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Owning The Disease II: Adapting Strategy Into Successful Business Tactics

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Executive Summary

Owning the Disease represents a powerful new business model for medical technology companies as they seek to adapt to health care reform and a changing environment. Organizations that successfully own a disease align their incentives with those of other stakeholders in the market by developing the capabilities to deliver compelling new value propositions.

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- Owning the disease represents a powerful new business model for medical technology.
- Business model design focuses on stakeholders, benefits, capabilities and impact.
- This business model enables alignment around more affordable care with all stakeholders.
- Novel value propositions require new capabilities and new revenue models.
- Novelty requires expanding capabilities by engaging third parties in innovation platforms.

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- Owning the disease changes a business from selling products and services to selling solutions, with information and analytics becoming key differentiators and drivers of value.

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Financial constraints, policy reforms, demonstration of value via outcomes data and technological advances over the past decade have altered the economics and operational dynamics of health care. Enabled by a confluence of disruptive technologies, novel collaborations and consolidation of related industries, participants in the historically linear health care value chain are creating new markets and business models that deliver greater health benefit more efficiently (*See* "The Changing Face of Medical Technology Innovation" — *IN VIVO,* September 2010 *and* "Owning the Disease: A New Business Model For Medical Technology Companies" — *IN VIVO,* December 2011.)

Faced with the need to change their historical business models, some of the most advanced medical technology companies are adapting by migrating from an episodic or intervention-focused business model to a convergent care model that enables them to provide solutions along the continuum of care. The integrated solutions inherent in this approach to “owning the disease” combine drug, device, diagnostic, and consumer-centric solutions to establish creative platforms in which a company can dominate the diagnosis and treatment of a disease or condition.

While some organizations have made progress toward adopting the ideas behind owning the disease, no company has succeeded entirely to this point. Although regulatory and reimbursement challenges exist in the current health environment, the larger issue facing manufacturers is the need to adopt a holistic approach to enterprise innovation and transformation.

Based on our experience and insight within health care and in other industries, this article presents our view on how early adopters of owning the disease are implementing changes to their operations, the results they have seen so far and what other medical technology companies should do to incorporate the principles of owning the disease into their own business operations.

Transformative Forces At Play

Familiar forces are radically transforming all health care systems, including a shift to outcomes-based reimbursement, scientific advances in the understanding of disease and human condition, financial pressures, including reimbursement and payment changes, and a critical lack of infrastructure, including providers in the United States and both providers and facilities in emerging markets.

The changes in health systems are simultaneously driving technological developments and providing opportunities for new models of care delivery enabled by ubiquitous mobile applications, affordable and intuitive monitoring sensors and devices, and the resultant avalanche of data. The data generated thereby are providing opportunities to better understand disease-specific and longitudinal population responses, making data archiving, access and analytics increasingly critical. In the future, value in the medical technology industry is likely to arise from bits, not atoms, as the defining characteristics of innovation shift to social media, mobile technologies, analytics, and the Cloud.

These changes extend to the consolidation of payors and providers in the US market, which is making the provision of care in the US a more integrated system

rather than a series of federated islands of care. This trend, which reflects ongoing movements in global markets, expands upon the existing systemic views of care seen in the Medicaid and Medicare programs, both of which by definition reflect limited elements of the population.

Other issues compelling change include the growing pressure among payors for genuine breakthrough solutions, as opposed to the merely “me-too” and incremental innovation exemplified by such measures as pharmaceutical products reconstituted into extended-release formats or many next-generation device iterations. Companies and governments are no longer rewarding health care companies for such limited improvements.

Another factor is the shift from a siloed approach to a systems perspective, as providers recognize the value, in terms of improved care and reduced pressure on staffing, of delivery networks and systems with integrated electronic health records and health information exchanges. Increasingly, data, information, and analytics are organizations’ only competitive advantage as they position themselves for the future of health care.

Finally, the industry’s shift from volume-based care to personalized diagnostic and treatment solutions is placing greater pressure on companies to deliver personalized and individualized care. While much of this is attributable to recent advances in genomics, the availability of personal information technology and the deployment of smart sensors and devices also play a factor, as do new insights into the role of microbiomes in health.

A Premium On Innovation

The forces reshaping health care are creating a market environment that puts a greater premium on innovation than ever before. The value placed on innovation is not that of the traditional, legacy forms of innovation produced by scientific advances, although those are still valued. In fact, scientific innovation has generated limited results in recent years, as witnessed by the patent cliff in pharmaceuticals and the similar innovation challenges facing the medical technology industry.

Instead, the focus increasingly is on business models that deliver quality care with demonstrable outcomes in a more cost-effective manner. Today, only 16% of health plans use innovative payment and contracting models, such as those based on patient outcomes. However, this number is expected to more than double to 37% in the next three years, according to a recent PwC report.

For medical technology and pharmaceutical companies that have had no visibility to outcomes because of how their businesses have operated historically, achieving this may require business model innovation through the development of new structures, in fact, the creation of entirely new ecosystems. The collapse of the traditional linear value chain of medical technology into a convergent environment has only ensured this change. For example, pacemaker manufacturers no longer can develop and deploy their technologies without considering other things such as compatibility with MRI devices, remote monitoring in real time by health care providers and the use by patients of smartphone apps to self-monitor in real time.

