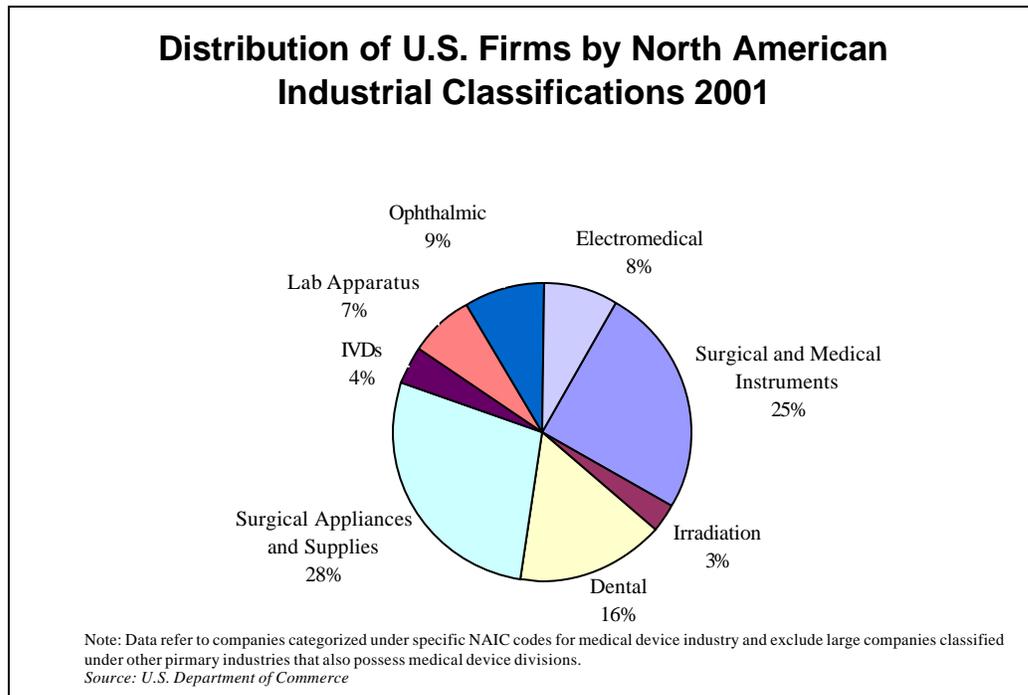
The U.S. market represents such a large percentage of the global market that a low reimbursement rate in the U.S. market may make a product uneconomical to produce globally. Reimbursement rates are considered so important that firms are advised to start working with CMS as early as possible in the product approval process. Notably, many medical device firms in the U.S. apply for and receive the CE mark (the regulatory approval process used in the European Union) before seeking FDA approval, or work on certifying their products in both systems concurrently.

While advanced medical technologies often have a higher purchase price, other factors may make the long term cost less than a similar medical device using more basic technology and a lower purchase price. These other factors include: treating more patients per day, recovery times, early diagnosis of medical problems, and higher quality of life.

Venture capital is extremely important in medical technologies, especially for small- and medium-sized companies with limited earnings in the early stages of development, a

⁴ U.S. Census Bureau, Annual Survey of Manufactures, 2004.

typical situation for many innovative firms. Medical device companies, who view the attraction of venture capital as a critical issue, complain that investors in medical technology must face greater regulatory and policy risk than virtually any other segment of the economy. Companies report that when regulatory obstacles impede venture capital funding of innovative companies there is a fall-off in innovative activity.

