

MEDICAL DEVICES INDUSTRY ASSESSMENT

I. Background of Industry

A. *Industry Definition:* The United States (U.S.) medical device manufacturing sector is a highly diversified industry that produces a range of products designed to diagnose and treat patients in healthcare systems worldwide. Medical devices differ from drugs in that they do not achieve their intended use through chemical reaction and are not metabolized in the body. Medical devices range in nature and complexity from simple tongue depressors and bandages to complex programmable pacemakers and sophisticated imaging systems.

B. *Key Products:* The key products that comprise the medical devices industry, include, surgical appliances and supplies, surgical and medical instruments, electro-medical equipment, in-vitro diagnostic substances, irradiation apparatus, dental and ophthalmic goods.

C. *NAICS Codes:* The following North American Industry Classification System (NAICS) codes comprise the medical devices industry that is covered by the Office of Health and Consumer Goods (OHCG):

325413 In-Vitro Diagnostic Substances Manufacturing
334510 Electro-medical and Electrotherapeutic Apparatus Manufacturing
334517 Irradiation Apparatus Manufacturing
339112 Surgical and Medical Instrument Manufacturing
339113 Surgical Appliances and Supplies Manufacturing
339114 Dental Equipment and Supplies Manufacturing
339115 Ophthalmic Goods Manufacturing

- In-vitro diagnostic substances (IVDs) (NAIC 325413); about 10 percent of the total measured by value of shipment (VOS) for medical devices include chemical, biological or radioactive substances used for diagnostic tests performed in test tubes, Petri dishes, machines, and other diagnostic test-type devices.
- Electro-medical equipment (NAIC 334510) manufacturers, the third-largest subsector accounts for about 19 percent of VOS, produce a variety of powered devices, including pacemakers, patient-monitoring systems, MRI machines, diagnostic imaging equipment (including informatics equipment), and ultrasonic scanning devices.
- Irradiation apparatus (NAIC 334517; accounts for about 8 percent of VOS includes X-ray devices and other diagnostic imaging, as well as computed tomography equipment (CT).
- Surgical and medical instruments (NAIC 339112) are the second-largest subgroup (about 26 percent of VOS) of the medical device industry. The category includes anesthesia apparatus, orthopedic instruments, optical diagnostic apparatus, blood transfusion device, syringes, hypodermic needles, and catheters.

- Surgical appliances and supplies (NAIC 339113) is the largest U.S. medical device subsector, about 28 percent of the total measured by VOS. The category covers a wide range of products, including artificial joints and limbs, stents, orthopedic appliances, surgical dressings, disposable surgical drapes, hydrotherapy appliances, surgical kits, rubber medical and surgical gloves, and wheelchairs.
- Dental equipment and supplies (NAIC 339114; about 5 percent of total measured by VOS consists of equipment, instruments, and supplies used by dentists, dental hygienists, and laboratories. Specific products include dental hand instruments, plaster, drills, amalgams, cements, sterilizers and dental chairs.
- Ophthalmic goods (NAIC 339115; about 5 percent of total measured by VOS include eyeglass frames, lenses and related optical and magnification products.
- Dental laboratories (NAIC 339116; about 4 percent of total measured by VOS include crowns, dentures, bridges and other orthodontic products.

II. Industry Overview and Global Competitiveness

A. Industry Characteristics

The U.S. medical devices industry is known for producing high quality products using advanced technology resulting from significant investment in research and development (R&D). There were approximately 5,300 medical device companies in the U.S. in 2007¹, mostly small and medium-sized enterprises (SMEs). In 2007, approximately 73 percent of medical device companies had fewer than 20 employees, with 15 percent having as many as 100 employees². Medical device companies are located throughout the country, but are mainly concentrated in specific regions known for other high-technology industries, such as microelectronics and biotechnology. The states with the highest number of medical device companies include California, Florida, New York, Pennsylvania, Michigan, Massachusetts, Illinois, Minnesota and Georgia.

In 2007, the total value of industry shipments for U.S. – manufactured medical devices covered by the NAICS categories identified above was valued at \$98 billion,³ and in prior years had experienced approximately 6 percent annual growth.⁴ Median state medical technology jobs paid 15% more than the average U.S. manufacturing job.⁵ In 2007, the medical device industry employed more than 365,000 people in the U.S., earning an average annual wage of approximately \$60,000.⁶ In addition, the U.S. holds a competitive advantage in several complementary industries on which the medical device industry relies, namely microelectronics, telecommunications, instrumentation, biotechnology, and software development.

¹ Manufacturing: Industry Series: Detailed Statistics by Industry for the United States; U.S. Department of Commerce, Bureau of the Census, 2007.

² Id.

³ Id.

⁴ The Lewin Group, *State Impacts of the Medical Technology Industry*, prepared for Advanced Medical Technology Association 2008

⁵ Id.

⁶ Manufacturing: Industry Series, Id.