These changes are coming rapidly, at a rate even faster than that seen in product innovation, as companies quickly and efficiently adopt new business and operating

practices and develop the flexibility necessary to adapt. Those segments that are undergoing the most rapid structural changes, such as rural markets in the US and emerging markets globally, are experiencing the fastest transformation of their business models. These qualities can result in heightened competitiveness for those medical technology companies adept enough to embrace them.

Some companies already are responding to the challenges they face by creating new models of innovation that concentrate on disease solutions instead of the types of silo-based institutional approaches to operations and research and development that are centered on historical departmental structures. For example, the changes resulting from advances in the field of personalized medicine, including new therapies, diagnostics and consumer products, illustrate how innovation can be powered by appropriately redesigned business models that revolve around solutions.

For instance, when bringing a new obesity drug to market, a pharmaceutical company also should consider the need for a companion molecular diagnostic to know, a priori, who will benefit from that drug. They should select or develop an appropriate smartphone app, paired with other mobile devices and sensors, not only to support adherence but also to help drive changes in behavior around eating habits, portion control and activity. A pharmaceutical company also should consider the development and/or integration of devices, diagnostics and consumer tools into a supportive social ecosystem to reinforce these new habits, and provide all of these things on a value-based, at-risk payment model under which the company gets paid only when people lose weight and achieve their goals.

Other medical technology companies are incorporating approaches originally developed by information technology companies such as IBM and Apple as they responded to analogous changes in their own industry. As IBM and Apple did in past decades, these companies are reinventing themselves, shifting from serving as hardware manufacturers to becoming providers of solutions through flexible innovation platforms.

As medical technology companies reformulate themselves, they are obtaining the capabilities they need to compete, whether through internal initiatives, via mergers and acquisitions, or through partnerships, sometimes with new entrants from other industries such as retail or telecommunications. This follows patterns set in other technology industries: the Ford SYNC system is the result of a partnership among Ford Motor, Microsoft, and Intel. Recently, participants in the health care value chain also have created a health data interoperability consortium called CommonWell Health Alliance that will set the standards and guidelines for sharing all types of health care information, including that generated by medical technology.

Channel domination is yet another approach, and here health care is beginning to resemble financial services. For years, banks have expanded their value proposition so that a single institution can provide mortgages, credit cards, savings and checking accounts, insurance, brokerage, and wealth management services. Those banks that control the channel and relationships can leverage them to provide more value with related services. In such situations, data, information, insight, and analytics provide the keys to the value proposition and the “stickiness” in the relationship.

Finally, select companies are attempting to establish creative dominions that develop solutions that no one else has and that cannot be easily replicated. Such

creative dominions, which are at the heart of owning the disease, are intended to be fully integrated into the care delivery ecosystem. This power arises from the network effects resulting from information technology-driven strategies that harness social, mobile, analytics and the cloud, enabling entirely new value propositions unimaginable in a physical world of chemistry, biology, plastic, steel, and electronics.

We see this development already in the worlds of online shopping, travel, media, and entertainment, and health care will be one of the next to benefit from these technologies. As such, they provide greater value and more powerful franchise protection than standard intellectual property around a physical device, which is how value is protected today. Yet, without access to the ecosystem, conventional intellectual property is without value.

Companies focused on owning the disease reorganize their teams, capital, operations, and market approaches in order to make themselves more competitive in an evolving environment. This is perhaps the most challenging path, since it requires organizational reinvention that entails major cultural changes as well as a fundamental operational reorientation.

When organized around products, services, and solutions across the entire continuum of care, these strategies collectively reflect a business model for the industry we call owning the disease. By owning the disease, companies establish creative platforms through the development of innovation platforms that leverage the discipline, rigor, and reliability of operating within health care with the alertness, independence, and foresight necessary to make the most of advances in science and technology. In doing so, they are the harbinger of a new, potentially dominant business model for the medical technology industry.

The Kinds Of Diseases That Can Be Owned

While many of the concepts underlying owning the disease are broadly applicable, some diseases and conditions appear to be more suitable than others for application of these ideas. The diseases that most lend themselves to being “owned” fall into two categories: chronic and episodic.

The first set includes chronic diseases and conditions that are highly prevalent, have long duration and entail high treatment costs. These chronic ailments collectively account for approximately 75% of health care spending in the United States and other developed countries. Despite the high share of spending focused on chronic conditions, they no longer are the automatic revenue generators they once were. Patient-focused customer relationships may be more suitable in diabetes, hypertension, obesity, and other large, population-based diseases with co -morbidities and diverse needs. Moreover, some organizations may be so large that they find it difficult to bring resources together because their structure is too complicated and too divided into silos, with a resultant inability to align organizations and incentives.

The chronic diseases that are most appropriate for owning the disease initiatives fall into four primary families that require comprehensive and integrated solutions (figures are for the US only):

- Metabolic diseases (obesity, diabetes) – 101.4 million obesity patients in 2015

- Cardiovascular diseases (hypertension, coronary artery disease) – 113.8 million hypertension patients in 2015
- Neurological diseases (Alzheimer's, epilepsy) – 5.7 million Alzheimer's patients in 2015
- Respiratory diseases (asthma, chronic obstructive pulmonary disease) – 28.6 million asthma patients in 2015

Many of these ailments lend themselves to a very consumer-oriented version of owning the disease because they can be managed effectively only by the patient in a non-clinical environment. In addition, they tend to be co-morbid with so many other conditions that it is difficult to provide a solution by treating the ailment alone without requiring daily changes in the habits and activities of patients, not simply changes in the practice of medicine. One example is diabetes, which frequently is associated or interrelated with obesity, congestive heart failure, and other conditions. Similarly, knee joint problems are often associated with obesity. Successfully treating one condition for the long term often requires addressing other problems through a comprehensive approach. In order to address overall health care issues and costs, companies need to create bundled solutions to own a portfolio of related diseases.

