Progressions
Navigating the payer landscape
The progression of *Progressions*

These word clouds show the most frequently used words in our first pharmaceutical industry report (top) and our two most recent reports (bottom). Larger font sizes indicate words used more frequently. Some common words have been removed from both clouds.
Welcome

To our clients and friends

Welcome to the 10th issue of EY’s pharmaceutical industry report.

The global pharmaceutical industry has changed dramatically over the last decade. Ten years ago, the industry stood on the sunnier side of the patent cliff. Products that gained marketing approval could count on being reimbursed without additional scrutiny. Companies focused their sales and marketing efforts almost exclusively on physicians, who had relatively free rein to prescribe drugs as they saw fit.

Our first pharmaceutical industry report reflected the times. The picture that emerges from the upper word cloud on the facing page is one of an industry preoccupied with issues such as drug research and development, generics, intellectual property, regulatory issues and patents.

Fast forward to 2012 and 2014, our two most recent reports, and the picture could not be more different. In the lower word cloud, the outsize presence of the word “pharmaceutical” has been replaced by a more balanced perspective on “health care,” “payers” and “patients.” Meanwhile, other issues have emerged in the conversations we are having with clients: data, value, outcomes and business models.

What has changed is that health care is being reshaped by a move to outcomes and value. This is a revolution led by payers — who are the focus of this year’s report.

For pharma companies, navigating a fragmented payer landscape at a time of tremendous change poses challenges and raises many questions. How soon is the move to outcomes and value becoming real? How does one make sense of a complex and changing payer landscape? To what extent, and in what ways, should pharma companies move beyond the product?

In this year’s report, we provide answers to these critical questions. Chapter 1 focuses on the pace of change across key markets and finds that things are moving quickly along many dimensions — health care reforms, data analytics, patient-empowering technologies, the drive to transparency, and more. Chapter 2 summarizes findings from our survey of US payers, European payers and pharma companies — and highlights some critical gaps between the industry and payers. Chapter 3 presents a structured approach for dealing with a complex and fragmented payer landscape: the strategic payer engagement framework, which allows companies to screen, segment and sequence payers and solutions.

Above all, this year’s report issues an urgent call to action around three imperatives that are critical for engaging payers: developing customer-centric solutions, developing data-driven insights and interventions, and restoring trust.

Engaging with payers may be challenging, but it is also critical — for the health of patients, the financial health of pharma companies and the fiscal health of health care systems. EY’s global organization stands ready to assist you as you navigate the payer landscape.
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Introduction

The story so far

Health care as we know it is being fundamentally disrupted by two megatrends:

1. **New incentives.** First, payers and systems across the world are grappling with the challenge of putting costs on a sustainable trajectory – a task that is exacerbated by a looming chronic disease epidemic, aging populations, expanding access, and rising expectations for health care in burgeoning middle classes across emerging markets, among other factors.

To address these sustainability challenges, public and private payers are increasingly moving from fee-for-service payment systems to pay-for-performance models – no longer paying for volume and activity, but rather for value and outcomes.

2. **New technologies.** Accompanying this shift is the second megatrend: the emergence of big data and new patient-empowering, information-leveraging (PI) technologies such as social media, smartphone apps, wirelessly connected devices, sensors and more. These technologies are empowering patients with transparent information and giving them more control over their own health. They are also potentially game-changing for managing chronic diseases.

The disruption of health care is attracting non-traditional entrants from a wide range of industries – information technology, data analytics, mobile telephony, retail trade and others. These companies are being drawn by the tremendous opportunity to apply their strengths to the challenge of making health care more sustainable.

Disrupting pharma’s business model

These trends promise to disrupt the pharmaceutical industry’s business model. For pharma, this represents the third iteration of its model in the last decade or so. The industry’s traditional blockbuster model (Pharma 1.0) was first disrupted by the patent cliff, giving rise to Pharma 2.0 – in which companies focused on increasing operating efficiency, finding new sources of growth in emerging markets, and expanding into or getting out of lines of business.

The new incentives and technologies described above are now challenging the industry’s business model again, leading to the latest iteration, Pharma 3.0. In Pharma 3.0, companies will need to simultaneously develop **multiple business models** to meet the needs of a broader and more fragmented customer base (payers vary from market to market; patients have diverse needs and preferences) and play across more fragmented channels (social media, m-health, etc.).

Building multiple business models across diverse channels to serve diverse customers will require a broader set of skills than pharma companies have in-house – sophisticated analytics capabilities, social media platforms, customer segmentation experience and more. Much of this will therefore be achieved through collaboration, often with companies from a wide variety of industries – something we refer to as **radical collaboration**.

The challenge, however, is that it is very difficult for mature incumbents to disrupt their own business models. Disruption typically comes from the outside. To help address this challenge, we have offered numerous paradigms for business model innovation over the last few years of Progressions, which could collectively be thought of as a business innovation toolkit:

- To facilitate the development of multiple business models, we described a process of **commercial trials**. Much like the clinical trials that companies conduct for drug development, commercial trials would consist of multiple phases, to encourage a large number of experiments, find out which ones work in concept, and then commercialize and scale up the ones that succeed.

- To help identify the best market opportunities for these new business models, we introduced the concept of **value pathways**. These disease-specific pathways map the patient journey in a certain disease, identify the biggest value leakages (opportunities to improve outcomes) and provide a starting point for identifying new solutions to fill these leakages, often through radical collaboration.

- To help them think through all the aspects of business models, we suggested pharma companies use the **business model canvas** developed by Alexander Osterwalder. This canvas provides a template for analyzing nine key aspects of every business model.

- Lastly, to enable the development of patient-centric solutions, we encouraged companies to use lessons learned from the field of **behavioral economics**, and to conduct “behavioral trials” to customize their offerings for patients.

The rise of the patient: Progressions 2012

Underlying the move from Pharma 2.0 to Pharma 3.0 is an expansion of the pharmaceutical industry’s historic customer base. While the industry traditionally has focused on providers, the new health care is making patients and payers more influential than they have so far been.
The last issue of Progressions focused on one aspect of this changing customer base: the patient. We described the transition to a world in which the delivery of health care would not be limited to the hospital and the clinic; instead, PI technologies would enable patients to manage their health and get access to care wherever they happened to be.

Much of our report focused on a key health care challenge: reducing the burden of chronic diseases, which account for about three-fourths of health care expenditures and have a big behavioral component. To address this challenge, we focused on behavioral economics, which has tremendous potential for nudging people toward healthier behaviors by building solutions based on well-documented behavioral biases.

The rise of the payer: this year’s report

This year’s report is about the second aspect of pharma’s changing customer base: the payer. For pharma companies, dealing with a fragmented and rapidly changing payer universe poses challenges and raises some key questions.

In addition, it has been two years since our last report came out, and much has happened in that time frame with respect to the industry’s business model innovation efforts. As a result, companies also have some important questions about business model innovation.

To address challenges in both of these areas, this year’s report focuses on a few key questions – issues that appear to be top-of-mind for our clients with respect to payers and business model innovation. These are shown in the accompanying chart.

Central questions explored in this report

1. The pace of change
   How soon is the move to outcomes and value becoming real? Is there any real urgency for us to act now?
   Health care is changing rapidly. Early-mover advantages could make it difficult to enter later. See Chapter 1.

2. Understanding payers
   What do payers want? How do we make sense of a complex and changing payer landscape?
   Our survey found broad similarities in payers’ needs (e.g., budgetary predictability) and key gaps between pharma and payers (e.g., comparative trials and trust). See Chapter 2.

3. Investment strategy
   How much should we invest now versus later? What approaches do we use with different payers? To what extent, and in what ways, do we need to move beyond the product?
   We add a new paradigm to the business model innovation toolkit: strategic payer engagement (SPE), a framework for screening, segmenting and sequencing payers and offerings. See Chapter 3.

4. Beyond pilots
   How do we move beyond pilots to larger-scale solutions?
   Payers are tired of pilots; companies need fewer dead-end experiments. SPE provides an answer, by creating a map for scaling up solutions from the outset. See Chapter 3.

Underpinning this is an urgent call to action around building sustained relationships with payers, based on three elements:

- Expanding into (customer-centric) solutions. While not all companies will choose to expand into services, it is critical that new approaches are designed to meet the needs of payers – not just to sell more drugs.

- Developing data-driven insights and interventions. To meet the needs of payers, pharma companies need comprehensive data and analytics that cover the entirety of the patient experience.

- Restoring trust. The most creative solutions and insightful data will go nowhere if pharma companies are not trusted. This is no longer just about doing the right thing, but rather about doing the right thing for business.

Lastly, a few definitional issues. While this report is ostensibly about payers, we often use the term loosely to refer to both traditional payers (insurance companies and governmental bodies) as well as other entities that are increasingly acting like de facto payers (e.g., many providers and employers). In the new health care, where financial risk is being shared more broadly, the lines between these entities are blurring. And from the perspective of pharma companies, these entities are all part of the same process – they are organizations that companies have to understand and work with to get from marketing approval to market uptick.

This report also focuses primarily on large markets in which all or most citizens have health insurance coverage. While there are interesting developments in emerging markets, the move to outcomes and value is being driven by institutional payers – meaning that self-pay markets are not being affected by these trends as quickly.
Three steps to shaping sustainable health systems

Global aging and the rise in non-communicable chronic diseases are causing a steady increase in demand for health services. Patients with new demands are flooding health care systems in the developed world, several emerging markets are expanding access to meet the rising expectations of their citizens, and many developing countries are attempting to increase access to basic health and sanitation. Meanwhile, public and private payers across the globe are grappling with an increasingly urgent challenge: the need to put runaway health care costs on a sustainable trajectory. The only way to bring costs under control while meeting the increasing demands of patients is to deliver care more efficiently and sustainably. As a result, many payers are moving toward value-based paradigms, in which stakeholders — providers, pharma companies, device manufacturers and others — are rewarded based on their ability to demonstrate improved health outcomes.

While these are significant steps toward sustainability, they create other sources of stress, such as pricing pressure on drugs and shortages of primary care physicians. There are three important things that we — payers, the pharmaceutical industry and others — should do to address some of these strains and better shape more sustainable outcome-focused health care systems.

(1) Prioritize and reward innovation. Global life expectancy has increased steadily for nearly 200 years, driven first by improvements in sanitation and education, then by vaccines and antibiotics in the 19th and 20th centuries. Lifespans are expected to stretch even more: from today’s average of 70 years to an estimated 89 years by 2100. But to achieve this, we need to amplify our efforts in innovation.

For pharma companies, this means finding more efficient and productive ways to conduct R&D. At Novartis, for instance, we follow the science: we often focus initially on understanding molecular pathways in rare diseases where there is a genetically homogeneous patient population. Once the pathway is proven, we then pursue parallel development of treatments for larger disease areas that are affected by that same pathway. For example, Afinitor, a drug we originally developed for kidney cancer, is now approved for five indications, including women with HR+ breast cancer, the most common form of advanced breast cancer.

The pharma industry also needs to think about innovation beyond product R&D. What can we do differently in our relationships with payers, providers and patients? For pharma companies, this means finding more efficient and productive ways to conduct R&D. At Novartis, for instance, we follow the science: we often focus initially on understanding molecular pathways in rare diseases where there is a genetically homogeneous patient population. Once the pathway is proven, we then pursue parallel development of treatments for larger disease areas that are affected by that same pathway. For example, Afinitor, a drug we originally developed for kidney cancer, is now approved for five indications, including women with HR+ breast cancer, the most common form of advanced breast cancer.

(2) Increase focus on prevention.

As we all know, pharma companies are faced with the daunting reality that most of the treatments we develop might never make it to market. As a result, developing a new medicine costs around US$1.5 billion on average and takes 10–12 years to reach patients. But while these costs haven’t gone down, payers’ willingness to pay for drugs at historic levels has. In this environment, pharma companies need to ensure that the drugs they develop are well differentiated from other treatments. But policy makers also need to provide appropriate long-term support for R&D, through grants, tax-based incentives and strong intellectual property legislation.

The pharma industry also needs to think about innovation beyond product R&D. What can we do differently in our relationships with payers, providers and patients? We are moving toward new commercial models, such as integrated care programs that bring pharma companies and payers together to offer patients a comprehensive package of products and services. Additionally, new risk-sharing models that link payment to health outcomes are starting to emerge. These models are a good start, but there is room for improvement. We need to work with payers and providers to make sure we’re offering patients the best possible health solution.

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the private sector, the public sector and academia to find ways to better prevent illness and disease. But our collaborative work must begin with a change in our

Too often when talking about health care, we position it as a cost center, when really, it’s a societal investment.

approach. We need to move from a “transactional” approach to health care toward a more outcomes-focused model to generate better value for patients and reduce costs for all.

We all need to work together to change health care, but there are also steps that each of the stakeholders in health can take independently to contribute to better disease prevention. For example, CVS Caremark, the largest pharmacy chain in the US, recently announced its plan to stop selling tobacco products, acknowledging their role as a health care provider and responsibility to help improve patient outcomes. Large employers are implementing corporate wellness programs to improve employee health and loyalty, increase productivity and lower health care costs. Through our “Be Healthy” initiative, Novartis offers trainings on blood pressure and cholesterol measurement, subsidized gym memberships and low-cost healthy meals in many of our cafeterias.

For pharma companies, the increased focus on prevention could represent a potential threat or an untapped opportunity. Historically, our industry has made money largely by treating people when they fall sick. To seize the opportunity in the shift to prevention, we now need to move across the cycle of care, through comprehensive services and solutions such as those described above.

(3) Fully exploit emerging technologies.

