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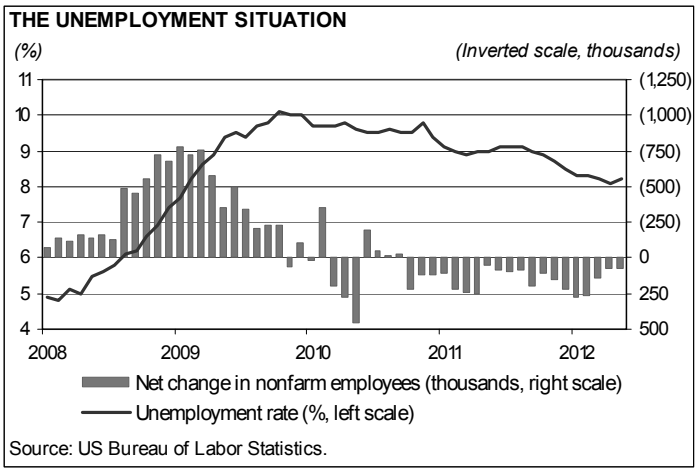
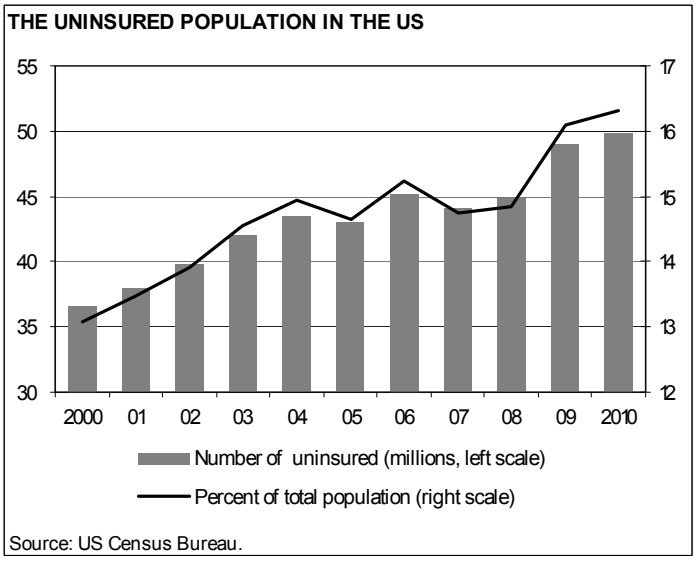
CURRENT ENVIRONMENT

With healthcare reform in focus, fundamentals stabilize, visibility improves

Continued economic weakness, along with high unemployment rates in the US and the European Union (EU), continue to crimp the growth prospects for medical device companies. However, with the healthcare reform bill signed into law in March 2010, S&P Capital IQ believes 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.

We believe that, 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, 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 believe 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—have not held up in the US, albeit for different reasons. Meanwhile, based on the quarterly results reported by medical device companies up to the time this *Survey* went to press in late July 2012, procedure rates in the EU appear to have slowed further in the second quarter of 2012, hurting medical device sales growth there. In addition, we still see pressure on those devices used for elective medical procedures, such as cosmetic surgery. The medical devices industry has begun to rely increasingly on other international markets, particularly emerging countries, to compensate for sluggish US and EU growth.





Favorable global demographic trends, such as aging populations, more active seniors, and an expanding middle class in emerging markets, has supported this highly diversified industry. We also note generally positive patient outcome data relative to competing pharmaceutical treatment options across many major therapeutic categories, and strong patent protection relative to branded pharmaceuticals. In addition, healthcare reform in the US promises to bring insurance coverage to millions of people who currently do not have it, thereby expanding the potential domestic customer base.

We believe these benefits outweigh the pressures medical device companies will face in coming years. These pressures include increased scrutiny and a lengthier product approval process by the US Food & Drug Administration (FDA); an excise tax enacted to support US healthcare reform measures; and the likelihood

of intensified competition among various therapies, partly as a result of the growing role of comparative effectiveness research.

Overall, S&P Capital IQ thinks that the industry will continue to witness slow growth through 2012 and likely into 2013 (particularly in the US and the EU), which will be only partly offset by growth in emerging markets such as India and China. This view of industry performance is not necessarily contrary to the findings of a survey released in June 2012 by Axendia Inc., a research and consulting firm focused on the life sciences and healthcare markets. Axendia surveyed 125 medical technology executives representing 89 different companies in 16 countries. A majority of the survey respondents (91%) expect strong annual growth in the medical technology industry in the next three years, with 88% expecting increased sales in emerging markets and 69% expecting increased sales in developed markets. This is a longer time horizon than S&P Capital IQ uses for its projections, and we think these forecasts may come to fruition due to demographic trends and assuming the macroeconomic crises impacting both sides of the Atlantic Ocean dissipate in that time. In addition, 65% of the survey respondents see the global regulatory environment as the top business threat over the next three years.

Meanwhile, we see a scarcity of life-altering new products coming out of R&D, such as ICDs and cardiac stents, which have led to 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. In April 2012, the Advanced Medical Technology Association (AdvaMed), the medical device industry trade association, announced a strategic three-year plan to help the US medical devices industry maintain its competitive edge and encourage innovation. The key objectives of the plan include the following: strengthen AdvaMed's presence in emerging markets such as Brazil, India, and China; build its own in-house research capability; focus its resources on important policy issues; and improve communication with, and among, member companies of AdvaMed and patient groups.

The US unemployment rate stood at 8.2% in June 2012, down from 8.5% in December 2011 (Standard & Poor's Economics, which operates separately from S&P Capital IQ, believes this measure peaked at 10.1% in October 2009). We expect the industry to continue to face a difficult but modestly improving macroeconomic environment in 2012 and afterward. While we continue to 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 the pricing pressures seen over the last several years, as the macroeconomic factors described contribute to slower sales growth.

IN RESPONSE TO HEALTHCARE NEEDS, HEALTHCARE REFORM ARRIVES

Despite the tremendous amount of resources it devotes to healthcare, the US ranks among the lowest in the industrialized world in terms of access to healthcare for its citizens. According to the US Census Bureau, the number of uninsured increased to 49.9 million (16.3% of the population) in 2010, from 49.0 million (16.1%) in 2009. Moreover, despite the expansion of Medicare, Medicaid, the Children's Health Insurance Plan, and other private and government programs, the percentage of uninsured has remained stubbornly high since 2002. The Census Bureau reported that the percentage of people covered by private health insurance has continued to decline, falling to 64.0% in 2010 from 64.5% in 2009 and 67.5% in 2008. Furthermore, although the unemployment rate declined to 8.2% as of June 2012 (from an October 2009 peak of 10.1%) and, as of June 2012, Standard & Poor's Economics projected the rate to reach 8.0% for the second quarter of 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, due to untenable insurance premium price hikes.

Healthcare reform, as defined by the Patient Protection and Affordable Care Act (PPACA; H.R. 3590), which was signed into law by President Obama on March 23, 2010, will require most US citizens and legal residents to have minimum essential health insurance coverage. (Accompanying that bill was the Health

Care and Education Reconciliation Act of 2010, or H.R. 4872, which was signed into law on March 30, 2010; its primary focus was to provide financing mechanisms to cover most of the healthcare reform costs.) The nonpartisan Congressional Budget Office (CBO), a research arm of Congress, estimated the cost of both bills at $938 billion over the 10 years from 2010 to 2019, with an estimated reduction in the deficit of $143 billion over that period.

Republican critics had been attempting (both through legislation and in the courts) to roll back some or all of the healthcare reform law. Several appeals courts have given various rulings on the validity of the healthcare law. On November 14, 2011, the US Supreme Court agreed to hear an Obama administration appeal defending the law, as well as two separate appeals by 26 states and an independent business group challenging the constitutionality of the law. On June 28, 2012, the US Supreme Court's ruling on the healthcare reform kept intact all but one of the insurance reforms of the PPACA (noting that states are not required to expand Medicaid eligibility).

Resistance to the device excise tax

To help finance healthcare reform, the PPACA introduced a number of new fees and taxes for almost everyone in the healthcare continuum, including manufacturers, providers, and even citizens and legal residents who choose not to acquire health insurance. For the medical device group, there is a 2.3% excise tax on all sales of nearly all types of supplies and equipment sold in the US. The tax will take effect in 2013 and generate up to $20 billion over the subsequent 10 years. Excluded from this tax are certain kinds of medical devices (such as eyeglasses, contact lenses, and hearing aids) that the FDA classifies as devices generally sold directly to the public for individual use, and all products sold outside of the US. While the medical devices industry was hoping that the US Supreme Court would repeal the tax in its June 2012 ruling, the 2.3% excise tax will now take effect as scheduled unless Congress legislates a change..

S&P Capital IQ (S&P) believes that the 2013 start date gives the industry time to take the actions needed to realign its cost structure to diffuse the tax's impact on future profitability. The industry also benefited from the levy being an excise tax, which is deductible for income tax purposes and should yield a net rate of 1.5%. A number of the larger device companies have already begun to reduce costs in light of the pending tax (see below), although we think that many of these cost-reduction activities eventually would have occurred in order to help earnings. However, we believe the levy will have the greatest impact on small and mid-sized companies, particularly those developing new technologies (and thus have relatively high R&D expenses as a percentage of revenues) and those deriving most of their sales in the US.

As we expected, AdvaMed, as well as hundreds of individual device companies, industry councils, and venture capital firms, have been pressing Congress to repeal the tax. Congressional Republicans, as well as Democrats from states that are home to large medical device makers, have put forward bills designed to eliminate the tax, saying it will stifle innovation. A study commissioned by AdvaMed and released in March 2012 said the tax, if implemented, could lead to the loss of 39,000 US medical technology jobs, along with a reduction of $8 billion in economic output. An earlier study commissioned by AdvaMed also found that the tax would add around $2.67 billion to the industry's annual tax bill, giving the industry the highest average effective corporate income tax rate in the world. As a result, US manufacturers may consider relocating their plants outside the US to save on other costs such as labor. Another result might be higher prices for their products, which would be paid by healthcare providers and consumers.

In his State of the Union address in January 2012, President Obama focused on rejuvenating the US manufacturing sector and creating more jobs. AdvaMed commented on the address by saying that medical technology companies fully support the President's emphasis on growth of the manufacturing sector and his efforts to generate employment, though it added that the tax would lead to further loss of employment and render the nation's tax system uncompetitive. In May 2012, the US House of Representatives' Ways & Means Committee passed a bill to repeal the medical device tax. On June 7, 2012, the House voted to repeal the tax (including 37 Democrats voting in favor); however, the US Supreme Court ruling on June 28 upheld the medical device tax. The industry is increasing pressure on Congress to repeal the tax; however, the CBO estimates that if the tax were repealed, the government would lose $29.1 billion in revenues in the coming 10 years.

Device makers have already started taking steps to prepare for the tax implementation. For example, in November 2011, Stryker Corp. announced plans to cut about 1,000 jobs (or 5% of its workforce) and to restructure operations to save more than $100 million by 2013 to allow for the impact of the tax. Similarly, in March 2012, Zimmer Holdings Inc. announced layoffs at its Warsaw (Indiana) headquarters, part of its plan to offset the entire burden posed by the impending tax through cost-cutting efforts aimed at finding $400 million in cost savings before 2016 and to pay for an estimated $60 million tax bill in 2013. S&P Capital IQ expects other device makers to follow suit. In addition, according to a survey of 190 financial executives in medical device firms, which was conducted by the audit, tax, and advisory firm KPMG LLP in March 2012, 40% of the respondents said that their companies are already planning such actions as price increases and cost reductions (such as downsizing the workforce and changing manufacturing processes) to stay competitive. Moreover, 61% said that the medical device tax would hurt their company's bottom line.

Let the sunshine in

The Physician Payment Sunshine Act, first introduced in 2007 and included as a provision in the PPACA, requires medical device and pharmaceutical manufacturers to disclose payments or other "transfers of value" (consulting fees, food, honoraria, gifts, travel, entertainment expenses, etc.) of $10 or more as of January 1, 2012. (The date has been delayed to January 1, 2013, as discussed below.) The information will be posted on a public Department of Health & Human Services website starting on September 20, 2013, and will include the amount and nature of each payment, the date it was made, and the recipient.

Drug and device makers covered by Medicare, Medicaid, and CHIP must report gifts made to physicians (including dentists, podiatrists, optometrists, and chiropractors) and to teaching hospitals. Knowingly failing to submit payment information will result in a fine of $10,000 to $100,000 for each omitted payment, up to $1 million per year. However, manufacturers can delay disclosing payments associated with product or R&D agreements and clinical trials until either the product is approved or cleared by the FDA, or four years after the applicable payment, whichever comes first. Excluded from reporting is anything under $10 (as long as the cumulative value to a single physician from the reporting company remains under $100 in one year), loaner devices for a physician to evaluate for purchase, free product samples for patient use, educational material that benefits patients, warranties, discounts, and legal services. Critics of the provision argue that this rule will lead to a decrease in physician compensation. This, in turn, will have negative effects on clinical research and education.

Many medical, consumer, and industry groups—such as the Medicare Payment Advisory Commission (MedPAC), an independent Congressional agency, and the Institute of Medicine (IOM), an independent, nonprofit organization—are in favor of the legislation. They believe it will bring greater transparency to the financial relationships between health professionals and teaching hospitals, and the pharmaceutical and medical device companies. In December 2011, the Centers for Medicare and Medicaid Services (CMS), the arm of the US Department of Health and Human Services (HHS) responsible for Medicare and Medicaid, released the proposed rule that would implement the "Transparency Reports and Reporting of Physician Ownership or Investment Interests" section of the Physician Payment Sunshine Act of the PPACA.

Certain organizations—such as the drug industry trade group Pharmaceutical Research and Manufacturers of America (PhRMA) and the Coalition for Healthcare Communication (CHC), an organization dedicated to the dissemination of healthcare information—believe that the CMS should not delay any longer in finalizing the rule and should lay down the reporting requirements for the industry to follow. The industry at large believes that the law should not only require a disclosure of the payments, but should also ask for the reasons for such payments. On May 3, 2012, the CMS announced a delay in implementation of the Sunshine Act. It said that data collection from manufacturers would not begin until January 1, 2013, giving the reason that the additional time would help the industry prepare for submission of the required information. Further, the CMS said that it should be out with the final rule later this year.

UNRELENTING PRICING PRESSURE

Since the onset of the recent recession, as hospitals have looked to control capital expenditures and as overall industry demand has softened in response to both macroeconomic and industry factors, the medical

device sector has faced increasing pricing pressure. We expect additional pricing pressure to come from some areas. First are pending declines in the rate of reimbursement for medical supplies and equipment that some providers (particularly acute-care hospitals) will experience; these cuts are being used to help cover the cost of healthcare reform. Second, hospitals' increasing recruitment of doctors and acquisitions of physicians' practices could shift control of product choice from the physician to the hospital. Finally, some hospitals are reducing the number of vendors with which they do business. Nonetheless, we expect the impacts from pricing pressures and the aforementioned excise tax to be more than offset by the companies' focus on improving administrative cost control and the increase in coverage and utilization of services by those who had previously been uninsured.

Cardiovascular: more competition in stents, slower growth for ICDs

We believe that pricing pressure, particularly in the drug-eluting stent (DES) market, reflects a number of factors. First is increased competition following the introduction of the XIENCE DES stent (from Abbott Laboratories) and the private-label PROMUS (Boston Scientific). Both were approved in July 2008 and demonstrated superior restenosis rates (restenosis is the repeat narrowing of a coronary artery) compared with existing stents. We believe that both Medtronic Inc., which received approval for its ENDEAVOR stent in February 2008, and Johnson & Johnson, whose Cypher stent was the first DES brought to market in April 2003, were forced to cut prices and seek volume deals. With Cypher sales continuing to decline, Johnson & Johnson exited the DES market at the end of 2011.

Second, in light of hospitals' deteriorating operating conditions and their desire to both leverage purchasing power and contain supply costs, a number of hospitals have sought preferred provider contracts or are deploying standardized purchasing initiatives. Lastly, because of the decline in industry volumes in the DES market seen between 2006 and early 2008, we believe price competition intensified for the reduced volumes available. We estimate that pricing declined in the high single-digits each year from 2008 to 2011. However, in its 2012 first- and second-quarter earnings calls (in April and July 2012, respectively), Boston Scientific indicated that it saw signs of stabilization in the US DES market and an easing of pricing pressures.

In the implantable cardioverter defibrillator (ICD) market, in contrast, we believe the issue has been decelerating growth following the Medtronic and Guidant ICD recalls between 2005 and 2007; volume growth rates declined from approximately 20% to the low single digits. We believe the market experienced price declines of 1%–2% in 2008, as volumes continued to remain soft, in part reflecting residual concerns by both doctors and patients about product safety due to recalls related to defibrillator lead wires. We believe that pricing deteriorated by this rate again in 2009, and worsened in 2010 and 2011, as clinicians adopted a more conservative approach in their practice of implanting ICDs. (For more details, see the ICD implantation discussion under the "Cardiovascular" subheading later in this section.)

In any event, we note that these trends are an approximation, reflecting the average of each company's experience in the ICD market. Medtronic, for example, said in February 2010 that a year earlier, it was experiencing price declines of 50 to 100 basis points (0.5%–1.0%); however, in November 2010 and again in February 2011, the company reported that it was seeing mid-single-digit price declines in the US. In May 2011, Medtronic said that its pricing stabilized in the April 2011 quarter for the first time in seven quarters, which it attributes to an ICD product line launched in the quarter. However, in November 2011, in its fiscal 2012 second-quarter earnings call, the company said that it had been seeing mid-single-digit price declines in its US market. Further, in its fiscal 2012 fourth-quarter earnings call in May 2012, the company said that the worldwide ICD market declined in mid-single digits, but showed sequential improvement over the third quarter. It also said that the US ICD market stabilized in the fiscal fourth quarter.

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. We attribute this trend mainly to still-high unemployment, following the 2007–09 recession, and the accompanying loss of health insurance coverage, as well as 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. Indeed, UnitedHealth Group Inc., one of the largest insurers, said, at its analyst day in late November 2010, that it viewed

orthopedics as "one of the highest cost conditions across all episode treatment groups. It's very frequent in terms of how it's used."

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 believe the competition remains very high in the 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.

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 addition, many continue to attempt to develop close relations with orthopedic surgeons, though the US government deemed some of these relationships illegal, based on the federal anti-kickback statute. Following an investigation that started in March 2005, many of the financial ties between surgeons and device makers (including consulting arrangements and other inducements) were suspended as a result of settlements between five leading orthopedic device manufacturers—Biomet Inc., DePuy (a division of Johnson & Johnson), Smith & Nephew plc, Stryker Corp., and Zimmer Holdings Inc.—and the US Department of Justice (DOJ). In 2007, these orthopedic device makers agreed to pay $311 million to settle DOJ claims that they paid kickbacks to surgeons in exchange for exclusively using their products.

The aforementioned settlement did not ban all consulting relationships or those wherein the device maker manufactures and markets devices invented by surgeons. The federal prosecutors deferred criminal charges against the companies and required them to disclose the consulting agreements, put payment amounts in their corporate websites, and allow federal monitors to see these activities. According to a report released in October 2011 by the *Archives of Internal Medicine*, a bimonthly medical journal, 939 orthopedic surgeons received 1,041 payments totaling $198 million in 2007, the year of the settlement. In 2008, there were 568 payments to 526 surgeons amounting to $119 million, plus $109 million in royalty buyouts from Zimmer.

According to a study published in the November/December 2008 issue of *Health Affairs*, patent data and the American Medical Association Physician Masterfile database provide evidence that physicians contribute to medical device innovation, accounting for almost 20% of about 26,000 medical device patents filed in the US from 1990 to 1996. While device makers suspended certain payments to surgeons, hospitals have begun to benefit from the relationships between their surgeons and the device makers, sometimes in the form of price discounts, according to a May 16, 2008, article in the *San Francisco Business Times*.

Hospitals seek best prices

Meanwhile, hospitals have become more active in attempting to elicit the best prices from device makers. Partly in response to individual hospitals paying different prices for devices that were functionally the same and vendors insisting in their contracts that the hospitals not reveal pricing information (other than to hospitals in the same hospital system), hospitals within the same system have begun to work together to negotiate prices with device makers.

According to *Pulse of the Industry: Medical Technology Report 2011*, from the accounting and consulting firm Ernst & Young (E&Y), the medical devices industry is facing a highly challenging environment owing to the reimbursement scenario in developed markets. Payers are requesting that medical device companies show how their products improve health outcomes in order to bring greater value for the users. According to the 2010 issue of the same report, some providers have formed joint ventures to share expensive technologies, such as CT scan equipment, within a geographic region. Kaiser Permanente, a large, not-for-profit hospital system, uses teams of surgeons to evaluate devices. We believe 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, a trend that hospitals believe helps them gain economies of scale to function better under healthcare reform.

Amid the controversy surrounding the rising cost of healthcare, the medical devices industry has been attempting to show that it is not the primary cause. According to a study conducted by AdvaMed, spending on medical devices has remained at about 6% of national health expenditures over the 20-year period ending in 2009. Further, the study reveals the price data for the 20-year period, according to which, the CPI for Medical Care Services has been at 5% for the period, while CPI for Medical Care has been at 4.7%, CPI has stood at 2.8% and medical device prices have increased at an annual average rate of as low as 1% in comparison. Similarly, for the 10 years ending in 2009, the average CPI has been 2.6%, while the medical device prices have risen at the same pace of 1%.

S&P Capital IQ believes that hospitals play an important role in limiting the impact of medical device costs on the overall rising cost of healthcare. According to a Reuters article dated November 29, 2011, hospitals are increasingly targeting expensive orthopedic and cardiac devices. The article also noted that hospitals are working closely with their physicians, meeting regularly to discuss brand preferences and encouraging lower-priced products that are shown to be equally effective. Some hospitals also use vendor-managed inventory, which means that the devices on their shelves are not paid for until they are used.

Even as hospitals are taking measures to curb their spending on devices, hospital costs are rising. In January 2012, the Government Accountability Office (GAO) released a study to analyze the trends in Medicare spending on implantable medical devices (IMDs) and to assess the level of transparency in the prices various hospitals pay for the IMDs. According to the report, there was a significant variation in the prices paid by different hospitals for cardiac devices. For example, for a particular automated implantable cardioverter defibrillator (AICD) model, the difference between the highest and the lowest reported price paid by hospitals was as high as $8,723, while for another model, the difference amounted to $6,844. The median cost for the four defibrillator models fell in the range of $16,445 to $19,007. The study identified the growing influence of physicians on hospitals' purchasing decisions as one of the main factors leading to such high disparity in the prices hospitals pay for devices. Although physicians do not directly participate in price negotiations with suppliers, they might be inclined to buy a specific model or device by a specific manufacturer, which in turn might lead to different physicians working in the same hospital who prefer different devices. This is an obstacle to hospitals getting discounts from manufacturers for bulk purchases, thus lowering their bargaining power. The report also noted that the confidential nature of negotiations between hospitals and device manufacturers adds to the lack of transparency.

Looking ahead, S&P expects comparative effectiveness research (discussed in more detail below) will increasingly be used and will likely include pricing as a determinant for what products offer the best cost efficiency. This means that manufacturers, including both orthopedic and cardiology device makers, will have to be aware of pricing in product design and marketing, and will be required to show that their newer, higher-priced products yield superior results compared with existing technologies.

OUTLAYS FOR HIGH-PRICED EQUIPMENT RECOVERING, BUT STILL DOWN SIGNIFICANTLY

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

In our view, hospitals are carefully evaluating both maintenance and upgrade capital expenditures in terms of return on investment and, given tighter capital budgets, 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—had also experienced lower sales amid spending cuts by US hospitals.