Within these categories, certain diseases and conditions have such significant economic costs that they represent attractive opportunities for companies seeking to provide solutions across the continuum of care. For instance, treatment expenditures for chronic diseases include hypertension, which is expected to total $51.7 billion in the US by 2015; coronary heart disease, $36.8 billion; and major depression, $22.9 billion.

The second group that is appropriate for owning the disease includes episodic diseases and conditions that typically develop over extended periods and could be delayed, or avoided entirely, through better prevention management, use of medication or devices. These owning the disease-centered solutions often have less of a focus on the consumer and more of an orientation to providers. As with chronic diseases, certain episodic diseases and conditions have substantial, and growing, economic costs. For instance, the value of the US hip and knee replacement market is expected to reach $14.8 billion in 2015, up from $6.7 billion in 2008.

When focused on the provider as the customer, it may be easier to own the disease in small and focused market segments such as urology, otolaryngology, ophthalmology, and orthopedics. In these segments, providers deliver episodic procedure care, are generally not more independent, and are not targets for roll-ups by larger health care systems. The specific needs of these smaller segments when it comes to drugs, devices, lab services, management systems, etc., may make it easier to create total solutions for such practices. In such instances, health care providers are tightly integrated with device and pharmaceutical manufacturers. Developing an integrated solution not only aligns with the concepts underlying health care reform but also provides a quadruple enhancement to the bottom line: It is good for the manufacturer, good for the health care provider, good for the payor and, especially, good for the patient. While this may clearly limit some choices by those that have preferred a best-of-breed approach to procurement, they can deliver much greater value due to their superior ability to integrate and interoperate all aspects of their solution.

Although these diseases typically are treated at least partly in hospitals, the legacy hospital business model is not appropriate either for owning the disease *or* for disease management. In fact, owning the disease is empowered by health care trends and initiatives that are shifting care away from traditional settings in acute care facilities such as intensive care units and community hospitals. Health care information technology and the devices that enable it tie disparate services together and enable them to be provided outside of acute care facilities. Residential care (such as in skilled-nursing facilities) and outpatient care (provided in doctors' offices or the home) represent attractive alternative channels for those seeking to own the disease.

Medical technology companies should evaluate their portfolios and create ecosystems around some solutions while providing components to other ecosystems. This is inevitable: aging populations, health care reform, and clear trajectories on health care provider education and entry into the medical workforce may force new business models for the treatment of the kinds of chronic conditions identified previously.

Those organizations that are based upon episodic-driven business models, such as providers of knee replacement components or producers of insulin, will either become component suppliers or will devise new pre- and post-intervention tools and services that support the patient and the physician. Moreover, there are related opportunities for addressing co-morbidities, such as the links between obesity and joint failure or obesity and Type 2 diabetes. This approach, in short, is part of the total channel management that is an essential element of owning the disease.

In fact, the concept of owning the disease is driven in great measure by a company's information and analytics strategy. As health care value migrates from products to information and from atoms to bits as part of providing a comprehensive solution, those companies that harness information most effectively are likely to have a competitive advantage. The advent of accountable care organizations and the "meaningful use" provisions of the Medicare and Medicaid Electronic Health Record Incentive Programs will serve to accelerate this trend. Besides, evidence-based solutions can be provided only if a company has the data and information to support its claims, both for what they can do and for what they have done.

In an information-driven world, a company's core strategy should reflect the growing importance of being able to collect and leverage data. Data analysis is critical to helping improve efficiency in operations for patients as well as for providers through greater clinical efficacy, and this can make a company the preferred channel for select products and services that can be leveraged to distribute others. Some companies will be able to leverage their expertise in information technology, data and analytics to achieve a near-equal division between products (therapeutics and devices) and services (software, data, information, labs, and analytics).

Because care increasingly will be provided outside of acute care facilities, connected health care through mobile, social media, analytics, and Cloud-based information systems is likely to be a critical element of owning the disease. Technologies such as remote patient monitoring that can connect patients with clinicians create new sources of value across the health care ecosystem to enable companies to own the disease, especially in the case of chronic illnesses that require long-term treatment. These devices function on a continuum that ranges from physician-provided clinical applications and FDA Class III devices at one end

to unregulated, consumer-based initiatives such as wellness and independent aging programs at the other.

Such efforts in the cardiac rhythm management (CRM) space have been fraught with challenges and past failure because medical technology manufacturers applied their old business model to these new social media, mobile, analytic, and cloud technologies – add premium features, charge premium prices, grow revenues and expand margins. But, in today's health care system, there is no ability to pay ever-increasing premiums for such features. These types of innovations are the price companies must pay to remain in the game. What providers, payors and patients want is the application of these technologies to make health care more affordable, with higher quality and ubiquitous access. Those CRM companies that do so will grow their share of a flat market by differentiating their products in valuable ways.

The Type Of Innovation That Enables Owning The Disease

Owning the disease requires what Tony Davila, Marc Epstein and Robert Shelton have termed "Radical Innovation" in their book "Making Innovation Work." Radical Innovation, in their view, leverages both new technologies and new business models. Apple's introduction of the iPod and Xerox's proposed erasable paper for copiers in anticipation of increased demand for paper recycling are examples of such innovation. This is in contrast to both "Incremental Innovation," which reflects technology and business models that are close to existing levels and are designed to protect current business, and "Breakthrough Innovation," in which either the technology or the business model, but not both, are new and tend to extend existing businesses and technologies.

