

Owning the disease: A new transformational business model for healthcare

A version of this paper appears in the December edition of In Vivo magazine

By Dr. Christopher L. Wasden,
Global Healthcare Innovation Leader, PwC, and
Brian S. Williams, Global Healthcare,
Director Clients and Markets, PwC

Introduction

The convergence of expanded access, lower reimbursement rates, higher velocity of innovation, diminished pools of venture capital, the advent of personalized care and a growing demand for improved patient outcomes has created ripples that already are altering the economics and operating dynamics of healthcare. These undulations are the precursor to a hurricane that will batter unprepared companies and fundamentally change how healthcare is delivered and evaluated. To survive the coming storm, biomedical companies must build new models of innovation that are anchored in consumer-centric disease solutions rather than the traditional R&D department approaches.

As previously discussed in this publication, these factors already have altered the longtime drivers of medical technology innovation. (See “The Changing Face of Medical Technology Innovation,” *In Vivo*, September 2010.) However, what has been less widely observed is that this same confluence of factors is also forcing a broader transformation of the fundamental business models under which medical technology companies operate.

Most notably, some of the most enterprising medical technology companies are preparing to weather the storm and thrive in the sunshine that follows. These early movers are attempting to secure their organizational and innovation efforts around the concept of “owning the disease” with products, services and solutions across the entire continuum of care. While the number of such companies attempting to own the disease is small and none has fully succeeded to date, their influence is growing. As their efforts advance, they serve as a harbinger of a new, dominant business model for the industry.

A Precedent: Transformation in the Information Technology Industry

The business model concepts underlying owning the disease have their precedents in other technology-based businesses. In fact, they closely mirror those seen in the information technology industry beginning a generation ago. These changes resulted in the industry not only transforming how it developed and introduced product innovations but also effectively compelled it to reinvent its business model, shifting from selling hardware to providing services and solutions.

Like healthcare today, information technology a generation ago was part of a classically maturing market that was about to enter an extended period of disruptive innovation, beginning with the shift in the early 1980s from the production of mainframe computer systems to the development of minicomputers, personal computers and client server applications. By the end of the decade, the big hardware companies found that the industry had become increasingly commoditized, with resultant fierce competition, tightening margins and merely incremental innovation.

The example of IBM is particularly instructive. The company had powerful core assets, such as long-term customer relationships developed by a strong sales force, skills in mainframe computer hardware, software and services, and robust research and development. It leveraged those assets by offering services to business clients, eventually delivering total outsourcing solutions for certain functions. IBM's customer service and client focus helped it protect and grow its state and federal government business, a relevant point for medical technology given that the largest buyers of products and services in healthcare, both in the United States and globally, ultimately are government entities.

Once change was deemed imperative to survival, it was swift, dramatic and highly visible. As Forrester Research Chairman and CEO George F. Colony later said, "IBM is not a technology company, but a company solving business problems using technology."¹

In becoming a solutions provider more than a hardware manufacturer, IBM added value, differentiated itself from its competitors and further strengthened client loyalty. Other companies, most notably Hewlett-Packard, began to follow suit, becoming focused on an idea of being problem solvers rather than technology product vendors and thereby converting themselves to solution providers.

A second transformation began approximately a decade ago, when the information technology industry embraced a broader focus on providing consumer solutions and not just hardware. Among the leaders this time was Apple, an innovative and uniquely ambidextrous hardware and software developer during the 1980s and 1990s but one that had lost its consumer-centric moorings during the latter decade and was threatened with bankruptcy at the time of Steve Jobs' return in 1997.²

This second transformation was away from corporate-oriented desktop hardware to consumer-oriented mobile devices that elegantly integrated hardware and software. These new offerings led to the creation of an entirely new business model based upon interoperable and connected hardware, software and operating system platforms.

The iTunes Store, iPod, iPhone, iPad, the App Store and, now, iCloud brought to the consumer sophisticated and powerful technology solutions—solutions more powerful than those found within corporate information technology departments and which paradoxically are now transforming corporate information technology operations. As Tony Davila, Marc J. Epstein and Robert Shelton explain in *Making Innovation Work: How to Manage It, Measure It, and Profit from It*,³ the Apple products further illustrate how innovation in technology can also drive innovation in business models, as the iPod drove the expansion and development of the iTunes Store.⁴

Apple's experience with the iPod and iTunes Store also demonstrates the distinction between radical innovation that entails advances in both a technology and a business model; breakthrough innovation that makes major changes to one or the other; and incremental innovation that makes smaller the distinctions among these to determine where to concentrate their resources and efforts.⁵

Finally, Apple's rapid innovation demonstrates how innovative companies can, in a matter of just a few years, enter new markets and become powerful disruptors, or, conversely, fall from dominating leader to struggling laggard.

During the past several years, as Apple introduced and then enhanced the iPhone, highly regarded and powerful incumbents such as Nokia, Research in Motion (RIM), Microsoft and Cisco rapidly and quite unexpectedly lost

significant market share. Nokia and RIM missed shifts within their own markets as Apple redefined the mobile smart phone. Both Nokia and RIM saw their devices as phones with some apps, while Apple created a small, mobile, powerful consumer computer where one app was a phone, another a camera and a third a browser, with an open innovation network that developed hundreds of thousands more applications for previously unimagined purposes.

Both Apple and IBM started as product manufacturers and, as their markets matured and evolved, they shifted to become providers of integrated and interoperable solutions instead. Certain other information technology firms, such as Xerox, have made the transition to becoming solutions providers, and this is the path that medical technology companies have begun to explore and must follow.

Healthcare's Shift to Solutions

Driven by a confluence of business and economic factors, strong empirical and anecdotal evidence demonstrates that a change similar to that experienced in the information technology industry is now beginning to take shape in the medical technology industry. Medical technology companies are confronting shifts in their own maturing markets and they are facing challenges on the periphery from new approaches, new technologies and new market entrants.

The dynamic of market maturity, new technologies and new competitors is analogous to the challenges faced in other industries, especially information technology. There are obvious differences, such as the fact that healthcare is a far more heavily regulated and complex industry than information technology was in the 1980s and '90s, and faces even more significant challenges. However, despite their differences, the information technology industry underwent the kind of change now confronting medical technology, an important shift and the key element of the transition to a new paradigm.

For example, in the information technology industry innovation has been driven by the expansion of computing power, storage capacity and communications bandwidth which made possible new features at the same or lower cost. Accordingly, incremental and sustainable innovations no longer generate sizeable income growth but instead are the price of admission to the market and necessary to remain relevant and maintain revenue.

The situation is much the same in medical devices, where institutional payers such as Medicare or private health plans are reluctant to pay more for incremental improvements. The focus on cost and outcomes is also evident in high-deductible health insurance plans where engaged consumers carefully evaluate the benefits of suggested treatments against the cost of such.

Historically, payers regarded innovation as a problem, not a solution, because most innovation in medical technology was defined by increased, not decreased, costs. Now, payers insist that innovation drives costs lower while significantly improving outcomes. The inability of device companies to generate a premium for MRI-compatible pacemakers shows that incremental product innovation does not improve pricing power.

Like information technology companies a generation ago, medical technology companies today are experiencing a decline from the double-digit growth during the past several decades to the low single digits. This decline is the result of market penetration, maturing technologies and increased competition.

