

# LIFE SCIENCE MEETS LIFESTYLE

**Market Opportunity Where Professional Medical and Consumer Health Technologies Converge**



A Frost & Sullivan White Paper

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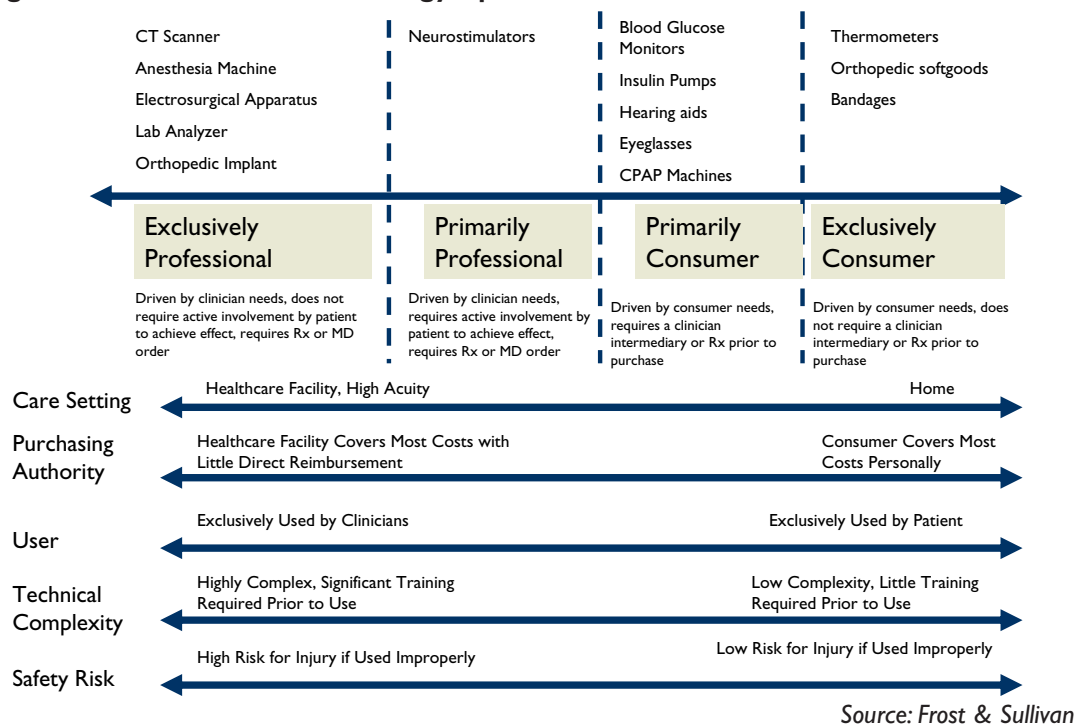
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For at least the last decade, there has been a quiet revolution underway in the healthcare field. Most Americans are well aware of the challenges facing the country's healthcare system – escalating costs, denied tests and treatments, fragmented care, less time available for a patient-physician relationship, medical errors and inefficiencies and other woes. However, a number of important cultural, technological, and demographic trends are increasingly putting more control into the hands of patients themselves to manage their health. This transformation has an enormous potential to change how medicine is practiced and how the healthcare system as a whole operates. In many cases, the catalyst for this change has been new technologies that have taken advances made in the realm of professional medical products, i.e. those used by doctors, nurses and others, and modified them for use by patients in a consumer environment. Laypeople have always had access to medical devices to meet their basic needs, such as first aid kits or thermometers, but in recent years, highly-advanced technologies have been increasingly rolled out to consumers themselves. Some of the best examples of this “convergence” between professional and consumer devices are automated external defibrillators (AEDs), blood glucose monitors, insulin pumps, home diagnostic kits and remote patient monitoring systems. Just as computers diffused into the culture starting as large, complex scientific instruments to ultimately become small, powerful consumer appliances for communication and entertainment, so too can we anticipate that medical technology will follow a similar path. This convergence zone represents one of the greatest opportunities to manufacturers in the medical technology and consumer health markets today.

The medical technology field, understood in its broadest sense under FDA regulation, spans across an incredibly wide spectrum, as shown in Figure 1. Very few companies compete across the entire spectrum, but it is important to take such a broad perspective in order to see how convergence is taking place and where the particular nexus points are occurring. The greatest point of convergence is occurring in the middle of the spectrum where products which were once primarily professional devices are now becoming primarily consumer technologies. Despite the exciting developments occurring relative to convergence, the professional and consumer medical technology markets have different dynamics as shown in Figure 2.

Convergence between professional and consumer medical technologies is being driven by a number of trends listed in Figure 3 on page 5.

**Figure 1 - The Medical Technology Spectrum**



**Figure 2 - Differences Between the Professional and Consumer Medical Technology Markets**

Marketing Mix	Professional	Consumer
Product	Clinical tool, greater demands for evidence, greater need for more information for differential diagnosis and treatment, use setting in controlled, clinical environment, often higher regulatory hurdles	Simpler, need for greater safety controls, more ergonomic and comfortable, aspirational, expression of self, clear instructions, use setting in home or other non-healthcare facility, scalability more of a challenge, shorter product life cycle
Price	More elastic - typical disconnect between user (clinician) and purchaser (facility), larger purchasing volumes, view of products as business investments, greater pricing flexibility through negotiations	More inelastic - especially if non-reimbursed, smaller purchasing volumes, sometimes direct impact on personal budgets, less of an ability to offer flexible price negotiations
Distribution	Concentrated distribution channels with fewer potential customers, Internet purchasing rare for most products	Less concentrated market, greater diversity, challenges getting product "the last mile," Internet distribution a powerful tool, will device be Rx or OTC?, will device require an intermediary to sell?
Promotion	Promotion easier because of common needs and concentrated users, intense personal selling and relationship building with clinicians	More transactional selling, more adherence and educational challenges, market segmentation more important, consumer psychology more important, greater challenge with positioning of product and benefits, more available market data resources for consumer market research compared to professional market
Service	More service oriented, often demand for intense 1-on-1 service provided by manufacturers	Less service oriented, 1-on-1 service often not practical across large populations, hotlines, Web sites, detailed instructions

Source: Frost & Sullivan

### Figure 3 - Major Drivers of Convergence Between Professional and Consumer Medical Devices

- Need to Reduce Healthcare System Costs
- Growing Incidence of Chronic Diseases
- More Empowered and Educated Patients
- Changing Payor Dynamics
- More Information Available to Consumers, Primarily Over the Internet
- Patient Expectations for Living a Longer, More Active and Independent Lifestyle
- Consideration that Medical Errors and Infections Might be Lower With Patients Cared for Outside the Hospital Contributing to Improved Outcomes
- Demographic Changes
- Greater Data Transparency and Benchmarking Among Healthcare Providers and Technologies Related to Cost and Outcomes
- Advances Being Made in Military Medicine Making their Way Back into Civilian Healthcare Technology
- New Technological Breakthroughs Outside of Healthcare Making their Way into Industry
- Technology Formerly Focused on Acute Care Moving Outside of the Hospital
- Changing Nature of Medicine and Roles – Overworked Clinicians Pushing Responsibility to Patients
- Less Expensive Medical Equipment Available to Consumers from Asian Manufacturers
- Interest Among Providers and Payors in Improving Patient Adherence/ Compliance
- More Cosmetic/Elective Procedures, Self Care
- More Options for Care Outside of Hospitals
- More Expendable Income Among Older Americans
- More Interest Among Manufacturers in Anticipating Patient Needs Due to Competition
- Growing Demand for Healthcare Services, Spending

Source: Frost & Sullivan

A major theme driving convergence of professional and consumer medical technology is the rise in “healthcare consumerism” in the United States. The term refers to a recent market phenomenon which describes how the healthcare system has begun to mimic and converge with the markets for other traditional consumer products. The term is somewhat broad but is largely driven by a shift of decision-making and purchasing power from entities in the healthcare system itself and more toward the patient. This shift has a number of underlying components all of which are giving consumers more control and responsibility over their healthcare than in the past:

- *Shift in Demographics* - population composition, attitudes, affluence, education, disease states, etc.
- *Shift in Technology* - smaller, wireless, Internet-enabled, information-gathering technologies creating new opportunities to extend the reach of care
- *Shift in Care Settings* - hospital based to non-hospital to home; inpatient to outpatient
- *Shift in Caregivers* – using technology to move care to lower skilled caregivers and the

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consumer himself; healthcare practitioners to patients, family or non-professionals; patients more informed on disease states and treatment options thanks to the Internet

- *Shift in Care Practices* - more scientific, data driven, preventive, technology-intense form of medicine than in the past; physicians more collaborative with patients; greater fragmentation across healthcare system, and more defensive medicine
- *Shift in Payment for Care* - more available technologies, but less willingness for insurers to pay leaves patients to pick up more costs associated with their own care, if they see value

## THE CHANGING HEALTHCARE CONSUMER

Convergence of professional and consumer medical technology is being driven by a variety of factors, but the most important is the changing healthcare consumer population itself. Who these people are, what they value and purchase and how they engage with the healthcare system is in many cases radically different from the previous generation of Americans.