The kinds of Radical Innovation that accompany owning the disease typically take place within a cycle that moves from failure of the current state to pain to creative tension to innovation to success and growth. The failure and pain are essential antecedents of the creative tensions that drive the innovation process to own the disease. We are seeing the failures and pain points within health care increasing at a rapid rate across all countries. This is creating powerful tensions in these systems that demand more radical innovations to address and remove them. Here, owning the disease represents a form of Radical Innovation that creates information-driven solutions.

Medicinal compliance provides an example. Approximately $400 billion is spent annually in the US on brand and generic drugs. Yet, three in four Americans report having not taken medication as prescribed, including nearly one-third who had not even filled a prescription. Such non-adherence has been estimated to have an economic impact of approximately $290 billion annually, with millions of patients sickening and thousands dying annually. An increase in adherence from the current level of approximately 25% to 100% theoretically could save approximately $7,800 annually per patient according to one study, with another study indicating potential savings of $8.3 billion annually.

Effectiveness is equally important from the standpoint of owning the disease; many therapies have no therapeutic benefit. It has been reported that more than 90% of pharmaceuticals worked in only 30% to 50% of the patients who took them. Accordingly, one of the first and simplest steps to owning the disease is through companion diagnostics to identify efficacy and proper dosage. For example, **Roche** recently reported that more than 60% of its pipeline pharmaceutical products will have companion diagnostics.

The challenge in cases such as that of Roche is integrating the research and development process to the point that the value of a therapy is clear and the linkages are comparatively easy to determine. Achieving this would enable companies to change a commercial model that extends beyond the dosing environment of a hospital or a physician's office to include patient behavior and other factors that are at least partly out of a provider's control or influence.

Innovative efforts to improve compliance produce added value at various levels. Incremental Innovation – illustrated in the case of compliance by disease management call centers – generates added value of 20% or less as measured by improved adherence to therapy. Breakthrough Innovation, such as texting and emailing patients about compliance, adds value in the range of 20% to 50% based upon empirical research of improved adherence.

Enter device startup **Proteus Digital Health Inc.**, which developed a miniaturized wireless device that was incorporated into oral solid dose form. When a medication is ingested, it sends a wireless signal to a patch transmitter, which in turn transmits compliance and diagnostic information to a provider via a smartphone or similar device. **Novartis AG**, which cooperated with Proteus on a clinical study of the device's effectiveness in increasing compliance with the blood pressure medication *Diovan* (valsartan), found that adherence grew from 30% to 80% within six months.

Such levels of added value are inherent in Radical Innovation, and this is a critical aspect of the business model changes that are important to owning the disease. Such innovation makes use of creative tension to generate additional value, at a level of 50% or more, as produced by the Proteus device, which recently received FDA approval. No other devices are as personal and have the breadth and depth of capabilities as mobile devices, making them central to owning the disease.

Four Themes Dominate The "Owning The Disease" Landscape

"Owning the disease" is built around four key themes. These themes, which run through all aspects of a company's attempts to improve competitiveness by owning the disease, reflect the challenges posed by an evolving business landscape.

1. *Innovation in business and enterprise models*: In order to own the disease, medical technology companies should look at innovation as an enterprise function that extends beyond the functional boundaries of the traditional organization, whether operations, marketing, sales, finance, customer service, or research and development. They should reappraise how teams are organized; what metrics are appropriate for measuring innovation; and, how innovation within and without the organization is sourced, evaluated and developed. Equally important, they need to reconsider how value is validated, documented and captured from the kinds of integrated solutions that are at the heart of owning the disease. In essence, they should have an operating model that drives their innovation processes.

Fundamental assumptions about the ways in which innovation occurs and how its results are leveraged across a global enterprise need to be challenged. This becomes particularly important when considering, for instance, how the advances in personalized medicine made possible by scientific discoveries in genomics and proteomics affect innovation and improve health outcomes in therapies, diagnostics and consumer products.

Another key issue is determining whom to target. While owning the disease is inherently consumer-centric, the patient is not necessarily the target from a business perspective, especially in cases in which treatment is primarily provided by a physician or other professional. Some organizations will own the disease in a B2-B2-C model, while others will do so in a B2-C model. For instance, **Endo Health Solutions Inc.** offers a pelvic health business model in which the provider is the primary targeted customer, with the company attempting to help the provider deliver greater value to patients. In contrast, **Sanofi**'s diabetes treatment model focuses on the patient as the primary targeted customer while providing additional tools and support for providers.

A crucial aspect of this targeting is portfolio selection. Given the high investment typically required to own the disease, many companies pursuing this strategy concentrate on only a limited part of their portfolio. **Merck KGAA** division **Merck Serono SA** is pursuing an owning the disease strategy only around growth hormone deficiency, through its treatment solution *Saizen* (somatropin). Sanofi is concentrating its efforts only around diabetes through such initiatives as its effort to acquire the blood glucose meter business of **Bayer AG**. Although it has reorganized its R&D model around diseases, Sanofi has not yet deployed a similar commercial strategy for other classes of therapy.

