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How Biomedical Companies Successfully Navigated Turbulent Economic Times

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While most giant corporations crashed during the worst economic climate since the Great Depression, the biomedical devices industry grew, invested, and prospered. The Great Recession (from 2007 to 2009) represents the worst downturn the western world has seen since the 1930s, a time when most companies saw revenue recede and profits disappear, and they resorted to widespread layoffs, investment freezes, and research cuts. In the midst of this storm, the worldwide biomedical devices industry went against the current. These companies grew their revenues and increased profits by investing in research and product development, increasing their marketing spend, and hiring new staff. They did this in all of their markets—North America, Europe, and Asia—and grew their profits without massive outsourcing, inventory liquidations, mass layoffs, or fire sale liquidations. This sector is not completely recession proof, as some firms did hit the bumps when consumers delayed expensive, elective medical procedures such as knee and hip replacements. But taken as a whole, the businesses that comprise this industry sector sailed through the Great Recession as if it never happened.

This industry review looks at 25 of the top independent biomedical device makers for an in-depth study that analyzes their business strategies, financial results, marketing investment, product portfolios, and research and development to better understand what drove growth and profitability in a time of worldwide downturn. The analysis sets out to discover why this particular sector thrived where others failed, analyze whether this success is sustainable over the long-term, and identify areas for improvement.

Summary and Key Findings

Why did so many companies in this industry sustain such growth, how have they achieved this success, and can they keep it up? We found three common characteristics shared by the most successful of the 25 biomedical technology firms that appeared to contribute to their growth during the recession and are still a factor today (see Table I):

- **High Value-Added Manufacturing.** Building advanced technology products in developed markets while adding a high level of value to base costs has and will continue to do well for this sector. For highly differentiated products sold as customized solutions, the United States and Europe have been great places to establish and grow businesses.
- **Increased Marketing Efforts.** These companies continued to increase spend on marketing efforts during the Great Recession.
- **Investment in R&D and New Products.** The most successful biomedical device companies developed a robust pipeline of new products and R&D capabilities, which allowed them to navigate challenging times successfully. Even during the Great Recession they were increasing their R&D spend.

In short, the best of biomedical device makers succeed by making very little very well, for sale at very high prices. Despite the unparalleled success of the biomedical device industry from a 10,000 foot view, our close study reveals operational fissures that, if left unchecked, could threaten future growth. For instance, some firms, having grown through acquisition of start-ups and by purchasing parts of organizations, now have too many plants and labs to be efficient. Based on our analysis of the firms and the industry, these companies could consolidate and restructure in order to achieve maximum efficiency by sweeping up the collections of purchased parts and turning these businesses into coherent and focused companies. The challenge is to rationalize and consolidate in a fashion that does not disrupt sales operations, disturb regulatory licensed manufacturing processes, or lose intellectual capital, while moving to a product portfolio mix that offers strategic diversification, builds on related technologies, and simultaneously adds

Table I. The BioMed 25 - Top Independent, Public Reporting Players in BioMedical Devices

Firm	HQ Country	2010 Revenue ($ Millions)	Profit %
Abbott Labs	US	35,166	13.2
Alcon	US / Switzerland	4, 626	30.8
B. Braun	Germany	5,900	6.3
Baxter	US	12,843	11.1
Beckman Coulter	US	2,969	7.8
Becton, Dickinson	US	7,372	17.9
Biomet, Inc.	US	2,504	(1.7)
Boston Scientific	US	7,806	(13.6)
C R Bard, Inc.	US	2,720	18.7
CareFusion	US	3,929	4.4
Covidien	US	10,429	15.6
Danaher*	US	4,123	8.4
Fresenius Medical Care	Germany	12,114	8.1
Getinge AB-B	Sweden	3,225 (2009)	8.3
Hospira	US	3,917	9.1
Medtronic	US	15,817	19.6
Smith & Nephew, Inc.	United Kingdom	3,962	15.5
St. Jude Medical	US	5,165	17.5
Stryker	US	7,320	17.4
Synthes	US	3,687	24.6
Terumo	Japan	3,508	12.9
Tornier	Netherlands	201	(27)
Varian Medical	US	2,357	15.3
Wright Medical Technology	US	519	3.4
Zimmer Holdings	US	4,220	14.1

*Medical devices and technology only; does not include planned acquisition of Beckman Coulter.

complementary applications. Consolidation will be a key driver facilitating growth over the coming years. History shows that if the current management will not do it, then someone else will. Recall that Alfred Sloan was brought in 1920 to clean up the loose collection of parts that Billy Durant had assembled under the name General Motors, a firm that had a very meaningful and industry-defining run for 80 years after that.

The big opportunity for the biomedical device business is to move beyond the sometimes bumpy revenue stream from selling things, and migrate to a business model focused on selling systems that provide a point of control and differentiation (usually from software) or that yield sustained revenues from related consumable products used in caring for patients. It is the kind of strategy that worked for King Gillette when his business first adopted the razor and blades model; it is a strategy that has also worked for IBM as it has moved from a hardware business to one driven by sustained revenue streams from software and services.