NOTE: The company, shipment and employment figures cited above come from the 2007 Census of Manufacturers, a comprehensive gathering of data from manufacturing companies conducted every five years. The \$98 billion shipment figure only includes medical devices from companies whose primary production resides within the seven NAICS industries described above; several billion dollars of additional shipments likely are secondary products for companies classified under other NAICS industry codes

Major U.S. medical device companies include Medtronic®, GE Healthcare Technologies®, Johnson & Johnson®, St. Jude®, Boston Scientific®, Baxter®, Becton Dickinson®, Beckman Coulter®, Abbott Labs® and Stryker Corporation®. In addition, the following trade associations closely follow the medical device industry: Advanced Medical Technology Association (AdvaMed), Medical Device Manufacturers Association (MDMA), Medical Imaging Technology Association (MITA), Dental Trade Alliance (DTA) and the International Association of Medical Equipment Remarketers & Servicers (IAMERS).

Announcements of progress in medical technology that allow for earlier detection of diseases and more effective treatment options are now almost daily occurrences. Particularly notable technological advances in the industry in recent years included new developments in neurology (e.g. deep-brain-stimulation devices for treating symptoms of Parkinson's), cardiology (e.g. artificial device designed to replace diseased heart valves) and Health IT (e.g. "data liquidity" to facilitate information sharing, wireless telemedicine devices, systems designed to track the cardiac activity of patients with implanted medical devices). Scientists have used nano-sensors for the quick detection of cancers through blood tests, with nano-material also enabling the release of medicine at targeted organs. Collaborations have led to advances in biomarkers, robotic assistance, implantable electronic devices, liquid bandages/wound dressings and ingestible diagnostic devices (capsules).

Minimally invasive surgery has also seen major gains - an exciting example of this trend is an endoscopic technique that integrates nontechnology and diagnostic imaging. Capsule endoscopy, which involves swallowing a tiny wireless camera pill that takes thousands of pictures as it travels through the digestive track, gives physicians more detailed information about hard to navigate sections of the digestive tract compared with earlier endoscopic technologies. The ability to navigate and detect conditions in the small intestine is the most promising aspect of this new technology; providing physicians with greater ability to diagnose conditions such as intestinal tumors and Crohn's disease.

B. Domestic Competitiveness

U.S. medical device companies are highly regarded globally for their innovations and high technology products. Investment in medical device R&D more than doubled during the 1990s, and R&D investment in the domestic sector remains more than twice the average for all U.S. manufacturers overall. The medical device sector also continues to benefit from a new generation of materials, manufacturing processes, and technology, such as nanotechnology and micro-electro-mechanical systems (MEMS). Since the industry is fueled by innovation and the ongoing quest for better ways of treating or diagnosing medical problems, future growth prospects for this sector remain positive.

The medical device sector was better positioned than some other industries to weather the recent economic downturn. Biotech and medical-device companies in California, for example, were able to employ more than 280,000 workers and commercialize 1,754 medical products in 2009 despite the economic downturn, according to a report released by trade group BayBio. In 2010 medical device companies will likely see continued gains from an improving economy and a clearer view of healthcare reform. However, the industry may have to contend with certain new challenges including strengthened regulatory oversight, efforts at cost containment and an anticipated multibillion-dollar tax as part of healthcare reform legislation.

C. Global Competitiveness

The U.S. is the largest consumer of medical devices and leads the world in the production of medical devices. The U.S. has a medical device market valued at more than \$100 billion in 2008, roughly 42 percent of the world's total. U.S. exports of medical devices in the key product categories identified in Section I (excluding IVDs) was valued at approximately \$31.4 billion in 2008 and imports were valued at \$33.6 billion.⁷

Over the past decade the value of imported medical devices has steadily increased, gradually eroding the previous trade surplus. The majority of imports are lower tech products, e.g. surgical gloves and instruments. Continuing shifts in trade patterns have resulted in China emerging as a significant export of lower tech equipment and supplies to the U.S.

The surgical and medical instruments category comprises the largest trade category within the medical device sector. This category includes numerous price-sensitive lower-technology devices where imports can be more easily substituted than with higher technology medical device products. While exports of surgical and medical instruments grew 61.54 percent from 2002 to 2007, imports more than doubled over the same period.⁸

Note: The Office of Health and Consumer Goods (OHCG) uses the North American Industry Classification System (NAICS) and export statistics are “domestic exports” only for this report to maintain continuity with past years and consistency with industry reports produced by other offices within ITA’s Manufacturing and Services Division. If “total exports” (including U.S. product originating outside the U.S.) were included, the value of U.S. exports would be \$36.58 billion and would show a trade surplus of nearly \$3 billion for 2008. Trade data drawn from the World Trade Atlas (WTA) also report a trade surplus for the industry. Trade Data for In-vitro diagnostic products is not readily available, and is therefore not included in export-import stats.

Most of the other product categories (NAICS) have shown steady growth in both exports and imports between 2002 and 2007. For example, imports of dental equipment [NAIC 339114] doubled in that period, and exports grew by over 50 percent. Ophthalmic goods [NAIC 339115],

⁷ Source: 2008 data compiled from tariff and trade data from the U.S. Department of Commerce and the U.S. International Trade Commission.

⁸ *Id.*

on the other hand, have experienced smaller growth rates, with imports growing by 59.2 percent and exports by 32.7 percent.⁹

The U.S. medical device industry is expected to remain highly competitive globally, due in part to national characteristics that facilitate bringing new and innovative technologies to market. An increasing number of multinational firms are seeking regulatory approval for their products in more countries worldwide. These firms are focusing greater attention on international sales, joint ventures, and mergers and acquisitions.

