



HEALTH CARE INDUSTRY MARKET UPDATE

Medical
Devices
& Supplies

October 10, 2002

Dear Friends of CMS:

As the regulators of over \$500 billion per year of Medicare, Medicaid, and S-CHIP funds, we believe it is incumbent on us to better understand the finances of our contractors, health providers, and other related businesses that provide services to the more than 70 million beneficiaries these programs serve. Health plans, hospitals, nursing homes, home health agencies, durable medical equipment (DME) suppliers, medical device manufacturers, and pharmaceutical companies are just some of those whose finances depend heavily on these public programs.

I have always been surprised at how little Wall Street and Washington interact—and how companies often provide different financial information to each. I am a strong believer in adequate funding for our major partners in these programs, but I do not think they should be saying one thing to investors and another to regulators (as it is occasionally in their interest to do). If health plans or providers need help, we should have a thorough understanding of their real financial status to assess the true level of need.

Many investment banking firms conduct detailed analyses of major health providers, both for the equity investors in for-profit companies, and for the debt holders of for-profit and nonprofit entities. Health systems typically provide these investors with clear financial data. These data can be used by regulators and legislators to assess funding adequacy or the need for regulatory reforms.

CMS' Office of Research, Development & Information (ORDI) has gathered research reports from the major investment firms, summarized their analyses, and condensed them into a short, and hopefully, understandable format. Our goal is to provide objective summary information that can be quickly used by CMS, HHS, Congress, and their staffs that oversee these programs. The primary person at CMS assigned to this task is Lambert van der Walde. Lambert previously worked for Salomon Smith Barney in New York and is experienced with corporate financial analysis and research review. Joining the team is Kristen Choi who previously worked for JPMorgan in New York in healthcare equity research.

This, our fifth report, focuses on the medical device and supply manufacturers. In coming months, we will review the financial and market performance of pharmaceutical companies, DME suppliers, labs, and virtually every other major provider and supplier sector. Though I am proud of this effort, and believe it will add to understanding of the programs, we welcome comments on the content and format of this report. We want to make this as consumer friendly as possible for everyone who reads it. Please provide comments to Lambert van der Walde at lvanderwalde@cms.hhs.gov or Kristen Choi at kchoi@cms.hhs.gov.

Sincerely,

Tom Scully



HEALTH CARE INDUSTRY MARKET UPDATE

Medical
Devices
& Supplies

October 10, 2002

Tom Scully
Administrator

*Office of Research, Development
& Information:*

Lambert van der Walde
lvanderwalde@cms.hhs.gov

Kristen Choi
kchoi@cms.hhs.gov

Tatyana Daniels

Wall Street's View of Medical Device and Supply Manufacturers

Medical device and supply companies continue to show strong financial performance.

- ◆ **Analysts believe that industry revenue and earnings growth will accelerate with major product launches in 2003.**
- ◆ **Investors are concerned with FDA and CMS approval and payment decisions for new technology.**
- ◆ **Large device and supply companies fund their businesses with cash generated from operations and continue to enjoy healthy capital access.**
- ◆ **The industry's small, emerging companies have more difficulty raising capital in the public equity markets and attaining private venture capital financing.**
- ◆ **Large companies are spending more on R&D and acquiring fewer small companies than in previous years.**

CONTENTS

Executive Summary	3
Wall Street's View	4
Industry Overview	8
Industry Performance	13
Revenue Growth	13
Revenue Sources	14
Medicare Coverage	14
Medicare Payment	15
Supplemental New Technology Payments	17
Expense Trends	20
Cost of Goods Sold	20
Research and Development	20
Selling, General, & Administrative	21
Net Income	21
Access to Capital	23
Large Device and Supply Companies	23
Public Equity and Debt Issuance	23
Stock Market Performance	24
Small Device and Supply Companies	27
Venture Capital	27
IPO Environment	28
Merger & Acquisition Activity	29
Summary	30

EXECUTIVE SUMMARY

Revenue growth is expected to accelerate in 2003.

Wall Street analysts generally believe that the fundamentals of the \$74 billion U.S. medical device and supply industry are sound, strong, and stable. In the near-term, analysts base their positive outlook on the strength of several major new product launches in 2003, focusing most on the launch of drug-eluting stents, cardiac resynchronization therapy (CRT) for congestive heart failure, and treatments to fuse the spine, all of which present large, untapped market opportunities. Analysts are notably optimistic about the industry's near-term growth prospects, after observing a deceleration in sales growth in recent years.

The speed of technology adoption often depends on a combination of clinical benefit data, regulatory decisions (including approval, coverage, and payment), and distribution. The medical device industry has benefited from a substantial acceleration in FDA approval timelines since the passage of the 1997 FDA Modernization Act. Medicare coverage and provider payment decisions are considered critical to technology adoption, resulting in substantial investor scrutiny over these regulatory decisions.

Profit margins have been improving over the past four years.

Many small, emerging medical device companies incur losses while developing their first product, while the major medical supply manufacturers have highly diversified product portfolios (often including a mix of devices, pharmaceuticals, hospital supplies, and consumer goods) and generate steady profits. Among the largest profitable companies, the average annual revenue growth for the past decade was about 23% for medical devices and 7% for medical supply companies. Gross margins have appeared relatively steady for the industry, around 69% for medical device companies and 54% for medical supply companies in 2001. Within the large medical device manufacturer universe, the average company's research and development costs have been rising (9% of sales in 2001), a trend which analysts often interpret as a sign of healthy, sustained commitment to a company's long-term success. For the last four years, the median net income (or profit) margin has improved for the sector and is currently about 18% and 14% for the major device and supply companies, respectively.¹

Data indicate that, through 2001, large medical device and medical supply companies have successfully raised capital in the debt and equity markets. The sector's performance in the stock market, which implies investor confidence in overall growth prospects, shows device manufacturers slightly outperformed supply companies over the past decade. This trend has reversed over the past two years with the markets generally rewarding lower-risk businesses such as the supply business.

Access to capital has diminished for small medical device companies.

Small medical device companies, however, have experienced diminishing access to capital in recent years. In addition to recent poor performance in the stock markets, small device companies are much less likely to be publicly traded, so they often rely on private equity investing their sole source of capital. Private equity investment for the medical device sectors declined over 30% in 2001.

¹ As of the quarter ending June 30, 2002.

WALL STREET'S VIEW

Wall Street analysts generally believe that the fundamentals of the medical device and supply industry are sound, strong, and stable. Most analysts' projections predict an acceleration in industry revenue growth, and even faster earnings growth, in the near-term. Daniel Lemaitre of Merrill Lynch notes, "[O]ver the last decade, the industry has been able to parlay 10% top line [revenue] growth into 15% earnings expansion..." due to selling more higher-margin products as a percent of total revenues, in addition to productivity benefits. Lemaitre predicts, "Earnings growth could accelerate to the high teens in 2002-2003."

Analysts based their positive near-term outlook on the strength of several major new product launches in 2003. Wall Street continues to be excited over growth opportunities from several major new product cycles in 2003, including drug-eluting stents, cardiac resynchronization therapy (CRT) for congestive heart failure,² and treatments to fuse the spine, all of which present large, untapped market opportunities. These new opportunities, writes Lemaitre, "could add \$2-3 billion to sales growth in each of the next two years." This new product cycle comes after the slowing of growth rates in the late 1990s, particularly as the stent market began to mature. "[S]trong earnings growth propelled by new market opportunities should drive share price appreciation," advises Lawrence Keusch of Goldman Sachs. "Stock picking remains critical, and we would focus on [companies with] solid long-term earnings growth owing to new product development, high-quality management, and visible catalysts."

Analysts anticipate several major device launches in 2003.

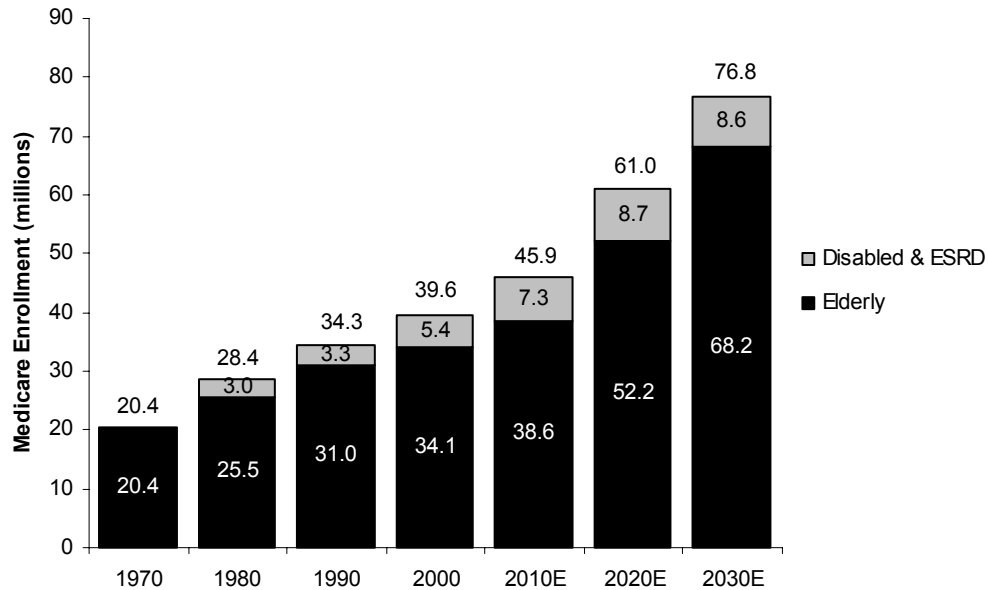
Medical device manufacturers already have the infrastructure in place to develop, manufacture, and market these new products without major additional costs. The key increasing profits is containing costs needed to support new product launches. Credit Suisse First Boston's Glenn Novarro finds that the industry is successfully containing costs while expanding revenue: "In general, most of the manufacturing infrastructure is in place to produce the new products that will be key to future growth... [because] capital expenditure and working capital needs are relatively modest."

Existing infrastructure will support these new launches.

The aging baby boom generation continues to contribute to the growing need for medical devices. As the baby boomers continue to age, the total number of Medicare beneficiaries is expected to double by 2030, as seen in Figure 1, thus expanding the market for medical devices. For example, about 61% of implantable cardioverter defibrillators (ICDs) are used in Medicare patients. Furthermore, while only about 16% of cochlear implants currently are used in Medicare patients, 54% of the target market (*i.e.*, those who are severely to profoundly deaf) are of Medicare age. Keusch notes, "As the use of medical devices such as pacemakers, defibrillators, stents and orthopedic implants increases in frequency in older patients, we believe that medical device companies are well positioned to benefit from these demographics over the long term."

² Description of major cardiology devices can be found on page 7.

Figure 1: Number of Medicare Beneficiaries Expected to Double by 2030



The number of Medicare beneficiaries is expected to nearly double from 40 million today to 77 million in 2030.

Source: CMS, Office of the Actuary.

Notes: Some totals may not sum due to rounding. ESRD refers to patients who are beneficiaries of the Medicare end-stage renal disease benefit.