High Value-Added Manufacturing

The biomedical devices sector is characterized by highly specialized manufacturing efforts that generally add a high level of value to complex products in processes subject to sophisticated quality control processes, subject to close regulatory review. High-value add is used here to mean the process of taking fairly inexpensive inputs such as metal, electronics, or materials, manufacturing them to build customized products that constantly evolve with advancing technology and practice, and then marketing them with sophisticated sales and distribution organizations to yield revenue that is a large multiple of the original input costs. Most biomed devices have been evolving at a fairly fast rate in the past decade, resulting in a fairly close pairing between the R&D function and the manufacturing operation; often the two functions are co-located.

Generally, there are three categories of products manufactured:

- **Internal or External Use.** Devices or materials that are used directly on or in the human body. Unsurprisingly, these products are subject to the highest level of quality control and regulatory scrutiny of manufacturing processes. Because of frequent product evolution and advancement, R&D is co-located with the production process. The designs are often highly customized to individuals, or adapted to local markets of patient populations and local medical usage. As a result, manufacturing normally occurs in individual or small quantity batches at plants located in or near the target national market, with limited scope for economies of scale.
- **Treatment Devices and Controls of Electronic Diagnostic Units.** These devices are used to diagnose or treat the patient, sometimes in direct contact and sometimes removed from the patient in a remote laboratory setting. Most devices can be compared to computers with materials handling capabilities. They are built in small batches on short runs, and customization is common. Quality controls on device performance are rigorous, while licensing authority is not as closely monitored. Because of generally rapid advances in product design, production runs tend to be in short batches and highly integrated interaction with R&D staff is required.
- **Consumables Used by Treatment Devices.** This category includes fluids or materials used in a treatment process, usually in a treatment device built by the same company. Because these items are used in direct patient contact, quality controls are often as rigorous as those applied to advanced pharmaceuticals, and regulatory scrutiny and review are also at the same level. The design and content of these offerings coevolves with the matching treatment devices, although they may be built or processed at different plant sites. There is often a strong requirement for time-sensitive freshness that, coupled with varying local regulatory approvals on fluids and materials, leads to market-localized manufacturing.

The high level of value comes from the advanced quality controls and high degree of customization that are required across most of the sector. The requirement for regulator licensing of manufacturing processes can also form a protective barrier to the entry of new competitors.

There are several results of this combination of customization, R&D and manufacturing pairing, and regulatory control. Most manufacturing plants in this sector are specifically licensed by the local regulator to produce only a specific product or set of products at a particular site; moving that license, and the intellectual property about the conduct and control of the manufacturing process to another site can incur long lead times for planning and expense for the transfer. Often multiple key people with skills and knowledge must move with the process. Closings, moves, and consolidations can take considerable time and incur considerable expense. Geographic areas served tend to be limited to a country or continent rather than the worldwide scale of production from a single plant than can be found in other high-tech sectors. Because many firms in the industry have grown by acquisition of smaller firms, it is common to find a legacy of multiple small- to mid-sized manufacturing facilities scattered across the landscape, each plant with its own process, products, paired R&D function, and manufacturing quality and control staff. Because many of the BioMed 25 originated in the United States, most have a manufacturing footprint that is dominated by U.S.-based plants. Those that originated in Europe have their primary plants there, in the UK, Germany, or in what is arguably the highest cost manufacturing location in the world, Switzerland.

It is interesting to note what the BioMed firms are not doing with respect to manufacturing. With only a few exceptions, they are not moving to lowest possible cost labor markets and building large single plants to supply the world. They are not

designing products and processes in one central high-cost, high-knowledge market, and then moving the actual production to a distant, low-labor cost manufacturing site. Where product standards differ across markets they are having limited success in getting regulators to agree to common product standards that allow common products and shared economies of scale. As a general observation, this is not (yet) an industry where everything you see or touch says "made in China". However, many of the firms are opening or acquiring plants in China or India with the intent to supply those markets.

Yet this industry is not static; companies are attempting to control costs, consolidate processes, and increase efficiency. While few firms have what might be described as a grand manufacturing strategy that is worldwide in scope, most are trying to trim back around the edges and step toward a bigger strategy. Many are making the necessary and often expensive moves to consolidate many little plants in a smaller number of larger R&D and manufacturing centers. But these moves notably can take two to four years to plan and execute, and generate substantial expenses and write-offs for the cost of transition. Obtaining new manufacturing licenses can have long lead times. Several firms are working to develop common shared upstream product components that can be built at a single or at a few locations and shipped into local markets for advanced processing and local customization. It is the classic operations management manufacturing idea of delayed differentiation. Companies are working to rationalize their supply chains and often build merged, common distribution functions. And they are building new plants in new markets, which are then paired with or linked to original, developed market sites for R&D support.

Substantial further consolidation is possible and may become a necessity if the device sector starts to come under cost pressures from a changing healthcare marketplace. For instance, the electronic elements of medical devices and diagnostics could be fully outsourced to third-party manufacturers that could use the electronic assembly supply chain in Taiwan and China to lower costs and gain efficiency from consolidated volumes. Consumable fluids and materials could develop partially processed material components in concentrated form that could then be bulked up and adapted to local market needs. Internal usage medical components could be standardized for use across more markets, common manufacturing processes could be developed, or production for one product line could be concentrated in a single plant supplying the world while other products are produced in other markets and shared across a worldwide supply chain.

Investment in R&D and New Products

Over the past few years the way the medical devices industry assesses innovation and new technology has changed. The old dynamic of the physician as judge of value has been replaced with the government, private insurers, and consumers increasingly determining what sells and at what price point. Consumers refuse to pay for incremental enhancements that add bells and whistles that do not improve health or reduce cost. The faster, better, smaller, cheaper innovations in medical devices are the devices that will maintain a sustainable advantage. We have witnessed a similar metamorphosis in the electronics industry over the past decade, and it will be the future of the medical device industry. Smaller and cheaper devices will dominate.