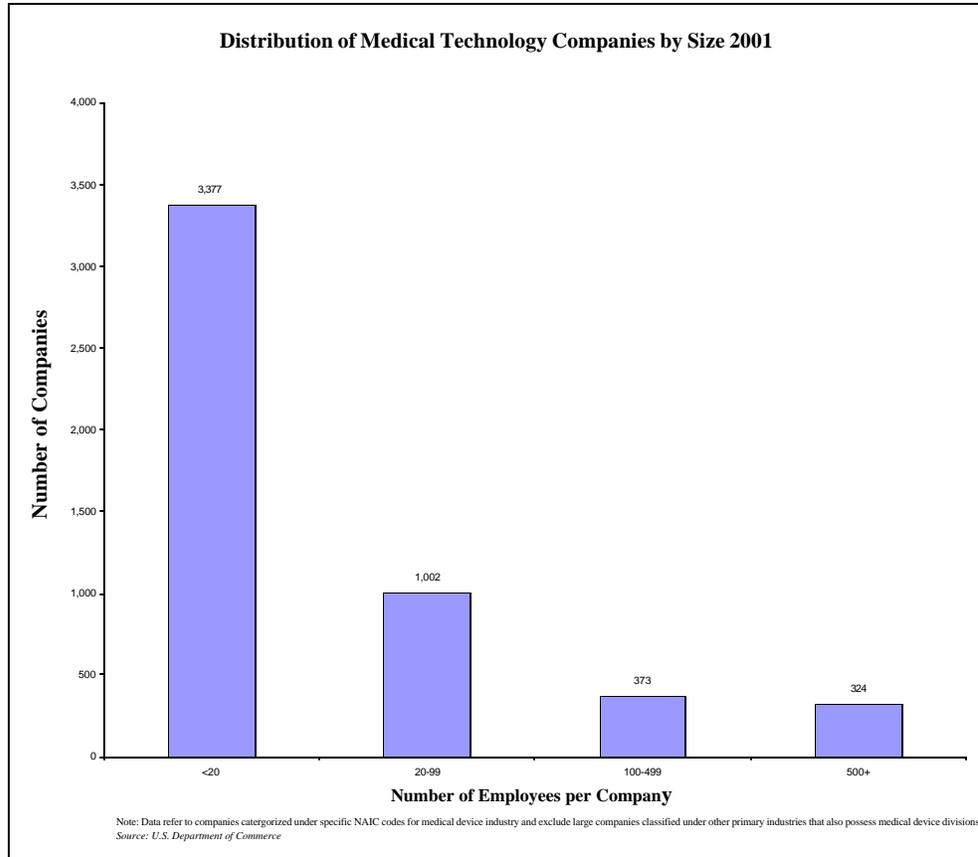


The top 10 U.S. companies in the medical device sector are: Johnson & Johnson, GE Medical Systems, Baxter International, Tyco Healthcare, Medtronic Inc., Abbott Laboratories, Becton Dickinson, 3M Healthcare, Guidant, and Stryker Corp.⁵

Nature of the Industry

The U.S. medical and dental equipment industry is known for producing high quality devices using advanced technology resulting from heavy investment in R&D. There are approximately 8,000 medical device firms in the United States. There are a limited number of large firms, but most are small start-up companies. There are relatively few mid-sized medical device companies for reasons described in the section above on Merger and Consolidation Trends. 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.

⁵ "Medtech Snapshot-Corporate Finance," *Medical Device and Diagnostic Industry*, December 2004, p. 53.



Value of Shipments by Sector, Electro Medical and Medical Equipment, 2004

| NAICS Code | Industry Name | Value of Shipments (\$ BN) | % Of Overall Total |
|------------|---|----------------------------|--------------------|
| 334510 | Electro Medical/ Electro-therapeutic Apparatus Mfg. | 18.2 | 22.1 |
| 334517 | Irradiation Apparatus Mfg. | 5.2 | 6.3 |
| 339112 | Surgical and Medical Instrument Mfg. | 23.7 | 28.8 |
| 339113 | Surgical Appliances and Supplies Mfg. | 26.8 | 32.5 |
| 339114 | Dental Equipment and Supplies Mfg. | 3.7 | 4.5 |
| 339115 | Ophthalmic Goods Mfg. | 4.8 | 5.9 |

Source: U.S. Bureau of Census, 2004 Annual Survey of Manufacturers

Employment

Employment in the medical device industries that comprise this sector totaled about 307,000 employees in 2005, including approximately 180,000 production workers.⁶

Industry Shows and Trade Events

January 22-25, 2006: Arab Health 2006, Dubai, United Arab Emirates

February 8-9, 2006: "...Connecting the Dots on FDA's Post-Market Safety Activities..."
www.advamed.com, Bethesda, MD

March 1-4, 2006: AdvaMed's 2006 Annual Meeting, www.advamed.com, Naples, FL

March 11-14, 2006: American College of Cardiologists Annual Meeting (ACC '06),
www.acc.org, Atlanta, GA

March 16-19, 2006: 22nd Korea International Medical & Hospital Equipment Show (KIMES), www.kimes.co.kr, Seoul, South Korea