### Demographics

Business, government and media have watched the Baby Boom generation, those Americans born between 1946 and 1964, every stage of their lives in an attempt to gauge how their habits will impact the future. According to the Institute for the Future, "Baby boomers will impact health care in ways never seen before. They will place more demands on hospitals and clinics not only for their own needs, but also for the needs of their children and parents. At the same time, health care is expected to be revolutionized by advancements in information technologies that will help improve patient flow, information sharing and administrative services."<sup>1</sup>

The Baby Boomer generation in particular has taken significant advantage of health information resources available on the Internet. Boomers in general are more interested in managing their own care than past generations. Combining this with the fact that the generation is more affluent, better educated, more active and better insured than their parents, makes Boomers one of the most important targets for consumer medical technology.

### Better Education and Higher Incomes

Between 1970 and 1998, the percentage of the older (65+) population who had completed high school increased from 28 to 67 percent. Approximately 15 percent of the older population had an undergraduate degree or more. As educational levels for older Americans increase, so does their average level of affluence and discretionary income, allowing for an increased ability to afford medical technology. Boomers are expected to be one of the wealthiest and best educated retirement generations in American history. Combining this access to material resources with Boomers' health concerns and tendencies toward self-indulgence results in significant growth opportunities for manufacturers.

1. Institute for the Future report "Health and Health Care 2010: The Forecast, The Challenge" [www.iftf.org](http://www.iftf.org)

## Increasing Empowerment of Patients

The availability of detailed health information on the Internet, television, and from other sources has given more people the power to learn about their health conditions, evaluate technologies, and consider treatment alternatives. Increased interest in the healthcare market from industry titans such as Microsoft, Google, and Intel clearly shows that the future of healthcare will be closely tied to information technology. A generation ago, health care professionals were the privileged sources of health care information and advice, but patients are now taking on more responsibility for their own health conditions because they feel empowered by publicly available information. Clinicians and insurers are also increasingly advocating more self-care for patients as a way to reduce costs and improve outcomes with a more preventive approach toward medicine. As patients become increasingly responsible for their own care, their level of knowledge and connection to the medical technology they use grows stronger.

“Twenty years ago, patients would go to the doctor and just say they are not feeling well and were totally at the mercy of the doctor. You hear doctors today say that the patient will actually show up at their office with a stack of printouts, have totally self-diagnosed themselves as to what was wrong with them and actually selected what treatment they want performed,” Dan Van Nyhuis, the strategic marketing manager for imaging at Philips Healthcare North America, states.

While more information on health conditions is certainly valuable, identifying accurate sources of information and interpreting the full implications of that information remains a challenge for consumers when they operate alone. This availability of information and changing cultural attitudes has contributed to a change in the nature of the doctor/patient relationship away from a patriarchal one to a more consultative style. Clinicians in the future will spend a greater portion of their time helping their patients find accurate information on their conditions and helping them to understand the information they gather. Physicians and nurses will be considered more as experts and guides to help people manage their own health problems as opposed to authoritative decision makers.

Susan Alpert, M.D., senior vice president and chief quality and regulatory officer at Medtronic, explains how continuous blood glucose monitoring (CBGM) was originally developed as a diagnostic tool for physicians to use on their patients similar to Holter monitoring, but for diabetes. In the early development of the technology, patients never saw their own data coming from the CBGM devices they wore. However, as diabetics as a population became increasingly interested in and capable of managing their own blood glucose thanks to modern, standard glucose monitors and insulin delivery systems, the comfort level of both physicians and the FDA



grew to the point where CBGM was ultimately approved for use by the patients themselves. The appreciation of the benefits of tighter glucose control by clinicians also grew over time encouraging the use of monitoring technologies which more closely approximated the real-time blood glucose values in the patient's bloodstream. Patients using CBGM are now able to constantly track their own blood glucose levels with a pager-like device and upload the collected data into their PC for analysis. This type of gradual learning process by clinicians, patients and regulators about the implications of patient self-diagnosis and self-care is expected to play itself out across many other consumer medical device sectors in the years to come.

“Patients are much more sophisticated in terms of their understanding of healthcare. Medicine has evolved, and there is now more science than art compared to the past. Our understanding of disease is now scientific enough that this kind of information can make a difference rather than relying only on the clinical experience of someone who has seen hundreds and thousands of patients,” Alpert states.

One of the effects of a more scientific approach toward medicine driven by technology is that diagnoses and treatments which were once based on the cumulative experience of a trained clinician are now supported by the more objective and quantitative measurement provided by a device. While consumers cannot themselves assimilate the experience of a clinician, they can, with training, use the same technology to manage their own health. “We are in a very different patient physician relationship environment today, where physicians are much more comfortable in partnering with the patient on care, but again we have to recognize this is not for everything,” according to Alpert.

### **Changing Dynamics of Healthcare Insurance Coverage**

The U.S. healthcare system is slowly shifting to become one where the patient is paying more out-of-pocket for medical products and services. As government and employers restrict their healthcare benefits, patients will take on more responsibility for finding the medical technology and services they want. Patients will consequently seek out products and health-related information on their own because they trust their insurers less to meet all their needs and expectations, at least beyond the bare minimum. For example, an insurer may be willing to pay for only a basic blood glucose meter, but if a patient wants a more advanced one, then they will be responsible for paying the difference in prices.

### **Shift of Patient Care Away from Acute Care Facilities**

During the last 20 years more medical care has shifted away from hospitals to long-term care facilities, outpatient surgery centers and the home. The shift has been motivated by the interest in reducing costs and improving patient outcomes and comfort, but it has also been supported by improvements in medications and medical technology. In the 1980s, 31 percent of medical procedures were done outpatient, but that percentage has since grown to 70 to 80 percent, according to the American Hospital Association's annual survey. In 1981, 89 percent of all outpatient procedures were done in hospitals, but that number has

since shrunk to approximately 50 percent.<sup>2</sup> As patient care transitions away from facilities where doctors and administrators have the most control, patients and their families will be making more decisions about what technology to use and who to purchase it from. The well-publicized shortage of nurses in the United States will also encourage more patient self-care, even while patients are still in the hospital.

## MAJOR OPPORTUNITY AREAS OF CONVERGENCE

The convergence of professional and consumer medical technologies opens up a significant number of market opportunities. Some of the hottest sectors to watch are listed in Figure 4.

**Figure 4 - Major Areas of Opportunity for Convergence**

<b>Products and Services</b>	<b>Focus Areas</b>
<ul style="list-style-type: none"> <li>• Home/ self-diagnostics – for identified conditions and “wellness monitoring”</li> <li>• Remote monitoring</li> <li>• Neuromodulation</li> <li>• Orthopedic braces and supports</li> <li>• Drug delivery</li> <li>• Ophthalmology / Eye care / Vision correction</li> <li>• Dental</li> <li>• Dermatology</li> <li>• Audiology</li> </ul>	<ul style="list-style-type: none"> <li>• Preventive medicine and self-care</li> <li>• Personalized medicine</li> <li>• Improving adherence/ compliance</li> <li>• Improving patient quality of life</li> <li>• Better pain management</li> <li>• Easing burden of caregivers</li> <li>• Simplifying technology</li> <li>• Reducing costs</li> <li>• Caring for patients in remote locales or who cannot travel easily</li> <li>• Providing aesthetic benefits to patients</li> <li>• Infection and medical error prevention</li> <li>• Weight loss/ fitness/ obesity/ sports; metabolic monitoring</li> <li>• Specific needs of women and children</li> <li>• Holistic approaches toward medicine; alternative medicine</li> <li>• Veterinary (not focused on human patients, but major crossover potential)</li> </ul>
<p><b>Enabling Technologies</b></p> <ul style="list-style-type: none"> <li>• Wireless technology</li> <li>• Microelectronics</li> <li>• Lab-on-a-chip</li> <li>• Bio-sensors</li> <li>• Video games and digital media</li> <li>• Drug delivery technologies</li> </ul>	
<p><b>Pathologies</b></p> <ul style="list-style-type: none"> <li>• Chronic conditions</li> <li>• Obesity</li> <li>• Deep vein thrombosis and pulmonary embolism</li> </ul>	