Recently, emerging-market countries such as China, India, and Brazil have been taking the lead in developing lean, frugal, and reverse innovation. This type of innovation simplifies devices and processes, retaining essential functions, while applying new technologies that are more versatile, mobile, and adaptable to consumer's needs and are less expensive.

We see three primary trends in the R&D environment for medical device technology:

- The medical device innovation centers dominated by the United States are gradually moving offshore. Increasingly, medical device innovators are going outside the United States to seek clinical data, new product registration, and the initial streams of revenue.
- U.S. consumers are not always the first to benefit from advances in medical technology. Innovators already have a preference for countries like Germany, the UK, France, and Israel. By 2020 they will likely move into emerging countries before entering the United States, due to growing complexity of regulation and reimbursement limitations in the U.S. market.
- The geographical locus of innovation has changed. Non-U.S. developed nations have become leaders in the medical device space. Outside of the United States, there are six countries with very strong R&D capacities and capabilities—Germany, the UK, France, Japan, Israel, and China.

Medical technology R&D has often been an outside-in approach. Iterative innovation has often originated at the bedside, as physicians provide feedback that sows the seeds for the next generation of product. Today, sunshine laws, which effectively limit a company's access to physicians, could potentially place some of this process at risk. With a new health environment there exists a need to cast a wider net. Medtronic for example, had begun crowdsourcing some of its innovation with the November 2010 launch of Medtronic Eureka, a European web-based portal that allows physicians and medical technology innovators to submit new product ideas.

During the past 40 years, the United States has provided an ideal and robust innovation environment that has facilitated significant advancements in medical technology. The U.S. dominance of this space has stemmed from its strength in the

five innovation pillars—powerful financial incentives made up of market incentives and financial incentives; innovative resources; the regulatory approval process; healthcare demand and price sensitivity; and a supportive investment environment.

In order to develop the type of medical technology environment required for success in 2020, countries and companies will have to adapt to what we view as the following new five pillars of innovation:

- System-oriented and value-based incentives.
- Global networks of medical centers and medical professionals.
- Competing regulatory systems.
- Individualized solutions and price sensitive customers
- Global financial networks.

The industry is shifting from U.S.-centric to a global span. Although we expect the United States to continue to play a leading role in medical device R&D for years to come, the country will most likely no longer dominate the industry. The supportive U.S. environment that created this dominance brings with it limits to change and encourages an incremental rather than a disruptive path to innovation. The radical innovations that are more likely to permanently change the cost curve are likely to emerge from developing countries such as China, India, and Brazil.

During the past few years and through the Great Recession, companies in the medical device industry have continued to increase spend on R&D. An anemic 2% increase between 2008 and 2009 was followed up by a 7% increase in R&D spend between 2009 and 2010. Overall R&D investments were up by 11% over two years (2007-2009) and up from $11.6 billion in 2009 to $12.4 billion in 2010.

One of the reasons that this industry segment weathered the storm of the past several years relatively well is because it continued to incrementally increase R&D spend. The companies that consistently did so had a more robust pipeline of potential products, another key ingredient to survival and success of the industry. The companies best positioned for success are those that will develop new products that are most relevant to this changing ecosystem. Medical device companies have always taken on the risk to innovate with new technologies. Going forward, one of the most significant risks may be the failure to innovate beyond the product and develop new technologies and services.

Industry Strengths

High Rate of Mergers & Acquisitions (M&A). Compared to many established industries, today's medical device business is characterized by strong topline revenue growth in the top firms, generally highly profitable, and not concentrated. The fact that there are 25 top-playing firms in a related sector focused on a common set of problems—human health—is testimony to the lack of concentration. While the largest firm in our Top 25 (Abbott) is roughly 130 times the size of the smallest (Tornier, a recent IPO), there is a large group of firms, 17 of the 25 companies, with revenue in the $2 to $7 billion range, and another group of 8 firms with revenue in the $7.5 billion to $15 billion range. The overall concentration ratio for the top 4 among the 25 firms covered in this study is a low 35.2%; the top 8 make up 47.6%, which is still in the low range of concentration ratios. Using the Herfindahl-Hirschman index, a more complex measure that weights for the size of all the firms in the sector, yields a concentration index of .08, which places this sector in the range described as "unconcentrated".1 While there has already been a small increase in the concentration of this sector in the years from 2006 to 2010, the low level of concentration present points to ample opportunity for further mergers and business combinations.

Barriers to entry for new startups are moderate when compared to large capital intensive businesses, consisting largely of the need for regulatory approval, to gain access to decision makers such as doctors and hospitals, and to distribute through the medical supply chain. There is evidence of continual new starts by new companies with novel ideas, usually based either on a lab-based development of a new technology, or sometimes the concept and development of a particular doctor that gets funded and gains traction with other medical specialists. Within our Top 25, this ongoing rate of formation is demonstrated by the high rate of acquisitions of smaller firms; taken across the full set of 25, acquisitions of small, nonpublic start-ups runs about five to 10 in any given year.