April 5-9, 2006: American Society for Laser Medicine and Surgery 26th Annual Meeting,
www.aslms.org, Boston, MA

April 12-14, 2006: 11th Southeast Asian Healthcare Show, Kuala Lumpur, Malaysia

April 25-29, 2006: 55th China Medical Equipment Fair, Guangzhou, China

April 27, 2006: MDMA 2006 Annual Conference, www.mdma.org, Minnetonka, MN

May 6-10, 2006: American College of Obstetricians and Gynecologists 54th Annual Clinical Meeting, www.acog.org, Washington, DC

May 18, 2006: British Dental Conference and Exhibition 2006, www.bda-dentistry.org, Birmingham, England

May 24-26, 2006: NAIDEX, Birmingham, United Kingdom

June 5, 2006: Hospitalar 2006, Sao Paulo, Brazil

September 7-9, 2006: Expomedica, Buenos Aires, Argentina

⁶ Bureau of Labor Statistics, *Employment and Earnings*, December 2005.

September 18-21, 2006: MEDTRADE Conference and Exposition 2006, www.medtrade.com, Atlanta, GA

October 11, 2006: Community Dental Services Group Annual, Presidential and Scientific Meeting 2006, British Dental Association, www.bda-dentistry.org.uk, Meriden, England

October 16-19, 2006: 147th American Dental Association Annual Session, www.ada.org, Las Vegas, NV

October 18-21, 2006: REHACARE International 2006, Dusseldorf, Germany

November 11-13, 2006: National Electrical Manufacturers Association's 80th Annual Meeting and Conference, www.nema.org, Washington, DC

November 15-18, 2006: MEDICA 2006, Dusseldorf, Germany

November 26-December 1, 2006: Radiological Society of North America 92nd Scientific Assembly and Annual Meeting, www.rsna2006.rsna.org, Chicago, IL

State and Local Issues

According to the July/August 2005 issue of *Medical Product Outsourcing*, medical device manufacturers consider two main factors when deciding where to locate a new facility:

- 1) Proximity to a knowledgeable, highly trained and productive workforce; and
- 2) Being part of a cluster of other medical device or high-tech companies to share in the infrastructure built to support such industries (e.g. consultants, distribution channels, and networking opportunities).⁷

An example of medical device firms using the availability of trained workers to locate their facilities occurred in the late 1980s, where many laid-off aerospace engineers in California moved to (or started their own) medical device companies. This factor helped California create the conditions for advancing the industry forward by encouraging related companies to collaborate on developing innovative new products.

As a result, several states have placed greater emphasis on attracting life sciences companies to locate manufacturing and administrative facilities, in part to develop the critical mass necessary to enhance the viability of the entire cluster of firms. This has occurred in two primary ways:

⁷ Bell, *Ibid.*, p.44.

- 1) Locating facilities near education and research institutes (for instance, the University of South Florida recently introduced a graduate certificate program for medical device regulatory affairs, the first of its kind in the country)⁸
- 2) Finding areas where large concentrations of companies with similar interests and needs currently exist, establishing facilities there, and possibly joining regional associations of companies with similar interests (states having such organizations include Florida, California, Minnesota and Massachusetts).⁹

Technology

Announcements of progress in medical technologies that allow for earlier detection of diseases and more effective treatment options are now almost daily occurrences. As an example of this trend, the integration of radiology with information systems is the most significant trend affecting diagnostic imaging, and 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 U.S. 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, which constitutes a considerable savings.

The development of PACS represents just one way in which technology has the potential to transform the health care system. The federal government would like to implement incentives to encourage doctors, health care providers and patients to become actively involved in using technology to create a more seamless health care system. These initiatives fall under several broad headings:

- 1) Adoption of electronic health records by physicians should result in workplace efficiencies as well as better levels of care for patients; however, training office staff to accept changes in workflow patterns, diffusing the costs among partners and clients, and certifying the quality of available technological aids represent just some of the challenges.
- 2) Ensuring that clinicians can share information seamlessly with each other (even if the offices do not share the same technology architecture) through regional groups ("Regional Health Information Organizations (RHIOs)") and a national collaborative organization of RHIOs called the National Health Information Network (NHIN) will make availability of patient records easier and more useful.
- 3) From the patient's perspective, wide use of Personal Health Records (PHR), based on national standards, that are truly portable and accessible could result in more educated patients able to make well-informed decisions regarding necessary treatments, as well as choosing qualified physicians and hospitals. Ensuring the accurate matching of a patient's identity will be one of many elements that will have to be addressed for this portion of the initiative to succeed.