Nonetheless, some medical equipment and supplies manufacturers reported a small pick-up in hospital purchasing starting in 2010, which we believe is 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. For example, Varian Medical Systems Inc., a leading maker of radiation-oncology equipment, reported strong demand for its new TrueBeam system for image-guided radiotherapy and radiosurgery. In its fiscal 2012 second- and third-quarter conference calls (in April and July 2012, respectively), the company said that the TrueBeam system accounted for over 45% and 50% of the high-energy machine orders received by the company in the quarters. In all, the company has received 550 orders for TrueBeam since the product's launch two years ago. Intuitive Surgical Inc. has reported similarly high demand for its da Vinci robotic surgical systems: the company sold 140 in its 2012 first quarter (versus 120 in the same quarter last year), and 150 in the second quarter (versus 129). The company also said that it expected the volume of da Vinci procedures to grow 25%–27% in 2012 from last year.

Although none of the small capital equipment companies under S&P's analytical coverage has highlighted pricing pressures in the US, we believe some manufacturers are discounting in order to reach sales targets. Others, while not actually discounting, are offering newer products with additional features, capabilities, and/or power, but are asking for only modestly higher prices, so buyers perceive they are receiving greater value. In this period of more-cautious hospital capital spending, we expect sales of small-ticket capital equipment, particularly items deemed by providers as vital, to remain relatively more active (albeit at a modest pace) than sales of big-ticket equipment, and to recover faster as hospitals strengthen financially.

In international markets, medical capital equipment makers have been realizing higher sales, but both large- and small-ticket items sold there typically have lower price tags than they would in the US. The reason is that healthcare providers in those markets are primarily government-run or -subsidized and thus seek to limit the rise in their healthcare costs. In our view, pricing practices in the US and overseas have been in place for many years and did not visibly change amid the economic downturn. Nevertheless, we believe healthcare reform and comparative effectiveness research will likely intensify price and feature competition.

A STRICTER 510(k) PRODUCT APPROVAL PROCESS AHEAD?

On January 19, 2011, following public comments by stakeholders (including medical device companies, industry representatives, and consumer and patient groups), the US Food and Drug Administration (FDA) unveiled a plan containing 25 actions it intended to implement during 2011 related to its abbreviated approval process—known as 510(k)—that enables devices categorized as Class II (relatively low-risk) to be marketed in the US. The FDA developed the new approval process in response to industry 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. The process in Europe involves relatively less strict barriers, a quicker response time, and a shorter clinical trial cycle.

To be eligible for consideration and approval under the 510(k) process, such a device must be shown to be "substantially equivalent" to an already approved device (known as a predicate device). 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 premarket approval (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.

In January 2012, the FDA's Center for Devices and Radiological Health (CDRH) announced its priorities for 2012, which include starting a pilot program aimed at enhancing the agency's efficiency in reviewing pre-market applications and coming up with a proposal stating the conditions under which the CDRH can use clinical studies conducted in and for other countries by December 31, 2012. The CDRH will also undertake steps to oversee Class III devices, which currently undergo the 510(k) process. By the end of October 2012, the agency also has plans to revamp and enhance the efficiency of the processes used to recall medical devices and radiation-emitting products. By October 31, 2012, the agency also plans to improve its post-market surveillance program by formulating effective strategies to evaluate the performance of sold-out devices. To address the issues related to slower approval of innovative medical devices, the agency said that by September 30, 2012, it would "create processes and tools that will improve the pipeline for innovative medical devices and transform the way CDRH works with medical device innovators." To this end, on

April 9, 2012, the CDRH launched the "Innovation Pathway 2.0" program aimed at reducing the time required to come out with effective products and improve collaboration between the FDA and the device manufacturers, starting with the pre-market submission stage.

IOM found existing 510(k) approval process flawed

The Institute of Medicine (IOM), the health arm of the National Academy of Sciences, is an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public. In July 2011, it released its report, *Medical Devices and the Public's Health: The FDA 510(k) Process at 35 Years*. The IOM said it did not believe that there is "a public-health crisis related to unsafe or ineffective medical devices," or that "medical devices cleared through the 510(k) process and currently on the market are unsafe or ineffective." However, it found that "available post-marketing–surveillance data do not provide sufficient information…to be a useful source of data about the safety and effectiveness of marketed devices."

The *New England Journal of Medicine* (NEJM) supported IOM's view on the FDA's process, but not all agreed that the 510(k) approval process should be scrapped. Indeed, AdvaMed, the medical device industry's trade association, views the current 510(k) process as having a notable safety record. In any event, S&P believes that based on the IOM's recommendations, the FDA might eventually require more pre- and post-clinical data for 510(k) submissions, which could make the approval process more expensive.

Pressure builds on the FDA, political and otherwise

Although the FDA is in the midst of revamping its 510(k) approval rules, the agency has come under political pressure to head off the new approval process and ease device approvals. Studies published in late 2010 and early 2011 by PricewaterhouseCoopers (PwC), Stanford University professor Josh Makower, M.D., 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.

As a result of the studies and, we believe, industry pressure, the House Energy & Commerce Health Subcommittee, which oversees the FDA, decided to explore why the European regulatory pipeline moves faster than its equivalent at the FDA, according to an article published on MassDevice.com, an online journal of the medical devices industry, on February 16, 2011. According to the article, at the House subcommittee meeting that day, Dr. Jeffrey Shuren, the director of the FDA's Center for Devices and Radiological Health (CDRH), noted that it is difficult to make direct comparisons between the US and European systems, due to fundamental differences. For example, the European Union "lacks the requirement in U.S. law that a device be shown to be effective." He also said that one of the three studies overestimated the review times because it counted the "substantial pre-submission assistance" the FDA offers applicants.

The GAO weighed in

The US Government Accountability Office (GAO), in a report to congressional requesters published June 21, 2011, has recommended that the FDA enhance its oversight of medical device recalls. According to information reviewed by the GAO, manufacturers initiated 3,510 device recalls (or an average of over 700 recalls per year) from 2005 to 2009. Of these recalls, as many as 83% were classified as class II, which implies a moderate degree of risk associated with usage of the device. About 40% included cardiovascular, radiological, or orthopedic devices. The GAO report identified numerous gaps in FDA processes and procedures that, if unaddressed, may increase the risk that unsafe medical devices could remain on the market. To aid its oversight of the medical device recall process, according to GAO recommendations, the FDA should routinely assess information on device recalls, develop enhanced procedures and criteria for assessing the effectiveness of recalls, and document its basis for terminating individual recalls.

Following the GAO's recommendations on improving the FDA's recall monitoring process, the Senate released a bill in December 2011 that provides the FDA with the authority to require post-market studies as a condition of the 510(k) process. AdvaMed, however, believes that such authority is not important, as the FDA already has the right to ask manufacturers to carry out post-market studies for higher-risk products.

Help arrives from Congress

On November 18, 2011, the Consolidated and Further Continuing Appropriations Act, 2012 was signed into law. The law set the spending level for the FDA for fiscal 2012 at $2.497 billion (excluding user fees), matching the amount the Senate Appropriations Committee set for the agency in August and $334 million more than that set by the House in its appropriations bill passed in June. Further, the amount exceeds the FDA's fiscal 2011 budget by $50 million. S&P believes the funding would allow the FDA's Center for Devices & Radiological Health (CDRH) to meet its $332 million budget, and may also help take some heat off the negotiations between the FDA's medical device arm and the industry relating to the user fees.

MDUFA III AGREEMENT

On July 9, 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. 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. The CBO estimated the FDA would collect about $609 million in fees from MDUFA during the fiscal 2013–17 period. The bill also included medical device regulatory reforms.

AdvaMed supports the recent reauthorization of MDUFA, which was worked out through negotiations between the FDA and industry representatives. It views the user fee agreement as having the potential to increase the predictability, consistency, and efficiency of the FDA's decision-making. The industry has long complained that past problems with the FDA are a main reason why the industry often launches new products in Europe before launching them in the US.

S&P views the changes to MDUFA as positive for the device industry in that 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.

While S&P Capital IQ believes the medical device makers, such as Boston Scientific, Covidien, Edwards Lifesciences, Medtronic, St. Jude Medical, Stryker, and Zimmer Holdings are likely to benefit from the aforementioned process changes by the reduced time and cost to bring new products to the US market, the reforms also sought to protect consumers. Indeed, the Consumers Union (CU), a nonprofit consumer products review organization, noted that the FDA can more easily up-classify problematic devices so that subsequent, similar devices will receive more scrutiny in the approval process, and that approval for high-risk devices depends on the completion of post-market studies. However, the CU and other consumer groups complain that the bill does not prohibit the FDA from approving new devices based on predecessor devices that have been found to be faulty and that it does not require national registries of patients with devices that would enable the FDA to quickly identify and track problem devices.

CDRH priorities for 2012

In January 2012, the FDA's Center for Devices and Radiological Health (CDRH) announced its priorities for 2012, which include starting a pilot program aimed at enhancing the agency's efficiency in reviewing pre-market applications and coming up with a proposal stating the conditions under which the CDRH can use clinical studies conducted in and for other countries by December 31, 2012. The CDRH will also undertake steps to oversee Class III devices, which currently undergo the 510(k) process. By the end of October 2012, the agency also has plans to revamp and enhance the efficiency of the processes used to recall medical devices and radiation-emitting products. By October 31, 2012, the agency also plans to improve its

post-market surveillance program by formulating effective strategies to evaluate the performance of sold-out devices. To address the issues related to slower approval of innovative medical devices, the agency said that by September 30, 2012, it would "create processes and tools that will improve the pipeline for innovative medical devices and transform the way CDRH works with medical device innovators." To this end, on April 9, 2012, the CDRH launched the "Innovation Pathway 2.0" program aimed at reducing the time required to come out with effective products and improve collaboration between the FDA and the device manufacturers, starting with the pre-market submission stage.

INDUSTRY CONSOLIDATION HAS BUILT MOMENTUM

According to S&P Capital IQ data, merger and acquisition (M&A) activity—in which healthcare products and supplies companies worldwide were buyers, sellers, and/or targets—grew markedly in 2010. In that year, 604 transactions were announced (including bids and letters of intent), for which the transaction values for 280 (those available publicly) totaled approximately $68.0 billion. Note, though, that the Novartis acquisition of Alcon accounted for $40.7 billion of the total. In any event, the number of transactions was up markedly from 2009, when 513 were announced, of which the transaction values of 232 were provided and had an aggregate value of $17.4 billion.

SELECTED MEDICAL PRODUCTS AND SUPPLIES ACQUISITIONS—2011-2012
(Ranked by deal size)

YEAR	PURCHASER	TARGET	DEAL SIZE (MIL. $)
FIRST-HALF 2012	Hologic Inc.	Gen-Probe	4,204.1
	Agilent Technologies	Dako A/S	3,000.4
	EQT Partners	BSN Medical	2,274.3
	Asahi Kasei Corp.	ZOLL Medical	2,216.2
	Boston Scientific	Cameron Health	1,350.0
	William Demant Invest	Ossur	762.2
	Corning Inc.	Discovery Labware	730.0
	Omega Pharma NV	GlaxoSmithKline's non-core consumer healthcare OTC brands in Europe	614.0
	Haemonetics Corporation	Pall Corp.'s blood collection, filtration, and processing product lines	550.6
	Bausch & Lomb	ISTA Pharmaceuticals	491.9
	Royal DSM	Kensey Nash Corp.	393.3
	AngioDynamics	Navilyst Medical	374.5
2011	Johnson & Johnson	Synthes	21,534.6
	Danaher Corp.	Beckman Coulter	7,392.9
	Apax Partners Worldwide; Canada Pension Plan Investment Board; Public Sector Pension Investment Board	Kinetic Concepts	6,291.6
	Apax Partners Worldwide	Smiths Medical	3,888.6
	Thermo Fisher Scientific	Phadia AB	3,512.8
	Endo Health Solutions	American Medical Systems Holdings	2,825.1
	Terumo Corporation	Terumo BCT	2,625.0
	DENTSPLY International	Astra Tech AB	1,948.2
	TPG Capital	Immucor	1,945.1
	Couckinvest NV	Omega Pharma NV	1,387.9
	FUJIFILM Holdings	SonoSite	931.4
	MAQUET Cardiovascular	Atrium Medical	680.0
	Elekta AB	Nucletron B.V.	525.1
	Biosensors International	Shandong JW Medical Products	507.2
	Kyowa Hakko Kirin Co.	ProStrakan Group	499.2
	Bain Capital Private Equity	Physio-Control	468.0
	Medtronic	Salient Surgical Technologies	452.0
	EQT Partners	Atos Medical AB	425.3
	Covidien	BÂRRX Medical	413.0
	Catalent Pharma Solutions	Aptuit's clinical trial supplies business	407.0
	Alere Inc.	Axis-Shield	396.1
	Boston Scientific	Atritech	375.0
	Baxter International	Baxa Corporation	367.0
	Hologic Inc.	Interlace Medical	351.8

Source: Capital IQ; Company reports.

In 2011, 610 transactions were announced, of which the transaction values of 273 were provided publicly and had an aggregate value of $71.3 billion. Only 263 transactions were announced in the first half of 2012 for which the transaction values for 111 totaled about $21.5 billion. Although the deal count was below the 306 announced in the first half of 2011, we do not view the difference as indicative of reduced M&A trends. In our view, it is too early to assume that there will be a slowdown for the year as a whole. Moreover, it may only reflect timing and the availability of acquisition candidates.

The rise in M&A activity in 2010 and the momentum into 2012 reflected a couple of factors, in our view. First,

despite the recent credit crunch, we believe that companies were able to build and preserve a lot of cash and retained balance sheet flexibility. Second, we believe 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 accounting giant PricewaterhouseCoopers, the device industry will consolidate to achieve cost savings and diversify product portfolios, driven by the need to combat the impact of the pending federal excise taxes, continued pricing pressures, and declining procedure volumes in certain high-cost treatment areas.

While credit markets are less constrained, the medical device group is also able to rely more on its own healthy balance sheets, cash flow, and existing lines of credit. One megadeal (having a transaction value of about $1 billion or more) was announced in 2009: Abbott's purchase of Advanced Medical Optics. In 2010, several were announced, including Novartis's purchase of the remaining shares of Alcon owned by Nestlé and the publicly traded shares owned by the minority shareholders, Covidien plc's acquisition of ev3 Inc., and Medtronic's acquisition of Ardian Inc. Those announced in 2011 include Johnson & Johnson's acquisition of Synthes, Danaher Corp.'s acquisition of Beckman Coulter, and DENTSPLY International's acquisition of Astra Tech AB, a division of AstraZeneca PLC. There have also been some significant deals announced in the first half of 2012, including Hologic, Inc.'s acquisition of Gen-Probe, Agilent Technologies acquisition of Dako, and Boston Scientific Corp.'s acquisition of Cameron Health, Inc.

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 the near term, we expect these smaller deals to dominate transaction activity, as opposed to wholesale purchases of new business lines or of competitors.

In addition to consolidation, a number of medical device makers have also been divesting businesses that they view as underperforming. Boston Scientific sold its Neurovascular segment to Stryker in January 2011 for $1.5 billion (announced in 2010); we believe the proceeds of this sale have been used to help fund acquisitions to improve Boston Scientific's growth prospects. Covidien embarked on a portfolio improvement program, divesting several underperforming units in recent years and replacing them with acquisitions of businesses it views as having promising growth prospects. In December 2011, it announced plans to spin off its pharmaceutical business to its shareholders, but the transaction could take up to 18 months to complete.

ORTHOPEDIC/CARDIOVASCULAR UPDATE

The medical devices industry's two largest subsectors, orthopedics and cardiovascular devices, fueled much of its spectacular growth between 1996 and 2006. Adding to the momentum were smaller, lucrative specialty niches with differentiated technologies: diabetes management devices, minimally invasive surgery equipment, cosmetic surgery devices, advanced wound care, and oncological radiation therapies.

In 2006, however, sales growth in certain segments eased. In orthopedics, for example, sales growth of hip and knee implants slipped because of a lag in new product introductions and increasing pricing pressures. Cardiovascular devices—notably, implantable cardioverter defibrillators and drug-eluting stents—fared worse, with sales actually falling. The declines were due to uncertainties about recalls of a few high-tech products, as well as the rapid introduction of new products by companies that had not previously competed in this category, which intensified price competition in many major markets.

Orthopedics

The Centers for Disease Control and Prevention (CDC) has estimated in its studies that around 43 million Americans are suffering from arthritis and the number of patients will grow to around 67 million (or 25% of the adult population in the US) by 2030. According to a June 2011 report released by GlobalData, a strategic business intelligence provider, the hip replacement implants market is expected to grow to $8.6 billion by 2017, a compound annual growth rate (CAGR) of 5% between 2010 and 2017. Within the hip replacement implants market, primary hip replacement is the key segment, estimated at around $4.7 billion in 2010. The segment is expected to reach $6.8 billion in sales by 2017, growing at a CAGR of 6% between

2010 and 2017. Another report by GlobalData on the knee-replacement implant market estimates its value at around $6.9 billion in 2010 and expects it to grow at a CAGR of 6.8% to $10.9 billion by 2017. Further, industry experts at a conference of the American Academy of Orthopedic Surgeons in February 2012 estimated a low single-digit growth rate for the hip and knee implant market in 2012, with pricing pressures expected to continue in 2012. Owing to weak economic conditions, the market is not likely to rebound strongly. A number of companies have reported mid-single-digit growth for the hip and knee implant market in the second quarter of 2012, but are not ready to consider the trend sustainable.

We view the slowdown that began in 2009 as due in part to economic factors: we believe that some patients (other than seniors, who are covered by Medicare) are deferring procedures, but most will eventually have to be treated. Even so, there appears to be resistance by health insurers to certain high-priced orthopedic implants.

On October 15, 2011, GBI Research, a market research firm, released a report that forecasts the global spinal surgery devices market will reach $12.6 billion by 2017 at a CAGR of 10%. The US spinal devices market was valued at $4.6 billion in 2010, which represented a 69% share of the global spine market. The spine market in the US is projected to grow to $9.2 billion at a CAGR of 10%. S&P believes 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.

Cardiovascular

Cardiology overall is experiencing healthy growth, but the recovery for flagging subsectors is more mixed. Troubles in the important ICD business appear to have worsened in early 2011. The DES market continues to grapple with the 2006 release of some adverse clinical trial data that raised questions about the efficacy and safety of drug-eluting stents, and has been experiencing rising competitive pressures and an associated decline in unit pricing, but has begun to show signs of stabilization.

◆ **ICD implantation declined.** From 2000 to 2004, cardiac rhythm management (CRM) was one of the medical devices industry's fastest-growing markets, with sales increasing at a CAGR of 16%. The CRM device category includes implantable pacemakers, which treat certain kinds of irregular slow heartbeats; implantable cardioverter defibrillators (ICDs), which deliver shocks to the heart to stop abnormal heart rhythms that are potentially fatal; and cardiac resynchronization therapy devices (CRTs), which synchronize contractions of multiple heart chambers. (For more background on CRTs, see "Cardiology" under "Market Sector Notes" in the "Industry Trends" section of this *Survey*.) However, in 2005 and 2006, major product recalls and safety concerns involving the ICD segment of the CRM device market slowed momentum.

The recalls affected Guidant Corp., the market leader, and Boston Scientific, which bought Guidant in April 2006. Patients and physicians took a wait-and-see attitude to determine if the problems were fixable, dampening near-term demand. The third largest company, St. Jude Medical Inc., did not have a recall, but was nonetheless affected by the fallout from concerns about device safety. In October 2007, Medtronic announced a worldwide recall of its Sprint Fidelis defibrillator leads due to a higher-than-expected rate of fracture—a problem that may have been connected with the deaths of five patients. Some rival ICD lead manufacturers benefited from the recall, and S&P believes a modest amount of market share remained in the hands of Medtronic competitors.

The ICD market began declining again, starting in late 2010/early 2011, mainly due to a US Justice Department probe and an article posted in the *Journal of the American Medical Association* in January 2011 on unnecessary implantations. Indeed, in its 2012 second-quarter earnings conference call on July 18, St. Jude's management said that it did not expect the US ICD market to stabilize until early 2013. Meanwhile, it had a company-specific issue: in December 2011, it announced a class I recall for its defibrillator Riata and Riata ST leads. Even so, in an investor conference in January 2012, the company said that it expects to gain a 1% market share in the global cardiac rhythm market in 2012. The company is largely relying on the healthy performance of its new quadripolar CRT-D, the Unify Quadra, for which it has already signed a large number of contracts with customers. The company also stated that the 1% improvement in market share might be an underestimation, given the increase in market share from 25% in

2010 to 26% in 2011, amid industrywide ICD market softness, without the full launch of Unify Quadra. Indeed, its prognostication came to pass. In its 2012 second-quarter earnings conference call, management said that "based on our preliminary data, we estimate that we gained approximately 1 to 1.5 points of share in the U.S. ICD market during the second quarter on a year-over-year basis, as well as on a sequential quarter basis due to the numerous competitive advantages of our ICD program."

Within the cardiac rhythm management market, the global demand for pacemakers had been picking up strength, thus making up for the drop in the demand for defibrillators. For instance, in its fiscal 2012 third quarter (ended January 2012), Medtronic reported an 8.3% drop in the demand for defibrillators, while the sales of pacemakers increased 3.8%. However, St. Jude noted in its 2012 second-quarter earnings conference call that its pacemaker sales declined 9% in the US and 3% internationally in constant currency.

◆ **DES sales remain under pressure.** Sales of drug-eluting stents (DES), which comprise the bulk of the interventional cardiology segment of cardiovascular devices, began to stabilize in 2008, growing approximately 5% over 2007, after several years of ongoing price declines in the US and Europe, and safety concerns based on clinical trial data. According to a report released by Transparency Market Research, the global coronary stents market was worth around $6.0 million in 2011 and is forecast to reach $8.3 million in 2016, for a CAGR of 6.6% from 2010 to 2016. The report also states that DES is the market's leading segment, accounting for 55%–60% of the global market in 2010. The global DES market is expected to reach $5.3 billion in 2016, growing at a CAGR of 9.5% from 2011 to 2016, driven by the expanding elderly population. On geographic terms, the market is growing fastest in the Asia-Pacific region (10%), followed by the US (9%) and Europe (3%).

Introduced in 2002, drug-eluting stents—tiny metallic tubes that prop open clogged arteries, a condition known as stenosis (the narrowing of blood vessels), and deliver a drug to the occluded site—represented the single largest new product launch in the history of the medical devices industry. However, according to the September 2009 issue of *Circulation: Cardiovascular Quality and Outcomes*, DES lost 30 percentage points of their market share from 2006 to 2007 following the release of studies indicating that the devices carry safety risks and may be overused. The studies indicated that DES patients had a slightly higher long-term risk of blood clots (thrombosis) than did patients with implanted bare-metal stents (BMS), which also prop open clogged arteries, but are not coated with drugs. The risk, though small, is important because stenting has become so common (four million procedures a year) and increases with the amount of time that has elapsed since the procedure was performed. As noted in a report published in the *American Journal of Cardiology* in February 2009, the condition, also known as late-stage thrombosis (LST), is rare (having an incidence of 0.2% to 0.7%, depending on the study), has a high mortality rate, and requires the long-term use of anti-clotting drugs, which can decrease the cost-effectiveness of DES. (However, see below for the results of a study published in the June 2011 issue of *Circulation*.)

A major study, largely funded by the US Department of Veterans Affairs added fuel to the debate over whether stents are overused. This study, known by the acronym COURAGE, found that the combination of percutaneous coronary intervention (PCI) plus stenting and optimal medical therapy (drugs) is no better than optimal medical therapy alone at preventing heart attacks in patients with stable coronary disease. (PCI—previously called angioplasty, percutaneous transluminal coronary, or balloon angioplasty—is a procedure that threads a thin tube or catheter through blood vessels leading to the heart in order to clear them and relieve pain from angina. A stent may or may not be used following PCI.)