Health care is one area that has not yet fully benefited from technology. Technology can impact medicine both from a discovery standpoint and from a patient standpoint, helping to drive down costs, increase patient compliance and deliver better patient outcomes.

There are three technologies in particular that I think will play an increasingly important role in bettering our health care systems. The first is bioinformatics. With the deep sequencing of the human genome and further expansion of bioinformatics, we are able to understand molecular pathways in new ways and draw linkages between diseases. In a similar vein, the increasing use of big data can help us unlock personalized medicine. Big data can lead us to improved patient response rates, shorter development times and safer therapies. Novartis is already employing big data to pre-screen clinical trial participants for certain biomarkers, to reach a targeted population and exclude patients unlikely to respond to treatment. The promise of big data is perhaps even greater across the health care system more broadly. For example, payers, providers and others are starting to look at the potential for using real-world data from numerous sources to make informed decisions about the comparative effectiveness of different treatments. Lastly, wearable technology has the potential to advance remote patient monitoring, patient compliance and self-care. We're already seeing the trend take hold. For example, Google recently unveiled a contact lens containing a small silicon chip, which helps diabetics track glucose levels in their tears. The wearable technology sector has expanded tremendously in just a few years and is expected to grow by as much as US$50 billion over the next five years.

Payers’ drive toward outcomes and value is accelerating the adoption of these technologies. As pricing pressures increase the need to find more efficient ways of developing drugs, the use of bioinformatics and big data in R&D becomes more attractive. Wearable technologies could significantly lower costs by enabling prevention, remote care and more. But payers need to make sure that such technologies are appropriately rewarded, and the pharma industry needs to embrace them now, for our own benefit and that of our patients.

Right now our health systems are struggling to keep up with higher demand and fewer resources. And we in the pharma industry won’t be able to meet the needs of our evolving health care systems without continuing to innovate, strengthening our efforts around disease prevention and leveraging cutting-edge technology in medicine.
Moving to value – and trust
A conversation with Mark McClellan, Brookings Institution

**EY:** What lessons emerge from the US experience to date with accountable care organizations (ACOs)?

**McClellan:** The most successful ACOs share a few common features. First, they have made a real commitment to cultural change throughout the organization. Often, they identify clinician leaders who are respected by their peers and can help drive the strategic shift.

Second, successful ACOs have taken specific steps to change delivery and achieve improvements in care and reductions in cost. There are different ways to accomplish this, depending on the type of organization. ACOs that are primary-care-based are focusing on primary care changes that can reduce hospitalizations and otherwise improve care. Those that have integrated care systems with hospitals and specialists have taken steps to reduce readmissions and even head off some primary admissions.

Early on, the fastest-growing component of ACO implementation was integrated or hospital-based systems. They had the size and scope to devote capital to such efforts and had a foundation of care coordination to build on. In the past year, the fastest-growing segment has been ACOs led by smaller physician groups. Private plans may prefer working with these organizations in part because they have less market power; also, these smaller ACOs can make changes more rapidly, because savings go straight to the bottom line in a physician group that doesn’t have to deal with the cost of inpatient systems.

**EY:** Much of the current experimentation with new models is in the form of pilots. What needs to be done to scale these up?

**McClellan:** Pilots are very useful where we don’t know exactly what the best approach to reform is. But the problem is that they often remain one-off experiments that aren’t easily expanded or scaled up.

There are some things that the Centers for Medicare & Medicaid Services, in particular, could do in its growing set of pilot payment reforms to help address this challenge. One is to have a common and clear set of meaningful performance measures across a wide range of pilot programs – medical home pilots, pioneer ACO reforms, etc. This would make it easier to set them up, could give participants timely and consistent data and would facilitate much faster evaluation and expansion of programs that work.

**EY:** What challenges need to be overcome in the drive to greater transparency?

**McClellan:** Transparency in drug pricing – through, for instance, plans with tiered benefits, where patients can save when they use cost-effective drugs – is clearly influencing patient behaviors. But the process has been slower in other areas of medicine, because quality and price information isn’t as easy to interpret. The problem is that for many patients – for example, diabetics – the decision isn’t about a specific service, but combinations of services, often from multiple providers. Unfortunately, there is very little clear information for patients on the overall cost of an episode of care, including all the services that they’re likely to need.

We’re starting to progress in areas such as colonoscopies and elective surgical procedures, where information on quality and overall cost to the patient is becoming more available, but we still have a ways to go.

**EY:** What could pharma companies and other health care stakeholders do to build more trust?

It’s worth remembering that many of the providers now working with payers on ACOs came from relationships where there wasn’t much trust historically. Their interactions instead involved hard negotiations on discounts relative to Medicare rates. But you can’t shift to a system where you’re aiming for the same shared goals – better outcomes and lower costs – without a foundation of trust. So providers and payers have engaged in specific pilots and come up with alternative success measures; and in the process, organizations that were previously antagonistic have been able to work together and build trust.

Pharma companies now have the opportunity to do the same. They are investing much more than they used to in pharmacoeconomic studies to demonstrate comparative effectiveness and in new approaches to deliver value to health care systems. Efforts such as these are an important first step in building the trust that will be essential for success in a value-driven health care system.
Chapter 1

The pace of change
Chapter 1
The pace of change

In brief

- The ways in which health care is delivered and paid for have changed rapidly over the last five years. Significant reforms are under way in major markets. Disruptive entrants and initiatives are emerging with novel approaches in data analytics, personalized medicine and PI technologies. The movement toward transparency is accelerating.

- For pharma companies, these trends are potentially disruptive. Companies could consider a range of potential responses – from developing value dossiers to support their products at one end of the spectrum to even moving into health care delivery at the other.

- Despite the scale of disruption, pharma companies’ responses have so far mostly been in the form of ad hoc experimentation. Instead of reactive and fragmented experimentation, companies now need a coordinated, strategic approach.

- While pharma companies may not feel much urgency to act because net margins in the traditional drug business have not yet shrunk significantly, wait-and-see may not be the best option. Early-mover advantages – for instance, from network effects and switching costs – will make it harder to enter the market later.

Health care reforms

Around the globe, governments and private payers are wrestling with a common challenge: the need to bring health care costs under control. This is being exacerbated by trends that are playing out to varying degrees in different markets – expanding health care coverage, economic austerity, rising prices of specialty drugs, and a growing chronic disease epidemic that is being fueled by aging populations, sedentary lifestyles and rising middle classes in emerging markets.

It has been four years since the release of Progressions 2010: Pharma 3.0, our first report on the move to outcomes-focused health care systems. A lot has happened since then. The world we envisioned – empowered by changing incentives, an explosion of big data and the rapid rise of new technologies – is swiftly becoming real on many fronts.

Markets worldwide are therefore launching major health care reforms to make their systems more sustainable. Things have changed dramatically in just a few years.

When our Pharma 3.0 report was launched in February 2010, for instance, the Affordable Care Act (ACA) had not yet been approved in the US. Nor was its passage a sure thing. It took considerable wrangling and last-minute legislative maneuvering for the law to be passed by the narrowest of majorities. Four years later, “Obamacare,” while still controversial, is gaining momentum and starting to reshape how care is delivered and paid for in the world’s largest health care market. There is a long way to go, but the law has given stakeholders the incentive, or perhaps the political cover, to make much-needed changes. Provider groups are not simply consolidating; they are reorganizing into new groups (e.g., accountable care organizations and patient-centered medical homes) that are reimbursed based on their ability to improve patient care at a lower cost. Patients, long shielded from the financial impact of their health consumption decisions, are becoming motivated to behave more like consumers, thanks to high-deductible plans, higher co-payments, increasingly transparent information and more.

Things have changed dramatically in just a few years.
The French are leading the way in embracing mobile health technologies.

The US isn’t the only major market undergoing reforms in this time period. Germany passed its own legislation in 2010, the Act on the Reform of the Market for Medical Products (Arzneimittelmarkt-Neuordnungsgesetz, or AMNOG). The legislation’s primary aim is to contain the cost of pharmaceuticals, and it has meant a sea change for pharmaceutical companies operating in the world’s third-largest health care market. For the first time, companies no longer have the freedom to determine the prices of their drugs – instead, they can set prices for an initial one-year term, during which governmental bodies assess whether the product offers additional benefit over the standard of care. Products deemed superior to the standard of care are subject to price negotiation; those that aren’t are put into the fixed price system.

Since AMNOG went into effect on 1 January 2011, Germany has become an entirely different place for drug companies. The pricing regime has become considerably tighter. In some cases, companies have withdrawn products from the German market altogether because of pricing concerns. At the end of 2013, the AMNOG system was slated to expand even further, to drugs already on the market. However, the country’s new coalition government decided to scrap such retroactive assessments – and instead expanded discounts and other price controls to achieve the same savings.

Across the border, France has been making similar moves in recent months. In late 2013, the country implemented changes bringing cost-effectiveness into its health technology assessment (HTA) system for the first time. Similar to the system in Germany, drugs that demonstrate a benefit will be subject to price negotiation, while those that do not either will not be reimbursed or will be paid for at a lower level.

In addition to these unprecedented changes to its drug reimbursement regime, France is implementing other measures to curtail drug spending and align incentives with outcomes. The government incentivizes providers to prescribe generics instead of branded drugs, and patients who refuse a generic equivalent are required to pay up front for the branded product. Since January 2012, the launch of the Remuneration of Public Health Goals (Rémunération sur Objectifs de Santé Publique, or ROSP) has supplemented French physicians’ fee-for-service payments with pay for performance based on four measures: practice modernization, chronic disease care, prevention and efficiency.

In their bid to improve outcomes while containing costs, the French are also leading the way in embracing mobile health technologies. While payers in many markets remain reluctant to provide adequate reimbursement for telemedicine services, for instance, France now provides reimbursement for such services at the same level as in-person visits in several indications. French authorities have recognized the tremendous potential that such technologies have for boosting adherence. In 2013, the government mandated that sleep apnea masks be fitted with sensors to monitor use; patients who do not use their masks regularly risk losing reimbursement for their treatment. In February 2014, this new system was dealt a setback when it was suspended by the French Supreme Administrative Court at the request of various nonprofit patient organizations. (For another example of French payers’ willingness to reimburse m-health solutions that improve adherence and care delivery, see the article by Pierre Leurent on page 11.)

The UK, of course, has been incorporating considerations of value in health decisions longer than just about any other market. For well over a decade, cost/benefit studies conducted by the National Institute for Health and Care Excellence (NICE) have informed coverage decisions by the country’s National Health Service (NHS).

But the UK, like many other markets, is struggling to keep health costs under control. And so British policy makers, like their counterparts elsewhere, are considering sweeping reforms. In 2012, the country enacted what is perhaps one of the biggest reorganizations of the NHS in that venerated institution’s 65-year history: the Health and Social Care Act. Among other changes, the Act gives general practitioners (GPs) expanded autonomy and budgetary control, introduces more competition in services and puts clinicians in leadership roles. (For more on these reforms, see the perspective by Mark Wilkinson of the NHS Barnsley Clinical Commissioning Group, on page 70.)

In 2013, mounting cost pressures in the UK resulted in proposed changes that would go straight to the pharmaceutical industry’s bottom line: a plan to adopt value-based pricing in the UK market. This would take away drug companies’ freedom to set prices for their own products by introducing a regime in which prices are determined by cost-benefit assessments of medicines. While the government ultimately backed away from this scheme, the underlying pressures were still visible in the compromise it reached: a deal in which spending on branded drugs will remain flat for the next two years (and the industry will reimburse the government if spending exceeds this level).
Meanwhile, the same cost pressures resulted in a truly noteworthy tactical shift. The UK, a pioneer of cost/benefit usage and a long-standing proponent of reimbursement decisions based on the value that products add, announced it is adopting an entirely different methodology for certain drugs. The new approach, called the Highly Specialized Technology (HST) process, appears to target high-priced orphan drugs that are very effective. Wary of the potential budgetary impact of these high-priced drugs, NICE announced it is abandoning its traditional cost/benefit approach (which would likely favor reimbursing these products) for the HST process, which considers the cost of developing a drug rather than the value it adds.

The markets described above are making dramatic shifts in the way they deliver and pay for health care. But they are by no means alone. Similar reforms are under way in other regions around the world. Australia’s National Health Reform Act, passed in 2011, essentially capitulates payment for public hospital services by linking them to an “efficient price” under a system of activity-based funding. In early 2014, an Australian think tank, the Grattan Institute, reported finding A$1 billion in waste that resulted from large differences in practices from hospital to hospital – which should give added impetus to the drive to reduce care variation and eliminate wasteful spending. Japan, faced with an aging population, is incentivizing better chronic disease management and prevention and increased use of generic drugs. In Spain, austerity has led to significant increases in out-of-pocket payments by patients – which are likely to increase individuals’ incentive to behave like true consumers.

More ahead

While these health care reforms are diverse and differ significantly from one market to the next, they can be broadly segmented based on a couple of criteria, and doing so helps define what lies ahead.

First, reforms can be grouped by how market-oriented they are. Payers are using some combination of approaches that impose artificial constraints (undifferentiated price controls, discounts or budget cuts) and approaches that move to value and outcomes (rewarding interventions based on their ability to demonstrate how they deliver value to the health care system). The first type of approach is inherently unsustainable because it imposes market distortions. Over time, therefore, payers will continue to gravitate toward the second type, which effectively attempts to create more efficient markets for health care.