⁸ Bell, *Ibid.*, p.46.

⁹ Bell, *Ibid.*, pp.45-46.

- 4) The overall net result might be a healthier nation able to integrate new technologies and medical advances more easily into the national system, with high confidence that the system is safe, secure and efficient.

To facilitate the efforts described above, Congress has appropriated \$61.7 million to the Office of the National Coordinator for Health Information Technology (part of the Department of Health and Human Services) for fiscal year 2006 that addresses the use of information throughout the health care system in an effort to help all parties make better decisions. This field, called health informatics, is still in its infancy, and would be strengthened by targeted investments aimed at multiple health care-related parties desiring to share information more easily. The ultimate goal of this initiative is to improve patient care and health outcomes through the efficient and effective use of data.

The U.S. 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. U.S. medical device companies are renowned for their innovations and high technology products. 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. According to a recently published study, total U.S. spending on medical research has doubled in the past decade to nearly \$95 billion a year.¹⁰

Medical device manufacturers are also benefiting from a new generation of materials and manufacturing processes. As medical device 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. Most industry experts view the impending convergence of medical devices with biotechnology with great enthusiasm, but also warn that if the regulatory and reimbursement issues are not addressed, problems will ensue as convergence takes place.

Technological advances in areas separate and apart from the medical device sector are also having an impact on future industry trends. One of these is harnessing the power of the Internet. For example, the introduction of e-commerce is having a significant effect on 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 U.S. and overseas are integrating on-line procurement into supply chain management programs, saving time and money. Patients are also gathering treatment and product information on the Internet and are having more input in decisions affecting their health care. Medical device manufacturers are realizing savings by an FDA regulatory change allowing device manuals to be available online and through “electronic labeling.” This change allows devices intended for use in health care facilities to use electronic, rather than traditional

¹⁰ Associated Press via CNN, “Study: \$95 Billion Spent on Medical Research”, September 20, 2005.

paper, labeling, as long as users have the option, upon request, of obtaining labeling in paper form.

E-commerce is changing medical device trade in other regulatory areas as well. In 1997, the FDA implemented the Electronic Records and Signatures Regulation. This rule (21 CFR 11) establishes the criteria under which the FDA will deem electronic records and electronic signatures equivalent to paper records and traditional handwritten signatures. While electronic filing should lighten the burden on manufacturers, there are significant differences between electronic records and signatures, and traditional paper systems that necessitate additional controls. Issues relating to confidentiality, permanency and the integrity of electronic signatures have challenged both the FDA and industry. However, as systems are established and evaluated, electronic submissions will likely become standard.

World Market and Trends

The U.S. is the largest single country consumer of medical and dental equipment and supplies, with a market valued at nearly \$80 billion in 2005 (including diagnostic products) and U.S. medical technology companies lead the world in medical device production. Until relatively recently, medical device exports have generated a consistent trade surplus: more than \$50 billion total from 1994 - 2000, and more than \$3 billion in 2001 alone. In 2002, however, exports and imports began to approach parity, and in 2003 the U.S. experienced a modest deficit (\$1.4 billion). In 2004, the U.S. reversed this trend and realized a small trade surplus (assuming ophthalmic products are excluded from the total).

Even though total U.S. industry shipments have remained solid, the rate of growth has slowed somewhat in recent years. In 2001 through early 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 less expensive, and imports have experienced double-digit growth for the past several years. However, it must be noted that most of the import increase has occurred among lower technology products, and the U.S. continues to be an important player in high-technology medical devices. Recent declines in the value of the dollar vs. currencies, including the Euro, are expected to reverse the trend somewhat.

Nevertheless, the U.S. is expected to remain competitive globally due to the U.S. lead in innovative technology, increased experience in exporting, aging populations in Japan and the EU, and through international harmonization of standards and regulatory requirements. However, some regulatory barriers in foreign markets have been difficult to surmount. 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 user fees. These national requirements, which can adversely impact U.S. exports, are sometimes established to protect the domestic industry, to earn hard currency for the government, or both.

