

Healthcare & Life Sciences

Issues and Opportunities Facing US Medical Device
Manufacturers

The Playing Field is Changing



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Medical Devices, products designed and manufactured to diagnose and treat healthcare patients worldwide, range from bandages to highly complex, programmable pacemakers and imaging systems. The US Medical Device industry will generate an estimated \$60.2 billion in 2011 revenues, having posted average annual growth of 16.3% from 2006 through 2011. The US Medical Device industry is expected to grow at a more moderate 6.4% in the five years through 2016 to an estimated \$82.1 billion in 2016 revenues. That growth largely will reflect increasing numbers of aging baby boomers requiring higher levels of medical care as constrained by a growing governmental role in healthcare distribution, related cost containment and regulatory intervention.

As a pivotal component in patient care today, Medical Devices may or may not be used in conjunction with pharmaceuticals from which they differ in two key respects: medical devices do not work via chemical reaction and are not metabolized in the body as is the case with pharmaceuticals.

The US Medical Device industry is comprised of as many as 100 industry subsectors that fall within seven major Medical Device industry segments ranked below in order of their respective 2007 shares of industry-wide total value of shipment (VOS):

Surgical Appliances and Supplies (NAICS Code 339113) accounts for some 27% of the industry's total VOS, including: artificial limbs, joints and orthopedic appliances; surgical dressings, kits, gloves and drapes; stents; hydrotherapy appliances and wheelchairs.

Surgical and Medical Instruments (NAICS Code 339112) generates some 25% of the industry's total VOS, including: anesthesia equipment; orthopedic instrumentation; optical diagnosis apparatus; catheters, and transfusion devices, syringes and hypodermic needles.

Electro-Medical Equipment (NAICS Code 334510) accounts for some 18% of the industry's total VOS, including: patient monitoring systems, MRI machines, pacemakers, diagnostic imaging (and informatics) equipment and ultrasonic scanners.

In-Vitro Diagnostic Substances (NAICS 325413) generates some 9% of the industry's total VOS while including: the chemical, biological and/or radioactive substances used in diagnostic tests, and other diagnostic test-type devices.

Irradiation Apparatus (NAICS 334517) accounts for some 7% of the industry's total VOS while including: x-ray and other diagnostic imaging devices and computed tomography equipment.

Dental Equipment and Supplies (NAICS 339114) generates some 5% of the industry's total VOS while including: the instruments, equipment and supplies used by dentists and dental hygienists (drills, hand instruments, amalgams, cements, plaster, sterilizers, and dental chairs).

Ophthalmic Goods (NAICS 339115) accounts for some 5% of the industry's total VOS while including: eyeglass frames and lenses and related optical and magnification products.

Dental Laboratories (NAICS 339116) generates some 4% of the industry's total VOS, including the production of dentures, bridges, crowns and other orthodontic products.

The US Medical Device Industry is world-renown for the technological innovations and high quality that reflect significant R&D investments over time. Of approximately 5,300 US medical device companies operating the US in 2007, most of them were small and medium-sized companies (SMEs): 73% of US medical device firms employed fewer than 20 people. While US medical device firms are scattered throughout the country, they tend to concentrate in regions best known for high-tech and biotech in such states as California, Florida, New York, Pennsylvania, Michigan, Massachusetts, Illinois, Minnesota and Georgia.

Leading medical device manufacturers include: Abbott Laboratories, American Medical Systems Holdings, Baxter International, Becton Dickinson, Beckman Coulter, GE Healthcare Technologies, Johnson & Johnson, Medtronic, Roche Holding, Smiths Group, St. Jude Medical, Stryker, Zimmer Holdings and Zoll Medical.

Innumerable advances in medical device design and distribution have facilitated often life-saving earlier detection of a host of diseases while increasing the number and effectiveness of treatment options. Nanotechnologies and minimally invasive surgical techniques have achieved dramatic advances. Historically, the US has led the world both in the production and consumption of medical devices. While many industries faced downturns during the 2008/2010 global recession, the US Medical Device industry weathered the storm by posting consistent, continuing growth.