A second way to categorize reform measures is by the extent to which they aim at the pharmaceutical industry. In Germany, drugs are very much in the cross hairs, with HTA and other measures being used to increase pressure on pharmaceutical prices. In other cases, reforms seem designed to target cost inflation through means that may not directly target drugs, at least in the short term. But regardless of the current focus of reforms in any individual market, the pressure on drug prices will only ratchet up over time. Even in the US – which is widely regarded as the most laissez faire health care market among industrialized nations, and which has legal prohibitions against using comparative effectiveness research for negotiating prices – many consider it inevitable that pharma companies will eventually face pressures similar to those in Europe.

Moreover, pricing pressures aren’t necessarily confined by national borders. The influence that payers have on each other, for reference pricing and otherwise, means that growing pressures in one market can swiftly ripple across continents and oceans. Germany’s AMNOG law was inspired, in part, by a study that found the country was paying much more for drugs than Scandinavian countries. Now, as Germany squeezes drug companies, its tighter price regime could, in turn, lead to more pressure in other countries thanks to reference pricing. Meanwhile, UK’s NICE is consulting with regulators in countries such as China, increasing the likelihood that HTA-like methodologies could spread more broadly.

The diverse, rapidly changing payer landscape is creating other challenges (and potential opportunities) for pharma. In many markets, payers are consumed with implementing health care reform measures and new delivery models, leaving them with less capacity for engaging with pharma companies. Payers need help with these implementation challenges, but the pharma industry isn’t always seen as an obvious partner on these issues – implications we’ll explore more closely in Chapters 2 and 3.
Voluntis is a new kind of mobile health company. Based in both Boston, Massachusetts, and Paris, France, we develop software to provide connectivity for existing drugs or devices while embedding medical intelligence in software. And, at a time when many life science companies are leery of m-health and e-health services because of the perception that payers are unwilling to reimburse in these areas, we have successfully marketed solutions that significantly expand the value of drugs and devices to the payers.

How have we done this? Quite simply, by collecting rigorous data. We believe payers will embrace, and yes, pay for, beyond-the-pill services – provided there is data to demonstrate a direct linkage between an improved health outcome and the use of a specific service.

That’s why we’ve invested in rigorous, prospectively designed clinical trials that measure how much our patient-centric software improves health outcomes. We also have built a strong expertise in medical algorithms. Last, we have a dedicated Quality Assurance department to ensure patients and providers have real-time, secure access to relevant data.

These investments have paid off. We currently market two solutions that bring value to payers: CoaguChek Link, an anti-coagulation monitoring service rolled out in the US in 2010; and Diabeo (branded outside France as Insulia), a diabetes service that received a CE mark in Europe in 2013.

Developed in conjunction with Roche to support Roche’s INR self-testing device, CoaguChek Link is a web-based application designed to enable home-based monitoring of clotting times in patients taking warfarin. Studies show rates of medical complications and emergency room visits fall when warfarin patients are tested weekly. The challenge is that patients can’t always get to a clinic for such testing, and home-based solutions haven’t provided the connectivity required for optimal patient management. With CoaguChek Link, physicians can view test results in real time, allowing them to modify as needed their patients’ warfarin testing schedules and medication regimens. The CoaguChek Link connectivity platform also streamlines reimbursement for our partner Roche. Before paying for warfarin self-testing, payers want evidence that this monitoring occurs according to medical guidelines. Via CoaguChek Link, Roche now collects real-world data demonstrating patients are using its home-based test appropriately.

Our second product, Diabeo, is equally exciting. In 2011, we partnered with Sanofi to develop an integrated diabetes tool to optimize insulin dosing and enable remote care management. It includes a smartphone app for patients and an online web portal for health care professionals. Patients use the app to enter blood glucose test results, nutritional intake data and physical activity levels. Via a sophisticated algorithm and decision support software, Diabeo helps patients calculate exactly how much insulin they need. This convenient tool can help them maintain healthy blood glucose levels and reduce their risk of complications such as cardiovascular disease or diabetic retinopathy.

Once again, we conducted rigorous trials to demonstrate the value of this tool. Trials in both type 1 and type 2 diabetes patients demonstrated that Diabeo usage is linked to statistically significant reductions in HbA1c, a marker of blood sugar levels. In 2013, we initiated one of the largest clinical studies ever for a digital diabetes product. The clinical trial will ultimately enroll 700 patients in France via 12 coordinating diabetic centers and more than 200 participating physician groups. In designing the protocol, we’ve worked closely with French payers to ensure that the clinical and economic endpoints being measured – e.g., HbA1c levels and reduction of hospitalizations, respectively – match their expectations.

Mobile health solutions have tremendous potential for improving health outcomes while using scarce resources efficiently. Payers are starting to recognize the merit of these platforms and services. But to get reimbursed, companies will need to demonstrate the value that their solutions deliver.

CoaguChek is a registered trademark of Roche, Diabeo is a registered trademark of Sanofi, and Insulia is a registered trademark of Voluntis.
The future of employer-sponsored insurance

The US insurance market is going through the most significant change in at least 20 years. Traditionally, most Americans have received coverage through employer-sponsored insurance plans. Employers had only two choices: provide employees with health insurance or don’t. Now there is a third option: employers who don’t want to directly manage their workers’ health care benefits can opt to outsource the capability to state-based or federal exchanges or to private marketplaces.

A few years from now, the US employer-sponsored insurance market could look different in some ways. In industries where competition for workers is high (e.g., technology and finance), health care benefits will remain important for recruiting and retaining top talent. Large employers in these industries will continue to offer insurance to their workers. Companies in health care – from manufacturers to hospital systems – will also continue to offer insurance; it is difficult philosophically to be part of the care chain and not directly provide workers with health benefits. However, in sectors where worker turnover is high (e.g., retail), companies will shift employees to the various exchanges.

The end result? By 2018, employers’ health coverage policies will bifurcate in a predictable manner based on company size, labor competitiveness and employee turnover rates. Firms that don’t have a compelling business reason to provide their workers with insurance will adopt a defined contribution approach and shift employees to either public or private insurance exchanges. Those that continue to actively manage health benefits will become more focused and proactively drive the trend away from paternalism toward consumerism, in a manner consistent with their unique cultures.

This shift won’t happen overnight. Many mid-size firms are waiting to see how the exchanges evolve. But over the next five or so years, up to one-quarter of workers currently receiving employer-sponsored insurance could be moved to newly created exchanges.

Implications for pharma

This shake-up has profound implications for drug manufacturers. So far, up to 30% of individuals purchasing coverage on the public exchanges, which control drug costs by limiting the available therapeutic choices on formulary, are “buying down.” They are choosing to spend less for coverage that is more limited. The early data indicates that this same trend is holding for workers buying insurance through the private exchanges, and many more people are purchasing cheaper coverage via so-called narrow networks. For pharmaceutical companies, this makes market access strategies even more complicated. Individuals will be paying significantly more of their own money for prescription medicines, particularly high-cost specialty products. So manufacturers will have to do a much better job explaining the value of their products to consumers at a time when direct-to-consumer marketing approaches are under greater scrutiny.

The health care consumerism trend doesn’t just apply to individuals receiving their benefits via the exchanges. As mentioned earlier, even companies that provide insurance have already moved away – or will soon – from traditional benefit designs that require the employer to pay the lion’s share of an employee’s health costs. There will be big growth in value-based insurance designs that emphasize shared risk and shared reward. Keeping employees healthy via disease management and wellness prevention programs will continue to be a top priority for this segment of companies; they will also protect workers from the high costs associated with catastrophic illness or injury. But those same employees will bear more of the financial responsibility for decisions in the middle – for instance, choosing between two imaging centers for an MRI or whether to take an oral multiple sclerosis treatment with an expensive co-pay or an older, less expensive injectable.

Drug companies also need to do a better job explaining pharmaceutical product value to employers that continue to provide insurance. This group of companies now has an institutional mandate to adopt best practices that provide workers with better care for a lower total cost. But top executives don’t fully appreciate how drug pricing decisions are made. Drug companies need to proactively reach out to these specific employers, providing transparent, credible information about their products and pricing decisions.

Indeed, drug companies should begin to look at employers that continue to provide insurance as potential partners with an avid interest in optimizing health care delivery. Such companies can help catalyze innovations like the delivery of novel adherence programs or evidence collection tied to improved worker productivity. In particular, manufacturers willing to engage in pay-for-performance contracts with specific individual employers will find greater reception in the marketplace.

Equity Healthcare is a health benefits firm that manages the health insurance needs of 43 firms owned by private equity groups. Roughly 350,000 individuals are covered by Equity Healthcare plans.
Big data and analytics

Back in 2010, our Pharma 3.0 report described an imminent explosion of health care data, thanks to trends such as the drive toward EHR adoption in the US, the emergence of social media platforms and smartphone apps dedicated to health care, and more.

We also discussed the disruptive potential of this real-world data and envisioned a future in which pharma companies would no longer monopolize data about their products. Instead, we argued, information would become widely available, giving a broad range of stakeholders the ability to use data mining to make informed decisions about the relative value of different interventions – something we termed “value mining.”

Indeed, over the last few years, we’ve seen an upsurge of approaches that seek to combine diverse data streams to understand the comparative effectiveness of different interventions. Much of this has happened through partnerships between companies from diverse parts of the health care ecosystem, and even a number of “non-traditional entrants” that were not historically associated with health care.

In many cases, such efforts are being initiated by the analytics units of large payers, often in collaboration with providers and other stakeholders. In January 2013, UnitedHealth Group and the Mayo Clinic announced a partnership to form a dedicated research unit, Optum Labs. The unit is analyzing vast reams of data – combining millions of health claims supplied by UnitedHealth, medical records from Mayo’s patients, as well as data obtained from other partners that have since joined the initiative – to drive new health innovations and assess the value of different medical interventions. (For more on Optum Labs, refer to the perspective by Paul Bleicher, its CEO, on page 14.) Another such partnership, between HealthCore, the health outcomes research subsidiary of WellPoint, and AstraZeneca, has been conducting analysis using real-world data since February 2011.

Meanwhile, new data analytics companies are entering the health space, seeking to apply their expertise to some of the biggest challenges facing payers and providers. In this year’s report, we feature perspectives from two of these entities: GNS Healthcare and Symphony Health Solutions. (For more, see the articles by Colin Hill on page 62 and Romesh Wadhwani on page 63.)

Data analytics is another area where things are changing rapidly. Symphony Health Solutions already has comprehensive, seven-year health histories for 170 million US patients – more than half the US population. Two years ago, the company didn’t even exist.

The tremendous expansion of health data and analytical capabilities has the potential to upend many aspects of pharma’s traditional business model. It diminishes companies’ ability to control the message about their products, demands new approaches for launching and marketing drugs, necessitates collaboration with a broader range of entities, and more.
Optum Labs is a new kind of open collaborative center for research and innovation on important questions about improving patient outcomes and containing health care costs. Founded in January 2013 as a partnership between Optum (the health services unit of UnitedHealth Group, a leading US insurer) and Mayo Clinic, and followed later by AARP as Founding Consumer Advocate Organization, the collaboration has since expanded to include a wide range of partners. Our approach – inspired, to some extent, by the success of Bell Labs in driving breakthrough innovations and technologies – convenes partners from across the health care ecosystem in a forum where they gain access to unique data and analytical resources.

This vision is based on four tenets:

- **Collaboration.** Health care research and innovation needs collaborative efforts to address shared challenges, such as medication adherence and mental disease.

- **Data and analytics.** To achieve such collaboration, we need high-quality, high-volume data sources, which, along with sophisticated analytics, is one of Optum’s key differentiators. We seeded the partnership with large amounts of claims and clinical data – Optum’s 150 million lives, 5 million lives from Mayo’s data and another 30-40 million lives from Humedica, which coincidentally was acquired just as Optum Labs was launched.

- **Prototyping and testing.** Health care innovation requires the ability to prototype and test new findings in the clinical environment. This is an area where Optum Labs – with world-class research partners such as Mayo Clinic and others – can create new tools, care pathways, guidelines and more.

- **Adoption.** Innovation isn’t meaningful until it achieves widespread adoption. The market presence and brand recognition of our partners helps ensure that solutions coming out of Optum Labs are rapidly deployed.

In February 2014, we welcomed seven new partners to Optum Labs: American Medical Group Association, Boston University School of Public Health, Lehigh Valley Health Network, Pfizer, Rensselaer Polytechnic Institute, Tufts Medical Center and University of Minnesota School of Nursing. Each partner contributes based on its strengths: data, financial resources, administrative responsibilities, management capabilities, diverse perspectives and/or other assets.

Above all, our partners take the lead in setting the research agenda. However, this is not the place for organizations to ask questions that directly advance their immediate commercial goals. Instead, we conduct research on issues that are broadly applicable to multiple stakeholders. So, a pharma company could not use Optum Labs to research whether its drug is better than a competitor’s product, but we could certainly explore how one class of drugs compares to another. Optum Labs enabling research on these questions by drawing on the considerable health analytics experience of the hundreds of health economists, actuaries and analysts at our co-founding partner, Optum.

Underlying this research are our robust data capabilities. One of our key strengths is our ability to link together data in a de-identified, seamless way, for instance by combining claims and electronic health records to create a 360-degree view of the patient. We create new encrypted identifiers that prevent anybody from working backward to identify a patient.

Our administrative claims data is 100% research-ready. But cleaning and combining data is a resource-intensive task. So, we don’t try to boil the ocean. Instead of trying to create a database in which every variable is ready for analysis, we focus on the data that matters – for instance, key diseases on which our partners are focused. These areas are typically ones with significant costs and a high potential for improving patients’ lives. For other diseases, the data are always available for our researchers to clean, shape and develop into a research-ready form.

While we conduct some data mining, our approach relies heavily on leveraging health care experts and using traditional health economics and outcomes research methodologies. We believe that big science has to be applied to big data. The danger in approaches that rely solely on data mining and Bayesian network analysis is that they often want the data to speak for itself – which can lead to spurious findings.