In developed countries where consumers drove demand and had the financial capacity to support incidental innovation, the fallout of the financial crisis demonstrated conclusively that governments and consumers have reached the limits of what they can or will pay for new medical technologies.

At the same time, while developing markets represent opportunities for growth, the governments and consumers in those markets cannot afford the same expensive, high-margin products typically offered by both medical device and pharmaceutical companies in developed markets.

Developing markets are forcing medical device companies to create new and different products designed to address the needs of their markets, in some cases “de-featuring” devices to make them simpler, easier to use and less expensive to purchase and operate. In India, for instance, General Electric has developed a hand-held electrocardiogram device with just four control buttons that sells for less than half the price of a full-scale EKG device, yet meets the needs of the local market from the standpoints of both cost and performance. Reverse innovation – adopting innovation first in a developing market and then bringing it to more mature, developed markets – raises new issues for manufacturers who are finding they need to reassess business and operational processes as they adapt and scale faster, better, cheaper, smaller products for worldwide use.

Market maturation has affected both the information and medical technology industries by substantially slowing technical innovation; in one sense, innovation is a victim of each industry's past successes. Current products are frequently so effective that the principle of diminishing returns applies: Each incremental gain in performance, not to mention outcome, costs multiples of earlier gains and as such yields proportionally less.

For instance, a new hip resurfacing technology that cost hundreds of millions of dollars to develop and introduce may be less effective and less lasting than implants that were inserted 20 years ago.⁶ Similarly, coronary stents, which have cost billions of dollars to develop and bring to market, have revolutionized percutaneous coronary interventions (PCI), improving both acute and long-term outcomes. Yet there are questions about whether incremental improvements in stent design have matched or exceeded earlier benefits already realized, as measured by case mortality rates and/or recurrent myocardial infarction. Next-generation technologies may improve these numbers by incremental amounts, perhaps tenths of a percent, but only at great cost and the risk of previously unrecognized complications.

Like information technology firms, medical technology companies in mature markets have been subject to swift market shifts. For instance, the Flip was introduced to acclaim in 2006. Its developer, Pure Digital Technologies, was acquired by Cisco in 2009 for \$590 million. Less than five years later, Cisco shut down the Flip rather than find a buyer because its market had been lost to newly powerful smart phones. Similarly, in medical technology, Johnson & Johnson's Cordis Corporation subsidiary announced that it was terminating its existing line of drug-eluting coronary stents and stopping development of its next-generation stent. Faced with pricing pressures, mounting liabilities and a declining enabling technology, Johnson & Johnson simply decided to exit a multibillion-dollar business because it could no longer compete and neither incumbents nor new entrants wanted to buy it.

The longtime focus on narrow categories of customers is a characteristic of information and medical technology companies alike. As senior EMC executive Chuck Hollis wrote recently, information technology companies too often are divided into specialized technology groups with little integration, connection or focus on the ultimate customer rather than the technology itself.⁷ Instead of focusing on end users, groups often are formed around technologies.

The situation is similar in healthcare, with its traditional concentration of providers by specialty on narrow diagnostic or therapeutic niches and few efforts to integrate or even coordinate care. Medical technology companies, too, have been centered on narrow spheres, and have sought to maximize revenue by increasing the number of procedures using their devices. Medical technology companies, like information technology companies before them, are now being compelled to shift to a more systems-based approach that reflects an integrated professional continuum.

The volume-based, fee-for-service approach to healthcare is being supplanted at the provider level by one that rewards quality and outcomes, a change driven by payers' demand for results and the growing capacity of personalized care being made possible by genomics and similar advances. Medical technology companies, in turn, are facing increased pressure to deliver greater value, generally defined as providing better outcomes at lower cost.

Increasingly, this is a global challenge: Both developed nations, with their aging populations and costly technologies, and emerging nations with fast-growing populations, scarcity of medical professionals and constrained finances, find cost a key variable in care.

Owning the Disease

In response to each of these forces, medical technology companies are changing their focus in three important ways, shifting from selling features to providing solutions; from focusing on silos to a broader systems approach; and from generating profits by increasing volume to winning by delivering greater value. In turn, these strategies are transforming the fundamental business model of medical device manufacturers, resulting in them taking a more comprehensive approach to their business that compels them to seek to “own” the diseases or conditions their products are intended to treat.

Owning the disease should not be confused with disease management, the early iterations of which evolved during the heyday of managed care but which lacked the connectivity and incentives to effectively understand, monitor, influence, and change patient behavior, as well as support care coordination or overcome the cultural divide between payers and providers. Old disease management models were blind, due to a lack of connectivity, and blunt, due to an inability to change patient behavior. Owning the disease, on the other hand, uses interoperable devices, real time integrated data, imbedded intelligence within an engaged social community to support patient behavioral change and improve outcomes.

By owning the disease, themselves, medical technology companies seek to create and make available a complete solutions platform across the entire value chain. In essence, they are focusing not on the episode of care but on the entire patient interaction suite: preventative health and wellness; diagnostics; devices; therapies; post-treatment processes; chronic disease management; and even structures for patient interaction and education. This approach is driven by a realization that companies that provide only a single element – for instance, an insulin pump for diabetic patients – will be confronted with the unfavorable economics and competitive positioning that are characteristic of commodities in mature markets.

Owning the disease can be especially effective for the treatment of patients who participate in more performance-based entities such as accountable care organizations (ACOs) as well as institutions that promote comprehensive approaches. In taking this approach, medical technology companies are delivering value to payers, providers and patients alike by developing, assembling, integrating and delivering the various aspects of care themselves.

In seeking to own the disease, companies need to build a business model that creates a platform capable of providing a total solution, just as Apple provides the iPhone as a

hardware platform, the iOS as an operating system and software platform and the App Store as a commercial platform. In a sector that is confronting many of the same challenges as the information technology industry of the past quarter-century, owning the disease will provide the most competitive path to long-term growth and profits. Medical technology companies that own the disease are moving from being product manufacturers and vendors, which is what IBM and Apple initially were, to becoming solution providers, creating platforms that integrate preventative care, diagnosis, treatment and management.

As IBM did beginning in the early 1990s, medical technology companies will need to leverage their own core assets and technologies, such as deep research and development and long-term customer relationships with government payers, healthcare plans and pharmacy benefit managers. Astute managers will use these capabilities to create new business models and change the incentives and basis for payment in ways that will begin to bend the healthcare cost curve.

Like Apple, medical technology companies need to take advantage of a self-reinforcing business ecosystem that they control. Apple’s three platforms (hardware, software and marketplace) mutually support one another and provide an open innovation environment in which partners can further innovate. Apple, through quality controls, integrated technology and consumer products marketing expertise, assuredly owns its ecosystem. Medical technology companies can pursue the same comprehensive approach to a disease by creating similar platforms that foster open innovation and a vibrant ecosystem.

In healthcare, chronic disease states—such as diabetes, some forms of cancer and, in some countries, AIDS—require active management over a lifetime. In the United States, more than 80 percent of healthcare expenditures relate to such chronic conditions.⁸ In such cases, owning the disease enables a company to provide behavioral, diagnostic and therapeutic solutions on an integrated platform, thereby improving patient outcomes, lowering system costs and capturing the full value of their solutions and innovation.

