AMERICAN ACTION FORUM

Primer: The Medical Device Industry

Han Zhong | Updated June 2012

Introduction

Medical device manufacturing is one of America's last unique frontiers. This is an industry that provides breakthrough treatment options that lengthen and improve the quality of life for millions. Broadly, medical devices are instruments used for the diagnosis and treatment of conditions in patients. Medical devices vary greatly in complexity from toothbrushes to implantable pacemakers. The Food and Drug Administration's Center for Device and Radiological Health (CDRH) branch is primarily responsible for the review and approval of medical devices.

Medical Device Categorization and Regulation

In contrast to prescription drugs, medical devices do not achieve their primary therapeutic or diagnostic purpose by way of a chemical reaction with a bodily process. This report focuses on medical devices that that have an electrical component, meaning that an electrical current is required for these devices to function. These devices can be placed into three broad categories: electromedical devices, electrotherapeutic devices and irradiation equipment. Electromedical devices are used for diagnosis of diseases and include a variety of visualization equipment (endoscopes, otoscops, retinoscopes, etc.), laser equipment and other types of analysis equipment.

Key Takeaways

Uniquely American industry

- The 828 companies in the high tech medical device industry generate in excess of $60 billion in revenue and employ over 88,000 workers.
- Medtronic, GE and St. Jude Medical are the top three grossing companies, controlling 31.9% of market share

Growing regulatory burden

- U.S. dominance in the global medical technology market is receding. The average total time for the FDA to reach a decision through the 510(k) procedure has risen from 90 days in 2005 to 140 days in 2010, an increase of over 55 percent

Slowing projected growth

- Although industry revenue is projected to grow on average 6.6 percent per year from 2012 to 2017, uncertainties introduced by the PPACA and lagging device approval times by the FDA is expected to slow growth after 2016
- The PPACA contains a medical device excise tax which will cost the industry $20 billion over the next decade

Electrotherapeutic devices are used in the treatment of diseases, specifically through the application of an electric impulse. Pacemakers and nerve stimulators are two types of devices that would fall under this category. Irradiation equipment utilizes high-energy electromagnetic waves such as X-rays and gamma-rays in both diagnostic and therapeutic settings. X-ray machines, X-ray computed tomography scanners (CT scanners) and associated parts (lamps, tubes, etc) are examples of irradiation equipment[i].

Medical devices can also be classified by the field of medicine in which they are intended to be used. The fields with the highest grossing markets are as follows: spinal devices, cardiovascular devices, neuromodulation devices, diabetes devices, urology devices and surgical technologies (Figure 1). The FDA categorizes devices in a similar manner with 1,700 specific types organized into 19 medical specialty panels[ii]. In addition to grouping devices by

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their specific medical field, the FDA also classifies devices based on their risk to inflict harm (Table 1). Depending on the level of risk a device poses, it is then subject to an approval process. Most devices are approved via the less costly 510(k) process that usually does not require clinical trial data. Premarket Approval (PMA) is reserved for pioneering devices and is a more complex process that requires clinical data before a device can be marketed.

Figure 1: Major Device Product Segmentation by Revenue[iii]