At Optum Labs, we are working on important challenges that affect all health care stakeholders: providers, payers, government, life sciences companies. So far, these constituents have approached these issues in different ways. What health care needs more than ever – and what we at Optum Labs hope to catalyze – is aligned thinking, collaborative approaches and shared solutions to these pressing problems.
It is clear that the US health care system is moving toward a focus on value and outcomes. But how value and outcomes are measured – as well as whose measures are trusted – is not so clear.

At GSK, when it comes to developing our products, we focus on three big buckets of evidence to quantify value: clinical, economic and humanistic.

Placebo-controlled studies are now considered “old world.” To ensure we’re reflecting the clinical value of our medicines, more of our studies are designed to test against an active comparator, preferably the standard of care. This is an art, not just a science, as standards of care can vary by region or demographic.

Thanks to advances in genomics, there are also now infinite ways to determine different test populations. Clinical studies need to be able to identify the specific patient populations where an innovative product will deliver the greatest outcomes. Additionally, when possible, we aim to prove benefit in populations that previously did not respond to the standard of care or demonstrate where our products may be able to reduce other health care costs.

While clinical testing has always been a strength of the pharmaceutical industry, the challenge now is adding in robust methods to test the economic and humanistic benefits of innovations. In evaluating results, more credence needs to be given to humanistic factors such as ease-of-use, convenience and patient friendliness, which can play a pivotal role in helping patients follow through with a treatment plan.

A vast majority of our data is internally generated, GSK-sanctioned data, mostly from clinical trials. However, as more economic and humanistic evidence is needed, we recognize that we need different kinds of data sources, including real-world evidence. This is leading us to collaborate with universities and integrated delivery networks that are also exploring new and creative ways to measure the benefit of health care treatments and delivery models, and have both the data and the capabilities for successful partnerships.

One new focus for us is what we call “small data.” “Small data” uses the 80/20 rule to isolate the 20% of data that can bring the 80% improvement in efficiency or costs. Rather than holding our breath waiting for the solution to the “big data” puzzle, our goal is to achieve quicker successes by identifying the small group of variables that can still have big impact.

Embracing change

Jack Bailey
GlaxoSmithKline
Senior Vice President, Policy, Payers & Vaccines

Once the data is in place, we need to ensure it gets into the hands of health care decision makers, including providers and payers, appropriately. The role of pharma in working with payers is continuing to evolve. We’re working to bring not only great innovations but also great information to help payers better manage key disease states in the best possible way for the patient, without spending more money. We realize there will be some reservations about pharma-generated evidence and information. But payers have realized that they could never be experts in key disease states, and that’s where pharma can play a role. We’ve made changes in the robustness of the information we’re providing to payers, and these have been well received. We continue to evolve and improve upon our non-branded care management disease education materials that help improve patient care.

On the provider side, our industry-leading incentive compensation initiative puts patients first by realigning field sales incentives to focus on the value of our interactions and the scientific knowledge of our field sales teams instead of the volume of sales. We’ve also made improvements in data transparency. Our Clinical Study Register provides access to data from all GSK-sponsored clinical trials, and we were the first to commit to providing researchers with anonymized patient-level data for our clinical trials.

We understand the importance of earning the trust of payers, providers, patients and the community as a whole. Perceptions will take time to change, but the momentum is with us.
Personalizing care

Personalized medicine has made major strides in the last 5-10 years. An increasingly large percentage of drugs approved in recent years have been targeted therapeutics. And one long-awaited tipping point, the thousand-dollar genome, appears to have finally arrived, with a few companies developing platforms that make it possible to sequence a human genome for less than US$1,000. (For an overview of developments in this space, see the perspective by Felix Frueh on page 45.)

The trend has been boosted by the move to value and outcomes. In an environment of increased scrutiny, pharma companies have flocked to targeted therapeutics, where it is easier to demonstrate that products are well differentiated. Orphan diseases, once the pariah of drug development because the economics were perceived to be so challenging, have been embraced by pharma companies like never before.

This shift is also creating new challenges. The economics of personalized medicine can sometimes be difficult. Targeted therapeutics often come with very high price tags, since manufacturers have to recover the cost of R&D over a much smaller patient population – increasing resistance from payers. Diagnostics are typically reimbursed at lower levels than drugs, making the numbers challenging for companies in this space. (For a perspective on securing reimbursement for diagnostics, see the article by Kristin Pothier on page 44.)

Personalized medicine has so far largely been applied to a few diseases such as cancer, while barely touching some of the biggest needs at the population level (for instance, chronic diseases, which account for about 75% of health care costs). In some cases, this might reflect the complexity of the scientific challenges involved and the poor understanding of the genetic mechanisms behind these diseases. But poorly aligned incentives are also a problem – there is little economic motivation for a company to develop a targeted version of a statin that has gone off-patent.

This creates an opening for a new kind of “personalized medicine” – one in which interventions are targeted based not just on genetic profiles but also on behavioral segmentation. In Chapter 3, we discuss the potential for “prescriptive analytics,” through which analytics companies are starting to identify the small patient subpopulations that are most likely to drive costs, and identifying the interventions most likely to change these suboptimal outcomes.

PI technologies

When our 2010 report came out, we were just starting to see a host of new technologies that promised to empower patients as never before. The smartphone revolution spawned by the release of the iPhone in 2007 – and, more important, the launch of Apple’s App Store in 2008 – had started to make its way into health care. Almost overnight, the phones we carry around in our pockets were being transformed into quasi-medical devices that could check our blood sugar, monitor our exercise regimens and answer our medical questions.

In the years since, the revolution has spread beyond phones to all sorts of everyday objects. We are still in the early days of this move from an internet of computers to an “internet of smartphones” to an “internet of things.” Increasingly ubiquitous and inexpensive sensors are showing up in everything from running shoes to clothing to weighing scales – with game-changing implications for how we monitor and manage health in our daily lives. Back in 2010, we were excited about the first smartphone app that interfaced with a glucometer. But that technology still required patients to remember to check their blood sugar, connect the glucometer extension to their phone and endure the pain of a pinprick every time they tested themselves. Four years later, Google, a non-traditional health entrant, has announced a contact lens that can read glucose levels in a user’s tears – potentially transforming blood sugar monitoring into something that can be done continuously, effortlessly and painlessly.
Like big data, these patient-empowering, information-leveraging (PI) technologies are emerging at the Moore’s Law pace of IT innovation rather than the regulation-constrained, decades-long pace of drug development. Four years ago, apps that transformed smartphones and watches into quasi-medical devices seemed astonishing. In the years since, the novelty has worn off and they have become a routine presence in many of our lives.

This is another trend that challenges pharma’s traditional business model. As PI technologies empower individuals with more information and control over their own health, patients’ expectations are changing – and pharma companies will need new ways of engaging these increasingly influential customers. (For more on these aspects, see Progressions 2012 and our medtech report, Pulse of the industry 2012.)

PI technologies also have tremendous potential in managing chronic diseases, by enabling remote monitoring, providing real-time data and empowering behavioral change. And this is where they could be truly disruptive. While medical technology is often blamed for driving cost inflation in health care, in most other industries, consumer-centric information technology has had the opposite effect, increasing productivity and lowering costs. PI technologies now have the potential to do the same in health care – with disruptive implications for pharma companies. Today, companies are adjusting to a world in which payers evaluate the comparative effectiveness of different drugs. In the not-too-distant future, pharma products may find themselves implicitly competing not just with each other but with other interventions that are very effective and much cheaper – a phone call, a nurse’s visit, a 99-cent smartphone app.

Pharma products may find themselves implicitly competing not just with each other but with other interventions that are very effective and much cheaper – a phone call, a nurse’s visit, a 99-cent smartphone app.
Transparency

“Transparent information is essential for markets to function efficiently,” says Risa Lavizzo-Mourey of the Robert Wood Johnson Foundation. “A lot of information in health care has not been transparent, leading to waste and inefficiency. Patients don’t know about the quality of different providers. Neither providers nor patients know the true price of products or services at the time they are making decisions. Information – for instance, on the relationships between pharma and providers or on rebates paid by pharma to payers – has often been opaque.”

So, transparency has become critical for the move to value – which is essentially a move to a more efficient health care market. Without transparent information, it would be very difficult to make informed decisions about which interventions deliver the most value. Payers need transparency in their drive to reduce care variation. Patients need transparency – and increasingly expect it – as they take more financial responsibility for their health care decisions.

Just as the demand for transparency is increasing, many of the trends listed above are rising to meet the demand. Big data is being aggregated and combined, giving stakeholders more insight into the full picture. Social media and app-driven solutions – Castlight Health, Healthcare Bluebook and many others – are giving patients transparent, easily digestible information on provider options, associated costs and insurance co-pays, and more. In some cases, these tools are remarkably customized and patient-specific. For instance, Charles Saunders of Healthagen (an Aetna company) talks about the WellMatch tool his company has developed, which gives patients information on the cost for a particular service, not based on averages, but rather on the specific health plan design for that patient. (For more, see the article by Charles Saunders on page 19.)

These apps are just one aspect of a larger movement. In recent months, we’ve seen a spate of transparency-driven measures. In May 2013, the US government initiated an unprecedented three-part initiative that is, for the first time, giving consumers information on what hospitals charge. In April 2014, it followed up by releasing data on payments made to providers who treat Medicare patients – the first such release of information in that program’s history. As we go to press in April 2014, the European Union is in the final stages of approving a new clinical trial regulation that would greatly increase the transparency of trial data. Indeed, pharma companies have come under growing criticism for not being open with their clinical trial data, and some firms have also responded with their own measures to make their data more transparent. This is now an urgent imperative for the industry – something we discuss more fully in Chapter 3.
Providers and patients are critical to the success of the new value-based models being adopted in the US, but they need new capabilities and tools to make the transition. Meanwhile, as accountable care models and insurance exchanges become more widespread, traditional insurance companies will need to add value in different ways to remain relevant. Recognizing these imperatives, Healthagen, an Aetna company, is creating tools and services specifically designed to serve the changing needs of providers and patients.

A key part of our strategy is that these offerings are typically not branded as Aetna offerings or even restricted to Aetna customers. Instead, they are turnkey tools that can be broadly adopted by physicians and patients — health care’s version of the “Intel Inside” model.

Providers

Our country is in the early stages of adopting value-based health care approaches. To assist providers interested in assuming more financial accountability, we’ve created a spectrum of solutions that can be customized based on health systems’ internal data and infrastructure needs as well as their willingness to accept financial risk. These offerings include accountable care organizations, patient-centered medical homes and even new insurance products that retain provider branding.

We want to enable providers to do what they do well — provide care to patients in their communities — while simultaneously empowering them to change their revenue models. Thus, we provide health systems with care management and population health tools, IT infrastructure, and actuarial and risk management services. Provider groups can select from a menu of tools that complement their current offerings without jettisoning existing services in which they’ve already invested.

To date, we’ve established 32 ACO agreements with large health systems. Our collaborators include Bon Secours, the Mercy Health System and the Medicare Pioneer ACO Banner Health Network, which in July 2013 reported shared savings in excess of $13 million. We’re also in discussions with another 200 provider groups about Aetna-enabled ACOs. If all of these collaborations came to fruition, nearly 60% of the US population would have access to care offered by value-based delivery models.

In some cases, providers are ready to take their ACOs directly to employers or the public exchanges via private label health plans. In 2012, we partnered with Inova Health System to establish Innovation Health Plans, a jointly owned health plan serving 1.1 million residents in Northern Virginia.

Via new Aetna Whole Health co-branded health benefits plans offered jointly with health systems, we’ve created new ACO-based insurance offerings that are priced 8%-15% lower than products currently in the market. Participating providers leverage not only our statutory capital and actuarial expertise, but also our geographic reach. That’s important, because it makes these new plans much more attractive to large employers and provides potential membership growth.

Patients

Just as providers are increasingly focused on value-based care, so, too, are patients. But if we want patients to be empowered consumers, we need to give them information and tools to better manage their health and interact with the health care system. So, Aetna is developing applications that enable better patient-physician communications as well as personal health management. These patient-centric applications include WellMatch, iTriage and CarePass. WellMatch is a cost-transparency tool that tells the cost for a service based on the user’s specific health plan design. iTriage — a smartphone app that has been downloaded more than 10 million times — allows consumers to research their symptoms and search for relevant, in-network providers for their specific health concerns. Finally, CarePass is a platform that synchronizes data from a variety of health and wellness apps at the consumer’s direction, such as FitBit and LoseIt!, so that individuals can see all their health-related app data in one place.

Many of our patient-focused tools are in use today and we are piloting others with large employers. We believe they differentiate us in the marketplace and — like our new provider-based collaborations — will drive membership growth by better serving the changing needs of patients and providers.

Aetna is a leading US diversified health care benefits company, serving an estimated 44 million people.
In 3-5 years, health care could look significantly different

For the first time, US patients will carry smart cards with all their health information on them – making it easy for providers to quickly access their medical histories.

Rita Shane, Cedars-Sinai Medical Center

Value-based pricing and formal HTA processes are going to become much more visible in Switzerland.

Thomas Szucs, Helsana Group

Formularies will be replaced by “Population Health 2.0,” where new tools and big data will match individual patients to optimal treatments at the time of diagnosis.

Colin Hill, GNS Healthcare

Significant variation in care leading to poorer outcomes is just not going to be acceptable.

Paul Bleicher, Optum Labs

In the US, specialty drug costs – accounting for only 4% of spending today, but growing at 20% annually – will face unprecedented scrutiny.