To date, no one entity owns the disease or has the complete solution by itself. While this is the goal, it is likely that many of those seeking to achieve it will have to create the total solution through various partnerships or alliances. The issue, then, becomes partly one of leadership: whether a company is going to lead the creation of a platform to own the disease or whether it will follow someone else’s leadership.

What Does Owning the Disease Really Mean?

Companies taking the first steps in owning the disease share a number of traits that, together, help to define what ownership of a disease means. Collectively, these characteristics reflect the kinds of transformation that medical technology companies need to undertake and the qualities they need to succeed, whether through internal changes, through M&A or through partnerships and joint ventures.

Expanding scope. At a minimum, owning the disease means moving beyond single-product offerings to providing comprehensive solutions to diseases. This does not simply entail offering more products; rather, it means providing a greater range of services and processes, ensuring they are integrated and providing a means of distributing each to providers and, through them, to patients. Scale will be important in achieving this: As GE Healthcare President John Dineen said during an analysts' call following the announcement of the Clariant acquisition in 2010, "We've got to move from just physiology and radiology into molecular medicine. We want to have the broadest portfolio in the game."⁹

Larger organizations such as GE Healthcare clearly could have a significant advantage when it comes to achieving the scale requisite to owning a disease. They have the risk capital to assemble the parts across the value chain, the resources to support innovation and the ability to take the time needed to ready a solution for market. But, owning the disease creates powerful tensions within these large organizations as an expansion of scope threatens existing power structures within the organization.

This is why we often find startups or small organizations better able to assemble the elements of a total solution on a virtual basis to compete against larger organizations. WellDoc, for example, has created a robust solution to own diabetes through an open approach that integrates payers, providers, telecommunications companies and patients through its mobile healthcare applications. WellDoc has done this in a more comprehensive and disruptive manner than any large diabetes-oriented company has yet been able to master.

Integration and interoperability are essential. For a solution to be comprehensive, it needs to be integrated into the care continuum through interoperable devices, across multiple therapies, in ways that gather robust metrics regarding activities and outcomes. Even for medical technology companies, this integration is only partly about

technology. It is primarily about ensuring that all parts of a solution work in concert with each other and that they fit effectively into the provider's clinical processes and workflow; behaviorally and socially within the patient's lifestyle; and, into payer or employer claims and reimbursement systems.

Integration and interoperability also needs to be across networks and platforms, so as to be accessible to providers or patients using the products or services of multiple developers. Such access is important for patient, provider and payer adoption, and such access is increasingly being done through mobile health technologies.

Fewer players and more categories. As competition increases and consolidation proceeds apace, it is possible that only a single company in each category may truly be able to own the disease, with perhaps one or two significant, viable competitors.

Healthcare providers are consolidating at an unprecedented rate, with more doctors employed in large provider organizations than in private practice. As a result, there will be fewer buyers and fewer providers in each category. The competition will shift from selling to physicians to reaching out to the executives of ACOs, to procurement officers and to chief medical officers. This has very disruptive implications for medical device sales forces. As the purchasing power shifts from individual doctors to larger corporate buyers, sales forces will have to change their go-to-market strategies, marketing and messaging.

While there will be fewer players in any given category, there will be more categories because of the inherent complexity of diseases, their treatments and the delivery mechanisms. This complexity will mean greater difficulty for companies to dominate multiple disease states or broad categories of diseases such as cancer.

Companies will make money differently when they own the disease. The focus on the patient experience in owning the disease will also drive a shifting basis for compensation. Those companies that succeed will find that delivering value becomes the basis of an entirely new business model in which a single company assembles the various parts and then is compensated based upon results, not from selling the component parts of care. Increasingly in the United States, such companies may receive a single payment for delivering a solution that aligns with the focus on quality and accountability that increasingly is an essential part of healthcare reform.

Medtronic is an example of how this ultimately may work in practice. Its CardioVascular division may be compensated not for selling pacemakers but for preserving heartbeats; for providing care in a comprehensive and integrated fashion that results in improved outcomes for patients and payers.

As an example of how this might work for a patient diagnosed with a heart ailment, Medtronic might want to own the first treatment: exercise. Medtronic has already deployed an application that links a patient's primary care physician and cardiologist. When exercise alone is not sufficient to mitigate the patient's condition and treatment becomes necessary, a Medtronic partner can provide medicinal therapy under the Medtronic brand. If a pacemaker is required, it would be produced by Medtronic. If surgery ultimately is indicated, post-operative care and management, including physical therapy, all would be under the Medtronic banner. A recently released, consumer-oriented iPhone app from Medtronic that provides wireless measurement of a patient's pacemaker, with the data then shared with a physician, is a sign of things to come.

As the wireless market evolves, key questions remain about its value as a revenue driver or a differentiator, and the development of appropriate price and performance levels that will deliver a high-quality user experience that stands out in a crowd and engages consumers. We increasingly see medical technology and pharmaceutical companies using connectivity to differentiate their products and services to gain market share, not as a means to increase the price of their products. Connected innovations are becoming the table stakes to remain in the game, not a source of new revenue growth. As these companies drive connected solutions forward, the greatest challenge will be adapting consumerism into the business model. For example, in the past patients had little or no awareness of the brand of their pacemaker. But once a pacemaker company provides an iPhone app, with metrics the patient can see and share with their healthcare providers, then all of a sudden the brand and consumer user experience becomes much more important.

Improving the consumer experience is crucial. When Apple develops each of its various "i" products, it concentrates on trying to deliver what the consumer wants in ways that are simpler, more effective and more elegant by eliminating complexity. In many respects, these products did not, at least initially, offer more than their competitors – but they offered the products and services in ways that were more consumer-friendly by creating a superior user experience. That is why, for instance, the iPhone centers on a single button, rather than the BlackBerry's 44-button

keyboard. Because the consumer is at the center of Apple's world, design thinking is at the center of its innovation efforts, which creates substantially greater engagement on the part of the consumer.

Healthcare is no different. Depending upon the disease state, patient experience will be a crucial factor. Device companies, most of which have virtually no consumer brand awareness and have focused primarily on pleasing physicians, will need to now address patient and consumer needs. In primary care, for example, a strong brand name will become desirable because brand loyalty will become the driving factor. In more complex cases, outcomes – curing or stabilizing the patient – will be most important and the outcomes associated with each step of treatment need to be controlled to capture maximal value.

Radical innovation will become a differentiator. As former Procter & Gamble Chairman and CEO A.G. Lafley wrote, "The heart of a company's business model should be game-changing innovation. This is not just the invention of new products and services, but the ability to systematically convert ideas into new offerings that alter the very context of the business."¹⁰ These radical innovations arise as companies innovate across multiple innovation types (products, services, processes, distribution, etc.), often incrementally, and bring these multiple innovations together as a total innovation solution across a disease platform through a new business model.

Accordingly, there will be fewer market opportunities for merely stand-alone incremental innovations. Payers, as noted earlier, are less likely to reward companies for "me-too" drugs and devices in an era of austerity, and greater competition from new entrants will make it harder to hold market share. Venture capitalists, looking for differentiation, will fund only more substantial or radical innovations, further reducing the return for such commoditized products.