Source: Frost & Sullivan

### Diagnosics

Manufacturers and clinicians recognize diagnostic technologies as a field with some of the greatest opportunity for the consumer market. Blood glucose monitoring evolved into a \$4 billion market in the United States in the span of a few decades by only tracking a single diagnostic indicator for a single patient population. Innovative companies see significant opportunity in developing similar markets around new diagnostic paradigms, especially for patients with chronic conditions. Compared to therapeutic devices, diagnostic technology

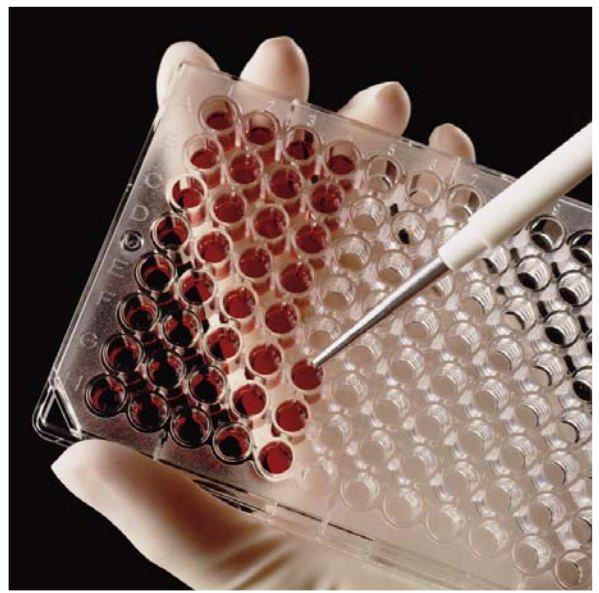
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2. The Lewin Group analysis of American Hospital Association Annual Survey data, 1980-2001 for community hospitals

is often simpler to develop and to get approved by the FDA. In addition, many manufacturers believe diagnostic devices are easier in terms of educating consumers on their use compared to therapeutic devices.

Welch Allyn, a leading company in medical technology used in “front line” care provided by primary care providers, launched in 2008 a subsidiary company named Blue Highway that is focused exclusively on innovation. Most of the development occurring in the organization is focused on healthcare, and within that, the company has decided to focus on technologies related to screening, diagnostics and prevention during its first year in existence. As such, consumer-level medical technology is clearly an area of interest by Blue Highway, according to Al Di Rienzo, president and CEO.

Like others in the medical technology market, Di Rienzo sees a major trend toward convergence between professional and consumer products, and that a major focus of Blue Highway is on preventive medicine. One concept the organization is pursuing is for technologies, whether used in an acute care, physician’s office, home or other setting, which can anticipate a catastrophic event, such as an abdominal aortic aneurysm (AAA), heart attack or respiratory failure, before it occurs.



Di Rienzo reports Welch Allyn has a chip technology that would allow a patient with an unidentified respiratory infection to spit into a vial and in less than 10 minutes be able to determine in their physician’s office whether they have influenza A, influenza B, mononucleosis or a strep infection. All four conditions present themselves in similar ways, and the test would give physicians and patients important information about which course of treatment to take. Similar technology is likely to become more common in the future in both physician’s offices as well as the home. Billions of dollars worth of home diagnostic kits are already sold every year for infertility, hepatitis, HIV, drugs of abuse, fecal occult testing, high cholesterol and other applications. While most of the kits currently require that patients mail their sample to a testing facility, future technologies are anticipated to be able to provide results much faster without having to mail off a sample. The market potential for such products is profound, especially when combined with genetic profiling and personalized medicine, but it raises a host of ethical, regulatory, clinical, technical, and reimbursement questions.

In September 2008, the Mayo Clinic Neural Engineering Laboratory reported that it was developing a wireless instantaneous neurotransmitter concentration sensor (WINCS) which could be surgically implanted in the brain to provide real-time measurement of critical neurochemicals, such as serotonin, dopamine and glutamate. Researchers are currently investigating how such sensors might allow for better placement of deep brain

stimulation electrodes, but the potential is clear for such devices when decades from now people with neurological and/or psychological conditions might be able to monitor their neurotransmitters in the same way that diabetics monitor their blood glucose scores, and to adjust their own treatment accordingly.

### **Remote Patient Monitoring**

Remote patient monitoring (RPM) is a branch of telemedicine that focuses on providing home healthcare to patients with chronic diseases. With the use of technology, patients can play a more central role in managing their conditions. RPM provides a remote interface that collects and transmits regular patient monitoring data between a home-based patient and the remotely located care provider.

RPM technology offers a strong value proposition for patients, providers, and physicians. It holds the potential to deliver improved quality of care to patients, to reduce costs associated with avoidable emergency room (ER) visits, and to help manage a host of chronic diseases by providing timely intervention and care.

The market for RPM is in its infancy. At present, there are 8 to 12 established players in the market. However, there are at least 35 to 40 new entrants with innovative solutions or technologies under development. By 2010, total revenues for the remote patient monitoring devices market are forecasted to reach \$260 million at the compound annual growth rate (CAGR) of 25 percent from 2004 to 2010.

In 2001, Philips launched the Motiva system which is a TV-based platform for remote patient management. The system does vital signs monitoring, and also serves as a communication platform between patients and care providers to help patients manage their lifestyle habits, nutrition, and self-care. Paul Bromberg is the senior vice president and general manager of the Senior Living Solutions group at Philips Healthcare which is a group focused on offering solutions to the residents of senior living communities and assisted living facilities to help improve their health and wellness. Bromberg states the Motiva is currently being tested in a number of focused pilot programs. The major challenge facing the Motiva, and remote monitoring in general, is finding payors willing to reimburse for the technology and related services. The same challenge could be expected for other types of revolutionary medical technologies which change how patients care for themselves.

“One of the greatest challenges in the remote monitoring market is determining the business or payor model. I think the technology has more or less proven itself, in different application areas, but because the health care environment is so complicated it significantly slows down the adoption of the technology,” Bromberg states. “The whole medical world is so focused on curative treatment. Anything that comes closer to prevention does not fit that model, and has a hard time penetrating the payer world.”

## Tests and Treatments for Chronic Conditions

Patients with chronic diseases and conditions are the top targets for most companies moving into the convergence zone between professional and consumer medical devices, and for good reason. According to the organization Partnership for Solutions, in 2000, more than 125 million Americans had chronic health conditions, such as cardiovascular disease, diabetes, asthma, and Parkinson's disease, and the care of these patients generated direct costs of \$510 billion. This number is expected to grow to 157 million people by 2020 with \$1.07 trillion in direct costs.<sup>3</sup> Approximately 80 percent of all healthcare spending will be on this population. Providing technologies that will allow patients with chronic conditions to manage their own care is a major opportunity for medical device companies according to David Nexon, senior executive vice president of the medical industry technology trade group AdvaMed. He also reports that remote monitoring, molecular diagnostics and lab-on-a-chip technologies are all areas of significant potential for the future of medicine and how patients will manage their own care. A list of the chronic conditions of greatest interest to both industry and the healthcare community is provided in Figure 5.

### Figure 5 - What is a Chronic Condition?

***A condition that lasts more than one year, limits a patient's abilities and requires ongoing care.***

- Cardiovascular disease
- Diabetes
- Arthritis
- End-stage renal disease (ESRD)
- Chronic obstructive pulmonary disease (COPD)
- Osteoporosis
- Hypertension
- Some types of cancers
- Asthma
- Neurodegenerative disorders (Alzheimer's, Parkinson's, etc.)
- Chronic pain
- Sleep apnea
- Stroke and other brain injuries

Source: Frost & Sullivan

"Caring for individuals with chronic health conditions will be the public health challenge of the 21st Century," according to Gerard Anderson, PhD, at the Johns Hopkins Bloomberg School of Public Health. Much of the increase in these costs is due to advances in medical practices and technology which often turn an acute condition into a chronic one. For example, since 1980 there has been a greater than 40 percent drop in mortality from coronary heart disease since, but more people are living with deleterious effects of these acute events. The same is true for patients surviving cancer, stroke, premature birth, renal failure, trauma and other conditions.

