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Healthcare: Products & Supplies

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CURRENT ENVIRONMENT

Fundamentals stabilize and visibility improves with healthcare reform in focus

Growth prospects for medical device companies are being crimped by the continued global economic weakness, particularly in Europe. With healthcare reform underway, S&P Capital IQ (S&P) thinks the visibility for the group is improving, as investors gain some clarity on the extent to which the industry will be involved in the reform process. However, one of the changes brought about by the healthcare reform is the 2.3% excise tax on medical devices, which will adversely impact the margins and profitability of medical device manufacturers.

The medical technology (medtech) sector is weathering a perfect storm caused by the move toward value-based healthcare due to healthcare reform, growing regulatory pressures, and resource constraints within the industry itself. According to Ernst & Young's *Pulse of the Industry: Medical Technology Report 2013* (latest available), the industry is undergoing a fundamental change, with the customer base shifting from medical practitioners to payers, health systems, and patients. Consumers have become more vocal than in the past and are asking for value-based healthcare. Companies are also facing resource constraints, as financing has become increasingly scarce for small companies, while slowing growth has resulted in "lost" revenues of $131 billion and "lost" research and development (R&D) valued at $12 billion between 2008 and 2012.

For the next 12 months, our fundamental outlook for the healthcare equipment sub-industry is neutral, and we think visibility has improved. In *Medtech Half-Year Review 2014*, market research company EvaluateMedTech revealed that the medtech market is enjoying improvements across the board, following weak performance over the past few years. According to a study released in September 2013 by Advanced Medical Technology Association (AdvaMed), a medical-device industry trade group, average inflation-adjusted prices for the seven largest categories of medical devices fell by nearly a third from 2007 through 2011. Further, between 1989 and 2011, device spending only grew from 5.3% to 5.9%. Even so, EvaluateMedTech noted in an earlier report published in September 2013 that despite a gloomy 2013, the medical devices and diagnostics market is expected to grow at a compound annual growth rate (CAGR) of 4.5% between 2012 and 2018 to reach $455 billion.

Moving into the specificities of the improvement in the industry, EvaluateMedTech highlighted in its 2014 half-year review that mergers and acquisitions (M&A) activity, Food and Drug Administration (FDA) approvals, and stock performances have outperformed 2013. First, the combined value of medtech mergers in the first half of 2014 ($27 billion) is more than it was in full-year 2013 ($19 billion). This value may further accelerate toward the end of 2014, largely due to the $42.9 billion deal between Medtronic and Covidien. Second, in the first half of 2014, the FDA awarded 17 first-time premarket approvals (PMAs) compared with nine PMAs during the same period in 2013. Finally, also in the first half of 2014, top risers in terms of stock price compared with year-end 2013 were Covidien plc (32%), Johnson & Johnson (14%), Stryker Corp. (12%), St. Jude Medical, Inc. (12%), and Zimmer Holdings Inc. (11%).

The tightening of regulatory standards, in both the US and Europe, is another trend affecting the industry. While the EU has proposed higher standards for device makers, the US is considering bringing laboratory-developed tests under its control. EvaluateMedTech has noted that the industry is facing a shortage of funds as venture capital funding is drying up, as investors have to wait longer for payback due to a lengthy approval process. In essence, changes in the regulatory standards of the EU and US would entail that medical device manufacturers will have a more burdensome product review and certification process, thereby potentially requiring a greater investment of time and resources. During the first quarter of 2014, the medical device industry saw a 5% increase in the value of venture capital investment on a year-on-year basis, although deal volume declined 17.6%, according to the *MoneyTree Report* published in May 2014 by PricewaterhouseCoopers LLP and the National Venture Capital Association (NVCA). Only 61 deals were

completed in the first quarter of 2014, the lowest deal activity in the industry since 2004, which captured $588 million dollar value.

Overall, in 2013 and year to date through September 12, 2014, both the S&P Health Care Equipment and the S&P Health Care Supplies subindices underperformed in the Health Care sector. Year to date through September 12, 2014, Health Care Equipment rose 12.4% whereas Health Care Supplies declined 0.1%, and these performances are below the 14.1% rise of the S&P Health Care index. Meanwhile, the S&P 1500 Composite Index rose 7.0% in year to date through September 12, 2014.

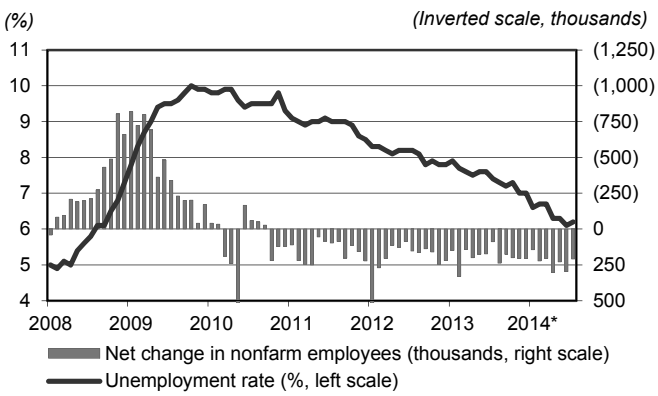
Challenging macroeconomic environment

While the high level of unemployment caused by the recession has resulted in lower hospital inpatient and outpatient utilization and higher hospital uncompensated care costs, we think that hospital capital expenditures (capex), now near historic lows, may have touched bottom. The drop in hospital capex had resulted in a slowing in demand for the medical devices industry. We think the demand has begun to improve selectively for devices that hospitals use to drive volume and that provide a relatively high return on investment. However, unit demand in certain categories—such as cardiac rhythm management (primarily implantable cardioverter defibrillators, or ICDs, and pacemakers), and hip and knee implants—has not held up in the US, albeit for different reasons. Meanwhile, procedure rates in the EU have also remained soft, with only mild signs of stabilization in countries such as the UK, Germany, and France. The medical devices industry has begun to rely increasingly on other international markets, particularly emerging countries, to compensate for sluggish US and EU growth.

This highly diversified industry has been supported by favorable global demographic trends, such as aging populations, more active seniors, and an expanding middle class in emerging markets. In addition, healthcare reform in the US has enabled insurance coverage for millions of people who did not have it, thereby expanding the potential domestic customer base.

We see a scarcity of life-altering new products coming out of R&D, such as ICDs and cardiac stents, which spurred industry growth over the past decade. Although we see products that will help expand existing categories (such as second-generation, bio-absorbable drug-coated stents, cardiac resynchronization therapy defibrillators, or CRT-Ds, and transcatheter aortic valves), we have seen little in the way of new products that would be considered revolutionary.

The medical device tax, which went into effect on January 1, 2013, is one of the fees and taxes the affordable care act (ACA) introduced to reform the healthcare system in the US, and it is adding pressure to the industry. For the medical device group, there is a 2.3% excise tax on sales of most kinds of supplies and equipment sold in the US. The tax is expected to raise nearly $30 billion over the next 10 years. In 2013, medical device excise tax paid by Johnson & Johnson, Boston Scientific, Covidien, Smith & Nephew, and Hill-Rom reached $369.3 million, according to a Kalorama Information report published in May 2014.



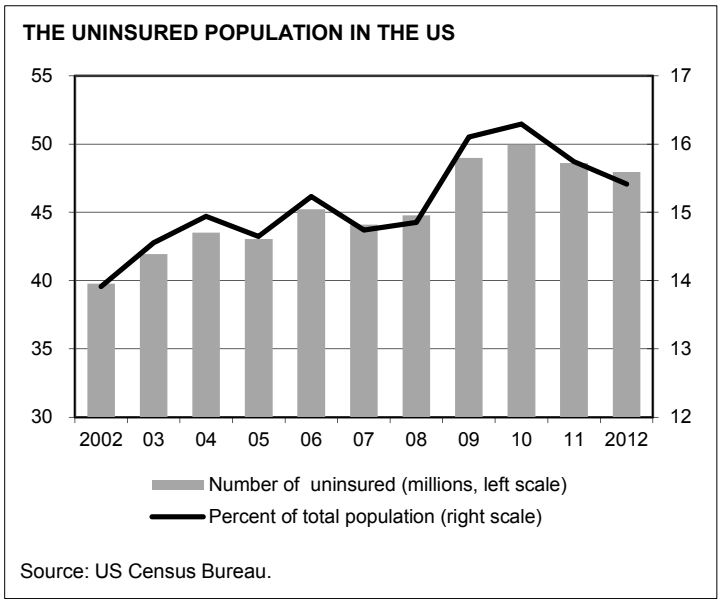
In addition to the medical device tax, price competition and tight hospital budgets also hurt the industry. In its *Pulse of the Industry: Medical Technology Report 2013* (latest available), Ernst & Young noted that the medtech sector is facing pricing pressure following the move toward value-based healthcare. This has pushed companies, which earlier focused on care practitioners, to find new ways to create, deliver, and capture value.

The US unemployment rate stood at 6.2% in July 2014, down from 7.4% in July 2013. Standard & Poor's Economics, which operates separately from S&P, thinks this measure peaked at 10.1% in October 2009. There were 209,000 additions to nonfarm payrolls in July 2014, much higher than the 149,000 additions a year prior.

For the remainder of 2014, we expect the industry to continue to face a difficult, but modestly improving, macroeconomic environment. While we still expect these conditions to lead to elongated capital equipment procurement cycles, additional deferrals of nonessential equipment, and reduced spending on add-on features, we see hospitals spending in areas where they can differentiate themselves from competitors. We also look for healthcare products and supplies companies to see a continuation of pricing pressures, as the macroeconomic factors described contribute to slower sales growth. Amid these headwinds, we think that the industry is turning to emerging markets (such as China and India) to continue its growth.

HEALTHCARE REFORM ARRIVES TO RESPOND TO HEALTHCARE NEEDS

The US ranks among the lowest in the industrialized world in terms of access to healthcare for its citizens, notwithstanding the tremendous amount of resources it devotes to healthcare. Moreover, even with the expansion of Medicaid, the Children's Health Insurance Plan, and other private and government programs, the percentage of uninsured has remained stubbornly high since 2002. The US Census Bureau reported that the percentage of people covered by private health insurance has continued to decline, falling to 63.9% (latest available) in 2012 (unchanged from 2011) from 67.5% in 2008. Although the unemployment rate declined to 6.2% in July 2014 from 7.4% in July 2013, we note that employment does not guarantee the availability of health insurance. Indeed, many small businesses have dropped health insurance coverage during the recession and afterward, most likely due to untenable insurance premium price hikes. However, in 2014 the Obama administration reported that eight million people obtained health insurance through the healthcare exchanges and an additional five million enrolled in Medicaid. The non-partisan Congressional Budget Office (CBO) had estimated that six million people would obtain health insurance through the healthcare exchanges created through healthcare reform.



PRICING PRESSURE CONTINUES

As hospitals have looked to control capex and as overall industry demand has softened in response to both macroeconomic and industry factors, the medical device sector has faced increasing pricing pressure since the onset of the recent recession. AdvaMed's June 2014 report highlighted that medical technology prices lag behind the Consumer Price Index (CPI). Medical device and diagnostic prices increased from 1989 to 2011 at an average annual rate of 1.0%, compared with the CPI increase of 2.7%, the Medical Care CPI increase of 4.6%, and the Medical Care Services CPI increase of 1.0%.

ICDs: slower growth

The market for implantable cardioverter defibrillators (ICDs), which shock hearts with abnormal heart rhythms into beating normally, experienced a decline in annual growth rates from approximately 20% several years ago to the low-single digits in 2014 .

Within the cardiac rhythm management market, the global market for pacemakers has been strong, aided by developments in design and technology, according to market intelligence company Transparency Market Research, thus compensating for the drop in demand for defibrillators.

Cardiovascular: more competition and new product development in stents

We think pricing pressure, particularly in the drug-eluting stent (DES) market, reflects a number of factors, including increased competition, and hospital purchasing changes. Despite the number of factors that affect the DES market, the global DES market is expected to grow at a CAGR of 5.8% between 2013 and 2018, according to TechNavio's published report in January 2014 (latest available).

Competition is increasing as other companies develop new products. For instance, in September 2013, W.L. Gore & Associates launched the clinical trial of a stent designed to treat carotid artery stenosis. Medtronic received the CE mark in January 2013 (and FDA approval in September) for its Complete SE vascular stent for a new indication, extending the treatment to the arteries that supply blood to the legs. In November 2013, BIOTRONIK SE & Co. KG, a privately held German company, and Italian company Sorin Group each received the CE mark for their stents.

Orthopedics: slower growth in hip, knee replacements

Orthopedic device makers are experiencing slower growth in the number of hip and knee replacement procedures in the US. According to an August 2012 article in *Orthopedics Today*, the Millennium Research Group estimated that the US orthopedic extremity device market (which covers devices that treat hands, wrists, elbows, shoulders, feet, and ankles) should reach a total value of $4.2 billion by 2016, reflecting an annual growth rate of 3.4%. We attribute this trend partly to increased cost sharing required by the health insurance policies of those still covered. In addition, health insurers may be showing increased resistance to procedures they deem pricey and, in many cases, unnecessary.

We would expect these factors to exacerbate competition among device makers and lead to further downward price pressure for their products. Nevertheless, in conference calls and interviews, companies continue to say that the pricing pressure in the orthopedics arena is no different than it had been before the recession. However, we think the competition remains very high, particularly in the US knee and hip implant markets. Indeed, we see indications that companies have been facing pricing pressure for the past few years from the legal, regulatory, and market fronts, and do not see this easing in the foreseeable future.

In an attempt to counter the pricing pressure, companies have sought innovative ways to meet customer needs, including the development of new technologies, biomaterials, and minimally invasive surgical techniques. In August 2013, Zimmer Holdings won FDA approval for its Patient Specific Instruments Shoulder device. The device features 3D visualization software to allow surgeons to customize implant size and placement to each patient. The company noted that the device works in conjunction with its Trabecular Metal Reverse Shoulder system used in patients undergoing reverse arthroplasty surgery.

However, not all companies have been successful in the orthopedics market. Wright Medical Group, Inc. sold its OrthoRecon segment (its hip and knee implant business) to a Chinese company in January 2014 amid weak demand, and pricing and volume pressure, experienced throughout the orthopedic market. The company retained a subset of its orthopedic business. It is continuing to pursue growth in its more successful Extremities (foot and ankle) business.

Hospitals and insurers seek best prices

In its *Pulse of the Industry: Medical Technology Report 2013* (latest available), Ernst & Young noted that the customer base is shifting for medical technology companies, with payers, health systems, and patients becoming more influential than in the past. The report noted that these companies, which earlier focused on care practitioners, need to find new ways to create, deliver, and capture value. Kaiser Permanente, a large, not-for-profit hospital system, uses teams of surgeons to evaluate devices. We think other hospital systems have adopted these practices or similar ones. In addition, we see hospitals considering limiting vendor choice, which could give them some leverage over the vendors, while possibly allowing them to obtain quantity discounts. We also see these practices spreading to more facilities as a result of hospital-chain consolidation.

The medical devices industry has been attempting to show that it is not the primary cause of the rising cost in healthcare. According to a study conducted by AdvaMed published in June 2014, spending on medical devices moved up negligibly between 1989 and 2011 (to 5.9% of national health expenditures, from 5.3%), with most of the growth between 1989 and 1992. The study found the CPI for Medical Care Services to be 5% over that period, and the CPI for Medical Care to be 4.9%; in comparison, the overall CPI was 2.7%, and device and diagnostic prices increased at an annual average rate of 1%.

Medicare payment rates to hospitals also pressure prices on medical devices. On August 2, 2013, the Centers for Medicare & Medicaid Services (CMS) released its fiscal 2014 (October 1, 2013–September 30, 2014) Inpatient Prospective Payment System (IPPS). The final rule increases Medicare operating payment rates to general acute-care and long-term-care hospitals by 0.7%, compared with the 0.8% increase proposed in May and the 2.3% hike in the fiscal 2013 final rule. The latest increase reflects a temporary 0.8% reduction to implement the American Taxpayer Relief Act's requirement to recoup overpayments from prior years.

Competitive bidding enters the fray

The CMS issued plans for expanding its competitive bidding programs to involve certain durable medical equipment, orthotics, prosthetics, and supplies in January 2013. However, the industry expressed concern over CMS's plans, believing that the competitive bidding program does not lead to the most competitive rate, but to a low rate chased to the bottom by low-ball bids. In April 2013, despite these concerns, the CMS completed the second round of its competitive bidding program and awarded contracts to suppliers for providing equipment, such as wheelchairs and oxygen cylinders, to beneficiaries across 91 communities in the US. The CMS also awarded contracts to the suppliers of mail-order diabetic testing supplies equipment. According to the CMS, the bidding program resulted in savings of $202 million in the first year of implementation. Going forward, it is estimated that between 2013 and 2022, the bidding program will help save the Medicare Part B Trust Fund $25.7 billion, and that beneficiaries will save $17.1 billion due to lower coinsurance and premium payments.

However, suppliers believe that the program, along with the new medical device excise tax, is contracting the industry. According to the CMS, the new prices based on the second round of competitive bidding are 45% lower than the prices paid for the same items under Medicare. For mail-order diabetic testing supplies, prices are almost 72% lower. These significantly lower new prices went into effect on July 1, 2013.

HIGH-PRICED EQUIPMENT OUTLAYS RECOVERING, BUT STILL DOWN SIGNIFICANTLY

US hospitals have dramatically reduced purchases of high-priced capital equipment that, because of reduced reimbursement and stricter limitations on its use by the government and private payers, does not assure a reasonably quick return on investment. This reflects a deteriorating operating environment, rising levels of bad debt, and tighter capital markets. Such big-ticket items include the newer ultra-high-field-strength MRI and premium performance computed tomography (CT) diagnostic imaging systems, robotic-assisted systems for surgery and endovascular catheterization, and radiation-oncology systems.

S&P thinks hospitals are carefully evaluating both maintenance and upgrade capital expenditures in terms of return on investment; given tighter capital budgets, they must find clear justification before undertaking such multimillion-dollar investments. Even when industry conditions spur manufacturers to discount such items, price tags nevertheless remain high. Smaller-ticket items—such as patient monitors, which are vital to operating rooms, emergency rooms, and critical care units, as well as blood analyzers and portable ultrasound imaging devices—also experienced lower sales amid spending cuts by US hospitals.

Despite sluggish medical device sales, some medical equipment and supplies manufacturers reported a small pick-up in hospital purchasing starting in 2010, which we think was a result of pent-up demand, the replacement of older products, and technological advances that make certain new products more efficacious and cost effective, and provide a high return on investment.

A MORE STRINGENT 510(k) PRODUCT APPROVAL PROCESS

Following public comments by stakeholders (including medical device companies, industry representatives, and consumer and patient groups), the US FDA unveiled a plan containing 25 actions on January 19, 2011, which will make 510(k) more effective and efficient. However, amid revamping its 510(k) approval rules, the FDA has come under political pressure to head off the new approval process and ease device approvals. Studies published in the late 2010 and early 2011 (latest available) by PricewaterhouseCoopers (PwC), Stanford University professor Josh Makower, MD, and the California Healthcare Institute (CHI) and Boston Consulting Group (BCG), cited over-regulation as the reason for sagging medical device innovation in the US. As the FDA has become more risk-averse, approval times have lengthened.

The 510(k) approval process enables devices categorized as Class II (relatively low-risk) to be marketed in the US. The industry had raised concerns that the process had become less predictable, less consistent, and less transparent, thus stifling innovation and sending companies and jobs overseas, where approvals could be garnered more quickly. In response to these concerns, the FDA developed a new approval process. The process in Europe involves relatively less-strict barriers, a quicker response time, and a shorter clinical trial cycle.

Essentially, a device must be shown to be "substantially equivalent" to an already approved device (known as a predicate device) in order to be eligible for consideration and approval under the 510(k) process. A Class II device is also less complex than Class III devices, which are considered to pose the highest risk to patient safety and therefore must go through a rigorous and lengthy PMA process involving multiple (and costly) clinical trials. (For a background on the FDA, how it categorizes medical devices, and its approval processes, see "Regulation: The FDA's Role" in the "How the Industry Operates" section of this *Survey*.) About 3,000 devices are cleared through the 35-year-old 510(k) process each year.

One recent change in the 510(k) review pathway is the decision of the FDA to prohibit manufacturers from using "split predicates" to establish that their new product is as effective as their devices already on the market. That is to say, medical device manufacturers can no longer split their primary substantial equivalence claims between multiple devices, according to an article published by *Mass Device* in July 2014.

In an effort to streamline its approval process, the FDA listed 107 medical devices that it will exempt from its 510(k) premarket notification regulations in August 2014. Some of these medical devices include hearing aids, teething rings, and thermometers. These medical devices listed do not present risks, and are therefore not subject to the criteria of the 510(k) process, according to a *FierceMedicalDevices* article published in August 2014.

The FDA has also simplified the 510(k) approval process for innovative devices that do not have a "substantially equivalent" predecessor. *FierceMedicalDevices* highlighted that the FDA's device arm, the Center for Devices and Radiological Health (CDRH), simplified the de novo pathway in August 2014. This clears the way for subsequent devices to be cleared via the standard 510(k) pathway.

MDUFA III SETS THE STAGE

In July 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act (FDASIA), which reauthorizes user fees from the drug and medical devices industries and contains medical device regulatory reforms. With regard to the medical devices industry, the FDASIA included the Medical Device User Fee Act (MDUFA). As this was the third authorization of user fees, it is known as MDUFA III, and provides up to a third of the FDA's device budget.

MDUFA III started to take effect in October 2012 and will expire in October 2017. The CBO estimated that the FDA would collect about $609 million in fees from MDUFA during the fiscal 2013–2017 period.

Under MDUFA III, the pricing structure for 2013 nearly doubled the total user fees at $595 million between 2013 and 2017, up from $295 million in 2012. The agreement also includes a discounted fee for companies with less than $100 million in annual revenues. According to the FDA, the higher fees would provide the agency with funds to hire 200 full-time employees over five years.

In our view, MDUFA changes are positive for the device industry since they streamline the overall new device approval structure, adding more certainty, predictability, and transparency to the overall process. Among the reforms are the following: streamlining the clinical trial processes by identifying key criteria required for product approvals; new requirements for FDA reviewers to provide scientific and regulatory rationale for major decisions and to allow expedited repeal of those decisions; and greater efficiency in the review process of *de novo*, or entirely new, innovative medical devices.

Other enhancements include more training for FDA reviewers, the hiring of additional experts, the requirement that the FDA provide more structure and clarity to the review process during pre-submissions, and decision targets be based on fixed deadlines. In addition, the review process would include greater interaction between the FDA and manufacturers, and oversight from a network of experts to help the FDA resolve complex scientific issues, which S&P thinks would ultimately yield more timely reviews.

FDA priorities for 2013–2017

The FDA released a guidance document in October 2012 that detailed the goals that would help it achieve a quicker pace of approvals, as it promised under MDUFA III. According to the guidance, the FDA plans to bring down the average waiting period for clearance applications from the current 150 days to 124 days by 2017. This will be achieved in steps, by reducing the period to 135 days in 2013–2014 and to 130 days in 2015–16. Under MDUFA III, the FDA aims to reduce the review time for PMAs from 680 days to 320 days, and for 510(k) applications from 138 days to 90 days. The new user fee agreement also makes it mandatory for the FDA to conduct preliminary reviews of applications within 15 days of receipt, after which the agency should decide on the device's substantial equivalence.