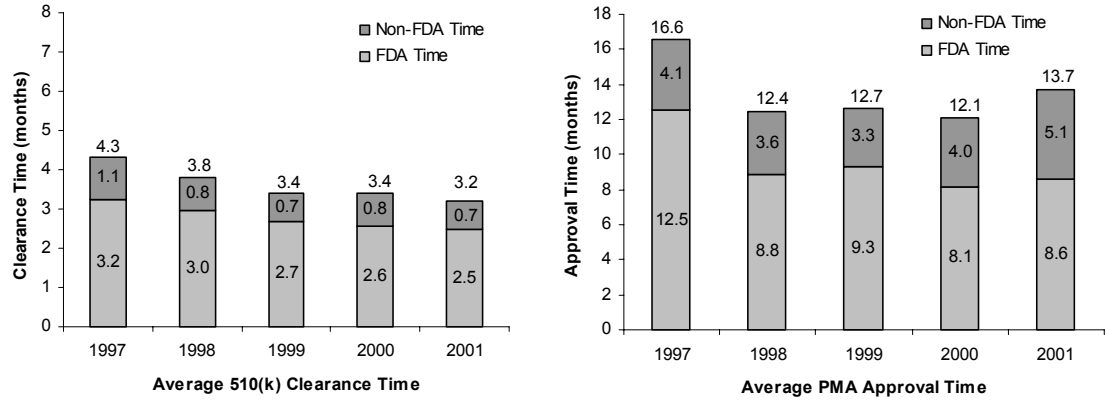
Wall Street observes that FDA approval timelines for new devices have improved.

Medical device analysts have noted that, in contrast to their pharmaceutical analyst counterparts, device stocks have been unaffected by any perception of a “slow-down” in Food and Drug Administration (FDA) approval timelines for new products. Lemaitre of Merrill Lynch says, “Fortunately, FDA review times continue to shorten and the regulatory review process has become more predictable.” Lemaitre believes that some investor concerns regarding FDA timelines have recently affected the hospital supply companies who derive a large part of sales from pharmaceuticals. Glenn Reicin of Morgan Stanley observes, “The FDA has been a bit more hospitable to medical device companies than to pharmaceutical companies.... [T]his, we believe, explains why hospital supply and medical technology companies trade at a slight premium to the pharmaceutical industry.”

A new medical device generally enters the marketplace after FDA approves a pre-market approval (PMA) application or clears a 510(k) premarket notification submission. (See page 12 for further discussion and explanation of FDA clearance and approval processes.) As Figure 2 illustrates, the actual 510(k) clearance timeline has been steadily declining over the past five years from 4.3 months to 3.2 months. In addition, despite a modest increase in PMA approval times in 2001 from 2000, the average over the past four years has been relatively stable around 12 to 13 months, a drastic improvement from average timelines of over 16 months in the mid-1990s before the implementation of the 1997 FDA Modernization Act (FDAMA).

Figure 2: FDA Has Shown Improving Trends in Approval Times for Medical Devices

FDA device approval timelines have shortened since 1997.



Source: Food and Drug Administration, Center for Devices and Radiological Health, Annual Report, Fiscal Year 2001.
 Note: "Non-FDA time" is approval time during which the applicant is responding to FDA inquiries.

The application process can also be somewhat faster and easier for medical device product line extensions, than for new breakthrough devices or pharmaceuticals, as they are incremental modifications to previously approved devices. Goldman Sachs' Keusch hypothesizes:

[E]stablished medical device firms have generally been more focused on line extensions and new iterations of existing products that only require PMA supplements for approval, which have generally come in line with or even earlier than expectations.

Medicare coverage and payment decisions affect investor expectations.

Investors consider Medicare payment important for the adoption of new medical technologies. Kris Jenner, portfolio manager at T. Rowe Price's Health Sciences Fund, comments that public equity investors are concerned about the lag time between a new device's commercial launch and obtaining Medicare coverage. In addition, he is concerned about the unpredictability of payment decisions for emerging therapies.

For example, Paul Heldman and Eric Weissenstein of the Schwab Washington Research Group note the relationship between Medicare payment and the uptake of drug-eluting stents: "Failure to win a higher Medicare reimbursement for drug-eluting stents could slow the growth of product sales once it hits the market..." (Note: in an attempt to be much more responsive to these concerns, CMS has created new codes for drug-eluting stents in the inpatient prospective payment system effective April 1, 2003 and conditional upon FDA approval.)

Cardiology Market: All Eyes Fixed on Drug-Eluting Stents

Medical technology investors have focused much interest and scrutiny on cardiology devices, which account for about \$13 billion in sales. Cardiovascular disease is the leading cause of death both domestically and worldwide, accounting for approximately 17 million deaths per year. Although cardiovascular disease is most commonly treated with medications, medical devices have become increasingly important for treating coronary artery disease and cardiac arrhythmias. Wall Street currently estimates that approximately 75% of the revenues in the cardiology device market come from pacemakers, implantable defibrillators, coronary stents, devices for angioplasty/angiography, and heart valves. The table below shows the five largest markets for cardiology devices.

Figure 3: Cardiology Device Market

(Dollars in millions)

Device	2001 Sales	Annual Growth	% of Total Market	Description
Pacemakers	\$2,939	5%	23%	Low-powered implantable devices to treat hearts that beat too slowly.
Coronary Stents	2,362	5%	18%	Metal scaffolds deployed in an artery following an angioplasty to prevent abrupt closure and reduce restenosis (recurrent narrowing).
Implantable Cardioverter Defibrillators (ICDs)	1,832	10%	14%	Implantable devices used to treat potentially fatal abnormal rhythms of the heart. These devices deliver pacing therapy and high-energy electrical charges to the heart to restore normal rhythm.
Angioplasty Products	1,627	-2%	13%	Used to clear clogged arteries during an angioplasty.
Heart Valves	812	2%	6%	Products (mechanical and tissue) to replace or repair failed heart valves.

Source: Merrill Lynch.

Within the cardiology device sector, stent market dynamics have been widely followed by analysts due to rapid adoption during the 1990s. A maturing market, however, has led to a deceleration in growth in recent years. Coronary stents are small mesh-like metal tubes used to prop open a diseased coronary artery following angioplasty, a procedure during which a catheter with a small balloon on the end is inserted into a blocked artery. After inflating the balloon to clear the blockage, the balloon catheter is removed, and a stent can be inserted to act as a scaffold to keep the artery open.

Throughout the late 1990s, new and improved stent introductions spurred rapid market growth. However, in recent years, technology improvements have been marginal and market growth has slowed. This was a key reason why overall cardiology market growth slowed to 8% in 2001, according to Daniel Lemaitre of Merrill Lynch. By dollar share, the major players are Guidant (38% share), Medtronic (25%), Johnson & Johnson's Cordis division (24%), and Boston Scientific (12%).

Despite the slow-down in market growth for the traditional bare-metal stent, Wall Street analysts have predicted rejuvenation and revolution of the market with the projected introduction of drug-eluting stents in 2003. Drug-eluting stents are stents coated with drugs that stifle the cell growth that leads to restenosis, or the recurrent re-narrowing of the vessel, a major complication of stent placement. If drug-eluting stents live up to their promise, adoption could be rapid, a cost-efficiency argument could drive premium pricing, and the overall market could be expanded. Glenn Novarro of Credit Suisse First Boston believes, "With the interventional cardiology community impatient for a device to reduce restenosis from the global average of 20% to less than 10%, the market will rapidly gravitate to the technology that provides such an outcome." Merrill Lynch's Lemaitre says, "Drug-eluting stents have the potential to lift the \$2B coronary stent market to \$4-5B in a few years due to a dramatic reduction in the need for re-intervention." According to Bank of America's Kurt Kruger, "Drug-eluting stents will likely carry a price tag that is 3x that of bare stents. They should also increase the addressable market size as the lower restenosis rates encourage cardiologists to treat smaller vessels and lesions that they previously would have referred to surgery."

INDUSTRY OVERVIEW

The U.S. medical device and supply manufacturing industry generated \$74 billion in sales in 2001.³ Medical devices and supplies are used in life-saving and life-enhancing medical procedures and include pacemakers, coronary stents, hip implants, catheters, wound dressings, surgical instruments, gauze, and implantable defibrillators.⁴ Wall Street analysts and investors typically split the industry into two major sectors: medical device companies, which manufacture devices such as pacemakers or stents, and medical supply companies, which manufacture hospital supplies such as syringes or wound dressings. The industry continually evolves as technology improves to serve broader patient populations, reduce complications, and improve medical outcomes.

Device makers are a “higher-risk, higher-reward” investment compared to supply companies.

Investors generally believe that medical device companies enjoy higher revenue and earnings growth compared to their supply counterparts. For example, implantable devices that are sold to medical specialists such as interventional cardiologists and orthopedic surgeons are more profitable than commodity products such as tongue depressors or gauze manufactured by medical supply companies. As such, device manufacturers can derive greater value in the market, although also assume more risk in product development, than the supply companies.

Supply companies’ stable financial performance can be attractive in volatile markets.

The supply business tends to have a more stable and predictable financial performance, which can be particularly attractive in volatile markets. The distinction, however, becomes less defined with major medical supply companies, like Johnson & Johnson and Abbott, that also derive a large portion of revenues from medical devices, pharmaceuticals, and consumer goods in addition to medical supplies. Figure 4 below shows the largest companies that comprise the medical device and supply industry.

Figure 4: Largest Medical Device and Supply Companies

(Dollars in Millions)	Ticker	Market Cap	Ticker	Market Cap	
Medical Device Companies			Medical Supply Companies		
<i>Cardiology</i>					
Medtronic Inc.	MDT	\$ 50,478	Johnson & Johnson	JNJ	\$ 163,941
Boston Scientific Corp.	BSX	12,809	Abbott Laboratories	ABT	63,037
Guidant Corp.	GDT	10,116	Baxter International Inc.	BAX	18,943
St. Jude Medical Inc.	STJ	6,488	Becton Dickinson & Co.	BDX	7,350
Edwards Lifesciences Corp.	EW	1,508	C.R. Bard Inc.	BCR	2,800
<i>Orthopedics</i>					
Stryker Corp.	SYK	\$ 11,131			
Zimmer Holdings Inc.	ZMH	7,564			
Biomet Inc.	BMET	7,109			
Smith & Nephew PLC	SNN	5,574			

Source: Bloomberg and company reports as of September 27, 2002.