A chronic disease is defined by the fact that a patient lives with it for a long time, therefore the management of the disease requires more involvement by patients and their families,

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3. Gerard F. Anderson, Ph.D. "Better Lives for People with Chronic Conditions" presentation, Partnership for Solutions, [www.partnershipforsolutions.com](http://www.partnershipforsolutions.com)

including the evaluation and use of medical products related to their care. Because patients with chronic conditions are likely to rely on their medical devices for such a long time and entrust them with their health, patients hold the potential to develop a strong relationship with the manufacturers of the devices they use. For example, users of insulin pumps are noted for their strong brand loyalty to particular pump manufacturers because these companies are renowned for their attentive and personalized service that includes patient education, insurance processing, and product delivery. Medical device companies that already serve patient populations suffering from chronic conditions should recognize that the number of these patients is on the rise, and that their long-term needs for medical technology will provide an ideal opportunity for building consumer relationships.

### **Products Focused on Wellness, Nutrition and Weight Loss**

With almost 2/3 of American adults now overweight and obesity classified by the American Heart Association as the second leading cause of death, the healthcare community, government entities, industry and consumers themselves are increasingly interested in new technologies related to

For example, sensors that could capture metabolic information on calories and fat consumed by an individual and calories burned could give a person real-time information on how they are tracking toward a diet.

weight loss and nutrition. A number of medical technology companies have pointed with admiration to the recent launch of the Nike + iPod Sport Kit which uses a sensor implanted in a Nike running shoe to capture and transmit information on the wearer's progress during their run to their iPod. The system is designed to motivate runners during exercise and give them information upon completion of their run to track their performance. Medical technology manufacturers believe similar sensor and data feedback solutions could be used to motivate consumers to adopt other healthy behaviors as well. For example, sensors that could capture metabolic information on calories and fat consumed by an individual and calories burned could give a person real-time information on how they are tracking toward a diet.

While the United States healthcare system does not have as strong an emphasis on preventive medicine as other Western countries, many manufacturers are counting on a slow revolution toward a healthcare model that is focused more on maintaining wellness and managing chronic conditions as opposed to a more reactive approach focused on acute interventions. David Lawson, the associate director of global health care at Proctor & Gamble, envisions a "wellness monitoring" device akin to the warning lights on a car dashboard which are early indicators of the vehicle's general functional status. Such a device would help patients to quantitatively know how well they are and their current predisposition toward future illnesses, as opposed to most consumer devices which already presume an existing health condition. Lawson sees significant opportunity in technologies that would give consumers information to know definitively how well they are from one day to the next, and what steps to take to avoid illness and track their progress toward health goals.

## Technologies and Services to Improve Adherence and Compliance

For some of the most serious health conditions, such as diabetes, high cholesterol, and hypertension, about half of adult patients stop taking their medications after 18 months. Poor adherence is estimated to cause approximately 125,000 deaths annually and account for 10 to 25 percent of hospital and nursing home admissions in the United States. Depending on the technology, non-adherence for medical devices used by consumers can be just as much a problem as with medication. As an example, one would anticipate that the aging population would be a boon to the hearing aid market, but the number of actual new customers for the devices has remained fairly flat for years despite significant advances in the size and functionality of the instruments. Many people who could expect significant benefits from hearing aids refuse to use them because they make them “feel old” despite the fact that new designs can be hidden nearly entirely in the ear canal.

Di Rienzo sees a major trend toward convergence. He also believes that a major challenge in the consumer medical technology market is motivating consumers to change old behaviors. “What is it that stops people from smoking, from abusing alcohol, from abusing drugs, from putting on their seat belt, to stop eating fast food and drinking down a bunch of sodas? People don’t change their behaviors. What incentivizes them a lot of times is the catastrophic thing that all of a sudden motivates them, but then that motivation is temporary,” Di Rienzo states. He believes that different people are motivated in different ways, and that motivation and a willingness to adhere to healthy behaviors often has little to do with educational levels, demographics or other easily identified variables.

One of the biggest barriers to improving adherence rates to treatment programs is the current disconnect between patients and their doctors. When approximately 90 million Americans are considered “health illiterate” and physicians do not have adequate time to educate and motivate patients who are already reluctant to talk about their health problems, how can we truly expect adherence to improve? It is here that that industry needs to step in and help to bridge the gap with technology that improves the clinician-patient relationship. A 2007 Consumer Reports survey found that 59 percent of physicians said their chief complaint about their patients was that they were non-compliant with their therapies, even though most patients said they always followed their doctor’s advice. A third of patients said doctors never discussed the side effects of drugs, and two-thirds never brought up the costs of treatments or tests. Despite many physicians’ complaints that pharmaceutical and device companies unduly influence patient preferences for their products, physicians clearly need more help in adequately communicating with their patients and working to maintain therapy adherence.



The company Zume Life is planning to launch in 2009 their Zuri system, an electronic device shaped similar to an iPod which sends messages to patients reminding them to take their medication, tracks reported compliance and allows physicians to track the patient's medication usage history. While the device is expected to list for approximately \$200, users would also be expected pay an additional \$40 to \$50 per month for access to Web-based services to manage their medication schedules and tap into other software applications. The primary target of the Zuri and other medication reminder systems like it are patients with chronic diseases requiring complex medication regimens. Microsoft and Intel are also exploring the "self-care" market. Intel's Digital Health Group is planning to launch in late 2008 or 2009 the Intel Health Guide.

Bromberg also sees significant potential for technologies that help improve patient adherence to their care programs. Philips Lifeline offers a telephone-based medical alert subscription service Cor"PERs"(Personal Emergency Response Solution) which also offers reminders for the subscribers to take their medication. Philips Lifeline also sells a dedicated medication compliance solution (MD2) which includes a monitored medication dispenser. The current medication compliance solutions are focused mostly on reminding the patient and dispensing the medication. Future solutions may include other parts of the medication "chain", such as physicians and pharmacists. These products are just one of many in the growing market for consumer adherence technologies and services. Bromberg notes that while these types of adherence devices are currently focused on changing very specific patient behaviors, that over time he expects similar technologies in the consumer medical device sector to expand beyond simply the patient to change the complete healthcare value chain.

### **Quality of Life and Pain Management**

The current population of older Americans has more disposable income than any other previous generation and is willing to spend it on products which improve comfort, save time, make them more attractive and provide a sense of well being, even if there is no additional clinical benefit provided. Compared to past generations, current patients have a much higher standard for what level of emotional and psychosocial benefits they expect to gain from the treatment of their health conditions. This places greater responsibility on clinicians for delivering more compassionate and personalized care, but it also provides medical device companies opportunities to market their products to patients based on more than simply clinical benefits and technological features.

In addition, while many insurers remain hesitant to reimburse for products whose benefits they deem to be unnecessary, patients may disagree and wish to assume financial responsibility for the products because they see value in them. The benefits of these products most commonly fall in the areas of improved aesthetics, decreased pain, more favorable designs, greater freedom for the patient, or other factors that are more subjective and indirectly related to treating the underlying condition.

## **CHALLENGES FACING CONVERGENCE**

Despite the opportunity, when attempting to bridge the professional and consumer medical devices markets, many manufacturers encounter significant challenges because of the need to think about product development in a different way.

### **Identifying Unmet Needs and Understanding Consumer Psychology**

Clinicians and consumers both generally agree that the most important elements to a new medical technology are functionality and ease-of-use; however, they can approach the same product from different perspectives and with different expectations. While clinicians are apt to see medical technology from a strictly utilitarian view as a tool of the trade, patients are inclined to see the technology as an expression of who they are and their prospects for the future. When manufacturers move from the highly-technical realm of professional sales to the more deeply psychological realm of consumer sales, understanding consumer behavior and the full context of the user experience becomes that much more important. Manufacturers targeting the consumer medical space note that when developing products and their associated business models, market segmentation is crucial. Whereas in the professional market manufacturers might assume potential customers have more homogenous needs, practices and attitudes, consumers are often significantly more diverse. Segmentation is necessary in order to isolate populations that have unmet needs which can be targeted with new products and services. Figure 6 list some of the most common ways that manufacturers are currently segmented in the market for consumer medical technologies. Figure 7 describes a basic approach to market segmentation.

### **Achieving Adequate Reimbursement and/or Payment**

Receiving adequate reimbursement for consumer medical technology continues to remain a significant barrier to the adoption of new technologies in the space. Nexon points out that to receive reimbursement for a medical device, most insurers require a doctor's order first. Therefore, consumers wishing to adopt new technology without their doctor's permission will have to assume more financial responsibility for the purchase themselves. While more and more medical device companies are looking to the potential of remote patient monitoring, Nexon notes that the United States' current reimbursement models have not adapted to this new care paradigm, often reimbursing for the cost of the device but not for the additional time spent by physicians with those patients or the revenues they lose from fewer office visits. In addition, many consumer medical devices reimbursed by the Centers for Medicare & Medicaid Services (CMS) would be classified as durable medical equipment (DME,) and this product category has been targeted by Congress for years as a candidate for required competitive bidding which could significantly drive down prices across the entire category, squeeze out premium products and stifle innovation.