Various efforts are being undertaken by the FDA to improve its review time and operational efficiency. In August 2013, it updated its system used to process Investigational Device Exemption (IDE) approval and Emergency Use Authorization (EUA) submissions to better track milestones in clinical trial development. The changes provide a mechanism for tracking multiple studies (such as feasibility or pivotal studies) under a single IDE submission number. Also in August, it released its final guidance, which is not legally enforceable, governing clinical trial oversight, encouraging drug and medical device sponsors to utilize more remote and targeted risk-based monitoring rather than relying solely on on-site methods.

Four broad areas where the FDA should improve its methods for clearing or approving medical devices for sale were identified in a study commissioned by the FDA and conducted by Booz Allen. The areas involve developing more consistent decision making, training staff on all three major IT systems, using appropriate metrics to effectively assess review training, and standardizing process lifecycle management processes for more consistent reviews.

INDUSTRY CONSOLIDATION CONTINUES

In its *Medtech Half-Year Review 2014,* EvaluateMedTech affirms the momentum of consolidation in the industry. Specifically, EvaluateMedTech highlighted in its report that in the first half of 2014, the total worth of M&A ($27.2 billion) has already exceeded full year 2013 M&A value of $19 billion. The value of M&A activity in the first half of 2014 still excludes pending mega-deals, such as Medtronic's planned acquisition of Covidien for $42.9 billion and Zimmer's planned acquisition of Biomet for $13.4 billion.

In our view, the revival in M&A activity in recent years reflects a number of factors. First, despite the recent credit crunch, we think that companies were able to build and preserve a lot of cash, and retained balance sheet flexibility. Second, we think the softness they had been experiencing in a number of product lines and markets, as highlighted by pricing pressures and reduced levels of elective and even non-elective procedures, encouraged them to rely on M&A to help grow their bottom lines.

According to PricewaterhouseCoopers, the device industry will consolidate to achieve cost savings and diversify product portfolios, driven by the need to combat the impact of the federal excise taxes, continued pricing pressures, and declining procedure volumes in certain high-cost treatment areas.

The most significant deal announced in 2014 is Medtronic's planned acquisition of Covidien plc for $42.9 billion, which was announced in June 2014 and structured as a tax inversion deal, with Medtronic re-domiciling in Ireland due to its much lower tax structure. This deal is expected to close either in late 2014 or early 2015.

SELECTED MEDICAL PRODUCTS AND SUPPLIES ACQUISITIONS—2013-2014
(Ranked by deal size)

YEAR	PURCHASER	TARGET	DEAL SIZE (MIL. $)
2014	Medtronic	Covidien	42,900.0
	Thermo Fisher Scientific	Life Technologies	13,600.0
	Zimmer	Biomet	13,350.0
	The Carlyle Group	Johnson & Johnson's Ortho-Clinical Diagnostics	4,150.0
	KKR	Panasonic Healthcare	1,700.0
	Smith & Nephew	ArthoCare	1,500.0
	GE Healthcare	Thermo Fischer Scientific's three business units	1,100.0
	Boston Scientific	Bayer - Interventional unit	415.0
	Stryker	Small Bones Innovations	375.0
	Rockwood Equity Partners	Invacare's Altimate Medical	23.0
	Cynosure	Ellman	13.2
2013	Valeant Pharmaceuticals	Bausch & Lomb Holdings	8,775.0
	Stryker Corporation	MAKO Surgical	1,548.4
	Bayer HealthCare	Conceptus	1,165.1
	Investor	Permobil	843.7
	Mitsui Chemicals	Heraeus Kulzer	578.8
	CareFusion	Vital Signs	500.0
	Kinetic Concepts	Systagenix Wound Management	485.0
	Illumina	Verinata Health	450.0
	Heartware International	CircuLite	401.8
	Abbott Laboratories	OptiMedica	400.0
	Argon Medical Devices	Angiotech Pharmaceuticals' interventional products business	362.5
	St. Jude Medical	Endosense	351.4
	ABB CONCISE Optical Group	Optical Distributor Group	350.0

Source: Capital IQ; Company reports.

In terms of transaction value, Thermo Fisher Scientific's acquisition of Life Technologies for $13.6 billion in February 2014 follows the Medtronic-Covidien deal.

S&P thinks the device tax is likely to put financial pressure on smaller companies, which, in turn, will adversely affect their valuations. This will allow bigger companies, pressured by government demands to lower prices, to consider acquisitions of innovative products. Further, device makers may be keen on acquiring foreign companies, as this would offer tax advantages and/or an expanded market presence.

We also expect to see more strategic (or "tuck-in") acquisitions (including a willingness to acquire early-stage companies that lack financing), driven by companies' demand for next-generation technologies and their desire to enter new product areas and take advantage of cross-selling opportunities through existing sales channels. In addition, as hospitals shrink the number of vendors from which they purchase certain types of devices (*e.g.*, orthopedic implants), we think they are more likely to purchase from larger companies with the broadest portfolio of such devices.

Divestitures

A number of medical device makers have also been divesting businesses that they view as underperforming. For example, in June 2013, Covidien spun off its pharmaceutical business, which now trades under the name Mallinckrodt plc. In January 2014, Covidien announced it would sell its Confluent Surgical line to Integra LifeSciences for $235 million. In June 2014, Johnson & Johnson divested its Ortho Clinical Diagnostic business to The Carlyle Group.

TWO PROMISING MEDICAL DEVICE TECHNOLOGIES

The continuous development and launch of new products that improve the diagnosis and/or treatment of various diseases and conditions characterizes the medical device market. They may be based on evolving or new technologies that have had an impact, some quite significant, on medical practice patterns. Below we highlight some notable medical devices based on new or improved technologies launched in recent years.

◆ **Transcatheter aortic valves.** Transcatheter aortic valves (TAVs) are heart valve replacement and repair technologies designed to treat heart valve disease using a catheter-based approach (as opposed to open-heart surgery). Transcatheter valve replacements can be done via minimally invasive surgical techniques, dramatically reducing recovery and rehabilitation times, as well as the cost of the procedure. In addition, while mechanical valves require patients to remain on blood thinners for the rest of their lives, TAVs do not have this requirement, greatly reducing the burden on the patient. TAVs are used predominantly for high-risk patients with severe aortic stenosis, who ordinarily would not be optimal candidates for conventional valve replacement—anywhere from 30%–60% of the heart valve patient population. According to Edwards Lifesciences Corp., a leading maker of TAVs, the global transcatheter heart-valve market is forecast to grow at a 15%–20% CAGR from 2013, to reach $2.5 billion–$3.0 billion in value by 2019.

Medtronic's CoreValve System TAV, which has been available in Europe, received FDA approval in January 2014. Consequently, in September 2014, Medtronic gained CE mark approval, which is a mandatory marking for products sold in Europe, for its CoreValve Evolut R catheter system.

In any event, competition is intensifying, as other device makers such as Boston Scientific, St. Jude Medical, and JenaValve, a small Germany-based TAV maker, plan to enter the US and China markets. JenaValve has been selling TAVs in the EU since 2011. St. Jude Medical's Portico device gained the EU's approval in November 2012. In October 2013, Boston Scientific received a CE mark for its Lotus Valve System, which offers alternative treatment for high-risk patients with severe aortic stenosis. In December 2013, St. Jude Medical received a CE mark for a larger size of its Portico transcatheter aortic heart valve implant.

Small players such as Direct Flow Medical Inc. are also trying to enter the market, learning from the bigger companies' experience. Direct Flow Medical came up with a metal-free frame for the valve and received the CE mark in January 2013.

◆ **3D printed devices.** Also known as additive manufacturing, 3D printing uses a special printer to make a three-dimensional solid object from a computer-aided design (CAD) or animation modeling software. 3D printing makes use of the additive process whereby material is added layer by layer to create objects of any shape. Anyone with access to a 3D printer and the design file (software) can create virtually any object in a matter of minutes. This technology has already made inroads in various fields of medical science. Transparency Market Research predicts the market for 3D printing in the medical device arena could rise from $354.4 million in 2012 to $965.5 million over the six years through 2019 (latest available), a CAGR of 18.2%.

S&P thinks that the technology is revolutionary and should eventually enable more effective treatment, particularly if the cells used to grow artificial organs are obtained from the patients and, hence, less likely to be rejected by their bodies after implantation. ■

INDUSTRY PROFILE

Strong growth in diversified industry

According to a May 2014 report by Kalorama Information, a medical market research firm, the global medical device market generated $348 billion in sales in 2013, up 5.1% from 2012 ($331 billion). The research firm thinks innovation and mergers drove growth in the medical device industry. Furthermore, the Kalorama Information report highlighted that despite reimbursement challenges and the impending threat of new legislation in Europe and US, emerging markets helped grow revenues in the industry for 2013, albeit not fast enough. S&P Capital IQ (S&P) thinks that the austerity programs rolled out by Western European governments have hampered growth in that region. The unfavorable policies implemented by governments for the medical device makers, together with the steps taken by hospitals to reduce device pricing, have affected the performance of a few prominent players such as GE Healthcare, Siemens Medical Systems, and Philips Medical Systems.

LARGEST GLOBAL MEDICAL DEVICE COMPANIES
(In millions of dollars, ranked by current year medical device sales)

COMPANY	LATEST SIX MO. ENDED	--- MEDICAL DEVICE SALES --- PREVIOUS YEAR	CURRENT YEAR	% CHG.	CURRENT TOTAL SALES	DEVICE SALES AS % OF TOTAL SALES
Johnson & Johnson	Jun. 14	14,256	14,302	0.3	37,610	38.0
GE Healthcare	Jun. 14	8,779	8,681	(1.1)	70,411	12.3
Siemens Medical Systems†	Mar. 14	8,659	8,643	(0.2)	47,422	18.2
Philips Medical Systems	Jun. 14	5,962	5,595	(6.2)	14,055	39.8
Covidien	Mar. 14	5,097	5,237	2.7	5,237	100.0
Baxter International	Jun. 14	3,949	4,856	23.0	8,215	59.1
Stryker	Jun. 14	4,402	4,468	1.5	4,468	100.0
Becton Dickinson	Mar. 14	3,901	4,086	4.7	4,086	100.0
Boston Scientific	Jun. 14	3,570	3,647	2.2	3,647	100.0
St. Jude Medical	Jun. 14	2,741	2,811	2.6	2,811	100.0
Zimmer	Jun. 14	2,308	2,344	1.6	2,344	100.0
Abbott Labs	Jun. 14	2,223	2,306	3.7	10,795	21.4
Smith & Nephew	Jun. 14	2,149	2,220	3.3	2,220	100.0
C.R. Bard	Jun. 14	1,500	1,626	8.4	1,626	100.0
Edwards Lifesciences	Jun. 14	1,014	1,098	8.2	1,098	100.0
Varian Medical Systems	Mar. 14	1,014	1,023	0.9	1,490	68.7
Medtronic⁒	Apr-14	16,590	17,005	2.5	17,005	100.0
Biomet⁒	May-14	3,053	3,223	5.6	3,223	100.0

†External revenues. Excludes biosciences, global injectibles, and anesthesia products.
⁒Data for year ended 2014.
Source: Company reports.

However, according to Espicom (a UK-based business intelligence provider), which we think measures the market differently, the global market for medical devices was worth $307.7 billion in 2012 (latest available). Further, Espicom estimates that the industry has grown at a compound annual growth rate (CAGR) of 7.9% between 2007 and 2011 and forecasts that the industry will reach $434.4 billion by 2017. Research and Markets offered a different CAGR estimate in its *Global Medical Devices Market 2014-2018* report. Specifically, the market research firm forecast that global medical devices would grow at a CAGR of 4.5% between 2014 and 2018. Finally, Johnson & Johnson has estimated the global medical device market at about $370 billion in 2013, and sees it expanding at a CAGR of 3%–6% (developed markets growing at 2%–4% annually and emerging markets at 10%–13%) to 2016, at which point the market should be $405 billion–$454 billion.

Within the European Union (EU), the largest markets are Germany, France, Italy, the United Kingdom, and Spain, according to Eucomed, the trade association for European medical device companies. According to an August 2012 report by TechNavio, a market research firm, the European medical device market is expected to grow at a CAGR of 3.7% between 2011 and 2015. Another report by Espicom released in July 2014 estimated the value of the UK medical device market at $9.9 billion for 2013 and projected that the UK market will grow 7.3% per annum to reach $14.1 billion in 2018. Espicom highlighted that in 2013, the UK is the third largest medical device market in Europe, behind France at $14.9 billion and Germany at $25.6 billion.

The large US manufacturers continue to be the dominant players in many parts of the world, and international markets generate a significant share of their revenues. In the US market alone, Espicom estimated the US market size at $127.1 billion for 2013, a 5.6% increase from $120.4 billion in 2012.

INDUSTRY TRENDS

We think that the medical products industry will face major challenges over the next several years. Problems are expected to include constrained hospital capital expenditure (capex) budgets, heightened cost-containment efforts, and the impact of healthcare information technology (HCIT), all of which will be partially offset by continuing favorable demographic trends.

Historically, the adoption of new technologies and expanded applications of existing ones are key areas of focus and sales drivers in the medical products industry. However, given the recent efforts of healthcare reform legislation, regulators, payers, and researchers, the incremental value of many of these new technologies in this new era of cost containment is increasingly questioned. In addition, although we see several new emerging technologies that will spur industry growth (*e.g.*, transcatheter aortic valve (TAV) replacement and renal denervation technology), we see little in the way of true breakthrough innovations, such as the introduction of implantable cardioverter defibrillators (ICDs) or drug-eluting stents (DES), which drove entirely new product categories or dramatically enlarged existing sales.

FOREIGN EXPOSURE MAY PRESSURE NEAR-TERM RESULTS

Medical device manufacturers in the US garner 40%–50% of their revenues in foreign markets (with approximately 30% coming from Europe), where their technological leadership allows for dominant market share positions in most of the leading-edge product areas. As a result, the operating environment outside the US and the movement of foreign currencies versus the US dollar, are both critical to the performance of US medical companies. In 2011, the US dollar weakened through the first half of the year, but started strengthening in the second half. It continued to strengthen throughout most of 2012 and into mid-2013; as a result, US medical device companies were hurt by unfavorable currency movements versus their major trading partners. Standard & Poor's Economics (which operates separately from S&P Capital IQ) expects the dollar to strengthen gradually through the third quarter of 2014, to weaken slightly in 2015, and to remain relatively stable afterward.

FOREIGN SALES OF SELECTED MEDICAL PRODUCTS COMPANIES

COMPANY	LATEST SIX MO. ENDED	FOREIGN SALES AS % OF TOTAL SALES
DIVERSIFIED		
C.R. Bard Inc.	Jun-14	32
Becton Dickinson	Mar-14	59
Johnson & Johnson*	Jun-14	56
Medtronic₩	Apr-14	46
CARDIOVASCULAR		
Boston Scientific†	Jun-14	NA
St. Jude Medical	Jun-14	53
ORTHOPEDICS		
Stryker Corp.	Jun-14	33
Zimmer Holdings Inc.	Jun-14	45

*Excludes pharmaceutical and consumer products. ₩Data for year ended 2014. †Data is for w orldw ide sales, company reorganized geographic regions to be fully operational global business units starting January 1, 2013.
Source: Company reports.

Device companies look to rationalize their cost structures in the face of the US healthcare reform tax and a general slowing in top-line growth, we expect US firms to continue to build manufacturing and marketing infrastructures abroad in order to better serve local markets and to improve manufacturing efficiency. Relocation of production and R&D facilities overseas offers many important advantages in terms of lowering production costs and being able to ship and deliver products on a timely basis. US firms have a heavy manufacturing presence in Asia and Latin America, and they plan further expansion in those regions.

Growing interest in developing markets

Market researcher BCC Research, in a report published in April 2011, expects the US to remain the world's largest medical aesthetics device market for at least a few more years, but notes that demand is increasing faster in emerging economies, particularly China, India, Mexico, and Brazil. S&P thinks that while the US market is the world's largest and most profitable, there are significant growth opportunities overseas for

medical device companies, particularly in emerging markets, including China, India, Latin America, and the Middle East, where the middle class is expanding, GDP is rising, and investments in healthcare are increasing.

Medical Device + Diagnostic Industry, a magazine for manufacturers of medical devices and in vitro diagnostic products, highlighted in a May 2013 article that the Asia-Pacific medical device market is expected to grow at a compound annual growth rate (CAGR) of 9.6%, to reach $71 billion by 2015. To help ensure that medical devices used in their countries meet international standards, three of the BRIC countries, Brazil, Russia, and China, are members of The International Medical Device Regulators Forum, a group of medical device regulators from the US, Europe, Australia, Canada, and Japan, whose goal is to accelerate international medical device regulatory harmonization and convergence.

US TRADE SURPLUS FOR SELECTED MEDICAL PRODUCT GROUPS

	SURPLUS (DEFICIT) IN MILLIONS OF DOLLARS					
					TWO --- QUARTERS ---	
PRODUCT GROUP	2010	2011	2012	2013	2013	2014
Medical instruments & appliances*	7,167	7,205	7,653	7,414	3,897	3,932
Mechano-therapy, psychological testing, and oxygen therapy apparatus	(687)	(736)	(802)	(1,010)	(432)	(487)
Orthopedic appliances	138	(340)	207	57	232	168
Radiology equipment	374	215	471	393	144	108

*Includes surgical, dental, and veterinary equipment (electrodiagnostic, ultraviolet, or infrared ray apparatus, syringes, needles, catheters, etc., and ophthalmic instruments and appliances.)
Source: US International Trade Administration.

Due to such factors as aging populations, growing numbers of smokers, and the increasing popularity of fast food, heart diseases are becoming widespread in Asia. According to the World Health Organization, Asia accounts for 60% of the total deaths caused by cardiovascular diseases in the world. The Asian market for cardiovascular devices reached $11 billion in 2012 (latest available), accounting for 30% of the world market. This share is expected to rise to 40% by 2021, according to management consulting firm Pacific Bridge Medical (PBM).

China lures industry players

PricewaterhouseCoopers believes that China's healthcare market will reach $1 trillion by 2020. Medical device market is already sizable and is likely to continue to grow rapidly in the next few years. The country's medical device market, in terms of revenues, is ranked second in the Asia-Pacific region (after Japan), and fourth globally. The medical device market ranks high in priority for policymakers in China. In September 2013, the policymakers proposed a draft bill that would allow tax reductions and subsidies to the manufacturers of high-risk medical devices. In mid-November 2013, the government announced a major economic reform plan and named the healthcare sector as an area in which private capital will be encouraged. As a result, companies are anticipating easier access to the healthcare market.

While China's demographics and growing wealth are very attractive to foreign businesses, the market is problematic. The booming economy has created an urban middle class that is eager for better medical care and is driving the government to improve standards. Although this group is only a small percentage of the country's total population, its numbers are large. In October 2013, China's Food and Drug Administration (CFDA) announced that it would expand the monitoring network for adverse events involving medical devices through the end of 2015. The CFDA plans to have a dedicated investigating and reporting team to handle such events in all provincial FDAs. For the rest of the nation, however, the healthcare infrastructure is extremely weak. According to the US Department of Commerce (DOC), about 700 million of China's 1.3 billion people did not have any kind of insurance coverage in 2006, and rural residents, which totaled 850 million people, paid for 80% of their medical expenses out of pocket due to the low level of subsidies from the government.

Medical device growth in India

Another key medical device market is India. According to PBM, the Indian medical device market reached $3 billion at the end of 2011, and it is estimated to grow to $10 billion by 2022. Similarly, according to a November 2012 report by Visiongain, India's medical device market is expected to grow to $11 billion by

2023, from $3 billion in 2011. The private healthcare sector in India is expanding rapidly to meet the needs of the country's growing middle class, a population of about 300 million (according to the DOC), with rising disposable income and increasing medical expectations. India has been working toward establishing a medical device regulatory regime that will distinguish between medical devices and pharmaceuticals; to minimize disparities across regions, greater central government control and involvement in treatment and approvals have been proposed—including the development of price regulations. According to the 12th five-year plan that started in 2013, the Indian government has labeled pharmaceutical and medical device sectors as priority areas, PBM reported.

Demand for high-technology products, such as cancer diagnostic, medical imaging, ultrasonic scanning, plastic surgery equipment, and polymerase chain reaction technologies, is met primarily by imports, which constitute 50% of the medical device market. However, the market is becoming increasingly competitive due to low barriers to entry, the increasing presence of multinational corporations, an increasing number of players, and an expanding consumer base. The medical devices market for exports from India is estimated at about $509 million with a CAGR of 22%. Domestic production consists primarily of low technology products like surgical textiles and other medical supplies. The exports mainly consist of dental instruments, surgical items, and other laboratory equipment. Despite strong growth rates, the market is relatively small, given the very low per capita spending, and the lack of health insurance and healthcare facilities, especially in rural areas, according to the National Institute of Pharmaceutical Education and Research (NIPER) report.

Mixed prospects in industrialized countries

As in the US, favorable drivers such as aging societies and high standards of living are fueling growth in developed markets such as Europe and Japan. At the same time, government efforts to clamp down on healthcare spending—in part by reforming reimbursement systems and placing more emphasis on proof of cost effectiveness of new technologies—are constraining the effects of the positive drivers.

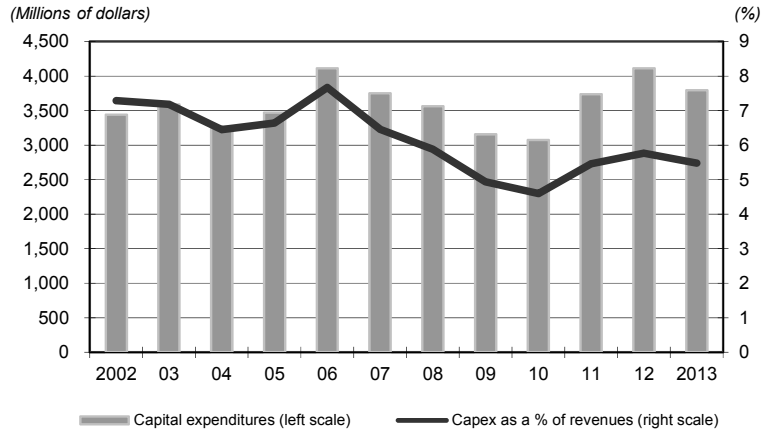
The medical device markets in the US and Europe have witnessed slower growth, according to accounting and consulting firm Ernst & Young's (E&Y) *Pulse of the Industry: Medical Technology Report 2013*. We think the medtech sector is weathering a perfect storm caused by three concurrent trends: the move toward value-based healthcare, growing regulatory pressures, and resource constraints within the industry itself. Moreover, its customer base is shifting, with payers, health systems, and patients much more influential than they have been in the past. This shift undermines medtech's fundamental business model, which was focused on care practitioners. Companies now must find new ways to create, deliver, and capture value. However, they face resource constraints precisely when they need to be investing in new kinds of innovation. Financing has become increasingly scarce for small companies. Indeed, E&Y notes that while US and European companies raised $29.5 billion in financing during the 12-month period ending June 30, 2013, this figure was only a 1.3% increase over the prior 12-month period. Moreover, E&Y estimates that venture capital funding for medtech dropped 21% in the more recent 12-month period, and overall slowing growth has resulted in "lost" revenues of $131 billion and "lost" R&D valued at $12 billion between 2008 and 2012. All told, it notes that, based on public company data, the revenues of US and European companies increased by a modest 2% in 2012, well below the double-digit levels realized prior to the financial crisis.