The US Medical Device industry is a global leader given its ability to introduce new, innovative and lifesaving technologies and is well-positioned for worldwide growth as global populations age and as demand for cutting edge healthcare increases in developed and developing nations alike.

The Future: Challenges Ahead

After averaging 16.3% annual growth in five years through 2011, US Medical Device industry growth is projected to fall to 6.4% in the five years through 2016's projected \$82.1 billion in revenues. While 6.4% annual growth likely will eclipse growth of the US economy by a significant margin through 2016, the US Medical Device industry faces numerous and significant challenges.

The Patient Protection and Affordable Care Act of 2010 ("PPACA") This highly controversial law, even now being challenged in court cases across the country, includes many provisions that could adversely impact the US Medical Devices industry, including an excise tax on medical devices that is expected to reduce industry profitability to 8.5% of revenue by 2016, vs. 9.0% in 2011. The extensive growth in governmental bureaucracies that likely will result should the PPACA become fully implemented could dictate the levels of care to be received by US citizens, quite possibly reducing demand for medical devices. As yet, many aspects of the law remain unknown, even unknowable. Among these is whether or not the Congress or the courts eventually might repeal the PPACA. Uncertainty, in any industry, is bad news for company owners and consumers alike: uncertainty causes companies to defer capital decisions, R&D, and hiring (or to off-shore some or all business operations). Yet now more than ever before, the future is uncertain.

Potential Patent and Intellectual Property Implications of the Patient Protection and Affordable Care Act of 2010

Middle market businesses, inventors, patent holders, among others, closely are following provisions and amendments concerning patent validity challenges. The current system has been criticized as too friendly to deep-pocketed infringers and other third parties that undermine the potential market value of IP generated by smaller innovators and middle market businesses. Current legislation contemplates forming an additional administrative track that would allow more robust reviews and challenges on a broader scale and scope than the existing patent challenges permit. Yet this alternative track has come under criticism by intellectual property litigators who believe that it could significantly reduce the value of patents by creating too many opportunities for third parties to disrupt and delay a filer's patenting process. Enacting appropriate safeguards that prohibit the gaming of the system by infringers and other third parties is necessary for any such legislation to effectively protect the patent process and promote new product development and innovation.

General Cost Containment Initiatives by Government Programs and Private Insurers Explosive growth in healthcare costs has forced government programs and private insurers to redouble cost containment efforts. The degree to which the PPACA, Medicare, Medicaid and private insurers limit payments for treatments involving medical devices, those devices will face increasing pricing pressures that are exacerbated by the large buying groups/distributors that force pricing concessions, thereby reducing US medical devices' profitability, their manufacturers' ability to operate and fund R&D, and making it significantly more difficult for smaller players that pervade the industry to survive.