Global demand for medical devices is being driven by increasing expenditures and greater attention to health care by developing markets, construction of hospitals and clinics, and establishment of public health insurance. In addition, global demand should continue to grow due to aging populations in major markets, new and significant emerging markets and rising global income levels in developing countries. Further, global harmonization of standards and regulatory requirements should help facilitate overall market growth.

The U.S., European Union (E.U.), Japan and Canada are extremely large and lucrative medical device markets; however, they are mature markets with stable but relatively low (3 - 5 percent) annual growth rates. In order to facilitate expansion, medical device companies recognize that they must look increasingly at developing countries to drive future growth. For example, demand for medical devices in China and India is growing at double digit growth rates compared to developed countries, albeit from a low base.

For the medical device industry to fully realize its potential in developing markets, standards and criteria for regulatory approval, risk management, and quality must be improved and most importantly harmonized to meet global international best practices based upon Global Harmonization Task Force (GHTF) guidance documents. To that end, the Global Harmonization Task Force (GHTF), a voluntary organization comprised of regulators and industry with five Founding Members (U.S., Canada, Japan, E.U., and Australia) has its core objective of streamlining and harmonizing regulatory practices through five study groups. Developing countries like India, China, Malaysia, Indonesia, Thailand, Vietnam, Mexico, Chile, South Africa and Brazil now participate in GHTF through their regional organizations, the Asian Harmonization Working Party (AHWP), and the Latin America Harmonization Working Party (LAHWP), respectively. The participation of the developing countries in these forums, coupled with guidance documents issued by GHTF will be critical in establishing regulatory regimes for medical devices that are distinct from traditional pharmaceuticals. Upon further development in this area, the medical device industry will continue to evolve as a global industry.

⁹ Source: 2008 data compiled from tariff and trade data from the U.S. Department of Commerce and the U.S. International Trade Commission.

III. Domestic Environment

A. Regulatory

The medical device industry is a highly regulated sector of the economy, and regulatory environments, both at home and abroad, have significant implications for the industry's performance. Accordingly, the U.S. medical device industry devotes considerable resources toward product approval processes, clinical trials, user fees and plant audits/inspections. The U.S. Food and Drug Administration's Center for Devices for Radiological Health (USFDA/CDRH) governs the regulatory oversight of medical devices. The USFDA maintains three risk categories that determine the type and depth of review necessary for the marketing of medical devices.

The USFDA will have a considerable increase in both responsibilities and resources in the coming years. Budget legislation for fiscal year 2009 contained more than \$2 billion for the USFDA -- a \$325 million increase over the FDA's FY 2008 appropriations. About \$43 million is for the Center for Devices and Radiological Health and activities in the medical-device field.

The USFDA is working toward increasing the number of electronic applications for approval and has published proposed rules that would require electronic reporting of post-market medical device adverse events. The Sentinel Initiative calls for a national electronic system that would allow the agency to search existing databases for safety information on medical products approved by the USFDA. The FDA has also proposed streamlining current good manufacturing practice standards for combination products in order to prevent the "...inconsistent or differing application of such requirements that could affect product safety and the public health".

The USFDA is also re-examining the "510(k)" process, an approval process for medical devices that are substantially equivalent to other products already authorized for sale on the marketplace. The USFDA is evaluating the 510 (k) process in an attempt to remove vague or nontransparent requirements and determine whether it should restrict the types of products that can pursue a 510 (k) clearance track.

In 2009 the U.S. Government Accountability Office (GAO) published a study on the USFDA's 510(k) process at the request of Congress. The study recommended that HHS direct the USFDA to issue regulations for a limited group of class III "pre-amendment" devices which currently enter the market through the 510(k) process. The GAO determined that the devices should either be "down-classified" or re-evaluated through the more stringent pre-market approval (PMA) process as class III products. Devices that would be affected include external counter-pulsating devices, implanted blood access devices, intra-aortic balloon and control systems, automated external defibrillators, pedicle screw spinal systems, and certain types of artificial hip joints. As a result of the GAO study, USFDA issued an order in April 2009 requiring the manufacturers of class III pre-amendment devices to submit information demonstrating the safety and effectiveness of their device. While the GAO report does not make any fundamental recommendations about the 510 (k) process, continued discussion and scrutiny of the process is expected in 2010. A committee within the Institute of Medicine, an

independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public, is assessing whether the 510(k) clearance process sufficiently protects patients and promotes public health.

In addition, the USFDA has been working closely with relevant stakeholders to implement a Unique Device Identifier (UDI) system for medical devices. This system was mandated by Food and Drug Administration Amendment Act (FDAAA) in September 2007 and is expected to be introduced in 2010. The potential benefits of a UDI system include: reduction in medical errors, improved adverse event reporting (AER) and post-market surveillance (tracking medical devices once they have been used in the market), and streamlined process for carrying out product recalls. The USFDA held a public workshop in February 2009 to discuss UDI implementation with relevant stakeholder holders such as healthcare providers, medical device manufactures and patient groups. In addition, with the cooperation of several manufacturers and hospitals, the USFDA held a pilot study in the third quarter of 2009 to test a UDI database. While the USFDA is still working on the regulation for implementation, USFDA representatives have indicated that they will begin mandating UDI implementation to the highest risk class of devices and gradually expand to all categories.