Many European governments are running severe budget deficits and have embarked on belt-tightening programs. However, their focus has been on cutting the cost of branded and generic pharmaceuticals, so medical devices have been largely exempted so far. One reason, we think, is that there has been a history of pricing pressure on medical devices, particularly in the orthopedic space, with competition causing prices to decline in the mid- to upper-single digits on an annualized basis. We expect medical devices to undergo additional pricing pressures as new country budget targets are introduced. As a result, some US device makers already note seeing a two-segment market. One is a small, high-end, clinician-driven segment comprising differentiated and innovative products that can command premium prices. The other is an enlarged low-end market comprising older and more-commoditized technologies, where pricing matters. US medical device makers are increasingly focusing on the former.

HOSPITAL CAPEX SHOWS SIGNS OF PICKING UP

Besides the growth of overseas markets and the resulting impact of foreign exchange movements, one of the major factors impacting the medical device industry is the pace and rate of capital expenditures (capex) by acute-care hospitals, one of their major customers. Acute-care hospitals traditionally have spent a fairly consistent percentage of revenues on capex, but as a result of the recession and the turmoil in the financial markets, this is changing. Typically, hospitals spend a small percentage of revenues (generally less than 3%) on capex to maintain and operate current facilities. However, hospitals spend a larger portion of their capex budgets to expand and improve facilities and to purchase the latest medical technology, primarily as a means of driving volumes and increasing pricing.

HOSPITAL CAPITAL EXPENDITURES*



*For four publicly held hospital chains and HCA Inc.
Source: Company reports.

Between 2002 and 2007, capital expenditures for the six leading hospital chains ranged from about 6.9% of revenues to a high of 7.7% in 2006. Given that less than half of that amount is generally required for maintenance, clearly hospitals were investing for growth.

Beginning in late 2007 and into 2008, however, hospitals cut back on non-maintenance capital outlays. Capex declined to 4.6% of revenues in 2010, from 4.9% in 2009 and 5.9% in 2008, all well below levels seen at the start of the decade. Capital spending rose to 5.2% in 2011 and to 5.8% of revenues in 2012, but dipped to 5.5% in 2013. Consensus estimates of Capital IQ, the business within S&P Capital IQ that provides business and financial information, pegs the ratio at 5.1% in 2014 and 5.0% in 2015. We think that the relative stability in capital spending as a percentage of revenues that the analyst community sees in 2014 and 2015 reflects the winding down or completion of most of the IT projects, offset by the spending to upgrade the acquired facilities from their earnings models. In fact, S&P estimates for hospital revenues for 2014 will increase significantly, mainly reflecting acquisitions in 2013 and the positive impact of healthcare reform with more insured patients, though admissions are likely to remain volatile amid pressure from payers (health insurers) and a decline in the Medicare reimbursement rate.

We think hospitals have become selective in spending for medical devices, focusing first on equipment that could help differentiate services and drive patient volumes. For example, Varian Medical Systems Inc., a leading maker of radiation-oncology equipment, reported strong demand for its TrueBeam system for image-guided radiotherapy and radiosurgery. Similarly, Intuitive Surgical Inc. reported an increase in sales for its da Vinci robotic surgical systems in the third quarter of 2012. These products help surgeons perform minimally invasive surgery, and are a technologically advanced alternative to conventionally performed surgeries. Since that time, however, demand for their products has slowed in the US. In particular, Intuitive Surgical has noted a drop-off in benign gynecological procedures using its robot. This had freed up time for other types of procedures and slowed the need for additional robots at the same facility.

Some of the more obvious elective procedures, such as cosmetic surgery, orthodontic products, and weight reduction, have already shown signs of slower demand and falling unit-selling prices. We also see evidence of slower demand for orthopedic hip and knee replacement surgeries due both to the lack of insurance (with patients putting off surgeries until pain becomes untenable) and to resistance to high-priced procedures by the insurers. Some medical device manufacturers indicated that they have seen some signs of stabilization (*i.e.*, a slowing decline) and possible recovery, albeit a modest one. However, we think it is too soon to view

this trend as sustainable. Meanwhile, we also think demand for certain diagnostic tests, including pap smears, mammograms, and other forms of cancer screening (such as colonoscopies), has fallen, which we believe is at least partially due to the continued economic weakness with patients deferring procedures due to lack of health coverage or their inability to meet co-pays and/or deductibles.

COMPARATIVE EFFECTIVENESS RESEARCH: GETTING MORE FOR THE HEALTHCARE DOLLAR

Comparative effectiveness research (CER), which seeks to eliminate waste and promote efficiency, particularly, as a support for evidence-based practice. President Obama called for support of CER in the American Recovery and Reinvestment Act of 2009 (ARRA), which authorized the expenditure of $1.1 billion by September 2010.

In June 2009, the Institute of Medicine (IOM) issued a priority list of 100 research topics for CER, 24 of which related to medical devices. Previously, medical technology (medtech) products had been largely exempt from CER undertaken by the Agency for Healthcare Research and Quality (AHRQ), a US federal agency, and others. We anticipate that it will take several years at least before comprehensive studies can be performed and any conclusions from those studies broadly implemented. While CER findings have the potential to identify savings in the health system and improve patient outcomes, the most effective treatments may not necessarily be the least costly ones.

CER: opportunities and challenges for manufacturers, but not without controversy

S&P expects healthcare reform and CER to present both promise and challenges for device and equipment manufacturers. Increased insurance coverage should expand the customer base of cardiology and orthopedic device makers, as well as manufacturers of healthcare capital equipment, but we also expect they will have to consider CER in product development and commercialization, which includes price—all of which could pressure their margins.

We believe the medical device industry was relieved when IOM recommended to Congress that the new CER studies focus on comparisons of entire treatment regimens rather than narrow comparisons of the particular technologies. However, we caution that in some cases, CER may call into question the need for expensive technologies for certain indications.

CER has stirred controversy. Critics claim that CER findings would lead the government to decide what treatments a patient can or cannot get, while others believe that health insurers can use CER to deny costly but needed treatment to patients. However, proponents say CER will foster more intelligent use of costly medical resources. AdvaMed believes that CER will improve clinical outcomes, but that certain standards should be followed to ensure that CER is conducted in an appropriate way. These include focusing on areas where CER would offer the highest return on investment for the healthcare system; supporting advances in healthcare delivery; transparency; and stakeholder input.

In our view, whether CER yields improved outcomes or adds value in healthcare treatment remains to be seen and may well depend on how it is executed. The Patient-Centered Outcomes Research Institute (PCORI, a nonprofit, non–federal governmental corporation that oversees CER and that was created by the ACA) may not mandate coverage, reimbursement, or policy changes. Nevertheless, we would not be surprised if CER findings eventually have an impact on Medicare and Medicaid reimbursement and, likely, private health insurance coverage (perhaps through tiered reimbursements or on pay-for-performance bonus payments). Under such circumstances, we would expect CER to significantly influence future product development and even the sales of certain technologies. While we think CER could increase the size and costs of clinical trials and, hence, delay the arrival of new treatments on the market, we think it will ultimately lead to devices that are more effective (though not necessarily lower-cost) and fewer "me-too" products.

COST CONTAINMENT TO BE MAJOR CHALLENGE OVER NEXT DECADE

Payers' focus on healthcare cost containment in the US and overseas presents a key ongoing challenge for the industry, as noted above. Also of concern is the industry's ability to maintain R&D productivity, especially given pricing pressures. Cost-containment efforts, even if only moderately successful, affect how

the medical products industry markets its products and the nature of the message that the industry communicates to payers, doctors, and patients.

Payers are attempting to control spending. Strategies include comparative effectiveness studies and evidence-based medicine, and consumer-driven healthcare (whereby consumers take more responsibility of their own medical costs). Underlying these approaches and often critical to them is the data and analysis provided by HCIT, that allow all parties involved to obtain the necessary information to research, compare and quantify the cost and quality of treatment for common diagnoses and conditions.

DEMOGRAPHICS CONTINUE TO REMAIN FAVORABLE

Demographics are considered an important factor for driving growth in the US medical technology industry. The world's population is aging and life spans are lengthening. According to a study conducted by the United Nations Department of Economic and Social Affairs' Population Division, the share of the world's population aged 60 or above will double from around 11% in 2012 to around 22% in 2050; the number will grow to more than two billion, from nearly 810 million in 2012. Further, this age group will represent 32% of the total population in developed nations by 2050, up from 22% in 2012. However, developing nations' populations, which comprise some 82% of the world population and which will reach 86% by 2050, are expected to remain relatively young because of high birth rates.

Aging population drives growth for medical equipment manufacturers, as older people are generally more prone to chronic diseases than the younger generation. In the US, around 80% of people aged 65 or above have at least one chronic condition, while 50% have two or more. Further, 19% of this age group has diabetes and 60% has arthritis, which is the leading cause of disability and frequently requires surgical treatment. The elderly also make up a large share of patients who undergo diagnostic imaging procedures, such as magnetic resonance imaging (MRI) and CT. Similarly, in the US, baby boomers are expected to drive growth in medical goods and services. According to the aforementioned UN report, people aged 60 or above represented around 19% of the US population in 2012, and are expected to reach around 27% by 2050. Most of the increase will occur after 2010 when the first wave of those born during the baby boom generation begins to turn 65. The percentage of people aged 80 or older will constitute 7.9% of the total US population by 2050, up from 3.8% in 2006.

MARKET SECTOR NOTES

In this section, we discuss market conditions in four major established categories (cardiology, diagnostic imaging, orthopedics, and in vitro diagnostics, or IVD), and in one emerging product category (vascular diseases and conditions).

Cardiology

Heart disease remained the leading cause of death for both men and women in the United States in 2011. Around 596,339 Americans died due to heart disease, according to preliminary data published in the National Vital Statistics Report released by the Centers for Disease Control and Prevention in October 2012 (latest available). Cardiovascular disease (CVD) is a broad category that includes high blood pressure, heart attack, stroke, congestive heart failure, and other ailments. Although the rate of death attributable to CVD has declined from 1998 to 2011, according to the report, CVD accounted for 23.7% of the total 2,512,873 deaths in the US in 2011.

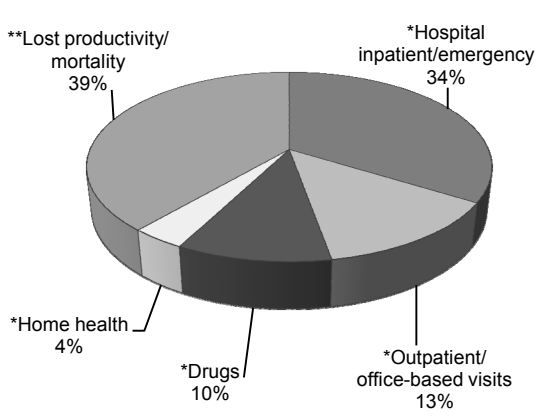
According to a September 2013 report (latest available) published by EvaluateMedTech, a market research firm, the global cardiovascular devices market is expected to grow at a CAGR of 4.2% for the period between 2012 and 2018, reaching $48.7 billion in 2018. The main factors responsible for the growth of the market will be the growing number of people suffering from cardiovascular diseases, along with a shift toward minimally invasive forms of surgery from conventionally performed surgeries, which S&P Capital IQ thinks partly reflects the growing use of TAVs used on patients unable to undergo open-heart surgery.

Cardiac rhythm management (CRM) products, which include pacemakers, ICDs, cardiac resynchronization therapy (CRT) devices, and related items, had an estimated $13.3 billion in worldwide sales in 2010, according

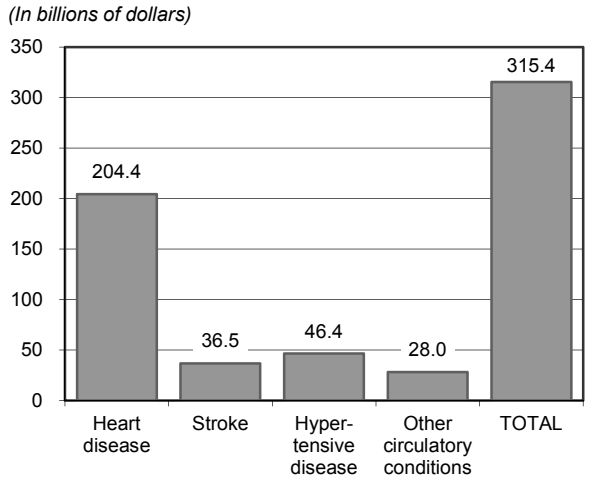
to Frost & Sullivan, a market research firm. ICDs accounted for slightly under $7.0 billion and pacemakers for some $4.0 billion.

In the cardiovascular devices segment, CRT still appears to be the biggest growth opportunity. About 30% of patients with heart failure could benefit from CRT-defibrillators (CRT-Ds), a relatively new device that combines a specialized pacemaker (to fix abnormal heartbeats) with an ICD (to help prevent sudden cardiac death). The CRT-D is effective in patients who suffer from both congestive heart failure and a condition known as ventricular tachyarrhythmia, a kind of heart arrhythmia previously treatable only with drugs.

COSTS OF CARDIOVASCULAR DISEASE AND STROKE — 2010†



Total: $315.4 billion



†Latest actual data available. *Direct costs. **Indirect costs.
Source: American Heart Association.

The global heart valve market includes tissue valves, mechanical valves, and heart-valve repair products. Frost & Sullivan estimated this market at about $1.9 billion in 2010, of which approximately $400 million in sales came from the newer transcatheter aortic valve (TAV) products available in Europe from Medtronic and Edwards Lifesciences. F&S found the growth between 2011 and 2015 hard to predict, since a great deal of its forecast had been dependent on the US commercial launch of the TAV. (For more information on the TAV, see "Promising medical device technologies" in the "Current Environment" section of this *Survey*.) F&S noted that the traditional valve market is growing with a CAGR in the low-single digits, but adoption of the TAV in Europe has been enthusiastic, with growth to $400 million in three years and it sees equal enthusiasm in the US. More recently, GBI Research, which publishes in-depth strategic intelligence reports in a broad range of business categories, released a report in January 2012 in which it forecast the global TAV market to grow at a CAGR of 22% from $293.1 million to $1.196 billion in 2017.

Diagnostic imaging

Diagnostic imaging can be categorized into nine modalities: X-ray, ultrasound, CT, positron emission tomography (PET), single photon emission computed tomography (SPECT), magnetic resonance imaging (MRI), nuclear medicine (NM), mammography, and fluoroscopy. While X-rays account for the bulk of diagnostic imaging at hospital settings, digital and computed radiography have been rapidly penetrating X-ray markets (including physician and dental offices) because they reduce processing time and produce higher-resolution images at lower radiation.

In a report published in September 2013 (latest available) by EvaluateMedTech, the global market for diagnostic imaging is expected to grow from $36.1 billion in 2012 to $45.1 billion by 2018, reflecting a CAGR of 3.8%.

Robotic surgery

Robotic surgery is also gaining traction. In September 2013, Titan Medical said it had developed a working prototype of its robot-aided surgical device called the Single Port Orifice Robotic Technology. The device, being prepared for a pilot launch, would enable doctors to perform surgeries using small instruments introduced into the patient's body through a 25-millimeter incision. In November 2013, Intuitive Surgical reported that a study of more than 33,000 lung cancer patients found that those who underwent procedures using its da Vinci robot-assisted device saw lower mortality rates, reduced overall complications, and decreased hospital stays, compared with those who received open surgery. This procedure yielded outcomes "similar to or better than" video-assisted thoracic surgery, the company noted. However, the segment is not without problems. In December 2013, Intuitive Surgical issued a recall affecting more than 1,300 robot arms worldwide because they may be producing too much friction in some of the surgical systems.

Orthopedics

According to EvaluateMedTech, the global orthopedic device market was $32.7 billion in 2012, and it is expected to reach $40.0 billion by 2018, representing a CAGR of 3.4%. The top seven companies in orthopedics hold more than a 78% market share. Five of these companies are based in the United States. They are Johnson & Johnson's DePuy division, Stryker Corp., Zimmer Holdings Inc., Biomet Inc., and Medtronic Inc. Other important global suppliers include Germany-based Arthrex Inc. and UK-based Smith & Nephew plc.

Among the most common orthopedic surgeries, hip and knee replacement procedures help people suffering primarily from three conditions: osteoarthritis, a common condition affecting more than half of people 65 or older, causing pain in the joints and impairing mobility; rheumatoid arthritis, which destroys cartilage at joint surfaces; and obesity. Sports-related injuries are another catalyst for these surgeries. The younger people who are most prone to sports injuries might not have sought joint replacement surgery in the past. Now, however, new implants specifically designed for them are more durable and improve quality of life. Because older people are more active than in the past, they too are encountering more sports injuries, particularly joint damage and stress fractures.

S&P thinks that people 65 years of age or older, who are covered by Medicare, account for a greater percentage of the spine market than they do of the large joint–reconstruction market, and because the senior population continues to expand, so, too, should the spine market. The growth in the European market for spinal devices would be aided by demographics, although there will be headwinds in the form of budget cuts and lower reimbursements. According to a June 2012 report released by the Millennium Research Group, the European spine-implant market is projected to grow slowly, reaching $755 million by 2016. Meanwhile, in a report dated September 2012, the Millennium Research Group expects the US spinal implant market to also show modest growth, reaching a value of slightly over $5.5 billion in 2016.

In vitro diagnostics

One of the largest medical products segments, in vitro diagnostics (IVD), totaled $46.3 billion in global sales in 2012, and it is expected to grow at a CAGR of 5.1% to $58.8 billion by 2018, according to a September 2013 report published by EvaluteMedTech. It notes that while the US will continue to account for the largest markets in the industry, followed by Europe, emerging regions like the BRIC countries represent areas of the fastest growth. This thinking is reinforced by a report by iData Research, a market research and consulting group, which expects the US IVD market to grow at a CAGR of 2.5% by 2017.

IVD refers to testing systems used to analyze blood, urine, tissue, or other body fluids to detect diseases or predisposition for diseases, or to test for health status. The systems consist of reagents or tests (chemicals) and analytical instruments (capital equipment). Companies sell or lease the instruments to hospitals, clinics, physicians' offices, and independent clinical laboratories; they also can place them in customer sites at no charge, making money on the ongoing revenue stream from reagents. The reagents mix with patient samples, and the instruments perform the analysis and interpretation of results.

While most basic laboratory segments are mature, particular kinds of tests are growing rapidly. The greatest near- to mid-term opportunities are in cardiac testing, human immunodeficiency virus (HIV) testing and monitoring, and new molecular diagnostics.

Molecular diagnostics are based on genetic analysis of patient samples and offer greater accuracy than conventional tests, albeit at much higher prices. This category, which did not exist 10 years ago, had global sales of almost $4.1 billion in 2010, according to Frost & Sullivan, which sees it expanding at a 12% CAGR to $6.2 billion in 2015. S&P thinks it is the fastest-growing subsector in IVD.

The IVD business is fairly concentrated. According to EvaluteMedTech, the top five companies held roughly 58% of the worldwide market in 2012. Roche Diagnostics Corp. (a subsidiary of Roche Holdings AG) was No. 1 (18.8% market share), followed by Siemens AG (11.8%), Danaher (10.6%), Abbott Laboratories (9.8%), and Thermo Fisher Scientific (6.7%).

The industry is thriving, helped by a steady stream of new (in some cases, proprietary) products, better reimbursement, and the increasing practice of personalized medicine. In addition, the emerging countries provide a promising market for IVD. Market researcher Kalorama figures that increased demand for healthcare services led by testing should enable IVD sales to the BRIC countries (Brazil, Russia, India, and China) to grow from $2.9 billion in 2009 to $5 billion in 2014, representing a CAGR of 12%.

Vascular diseases and conditions

The vascular category is considered a promising area by manufacturers in which they can extend their patient treatment capacity to both arterial and venous diseases and aneurysms. The highest profile segments are peripheral vascular disease, abdominal aortic aneurysms, and blood clots.

HOW THE INDUSTRY OPERATES

The medical products industry is extremely diversified—it is actually several related industries, supplying hundreds of thousands of products. The Federal Food, Drug, and Cosmetic Act of 1938 defines a medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar article that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease."

Medical products can be divided into two categories: conventional devices, which have little technological differentiation and a wide variety of uses; and high-technology products, which depend on cutting-edge science to address highly specific therapeutic and diagnostic applications.

Items in the first category, conventional devices, are sold based on price to professional buyers representing institutions. Their margins tend to be narrow, and manufacturers depend on high sales volumes for profits. Intravenous products, anesthesia items, surgical apparel, traditional wound dressings, kits, trays, and a wide range of other products fall into this first category.

Items in the second category consist of more technologically advanced products that can command premium pricing if they demonstrate clinical utility and face limited competition. Manufacturers profit from the attractive margins of these products, at least until competitors catch up—an evolution that is inevitable, given the weakness of patents in the medical device field. Implantable cardiovascular and orthopedic devices, advanced wound care management, and some surgical instruments fall into this second category, as do a few in vitro diagnostic tests.

The major segments of medical supplies and products are cardiovascular, orthopedics, wound care, in vitro diagnostics, diagnostic imaging, and surgical instruments. Large corporations with global scale—including Medtronic Inc., Baxter International Inc., Johnson & Johnson, and Becton, Dickinson & Co.—dominate these fields, offering comprehensive lines of conventional hospital supplies and high-tech products. Small and mid-sized companies, however, can find opportunities in selected niches, particularly those that depend

on innovation. Medical device manufacturers share common end markets, such as hospitals, physicians, and other healthcare providers, and they are subject to third-party reimbursement.

Nearly all of the world's leading medical products manufacturers are based in the United States; only a handful of foreign companies have major influences on the industry. Of these, Smith & Nephew plc (headquartered in London) and the diversified conglomerates Royal Philips Electronics NV (Amsterdam) and Siemens AG (Munich) are among the largest.

CONVENTIONAL SUPPLIES VERSUS THE HIGH-TECH SECTOR

Conventional hospital supplies—such as kits, trays, gloves, gowns, syringes, and disposables—typically are highly price sensitive, comparatively easy to manufacture, and sold in large volumes to institutional healthcare providers. New members into this segment of the business face low barriers to entry, intense competition, and subsequent low margins. Success for this business model usually requires obtaining long-term supply contracts with hospital chains, nursing homes, health maintenance organizations, and other large-scale institutional healthcare providers. For major diversified companies, these product lines provide steady cash flow that helps to fund investments in the development and commercialization of high-tech products.

However, most of the world's top medical device manufacturers devote considerable resources to developing sophisticated and technologically differentiated therapeutic and diagnostic devices, instruments, and analytical tools. While these products tend to require substantial research and development (R&D) and regulatory review before they go on the market, their inventive technology and ability to address previously unmet medical needs make them less vulnerable to competition and better able to command premium pricing. Recent examples include CRT for patients with certain kinds of heart failure; polymerase chain reaction (PCR), an analytical tool used by laboratories to analyze genetic material efficiently; hip resurfacing prostheses; and longer-lasting knee implants.

CRT-D is a relatively new kind of therapy for heart failure patients who suffer from irregular heartbeats and poor muscle contractions; it combines the capabilities of a pacemaker, which helps coordinate irregular heart muscle contractions, with a defibrillator that can send electrical shock signals to the heart to correct abnormal rhythms. For arthritis patients, hip resurfacing is a less invasive alternative to total hip implants; it involves replacing only the surface of the hip joint, thereby preserving more bone. Strong patents on PCR enabled Roche Diagnostics, a subsidiary of Roche AG, to become the leader in molecular diagnostics and keep out competition for more than a decade; however, patents with this much clout are the exception rather than the rule in the medical products arena.