Robert Galvin, Equity Healthcare

Even after the European economic crisis recedes, the pressure from payers will continue to increase. There simply isn’t enough money to pay for health care in the ways of the past.

Eduardo Sanchiz, Almirall

Payers may challenge today’s pricing environment, which allows for annual price increases on products.

Adrian Thomas, Johnson & Johnson

The drive for transparency will accelerate dramatically. Many are unprepared or simply hoping it won’t happen, but it will – and it’s a game-changer.

Jack Bailey, GlaxoSmithKline

In the Netherlands, decisions that factor in cost-effectiveness – so far, a politically touchy matter – will become unavoidable and very real.

Martin van der Graaff, Zorginstituut Nederland

Consumerization is coming sooner than most expect. More and more US employers are going to put workers on insurance exchanges, motivating patients to become engaged consumers.

Romesh Wadhwani, Symphony Health Solutions
Where's pharma?

In 3–5 years, pharmaceutical companies could face a very different competitive landscape. In the US, despite lingering uncertainty about implementation dates for the ACA, Obamacare has set in motion changes that are not about to be reversed. Five years from now, whatever the fate of this one piece of legislation, payers will be sharing more risk with providers, employers will be more proactively involved in their employees’ health decisions and patients will have more financial responsibility for their health care costs. In Europe, regardless of whether austerity lingers or economic growth rebounds, the use of cost-effectiveness criteria and the pricing pressures on drugs will be markedly higher. Nor will the trend be restricted to Europe — many countries that have not previously used HTA are actively considering moving in this direction, and in five years’ time, a good number of them might well have done so.

The change may not always be smooth or linear. Revolutions seldom are. In many markets, we may see setbacks similar to the UK’s decision to hold back on moving to value-based pricing or the opposition the ACA engendered in the US. But these will not be full-scale reversals as much as course adjustments on the way to a new health care.

Whatever doubts one might have about the speed with which health care systems will adapt, there is little doubt that the technological shifts described above are only accelerating. We have already seen dramatic changes with respect to big data, analytics and PI technologies — and things are only getting started.

A range of options

These changes represent a disruptive threat to pharma’s existing business model, requiring new approaches for everything from portfolio optimization to product launch, marketing and stakeholder engagement. To remain relevant, companies will need to respond in appropriate ways.

Ever since our first Pharma 3.0 report, we have said that pharma companies need to get into the outcomes business. Behind this general statement, though, is a range of possible responses. On one end of the spectrum are approaches designed to make drugs more appealing in the current payer environment. This includes personalized medicine — developing targeted therapeutics and companion diagnostics to make products that are much more efficacious at improving outcomes for small subpopulations of patients. It also includes building value dossiers to make the case for why products should be reimbursed — for instance, by demonstrating that they create cost offsets or otherwise lower the total cost of care. Such approaches are the new de minimis standard for market entry, and as one would expect, all pharma companies are using them.

In addition to this minimum threshold, there are approaches that expand beyond the product. This includes services and solutions aimed at payers, providers and patients (examples include adherence, disease management, patient education, decision support and m-health platforms). It also includes using big data and analytics to create personalized medicine approaches based not just on genetic profiles but also on behavioral segmentation. At the far end of the spectrum are approaches that move into health care delivery itself, for instance by taking responsibility for a cohort of patients in a capitated payment model.

Responding strategically

Without exception, pharma companies are using the first set of approaches described above — those that enhance or better communicate the value proposition of therapeutics. But so far, companies are only dabbling in efforts that go beyond the product. In many cases, they are experimenting with new models in ad hoc ways, perhaps with a specific payer.

We would argue that these responses do not measure up to the size of the disruption under way. Instead of reactive and fragmented experimentation, companies need a coordinated, strategic approach. In Chapter 3, we present a framework for doing this: strategic payer engagement (SPE). This paradigm enables companies to identify the most appropriate models for different segments of payers and scale up these solutions in a structured way.

It is also critical that companies move quickly to develop coordinated approaches for payer engagement. So far, they may not have felt much urgency to move beyond pilots, because the profits in pharma’s traditional product business have held up pretty well, thanks to a range of measures such as cost-cutting, spin-offs and share repurchases. But such tactics cannot be used indefinitely and, as already discussed, the pressure on drug prices and pharma margins will only increase in the years ahead.
Moreover, while companies may not feel any urgency to approach business model innovation in a broader, more strategic way until net margins shrink significantly, this tactic may ultimately prove flawed, for several reasons:

1. Recognizing change

Much of this chapter has discussed the tremendous changes that have started to disrupt health care delivery and payment over the last five years. As we look back on these trends, they may seem like a logical progression of expectable developments. But five years ago, they were anything but obvious. There was considerable disagreement in the pharma industry even about the move to outcomes and value—something that is widely accepted now. Five years ago, few imagined that patients would soon be able to pull up an app on their phones and get personalized, transparent information on costs and quality. Few could have predicted how quickly and extensively the environment for drugs would change in several key markets.

To quote Michael McFaul, the recently retired US Ambassador to Russia, “In retrospect, all revolutions seem inevitable. Beforehand, all revolutions seem impossible.” For companies developing their medium-term strategies, it may be tempting to assume that the disruptions to pharma’s business model will play out slowly. But history tells us that we often underestimate the pace of change. Time may not be on your side.

2. Early-mover advantages

By not investing strategically and broadly in outcomes-focused approaches, companies are, implicitly or explicitly, assuming they will be able to catch up at a later date, when increased margin compression creates urgency for action. But late entrants may find it difficult to get traction, for at least two reasons:

▶ Network effects. Fifteen years ago, when e-commerce first emerged, there was considerable debate about whether the trend would prove to be an unsustainable bubble or would quickly become commercially viable. Several years later, similar uncertainty greeted the emergence of Web 2.0 and social media. But in both cases, investors who decided to hold back until the uncertainty was resolved faced an almost insurmountable challenge at the later date: network effects. It’s very difficult to create the next Amazon or Facebook because these are network-dependent businesses. Even if a newcomer has a superior offering, customers have a strong incentive to stick with the most popular service, because these services are only useful when they have large numbers of users.

Many of the outcomes-focused approaches that will emerge in the new health care—from common platforms for pooling data, to social network-based apps for interacting with peers and motivating behavioral change, to online disease-specific communities for patient interaction and education—are similarly network-dependent. Once standards are established and networks are built, it will be very difficult for latecomers to enter the market.

▶ Switching costs. Moving to new models for delivering and paying for health care involves significant investments of time and money. Payers, providers and others are involved in years-long projects to upgrade IT systems, develop common platforms, create reporting systems for stakeholders and more. Once these investments are made, it will be very difficult for late entrants to develop their own offerings, because switching to a new solution would involve significant expense and disruption.

3. Making the right comparison

Pharma companies are a competitive lot. They have a long history of watching each other to gauge strategic shifts and seek competitive advantage. To a large extent, this is exactly what one would expect in a competitive industry.

But it is precisely the wrong kind of comparison for the new health care. The competitors that matter are no longer just other pharma companies, but new disruptors. Entrants like the start-up that emerged almost overnight with a comprehensive database, cutting-edge analytics—and the power to change payers’ perceptions of your product. The smartphone app that empowers patients to manage their chronic disease far more efficiently—and reduces their need for medication. The social media platform that generates real-time, transparent information about your product—and forever changes how you will need to engage with patients and providers.

If you focus only on your traditional competitors, it may seem like the world is changing slowly, because other pharma companies are experimenting in small, disjointed pilots. But if you change your perspective, and focus instead on the new sources of competition, you get a very different message: things are moving rapidly, and wait-and-see may not be the best option.
Chapter 2

Surveying the payer landscape
Chapter 2
Surveying the payer landscape

In brief

- Our stakeholder interviews and survey of US payers, European payers and pharma companies reveal some common themes.
- Payers are more focused on cost containment than on outcomes-based approaches to containing costs.
- While prescription drugs are only about 10% of health care spending, payers see drug costs as their biggest challenge.
- While pharma companies are generally well aligned with payers’ data needs, one area of disconnect is clinical trial data. Payers want data from comparative trials, but pharma companies are most invested in placebo-controlled trials.
- Payers are preoccupied with implementation challenges related to health care reforms. They could use help on these matters, but they do not trust pharma companies to have the impartiality required.

To better understand the complex and changing payer landscape, we conducted a survey of US and European payer organizations and pharmaceutical companies. Through the survey, we set out to explore four questions:

1. **What do payers want?** We asked payers about their business challenges and attitudes as well as the evidentiary standards and methodologies that they regard as most important.

2. **How do payers see these issues changing over the next 3-5 years?**

3. **What are the most significant differences between US and European payers?** We segmented the survey responses of US and European payers and identified areas where the two diverged.

4. **How well do pharmaceutical companies understand payers’ needs and attitudes?** We asked pharmaceutical companies to identify what they believe payers’ needs and attitudes to be and compared their answers to those provided by payers. We then identified some areas where there are significant gaps between the two.

Second, we supplemented the survey with in-depth interviews with over 30 executives from numerous countries, including the US, Germany, UK, Japan, Switzerland, the Netherlands and France. Our primary focus was on interviewing payer organizations as traditionally defined. But, as payers share more financial risk with other entities, providers and employers are becoming de facto payers in many markets. So, we also interviewed a number of other stakeholders with relevant insights into the changing payer environment.

As payers share more financial risk with other entities, providers and employers are becoming de facto payers in many markets.
Rising pressures
A conversation with Tomohiko Makino, The University of Tokyo

**EY:** What major health care reforms are being introduced in the Japanese market? What are the biggest pressures on the sustainability of the Japanese health care system and what is being done to address them?

**Makino:** There are some big pressures on the sustainability of Japanese health care. Chief among them are demographic shifts. Japan has an aging population, which means we face the prospect of increasing costs from chronic diseases and other ailments related to aging, as well as a relative decline in the number of working people to bear these costs. Some other factors have also been driving up costs, including adoption of new medical technologies and detection of illness with the advance of medical science.

The Japanese health care system is implementing dozens of measures to help reduce the pressure on costs. Japan has long relied on periodic reviews of, and reductions in, pharmaceutical prices to keep drug costs under control, and this continues to be the case. The Ministry of Health, Labor and Welfare is also doing more to promote the use of generic drugs and has enacted a consumption tax increase to help pay for health care. But these measures, even in aggregate, are not enough to counter rising cost pressures.

New ways of using data have tremendous potential for making the delivery of health care more efficient and sustainable. To this end, the records of health care insurance reimbursement have now become available to certain organizations under a National Database Initiative, though there are also strict restrictions in place because of privacy and security concerns.

Another challenge that the Japanese health system has faced is drug lag — it typically takes longer for new medicines to be approved and reach the market in Japan than in most other industrialized nations. The health insurance system has therefore introduced incentives for innovative new drugs, in contrast with cost-management approaches that might have provided insufficient incentives for pharmaceutical companies to enter the Japanese market. In November 2013, the Pharmaceutical Affairs Law was revised to clarify the distinction between medicines, medical devices and regenerative medicines in order to simplify the approval process while ensuring safety.

**EY:** To what extent is Japan adopting value-based health care measures?

**Makino:** This is clearly an area where there is growing interest, given the large number of studies being conducted on the introduction of value-based health care measures. However, relatively little concrete action has been taken so far.

For the most part, safety and efficacy continue to be the principal considerations in approving new drugs. Comparative effectiveness research is being introduced in limited areas, such as new cancer therapeutics. In the vaccines segment, which has been growing rapidly in recent years, cost-effectiveness assessments are reviewed as part of the process of including new vaccines into the routine schedule. Lastly, quality improvement measures are being partially implemented in certain areas.

**EY:** What could pharma companies do to be more trusted by other health care stakeholders?

**Makino:** This is an important issue. In recent years, there have been several scandals in clinical research involving pharmaceutical companies. This has reduced the public’s trust in them to the lowest level. The industry will need to do more to rebuild the trust that has been lost. This could include, for instance, proactive and more effective communication about the value of drugs, the industry’s role in innovation and its mission to improve patient outcomes. A public affairs approach may be more effective than conventional lobbying in mobilizing the entire health community. Ultimately, the industry should keep in mind that scientific evidence is what will prove the tangible value of its products.
Growing pains

While Brazil is an emerging market, its health care system has much in common with those of industrialized nations. The country has provided universal coverage for its citizens for over a quarter century, thanks to the Unified Health System (Sistema Único de Saúde, or SUS) which was created in 1988. Today, about 75% of Brazilians depend on SUS for their health care needs, while 25% get coverage from the private sector — either by paying out of pocket or through employer-sponsored insurance.

Brazil spends about 9% of GDP on health care – roughly the same as countries like the UK and Australia, and well ahead of China (which spends about 5%) and India (4%). But, since Brazil has a smaller overall economy, this still translates into considerably less spending on a per capita basis. Annual health care expenditures in Brazil are about US$1,000 per capita, compared to US$7,600 in the United States. Consequently, the coverage provided by the publicly funded health system is relatively basic, and SUS only accounts for 44% of health care expenditures, despite covering 75% of the population.

Pressures on the system

The system is now coming under pressure thanks to several trends. One of these is the country’s growing middle class. Compared to the other BRIC nations, Brazil has done a much better job of achieving equitable growth. Since 2003, approximately 50 million Brazilians – a group larger than the population of Spain – have risen into the upper and middle classes. As more people enter the middle class, their expectations and desires are increasing, and they are looking for coverage beyond what SUS can provide. Expanding access to private health care for this rapidly growing cohort is likely to strain the capacity of private insurers and providers. To meet this growing demand, players in both the private and public sectors are looking for ways to expand their services through both organic and inorganic growth.

