

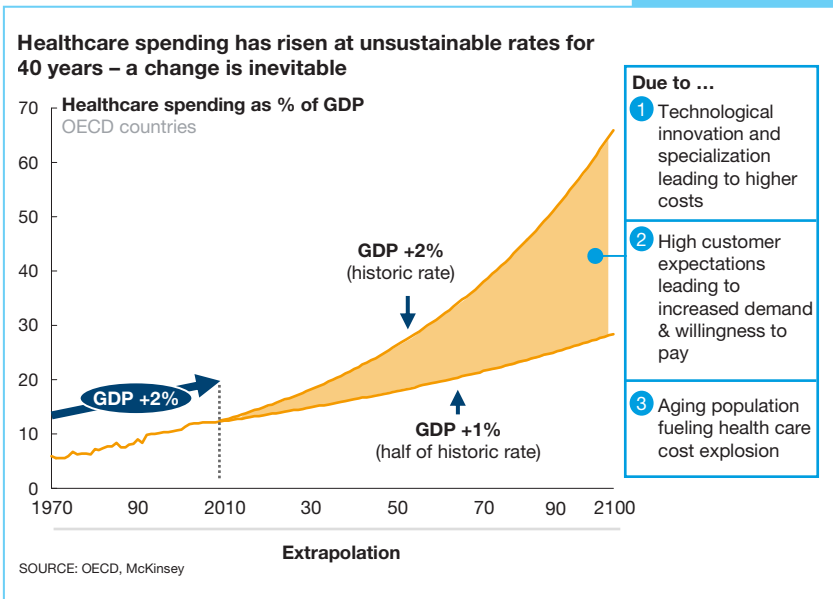
Beyond the pill:

Creating medical value through technology enablement

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Economic and demographic pressures on health systems around the world are forcing providers to improve their performance. New technology not only can help companies to address several major care challenges—such as compliance and chronic disease management—but also can help them to create hundreds of billions of dollars in value. Already, technology has transformed many industries, and healthcare is ripe for change. Although high-tech and telecom firms have made significant investments in this space, pharma and medical device companies are better positioned for success. Capturing this opportunity, however, will require the involvement of top management as well as major changes to organizations and capabilities.

As health systems face increasing pressure, they are looking to improve quality, reduce cost, and increase safety and access (Exhibit 1). England's National Health Service, for example, has expanded its oversight on quality and has restructured hospital providers. In the United States, where healthcare costs as a percent of GDP are the highest, the system is slowly shifting from



fee-for-service payments to outcome-based reimbursement. Healthcare reform is accelerating this shift.

Under tremendous cost pressure, payors are taking strong actions to stay alive. They are scrutinizing all aspects of utilization, including high-spend pharmaceuticals and medical devices (see sidebar “Payors Speak Up about Opportunities”). Their major targets are:

- High-cost therapeutic areas, such as chronic diseases, oncology, and rheumatology.
- Inefficiencies in care modalities, such as inappropriate drug spending, unnecessary surgeries, and avoidable hospitalizations. A small number of patients account for the majority of costs.
- High-cost venues of care, when lower-cost settings such as specialized homes could be developed and used effectively.
- Health system issues, such as the fragmentation of providers and the sub-optimal use of healthcare data.
- Underuse of preventive and population-based services due to misaligned incentives and systemic waste.

The numbers on medical effectiveness are alarming, and payors are increasingly focusing on them. In the United States, for example, 40 to

Payors Speak Up about Opportunities

"If the current trends continue, we'll be out of business and the pain will ripple through the entire value chain."

– CEO of a major health plan

"We're always interested in unique business models provided they create value...but can you get a return given the state of the science?"

– SVP for clinical advancement

"Personalized medicine is what keeps me up at night... We lack the analytic and technological capabilities on this."

– VP for health affairs

"It would be ideal to have the tools [for personalized medicine and clinical diagnostics] in the provider environment."

– SVP for health affairs

Source: Interviews with payors and key opinion leaders.

70 percent of patients, by disease condition, are noncompliant with drug regimens. Poor provider or patient adherence to protocols leads not only to inadequate treatment, but also to 20 to 35 percent of all adverse drug events. Together, they have been blamed for 125,000 deaths and \$100 billion in healthcare and productivity costs every year—not to mention the \$80 billion in lost pharmaceutical sales¹.

Of those patients who do comply, 20 to 90 percent, depending on the treatment, do not respond to the prescription. The average is roughly half for medicine as a whole. Similarly, much of the diagnostic testing and imaging, as well as potentially some surgical procedures, are unnecessary.

We have already seen some examples of this new pressure in pharmaceuticals. The French national health insurance program recently created an independent overseer for quality, and it is employing new metrics to boost the results of its spending. Xavier Bertrand, the health minister, recently said, "We consume too many drugs in France²." England's National Institute for Health and Clinical Excellence declined Johnson & Johnson's Velcade biologic for multiple myeloma, which costs more than \$24,000 per treatment cycle. Only after the company agreed to refunds for non-responders did the government reverse its decision.