Linking operations to the strategy is an important step. When pursuing owning the disease, broader ecosystem management and operations are needed, including in such areas as cost structure, revenue, and margins. When supplying another ecosystem, the cost structure and margins look more like those associated with component suppliers in the automotive or aerospace industries, with lower margins, greater volatility in stock valuation, etc. Companies and their investors should understand this challenge and be prepared for it.

While organizational size does not necessarily reflect a dominant position in companies' attempts to own large, population-based diseases, a certain critical mass is necessary to be relevant to customers as an owning the disease solutions provider. Endo Health Solutions, for instance, made acquisitions to gain scale in the urology sector. As a result of this, it also gained greater insights in to what urologists need.

Endo Health Solutions is an example of how companies actively attempting to leverage their size to become the conduit through which they deliver not only their own products but also third-party products and services. A minimum number of tools, insights, capabilities, and relationships are necessary to become a player in owning the disease on this basis; beyond that, gaps can be filled through partnerships rather than acquisitions. In essence, companies have to earn the right to own the disease.

An example of how to own the disease through this approach is seen in one of the nation's five largest pharmaceutical companies, which operates a US-based innovation incubator that is promoting a form of owning the disease focused on cardiovascular health. Operating much like a venture capital fund, the incubator makes individual investments in the low tens of millions of dollars in information and analytics-driven health care organizations that already have revenues and are raising third or fourth rounds of financing. By so doing, it is creating a portfolio of solutions to own cardiovascular disease in the future through applications of information technology.

The company's investment thesis focuses on new sources of value that arise from combining data, information and analytics to produce improved health care outcomes and lower system costs. It is assembling a virtual owning-the-disease solution for cardiovascular health through investments in companies that develop products intended for early detection, remote monitoring and other diagnostic and mHealth initiatives. Many of the new technologies use emerging information tools – including point-of-care diagnostics, molecular diagnostics, molecular imaging and remote monitoring – to analyze existing data sources, including patient health records and electronic medical records.

In the past two years, the incubator has invested hundreds of millions of dollars and has a commitment from the company's leadership to invest additional hundreds of millions – a fraction of the billions of dollars the company invests in core research and development initiatives, but a significant amount since it is concentrated on stitching together options that will provide total solutions around disease families.

Companies also may explore the use of adjacent channels to expand sales of their products. For example, Roche, the world's biggest producer of anticancer drugs, was faced with a ceiling on product sales in China: many of its products cost more than the average patient earned in a year. Rather than reducing prices to unprofitable levels or resorting to charitable giveaways, Roche has partnered with Swiss Re to develop private insurance products that will enable patients to buy the medicines they need. Another example of this is grocery-store company Kroger's acquisition of Axium Pharmacy Holdings in an effort to generate synergies in adjacent channels.

Such creative approaches to owning the disease are increasingly common. As companies look to own the disease, they should consider how to build the capabilities required. Currently, no organization has all of the requisite competencies needed to own the disease. Determining how to acquire these capabilities, whether through in-house development, M&A or alliances and partnerships, is a vital decision that can well determine the effort's success.

2. *Navigating an increasingly dynamic regulatory landscape*: Pharmaceutical and medical device companies seeking to own the disease will need to cope with an increasingly demanding regulatory environment. For instance, the emerging requirements associated with the comparative effectiveness of various medical interventions require that companies understand and manage cross-jurisdictional obligations at multiple agencies – in the US alone, these include the Federal Trade Commission, the Federal Communications Commission, and the Food and Drug Administration's Centers for Devices and Radiological Health, Biologics Evaluation, and Research and Drug Evaluation and Research.

Tips For Driving Data Innovation

Significant change is underway in the medical technology industry. As blockbuster drugs lose patent protection, approvals slow for new devices and consumers evolve their buying behavior, medical technology companies need to constantly look beyond their R&D labs for innovation. Cutting-edge companies are driving innovation by:

- Linking mobile sensors to their products to generate new data and sources;
- Equipping experts to investigate their own and others' data;

- Creating interactive Big Data analysis to answer questions at the speed of thought;
- Blending Big Data sources within and without to generate a more complete picture; and,
- Making it easier to share analyses for cross-team and ecosystem collaboration.

A further challenge is associated with the evolving standard for regulatory approval. Formerly, this was *efficacy*, whether a product did what it claimed to do. The newly accepted standard for most drugs and devices is now *effectiveness*, not simply whether a product does what it claims to do but also whether it produces the *clinical outcome* it claims to produce. While FDA guidance and physician opinion formerly were the primary influencers for formulary placements, a new survey by PwC's Health Research Institute revealingly found that 60% of insurers "strongly" agree that pharmaceutical companies need to demonstrate a comparative clinical benefit to be considered for formulary placement.

Moreover, pharmaceutical and medical device companies should address efficiency issues, whether the clinical effect is superior to and/or less costly than currently available comparable therapies. Meeting these new standards often means greater investment in product development, product design, and clinical trials. Indeed, entrants into new markets should proactively deliver this level of evidence to be competitive; it eliminates the formerly popular strategy of creating "me-too" therapies, devices, and solutions that provided little additional benefit.

This illustrates the power of creative platforms. Incremental therapeutic differences, such as those epitomized by some extended-release formulations, have little or no added value. Patent expirations have smaller economic risk in creative platforms because integrated solutions require that any replacements have higher therapeutic, economic and customer value. And margins are protected, and the penalties associated with health care reform are better managed, because creative platforms entail integrated solutions that include access to data. Data analytics, as a result, drive the power of extending creative platforms.