Another key regulatory development is an announcement by the FDA in August 2009 that beginning February 2011 medical device manufacturers, importers and facilities would be required to submit Adverse Event Reports (AERs) to CDRH electronically. Currently, CDRH receives most incident reports on paper which then needs to be input into the Manufacturer and User Facility Device Experience (MAUDE) database. The FDA says the existing process is not only costly, but hinders CDRH's ability to review safety data quickly to uncover potential public health problems. USFDA has posted information about this new initiative to its website.

B. Key Non-Regulatory Policy Areas

There are a number of key non-regulatory areas that significantly impact the viability of the U.S. medical device industry, ranging from financial investments to legislative changes to innovation and product convergence.

- *Reimbursement:* Valuation and reimbursement of products by public and private sector financial entities are crucial to the success of the medical device industry. The U.S. market is so large that reimbursement decisions made in the U.S. have the potential to impact the viability of manufacturing the product for other markets. In the U.S., there are several government organizations that are involved in establishing reimbursement rates. The Department of Health and Human Services' Center for Medical and Medicaid Services (HHS/CMS) administers both the Medicaid and Medicare program that covers the reimbursement of medical devices. In addition, the Veterans Administration is the key agency responsible for negotiating an agreement with manufacturers/distributors of medical devices (Federal Supply Schedules) for procurement of medical devices by certain government agencies.

- *Healthcare Reform:* In March, 2010, the U.S. House of Representatives passed the Patient Protection and Affordable Care Act (H.R. 3590). The bill had been previously approved by the Senate in December, 2009 and was subsequently signed into law by President Obama. Health care reform will have a wide ranging impact and will impose new mandates on individuals, employers, medical service providers and health products manufacturers.
- *Comparative Effectiveness:* As policy-makers contend with rising healthcare costs it is likely that some form of comparative effectiveness, a system based on the relative benefits a product delivers, will be implemented or expanded both in the U.S. and abroad. Comparative effectiveness employs research that compares the clinical effectiveness of different drugs, devices and procedures with an eye toward improving quality of care. However, issues remain as to who should conduct the research or when and how cost-effectiveness should be factored in.
- *Attracting Venture Capital:* Small to medium enterprises (SMEs) with limited earnings in the early stages of development, and the medical device sector is particularly reliant on venture capital funding. Venture capitalists need a predictable system in order to assess risk, and when uncertainties prevent access to venture capital funds, there tends to be a fall-off in innovative activity. The downturn in the U.S. economy which accelerated in late 2008 took a toll on the valuation of medical device start-ups seeking injections of capital. A number of venture capital firms, including some long time investors, began withdrawing from early-stage investing as the economic slump deepened, choosing instead to hold on to capital until higher levels of certainty asset valuations return. While the medical device sector fared somewhat better than others during the economic downturn of 2009 reports have been mixed. Medical-device makers raised \$628 million in venture funding during the second quarter 2009, a 38% increase over the second quarter of 2008 according to a report by PricewaterhouseCoopers and the National Venture Capital Association (NVCA). A subsequent release from the NVCA, however, reported that members of NVCA invested nearly \$617 million in device companies in the third quarter of 2009, down from \$890 million for the same period in 2008. While the recession likely played a primary role in the decrease, extended product approval periods and stricter insurance reimbursement policies may have also kept some investors away.
- *Group Purchasing Organizations (GPOs):* GPOs negotiate contracts with health product suppliers on behalf of cooperatives of healthcare facilities. The role that GPOs play in the health care system has come under scrutiny by Congress in recent years. With the economic downturn in recent years the bond between hospitals and GPOs seems to be strengthening. The recession prompted some hospitals to enact cost-cutting initiatives, including in the area of product procurement. Hospital materials management departments have been empowered by administrators to make money-saving decisions. For the future, products that provide superior clinical value and contain costs will likely attract investors.
- *Industry Consolidation - Mergers and Acquisitions:* In the medical device industry small firms faced with devoting significant resources to innovations often merge with larger

firms with the financial resources necessary to bring products to market. The results was mutually beneficial - larger firms receive the benefit of the new technology and, therefore, maintain market share; small firms can afford to continue to produce and get the benefit of the large firms devoting resources to continued incremental improvements that are crucial in the industry. This trend has continued in part due to economic realities in 2009 led to further consolidation in the medical device sector, both in terms of company mergers, companies combining profit centers and companies outsourcing for greater efficiencies. Two prominent examples: in 2009 Abbott Labs and Covidien made significant acquisitions adding to their product portfolio while Medtronic took major steps to consolidate its various businesses into two major groups. International joint venture designed to develop health care technologies and establishing local research and development capabilities have also grown in size and significance. Asia – notably China and Korea – have been the site of a number of collaborations with U.S. firms. Some firms are also gravitating toward a launch in Europe followed by a move to the U.S. or perhaps a move to China or India. It definitely adds a level of complexity to the development process.