Following the release of COURAGE results at the March 2007 meeting of the American College of Cardiology (ACC), Boston Scientific, the US market leader, reported that US DES market penetration fell to 65% (it peaked in early 2006 at close to 90%), and European penetration declined by 4% to 50%. The aforementioned *Circulation* article noted that DES market share fell to a low of 58% by early 2008. According to the National Hospital Discharge Surveys of 2007 (latest available) and 2006, published by the Centers for Disease Control and Prevention (CDC), US procedure volume involving the insertion of coronary artery stents declined to 560,000 in 2007 from 652,000 in 2006. While the data do not differentiate between drug-eluting and bare-metal stents, we believe the decline in procedure rates related to DES and that the number of procedures involving bare-metal stents was stable or rose slightly.

However, subsequent studies paint a more nuanced picture. According to the results of a three-year study conducted at one hospital and published in the June 2011 issue of *Circulation: Cardiovascular Quality and Outcomes,* researchers noted that while stenting costs were higher for patients using DES compared with BMS, the use of DES reduced the amount of repeat target vessel revascularization (TVR), offsetting the price difference. The extensive use of the anti-clotting drug clopidogrel (Plavix) with DES means that DES can be more cost-effective to use than BMS, according to the study. A study done by the New York-Presbyterian Hospital and Columbia University Medical Center in collaboration with the Cardiovascular Research Foundation and published in the *New England Journal of Medicine* (May 7, 2009), found drug-eluting stents more effective than bare-metal stents in heart-attack patients. However, another recent study published in the *Journal of the American College of Cardiology* shows that for patients over age 85, the mortality risk using DES is a much lower (29%, compared with 38% in patients using BMS) and that the usage of DES in these patients resulted in lower rates of adverse events compared with BMS. The study compared the effectiveness of the two types of stents for older patients in particular and found that the re-hospitalization rate for patients using DES is 9%, while that for patients using BMS is 12%; however, the difference in the hospitalization rate went down for younger patients.

Another factor in recent sales results for stents is increased competition, particularly abroad, which is holding down pricing. Medtronic's stent, the Endeavor, has been marketed in the European Union (EU) since the fourth quarter of 2005 and has captured market share in the high teens, according to Boston Scientific. In December 2007, Abbott received European approval to begin marketing its XIENCE drug-coated stent, and that product obtained US marketing approval from the FDA in July 2008.

We estimate that the number of percutaneous procedures involving coronary artery stents rose in the low single digits in 2008 and continued to rise at that level through 2010. The slow recovery of DES market share in PCI treatments may be due to the release of the zotarolimus-eluting stent, according to an article published July 28, 2009, in *MedPage Today*. Zotarolimus, used in Medtronic's stent, prevents restenosis, but does not reduce the incidence of LST. While additional studies (including one in Switzerland, with results released in November 2010) show the efficacy and safety of DES, others show that risks still exist.

We think long-term growth in worldwide volumes will stabilize in the flat to low-single-digit growth range going forward, partly because the risks of DES versus BMS use for PCI remain uncertain. Moreover, there are concerns about the overuse of either DES or BMS. A study published in the July 6, 2011 issue of the *Journal of the American Medical Association*, and cited by Reuters, found that stenting procedures were inappropriate for the 12%, or one in eight, US patients who have non-emergency procedures to clear blocked arteries. In fact, researchers found that more than one-half of the inappropriate procedures were performed on patients without any symptoms of heart disease. A study published July 11, 2011, in the *Archives of Internal Medicine* found that the controversial use of stents days after a heart attack has continued unabated, despite the 2006 studies noted above.

However, a more recent study conducted by a multi-institutional team that analyzed data from 1.5 million PCI procedures included in the National Cardiovascular Data Registry (NCDR) CathPCI registry and published on July 10, 2012 in the *Archives of Internal Medicine* found that drug-eluting stent use is prevalent, even among patients at low risk for restenosis, there was a significant variation in the rate of DES use by physicians, and there was risk in the need by patients to take anticlotting medications for at least a year, as complications could occur if the medications were ended early. The authors noted that drug-eluting stents are effective in reducing restenosis and the benefits are greatest in patients at the highest risk of target-therapy revascularization (a procedure to unblock or bypass a clogged artery when a patient experiences a recurrence of symptoms). However, DES cost more than BMS, and requires prolonged dual antiplatelet therapy (the use of anticlotting medications), which increases costs. Hence, "the reduction of DES use among patients at low risk for restenosis was projected to be associated with substantial cost savings with only a small increase in TVR events." They projected that a 50% reduction in the use of DES in low-TVR-risk patients would reduce healthcare expenditures by about $205 billion a year in the US, while increasing the overall TVR event rate by 0.5%.

PROMISING MEDICAL DEVICE TECHNOLOGIES

The medical device market is characterized by the continuous development and launch of new products that improve the diagnosis and/or treatment of various diseases and conditions. 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 don't 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 a January 2012 report published by GBI Research, the global transcatheter heart valve market is forecast to grow at a 20% CAGR from 2010 to 2017 to reach $691 million in value by 2017.

In November 2011, the Sapien TAV from Edwards Lifesciences Corp. received the FDA's approval for US marketing. This is the first commercial approval for a transcatheter device. So far, it has been approved for the treatment of inoperable patients (*i.e.*, those unable to undergo open-heart surgery). Sales in the US were so robust in the second quarter of 2012 that Edwards increased its outlook for US sales for the year.

In November 2011, the company received permission to conduct clinical trials in the US for its next-generation TAV, the Sapien XT, which is already available in Europe. In December, the company announced it had two additional TAVs under development. Meanwhile, Medtronic's CoreValve TAV, also available in Europe, started its clinical trials in the US. In March 2012, Medtronic announced the results of its CoreValve ADVANCE study, which showed that the survival rates were high after both 30 days and six months, with high procedural success rates and low rates of overall complications.

◆ **Atrial ablation.** As defined by the Heart Care Centers of Illinois, atrial fibrillation (AF) is a very common abnormal heart rhythm (arrhythmia) caused by chaotic and unorganized electrical activity in the upper chambers of the heart called the atria. Johnson & Johnson says AF affects an estimated 10 million people worldwide and is the leading cause of stroke among those 65 and older. Catheter ablation, an emerging and promising treatment, is a therapy that corrects the arrhythmia AF causes by using an electrical pulse to purposely scar the heart, normalizing inappropriate rhythms. In February 2009, Biosense Webster Inc. (a Johnson & Johnson company) received FDA approval to market its Navistar Thermocool catheter for the treatment of AF.

In mid-December 2010, the FDA approved Medtronic's Arctic Front Cardiac CryoAblation Catheter system, the first and only cryoballoon in the US indicated for the treatment of drug refractory paroxysmal atrial fibrillation (PAF). Paroxysmal atrial fibrillation indicates that the arrhythmia occurs at varying intervals, rather than consistently or constantly. The result of the rapid, irregular beats is ineffective filling of the ventricles, the bottom two chambers of the heart that pump blood out to the body. The device uses a wire and a tiny inflatable balloon threaded into the pulmonary vein near the heart to deliver coolant to freeze dead tissue that carries extraneous electrical signals that cause the irregular heartbeat.

Two more new catheter technologies—laser balloon catheter and multielectrode RF ablation catheter—are currently in the development phase. While these might be years away from commercialization, they seem to be quite promising for the treatment of AF. The balloon of the laser catheter is variable in size and can be positioned in a vein opening to encircle the vein. The technology involves two overlapping laser ablations, which can completely isolate the vein. The catheter allows the physician to look directly at the ablation, thus reducing radiation exposure to patients and medical staff. Further, the catheter is better suited to fit different sizes of pulmonary openings due to its variable size. The other technology is the multielectrode RF ablation catheter, which is circular and shaped like a mesh array. It functions like a laser balloon catheter by

fitting into a pulmonary opening and isolating the opening in two or more passes. Further, the catheter can also perform ablation at specific poles for pinpoint ablation of atrial fibrillation spots in the heart.

According to a new study, the results of which were revealed at the Hearth Rhythm Society conference in May 2012, atrial fibrillation patients who opt for cardiac ablation as a first-line treatment were 20% less likely to see the symptoms recur and 12% less likely to face any treatment-related adverse events than patients who take drugs. After a two-year research period, the study concluded that among the patients who used cardiac ablation, only 52% experienced recurring symptoms of atrial fibrillation, while among those relying on anti-arrhythmic medication, the rate was as high as 72%. Further, 8% of the patients having undergone cardiac ablation experienced treatment-related adverse events, while 20% of the patients depending on drugs faced such events.

◆ **3-D digital mammography tomosynthesis system.** Unlike prior-generation mammography systems that generate two-dimensional images, this new method produces three-dimensional images intended to reveal the inner architecture of the breast, free from the distortion typically caused by tissue shadowing or density. The device functions by driving an x-ray tube in an arc across the breast, producing a series of low-dose images acquired from different angles; the projection images are then reconstructed into 1mm slices. The radiation dose is close to that of 2-D mammography. In mid-February 2011, Hologic Inc. received final approval from the FDA for the system, which has been available commercially in 40 countries outside the US, including countries in Europe, Latin America, and Asia, as well as Canada and Mexico.

INVESTORS LESS WORRIED ABOUT SLUGGISH SURGERY ENVIRONMENT ON MEDICAL DEVICES

For stock analysis purposes, S&P Capital IQ divides the medical devices industry into two sub-industries: healthcare equipment companies and healthcare product suppliers. The former group comprises manufacturers of surgical equipment and high-tech products for orthopedics and interventional cardiology. The latter is a diverse group that manufactures blood collection, diabetes, and low-end hospital capital equipment. These products tend to be less differentiated by patents and complex technologies, and often are low-tech commodities.

We think the outlook for manufacturers of high-tech devices is positive in the long term, driven by the demographics of an aging population, more active lifestyles, and the rise of obesity. However, we believe the current challenging operating environment (including a reduction in elective and certain nonelective surgical procedures, and hospital groups' increased focus on M&A) has sharply reduced hospitals' capital equipment purchases. Healthcare reform also may be delaying certain spending plans.

Although we believe many supply categories are historically largely recession-resistant, there are concerns about demand trends in areas typically viewed as non-elective, such as basic hospital supplies, sterilization equipment, beds and stretchers, and blood collection products, which are tied to hospital spending budgets. Slow US economic growth has also put pressure on government reimbursement programs, such as Medicare and Medicaid, and on private payers. Even so, in 2011 and 2012's first half, we have seen a pickup in spending for some products, suggesting to us that many hospitals have begun replacing aging supplies.

In the first half of 2012, the S&P Health Care Equipment subindex slightly outperformed the sector, rising 11.6%, while the consolidated S&P Health Care sector index gained 10.3%, held back by a 7.1% rise in the Pharmaceuticals subindex (which accounts for 47.3% of the weight of the index) and a 3.4% rise in the Managed Health Care subindex (8.2%). The S&P Health Care Equipment subindex (12.3%) also outperformed the broader market, as the S&P 1500 Composite Stock index grew 8.2% in 2012's first half. The S&P Health Care Supplies subindex (1.1%) gained 18.3% in the first half, also beating the performance of the overall Health Care sector. In 2011, the S&P Health Care Equipment subindex declined 2.2%, while the S&P Health Care Supplies subindex grew 7.7%, both underperforming the S&P Health Care sector index, which gained 9.6%; the S&P 1500 index declined 0.3%. ■

INDUSTRY PROFILE

A diversified industry maintains strong growth

The medical products industry is highly diversified and lacks a common definition, making it difficult to generalize about its size, performance, and prospects. With this caveat, we review the latest available estimates from several sources. According to Kalorama Information, a medical market research firm, the global medical device market generated $322 billion in sales in 2011, up 5% from the previous year. The research firm believes that the sector growth in 2011 was due to new product launches, and increased research and development funding. However, S&P Capital IQ believes the austerity programs being rolled out by governments worldwide will hamper growth in the near future. 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 Johnson & Johnson, Medtronic, and Siemens Healthcare, whose revenue growth could not match the overall growth of the industry in 2011.

LARGEST GLOBAL MEDICAL DEVICE COMPANIES
(In millions of dollars, ranked by 2011 medical device sales)

	--- MEDICAL DEVICE SALES ---			2011 TOTAL	2011 DEVICE SALES AS % OF
COMPANY	2010	2011	% CHG.	SALES	TOTAL SALES
Johnson & Johnson	24,601	25,779	4.8	65,030	39.6
GE Healthcare	16,897	18,083	7.0	147,300	12.3
Siemens Medical Systems[1,2]	16,678	17,436	3.3	102,847	17.0
Medtronic[3]	15,508	16,184	9.1	16,184	100.0
Philips Medical Systems	11,407	12,308	4.3	31,395	39.2
Abbott Labs	9,785	10,410	8.3	38,851	26.8
Covidien[1]	8,438	9,607	(4.7)	11,574	83.0
Boston Scientific	7,806	7,622	5.5	7,622	100.0
Becton Dickinson[1]	7,372	7,829	8.9	7,829	100.0
Stryker	7,320	8,307	10.8	8,307	100.0
St. Jude Medical	5,165	5,612	10.3	5,612	100.0
Baxter International[4]	7,370	7,804	4.3	13,893	56.2
Zimmer	4,220	4,452	3.1	4,452	100.0
Smith & Nephew	3,962	4,270	5.0	4,270	100.0
Biomet[5]	2,732	2,838	1.3	2,732	103.9
C.R. Bard	2,720	2,896	7.3	2,896	100.0
Varian Medical Systems[1]	2,357	2,597	6.5	2,597	100.0
Edwards Lifesciences	1,447	1,679	9.5	1,679	100.0

[1]Fiscal years ended September. [2]External revenues. [3]Fiscal years ended April. [4]Adjusted 2011 revenues. Excludes biosciences, global injectibles, and anesthesia products. [5]Fiscal years ended May.
Source: Company reports.

According to Espicom (a UK-based business intelligence provider), which we believe measures the market differently, the global market for medical devices was worth $273.3 billion in 2011. Further, Espicom estimates that the industry has grown at a compound annual growth rate (CAGR) of 5.3% between 2006 and 2010 and forecasts that the industry will reach $348.6 billion by 2016.

Earlier, Johnson & Johnson had estimated the global medical device market at about $350 billion in 2009 (latest available), with a CAGR of about 5% over the previous five years. It pegged the US as accounting for 47% of the market in 2009, and outside the US for 53%. It also expected the global market to expand at a CAGR of over 5.0% to 2014, at which point the market should be about $445 billion.

Espicom estimated the US market size at $95 billion for 2010 and $105.8 billion for 2011. 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. Germany, the UK, and France together accounted for 57% of European sales of approximately $132 billion in 2009 (latest available), according to Eucomed. The large US manufacturers are dominant players in many parts of the world, and international markets generate a significant share of their revenues.

INDUSTRY TRENDS

While we expect foreign exchange to have a favorable impact for the foreseeable future, we believe 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.

Traditionally, 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 at federal healthcare reform legislation, regulators, payers and researchers are increasingly questioning the incremental value of many of these new technologies in this new era of cost containment. In addition, although we foresee several new emerging technologies on the horizon that will spur industry growth, we see little in the way of true breakthrough innovations (such as the introduction of implantable cardioverter defibrillators (ICDs) or drug eluting stents (DES) that drove entirely new product categories or dramatically enlarged existing sales.

FOREIGN EXPOSURE MAY PRESSURE NEAR-TERM RESULTS

US medical device manufacturers 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. Revenues come from direct exports, as well as from sales made by foreign subsidiaries. As a result, the operating environment outside the US, as well as the movement of foreign currencies versus the US dollar, are both critical to the performance of US medical companies. As the US dollar strengthened throughout most of 2008 and through April 2009, US medical device companies were hurt by unfavorable currency movements versus their major trading partners. The dollar then weakened through November 2009, enabling companies with more significant overseas operations to benefit. The dollar temporarily strengthened in the first half of 2010, due to fiscal problems in Europe at the time, but has weakened since then. As of June 2012, Standard & Poor's Economics (which operates separately from S&P Capital IQ) expected the dollar to strengthen slightly through the third quarter of 2013, and to weaken afterward.

FOREIGN SALES OF SELECTED MEDICAL PRODUCTS COMPANIES—2011

	FOREIGN SALES AS % OF TOTAL SALES
DIVERSIFIED	
C.R. Bard Inc.	33
Becton Dickinson	57
Johnson & Johnson*	56
Medtronic**	45
CARDIOVASCULAR	
Boston Scientific	46
St. Jude Medical	53
ORTHOPEDICS	
Stryker Inc.	37
Zimmer Holdings Inc.	45

*Excludes pharmaceutical and consumer products. **12 months ended April 27, 2012.
Source: Company reports.

In any event, 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.

US TRADE SURPLUS FOR SELECTED MEDICAL PRODUCT GROUPS

	SURPLUS (DEFICIT) IN MILLIONS OF DOLLARS					
					FIRST -- QUARTER --	
PRODUCT GROUP	2008	2009	2010	2011	2011	2012
Medical instruments & appliances*	5,988	6,922	7,168	7,148	1,838	1,989
Mechano-therapy, psychological testing, and oxygen therapy apparatus	(606)	(601)	(687)	(738)	(141)	(185)
Orthopedic appliances	488	794	137	(341)	(0)	71
Radiology equipment	(246)	283	374	207	68	78

*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.

Interest in developing markets is on the rise

While the US market is the world's largest and most profitable, S&P Capital IQ (S&P) sees 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 has been rising, and the public and private sectors are increasing their investments in healthcare. For example, market researcher BCC Research, in a report published 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, and highlights China, India, Mexico, and Brazil. According to an October 2011 report by Espicom, a UK-based business intelligence provider, 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.

The emerging markets, particularly China and India, are also attracting multinational companies, including medical device manufacturers, to set up shop there. In May 2012, Johnson & Johnson agreed to buy (for an undisclosed sum) Guangzhou Bioseal Biotech Co. Ltd., maker of a sealant used to contain bleeding during surgical procedures. The deal, which marks J&J's first Chinese medical device acquisition, will allow the company to add the Bioseal brand to its expanding portfolio of hemostasis devices in China. Previously, in June 2011, it opened a product development center in Suzhou.

In February 2012, Dynamic Medical Technologies Inc. announced its plan to spend about $1 million to establish an indirect subsidiary in Beijing, which will focus on medical device sales and maintenance services. In the same month, Covidien plc opened its first research and development facility in India, part of its strategy to tap into emerging markets. The company, which initially had about 30 people working at the new 40,000-square-foot space, plans to add more than 350 employees in the next couple of years. In March 2011, St. Jude Medical unveiled a product development center in Beijing. In June 2011, Hologic acquired a Beijing-based healthcare distributor.

Earlier, in December 2010, Zimmer Holdings Inc. acquired Beijing Montagne Medical Device Co. Ltd., a maker of hip and knee replacements, and powered surgical instruments suited specifically for the Chinese market. In November 2011, Zimmer announced its plan to establish a new research and development center in Beijing to come out with products better suited for local patients. In October 2011, Advanced Medical Technology Association (AdvaMed), the medical device industry trade association, approved plans to construct two hospitals and 10 clinics in central China as per its agreement with the national nonprofit organization, the China Youth Development Foundation; construction was expected to begin in the next two months. Finally, while we note that Medtronic Inc. has reduced its global workforce by 1,700 positions, it plans to hire 1,000 workers in China and more than 600 in India over the next five years.

Everyone's eyes are on China…

A number of market research and business consulting firms have provided varying estimates about the size of China's medical device market and its growth prospects. Infiniti Research, a London-based market intelligence firm, sees the size of China's medical device market growing to $25.8 billion in 2013, from $16.7 billion in 2009. Companiesandmarkets.com, market research website, sees an increase to $30.6 billion in 2017, from $14.8 billion in 2010. China contract manufacturing consulting firm NPI thinks the market will increase to $50 billion in 2020, from $14 billion in 2010. Management consulting firm Pacific Bridge Medical (PBM) sees the market growing at 15%–20% over the next five years, from $7.5 billion in 2010.

S&P believes the figures differ based on types of devices included in the surveys, assumptions about economic prospects and currency exchange, and probably a slew of other factors. What they have in common is that China's medical device market is already sizable and is likely to continue to grow rapidly in the next few years. In any event, 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 the policy makers in China. According to PBM, Chinese investors' interest in medical device research is expected to rise sharply.

Growth of China's medical device market is also seen in import data: from 2001 to 2009, device imports recorded a 10% CAGR from $1.64 billion to $6.11 billion, according to a June 2009 US Department of Commerce (DOC) report and the China Chamber of Commerce for Import & Export of Medicine and

Health Products. Further, according to PBM, the overall Chinese drug-eluting stent (DES) market five years ago was comprised of 90% foreign DES products, while today domestic Chinese companies account for as much as 75% of the Chinese DES market. S&P believes that such growth has been enabled by the Chinese government's decisions to relax tariffs, set up tax incentives for foreign investors, and improve intellectual property protection (IPP) laws. There are still challenges, including inefficient enforcement of IPP laws and an uncertain regulatory environment characterized by frequent change, according to the Canadian Foreign Affairs and International Trade Center (CFAITC).

China's medical device market is highly fragmented and competitive. According to the CFAITC, more than 13,000 domestic medical device manufacturers and a large number of foreign suppliers compete in China. It notes that Chinese capacity remains low in high-end products, with 90% of value-added high-tech devices (70% of China's medical device market) being foreign made. Smaller, less sophisticated domestic producers supply the lower end of the market, but S&P believes that they are making significant market-share gains since they offer their products at a fraction of the price charged by the larger, foreign device makers, and some, such as Mindray Medical International Ltd., are attempting to push into the higher end. The CFAITC sees China's domestic manufacturers strengthening, while mergers and joint ventures with overseas companies will occur at the lower end of the market.

In any event, 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. Even though this class represents only a small percentage of the country's total population, its numbers are large. 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.

In April 2009, China launched its healthcare reform implementation plan, the New Healthcare Reform, through which the central government will invest $123 billion to improve health services nationwide. The plan includes funds to allow a wide variety and a significant number of healthcare providers—about 20,291 hospitals, 270,000 community health centers, 38,000 central township hospitals, 175,000 clinics, and 633,000 village clinics (as of 2009; figures supplied by the CFAITC)—to afford medical devices. The government was expected to finance the construction of 2,000 county-level hospitals and 5,000 clinics by 2012. Management consultant Pacific Bridge Medical notes that China's healthcare priorities in 2011 included increased focus on suburban and rural health. This has been verified by trends seen by the publicly traded Chinese medical device maker Mindray Medical International, as voiced in its conference calls with analysts and investors in 2011 and 2012.

In addition, according to China's 12th five-year plan, passed in March 2011 and covering the years 2011–15, the government is planning to take three initiatives in the medical devices space: bolster the development of China-made medical equipment, implement centralized procurement, and purchase locally manufactured devices. Even so, the proposed price controls in China will be a limiting factor for foreign device makers. In December 2011, the Senate Foreign Affairs Committee warned China against such controls and expressed concerns over the problems they would create for American companies and Chinese patients alike.

…while India and other emerging countries are smaller, yet still fast-growing, markets

India, too, is a key market for medical devices. 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. As of June 2011, PBM expected the Indian medical device market, then valued at $3 billion, to experience a CAGR of 15% over the next five years. According to the recently released 12th five-year plan that starts 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 NIPER report.

Meanwhile, Frost & Sullivan (F&S), seeing Asia becoming increasingly important as a market and outsourcing hub, forecasts the Asia-Pacific medical device market growing at a CAGR of 10.2%, from $46.5 billion in 2009 to $62.3 billion in 2012. (The region, as defined by F&S, comprises developed and emerging countries: Australia, China, Hong Kong, India, Indonesia, Japan, Malaysia, New Zealand, Philippines, Singapore, South Korea, Taiwan, and Thailand.) In contrast, it sees the total global medical device market expanding at a CAGR of 5.8%, from $203 billion in 2009 to $240.7 billion in 2012. As a result, the Asia-Pacific market will expand from a 23.8% share of the global market in 2009 to a 25.8% share in 2012. According to PBM, the Vietnamese medical device market also offers potential, with its government having pledged $2.2 billion to construct specialty and general hospitals in under-developed regions by 2013. It estimated that the device market in Vietnam was worth $515 million in 2010 and expected that the market would grow at around 15% per year.