Examples of start-ups and small firms acquired abound. Picking one large firm, Medtronic (2010 revenue $15.8 billion) made purchases in 2010 of ATS Medical for $370 million, Invatec for $350 million plus contingent payments, Arbor Surgical for $11 million; and acquisitions in 2009 of CoreValve for $700 million, Ablation Frontiers for $225 million, CryoCath Technologies for $352 million, Restore Medical for $28 million, and Ventor Technologies for $308 millino. Other examples of frequent and ongoing acquisitions abound and display ongoing evidence of a steady start-up rate of new firms with new technologies, treatments, or relationships.

Organic Growth in New Markets. Companies also drive for organic growth through more intensive coverage within existing markets, usually by expanding direct sales force coverage, or by acquiring established business partners in growing markets

or local firms in growth markets that can provide a fast extension in distribution and sales reach. Organic growth is also fed by adding complementary products to existing product lines. The R&D section below will provide further examples of how R&D is used to extend product lines.

Companies in the Top 25 have taken successful several approaches to growth, including growth through product line extension by acquisition and geographic expansion to sell existing products to new markets. (Organic, internal new product development will be discussed in the R&D section.) Here are some examples:

- **Hospira.** Drove geographic expansion via purchases of Mayne Pharma (Australia) in 2007, and Orchid Pharma (India) in 2009.
- **Fresenius.** Acquisitions in Malaysia and distribution agreements to expand reach in Japan, Korea, and Russia in 2010. The firm's 2011 annual report clearly stated their intent to "continue growth through acquisition of small and mid-sized companies."
- **B. Braun.** Acquisitions of partners to extend distribution in Asia and in the Balkans.
- **Getinge.** Acquisitions in Brazil, and sales force expansions in China and Singapore from 2005.
- At the level of governance, several firms still have their original founders on the board or in leading executive roles. The founder of Synthes served as chairman on the board until their recent acquisition by Johnson & Johnson. A cofounder of Boston Scientific remains on their board, despite five years of money-losing performance following the firm's acquisition of Guidant.

Manufacturing Devices for Regional Consumption. Another characteristic of the sector is a general practice to manufacturer products in the area of the globe where they are used and consumed. Thus many firms have plants in Europe for the European Union (EU) markets, plants in the United States or Canada for North America, and in Japan or China to serve the major Asian markets. For instance, Terumo, based in Japan, does manufacturing for the home and near Asian markets in Japanese plants, but builds products for the North American market at plants located in the United States. There is a sense—not often explicit—of wanting to make products or consumables for patients at close proximity in geography to where they live. For some firms, especially the joint replacement businesses such as Wright Medical Group and Zimmer, there is the demand for speedy, semicustomized manufacturing so that products can be adapted to unique patient needs.

For example, here's a closer look at Wright Medical, which makes bone and joint replacement products for the knees and hips, and small joints (ankles). These products are manufactured largely from titanium and other high-tech materials that are expensive, difficult to machine, and require cutting-edge machine tools and computer aided design (CAD) systems. Wright and its competitors, such as Stryker and Zimmer, constantly innovate to adapt designs to varying patient bodies. They do this by constant and close consultation with doctors and surgeons—to the extent that their sales force working with the doctors is part of the R&D loop. As they receive feedback on the fit and use experience, the designs are adapted for future patients. The development process of a new device or material is iterative in nature and can take multiple iterations to perfect. To build the products, the adapted products are then fed in to a highly customized manufacturing operation that makes very few, highly adapted products to extremely demanding specifications and standards.

Wright recently closed its European manufacturing operation in France to concentrate manufacturing for its high-value, low-volume, and high-customization joint replacement products at a single plant in the United States. In general, this industry is not characterized by the highly integrated, single-source supply chains that have come to characterize the high-tech device industries such as computers, cell phones, or LCD displays and TVs.

Low Debt. On the financial front, most businesses have relatively low or no levels of debt financing. These businesses are generally not capital intensive because the high value-add in the manufacturing process and the relatively high margins that are paid for the expectation of quality control means that heavy borrowing is not required to fund infrastructure. The prime source of expense is usually marketing and sales, which is funded from and for ongoing operations.

One exception to the low debt rule is Biomet, which was taken private in 2007 in a classic equity investor privatization that added high levels of debt. Although privately held, the firm issues 10-K reports for the many continuing bondholders, which reveal it has lost money consistently since the privatization. This leverage-based technique may work for mature, low technology businesses like automotive parts, and even in rapidly consolidating businesses, such as software. It has been less successful in a business that requires continual investment in product technology improvements and high levels of spend on marketing, the characteristics of this medical device sector. However, Biomet has been losing less each year since 2008, with losses down to mere $47 million in 2011, and it will likely be positioned for an IPO once the economy is on a more solid footing, so the equity investors can cash out.

Key Challenges to Continued Success

Lack of Focus. As a result of the ongoing acquisitions and continuing investment in R&D, many firms struggle to continuously define and refine what they are and their core focus. There is a steady stream of spin-outs or sell-off of divisions, subsidiaries,

or business lines that are perceived as no longer fitting with the core strategy of the firm. The result is ongoing trading of business units between the major and mid-tier players; examples include Boston Scientific selling off its cardiac and vascular surgery businesses to Getinge in 2007, the further sale of the Boston Scientific Neurovascular division to Stryker in January of 2011, and the Abbott spin out of Hospira in 2004. This corporate restructuring allowed Abbott to focus on pharmaceuticals, and the medical supply business of nonpatented products was spun out as a stand-alone corporation. In another recent move, Medtronic announced plans to spin out its defibrillator business, comprising the Physio-Control division; this is a second attempt to spin out the division after the first attempt failed following the 2006 FDA recalls on the product line. Tyco Corp., following their CEO governance scandals in 2002, spun out their medical products organization in 2007 to form Covidien as a stand-alone business; it ranks 10th on the BioMed 25 list for 2010 revenues.

