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This Week's Industry Focus: Medical Devices

Recharging Healthcare: How the Focus of Marketing and Business Planning are Changing in the Healthcare Industry

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Finding the Next Blockbuster

The healthcare industry has been well known for its knack of over projecting the market potential of its products. Often times in the past a simple multiplication involving the number of disease sufferers in the United States by the cost of the device, tabulated to massive market opportunities that had dollar signs spinning in the heads of investors and executives. For the most part, quality and technology have never been major industry concerns. Companies employ some of the brightest engineers and scientists in the country, ensuring products are more thoroughly developed on the front-end than in other industries. By the time a product is pushed through clinical trials, and musters regulatory approval, the weaker technologies have already been weeded out.

On paper, each manufacturer believes their next product is the next major advancement in healthcare. With the soaring industry growth rates between 1990 and 2005, funding for new product development and ideas was of no short supply. Venture capital spending shifted from computers and telecom, to biotech and healthcare. However, all these new technologies with higher price points compounded costs for payers. Since 2000 it is believed insurance premiums have increased 87%, far exceeding general inflation. As those costs were passed along to corporate America, healthcare costs came to affect profit margins more so than most production costs. Recently this backlash has led the industry to witness next-generation technologies rushed to market but end up waiting on the sideline.

Is this the end of the golden age in healthcare? Has the industry reached saturation? All are questions weighing heavily on the minds of manufacturers as they develop their business plans for the next 10 years.

In the past if there was any clinical need or issue, manufacturers tirelessly sought to develop a solution. The assumption in that process was that once the product hit the market, it would be welcomed with open arms. With the changing market landscape, the truth that many have realized is that there are factors beyond simple clinical need that guide market success. Recognizing these changing trends in the healthcare industry, and incorporating these factors will be an important aspect of business planning for the industry as it moves forward.

Hubris and Self-Inflicted Wounds Lead to Market Slump

Over the past twenty years healthcare stocks, have been one of the soundest investments on Wall Street. During that time period the healthcare industry has witnessed astronomical growth, making it one of the most profitable and robust industries in the United States.

Consumer sectors such as the automotive industry, computers, home electronics, were seen as prone to recession and general fluctuations in demand. However for the healthcare industry, a confluence of some of the most innovative advancements in technology and surging patient demands, created an environment of unlimited potential. Each year financial analysts continued to raise their estimates, and each year the industry continued to surpass those lofty expectations. Pharmaceutical and other healthcare companies in turn based their planning and expectations for revenue from those financial experts, instead of a more scientific clinical market valuation. In essence the industry was spending money based on the revenues they expected to make, and not what was available.

Heightened competition from generics and low cost providers, expiring patents, weak product pipelines, a changing regulatory environment, and restrictions in reimbursement have all culminated in a breaking point for an industry showing its first signs of weakness. The same Wall Street analysts whose positive praise propelled industry investment, have now curbed investment with their tempered market projections.

The ramifications have led to several industry giants to announce plans to restructure, and even scale back their workforce. Over the past several months, J & J announced it was cutting 4,800 jobs, Pfizer is eliminating 10,000 positions, Merck 7,000 positions, AstraZeneca 7,600 jobs, and Schering- Plough 1,000. Job cuts don't necessarily mean these companies are on the brink of failure, or no longer successful. However, it does indicate that these corporations are looking to cut costs, and do not see a strong enough future pipeline that it warrants investing that much money in human capital.

In the medical device industry, the two largest segments are orthopedic and cardiovascular products. Cardiovascular device sales account for 30 % of revenues, while the next closest segment, orthopedics, account for 19 % of industry revenues. The two products that account for the majority of cardiovascular device sales are implantable cardioverter defibrillators (ICD), and drug eluting stents (DES). Both markets which had been viewed with nearly limitless ceilings, stalled in 2006. In 2005 Guidant, the worlds second leader of implantable heart rhythm devices, announced it was recalling over 109,000 faulty defibrillators that had resulted in seven deaths. Boston Scientific which purchased Guidant in 2006 for \$27.5 billion, has since settled those claims for \$195 million. Market leader Medtronic, themselves recalled more than 87,000 of its implantable cardioverter defibrillators (ICDs), that have led to over 34,000 patients undergoing surgery to remove the devices. In each case the issue that drew the most anger from the clinical community, was not the device failure itself, but the failure of manufacturers to inform them in a timely manner.