¹ Academic literature; National Pharma Council; Pharmaceutical executive, McKinsey 2005 survey of hypertensive patients on persistency/compliance, McKinsey analysis.

² "French pop too many pills, says health minister," *Radio France International*, June 23, 2011.

Emerging opportunities

Over the next several years, health systems and payors will actively seek ideas from all stakeholders to increase medical value. Five opportunities are highly attractive: patient adherence, chronic disease management, closed-loop monitoring, drug-test combinations, and data transparency. Cost-savings could run into the hundreds of billions of dollars—while still boosting total revenues for pharma and medical device companies.

Patient adherence. Pharma companies have struggled for years to overcome the challenge of poor adherence to treatment regimens. Taken together, the challenges posed by the complexity of drug treatments, the episodic and infrequent nature of interactions with providers, the involvement of multiple stakeholders—payors, pharmacies, physicians, and patients—and the limited visibility into patient homes have proven to be insurmountable by conventional means. While experts have long seen a solution in enabling patients to have a robust dialogue with providers, the necessary tools have been missing, while websites, call centers, letters, and customer relationship management (CRM) software have all proved limited.

New technologies offer significant potential, however. They collect a wealth of personalized patient adherence data to facilitate a stronger dialogue. A new “smart cap” for insulin injection pens tells users how long it has been since their last injection. “Smart bottles,” such as those offered by Boston-based startup Vitality, provide escalating reminder levels. First the device glows; then it makes a noise; and finally it calls your phone. It also regularly reports on bottle use for patients, caregivers, pharmacy, and physicians. Electronic pillboxes offer similar benefits.

“Chip-on-a-pill” technologies go even further to record the actual consumption of medicine. For example, Proteus Biomedical and other companies implant ingestible chips that can send a signal to an external device. Once in the digestive tract, the chip transmits vital signs and confirms the dose taken.

While aligning the various stakeholders in the healthcare landscape will be challenging, we believe that these technologies are already ripe for adoption in more closed or self-contained settings such as specialty care. Pharma companies could partner directly with specialty pharmacies to deploy these solutions. Improved adherence also could significantly increase medical value. As patients step up their treatments and see better outcomes, they will consume more medicines while requiring less intervention from providers.

Chronic disease management. This accounts for 75 percent of U.S. healthcare spend— amounting to more than \$1 trillion and to \$3 trillion worldwide. And it will only continue to grow as more conditions, including heart disease and certain cancers, go from an acute to a chronic condition.

The World Health Organization (WHO) estimates that in 2008 chronic non-communicable diseases accounted for 63 percent of all deaths worldwide³. Treating these conditions effectively requires new tools and technologies that can change the standard of care from episodic to continuous, including remote-monitoring capabilities, apps on smartphones, and location-based services.

A recent study of the Veterans Affairs hospital system in the United States demonstrated a 7 to 13 percent reduction in monthly costs per person through a carefully designed and implemented care management and telehealth program. Patients with diabetes, congestive heart failure, and chronic obstructive pulmonary disease used a remote-monitoring device to answer daily questions about their symptoms, vital signs, and health behavior. Care managers reviewed their answers and responded with timely escalations or interventions⁴.

Several interesting applications are available on the Apple app store that allow patients with chronic conditions to better manage their disease state. In India, for example, mobile phone services provide tele-counseling and algorithm-based diagnosis for chronic disease conditions for more than 20,000 patients today. We believe that solutions for these three disease areas—diabetes, congestive heart failure (CHF), and chronic obstructive pulmonary disease (COPD)—are mature with key stakeholders aligned and ready for broader adoption. Other disease areas, such as rheumatoid arthritis, oncology, and back pain, will soon see advances in care as well.

Closed-loop monitoring. This represents the next wave of drug-device decision-support integration in chronic care. Here, monitoring devices are equipped with intelligence to act in real time on readings and to deliver treatment. Continuous glucose monitoring, for example, aims to integrate a monitor and an insulin pump, and provide intelligence to administer optimal doses of insulin at the right time. Several companies are currently pursuing this opportunity.

Similarly, implanted defibrillators are equipped with advanced intelligence to deliver the right pulse to maintain heart performance. The technology challenges are still significant, and the regulatory hurdles will be difficult. Still, this opportunity promises to deliver significant medical value for all key stakeholders.

Drug-test combinations. Physicians have long been aware of significant variations in patient response to various drugs. Over the last century, the ability to measure individual variations and tailor therapy has grown

3 "Global status report on non-communicable diseases," *World Health Organization*, 2010.

4 Laurence C. Baker et al., "Integrated Telehealth and Care Management Program for Medicare Beneficiaries with Chronic Disease Linked to Savings," *Health Affairs*, 30:1689–1697, 2011.

exponentially from physical characteristics (age, gender, and race) and family history in the mid 20th century to diagnostic tests for characterizing protein, antibody/antigen, sugar, and metabolite levels in the late 20th century.