- *Demographics*: Marked increases in the average age of U.S. and foreign populations has already influencing the direction of the medical device industry through the changing health needs of senior citizens and shifts in thinking on how and where they will be treated. As pressures mount to contain costs, expensive and/or extended stays in healthcare facilities will be discouraged and healthcare will be increasingly delivered in alternative settings such as nursing homes, hospices, and, especially, the patient's own home. Home health-care is one of the fastest growing segments of the industry, and is branching out into new areas. What used to be limited to only the lowest technology products is now encompassing a proliferation of high technology medical devices that are intended to be used by unskilled health care workers or patients. In addition, demographics and technological advances will continue to increase demand for advanced medical device products (such as pacemakers and defibrillators) well into the 21st century.
- *Health Information Technologies (HIT)*: The 2009 American Recovery and Reinvestment Act (ARRA) appropriated approximately \$19 billion towards increased utilization of Health IT, including requiring “meaningful use” of electronic health records (EHRs), and new governance boards for setting Health IT policy and standards. ARRA also conferred statutory authority upon the HHS Office of the National Coordinator for Health IT (ONC). Development and application of relevant Health IT standards (including increasing medical device interoperability) has been an ongoing focus of key stakeholders since 2005. At the end of 2009, ONC published draft rules for public comment specifying the conditions where federal programs will reimburse for “meaningful use” of EHRs. The use of HIT-related medical devices alone, however, will not provide all of the promising synergies and benefits for delivering effective and efficient healthcare. Reviewing treatment and decision-making processes, while expanding the range of services available to patients, are additional elements that will enable the medical device industry to play an increasingly critical role in the rollout of Health IT.

- *Product Convergence:* As medical device and biotechnology products converge, medical devices will act as delivery systems for pharmaceutical treatments and research resulting from genetic engineering and biotechnology research. Many industry experts view the impending convergence of medical devices with biotechnology and nanotechnology with cautious optimism, but also warn that if the regulatory and reimbursement issues are not addressed problems will ensue as convergence takes place.

IV. Industry Trading Environment

A. Key Export Destinations

The largest markets for medical devices are the U.S. (which constitutes about half the world market), EU, Japan, Canada, China, Brazil, Taiwan, Korea and Australia.

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 U.S.-made high-technology products due to high per capita income in EU countries, a favorable regulatory environment and an aging population. Shipments of U.S. medical devices to EU 15 markets totaled about \$13.8 billion in 2008. Significant individual markets in the EU for U.S. medical device exporters include Germany, France, the UK and Italy.

The EU's regulatory system for medical devices is generally considered open and transparent, is based on international standards, and accounts for about one quarter of the global medical device market. The EU's regulatory structure is contained in the Medical Device Directives (MDD), which recently underwent amendments imposing more stringent requirements as to what constitutes "clinical evidence" and mandating stronger enforcement by authorities. These changes will be completed and in place in 2010. In 2009 the EU was considering additional significant revisions to its MDD, but consultations with industry on what was known as the "recast" led the European Commission to delay implementation and revisit the numerous issues associated with the planned changes.

Japan is the second largest medical device market in the world, and the second largest export market for U.S. medical devices.¹⁰ Its total medical device market value is estimated at \$23 billion for 2008.¹¹ U.S. exports of medical devices to Japan totaled about \$3.5 billion in 2008.¹² As its elderly population grows and the overall contribution to Japan's national healthcare system decreases as a result of its shrinking population, the Japanese Government will be forced to take additional measures to contain healthcare spending. These cost-containing measures coupled with the unique costs of Japan's approval system are forecast to cause a

¹⁰ Source: 2008 data compiled from tariff and trade data from the U.S. Department of Commerce and the U.S. International Trade Commission.

¹¹ Source: Espicom *World Medical Market Forecast 2008*, Espicom Business Intelligence, Princeton, N.J.

¹² *Id.* USDOC/USITC

contraction in Japan's medical device market of approximately 0.9 percent through 2013. However, medical devices used to treat age-related diseases should see steady growth in demand. These include equipment to assist bio-functions such as pacemakers, cardiac valve prosthesis, and orthopedic implants. Because there are very few domestic manufacturers in Japan in these areas, market opportunities for these products will continue to be promising for U.S. firms in the foreseeable future.

China is increasingly a target market for U.S. exporters of high-technology medical devices in light of China's large population and strong economic growth. China (including Hong Kong) is the second largest market for U.S. medical device exports in Asia, with exports of about \$1.5 billion in 2008.¹³ U.S. medical device exports to China are expected to increase 5 to 10 percent annually for the foreseeable future. China's overall market for medical devices is estimated to reach \$5 billion in 2010.¹⁴

China is focusing on developing its medical device regulatory regime and domestic medical devices sector, and medical device exports from China to the U.S. have risen significantly in the past few years. The issue of import safety came to the fore in 2007, as certain products imported from China, including some medical devices, raised safety concerns. In December 2007, HHS and China's State Food and Drug Administration (SFDA) signed a product-safety Memorandum of Agreement (MOA) in which China agreed to adopt approaches to import safety based on risk-management, transparency, and rigorous science-based international standards. The MOA was renewed in September 2009 with the same fundamental principles and will extend until December 10, 2011. USFDA officials have been stationed in China since late 2008 to provide advice and assistance to the Government of China as well as function as an oversight conduit to the U.S. Government for products under their purview. In addition, the U.S. Department of Commerce (USDOC) and China have engaged in bilateral discussions since 1996 through the U.S. – China Joint Commission on Commerce on Trade (JCCT) Pharmaceuticals and Medical Devices Subgroup that facilitates a forum for both regulators and industry to discuss non-tariff barriers in China.