Beyond lawsuits, the ramifications of those recalls with regards to consumer demand have been quite dramatic, leading to a world wide slump in sales. While ICD and pacemaker sales have stagnated, DES sales have plummeted. Market leader Boston Scientific over the past quarter have seen sales of their Taxus device drop by 32 % over the previous year during that same period. J&J the only other company with an FDA approved product saw sales drop by 42%.

These market events have led to several questions regarding the fate of the industry. Will revenues continue to stagnate, or are there opportunities to revive growth? With over aggressive marketing, are drugs and devices being over utilized? Are manufacturers developing products that have price points that far exceed what customers are willing to or able to spend? Is the industry cannibalizing the growth of early stage markets, by price gauging in more profitable sectors?

Despite having easy access to the most advanced healthcare products, with a life

U.S. Death Rate for Diseases of the Heart
1950-2004

Year	Deaths per 100,000 resident population
1950	586.8
1960	559.0
1970	492.7
1980	412.1
1990	321.8
1995	293.4
2000	257.6
2004	217.0

Source CDC, NCHS

expectancy of 77.9 years the U.S. ranks right above Mexico slipping to 42nd in worldwide rankings. This raises questions as to the true efficiency of certain new forms of therapy. A look at death rates in the U.S. shows the diminishing impact of new treatment options.

While it might be nearly impossible to say which specific product will be the next major blockbuster to recharge growth, it is possible to identify the factors that will influence the rise of such a product.

Competitive Factors

- **Patient Safety:** The concern of safety obviously is paramount to the usage of any technology, any reports of device failure or malfunction can have an immediate and drastic effect on a given technology.
- **Access to Product:** Distribution channels play an important role in the competitive landscape for surgical devices. Since the majority of procedures are performed in hospital settings, if a certain manufacturer does not have a distribution agreement in that region or with that facility their market opportunity is restricted. A mid sized competitor is facing an uphill battle when trying to compete against a large manufacturer such as Medtronic who has large well established distribution channels, and can package multiple product lines together in sales.
- **Quality of Materials:** The quality of the metals, plastics, polymers, and other materials used in a device can affect procedural efficiencies and be a significant factor in device selection.
- **Ease of Use:** Simplified device operation allows doctors more degrees of freedom in movement, can reduce procedure times, and minimize the amount of time required for training.
- **Cost:** The majority of cardiac surgical devices are competing in mature markets with long established and fixed reimbursement rates. Identifying the most cost effective devices helps care facilities ensure profitability
- **Training:** Devices that require specialized training of clinicians and other hospital staff can face limitations in market adoption.
- **Uniqueness:** Though not a primary factor in device selection, a certain faction of clinicians like to be seen as progressive and are enthusiastic about incorporating new approaches that are generating buzz in the industry.
- **Physician Relationships:** Involving key clinicians and health care providers in the multiple stages of device design and testing can help accelerate market adoption upon launch.

Keying in on the Marketing Trends that will Affect the Next Generation of Healthcare Products

I. Saving Lives is Not Enough, Patients Want Their Life Back.

The primary goal of the healthcare industry has always been saving lives. Maturation of products that address some of the most life threatening ailments, and declining death rates have allowed companies to focus on more advanced forms of treatment. In the past, patients who survived a life threatening trauma were generally resigned to accept disability as a compromise for their survival. Additionally, issues like chronic pain, stiff joints, declining mental function were ignored as the natural process of aging. Moving forward the industry has increasingly shifted its attention to a mantra of restoration of quality of life. Therapies congruent with an active lifestyle continue to increase in prominence. Quality of life products account for a significant allocation of research resources for the industry, and represent some of the most promising product pipelines. Manufacturers believe the rising prevalence of consumer directed health plans will lead consumers to evaluate the benefit of these forms of therapy.