Small companies often lay the foundation for innovative work in the medical device field. These companies have flexibility and close ties to researchers, and they do not stand to lose much by developing a new product that replaces existing technologies. Due to the time and risk involved in designing successful high-tech products, large, well-funded medical product manufacturers tend to buy the small companies or ink out alliances with them. As a result, the larger companies are often the chief suppliers (either directly or indirectly) of most breakthrough medical devices.

Products in one category of medical supplies sometimes evolve over time into another. For example, classic wound dressings, a mature sector, are slowly being replaced by faster-growth, higher-margin advanced wound care materials that incorporate biologically derived materials to stimulate healing. Another example is bare-metal stents (*i.e.*, stents that are not coated by anti-inflammatory drugs). These began as high-value innovative products facing little competition, but subsequently came under intense pricing pressure as patent controversies were resolved, new players entered the market, and more effective next-generation technology caught on. The successor product, drug-eluting stents (DES), grew to a market of $5.4 billion in 2006 from nothing in 2002. The market declined until early 2008, but began to expand afterward, albeit slowly. (For detailed information on the history of the DES market, see the "Current Environment" section of this *Survey*.)

INNOVATION: A HALLMARK OF INDUSTRY GROWTH

New products drive growth in the medical device industry. Fueled by aggressive spending on R&D, a plethora of sophisticated new medical instruments has come on the market in recent years.

R&D spending varies significantly among medical device makers. In general, companies that make conventional hospital-supply items do not invest much in R&D. Those that pursue cutting-edge, high-tech innovation maintain the highest R&D levels; overall, the medical technology equipment group plows an average 9% to 11% of annual revenues back into R&D, versus 3% to 4% for all US manufacturers.

Ideas for new devices come from many sources and develop in many ways. Unlike pharmaceutical companies, device manufacturers working on new products often collaborate closely with their customers, seeking input on applications and design from the earliest stages. Physician-inventors sometimes approach companies with ideas either for completely novel products or for ways to improve existing ones. Studies have shown that up to 80% of important scientific instrument inventions originate from users, not from product manufacturers. Academics are also sources of information, but they may have less incentive to commercialize their ideas. To help design improvements, companies often solicit feedback from practitioners who use their products.

Engineering, electronics, and material sciences are necessary skill sets within medical device companies. Specific sectors of the industry may require additional expertise as well, such as physics for medical imaging equipment, computer science for automated laboratory instruments, and biology and pharmacology for tissue engineering and development of drug-device combination products, such as drug-eluting stents (DES).

Device development is generally faster and less costly than pharmaceutical development. R&D for devices is largely focused on incremental improvements to existing products, rather than the introduction of completely novel technologies. Pacemakers are in their tenth generation; in each succeeding generation, incremental improvements are added. Product life cycles are shorter, and so are payback periods. As a result, devices often appear to be less risky investments—but successful devices rarely garner rewards as huge as those for blockbuster drugs.

REGULATION: THE FDA'S ROLE

The US Food and Drug Administration (FDA) is the principal federal agency responsible for protecting the public from unsafe or ineffective products. The FDA today employs more than 9,000 people who monitor the manufacture, transport, storage, importation, and sale of foods, drugs, medical devices, and cosmetics. Sales of these items total more than $1 trillion annually.

Manufacturers must obtain FDA approval of their products before they can sell them in the United States or export them abroad. (The FDA does not regulate devices that are both made and sold abroad by US companies.) The agency requires medical device manufacturers to provide extensive documentation of their products' safety and effectiveness before granting approval. The FDA has the authority to encourage (or even force) manufacturers to recall products, restrict approvals of manufacturers' new products, suspend the sale of items that it believes to be harmful, and levy fines and penalties on companies that violate its regulations within US borders.

The agency's origins

The Federal Food, Drug, and Cosmetic Act of 1938 laid the foundation for federal regulation of medical devices by enabling the FDA to prosecute people who misuse or misbrand devices for commercial purposes. Although this law was important, it did not require manufacturers to get FDA approval before launching new products into the market, as pharmaceutical manufacturers had to do.

This situation changed during the 1970s, when the public became increasingly concerned about the malfunctioning of many new medical products, such as pacemakers, heart valves, intrauterine contraceptive devices, and other items. To address these concerns, Congress passed comprehensive watershed legislation

in 1976, establishing a new regulatory system, with the strictness of regulatory controls based on the level of risk associated with a given product.

Medical Device Amendments of 1976

Under this law, the FDA reviews all new medical devices for safety and effectiveness before granting marketing approval. Manufacturers must give the agency data supporting their claims for their devices; the amount of evidence required depends on the degree of risk to the patient using the device. Depending on their potential risks, devices fall into one of three general classifications for new submissions:

◆ **Class I.** These devices include commodity products, such as stethoscopes and surgical scalpels, which pose relatively little patient risk. Makers of these products need only register their manufacturing facilities and list their products with the FDA, notify the agency at least 90 days before they start marketing the devices, and conform to good manufacturing practices (GMPs). Established by the FDA, GMPs set standards for ensuring manufacturing quality.

◆ **Class II.** This group includes devices that entail a moderate degree of risk to the patient. Examples include X-ray machines, endoscopes (used to view body cavities and internal organs), and surgical lasers. Manufacturers have to provide the FDA with some evidence of safety and efficacy and meet certain performance standards; in addition, they are responsible for postmarket surveillance and maintenance of patient registries.

◆ **Class III.** This group of technologically sophisticated products entails significant risk to patients and must undergo extensive clinical trials before FDA review. Included in this category are many devices, such as implantable cardiac pacemakers, angioplasty catheters, stents, and similar devices that are used to support life or prevent potentially dangerous medical conditions, such as heart attacks and cardiac arrhythmias.

The Safe Medical Device Act of 1990

The Safe Medical Device Act of 1990 (SMDA) offered additional protections to the public. It established new FDA rules requiring manufacturers to ensure that new products are safe and effective, especially in the areas of premarket approval (PMA) and postmarket surveillance. Although manufacturers and importers of medical devices have been required since 1984 to report to the FDA all device-related deaths, serious injuries, and certain malfunctions, investigations have revealed widespread abuse or underreporting.

Under the SMDA, manufacturers and "device user facilities" must report deaths and serious injuries that a device may have caused (or to which it may have contributed); they also must establish and maintain adverse event files. A device user facility is defined as a hospital, ambulatory surgery facility, nursing home, outpatient treatment facility, or outpatient diagnostic facility that is not in a physician's office.

Once a product is on the market, the ability to detect actual adverse incidents is very low. At the same time, however, the greatly increased number of people using the device may expose safety problems that were undetectable in controlled clinical trials.

The SMDA also created the Humanitarian Device Exemption (HDE). This exempts a device manufacturer from conducting clinical trials on products that have been shown to be reasonably safe and present a probable benefit for a US patient population of fewer than 4,000.

The FDA Modernization Act of 1997

Following years of industry pressure to streamline the FDA's regulatory system for medical devices, Congress passed legislation in the fall of 1997 designed to make the new device approval process more efficient. The bill exempted low-risk Class I devices from certain filing requirements, allowed outside third-party experts to review certain Class II medium-risk devices, and freed up valuable FDA review time for high-risk but potentially more lucrative Class III devices.

The Medical Device User Fee and Modernization Act of 2002

Signed into law in October 2002, MDUFMA amended the Federal Food, Drug, and Cosmetic Act of 1938, providing the FDA with new responsibilities, resources, and challenges. The law has three particularly significant provisions:

◆ **Fees.** The law established user fees for premarket reviews of medical devices to fund the review of device applications. The premarket review process also includes reprocessed single-use medical devices.

The user fees were reauthorized in 2007, under the Medical Device User Fee Amendments of 2007, known as MDUFA II, which was part of the larger Food and Drug Amendments Act of 2007. (The FDA's authority to collect fees was first authorized by Congress under the Medical Device User Fee and Modernization Act of 2002, or MDUFMA.) MDUFA II allowed the FDA to collect fees in new categories starting in fiscal 2008. It included an annual registration fee for all medical device manufacturers, reprocessors, and sterilizers registered with the agency. In exchange for the new fees, the amounts companies are required to pay for premarket approvals (PMAs), 510(k) clearances, and biologic applications were reduced (though annual hikes in each category were allowed). In exchange, the FDA was tasked with reducing review times to benchmarks set in the MDUFA II. According to a July 2010 financial report to Congress by Department of Health & Human Services Secretary Kathleen Sebelius, the FDA met MDUFA II goals for 510(k) clearances, but not all PMA goals.

With MDUFA II expiring in 2012, Congress passed, and the President signed into law, MDUFA III in early July 2012, following extended negotiations between the FDA and the medical device industry. (For further information, see "MDUFA III Agreement" in the "Current Environment" section of this *Survey*.)

◆ **Inspections.** Accredited third parties conduct inspections of manufacturing facilities under carefully prescribed conditions.

◆ **Rules for reprocessed devices.** The law established new regulatory requirements for reprocessed single-use devices, including a new category of premarket submissions that has become known as the premarket report. These devices are defined as those originally intended for one use, or for a single patient during a single procedure, which have been previously used and subsequently reprocessed.

In 2007, President Bush signed legislation that reauthorized the regulatory requirements for reprocessed single-use devices. It was part of a broader bill, The Food and Drug Administration Amendments Act of 2007, which affects many other FDA programs.

The long road to approval

Medical devices—most of which, in contrast to pharmaceuticals, do not have systemic biological interaction with the body—generally are not required to undergo as stringent a review process as pharmaceuticals before commercialization. To get on the market, manufacturers generally must undertake one of two kinds of filings, either a premarket notification or a premarket application. In addition, those working on the most complex devices need an investigational device exemption (IDE), which is an FDA approval to use those devices in clinical trials.

◆ **Premarket notification.** Commonly known as 510(k), this is the more common filing and applies to devices that are substantially similar to approved products already on the market. For some Class I, most Class II, and many Class III devices, 510(k) notifications must be filed at least 90 days prior to the launch of new products into the market. Many Class I products are exempt from the 510(k) review process, although other regulations apply.

In a 510(k) filing, applicants must compare the safety and efficacy of their devices to similar products already on the market and back their claims with evidence. The FDA has established criteria for the nature of the supportive data required, depending on the degree of risk associated with the device. In most cases, descriptive data and a labeling review are enough, but a few devices may require clinical studies to support a 510(k). The FDA reviews 510(k) submissions and gives marketing clearance (rather than formal approvals) to those that it accepts. In January 2011, the FDA released its recommendations for an updated 510(k)

approval process to be implemented. (For details, see "A stricter 510(k) product approval process ahead?" in the "Current Environment" section of this *Survey*.)

◆ **Premarket application (PMA).** For Class III medical devices that employ novel methods of treatment and are not similar to currently marketed devices, manufacturers must submit a premarket application to the FDA. A PMA is much more complex and time-consuming to prepare than a 510(k). The submission typically contains a significant quantity of clinical and animal testing, as well as manufacturing and other data—all of which the FDA carefully scrutinizes. Hence, the costs for clinical trials via the PMA process are substantially higher than the 510(k) process.

After a PMA is submitted, an FDA scientific advisory panel, consisting of physicians, researchers, and other experts in related fields, evaluates the product. The panel may hold a public meeting, during which the PMA application is reviewed and discussed. After evaluating the device, the panel will recommend whether the product is approvable. Although the FDA is not bound to follow the panel's recommendations, it tends to give them considerable weight. All told, the PMA process often takes 18 months to two years, while the 510(k) process can take as little as three to six months.

◆ **Investigational device exemption (IDE).** Manufacturers must file IDEs to get FDA permission to use their devices in clinical trials that will support a PMA filing. If granted, this exemption lets a manufacturer conduct limited human clinical trials (typically involving fewer than 100 people) using the device.

OVERSEAS REGULATION

Non-US regulatory requirements for new medical devices vary significantly. Many developing countries—particularly those in Latin America and Asia—have minimal regulatory oversight. Japan, Australia, and most Western European countries, in contrast, have protocols that are broadly similar to those in the US: They establish criteria for approval based on the device's risk to the patient and the commercial availability of similar devices.

The time required to obtain marketing rights in foreign nations also ranges from months to years. Some nations permit human studies earlier in the product development cycle than the United States; other countries, such as Japan, have standards very similar to those of the FDA.

In the European Union (EU), medical devices and products need a Conformité Européene (CE) marking before they can be sold. The CE marking indicates that a product conforms to EU standards for safety, construction, and performance. Member states select oversight organizations—either government or private—to review supporting data and grant a CE marking. A product with a CE marking can be sold in any EU country, and it does not require separate approval from individual countries. Although the European Commission device regulatory process is becoming more stringent, it traditionally has been less demanding than that of the United States; it also differs from the US process technically. Moreover, because it is newer, it tends to be more subject to interpretation.

PROHIBITIVE BARRIERS TO ENTRY

The medical device industry has high barriers to entry compared with other US industries. Economic, regulatory, and legal obstacles stand in the way of potential new competitors. Small and mid-sized manufacturers often have to go up against powerful large device manufacturers when competing for contracts with large hospital supply purchasing collectives, individual clinical sites, and physicians' offices.

Significant R&D expenditures are required for the device discovery and development process. Would-be rivals usually have a tough time dislodging existing products that are already accepted as safe and effective, unless the new device proves to be significantly better or more affordable. In many industry sectors, physicians tend to have long-standing loyalties to favorite brands or sales people, and they do not readily change to alternative manufacturers selling similar products.

Regulatory barriers include lengthy animal and human clinical tests and voluminous documentation required by the FDA before submission of a new device application. To launch a new device successfully, a company must also have manufacturing site clearance from the FDA and a well-established marketing network to distribute the product to key institutional and physician buyers.

Protective patents

Makers of innovative medical devices can protect their products through US and foreign patents. Patent protection can cover highly novel technologies, as well as incremental improvements to existing products and even manufacturing processes. More than 75,000 medical device patents have been filed with the US Patent and Trademark Office over the past 30 years.

Patent specifications are generally less precise for medical devices than for pharmaceuticals, which leads to much litigation throughout the industry. Many medical technology firms are involved in some type of patent infringement action with competitors; in order to resolve challenges and get their products on the market, companies often cross-license the rights to each other's patents.

Medical product companies are less reliant on patents than are drugmakers; however; their patents are weak and easy to circumvent, and the product life cycles are short. Manufacturers develop new technologies that render older ones obsolete even before patents expire on older technologies. While manufacturers of pioneer pacemakers and angioplasty catheters, for example, received 17-year patents for their original offerings, technological advancements quickly made those products obsolete and the patents of little value in preventing new competition. The rapid evolution of technology, while weakening an individual patent, also creates opportunities for more disputes.

Overseas patent protections vary by country. Some nations do little to enforce patents; as a result, their domestic markets are flooded with copycat products, which discourage innovation. These nations tend to have few domestic companies that invest heavily in R&D, and foreign companies are not willing to supply them with their state-of-the-art patent protected products. Thus, intellectual property protection (IPP) is a key element of US and international trade negotiations.

The World Trade Organization (WTO), a global forum for international commerce, set the minimum length of member countries' international patent rights at 20 years from the date of filing of a patent application (effective in mid-1995). Previously, patents in the United States lasted 17 years from the date the patent was granted; elsewhere, patent terms varied by country, and patents did not exist in many developing countries. While most industrial countries comply with WTO guidelines, developing nations that are members of the WTO have several years to meet these criteria. China and India, two of the fastest-growing device markets, came into compliance with WTO guidelines in 2001 and 2005, respectively, but they are still in the process of building a framework for patent laws and enforcement. Other developing countries with market potential are moving more slowly and have not yet come into compliance.

Product liability: a major concern

Medical device companies have recently faced increased product liability risks for injuries allegedly resulting from the use of their products. Although most companies protect themselves with product liability insurance, their coverage does not absorb the entire risk for their most widely used products. Thus, many firms must assume some risk themselves.

A US Supreme Court ruling in June 1996 dealt a setback to the device industry in product liability issues. The court ruled that device makers could be sued for injuries, even if the FDA had approved the product for safety and efficacy. In a well-publicized case, Dow Corning Corp. declared bankruptcy in May 1995 to protect itself from numerous lawsuits stemming from its past sales of silicone breast implants, which had been discontinued.

The subject of silicone breast implants has remained particularly controversial. In November 2006, the FDA reapproved silicone gel-filled breast implants made by two companies, noting that a decade of studies showed no convincing evidence that the implants are associated with severe side effects, such as connective tissue disease or cancer. As a condition of the approval, the companies, Mentor Corp. and Allergan Inc.

(formerly Inamed Corp.), must conduct rigorous postmarket studies, following 40,000 women who receive implants for at least 10 years.

The Biomaterials Access Assurance Act of 1998 gave important legal protections (including a general grant of immunity) to device manufacturers' raw materials suppliers in liability lawsuits alleging faulty implants. Tort cases can determine supplier liability only if plaintiffs can prove one of three narrow exemptions: that the supplier was the manufacturer of the implant and registered as such; that the supplier was the seller of the implant (*i.e.*, it resold the implant after it had been manufactured); or that the supplier provided materials that differed from what the manufacturer agreed to buy or failed to meet certain specifications and such failures caused the injury. These protections should encourage materials and parts suppliers to return to the implantable device market, but they do not protect manufacturers from liability.

A VARIED AND COMPLEX CUSTOMER BASE

In the medical products sector, as in other parts of the healthcare industry, decision making for the purchasing process is often complex and varied, and the people making buying decisions may or may not be the end users or the payers. Hospitals, physician offices, clinics, clinical laboratories, nursing homes, and standalone imaging centers may have dedicated administrators who select suppliers for most items; the users of the products selected are physicians, nurses, or patients, and the payers may be the offices involved or insurance companies.

Purchases of commodity supplies are often dictated by long-term contracts. In some cases, the buyers negotiate the contracts directly with manufacturers. Often, however, hospitals and integrated delivery networks (IDNs; groups of hospitals that are either jointly owned or independent but aligned for purchasing purposes) belong to group purchasing organizations (GPOs), which negotiate contracts with suppliers. GPOs can often use the combined leverage of all of their members to obtain substantial price discounts on products in exchange for guarantees of a minimum number of orders. The contracts can be on a product-by-product basis or cut across broad groups of products. Hospital members do not have to accept GPO contracts, but the GPOs often offer the best deals. GPOs can try to achieve further discounts by cutting the number of suppliers on their contracts for particular product categories, sometimes to one (an exclusive contract) or two choices.

With high-tech, cutting-edge products, exclusive or semi-exclusive GPO contracts often do not work. Hospitals have had great difficulty countering physicians' individual preferences for certain brands regardless of cost; surgeons, in particular, have enormous clout in purchasing decisions. GPO contracts in these situations may be used but on a nonexclusive basis, which results in terms that are not always as good as they might have been with exclusive contracts. Manufacturers are well aware that continual introduction of new technologies keeps surgeons loyal to particular brands and makes them less likely to consider cost a priority when advocating for specific products. We think this trend may change as hospitals increasingly buy up physicians' practices amid the advent of new rules of healthcare reform.

REIMBURSEMENT ISSUES

Hospitals, outpatient centers, and physicians' offices represent the primary end markets for medical devices. Because these providers rely on third-party insurers for payment, however, reimbursement is a critical issue. Manufacturers almost always have to obtain attractive reimbursement coverage for their devices and for physicians if their products are to succeed. Reimbursement rates affect not only a product's overall success, but also its rate of adoption by clinicians.

Indirectly, the US government's Centers for Medicare & Medicaid Services (CMS)—which partly reimburses at least two-thirds of US hospital admissions—is a major customer for medical devices. Under the federal diagnosis-related group (DRG) system, the CMS pays hospitals a set amount for each Medicare patient, based on the patient's diagnosis and other specifics of the disease.

The current fixed-fee schedule does not take into account the hospital's actual costs of treating the patient. Standards established for Medicare and Medicaid usually have a strong influence on overall reimbursement

decisions by health maintenance organizations and other cost-conscious managed care insurers. (See the "Industry Trends" section of this *Survey* for a discussion of the impact that recent changes to Medicare reimbursement have had on hospitals.)

KEY INDUSTRY RATIOS AND STATISTICS

◆ **National healthcare expenditures.** The Centers for Medicare & Medicaid Services (CMS) publishes a wide range of data on US healthcare expenditures, including historical data and governmental projections. The bulk of these data are available on the CMS website (www.cms.gov). The data are structured by type of expenditure, such as hospital care, physician care, or drugs and other medical nondurables.

PROJECTED NATIONAL HEALTH EXPENDITURES AND SELECTED ECONOMIC INDICATORS

ITEM	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
National health expenditures (bil.$)	3,057	3,207	3,386	3,579	3,797	4,042	4,307	4,578	4,862	5,159
Private health insurance expenditures, total (bil.$)	1,012	1,082	1,137	1,191	1,253	1,330	1,410	1,489	1,569	1,653
Gross Domestic Product (bil.$)	17,354	18,204	19,133	20,128	21,195	22,275	23,367	24,465	25,566	26691
Health expenditures as % of GDP	17.60	17.60	17.70	17.80	17.90	18.10	18.40	18.70	19.00	19.30
Health expenditures per capita ($)	9,596	9,983	10,447	10,943	11,504	12,131	12,808	13,490	14,202	14,944
U.S. population (mil.)	319	321	324	327	330	333	336	339	342	345.2
Under 65	45	47	48	50	51	53	55	57	58	60.3
65 and older	273	275	276	277	279	280	282	283	284	284.9

Source: Centers for Medicare & Medicaid Services.

According to the latest CMS projections, US healthcare spending is expected to reach $5.1 trillion by 2023 compared with the 2014 estimate of $3.05 trillion, accounting for 19.3% of GDP (up from 17.6% in 2014). The CMS projections pegged spending growth at 3.9% in 2012, matching the 3.9% seen in 2011 and then projected it to grow at 3.8% in 2013, before accelerating to 6.1% in 2014. The slowdown in 2013 reflects a combination of consumer cost sensitivity related to low-income growth, employer efforts to control costs, several prescription drug patent expirations, the scheduled 30.9% physician payment-rate reduction mandated under the Sustainable Growth Rate formula, and an additional 2% payment reduction across all providers from the sequester under the Budget Control Act of 2011.

The American Taxpayer Relief Act of 2012, which was passed by Congress on January 1, 2013, and signed by President Obama on January 2, suspended the physician payment-rate reduction, delaying it by one year, and delayed the budget sequestration by two months. In any event, the CMS sees US healthcare spending growth accelerating to 6.1% in 2014, mainly reflecting the major Medicaid coverage expansions from the Patient Protection and Affordable Care Act (PPACA). Overall, US health spending per capita was projected to approximate $14,664 in 2022, up from $8,680 in 2011.

◆ **Public spending.** Changes to spending levels and reimbursement rates for Medicare and, to a lesser extent, the much smaller federal Medicaid program can have a significant impact on the healthcare products and supplies industry. The changes are especially important for makers of expensive, high-tech products, because Medicare sets reimbursement codes for device categories, and these codes affect pricing for large segments of their markets. The CMS estimates that spending by federal, state and local governments represented 45.0% of total healthcare expenditures in 2011 (latest actual) and is projected to reach 48.9% of total spending by 2022 (latest projected).