High Rate of M&A. One downside to the extensive practice of growth and extension by acquisition is that many small plants get picked up and added to an existing infrastructure. Often those plants are located next to the R&D teams that develop and push the products into the marketplace. The result can be a mish-mash of small facilities, each with its own overhead, management, and cost structure, often spread out at locations that make no sense for optimal product distribution and have high labor costs. The need to co-locate manufacturing work with product development leads to additional challenges. While plants and manufacturing functions can be moved for parts and technology manufacturing, it is much harder to move a research staff and keep intact its intellectual core. As a result, some firms have been reluctant to address the inherent inefficiencies of their physical structure and personnel locations, because a move often causes severe losses of important intellectual capital.

However, a counter pressure that emerges is the need to host key customers for education and training at a centralized, key campus. A core component of the marketing is training the doctors and other medical professionals on how to use and deploy the products. However doctors will not travel to many small facilities; it makes more sense to build one central research campus with a co-located education facility. Terumo has made major investments in its Japanese home market education facilities; B. Braun has made similar investments in its core campus in Melsungen, Germany.

In response, many firms have launched restructuring plans to consolidate facilities for both manufacturing and research. Medtronic launched a One Medtronic campaign in 2008 to reduce the number of locations and trim duplicative headcount, both in the U.S. and key European markets, recording charges of $742 million in 2008, $1 billion in 2009 and $374 million in 2010. Boston Scientific, a serial acquirer in earlier years, has launched several rounds of restructuring to reduce plant locations, in addition to its serial sales of divisions to competitors. Baxter restructured product lines and facilities in 2005 that set the base for profit growth through the Great Recession. A review of the facilities and locations supporting other firms in the Top 25 reveals ample opportunity for rationalizing and optimizing manufacturing and distribution facilities and research locations.

During early 2011, the BioMed Top 25 was reshaped by major M&A activity. Looking to diversify into medical products and reduce its dependence on a shrinking drug pipeline, Swiss pharmaceutical giant Novartis acquired Alcon. Johnson & Johnson, after a rumored pass at Smith and Nephew, closed on the acquisition of Synthes. Within the Top 25 list, Danaher Corp. added to its base of instrument and technology businesses by acquiring Beckman Coulter. With the closing of these acquisitions, the BioMed Top 25 will shrink to the Top 22.

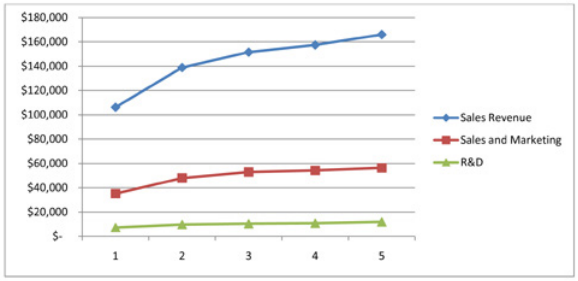
One company stands in contrast to the growth through acquisition and expansion strategy. Terumo, using Japanese GAAP for reporting, draws revenue from two primary lines—a variety of general hospital products including disposable devices, infusion pumps, continuous ambulatory dialysis, and hemodialysis care items, for 47.4% of revenue; cardiac and vascular products that include vascular grafts, and related neurological and cardiovascular systems, comprising 43% of revenue; and a variety of blood transfusion and processing systems, making up 8% of revenue. While 55% of its 2009 revenue came from Japan, the European market comprised 17% and the Americas 18% of revenue, with the balance from the rest of Asia. Growth was strongest in the home Japanese market (+7.3% year to year), compared to essentially flat revenues from Europe. Terumo manufactures its products regionally, with core manufacturing and pilot production in Japan. Local production takes place in factories in the United States and Europe, and new investments are strengthening manufacturing in China. In contrast to the U.S. and European firms that have boosted growth by acquisitions, Terumo has driven its growth through organic extension of existing product lines and addition of new products driven by internal R&D, complemented by new offerings from joint development partnerships with peer Japanese firms such as Olympus Medical Systems. The customary exchange of cross-shareholdings that mark a Japanese partnership left Terumo as the largest single shareholder in Olympus at the time of the recent discovery of long-hidden losses and irregular dealings that has materially damaged the value of the Olympus investment.

Key Characteristics Lead to Success

Increased Marketing Efforts. The high and increasing levels of marketing expenditures are a notable feature of the biomedical device sector, which increased from a 26.2% of revenue to 27.5% of revenue across the five years from 2006 to 2010.

Furthermore, the aggregate dollars spent grew by 59% over the time period, against revenue growth of 48% (see Figure 1). Marketing expenses usually decline as revenue and volumes increase and efficiencies of scale begin to kick in. Thus when marketing expenses grow faster than revenue, something unusual is afoot—either a massive and mutually self-destructive foot race to grab share is underway, or something about the nature of the business is causing firms to invest more in marketing and sales. There are very few businesses that spend as much on marketing and sales as the biomedical device industry. In contrast, the IT business, generally noted for making complex products requiring long sell cycles, spends only 15% to 20% of revenues on sales and marketing.