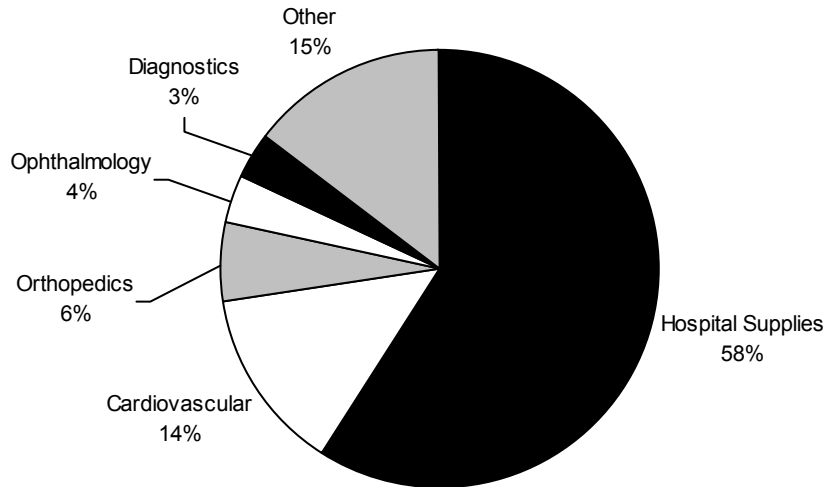
Note: Market capitalization is a measure of a company’s value or size, calculated by multiplying share price by the number of shares outstanding. Wall Street medical technology analysts typically categorize Johnson & Johnson and Abbott as medical supply companies despite their diversified revenue bases, particularly in pharmaceuticals.

³ Source: U.S. Department of Commerce, U.S. International Trade Commission, Bureau of Labor Statistics.

⁴ Durable medical equipment (DME) such as wheelchairs and walkers are not covered in this report and will be analyzed as a separate industry in the future.

The U.S. medical device and supply industry can be divided into six major sectors. The Merrill Lynch Medical Technology Composite Index, which consists of 117 companies, serves as a good proxy for the medical device and supply industry. Industry sector division is illustrated in Figure 5 below.

Figure 5: Top Six Sectors of the Medical Device and Supply Industry by Sales, 2001



Source: Merrill Lynch Medical Technology Index.
 Note: Composite index of 117 companies in the medical technology sector.

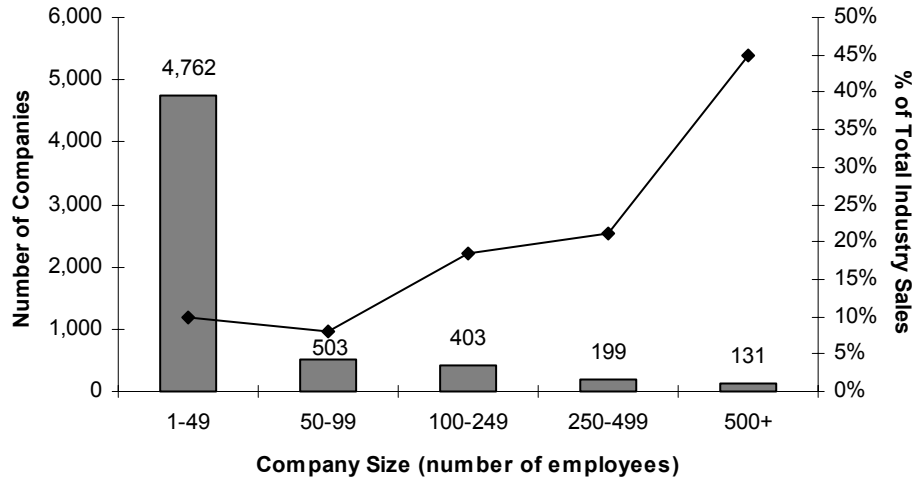
Medical supply companies, represented by Johnson & Johnson, Abbott Laboratories, Baxter International, Becton Dickinson, and C.R. Bard, account for about 58% of the industry's sales. The cardiovascular device companies, who manufacture items such as stents, pacemakers, and defibrillators, follow at a distant second place with approximately 14% of the revenues of the industry. The major cardiology device manufacturers, including Medtronic, Guidant, Boston Scientific, St. Jude Medical, and Edwards Lifesciences, comprise the majority of this sub-sector's revenue. Orthopedics, including hip and knee replacements and orthobiologics that stimulate bone growth, have 6% of the total industry revenues. The remainder includes ophthalmology devices, instruments, diagnostic equipment, blood products, respiratory/patient monitoring equipment, imaging devices, lasers, surgical instruments, urology products, and other implantable devices.

The largest 2% of the 6,000 U.S. medical device firms log nearly half of the industry's sales. Distribution of the 6,000 U.S.-based medical device companies shows a high concentration of revenues in the largest companies. Company sizes vary greatly, ranging from small companies consisting of a single inventor to Johnson & Johnson's staff of over 100,000 employees. The Lewin Group estimates that 80% of these medical device companies are small and emerging firms. Figure 6 depicts the distribution of companies and sales by size.

The largest 2% of medical device companies book 45% of industry sales.

Figure 6: Distribution of Companies and Sales by Size

80% of medical device companies have less than 50 employees.



Source: U.S. Department of Commerce as reference in Lewin Group report.

Although the largest companies dominate revenue share, the small companies have historically made a critical contribution to medical device innovation. Small and emerging companies have been responsible for the innovation and early development of many novel devices. Often these small companies collaborate or combine with larger companies to bring their products to market. The advantages of larger companies compared to smaller companies include steady funding, greater manufacturing capabilities, and marketing distribution channels. In addition, larger companies may have more experience and capacity to conduct clinical trials to surmount regulatory and payment hurdles. Morgan Stanley’s Reicin describes this relationship: “Smaller companies in the sector are likely to play important roles in feeding the larger companies with smaller-scale innovative technologies. In turn, these companies will rely on larger companies as distribution partners and investors.” Some smaller companies also try to self-market new devices, but must tackle barriers to entry including funding of research and development, manufacturing, and distribution.

Smaller firms often combine or collaborate with larger firms.

Clinical benefit, technological advancement, and first-mover advantages are key drivers for product development. A new medical device can generate demand and command a premium price if it is believed to reduce medical complications and lead to better medical outcomes. Clinical data and technology open up new markets and have the ability to significantly change a company’s market share in this highly competitive industry. According to Robert Faulkner of Prudential Securities, “Clinical value, or the extent to which a product meets an unmet clinical need, drives market demand and allows value pricing and high profit margins.” Reicin predicts that industry “winners” are:

Devices that reduce complications and improve outcomes drive demand.

... the well-capitalized companies that have made early inroads into large disease states.... Unlike the pharmaceutical industry, first-mover advantage counts in the medical technology arena. In looking at the great inventions of the 20th century, first-mover advantage appears to be critical. In most cases, companies that were the leaders at the time of commercialization maintained their lead for five and ten years.... We expect this pattern to continue as distribution plays an important role, helping investors identify the winners in the new millennium.

The industry continually is developing smaller, faster, and cheaper devices.

Relatively short product life cycles for medical devices amplify the need for strong management skill and execution strategy. Because medical device product life cycles are short, a medical device company's management team and execution strategy are crucial to a new product's success. Product life cycles are relatively short because medical device manufacturers and their competitors continually can develop smaller, faster, and cheaper improvements of existing devices. In addition, patent protection of a new technology can often be challenged or circumvented, with no analogous patent to a pharmaceutical company's "composition of matter" patent on the molecule itself.

Regulatory hurdles provide high barriers to entry and drive competition within the industry. The private sector funds the majority of research and development costs, and relies on strong intellectual property rights to protect this investment in research. Any new device requires clinical studies to show the device is safe and effective, which are then submitted to FDA for review. If the device obtains FDA approval, the company typically seeks Medicare coverage and payment from CMS. The manufacturer may seek favorable distribution terms with a group purchasing organization (GPO) contract, which offers products to member hospitals in volume for lower prices. The speed of technology adoption often depends on a combination of clinical benefit data, regulatory decisions (including approval, coverage, and payment), and distribution. We summarize FDA approval process for medical devices on page 12, and review Medicare coverage and payment policies on pages 14-19.

FDA Clearance and Approval of New Medical Devices

Medical devices are regulated and approved by the Food and Drug Administration's Center for Devices and Radiological Health (CDRH). As discussed on pages 5-6, approval timelines have dramatically shortened since the implementation of the 1997 FDA Modernization Act (FDAMA) passed by Congress.

Medical devices are classified into three categories: Class I devices represent minimal potential for harm, and are subject to the least regulatory control (*e.g.*, elastic bandages and enema kits). Class II devices are moderate risk (*e.g.*, some surgical lasers). Class III devices are devices that sustain or support life, are implanted, or present potential unreasonable risk (*e.g.*, implantable infusion pumps and heart valve replacements) and are subject to premarket approval, the most stringent regulatory control.

Medical devices generally enter the marketplace after FDA either approves a premarket approval application (PMA) for the device or clears a 510(k) premarket notification submission.

510(k) Premarket Notification

Manufacturers of Class I and II devices, as well as some older Class III devices, seek marketing clearance through a 510(k) premarket notification process. However, 95% of Class I devices and 27% of class II devices fall into approximately 700 categories of exempt devices (*e.g.*, oxygen masks, pacemaker chargers, dental floss). For the devices that are required to clear the 510(k) process, a manufacturer must demonstrate that its device is substantially equivalent to another legally marketed device for which premarket approval is not required. Premarket notification submissions under the 510(k) process generally do not require clinical studies, although FDA might require such studies if determined to be necessary to demonstrate substantial equivalence. More than 90% of FDA's clearance of medical devices is accomplished through the 510(k) process.

Premarket Approval (PMA)

FDA requires most Class III device manufacturers to submit PMA applications instead of a 510(k) submission. PMAs are subject to a scientific review by CDRH and must establish a reasonable assurance of safety and efficacy, usually in clinical trials. Analogous to a new drug application (NDA) for a pharmaceutical, a PMA is, in effect, a private license granted to the applicant for marketing of a particular device. An alternative process, known as a product development protocol (PDP), exists but is rarely used.

Before conducting any clinical studies for a "significant risk" device, CDRH must approve an Investigational Device Exemption (IDE) application. An IDE is required to satisfy concerns that human subjects are protected, patient benefits outweigh the risks, and the study is properly designed to determine safety and efficacy of the device. There are two types of IDEs: "A" for new devices and "B" for incremental improvements on or new indications for already approved devices. Medicare contractors can pay for devices with an IDE category B designation, but not for category A.

As part of the implementation of FDAMA, CDRH created an abbreviated 510(k) application process for certain devices, as well as modular review of PMAs, which allowed approval of applications in sections so that the manufacturer and agency could be in active dialogue throughout the review process. Review times for PMAs that had modular submissions were slightly lower than for traditional PMAs.