According to the CMS, federal Medicare expenditures in 2011 rose 6.2% to $554.3 billion. According to actuarial estimates in the *2013 Annual Report of the Boards of Trustees of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund*, Medicare spending is expected to rise at a compound annual growth rate (CAGR) of 6.6% from 2012, reaching $1.087 trillion by 2022. The CMS projects combined federal and state Medicaid spending to more than double from $407.7 billion in 2011 to $839.2 billion in 2022 (a CAGR of 6.8%), accounting for nearly 17.0% of US healthcare spending by that time.

◆ **Consumer Price Index (CPI).** The CPI is compiled by the Bureau of Labor Statistics (BLS), a fact-finding agency within the US Department of Labor. This index tracks price inflation in key segments of the economy, including medical care. The medical care component is further subdivided into various products and services.

According to the BLS, the overall medical care CPI-U (CPI for all urban consumers) advanced 2.6% in July 2014 on a year-on-year basis. However, medical equipment and supplies CPI-U grew only by 0.2% in July 2014 compared with the prior-year period. As of August 2014, Standard & Poor's Economics (which operates separately from S&P Capital IQ) was projecting the overall US CPI to rise by 1.9% in 2014, following an increase of 1.5% in 2013 and an increase of 2.1% in 2012.

◆ **Research and development (R&D) as a percentage of sales.** New devices represent the lifeblood of the medical technology industry, so changes in R&D spending can have an important impact on future sales and earnings. R&D statistics are available from individual company reports. The companies followed by S&P's equity analysts devote around 9%–11% of sales to R&D, on average.

◆ **Foreign currency exchange rates.** The leading medical device makers derive about half of their total sales from foreign customers, although the percentage varies significantly among the players. Manufacturers carefully monitor fluctuations in the value of the dollar relative to foreign currencies, because such changes can have a substantial impact on their sales and earnings.

A rise in the value of the dollar against other major world currencies lowers sales and earnings: foreign sales translate into fewer dollars, assuming that all other variables remain constant. A stronger dollar also makes US goods more expensive abroad and foreign-manufactured products more competitive in the United States. In 2011, the US dollar weakened through the first half of the year, but started strengthening in the second half. It continued to strengthen throughout most of 2012 and, as a result, US medical device companies were hurt by unfavorable currency movements. As of January 2014, Standard & Poor's Economics expected the dollar to strengthen through the third quarter of 2014 and to remain relatively stable through 2015.

◆ **Interest rates.** Major medical device makers, like most other large corporations, closely monitor changes in interest rates, as those rates affect the cost of capital expansion projects, acquisitions, stock repurchases, and dividends. In mid-December 2013, the Federal Reserve Open Market Committee maintained a Fed funds rate of 0%–0.25%, the level it has held since December 2008. Standard & Poor's Economics sees little likelihood of any changes in the Fed funds rate before the economy shows clearer, firmer signs of recovery.

HOW TO ANALYZE A MEDICAL DEVICE COMPANY

The commercial success of a new medical device does not come easily. A manufacturer must invest heavily in R&D, obtain product approval from the US FDA, get clearance for reimbursement by Medicare and private-sector managed care payers, and achieve acceptance of the product in key hospital and physician markets. Leading companies also need global marketing capabilities and must compete effectively with foreign device manufacturers.

RESEARCHING THE BUSINESS

In analyzing a medical device company, first look at the business. Here are some important questions to ask.

◆ **What are the company's principal products?** Most leading companies offer both commodity medical products and proprietary items. Proprietary items, especially high-tech devices, have high margins when they are introduced, since competition is relatively thin or, in some instances, nonexistent.

Margins are typically lower on commodity-type products that have been on the market for a long time, though cash flow from these products helps to support R&D. Indeed, investors and analysts generally do not assign as much value to this important revenue stream as they should, since cash flow from these product lines, while important to the aims of the organization, is not seen as a growth area. However, these revenue streams tend to have a high level of consistency and help to fund working capital requirements.

◆ **What are the growth dynamics of core business lines?** For companies participating in the medical device industry, sales growth is influenced by several factors, including pricing, foreign currency fluctuations, the establishment of insurance reimbursement, and marketing prowess. With relatively short life cycles and volatile market share swings evident in many categories, it is important to determine whether a company has the ability to sustain growth within given product areas, including its core competencies, and whether it is likely to achieve attractive returns on new areas of investment.

◆ **How does the company rank within its principal markets?** While size is important to all businesses, its significance is heightened in the medical product areas. Large firms usually have the financial resources to support the R&D expenditures needed to move experimental devices through the discovery, testing, and regulatory filing stages. These companies also have the funds to maintain the large sales forces needed to market products in key domestic and foreign areas. Large suppliers are increasingly attractive to consolidating hospital and physician clinics, because they can provide a full range of products, often on a volume-discounted basis.

◆ **How efficient is manufacturing?** Being the low-cost producer in a competitive segment of the medical device industry often makes the difference between success and failure. This is especially true as governments worldwide are seeking to rein in healthcare costs by limiting reimbursement, and, in some countries, controlling the pricing of medical products. Many Western medical products companies are outsourcing manufacturing to countries with low production costs, mostly in Latin America and the Far East. Tax credits provide an incentive to manufacture in regions—such as Ireland and Puerto Rico, for example—which previously had been ignored by major foreign manufacturers.

◆ **Have R&D efforts been productive?** Most leading technology-oriented medical device makers spend between 8% and 12% of their sales dollars on R&D programs. However, their success in creating lucrative new medical products differs markedly. For example, Medtronic Inc. has maintained dominance in cardiac pacemakers by investing heavily in new technologies that have spawned a steady stream of state-of-the-art products. These successes notwithstanding, the company is also channeling significant R&D toward emerging technologies in spinal repair, diabetes management, and electronic patient management systems.

Generally, the larger, well-funded firms have a decided advantage in developing new medical technologies. They can typically afford to hire top scientists and conduct more of the costly clinical trials necessary to obtain FDA approval of their products.

In a market dominated by managed care and the US government (via Medicare), a key determinant of success is a manufacturer's ability to develop new devices that are both therapeutic breakthroughs and cost effective. New products that provide essentially identical results to existing therapies are not as likely to achieve commercial success.

◆ **To what extent has the firm diversified abroad?** The United States remains the most important market for US medical device makers, as well as for many foreign-based firms. Even so, the US industry generates about half of unit shipments from foreign markets. Without representation in key markets such as Germany and Japan, as well as in developing nations, a company faces the risk of relying on an increasingly price-competitive US market. However, for firms with international business, foreign exchange fluctuations have an impact on revenues and gross margins. Although generally transitory in nature, these fluctuations must be considered in near-term revenue and earnings projections.

◆ **How effective is the company in working with the FDA?** All medical devices sold in the United States must first be cleared by the FDA. Therefore, firms must be able to work with the agency and understand its criteria. Here again, size and experience can help. While most large, well-established medical products manufacturers are adept at working with the FDA, smaller and newer firms are less proficient and often encounter major snags in seeking approval for their products.

◆ **Is management astute at making strategic acquisitions?** Many companies seek to grow through acquisitions as part of a broader effort to fill out product lines and reposition themselves as "one-stop shops" for hospital-supply buying collectives and other large purchasers of medical products. In a relatively

mature industry, mergers and acquisitions (M&As) are viewed as an important method of sustaining both revenue growth and margin expansion.

◆ **Have alliances been fruitful?** Analysis of a major producer's strategic alliances with smaller start-ups and development-stage device makers also can provide clues to future growth prospects. Leading companies, such as Johnson & Johnson, Medtronic, and Boston Scientific Corp., have benefited from acquisitions and alliances with development-stage companies. The smaller firms are typically eager to align themselves with big producers, which can provide them with funds to finance needed clinical trials and eventually to commercialize their products. Many companies also maintain relationships with scientists at leading medical colleges or other organizations, such as the federal government's National Institutes of Health. These connections can be helpful in developing new products.

ANALYZING FINANCIAL STATEMENTS

When comparing the financial statements of medical device companies, some key financial figures and ratios to examine are sales, operating margins, pretax and net returns, return on equity (ROE) and return on assets (ROA), and cash flow. The balance sheet also provides some useful measures.

◆ **What are sales trends?** Was growth generated through volume, pricing, acquisitions, or through some combination of the three? To what extent are foreign currency translations built into forward revenue expectations? The analyst should look for growth that is sustainable and should evaluate the company's ability to fuel growth over future years. In both cases, it is critical for the company to have proprietary cost-saving technologies. Patent protection can also be key.

◆ **How healthy are operating margins?** Medical product companies typically have high operating margins, reflecting their value-added products and the industry's generally high barriers to entry. (Operating margins comprise earnings before interest, taxes, and nonrecurring expenses, expressed as a percentage of sales.) Therapeutic and diagnostic products tend to command the highest margins, as shown by the performance of market leaders such as Medtronic, St. Jude Medical Inc., Boston Scientific, Zimmer Holdings Inc., and Stryker Corp., which have historically generated operating margins in the range of 25% to 30%.

The industry's high margins also reflect relatively low raw material and selling, general, and administrative (SG&A) costs. R&D costs are often quite high, and substantial expenses are incurred in developing a device. Once those costs are covered, however, the bulk of revenues flow to the bottom line. A company's SG&A and R&D expenses must be compared with industry averages. Margins of established firms should at least match industry norms. Companies in the development stage, however, typically invest heavily to build R&D, production, and marketing infrastructures, and thus are likely to have lower-than-average operating margins.

◆ **What are pretax and net returns?** Medical products companies have above-average pretax and net income returns. Reasons for these lofty margins include successful product innovation; favorable unit pricing; high R&D productivity; the benefits of expanded manufacturing capabilities in lower taxed locations such as Ireland, Puerto Rico, and, to a lesser extent, Costa Rica; and general operating cost disciplines enacted by most of the major industry participants.

◆ **What are the company's ROE, ROA, retention rate, and reinvestment rate?** Return on equity (ROE), or net earnings as a percentage of average stockholders' equity, is a key measure of managerial effectiveness in the medical device industry. Generally, the more sophisticated and value-added a company's product mix is, the higher its ROE.

Those medical device manufacturers that operate in the higher-technology markets, such as Abbott Laboratories, St. Jude Medical, Stryker, and Medtronic, generated ROEs that averaged about 19.5%–22.0% a year between 2006 and 2011. For companies with a more commodity-oriented sales mix, ROE can often fall into the low double-digit or even high single-digit area. Sometimes, ROE ratios can be misleading, as in the case of a firm that had its equity depleted by a sustained period of losses. Thus, analysts also look

at a company's return on assets (ROA), a ratio that measures earnings against total assets, which do not fluctuate in value as much as stockholders' equity does.

Another important financial measure is the retention rate (net earnings minus dividends, divided by net earnings), which reveals the percentage of earnings available for reinvestment in the business. Companies that finance growth through reinvested earnings tend to be among the most profitable. The reinvestment rate (ROE times the retention rate) is another tool for evaluating a company's growth potential.

◆ **How healthy is cash flow?** Analysts and corporate finance directors often refer to "free cash flow" as a measure of the company's operational strength, and one that can help remove some of the manipulations built into per-share earnings calculations. Essentially, free cash flow reveals how much cash is available after deducting all operating costs and capital expenditures from revenues. This free (or discretionary) cash flow figure tells investors the level of excess cash that an organization is generating. This cash can be used in various ways, including common share buybacks, special dividends, acquisitions, debt paydowns, and the like. Ultimately, analysts seek to project free cash flows in future years and discount these flows at an appropriate rate to determine the current value of these future cash streams.

◆ **Looking at the balance sheet.** An analysis of current assets and liabilities gives an indication of the firm's short-term financial health. This is usually less of a concern for an established firm than for a smaller start-up. For example, if the start-up's experimental product takes longer than expected to develop, the firm might run low on cash and need external financing to continue operating. A useful tool in testing liquidity is the current ratio, which is calculated by dividing current assets by current liabilities. When this ratio dips below 1.0, it can be a danger signal.

Given the rapidity with which many high-tech medical devices and diagnostic instruments become obsolete, it is also important to check inventory levels. When inventory levels rise at a faster pace than sales, it may signal that the company being analyzed is building inventory for future sales. Alternatively, it may indicate that older products simply are not moving. The inventory turnover ratio (cost of goods sold divided by average inventory) measures the speed at which inventories are sold.

EQUITY VALUATION

The process of assigning a value to the stocks of medical device companies is similar to that applied to stocks in other industries. Many analysts utilize comparative price-to-earnings (P/E) ratios and price-to-earnings growth (known as PEG) ratios. One may set an average target P/E or PEG ratio for the group, based on the membership and/or earnings growth prospects one sees, and set the individual company target P/E or PEG ratios above or below the average set for the group, based on where one expects the performance and/or risk level of the company to be versus what they would be for the group as a whole. The analyst may sometimes base valuations on P/E and PEG comparisons with those of the S&P 500 or S&P 1500 SuperComposite indices. Another useful method is Discounted Cash Flow, which arrives at a stock price by deriving the net present value of future cash flows. The problem we see here is that the net present value is really the stock's current intrinsic value, and not a value one would see 12 months hence.

Another comparative technique involves using the ratio of enterprise value (market cap, or the number of shares times the share price, plus debt, minority interest, and preferred shares, minus total cash and cash equivalents) to the company's EBITDA (earnings before interest, taxes, and depreciation and amortization). Finally, one could use a variety of methods and derive an average target price.

The difficulty in making valuation comparisons of medical device companies is that they are not all alike. Some medical device companies specialize in either orthopedic or cardiology devices, some in diagnostic imaging devices, some in dental products, while most mid- and large-cap companies under our analytical research have diversified product lines, with the diversification varying by company. ■

GLOSSARY

Angioplasty—A surgical procedure that employs a balloon catheter threaded into a constricted blood vessel to widen it and improve blood flow.

Atrial fibrillation (AF)—A condition in which the heart beats irregularly and rapidly. It is not life threatening, but can lead to other heart disorders and increases the risk of stroke. More than two million people in the US have experienced AF, according to the Heart Rhythm Society.

Blood gas monitors—Instruments that determine the levels of oxygen and carbon dioxide in a patient's blood. These levels must be monitored during the administration of anesthesia and in other operating room procedures.

Breakthrough device—A medical instrument that employs novel technology to treat or diagnose medical conditions. Typically, such devices target medical problems for which no other therapy is available.

Cardiac catheterization—A technique used to assess heart vessels by threading a catheter (a thin tube) through a patient's blood vessels into the heart.

Cardiac pacemaker—A device that supplies electrical impulses to the heart to keep it beating at a regular rate. It consists of a small electronic device and a power source connected to the heart by electrical wire.

Cardiac resynchronization therapy (CRT)—Implantable device used to correct certain kinds of abnormal heart rhythms (in which the heart's left and right ventricles are unable to contract in the proper sequence) that are associated with congestive heart failure.

Cardiac rhythm management (CRM)—A field of cardiovascular medicine that deals with the diagnosis and treatment of abnormal heart rhythms. It includes but is not limited to rhythm abnormalities, such as tachycardia, atrial and ventricular fibrillation, and ventricular dyssynchrony.

Clinical trials—Studies that must be performed before a new medical device or drug can be approved by the US Food and Drug Administration (FDA). The new product is administered to humans in a controlled setting in order to determine its safety and efficacy.

Computed tomography (CT)—A diagnostic technique that employs X-rays and a computer to produce cross-sectional images of body tissue; also known as computed axial tomography, or CAT scanning.

Coronary bypass—A surgical procedure in which an artery or vein taken from another part of the patient's body is used to create an alternative passage around narrowed or blocked heart arteries.

Defibrillator—An electronic instrument that delivers a brief electric shock to restore normal rhythm to a malfunctioning heart. Implantable cardioverter defibrillators (ICDs) are implanted in the patient and programmed to deliver the shock automatically if the heart rhythm malfunctions, while external defibrillators are administered manually.

Evidence-based medicine—The systematic use of the best current clinical expertise linked to the best available scientific research to make medical decisions. Its increasing use in the development of medical guidelines for treating various diseases means it affects the use of many medical devices.

Gainsharing—An arrangement in which hospitals give physicians who help to reduce costs of patient care a percentage of the savings, as incentive for helping hospitals to achieve their budgetary goals. By law, the cost-saving efforts cannot have a negative effect on patient care.

In vitro diagnostics (IVD)—Tests performed on samples taken from the body (blood, urine, tissue, saliva, or other substances) in order to identify abnormalities that indicate disease. (In vitro translates literally as "in glass.")

In vivo diagnostics—Tests, performed in or on a body, which do not involve extracting samples from the patient. These often use imaging techniques (such as an MRI scan or X-ray), but other technologies (such as infrared sensors or external biosensors) also work in specialized circumstances.

Magnetic resonance imaging (MRI)—A diagnostic technique that provides high-quality cross-sectional anatomical images of organs and structures in the body using short bursts of a powerful magnetic field, rather than X-rays or other radiation.

Medicaid—A joint US federal/state program that pays for medical treatment for low-income patients, as well as nursing home services for the indigent elderly. Overseen by the Centers for Medicare & Medicaid Services (CMS).

Medicare—A federally funded US national health insurance program for persons aged 65 and older, as well as for all disabled persons. Overseen by the CMS, Medicare is the single largest health insurer in the United States.

Minimally invasive surgery (MIS)—Surgery that requires the least amount of incision in the body. In certain situations, it is as effective as conventional surgery, but also faster, cheaper, and has less recovery time for the patient. MIS techniques are used in surgeries of the heart, colon, and gastric and vascular systems, as well as in orthopedics and urology.

Percutaneous coronary intervention (PCI)—A procedure in which a thin tube or catheter is threaded from the femoral artery through blood vessels to the heart muscle in order to relieve blockages or obstructions in those vessels. It can be done alone or in conjunction with stenting, relieving pain caused by the blockages (angina), and preventing or minimizing heart attacks.

Positron emission tomography (PET)—A specialized imaging technique that uses short-lived radioactive substances to produce three-dimensional images of metabolic activities in the body for diagnostic purposes.

Premarket approval (PMA)—The formal filing submitted to the FDA by device makers seeking approval to market an innovative (Class III) product—one that is not similar to anything already on the market. The document must contain clinical evidence of the device's safety and efficacy.

Premarket notification/510(k) filing—A submission made to the FDA by a manufacturer of a new product that is substantially equivalent to products already on the market.

Stent—Tiny tubes made of wire mesh that are implanted into an artery, providing the necessary scaffolding to hold the artery open and ensure proper blood flow. Used primarily in coronary arteries, stents are increasingly being used in peripheral (noncoronary arteries), as well. The stent procedure has become common, and it is sometimes used as an alternative to coronary artery bypass surgery. Stents can be made of plain metals (bare-metal stents) or metals coated with a thin layer of an anti-inflammatory drug (drug-eluting stents or DES). ■

INDUSTRY REFERENCES

PERIODICALS

Health Affairs
http://www.healthaffairs.org
Bi-monthly journal covering public policy issues related to healthcare.

IN VIVO Magazine: The Business and Medicine Report
https://www.pharmamedtechbi.com/publications/in-vivo
Monthly trade publication analyzing strategies, technologies, and deal-making activities in the biopharma, medtech, and diagnostics industries.

JAMA: The Journal of the American Medical Association
http://jama.jamanetwork.com/journal.aspx
Weekly; publishes medical research papers on a wide range of topics, as well as commentary from industry experts and physicians.

MDDI: Medical Device & Diagnostic Industry
http://www.mddionline.com
A monthly publication that covers medical product design, manufacturing, marketing, and regulatory affairs.

MassDevice
http://www.massdevice.com
An online journal of the medical devices industry, with daily and sometimes more than once-a-day news coverage.

Medical Device Daily
http://www.medicaldevicedaily.com
Daily; covers current events within the medical technology industry.

New England Journal of Medicine
http://www.nejm.org
Weekly professional medical journal; contains detailed scientific articles on medical treatments and health issues.

MARKET RESEARCH COMPANIES

Frost & Sullivan
http://www.frost.com
Market research firm with a division devoted to the analysis of global and regional healthcare industries, including medical technologies, life sciences, and devices.

IHS Inc.
http://www.ihs.com
Economic research and forecasting company with a division devoted to analysis of global healthcare economies and trends. Primarily focuses on the pharmaceutical industry, but provides insight into global and regional healthcare infrastructures, economics, and regulations.

BOOKS

The American Medical Association Home Medical Encyclopedia
New York: Random House
The Reader's Digest Association, 1989
Illustrated encyclopedia of technical medical terms.

Harrison's Principles of Internal Medicine, 17th Edition
New York: McGraw Hill Medical Publishing Division, 2008
Comprehensive reference guide concerning a broad range of disease states and associated treatment protocols.

Health Devices Sourcebook
Plymouth Meeting, PA: ECRI
http://www.ecri.org
Annual guide to medical devices, manufacturers, and distributors.

TRADE AND PROFESSIONAL ASSOCIATIONS

Advanced Medical Technology Association (AdvaMed)
http://www.advamed.org
Represents manufacturers of medical devices and similar items in legislative, regulatory, and related matters.

American Heart Association (AHA)
http://www.heart.org
Nonprofit volunteer health organization with a mission to reduce disability and death from cardiovascular disease and stroke. Publishes a wide range of statistics on these diseases and their treatments.

American Hospital Association (AHA)
http://www.aha.org
Represents hospitals and healthcare networks in national health policy development, legislative and regulatory debates, and judicial matters.

American Medical Association (AMA)
http://www.ama-assn.org
The largest physician organization in the United States, the AMA represents its members in legislative, economic, and scientific matters.

Medical Device Manufacturers Association (MDMA)
http://www.medicaldevices.org
Represents independent makers of medical devices and related products.

National Electrical Manufacturers Association (NEMA)
http://www.nema.org
Represents electrical products firms, including makers of medical products; publishes industry shipment data for goods such as diagnostic imaging and therapeutic equipment.

Many professional medical societies publish information on their respective specialties and subspecialties. Some of the largest include the following:
The American Academy of Orthopedic Surgeons (AAOS)
http://www.aaos.org
The American Association for Clinical Chemistry (AACC)
http://www.aacc.org
The American College of Cardiology (ACC)
http://www.cardiosource.org
The American College of Surgeons (ACS)
http://www.facs.org
The Radiological Society of North America (RSNA)
http://www.rsna.org
The Society of Nuclear Medicine (SNM)
http://www.snm.org

GOVERNMENT AGENCIES

Centers for Medicare & Medicaid Services (CMS)
http://www.cms.gov
The CMS supervises the Medicare program, the federal portion of Medicaid, and several related programs; formerly called the Health Care Financing Administration (HCFA).

Food and Drug Administration's (FDA)
Center for Devices and Radiological Health (CDRH)
http://www.fda.gov/MedicalDevices/default.htm
The FDA, a division of the Department of Health and Human Services (HHS), is the chief US government agency in charge of supervising the food and pharmaceutical industries. Its CDRH unit regulates medical device manufacturers.

National Center for Health Statistics (NCHS)
http://www.cdc.gov/nchs
The federal government's principal agency that collects vital and health statistics; it is a division of the Centers for Disease Control and Prevention (which is under the umbrella of the Department of Health and Human Services, or HHS).

National Institutes of Health (NIH)
http://www.nih.gov
Government-funded medical research agency, consisting of nearly 20 specialized institutes. It undertakes basic and clinical research on medical conditions and funds external research at academic medical centers. With a large budget (more than $30 billion in fiscal 2009), it has a huge impact on the direction of medical research in the US, though it does not directly support corporate R&D programs.