When faced with the prospect of not receiving reimbursement coverage for their technology, many manufacturers targeting the consumer market simply anticipate they will be able to build a business model around out-of-pocket payments from patients; however, that strategy alone does not work well for all products. “The penetration potential [for devices that are paid for out-of-pocket] is significantly lower because ultimately the consumers basically expect either the government or the insurance company to pay for it. Many of them are just simply not prepared to spend. We believe there is a greater opportunity once they experience some of the benefits and then would transition to paying for it themselves. One of the areas where we are having success is in the post-discharge monitoring market,” Bromberg states.

**Figure 6 - Valuable Ways to Segment the Market**  
**Segment a market using one or more variables to focus on customers with the greatest unmet needs and highest potential for ROI**

- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>• Demographics and psychographics</li> <li>• Pathology, indications, diagnoses and symptoms</li> <li>• Product preferences and usage patterns</li> <li>• Care settings</li> <li>• Distribution channel</li> <li>• Therapy progression</li> <li>• Reimbursement method</li> <li>• Price sensitivity</li> <li>• Patient income</li> </ul> | <ul style="list-style-type: none"> <li>• Regimens</li> <li>• Activity level</li> <li>• Insurance status</li> <li>• Source of business</li> <li>• Payment method</li> <li>• Treatment/ utilization</li> <li>• Compliance/ adherence/ degree of motivation</li> <li>• Referral patterns</li> <li>• Others....</li> </ul> |
|--|--|

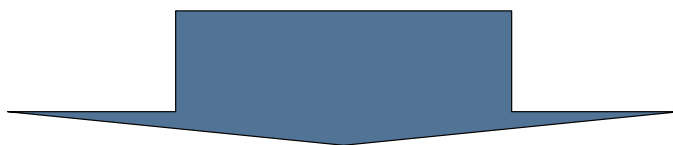
Source: Frost & Sullivan

**Figure 7 - Market Segmentation Process**

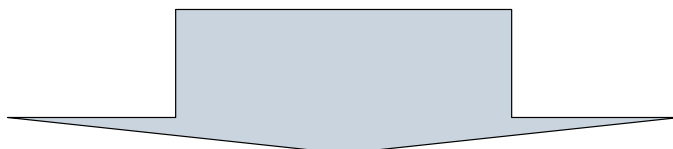
1) Identify Unmet Customer Need Sets



2) Determine How Current or Future Product Could Meet the Needs



3) Group and Describe Customers Having Similar Need Sets



4) Select Those Customer Segments Where the Current or Future Product Could Deliver the Greatest Net Value

Source: Frost & Sullivan

Frost & Sullivan

In this scenario, patients immediately leaving the hospital are remotely monitored from home for the first 30 to 60 days, and that service is covered by insurance. During that time, patients, family, clinicians and payors can see the benefits associated with the technology. When the insurance coverage period for the technology expires, patients and their families are more willing to take on the costs themselves since they have already seen the benefits. This strategy has worked well for other medical device products very different from remote monitoring technologies. According to Marcus Schabacker, senior vice president and chief scientific officer at ConvaTec, the company works very closely to educate patients undergoing ostomy surgery as they transition from the hospital back to home. The result is a very close relationship that patients build with ConvaTec as their supplier of ostomy supplies, ensuring loyalty from patients who are likely to be maintaining their ostomies for years and decades to come.

“The penetration potential [for devices that are paid for out-of-pocket] is significantly lower because ultimately the consumers basically expect either the government or the insurance company to pay for it.”

Rob Schneider, the general manager of marketing at Omron Healthcare, laments how reimbursement cuts by payors for particular medical technologies, tests and therapies can stall innovation as manufacturers reduce their research in those segments because margins become too slim to justify investment. Schneider indicates that this trend has recently played out in the home nebulizer and respiratory segment causing many of these same manufacturers to redirect their research into new areas, particularly the diagnosis and treatment of sleep disorders.

Yet, Schneider states that sometimes lack of reimbursement can be a blessing. “Home blood pressure monitors are not reimbursed today, but there are some proponents out there that are really trying to drive it to be reimbursed. We are not so sure that that is the best way to go, because what we have seen in some of the other industries is that once a device is reimbursed, that reimbursement amount can then get cut and cut, and then the innovation starts to leave the product category,” Schneider states.

### **Negotiating Regulatory Hurdles**

The U.S. Food and Drug Administration (FDA) regulates both professional and consumer health products. For consumer goods companies that lack experience negotiating the often complex FDA pathway for new devices, a lack of regulatory experience can be a major barrier to entering new markets. The regulatory requirements that products must meet vary based on the device as well as the intended user and use setting. The FDA has also been reportedly adding additional requirements to self-care devices out of a concern that patients might misdiagnose or hurt themselves. In addition, home HIV testing kits and other home diagnostics now available have caused the agency to consider the appropriateness of allowing patients to test themselves without associated counseling at the time they receive the results.

Di Rienzo also believes that regulatory bodies are expected to broaden their coverage across new technology and product areas in the coming future, which will have significant

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implications for medical device manufacturers looking for opportunities in new sectors, such as the consumer market, where regulation has historically been lower than for professional healthcare products. “I sit on the National Biodefense Science Board for the U.S. government and I work very closely with CDRH and CMS and I can tell you that things that aren’t being regulated today are planned to be regulated in the future... eventually you are going to see things like Electronic Medical Records (EMR) and some of these other consumer devices falling under regulatory screening,” Di Rienzo states.

As one of the world’s leading medical technology companies, Medtronic is at the edge of new advances in devices used by consumers, in particular continuous blood glucose monitors, insulin pumps and automated external defibrillators (AEDs.) The company is also the leading manufacturer of neurostimulators for chronic pain and other neurological conditions. While they are highly-sophisticated surgical implants, these neurostimulators are increasingly being designed to allow patients to adjust the range of stimulation they receive to better meet their pain management needs.

Alpert points out that taking a medical device into the home environment raises a number of important regulatory challenges since the FDA considers the threshold for acceptable risk to be different than in a healthcare facility. The agency is more risk tolerant when considering a new device for use in a controlled environment by highly-trained professionals compared to a device used by a layperson outside of a hospital’s walls. Before granting approval to devices used in the home, Alpert notes that the FDA wants to clearly understand how the device will be used in the real world and how the manufacturer intends to study the use of that device in that setting to demonstrate safety and efficacy. In addition, the FDA looks closely at the societal and individual benefit versus risk ratio.

In many cases, such as with public access AEDs, features need to be added or removed to make the device safe for use by untrained individuals. For example, many AEDs for public use automatically diagnose for arrhythmia on their own and will only allow a shock to be delivered if one is found thereby removing the human using the device from both the diagnostic and shock administration process.

Lawson notes all of P&G’s medical products are regulated by the FDA and that at-home disease monitoring has become a “hot area” of interest by the government agency because it believes the data derived from such devices still needs to be put in context by trained clinicians. “Proctor & Gamble spends a great deal of money ensuring label compliance is correct when it is involved in switching drugs from prescription to OTC status. The challenge in the process is to ensure that the OTC labeling used will allow consumers of all different backgrounds to safely and accurately self-diagnosis and self-treat with the product. The challenges are similar with devices used by consumers. A manufacturer needs to make



sure a patient understands their condition, they can safely self-diagnose, and if they misinterpret the results, that the implications are not severe,” Lawson states.

While Lawson believes the FDA will continue its vigilance as it relates to the regulation of devices targeting specific disease-states, its jurisdiction does not apply in the same way to devices targeting lifestyle improvements and wellness.

### **Overcoming Resistance from Clinicians**

Physicians, nurses and other health care providers are trained to be cautious in their adoption of new technologies and practices of care and to base their decision on clinical evidence and doing the least potential harm to their patients. Manufacturers already in the professional medical technology market are aware of how to manage

“Suppose we have a technology that allows everybody to check their cholesterol at home. Does it make any difference?”

these types of customers, but their aversion to risk also influences the consumer medical technology market as well. Many clinicians are concerned about the impact of new consumer technologies that will distance them in any way from their patients out of fear that a patient’s clinical needs will be neglected. Concerns over loss of compensation are an issue as well. Health care professionals are also insistent that new technologies in the consumer market actually be able to deliver outcomes or information that will improve the standard of care.