The biggest strain on the sustainability of the system, though, is health care costs, which have been rising as a result of demographic changes (Brazil’s elderly population is growing at nearly triple the rate of the overall population), increasing rates of chronic diseases and an increasing use of expensive medical technologies.

Therefore, the government is stepping up its efforts to reduce mortality rates and prevent an epidemic of chronic non-communicable diseases, mainly through investment in education and prevention. Regulators are actively encouraging prevention programs with payers, though they are not using financial incentives.

This could create challenges for drug companies to the extent prevention succeeds in lowering the need for medicines. But it could also create growth opportunities for drug and diagnostics companies whose products can help the government achieve this goal. Already, pharma and device companies are starting to collaborate and participate in prevention programs.

The use of value-based measures and initiatives is still in very early stages in Brazil. Only the top hospitals have the ability to measure cost-effectiveness and medical performance and relate these metrics to compensation in some way. So far, it has been difficult to implement such measures, since physicians are often not in favor of it.

But as cost pressures continue to build, I expect that the ways in which health care is paid for will also adapt. Over the next five years or so, we could see a heightened emphasis on prevention and cost efficiency, as well as an increased investment in data analytics to help identify the most cost-efficient medical interventions. For Brazil to continue offering its citizens high-quality universal health care in sustainable ways, I expect we will see closer collaboration between payers, providers, drug companies and device companies.
Five common threads

While there were differences across payers and markets, the survey and interviews also revealed some common threads. These are discussed below.

1. Payers want cost containment over outcomes-based approaches

For all the talk about outcomes and new delivery models, what emerges clearly from the survey responses is that the top priority for payers is quite simply to contain costs. While it is unremarkable that payers care about cost containment in the current environment, it is certainly striking that there is a significant gap between their high focus on costs and their relatively low interest in the outcomes-based approaches that are widely regarded as the most sustainable way to bring costs under control.

As shown in Chart 2.1, for instance, the top two business challenges payers report being focused on are “curbing rising drug costs” and “curbing rising medical (non-drug) costs,” with scores of 3.53 and 2.62, respectively (higher scores represent business challenges on which payers are more focused). Meanwhile, the sorts of value- and outcomes-based initiatives that are frequently heralded for promising to lower costs by reducing inefficiency and waste – “engaging patients,” “reducing variation in care” and “contracting with providers via new payment models” – rank at the bottom of the list, with scores of 1.50 or lower (less than half the 3.53 score of “curbing rising drug costs”).

Source: EY Progressions 2014 Payer Survey. Payers’ higher scores indicate business challenges on which payers are more focused today. For pharma companies, higher scores indicate business challenges on which pharma companies perceive payers to be more focused today.
The most attractive proposition is mechanisms that give payers a high degree of budgetary predictability.

For public payers trying to stretch finite budgets and private payers facing tighter margins, the most attractive proposition is mechanisms that give them a high degree of budgetary predictability. So, when we asked payers to identify the comparative effectiveness measures that they consider most important in coverage decisions, “lowering total cost of care” and “producing cost offsets” ranked first and second, while “boosting drug adherence,” “improving care coordination” and “improving worker productivity” scored considerably lower (see Chart 2.3).

Payers are also moving to closely monitor drug utilization, particularly for higher-priced products. “For very expensive products in certain classes, such as rare diseases or oncology, it’s not really about formulary placement,” says Eric Cannon of SelectHealth. “Instead, it’s more about appropriate utilization. We could negotiate a contract with a manufacturer for a 5% discount, but that discount means nothing if we have even one patient over the year for whom the drug is inappropriately prescribed.” Reflecting this trend, payers responding to our survey said that their number one strategy for managing drug costs is “using stricter coverage criteria” (see Chart 2.2).

Source: EY Progressions 2014 Payer Survey. Payers’ higher scores indicate cost management strategies that payers use more frequently. For pharma companies, higher scores indicate cost management strategies that pharma companies perceive payers to use more frequently.

Source: EY Progressions 2014 Payer Survey. Payers’ higher scores indicate comparative effectiveness measures that payers consider more important in coverage decisions. For pharma companies, higher scores indicate comparative effectiveness measures that pharma companies utilize more in market access.

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Source: EY Progressions 2014 Payer Survey. Payers’ higher scores indicate comparative effectiveness measures that payers consider more important in coverage decisions. For pharma companies, higher scores indicate comparative effectiveness measures that pharma companies utilize more in market access.
Living with AMNOG

The introduction of the AMNOG early benefit assessment in the past year has been one of the biggest changes in German health care. But the new law leaves several issues unresolved. For instance, diabetes drugs without additional benefit can only be covered based on the generic reference price and we do not have the option to provide targeted subpopulations with more expensive drugs. Another issue is the high price of oncology drugs.

**Paying for pharmaceuticals**

In Germany, health care costs are under tremendous pressure. The most effective – or at least, the most pursued – way to control health care costs, at the moment and going forward, will be through savings on pharmaceuticals.

Under AMNOG, we do not conduct formal value-based assessments of pharmaceuticals. Instead, we base evaluations of drugs on patient-relevant clinical outcomes. While this will be adjusted as the new law continues to be implemented, I do not foresee any major changes to the basic process.

Head-to-head trials are the most important type of data in assessing drugs, with placebo-controlled trials only being accepted when head-to-head trials are not possible. Since AMNOG requires reassessments of products after a few years on the market, real-world evidence could play an important role over time, to demonstrate whether a drug really delivers the estimated benefits in a real-life setting. While real-world evidence is not as rigorous as clinical trial data, it is valuable as add-on information. At the time of the initial coverage decision, pharma companies should communicate with payers about real-world evidence and find out what types of data AMNOG would like for a positive reassessment.

While real-world data could potentially measure outcomes more broadly than the clinical trial data, pharma companies should keep in mind the sorts of measures that matter to payers. Germany’s sickness funds are mostly focused on direct costs, so direct cost data is very valuable. And since sickness funds have annual budgets, they are interested in cost offsets today – not 20 years in the future.

**A dialog with pharma**

I do not see a Europe-wide, harmonized reimbursement system in the near future. Harmonization in terms of regulatory approval is quite easy – safety and efficacy measures are easy to align. But health care systems are traditionally so different in the way they reimburse, how they are structured, how they pay their physicians and how they pay for drugs.

That said, communication between regions has increased, and we talk more with colleagues in other countries. Pharma companies should be aware that payers are more informed of what is happening in other markets through initiatives such as payers-insights.com. This means that pharma companies have to be more open and honest when communicating with payers. They do not like it when pharma only presents positive data. Payers would have more trust in drug companies if they proactively presented data on all aspects of their drugs, rather than waiting for information about negative effects to emerge later.

Payers need the scientific information, of course, but it’s also valuable to talk about the business case: how many patients are eligible for a product and how can we work together to identify them? Pharma companies that approach us are rarely prepared with such information. It would be helpful if they talked earlier about products in development, how they are designing trials, what they see as the standard of care, and what incremental benefits they think their product can deliver. Such conversations don't happen currently.

Kassenärztliche Vereinigung Westfalen-Lippe (The Physicians’ Association of Westphalia, or KVWL) represents the interests of all 13,000-plus doctors and psychotherapists in Westphalia and is responsible for ensuring outpatient medical care.
Formulating the formulary

As Chief of Pharmacy at SelectHealth, one of my responsibilities is to create a high-quality, evidence-based drug formulary. This task is more challenging than ever before. Certain therapeutic drug classes – for instance, DPP-IV inhibitors for diabetes – are essentially commoditized, and doctors can choose between multiple products which seem clinically equivalent based on the available data. In such cases, the primary differentiator is therefore cost.

Contracting with pharma manufacturers is one mechanism to control formulary costs, especially for specialty products. Strict tiering informed by manufacturers’ rebates works well in mature therapeutic areas such as rheumatoid arthritis or multiple sclerosis. In these two drug categories, we can use benefit design (e.g., higher co-pays) to drive utilization to the preferred products.

But for very expensive products in certain classes, such as rare diseases or oncology, it’s not really about formulary placement. Instead, it’s more about appropriate utilization. We could negotiate a contract with a manufacturer for a 5% discount, but that discount means nothing if we have even one patient over the year for whom the drug is inappropriately prescribed.

**Head-to-head data matters most**

In creating the formulary, we really want head-to-head data. Unfortunately, all too often we don’t have strong comparative effectiveness results. Thus, when designing our formulary, we must either make apples-to-oranges comparisons across trials or rely heavily on expert opinions, which can be biased.

Without comparative data, there is a tendency to limit a drug’s utilization via higher co-pays or stricter prior authorization requirements. Neither is optimal; we understand formulary design affects real-world compliance, which in turn affects patient outcomes. We don’t want to be in the situation of consigning all the products to the highest tier because we don’t have the data to discriminate between them. We’d rather know up front, for instance, which hepatitis C protease inhibitor has the top efficacy and the top adherence, and design the formulary to encourage that drug’s utilization.

**Partnering with providers and pharma**

We work closely with the clinical team at Intermountain Healthcare to standardize the care delivered. As a group, we assess the current clinical guidelines and develop protocols for drug prescribing that are consistent with the emerging evidence. For instance, as a team, we reviewed the data and created our own practice guidelines for the use of Synagis in newborns at risk of respiratory syncytial virus. By involving the physicians in the decision-making process and giving them tools to monitor their prescribing patterns, we were able to standardize newborn care, simultaneously improving outcomes and reining in drug costs. We’re hoping to do something similar in hepatitis C later this year, working with the gastroenterologists in our network.

Outcomes-focused partnering with manufacturers has been more challenging, apart from some successes in areas such as the collection of real-world outcomes data. It is often difficult for pharma companies to develop services that align with our goals. For example, a couple of years ago, we had a goal in diabetes that combined better A1C control, blood pressure control, lipid control, adherence to medications, etc. A pharma company was eager to work with us on this, but when it came down to it, they said that the only area in which they would help us was around adherence with their cholesterol medication. This meant that we had to drive adherence on every single one of the other measures. Working with a manufacturer on such a narrowly circumscribed goal simply wasn’t worth it – especially given how long it took to get their legal, regulatory and compliance people to agree with ours. It would have been quicker and easier to just do it ourselves. I would encourage pharmaceutical companies to think more broadly if they want to develop services for payers and providers.

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SelectHealth is a nonprofit health care plan affiliated with Intermountain Healthcare, an integrated delivery network of 22 hospitals and more than 180 physician clinics serving patients in Utah and southeastern Idaho.
2. Payers see drug costs as the biggest problem

While prescription drugs account for only about 10% of total health care expenditures, they are often first in line when it comes to payers’ cost-containment efforts. As already noted, payers said that “curbing rising drug costs” was their top business challenge, easily beating out the importance attached to non-drug costs. Interestingly, pharma companies’ perception of payers’ strategic focus is not far off, though they tend to underestimate the importance given to drug costs and overestimate the significance of non-drug costs.

When we asked payers whether they agreed with certain statements about the pharmaceutical industry, the statement they most emphatically agreed with was “drug prices are a major driver of health care cost increases” – 88% of payers strongly or somewhat agreed. Meanwhile, only 42% of pharma respondents strongly or somewhat agreed with this statement. (See Chart 2.5, as well as the more extensive discussion of this chart later in this chapter.)

The pressure on drug costs is only expected to increase in the near future, driven in part by the rapid growth in the prices of specialty drugs, particularly in indications such as oncology and hepatitis C. As Robert Galvin of Equity Healthcare LLC puts it, “in the US, specialty drug costs – accounting for only 4% of spending today, but growing at 20% annually – will face unprecedented scrutiny.” When assessing their most important business challenges 3–5 years from now, payers still rank drug costs as the top challenge, followed by non-drug costs (though the gap between the two does narrow slightly).

3. Pharma is not moving quickly enough on comparative trials

The ways in which pharma companies are collecting data and conducting comparative effectiveness research (CER) are mostly well aligned with what matters to payers. As shown in Chart 2.3, pharma companies’ ranking of the CER measures they use most is the same as payers’ ranking of the measures that are most important to them in coverage decisions. “Lowering total cost of care” and “producing cost offsets” are the metrics that both sets of respondents rank highest (reflecting, as already discussed, payers’ focus on cost containment), followed by “boosting drug adherence,” “improving care coordination” and “improving worker productivity.”

However, when it comes to the types of data pharma companies are collecting for CER, they are not as well aligned with payers. One big area of difference is with respect to clinical trial data, which payers – in both the survey and the in-depth interviews – still view as the gold standard. Payers are most interested in comparative trial data (e.g., head-to-head trials versus standard of care), which best measure the differential value of a new product. But, while payers rank comparative trial data as their most important data type, pharma companies report that the data they use most for demonstrating value is instead placebo-controlled trial data (see Chart 2.4).