Figure 1. Sales & Marketing Expenditure Levels



Why is marketing and sales expense so relatively high? In general the nature of the products and services offered demands a high touch level in the selling process. Almost all the firms in this business heavily use high-cost direct sales forces, working in high-cost markets with little opportunity for extensive productivity gains. A few use distributors for products in some more remote developing markets, but one theme between many companies is the steady stream of acquisitions of partners or distributors as they grow their presence to reach sustainable levels in new country markets.

In the selling process, individual medical specialists, often doctors, surgeons, and their support teams must be met, convinced, coached, and trained to use the products. Many firms invest heavily in education, bringing doctors to seminars and training sessions, and vice versa; some have invested in training facilities and supporting staff. Further expenses are incurred for consulting fees, to fund doctors who have used the products to exhort and train other doctors to join them as users. Key hospital staff must also be contacted, cajoled, encouraged, and entertained. We have referred to the costs of this highly hands-on marketing as an investment because it so expensive and intricate, with benefits so far beyond the current period that, although accounting may treat these as items to be immediately expensed in the current period, the clear reality is that the multiperiod payback makes these sales and marketing activities more of an intermediate term investment.

In reaction to the practices of this sector and the pharmaceutical sector, some medical schools have begun to either ban their faculty from accepting drug and biomedical device consulting contracts, or forced them to disclose the extent and nature of their support. Similarly, some firms post the names and amounts paid to consulting physicians and other researchers online. These actions may slow the escalating arms race of sales expenditures, but they are unlikely to materially lower the level of spending relative to sales.

Some firms have made particularly large increases in their ongoing investment in sales and marketing:

- Covidien increased sales and marketing spend by 9.3 percentage points from 2006 to 2010, a 55% increase in dollars spend against a 6% increase in sales. The cause is a shift in product mix from lower margin, lower sales touch pharmaceutical products to a new set of medical devices for bariatrics and hernia repair, which required a more hands-on sales approach. As a result, the company hired about 2000 sales representatives between 2007 and 2009.
- Tornier also increased its sales and marketing spend by 9.1 percentage points, from 46.7% in an early start-up year to an astonishing 55.8% of revenue in 2010.
- Zimmer Holdings increased S&M spend by 6.9 percentage points to 41.6% of sales in 2010.

However, some firms managed to cut their percentage spend on S&M:

- Wright Medical Group cut from a high level of 56.8% of sales to a 54.4%, for a 2.4 percentage point cut in relative spend.
- CR Bard cut spend from 31.1% in 2006 to 27.9% in 2010, a savings of nearly 3.1 percentage points over the period, based on the realignment and restructuring of their non-U.S. marketing functions in 2009. Relative to its medical device peers, Bards sells a large share (33%) of products primarily through distributors.

There is logic to the high levels of marketing spend, which can be demonstrated by grouping the S&M spend into relative brackets and then looking at the product-market strategies for firms in the bracket (see Table II).

Very High: 40% to 55% of revenue spent on S&M. This includes (at 2010 levels) Smith & Nephew (46.9%), Tornier (55.8%), Wright Medical (54.4%), and Zimmer (41.6%). The common thread here is that these firms focus on joint replacement products, for core body joints (hips and knees), or extremities (wrists and ankles); and all have high costs for selling to, training, and supporting surgeons.

Medium High: 20% to 40% of revenue spent on S&M. This larger group includes, inter alia, Abbott Labs (29.5%), Alcon (28.8%), Baxter (22.6%), Beckman Coulter (30.2%), Biomet (38.6&), Boston Scientific (33.1%), Getinge AB-B (21.5%); Medtronic (34.2%), etc. This group contains firms with complex products that demand a high-touch sales approach to reach

Table II. The BioMed 25 - Top Independent, Public Reporting Players in BioMedical Devices Investments in R&D, Sales and Marketing

Firm	R&D Expense 2010*: %	Change: 2007-1020	S&M %
Abbott Labs	10.6	-0.8	29.5
Alcon	10.4	+0.2	28.8
B. Braun	3.5	+0.2	5.0
Baxter	7.1	+0.2	22.6
Beckman Coulter	10.1	+0.6	30.2
Becton, Dickinson	5.8	+0.1	24.4
Biomet, Inc.	4.0	-0.3	38.6
Boston Scientific	12.0	-0.4	33.1
C R Bard, Inc.	6.8	+0.9	27.9
CareFusion	4.0	+1.0	31.3
Covidien	4.3	+1.5	30.9
Danaher**	5.4	-0.2	n/a
Fresenius Medical Care	0.8	+0.1	16.7
Getinge AB-B	2.3	+0.2	21.5
Hospira	7.7	0.7	17.2
Medtronic	9.2	-0.9	34.2
Smith & Nephew, Inc.	3.8	-0.1	46.9
St. Jude Medical	12.2	-0.4	35.2
Stryker	10.7	+3.6	37.0
Synthes	4.7	-0.7	29.3
Terumo	5.5	-0.6	32.6
Tornier	7.9	-4.3	55.8
Varian Medical	6.7	0.0	14.2
Wright Medical Technology	7.2	-0.1	54.4
Zimmer Holdings	5.2	-0.4	41.6

*2010 or most recent fiscal year end avaliable **Medical devices and technology only; does not include planned acquisition of Beckman Coulter

heart surgeons and internists, but not the ultrahigh expense levels required to reach and support orthopedic surgeons.