COMPARATIVE COMPANY ANALYSIS

Operating Revenues

Ticker		Company	Yr. End	Million $ 2013	2012	2011	2010	2009	2008	2003	CAGR (%) 10-Yr.	5-Yr.	1-Yr.	Index Basis (2003 = 100) 2013	2012	2011	2010	2009
HEALTH CARE EQUIPMENT‡																		
ABAX	§	ABAXIS INC	# MAR	171.9	186.0	156.6	143.7	124.6	105.6	46.9	13.9	10.2	(7.6)	367	397	334	307	266
ABT	[]	ABBOTT LABORATORIES	DEC	21,848.0 A	39,873.9	38,851.3	35,166.7 A	30,764.7	29,527.6 D	19,680.6	1.1	(5.8)	(45.2)	111	203	197	179	156
ABMD	§	ABIOMED INC	# MAR	183.6	158.1	126.4	101.2	85.7	73.2	25.7	21.7	20.2	16.1	713	614	491	393	333
ALOG	§	ANALOGIC CORP	JUL	550.4 A	516.6	473.6 D	423.6	396.1	413.5 A	471.5 C	1.6	5.9	6.5	117	110	100	90	84
BCR	[]	BARD (C.R.) INC	DEC	3,049.5 A	2,958.1 C	2,896.4	2,720.2	2,534.9	2,452.1 A	1,433.1	7.8	4.5	3.1	213	206	202	190	177
BAX	[]	BAXTER INTERNATIONAL INC	DEC	15,259.0 A	14,190.0	13,893.0	13,056.0	12,562.0	12,348.0	8,916.0 A	5.5	4.3	7.5	171	159	156	146	141
BDX	[]	BECTON DICKINSON & CO	SEP	8,054.0	7,708.4 D	7,828.9	7,372.3 D	7,160.9 D	7,155.9	4,527.9	5.9	2.4	4.5	178	170	173	163	158
BSX	[]	BOSTON SCIENTIFIC CORP	DEC	7,143.0	7,249.0	7,622.0	7,806.0	8,188.0	8,050.0	3,476.0	7.5	(2.4)	(1.5)	205	209	219	225	236
CMN	§	CANTEL MEDICAL CORP	JUL	425.0	386.5 A	321.7	274.0	260.0	249.4	129.3	12.6	11.3	10.0	329	299	249	212	201
CFN	[]	CAREFUSION CORP	JUN	3,550.0	3,598.0 D	3,528.0 D	3,929.0 D	4,501.0	4,518.4	NA	NA	(4.7)	(1.3)	**	**	**	**	NA
CNMD	§	CONMED CORP	DEC	762.7	767.1 A	725.1	713.7	694.7	742.2 A	497.1 A	4.4	0.5	(0.6)	153	154	146	144	140
COV	[]	COVIDIEN PLC	SEP	10,235.0 A,C	11,852.0 A	11,574.0 D	10,429.0 A,C	10,677.0 A	9,910.0 D	NA	NA	0.6	(13.6)	**	**	**	**	NA
CRY	§	CRYOLIFE INC	DEC	140.8	131.7 A	119.6 A	116.6	111.7	105.1	59.5	9.0	6.0	6.9	236	221	201	196	188
CYBX	§	CYBERONICS INC	# APR	282.0	254.3	218.5	190.5	167.8	143.6	110.7	9.8	14.5	10.9	255	230	197	172	152
CYNO	§	CYNOSURE INC	DEC	226.0 A	153.5	110.6 A	81.8	72.8	139.7	27.1	23.6	10.1	47.2	833	566	408	301	268
EW	[]	EDWARDS LIFESCIENCES CORP	DEC	2,060.7	1,899.6	1,678.6	1,447.0	1,321.4	1,237.7	860.5	9.1	10.7	8.5	239	221	195	168	154
GB	§	GREATBATCH INC	DEC	663.9	646.2 A	568.8 A	533.4	521.8	546.6 A	216.4	11.9	4.0	2.7	307	299	263	247	241
HRC	†	HILL-ROM HOLDINGS INC	SEP	1,716.2	1,634.3 A	1,591.7	1,469.6	1,386.9	1,507.7 D	2,103.0 D	(2.0)	2.6	5.0	82	78	76	70	66
HOLX	†	HOLOGIC INC	SEP	2,512.0	2,014.3 A	1,789.3 A	1,679.6	1,637.1	1,674.5	204.0	28.5	8.4	24.7	1,231	987	877	823	802
IDXX	†	IDEXX LABS INC	DEC	1,377.1	1,293.3	1,218.7	1,103.4	1,031.6	1,024.0	476.0	11.2	6.1	6.5	289	272	256	232	217
IART	§	INTEGRA LIFESCIENCES HLDGS	DEC	836.2	830.9	780.1 A	732.1	682.5	654.6 A	185.6 A	16.2	5.0	0.6	451	448	420	394	368
ISRG	[]	INTUITIVE SURGICAL INC	DEC	2,265.1	2,178.8	1,757.3	1,413.0	1,052.2	874.9	91.7 A	37.8	21.0	4.0	2,471	2,377	1,917	1,541	1,148
IVC	§	INVACARE CORP	DEC	1,352.4 D	1,455.5 D	1,801.1 A	1,722.1	1,693.1	1,755.7 A	1,247.2 A	0.8	(5.1)	(7.1)	108	117	144	138	136
MASI	§	MASIMO CORP	DEC	547.2	493.2	439.0	405.4	349.1	307.1	NA	NA	12.3	11.0	**	**	**	**	NA
MDT	[]	MEDTRONIC INC	# APR	17,005.0	16,590.0	16,184.0 D	15,933.0	15,835.0	14,599.0	9,087.2	6.5	3.1	2.5	187	183	178	175	174
BABY	§	NATUS MEDICAL INC	DEC	344.1 A	292.3 A	232.7 A	218.7 A	166.5 A	161.8 A	31.6 A	27.0	16.3	17.7	1,089	925	736	692	527
NUVA	§	NUVASIVE INC	DEC	685.2	620.3	540.5 A	478.2	370.3 A	250.1	22.7	40.6	22.3	10.5	3,024	2,738	2,386	2,111	1,635
RMD	†	RESMED INC	JUN	1,514.5	1,368.5 C	1,243.1	1,092.4	920.7	835.4	273.6 A	18.7	12.6	10.7	554	500	454	399	337
SIRO	†	SIRONA DENTAL SYSTEMS INC	SEP	1,101.5	979.4	913.9	770.3	713.3	767.1	NA	NA	7.5	12.5	**	**	**	**	NA
STJ	[]	ST JUDE MEDICAL INC	DEC	5,501.0	5,503.0	5,611.7	5,164.8	4,681.3	4,363.3	1,932.5	11.0	4.7	(0.0)	285	285	290	267	242
STE	†	STERIS CORP	# MAR	1,622.3	1,479.5	1,391.5	1,309.8	1,257.7	1,298.5	1,087.0 A	4.1	4.6	9.6	149	136	128	120	116
SYK	[]	STRYKER CORP	DEC	9,021.0	8,657.0	8,307.0	7,320.0	6,723.1	6,718.2	3,625.3	9.5	6.1	4.2	249	239	229	202	185
SRDX	§	SURMODICS INC	SEP	56.1	51.9 D	67.8	69.9	120.2	97.1	42.6	2.8	(10.4)	8.1	132	122	159	164	282
SMA	§	SYMMETRY MEDICAL INC	DEC	400.0	410.5	359.0 A	360.8	365.9	423.4	122.0 A	12.6	(1.1)	(2.6)	328	336	294	296	300
TFX	†	TELEFLEX INC	DEC	1,696.3	1,551.0 D	1,528.9 D	1,801.7 D	1,890.1 D	2,420.9	2,282.4	(2.9)	(6.9)	9.4	74	68	67	79	83
THOR	†	THORATEC CORP	DEC	502.8 A	491.7	422.7 A	383.0 D	373.9	313.6	149.9 A	12.9	9.9	2.3	335	328	282	255	249
VAR	[]	VARIAN MEDICAL SYSTEMS INC	SEP	2,942.9	2,807.0	2,596.7	2,356.6	2,214.1	2,069.7 A,C	1,041.6	10.9	7.3	4.8	283	270	249	226	213
ZMH	[]	ZIMMER HOLDINGS INC	DEC	4,623.4	4,471.7	4,451.8	4,220.2	4,095.4	4,121.1	1,901.0 A	9.3	2.3	3.4	243	235	234	222	215

Operating Revenues

Ticker		Company	Yr. End	2013	2012	2011	2010	2009	2008	2003	CAGR (%) 10-Yr.	5-Yr.	1-Yr.	Index Basis (2003 = 100) 2013	2012	2011	2010	2009
				Million $														
HEALTH CARE SUPPLIES‡																		
ALGN	†	ALIGN TECHNOLOGY INC	DEC	660.2	560.0	479.7 A	372.8	312.3	304.0	122.7	18.3	16.8	17.9	538	456	391	304	254
ANIK	§	ANIKA THERAPEUTICS INC	DEC	75.1	71.4	64.8	55.6	40.1 A	35.8	15.4	17.2	16.0	5.2	487	463	421	361	261
XRAY	[]	DENTSPLY INTERNATL INC	DEC	2,950.8	2,928.4	2,537.7 A	2,221.0 A	2,159.9 A	2,193.7 A,C	1,570.9 D	6.5	6.1	0.8	188	186	162	141	137
HAE	§	HAEMONETICS CORP	# MAR	938.5	892.0 A	727.8	676.7 A	645.4 A	597.9 A	364.2	9.9	9.4	5.2	258	245	200	186	177
ICUI	§	ICU MEDICAL INC	DEC	313.7	316.9	302.2	284.6	231.5	204.7	107.4	11.3	8.9	(1.0)	292	295	281	265	216
VIVO	§	MERIDIAN BIOSCIENCE INC	SEP	188.7	173.5	159.7	143.0 A	148.3	139.6	65.9	11.1	6.2	8.7	286	263	243	217	225
MMSI	§	MERIT MEDICAL SYSTEMS INC	DEC	449.0	394.3 A	359.4	296.8 A	257.5 A	227.1	136.0	12.7	14.6	13.9	330	290	264	218	189
NEOG	§	NEOGEN CORP	# MAY	247.6 A	207.9 A	184.4	173.0	140.7 A	118.8 A	55.5 A	16.1	15.8	19.1	446	375	332	312	254
COO	†	COOPER COMPANIES INC	OCT	1,587.7	1,445.1	1,330.8	1,158.5	1,080.4	1,063.2	411.8	14.4	8.4	9.9	386	351	323	281	262
WST	§	WEST PHARMACEUTICAL SVSC INC	DEC	1,368.4	1,266.4	1,192.3	1,104.7 A	1,055.7	1,051.1	490.7	10.8	5.4	8.1	279	258	243	225	215
OTHER COMPANIES WITH SIGNIFICANT HEALTHCARE PRODUCTS & SUPPLIES OPERATIONS																		
BMY	[]	BRISTOL-MYERS SQUIBB CO	DEC	16,385.0	17,621.0	21,244.0	19,484.0	18,808.0 D	20,597.0 D	20,894.0	(2.4)	(4.5)	(7.0)	78	84	102	93	90
JNJ	[]	JOHNSON & JOHNSON	DEC	71,312.0 A	67,224.0 A	65,030.0	61,587.0	61,897.0	63,747.0	41,862.0 A	5.5	2.3	6.1	170	161	155	147	148

Note: Data as originally reported. CAGR-Compound annual growth rate. ‡S&P 1500 index group. []Company included in the S&P 500. †Company included in the S&P MidCap 400. §Company included in the S&P SmallCap 600. #Of the following calendar year. **Not calculated; data for base year or end year not available. A - This year's data reflect an acquisition or merger. B - This year's data reflect a major merger resulting in the formation of a new company. C - This year's data reflect an accounting change. D - Data exclude discontinued operations. E - Includes excise taxes. F - Includes other (nonoperating) income. G - Includes sale of leased depts. H - Some or all data are not available, due to a fiscal year change.

Net Income

Ticker		Company	Yr. End	Million $ 2013	2012	2011	2010	2009	2008	2003	CAGR (%) 10-Yr.	5-Yr.	1-Yr.	Index Basis (2003 = 100) 2013	2012	2011	2010	2009
HEALTH CARE EQUIPMENT‡																		
ABAX	§	ABAXIS INC	# MAR	14.2	27.5	13.1	14.5	13.0	12.0	24.0	(5.1)	3.4	(48.3)	59	114	54	60	54
ABT	[]	ABBOTT LABORATORIES	DEC	2,383.0	5,962.9	4,728.4	4,626.2	5,745.8	4,734.2	2,753.2	(1.4)	(12.8)	(60.0)	87	217	172	168	209
ABMD	§	ABIOMED INC	# MAR	7.4	15.0	1.5	(11.8)	(19.0)	(31.6)	(9.4)	NM	NM	(51.0)	NM	NM	NM	NM	NM
ALOG	§	ANALOGIC CORP	JUL	31.1	43.1	16.6	15.6	3.7	23.5	49.5	(4.5)	5.8	(27.7)	63	87	34	31	7
BCR	[]	BARD (C.R.) INC	DEC	689.8	530.1	328.0	509.2	460.1	416.5	168.5	15.1	10.6	30.1	409	315	195	302	273
BAX	[]	BAXTER INTERNATIONAL INC	DEC	2,012.0	2,326.0	2,224.0	1,420.0	2,205.0	2,014.0	922.0	8.1	(0.0)	(13.5)	218	252	241	154	239
BDX	[]	BECTON DICKINSON & CO	SEP	929.0	1,109.5	1,264.9	1,176.3	1,213.1	1,127.9	547.1	5.4	(3.8)	(16.3)	170	203	231	215	222
BSX	[]	BOSTON SCIENTIFIC CORP	DEC	(121.0)	(4,068.0)	441.0	(1,065.0)	(1,025.0)	(2,036.0)	472.0	NM	NM	NM	(26)	(862)	93	(226)	(217)
CMN	§	CANTEL MEDICAL CORP	JUL	39.2	31.3	20.4	19.9	15.6	8.7	7.9	17.4	35.2	25.2	496	396	258	252	197
CFN	[]	CAREFUSION CORP	JUN	389.0	361.0	291.0	171.0	568.0	662.7	NA	NA	(10.1)	7.8	**	**	**	**	NA
CNMD	§	CONMED CORP	DEC	35.9	40.5	0.8	30.3	12.1	44.6	32.1	1.1	(4.2)	(11.2)	112	126	2	95	38
COV	[]	COVIDIEN PLC	SEP	1,600.0	1,902.0	1,883.0	1,563.0	902.0	1,443.0	NA	NA	2.1	(15.9)	**	**	**	**	NA
CRY	§	CRYOLIFE INC	DEC	16.2	7.9	7.4	3.9	8.7	32.9	(32.3)	NM	(13.2)	103.5	NM	NM	NM	NM	NM
CYBX	§	CYBERONICS INC	# APR	54.9	46.4	36.1	46.7	78.4	26.7	6.8	23.3	15.5	18.4	812	686	534	691	1,160
CYNO	§	CYNOSURE INC	DEC	(1.6)	11.0	(2.9)	(5.5)	(22.8)	10.2	(0.5)	NM	NM	NM	NM	NM	NM	NM	NM
EW	[]	EDWARDS LIFESCIENCES CORP	DEC	391.7	293.2	236.7	218.0	229.1	128.9	79.0	17.4	24.9	33.6	496	371	300	276	290
GB	§	GREATBATCH INC	DEC	36.3	(4.8)	33.1	33.1	(9.0)	18.6	23.3	4.5	14.3	NM	156	(21)	142	142	(39)
HRC	†	HILL-ROM HOLDINGS INC	SEP	105.0	120.8	133.3	125.3	(405.0)	67.1	182.0	(5.4)	9.4	(13.1)	58	66	73	69	(223)
HOLX	†	HOLOGIC INC	SEP	(1,172.8)	(73.6)	157.1	(62.8)	(2,176.2)	(385.6)	3.1	NM	NM	NM	NM	(2,384)	NM	(2,033)	NM
IDXX	†	IDEXX LABS INC	DEC	187.8	178.3	161.8	141.3	122.2	116.2	57.1	12.6	10.1	5.3	329	312	283	247	214
IART	§	INTEGRA LIFESCIENCES HLDGS	DEC	(17.0)	41.2	28.0	65.7	51.0	34.9	26.9	NM	NM	NM	(63)	153	104	244	190
ISRG	[]	INTUITIVE SURGICAL INC	DEC	671.0	656.6	495.1	381.8	232.6	204.3	(9.6)	NM	26.8	2.2	NM	NM	NM	NM	NM
IVC	§	INVACARE CORP	DEC	(51.0)	(8.3)	(4.1)	25.3	41.2	38.6	71.4	NM	NM	NM	(71)	(12)	(6)	35	58
MASI	§	MASIMO CORP	DEC	58.4	62.3	63.7	73.5	53.2	31.9	NA	NA	12.8	(6.2)	**	**	**	**	NA
MDT	[]	MEDTRONIC INC	# APR	3,065.0	3,467.0	3,415.0	3,096.0	3,099.0	2,169.0	1,959.3	4.6	7.2	(11.6)	156	177	174	158	158
BABY	§	NATUS MEDICAL INC	DEC	22.9	3.9	(11.7)	11.9	11.1	17.5	(2.7)	NM	5.5	489.2	NM	NM	NM	NM	NM
NUVA	§	NUVASIVE INC	DEC	7.9	3.1	(69.8)	78.3	5.8	(27.5)	(10.1)	NM	NM	151.3	NM	NM	NM	NM	NM
RMD	†	RESMED INC	JUN	307.1	254.9	227.0	190.1	146.4	110.3	45.7	21.0	22.7	20.5	672	557	496	416	320
SIRO	†	SIRONA DENTAL SYSTEMS INC	SEP	146.7	133.8	121.8	90.0	53.4	29.4	NA	NA	37.9	9.6	**	**	**	**	NA
STJ	[]	ST JUDE MEDICAL INC	DEC	723.0	752.0	825.8	907.4	777.2	384.3	339.4	7.9	13.5	(3.9)	213	222	243	267	229
STE	†	STERIS CORP	# MAR	129.4	160.0	136.1	51.3	128.5	110.7	94.2	3.2	3.2	(19.1)	137	170	144	54	136
SYK	[]	STRYKER CORP	DEC	1,006.0	1,298.0	1,345.0	1,273.4	1,107.4	1,147.8	453.5	8.3	(2.6)	(22.5)	222	286	297	281	244
SRDX	§	SURMODICS INC	SEP	14.6	10.1	(12.8)	(21.1)	37.5	14.7	13.9	0.5	(0.2)	43.9	105	73	(92)	(151)	269
SMA	§	SYMMETRY MEDICAL INC	DEC	(35.8)	9.1	2.9	14.0	21.8	24.0	5.9	NM	NM	NM	(606)	155	49	237	369
TFX	†	TELEFLEX INC	DEC	151.3	(182.7)	120.7	124.5	141.8	134.0	109.1	3.3	2.5	NM	139	(167)	111	114	130
THOR	†	THORATEC CORP	DEC	73.3	56.2	72.6	59.0	28.6	22.5	(2.2)	NM	26.6	30.6	NM	NM	NM	NM	NM
VAR	[]	VARIAN MEDICAL SYSTEMS INC	SEP	438.2	427.0	408.6	367.5	331.5	295.3	130.9	12.8	8.2	2.6	335	326	312	281	253
ZMH	[]	ZIMMER HOLDINGS INC	DEC	761.0	755.0	760.8	596.9	717.4	848.6	291.2	10.1	(2.2)	0.8	261	259	261	205	246

Net Income

Ticker		Company	Yr. End	Million $ 2013	2012	2011	2010	2009	2008	2003	CAGR (%) 10-Yr.	5-Yr.	1-Yr.	Index Basis (2003 = 100) 2013	2012	2011	2010	2009
HEALTH CARE SUPPLIES‡																		
ALGN	†	ALIGN TECHNOLOGY INC	DEC	64.3	58.7	66.7	74.3	(31.3)	80.0	(20.1)	NM	(4.3)	9.5	NM	NM	NM	NM	NM
ANIK	§	ANIKA THERAPEUTICS INC	DEC	20.6	11.8	8.5	4.3	3.7	3.6	0.8	37.9	41.5	75.0	2,488	1,422	1,024	522	446
XRAY	[]	DENTSPLY INTERNATL INC	DEC	313.2	314.2	244.5	265.7	274.3	283.9	169.9	6.3	2.0	(0.3)	184	185	144	156	161
HAE	§	HAEMONETICS CORP	# MAR	35.1	38.8	66.9	80.0	58.4	59.3	29.3	1.8	(9.9)	(9.4)	120	132	228	273	199
ICUI	§	ICU MEDICAL INC	DEC	40.4	41.3	44.7	30.9	26.6	24.3	22.3	6.1	10.7	(2.1)	181	185	200	139	119
VIVO	§	MERIDIAN BIOSCIENCE INC	SEP	38.0	33.4	26.8	26.6	32.8	30.2	7.0	18.4	4.7	14.0	542	476	382	380	467
MMSI	§	MERIT MEDICAL SYSTEMS INC	DEC	16.6	19.7	23.0	12.5	22.5	20.7	17.3	(0.4)	(4.4)	(15.9)	96	114	133	72	130
NEOG	§	NEOGEN CORP	# MAY	28.2	27.2	22.5	22.8	17.5	13.9	5.1	18.6	15.2	3.6	552	533	442	448	344
COO	†	COOPER COMPANIES INC	OCT	296.2	248.3	175.4	112.8	100.5	65.5	68.8	15.7	35.2	19.3	431	361	255	164	146
WST	§	WEST PHARMACEUTICAL SVSC INC	DEC	112.3	80.7	75.5	65.3	72.6	86.0	31.9	13.4	5.5	39.2	352	253	237	205	228
OTHER COMPANIES WITH SIGNIFICANT HEALTHCARE PRODUCTS & SUPPLIES OPERATIONS																		
BMY	[]	BRISTOL-MYERS SQUIBB CO	DEC	2,563.0	1,960.0	3,709.0	3,102.0	3,239.0	3,155.0	3,106.0	(1.9)	(4.1)	30.8	83	63	119	100	104
JNJ	[]	JOHNSON & JOHNSON	DEC	13,831.0	10,853.0	9,672.0	13,334.0	12,266.0	12,949.0	7,197.0	6.8	1.3	27.4	192	151	134	185	170

Note: Data as originally reported. CAGR-Compound annual growth rate. ‡S&P 1500 index group. []Company included in the S&P 500. †Company included in the S&P MidCap 400. §Company included in the S&P SmallCap 600. #Of the following calendar year. **Not calculated; data for base year or end year not available.