Focused and open innovation structures and processes will be crucial enablers for companies as they seek to fill specific gaps within the value chain. The most valuable form of innovation will not be technical but instead be in business models, as companies seek to transform themselves to become more competitive and more profitable with business models that enable them to own the disease. Oftentimes, this is something that larger companies are better positioned to develop and implement, if they can overcome the organizational inertia associated with their existing business model.

These pressures will have an impact on how innovation occurs. Once, innovation may have been the result of serendipity, happy accidents in laboratories. The pace of innovation no longer allows companies the luxury of waiting for lightning to strike. Companies must create enterprise innovation structures and practices that drive innovation into the DNA of their organizations and accelerate and increase the probability of serendipity.

Yet putting the structures in place to accelerate development of new technologies and innovation is a significant challenge, for organizations focused on efficiently scaling the business of today. The greatest tension in all organizations is between running the business of today and creating the business of tomorrow. Most organizations fail to harness this tension and work at this simultaneously. To do so requires different structures and practices for each type of activity. Where we continually see large organizations fail is applying their lean process for their existing products to create new innovative offerings. Innovation is its own discipline, separate from a lean discipline, and until leaders create and adopt this innovation discipline they will find they can't keep pace with the rate of innovation in the marketplace and can't own the disease.

Achieving this requires innovation disciplines, structures and processes that are generally foreign to many medical technology companies that, in the past, have relied upon their R&D organizations to drive innovation. For example, Apple spends significantly less on R&D than Microsoft in total dollars and as a percentage of revenue,¹¹ but which company would most people say is more innovative? It is not the dollars spent but the processes, structures and practices that drive an innovation culture that leads to success.

Innovation must occur across the enterprise. One of the most common misconceptions is that innovation is primarily, if not exclusively, about changing technology. But high-performing companies innovate by leveraging customer insight to form new business models and improved technologies to create important value for the consumers and the company. In *Making Innovation Work*, Davila, Epstein and Shelton defined the Six Levers of Innovation.

Three business model levers affect how a company creates, sells, delivers and monetizes value to its customers. Business model innovation includes creating new value

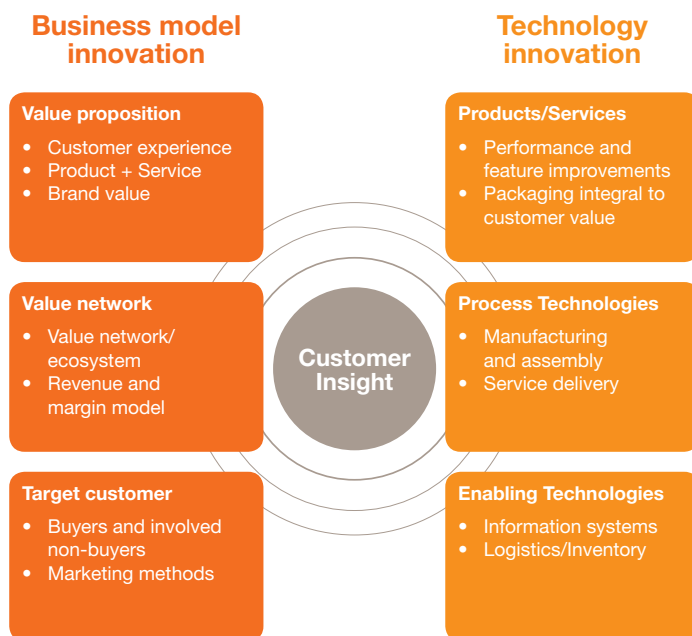
for customers, e.g., combining products and services to deliver complete solutions, delivering and monetizing it in new ways and finding new or under-served customers, an important but often overlooked form of innovation.

Three technology innovation levers provide new technologies that enhance the existing product or service, improved processes for manufacturing or delivery and upgraded enabling technologies that operate behind the scenes but that can provide important support to the other levers.

Focusing narrowly on technology or limiting innovation to business modes severely curtails the possible benefits and impact of the potential innovation. Leaders select the specific levers, combining business model and technology change, to create and deliver blockbuster innovations.

The application of this framework to healthcare generally, and medical technology specifically, offers the opportunity to rethink how a company builds itself for the future. Using the Six Levers can generate innovation across the enterprise, resulting in often-unexpected synergistic benefits.

Six levers of product and service innovation



How Medical Technology Companies Are Trying to Own Diseases

Real-life examples of how medical technology firms are seeking to own disease states already exist. In these cases, companies are moving beyond playing in just the product offering segment of the value chain and shifting to an innovation-focused business model that encompasses services, processes, distribution and the customer experience, with mobile healthcare technology playing an important role in engaging the customer.

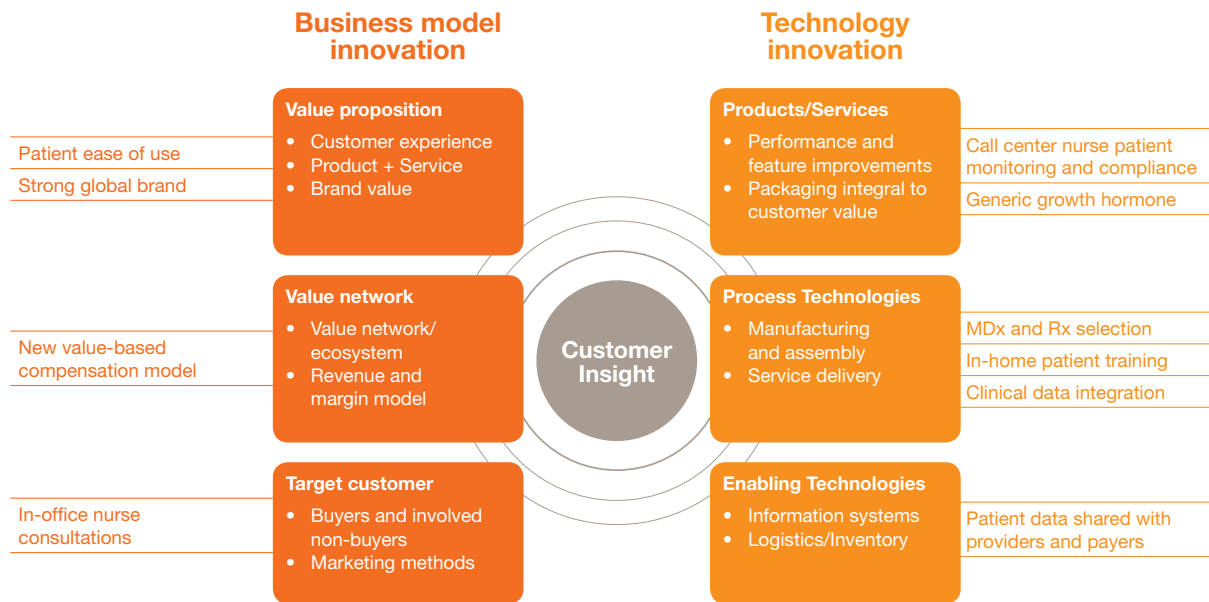
Merck Serono and Easypod – Owning Growth Disorders

Merck Serono S.A. has deployed a solution within the United Kingdom market to own human growth hormone therapy for endocrine and metabolic disorders. It is doing so by integrating diagnostic screening, counseling and monitoring services with its Easypod™ wireless injection device. Approved for use in more than 40 countries, including the United States and the European Union, the Easypod is employed in the injection of pharmaceuticals,

and merges the delivery of drugs, the documentation of the dosages and the monitoring of compliance.¹² Data are shared automatically with physicians to promote compliance and integrated into electronic medical records for provider accessibility.¹³

The use of the Easypod reflects a changed business model. Merck Serono no longer concentrates solely on selling pharmaceuticals to providers but instead delivers value, with compensation linked to overall results. Quality of results, rather than quantity of sales, determines profitability, which aligns Merck Serono with the primary payer, the National Health Service (NHS). Because the higher levels of patient compliance with medication regimens produce better health and reduced lifetime treatment costs, the overall cost of the therapy for the NHS is lower. However, Merck Serono has greater market share and higher profits. As shown by the chart below, based upon the *Making Innovation Work* framework, Merck Serono orchestrated innovation using multiple innovation levers.