Medium Low: 5% to 20% of revenue spent on S&M. This smaller group includes Varian Medical (14.2%), Hospira (12.2%), and Fresenius (16.7%). These companies either sell lower-value services along with devices and consumables, and also sell them to labs, nurses, and other medical users, or go to market through distributors with higher volume, lower margin products where the system element is sold by its sales force. The high-dollar revenue consumables move through the distributors (e.g. Hospira).

The common elements here are that the level of marketing spend required is set by the earning power of the key decision maker and the time and effort required to reach and influence the decision makers to favor and use a particular firm's products.

The larger question raised by this high level of sales and marketing expenditure—Are these businesses technology focused, or are they focused on the customer? These businesses invest a lot in R&D, and it is a critical factor facilitating their ability to keep up in the marketplace. But it is also increasingly clear that their customer is the medical professional who makes decisions about which brand or product to use for which application. The acquisition strategy for many firms in this business is to complement their existing offerings with complementary products targeted to extend their array of offerings to the medical professional they already reach, or to those closely related. In short, the high cost of marketing is, for many firms, driving the strategy for growth and acquisition as they search for more products to sell to the same decision makers, in the search for improved sales efficiency.

Strategic Development: Winners and Losers. There are some clear winners and losers to be found in this group. The following companies are the best performers (see Figure 2 and Figure 3):

- Abbott Labs leads with top profit growth, up 169% from 2006 to 2010, on revenue growth of 56%, based in part on the performance of its biomedical device businesses that focus on cardiac stents and related vascular instruments, and in diagnostic products.
- Fresenius grew profits 83% over the five-year period, on a 32% revenue gain, based on extending its sales of consumables and devices to the dialysis service centers.

Figure 2. Profit Trends in Medical Devices Versus All U.S. Durable Manufacturers Index

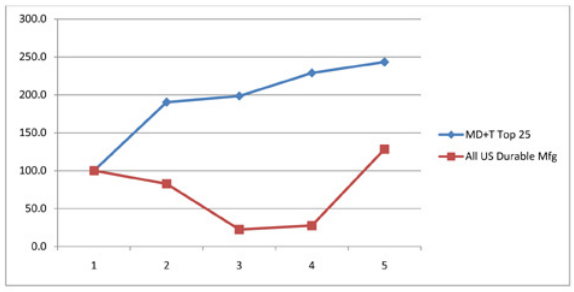
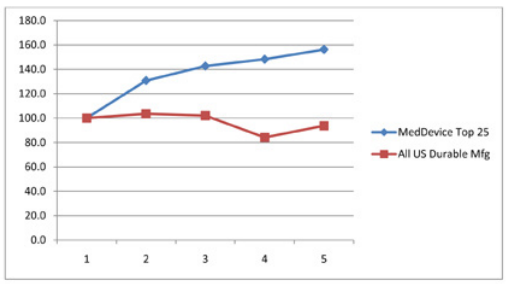


Figure 3. Sales Growth in Medical Devices Versus All U.S. Durable Manufacturers Index



- Alcon grew profits by 64% on revenue gains of 47%, based on extending sales of devices and consumables for eye surgery and care.

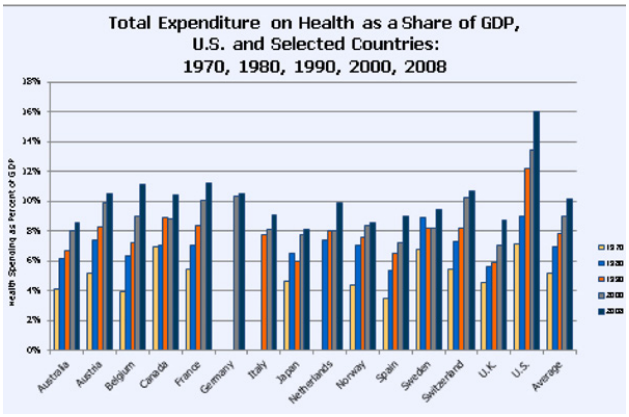
The following companies were poor performers that either reduced profitability or sustained losses:

- Biomet, taken private in 2007, was saddled with a large load of debt in a sector that usually runs on low or no debt, and struggled to cover interest charges and pay down debt. With revenues up 19% from 2006 to 2010, profits declined some 323%.
- CareFusion, spun out of Cardinal Health in 2008, saw low revenue growth from 2007 to 2010, and a profit decline of 66% on the costs of transitioning to a stand-alone company after the spin-off from Cardinal, and the expiration of one-time tax benefits that will raise tax rates going forward.
- Terumo, based in the slow-growing Japanese home market, saw the lowest revenue growth in the group, a mere 14% from 2007 to 2010.
- Finally, the perennial loser of the group is Boston Scientific, which lost money in all five years from 2006 to 2010, and after several ill-fated acquisitions (Guidant) and divestitures to Getinge and Stryker, saw essentially flat growth in revenues and a 70% decline in annual profits.

Future Risks and Dangers

After five relatively good years, the medical device industry faces a more challenging future, with significant risks to growth and profitability. Regulation of medical devices is growing, with new certifications and testing required in the United States by FDA, many under the terms of the 510(k) process. This issue has already raised costs and extended time to market and realization of revenue for several firms. As implants increasingly include elements of pharmaceuticals in them (e.g. drug coated stents, joint replacements), or components designed to promote tissue growth, regulatory review will lengthen. Nevertheless, if the value delivered reflects in pricing, there may be some recompense for the delay.