				Return on Revenues (%)					Return on Assets (%)					Return on Equity (%)				
Ticker		Company	Yr. End	2013	2012	2011	2010	2009	2013	2012	2011	2010	2009	2013	2012	2011	2010	2009
HEALTH CARE EQUIPMENT‡																		
ABAX	§	ABAXIS INC	# MAR	8.3	14.8	8.4	10.1	10.5	6.8	14.3	7.1	8.2	8.4	7.7	16.3	8.0	9.2	9.5
ABT	[]	ABBOTT LABORATORIES	DEC	10.9	15.0	12.2	13.2	18.7	4.3	9.4	7.9	8.3	12.1	9.2	23.3	20.2	20.4	28.5
ABMD	§	ABIOMED INC	# MAR	4.0	9.5	1.2	NM	NM	3.9	9.3	1.0	NM	NM	4.8	11.4	1.3	NM	NM
ALOG	§	ANALOGIC CORP	JUL	5.7	8.3	3.5	3.7	0.9	5.4	8.0	3.3	3.3	0.8	6.7	9.9	4.0	3.9	0.9
BCR	[]	BARD (C.R.) INC	DEC	22.6	17.9	11.3	18.7	18.2	15.0	13.1	9.2	16.8	16.5	34.4	28.6	19.2	26.6	22.1
BAX	[]	BAXTER INTERNATIONAL INC	DEC	13.2	16.4	16.0	10.9	17.6	8.7	11.8	12.2	8.2	13.5	26.1	34.4	33.8	20.6	32.9
BDX	[]	BECTON DICKINSON & CO	SEP	11.5	14.4	16.2	16.0	16.9	7.9	10.2	12.6	12.4	14.1	20.2	24.8	24.6	22.2	24.1
BSX	[]	BOSTON SCIENTIFIC CORP	DEC	NM	NM	5.8	NM	NM	NM	NM	2.0	NM	NM	NM	NM	3.9	NM	NM
CMN	§	CANTEL MEDICAL CORP	JUL	9.2	8.1	6.4	7.3	6.0	8.5	8.3	6.8	7.1	5.6	13.1	12.3	9.2	10.1	8.8
CFN	[]	CAREFUSION CORP	JUN	11.0	10.0	8.2	4.4	12.6	4.6	4.3	3.6	2.1	6.8	7.3	7.0	5.9	3.4	10.8
CNMD	§	CONMED CORP	DEC	4.7	5.3	0.1	4.3	1.7	3.3	4.0	0.1	3.1	1.3	5.9	6.9	0.1	5.2	2.2
COV	[]	COVIDIEN PLC	SEP	15.6	16.0	16.3	15.0	8.4	7.6	8.9	9.2	8.3	5.4	16.2	18.7	20.0	18.4	11.5
CRY	§	CRYOLIFE INC	DEC	11.5	6.0	6.2	3.4	7.8	9.7	5.2	5.2	2.9	6.7	11.9	6.4	6.3	3.5	8.3
CYBX	§	CYBERONICS INC	# APR	19.5	18.2	16.5	24.5	46.8	19.7	19.5	17.0	25.4	58.6	22.5	22.4	20.1	32.6	116.0
CYNO	§	CYNOSURE INC	DEC	NM	7.1	NM	NM	NM	NM	5.7	NM	NM	NM	NM	6.9	NM	NM	NM
EW	[]	EDWARDS LIFESCIENCES CORP	DEC	19.0	15.4	14.1	15.1	17.3	15.8	14.0	12.6	12.9	15.2	25.8	20.8	17.9	17.7	22.5
GB	§	GREATBATCH INC	DEC	5.5	NM	5.8	6.2	NM	4.1	NM	4.0	4.1	NM	7.1	NM	7.4	8.2	NM
HRC	†	HILL-ROM HOLDINGS INC	SEP	6.1	7.4	8.4	8.5	NM	6.5	8.3	10.5	10.1	NM	12.6	15.5	18.4	19.0	NM
HOLX	†	HOLOGIC INC	SEP	NM	NM	8.8	NM	NM	NM	NM	2.7	NM	NM	NM	NM	5.6	NM	NM
IDXX	†	IDEXX LABS INC	DEC	13.6	13.8	13.3	12.8	11.8	16.1	16.7	16.8	16.6	15.5	32.5	30.3	29.1	26.0	25.7
IART	§	INTEGRA LIFESCIENCES HLDGS	DEC	NM	5.0	3.6	9.0	7.5	NM	3.6	2.6	6.7	5.2	NM	8.2	5.6	13.9	12.8
ISRG	[]	INTUITIVE SURGICAL INC	DEC	29.6	30.1	28.2	27.0	22.1	16.8	18.4	18.2	18.2	14.2	19.0	21.1	21.1	21.4	16.6
IVC	§	INVACARE CORP	DEC	NM	NM	NM	1.5	2.4	NM	NM	NM	1.9	3.1	NM	NM	NM	3.7	7.0
MASI	§	MASIMO CORP	DEC	10.7	12.6	14.5	18.1	15.2	14.3	16.8	18.8	22.1	16.4	19.5	22.6	25.3	28.5	21.0
MDT	[]	MEDTRONIC INC	# APR	18.0	20.9	21.1	19.4	19.6	8.4	10.2	10.8	10.6	12.0	16.1	19.4	20.6	20.2	22.6
BABY	§	NATUS MEDICAL INC	DEC	6.6	1.3	NM	5.5	6.7	5.6	1.1	NM	3.8	4.0	8.0	1.5	NM	4.7	4.7
NUVA	§	NUVASIVE INC	DEC	1.2	0.5	NM	16.4	1.6	0.7	0.3	NM	10.8	1.0	1.4	0.6	NM	21.4	2.4
RMD	†	RESMED INC	JUN	20.3	18.6	18.3	17.4	15.9	14.1	12.1	12.3	12.1	10.1	19.1	15.3	15.0	15.8	13.3
SIRO	†	SIRONA DENTAL SYSTEMS INC	SEP	13.3	13.7	13.3	11.7	7.5	9.1	8.3	7.3	5.6	3.2	13.7	13.9	14.0	11.6	7.6
STJ	[]	ST JUDE MEDICAL INC	DEC	13.1	13.7	14.7	17.6	16.6	7.4	8.2	9.4	12.1	12.8	17.4	17.6	18.7	23.6	23.7
STE	†	STERIS CORP	# MAR	8.0	10.8	9.8	3.9	10.2	7.1	10.1	9.6	3.8	10.5	13.1	18.1	16.9	6.7	17.5
SYK	[]	STRYKER CORP	DEC	11.2	15.0	16.2	17.4	16.5	7.0	10.1	11.5	12.8	13.3	11.4	15.9	18.1	18.5	18.5
SRDX	§	SURMODICS INC	SEP	26.0	19.5	NM	NM	31.2	14.2	7.6	NM	NM	19.9	15.5	8.5	NM	NM	23.9
SMA	§	SYMMETRY MEDICAL INC	DEC	NM	2.2	0.8	3.9	6.0	NM	1.5	0.5	3.1	4.9	NM	3.0	1.0	4.8	8.1
TFX	†	TELEFLEX INC	DEC	8.9	NM	7.9	6.9	7.5	3.8	NM	3.2	3.3	3.7	8.2	NM	6.4	7.4	10.0
THOR	†	THORATEC CORP	DEC	14.6	11.4	17.2	15.4	7.6	9.8	8.1	9.6	7.4	4.0	11.6	9.5	12.0	10.3	5.8
VAR	[]	VARIAN MEDICAL SYSTEMS INC	SEP	14.9	15.2	15.7	15.6	15.0	13.8	15.9	16.9	15.9	15.5	27.2	31.0	32.4	28.4	28.3
ZMH	[]	ZIMMER HOLDINGS INC	DEC	16.5	16.9	17.1	14.1	17.5	8.2	8.6	9.2	7.6	9.5	12.5	13.3	13.5	10.5	12.7

Ticker		Company	Yr. End	Return on Revenues (%) 2013	2012	2011	2010	2009	Return on Assets (%) 2013	2012	2011	2010	2009	Return on Equity (%) 2013	2012	2011	2010	2009
HEALTH CARE SUPPLIES‡																		
ALGN	†	ALIGN TECHNOLOGY INC	DEC	9.7	10.5	13.9	19.9	NM	8.1	8.4	11.8	17.8	NM	10.6	10.9	15.4	22.8	NM
ANIK	§	ANIKA THERAPEUTICS INC	DEC	27.4	16.5	13.1	7.8	9.2	13.8	8.6	6.5	3.3	3.3	16.8	11.5	9.4	5.2	5.2
XRAY	[]	DENTSPLY INTERNATL INC	DEC	10.6	10.7	9.6	12.0	12.7	6.2	6.5	6.1	8.4	9.3	13.2	15.5	13.3	14.5	16.0
HAE	§	HAEMONETICS CORP	# MAR	3.7	4.3	9.2	11.8	9.0	2.4	3.3	7.7	10.0	8.3	4.4	5.2	9.4	12.5	10.3
ICUI	§	ICU MEDICAL INC	DEC	12.9	13.0	14.8	10.9	11.5	8.7	10.5	13.3	10.0	9.0	9.4	11.6	15.0	11.5	10.3
VIVO	§	MERIDIAN BIOSCIENCE INC	SEP	20.2	19.2	16.8	18.6	22.1	22.5	21.1	17.3	17.1	21.7	25.5	23.7	19.5	19.4	24.6
MMSI	§	MERIT MEDICAL SYSTEMS INC	DEC	3.7	5.0	6.4	4.2	8.8	2.3	3.4	5.6	3.9	9.0	4.2	5.3	7.8	5.5	10.9
NEOG	§	NEOGEN CORP	# MAY	11.4	13.1	12.2	13.2	12.5	8.9	10.0	9.6	11.4	10.9	10.0	11.4	11.0	13.4	12.5
COO	†	COOPER COMPANIES INC	OCT	18.7	17.2	13.2	9.7	9.3	9.7	8.9	6.8	4.4	3.9	12.9	12.0	9.7	7.0	6.8
WST	§	WEST PHARMACEUTICAL SVSC INC	DEC	8.2	6.4	6.3	5.9	6.9	6.9	5.4	5.6	5.1	6.0	13.7	11.7	11.8	10.8	13.6
OTHER COMPANIES WITH SIGNIFICANT HEALTHCARE PRODUCTS & SUPPLIES OPERATIONS																		
BMY	[]	BRISTOL-MYERS SQUIBB CO	DEC	15.6	11.1	17.5	15.9	17.2	6.9	5.7	11.6	10.0	10.7	17.8	13.3	23.4	20.3	23.9
JNJ	[]	JOHNSON & JOHNSON	DEC	19.4	16.1	14.9	21.7	19.8	10.9	9.2	8.9	13.5	13.7	19.9	17.8	17.0	24.9	26.4

Note: Data as originally reported. ‡S&P 1500 index group. []Company included in the S&P 500. †Company included in the S&P MidCap 400. §Company included in the S&P SmallCap 600. #Of the following calendar year.

Ticker		Company		Yr. End	Current Ratio					Debt / Capital Ratio (%)					Debt as a % of Net Working Capital				
					2013	2012	2011	2010	2009	2013	2012	2011	2010	2009	2013	2012	2011	2010	2009
HEALTH CARE EQUIPMENT‡																			
ABAX	§	ABAXIS INC	#	MAR	9.8	7.6	7.3	7.5	5.7	0.3	0.4	0.5	0.4	0.0	0.4	0.5	0.7	0.7	0.0
ABT	[]	ABBOTT LABORATORIES		DEC	2.0	2.4	1.5	1.3	1.8	11.7	39.7	33.0	35.9	33.0	34.8	100.2	145.3	247.7	109.8
ABMD	§	ABIOMED INC	#	MAR	3.9	4.3	4.9	3.8	4.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ALOG	§	ANALOGIC CORP		JUL	4.0	4.1	4.3	5.0	5.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BCR	[]	BARD (C.R.) INC		DEC	3.6	4.1	1.9	3.8	5.3	38.5	41.9	33.6	35.3	6.3	93.5	100.7	116.2	79.3	12.4
BAX	[]	BAXTER INTERNATIONAL INC		DEC	1.7	1.9	1.8	2.0	1.9	49.0	44.6	41.9	39.9	32.4	198.3	124.0	125.2	110.5	90.4
BDX	[]	BECTON DICKINSON & CO		SEP	2.8	2.7	2.6	2.7	2.6	41.8	47.2	33.7	21.5	22.4	100.5	112.5	87.3	52.8	51.9
BSX	[]	BOSTON SCIENTIFIC CORP		DEC	1.7	1.7	1.7	1.4	1.3	34.8	33.1	24.4	27.6	29.4	357.0	340.2	328.0	490.5	569.3
CMN	§	CANTEL MEDICAL CORP		JUL	2.5	2.4	2.6	2.3	2.3	19.9	21.3	8.7	4.6	14.1	92.9	101.6	35.3	20.5	66.9
CFN	[]	CAREFUSION CORP		JUN	5.3	3.3	4.6	3.3	3.1	19.3	16.4	19.5	20.5	16.1	56.8	52.7	61.7	79.0	71.2
CNMD	§	CONMED CORP		DEC	3.3	2.8	2.7	1.9	4.1	23.0	18.4	11.8	11.0	21.3	82.2	71.9	39.4	50.0	73.9
COV	[]	COVIDIEN PLC		SEP	2.2	2.2	2.4	1.8	2.4	33.8	28.5	28.4	31.6	25.9	155.5	134.9	124.4	170.3	91.9
CRY	§	CRYOLIFE INC		DEC	5.1	3.6	3.9	5.3	5.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.4
CYBX	§	CYBERONICS INC	#	APR	7.4	7.1	7.0	5.2	4.9	0.0	0.0	0.0	0.0	12.2	0.0	0.0	0.0	0.0	16.8
CYNO	§	CYNOSURE INC		DEC	3.7	5.4	3.7	5.8	6.3	4.3	0.2	0.4	0.0	0.1	9.0	0.3	0.6	0.0	0.2
EW	[]	EDWARDS LIFESCIENCES CORP		DEC	5.0	3.7	3.5	3.1	3.1	27.5	11.3	10.1	0.0	7.2	43.0	20.0	18.0	0.0	15.1
GB	§	GREATBATCH INC		DEC	3.1	2.9	2.8	3.5	1.9	25.0	28.6	30.3	31.0	37.4	103.5	127.8	138.1	146.2	215.9
HRC	†	HILL-ROM HOLDINGS INC		SEP	2.0	1.8	2.4	2.6	2.0	19.6	21.2	6.1	11.6	13.7	65.9	78.2	11.1	21.9	28.4
HOLX	†	HOLOGIC INC		SEP	1.5	2.4	2.6	2.5	2.5	55.2	51.4	28.1	28.8	35.6	798.1	555.0	182.5	225.2	385.3
IDXX	†	IDEXX LABS INC		DEC	1.4	1.4	1.2	1.6	1.5	21.4	0.2	0.4	0.6	0.8	86.2	0.9	2.9	1.9	3.6
IART	§	INTEGRA LIFESCIENCES HLDGS		DEC	4.4	4.2	4.4	2.2	2.3	36.8	49.8	51.6	36.6	40.5	96.6	150.1	151.9	120.4	148.0
ISRG	[]	INTUITIVE SURGICAL INC		DEC	5.1	4.7	4.6	4.7	4.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
IVC	§	INVACARE CORP		DEC	1.5	1.9	1.8	1.8	1.8	4.2	26.1	28.4	25.8	27.1	21.8	85.5	108.1	100.9	114.3
MASI	§	MASIMO CORP		DEC	2.6	2.4	3.5	3.1	4.9	0.1	0.0	0.0	0.1	0.1	0.1	0.0	0.0	0.1	0.1
MDT	[]	MEDTRONIC INC	#	APR	3.8	4.6	1.6	1.9	1.9	34.2	33.9	29.3	33.4	32.1	65.9	70.1	201.2	184.2	147.2
BABY	§	NATUS MEDICAL INC		DEC	2.5	1.7	3.2	2.9	3.3	8.0	4.5	0.3	0.3	0.4	23.6	18.5	0.8	0.9	1.2
NUVA	§	NUVASIVE INC		DEC	4.6	3.1	2.9	3.4	5.8	36.6	37.7	43.7	33.8	41.3	82.7	95.2	102.7	87.5	87.7
RMD	†	RESMED INC		JUN	2.5	5.4	6.2	3.2	3.2	0.0	13.4	5.4	0.0	7.7	0.1	22.6	9.2	0.0	16.1
SIRO	†	SIRONA DENTAL SYSTEMS INC		SEP	2.3	2.2	1.1	2.9	2.7	5.5	6.3	0.0	28.0	34.2	23.7	33.6	0.0	123.6	187.3
STJ	[]	ST JUDE MEDICAL INC		DEC	2.8	2.0	3.2	2.9	2.4	44.0	36.6	36.3	34.2	31.5	139.1	143.6	116.5	128.3	106.3
STE	†	STERIS CORP	#	MAR	2.7	2.8	2.3	2.0	2.9	31.0	33.2	19.6	20.5	21.3	117.4	124.6	56.2	58.2	55.4
SYK	[]	STRYKER CORP		DEC	3.1	4.3	3.9	4.8	4.1	22.5	16.6	17.7	11.7	0.0	48.2	27.8	32.5	16.5	0.0
SRDX	§	SURMODICS INC		SEP	6.0	5.8	4.9	4.9	4.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SMA	§	SYMMETRY MEDICAL INC		DEC	2.5	2.6	3.4	3.7	2.2	36.3	37.7	45.0	22.2	19.4	204.9	212.9	213.0	84.6	102.3
TFX	†	TELEFLEX INC		DEC	1.9	3.9	4.7	2.2	3.0	27.7	30.5	28.4	27.4	37.6	164.5	121.5	94.6	162.5	178.8
THOR	†	THORATEC CORP		DEC	6.3	5.8	7.8	3.2	10.0	0.0	0.0	0.0	0.0	19.2	0.0	0.0	0.0	0.0	32.0
VAR	[]	VARIAN MEDICAL SYSTEMS INC		SEP	2.3	1.8	1.6	1.9	2.0	20.7	0.4	0.5	1.4	1.7	29.1	0.7	0.9	2.3	2.8
ZMH	[]	ZIMMER HOLDINGS INC		DEC	4.1	4.3	3.8	4.3	4.0	21.0	22.7	22.2	16.5	16.7	52.8	60.5	65.4	49.5	55.1

Ticker		Company	Yr. End	Current Ratio					Debt / Capital Ratio (%)					Debt as a % of Net Working Capital				
				2013	2012	2011	2010	2009	2013	2012	2011	2010	2009	2013	2012	2011	2010	2009
HEALTH CARE SUPPLIES‡																		
ALGN	†	ALIGN TECHNOLOGY INC	DEC	3.1	3.1	2.6	4.2	3.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ANIK	§	ANIKA THERAPEUTICS INC	DEC	10.2	5.4	4.4	2.9	3.0	0.0	6.5	8.6	10.9	12.3	0.0	12.7	19.4	30.3	38.5
XRAY	[]	DENTSPLY INTERNATL INC	DEC	1.4	1.2	1.4	3.7	2.7	29.6	33.4	41.5	24.0	16.9	335.7	666.6	515.9	63.3	50.1
HAE	§	HAEMONETICS CORP	# MAR	2.9	3.3	4.0	4.1	2.8	31.1	36.4	0.4	0.6	0.8	96.6	109.6	0.7	1.2	1.8
ICUI	§	ICU MEDICAL INC	DEC	14.7	11.2	8.9	8.1	6.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VIVO	§	MERIDIAN BIOSCIENCE INC	SEP	5.3	5.2	5.9	6.6	7.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MMSI	§	MERIT MEDICAL SYSTEMS INC	DEC	2.5	2.2	3.1	2.8	2.8	36.9	37.2	7.9	25.6	0.0	238.1	255.7	34.2	113.1	0.0
NEOG	§	NEOGEN CORP	# MAY	7.6	9.5	7.2	6.9	5.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
COO	†	COOPER COMPANIES INC	OCT	2.3	2.5	2.0	2.5	2.9	11.0	13.5	14.3	26.0	33.1	70.8	88.1	119.9	202.9	234.9
WST	§	WEST PHARMACEUTICAL SVSC INC	DEC	2.7	2.1	1.9	2.6	2.3	28.6	33.6	30.7	35.7	38.6	89.7	128.2	130.8	134.2	167.7
OTHER COMPANIES WITH SIGNIFICANT HEALTHCARE PRODUCTS & SUPPLIES OPERATIONS																		
BMY	[]	BRISTOL-MYERS SQUIBB CO	DEC	1.5	1.2	2.0	2.0	2.2	34.4	31.9	25.1	25.3	29.2	123.2	528.8	71.3	81.5	80.2
JNJ	[]	JOHNSON & JOHNSON	DEC	2.2	1.9	2.4	2.1	1.8	14.6	14.5	18.1	13.6	13.7	43.4	52.6	41.2	37.8	46.2

Note: Data as originally reported. ‡S&P 1500 index group. []Company included in the S&P 500. †Company included in the S&P MidCap 400. §Company included in the S&P SmallCap 600. #Of the following calendar year.