PBM values the Malaysian market at $600 billion and thinks that this market holds huge opportunity for foreign players, with 90% of the market comprising imports. According to Espicom, the medical device and supplies import market in Malaysia totaled $938.8 million in 2011, up 14.9% from 2010. In the five-year period between 2007 and 2011, total imports in Malaysia grew at a CAGR of 13.2%. Growth is expected to continue in line with the growing healthcare expenditures in that country and given its dependence on imports to meet its healthcare requirements. The US contributes around 25% to the total medical imports. The medical device exports from Malaysia are also rising in value due to demand from the emerging markets of India and China. According to the Association of Malaysia Medical Industries, demand in Japan and the US is slower, but is being offset by stronger demand in Europe and Asia.

Medical device maker Medtronic has plans to expand its share in the Indian healthcare market and capitalize on the country's patient pay-based healthcare system. Similar to the strategy that Zimmer is adopting in China, Medtronic wants to employ more local Asian engineers in its R&D process. In response to the rising interest by the foreign device makers, India will have to address issues such as high costs, limited geographical accessibility, and lack of awareness of the latest technologies.

Current prospects mixed in industrialized countries

In 2009 (latest available), the US accounted for 41% of the global medical device market, followed by Europe with 32%, and Asia Pacific (including Japan) with 15%, according to market researcher Frost & Sullivan. In Europe and Japan, as in the US, favorable drivers such as aging societies and high standards of living are fueling growth. 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.

According to accounting and consulting giant Ernst & Young's (E&Y) "*Pulse of the industry: Medical technology report 2011*," the medical device markets in the US, Europe, and Japan have witnessed slower growth. However, there are opportunities that exist in unmet clinical needs in these countries.

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 believe, 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

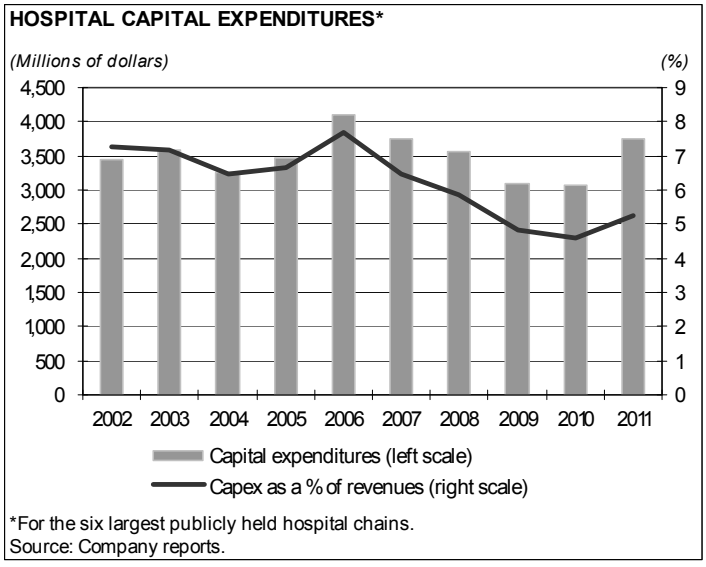
additional pricing pressures as new country budget targets are introduced. As a result, some US device makers already note seeing a two-segment market. One is a small, high-end, clinician-driven segment comprising differentiated and innovative products that can command premium prices. The other is an enlarged low-end market comprising older and more-commoditized technologies, where pricing matters. US medical device makers are increasingly focusing on the former.

Japan is a primary example of a market with conflicting influences on demand for medical products. Japan has the world's second largest medical device market, after the US, with sales of about $25 billion in 2010, according to PBM. According to Espicom, the US and Germany are the only countries that import more medical equipment, and Japan is the eighth-highest exporter of medical devices in the world. According to the DOC, US exports of medical devices to Japan totaled about $3.5 billion in 2008. The DOC also notes that as Japan's elderly population grows and the overall contribution to Japan's national healthcare system decreases as a result of its shrinking population, the Japanese government will be forced to take additional measures to contain healthcare spending. According to Espicom, Japan has the most expensive medical equipment in the world, due in part to a distribution system that hikes up retail prices with hidden costs. It also noted that in 2008, most reimbursement price provisions were made to medical devices, bringing the total price cuts to 126 functional categories since the foreign reference price system was launched in 2002. However, the latest revisions raised reimbursement prices for innovative medical devices as an incentive to manufacturers to develop such devices. In any event, the DOC thinks that medical devices used to treat age-related diseases, such as pacemakers, cardiac valve prostheses, and orthopedic implants, will realize a steady growth in demand. Moreover, because there are very few domestic manufacturers in Japan in these areas, the DOC sees market opportunities for US firms making these products to continue for the foreseeable future.

Meanwhile, medical device makers in Japan were hit in early March 2011 by the devastating earthquake and its aftermath, including the tsunami and nuclear plant meltdown. The situation is delaying (albeit temporarily) shipments of medical devices, elective medical procedures, and regulatory approvals for new products in the country. According to PBM, with patients affected by the disaster flooding hospitals, US sales of medical supplies to Japan are likely to increase, though hospitals that were ruined will not be buying supplies until they are rebuilt.

HOSPITAL CAPEX STILL UNDER PRESSURE, BUT SHOW SIGNS OF A PICK-UP

In addition to 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.



*For the six largest publicly held hospital chains.
Source: Company reports.

In fact, prior to 2008, most hospitals needed to offer improved facilities and services in the hopes of attracting both doctors and patients simply to remain competitive. For example, between 2000 and 2007, capital expenditures for the six leading hospital chains (the five publicly

traded hospitals followed by S&P Capital IQ, plus HCA, which went private in 2006 but has publicly traded debt) ranged from about 6.3% 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.

However, beginning in late 2007 and into 2008, hospitals cut back on non-maintenance capital outlays. Many hospitals have relied almost completely on the credit markets to fund most non-maintenance capex, and credit markets froze in 2007. In addition, most hospitals' financial condition began to deteriorate due to increases in uncompensated care, as more people lost their employer-based coverage and could no longer afford to maintain health insurance coverage. Finally, due to the decline in both the equity and fixed-income markets, most hospitals saw a marked decline in the value of their charitable endowments and the amount of non-operating income these charitable endowments generated, which often went to support non-operating budget items.

Reflecting these factors, capex declined to 4.7% 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. Despite some improvement in the liquidity of the capital markets during most of 2009, capex expenditures continued to contract. S&P Capital IQ believes that part or all of the decline may be due to consolidation of the hospital industry, as hospital groups continue to use their cash flow for acquisitions, moves that build revenues, but not on capital expenditures. The acquisitions included those of other hospitals, physician groups, and independent outpatient services, with the purpose of building large-scale integrated delivery networks (otherwise known as IDNs) that would provide them with the scale to save on operating costs and strength in negotiations with health insurers.

Capital spending rose to 5.2% of revenues in 2011, and consensus estimates of Capital IQ, the business within S&P Capital IQ that provides business and financial information, pegs the ratio at 5.5% in 2012, before turning down again to 5.3% in 2013. The rise in capital spending as a percentage of revenue in 2011 and the further advance seen in 2012 by the healthcare facilities analyst community in 2013 may be attributed to a number of factors that are not mutually exclusive, in out view. One possible reason is that hospital utilization by the insured population has declined, which can lead to slower growth of hospital revenues, if not actual declines. A second is that the hospital groups have to invest in upgrading their acquisitions. A third is that hospitals have had to focus on the development of an IT system to support electronic health records. We think that the decline in capital spending as a percentage of revenues that the analyst community sees in 2013 reflects not only the completion of most of the IT projects, but also the fact that analysts exclude future acquisitions (and the spending to upgrade the acquired facilities) from their earnings models. Finally, a fourth may be that as of 2012, hospitals start reporting net revenue (gross revenue minus bad debt expense, or uncollected revenue); previously, they reported only gross revenue.

In any event, we believe that even amid the decline in capital spending from 2008 and the present recovery, 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 new 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 first quarter of 2012. These products help surgeons perform minimally invasive surgery, and are a technologically advanced alternative to conventionally performed surgeries.

Nevertheless, capital spending as a percentage of revenues is below pre-recession levels and we still feel this will be an issue that the device industry will have to contend with through 2012. The healthcare reform law, the Patient Protection and Affordable Care Act (PPACA) of 2010, adds a productivity adjustment to the market basket update for certain providers this year, resulting in lower rates than otherwise would have been paid. We project that the most vulnerable areas to the hospital spending budget pullback within our coverage universe will continue to be the more expensive pieces of capital equipment such as robotic surgery systems, radiation therapy equipment, magnetic resonance imaging devices (MRIs) and digital mammography equipment. Within these categories, much of the revenue growth in recent years came through both first time equipment installations and/or multiple installations, either within a single facility or throughout a range of affiliated facilities, partly reflecting hospitals seeking to build their competitive position, we believe. However, product upgrades and rising levels of service/maintenance revenue also generated a substantial portion of the recent growth.

Normally, one would expect reduced new product sales to lead to lower selling prices, which would be reflected in declining gross profit margins. However, we believe many manufacturers have been "saved" by improved production processes and the shift of some manufacturing to low-wage countries, the development of new and next-generation products that also cost less to make, competitive dynamics in the US, and continued rising demand in emerging markets. From our perspective, gross margin performance and management comments regarding their expected direction will remain key indicators regarding the health of the medical equipment group.

Looking beyond the developing trends for the large capital equipment manufacturers, we see evidence that the deterioration in global economic growth has had a materially negative impact on the sale of "pure" medical devices. Based on our observation of the performance of the medical device group during the 2007–09 recession and afterward, we believe implantable cardioverter defibrillators (ICDs), pacemakers, heart valves, cardiac and peripheral stents, and orthopedic joint replacements, are not as well insulated from economic cycles as they had been previously, despite the non-elective nature of the associated procedures. There are also a large number of device categories that are traditionally viewed as elective and, hence, are even more sensitive to economic swings, particularly in the developed markets, such as the US and EU. However, demand for both sets of products has been growing at a healthy pace in the developing, or emerging, markets, which were not affected as much by the recent recession.

Some of the more obvious areas 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 as unemployment increases (with patients putting off surgeries until pain becomes untenable) and to resistance to high-priced procedures by the insurers. We have seen some signs of stabilization and possible recovery, albeit a modest one, in the second quarter of 2012. But we believe it is too soon to view this trend as sustainable. Meanwhile, we also believe 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.

COST CONTAINMENT TO BE MAJOR CHALLENGE OVER NEXT DECADE

As noted above, payers' focus on healthcare cost containment in the United States and overseas presents a key ongoing challenge for the industry. 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 healthcare information technology systems (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.

Healthcare information technology and its impact on medical device demand

President Obama saw substantial savings from investments in healthcare information technology (HCIT), including electronic health/medical records (EHR/EMR), decision support systems, and computerized physician order entry. These expected savings were the primary impetus behind the up-to-$27 billion investment in HCIT over a 10-year period proposed as part of the American Recovery and Reinvestment Act of 2009 (ARRA). On July 13, 2010, the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC), a unit of the US Department of Health & Human Services, issued final regulations defining "meaningful use" and setting standard for the electronic health record incentive program.

In essence, an EHR system can make a patient's health information available when and where it is needed, and clinicians do not have to worry about drugs or treatments prescribed by another provider, so care is coordinated. It can identify safety issues, such as a patient's drug allergies and inform clinicians whether the drug they would prescribe using the EHR system would interact with another drug the patient is already taking. Linked to the patient's computer, the system can be used to provide follow-up care for the patient and provide the patient with additional resources. The system can also reduce paperwork time for providers and reduce the duplication of testing.

S&P Capital IQ believes HCIT's biggest impact on medical device manufacturers will be its utilization to promote evidence-based medicine and to help curtail duplicative testing. In particular, we look for regulators to seek changes to reimbursement systems that promote the sharing and use of existing testing and imaging data where appropriate, as opposed to the current system where incentivizes providers based on the provision of additional tests and procedures.

In addition, we see HCIT as being used in the promotion of evidence-based medicine—allowing researchers to mine databases of patient information to find patterns of best practices. Once these standards are discovered, we look for them to be promulgated around what treatments work best for specific patient diagnoses and what procedures yield the best and most cost-effective outcomes, as well as the communication of these results to patients in the form of quality studies. We also expect patients' electronic health records to lead to reduced numbers of diagnostic tests. Because EHRs may include results from costly in vitro diagnostic tests and/or copies of diagnostic images from MRI, CT, positron emission tomography (PET), and digital radiography (digital x-ray) scans, practitioners will be prevented from conducting or ordering the same tests or images unless they are dated.

These programs' real-world impact on product utilization and reimbursement rates is not yet clear. Nevertheless, medical device manufacturers (particularly those offering big-ticket items) acknowledge the trend and are working to make cost effectiveness part of their marketing pitch to buyers and payers. In some cases, they are undertaking studies, albeit limited, designed to demonstrate in a disciplined manner the cost effectiveness of their products. (For additional information on comparative effectiveness, see the "Current Environment" section of this *Survey*.)

COMPARATIVE EFFECTIVENESS RESEARCH: GETTING MORE FOR THE HEALTHCARE DOLLAR

While the primary focus of healthcare reform has been on expanding health insurance coverage, comparative effectiveness research (CER), which seeks to eliminate waste and promote efficiency, is also a major element of health reform and, 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 the comparative effectiveness research 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.

While 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, we caution that in some cases, CER may call into question the need for expensive technologies for certain indications.

Comparative effectiveness research has stirred controversy. Critics, particularly conservatives, claim that CER findings would lead the government to decide what treatments a patient can or cannot get, while some liberals 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 government corporation overseeing CER and created by the PPACA) 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 believe 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.

ECONOMIC, BUDGETARY POLICY ARGUMENTS INFLUENCE COST DETERMINATIONS

In his federal fiscal 2010 budget, President Obama introduced a number of proposals aimed at reining in the spiraling costs of healthcare and the proportion of the budget devoted to healthcare. (Some of the funding in the fiscal 2011 and 2012 budgets had the same goals.) Increasingly, we expect that both the prospect of a ballooning federal budget and the looming bankruptcy of Medicare to be the auspices under which additional controls on healthcare costs would be imposed. Going forward, we expect regulators, relying heavily upon the MedPAC recommendations, to use long-term economic growth and stability, in addition to the traditional arguments of access and affordability, as justifications for cost controls.

A number of these will follow up upon pilot programs instituted under earlier budget acts or Medicare programs. For instance, the Deficit Reduction Act of 2006 (DRA), which Congress passed in February 2006, mandated cuts in Medicare and Medicaid spending of $11 billion over five years and also specified some areas to cut. Diagnostic imaging procedures were hit particularly hard, after critics charged that some providers were performing unnecessary imaging tests. Congress imposed reimbursement cuts that went into effect on January 1, 2007, aimed at saving $2.8 billion through 2012.

The DRA also established a gainsharing pilot program, in which hospitals provide financial incentives to physicians to reduce the cost of caring for Medicare inpatients. Under the current system, hospitals receive a fixed payment for each patient, based on the patient's illness or diagnosis-related group (DRG). Hospitals use that money to cover the costs of treatment and services. In a gainsharing program, hospitals also establish measures for reducing hospital costs, then give physicians an incentive to participate by paying them a percentage of the savings. Critics charge that gainsharing programs jeopardize patient care and present conflicts of interest for physicians.

Nonetheless, Medicare began a three-year program, known as the Medicare Hospital Gainsharing Demonstration, in 2007, involving six hospitals that aimed to measure improvements in patient care during a patient's stay and immediately after a patient is discharged from a facility. A separate gainsharing pilot project, the Physician Hospital Collaboration Demonstration, was authorized by Congress in 2003 and also began in 2007. It is much larger, including up to 72 hospitals, and seeks to measure hospital-doctor interactions after discharge to determine the long-term savings potential from greater cooperation and elimination of complications through greater information sharing. We believe these projects have been supplanted by the development in 2011 of Accountable Care Organization (ACO) pilot programs for

Medicare beneficiaries by the Centers for Medicare and Medicaid Services, an agency of the US Department of Health and Human Services, as called for by the PPACA. An ACO is an arrangement in which physicians, hospitals and other caregivers share in the cost savings, as well as the risk, in caring for the Medicare patient.

DEMOGRAPHICS CONTINUE TO REMAIN FAVORABLE

Demographics are considered an important factor driving growth in the US medical technology industry. The world's population is aging, with the birth rate declining and life spans lengthening. According to a study conducted by the United Nations Department of Economic and Social Affairs, Population Division, the share of people aged 60 or above in the world population will double from 11.2% in 2011 to 21.8% in 2050; the number will grow to more than two billion, from 784 million in 2011. Further, this age group will represent 32% of the total population in developed nations by 2050, up from 22% in 2011. However, developing nations' populations, which constitute around 82% of the total world population and will reach 86% by 2050, are expected to remain relatively young because of high birth rates.

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 18.8% of the US population in 2011, and are expected to reach 26.6% 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.

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 computed tomography (CT).

Increasingly, the industry is eyeing other techniques and solutions aimed at keeping an aging population in good physical and mental shape, as older seniors also seek to maintain active lifestyles. Examples include development of new and simpler medical kits for the home, less invasive treatments, restorative treatments, and approaches to early diagnosis of disease that can lead to early intervention.

However, an aging population places tremendous demands on payers. The Centers for Disease Control and Prevention (CDC), a division of the US Department of Health and Human Services, estimates that the healthcare cost per capita for people aged 65 or older, in the United States and in other developed countries, is three to five times higher than for younger people. Developing countries will face an even greater strain on resources, as their basic public health infrastructures are weaker.

THE EMERGENCE OF CONVERGENCE IS UNEVEN AND SOMETIMES CONTROVERSIAL

In some sectors of the medical goods and supplies industry, a transition is occurring from an emphasis on mechanical to biological innovations—or to combinations of the two. This shift, known in industry circles as convergence, incorporates biologically active ingredients into medical devices with the intent to both speed the repair of problems and fully heal them. Convergence is not only leading to new products, it is also stimulating changes in business strategy and industry structure, as engineering-oriented companies scramble to gain expertise in biologics and patents. Device companies are becoming more aggressive about patenting their products, partly because biologics are easier to patent than devices that depend on mechanical innovations.

In a presentation to analysts in June 2007, Medtronic, for example, cited its push to develop several combination drug-device therapies and take them through clinical trials as one of its long-term growth drivers. Among these combination therapies are coating joint implants with drugs that speed healing, and using implantable pumps to deliver drugs directly to the site of injury. Medtronic already derives more than 20% of its revenues from such products, including implantable pumps, external pumps, drug-coated stents, and tissue-regeneration devices for spinal cord injuries.

Therapeutic areas that are ripe for convergence include chronic pain, age-related macular degeneration, heart muscle regeneration, and many diseases that could benefit from site-specific therapies. Orthopedics and wound care are perhaps the most active areas. Orthobiology, which has acquired significance in orthopedics, refers to the inclusion of biology and biochemistry in the development of bone replacement materials for muscular-skeletal healing. In March 2007, Medtronic bought a stake in OsteoGenix Inc., a biotech company that is developing a compound that stimulates bone growth. Since 2002, the company has been selling a bone-growth product called Infuse, which it uses to coat several of its joint implants, but the OsteoGenix product would be directed at accelerating the healing of fractures.

Orthobiologics products can have serious side effects, in our view. In June 2011, a US Senate committee began investigating whether surgeons that were paid consulting and other fees by Medtronic failed to report complications associated with Infuse. These unreported complications included abnormal bone growth, swelling in the neck and throat, and a form of sterility. While these side effects were listed on the Infuse product label, the *New York Times* noted on June 22, 2011, that the senators' query was prompted in part by the forthcoming *Spine Journal* issue (published June 28). That issue was fully devoted to articles highlighting that the 13 Medtronic-sponsored clinical trials of Infuse failed to properly disclose serious complications. On June 29, the *Wall Street Journal* noted that 15 of the surgeons involved in the trials collectively received about $62 million for unrelated work over the past decade. Medtronic responded stating that the *Spine Journal* articles do not question the data it supplied the FDA, and that it noted the negative side effects in the brochure attached to each product sold. S&P Capital IQ believes the problem has less to do with the unreported side effects, and more with financial ties. In this regard, Medtronic said it implemented reforms to reduce conflicts of interest. (For information about how Congress addressed conflicts of interest, see "Let the sunshine in" in the "Current Environment" section of this *Survey*.) In August 2011, Medtronic announced that it has provided a grant to Yale University for carrying out two independent third-party systematic reviews of the safety and effectiveness of its recombinant bone morphogenic protein-2 product that stimulates bone formation.

Another large medical device company expanding in the orthobiologics business is Stryker Corp. In June 2011, the company acquired Orthovita, which manufactures products for the fusion, regeneration, and fracture fixation of human bone, including Vitoss synthetic bone graft substitute, and Cortoss, a vertebral (spinal) augmentation material. Othovita also has a biosurgery business, which manufactures homeostasis products.

The most prominent example of convergence in today's market is in cardiology. Drug-eluting stents (DES) combine a basic metallic stent, which props open a clogged artery, with a drug coating, reducing the rate of inflammation (or restenosis) in the stented artery.

Despite the success of DES and rampant discussions about convergence, the field of combination products is still in the emerging stages, with corporate funding still proportionately small. One reason is that combination devices incorporating converging technologies present additional challenges. Two very different businesses—with dissimilar profit structures and financial time frames—need to collaborate, and also need to determine which party possesses the value-defining technology (and therefore is entitled to a bigger cut of returns). In addition, from an investor perspective, convergence technologies combine the risks of drug development with the quite different risks of device development, without decreasing overall risk. If these products involve more market risk than traditional devices, they will need higher prospective returns to attract investors. Indeed, not all product lines involving convergence are successful. In February 2011, Stryker Corp. sold its OP-1 product family for spinal applications, which appears to have fit well within its plan to divest underperforming products and to acquire and/or invest in promising ones. The company kept the rights to seek future use of bone morphogenetic protein, OP-1's main biologic ingredient, in other product areas, such as osteoarthritis treatment.

MARKET SECTOR NOTES

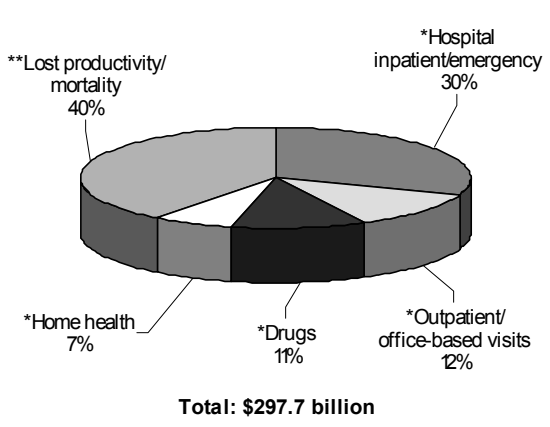
In this section, we discuss market conditions in four major established categories (cardiology, diagnostic imaging, orthopedics, and in vitro diagnostics, or IVD), and in one emerging product category (vascular diseases and conditions).

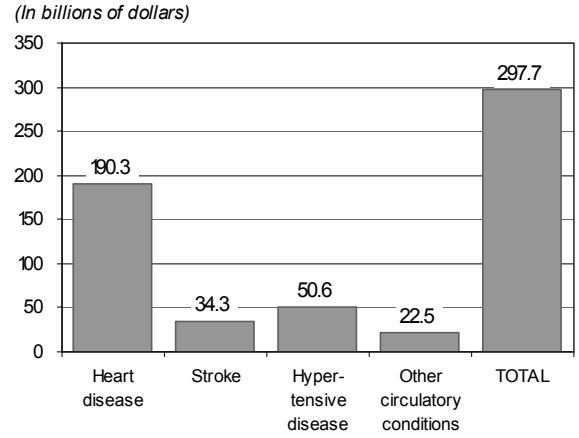
Cardiology

Heart disease remained the leading cause of death for both men and women in the United States in 2008. Some 82.6 million Americans (more than one in four) had one or more types of cardiovascular disease (CVD), according to *Heart Disease and Stroke Statistics—2012 Update* from the American Heart Association, a nonprofit group focused on improving the treatment of heart disease in the United States. (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 declined from 1998 to 2008, according to the report, CVD accounted for 32.8% of the total 2,471,984 deaths in the US in 2008.