Figure 4. National Expenditures on Healthcare by Country



The second major risk is simple: Reaching the limits of what people and countries are willing and able to spend on healthcare, with consequent controls and limitations, or behavior changes that turn patients into active shoppers for medical devices. Figure 4 shows the increase in share of gross domestic product (GDP) spent on healthcare, with the United States increasing by 10 points, from 7% in 1970 to 17.4% of GDP in 2009, the most recent year surveyed. This places the United States at the top of the world heap in share of GDP spent on healthcare; Germany, in contrast, seems able to deliver high-quality care for a substantially lower share of GDP, 10.5% in 2008, while Switzerland expends 10.6%. Even the UK, famous for its National Health Service funded from tax revenues, delivers high quality care for 8.5%. The question is, when will countries and individuals run out of the ability to pay? While it not clear exactly where the spending wall lies, it is clear that a limit is approaching.

There is also the potential for substantial consolidation in this industry, which as noted is relatively nonconcentrated at this time. The pharmaceutical industry is emerging from a series of mergers that have created pharmaceutical giants; and consolidation has occurred in many other industries, even those with high technology, high value add products, such as computers and software. It is hard not to look at the many large- and mid-sized firms in this business, some with complementary products or geographic markets, and not see the potential for a strong period of consolidation into a few large powerhouses. An early sign of this potential is the recent offer by Danaher Corp. to buy Beckman Coulter.

The final danger lies in the prospect for low-cost products and consumables offered by businesses focused on supply chains and production efficiencies. There appears to be some potential to save on costs by moving production from North America and Europe to countries with lower wage costs. While an individual consumer might not want to have a hip replacement from a low-cost bidder, eventually the insurance provider may start to push for lower costs for comparable quality. This substitution of lower cost alternatives has started in pharmaceuticals, where there is growing pressure to replace branded drugs coming off patent with approved generics. If medical device technologies begin to stabilize and the quality of both imported substitutes and their local regulation increases, the possibility of the perfect storm of stringent reimbursement requirements, and more competitive R&D and manufacturing landscapes could squeeze U.S. medical device industry profits. The industry sector will need to rely on its resilience, durability, creativity, and innovation to face and overcome some very challenging years ahead.

Conclusion

Across the developed world, companies developing medical devices face multiple challenges. These hurdles include increased regulatory scrutiny, more severe reimbursement requirements, global talent and innovation wars, and aggressive new procurement practices. In search of top line growth, manufacturers are all looking to Brazil, China, and India, while cutting-edge innovations are gradually moving to Germany, France, Israel, and Japan.

Today, the United States is the acknowledged world leader in medical technology, but that leadership is being challenged. In order to preserve America's leadership, there needs to be a focused and concerted effort by industry and government to making innovation in the life sciences a top priority. In addition, the U.S. R&D structure must be sustained and enhanced. Furthermore, there needs to be a close examination of the FDA review process in order to achieve a process that is predictable, consistent, and timely similar to what European biomedical device companies experience.

The U.S. medical device industry has many groundbreaking and transformational products on the market and under development today due to a continuous focus on R&D and changing consumer needs. These companies ask the U.S. government to look out for their interests in both the domestic and overseas markets through ongoing efforts to lower tariffs, streamline and simplify regulations, and ensure a level playing field against foreign competitors based in countries throughout the world. Despite the steady growth seen in the largest medical device markets (the United States, European Union, and Japan), the most promising markets for these products are located elsewhere, including China, India, and markets in Southeast Asia and Latin America, most notably Brazil. Through bilateral and multilateral forums, the U.S. government must be ready to help the medical device sector further develop and enhance its global competitiveness and make a meaningful contribution towards improving public health worldwide.

Companies face many risks, from public policy uncertainty to regulatory pressures, and payer pressures, which in aggregate are placing unprecedented challenges on medical device innovation. It is affecting the investor sector, with funding going towards the later stage and more mature companies. Yet even with all these challenges medical device companies have a lot of potential growth ahead.

To take advantage of these potential opportunities, medical device companies take the following actions:

- Emerging companies must ensure that they can survive and sustain innovation through the challenging funding climate.
- Companies of all sizes will need to continue exploring ways to leverage OUS (Outside United States) markets to offset domestic challenges from emerging markets. The opportunities must offer high growth potential to European countries and provide more efficient and effective routes to launch new products and expedite early cash flow.
- As companies continue to grow it will be critical for them to maintain a focus on operational efficiency and effectiveness.
- Companies must realign into a consumer-centric future where providing successful outcomes is paramount. In other words, innovation that goes beyond the product to include the support services and data analytics.
- Companies will be required to evaluate and potentially reinvent parts of their business models to ensure that what they are offering is what the customer wants, and that these offerings are developed as efficiently as possible.

Going forward, biomedical device companies will need to demonstrate that a particular intervention improves patient outcomes and enhances the efficiency of the healthcare system. The need to offer a complete product—including the addition of services and data as part of the complete offering and solution—exists. Real-time patient diagnostic data could prove as valuable as the newly developed medical device for some product categories. In tandem, a new device, with rich patient diagnostic data and a full array of supportive services might prove to be the key for the future success of the medical device industry.

Reference

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