The aging of the much heralded baby boomer generation, has been the focus for the majority healthcare companies for years. This generation has been characterized as being more active than previous generations at the same age. With deeper pockets at the time of retirement and a more demanding perception of healthcare, consumers have drastically different view of what is a satisfactory clinical outcome.

Compared to other developed nations in Europe and around the world, the United States work force logs more hours worked in a year. With work weeks that far exceed the traditional 40 hour work week, and communication devices that allow for immediate access Americans have redefined the term 'full-time employee'. Declining vacation days and year round stress have led to a rise in the ailments of the 'rich' such as atherosclerosis, hypertension, diabetes, osteoporosis, spinal compression, depression, and insomnia among others.

With 401K plans, investments, and other financial planning, retirement is viewed as the time for these individuals to enjoy the fruits of their labor. The time after retirement was planned for traveling the world, recreation, leisure, and spending time with family. These individuals are looking for treatment solutions that enable and enhance an active lifestyle.

Evidence of this growing is no more evident than in the development of next generation orthopedic products. Anatomical products that better mimic the body's natural functionality represent the next generation of therapeutic solutions. Artificial ankles, knees, and hips that merely provide support are no longer sufficient. Improved flexibility, advances in material and surface design, and polymer drug matrices to stimulate healing are among the advances in technology enabling creative product offerings.

Where do industry experts believe payment will come for these products that are a 'nice to have', but not necessarily critical? These products are not expected to gain universal adoption, but will be designed for a high end clientele with premium insurance carriers, or even willing to pay out of pocket. Analysts believe there is a changing market dynamic, whereby Americans are more accepting of spending disposable income on healthcare technologies.

Technologies designed with restoration and recovery in mind will be a significant influencer in adoption of new technologies.

2. Enabling Doctors to Cross the Next Frontier

The practice of medicine is a complicated science, where certain symptoms might have a countless number of causes. Treating patients immediately and accurately is the difference between recovery and survival, or death. Clinicians are interested in devices that can improve the confidence of their diagnosis. The most brilliant clinicians are essentially limited by their own faculties. Doctors can not see their patients at a molecular level, and even the best surgeons can not replicate the dexterity of a robot.

Under the weight of current demand, hospitals and private clinics have witnessed the time that their trained specialists and physicians have been able to spend with patients has become less and less. Patients would like to know that their effectiveness of the care was not compromised due to fatigue or experience of their clinician. Any refinement of procedures or devices that are able to expedite the time a doctor is able to allot for a patient, without sacrificing accuracy or thoroughness will be seen as a significant advancement.

In his book, A Surgeon's Notes on an Imperfect Science, author Atul Gawande describes that treatment approaches and diagnosis of patients is based on "constantly changing knowledge, uncertain information, fallible individuals", not unlike any other profession. However in this case obviously there is the added pressure of having "lives on the line." In one instance Dr. Gawande outlines essentially a competition between one of the worlds leading cardiologists, and a diagnostic program for reading EKG profiles. Similar to the famous chess match between world chess champion Gary Kasparov, this battle placed man against machine. In this case, this software with a neural network structure was fed a countless number of actual patient EKG's that helped it learn between normal heart function and profiles post a traumatic event. The software caught 20% of cases that this world class physician was unable to distinguish. This competition was not conducted as an indictment of clinicians, but merely to show how these tools can help increase accuracy of diagnoses.

Another significant advancement allowing doctors to make more accurate determination on treatment, is the growing adoption of electronic patient records. To a doctor, patient history files are the clues and nuggets that aid in uncovering clinical culprits. Without a history, based on symptoms a doctor might be able to assume a couple likely ailments. However, with the best tools and an understanding of that patients history they can improve the confidence of their diagnosis. Electronic patient records allow hospitals immediate access to the patient profile, their past

history, and basic information regarding blood type and allergies.