INDUSTRY PERFORMANCE

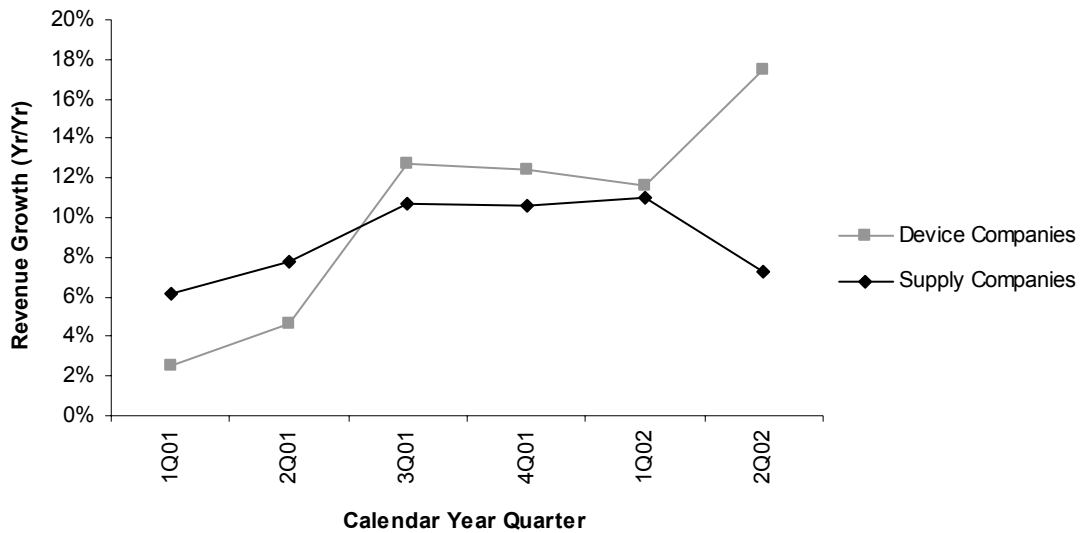
Profitability within the device industry varies. Many small, emerging medical device companies incur losses while developing their first product, while the major medical device manufacturers have highly diversified product portfolios and generate steady profits. This analysis focuses on the financial performance of the largest medical device and supply companies that are most widely followed by Wall Street analysts.

Revenue Growth Predicted to Accelerate

Over the last decade, the average annual revenue growth of the medical device and supply industry was about 15%, or 23% for medical devices and 7% for medical supply companies. Revenue growth for device makers through most of the 1990s accelerated due to new product launches, while supply companies' growth was relatively steady. (Importantly, what this report—and Wall Street—have classified as medical supply companies often have large, diversified revenue bases that include supplies, devices, pharmaceuticals, and consumer goods.) Device maker revenue growth began to slow, dropping from 20% average annual growth in 1999 to 5% in 2000, due to slowed growth of key market segments including bare-metal stents and ICDs. As noted earlier on page 4, most analysts now predict an upswing in revenue acceleration due to the launch of several major new product cycles in 2003, including drug-eluting stents and cardiac resynchronization therapy (CRT) for congestive heart failure. Some growth acceleration has already been apparent in recent quarters, as seen in Figure 7.

For device makers, average annual revenue growth dropped from 20% in 1999 to 5% in 2000, but...

Figure 7: Median Revenue Growth Rate Quarterly Trends, 2001 to present



...re-acceleration has already begun.

Source: Bloomberg.

Note: Medical supply companies include Abbott Laboratories, Baxter International, Becton Dickinson, C.R. Bard, and Johnson & Johnson. Medical device companies include Biomet, Boston Scientific, Edwards Lifesciences, Guidant, Medtronic, St. Jude Medical, Stryker, and Zimmer.

Revenue Sources

Medical device companies sell products directly to providers (*e.g.*, hospitals and skilled nursing facilities), while third-party payors (*e.g.*, private insurance, Medicare, and Medicaid) typically pay providers a bundled rate. This bundled rate covers the various costs of the procedure, including the devices and supplies used. The Medicare coverage and payment process for prospective payment systems is explained below.

Medicare Coverage of Medical Devices

In order for Medicare to pay for a provider's use of a device, it must be covered. To obtain Medicare coverage, a medical device must first fit into a benefit category that is defined by federal statute. For example, preventive services and tests generally are not covered under Medicare, unless specifically provided for by Congressional action. (For example, Medicare currently covers mammography, prostate cancer screening, and influenza vaccinations.) The second criterion is that the item or service must be reasonable and necessary to treat the patient's medical condition.

The majority of coverage decisions are made at the local level by Medicare contractors: fiscal intermediaries who process claims from facilities and carriers who process claims from physicians and labs. To allow for regional differences in medical practice, Medicare allows contractors some flexibility in making coverage decisions. Most new devices are paid without specific review by contractors. Coverage for a specific medical device or for a procedure involving a specific medical device may be determined on a case-by-case basis if the new device or procedure is brought to the contractor's attention or if the contractor becomes aware of the new device or procedure when reviewing trends in previously paid claims. If there is an unusually high volume of high-cost claims or denials for a specific device, the contractor may issue a local medical review policy (LMRP). During the LMRP development process, a contractor gathers and examines the clinical evidence and determines whether the item or service 1) has a benefit category, 2) is not statutorily excluded, and 3) is reasonable and necessary. The contractor usually posts the draft LMRP for 45 days of public comment, reviews these comments and any new data, and finally, posts the final LMRP. During the development of most LMRPs, carriers are required to consult with the Carrier Advisory Committee (CAC), a panel of local physicians. Fiscal intermediaries generally develop their LMRPs with input from medical providers and organizations. In addition, all contractors ask for public comment and hold open meetings to discuss their draft LMRPs. Effective October 1, 2002, each contractor must develop an LMRP Reconsideration process to allow beneficiaries and providers to submit suggested revisions to LMRPs along with clinical evidence that supports the change.

A National Coverage Determination (NCD), which supercedes local policies, is triggered by either the request of an outside party (typically the manufacturer) or by decision of CMS. In the absence of an external request, CMS generally initiates an NCD when the item or service raises significant scientific issues, could have a substantial impact on the Medicare population, or has major variation in local policies. CMS conducts a complete evidence-based review to determine if the item or service is clinically effective and therefore, reasonable and necessary. At the beginning of each NCD, CMS posts a tracking sheet and allows for 30 days of comment to be reviewed during the decision process. Each NCD includes a complete technology assessment process, including collection and careful evaluation of all relevant data. For some NCD assessments, CMS requests external

Most Medicare coverage decisions are made at the local level by Medicare contractors.

National Coverage Determinations (NCDs) are triggered by the manufacturer or by CMS when a universal policy is necessary.

assistance and/or the independent review of the Medicare Advisory Committee (MCAC). A Decision Memo is posted to summarize the analysis and inform the public of the intent to implement the policy decision. The NCD process currently allows as many as 270 days between the issuance of an NCD and the deadline by which individual Medicare contractors must reflect the coverage decision in their processing systems.

Medicare Payment of Medical Devices and Supplies

Medicare does not make direct payments to manufacturers for any medical devices or supplies (except for some DME and home health products). Instead, it pays bundled rates to hospitals and other providers for care provided to beneficiaries under its various prospective payment systems (PPSs). Thus, the price that a device manufacturer charges a hospital will likely be different from the payment the provider receives for the total case. Medicare does make direct payment on a fee schedule basis for medical devices and supplies covered under various item-specific Part B benefits such as durable medical equipment (DME). A report focusing on the DME industry will be forthcoming.

Medicare pays bundled rates for procedures—not for the provider’s acquisition cost of a specific device.

Prospective Payment Systems

A PPS encourages providers to operate efficiently by paying the same base amount to all providers for similar cases. The base rate in each PPS is adjusted for several factors. Some factors are common across PPSs (*e.g.*, geographic differences in costs) while others are unique to an individual PPS (*e.g.*, an adjustment for physician medical education in the inpatient PPS). Provider costs vary from case to case. The bundled payment rate is based upon the average resources required to treat a specific category of clinically similar patients relative to the resources required to treat patients in other categories. In some payment systems, the relative cost is compared to the average cost for all patients in that payment system (*e.g.*, inpatient PPS) while in others the relative cost is compared to the average cost for patients in one “benchmark” category (*e.g.*, outpatient PPS). In both cases, it is expected that the gains providers incur for low-cost cases will offset losses for high-cost cases, assuming sufficient patient volume and mix. The resources required to complete treatment may include labor, facilities, malpractice insurance, pharmaceuticals, medical devices, and medical supplies. Expected resource utilization can vary because of the diagnosis, procedure(s) to be performed, or the relative acuity of each patient.

Medicare PPS payments are reweighted annually.

PPS Updates

As noted above, Medicare calculates the payments for each case based on the relative weight of resource utilization for the category in which the case is assigned compared to other cases. These relative weights are multiplied by a dollar amount (known as the standardized amount in the inpatient PPS and the conversion factor in the outpatient PPS) to calculate the actual payment for each case. These amounts are further adjusted for various factors that vary across payment systems.

Medicare PPSs are designed to be flexible over time—each payment classification is reweighted annually based on the most recently available claims information submitted by providers. Medicare analyzes claims information annually to account for changes in resource utilization. Changes in resource utilization may be due to a number of factors, including changes in the relative cost of providing services, changes in medical practice or technological improvements that result in price changes.

New devices that represent incremental or marginal changes to existing technology and whose cost is similar to existing technology are almost always automatically covered by

Medicare contractors as described above. Providers use existing codes to submit claims for these items. In fact, Medicare may not even be aware that providers have begun using a new version of existing technology.

New technologies that are significantly more expensive than existing technology may take more time to get additional costs recognized under Medicare's payment systems. (These new technologies may represent either incremental or substantial innovation.) The delay in any upward adjustment in payment on the front end for more expensive technologies, however, is often later offset by a delay in the reduction to payment on the back end. This occurs as the result of hospital acquisition costs declining over time due to market forces such as competition from other manufactures or provider adoption of even more advanced technologies. It is important to note that Medicare will almost always begin making some sort of payment once the technology is approved.

Figure 8 presents the requirements of the traditional Medicare coverage and payment process for the inclusion of new technology.

Figure 8: Medicare New Technology Coverage and Payment Process Requirements

In order to be covered and paid by Medicare, these five requirements must be met. The process for each may overlap and may vary in order.

-
- FDA approval/clearance:
 - Device must be deemed safe and effective.

 - Medicare benefit category decision:
 - Device must fit into a benefit category defined by federal statute.

 - Coverage:
 - Device must be medically reasonable and necessary for treatment.

 - Coding, the device may be placed into a(n):
 - existing code
 - a temporary "catch-all" code
 - a new code

 - Payment adjustments are made to:
 - Inpatient PPS
 - Outpatient PPS
 - other fee schedule
-

Source: CMS, Center for Medicare Management

While the bundled payment amounts may not always fully reflect new technology cost, new devices and procedures can be reflected in and adjustments made to these bundled payments in as little as twelve months for the inpatient PPS and as little as four months in the outpatient PPS. There have been recent cases in which CMS has accelerated certain new technologies (such as drug-eluting stents) through this process in order to ensure faster beneficiary access to new technology.

Medicare makes special new technology payments based upon manufacturer-supplied prices.

Medicare Supplemental New Technology Payments

Historical claims data typically do not exist for a new device. Medicare instead relies on the manufacturer-supplied price to determine initial payment rate. Under the inpatient and outpatient PPSs, Medicare uses this price to calculate supplemental new technology payments to increase beneficiary access to new, more expensive technologies. The list price is determined before the manufacturer negotiates final prices with providers and volume purchasers such as group purchasing organizations (GPOs).

Over time, Medicare uses actual hospital claims data to adjust payments of bundled rates, ending the use of supplemental payment for the device. This system can cause wide fluctuations in payment rates, especially during the early years of a new device.