Merck Serono Owning Growth Disorders



Making Innovation Work, Davila, Epstein, Shelton: Wharton School Publishing, 2006

How Medical Technology Companies Are Trying to Own Diseases

Medtronic Ibérica – Owning Heart Disease

An open innovation approach has been taken by Medtronic Ibérica S.A., which is responsible for the global medical technology firm’s operations in Spain. Key Medtronic Ibérica customers, including large government-owned hospitals and medical centers, were attempting to control costs. One of the areas in which they hoped to reduce expenses was coronary care. Hospital officials repeatedly pressured Medtronic Ibérica executives for discounts on the firm’s pacemakers.

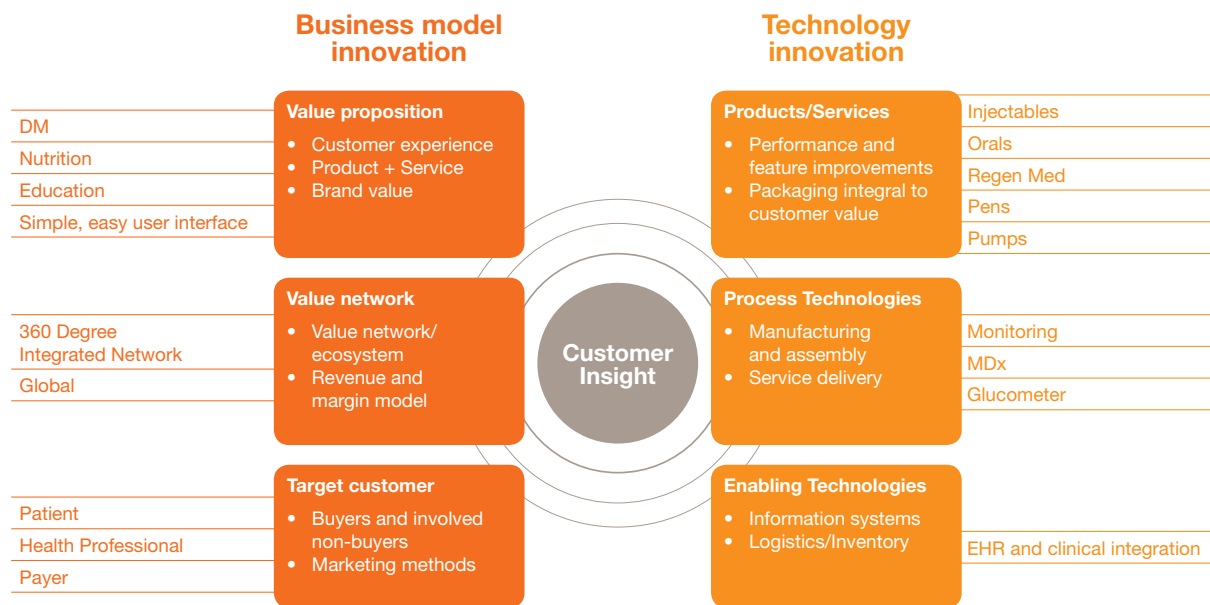
Recognizing that continued discounting of one of the firm’s signature products would not only be economically damaging for the company but destructive to the brand, Medtronic Ibérica’s country leadership instead made a counteroffer: It would leverage its deep knowledge of the hospital system’s practices – developed through the involvement of company representatives in surgeries and during follow-up treatment – to help the system reduce its operating costs by the same percentage – a far greater amount in dollar terms – by applying best practices, monitoring patients and leveraging information to improve patient outcomes.

In doing so, Medtronic Ibérica would create efficiencies and help control costs associated with long-term coronary care, which in the end would save hospitals much more than the *entire* cost of the devices, let alone any discounts that they could possibly negotiate. In essence, Medtronic Ibérica was transforming its business model from selling devices to preserving heartbeats.

Sanofi’s Diabetes Division – Owning Diabetes

French pharmaceutical firm Sanofi S.A.’s Diabetes Division, launched in 2010, has set as its goal establishing itself as the world’s leading diabetes care company by becoming “a ‘360’ partner of the patient; delivering best-in-class and integrated solutions to diabetic patients ... through the integration of new pharmacological targets and innovative approaches and the seamless connection of diagnostics, treatment and monitoring.”¹⁴ This includes the full range of products and services, including monitoring devices, oral and injectable therapies, mobile applications and patient education.¹⁵

Sanofi Owning Diabetes



Making Innovation Work, Davila, Epstein, Shelton: Wharton School Publishing, 2006

Outlining the need for a more comprehensive approach, Pierre Chancel, senior vice president in the Global Diabetes Division, told Reuters, “We want to become the first and most integrated health groups on diabetes. Today, there is no integrated partner; the patient suffers from the fragmentation of care provision. For each type of diabetes, specialized groups tend to focus on their own range of activities, no bridge between pharmaceutical companies, equipment manufacturers and specialists in insulin pumps, while patients in need of care security to cope with complex and chronic illness.”¹⁶

The firm’s Lantus is described as already being the “number-one Diabetes brand worldwide,” positioning Sanofi to form the alliances and partnerships it needs to own the disease.¹⁷ Through the Diabetes Division, the firm is developing a more integrated structure composed of all of the key units working on diabetes, including R&D, device development, medical affairs, commercial operations and business development. As the graphic shows, Sanofi in essence seeks to own diabetes by comprehensively integrating multiple types of innovation across a semi-open platform.¹⁸

Endo Pharmaceuticals and American Medical Systems – Owning Pelvic Health

The announced acquisition of American Medical Systems by Endo Pharmaceuticals is explicitly intended to advance “Endo’s evolution from a product-driven company to a healthcare solutions provider” with an integrated business model. Endo’s CEO said that the acquisition would position the firm “as a leading provider of healthcare solutions in the field of pelvic health, with a full spectrum of product offerings ranging from pharmaceuticals to medical devices.” In particular, the deal would build on Endo’s core urology franchise by enabling it to “offer patients solutions through the entire course of urology treatment options.”¹⁹

The deal continued Endo’s effort to build scale in related businesses through the strategic acquisitions of Indevus (urological pharmaceuticals); HealthTronics (urological devices and services); Penwest (pain management); and

Qualitest (genetics). By combining the operations from these prior acquisitions with American Medical Systems’ pelvic health products, Endo seeks to provide care across the entire urology spectrum, including oncological pharmaceuticals, medical devices such as lithotripsy equipment, benign prostatic hyperplasia lasers and cryosurgery devices, and surgical devices and implants for the treatment of conditions such as urinary incontinence and erectile dysfunction.²⁰

As with similar efforts to build solutions to own the disease, the Endo-American Medical Systems deal really is an example of classical vertical integration, in which companies seek involvement in all aspects of a sector, in this case through mergers and acquisitions rather than solely through organic growth or internal expansion or through partnerships and alliances (the latter of which effectively are virtual vertical integration).