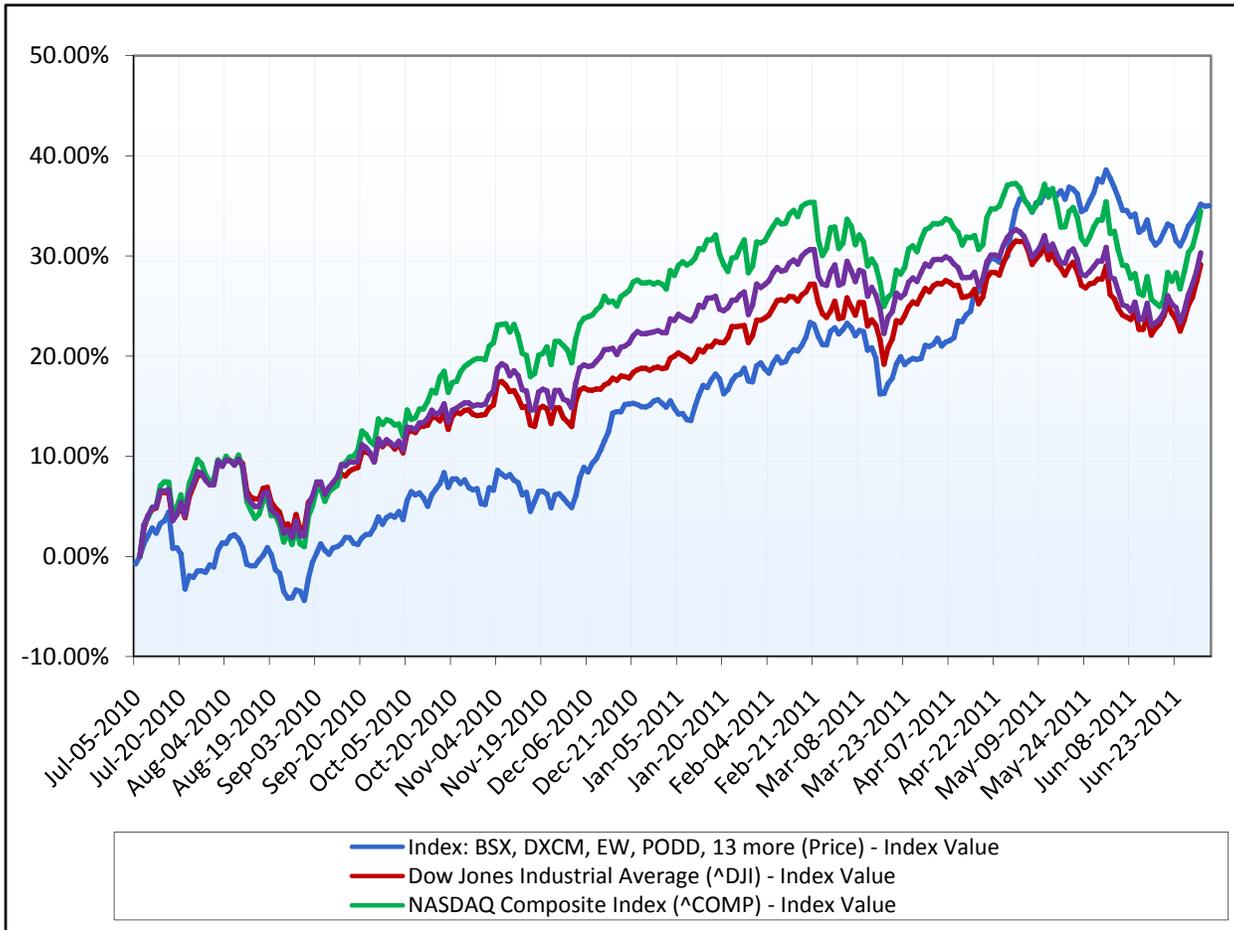
Increasing Regulatory Oversight and Intervention Despite astonishing technological advances in recent years, the US medical device industry also has faced setbacks when devices failed to perform as required, resulting in injuries, deaths or serious inconvenience. Such failures have triggered costly recalls and more stringent – and oftentimes more ambiguous – oversight by the US Food and Drug Administration in particular. Going forward, anticipated changes in FDA 510(k) approvals are expected to increase regulatory costs significantly while hindering innovation. Here, too, uncertainty as to future bureaucratic approaches has been blamed for increased outsourcing of medical device design and fabrication activities abroad to the detriment of profit margins and industry long-term effectiveness. An increasingly complex global regulatory environment promises further challenges and complicated – at significant expense – in years to come.

Double-Dip Recession? As global economies face increasingly unprecedented stresses, particularly in Europe, the US faces a growing likelihood of double-dip recession and possible “stagflation.” While the “baby boomer” generation – Americans born between 1946 and 1964 – is now reaching retirement age and becoming a significant factor in US medical device consumption, financial strains on this and other US demographics may undercut medical device industry growth that otherwise has been projected.

Given that the US medical devices industry is dominated by the 73% of firms having 20 people or less, the challenges facing the industry likely will lead to further consolidation because the larger firms in the industry tend to be better-positioned to negotiate the complexities of government bureaucracies and regulation while also enjoying the economies of scale that foster continued profitability in price-constrained environments. On the flip side, smaller medical device firms tend to be drivers of innovation that may be highly attractive acquisition candidates for their larger, US and multinational counterparts.