CVD is a leading cause of death in Europe as well. According to the *Annual Report 2010* (published August 2011) of the European Heart Network, an alliance of heart foundations and like-minded non-governmental organizations throughout Europe, cardiovascular disease causes over 4.3 million deaths in Europe annually, including over 2.0 million in the European Union. It is also becoming more prevalent in emerging markets, where an expanding middle class, urbanization, and the adoption of Western diets are leading to an increase in non-communicable, "lifestyle" diseases, including CVD. Likely as a consequence, Johnson & Johnson estimates that 300 million people worldwide suffer from CVD today and expects the global cardiovascular device market to expand to $41 billion in sales in 2014 from $32 billion in 2009 (latest available).

COSTS OF CARDIOVASCULAR DISEASE AND STROKE — 2008†





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

According to a June 2012 report published by Infiniti Research Ltd., a market research firm, the global cardiovascular devices market is expected to grow at a CAGR of 5.7% for the period between 2011 and 2015. 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 transcatheter aortic valves used on patients unable to undergo open-heart surgery. (See "Promising medical device technologies" in the "Current Environment" section of this *Survey*.) However, the market is likely to face pressure from a likely decline in the selling prices of cardiovascular devices.

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. Some portions of CRM, such as pacing devices, are mature; this segment is experiencing a slowdown to low-to-flat growth worldwide. CRT has been the fastest-growing cardiology segment, driven by the introduction of new, device-oriented treatments for congestive heart failure. CRTs are available in two forms: CRTs (also known as CRT-Ps) and CRT-Ds. A CRT is a specialized pacemaker, also known as a biventricular pacemaker. Traditional pacemakers have two leads, which regulate the right

atrium and right ventricles, two of the heart's chambers, to maintain a good heart rate and keep the atriums and ventricles working together. A CRT has a third lead to help the left ventricle contract concurrently with the right ventricle. Previously, congestive heart failure was addressed only by drug therapies, although new scientific studies are encouraging for emerging CRM device technologies.

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.

Frost & Sullivan previously forecast a compound annual growth rate (CAGR) of nearly 17% for CRTs between 2005 and 2011. However, expectations have shifted downward because the ICD subsector experienced an abrupt slowdown in 2006 as a result of major product recalls. In addition, the subsector declined in late 2010 and early 2011, mainly due to a US Justice Department probe and an article posted in the *Journal of the American Medical Association* in January 2011 on unnecessary implantations. Indeed, while Frost & Sullivan sees the US ICD market growing from $4.3 billion in 2010 to about $5.0 billion in 2015, reflecting a 4.0% CAGR, it is projecting that all of the growth will be from the sale of CRT-Ds, which it estimates accounts for 45% of the ICD market. In contrast, it expects US sales of standard ICDs (55% of the global ICD market) to show no growth and possibly continue to decline over the period to 2015. Previously, ICDs, which shock hearts with abnormal heart rhythms into beating normally, had enjoyed annual worldwide growth of roughly 20% a year.

Ventricular assist devices, which help weak hearts to pump blood, also are gaining traction for treating heart failure, although the patient base is much more limited. These devices were approved initially for the short term in patients awaiting heart transplant, but now they are used for the long term in patients with severe disease who are ineligible for transplants. Frost & Sullivan estimates that the ventricular assist devices global market was worth $500 million in 2010 and growing at a CAGR of 11%; this would mean a market of more than $1 billion in 2017. Further, the US market accounted for 61% of the global market at $306 million and is expected to grow at a CAGR of 13% to reach $726 million by 2017.

The global drug-eluting and bare-metal coronary stents market was estimated to be $6.0 billion in 2011 and is expected to reach $8.3 billion in 2016 at a CAGR of 6.6% over the period 2010 to 2016, according to a report published by Transparency Market Research in November 2011. Beginning with their introduction in Europe in 2002 through 2005, drug-eluting stents have dominated this group of products and provided extraordinary growth. However, growth slowed in 2005 as the US market reached nearly 90% penetration, European penetration got closer to saturation, and competitors began to enter the market for the first time. (See the "Current Environment" section of this *Survey* for more details on DES.) As a result of safety concerns, US penetration of DES had declined substantially between 2006 and early 2008, but has risen slowly since that time and S&P Capital IQ's estimates it is now in the mid-70% range.

The global heart valve market includes tissue valves, mechanical valves, and heart valve repair products. According to Frost & Sullivan, this market was estimated 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. The growth out to 2015 is hard to predict, according to Frost & Sullivan, since a great deal of the forecast is 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*.) Frost & Sullivan notes 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.

Diagnostic imaging

Diagnostic imaging can be categorized into nine modalities: X-ray, ultrasound, computed tomography (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. According to research published on May 2011 by healthcare market research firm TriMark Publications, there are about 108 million x-ray exams per year globally. MRI ranks second with 26 million exams per year; and PET, SPECT, CT, and NM rank third with a combined 30 million examinations per year.

◆ **MRI.** Although MRI is superior to other imaging modalities for picturing internal organs, total US sales have shrunk in recent years, partly due to market saturation, equipment expense, and the relatively high cost of MRI diagnostic imaging procedures. In addition, growth in the number of MRI procedures has been decelerating, as provider reimbursement cuts and increasingly stringent pre-authorization requirements have helped reduce procedure volume growth from 15% annually during 1999–2003 to 3% during 2003–07. Market research firm Frost & Sullivan (F&S) cites these reasons for expecting the total US MRI scanners market to shrink at an average annual rate of 2.2% through 2015, from an estimated $858.0 million.

◆ **CT.** As they became becoming increasingly advanced and expanded beyond traditional areas of diagnostic imaging, CT scanners had been a growth product line. However, the latest technological developments have not gained traction, due to the absence of clinical evidence to support the extra cost of the newer, more advanced systems; a lack of reimbursement for emerging CT procedures; and the drop in hospital capital spending, says Frost & Sullivan. F&S notes that since 2008, many customers that have stopped making large capital purchases, focusing instead on the equipment upgrades and servicing market; it expects this trend to continue for at least the next few years due to the slow economic recovery and the healthcare industry's persistent challenges. Frost & Sullivan estimates the total US CT scanners market (excluding hybrid scanners, such as PET/CT and SPECT/CT systems) at $770 million in 2010. It sees the market expanding at a compound annual growth rate (CAGR) of 1.9% through 2015, driven by a broadening range of applications.

◆ **Ultrasound.** Meanwhile, given its increasing sophistication, improving image quality, and relatively low cost, ultrasound is being used beyond its traditional applications. In addition, hand-carried ultrasound (HCU) devices are being used increasingly for point-of-patient care globally, though US sales have been limited by reduced hospital spending. According to a March 2012 report by Transparency Market Research, the increase in the number of diseases that can be diagnosed early through sonography means ultrasound will likely get a boost over the next few years: the global ultrasound market, valued at $4.82 billion in 2012, will grow at a CAGR of 5% to reach $6.11 billion by 2017.

◆ **Digital mammography.** Another market on the rise is the digital mammography market. According to a January 2012 report released by market research firm GlobalData, the global full-field digital mammography (FFDM) market is forecast to grow at a CAGR of 8% from $801 million in 2010 to reach $1.3 billion by 2017. Further, the report states that the US accounted for around 51% of the market at $407 million in 2010 and is expected to reach $714 million over the next five years.

A mix of factors in growth outlook for advanced imaging

Factors favoring diagnostic imaging growth include advances in technology (including the growing use of hybrid PET/MRI, PET/CT, and SPECT/CT systems), new clinical applications for imaging modalities, the need for replacement systems, and rising demand from developing markets, such as China, India, and Eastern Europe, particularly for HCU devices. According to a July 2011 report published by MarketsandMarkets, a market research firm, the global diagnostic imaging market is expected to grow at a CAGR of 4.2% to reach $26.6 billion by 2016, up from $20.7 billion in 2010, driven by an aging population and development of new techniques. A report released by GBI Research in January 2012 also sees the diagnostic imaging market benefiting from growth in emerging markets and sees the US market suffering from reimbursement cuts, noting it was worth $71.3 billion in 2008 and declined to $61.4 billion in 2010. Even so, in 2010, the US still led the global market, with a 36.6% market share, followed by Europe (27.3%), and Asia (27%), according to the MarketsandMarkets report.

However, we expect growth in advanced imaging is ending. Medicare spending on medical imaging has dropped 13.2% since 2006, according to an analysis of Medicare data done by the Medical Imaging and Technology Alliance (MITA). According to MITA, MedPAC also confirmed that fee-for-service Medicare imaging service utilization declined 2.5% in 2010. Meanwhile, spending for non-imaging Medicare services

has grown by 20%, according to MITA. According to researchers at Thomas Jefferson University in Philadelphia, excess radiation exposure and high healthcare costs have forced patients, policymakers, and service providers to shift treatment methodologies. According to the same study, use of nuclear medicine declined at a CAGR of 1.8% between 2007 and 2009, versus growth at a CAGR of 8% between 2000 and 2006. Growth for all three advanced imaging modalities dropped to 1.4% between 2007 and 2009, from 9.9% between 2000 and 2006. Further, at a December 2011 public meeting, MedPAC confirmed the decline in Medicare spending on medical imaging procedures, saying that the drop is consistent with the 2.5% drop in 2010 stated by MITA.

More recently, according to a study from the August 2012 issue of *Health Affairs*, the growth of advanced diagnostic imaging in Medicare and non-Medicare patients slowed to single-digit rates starting in 2006, a trend that has extended to private payors. Based on claims file data and interviews with healthcare professionals, the researchers found that growth of CT use in the Medicare system fell from an average annual rate of 14.3% in the 2000–2005 period to 1.4% in 2009, while growth of MRI use fell from 14% to 2.6% during the same period. They attributed the deceleration to several factors: required prior authorization for those covered by private insurers, increased cost sharing by insurers and employers, Medicare reimbursement reductions, and fear of radiation exposure. In contrast, however, a study published in the June 13, 2012, issue of the *Journal of the American Medical Association*, and referenced on AuntMinnie.com, an Internet web site for radiologists and other imaging professionals, imaging use has been growing at HMOs: from 1996 to 2010, the growth rates tripled for CT and quadrupled for MRI. The researchers attributed the increase to expanded clinical applications, patient- and physician-generated demand, and the practice of defensive medicine.

In the past few years, a controversy regarding the increasing use of certain forms of diagnostic imaging has been brewing. A study published by the Government Accountability Office (GAO; a nonpartisan research arm of the US Congress) in June 2008 and a study in the *Journal of the American College of Radiology* in March 2010 found many CT and MRI scans to be inappropriate or unnecessary. In late 2009, the FDA reported patients receiving up to eight times the recommended radiation dose during CT exams. Finally, we note that according to a study published in the June 2011 issue of *Radiology*, between 1995 and 2008, the number of children getting CT scans when visiting the emergency room at nonpediatric hospitals increased five-fold. While the doses were not high enough to produce obvious signs of radiation injury, they may increase patient risk for long-term radiation effects. According to a May 2012 press release from the FDA, the agency has issued draft guidance for the X-ray imaging devices manufacturers for cases involving children. Further, the agency demands that manufacturers who are not able to prove that their X-ray imaging device is safe for use on pediatric patients should include a label on the device stating the same.

The *New York Times* and the *Washington Post* reported on June 18, 2011, that "long after questions were raised about the overuse of powerful CT scans, hundreds of hospitals across the country needlessly exposed patients to radiation by scanning their chests twice on the same day," based on CMS records and interviews with researchers. One scan was taken with a contrast agent to check blood flow, and one was taken without the agent. Radiologists say that only one or the other is needed depending on the patient's condition. We expect the National Institutes of Health (NIH), an agency of the US Department of Health and Human Services (HHS), and the FDA to issue guidelines and/or regulations for CT, MRI, PET, and NM device manufacturers to include dose-tracking technology in their products.

At its meeting on April 7, 2011, MedPAC noted the sharp rise in diagnostic imaging volumes. In addition, the top 10% of physicians account for more than 50% of advanced imaging use, and a significant share of this group self-refer. A white paper published by Thomson Reuters reported that 20% to 50% of high-tech scans such as CT and PET should not have been done because their results did not diagnose ailments or treat patients. MedPAC seeks to reduce reimbursement and to require clinicians who order more imaging studies than their peers do to obtain prior authorization for these services. The American Medical Association, a physician trade group, warned that the initiative could reduce payments to primary care physicians and drive imaging services to more expensive hospital settings. In any event, we expect imaging device makers to face pricing pressures from MedPAC and from provisions in the healthcare reform law cutting Medicare reimbursement for imaging procedures, with private health insurers following suit.

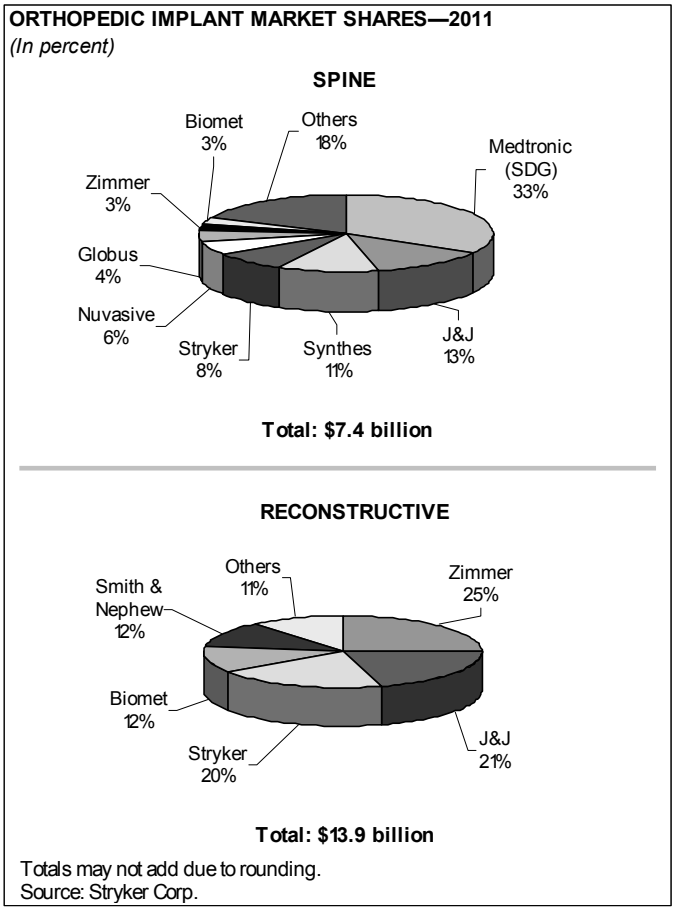
More recently, at a meeting on March 8, 2012, MedPAC researchers proposed that Congress should ask the US Department of Health and Human Services (HHS) to start a new Medicare fee-for-service benefit program that would include higher co-payments by patients for advanced diagnostic imaging services. Their thinking was that this would reduce beneficiaries' exposure to the risk of unexpectedly high out-of-pocket spending by discouraging the use of lower-value services. In other words, this would create "incentives for beneficiaries to make informed decisions about the use of care…and would lower the risk of very high cost-sharing liability." However, we believe the impact from such pressures to reduce imaging volumes will be outweighed by an expected rise in patient volumes as a result of the healthcare reform law and new imaging applications.

These concerns notwithstanding, the American Association of Physicists in Medicine (AAPM) has cautioned patients not to skip medical imaging tests due to speculation about the risks related to radiation exposure. It also noted that any predictions regarding the effect of low radiation doses should be discouraged, as they scare patients and cause them to avoid necessary tests that could reduce health risks.

Orthopedics

According to Johnson & Johnson, a leading player in the orthopedic device market, the global orthopedic market grew 6.4% in 2009 (latest available), to $38.6 billion. Although elective orthopedic surgical procedures have been delayed in the US amid the recession, Johnson & Johnson, projects the global orthopedic device market to reach $53.6 billion in 2014, reflecting a compound annual growth rate (CAGR) of 6.8%.

ORTHOPEDIC IMPLANT MARKET SHARES—2011
(In percent)



Totals may not add due to rounding.
Source: Stryker Corp.

The top seven companies in orthopedics hold more than 70% market share. Five of these companies are based in the United States. They are Stryker Corp., Johnson & Johnson's DePuy division, Zimmer Holdings Inc., Medtronic Inc., and Biomet Inc. Other important global suppliers include Switzerland-based Synthes Inc. (acquired in June 2012 by Johnson & Johnson), 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. According to the Arthritis Foundation, 27 million Americans already suffer from osteoarthritis, which we believe reflects promising growth potential of orthopedic implant market. In addition, the privately owned company figured that the reconstructive products (hips, knees, shoulders, and other) segment of the overall orthopedics market would generate US sales of $7.4

billion. Knee products will account for an estimated 56% of this figure, hip implants 38%, and the rest, including shoulders, 6%.

The spinal products market, which includes cages, rods, and screws used in spinal fusion procedures, has declined. Demographics and new, non-fusion technologies, such as motion preservation technologies, artificial disks, nucleus replacement, and dynamic stabilization devices, are driving demand. Because of its attractive prospects and profitability, the field is attracting start-ups interested in innovating, which could lead to M&A activity down the road, in our view.

In vitro diagnostics

One of the largest medical products segments, in vitro diagnostics (IVD), totaled $44 billion in global sales in 2011, and is expected to grow at a CAGR of 7.8% from 2011 to 2016, according to a January 2012 report published by MarketsandMarkets. According to the report, the US accounted for the largest share of the global IVD market in 2011 (47%), followed by Europe (31%). Further, according to another report by iData Research, a market research and consulting group, the US IVD market is expected 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 Capital IQ believes it is the fastest growing subsector in IVD. Many new molecular tests are in development, making future prospects for the subsector excellent. Roche Diagnostics, Gen-Probe Corp., Siemens Healthcare Diagnostics, and Abbott Laboratories are the four leading suppliers of molecular tests.

A rapidly growing area within the IVD arena is companion diagnostics, which are protein or genetic tests used to identify if patients will benefit from particular treatments. This field is being driven by the growth of "personalized medicine," which is being encouraged by pharmacy benefit managers and health insurers as a way of finding the most effective and, hence, likely least costly treatment for each individual patient. One area of growth is personal genetic tests, which has stirred some controversy. In March 2011, a Food and Drug Administration (FDA) advisory panel said that genetic tests directly marketed to consumers should be allowed only under a doctor's supervision. That's because personal testing, which is mainly available from firms operating outside traditional medical institutions, can produce ambiguous or misleading results without proper analysis. Indeed, in May 2011, the FDA formally warned three small providers of direct-to-consumer DNA tests about medical claims the companies make that the agency has not approved.

Strong drivers of IVD sector growth include tests for whole blood glucose, chlamydia and gonorrhea, HIV-AIDS, cholesterol, diabetes/glucose, HER2 (Human Epidermal growth factor Receptor 2, a protein associated with more aggressive breast cancer), Strep-A, and C-reactive protein (CRP). These also are among the most profitable subsegments. They are expected to exhibit annual growth rates in the low teens over the next few years, particularly buoyed by increasing prevalence of chronic and infectious diseases, and the continuous introduction of new products, including more complex immunochemistry tests and those for point-of-care testing (including consumer self-testing). In addition, we think that more hospitals will embrace IVD for screening patients amid rising concern about hospital-acquired infections.

The IVD business is fairly concentrated. According to Frost & Sullivan, the top five companies held roughly 59% of the market in 2009 (latest available). Roche Diagnostics Corp. (a subsidiary of Roche Holdings AG) was No. 1 (19.9% market share), followed by Siemens AG (12.3%), Johnson & Johnson (11.2%), Abbott Laboratories (9.0%), and Beckman Coulter Inc. (7.2%). Other players include Bayer Diabetes Care (4.6%), bioMerieux (3.7%), Sysmex (2.9%), Alere (2.6%), Becton Dickinson (1.8%), Instrumentation Laboratory (1.5%), Qiagen (1.2%), Radiometer (1.2%), Gen-Probe Inc. (1.1%), and all others (19.8%).

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%.

In February 2012, the Global Harmonization Task Force (GHTF) proposed several guidelines, explaining to various companies the different factors they should consider in deciding which studies they should conduct while undertaking clinical performance evaluations for their in vitro diagnostic devices. The task force had put out these guidelines inviting comments until June 2, 2012. The GHTF is a partnership formed among the regulatory authorities of the European Union, the US, Canada, Australia, and Japan, and the medical devices industry that seeks greater uniformity among national regulatory systems.

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.

◆ **Peripheral vascular disease (PVD).** Also known as peripheral arterial disease (PAD), this is a condition where atherosclerotic plaque builds up in the arteries outside the heart, which can lead to thickening of blood vessel walls or blood clots, similar to what happens in the coronary arteries. The main factors causing this disease are hypertension and atherosclerosis, which are also the main causes for most cardiovascular diseases. PVD generally affects between 12% and 20% of American population aged 65 and older as per the Society of Interventional Radiology (SIR), a professional medical society. The majority of products on the market for PVD are guidewires, catheters, balloons, and stents; these are used to clear blocked peripheral arteries. Major companies in this segment are Johnson & Johnson (Cordis division), W.L. Gore & Co., Boston Scientific, Edwards Lifesciences Corp., Abbott Laboratories, and Medtronic.

◆ **Abdominal aortic aneurysms (AAAs).** This condition is caused by a weakened area in the aorta, the main vessel that supplies blood from the heart to the rest of the body. When blood flows through the aorta, an aortic wall that is abnormally weak bulges like a balloon. If the balloon grows large enough, it can burst. Ruptured aortic aneurysms result in death in 80% to 90% of cases. According to the SIR, AAAs are the seventeenth leading cause of death in the United States, accounting for more than 15,000 deaths each year.

Ruptures can be prevented if AAAs are caught early and treated. The problem is that, in most cases, patients have no disease symptoms. More efforts are underway to identify people at risk of rupture earlier and treat them with new procedures involving the replacement of the diseased portion of the aorta with a synthetic graft. Leading innovators in this market include Abbott Laboratories, Medtronic, and Boston Scientific.

◆ **Blood clots.** Another vascular segment of interest to medical device manufacturers is the treatment of blood clots, generally in the venous system in the lower extremities and the lungs. The principal focus is on two conditions: deep vein thrombosis (DVT) and pulmonary thromboembolism (PT). The incidence of DVT runs as high as two million patients a year, according to the American Heart Association, and up to 20% of patients with DVT develop PT at some point. Patients for whom DVT becomes a recurring problem require the insertion of a vena cava filter; producers include Boston Scientific, Johnson & Johnson, and C.R. Bard Inc. In March 2012, Covidien received FDA approval to market its revascularization device, the Solitaire FR. For patients suffering from acute ischemic stroke, the device will be used to remove blood clots from blocked vessels to restore blood flow to the brain. The product received the Conformité Européene (CE) marking in Europe and has been selling internationally since November 2009; it hit the US market in April 2012.

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 invariable, 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. Because of 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.

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 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 pre-market 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 the MDUFA II set to expire 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 a 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 (as it existed when this *Survey* went to press in mid-January 2010): even simple trials can cost anywhere from four to 10 times more, according to industry sources.

After a PMA is submitted, an FDA scientific advisory panel, consisting of physicians, researchers, and other experts in related fields, evaluates the product. They 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 does not require separate approval from individual countries. Although the EC 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.

Three European Commission (EC) directives and their updates outline the criteria for granting CE markings. The first directive (issued in 1990) covers implantable devices; the second (1993) applies in general to medical devices, including those that incorporate human blood or plasma; and the third (1998) is specific to in vitro diagnostics. The directives require greater scrutiny for some devices than others, based on safety risk, the amount of time the product is in contact with the human body, and the device's degree of invasiveness. Products with the lowest risk need the least safety data, while the riskiest products have to undergo clinical trials and meet other stringent requirements.