Today, thousands of genomic and combinatorial measurements are transforming the ability of physicians to adjust medication to individual patient profiles. For example, anesthesiologists have long suspected that red-haired females need more anesthetics. Now that information can be linked to the MC1R gene on chromosome 16 and pheomelanin to potentially guide dosage levels⁵.

To realize the full potential of these developments, however, major challenges must still be met. These include improving the molecular understanding of disease, aligning incentives among various stakeholders, and developing the necessary informatics. Until that time, “personalized medicine” will continue to focus on companion diagnostics.

Most of the value will accrue to players demonstrating the usefulness of biomarkers, especially the pharma companies. Herceptin was the first major example of this, as the availability of the HER2 FISH (fluorescence in situ hybridization) test is thought to have resulted in Herceptin coming to market eight years earlier than estimated. It required only a 20-month clinical trial, ending in 1998, rather than a 10-year full population trial⁶.

Pharma companies are starting to take the next step and are including distinct biomarkers and companion diagnostics in the FDA labeling of pharmaceuticals. Gleevec, Erbitux, and Tarceva are prime examples. Rather than develop an in-house expertise, many are partnering with or acquiring diagnostics companies. We thus expect the number of diagnostics–pharma deals to grow.

Data transparency. Growing volumes of medical data, advanced computing capabilities, and increasing levels of access have resulted in pockets of unprecedented transparency and insights. Data transparency has the potential to reduce medical errors, raise the standard of care, reduce healthcare consumption, and improve outcomes. This, in turn, has the potential to completely change pharma and medical device offerings and reimbursement patterns.

While significant obstacles remain in linking inpatient, lab, outpatient, claims, pharmacy, and imaging data, a few exciting examples already exist. WellPoint has started using IBM’s Watson to evaluate patient claims data and identify

5 E.B. Liem et al., “Anesthetic requirement is increased in redheads,” *Anesthesiology* 2:279–83, 2004.

6 Per public comment of CEO Art Levinson and President Susan Hellmann of Genentech, 2009; also Genentech websites, company reports, and news and analyst reports.

treatment options, for example. And Novo Nordisk has conducted a virtual retrospective clinical trial across millions of health records in Denmark to demonstrate there was no increased risk of cancer with a particular type of insulin. On the consumer end are such companies as Castlight Health, a San Francisco-based startup aiming to become the “Travelocity of healthcare.” It offers pricing transparency so that patients can choose the most cost-effective providers.

While creating “perfect data” is fraught with challenges, we believe that increasingly workable solutions are being created. Key stakeholders in the healthcare value chain, for example, are building advanced capabilities and establishing a competitive advantage.

An increasingly complex competitive landscape

Several large (and small) technology, telecom, and other players have made significant investments in this space. Intel, has developed a “Healthcare Management Suite” for providers to use with patients employing the company’s electronic monitoring equipment. AT&T and Orange are establishing mobile health platforms to deliver remote care, and even Ford Motor Company has jumped on the bandwagon to offer heart-monitoring car seats.

Despite their first-mover advantages, these companies face major barriers in fully commercializing their innovations. Established drug and device companies have a deep understanding of disease states, credibility with payors and providers, and extensive regulatory experience. They also have advanced marketing capabilities with global brand recognition and mature channels to distribute products and services worldwide. This not only places them in an enviable position of strength but also makes them a partner of choice for technology companies. Intel, for example, relies on a joint venture with General Electric for its “Care Innovations” effort.

Even for pharma and medical device companies, creating and capturing value in this space has proved to be elusive. We believe that success in most areas will depend on four key components across the value chain: a recorder that collects data from the treatment sites, a repository that converts data to information, an analytics and intelligence engine to guide clinical decisions, and behavioral mechanisms that guide or enforce appropriate clinical intervention. Few models have succeeded in both establishing these components and determining how to capture the most value.

Getting started

Beyond creating a profitable strategy and business model, pharma and medical device CEOs need to build intensive capabilities in operations, technology, and business development. This will require answering some tough and candid questions, such as:

- Is our CIO the right person to help us **navigate the technology landscape**, or do we need a CTO? How can our IT organization—which to date has focused on efficiently delivering large capital projects—supply these solutions? How can we successfully incubate these technology ideas and ventures within our company?
- Do we have the **operational capabilities** to integrate technologies with our products? Are we in a position to drive economies of scale to make some of these components cost-viable? Do we have the cold-chain logistical capabilities, for example, to supply a batch of one to a patient?
- Is our **business development** group equipped to scout for appropriate targets? Are our traditional criteria for success around defensibility, barriers to entry, ROI, and IRR applicable for these spaces?
- More broadly speaking, does our organization have the **intellectual curiosity** to explore new realms of possibility and deliver distinctive patient value? In the coming decade, could we become the Apple that transforms healthcare through developing attractive products and services?

* * *

These new technologies not only will add enormous medical value but also will shift the healthcare landscape. Pharmaceutical and medical device companies that are able to integrate them into their product development and delivery processes will stand to gain revenue and market power. While most of these advances are still emerging, companies will need time to develop the capabilities necessary for speedy integration. Rather than wait to see the technologies mature, smart executives will start preparing now.

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