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**Chart 2.4. Importance of data types**

<table>
<thead>
<tr>
<th>Data Type</th>
<th>Importance for Payers in Coverage Decisions</th>
<th>Pharma’s Utilization for Demonstrating Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparative clinical trial data (e.g., head-to-head)</td>
<td>5.00</td>
<td>4.28</td>
</tr>
<tr>
<td>Cost-effectiveness data</td>
<td>4.20</td>
<td>4.20</td>
</tr>
<tr>
<td>Real-world outcomes data (excluding patient-reported outcomes)</td>
<td>3.62</td>
<td>3.62</td>
</tr>
<tr>
<td>Placebo-controlled clinical trial data</td>
<td>2.83</td>
<td>3.32</td>
</tr>
<tr>
<td>Drug discontinuation rate</td>
<td>2.83</td>
<td>2.70</td>
</tr>
<tr>
<td>Patient-reported outcomes</td>
<td>2.78</td>
<td>2.78</td>
</tr>
</tbody>
</table>

Source: EY Progressions 2014 Payer Survey. Payers’ higher scores indicate data types that are more important for payers in coverage decisions. For pharma companies, higher scores indicate data types they use more frequently in demonstrating value to payers.
In some cases, manufacturers may still be somewhat reluctant to invest in head-to-head trials because they perceive them to be more risky (a company might fear a worst-case scenario in which it ends up paying to demonstrate the superiority of a competitor’s product). In others, they may be constrained by practical considerations — for instance, when two competing products are still in clinical development, it isn’t feasible to test them against each other based on current clinical trial paradigms. This is an area where adaptive trials could provide useful data — a topic that our upcoming biotechnology annual report, Beyond borders 2014, will explore in greater depth.

While trial data remains most important to payers for now, many expect real-world evidence to become increasingly significant over time — for instance, to incorporate real-time data and information about the patient experience. Here, too, there is a gap between payers and pharma, with payers ranking “real-world outcomes data” significantly higher (3.62 versus 2.83).

The good news is that, when we asked payers and pharma companies about the importance of data types 3–5 years from now, these gaps all but disappear. While the overall ranking of the six data types remains essentially unchanged relative to today, the data types that pharma companies expect to use in this time frame (less placebo-controlled trial data, more head-to-head trial data and real-world evidence) are well aligned with payers’ priorities.

While trial data remains most important to payers for now, many expect real-world evidence to become increasingly significant over time.
Switzerland has been reforming its health care system for quite some time now. One of our biggest challenges is to respond to Switzerland’s new diagnosis-related group (DRG) payment system for hospital care, introduced in 2012. Hospitals are still upgrading their systems, which is leading to delays in their invoicing of insurers. Another complexity is that Switzerland will include capital investments such as medical equipment in the DRG – a unique approach, given that other countries with DRGs finance such investments separately. It remains uncertain how this approach will evolve in the long run.

Paying for pharmaceuticals
Central governments are perceived as being tough on pharmaceutical prices. However, payers want to pay for value and want to negotiate better prices in order to increase quality. Helsana has teamed up with three other insurers in Switzerland, forming a buyers’ group through which we try to contract providers selectively. We think that as a pooled group of insurers, we can make better pricing arrangements in the future. We hope this will also apply to pharmaceuticals.

Switzerland has new legislation in place that focuses on the off-label use of drugs in cases of life-threatening or rare diseases. In such cases, an insurer has the option to negotiate with a pharmaceutical company and cover off-label drug use. This approach also allows insurers to assess the benefit of the off-label use over time and on a per-patient basis. Several such risk-sharing market access agreements exist for off-label drug use in small populations.

The Swiss national formulary system is not like the UK’s National Institute for Health and Care Excellence (NICE) or Australia’s Pharmaceutical Benefits Scheme (PBS), which explicitly demand cost-effectiveness. However, the drug’s price has to be justified, mainly by comparing prices with other countries and on the basis of therapeutic cross-comparison.

HTA and harmonization
Due to important differences among European health care systems, the harmonization of standards is perceived as difficult, even though it has great advantages. We have different financing systems, different purchasing power parities, different cost structures and different cultures. For example, certain diseases are handled in an inpatient setting in some countries and in an outpatient setting in others.

But for clinical effectiveness, as opposed to efficacy, and for health technology assessment (HTA) in a broader sense, harmonized guidance could be helpful. If Europe aims at harmonization, it remains unclear which course Switzerland will adopt. We don’t always follow the European Medicines Agency’s recommendations. Since Switzerland has its own reimbursement authority, it is very likely that we will also have our own HTA system. At present, HTA still remains an academic discussion within the government without any real influence on reimbursement strategy. But HTA is also the basis for making decisions about social values, which is why the harmonization of HTA will always have its natural limits.

Beyond the pill
In Switzerland, insurers have the option to negotiate with pharma companies to enhance drug effectiveness, e.g., by adding services to treatments, resulting in higher quality for patients. Clearly, these negotiations represent great added value for the patient and I would like to see more of this successful collaboration with the pharmaceutical industry in the future.

At Helsana, I want to ensure that our staff and clients understand what pharmaceuticals are, how they are developed and what role they play. I would like to see a regular dialog between the drug industry and the insurance industry to discuss developments in drug R&D. By the same token, it’s important for drug companies to learn about developments in the payer world, because there is a lot of change on the way.

Thomas Szucs has been Chairman of the Helsana Group, the largest health and accident insurer in Switzerland, since 2010. He is also Professor and Director of the European Center of Pharmaceutical Medicine at the University of Basel, Switzerland.
4. Payers are preoccupied by implementation challenges – and need help

Payers’ top two business priorities are curbing drug and non-drug costs. But these two issues are closely followed by a couple of implementation challenges: “responding to health care reforms” and “upgrading infrastructure/IT reforms.” These are closely linked – new models for delivering and paying for care are often dependent on collecting and analyzing large amounts of data.

The payers we interviewed frequently echoed these themes. Thomas Szucs, CEO of Switzerland’s Helsana Group, for instance, reports, “One of our biggest challenges is to respond to Switzerland’s new diagnosis-related group (DRG) payment system for hospital care, introduced in 2012. Hospitals are still upgrading their systems, which is leading to delays in their invoicing of insurers. Another complexity is that Switzerland will include capital investments such as medical equipment in the DRG – a unique approach, given that other countries with DRGs finance such investments separately. It remains uncertain how this approach will evolve in the long run.”

Many of the big reforms under way require payers to expend significant resources on related information technology (IT) requirements. As Michael Sherman of US insurer Harvard Pilgrim Health Care puts it, “Almost everything new that we are undertaking – related to the ACA, the exchanges, the transition to ICD-10, building new products and more – comes with big IT costs. Meanwhile, we are in an environment where employers and regulators don’t want to see cost increases – putting us between a rock and a hard place.”

The specifics differ from market to market and payer to payer. But the bottom line is that payers in many markets are consumed by tactical issues – responding to and implementing the big reforms that are under way.

This has two critical implications for pharmaceutical companies looking to engage with payers. First, payers are simply too preoccupied with implementation issues to enter into broader conversations with pharma at the present time. Margaret Anderson of FasterCures, for instance, recounts such an experience. “We recently organized sessions to connect a few payers with disease foundations that have developed robust data sets,” says Anderson. “The foundations wanted to use their data to measure the value of particular treatments or interventions, but to do so they needed the payers to identify the data in which they are most interested. Unfortunately, while the payers recognized the importance of such collaborations, their response was that they couldn’t focus on these initiatives right now, because they are consumed by the biggest sea change they have ever witnessed – health care reform.”

But there is also a second implication to this finding – one that is decidedly more promising for pharma companies looking to work closely with payers. Many value-based paradigms will inevitably require those on the front lines of care delivery to develop radically different skills, capabilities and processes – meaning that there is a potential market for entities that can help with such solutions.

For many pharma companies, expanding into the services business may seem like a drastic departure from their core strengths. But it’s worth remembering that, even as pharma companies wrestle with whether to “servitize” their products, payers and providers are trying to figure out how to move in the opposite direction, by productizing their services. A common thread through outcomes-based approaches is that they aim to reduce variation in care, thereby making health care delivery less like a traditional service (unique, artisanal, variable) and more like a product (mass-produced, industrialized, with uniform standards for quality and price). This “productization” requires building
standardized practices. It requires identifying relevant metrics and creating dashboards to measure progress. It requires processes for scaling up successful approaches and replicating them across organizations. These are areas in which pharma companies might be able to help.

Examples of such needs emerged repeatedly in our interviews with payers and providers. Several US interviewees reported that they have started creating periodic information reports for physicians and other health care providers in outcomes-based models. Such information is critical for ensuring that value-based incentives really do change behaviors for the better. Among other things, it gives physicians timely information, allowing them to target at-risk patients with preventive measures, and gives providers the complete picture on their patients, by including cost “leakages” that patients incur when they visit other hospital systems. While many payers mentioned creating data reports for providers, they are still figuring out the best way to do this. Some payers are experimenting with daily read-outs, while others are creating ones that are less frequent. The underlying tension – how to share information in a timely enough manner to provoke action without overwhelming providers and creating “report fatigue” – is one that payers and providers continue to grapple with, and there is likely appetite for solutions that address the challenge with succinct ways of reporting only the most relevant information.

Or consider the challenge of adherence. “We have a success-sharing program that, among other things, rewards physicians for their ability to drive drug adherence,” says Eric Cannon of SelectHealth. “Doctors often objected, saying that adherence is something they can't influence. In response, we showed them research demonstrating that the more physicians communicate the benefits of a therapy, the more compliant patients tend to be. We are also sharing information on which patients aren't in compliance, allowing them to identify which individuals to target with such communications.”

This suggests that payers and providers could be receptive to solutions that go beyond just communicating the benefit of drugs. Behavioral economics approaches, for instance, have demonstrably improved adherence far beyond efforts based on education and communication. (For more, see Chapter 2 of Progressions 2012.)

As payers and providers continue to adapt and refine their outcomes-based models, this will create both new challenges and new opportunities for pharma companies to expand beyond the pill. For instance, many payers are experimenting with bundled episode-of-care approaches, in which payments are capitated for a group of medical interventions related to a certain procedure (e.g., a knee transplant). Over time, these approaches are likely to expand in scope. Drugs, which have not always been included in such bundles, could be added over time – increasing the pressure on pharmaceutical prices as well as the imperative for manufacturers to explore risk-sharing approaches with payers.

More broadly, bundled episode-of-care programs may themselves need to evolve into broader risk-sharing arrangements – for instance, global payment models in which fees are not set per procedure, but rather per patient. Angelo Moesslang, the CFO of Fresenius Medical Care North America – a leading provider in renal care – points out that payers and providers will eventually need to move beyond bundled payments approaches. “The bundle is an intermediate step,” says Moesslang. “The ultimate destination will be risk-sharing programs. Risk-sharing has been discussed for a long time, and it might still take a while, but that's where things are headed.”
Sharing savings - and data

Sharing savings
At UPMC Health Plan, we are adopting new models to move beyond fee-for-service payment. We’ve already transitioned our larger physician groups – some employed by UPMC and others contracting with us – to a shared savings model. As of early 2014, more than 200,000 patients receive care from primary care doctors who are participating in the program.

The concept behind shared savings is simple: we still reimburse providers on a fee-for-service basis, but we provide an important financial carrot. To the extent providers lower the total health care spending for their patients below what we expect to pay based on historical claims data, those savings are shared with them. Practices must meet the UPMC Health Plan quality threshold to be eligible for a shared savings payment.

At present, the only savings models we have adopted are the upside-only models. This year, we want the primary focus to be on understanding how lowering total health care spending can also be consistent with an overall increase in quality care. We will continue to be cautious about any steps we ask primary care physicians to take toward full risk sharing. We do not want to potentially depress participation in this important program by asking them to take on too much risk.

Sharing data
As physicians start to share more risk, it’s critical that they also have access to timely information. We can’t provide data many months after an event and expect physicians to optimally manage their patient populations. That is why UPMC Health Plan has partnered closely with physicians in our network to boost our data infrastructure. Providers now receive monthly reports via a care management platform. For high-risk patients who have visited the emergency room or been admitted to the hospital, we provide daily updates. Every month, a medical director from the health plan also visits the provider groups to review their practice-specific data and identify opportunities for additional savings. We use our claims data to help providers identify which patients in their populations are high health care utilizers or at risk of emergency room visits.

This access to real-time data is already encouraging physicians to redesign their care delivery. Sometimes, remarkably low-tech changes can have a big impact. For instance, after we found that a high proportion of patients use emergency rooms immediately after work or on Saturdays, certain practice groups extended their night and weekend office hours, leading to significant savings.

Implications for pharma
Right now, our shared savings model doesn’t include pharmacy risk, in part because the effort seemed unlikely to generate much additional return. Because physician compliance to our closed formulary is already very good, our pharmacy spending is already below national benchmarks. Still, one of the quality-of-care metrics physicians monitor closely under the program is medication adherence. Thus, even though they aren’t at risk for pharmaceuticals, providers have an interest in making sure patients are taking their medicines as prescribed. Certainly as providers move to full-risk models that make them liable for the cost of the drugs used, they will look even more closely at utilization to ensure the right patients are on the right medicines.

Pharmaceutical companies are interested in partnering to develop programs to promote medication adherence. Yet, pharma-sourced adherence programs can fall flat if they are not done the right way. Today, many such programs are disjointed from the patient-provider relationship, and patients don’t understand why a group that’s not a part of their care team is calling them. To succeed, pharma companies will need to construct services that align better with the continuum of care, and serve our needs. One example would be collecting real-world outcomes data to help us understand the impact pharmaceuticals have on hard-to-treat populations with multiple comorbidities.

UPMC Health Plan is owned by the University of Pittsburgh Medical Center, an integrated health care delivery system in Pennsylvania. The plan, which serves more than 1 million members via Medicare, Medicaid and commercial plans, is the front door to a network of 22 hospitals, 400 outpatient centers and roughly 3,500 physicians.
To elevate health, we need more risk-sharing

These are challenging times for payers. At Harvard Pilgrim, almost everything new that we are undertaking – related to the ACA, the exchanges, the transition to ICD-10, building new products and more – comes with big IT costs. Meanwhile, we are in an environment where employers and regulators don’t want to see cost increases – putting us between a rock and a hard place.