Several classifications are or have been controversial. In 2003, for example, the EC moved breast implants from Class IIB, a medium-risk category, to Class III, which requires the greatest premarket scrutiny. In May 2007, the EC also instituted a regulation covering the approval and marketing of advanced therapies engineered from human tissue. This directive took years to wind its way through the political process due to controversy over whether to categorize certain products as devices or drugs.

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 discourages 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 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 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 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 often are 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 believe 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—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, 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 Web site (www.cms.gov). The data are structured by kind of expenditure, such as hospital care, physician care, or drugs and other medical nondurables.

According to CMS projections released in January 2012, US healthcare spending is expected to almost double by 2020, reaching nearly $4.5 trillion and accounting for 19.2% of GDP (up from 17.9% in 2010). The CMS projections assume spending growth to accelerate to 3.9% in 2011 and then grow at a slightly higher 4.2% in 2012. The payment cut had taken effect June 1, but the US Senate reversed the cut on June 25 and raised payments 2.2% until December 31. Physicians then faced a 25% payment cut on January 1, but in mid-December, President Obama signed into law a bill that shelved the cut and guaranteed a stable Medicare reimbursement rate through 2011. Prior to the deferral of the cut and actual 2009 data had been determined, healthcare spending had been forecast to rise by an average of 6.1% annually over the next

decade, 1.7 percentage points higher than the general economy each year, according to the CMS. Overall, US health spending per capita was projected to approximate $13,652 in 2019, up from $8,086 in 2009.

◆ **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 44.9% of total healthcare expenditures in 2010 (latest actual) and is projected to reach 49.2% of total spending by 2020 (latest projected).

According to the CMS, federal Medicare expenditures in 2010 rose 2.7% to $523 billion. According to actuarial estimates in the *2011 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 6.0%, reaching $932 billion by 2020. The CMS projects combined federal and state Medicaid and CHIP spending to more than double from $413 billion in 2010 to $895 billion in 2020 (a CAGR of 9.0%), accounting for 19.9% of US healthcare spending by that time.

PROJECTED NATIONAL HEALTH EXPENDITURES AND SELECTED ECONOMIC INDICATORS

ITEM	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
National health expenditures (bil.$)	2,809	2,916	3,130	3,308	3,514	3,723	3,952	4,207	4,487	4,781
Private health insurance expenditures, total (bil.$)	776	800	864	920	982	1,039	1,096	1,166	1,239	1,314
Gross Domestic Product (bil.$)	15,697	16,387	17,223	18,205	19,224	20,243	21,296	22,318	23,345	24,395
Health expenditures as % of GDP	17.9	17.8	18.2	18.2	18.3	18.4	18.6	18.9	19.2	19.6
Health expenditures per capita ($)	8,953	9,214	9,808	10,272	10,818	11,360	11,955	12,618	13,346	14,103
U.S. population (mil.)	272	273	274	276	277	279	280	281	282	283
Under 65	42	44	45	46	48	49	51	52	54	56
65 and older	889	925	998	1,060	1,131	1,191	1,253	1,329	1,412	1,495

Source: Centers for Medicare & Medicaid Services.

◆ **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 according to various products and services.

According to the BLS, the aggregate medical care CPI-U (CPI for all urban consumers) advanced 3.4% in 2011, versus a 3.1% increase in overall CPI. In 2010, the healthcare CPI grew 3.4%, versus a 1.6% increase in overall CPI. As of June 2012, Standard & Poor's Economics (which operates separately from S&P Capital IQ) was projecting the overall US CPI to rise by 1.7% in 2012 and 1.2% in 2013.

◆ **Research and development (R&D) as a percentage of sales.** With new devices representing the lifeblood of the medical technology industry, changes in R&D spending can have an important impact on future trends in sales and earnings. These statistics are available from individual company reports. The companies followed by S&P Capital IQ's equity analysts devote around 9% to 11% of sales to R&D, on average, although the range is wide—from 5% to 15%. Although 10% is about double the percentage of the average industrial company, it is below the historical average of approximately 15% of sales spent by the pharmaceutical industry.

◆ **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, because it means that 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. As the US dollar strengthened throughout most of 2008 and through April 2009, US medical device companies were negatively impacted by unfavorable currency movements versus their major trading partners. The dollar then weakened through November 2009, enabling companies with more significant overseas operations to benefit. It had temporarily strengthened in the first half of 2010, due to fiscal problems in Europe at the time, but subsequently weakened again. As of June 2012, Standard & Poor's Economics expected the dollar to strengthen through the third quarter of 2013 and to weaken afterward.

◆ **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 December 2010, 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. Following 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 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 also can be key.

◆ **How healthy are operating margins?** Medical products 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 often can 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, 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.

Arrhythmia—An abnormality in the rhythm or rate of the heartbeat. There are two main kinds: tachycardia, in which the rate is faster than normal (more than 100 beats per minute), and bradycardia, in which the rate is slower than normal (less than 60 beats per minute).

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.

Congestive heart failure—A condition, primarily found in the elderly, which results in the heart's inability to pump blood. One of the first symptoms is retention of salt and water by the kidneys and shortness of breath due to fluid accumulation in the lungs.

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 are implanted in the patient and programmed to deliver the shock automatically if the heart rhythm malfunctions, while external defibrillators are administered manually.

Diagnosis-related groups (DRGs)—Established in 1983 by amendments to the Social Security Act, the DRG system is used by the Centers for Medicare & Medicaid Services (CMS) to standardize payments to medical providers treating Medicare patients. The system is intended to spur hospitals to manage patient care more efficiently. Under Medicare reimbursement guidelines, DRGs constitute approximately 500 different classes of illnesses, each with a separate reimbursement schedule.

Electrocardiogram (EKG)—A record of the heart's electrical impulses. It is used to diagnose heart disorders.

Endoscope—An illuminated optical instrument that is inserted into body cavities for diagnostic and treatment purposes.

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.

Gain-sharing—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, that 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.

Managed care organizations (MCOs)—A method of delivering and paying for healthcare through a system of provider networks. Managed care plans include health maintenance organizations (HMOs), which were once popular but are used less frequently because they limit access to providers; preferred provider organizations (PPOs); point-of-service (POS) plans; and similar coordinated plan networks. PPOs and POS are favored models because of the range of choices they offer.

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 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). ■

INDUSTRY REFERENCES

PERIODICALS

AdvaMed Smart Brief
http://www.advamed.org
Free, daily e-newsletter highlighting the day's important news stories about the medical devices and diagnostics industries. Includes access to a useful archive and links to articles printed in a variety of publications.

FDA Consumer
http://www.fda.gov
Monthly; covers the US Food and Drug Administration and contains medical articles of interest to consumers.

The Gray Sheet
http://www.windhover.com
Weekly; covers trade and regulatory news in the medical devices, diagnostics, and instrumentation industries.

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

IN VIVO Magazine: The Business and Medicine Report
http://www.windhover.com
Monthly trade publication analyzing strategies, technologies, and deal-making activities of medical device and pharmaceutical companies.

The Journal of the American Medical Association
http://jama.ama-assn.org
Weekly; publishes medical research papers on a wide range of topics, as well as commentary from industry experts and physicians.

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

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 Global Insight
http://www.ihsglobalinsight.com
Economic research and forecasting company with a division devoted to analysis of global healthcare economies and trends. Primarily focused 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.americanheart.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 Orthopaedic 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

Agency for Healthcare Research and Quality (AHRQ)
http://www.ahrq.gov
Part of the Department of Health and Human Services, the AHRQ's mission is to improve the quality, safety, efficiency, and effectiveness of healthcare for all Americans.

Centers for Medicare & Medicaid Services (CMS)
http://www.cms.hhs.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, 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).

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 $ 2011	2010	2009	2008	2007	2006	2001	CAGR (%) 10-Yr.	5-Yr.	1-Yr.	Index Basis (2001 = 100) 2011	2010	2009	2008	2007
HEALTH CARE EQUIPMENT‡																		
ABAX	§	ABAXIS INC	# MAR	156.6	143.7	124.6	105.6	100.6	86.2	30.6	17.7	12.7	9.0	511	469	407	345	328
ALOG	§	ANALOGIC CORP	JUL	473.6 D	423.6	396.1	413.5 A	340.9	351.4 D	352.1	3.0	6.1	11.8	134	120	112	117	97
BCR	[]	BARD (C.R.) INC	DEC	2,896.4	2,720.2	2,534.9	2,452.1 A	2,202.0 D	1,985.5	1,181.3	9.4	7.8	6.5	245	230	215	208	186
BAX	[]	BAXTER INTERNATIONAL INC	DEC	13,893.0	13,056.0	12,562.0	12,348.0	11,263.0	10,378.0	7,663.0 A	6.1	6.0	6.4	181	170	164	161	147
BDX	[]	BECTON DICKINSON & CO	SEP	7,828.9	7,372.3 D	7,160.9 D	7,155.9	6,359.7 D	5,840.2	3,754.3 C	7.6	6.0	6.2	209	196	191	191	169
BSX	[]	BOSTON SCIENTIFIC CORP	DEC	7,622.0	7,806.0	8,188.0	8,050.0	8,357.0	7,821.0 A	2,673.0 A	11.0	(0.5)	(2.4)	285	292	306	301	313
CMN	§	CANTEL MEDICAL CORP	JUL	321.7	274.0	260.0	249.4	219.0	192.2 A,C	49.0	20.7	10.9	17.4	656	559	531	509	447
CFN	[]	CAREFUSION CORP	JUN	3,528.0 D	3,929.0 D	4,501.0	4,518.4	3,477.8 A	NA	NA	NA	NA	(10.2)	**	**	**	**	NA
CNMD	§	CONMED CORP	DEC	725.1	713.7	694.7	742.2 A	694.3	646.8	428.7	5.4	2.3	1.6	169	166	162	173	162
COV	[]	COVIDIEN PLC	SEP	11,574.0 D	10,429.0 A,C	10,677.0 A	9,910.0 D	10,170.0	9,647.0 D	NA	NA	3.7	11.0	**	**	**	**	NA
CRY	§	CRYOLIFE INC	DEC	119.6 A	116.6	111.7	105.1	94.8	81.3	87.7	3.2	8.0	2.6	136	133	127	120	108
CYBX	§	CYBERONICS INC	# APR	218.5	190.5	167.8	143.6	121.2	131.0	70.1	12.0	10.8	14.7	312	272	239	205	173
EW	[]	EDWARDS LIFESCIENCES CORP	DEC	1,678.6	1,447.0	1,321.4	1,237.7	1,091.1 A	1,037.0	692.0	9.3	10.1	16.0	243	209	191	179	158
GPRO	†	GEN-PROBE INC	DEC	576.2	543.3	498.3	456.3	392.7	349.8	129.7	16.1	10.5	6.1	444	419	384	352	303
GB	§	GREATBATCH INC	DEC	568.8 A	533.4	521.8	546.6 A	318.7 A	271.1	135.6 A	15.4	16.0	6.6	420	393	385	403	235
HRC	†	HILL-ROM HOLDINGS INC	SEP	1,591.7	1,469.6	1,386.9	1,507.7 D	2,023.7	1,962.9	2,131.0	(2.9)	(4.1)	8.3	75	69	65	71	95
HOLX	†	HOLOGIC INC	SEP	1,789.3 A	1,679.6	1,637.1	1,674.5	738.4	462.7 A	176.3	26.1	31.1	6.5	1,015	952	928	950	419
IDXX	†	IDEXX LABS INC	DEC	1,218.7	1,103.4	1,031.6	1,024.0	922.6	739.1	386.1	12.2	10.5	10.4	316	286	267	265	239
IART	§	INTEGRA LIFESCIENCES HLDGS	DEC	780.1 A	732.1	682.5	654.6 A	550.5 A	419.3 A	93.4 A	23.6	13.2	6.6	835	783	730	701	589
ISRG	[]	INTUITIVE SURGICAL INC	DEC	1,757.3	1,413.0	1,052.2	874.9	600.8	372.7	51.7	42.3	36.4	24.4	3,401	2,735	2,036	1,693	1,163
IVC	§	INVACARE CORP	DEC	1,801.1 A	1,722.1	1,693.1	1,755.7 A	1,602.2	1,498.0	1,053.6	5.5	3.8	4.6	171	163	161	167	152
KNSY	§	KENSEY NASH CORP	JUN	71.6 A	80.6	82.1	79.8	69.8	60.4 A	23.2 A	11.9	3.5	(11.2)	309	348	354	344	301
MASI	†	MASIMO CORP	DEC	439.0	405.4	349.1	307.1	256.3	224.3	NA	NA	14.4	8.3	**	**	**	**	NA
MDT	[]	MEDTRONIC INC	# APR	16,184.0 D	15,933.0	15,835.0	14,599.0	13,515.0 A	12,299.0	6,410.8 A	9.7	5.6	1.6	252	249	247	228	211
BABY	§	NATUS MEDICAL INC	DEC	232.7 A	218.7 A	166.5 A	161.8 A	118.4 A	89.9 A	27.4	23.8	20.9	6.4	849	798	608	591	432
NUVA	§	NUVASIVE INC	DEC	540.5 A	478.2	370.3 A	250.1	154.3	98.1 C	NA	NA	40.7	13.0	**	**	**	**	NA
PMTI	§	PALOMAR MED TECHNOLOGIES INC	DEC	73.6	63.7	60.6	86.7	122.9	126.5	16.7	16.0	(10.3)	15.6	442	383	364	520	738
RMD	†	RESMED INC	JUN	1,243.1	1,092.4	920.7	835.4	716.3 A	607.0 A	155.2 A	23.1	15.4	13.8	801	704	593	538	462
STJ	[]	ST JUDE MEDICAL INC	DEC	5,611.7	5,164.8	4,681.3	4,363.3	3,779.3	3,302.4	1,347.4	15.3	11.2	8.7	416	383	347	324	280
STE	†	STERIS CORP	# MAR	1,391.5	1,309.8	1,257.7	1,298.5	1,265.1	1,197.4	866.7	4.8	3.1	6.2	161	151	145	150	146
SYK	[]	STRYKER CORP	DEC	8,307.0	7,320.0	6,723.1	6,718.2	6,000.5 D	5,405.6	2,602.3	12.3	9.0	13.5	319	281	258	258	231
SRDX	§	SURMODICS INC	SEP	67.8	69.9	120.2	97.1	73.2 A	69.9	22.7	11.6	(0.6)	(3.0)	299	308	530	428	322
SMA	§	SYMMETRY MEDICAL INC	DEC	359.0 A	360.8	365.9	423.4	290.9	253.6 A	NA	NA	7.2	(0.5)	**	**	**	**	NA
TFX	†	TELEFLEX INC	DEC	1,528.9 D	1,801.7 D	1,890.1 D	2,420.9	1,934.3 A,C	2,646.8 A,C	1,905.0 A	(2.2)	(10.4)	(15.1)	80	95	99	127	102
THOR	†	THORATEC CORP	DEC	422.7 A	383.0 D	373.9	313.6	234.8	214.1	113.4 A	14.1	14.6	10.4	373	338	330	277	207
VAR	[]	VARIAN MEDICAL SYSTEMS INC	SEP	2,596.7	2,356.6	2,214.1	2,069.7 A,C	1,776.6	1,597.8	773.6 C	12.9	10.2	10.2	336	305	286	268	230
ZMH	[]	ZIMMER HOLDINGS INC	DEC	4,451.8	4,220.2	4,095.4	4,121.1	3,897.5	3,495.4	1,178.6	14.2	5.0	5.5	378	358	347	350	331
HEALTH CARE SUPPLIES‡																		
ALGN	§	ALIGN TECHNOLOGY INC	DEC	479.7 A	372.8	312.3	304.0	284.3	206.4	46.4	26.3	18.4	28.7	1,034	804	673	655	613
COO	†	COOPER COMPANIES INC	OCT	1,330.8	1,158.5	1,080.4	1,063.2	950.6 A	859.0 A	234.6 A	19.0	9.2	14.9	567	494	461	453	405
XRAY	[]	DENTSPLY INTERNATL INC	DEC	2,537.7 A	2,221.0 A	2,159.9 A	2,193.7 A,C	2,009.8 A	1,810.5 A	1,129.1 A	8.4	7.0	14.3	225	197	191	194	178
HAE	§	HAEMONETICS CORP	# MAR	727.8	676.7 A	645.4 A	597.9 A	516.4 A	449.6 A,C	320.0	8.6	10.1	7.6	227	211	202	187	161
ICUI	§	ICU MEDICAL INC	DEC	302.2	284.6	231.5	204.7	188.1	201.6	69.1	15.9	8.4	6.2	438	412	335	296	272
VIVO	§	MERIDIAN BIOSCIENCE INC	SEP	159.7	143.0 A	148.3	139.6	123.0	108.4	56.5	10.9	8.1	11.7	283	253	262	247	218
MMSI	§	MERIT MEDICAL SYSTEMS INC	DEC	359.4	296.8 A	257.5 A	227.1	207.8	190.7	104.0	13.2	13.5	21.1	346	285	247	218	200
NEOG	§	NEOGEN CORP	# MAY	NA	173.0	140.7 A	118.8 A	102.4 A	86.1	41.1 A	NA	NA	NA	NA	421	342	289	249
WST	§	WEST PHARMACEUTICAL SVSC INC	DEC	1,192.3	1,104.7 A	1,055.7	1,051.1	1,020.1	913.3	396.9 D	11.6	5.5	7.9	300	278	266	265	257

Operating Revenues

Ticker	Company	Yr. End	Million $ 2011	2010	2009	2008	2007	2006	2001	CAGR (%) 10-Yr.	5-Yr.	1-Yr.	Index Basis (2001 = 100) 2011	2010	2009	2008	2007
OTHER COMPANIES WITH SIGNIFICANT HEALTHCARE PRODUCTS & SUPPLIES OPERATIONS																	
ABT	[] ABBOTT LABORATORIES	DEC	38,851.3	35,166.7 A	30,764.7	29,527.6 D	25,914.2	22,476.3	16,285.2 A	9.1	11.6	10.5	239	216	189	181	159
BMY	[] BRISTOL-MYERS SQUIBB CO	DEC	21,244.0	19,484.0	18,808.0 D	20,597.0 D	19,348.0 D	17,914.0	18,213.0 A,C	1.6	3.5	9.0	117	107	103	113	106
JNJ	[] JOHNSON & JOHNSON	DEC	65,030.0	61,587.0	61,897.0	63,747.0	61,035.0	53,194.0	33,004.0 A	7.0	4.1	5.6	197	187	188	193	185

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 $ 2011	2010	2009	2008	2007	2006	2001	CAGR (%) 10-Yr.	5-Yr.	1-Yr.	Index Basis (2001 = 100) 2011	2010	2009	2008	2007
HEALTH CARE EQUIPMENT‡																			
ABAX	§	ABAXIS INC	#	MAR	13.1	14.5	13.0	12.0	12.5	10.1	1.3	25.9	5.4	(9.9)	1,004	1,115	999	921	959
ALOG	§	ANALOGIC CORP		JUL	16.6	15.6	3.7	23.5	15.4	4.6	13.6	2.0	29.3	6.8	122	114	27	173	113
BCR	[]	BARD (C.R.) INC		DEC	328.0	509.2	460.1	416.5	406.4	272.1	143.2	8.6	3.8	(35.6)	229	356	321	291	284
BAX	[]	BAXTER INTERNATIONAL INC		DEC	2,224.0	1,420.0	2,205.0	2,014.0	1,707.0	1,398.0	664.0	12.8	9.7	56.6	335	214	332	303	257
BDX	[]	BECTON DICKINSON & CO		SEP	1,264.9	1,176.3	1,213.1	1,127.9	856.2	755.6	438.4	11.2	10.9	7.5	289	268	277	257	195
BSX	[]	BOSTON SCIENTIFIC CORP		DEC	441.0	(1,065.0)	(1,025.0)	(2,036.0)	(495.0)	(3,577.0)	(54.0)	NM	NM	NM	NM	NM	NM	NM	NM
CMN	§	CANTEL MEDICAL CORP		JUL	20.4	19.9	15.6	8.7	8.1	6.7	4.2	17.3	25.1	2.4	491	480	375	209	195
CFN	[]	CAREFUSION CORP		JUN	291.0	171.0	568.0	662.7	502.4	NA	NA	NA	NA	70.2	**	**	**	**	NA
CNMD	§	CONMED CORP		DEC	0.8	30.3	12.1	44.6	41.5	(12.5)	24.4	(29.4)	NM	(97.5)	3	124	50	183	170
COV	[]	COVIDIEN PLC		SEP	1,883.0	1,563.0	902.0	1,443.0	(337.0)	1,470.0	NA	NA	5.1	20.5	**	**	**	**	NA
CRY	§	CRYOLIFE INC		DEC	7.4	3.9	8.7	32.9	7.2	0.4	9.2	(2.2)	82.4	86.9	80	43	95	359	79
CYBX	§	CYBERONICS INC	#	APR	36.1	46.7	78.4	26.7	(10.3)	(51.2)	(26.1)	NM	NM	(22.8)	NM	NM	NM	NM	NM
EW	[]	EDWARDS LIFESCIENCES CORP		DEC	236.7	218.0	229.1	128.9	113.0	130.5	(10.0)	NM	12.6	8.6	NM	NM	NM	NM	NM
GPRO	†	GEN-PROBE INC		DEC	50.1	106.9	91.8	107.0	86.1	59.5	4.6	26.9	(3.4)	(53.1)	1,086	2,316	1,988	2,317	1,866
GB	§	GREATBATCH INC		DEC	33.1	33.1	(9.0)	18.6	15.1	16.1	11.6	11.1	15.5	(0.0)	286	286	(78)	160	130
HRC	†	HILL-ROM HOLDINGS INC		SEP	133.3	125.3	(405.0)	67.1	190.6	221.5	170.0	(2.4)	(9.7)	6.4	78	74	(238)	39	112
HOLX	†	HOLOGIC INC		SEP	157.1	(62.8)	(2,176.2)	(385.6)	94.6	27.4	(20.9)	NM	41.8	NM	NM	NM	NM	NM	NM
IDXX	†	IDEXX LABS INC		DEC	161.8	141.3	122.2	116.2	94.0	93.7	37.6	15.7	11.5	14.5	430	376	325	309	250
IART	§	INTEGRA LIFESCIENCES HLDGS		DEC	28.0	65.7	51.0	34.9	33.5	29.4	26.4	0.6	(1.0)	(57.4)	106	249	193	132	127
ISRG	[]	INTUITIVE SURGICAL INC		DEC	495.1	381.8	232.6	204.3	144.5	72.0	(16.7)	NM	47.0	29.7	NM	NM	NM	NM	NM
IVC	§	INVACARE CORP		DEC	(4.1)	25.3	41.2	38.6	1.2	(317.8)	35.2	NM	NM	NM	(12)	72	117	110	3
KNSY	§	KENSEY NASH CORP		JUN	2.1	19.5	20.1	4.8	3.6	3.7	3.6	(5.4)	(11.0)	(89.3)	57	538	555	132	100
MASI	†	MASIMO CORP		DEC	63.7	73.5	53.2	31.9	42.3	181.8	NA	NA	(18.9)	(13.4)	**	**	**	**	NA
MDT	[]	MEDTRONIC INC	#	APR	3,415.0	3,096.0	3,099.0	2,169.0	2,231.0	2,802.0	984.0	13.3	4.0	10.3	347	315	315	220	227
BABY	§	NATUS MEDICAL INC		DEC	(11.7)	11.9	11.1	17.5	9.8	(0.9)	(3.9)	NM	NM	NM	NM	NM	NM	NM	NM
NUVA	§	NUVASIVE INC		DEC	(69.8)	78.3	5.8	(27.5)	(11.3)	(47.9)	NA	NA	NM	NM	**	**	**	**	NA
PMTI	§	PALOMAR MED TECHNOLOGIES INC		DEC	7.4	(8.8)	(10.5)	(0.1)	20.5	53.0	(5.5)	NM	(32.5)	NM	NM	NM	NM	NM	NM
RMD	†	RESMED INC		JUN	227.0	190.1	146.4	110.3	66.3	88.2	11.6	34.6	20.8	19.4	1,952	1,634	1,259	948	570
STJ	[]	ST JUDE MEDICAL INC		DEC	825.8	907.4	777.2	384.3	559.0	548.3	172.6	16.9	8.5	(9.0)	478	526	450	223	324
STE	†	STERIS CORP	#	MAR	136.1	51.3	128.5	110.7	77.1	81.1	46.2	11.4	10.9	165.5	295	111	278	240	167
SYK	[]	STRYKER CORP		DEC	1,345.0	1,273.4	1,107.4	1,147.8	986.7	777.7	271.8	17.3	11.6	5.6	495	469	407	422	363
SRDX	§	SURMODICS INC		SEP	(12.8)	(21.1)	37.5	14.7	3.3	20.3	6.8	NM	NM	NM	(188)	(309)	551	216	49
SMA	§	SYMMETRY MEDICAL INC		DEC	2.9	14.0	21.8	24.0	(0.1)	24.1	NA	NA	(34.6)	(79.3)	**	**	**	**	NA
TFX	†	TELEFLEX INC		DEC	120.7	124.5	141.8	134.0	(42.4)	139.9	112.3	0.7	(2.9)	(3.1)	107	111	126	119	(38)
THOR	†	THORATEC CORP		DEC	72.6	59.0	28.6	22.5	3.2	4.0	(87.9)	NM	78.8	23.0	NM	NM	NM	NM	NM
VAR	[]	VARIAN MEDICAL SYSTEMS INC		SEP	408.6	367.5	331.5	295.3	239.5	243.6	68.0	19.6	10.9	11.2	601	541	488	434	352
ZMH	[]	ZIMMER HOLDINGS INC		DEC	760.8	596.9	717.4	848.6	773.2	834.5	149.8	17.6	(1.8)	27.5	508	398	479	566	516
HEALTH CARE SUPPLIES‡																			
ALGN	§	ALIGN TECHNOLOGY INC		DEC	66.7	74.3	(31.3)	80.0	35.7	(35.0)	(97.5)	NM	NM	(10.2)	NM	NM	NM	NM	NM
COO	†	COOPER COMPANIES INC		OCT	175.4	112.8	100.5	65.5	(11.2)	66.2	37.1	16.8	21.5	55.5	472	304	271	176	(30)
XRAY	[]	DENTSPLY INTERNATL INC		DEC	244.5	265.7	274.3	283.9	259.7	223.7	121.5	7.2	1.8	(8.0)	201	219	226	234	214
HAE	§	HAEMONETICS CORP	#	MAR	66.9	80.0	58.4	59.3	52.0	49.1	27.7	9.2	6.4	(16.4)	241	288	211	214	187
ICUI	§	ICU MEDICAL INC		DEC	44.7	30.9	26.6	24.3	23.1	25.7	15.4	11.2	11.7	44.4	290	201	173	158	150
VIVO	§	MERIDIAN BIOSCIENCE INC		SEP	26.8	26.6	32.8	30.2	26.7	18.3	(10.3)	NM	7.9	0.7	NM	NM	NM	NM	NM
MMSI	§	MERIT MEDICAL SYSTEMS INC		DEC	23.0	12.5	22.5	20.7	15.6	12.3	6.7	13.1	13.4	84.9	342	185	334	308	231
NEOG	§	NEOGEN CORP	#	MAY	NA	22.8	17.5	13.9	12.1	9.1	3.9	NA	NA	NA	**	579	444	352	307
WST	§	WEST PHARMACEUTICAL SVSC INC		DEC	75.5	65.3	72.6	86.0	71.2	61.5	19.6	14.4	4.2	15.6	385	333	370	439	363
OTHER COMPANIES WITH SIGNIFICANT HEALTHCARE PRODUCTS & SUPPLIES OPERATIONS																			
ABT	[]	ABBOTT LABORATORIES		DEC	4,728.4	4,626.2	5,745.8	4,734.2	3,606.3	1,716.8	1,550.4	11.8	22.5	2.2	305	298	371	305	233
BMY	[]	BRISTOL-MYERS SQUIBB CO		DEC	3,709.0	3,102.0	3,239.0	3,155.0	1,968.0	1,585.0	2,043.0	6.1	18.5	19.6	182	152	159	154	96
JNJ	[]	JOHNSON & JOHNSON		DEC	9,672.0	13,334.0	12,266.0	12,949.0	10,576.0	11,053.0	5,668.0	5.5	(2.6)	(27.5)	171	235	216	228	187