“Suppose we have a technology that allows everybody to check their cholesterol at home. Does it make any difference? Another question in terms of putting things over the counter is how is that information to be used and is there a value in having the information?” Alpert states.

Physicians may also be skeptical of technologies consumers use outside of their visibility and control. Di Rienzo states that in his experience working with primary care physicians, they almost always rerun a pregnancy test with their patients who are reporting that they are pregnant. Doctors see home pregnancy tests as screeners and not a diagnostic, and cannot trust their clinical decision making on a test that the patient herself has conducted at home. This lack of trust that physicians have in the results of tests conducted by patients themselves contributes to inefficiencies and added costs in the healthcare system. Di Rienzo states there is a real need for technologies in the home to provide real clinical value that both patients and clinicians can use for better understanding disease states themselves and what diagnostic indicators are the most accurate, relevant and actionable.

Van Nyhuis anticipates the day soon when low-cost, palm-sized ultrasound systems will be available to consumers for purchase or lease whether for tracking fetal development or other applications. He points out that stethoscopes and sphygmomanometers were once exclusive used by clinicians, but patients can now easily buy inexpensive consumer versions in an average drugstore.

Van Nyhuis is quick to point out that while there might be market demand for home ultrasound, there is a significant debate occurring among clinicians and regulators about what types of tests and treatments patients should be allowed to do independently from the established healthcare system. The motivations are due in part to a fear of losing potential revenue and an increase in liability, but they are also driven by real clinical and ethical concerns. While clinicians are by nature conservative in terms of adopting new technologies, tests and treatment methods, patients themselves are much more willing to experiment with new approaches to caring for their health problems, especially when conventional approaches have proven ineffective. Legally, regulators, payors and clinicians have little recourse to prevent patients from using whatever products they are able to obtain on their own bodies.

“The medical device manufacturers as well as the medical schools don’t get into human factors to the degree we should. Probably 40 percent of the medical errors are human factors related. So work flows need to be different and devices need to be designed correctly.”

### **Overcoming Resistance from Patients**

The greatest patient-related challenges facing manufacturers is the ability to effectively identify unmet needs and to then design a product and associated business model that will ensure a high rate of adherence of use for their device. In addition, recent estimates are that approximately 90 million Americans are “health illiterate,” and the problem is especially acute among older consumers. Health literacy is the ability of a patient to understand instructions provided to them by clinicians, manufacturers or other information sources about their health condition, medical terminology, and how to care for themselves.

Another challenge to marketing consumer medical devices is that, if the device is optional in nature, patients might not want to use it because it will remind them of their disease state which can elicit negative feelings. Similarly, many patients may show resistance to any device that monitors them or tracks their adherence to certain care programs because they might feel it violates their privacy and autonomy. This affective, emotional nature of the relationship between the patient and the technology is significantly more pronounced with consumer users compared to professional users. Patients with an illness, particularly a chronic one, want simple solutions that provide them with feelings of freedom, vitality, control, normalcy and hope.

In addition, Di Rienzo believes that addressing human factors that relate to poor outcomes, errors and inefficiencies represent a major opportunity for improvement in healthcare. He notes that until recently, most medical devices companies paid insignificant attention to the discipline of human factors, but that that is changing. “The medical device manufacturers as well as the medical schools don’t get into human factors to the degree we should. Probably 40 percent of the medical errors are human factors related. So work flows need to be different and devices need to be designed correctly,” Di Rienzo states. This focus on human factors can apply both toward patients and healthcare professionals.

## SUCCESS STRATEGIES FOR TAPPING THE CONSUMER MEDICAL TECHNOLOGY SECTOR

### Develop a Deep Understanding of Patient and Clinician Needs Across the Continuum of Care

Because of the intimate nature of ostomy management and the fact that customers are often customers for life, ConvaTec works extremely closely with its customers in developing new products. In addition to regularly gathering feedback from advocacy groups, the company also conducts one-on-one interviews, focus groups and surveys with customers and the healthcare professionals who care for them. Marcus Schabacker, senior vice president and chief scientific officer at ConvaTec, notes the research approach they take with consumers is less scientific and technical than with physicians and is focused on understanding what the patient needs to feel as normal as possible. While clinicians are typically interested in clinical and technical data, ostomy patients generally have more practical concerns. “The patient is asking themselves ‘If I put this device on, am I going to have a leak? How often do I need to change this? Is it going to hurt? Can somebody smell it? Can somebody see it?’ This is a totally different perspective that the surgeon probably is not even aware of that is a problem to the patient,” Schabacker states.



### Focus on a Clear Unmet Need with a Simple-to-Use Solution

Freedom Meditech is a development stage medical device company working to develop a non-invasive ocular glucose measurement device that would free diabetics from the need for current finger-prick testing. The product is designed to operate like a pair of binoculars that shine light on the eyes and displays a glucose reading. Craig Misrach, president and CEO, states the motivation for developing the technology was rooted in the fact that diabetics do not like the pain and inconvenience associated with finger prick testing, which causes the vast majority of diabetics to avoid testing their blood sugar as regularly as they should contributing to associated complications. Misrach also describes the device as a potential future platform for measuring other analytes and detecting and monitoring other diseases of the body that manifest throughout the eye.

Misrach notes that the current design of their device does not have the same disposable revenue streams that conventional blood glucose meters do with their strips. In order to make up for that loss, the company has been considering other business models where a user might connect the device to the Internet pay a fee to “recharge” the device for a period of time or number of uses. Misrach notes that while the idea of adopting an iTunes-style strategy like this one is appealing, challenges exist related to data privacy and reimbursement. “The Internet is absolutely important in order to try to create ease-of-use for the consumer. We think there is a lot of opportunity in data management and the Internet with healthcare,” Misrach states.

“At Freedom Meditech we are interested in hearing about behavioral characteristics of the consumer that the consumer may not recognize themselves. Many times you will hear consumers say ‘I will use that or I will do that,’ but then when push comes to shove, they won’t do what they said they would do, because they are behaviorally disposed to doing something else,” Misrach states.

Misrach affirms that simplicity is often the key to getting patients to adopt new devices because it promotes use by the patient. “As more bells and whistles are added to technologies they sometimes become more advanced than what the market is ready for. Manufacturers should focus on what exactly is going to increase the use by the individual, especially for screening and diagnostic devices. That is integral to continue health maintenance.”

“So I think it is very useful to work with agencies who are used to researching consumers and can help you interpret that kind of input.”

### **Exploit Synergies and Co-Promotion Opportunities**

Being one of the world’s largest consumer goods conglomerates, Proctor & Gamble has significant opportunities for product synergy and co-promotion in the consumer medical devices space. Lawson notes as an example that the company might launch a home cholesterol test that prompts people to take the company’s Metamucil fiber supplement to reduce their cholesterol levels. He notes that opportunities targeting weight loss and improving adherence/ compliance with consumers are also of great interest. “Everyone has a bathroom scale in their homes, but we are all still obese. So, will people really do anything about their health conditions with the extra information they are getting from these devices?”

### **Enter Joint Partnerships with Complementary Companies**

In 2007, Proctor & Gamble and Inverness Medical Innovations formed a company named SPD Swiss Precision Diagnostics as a joint venture to develop, manufacture and market rapid at-home diagnostic products in fields other than cardiology, diabetes and oral care. The company is now the leading provider of home pregnancy tests and fertility/ovulation monitoring products in the world. Proctor & Gamble’s acquisition of Gillette in 2005 is also causing the company to look at new product categories in the healthcare space which might have a similar “razor/ razor blade” business model generating consumable revenue streams, such as test strips or sensors. Lawson notes that partnerships like the one between P&G and Inverness are an excellent way for companies to make a quick entry into the market for consumer medical technology.

“I think it might be a little bit more difficult for the consumer company to drive into the medical space because I think there is potentially more infrastructure that is required. So, at least at first glance, I probably recommend a partner...[consumer companies] are better off initially partnering with [medical device companies] if they want to bring true clinical relevance or they [had] better be prepared to spend a heck of a lot of money and hire a lot of talented folks,” Di Rienzo states.

## **Bring in Outside Expertise in Product Development Focused on Consumer Medical Technology**

Even leading medical device and consumer products companies dominating their current markets recognize that a move into the convergence zone of professional and consumer medical technology poses new challenges to how they conduct market research and develop new products. Many of these companies have found value in working with outside firms that focus on consumer research, in the case of medical device companies, or on the professional healthcare market, in the case of consumer companies.