And so it is that with the challenges that lie ahead come opportunities in the US medical devices industry.

Mid-Tier Indexes vs. Major Indexes



The McLean Group’s Medical Device Index is comprised of the following companies: Boston Scientific Corporation (NYSE: BSX); DexCom, Inc. (NasdaqGM: DXCM); Edwards Lifesciences Corp. (NYSE:EW); Insulet Corporation (NasdaqGM:PODD); Integra LifeSciences Holdings Corporation (NasdaqGS:IART); Olympus Corporation (TSE:7733); Roche Holding AG (SWX:ROG); Smiths Group plc (LSE:SMIN); Sorin SpA (BIT:SRN); St. Jude Medical Inc. (NYSE:STJ); Stryker Corp. (NYSE:SYK); Synthes Inc. (SWX:SYST); Terumo Corporation (TSE:4543); Urologix, Inc. (NasdaqCM:ULGX); Zimmer Holdings, Inc. (NYSE:ZMH); ZOLL Medical Corp. (NasdaqGS:ZOLL), and American Medical Systems Holdings Inc. (NasdaqGM:AMMD).

Recent Merger & Acquisition Transactions

Closed Date	Target	Buyer/Investors	Size (\$mm)	LTM Total Rev (\$mm)	LTM Net Income (\$mm)	EBITDA (\$mm)	TTV/ Total Rev (\$mm)	TTV/NI	TTV/ EBITDA
6/30/11	Beckman Coulter	Danaher Corp. (NYSE:DHR)	\$7,392.9	\$3,663.4	\$230.7	\$796.6	2.0	32.0	9.3
6/17/11	American Medical Systems Holdings	Endo Pharmaceuticals Holdings Inc. (NasdaqGS:ENDP)	\$2,825.1	\$548.2	\$87.6	\$178.1	5.2	32.2	15.9
4/14/11	CaridianBCT	Terumo Corporation (TSE:4543)	\$2,625.0	\$0.0	\$0.0	\$0.0	N/A	N/A	N/A
4/4/11	Athena Diagnostics	Quest Diagnostics Inc. (NYSE:DGX)	\$740.0	\$36.3	\$6.9	\$13.8	20.4	107.1	53.8
3/4/11	Genoptix	Novartis Finance Corporation	\$449.5	\$196.9	\$22.7	\$47.0	2.3	19.8	9.6
3/3/11	Atritech	Boston Scientific Corporation (NYSE:BSX)	\$375.0	\$0.0	\$0.0	\$0.0	N/A	N/A	N/A
1/6/11	Interlace Medical	Hologic Inc. (NasdaqGS:HOLX)	\$351.8	\$0.0	\$0.0	\$0.0	N/A	N/A	N/A
5/27/11	Orthovita	Stryker Corp. (NYSE:SYK)	\$331.1	\$94.4	-\$5.7	\$2.9	3.5	-58.2	115.5
6/1/11	TCT International	Hologic Inc. (NasdaqGS:HOLX)	\$300.0	\$0.0	\$0.0	\$0.0	N/A	N/A	N/A
6/15/11	Vital Images	Toshiba Medical Systems Corporation	\$269.8	\$59.8	\$0.2	\$1.6	4.5	1,404.5	167.5
5/4/11	NovaMed	Surgery Partners LLC	\$216.7	\$151.8	\$7.2	\$42.0	1.4	29.9	5.2
4/29/11	Cadent	Align Technology Inc. (NasdaqGS:ALGN)	\$190.0	\$0.0	\$0.0	\$0.0	N/A	N/A	N/A
4/2/11	CITIC Pharmaceutical	Shanghai Industrial Medical Technology (Group) Co., Ltd., Shanghai Pharmaceutical Co., Ltd. (SHSE:601607)	\$188.4	\$0.0	\$0.0	\$0.0	N/A	N/A	N/A
4/4/11	CareFusion Corporation, International Surgical Products Distribution Business	Medline Industries, Inc.	\$130.0	\$3,921.0	\$156.7	\$713.0	0.0	0.8	0.2
3/8/11	Medicel AG	Halma plc (LSE:HLMA)	\$107.5	\$0.0	\$0.0	\$0.0	N/A	N/A	N/A
5/23/11	SeaSpine	Integra LifeSciences Holdings Corporation (NasdaqGS:IART)	\$89.0	\$0.0	\$0.0	\$0.0	N/A	N/A	N/A
7/1/11	Spirus Medical	Gyrus ACMI, Inc.	\$60.0	\$0.0	\$0.0	\$0.0	N/A	N/A	N/A