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.

Ticker		Company	Yr. End	Return on Revenues (%)					Return on Assets (%)					Return on Equity (%)				
				2011	2010	2009	2008	2007	2011	2010	2009	2008	2007	2011	2010	2009	2008	2007
HEALTH CARE EQUIPMENT‡																		
ABAX	§	ABAXIS INC	# MAR	8.4	10.1	10.5	11.4	12.4	7.1	8.2	8.4	9.2	11.2	8.0	9.2	9.5	10.4	13.0
ALOG	§	ANALOGIC CORP	JUL	3.5	3.7	0.9	5.7	4.5	3.3	3.3	0.8	4.8	3.2	4.0	3.9	0.9	5.7	3.7
BCR	[]	BARD (C.R.) INC	DEC	11.3	18.7	18.2	17.0	18.5	9.2	16.8	16.5	16.2	17.1	19.2	26.6	22.1	21.8	22.9
BAX	[]	BAXTER INTERNATIONAL INC	DEC	16.0	10.9	17.6	16.3	15.2	12.2	8.2	13.5	13.1	11.4	33.8	20.6	32.9	30.6	25.9
BDX	[]	BECTON DICKINSON & CO	SEP	16.2	16.0	16.9	15.8	13.5	12.6	12.4	14.1	14.8	12.1	24.6	22.2	24.1	24.3	20.9
BSX	[]	BOSTON SCIENTIFIC CORP	DEC	5.8	NM	NM	NM	NM	2.0	NM	NM	NM	NM	3.9	NM	NM	NM	NM
CMN	§	CANTEL MEDICAL CORP	JUL	6.4	7.3	6.0	3.5	3.7	6.8	7.1	5.6	3.2	3.2	9.2	10.1	8.8	5.4	5.5
CFN	[]	CAREFUSION CORP	JUN	8.2	4.4	12.6	14.7	14.4	3.6	2.1	6.8	8.2	NA	5.9	3.4	10.8	13.3	NA
CNMD	§	CONMED CORP	DEC	0.1	4.3	1.7	6.0	6.0	0.1	3.1	1.3	4.9	4.7	0.1	5.2	2.2	8.6	8.8
COV	[]	COVIDIEN PLC	SEP	16.3	15.0	8.4	14.6	NM	9.2	8.3	5.4	8.4	NM	20.0	18.4	11.5	19.9	NM
CRY	§	CRYOLIFE INC	DEC	6.2	3.4	7.8	31.3	7.6	5.2	2.9	6.7	30.1	8.1	6.3	3.5	8.3	40.6	12.1
CYBX	§	CYBERONICS INC	# APR	16.5	24.5	46.8	18.6	NM	17.0	25.4	58.6	21.5	NM	20.1	32.6	116.0	581.6	NA
EW	[]	EDWARDS LIFESCIENCES CORP	DEC	14.1	15.1	17.3	10.4	10.4	12.6	12.9	15.2	9.4	8.7	17.9	17.7	22.5	15.0	14.3
GPRO	†	GEN-PROBE INC	DEC	8.7	19.7	18.4	23.4	21.9	4.5	9.3	9.1	12.9	12.2	6.6	13.4	11.6	13.8	13.2
GB	§	GREATBATCH INC	DEC	5.8	6.2	NM	3.4	4.7	4.0	4.1	NM	2.5	2.5	7.4	8.2	NM	5.5	4.8
HRC	†	HILL-ROM HOLDINGS INC	SEP	8.4	8.5	NM	4.5	9.4	10.5	10.1	NM	3.5	9.4	18.4	19.0	NM	5.7	15.8
HOLX	†	HOLOGIC INC	SEP	8.8	NM	NM	NM	12.8	2.7	NM	NM	NM	9.8	5.6	NM	NM	NM	13.4
IDXX	†	IDEXX LABS INC	DEC	13.3	12.8	11.8	11.3	10.2	16.8	16.6	15.5	15.8	14.9	29.1	26.0	25.7	26.5	22.2
IART	§	INTEGRA LIFESCIENCES HLDGS	DEC	3.6	9.0	7.5	5.3	6.1	2.6	6.7	5.2	3.8	4.7	5.6	13.9	12.8	11.4	12.0
ISRG	[]	INTUITIVE SURGICAL INC	DEC	28.2	27.0	22.1	23.4	24.1	18.2	18.2	14.2	16.3	16.9	21.1	21.4	16.6	19.0	19.6
IVC	§	INVACARE CORP	DEC	NM	1.5	2.4	2.2	0.1	NM	1.9	3.1	2.7	0.1	NM	3.7	7.0	7.5	0.2
KNSY	§	KENSEY NASH CORP	JUN	2.9	24.1	24.5	6.0	5.2	1.4	12.0	12.0	3.2	2.7	2.2	17.1	16.9	4.0	3.1
MASI	†	MASIMO CORP	DEC	14.5	18.1	15.2	10.4	16.5	18.8	22.1	16.4	12.1	21.4	25.3	28.5	21.0	17.3	71.2
MDT	[]	MEDTRONIC INC	# APR	21.1	19.4	19.6	14.9	16.5	10.8	10.6	12.0	9.5	10.7	20.6	20.2	22.6	17.8	19.8
BABY	§	NATUS MEDICAL INC	DEC	NM	5.5	6.7	10.8	8.3	NM	3.8	4.0	7.8	6.2	NM	4.7	4.7	10.2	9.0
NUVA	§	NUVASIVE INC	DEC	NM	16.4	1.6	NM	NM	NM	10.8	1.0	NM	NM	NM	21.4	2.4	NM	NM
PMTI	§	PALOMAR MED TECHNOLOGIES INC	DEC	10.1	NM	NM	NM	16.7	4.4	NM	NM	NM	13.3	5.1	NM	NM	NM	15.7
RMD	†	RESMED INC	JUN	18.3	17.4	15.9	13.2	9.3	12.3	12.1	10.1	8.3	5.9	15.0	15.8	13.3	11.0	7.9
STJ	[]	ST JUDE MEDICAL INC	DEC	14.7	17.6	16.6	8.8	14.8	9.4	12.1	12.8	7.0	11.0	18.7	23.6	23.7	12.5	19.0
STE	†	STERIS CORP	# MAR	9.8	3.9	10.2	8.5	6.1	9.6	3.8	10.5	9.0	6.3	16.9	6.7	17.5	15.5	10.4
SYK	[]	STRYKER CORP	DEC	16.2	17.4	16.5	17.1	16.4	11.5	12.8	13.3	15.3	14.9	18.1	18.5	18.5	21.3	20.6
SRDX	§	SURMODICS INC	SEP	NM	NM	31.2	15.2	4.6	NM	NM	19.9	8.1	2.0	NM	NM	23.9	10.8	2.4
SMA	§	SYMMETRY MEDICAL INC	DEC	0.8	3.9	6.0	5.7	NM	0.5	3.1	4.9	5.6	NM	1.0	4.8	8.1	9.8	NM
TFX	†	TELEFLEX INC	DEC	7.9	6.9	7.5	5.5	NM	3.2	3.3	3.7	3.3	NM	6.4	7.4	10.0	10.4	NM
THOR	†	THORATEC CORP	DEC	17.2	15.4	7.6	7.2	1.4	9.6	7.4	4.0	3.5	0.5	12.0	10.3	5.8	5.3	0.8
VAR	[]	VARIAN MEDICAL SYSTEMS INC	SEP	15.7	15.6	15.0	14.3	13.5	16.9	15.9	15.5	16.1	15.0	32.4	28.4	28.3	31.9	29.6
ZMH	[]	ZIMMER HOLDINGS INC	DEC	17.1	14.1	17.5	20.6	19.8	9.2	7.6	9.5	12.2	12.3	13.5	10.5	12.7	15.3	14.9
HEALTH CARE SUPPLIES‡																		
ALGN	§	ALIGN TECHNOLOGY INC	DEC	13.9	19.9	NM	26.3	12.6	11.8	17.8	NM	31.9	19.1	15.4	22.8	NM	42.1	29.2
COO	†	COOPER COMPANIES INC	OCT	13.2	9.7	9.3	6.2	NM	6.8	4.4	3.9	2.5	NM	9.7	7.0	6.8	4.6	NM
XRAY	[]	DENTSPLY INTERNATL INC	DEC	9.6	12.0	12.7	12.9	12.9	6.1	8.4	9.3	10.3	10.7	13.3	14.5	16.0	18.3	18.6
HAE	§	HAEMONETICS CORP	# MAR	9.2	11.8	9.0	9.9	10.1	7.7	10.0	8.3	9.4	8.8	9.4	12.5	10.3	11.5	10.7
ICUI	§	ICU MEDICAL INC	DEC	14.8	10.9	11.5	11.9	12.3	13.3	10.0	9.0	9.2	9.5	15.0	11.5	10.3	10.4	10.5
VIVO	§	MERIDIAN BIOSCIENCE INC	SEP	16.8	18.6	22.1	21.6	21.7	17.3	17.1	21.7	21.6	21.1	19.5	19.4	24.6	25.0	25.7
MMSI	§	MERIT MEDICAL SYSTEMS INC	DEC	6.4	4.2	8.8	9.1	7.5	5.6	3.9	9.0	9.6	8.1	7.8	5.5	10.9	11.6	9.9
NEOG	§	NEOGEN CORP	# MAY	NA	13.2	12.5	11.7	11.8	NA	11.4	10.9	10.3	10.4	NA	13.4	12.5	11.6	11.9
WST	§	WEST PHARMACEUTICAL SVSC INC	DEC	6.3	5.9	6.9	8.2	7.0	5.6	5.1	6.0	7.3	6.8	11.8	10.8	13.6	17.7	15.8
OTHER COMPANIES WITH SIGNIFICANT HEALTHCARE PRODUCTS & SUPPLIES OPERATIONS																		
ABT	[]	ABBOTT LABORATORIES	DEC	12.2	13.2	18.7	16.0	13.9	7.9	8.3	12.1	11.5	9.5	20.2	20.4	28.5	26.9	22.7
BMY	[]	BRISTOL-MYERS SQUIBB CO	DEC	17.5	15.9	17.2	15.3	10.2	11.6	10.0	10.7	11.3	7.6	23.4	20.3	23.9	27.7	19.2
JNJ	[]	JOHNSON & JOHNSON	DEC	14.9	21.7	19.8	20.3	17.3	8.9	13.5	13.7	15.6	14.0	17.0	24.9	26.4	30.2	25.6

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				
					2011	2010	2009	2008	2007	2011	2010	2009	2008	2007	2011	2010	2009	2008	2007
HEALTH CARE EQUIPMENT‡																			
ABAX	§	ABAXIS INC	#	MAR	7.3	7.5	5.7	9.8	4.7	0.5	0.4	0.0	0.0	0.0	0.7	0.7	0.0	0.0	0.0
ALOG	§	ANALOGIC CORP		JUL	4.3	5.0	5.4	4.9	5.6	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	1.9	3.8	5.3	5.0	4.4	33.6	35.3	6.3	7.0	7.4	116.2	79.3	12.4	13.9	15.6
BAX	[]	BAXTER INTERNATIONAL INC		DEC	1.8	2.0	1.9	2.0	2.0	41.9	39.9	32.4	35.1	27.8	125.2	110.5	90.4	95.7	71.2
BDX	[]	BECTON DICKINSON & CO		SEP	2.6	2.7	2.6	2.6	2.1	33.7	21.5	22.4	16.1	17.8	87.3	52.8	51.9	43.4	57.9
BSX	[]	BOSTON SCIENTIFIC CORP		DEC	1.7	1.4	1.3	1.7	1.8	24.4	27.6	29.4	30.4	31.3	328.0	490.5	569.3	303.9	297.0
CMN	§	CANTEL MEDICAL CORP		JUL	2.6	2.3	2.3	2.2	2.1	8.7	4.6	14.1	21.2	22.6	35.3	20.5	66.9	110.3	125.3
CFN	[]	CAREFUSION CORP		JUN	4.6	3.3	3.1	2.9	3.2	19.5	20.5	16.1	21.4	18.5	61.7	79.0	71.2	101.1	73.6
CNMD	§	CONMED CORP		DEC	2.7	1.9	4.1	3.9	3.6	11.8	11.0	21.3	24.2	27.6	39.4	50.0	73.9	89.4	108.8
COV	[]	COVIDIEN PLC		SEP	2.4	1.8	2.4	2.5	1.4	28.4	31.6	25.9	27.0	32.8	124.4	170.3	91.9	93.6	162.9
CRY	§	CRYOLIFE INC		DEC	3.9	5.3	5.0	3.8	2.6	0.0	0.0	0.3	0.3	0.1	0.0	0.0	0.4	0.6	0.2
CYBX	§	CYBERONICS INC	#	APR	7.0	5.2	4.9	5.9	7.3	0.0	0.0	12.2	71.9	113.9	0.0	0.0	16.8	71.7	113.9
EW	[]	EDWARDS LIFESCIENCES CORP		DEC	3.5	3.1	3.1	2.7	1.5	10.1	0.0	7.2	16.6	6.9	18.0	0.0	15.1	40.5	29.9
GPRO	†	GEN-PROBE INC		DEC	1.5	1.3	2.0	13.5	13.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GB	§	GREATBATCH INC		DEC	2.8	3.5	1.9	2.5	2.8	30.3	31.0	37.4	47.2	40.3	138.1	146.2	215.9	248.2	206.5
HRC	†	HILL-ROM HOLDINGS INC		SEP	2.4	2.6	2.0	2.0	2.6	6.1	11.6	13.7	8.4	21.0	11.1	21.9	28.4	26.5	62.8
HOLX	†	HOLOGIC INC		SEP	2.6	2.5	2.5	2.0	2.2	27.7	28.4	35.3	28.0	1.1	178.6	220.3	378.9	613.1	4.2
IDXX	†	IDEXX LABS INC		DEC	1.2	1.6	1.5	1.2	1.4	0.4	0.6	0.8	1.1	1.2	2.9	1.9	3.6	8.4	7.0
IART	§	INTEGRA LIFESCIENCES HLDGS		DEC	4.4	2.2	2.3	2.8	1.8	51.6	36.6	40.5	58.3	54.4	151.9	120.4	148.0	151.9	222.6
ISRG	[]	INTUITIVE SURGICAL INC		DEC	4.6	4.7	4.2	4.3	4.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
IVC	§	INVACARE CORP		DEC	1.8	1.8	1.8	1.9	1.8	28.4	25.8	27.1	47.6	46.8	108.1	100.9	114.3	172.9	194.1
KNSY	§	KENSEY NASH CORP		JUN	6.5	8.7	10.4	8.1	8.9	24.8	22.2	20.3	22.2	5.9	60.9	37.3	33.0	39.5	14.7
MASI	†	MASIMO CORP		DEC	3.5	3.1	4.9	3.5	3.0	0.0	0.1	0.1	0.1	11.5	0.0	0.1	0.1	0.1	16.0
MDT	[]	MEDTRONIC INC	#	APR	1.7	1.9	1.9	2.4	2.1	29.3	33.4	32.1	34.3	33.3	184.9	184.2	147.2	155.8	152.3
BABY	§	NATUS MEDICAL INC		DEC	3.2	2.9	3.3	5.4	1.4	0.3	0.3	0.4	0.5	13.0	0.8	0.9	1.2	1.1	95.3
NUVA	§	NUVASIVE INC		DEC	2.9	3.4	5.8	6.6	5.2	43.7	33.8	41.3	55.1	0.0	102.7	87.5	87.7	89.7	0.0
PMTI	§	PALOMAR MED TECHNOLOGIES INC		DEC	5.9	6.2	7.4	6.9	8.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
RMD	†	RESMED INC		JUN	6.2	3.2	3.2	3.8	3.3	5.4	0.0	7.7	7.9	8.5	9.2	0.0	16.1	17.2	18.8
STJ	[]	ST JUDE MEDICAL INC		DEC	3.2	2.9	2.4	2.0	1.2	36.3	34.2	31.5	25.2	5.7	116.5	128.3	106.3	107.1	65.4
STE	†	STERIS CORP	#	MAR	2.3	2.0	2.9	2.7	2.2	19.6	20.5	21.3	22.2	20.1	56.2	58.2	55.4	59.8	63.3
SYK	[]	STRYKER CORP		DEC	3.9	4.8	4.1	3.4	3.7	17.7	11.7	0.0	0.0	0.0	32.5	16.5	0.0	0.0	0.0
SRDX	§	SURMODICS INC		SEP	4.9	4.9	4.6	3.7	2.4	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.9
SMA	§	SYMMETRY MEDICAL INC		DEC	3.4	3.7	2.2	2.0	1.5	45.0	22.2	19.4	29.1	22.5	213.0	84.6	102.3	158.6	200.7
TFX	†	TELEFLEX INC		DEC	4.7	2.2	3.0	1.8	1.5	28.4	27.4	37.6	47.2	46.1	94.6	162.5	178.8	333.2	469.8
THOR	†	THORATEC CORP		DEC	7.8	3.2	10.0	7.8	11.3	0.0	0.0	19.2	22.8	24.9	0.0	0.0	32.0	43.2	47.6
VAR	[]	VARIAN MEDICAL SYSTEMS INC		SEP	1.6	1.9	2.0	1.8	1.5	0.5	1.4	1.7	3.0	4.6	0.9	2.3	2.8	5.3	10.7
ZMH	[]	ZIMMER HOLDINGS INC		DEC	3.8	4.3	4.0	2.8	2.8	22.2	16.5	16.7	7.5	1.9	65.4	49.5	55.1	32.7	7.8
HEALTH CARE SUPPLIES‡																			
ALGN	§	ALIGN TECHNOLOGY INC		DEC	2.6	4.2	3.2	2.9	3.0	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	2.0	2.5	2.9	2.1	1.8	14.3	26.0	33.1	37.6	36.7	119.9	202.9	234.9	318.4	359.3
XRAY	[]	DENTSPLY INTERNATL INC		DEC	1.4	3.7	2.7	2.6	3.1	41.5	24.0	16.9	19.7	23.4	515.9	63.3	50.1	71.8	72.0
HAE	§	HAEMONETICS CORP	#	MAR	4.0	4.1	2.8	4.1	3.7	0.4	0.6	0.8	1.0	1.2	0.7	1.2	1.8	1.8	2.3
ICUI	§	ICU MEDICAL INC		DEC	8.9	8.1	6.2	8.2	7.1	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	5.9	6.6	7.0	6.2	5.5	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	3.1	2.8	2.8	5.0	3.8	7.9	25.6	0.0	0.0	0.0	34.2	113.1	0.0	0.0	0.0
NEOG	§	NEOGEN CORP	#	MAY	NA	6.9	5.1	7.8	5.9	NA	0.0	0.0	0.0	0.0	NA	0.0	0.0	0.0	0.0
WST	§	WEST PHARMACEUTICAL SVSC INC		DEC	1.9	2.6	2.3	2.3	2.3	30.7	35.7	38.6	43.0	42.3	130.8	134.2	167.7	184.5	172.0
OTHER COMPANIES WITH SIGNIFICANT HEALTHCARE PRODUCTS & SUPPLIES OPERATIONS																			
ABT	[]	ABBOTT LABORATORIES		DEC	1.5	1.3	1.8	1.5	1.5	33.0	35.9	33.0	33.3	34.8	145.3	247.7	109.8	159.9	192.1
BMY	[]	BRISTOL-MYERS SQUIBB CO		DEC	2.0	2.0	2.2	2.2	1.2	25.1	25.3	29.2	34.9	29.2	71.3	81.5	80.2	81.8	257.1
JNJ	[]	JOHNSON & JOHNSON		DEC	2.4	2.1	1.8	1.6	1.5	18.1	13.6	13.7	15.6	13.6	41.2	37.8	46.2	60.0	70.0