“[Convatec is] very used to talking to health care professionals, but we are not so good in listening to the patients. So I think it is very useful to work with agencies who are used to researching consumers and can help you interpret that kind of input,” Schabacker states.

Sagentia, the technology innovation and IP development consultancy company, has particularly strong experience in both consumer products and medical devices, including remote monitoring in cardiology - having developed the CES award-winning Housecall Plus™ monitoring system for implanted cardioverter defibrillators (ICD) with St. Jude Medical – a technology that is used by consumers in their home environment. In the consumer space, Sagentia has also developed consumer products such as Boardbug, the multi-functional mobile child monitor that won the CES Innovations Design and Engineering Award.

Because of this dual customer constituency, the company has found itself at the forefront of the trend toward convergence in the medical devices and consumer products sector. The company works with both constituents on identifying technologies that meet the needs of their customers, providing Sagentia with truly unique cross-over insights.

“Our clients in the medical-consumer convergence space are looking for guidance in bridging the gap between consumer aspirations and real technology. We are uniquely positioned to integrate the skills traditionally found within consumer goods marketing departments and medical device R&D groups. For example, our ethnography [consumer research] teams are made up of the PhD technologists who will later find themselves creating product concepts. This is key – that innovation be integrated at the level of the individual as well as the team,” states Dan Edwards, Vice President Innovation Healthcare at Sagentia.

## CASE STUDIES

Frost & Sullivan has identified a number of companies that are making major headways in the consumer medical technology market.

### Philips – Long-Term Positioning for the Consumer Medical Technology Market

Because of its presence in both the professional healthcare and consumer goods markets, Philips has been taking steps since 2004 to become a major leader in the field of consumer medical devices. The company has been committed to the goal for years, but the capstone to its strategy was its acquisition of Respironics in 2008. Respironics has provided Philips with not only a deep product line of diagnostic and treatment products for respiratory and sleep conditions in high growth markets, but, more importantly, a solid distribution channel into the home health marketplace for future products and services. Philips has one of the strongest positions of any company to make remote patient monitoring a widespread reality in the U.S. healthcare system. As part of its move to become a leader in the consumer healthcare market, the company also acquired the medical alert emergency response service companies Lifeline in 2006 and Health Watch in 2007. Raytel Cardiac Services, a provider of home cardiac monitoring services, was also acquired in 2007 and added to Philips Home Healthcare Solutions group.

Philips boasts one of the broadest portfolios of medical technologies and services targeting both consumers and healthcare professionals. When these medical technologies are considered alongside Philips' other product offerings in computers, audio/visual equipment, home appliances, wireless technology and personal care (Norelco razors, Avent breast pumps and bottles, Sonicare toothbrushes, etc.) the company has an enviable position for synergy. The company's healthcare division sells diagnostic imaging equipment, patient monitors, healthcare IT solutions and external defibrillators to professional healthcare clients. Philips markets its HeartStart Home Defibrillator to consumers through this division. The company's consumer products division supports personal care, mother and child care and consumer electronics groups.

One goal of the Senior Living Solutions group at Philips Healthcare is to provide technologies and services that allow seniors to "age in place" with solutions like remote monitoring and self-care products. Bromberg notes that technology like theirs is enabling a larger trend toward healthcare being pushed out of institutional settings into residential settings because of better patient outcomes, improved quality of life and the ability to reduce costs. Home and consumer health technologies have been the hottest areas for acquisitions by Philips in recent years since the company sees growth opportunities thanks to an aging population, rising healthcare costs and a desire among patients to have greater control over their own healthcare. In particular, Bromberg states its strategy in the home and consumer health market will be focused on patients with chronic conditions and leveraging the company's extensive capabilities in remote monitoring.

“We start with the consumer experience and the consumer benefit of a solution that we want to offer. Manufacturers have to be very explicit and clear about the benefit they are offering the end user. At the same time, in this space you also have to consider who all the various influencers are since many of these devices require some form of professional endorsement or recommendation. You need to ask what it would take for a healthcare professional to support and endorse such propositions. Finally, new technology needs to have proven patient outcomes and evidence to support medical claims,” Bromberg states.

Van Nyhuis states that successful products in the consumer medical devices space are both simple and highly-targeted at very specific applications and customers. “A very good example of a medical device successfully entering the consumer industry is Philips’ HeartStart Home Defibrillator. That is extremely sophisticated technology. If you would have said 20 years ago that we are going to sell defibrillators to anybody who wants to buy them, physicians and everybody else would have thought you were crazy. But the device is successful because of its simplicity. You pull this thing off the wall and you push a button and it actually talks to you and tells you exactly what to do and exactly where to put the electrodes. It walks you through the whole thing, so you don’t have to have any medical training whatsoever. A small grade school child could actually use it,” Van Nyhuis states.

## Proctor & Gamble – Focusing on the Consumer Experience

As one of the world's leading consumer goods companies, Proctor & Gamble sees significant potential in new medical technology developed for the consumer market. To date, the company's new product launches and development initiatives have been focused on self-diagnostics and monitoring. Proctor & Gamble's strategy is looking for ways in which they can empower patients, make products easier to use, change lifestyle behaviors or help consumer reach aspirational goals they might have. This focus indicates that there are opportunities for consumer medical devices beyond simply the provision of testing or treatment if the product can provide other benefits in terms of improving the patient environment, safety, reducing clinician or caregiver workloads, reducing costs or improving compliance. Developing an effective customer segmentation strategy early on in the product development process is also fundamental to Proctor & Gamble's approach.

Proctor & Gamble spends a significant amount of time understanding how to provide consumers with a more desirable experience related to their health condition. For example, in a market for at home pregnancy tests where all tests are equally accurate, Proctor & Gamble instead focused on making the experience of testing easier and more desirable. The company developed a test stick with a digital read out that says "Pregnant" or "Not Pregnant" as opposed to the traditional style with one vs. two lit indicators. The change allowed the company to command a premium price for their device. The company currently has a pregnancy test awaiting market launch that would allow women to peel off a printable film on the digital display showing the test results for placement in a baby book. Proctor & Gamble developed the feature after it found women were placing the entire used test stick in baby books, but the stick's contour posed problems for closing the book.

"When we look for opportunities, we want to make sure that we are empowering consumers. The information they receive from our product has to be actionable. For example, P&G would not want to make an at-home test for Alzheimer's disease because a consumer could not do anything with a positive result given current treatment options available. But at-home cholesterol testing would be a good fit because the patient could do something to improve their scores," Lawson explains.

The company also pays special attention to the environment and infrastructure in which the patient is located when using their device. Some very innovative remote monitoring technologies have been limited in their adoption because of poor telecommunications infrastructure in certain portions of the United States. Lawson also notes that as manufacturers become more committed to the consumer medical marketplace, consumers increasingly turn to them for technical, and sometimes clinical, support related to the use of their devices. The line between providing product related support and medical advice can quickly become blurry and pose a threat to the traditional patient-physician relationship. New consumer technology does not always need to pose a threat to physician's revenue streams though if the device can manage to get a patient into a physician's office more often than they would have without the device. A technology might actually give consumers and physicians more information and incentives to take courses of action that can have a net benefit to a physician's bottom line.

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## Empi Recovery Sciences / DJO – Redesigning Products to Match New Treatment Practices

Empi Recovery Sciences is a distributor of electrical stimulation and other orthopedic products used for pain management, rehabilitation, physical therapy, and fitness enhancement. For years the company had been manufacturing its electrical stimulation systems as treatment tools for use by physicians, athletic trainers and physical therapists in clinical settings. The systems were relatively large and complex with lots of features that allowed specially trained clinicians to fine tune treatment programs for patients. Empi began noticing from its feedback from clinicians that electrostimulation therapy was facing significant competition from topical pain patches and other pharmaceutical treatments. The company also found that when the systems were sent home with patients for self-administration that compliance was low because the systems were too complex. Consequently, clinicians often gave up on using electrostimulation on patients in the home and kept it for use in the clinical setting. Yet, clinicians were often unable to support patients with the therapy because the amount of training they had received in their own education related to electrostimulation therapy was on average less than 1/3 of past generations. The perception was that electrostimulation was complex and time consuming because it could not be used outside the clinical setting.

Empi clearly recognized the opportunity for its products outside of the clinical setting, and began a significant redesign of its product line. The company's newest generation of electrostimulation devices features pre-set programs so that busy clinicians and patients do not have to read manuals and receive special training before beginning treatment. Empi also reduced the number of buttons, simplified the user interface and reduced their overall size of the devices. While older electrostimulation system models used multiple electrodes attached by leadwires to a generator box, the new Empi designs are specifically designed for particular anatomical locations. The designs have the electrodes and power source built entirely into a single system and feature no leadwires.