Harmonization of medical device regulations is one way to reduce the industry's burden while ensuring maximum accessibility of safe, effective medical devices by patients. ITA is encouraging foreign governments to participate in the efforts of international bodies, most notably the medical devices Global Harmonization Task Force (GHTF), to create regulatory harmonization and to eliminate or reduce redundant regulatory procedures. The GHTF is a voluntary organization of regulators and the regulated industry from the U.S., EU, Canada, Japan and Australia that works on identifying feasible areas for harmonization of medical device regulation. U.S. industry would like to see products, "approved once, accepted everywhere." Many developing countries have been invited to participate in these meetings, and Latin America and Asia regional harmonization working groups have been established.

Global reimbursement strategies also work against U.S. medical devices when they do not take into consideration incremental improvements made to existing technologies, and some foreign governments refuse to put these improved device alternatives on the reimbursement list at all. U.S. firms lead the global industry in research and development, and they are known for providing continuous improvements and upgrades to existing medical devices. U.S. firms would like to see the officials in foreign markets accept the concept of "value of technology" wherein the long-term benefit of an advanced medical technology is taken into account.

Many countries around the world are facing the same skyrocketing costs of health care as in the U.S., and are trying to trim costs by cutting back on reimbursement rates, by establishing price caps or by requiring inappropriate information or pricing from the manufacturer. Germany, France, Japan, Taiwan, Korea, China and Brazil are all examples of markets where prices for medical devices and reimbursement rates have been set lower than the value of the technology, making it difficult for U.S. firms to be profitable in these markets. The U.S. Government is encouraging foreign governments to take the value of advanced technologies into greater consideration in establishing their reimbursement rates.

The medical device industry has become increasingly competitive as 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. Global demand for medical devices and supplies is being driven by increasing expenditures on health care by nations around the world - building hospitals and clinics, establishing public health insurance, and focusing more attention on the health of its citizens. This is increasing demand for medical and dental equipment and supplies at double-digit growth rates in much of the world. In order to facilitate expansion, medical device firms are recognizing that they must look increasingly at developing economies for future growth. As a result, the medical equipment industry has increasingly become a global industry.

The major competitors

The U.S. industry is mainly facing competition from Germany (Siemens), Japan (Hitachi Medical Corp. and Toshiba), the Netherlands (Philips Electronics) and Italy (Marconi Medical Systems) in high-technology products. It is important to note that most of these foreign companies manufacture a significant amount of their products in the United States. High-quality but lower technology medical firms are being challenged by numerous lower-cost producers in China, Brazil, Korea, Taiwan and India, countries which are building up their domestic industries and also compete globally.

Imports

The U.S. imported \$23.5 billion of medical equipment products in 2004, an increase of 15.1 percent (or more than \$3 billion) compared to 2003. Just over half of these imports (\$12 billion) were in the surgical and medical instrument and supplies industry sector (NAICS 339112/3), which includes numerous price-sensitive lower-technology devices, making a substitution for imported products easier than in higher medical device technology sectors. Over the past few years, devalued currencies in certain key foreign markets have also made U.S. devices more expensive, and a relatively strong dollar that made purchasing foreign equipment cost-effective.

In 2004, five countries accounted for 57 percent of U.S. imports of medical devices: Ireland (18%), Germany (13%), Mexico (12%), Japan (8%), and China (6%).

U.S. Trade Patterns in the Medical Equipment Industry (NAICS 334510, 334517, 339112, 339113, 339114, 339115) in 2004 (\$ million; percent)

Imports

| Region | Value | % Share of Total |
|-----------------------------|---------------|-------------------------|
| EU25 | 11,113 | 47.2 |
| Japan/Chinese Economic Area | 3,385 | 14.4 |
| NAFTA | 3,359 | 14.3 |
| Rest of World | 3,020 | 12.8 |
| Other Asia | 1,637 | 6.9 |
| Latin America | 1,024 | 4.4 |
| Total | 23,538 | 100.0 |

| Top 5 Countries | Value | % Share of Total |
|------------------------|--------------|-------------------------|
| Ireland | 4,249 | 18.0 |
| Germany | 3,064 | 13.0 |
| Mexico | 2,841 | 12.1 |
| Japan | 1,789 | 7.6 |
| China | 1,507 | 6.4 |

Source: U.S. International Trade Commission

Exports

Aggregate exports for 2004 were valued at \$20.7 billion. Surgical and medical instruments and supplies [NAIC 339112/13] is the largest category within the medical devices sector. The U.S. export of this category was valued at \$11.84 billion in 2004, an increase of 10.4 percent over 2003.