GE Healthcare and Clariant – Owning Cancer

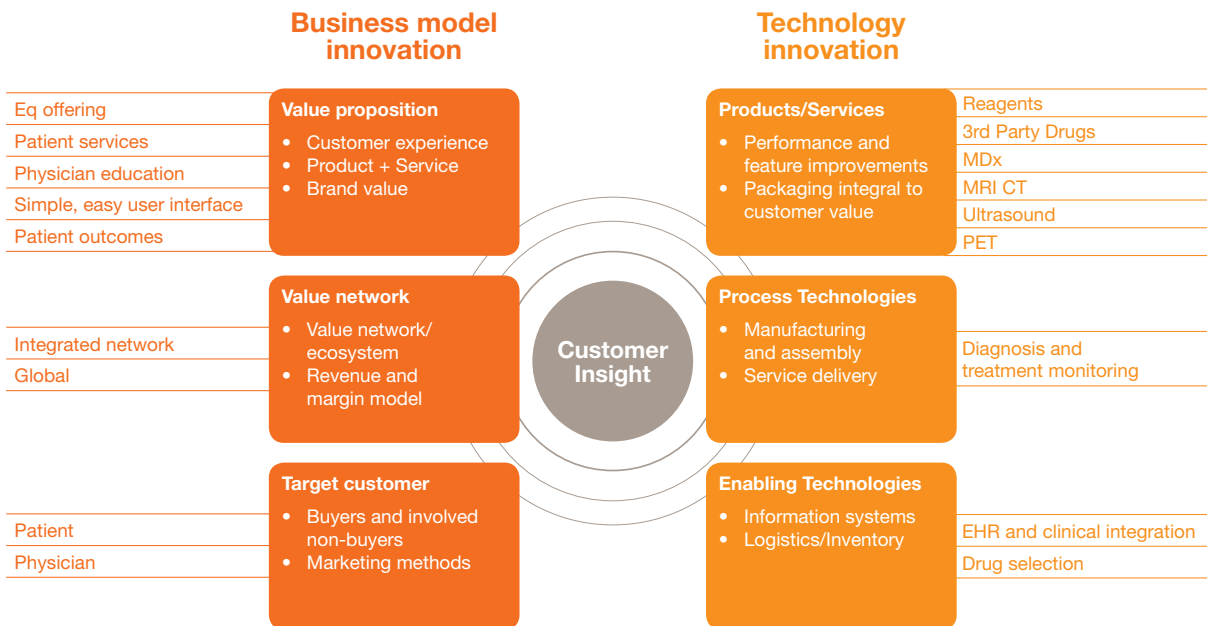
The acquisition of Clariant Inc. by GE Healthcare in 2010 is similarly intended to, in the words of its CEO, achieve “the broadest portfolio in the game.”²¹ By acquiring a leading clinical molecular diagnostics firm to complement its historically strong capabilities in anatomical radiology, GE Healthcare will be able to become a leading player in the emerging market for predictive diagnostics. Such integrated imaging technologies are seen as having particularly strong potential in such fields as oncology, including the creation of “integrated tools for the diagnosis and characterization of various cancers,”²² where Clariant already has a formidable portfolio of tests.²³

As Pascale Witz, CEO of GE Healthcare, Medical Diagnostics, said, “Cancer is complex and requires the ability to detect and integrate data from multiple sources. With more information, particularly at the molecular level, we can stratify patients and enable confident medical decisions that will adjust treatment to the individual. With Clariant, we will be able to accelerate the development of tests for the characterization and diagnosis of cancer, which will bring benefits to millions of patients worldwide.”

The mix could have significant benefits by helping pharmaceutical drug companies develop new pharmacological targets, managing genetic variations and biomarkers with reagents and devices and supporting diagnosis, drug selection based upon molecular diagnostics, targeting, monitoring and validating outcomes. Through this integrated approach, GE Healthcare will assist the physician in selecting the best therapy and be able to significantly improve outcomes and decrease costs, and by so doing commoditize the therapeutic offerings.

As Clariant's CEO said at the time of the announcement, the arrangement would provide the resources and technical capabilities needed to create "one of the industry's most relevant companies in the management of cancer."²⁴ With Clariant's superior capabilities in developing diagnostics to identify breast, prostate, lung, colon and blood-based cancers, GE Healthcare seeks to own oncology diagnostics for those diseases, positioning it to provide a total solution for cancer short of therapeutic drug development. As the chart below shows, GE Healthcare's efforts to own cancer, while in their earliest stages and with a long way to go, have the potential to generate innovation across its operations.

GE Healthcare Owning Cancer

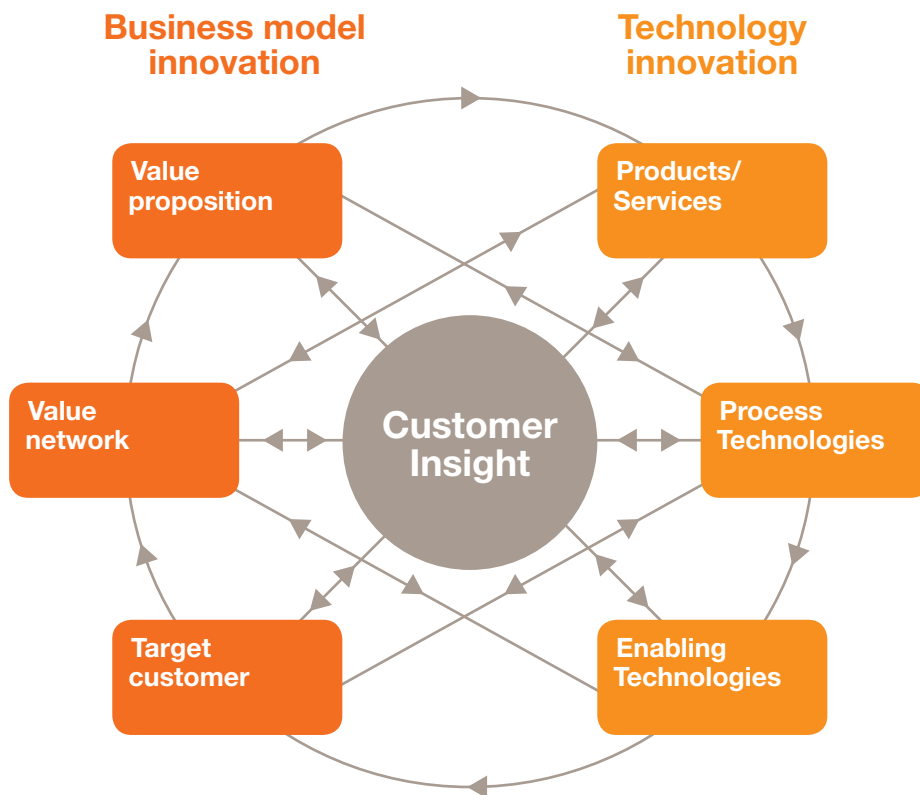


Making Innovation Work, Davila, Epstein, Shelton: Wharton School Publishing, 2006

These are examples of the first steps in owning the disease, rather than instances of wholesale enterprise transformation. From these examples, it is clear owning the disease does not mean owning all indications of it; many, such as cancer, are part of hundreds of different diseases and are

simply too large of a playing field. Specificity is necessary, and companies will need to own disease states where pathways and treatments are aligned or similar so that they will be able to leverage their infrastructure. However, the key is to understand and use the Six Levers of Innovation.