Stryker Corporation Buys Orthovita Inc.

Stryker Corporation (SYK), a leading medical technology company acquired orthobiologic and biosurgery products maker **Orthovita Inc. (VITA)** for a reported \$316 million in cash, including the assumption of \$12 million in Orthovita debt.

Orthovita shareholders will receive \$3.85 per share, a 41% premium vs. Orthovita's \$2.73 closing price as of May 13, 2011. The company booked \$95 million in 2010 sales. Pennsylvania-based Orthovita, a leader in synthetic bone grafts, competes in the \$5 billion orthobiologics – substances that help heal injuries – market. Orthovita's orthobiologics include its Vitoss bone graft substitute and Cortoss bone augmentation material. Orthovita's biosurgery business offers such hemostasis products as the Vitagel surgical hemostat.

Stryker's acquisition of Orthovita reflects an ongoing medical devices industry consolidation strategy as top-tier devices makers pursue growth by acquisition to enter new markets and diversify their product portfolios.

With \$7.3 billion in annual sales, Stryker aggressively is acquiring complementary businesses by leveraging its solid balance sheet. Its \$1.5 billion acquisition of **Boston Scientific's** (BSX) Neurovascular assets in January 2011 accelerated Stryker's diversification into fast-growing therapy markets. Stryker previously acquired privately-held medical products maker Gaymar Industries, thereby boosting its acute-care product offerings. This transaction also demonstrates the flexibility companies with strong balance sheets can exert in developing a target acquisition strategy to meet specific growth goals and market penetration points.

Stryker's Orthovita acquisition complements its existing orthobiologics offerings. Stryker is well-positioned to drive growth via new product launches, acquisitions and an improving hospital capital spending backdrop.

Toshiba Medical Systems Corporation Buys Vital Images, Inc.

Toshiba Medical Systems Corporation (TMSC) acquired Vital Images, Inc. (Nasdaq: VTAL) in a \$273 million cash tender offer transaction for \$18.75 per share. The deal allows TMSC to significantly strengthen its Imaging Solutions business by integrating technologies to deliver advanced visualization and imaging informatics to healthcare professionals and healthcare IT providers. Technology acquisitions such as this, offer companies to integrate efficiencies in existing product and service lines that generate organic sales growth and improve profitability.

Danaher to Buy Beckman Coulter, Inc.

Danaher Corporation (NYSE:DHR) acquired Beckman Coulter, Inc. (NYSE: BEC) for \$6.8 billion or \$83.50 per share, including debt assumption.

With \$3.7 billion in annual revenues, Beckman Coulter develops, manufactures and markets biomedical testing products. Physicians in hospitals and other clinical settings worldwide use Beckman Coulter systems to diagnose disease, make treatment decisions and monitor patients. Scientists use Beckman Coulter life science research instruments to study complex biological problems, to identify causes of disease and to explore potential new therapies or drugs.

As part of Danaher's Life Sciences & Diagnostics segment, Beckman Coulter will join Danaher's Leica, AB Sciex, Radiometer and Molecular Devices businesses. This is a good example of an acquisition strategy whereby new technologies are purchased as opposed to developed internally to meet growing customer needs.