Hospitals and clinics now have the infrastructure to transmit large quantities of data from one location to another around the world. By being able to send images, or streaming content, the clinical world has shrunk. Experts can be trained remotely via video for complex, or rare procedures. Scans can be inspected by leading experts around the world. By expanding the clinical knowledge pool for providers, they can improve treatment options for their patients and minimize the risk of performing unnecessary procedures.

Technologies that might not have been feasible ten or even five years ago are now possible given advances in information communication technology, and general hospital infrastructure.

3. Profiling: Getting in the Head of Your Customer

Understanding your customer, including their likes and dislikes, are all essential questions that must be answered for marketing any product. In the healthcare industry the direct user and beneficiary of products is not necessarily the decision maker. The decision makers for purchasing products and services in the hospital are doctors, surgeons, hospital administrators, and insurance payers. Understanding who has the majority of influence on product selection can help to determine the types of technologies that will thrive in that market. Moreover, each individual has a specific role and responsibility based on those incentives one can deduce the impact of a product. The more patients that individual is responsible for, the more conscientious they are of economies of scale.

While these aspects of the healthcare industry are well recognized, what often gets ignored is the identification of the personality profiles among clinical specialists.

Doctors, surgeons, different specialists, each represent sub groups of the clinical community. Delineations between the specialties are typically drawn along the lines of the organ system they treat, and even further by their form of treatment. For instance, in the cardiovascular space; thoracic surgeons, interventionalists, electrophysiologists, each focus on a different disorder of the heart and how it must be treated.

Certain specialties are time consuming and arduous, others are simple and less complex. While each individual has their own personality, it can be assumed for the most part that individual has selected that specialty due to a specific challenge or lifestyle. Specialties that are well known for employing innovative gadgets and technology are typically more active in identifying and learning about new devices. On the other hand, there are specialists who prefer a more traditional approach. Clinicians who conduct a procedure they have repeated a thousand times, a procedure that they can perform with assembly line like efficiency makes them more resistant to change. Often times, manufacturers with an innovative product idea, move forward on the recommendation of a select few clinicians, failing to understand the wider clinical perspective. A select few clinicians who serve as advisors, or members of a company's executive board can often times misguide the true market value of a new technology. That is not to say the device is faulty, or even that their advice does not have value. In addition, specialty clinicians can further be broken down by which region of the country the practice in, the economic affluence of their local community, and even which academic institution they trained at. Front end customer research from a wide sampling of clinicians is essential in the design and scoping of any product.

4. The Patient Knows More than You Do: Why That's a Good Thing

The age of information means patients can access information on the latest clinical procedures. The availability of clinical articles, and case histories, allows patients access to the majority of sources for information that medical professionals rely on.

Most manufacturers utilize this medium to conduct non-branded marketing campaigns. Having information readily available regarding the most advanced and latest technologies arms patients with the ability to conduct open discussions with their doctors. Aggressive direct to consumer marketing has always been a sore spot in the industry, as critics believe it inflates costs and the proliferation of unnecessary treatments. When

utilized correctly, it helps patients understand the full range of treatment options available to them. In the past that patient might have only been informed of the procedures and treatments that healthcare facility was equipped to perform. If patients start flocking to the health center across town, because they perform some new procedure then the hospital without those resources is at a significant competitive disadvantage. Through this means manufacturers can utilize patients to instigate market adoption of new forms of therapy.

Contrarily there is a negative side of the information age for manufacturers. Patients and doctors can quickly jump on sensational news items, such as a device recall or failure. In these instances, massive declines in usage can occur within a very short time period, even before the industry is able to provide a well developed rebuttal. Patients or clinicians reacting based on one opinion or view-point, are capable of creating first impressions based on skewed or slanted views of a certain form of therapy.