Six levers of innovation work together with insight



Making Innovation Work, Davila, Epstein, Shelton: Wharton School Publishing, 2006

Owning the Disease: What are the Business Model Challenges and Implications?

Once a company commits to owning a disease, it must address a lengthy series of strategic challenges that result from such a transformative goal, the most significant of which revolve around changes to a company's fundamental business model.

The most basic question is: How does the operational model change in order to accommodate the requirements of owning a disease? The question is complex because of the potentially disruptive secondary and tertiary impacts of each choice. For instance, firms currently are using every avenue imaginable to capture a larger piece of the value chain. But which are the right choices? Are fill-in mergers or acquisitions of disease state technologies or platforms the way to proceed? Can organic growth or internal expansion work for most companies? Do external partnerships or alliances have the ability to plug holes? It is easy to say that the correct choice is always situational, but the choice of which approach to take will have its own impacts on the organization through financing, the ability to complete the offering and integration.

Selecting the right compensation and payment structure is essential but difficult. Owning the disease entails a new way of looking at how a company is paid, driven by results. New modes of compensation are emerging to drive a more systemic, quality-based approach, such as PROMETHEUS Payment[®], which "has developed evidence-informed case rates, designed to create fair payments for providers delivering care to a patient for conditions such as diabetes and heart attacks."²⁵

Another significant challenge is organizational. For any given approach to owning a disease, how does the company organize itself from the standpoint of personnel? How does it recruit and retain talent that can understand not simply selling a product but a more holistic approach to treatment, new forms of reimbursement and paths to market that cut across the device, pharmaceutical and provider consumer marketplaces? This can be a barrier for even the best-performing organizations. GE Healthcare, for example, has chosen not to integrate its sales force with that of newly acquired Clariant because of the substantial difference in the products and services each sells – despite the fact that such synergies are frequently part of the reason for such deals.

There are other governance and structural issues. In order for companies to have the holistic view of systems needed to own the disease, information technology networks need to be integrated. The challenge for these companies is to build systems that support and facilitate management and operations in an integrated marketplace. Supply chain management, for instance, must change dramatically. How does a company implement and manage a supply chain that seeks to provide everything from soup to nuts when it previously provided only the knife, fork or spoon? The tax function at companies needs to be sufficiently robust and forward-looking to reflect developments, such as the 2.3 percent medical device excise tax scheduled to go into effect in 2013, assess their impact on corporate earnings and identify pathways to maintaining profitability, including innovative operational strategies that control operating expenses and expand margins without cutting functions or talent that are essential for long-term success.

A related question is whether and how the choice of business model varies by jurisdiction – not simply the controlling political entity but also the governing regulatory regime. For companies that seek to span traditional divisions between sectors, the regulatory backdrop will be a continuing challenge. Companies that have had comparatively clear regulatory pathways, with identifiable relationships and expectations, now may be faced with overlapping, conflicting or even undefined regulatory landscapes. Ongoing evaluations of regulatory processes within the FDA and in Congress ensure continued uncertainty about future approvals as companies seek to own the disease.

The Future of Owning the Disease: Six Design Principles

In their efforts to own the disease, medical technology companies are moving beyond playing in just the product offering segment of the value chain and moving into all of the related areas, such as services, processes, distribution and the patient experience, each of which is resulting in changes to these companies' business models. This more comprehensive and integrated approach is truly the future of healthcare, and it requires breakthrough and radical innovations as well as the more traditional incremental innovations.

Ultimately, the most important determinant of whether a company will succeed in owning the disease is whether it can become more consumer-friendly and more intensely focused on the patient's needs. While disease states can be patient-centric or provider- and physician-centric, the solutions themselves, whether product- or service-based, will need to focus on the patient, especially in a more consumer-empowered healthcare environment.

For companies seeking to own the disease, such a consumer-focused approach must be embedded in the design of solutions from the start to create better user experiences. There are six core design principles that must be incorporated to deliver maximum value.

Solutions should be *interoperable* with other relevant applications, devices, software, personal health records and other aspects of treatment. This is an essential element of the comprehensive approach to therapy and care.

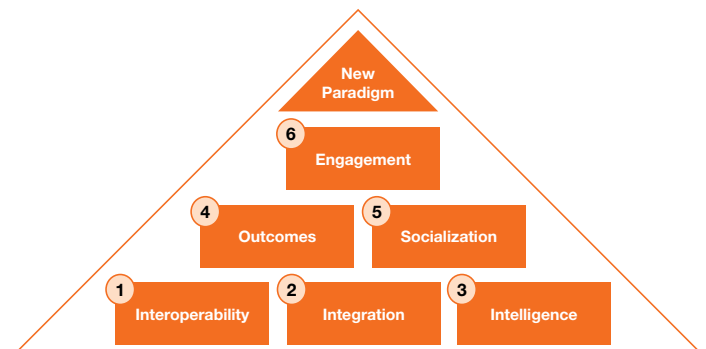
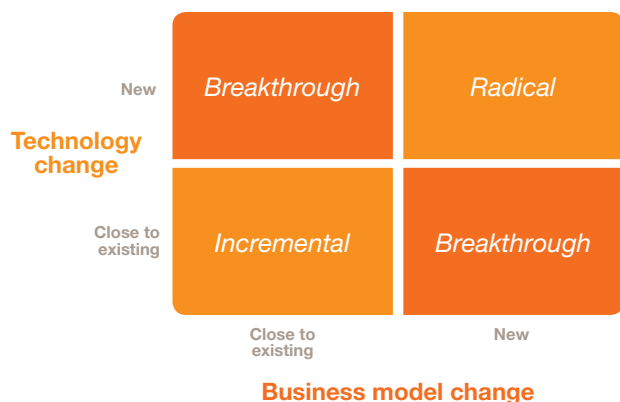
Whether they involve devices, pharmaceuticals or other products or services, the solutions need to be fully *integrated* into not only the care continuum but also into patients' lifestyles. Especially in the case of chronic, nonfatal conditions, integration is an essential aspect of owning the disease.

Solutions must be *intelligent* and capable of providing data and information to patients and providers that is actionable in treatment. Just providing data is no longer enough; they must provide knowledge and intelligence to change behavior.

Similarly, solutions must be *outcome-oriented* and able to document and measure outcomes to confirm performance. In a healthcare sector that increasingly will become more quality-focused and results-oriented, being able to validate the impact of treatment is crucial. As providers will increasingly be paid for performance, they will naturally select those solutions that collect and share outcome measures.