In addition to China, India has been identified as a key market in Asia for U.S. exporters of medical devices. The private healthcare sector in India is expanding significantly to meet the needs of India's growing middle-class, a population of around 300 million, with rising disposable income and increasing medical expectations. India is working toward establishing a medical device regulatory regime that will distinguish between medical devices and pharmaceutical, and greater federal control and involvement in treatment and approvals have been proposed to minimize disparities across regions. Imports of healthcare products into India grew tenfold in the 1990s, and increased by a combined annual growth rate of about 12 percent from 2000-2008. High quality healthcare products like those produced in the U.S. are valued in India, and the U.S. is currently the leading supplier to India with more than 28 percent of the medical devices import market in 2008. U.S. exports to India in 2008 totaled nearly \$400 million. Similar to the JCCT with China, the USDOC is actively involved in the High-Technology Cooperation Group's (HTCG's) Biotechnology and Life Sciences Working Group

¹³ *Id.* USDOC/USITC

¹⁴ *Id.* *World Medical Market Forecast 2008*

(BLSWG) that provides a forum for regulators and industry to discuss non-tariff barriers that improve U.S. exports of medical devices to India.

Medical device exports to Asian countries outside of Japan, China and India also continue to grow impressively. In 2008, U.S. exports of medical devices to Asia (excluding Australia, Japan and China) exceeded \$5.5 billion. U.S. exports to South Korea (\$625 million), Singapore (\$422 million), and Taiwan (\$250 million) were all ranked among the top 25 export markets for U.S. medical equipment and supplies.¹⁵ 2008 exports to each of the markets above increased compared with the same period in 2007. Free Trade Agreements (FTAs) already in force with Australia and Singapore, along with a pending FTA with Korea also bode well for continued medical device export growth in this region.

As one of the more highly dependent regions on imported medical products, Latin America provides potential growth opportunities for U.S. exporters of medical devices, with Mexico (\$3.6 billion), Brazil (\$1.3 billion) and Venezuela (\$573 million) as the lead destinations in 2008. U.S. exports of medical devices to Latin America and the Caribbean in 2008 totaled approximately \$7.7 billion.¹⁶ Despite challenging market access issues and economic difficulties in the Latin American region, companies are pursuing these markets based on their potential for growth. The USDOC is engaged in bilateral discussions in this region through various forums including the U.S. – Brazil Commercial Dialogue.

B. Key Competitors

The U.S. industry is mainly facing competition from Germany (Siemens®, and Braun®), Japan Hitachi® , Medical Corporation®, and Toshiba®),the Netherlands (Philips Electronics®), and Bermuda (Covidien®) in high-technology products. It is important to note that most of these foreign companies manufacture a significant amount of medical devices (or components) in the U.S. For example, as a result of recent acquisitions Philips currently produces more medical devices in the U.S. than in Europe. High-quality but lower technology medical device firms are being challenged by numerous lower-cost producers from China, Brazil, Korea, Taiwan and India, all of which are building up their domestic industries and beginning to compete globally. While the U.S., will likely retain its competitive edge for the foreseeable future, these countries will become more competitive in Africa, South America and some Asian markets.

C. Key Export Policies

The opportunities for expansion of U.S. medical device exports will come from certain key ongoing policy and activities. With respect to accessing developing countries, the contributions of GHTF, Latin American Harmonization Working Party LAHWP and Asian Harmonization Working Party (AHWP), will play a significant role in the international harmonization of regulatory requirements that can lead to greater penetration. In addition, continued focus on reducing or eliminating tariffs in key markets, and higher reimbursement

¹⁵ Source 2008 data compiled from tariff and trade data from the U.S. Department of Commerce and the U.S. International Trade Commission

rates will also significantly influence growth. Further, assisting SMEs in export opportunities through market information, trade missions, and other trade promotion activities can also increase overall U.S. exports for this industry.

The U.S. medical device industry needs and expects the U.S. Government to remain involved in several areas that will establish and improve trade conditions:

- Negotiate strongly to reduce or eliminate tariffs on medical devices;
- Address foreign governments' regulatory policies that are inconsistent with international harmonization efforts and that may cause unfair discrimination against U.S. industry;
- Educate the industry on how to comply with foreign regulatory requirements and
- provide similar export assistance opportunities that foreign governments do for their industries;
- Encourage developing countries to consider the advantages of the appropriate use of advanced medical technologies;
- Export facilitation services provided by the U.S. Commercial Service.

D. Export Barriers

As noted above, there are a myriad of trade issues for medical devices which vary from country to country that need to be either harmonized or re-evaluated. Certain countries, including India, some Latin American countries, and parts of Asia, still maintain high tariffs on some medical products that reduce the net sale price of medical devices. 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. The following highlight some of the key challenges:

- *International Regulatory Environments:* An increasingly common practice among developing countries is the establishment of national regulatory requirements that are consistent with regulatory systems in developed countries. Specifically, these systems tend to require information in dossiers that may be unnecessary or burdensome in determining product quality, safety and effectiveness. Device firms are devoting tremendous amounts of time and money to determine the requirements, conduct additional clinical trials, and pay additional user fees. These national requirements are sometimes established to protect the domestic industry, to earn hard currency for the government, or both. The U.S. Government has been promoting regulatory systems that are based on international best practices and sound science.
- *International Reimbursement Payment Environments:* Reimbursement or payment practices in certain countries have a negative impact on U.S. industry sales prospects. Many countries around the world are facing skyrocketing costs of health care and are addressing costs by reducing reimbursement rates, establishing price caps, requiring mandatory price reductions, using diagnostic related groups (DRGs), limiting funds available for medical devices, and/or requiring inappropriate information or pricing from the manufacturer. Many high tech medical devices have a life-cycle of 18-24 months, which makes reimbursement key for continued product innovation, including incremental

improvements. The U.S. Government (USG) has encouraged foreign governments to take the overall value of advanced technologies into greater consideration when establishing their reimbursement rates.