New Technology Special Add-on Payment in Inpatient PPS

In BIPA 2000, Congress instructed CMS to create procedures and criteria for new technology payments for inpatient prospective payment system (IPPS). These payments are capped at 1% of total IPPS spending. CMS set three new technology payment criteria for the new technology add-on payment, all of which must be met. The new technology must be:

- 1) new,
- 2) a substantial medical improvement relative to existing technology, and
- 3) of sufficient cost.

New devices can affect other costs of the procedure.

To be eligible to receive any new technology add-on payment, the expected average charge for cases using the new technology must be greater than one standard deviation above the standardized average charge for all other cases in the diagnosis related group (DRG) to which the cases using the new technology would be assigned. CMS compares total charges for cases using new technology to other cases in the same DRG because a new technology can affect other costs of the procedure (*e.g.*, increased use of other supplies, decreased length of stay, etc.). If the new technology meets the three requirements above, for each case using the new technology CMS will pay the sum of: (a) the DRG payment for the DRG into which the case is assigned and (b) half of the difference between the DRG payment and the cost of the particular case using the new technology. If the actual costs of the new technology case exceed the DRG payment by more than the cost of the new technology, Medicare payment would be limited to the DRG payment plus 50% of the new technology.

An example of the new technology special add-on payment in inpatient PPS follows.

Example of Inpatient PPS New Technology Add-on Payment Process:

Manufacturer Application

A manufacturer whose new device may qualify for the new technology add-on payment applies to CMS for such payment status. CMS then reviews the application to determine if the new device meets the three criteria listed above. If the new device meets the criteria, CMS will pay providers the DRG amount (\$2,000 in this example) plus the add-on payment.

In the application, the manufacturer lists:

Device price:	\$1,500
Estimated new average case charge:	\$8,000

CMS provides:

Current average case charge:	\$3,000
Standard deviation:	\$4,000
DRG payment:	\$2,000
Hospital cost-to-charge ratio:	55%

CMS then makes the following calculation:

Current average case charge:	\$3,000
Standard deviation:	+ 4,000
Std. Dev. + Current average case charge:	\$7,000

The estimated new case charge exceeds original case charge plus one standard deviation...

$$\$8,000 > \$7,000$$

...therefore cases using this new technology are eligible for special payment. The estimated total sum of add-on payments are not to exceed 1.0% of the entire expected payments under inpatient PPS.

Medicare Payment

In this case, assume that the actual case charge for an individual patient is \$7,500, which is less than the estimated new average of \$8,000. To calculate cost of this case, CMS reduces the actual charge to a cost amount, using the hospital's cost-to-charge ratio.

Upon the receipt of a claim using the new device, CMS pays the DRG payment plus the add-on payment of half of the difference between the cost of that case and the DRG payment, but is limited to half of the new device price.

Original DRG Payment	+	Half of: The actual case charge reduced by the hospital's cost- to-charge ratio, less the DRG	=
\$2,000	+	$\frac{(\$7,500 \times 0.55) - (\$2,000)}{2}$	= \$2,000 + \$1,063 = \$3,063

Because the new technology add-on payment (\$1,063) exceeds half of the estimated new device price (\$1,500) the add-on is reduced to \$750. This add-on payment is added to the DRG results in a **final payment of \$2,750.**

New Technology Transitional Pass-through Payments in Hospital Outpatient PPS

CMS uses hospital claims data to determine the relative weights and payment rates for ambulatory payment classifications (APCs) in the outpatient prospective payment system (OPPS). Certain new technology items, such as drugs, biologicals, and devices for which costs are not adequately represented in this claims data receive transitional pass-through payments in addition to the payment for the APC with which the new technology is associated. Pass-through payments are based on a hospital's cost⁵ for the device less any amount that is already incorporated into the APC procedure for device-related costs. In order to be considered for a pass-through payment, a device must be considered to have a cost that is "not insignificant" in relation to the APC payment for the procedures or services associated with the device.⁶ Pass-through payments are made for at least two years but not more than three years, after which the hospital claims data for those new devices are folded into the applicable APC payment.

Pass-through payments for new technologies are in addition to APC payments.

By law, total projected pass-through payments for calendar year 2003 are limited to 2.5% of total projected OPPS payments. Because pass-through payments are carved out of total OPPS payments to keep the program budget-neutral, each APC payment is reduced by 2.5%. For 2004 and subsequent years, CMS has the authority to set the pass-through at a percentage of the projected total payments up to 2.0%. If CMS estimates before the beginning of a calendar year that the total pass-through payments will exceed the limit for that year, CMS is required to impose a pro-rata reduction across all transitional pass-through payments to ensure that the limit is not exceeded.

For 2002, CMS incorporated some additional device costs into APCs associated with pass-through devices. This fold-in was an effort to reduce total pass-through spending. However, CMS estimated that total pass-through spending still would exceed the 2.5% limit. Consequently, CMS imposed a pro-rata reduction of 63.6% for all pass-through payments from April 1, 2002 through December 31, 2002.

This outpatient PPS policy has caused payments for many device procedures to vary considerably from year to year. Two examples of this are shown in Figure 9.

Figure 9: Examples of Device-Related APC Payment Fluctuations

Calendar Year	ICD Insertion (APC 107)		Permanent Pacemaker (APC 89)	
	APC Payment	% Increase	APC Payment	% Increase
2001	\$ 7,411	-	\$ 3,940	-
2002	\$ 19,428	162.2 %	\$ 7,640	93.9 %
2003 (Proposed Rule) ⁽¹⁾	\$ 9,440	(51.4)%	\$ 5,665	(25.9)%
Change 2001-2003	\$ 2,029	27.4 %	\$ 1,720	43.7 %

Note: Does not include additional pass-through amount paid which varies from provider to provider.

(1) The 2003 figures may change in the final OPPS rule to be published on November 1, 2002.

Although some 2003 APC payments are expected to decline from 2002, the increase from 2001 to 2003 remains significant.

⁵ A hospital's cost for a device is calculated by adjusting the hospital's reported charge for the device using the hospital's own cost-to-charge ratio.

⁶ To meet the "not insignificant" cost threshold: (a) the average cost of the new device must exceed 25% of the OPPS payment for that APC, (b) the average cost of the new device must exceed the cost of the device-related portion of that APC by at least 25%, and (c) the difference between the average cost of the new device and the cost of the device-related portion of that APC must exceed 10% of the total APC payment.

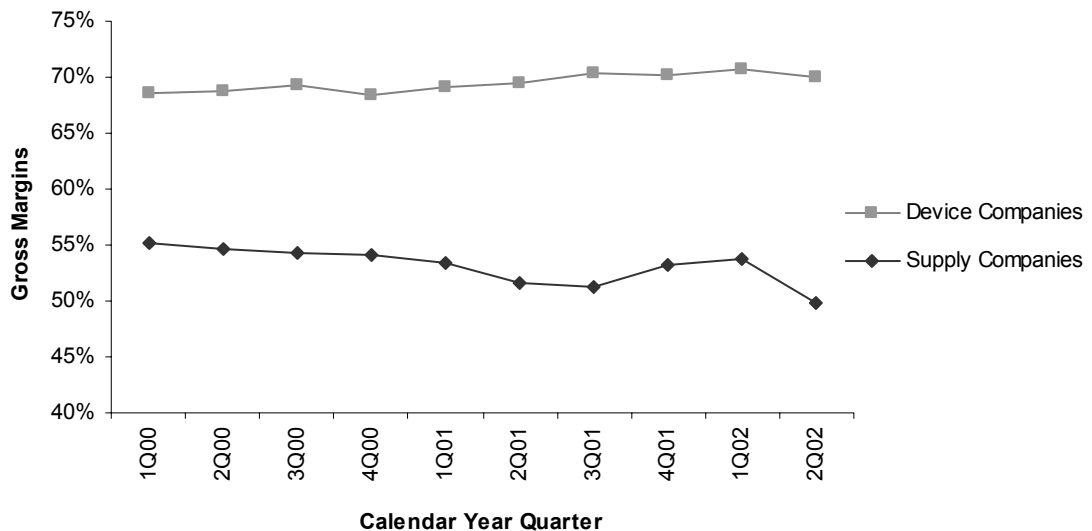
Expense Trends

Costs of Goods Sold

Costs of good sold (COGS) is a manufacturer's cost of buying raw materials and producing finished goods. The gross margin is the percent of total revenues remaining after deducting COGS. According to Lemaitre of Merrill Lynch, the industry has steadily improved gross margins over time due to productivity gains and product mix shifts, successfully offsetting perennial pricing pressure. Over the past two years, gross margins have appeared relatively steady for medical device manufacturers (69% in 2001) and have been declining slightly for supply companies (54% in 2001). This is seen in Figure 10.

Figure 10: Median Gross Margin Quarterly Trends, 2000 to present

Gross margins have been steady for device companies and have declined slightly for supply companies.



Source: Bloomberg.

Note: Medical supply companies include Abbott Laboratories, Baxter International, Becton Dickinson, C.R. Bard, and Johnson & Johnson. Medical device companies include Biomet, Boston Scientific, Edwards Lifesciences, Guidant, Medtronic, St. Jude Medical, Stryker, and Zimmer.

Research and Development

Research and development (R&D) is perhaps the single most important expense of a medical device company. The competitive nature of the industry, characterized by the rapid pace of innovation and short product life cycles, demands a huge commitment to R&D. One useful measure of R&D across companies of different sizes is the amount of R&D spending relative to the amount of the company's total revenues. Within the large medical device manufacturer universe, the average company's research and development costs approximated 9% of sales in 2001 and has been rising, as seen in Figure 11. According to Merrill Lynch, this is lower than the pharmaceutical industry because clinical trials tend to be smaller (usually only a few hundred patients) and therefore less costly. Notably, smaller innovative companies often spend a very large portion of their revenue on R&D.

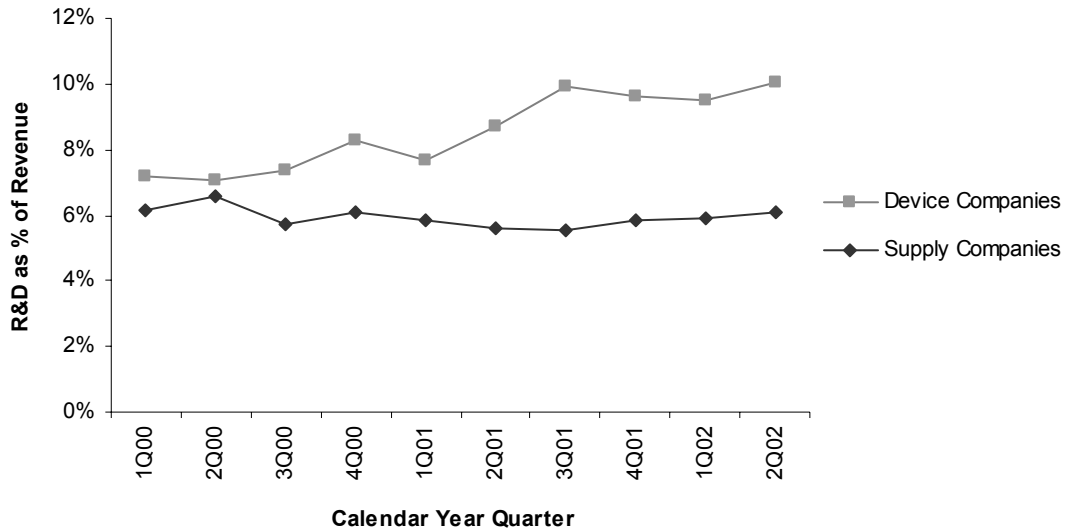
Smaller companies often spend a very large portion of their revenue on R&D.