Certain export markets have experienced severe economic downturns or financial instability in recent years, with major repercussions for the industry. In recent years, devalued currencies in Brazil, Colombia and certain other Latin American countries have severely impacted U.S. sales to these markets. Ever since Russia's financial crisis in the late 1990s, U.S. sales to Russia have struggled. While the U.S., EU, Japan and Canada are extremely large and lucrative markets for medical devices, they are mature markets with stable but low (3 - 5 percent) annual growth rates. Sales to developing economies in Central Europe have been somewhat disappointing in the past; however, once their regulatory environment has been synchronized with the EU, Central Europe has promising future sales potential. Many U.S. medical device companies view China as the next major frontier.

The largest markets for medical equipment are the U.S. - which constitutes about half the world market - the European Union (EU), Japan, Canada, China, Brazil, Taiwan and Australia. Export shipments of U.S. medical equipment and supplies to the fifteen leading national markets totaled \$16.8 billion in 2004. This represents an 8.6 percent increase from the previous year.

U.S. Trade Patterns in the Medical Equipment Industry (NAICS 334510, 334517, 339112, 339113, 339114, 339115) in 2004 (\$ million; percent)

Exports

| Region | Value | % Share of Total |
|-----------------------------|---------------|-------------------------|
| EU25 | 9,736 | 47.2 |
| Japan/Chinese Economic Area | 3,507 | 14.4 |
| NAFTA | 3,027 | 14.3 |
| Rest of World | 2,040 | 12.8 |
| Other Asia | 1,395 | 6.9 |
| Latin America | 1,002 | 4.4 |
| Total | 20,707 | 100.0 |

| Top 5 Countries | Value | % Share of Total |
|------------------------|--------------|-------------------------|
| Japan | 2,701 | 13.0 |
| Netherlands | 1,992 | 9.6 |

| | | |
|---------|-------|-----|
| Canada | 1,852 | 8.9 |
| Germany | 1,770 | 8.5 |
| Ireland | 1,367 | 6.6 |

Source: U.S. International Trade Commission

The EU 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-made high-tech products due to Europe's high per capita income, a favorable regulatory environment and aging populations. The EU maintains a uniquely open and transparent regulatory system for medical devices, based on international standards. Steady economic growth and political and currency stability make the region an attractive market, which accounts for about one quarter of the medical device global market. The largest individual European markets for U.S. exporters in 2004, with corresponding U.S. export figures are:

| Country | \$ Value (Billion) |
|----------------|---------------------------|
| Netherlands | 1.99 |
| Germany | 1.77 |
| Ireland | 1.37 |
| United Kingdom | 1.26 |
| France | 0.969 |
| Belgium | 0.784 |
| Switzerland | 0.485 |
| Italy | 0.447 |

In 1998, the U.S. and EU entered into a Mutual Recognition Agreement (MRA) covering medical devices. Once implemented, this MRA will allow U.S. medical device firms to use U.S.-based third party organizations called Conformity Assessment Bodies (CABs) to review products based upon criteria of the EU Medical Device Directive (MDD) for sale in the EU market. In addition, EU firms will be able to use EU-based CABs to recommend approval to the U.S. FDA for a limited number of medical device products based on U.S. FDA requirements for sale in the U.S. market. The MRA will also allow for CABs to perform quality system evaluations in both the United States and the EU according to each other's requirements.

With over 1.3 billion people and steady economic growth for two decades, China is increasingly a target market for U.S. exporters of high-technology medical equipment. China, including the Special Administrative Region of Hong Kong, is the second largest market for U.S. medical device exports in Asia. U.S. medical device exports to China will increase 5 to 10 percent annually for the foreseeable future (where does this come from?). U.S. medical device exports to China totaled \$805 million in 2004. China's overall market for medical equipment and supplies was estimated at \$2.5 billion in 2005. Many in the industry believe this figure understates the actual size of China's market.