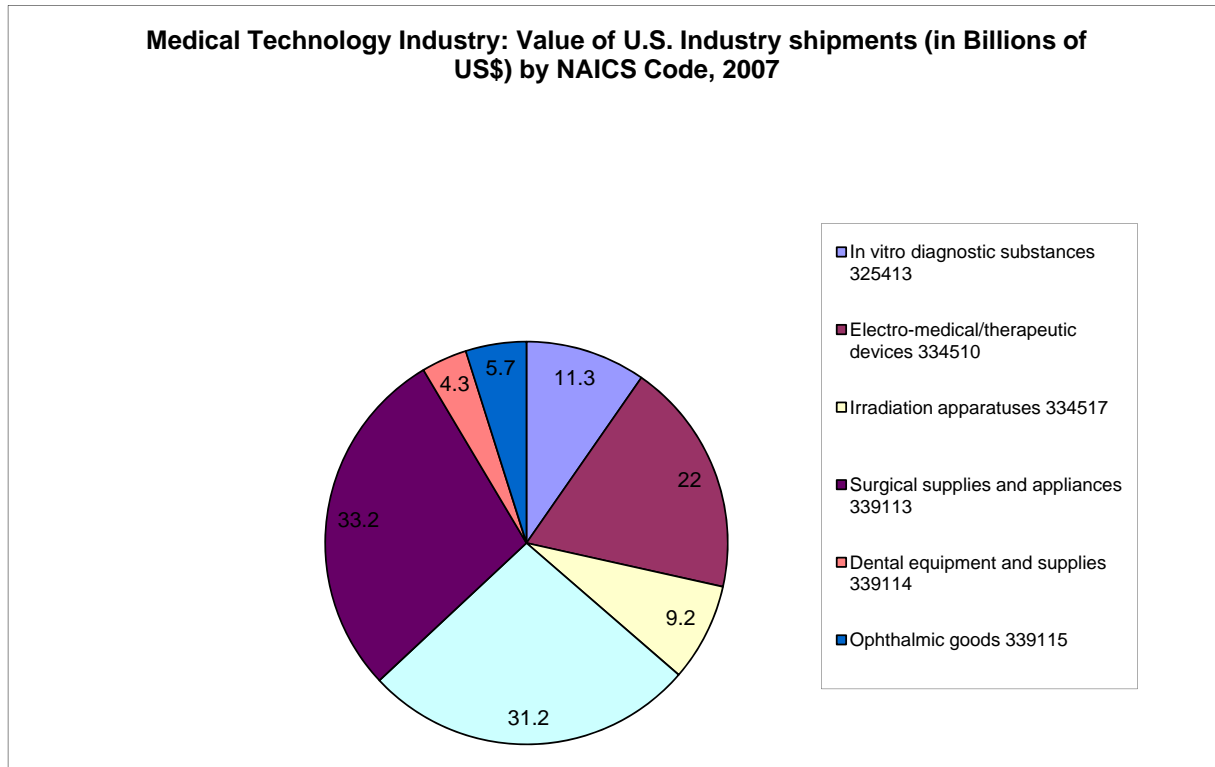
- *Harmonization Efforts:* Harmonization of medical device regulations is one way to reduce the industry's burden and ensure maximum accessibility of safe, effective medical devices by patients. U.S. industry would like to see products "approved once, accepted everywhere." ITA is encouraging foreign governments to make use of guidance documents produced by international bodies, most notably GHTF, to promote international regulatory harmonization, and to eliminate or reduce redundant regulatory procedures.
- *IPR and Counterfeit Medical Devices:* Although intellectual property rights (IPR) and counterfeiting have not yet become significant problems for medical device firms (as compared to pharmaceutical firms), the sector is beginning to face increased revenue losses due to these activities. IPR violations include using medical device firms' patented technology to manufacture a competing medical device. Similarly, counterfeit medical devices are copies of patented medical devices that are manufactured and marketed without following the requisite approval process (may need to tweak this sentence in future versions). IPR violations occur in markets that may not fully respect or enforce patent protection, such as China. There is limited data on counterfeit medical devices, but based on industry feedback, the most frequent incidences to date are in IVD reagents and solutions, contact lenses, medical test kits, combination products, and component parts, such as semiconductors used in imaging equipment. U.S. industry loses market share to these counterfeit products and patients are subject to unnecessary risks. The USG is actively engaged in global and regional dialogues to address this problem.

ITA/OHCG has several activities focused on stopping the spread of counterfeit medical products (including both pharmaceuticals and medical devices). OHCG serves as a member of the WHO Anti-counterfeit Medical Products Task Force.