The solutions that companies develop also must connect with the patient, her family and friends. They have to be *socialized*, so that they expand the community of care to support patients, providers and payers in changing behaviors and improving outcomes.

Owning the disease requires a mix of innovation types



Finally, these solutions must be *engaging*, so they are used regularly and as prescribed rather than avoided and ignored.

If these six principles are not incorporated into the very DNA of solutions, they will be likely to fail, and companies will fall short in their efforts to own the disease.

The most innovative medical technology companies are incorporating these principles as part of total solutions that move beyond individual products and services to address the full spectrum of disease management, including prevention, screening, diagnosis, treatment and monitoring.

In doing so, they are developing new operating models that develop game-changing products through open innovation processes and breakthrough practices such as enterprise co-creation, in which both internal and external stakeholders become active participants in the creation of value. The balanced approach to innovation strategy they are pioneering reflects business model changes that support the technology advances through innovations that range from incremental to breakthrough to truly radical.

Assuming that the six design principles are fully incorporated into the products, services and initiatives that medical technology companies create, what are the industry's prospects for owning the disease? In a word, excellent – if only because owning the disease is so strongly in its self-interest.

Medical technology companies face greater challenges now than at any time in the past half-century. Yet by becoming more flexible and attuned to the markets and adapting their business models accordingly, they can develop system-oriented solutions that patients and providers want, that payers are willing to reimburse and that regulators will approve.

Early movers in this space, such as GE Healthcare, Merck Serono and Sanofi, have made significant strides. While the challenges of expanded access and lower reimbursement rates may seem daunting and will consume those who are unprepared, those companies that devise sustainable enterprise innovation structures can fulfill the promise of personalized care, meet payers' and patients' demands for improved outcomes and capture economic rewards by owning the disease.

Owning the disease: A new transformational business model for healthcare

-
- 1 "1100100 and counting," *The Economist*, June 9, 2011; <http://www.economist.com/node/18803123>
 - 2 "Apple Formally Names Jobs as Interim Chief," by the Associated Press. *The New York Times*, September 17, 1997: <http://www.nytimes.com/library/cyber/week/091797apple.html>
 - 3 *Making Innovation Work: How to Manage It, Measure It, and Profit from It*, by Tony Davila, Marc J. Epstein and Robert Shelton: Wharton School Publishing, 2006
 - 4 "Making Innovation Work" homepage, <http://www.prtm.com/makinginnovationwork/>
 - 5 "Innovation That Delivers Results: Product and Service Innovation," PRTM Service Offering.
 - 6 "In Medicine, New Isn't Always Improved," by Barry Meier, *The New York Times*, June 26, 2011. <http://www.nytimes.com/2011/06/26/health/26innovate.html>
 - 7 "Organizing From Silos To Services," on "Chuck's Blog," July 22, 2011: http://chucksblog.emc.com/chucks_blog/2011/07/organizing-from-silos-to-services.html
 - 8 PwC's PRTM Management Consulting Web page: <http://www.prtm.com/strategiccategory.aspx?id=583&langtype=1033>
 - 9 "GE Boosts Outlook For Health Business," by Paul Glader and Bob Sechler, *The Wall Street Journal*, November 10, 2010; (http://professional.wsj.com/article/SB10001424052748703585004575604851912501736.html?mod=googlenews_wsj&mg=reno-secaucus-wsj)
 - 10 "P&G's Innovation Culture," by A.G. Lafley, with an introduction by Ram Charan: <http://www.strategy-business.com/media/file/enews-08-28-08.pdf>
 - 11 "Why Not All Earnings Are Equal; Microsoft Has the Wal-Mart Disease," by Adam Hartung, *Forbes.com*, May 3, 2011. <http://www.forbes.com/sites/adamhartung/2011/05/03/why-not-all-earnings-are-equal-and-microsoft-has-the-wal-mart-disease/>
 - 12 <http://www.merck.de/en/company/innovation/pharmaceuticals/endocrinology.html>
 - 13 "Saizen® [somatropin (rDNA origin) for injection]," http://www.emdserono.com/en/therapies/metabolic_endocrinology/saizen/saizen.html
 - 14 "Partner to Your Idea," by Sanofi: <http://interactivepdf.sanofi-aventis.com/BrochurePartner2010-06/index-13.html> (page 13).
 - 15 "Sanofi wants to take the lead in the treatment of diabetes," blog item, <http://sglleathers.com/sanofi-wants-to-take-the-lead-in-the-treatment-of-diabetes/>
 - 16 *Ibid.*
 - 17 Sanofi Annual Results 2010, February 9, 2011: http://en.sanofi.com/binaries/2011-02-09_FY2010_PresseConf_EN_tcm28-30362.pdf
 - 18 "Sanofi wants to take the lead in the treatment of diabetes," blog item, <http://sglleathers.com/sanofi-wants-to-take-the-lead-in-the-treatment-of-diabetes/>
 - 19 "Endo Announces Agreement to Acquire American Medical Systems for \$2.9 Billion," news release, April 11, 2011: <http://phx.corporate-ir.net/phoenix.zhtml?c=123046&p=irol-newsArticle&ID=1548626&highlight=>
 - 20 Presentation, "Endo to Acquire American Medical Systems (April 11, 2011), <http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NDIxMTM2fENoaWxkSUQ9NDM0NzU0fFR5cGU9MQ==&t=1>
 - 21 "GE Boosts Outlook For Health Business," by Paul Glader and Bob Sechler, *The Wall Street Journal*, November 10, 2010; (http://professional.wsj.com/article/SB10001424052748703585004575604851912501736.html?mod=googlenews_wsj&mg=reno-secaucus-wsj)
 - 22 "GE Healthcare to Acquire Cancer Diagnostic Company Clariant Inc.," news release, October 22, 2010: <http://www.genewscenter.com/Press-Releases/GE-Healthcare-to-Acquire-Cancer-Diagnostic-Company-Clariant-Inc-2bfc.aspx>
 - 23 Clariant Test Menu, <http://www.clariantinc.com/test-menu.aspx>
 - 24 "GE Healthcare to Acquire Cancer Diagnostic Company Clariant Inc.," news release, October 22, 2010: <http://www.genewscenter.com/Press-Releases/GE-Healthcare-to-Acquire-Cancer-Diagnostic-Company-Clariant-Inc-2bfc.aspx>
 - 25 <http://www.prometheuspayout.org/node/4/#/1>

About PwC

PwC's Pharmaceutical and Life Sciences Industry Group (www.pwc.com/us/pharma and www.pwc.com/us/medtech) is dedicated to delivering effective solutions to the complex strategic, operational and financial challenges facing pharmaceutical, biotechnology and medical device companies. We provide industry-focused assurance, tax and advisory services to build public trust and enhance value for our clients and their stakeholders. More than 163,000 people in 151 countries across our network share their thinking, experience and solutions to develop fresh perspectives and practical advice.

Contacts

Dr. Christopher L. Wasden

Global Healthcare Innovation Leader
christopher.wasden@us.pwc.com
(646) 471 6090

Brian S. Williams

Global Healthcare Director Clients and Markets
brian.s.williams@us.pwc.com
(317) 940 7065

Attila Karacsony

US Pharmaceutical and Life Sciences Marketing Director
attila.karacsony@us.pwc.com
(973) 236 5640

www.pwc.com/medtech