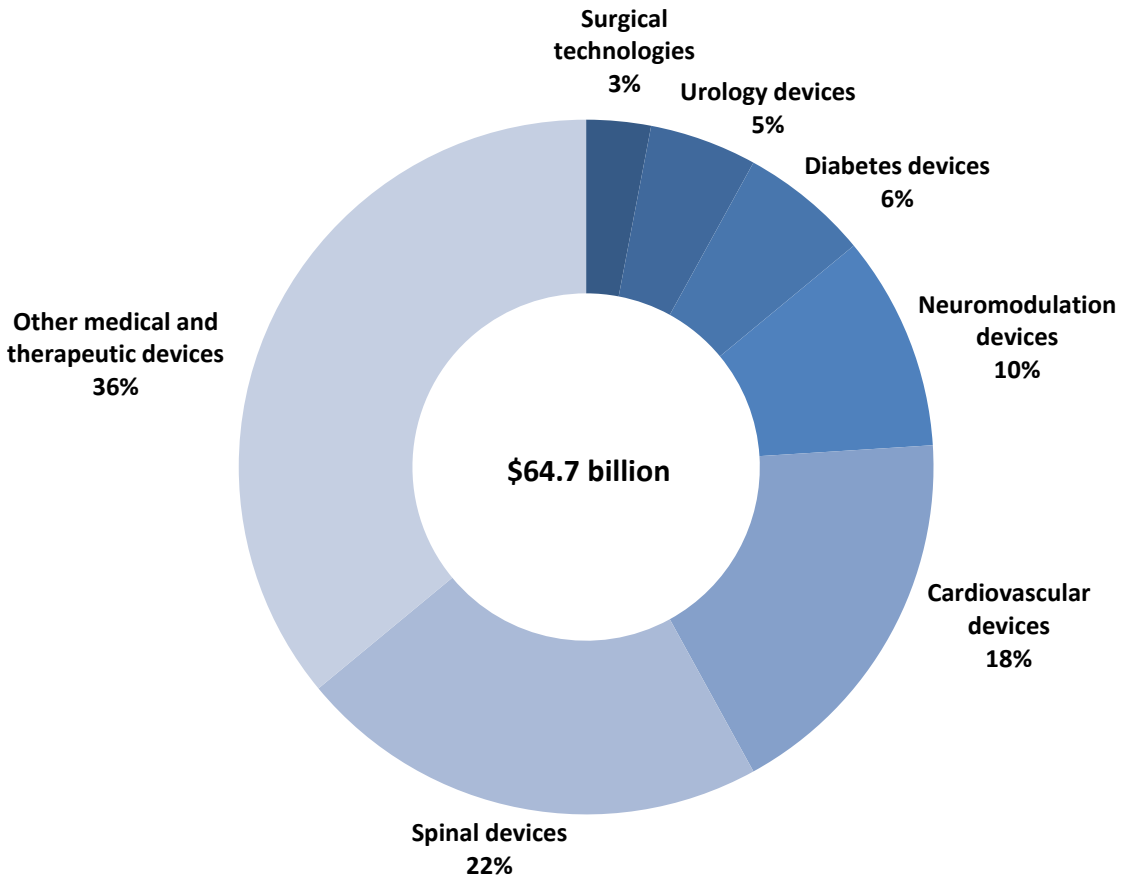


Table 1: FDA Device Classifications[iv]

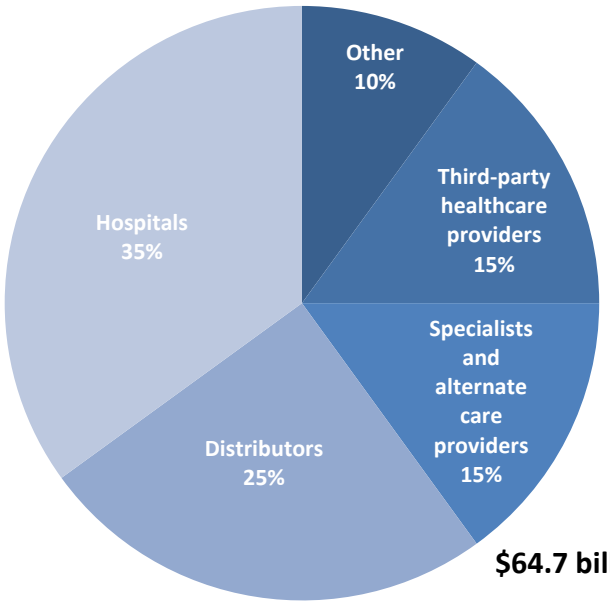
Device Classification	Examples	Required Submission
Class I (low-risk)	Elastic bandages, examination gloves, hand-held surgical instruments	Registration only unless 510(k) specifically required
Class II (moderate-risk)	Powered wheelchairs, infusion pumps, surgical drapes	510(k) clearance unless exempt; IDE[1] possible
Class III (high-risk)	Heart valves, silicone gel-filled breast implants, implanted cerebella stimulators	PMA approval unless 510(k) exempt; IDE probable

[1] IDE: Investigational Device Exemption; application to FDA that allows for the use of a device in clinical trials.

Major Markets and Determinants Driving Demand

Although the end-users of certain medical devices like pacemakers and insulin pumps are patients, devices are primarily marketed to healthcare providers (Figure 2). Only hospitals and other large healthcare provider groups have the purchasing power to buy expensive equipment such as a magnetic resonance imaging (MRI) machine or a CT scanner. Like the pharmaceutical industry, the demand of medical devices is largely based on insurance coverage, age demographics, and the health of the public—the sicker the insured population, the greater the demand for medical devices. Medical specialists also place a high demand on new technologies to better serve their patients. The demand for better devices necessitates the industry to develop new and innovative products.

Figure 2: Major Market Segmentation[v]



$64.7 billion

Economic Impact

The medical device industry is profitable and has grown despite the recent recession. Its 1,494 establishments employ nearly 88,000 workers and pay over $13.8 billion in wages. In 2012, the industry is expected to bring in $64.7 billion in revenue, $5.8 billion of which will be profit. The growth trend is projected to continue through 2016, but is expected to slightly decline (Table 2).