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	Price / Earnings Ratio (High-Low) 2011	2010	2009	2008	2007	Dividend Payout Ratio (%) 2011	2010	2009	2008	2007	Dividend Yield (High-Low, %) 2011	2010	2009	2008	2007
HEALTH CARE EQUIPMENT‡																	
ABAX §	ABAXIS INC	# MAR	54 - 33	44 - 27	51 - 22	69 - 18	69 - 29	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
ALOG §	ANALOGIC CORP	JUL	44 - 32	41 - 30	NM - 84	43 - 15	71 - 45	30	32	138	22	36	0.9 - 0.7	1.1 - 0.8	1.6 - 1.0	1.5 - 0.5	0.8 - 0.5
BCR []	BARD (C.R.) INC	DEC	30 - 22	18 - 14	19 - 15	24 - 17	24 - 19	20	13	14	15	15	0.9 - 0.7	0.9 - 0.7	1.0 - 0.7	0.9 - 0.6	0.8 - 0.6
BAX []	BAXTER INTERNATIONAL INC	DEC	16 - 12	26 - 17	17 - 13	22 - 15	23 - 17	32	49	29	28	27	2.7 - 2.0	2.9 - 1.9	2.4 - 1.8	1.9 - 1.3	1.6 - 1.2
BDX []	BECTON DICKINSON & CO	SEP	16 - 12	17 - 13	16 - 12	20 - 13	25 - 20	29	29	26	25	28	2.4 - 1.8	2.2 - 1.7	2.2 - 1.7	2.0 - 1.2	1.4 - 1.1
BSX []	BOSTON SCIENTIFIC CORP	DEC	27 - 17	NM - NM	NM - NM	NM - NM	NM - NM	0	NM	NM	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	24 - 16	20 - 11	22 - 12	28 - 13	40 - 25	10	8	0	0	0	0.6 - 0.4	0.7 - 0.4	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
CFN []	CAREFUSION CORP	JUN	23 - 17	39 - 27	11 - 7	NA - NA	NA - NA	0	0	0	NA	NA	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	NA - NA	NA - NA
CNMD §	CONMED CORP	DEC	NM - NM	26 - 16	58 - 28	23 - 13	22 - 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
COV []	COVIDIEN PLC	SEP	15 - 11	17 - 11	27 - 15	20 - 11	NM - NM	16	29	36	22	NM	1.5 - 1.0	2.6 - 1.8	2.3 - 1.3	2.0 - 1.1	0.0 - 0.0
CRY §	CRYOLIFE INC	DEC	24 - 15	53 - 34	32 - 13	14 - 6	58 - 24	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
CYBX §	CYBERONICS INC	# APR	28 - 18	21 - 10	8 - 4	29 - 10	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
EW []	EDWARDS LIFESCIENCES CORP	DEC	44 - 30	45 - 22	22 - 13	29 - 18	27 - 23	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
GPRO †	GEN-PROBE INC	DEC	82 - 51	27 - 19	27 - 20	33 - 15	44 - 28	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	20 - 13	17 - 13	NM - NM	33 - 19	51 - 27	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
HRC †	HILL-ROM HOLDINGS INC	SEP	23 - 13	22 - 12	NM - NM	53 - 14	23 - 17	20	21	NM	72	37	1.6 - 0.9	1.8 - 0.9	4.8 - 1.7	5.1 - 1.4	2.2 - 1.6
HOLX †	HOLOGIC INC	SEP	39 - 23	NM - NM	NM - NM	NM - NM	40 - 26	0	NM	NM	NM	0	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	31 - 22	30 - 20	27 - 13	33 - 12	42 - 25	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	55 - 29	23 - 15	21 - 11	40 - 21	44 - 33	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
ISRG []	INTUITIVE SURGICAL INC	DEC	37 - 21	40 - 25	51 - 14	68 - 21	94 - 23	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	40 - 25	20 - 11	22 - 11	NM - NM	NM	5	4	4	125	0.4 - 0.2	0.2 - 0.1	0.4 - 0.2	0.4 - 0.2	0.3 - 0.2
KNSY §	KENSEY NASH CORP	JUN	NM - 76	17 - 11	17 - 9	95 - 41	NM - 72	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
MASI †	MASIMO CORP	DEC	33 - 16	26 - 17	34 - 23	74 - 38	52 - 23	0	220	0	0	0	0.0 - 0.0	13.1 - 8.4	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
MDT []	MEDTRONIC INC	# APR	13 - 9	16 - 11	16 - 9	29 - 15	29 - 23	30	31	29	39	25	3.2 - 2.2	2.9 - 1.9	3.4 - 1.8	2.6 - 1.3	1.1 - 0.9
BABY §	NATUS MEDICAL INC	DEC	NM - NM	43 - 28	44 - 16	38 - 13	44 - 31	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
NUVA §	NUVASIVE INC	DEC	NM - NM	24 - 11	NM - NM	NM - NM	NM - NM	NM	0	0	NM	NM	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
PMTI §	PALOMAR MED TECHNOLOGIES INC	DEC	41 - 17	NM - NM	NM - NM	NM - NM	49 - 14	0	NM	NM	NM	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	24 - 16	28 - 20	28 - 16	37 - 20	65 - 45	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	21 - 13	16 - 12	18 - 13	43 - 22	30 - 21	33	0	0	0	0	2.6 - 1.6	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
STE †	STERIS CORP	# MAR	16 - 12	44 - 30	16 - 9	21 - 11	26 - 20	28	65	112	16	19	2.4 - 1.8	2.2 - 1.5	12.7 - 6.9	1.4 - 0.8	0.9 - 0.7
SYK []	STRYKER CORP	DEC	19 - 13	19 - 13	19 - 11	27 - 13	32 - 23	22	20	9	14	14	1.7 - 1.2	1.5 - 1.1	0.8 - 0.5	1.1 - 0.5	0.6 - 0.4
SRDX §	SURMODICS INC	SEP	NM - NM	NM - NM	14 - 7	68 - 23	NM - NM	NM	NM	0	0	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 - 86	31 - 21	19 - 6	32 - 10	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
TFX †	TELEFLEX INC	DEC	22 - 17	21 - 15	15 - 10	20 - 12	NM - NM	46	44	38	40	NM	2.8 - 2.1	2.8 - 2.1	3.7 - 2.5	3.4 - 2.0	2.2 - 1.4
THOR †	THORATEC CORP	DEC	31 - 18	47 - 24	67 - 40	80 - 32	NM - NM	0	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
VAR []	VARIAN MEDICAL SYSTEMS INC	SEP	21 - 14	24 - 12	18 - 10	28 - 14	28 - 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
ZMH []	ZIMMER HOLDINGS INC	DEC	17 - 12	22 - 16	18 - 9	22 - 9	29 - 19	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
HEALTH CARE SUPPLIES‡																	
ALGN §	ALIGN TECHNOLOGY INC	DEC	30 - 17	22 - 13	NM - NM	14 - 4	56 - 25	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
COO †	COOPER COMPANIES INC	OCT	23 - 14	24 - 14	17 - 7	29 - 7	NM - NM	2	2	3	4	NM	0.1 - 0.1	0.2 - 0.1	0.4 - 0.2	0.6 - 0.1	0.2 - 0.1
XRAY []	DENTSPLY INTERNATL INC	DEC	23 - 16	21 - 15	20 - 12	25 - 12	28 - 17	12	11	11	10	10	0.7 - 0.5	0.7 - 0.5	0.9 - 0.5	0.8 - 0.4	0.6 - 0.3
HAE §	HAEMONETICS CORP	# MAR	27 - 21	20 - 16	29 - 20	29 - 21	32 - 21	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	14 - 11	17 - 13	24 - 15	22 - 13	28 - 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
VIVO §	MERIDIAN BIOSCIENCE INC	SEP	41 - 22	37 - 24	33 - 18	49 - 26	51 - 24	115	112	80	71	60	5.1 - 2.8	4.6 - 3.0	4.4 - 2.5	2.7 - 1.4	2.5 - 1.2
MMSI §	MERIT MEDICAL SYSTEMS INC	DEC	34 - 19	45 - 31	25 - 12	28 - 16	29 - 19	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	NA - NA	43 - 21	32 - 14	34 - 20	33 - 16	NA	0	0	0	0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
WST §	WEST PHARMACEUTICAL SVSC INC	DEC	21 - 16	23 - 17	19 - 13	20 - 11	25 - 16	31	33	28	22	24	1.9 - 1.4	2.0 - 1.4	2.2 - 1.5	1.9 - 1.1	1.5 - 1.0
OTHER COMPANIES WITH SIGNIFICANT HEALTHCARE PRODUCTS & SUPPLIES OPERATIONS																	
ABT []	ABBOTT LABORATORIES	DEC	19 - 15	19 - 15	15 - 11	20 - 15	25 - 21	62	58	42	46	54	4.2 - 3.3	3.9 - 3.0	3.8 - 2.7	3.1 - 2.3	2.6 - 2.1
BMY []	BRISTOL-MYERS SQUIBB CO	DEC	16 - 11	16 - 12	16 - 11	17 - 10	32 - 26	61	53	77	97	112	5.3 - 3.7	4.3 - 3.4	7.3 - 4.7	9.7 - 5.7	4.4 - 3.5
JNJ []	JOHNSON & JOHNSON	DEC	19 - 16	14 - 12	15 - 10	16 - 11	19 - 16	64	44	43	39	44	3.9 - 3.3	3.7 - 3.2	4.2 - 3.0	3.4 - 2.5	2.7 - 2.4

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	Earnings per Share ($) 2011	2010	2009	2008	2007	Tangible Book Value per Share ($) 2011	2010	2009	2008	2007	Share Price (High-Low, $) 2011	2010	2009	2008	2007
HEALTH CARE EQUIPMENT‡																		
ABAX	§ ABAXIS INC	#	MAR	0.59	0.65	0.59	0.55	0.58	7.18	7.28	6.45	5.55	4.80	31.69 - 19.68	28.57 - 17.54	29.80 - 13.24	38.09 - 10.17	40.00 - 16.94
ALOG	§ ANALOGIC CORP		JUL	1.33	1.24	0.29	1.78	1.11	30.52	28.27	27.30	27.96	29.51	58.96 - 42.90	50.98 - 37.35	42.01 - 24.39	76.93 - 26.11	79.02 - 50.00
BCR	[] BARD (C.R.) INC		DEC	3.75	5.39	4.66	4.19	3.96	0.17	5.69	13.34	11.62	10.73	113.84 - 80.80	95.72 - 75.16	88.43 - 68.94	101.61 - 70.00	95.33 - 76.61
BAX	[] BAXTER INTERNATIONAL INC		DEC	3.91	2.41	3.63	3.22	2.65	6.14	6.98	8.08	6.79	7.53	62.50 - 47.55	61.88 - 40.25	60.99 - 45.46	71.53 - 47.41	61.09 - 46.07
BDX	[] BECTON DICKINSON & CO		SEP	5.72	5.02	5.04	4.62	3.50	12.67	16.87	16.52	15.38	12.82	89.75 - 69.59	85.50 - 66.47	79.97 - 60.40	93.24 - 58.14	85.89 - 69.30
BSX	[] BOSTON SCIENTIFIC CORP		DEC	0.29	(0.70)	(0.68)	(1.36)	(0.33)	(3.37)	(3.44)	(4.52)	(4.32)	(5.34)	7.96 - 5.01	9.79 - 5.04	11.77 - 6.08	14.22 - 5.41	18.69 - 11.27
CMN	§ CANTEL MEDICAL CORP		JUL	0.79	0.79	0.64	0.36	0.35	2.33	2.37	1.41	0.55	0.35	19.03 - 12.68	16.11 - 8.93	14.27 - 7.43	9.96 - 4.73	13.94 - 8.57
CFN	[] CAREFUSION CORP		JUN	1.31	0.77	2.53	2.95	2.23	5.60	3.43	NA	NA	NA	29.97 - 22.01	30.08 - 20.63	26.99 - 17.25	NA - NA	NA - NA
CNMD	§ CONMED CORP		DEC	0.03	1.06	0.42	1.55	1.46	5.11	3.59	3.26	1.57	0.83	29.73 - 20.51	27.05 - 16.75	24.43 - 11.56	34.98 - 20.09	32.02 - 22.37
COV	[] COVIDIEN PLC		SEP	3.82	3.13	1.79	2.89	(0.68)	(1.31)	(3.33)	0.79	1.41	(0.98)	57.65 - 41.35	52.48 - 35.12	49.13 - 27.27	57.00 - 32.27	49.70 - 36.90
CRY	§ CRYOLIFE INC		DEC	0.26	0.14	0.31	1.18	0.26	3.49	3.77	3.63	3.29	2.01	6.17 - 4.00	7.45 - 4.80	9.79 - 3.93	16.64 - 6.65	15.20 - 6.20
CYBX	§ CYBERONICS INC	#	APR	1.30	1.67	2.83	1.00	(0.39)	6.49	6.02	3.93	0.89	(0.57)	35.88 - 23.58	34.43 - 16.55	21.36 - 12.31	28.95 - 9.59	23.02 - 11.51
EW	[] EDWARDS LIFESCIENCES CORP		DEC	2.07	1.92	2.04	1.15	0.99	8.07	8.05	6.65	4.17	3.20	91.82 - 61.59	85.47 - 42.31	44.13 - 26.43	33.49 - 20.84	26.48 - 22.77
GPRO	† GEN-PROBE INC		DEC	1.06	2.20	1.82	1.99	1.63	8.59	10.13	9.74	13.87	12.22	86.96 - 53.92	59.75 - 42.00	49.29 - 35.69	64.68 - 30.01	71.84 - 46.22
GB	§ GREATBATCH INC		DEC	1.42	1.44	(0.39)	0.82	0.68	0.35	1.03	(1.15)	(3.39)	(1.32)	29.06 - 18.55	25.11 - 18.99	27.45 - 17.27	27.08 - 15.49	34.96 - 18.52
HRC	† HILL-ROM HOLDINGS INC		SEP	2.11	1.99	(6.47)	1.07	3.08	8.57	7.80	6.29	8.49	11.19	48.80 - 26.90	43.80 - 23.11	24.27 - 8.57	56.41 - 15.16	69.45 - 51.25
HOLX	† HOLOGIC INC		SEP	0.60	(0.24)	(8.48)	(1.57)	0.88	(5.51)	(5.90)	(7.84)	(9.52)	2.03	23.24 - 13.90	19.72 - 13.22	17.83 - 9.31	36.44 - 10.54	35.78 - 22.94
IDXX	† IDEXX LABS INC		DEC	2.85	2.45	2.08	1.94	1.53	5.40	6.45	5.19	3.90	3.31	87.29 - 63.83	72.40 - 49.03	55.69 - 27.68	63.58 - 24.11	64.68 - 38.85
IART	§ INTEGRA LIFESCIENCES HLDGS		DEC	0.97	2.21	1.75	1.26	1.21	(1.40)	1.51	(0.98)	(3.14)	(5.51)	52.90 - 28.07	49.85 - 33.63	37.41 - 18.97	49.89 - 26.03	52.85 - 39.44
ISRG	[] INTUITIVE SURGICAL INC		DEC	12.63	9.74	6.07	5.26	3.82	62.54	47.67	35.59	28.07	19.61	469.25 - 261.80	393.92 - 246.05	309.09 - 84.86	357.98 - 110.35	359.59 - 86.20
IVC	§ INVACARE CORP		DEC	(0.13)	0.78	1.29	1.21	0.04	1.46	2.30	1.85	(2.46)	(2.93)	34.52 - 14.54	30.92 - 19.58	26.27 - 14.23	26.58 - 13.30	27.75 - 17.24
KNSY	§ KENSEY NASH CORP		JUN	0.24	1.83	1.74	0.40	0.31	7.46	10.43	10.43	9.14	8.96	29.39 - 18.17	30.50 - 19.70	29.73 - 15.11	38.15 - 16.31	33.00 - 22.26
MASI	† MASIMO CORP		DEC	1.07	1.25	0.92	0.57	0.80	4.55	3.64	4.81	3.69	2.63	35.15 - 17.62	32.79 - 21.05	31.32 - 21.00	42.00 - 21.70	41.99 - 18.70
MDT	[] MEDTRONIC INC	#	APR	3.24	2.87	2.80	1.94	1.97	4.37	3.41	3.35	1.95	1.62	43.33 - 30.18	46.66 - 30.80	44.94 - 24.06	56.97 - 28.33	57.99 - 44.87
BABY	§ NATUS MEDICAL INC		DEC	(0.41)	0.42	0.40	0.69	0.45	3.63	3.35	2.85	3.86	0.30	17.50 - 7.43	18.09 - 11.68	17.51 - 6.46	26.00 - 8.95	19.68 - 13.87
NUVA	§ NUVASIVE INC		DEC	(1.73)	1.99	0.16	(0.77)	(0.32)	5.34	5.67	2.32	3.59	4.87	34.91 - 11.02	46.83 - 22.11	45.06 - 24.17	58.88 - 29.27	44.96 - 21.59
PMTI	§ PALOMAR MED TECHNOLOGIES INC		DEC	0.40	(0.47)	(0.58)	0.00	1.12	7.90	7.36	7.75	8.13	7.89	16.57 - 7.00	15.08 - 8.56	18.94 - 5.83	16.04 - 7.43	55.02 - 15.25
RMD	† RESMED INC		JUN	1.49	1.26	0.97	0.71	0.43	9.54	NM	5.76	5.27	4.37	35.36 - 23.37	35.90 - 25.03	26.69 - 15.74	26.21 - 14.45	28.08 - 19.17
STJ	[] ST JUDE MEDICAL INC		DEC	2.55	2.76	2.28	1.12	1.63	2.08	1.30	2.65	2.19	2.25	54.18 - 32.13	42.98 - 34.00	41.96 - 28.86	48.49 - 24.98	48.10 - 34.90
STE	† STERIS CORP	#	MAR	2.33	0.86	2.18	1.88	1.22	8.38	7.93	7.57	7.06	6.21	37.38 - 27.08	38.16 - 25.65	35.42 - 19.20	38.93 - 20.71	31.71 - 24.25
SYK	[] STRYKER CORP		DEC	3.48	3.21	2.79	2.81	2.41	10.94	13.80	12.58	11.28	10.83	65.21 - 43.73	59.72 - 42.74	52.66 - 30.82	74.94 - 35.38	76.89 - 54.89
SRDX	§ SURMODICS INC		SEP	(0.73)	(1.21)	2.15	0.82	0.19	7.23	7.52	7.66	5.93	5.33	15.50 - 8.73	23.31 - 8.28	31.00 - 15.96	55.40 - 18.95	56.75 - 30.10
SMA	§ SYMMETRY MEDICAL INC		DEC	0.08	0.39	0.61	0.68	0.00	(1.43)	2.85	2.40	1.50	1.44	10.29 - 6.91	12.05 - 8.00	11.55 - 3.90	21.99 - 7.14	18.62 - 12.52
TFX	† TELEFLEX INC		DEC	2.98	3.12	3.57	3.38	(1.08)	(8.29)	(14.44)	(21.40)	(31.35)	(31.91)	64.56 - 49.40	66.07 - 47.92	55.30 - 37.21	68.23 - 40.00	87.00 - 56.86
THOR	† THORATEC CORP		DEC	1.23	1.02	0.50	0.41	0.06	5.16	7.48	5.71	4.38	3.29	38.07 - 22.33	47.93 - 24.25	33.43 - 20.22	32.70 - 12.92	21.74 - 16.45
VAR	[] VARIAN MEDICAL SYSTEMS INC		SEP	3.50	3.02	2.67	2.37	1.88	9.07	8.96	8.72	6.43	4.79	72.19 - 48.72	70.97 - 35.50	47.78 - 27.10	65.84 - 33.12	53.22 - 37.30
ZMH	[] ZIMMER HOLDINGS INC		DEC	4.05	2.98	3.34	3.73	3.28	11.70	12.08	9.78	8.96	8.95	69.93 - 47.00	64.77 - 46.27	60.64 - 30.67	80.92 - 34.10	94.38 - 63.00
HEALTH CARE SUPPLIES‡																		
ALGN	§ ALIGN TECHNOLOGY INC		DEC	0.86	0.98	(0.45)	1.20	0.53	3.88	4.91	3.59	3.20	2.19	25.94 - 14.25	21.40 - 13.18	18.85 - 6.10	17.22 - 4.88	29.71 - 13.07
COO	† COOPER COMPANIES INC		OCT	3.74	2.48	2.23	1.46	(0.25)	11.13	6.34	3.73	0.77	0.54	84.20 - 52.60	59.11 - 34.28	38.99 - 16.50	41.66 - 10.17	57.60 - 36.68
XRAY	[] DENTSPLY INTERNATL INC		DEC	1.73	1.85	1.85	1.90	1.71	(8.00)	3.23	2.93	1.39	2.07	40.37 - 28.35	38.15 - 27.76	36.80 - 21.80	47.06 - 22.85	47.84 - 29.44
HAE	§ HAEMONETICS CORP	#	MAR	2.64	3.19	2.29	2.34	2.01	20.59	18.28	15.19	16.32	14.62	70.40 - 54.99	64.83 - 50.50	65.34 - 46.78	67.49 - 48.79	64.29 - 42.64
ICUI	§ ICU MEDICAL INC		DEC	3.23	2.27	1.80	1.72	1.62	22.18	18.89	17.33	16.44	14.76	45.99 - 35.38	39.20 - 30.55	44.06 - 26.18	38.08 - 22.14	45.02 - 31.96
VIVO	§ MERIDIAN BIOSCIENCE INC		SEP	0.66	0.66	0.81	0.75	0.67	2.53	2.47	2.98	2.72	2.35	27.37 - 14.81	24.44 - 16.03	26.41 - 14.79	37.00 - 19.43	34.24 - 16.25
MMSI	§ MERIT MEDICAL SYSTEMS INC		DEC	0.59	0.35	0.64	0.60	0.46	5.70	3.37	4.51	4.96	4.34	19.94 - 11.38	15.88 - 11.02	15.92 - 7.66	17.09 - 9.88	13.20 - 8.71
NEOG	§ NEOGEN CORP	#	MAY	NA	0.99	0.78	0.63	0.56	NA	4.92	3.50	3.44	3.13	47.92 - 25.59	42.47 - 20.51	24.70 - 11.00	21.30 - 12.73	18.62 - 9.21
WST	§ WEST PHARMACEUTICAL SVSC INC		DEC	2.24	1.96	2.21	2.65	2.18	14.58	13.76	12.40	10.15	9.94	47.96 - 35.50	44.84 - 32.74	41.77 - 27.85	52.00 - 29.52	54.83 - 35.20
OTHER COMPANIES WITH SIGNIFICANT HEALTHCARE PRODUCTS & SUPPLIES OPERATIONS																		
ABT	[] ABBOTT LABORATORIES		DEC	3.03	2.98	3.71	3.06	2.34	(0.80)	(3.68)	2.17	1.51	1.24	56.44 - 45.07	56.79 - 44.59	57.39 - 41.27	61.09 - 45.75	59.50 - 48.75
BMY	[] BRISTOL-MYERS SQUIBB CO		DEC	2.18	1.80	1.63	1.60	1.00	4.29	4.17	3.94	3.16	2.14	35.44 - 24.97	28.00 - 22.24	26.62 - 17.23	27.37 - 16.00	32.35 - 25.73
JNJ	[] JOHNSON & JOHNSON		DEC	3.54	4.85	4.45	4.62	3.67	8.37	8.97	7.04	5.35	5.12	68.05 - 57.50	66.20 - 56.86	65.41 - 46.25	72.76 - 52.06	68.75 - 59.72

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.