Analysts also scrutinize R&D spending as a sign of ongoing, sustained commitment to ensure a company's long-term success. Morgan Stanley's Reicin considers R&D spending to be "an important indicator of success." Companies such as Medtronic and Guidant, which are focused on higher technology companies, have a greater R&D expense than companies focused on lower-tech (and thus lower-risk) devices.

Strong R&D spending is considered a key to long-term success.

Figure 11: Median R&D, as a Percent of Revenue, Quarterly Trends, 2000 to present

R&D spending has been rising for device manufacturers.



Source: Bloomberg.

Note: Medical supply companies include Abbott Laboratories, Baxter International, Becton Dickinson, C.R. Bard, and Johnson & Johnson. Medical device companies include Biomet, Boston Scientific, Edwards Lifesciences, Guidant, Medtronic, St. Jude Medical, Stryker, and Zimmer.

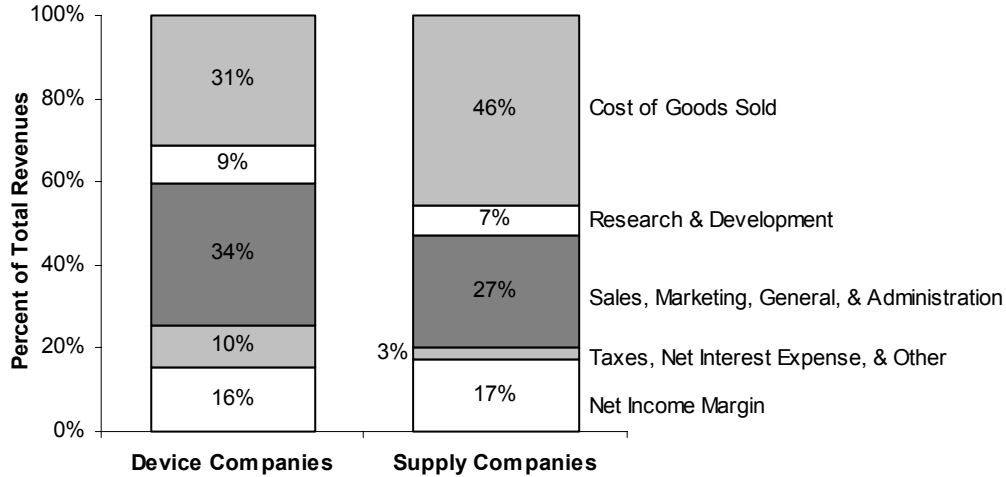
Selling, General, and Administrative

The medical device industry spends an average 34% of revenue on selling, general, and administrative (SG&A) expenses, while the supply industry averages about 27%. This expense item includes the cost of marketing, and thus the specific clinical expertise required to sell new devices over new hospital supplies may account for part of the difference between the two subsectors.

Net Income

To calculate net income (*i.e.*, profit or the “bottom line), COGS, SG&A, R&D, and other expenses (including depreciation, amortization, interest and taxes) are subtracted from total revenue. Net income is the amount that the business can reinvest in itself, and in the case of a for-profit company, may distribute to shareholders. Figure 12 shows a side-by-side comparison of average medical device and supply company spending for each expense, as a percent of total revenue, as well as average net income margins.

Figure 12: Comparison of Expenses: Device vs. Supply Companies, Year Ended 2001



Although device makers have a higher gross margin than supply companies, the two enjoy a similar profit level.

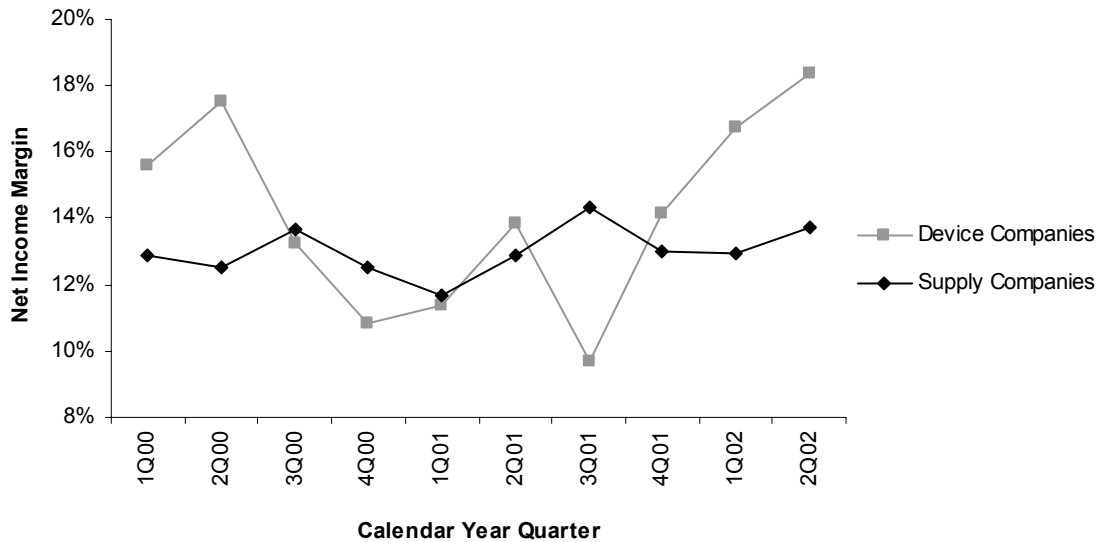
Source: Bloomberg.

Note: Figures are averages. Medical supply companies include Abbott Laboratories, Baxter International, Becton Dickinson, C.R. Bard, and Johnson & Johnson. Medical device companies include Biomet, Boston Scientific, Edwards Lifesciences, Guidant, Medtronic, St. Jude Medical, Stryker, and Zimmer.

Device Company Margins Improve

Although each subsector earned a similar net income margin for the year ended 2001, the median net income margin for the device sector has improved to 18% for the quarter ending June 2002, as shown below in Figure 13.

Figure 13: Median Net Income Margin, Quarterly Trends, 2000 - Present



Net income (or profit) margins have recently improved for the device sector.

Source: Bloomberg.

Note: Medical supply companies include Abbott Laboratories, Baxter International, Becton Dickinson, C.R. Bard, and Johnson & Johnson. Medical device companies include Biomet, Boston Scientific, Edwards Lifesciences, Guidant, Medtronic, St. Jude Medical, Stryker, and Zimmer.

ACCESS TO CAPITAL

Large Medical Device and Supply Companies

Healthy Access to Public Equity and Debt Markets

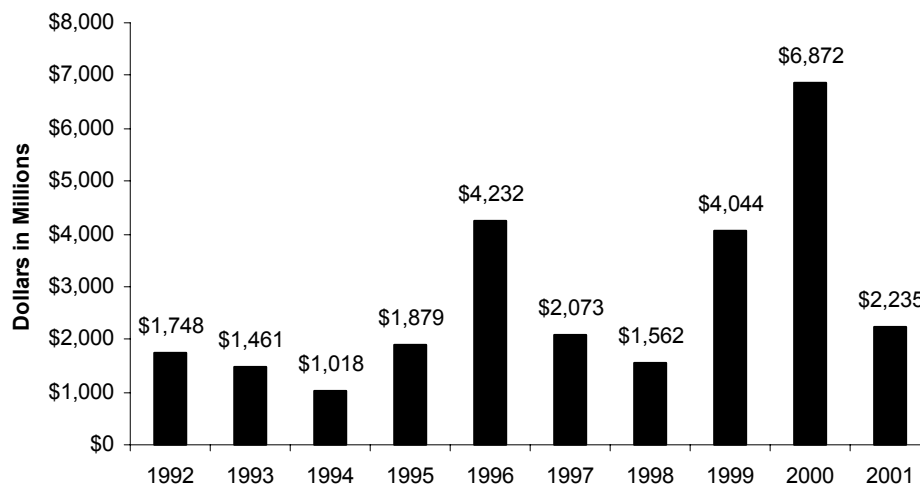
Large device manufacturers typically generate enough cash from operations to fund most of their capital needs.

Capital sources consist of the public equity and debt markets for the publicly traded companies. Large medical device manufacturers are able to generate enough cash from operations to fund a significant amount of their capital needs. The median earnings before interest and taxes (EBIT) for the largest medical device and supply companies was about 20% of revenue in 2001. Because of their ability to generate cash flow, these large companies have less need to tap into the public debt and equity capital markets for capital. These large companies, however, may choose to access the capital markets to fund acquisitions or to refinance existing debt.

An example of this is Johnson & Johnson (J&J), which has a AAA credit rating, the highest rating for a corporation. Because J&J generates approximately \$1 billion in cash flow each quarter from operations, it has less of a need to attain funding from the capital markets.

According to the graph below, U.S. equity issuance for medical device companies totaled \$2.2 billion in 2001. (For comparison, U.S. hospital equity issuance totaled \$727 million in 2001.)⁷ Figures 14 and 15 below indicate that the large medical device and supply companies have successfully raised capital in the public debt and equity markets.

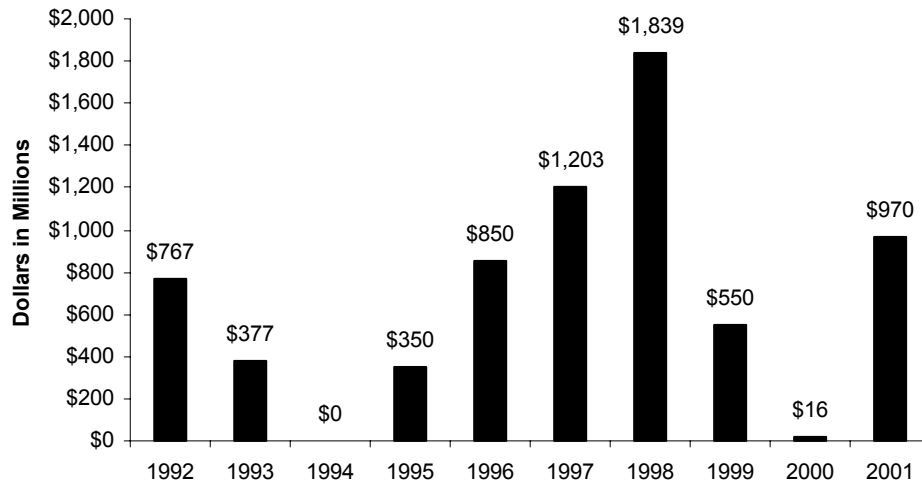
Figure 14: U.S. Medical Device Equity Issuance, 1992-2001



Source: Goldman Sachs and SDC.