Understanding the delicate difference between overzealous marketing and solid research based information allows manufacturers the ability to reach patients without raising the ire of clinicians. When in doubt, the best policy is to deal only in facts.

5. What is your Product: Luxury, Accessory, or Necessity?

Limitations in reimbursement spending require that manufacturers ask questions about where their device fits in the clinical landscape. From a clinical standpoint there are essentially three types of products, those that are a luxury, accessories, and those that a necessity. Each category has its benefits and drawbacks, weighing those issues are important before initiating the launch of a new product line.

Luxury items are expensive equipment or product features that offer noticeable advantages over standard forms of treatment, but the increase in costs often preclude it from witnessing full scale adoption. Due to clinical superiority, these products typically easily clear regulatory hurdles on their way to market launch. However, once on the market they struggle to gain reimbursement or find facilities unwilling to spend the money for capital equipment. A striking example of this can be witnessed in the imaging industry where capital equipment costs can range anywhere from \$250,000 to over \$1,000,000 depending on the technology. In addition to the equipment, hospitals must then hire or train technicians capable of managing the systems and data. That's not to say that there is not a significant market for these products. They have core niche applications, and when targeted to the right consumer can be among the most profitable sectors of the industry. Similar to the automotive industry, when products are designed as luxury item they must be scaled and marketed as such.

Accessory products and forms of therapy bolster or enhance an existing core clinical approach. These products are probably the quickest way to market entry. These are relatively inexpensive products that are used in conjunction with a certain popular form of therapy. As that therapeutic approach continues to grow in prominence, so do sales of its accessories. Manufacturers are able to quickly adapt to the market and develop profitable products without the high overhead costs of research associated with breaking ground in a new form therapy.

Products that can be classified as necessities are self explanatory. Any product or device, regardless of cost that is able to vastly improve clinical outcomes over previous forms treatment will undoubtedly force market adoption. These products when developed are capable of revolutionizing standards of care for various ailments. As a necessity these products almost dictate that providers provide reimbursement. The main challenge in developing products at this level is being able to markedly prove a vast clinical benefit over alternate approaches. Depending on how a manufacturer envisions their product in the market place, they must allocate their production and marketing resources accordingly.

Conclusions

Launching a new device with only a marginal benefit over existing products on the market might only have a slight impact in the market place. However, instead of launching a me-too device, solutions designed and tailored to alleviate some of the key issues for macro-patient demand will witness higher levels of market adoption and success. Firms need to make themselves aware of the features that will best serve the market six to seven years down the line. For example, the market has no need for another drug eluting metallic stent, but it is curious about the

applicability of biodegradable stents. Due to the accelerating influx of patients, time constraints, and the tightening controls on reimbursement dollars, the healthcare industry is facing a great deal of challenges. Being able to design solutions that maximize the number of patients they can treat with clinical and cost effectiveness are the most sought after approaches.

The Future	
<ul style="list-style-type: none"> • Integrated Systems <ul style="list-style-type: none"> • On Board Imaging • In-situ Diagnostic Monitoring • IT Communications Networking • MEMS Drug Delivery • Prevention over Reaction <ul style="list-style-type: none"> • Increasing Awareness and Screening 	<ul style="list-style-type: none"> • Home and Consumer Healthcare <ul style="list-style-type: none"> • Real-time Diagnostics: Tracking therapeutic efficiencies • Emergency Assist Systems • Elderly Assistance • Recovery over Survival <ul style="list-style-type: none"> • Quality of Life Technologies

Despite the fact that reimbursement agencies are finally curtailing spiraling healthcare costs, there are still a great deal of opportunities for forward thinking. As the industry shifts its focus from rehabilitation to prevention, the landscape for the healthcare industry is poised to significantly evolve over the next 20 years. Integration of technologies such as information systems, imaging, pharmaceuticals, devices, and diagnostic tools provide an endless possibility of combinations. The total number of healthcare dollars the industry have available to spend might not be changing drastically, but the types of technologies and therapies they wish to spend those dollars on will be.