Endo Pharmaceuticals Holdings Inc. Buys American Medical Systems

Endo Pharmaceuticals Holdings Inc. (NasdaqGS: [ENDP](#)) purchased American Medical Systems, a leading pelvic-health device provider, in a \$2.9 billion all-cash deal. The acquisition diversifies Endo Pharma's specialty healthcare solutions, including branded products and specialty generics, while bolstering its urology portfolio.

American Medical is Endo Pharma's fourth major acquisition since 2010. Endo Pharma previously acquired generic company Qualitest Pharmaceuticals for \$1.2 billion, Penwest Pharmaceuticals Co. and HealthTronics, Inc. Such acquisitions may help Endo Pharma counter revenue losses posed by generic pharmaceuticals, especially where Endo Pharma's leading pain medication, Lidoderm, is considered. Endo Pharma's pain products compete with such leading pharmaceutical firms as **Pfizer** (NYSE: [PFE](#)) and **Cephalon Inc.** (NasdaqGS: [CEPH](#)).

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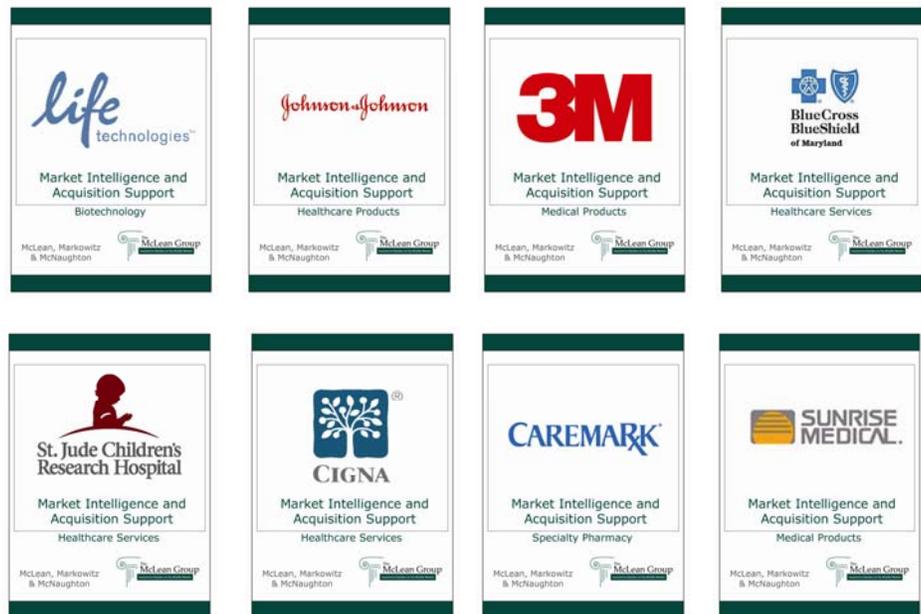
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THE MCLEAN GROUP HEALTHCARE & LIFE SCIENCES SERVICES PRACTICE

The McLean Group’s Healthcare team supports middle market healthcare companies by leveraging exceptional expertise in mergers and acquisitions and capital formation services. From identifying suitable acquisition targets to augment organic growth or build strategic capabilities, to providing advice on how to maximize the value owners realize when selling their businesses, to raising capital from private institutional sources to scale up operations, our Healthcare practice is committed to helping clients achieve their specific goals.

Our Healthcare team focuses on various industry sectors, including: healthcare information technology, medical devices, and biotechnology, among others.

Select Healthcare & Life Sciences Engagements



THE MCLEAN GROUP OVERVIEW

About the Author

Brian Sullivan, Managing Director of The McLean Group’s Silicon Valley, CA office, specializes in providing M&A solutions to middle market businesses.

The McLean Group is an investment bank providing mergers and acquisitions (M&A), capital formation, market intelligence, business valuation, litigation support and exit planning services to middle market businesses. Headquartered in the Washington, DC metropolitan region, the firm has a presence in more than 30 cities in the US, serving domestic and international clients with a broad resume of successfully consummated financial transactions. Our research staff leverages state-of-the-art, proprietary corporate information and transaction data, providing our clients with unmatched information on which to make transaction decisions.