Strategic considerations around how intellectual property is protected in these environments, how existing tax policy affects organizational structures and intellectual property, and how adverse events are identified and responded to all should change when companies attempt to own the disease. Companies may need to adopt new strategies, staffing, and operating principles.

Finally, the complexity of regulatory compliance increases for companies operating in a global environment, since owning the disease will almost always require cross-border operations and the demands on companies increase exponentially. Movement toward greater harmonization in regulation and payment will help, but this will remain a challenge for some time to come.

3. *Streamlining business operations around patients, not products*: Owning the disease requires companies to re-think their operating principles, organizational structures and business strategies not only within the disease but also throughout the company. The focus needs to shift from making products to

PRICE To Own the Disease: Five Steps

Predict the risks customers face in their business or consumers face personally and provide solutions to mitigate and manage them:

creating solutions that serve patient needs regardless of whether they fit into preconceived categories.

Owning the disease need not mean complete ownership of every product and service. As part of an effort to own the pelvic health space, Endo Health Solutions seeks to control its entire channel, so as to become the conduit through which others sell their products. It can serve this function by partnering with other companies in select areas because it will have the most dominant sales force in the urology market, one that already provides its physician customers and their patients with branded and generic drugs, medical devices, information technology systems, and lab services.

Indeed, innovation that drives channel growth, data and analytics and information technology strategies will be even more important than traditional drug or device product development when it comes to owning the disease. While the lifetime of a product may end within 10 to 15 years after its launch, the sustainable competitive advantage from investments in, for instance, analytics may be available for a much longer period, especially if it enables the acquisition of valuable patient data sets that are otherwise difficult to assemble.

Sales forces may need to be realigned and new management structures adopted to provide such customer-focused solutions. In diversified drug and device firms, marketing may need to be coordinated in different ways, with client account leaders that focus on selling total solutions as opposed to single products. The release of an integrated solution could require new pricing and promotional policies. There may be broad implications for an organization's supply chain, its technology strategy and platform and its personnel operation, including recruitment, training, and retention programs.

Leveraging social, mobile, and cloud data, information and analytics to predict, prevent and manage risk is the primary purpose of Big Data-based strategies.

Run an innovation operating model: Most organizations limit innovation to R&D; to own the disease, companies should have an operating model that requires innovation to emerge and develop across and throughout the enterprise.

Incentivize people to do the right thing: Incentives should focus on selling solutions (which often will include products and services from others), delivering the entire platform and solving the total problem.

Converge programs, products and services into solutions on a common platform: This may require co-creating and delivering solutions with partners on a platform, since companies can't always be the platform leader for every product area. In some situations, companies may own the disease with others participating with it; in others, they will participate in providing solutions for diseases owned by others.

Expand the value proposition: Companies should put themselves in their customers' shoes. Customers do not want to buy products and services; they want their problems solved, their pain points removed and the ability to lead healthy lives. Products and services are merely a means to those ends, and so solutions should address the total problem. Strategy should reflect this understanding.

Other units face similar challenges, as entire business eco-systems may need to be created, revamped or managed to provide the integrated care solutions inherent in owning the disease. A research and development structure originally developed for siloed products developed from the top down may need to be redesigned to focus on consumer engagement.

In an age in which outcomes, and not necessarily sales, will increasingly drive revenue, finance, and accounting operations are likely to require restructuring and new management techniques to address an evolving set of dynamics. Customer service and support probably will require a reorientation to improve user experiences and interfaces since companies that own the disease should become much more consumer-centric and customer-oriented than in the past.

4. *Business development as we know it is finished*: Owning the disease requires a broad reappraisal of business development, licensing and joint ventures. The standard model of corporate business development emphasizes efficiency at the level of the sales force and putting new products in the hands of representatives. However, new limitations on what salespeople can offer to physicians means that marketing and co-promotion should be crafted in a far more sophisticated fashion in order to be effective.

Beyond enhancing sales operations, business development executives are likely to need to consider cross-sector opportunities incorporating diagnostics, pharmaceuticals and devices into a potential offering. As they do so, they likely will need to re-examine their models for payments, revenue, financials and intellectual property ownership.

The hierarchical structure that characterizes most organizations in the health industries makes adaptation to this new environment challenging. While medical device companies, on the whole, have proven themselves to be more nimble than pharmaceutical firms in developing and offering new products, they find themselves less agile than the technology and consumer products companies now entering the health care field. The simple willingness to enter a new field proves the flexibility of these companies; many also bring with them advantages, whether it is an existing customer-centric culture or robust finances.

Having The Right Strategy In Place

From a strategic standpoint, owning the disease has four stages. First, portfolio evaluation. Companies should affirm their business goals in owning a disease and then adopt the appropriate strategy. Identifying the correct strategy includes defining innovation needs and capabilities, determining innovation boundaries and creating an innovation strategy.

Second, operating model alignment. Companies should have both the right innovation operating model with its appropriate strategies for both technology innovation and business model innovation. They should determine what components they already possess and then identify which they need to address, whether through internal development, M&A, or partnerships.

Implementing the right operating model is more difficult than choosing the appropriate innovation strategy. The appropriate operating model will vary by company and sector, but it is characterized by the presence of key levers of innovation. Companies need organizational effectiveness, ensuring that the right

skill sets, capacities, leadership and culture are in place to support the planned development programs. They should put in place institutional decision-making and governance processes to generate accountability and ensure timely decisions. They also should have technologies and tools to optimize their development. And they should have the processes, standards and metrics needed to identify, establish, and maintain leading practices.