VI. Conclusion

The U.S. medical device industry has many groundbreaking and transformational products on the market and under development today due to a continuous focus on R&D, innovation, and changing consumer needs. These companies ask the U.S. government to look out for their interests in both the U.S. and overseas markets through ongoing efforts to lower tariffs, streamline and simplify regulations, and ensure a level playing field against foreign competitors based in countries throughout the world. Despite the steady growth seen in the largest medical device markets (the U.S., EU and Japan), the most promising markets for these products are located elsewhere, including China, India, and countries and markets in Southeast Asia and Latin America, most notably Brazil. Through bilateral and multilateral forums, the U.S. government stands ready to help the medical device sector further develop and enhance its global competitiveness and make a meaningful contribution towards improving public health worldwide.

ATTACHMENT 1



Source: "State Impacts of the Medical Technology Industry," prepared by The Lewin Group, Inc. and AdvaMed.

The table below summarizes trade flows by NAICS code for the medical device sector (separate trade data for in-vitro diagnostics is not currently available; export/import figures are in billions of dollars).

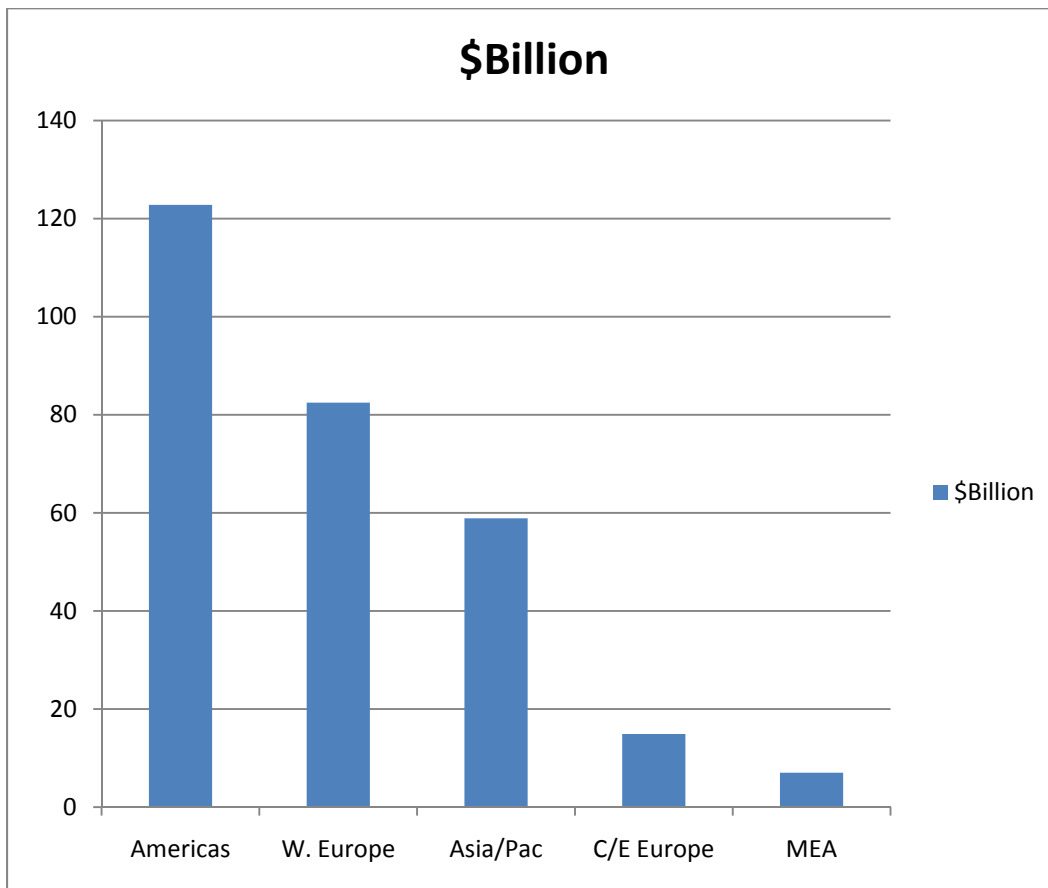
NAICS Code/Description	2007 Exports	2008 Exports	2007 Imports	2008 Imports
334510 – Electro-medical Apparatus	7.2	8.08	6.8	7.22
334517 - Irradiation Apparatus	3.1	3.34	3.6	3.72
339112 - Surgical and Medical Instruments	8.8	9.98	8.8	9.14
339113 - Surgical Appliances and Supplies	6.8	7.39	7.3	9.01
339114 - Dental Equipment and Supplies	1.1	1.22	1.2	1.28
339115 - Ophthalmic Goods	1.3	1.39	3.3	3.26
Total	28.3	31.40	31.0	33.63

Medical Devices Market: Forecast for Growth

Region	2009	2010	2011	2012	2013
Americas	102.4	107.1	112.1	117.4	122.8
Asia/Pacific	42.5	46.1	49.9	54.3	58.9
Central/E Europe	10.3	11.3	12.4	13.6	14.8
M East/Africa	5.7	6.0	6.3	6.7	7.0
Western Europe	62.3	66.7	71.6	76.9	82.5
Total	223.2	237.2	252.3	268.9	286.0

Source: Medical Market Fact Book 2008

World Overview - Projected Total Medical Devices Market by Region 2013



Source: Medical Market Fact Book 2008