John Velure, senior director of marketing at Empi, states that this product redesign which simplifies the technology has meant that now clinicians are turning to Empi to provide them with the technological and clinical expertise that they lack related to electrostimulation therapy. The responsibility is a significant one, because it positions Empi as a more valued partner in the treatment process. The new site-specific product designs are less flexible in terms of the program settings, but Empi recognized that clinicians and patients were willing to accept this tradeoff for a simpler device. Velure also notes that while Empi's older electrostimulation systems were all unique designs, their new designs, while still being anatomically site-specific, are highly standardized and built around a common technological platform. The result is a more streamlined regulatory process, cost savings and operational efficiencies that allows Empi to get new product designs to the market faster and more in-tune with their customers' needs.

“In the area of pain management, compliance becomes very important. Our patients needed to be able to wear their electrostimulation devices all day. They have to be easy to use and apply. When we developed our products, ease of use and ease of wearing were the top features that we focused on. Our electrostimulation devices needed to be just as simple to use as a transdermal [pain medication] patch – our biggest competition.”

Empi's process for developing its new line of electrostimulation products followed its internal funneling approach toward identifying new ideas and carrying them through every step of development toward commercialization. The process relies on standard voice of the customer (VOC) techniques. The company begins its process with general focus groups with both clinicians and patients to better understand their unmet needs. One-on-one interviews typically follow these focus groups. Empi engineers take the ideas from these sessions and use them to develop product concepts which are then tested in more focus groups and interviews. The feedback on the concepts allows Empi to develop prototypes for those concepts with the most potential for success. Those prototypes are then subjected to a final round of focus groups, interviews and surveys. Patients also have the opportunity to wear the prototype devices and record their experiences in daily journals which are provided back to Empi. “This type of rigorous approach to understanding the needs of patients is new to the medical device industry compared to consumer product companies. Most medical device companies only began adopting voice-of-the customer research in the last 10 years,” Velure states.

Long known for its dominance in the orthopedic braces and supports market, Empi's parent company, DJO, has expanded in recent years to become a full spectrum orthopedics company with one of the broadest product portfolios on the market, from ankle supports and bone stimulators to knee implants and tables for rehabilitation treatment. In its product development process, DJO has historically relied heavily on clinician requirements, but in recent years the company has been incorporating more VOC research practices and getting feedback from patients on product concepts earlier on in the product development cycle, and the results have been very positive to their development initiatives.

Bryti Ketchum, director of marketing, business development and professional relations at DJO points out that while the company continues to remain focused on its core customer base of clinicians, that it recently made its first foray into the consumer market with a recently launched knee brace for pain relief associated with osteoarthritis. The company is positioning the brace with consumers as a first line treatment option for patients and a way for many of them to avoid or delay knee replacement surgery. Ketchum states that while this type of wide-scale patient education is common for pharmaceutical companies with deep budgets, it poses a challenge for most medical device companies which typically operate with smaller budgets to devote toward marketing and advertising. With its relatively low cost and ability to be highly targeted, Ketchum believes the Internet represents a major distribution channel for medical device companies looking to reach consumers.

Launching a knee brace into a consumer marketplace already awash with retail orthopedic softgoods posed a positioning challenge to DJO. “The consumers we are targeting with our knee brace might pick up a different knee brace off the shelf at Wal-Mart, but it might not be what they really need. Educating them on the difference between our device and others already in the market is a challenge,” Ketchum states.

## Omron – Focusing on Wellness and Preventive Medicine

Omron Healthcare is a leading marketer and distributor of medical, home healthcare, and wellness products, including blood pressure monitors, pedometers, thermometers and other devices. The company sells products to healthcare providers as well as consumers themselves. Schneider points out that the United States healthcare system is slowing moving toward more preventive care because of the clinical and economic benefits. Still, the country is behind other Western countries and Japan due in part to cultural attitudes and a more privatized healthcare funding system.

Schneider says his company has found that there are huge variations in the consumer population in terms of education, health needs, compliance rates, income and other variables making segmentation critical for success when launching medical technology into the space. In addition, Omron has also found success in supporting a broad product portfolio with different devices targeting consumers with different healthcare needs, budgets, co-morbidities and educational levels.

Home blood pressure monitoring continues to be one of Omron's largest segments in the consumer market. Physicians have recognized the value in having patients with hypertension monitor their blood pressure on a more regular basis at home to keep closer tabs on their condition. In addition, Schneider points out that research shows that home monitoring can capture a more accurate assessment of a patient's blood pressure since they are in a more natural setting without the effect of "white coat syndrome."

"Consumers, especially if they are of a younger age, don't want [consumer medical devices] looking like a piece of hospital equipment. They want it looking more like a consumer electronics device, so it is not so obvious that the device is a blood pressure monitor or a nebulizer. Some of the designs now are almost like iPod-type designs. It is really important to understand not just the functionality of the product, but also the style and consumer desires around it as well," Schneider states.

Schneider states that ease-of-use and accuracy are the two most important product factors they focus on in the development of their consumer devices. Since most of the devices Omron sells are not critical to sustaining life and more "optional" in nature, the company works to ensure that ease-of-use does not stand in the way of a patient's use of its products. While ease-of-use is clearly an important requirement for consumers when they are selecting a medical device, the factor is important to clinicians as well since it has a direct impact on a patient's compliance with their treatment plan. Simplicity and ease-of-use can also have a direct impact on clinical outcomes as well. Omron and other manufacturers have developed new generations of home nebulizers which are smaller and quieter than older models. These new nebulizer designs are more portable and allow patients to administer their therapy more discretely and with greater freedom which in turn boosts compliance with their drug regimens. In the long run, this improved compliance is able to reduce the number of visits patients will make to their doctor's office or hospital emergency room.

Schneider has found there are significantly different market dynamics for consumer medical devices that are sold with a prescription compared to those that are over-the-counter. Consumers purchasing prescription devices are going to be much more heavily influenced by their physicians, pharmacists and other clinicians. In addition, retailers demand that products stocked on their shelves demonstrate an ability to actually move otherwise they will be dropped quickly.

## CONCLUSION

There is near universal agreement in the medical technology industry that significant market opportunities exist for more advanced medical technologies placed in the hands of consumers. More educated, empowered and affluent consumers are demanding new approaches to dealing with their health conditions. A growing burden of chronic disease, soaring healthcare costs and a shortage of clinicians are further driving the shift toward healthcare consumerism. The technology available to address many of these challenges is already well-developed, but regulatory and reimbursement barriers stand in the way, as well as resistance from the healthcare establishment to adopt new clinical paradigms. To succeed in this market, manufacturers must have a strong understanding of consumer psychology and a commitment to developing products that provide simple, easy-to-use solutions that address unmet needs. Superior product design must also be coupled with a strong business model for payment, distribution and regulatory approval. Few companies currently in the professional medical devices or consumer goods industries possess the complete breadth of knowledge across both sectors to develop and commercialize products in this convergent space all on their own. Companies interested in this space should strongly consider partnerships with other complementary companies. In addition, engaging with outside consulting and research organizations specializing in new product development in this highly specialized convergence area between professional and consumer medical technology can prove highly valuable.

Manufacturers can expect a much more competitive consumer marketplace in the future, both within product categories and across product categories. With an ever widening variety of testing and treatment choices available to consumers, manufacturers will not only need to make a case for why their products are better, but why the particular care pathway which they are a part of is the most beneficial to the patient.

Recommendations for manufacturers entering the consumer medical technologies market include:

- Conduct consumer research early in the product development process and incorporate VOC research into each stage
- Segmentation strategies are even more critical in consumer markets compared to professional clinician markets – segment the market in novel ways. Look for niches where unmet needs are high and patients are motivated and willing to pay.
- Recognize the different needs of consumers compared to clinicians

- Look for opportunities to create stronger ties between consumers and the various clinicians, caregivers and other resources supporting their care
- Develop consumer products and services that can be sold by traditional healthcare providers as new revenue sources
- Keep the design simple and the value proposition focused in order to provide the greatest value to consumers
- Spend time developing the complete business model for the product and not just the product design – Who is going to pay for it? How will it be distributed? etc.
- Plan for product platforms and broader portfolios
- Look outside of the healthcare field for new technologies that can be brought to bear on healthcare challenges
- Incorporate healthcare applications into existing non-healthcare devices, i.e. cell phones, personal care products, clothes, etc.
- Partner with clinicians caring for consumers. Understand the referral patterns and influencers surrounding the consumer.

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