The third stage of owning the disease is execution. Externally, companies should identify and enter into partner relationships and collaborations that are appropriate for their objectives, especially to acquire the global assets and footprint required to maximize access to the talent, technology, and innovation essential to owning the disease.

Internally, companies should adopt several core design principles to achieve value. WellDoc's DiabetesManager solution, as used by AT&T for its workers, is *interoperable* with other relevant applications, including the Allscripts electronic health records. DiabetesManager is *integrated* into AT&T's existing health care network. It is *intelligent*, providing usable data that are acted on by participating physicians at a rate quadruple that of non-participating doctors. It is *outcome-oriented*, targeted at measureable and relevant metrics that are crucial to producing results. It is *socialized*, with personal coaching and direct clinician support to reinforce behavior. And it is *engaging*, to more fully involve the patient and ensure "stickiness" and daily use.

The fourth and final stage of owning the disease is continuing refinement based on science and technology advancement, in which companies continually adjust their business model to reflect developments in their industry. In some cases, the change may be significant. Companies should assess their product portfolio, and it is possible that they will find that owning the disease is the appropriate strategy for certain therapies or indications and that becoming a component supplier to another party is preferable. Either approach is acceptable, given the difficulty of owning the disease in multiple areas. Regardless, the business model should be transformed to the reality of the chosen strategy.

Evaluating Progress In Owning The Disease

The success of owning disease can be measured according to several criteria in both the business model and technology, in accordance with the principles articulated in Davila, Epstein, and Shelton's *Making Innovation Work*. The effectiveness of business model innovation can be measured through changes to the company's value proposition (as defined through such metrics as customer experience), its value network (calculated through such measures as its revenue and margins), and its customer targeting. Technology innovation, in contrast, can be evaluated through the performance and feature improvements of its products, enhancements to process technologies such as manufacturing and assembly and enabling technologies (such as information systems).

Merck Serono provides an example of how progress toward owning the disease can be evaluated according to these standards. Its *easypod* wireless injection device, now used in more than 40 countries, is part of a strategy to own human growth hormone therapy for endocrine and metabolic disorders. The *easypod* is used to inject the hormone therapy, and combines the delivery of the drug, the documentation of the dosage and the monitoring of compliance with data shared

automatically with physicians both to support compliance and to be recorded on the patient's electronic medical records.

Value-based reporting to the United Kingdom's National Health Service in a pilot program for the *easypod* demonstrated compliance and improved patient outcomes at lower cost. It also resulted in a number of benefits, including sales growth in a declining, off-patent brand, a reduction in sales force, lower provider administrative costs, better clinical integration, and a shift to more efficient home-based care. Finally, Merck Serono's compensation in the pilot program was based upon the quality of results it achieved, rather than the quantity of sales it closed.

Measured against the business model innovation levers described previously, Merck Serono enhanced its value proposition by improving its customer experience through an easier-to-use interface and shifting to a value-based compensation model. And it better targeted customers through in-office nurse consultations. In this, Merck Serono acted to reflect the principle that owning the disease is about expanding the client value proposition by finding or creating new sources of value.

On the technology innovation side of the ledger, Merck Serono used a clinical nurse -staffed call center to improve product compliance, and advanced its use of process technologies through sophisticated mobile device and medication selection, in-home patient training and clinical data integration. It also applied enabling technologies well by sharing data with providers (to improve compliance) and payors (to demonstrate the value of the technology).

Challenges Facing The Industry

The future potential of the owning the disease concept is highly positive. Yet there are roadblocks that could present barriers for many companies.

While most or all companies see the same or a similar future, many of them cannot change their internal structures and practices to align with that future. They are too large, too silo-based, or too focused on yesterday – or today – to modify their organizational structures in a productive way for tomorrow. Some lack the right leadership. Some are waiting for others to change and hope to become "fast followers" instead of leaders and innovators.

As with most innovations, creative destruction and disruption are emerging from new companies that do not suffer from the stifling structures seen in large organizations. A leading molecular diagnostics laboratory is doing this in rheumatoid arthritis by combing apps, algorithms, and molecular diagnostics to provide patients and physicians better tools to manage the disease.

Another example is a life science diagnostic company that is applying its molecular diagnostics around Galectin-3 to change the practice of medicine around chronic heart failure and hospital readmissions. While big companies have many advantages in assets, capabilities, resources and brand, they lack the focus, energy and incentives that startups use to disrupt the status quo.

Yet another issue for some companies is the nature of the provider workforce. Owning the disease can require fundamental changes that can be disconcerting. Many older physicians, nurses, and other health professionals are reluctant to make broad changes to their practices or how they interact with device or pharmaceutical companies. Younger professionals, while more willing to adapt, often are employed

by large companies, hospitals, or practices and lack the autonomy to make decisions about products or services.

One point that many who are attempting to adopt the concepts underlying owning the disease into their own businesses do not appreciate is the complexity of the concept when it is applied to health care. Apple, which can serve as a model for companies seeking to transfer their success to health care, has a notably different business portfolio and product management approach: only a single profit and loss model for the entire company; a very limited product portfolio; limited regulatory constraints; and products that typically can come to market quickly but yet can be replaced just as speedily.