Japan's medical device market, estimated to exceed \$17 billion in 2005, is the largest market for U.S. medical equipment and supplies companies. U.S. exports to Japan have increased from \$2.24 billion in 1999 to \$2.7 billion in 2004, which is slightly below the peak level of exports (\$2.73 billion) reached in 2001. Medical device-related trade issues with Japan are being addressed in the Market-Oriented, Sector-Selective (MOSS) Agreement signed on January 9, 1986. It has served since then as the basis for continuous bilateral discussions to improve market access for American exporters of pharmaceuticals, cosmetics, and medical devices. Korea and Taiwan are also in the top twenty markets for U.S. medical and dental products, where U.S. exports in 2004 were valued at \$668 million. Finally, India is one of the fastest growing markets in Asia for U.S. medical equipment.

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 be a promising market for U.S. medical device manufacturers. As one of the most highly dependent regions on imported medical products, Latin American countries currently provide significant opportunities to U.S. exporters. In 2004 exports of medical products to Latin American markets totaled over \$1 billion. Despite economic difficulties in the Latin American region, companies are pursuing these markets based on their potential for growth.

Key opportunities for expanding exports

Opportunities for expansion of exports will come from international harmonization of regulatory requirements, reduced or eliminated tariffs in key markets, increased understanding of global regulatory and reimbursement policies, and improvement of regulatory environments in difficult markets such as China and Russia. Other opportunities for export expansion come from assisting SMEs (small and medium-sized enterprises) with entering the foreign markets through market information, trade missions, and other trade promotion activities.

Because much of these efforts involve the policies of foreign governments, the U.S. government can play an important role in expanding medical device exports on a bilateral or multilateral basis. U.S. industry needs and expects the U.S. Government to negotiate strongly to reduce or eliminate tariffs on medical devices; to address foreign governments' regulatory policies that are at odds with international harmonization efforts and that may cause unfair discrimination against U.S. industry; to educate the industry on how to comply with foreign regulatory requirements; and to provide similar opportunities that foreign governments do for their own industries in terms of export assistance.

What U. S. Government is Doing to Assist Industry

ITA is involved in a variety of programs to support the U.S. medical device industry. These efforts include participating in the medical devices Global Harmonization Task Force (GHTF) and training other countries' officials in the GHTF's regulatory best practices; addressing non-tariff barriers through government-to-government discussions

with regulators; and providing export opportunities in the form of missions and conferences. TD/OHCG has advanced these objectives through:

- Utilizing the JCCT Medical Device and Pharmaceuticals Subgroup to address Chinese regulatory policies and provide training to Chinese officials on international regulatory best practices.
- Providing training to foreign regulatory officials on international regulatory best practices.
- Raising industry concerns regarding tariffs and non-tariff barriers for medical devices in India, Mexico, Brazil, China, Korea, Taiwan, and Russia, Thailand and Singapore.
- Support Department of Commerce-led medical device industry delegations to key markets
- Supporting the Doha round, supporting other trade agreements
- Educating the U.S. medical device industry on global regulatory and reimbursement policies.
- Write market research reports on priority markets.

Because of the medical device industry's focus on major markets, TD/OHCG works in conjunction with the major medical device associations – including AdvaMed, National Electrical Manufacturers Association (NEMA), and the Medical Device Manufacturers Association (MDMA) - to address regulatory and reimbursement issues in some of the markets that have both market potential and significant market access issues that make them less attractive markets for risk-averse small firms. This coordination of efforts allows TD/OHCG to raise regulatory and reimbursement issues in a government-to-government setting. This is supportive of medical device industry associations' efforts to provide information on markets where their members are most active.

Obstacles to export expansion: The obstacles to export expansion include a myriad of complex regulatory and reimbursement requirements (addressed above) that are different for every country. Certain countries, including India, certain Latin American countries, and parts of Asia, still maintain high tariffs on some medical products.

U.S. firms also face increasing competition globally, especially from those foreign firms that can successfully compete on the basis of price. U.S. firms without sufficient resources to conduct necessary market research are especially vulnerable. Since the majority of the U.S. medical device industry consists of small and medium firms that reinvest much of their revenue back in the form of research and development and into making incremental improvements to their technology, many do not have the resources to conduct sophisticated export market research.

Many smaller companies are so focused on entering the U.S. market first that they put off exporting until they have become profitable in the U.S. However, the domestic market is sometimes even more difficult to enter than some foreign markets, due to stringent U.S. Food and Drug Administration regulations and complex reimbursement policies with Medicare and Medicaid.

Richard Paddock, DOC/ITA/MAS/OHCG, (202) 482-3360

Matthew Hein, DOC/ITA/MAS/OHCG, (202) 482-5014