Table 2: Medical Device Industry Statistics and Projections[vi]

Year	Revenue		Companies	Employment	Wages ($m)	Share of the economy (% GDP)
	($ million)	% change from previous year				
2010	55,399.1	+15.9	904	87,280	12,741.8	0.15
2011	60,243.3	+8.7	868	87,804	13,856.0	0.16
2012	64,681.4	+7.4	828	88,506	14,876.7	0.16
2013	68,228.1	+5.5	782	89,037	15,521.9	0.16
2014	71,440.4	+4.7	735	89,571	16,252.7	0.17

Major Companies (Table 3)

Medtronic Inc., General Electric Company (GE) and St. Jude Medical Inc. control 31.9 percent of the market share on medical devices[vii]. Cardiac rhythm management devices (defibrillators, pacemakers, etc.) are the largest source of revenue for both Medtronic and St. Jude whereas GE focuses on the manufacturing of diagnostic imaging technologies like CT and MRI machines and parts. Medical device companies spend a large percentage of total sales on research and development (R&D) to create the next wave of treatment options. In 2011, Medtronic and St. Jude spent $1.5 billion[viii] and $705 million[ix] on R&D, respectively.

Table 3: 2010 US Sales Statistics for Top Three Medical Device Companies[x]					
Company	Revenue			Operating Income	
	($ million)	% change from previous year	Market share (%)	($ million)	% change from previous year
Medtronic Inc.	9,120	-2.6	14.8	2,421.2	-6.2
General Electric Company	8,091.1	+7.0	12.9	1,254.2	+11.6
St. Jude Medical Inc.	2,647.6	-0.3	4.2	627.0	-12.8

Industry Prospects

The revenue of the medical device industry is projected to grow by 6.6 percent annually between 2012 and 2017.[xi] Factors that contribute to the growth include the growing number of seniors, who are more likely to develop chronic diseases like diabetes, and the expansion of coverage by the Patient Protection and Affordable Care Act (PPACA). Because more Americans will have insurance due to the PPACA, a greater number of individuals will seek out physicians for their illnesses, leading to a greater demand for medical devices. However, the PPACA also contains a 2.3 percent excise tax on the sale of medical devices starting 2013.[xii] The tax is projected to generate $29.5 billion in revenue for the federal government over the next decade. It has a negative impact on the innovative nature of the industry: jobs will be cut and fewer devices will be developed for patients in need of treatment.

Changes to the approval processes in the upcoming reauthorization of the Medical Device User Fee Amendments (MDUFA) will affect the medical device industry. Approvals through the 510(k) and PMA process have slowed considerably since the implementation of MDUFA II. The average total time for the FDA to reach a decision through the 510(k) procedure has risen from 90 days in 2005 to 140 days in 2010, an increase of over 55 percent.[xiii] Recent recalls of malfunctioning devices have caused patient protection groups to cry foul, leading to the FDA's increasingly risk-averse regulatory approach. These recalls, however, only represent a miniscule percent of the medical devices that are approved by the FDA.[xiv] The Center for Device and Radiological Health is in the midst of an internal review of the 510(k) process with the goal of addressing factors that are slowing the approval process and hampering the industry's ability to introduce novel medical treatment technologies.

As a result of the review, the proposal includes provisions to streamline the application and approval process for medical devices and a plan to hire 240 new full-time employees to expedite the process. The FDA will fund these improvements with a 14 percent increase in fees by 2017 and will also create an inflation adjustment mechanism for future fee structures. Other changes include removing exemptions for registration fees that were previously available for certain establishments, as well as granting the secretary of Health and Human Services the right to waive fees in cases of pressing public health concerns. The proposal was included in legislation that passed both the House of Representatives and the Senate in June 2012. Together, the bills received bipartisan support and were passed by both the House and the Senate.

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[ii] Food and Drug Administration, *Device Classification Panels.* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051530.htm, Accessed August 16, 2011.
[iii] Adapted from Samadi N. Op cit.
[iv] Adapted from Congressional Research Service. "CRS Report for Congress: Medical Device User Fee and Modernization Act (MDUFMA) Reauthorization." 2005.
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[vi] Samadi N. Op cit.
[vii] Samadi N. Op cit.
[viii] Medtronic. *2011 Annual Report*.
[ix] St. Jude Medical. *2011 Annual Report.*
[x] Samadi N. Op cit.
[xi] Samadi N. Op cit.
[xii] 111th Congress. *Health Care and Education Reconciliation Act of 2010, Section 1405*.
[xiii] Shuren J testimony found in Congressional Hearing on "Regulatory Reform Series #5 - FDA Medical Device Regulation: Impact on American Patients, Innovation, and Jobs," July 20, 2011.
[xiv] California Healthcare Institute. "Upcoming Changes to the 510(k) Process." 2011.