The challenges of owning the disease should not be underestimated for health care companies. Yet, the consumer and physician experience in these consumer technology markets is informing and creating their expectations in health care. Patients want, and increasingly demand, that same experience in both worlds, and do not understand when they cannot have it. Patients' awareness of developments in technology supports this. In fact, patient expectations for care may be growing as diagnostic capabilities become more advanced: a recent PwC/Economist Intelligence Unit research report found consistent support among patients, providers, and payors for engaging in health diagnosis, treatment, and monitoring using consumer tools such as mobile phones.

Increasingly, the ubiquity of mobile phones and the proliferation of smart phones make these consumer expectations global. Other factors come into play, including global mobility that facilitates increasing cross-border knowledge and greater access to data which is driving understanding, heightening expectations for quality care in all markets.

In this world, manufacturers are at risk not from lower-cost manufacturers of similar products but from the development of owning the disease-like ecosystems in emerging markets that adapt to the regulatory and reimbursement demands of developed markets, providing quality care at a lower price. Increasingly, this dynamic is a manufacturer's greatest risk.

None of this is really new. In the 1920s, the Australian Royal Flying Doctor Service pioneered telemedicine, with patients contacting physicians using two-way radios, powered by a dynamo driven by a set of bicycle pedals. Today, the near-ubiquity of mobile technology promotes health care access. In Australia, Ericsson supports a broadband project that gives rural women access to the latest digital mammography technology.

Other countries have seen similar developments. In Finland, patients with diabetes and cardiovascular disease use monitoring devices to transmit information to physicians and obtain advice through phone consultation. In the US, small hospitals in Montana have video ICU referrals that enable remote monitoring of patients. In Bangladesh, Telenor supports a 24/7 medical call center that provides medical advice and information to remote areas. In Africa, PwC recently predicted that nearly 60% of mobile health revenues will come from diagnostic-related services, compared to the worldwide average of only15% of all services.

Those organizations that can meet these customer demands by owning the disease are likely to be the future market leaders.

Choosing The Right Business Model

Today, medical technology companies face more, and more daunting, challenges than at any time in their history. The status quo is simply not an option in a world in which revenues are declining, expenses are climbing and secular, structural changes make the prospects for any long-term recovery questionable, unless linked to significant change through technology and business model innovation.

The shift of health care from a linear value chain to an ecosystem or convergent environment is perhaps the most significant of these changes, transforming the fundamental business model for health care organizations. Medical technology companies seeking to master these changes should consider their business model options, identifying how the options available to them fit their value proposition in this new environment and how to both generate incremental revenue and leverage their customer insights, current partners and sales channels.

Part of this effort includes identifying the most attractive business models, considering each company's own internal capabilities, attractiveness and fit with their existing and desired organizational structure. Among the points to consider are the best ways to delivery products and services and monetize new concepts, bearing in mind channel, partners, and pricing.

Each company should determine the best model for its situation, taking into consideration its financial impact, what changes should be made to enhance or deliver value, the resources and partners to which it has access and the capability and technology trade-offs it can make to allow for maximum profitability.

Providing products and service that deliver value across the full continuum of care is the essence of owning the

10 Things to Remember About Owning the Disease

1. Expanding the value proposition for clients is *the* crucial part of owning the disease. This may require both a more focused effort on innovation and a greater tolerance for risk and failure.
2. Concern about destroying cultures that have been successful is merited, but owning the disease ultimately entails the creation of a new, convergent culture to generate new sources of value for clients.
3. Owning the disease entails breaking down silos to better understand a customer's total needs while decreasing the complexity in providing solutions.
4. Scale matters in owning the disease – but not in the way many expect. Some large organizations may find it difficult because they are too complex, too divided into silos, and too incapable of leveraging resources.
5. Owning the disease changes a business from selling products and services to selling solutions. As a result, the mix of revenues will gradually shift to a roughly equal split between products and services, in which information and analytics will become the key differentiators and drivers of value.
6. Owning the disease can involve controlling a channel so that the company becomes the essential conduit through

disease. The gradual shift to preventive measures and early diagnosis and intervention support this change. As Jeffrey R. Binder, president and CEO of **Biomet Inc.**, recently noted, there increasingly are "tremendous opportunities for us to intervene earlier in the disease process." As companies actually adopt the business model changes needed to incorporate the concepts behind owning the disease, they also should adopt the leading-edge techniques – Big Data analytics, platform innovation, and co-creation – that support the implementation of these ideas.

Endo Health Solutions is an example of a company that has embraced the ideas behind owning the disease, moving from episodic-based businesses to total channel management. For many companies, the answer is clear: Swimming with the current is much easier than going against it, and there is no going back upstream. By choosing to own the disease, medical technology companies can build solutions that patients, payors, and providers alike want, can build more sustainable sources of revenue and will be better-positioned to navigate the current and coming storms. Some early movers, such as Merck Serono and Endo Health Solutions, have made progress. The question is whether these companies will remain outliers, or whether they are in the vanguard of significant change.

which others sell their products.

7. Information strategy drives owning the disease. As value in health care migrates from things to information, organizations that harness data most effectively may have a competitive advantage.
8. Owning the disease is *not* a diversification play. Instead, it is focused on integration and cooperation to bring an integrated solution to the customer, whether that is the patient or the provider.
9. When focused on the provider as the customer, it may be easier to own the disease in small, focused segments rather than large diseases in which patients have co-morbidities and multiple needs and where owning the disease should be focused on the end consumer.
10. Analytics are the "secret sauce" to owning the disease. The challenge in creating analytics is obtaining the complete sets of underlying data needed for the study.

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