⁷ Further discussion on hospitals can be found in the April 29, 2002 CMS Market Update on Acute Care Hospitals.

Figure 15: U.S. Medical Device Debt Issuance, 1992-2001



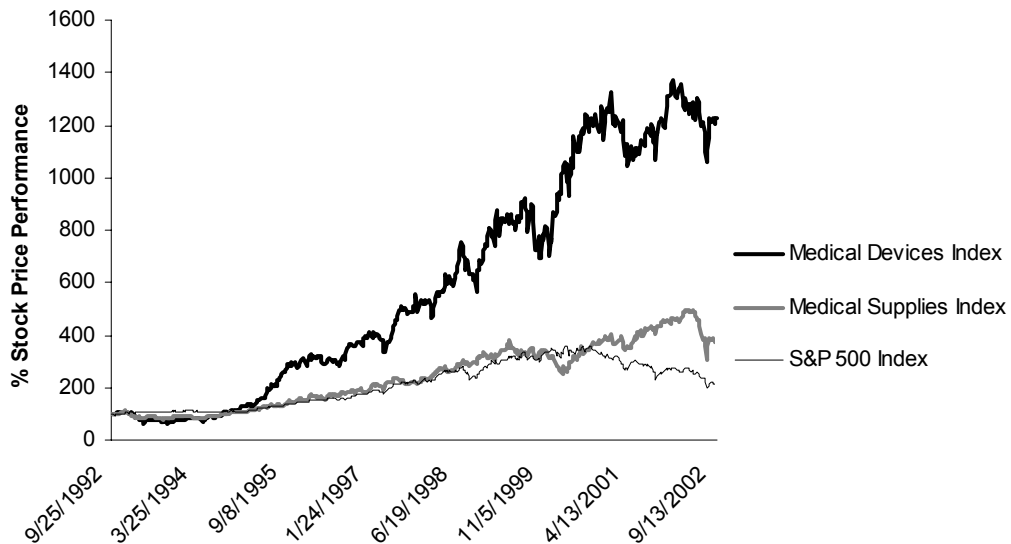
Source: JPMorgan and SDC.

Stock Market Performance

Stock market performance is a quantitative reflection of future expectations for risk and reward. Successful stock market performance can increase the ability of a company to raise capital by issuing stock. Over the past decade, the medical device and supply industry has outperformed the S&P 500 Index, with device manufacturers slightly outperforming supply companies. This is shown in Figure 16 below.

Figure 16: Relative Stock Market Performance over Previous Decade

Over the past decade, the medical device and supply industry has outperformed the S&P 500 Index.

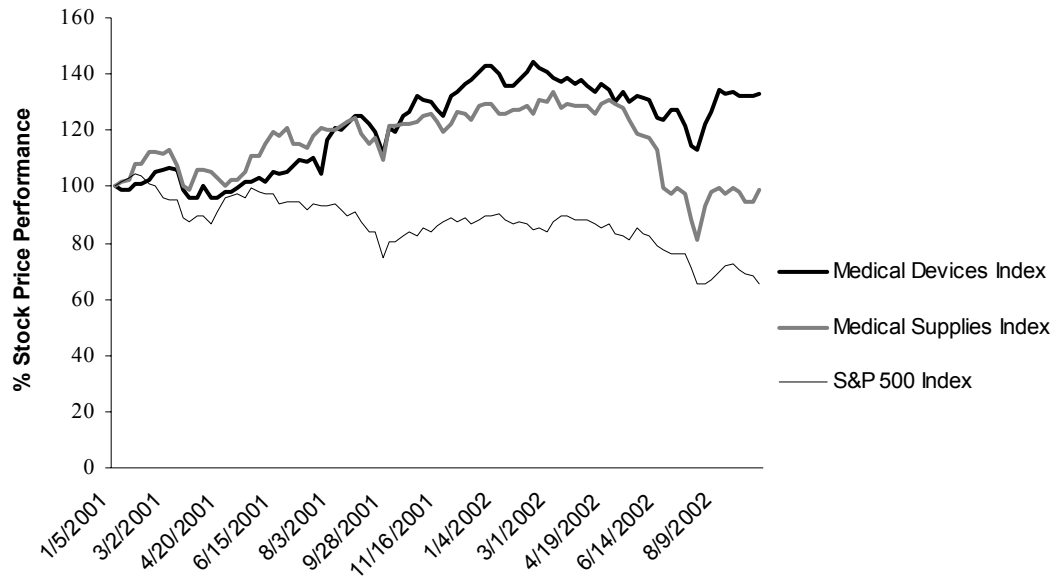


Source: Bloomberg.

Notes: Indices are market cap-weighted. Medical Supplies Index includes Biomet, Boston Scientific, Edwards Lifesciences, Guidant, Medtronic, St. Jude Medical, Smith & Nephew, Stryker, and Zimmer. Medical Devices Index includes Abbott Laboratories, Becton Dickinson, Baxter International, C.R. Bard, and Johnson & Johnson.

Since 2001 medical supply stocks were better performers than medical device stocks due to the market's lower tolerance for risk. This is shown in Figure 17.

Figure 17: Relative Stock Market Performance since 2001



Due to the market's lower tolerance for risk, medical supply stocks have outperformed device stocks since 2001.

Source: Bloomberg.

Notes: Indices are market cap-weighted. Medical Supplies Index includes Biomet, Boston Scientific, Edwards Lifesciences, Guidant, Medtronic, St. Jude Medical, Smith & Nephew, Stryker, and Zimmer. Medical Devices Index includes Abbott Laboratories, Becton Dickinson, Baxter International, C.R. Bard, and Johnson & Johnson.

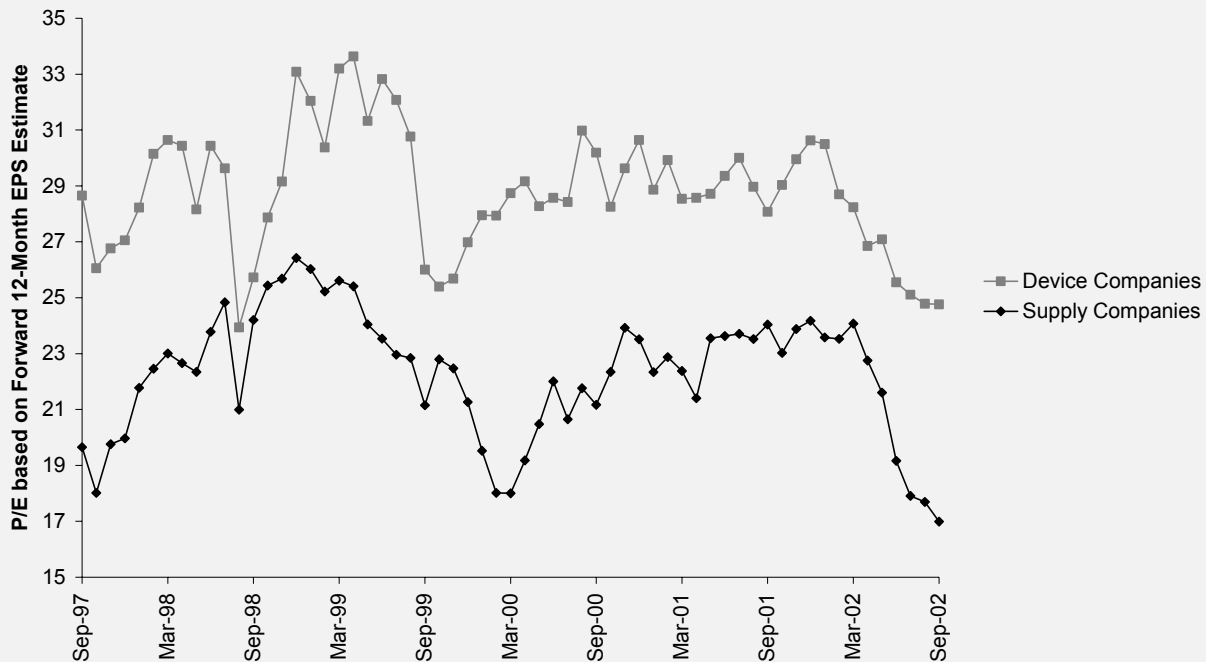
The industry is considered "defensive," or generally independent from an economic downturn.

Sector performance of the medical device and supply industry is influenced by investors seeking stability in volatile markets. Medical device and technology stocks are considered largely "defensive" as sales in this industry are generally independent of the performance of the overall economy. Goldman Sachs' Keusch writes, "Should concern about the US economy persist, medical device company shares could remain strong." Michael Weinstein of JPMorgan notes, "[D]eclines in S&P earnings growth pushed investors to seek safer ground, and for much of 2001, the medical products space proved a worthy place to hide."

P/E Multiples

One simple valuation measure used by analysts and investors is the price-to-earning (P/E) ratio or multiple. A P/E multiple shows what the market is willing to pay for a company's stock as a multiple of the earnings that the company generates. (To calculate P/E, divide the price per share by the annual earnings per share.) P/E multiples can provide relative valuations between companies within the same industry. Similarly, industry average P/E multiples can also be used to compare relative valuations between sectors. P/Es tend to show that investors pay more for stocks with greater confidence in higher earnings expectations. In Figure 18 below, we illustrate that medical device companies trade at a higher P/E valuation than do the medical supplies, which is consistent with the industry's higher margins and higher earnings growth. The 5-year average historical P/E for medical device stocks is 29 times forward-12-month earnings estimates, while the average historical P/E for supply company stocks is 22 times.

Figure 18: Average P/E Multiples for Medical Device and Supply Companies, Previous 5 Years



Source: JPMorgan and FactSet.

Note: Medical device companies include Biomet, Boston Scientific, Edwards Lifesciences, Guidant, Medtronic, St. Jude Medical, Stryker, and Zimmer. Medical supply companies include Abbott Laboratories, Baxter International, Becton Dickinson, C.R. Bard, and Johnson & Johnson.

Daniel Lemaitre of Merrill Lynch notes that the medical device and supply sector tends to trade in three bands: companies with earnings growth in the 20% vicinity are currently trading between 25 and 30 times earnings, mid-teens growth trades between 20 and 25 times, and low double-digit growth trades between 7 and 13 times. These ranges are constantly moving dependent on the broader industry performance. The sector performed especially well (compared to the broader market) during the second half of 2001 as investors grew excited by the prospect of upcoming new device launches, including drug-eluting stents and cardiac re-synchronization therapy for heart failure, although in 2002, the sector has not escaped a broad overall stock market P/E compression and perhaps sector rotation.

Small Medical Device and Supply Companies

Investors believe that the small medical device companies have less access to capital. The small medical device companies are also much less likely to be publicly traded than large companies, and thus private equity investing is a critical source of capital.