Ticker		Company		Yr. End	Price / Earnings Ratio (High-Low) 2013	2012	2011	2010	2009	Dividend Payout Ratio (%) 2013	2012	2011	2010	2009	Dividend Yield (High-Low, %) 2013	2012	2011	2010	2009
HEALTH CARE EQUIPMENT‡																			
ABAX	§	ABAXIS INC	#	MAR	81 - 50	32 - 20	54 - 33	44 - 27	51 - 22	0	80	0	0	0	0.0 - 0.0	3.9 - 2.5	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
ABT	[]	ABBOTT LABORATORIES		DEC	26 - 21	19 - 14	19 - 15	19 - 15	15 - 11	37	53	62	58	42	1.8 - 1.4	3.7 - 2.8	4.2 - 3.3	3.9 - 3.0	3.8 - 2.7
ABMD	§	ABIOMED INC	#	MAR	NM - 63	69 - 31	NM - NM	NM - NM	NM - NM	0	0	0	NM	NM	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
ALOG	§	ANALOGIC CORP		JUL	39 - 27	24 - 15	44 - 32	41 - 30	NM - 84	16	11	30	32	138	0.6 - 0.4	0.7 - 0.5	0.9 - 0.7	1.1 - 0.8	1.6 - 1.0
BCR	[]	BARD (C.R.) INC		DEC	17 - 11	17 - 14	30 - 22	18 - 14	19 - 15	10	13	20	13	14	0.8 - 0.6	0.9 - 0.7	0.9 - 0.7	0.9 - 0.7	1.0 - 0.7
BAX	[]	BAXTER INTERNATIONAL INC		DEC	20 - 17	16 - 12	16 - 12	26 - 17	17 - 13	52	37	32	49	29	3.1 - 2.6	3.2 - 2.3	2.7 - 2.0	2.9 - 1.9	2.4 - 1.8
BDX	[]	BECTON DICKINSON & CO		SEP	23 - 17	15 - 13	16 - 12	17 - 13	16 - 12	42	33	29	29	26	2.5 - 1.8	2.5 - 2.2	2.4 - 1.8	2.2 - 1.7	2.2 - 1.7
BSX	[]	BOSTON SCIENTIFIC CORP		DEC	NM - NM	NM - NM	27 - 17	NM - NM	NM - NM	NM	NM	0	NM	NM	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
CMN	§	CANTEL MEDICAL CORP		JUL	40 - 20	26 - 15	24 - 16	20 - 11	22 - 12	8	8	10	8	0	0.4 - 0.2	0.5 - 0.3	0.6 - 0.4	0.7 - 0.4	0.0 - 0.0
CFN	[]	CAREFUSION CORP		JUN	23 - 16	18 - 14	23 - 17	39 - 27	11 - 7	0	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
CNMD	§	CONMED CORP		DEC	35 - 21	22 - 17	NM - NM	26 - 16	58 - 28	50	42	0	0	0	2.3 - 1.4	2.4 - 1.9	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
COV	[]	COVIDIEN PLC		SEP	20 - 17	15 - 11	15 - 11	17 - 11	27 - 15	30	23	16	29	36	1.8 - 1.5	2.0 - 1.5	1.5 - 1.0	2.6 - 1.8	2.3 - 1.3
CRY	§	CRYOLIFE INC		DEC	19 - 9	25 - 14	24 - 15	53 - 34	32 - 13	18	17	0	0	0	1.9 - 1.0	1.2 - 0.7	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
CYBX	§	CYBERONICS INC	#	APR	36 - 21	32 - 19	28 - 18	21 - 10	8 - 4	0	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
CYNO	§	CYNOSURE INC		DEC	NM - NM	34 - 14	NM - NM	NM - NM	NM - NM	NM	0	NM	NM	NM	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
EW	[]	EDWARDS LIFESCIENCES CORP		DEC	27 - 17	43 - 27	44 - 30	45 - 22	22 - 13	0	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
GB	§	GREATBATCH INC		DEC	30 - 15	NM - NM	20 - 13	17 - 13	NM - NM	0	NM	0	0	NM	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
HRC	†	HILL-ROM HOLDINGS INC		SEP	24 - 17	19 - 13	23 - 13	22 - 12	NM - NM	30	25	20	21	NM	1.8 - 1.2	2.0 - 1.3	1.6 - 0.9	1.8 - 0.9	4.8 - 1.7
HOLX	†	HOLOGIC INC		SEP	NM - NM	NM - NM	39 - 23	NM - NM	NM - NM	NM	NM	0	NM	NM	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
IDXX	†	IDEXX LABS INC		DEC	32 - 23	31 - 24	31 - 22	30 - 20	27 - 13	0	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
IART	§	INTEGRA LIFESCIENCES HLDGS		DEC	NM - NM	30 - 16	55 - 29	23 - 15	21 - 11	NM	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
ISRG	[]	INTUITIVE SURGICAL INC		DEC	34 - 21	36 - 26	37 - 21	40 - 25	51 - 14	0	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
IVC	§	INVACARE CORP		DEC	NM - NM	NM - NM	NM - NM	40 - 25	20 - 11	NM	NM	NM	5	4	0.6 - 0.3	0.3 - 0.2	0.4 - 0.2	0.2 - 0.1	0.4 - 0.2
MASI	§	MASIMO CORP		DEC	29 - 18	23 - 17	33 - 16	26 - 17	34 - 23	0	93	0	220	0	0.0 - 0.0	5.5 - 3.9	0.0 - 0.0	13.1 - 8.4	0.0 - 0.0
MDT	[]	MEDTRONIC INC	#	APR	19 - 13	13 - 10	13 - 9	16 - 11	16 - 9	37	31	30	31	29	2.7 - 1.9	2.9 - 2.3	3.2 - 2.2	2.9 - 1.9	3.4 - 1.8
BABY	§	NATUS MEDICAL INC		DEC	31 - 15	NM - 74	NM - NM	43 - 28	44 - 16	0	0	NM	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
NUVA	§	NUVASIVE INC		DEC	NM - 87	NM - NM	NM - NM	24 - 11	NM - NM	0	0	NM	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
RMD	†	RESMED INC		JUN	27 - 20	25 - 14	24 - 16	28 - 20	28 - 16	32	0	0	0	0	1.6 - 1.2	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
SIRO	†	SIRONA DENTAL SYSTEMS INC		SEP	28 - 23	27 - 17	26 - 18	27 - 18	37 - 10	0	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
STJ	[]	ST JUDE MEDICAL INC		DEC	25 - 14	19 - 13	21 - 13	16 - 12	18 - 13	40	38	33	0	0	2.8 - 1.6	3.0 - 2.1	2.6 - 1.6	0.0 - 0.0	0.0 - 0.0
STE	†	STERIS CORP	#	MAR	22 - 16	14 - 10	16 - 12	44 - 30	16 - 9	37	27	28	65	112	2.4 - 1.7	2.7 - 2.0	2.4 - 1.8	2.2 - 1.5	12.7 - 6.9
SYK	[]	STRYKER CORP		DEC	28 - 21	17 - 14	19 - 13	19 - 13	19 - 11	41	26	22	20	9	2.0 - 1.5	1.8 - 1.6	1.7 - 1.2	1.5 - 1.1	0.8 - 0.5
SRDX	§	SURMODICS INC		SEP	28 - 19	39 - 23	NM - NM	NM - NM	14 - 7	0	0	NM	NM	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
SMA	§	SYMMETRY MEDICAL INC		DEC	NM - NM	43 - 26	NM - 86	31 - 21	19 - 6	NM	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
TFX	†	TELEFLEX INC		DEC	27 - 20	NM - NM	22 - 17	21 - 15	15 - 10	37	NM	46	44	38	1.9 - 1.4	2.4 - 1.9	2.8 - 2.1	2.8 - 2.1	3.7 - 2.5
THOR	†	THORATEC CORP		DEC	34 - 23	42 - 30	31 - 18	47 - 24	67 - 40	0	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
VAR	[]	VARIAN MEDICAL SYSTEMS INC		SEP	20 - 16	19 - 14	21 - 14	24 - 12	18 - 10	0	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
ZMH	[]	ZIMMER HOLDINGS INC		DEC	21 - 15	16 - 12	17 - 12	22 - 16	18 - 9	18	17	0	0	0	1.2 - 0.9	1.4 - 1.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0

Ticker		Company	Yr. End	Price / Earnings Ratio (High-Low) 2013	2012	2011	2010	2009	Dividend Payout Ratio (%) 2013	2012	2011	2010	2009	Dividend Yield (High-Low, %) 2013	2012	2011	2010	2009
HEALTH CARE SUPPLIES‡																		
ALGN	†	ALIGN TECHNOLOGY INC	DEC	75 - 32	55 - 31	30 - 17	22 - 13	NM - NM	0	0	0	0	NM	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
ANIK	§	ANIKA THERAPEUTICS INC	DEC	26 - 7	20 - 10	18 - 8	23 - 14	29 - 9	0	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
XRAY	[]	DENTSPLY INTERNATL INC	DEC	23 - 18	19 - 16	23 - 16	21 - 15	20 - 12	11	10	12	11	11	0.6 - 0.5	0.6 - 0.5	0.7 - 0.5	0.7 - 0.5	0.9 - 0.5
HAE	§	HAEMONETICS CORP	# MAR	68 - 55	55 - 40	27 - 21	20 - 16	29 - 20	0	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
ICUI	§	ICU MEDICAL INC	DEC	31 - 19	22 - 15	14 - 11	17 - 13	24 - 15	0	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
VIVO	§	MERIDIAN BIOSCIENCE INC	SEP	29 - 21	26 - 20	41 - 22	37 - 24	33 - 18	83	94	115	112	80	4.0 - 2.9	4.7 - 3.6	5.1 - 2.8	4.6 - 3.0	4.4 - 2.5
MMSI	§	MERIT MEDICAL SYSTEMS INC	DEC	44 - 23	33 - 24	34 - 19	45 - 31	25 - 12	0	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
NEOG	§	NEOGEN CORP	# MAY	67 - 39	42 - 26	50 - 27	43 - 21	32 - 14	0	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
COO	†	COOPER COMPANIES INC	OCT	22 - 15	19 - 13	23 - 14	24 - 14	17 - 7	1	1	2	2	3	0.1 - 0.0	0.1 - 0.1	0.1 - 0.1	0.2 - 0.1	0.4 - 0.2
WST	§	WEST PHARMACEUTICAL SVSC INC	DEC	31 - 17	24 - 16	21 - 16	23 - 17	19 - 13	24	31	31	33	28	1.4 - 0.8	2.0 - 1.3	1.9 - 1.4	2.0 - 1.4	2.2 - 1.5
OTHER COMPANIES WITH SIGNIFICANT HEALTHCARE PRODUCTS & SUPPLIES OPERATIONS																		
BMY	[]	BRISTOL-MYERS SQUIBB CO	DEC	35 - 21	31 - 26	16 - 11	16 - 12	16 - 11	113	116	61	53	77	5.4 - 3.2	4.4 - 3.7	5.3 - 3.7	4.3 - 3.4	7.3 - 4.7
JNJ	[]	JOHNSON & JOHNSON	DEC	20 - 14	18 - 16	19 - 16	14 - 12	15 - 10	53	61	64	44	43	3.7 - 2.7	3.9 - 3.3	3.9 - 3.3	3.7 - 3.2	4.2 - 3.0

Note: Data as originally reported. ‡S&P 1500 index group. []Company included in the S&P 500. †Company included in the S&P MidCap 400. §Company included in the S&P SmallCap 600. #Of the following calendar year.

Ticker		Company		Yr. End	Earnings per Share ($)					Tangible Book Value per Share ($)					Share Price (High-Low, $)									
					2013	2012	2011	2010	2009	2013	2012	2011	2010	2009	2013		2012		2011		2010		2009	
HEALTH CARE EQUIPMENT‡																								
ABAX	§	ABAXIS INC	#	MAR	0.64	1.25	0.59	0.65	0.59	8.62	7.82	7.18	7.28	6.45	51.84 -	32.11	40.58 -	25.56	31.69 -	19.68	28.57 -	17.54	29.80 -	13.24
ABT	[]	ABBOTT LABORATORIES		DEC	1.52	3.76	3.03	2.98	3.71	6.24	1.50	(0.80)	(3.68)	2.17	38.81 -	31.64	72.47 -	53.96	56.44 -	45.07	56.79 -	44.59	57.39 -	41.27
ABMD	§	ABIOMED INC	#	MAR	0.19	0.38	0.04	(0.32)	(0.52)	3.27	2.63	2.27	1.70	1.81	29.24 -	11.96	26.17 -	11.80	21.50 -	9.42	12.25 -	7.80	16.74 -	4.67
ALOG	§	ANALOGIC CORP		JUL	2.54	3.51	1.33	1.24	0.29	31.12	33.70	30.52	28.27	27.30	98.00 -	68.86	84.71 -	53.68	58.96 -	42.90	50.98 -	37.35	42.01 -	24.39
BCR	[]	BARD (C.R.) INC		DEC	8.54	6.24	3.75	5.39	4.66	(2.28)	1.10	0.17	5.69	13.34	141.02 -	97.14	108.31 -	84.42	113.84 -	80.80	95.72 -	75.16	88.43 -	68.94
BAX	[]	BAXTER INTERNATIONAL INC		DEC	3.70	4.22	3.91	2.41	3.63	3.62	6.63	6.14	6.98	8.08	74.60 -	62.80	68.91 -	48.98	62.50 -	47.55	61.88 -	40.25	60.99 -	45.46
BDX	[]	BECTON DICKINSON & CO		SEP	4.76	5.40	5.72	5.02	5.04	14.07	9.65	12.67	16.87	16.52	110.94 -	78.73	80.56 -	71.56	89.75 -	69.59	85.50 -	66.47	79.97 -	60.40
BSX	[]	BOSTON SCIENTIFIC CORP		DEC	(0.09)	(2.89)	0.29	(0.70)	(0.68)	(3.86)	(3.98)	(3.37)	(3.44)	(4.52)	12.48 -	5.76	6.41 -	4.79	7.96 -	5.01	9.79 -	5.04	11.77 -	6.08
CMN	§	CANTEL MEDICAL CORP		JUL	0.96	0.78	0.53	0.53	0.43	0.82	0.52	1.55	1.58	0.94	38.04 -	19.11	20.17 -	12.00	12.68 -	8.45	10.74 -	5.95	9.52 -	4.96
CFN	[]	CAREFUSION CORP		JUN	1.76	1.62	1.31	0.77	2.53	7.07	6.26	5.60	3.43	NA	40.29 -	28.74	29.07 -	22.55	29.97 -	22.01	30.08 -	20.63	26.99 -	17.25
CNMD	§	CONMED CORP		DEC	1.30	1.43	0.03	1.06	0.42	1.39	5.62	5.11	3.59	3.26	45.57 -	27.86	31.93 -	24.78	29.73 -	20.51	27.05 -	16.75	24.43 -	11.56
COV	[]	COVIDIEN PLC		SEP	3.43	3.96	3.82	3.13	1.79	(3.57)	(2.25)	(1.31)	(3.33)	0.79	68.88 -	56.79	60.81 -	44.52	57.65 -	41.35	52.48 -	35.12	49.13 -	27.27
CRY	§	CRYOLIFE INC		DEC	0.59	0.29	0.26	0.14	0.31	4.00	3.37	3.49	3.77	3.63	11.15 -	5.52	7.27 -	4.19	6.17 -	4.00	7.45 -	4.80	9.79 -	3.93
CYBX	§	CYBERONICS INC	#	APR	2.02	1.68	1.30	1.67	2.83	9.25	8.02	6.50	6.02	3.93	71.93 -	42.31	54.00 -	32.00	35.88 -	23.58	34.43 -	16.55	21.36 -	12.31
CYNO	§	CYNOSURE INC		DEC	(0.09)	0.83	(0.23)	(0.44)	(1.79)	8.18	10.87	7.65	9.57	9.74	30.20 -	21.09	28.00 -	11.64	15.21 -	8.84	14.06 -	8.80	12.62 -	4.50
EW	[]	EDWARDS LIFESCIENCES CORP		DEC	3.51	2.55	2.07	1.92	2.04	10.22	8.99	8.07	8.05	6.65	94.98 -	60.62	110.79 -	67.86	91.82 -	61.59	85.47 -	42.31	44.13 -	26.43
GB	§	GREATBATCH INC		DEC	1.51	(0.20)	1.42	1.44	(0.39)	4.05	1.00	0.35	1.03	(1.15)	45.02 -	23.22	27.22 -	20.29	29.06 -	18.55	25.11 -	18.99	27.45 -	17.27
HRC	†	HILL-ROM HOLDINGS INC		SEP	1.75	1.94	2.11	1.99	(6.47)	4.50	3.07	8.57	7.80	6.29	42.56 -	28.94	36.13 -	24.69	48.80 -	26.90	43.80 -	23.11	24.27 -	8.57
HOLX	†	HOLOGIC INC		SEP	(4.36)	(0.28)	0.60	(0.24)	(8.48)	(17.58)	(19.90)	(5.51)	(5.90)	(7.84)	23.96 -	18.45	22.16 -	16.18	23.24 -	13.90	19.72 -	13.22	17.83 -	9.31
IDXX	†	IDEXX LABS INC		DEC	3.53	3.24	2.85	2.45	2.08	5.41	7.31	5.40	6.45	5.19	113.11 -	81.57	101.18 -	77.81	87.29 -	63.83	72.40 -	49.03	55.69 -	27.68
IART	§	INTEGRA LIFESCIENCES HLDGS		DEC	(0.60)	1.46	0.97	2.21	1.75	6.95	0.41	(1.40)	1.51	(0.98)	48.24 -	30.87	43.12 -	23.09	52.90 -	28.07	49.85 -	33.63	37.41 -	18.97
ISRG	[]	INTUITIVE SURGICAL INC		DEC	17.12	16.50	12.63	9.74	6.07	86.38	83.54	62.69	47.67	35.59	585.67 -	351.14	594.89 -	429.26	469.25 -	261.80	393.92 -	246.05	309.09 -	84.86
IVC	§	INVACARE CORP		DEC	(1.60)	(0.26)	(0.13)	0.78	1.29	4.56	2.73	1.46	2.30	1.85	23.40 -	10.26	19.25 -	12.87	34.52 -	14.54	30.92 -	19.58	26.27 -	14.23
MASI	§	MASIMO CORP		DEC	1.03	1.08	1.07	1.25	0.92	4.87	3.89	4.55	3.64	4.81	29.66 -	19.03	25.35 -	18.08	35.15 -	17.62	32.79 -	21.05	31.32 -	21.00
MDT	[]	MEDTRONIC INC	#	APR	3.06	3.40	3.24	2.87	2.80	6.57	5.58	4.37	3.41	3.35	58.85 -	41.16	44.79 -	35.67	43.33 -	30.18	46.66 -	30.80	44.94 -	24.06
BABY	§	NATUS MEDICAL INC		DEC	0.76	0.13	(0.41)	0.42	0.40	3.51	2.66	3.63	3.35	2.85	23.38 -	11.27	13.84 -	9.59	17.50 -	7.43	18.09 -	11.68	17.51 -	6.46
NUVA	§	NUVASIVE INC		DEC	0.18	0.07	(1.73)	1.99	0.16	7.72	6.46	5.34	5.67	2.32	33.91 -	15.70	25.99 -	11.25	34.91 -	11.02	46.83 -	22.11	45.06 -	24.17
RMD	†	RESMED INC		JUN	2.15	1.75	1.49	1.26	0.97	9.06	NM	9.54	6.99	5.76	57.34 -	41.98	42.94 -	24.41	35.36 -	23.37	35.90 -	25.03	26.69 -	15.74
SIRO	†	SIRONA DENTAL SYSTEMS INC		SEP	2.67	2.41	2.19	1.63	0.97	3.31	1.27	(1.22)	(3.87)	(7.30)	75.81 -	62.48	64.57 -	40.59	57.87 -	38.69	43.45 -	29.55	36.05 -	9.91
STJ	[]	ST JUDE MEDICAL INC		DEC	2.52	2.40	2.55	2.76	2.28	(0.71)	1.11	2.08	1.30	2.65	63.15 -	36.12	44.80 -	30.25	54.18 -	32.13	42.98 -	34.00	41.96 -	28.86
STE	†	STERIS CORP	#	MAR	2.20	2.74	2.33	0.86	2.18	4.93	4.09	8.38	7.93	7.57	48.50 -	34.80	37.18 -	27.70	37.38 -	27.08	38.16 -	25.65	35.42 -	19.20
SYK	[]	STRYKER CORP		DEC	2.66	3.41	3.48	3.21	2.79	8.50	13.24	10.94	13.80	12.58	75.55 -	55.24	57.15 -	49.43	65.21 -	43.73	59.72 -	42.74	52.66 -	30.82
SRDX	§	SURMODICS INC		SEP	1.01	0.58	(0.73)	(1.21)	2.15	5.91	5.55	7.23	7.52	7.66	27.98 -	19.24	22.42 -	13.30	15.50 -	8.73	23.31 -	8.28	31.00 -	15.96
SMA	§	SYMMETRY MEDICAL INC		DEC	(0.99)	0.25	0.08	0.39	0.61	(0.06)	(0.84)	(1.43)	2.85	2.40	12.83 -	7.44	10.64 -	6.41	10.29 -	6.91	12.05 -	8.00	11.55 -	3.90
TFX	†	TELEFLEX INC		DEC	3.68	(4.47)	2.98	3.12	3.57	(16.91)	(12.92)	(8.29)	(14.44)	(21.40)	99.13 -	71.84	71.59 -	57.26	64.56 -	49.40	66.07 -	47.92	55.30 -	37.21
THOR	†	THORATEC CORP		DEC	1.28	0.96	1.23	1.02	0.50	7.46	6.41	5.16	7.48	5.71	43.58 -	29.91	39.86 -	28.69	38.07 -	22.33	47.93 -	24.25	33.43 -	20.22
VAR	[]	VARIAN MEDICAL SYSTEMS INC		SEP	4.04	3.83	3.50	3.02	2.67	13.76	11.52	9.07	8.96	8.72	80.66 -	63.10	72.61 -	52.90	72.19 -	48.72	70.97 -	35.50	47.78 -	27.10
ZMH	[]	ZIMMER HOLDINGS INC		DEC	4.49	4.32	4.05	2.98	3.34	17.54	14.85	11.70	12.08	9.78	93.70 -	67.33	69.09 -	52.70	69.93 -	47.00	64.77 -	46.27	60.64 -	30.67

Ticker		Company	Yr. End	Earnings per Share ($) 2013	2012	2011	2010	2009	Tangible Book Value per Share ($) 2013	2012	2011	2010	2009	Share Price (High-Low, $) 2013	2012	2011	2010	2009
HEALTH CARE SUPPLIES‡																		
ALGN	†	ALIGN TECHNOLOGY INC	DEC	0.80	0.73	0.86	0.98	(0.45)	6.81	5.41	3.88	4.91	3.59	60.00 - 25.61	39.82 - 22.39	25.94 - 14.25	21.40 - 13.18	18.85 - 6.10
ANIK	§	ANIKA THERAPEUTICS INC	DEC	1.46	0.89	0.65	0.34	0.32	7.50	5.74	4.60	3.73	3.05	38.68 - 10.00	17.70 - 9.00	11.67 - 5.24	7.97 - 4.83	9.25 - 2.96
XRAY	[]	DENTSPLY INTERNATL INC	DEC	2.20	2.22	1.73	1.85	1.85	(3.81)	(5.85)	(8.00)	3.23	2.93	50.99 - 39.36	41.38 - 34.77	40.37 - 28.35	38.15 - 27.76	36.80 - 21.80
HAE	§	HAEMONETICS CORP	# MAR	0.68	0.76	1.32	1.60	1.14	4.42	3.42	10.30	9.14	7.60	45.90 - 37.71	41.57 - 30.60	35.20 - 27.50	32.42 - 25.25	32.67 - 23.39
ICUI	§	ICU MEDICAL INC	DEC	2.75	2.90	3.23	2.27	1.80	30.11	26.24	22.18	18.89	17.33	85.00 - 53.01	63.32 - 43.51	45.99 - 35.38	39.20 - 30.55	44.06 - 26.18
VIVO	§	MERIDIAN BIOSCIENCE INC	SEP	0.92	0.81	0.66	0.66	0.81	2.98	2.65	2.53	2.47	2.98	26.65 - 19.15	21.06 - 16.19	27.37 - 14.81	24.44 - 16.03	26.41 - 14.79
MMSI	§	MERIT MEDICAL SYSTEMS INC	DEC	0.39	0.47	0.59	0.35	0.64	2.36	2.08	5.70	3.37	4.51	17.08 - 9.15	15.37 - 11.51	19.94 - 11.38	15.88 - 11.02	15.92 - 7.66
NEOG	§	NEOGEN CORP	# MAY	0.77	0.76	0.64	0.66	0.52	5.22	4.72	4.07	3.28	2.33	51.22 - 29.93	31.99 - 20.10	31.95 - 17.06	28.31 - 13.67	16.47 - 7.33
COO	†	COOPER COMPANIES INC	OCT	6.09	5.18	3.74	2.48	2.23	17.05	12.55	11.13	6.34	3.73	135.41 - 93.46	100.92 - 67.98	84.20 - 52.60	59.11 - 34.28	38.99 - 16.50
WST	§	WEST PHARMACEUTICAL SVSC INC	DEC	1.61	1.18	1.12	0.98	1.11	10.60	8.25	7.29	6.88	6.20	50.60 - 27.31	28.01 - 18.67	23.98 - 17.75	22.42 - 16.37	20.89 - 13.93
OTHER COMPANIES WITH SIGNIFICANT HEALTHCARE PRODUCTS & SUPPLIES OPERATIONS																		
BMY	[]	BRISTOL-MYERS SQUIBB CO	DEC	1.56	1.17	2.18	1.80	1.63	3.48	(1.70)	4.29	4.17	3.94	54.49 - 32.50	36.34 - 30.64	35.44 - 24.97	28.00 - 22.24	26.62 - 17.23
JNJ	[]	JOHNSON & JOHNSON	DEC	4.92	3.94	3.54	4.85	4.45	8.26	4.91	8.37	8.97	7.04	95.99 - 70.30	72.74 - 61.71	68.05 - 57.50	66.20 - 56.86	65.41 - 46.25

Note: Data as originally reported. ‡S&P 1500 index group. []Company included in the S&P 500. †Company included in the S&P MidCap 400. §Company included in the S&P SmallCap 600. #Of the following calendar year.
J-This amount includes intangibles that cannot be identified.

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