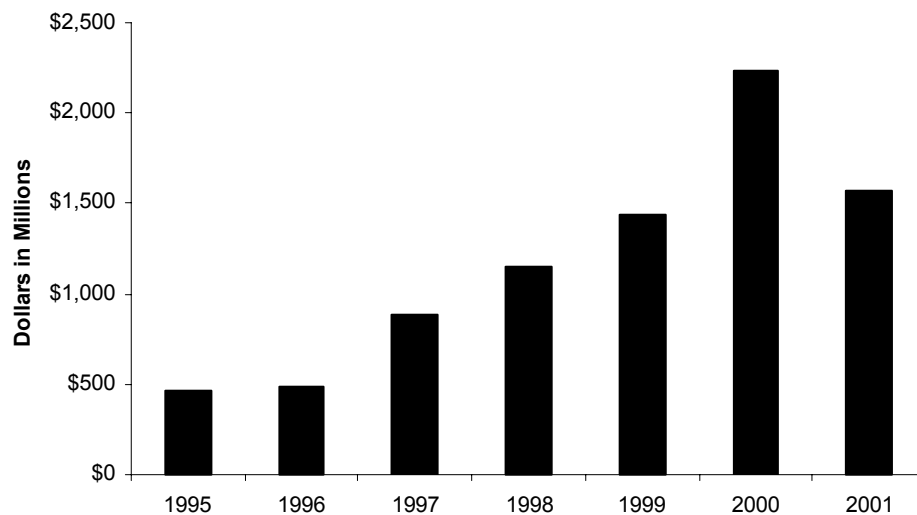
Venture Capital Financing Shrinking

Venture capital is a type of private equity investment that historically has played a vital role in funding and helping develop emerging medical device companies. Venture capital funds are invested in relatively early-stage, high-risk companies. The small device companies that may not yet have reached profitability rely on this type of private equity investing in order to provide cash flow for continued operations. This is very different from the large profitable companies that generate positive cash flow to fund operations.

Venture capital has been vital in funding emerging medical device companies.

Although analysts believe that venture capital financing is still available to companies with novel ideas for promising emerging technologies, investors have become more cautious about investing in early stage medical device companies, as well as other early-stage companies in other high-risk sectors. This is portrayed in Figure 19, which indicates that the financing environment for small and emerging medical device companies has been declining since peaking in 2000.

Figure 19: Venture Capital Investment in Medical Device Firms, 1995 - 2001



Venture capital financing of medical device companies, as for many other industries, was down 30% in 2001.

Source: PricewaterhouseCoopers/Thomson Venture Economics/National Venture Capital Association MoneyTree™ Survey.

According to David Skanderson of KPMG, venture capitalists have slowed their funding for the most innovative, emerging medical device companies because investors are concerned about regulatory uncertainty. Venture capital investors such as Robert Ulrich of Vanguard Ventures continue to fund companies, but have switched their focus away from the risky therapeutic and diagnostic companies to companies that do not require regulatory approval, such as companies that make screening tools. Ulrich believes that venture capital investors are currently biased against the most innovative (and most unpredictable) investments because they are looking for predictability. Investors such as Jonathan Osgood of Cutlass Capital will accept some risk, but do not wish to take on the uncertainty of achieving a return on their investment that comes with what they perceive

Venture capitalists point to regulatory uncertainty as a major deterrent against investing in emerging device companies.

as an unpredictable regulatory pathway. He and other venture capitalists have become much more selective in the investments they make in the emerging medical device arena.

Because venture capital investing assumes the higher risk of investing in an early-stage company, the investment demands higher returns in exchange. Venture investors generally have two ways to realize the return on their investments: either through an initial public offering (IPO) on the equity markets, or through an acquisition. However, both of these liquidity opportunities have been diminishing for small medical device companies.

Difficult IPO Environment and Poor Stock Performance

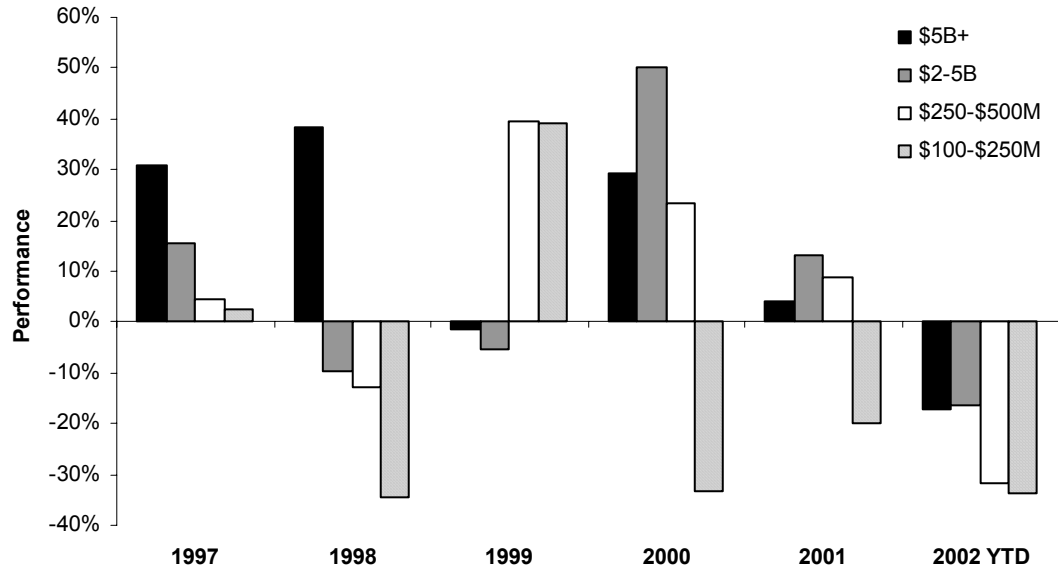
The typical small medical device company's access to the public equity capital markets has diminished. Given the continuing volatility of the stock markets, IPO volume has slowed tremendously over the past two years. Volatile markets have trouble supporting a new IPO issue and generally discourage investors from taking new positions in riskier companies. In addition, as shown in Figure 20, the stock performance of small-capitalization medical device companies has underwhelmed investors. Public equity investors are less willing to invest in small medical device companies after watching the majority of the medical device firms that raised money through initial public offerings in 2000 offer negative return on investments. According to Reicin of Morgan Stanley, "Many IPOs priced in 2000 did not perform well, and we do not see a large pipeline of high-quality businesses."

The majority of medical device companies that went public in 2000 offered a negative return.

Figure 20 also shows that over the past five years, stock performance has diverged significantly for the medical device industry based on the market capitalization of the company. In all but one of the past five years, the large cap stocks outperformed the small cap stocks. The exception was 1999 when the small cap stocks significantly outperformed the large cap stocks. This is largely a part of the "emerging growth" phenomenon that also took place in other industries such as telecommunications and internet. It is clear from the graph below that the market places a higher premium on large medical device companies, which have more predictable revenue and earnings growth than the smaller companies.

Figure 20: Stock Performance by Market Capitalization – Large vs. Small

The large medical device stocks outperformed small device stocks in five of the past six years.



Source: Goldman Sachs and FactSet. As of September 27, 2002.

Note: Market capitalization is a measure of a publicly traded firm’s size or value. It is calculated by multiplying the share price times the number of shares outstanding.

According to Goldman Sachs’ Keusch, “Large-cap medical device issues have provided some stability in an otherwise tough environment over the past year.... Small-cap shares largely underperformed the market.” Prudential Securities’ Faulkner believes that, “Although several important new technologies have driven unprecedented industry growth, small medical device stocks, as a group, have been a resounding disappointment.”

Merger and Acquisition Activity Slowing

The lack of a thriving public market for small device stocks has made acquisitions an important liquidity opportunity for some investors. The continual innovation of startup device companies historically has resulted in new products and companies, which can be sold to larger companies who offer steady funding, better manufacturing, deeper distribution, and more experience in regulatory and payment processes. (Even so, 40% of PMA submissions are from companies bringing their first product to market.)

The device industry’s merger and acquisition (M&A) activity has recently slowed for industry-specific reasons that may be in addition to a broader slow-down in M&A activity. According to Merrill Lynch’s Lemaitre, “The medical device industry has had a long history of successful M&A activity since larger companies can extract sales and cost synergies while providing the marketing muscle to position new technology in a cost containment environment.” However, Prudential Securities’ Faulkner observes:

[T]he level of innovation among small companies is not as strong as it used to be. As fewer little companies are emerging and the larger companies are spending more on R&D, there is a trend toward less M&A in which large companies purchase small public companies. Increasingly, small companies are acquired when they are still private, and larger companies fund innovative research internally. There will be a role for innovative small companies for the foreseeable future, however.

M&A activity in the industry has slowed, both due to an overall economic slowdown and increased internal R&D efforts by larger companies.

SUMMARY

- Overall, the medical device and supply industry enjoys robust financial health.
- Industry spending on research and development has been increasing—a sign of a healthy, sustained commitment to the industry’s long-term success.
- Profit margins are strong among the large-cap medical supply and device companies.
- Large medical device and supply companies have successfully raised capital in the public debt and equity markets.
- Small medical device companies are struggling to find venture capital financing—a phenomenon that is occurring across all industries.
- Generally, investors consider the industry as a safe, counter-cyclical sector in a volatile market.
- Investors scrutinize FDA approval process and Medicare coverage and payment decisions that can affect the speed of technology adoption.
- Medicare policy under the outpatient prospective payment system has caused wide fluctuations in payment rates for new technology but is expected to stabilize as the PPS system matures.

NOTICE AND DISCLAIMER: The CMS Health Care Industry Market Update is published at the direction of and solely for the benefit of the Centers for Medicare & Medicaid Services (“CMS”) and the United States Department of Health & Human Services (“HHS”) and interested health care policy makers in the Congress, the Federal agencies, and State governments. The CMS Health Care Industry Market Update is not intended to be, nor should it be relied upon in any way, as investment advice to any individual person, corporation, or other entity. CMS and HHS make no recommendations or advice with respect to any particular stocks, bonds, or securities or any particular industry sectors and make no recommendation whatsoever as to the purchase, sale, or exchange of securities and investments. While CMS and the Office of Research, Development & Information attempt to present appropriate factual data from a variety of sources, CMS makes no representation or assurances as to the accuracy or truthfulness of information or data published or provided by third parties used or relied upon in this report. CMS has no duty or obligation and does not undertake to independently verify the accuracy or truthfulness of information or data published or provided by third parties, nor does it have a duty to update any such data provided. Although the CMS Health Care Industry Market Update generally discusses health care policy and regulatory and enforcement matters, including regulatory policy and enforcement authority under the jurisdiction of CMS and HHS, the CMS Health Care Industry Market Update does not constitute in any way formal rulemaking or guidance or enforcement policy and procedures by CMS or HHS to any interested party. Information contained in the CMS Health Care Industry Market Update may be reproduced freely, provided that appropriate citation to authority is made.

If you would like to receive the CMS Health Care Industry Market Update via email, please send a request to: capitalmarkets@cms.hhs.gov, Subject: Market Update Distribution

The CMS Health Care Industry Market Update is also available on the web at: www.cms.hhs.gov/marketupdate