Elevating health

Despite – or perhaps, because of – these pressures, we’re continuing to innovate. In 2013, we launched several new initiatives to engage patients in their health care. These include the web-based transparency tool Now I Know, powered by Castlight Health, and SaveOn, a program that rewards patients financially for choosing quality, lower-cost providers for outpatient procedures such as mammograms and ultrasounds.

On the provider side, we’ve shifted most physicians in our network to outcomes-based payments. At a minimum, their fee-for-service payments now include some kind of pay-for-performance incentive based on a quality metric. Many provider groups are also participating in shared savings and shared risk programs that reward them for reducing total medical expenditures across their patient populations. I’m particularly excited about two initiatives: first, a joint venture between Harvard Pilgrim and two New Hampshire-based health systems to create a co-branded insurance offering, ElevateHealth; second, pilots to create bundled payments for procedures such as colonoscopies and coronary artery bypass grafting and, eventually, for chronic conditions such as diabetes, where we are in discussions with organizations such as Joslin Clinic.

ElevateHealth is structured to allow the participating providers (from Dartmouth-Hitchcock Medical Center and the Elliot Health System) to share in the profitability of the HMO product. In return, they charge Harvard Pilgrim lower fees for their services. To keep costs low and quality high, the participating partners collectively decided how to allocate resources to care management programs, informatics development and formulary creation.

I’m a big believer in bundled payments, which reward excellence for specific episodes of care rather than taking on the entire system. Bundled payments align incentives around doing the right thing for the patient and lead to more appropriate utilization of dedicated equipment and personnel. To date, our pilots have focused on procedures rather than chronic care. That’s because it’s a lot harder to define an episode of care for diabetes or heart disease than for rotator cuff surgery. Moreover, under health care reform, preventive care is something we, not the member, pay for. How do you tease apart which portion of a diabetes bundle constitutes preventive care?

A message for industry

Drug manufacturers should pay attention to how provider behavior changes when physicians operate in at-risk environments. We’ve found, for instance, that physicians in risk agreements, some of whom serve on our P&T Committee, sometimes argue for tougher utilization criteria for high-cost therapeutics. This suggests that the old pharma sales model, in which companies went around the payer to try to influence physicians to use their products, won’t work anymore. Now, providers are saying, “We’re sharing in the profitability. We don’t want our physicians using high-cost drugs unless they add real value.”

Our bundled payment pilots may be procedure-based, but because of the way they are structured, these risk-sharing agreements are driving more generic drug utilization. For instance, anesthesiology fees – both for drugs and for the doctor’s services – are included in our colonoscopy bundled payment. The physicians performing the procedure will get the same global reimbursement whether they use a generic such as fentanyl, or a newer, more expensive agent. In this instance, when making a drug choice, the physician isn’t spending other people’s money; she’s spending hers.

Providers have jumped on the outcomes bandwagon. Drug companies need to do the same. In our discussions with pharmaceutical companies, some understand that they need to provide solutions, not pills. However, it’s still very tough for these same groups to enter risk-sharing agreements with us. There’s a lot of “Here’s why risk-sharing is hard to do.” I understand their concerns, but the reality is that some companies are already sharing risk in Europe. Why can’t they do so in the US?

Harvard Pilgrim is a not-for-profit health plan with more than 1 million combined members in Massachusetts and Maine (Harvard Pilgrim Health Care) and New Hampshire (Harvard Pilgrim Health Care of New England). Harvard Pilgrim Health Care has been ranked the #1 private health plan in the US for the past 10 consecutive years by the National Committee for Quality Assurance (NCQA).
5. Pharma has a trust deficit

The examples above illustrate that while payers and providers are consumed by challenges related to health care reform implementation, they are also potentially interested in creative services and solutions to address these challenges. However, pharma companies aren’t necessarily the most obvious candidates to provide such services, because they face a significant roadblock: they are not seen as trustworthy partners.

Indeed, some of the most dramatic findings from our survey were in response to questions about attitudes toward pharma companies (summarized in Chart 2.5). As already mentioned, by far the biggest gap between payers and pharma emerged when we asked respondents whether they agreed that “drug prices are a major driver of health care cost increases” – 88% of payers strongly or somewhat agreed, compared to only 42% of pharma respondents. The two other statements with which more than half of payers agreed are “boosting drug adherence is a critical component of lowering health care costs” and “pharmaceutical companies have data that is vital for measuring and improving outcomes.”

Those responses, by themselves, could imply that pharma companies are well positioned to engage with payers around adherence-based services or solutions that involve pharma company data. But the remaining

![Chart 2.5. Attitudes toward the pharmaceutical industry](image)

Source: EY Progressions 2014 Payer Survey. Length of bars indicates percentage of respondents who strongly or somewhat agree with each statement.
questions — the ones with which fewer than half of payers agreed — paint a very different picture. Most payers do not believe that pharma companies developing services can be trustworthy partners or unbiased between their products and those of competitors. While they do consider pharma data to be vital, fewer than half of payers find the industry’s data to be credible. And payers don’t hold a very high opinion of pharmaceutical innovation — only 20% agree that new pharma products are significantly differentiated from standard-of-care, and a mere 13% believe pharma companies bring affordable products to market — which probably exacerbates the low level of trust.

As stated earlier, a primary goal of our survey was to measure the extent to which pharma companies are aligned with payers’ needs. For the most part, the survey results suggest that pharma companies understand payers’ broad needs and objectives and are investing in the right kinds of data and metrics. The problem, therefore, isn’t pharma’s perception of payers — it’s payers’ perception of pharma. Despite having useful data and potential answers to important challenges such as drug adherence, pharmaceutical companies are unlikely to get much traction because payers simply don’t trust that they can have the impartiality required to play in the services space.

So what can the industry do to improve its perception? As shown in Chart 2.6, both payers and pharma recognize that publishing all study findings, whether positive or negative, is the most important trust-building initiative. A number of payers also provided free-text answers in the “other” field. Many of these respondents indicated that they want to be engaged with in a different way, asking pharma companies to, for instance, “respect [payers’] role in managing care,” “[participate in] multi-party consortia,” “[conduct] executive-level interactions,” and “support doctors” by providing “pathway data support,” among other suggestions. The common thread through these responses is that payers want interactions that are not mere negotiations around access and price, but instead are enduring relationships that respect the role of payers and providers and help them address their biggest challenges.

Restoring trust is now an inescapable strategic imperative — something we discuss extensively in Chapter 3.

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**Chart 2.6. Actions to build trust between pharma and payers**

<table>
<thead>
<tr>
<th>Payers</th>
<th>Pharma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publishing all study findings (positive and negative)</td>
<td>4.63</td>
</tr>
<tr>
<td>Increasing price transparency</td>
<td>4.17</td>
</tr>
<tr>
<td>Participating in real-world evidence/comparative effectiveness research partnerships</td>
<td>4.13</td>
</tr>
<tr>
<td>Eliminating drug couponing</td>
<td>3.47</td>
</tr>
<tr>
<td>Eliminating direct-to-consumer advertising (US market)</td>
<td>3.47</td>
</tr>
</tbody>
</table>

Source: EY Progressions 2014 Payer Survey. Higher payer scores indicate pharmaceutical company actions that are more important for building trust between payers and pharmaceutical companies.
Health care systems around the globe are dealing with challenges related to sustainability. In the Netherlands – where we have a long history of consensus-based policy-making, such as through the Polder model – we are bringing together health care stakeholders to find a common path forward.

This includes raising awareness of sustainability challenges in the market, for example by reaching out to the general public. We organize conferences to increase familiarity with the subject of cost-effectiveness, which is very difficult for most people to appreciate when making decisions about their own health care.

The pharmaceutical sector has a role to play in these conversations. Pharma companies are aware that the current system is unsustainable and realize they have to contribute creatively to new solutions. In that spirit, they are quite willing to try innovative approaches in cooperating with payers. For this to succeed, however, the industry will need to move away from sales and marketing practices that have hurt trust in the past.

A number of new drugs have very strong restrictions on use, because payers and regulators are afraid that extensive use in patients for whom these products are not suited could drive large cost increases without improving outcomes. As an alternative, we are looking to create multi-stakeholder agreements in which every stakeholder makes explicit how it will help boost the sustainable use of interventions to improve patient outcomes and increase efficiency. Ideally, the stakeholders should define the boundaries of these agreements together, instead of having them defined by Zorginstituut Nederland.

In areas where outcomes research is considered useful, the challenge is to improve international coordination in the data used for evaluation. What types of data and analysis are most useful in demonstrating value? We love head-to-head trials and, where such trials are not feasible, good indirect comparisons with the current standard of care. We have become a little disenchanted with outcomes research because it usually takes huge amounts of time and administrative effort and rarely helps us make a better decision by the time the results come in.

There has been an enormous increase in new registries across all types of diseases recently; we’re enthusiastic about them because they help medical doctors to check for themselves whether they are doing the right things to provide optimal value to patients. But registries rarely give you solid extra evidence for reviewing or making a reimbursement decision. Even in areas that have been around for a long time, such as multiple sclerosis, there is much disagreement about the relative importance of some outcome measures. Still, registries have the potential to be very valuable, and therefore a Europe-wide registry governed by an international board should be demanded by EMA when approving drugs for which the evidence base is still shaky.

One of the troubles in most registries is that quality-of-life data is sketchy, if it is collected at all. That doesn’t help us very much, particularly in oncology, because you want to know not only about progression-free survival but also about the quality of the extended lifespan.

At the moment, we are discussing the best way to make cost-effectiveness data an integral part of decision-making on the agenda, and it’s a very touchy subject. No health care minister wants to endorse a decision or a proposal that actually denies certain types of drugs to critically ill patients. But I think that sooner or later we’ll have to face that issue.

Until 1 April 2014, Zorginstituut Nederland (National Health Care Institute) was known as the College voor zorgverzekeringen (CVZ, Health Care Insurance Board). Acting independently of the Dutch Minister of Health, Welfare and Sport, the Institute’s aim is to contribute substantially to maintaining the quality, accessibility and affordability of health care in the Netherlands.
Navigating through complexity
Chapter 3
Navigating through complexity

In brief

• The payer landscape is very complex and fragmented. Payers’ requirements differ across markets. Their attitudes vary across products and therapeutic categories. And the ranks of payers are growing as providers, large employers and others start acting like de facto payers.

• In this environment, pharma companies need a strategic and comprehensive approach for dealing with payers. We suggest a paradigm we call strategic payer engagement (SPE) consisting of four components:

  ▶ **Screening** payers to identify the most relevant markets for a particular offering
  ▶ **Segmenting** payers to customize offerings for the preferences of different behavioral archetypes
  ▶ **Sequencing**, in which offerings are expanded and scaled up
  ▶ **Sustaining** – the foundation underlying the other three components, which consists of building payer relationships that are high-level, collaborative and ongoing

• Sustaining requires action on three fronts:

  ▶ Building solutions that are customer-centric rather than pharma-centric
  ▶ Developing data-driven insights and interventions
  ▶ Restoring trust through greater transparency

A complex and fragmented payer landscape

The payer survey and interviews summarized in Chapter 2 reveal that there are some common threads in what payers say they want. But one doesn’t have to talk long to pharma executives to get a very different perspective: one of an industry struggling with a payer environment that is fragmented, opaque and fraught with uncertainty.

As Eduardo Sanchiz, CEO of Spanish pharma Almirall, puts it: “One of the key challenges we face as an industry is that payers are very dissimilar across countries. Their requirements differ from country to country – and sometimes even within the same country. Products struggle to gain approval in some European markets, even though they are approved and marketed in neighboring nations. Payers’ views change over time, and so companies may have to run new studies to meet changing requirements, which prolongs development cycles.”

Indeed. It may sound contradictory to say that the payer landscape is characterized by both broad similarities and tremendous heterogeneity, but both statements are in fact accurate. While payers may have similar business goals and needs, they can be very dissimilar in the ways they fulfill their goals and meet these needs. As discussed below, this heterogeneity is driven by three factors: differences in interpretation, implementation and behavior; differences by product class and disease segment; and a broadening universe of payers.

While payers may have similar business goals and needs, they can be very dissimilar in the ways they fulfill their goals and meet these needs.
The devil in the details

While our survey results found common themes in payers’ needs, challenges and areas of focus, there are also significant dissimilarities in how things actually get implemented on the ground.

For instance, the vast majority of payers in the survey rate head-to-head trials as the most important source of data. But the reality is that there are significant differences in expectations across markets. Which standard of care gets used as the basis of comparison? Which surrogate or final endpoints do payers want to see? How should survival and quality-of-life measures be weighted? The devil, as always, is in the details. (For a perspective on how the needs of different segments of US payers affect the reimbursement of diagnostics, refer to the article by Kristin Pothier on page 44.)

Beyond the details of implementation and interpretation are behavioral attributes, which can also differ considerably between payers. Organizations, much like individuals, have personalities and preferences: cautious versus innovative, cost-conscious versus focused on other attributes. These institutional personalities can further influence how data is interpreted and acted upon.

It's all relative

Nor are payers monolithic, unchanging actors. Their behaviors and attitudes vary from product to product and therapeutic area to therapeutic area. The same payer may have very different attitudes — e.g., toward surrogate versus final endpoints, the significance of side effects and the importance of quality-of-life measures — for a fast-moving, lethal disease compared to a slow-moving chronic indication. A payer’s price sensitivity may be influenced by the number of competing products (particularly if some of these are generic) and the number of patients in a particular indication. A payer may be much more receptive to beyond-the-pill solutions in an indication with a strong behavioral component such as type 2 diabetes.

Even within a single therapeutic area, payers’ attitudes and preferences can vary from product to product. How differentiated is a drug compared to the standard of care? Is it an early mover or a late entrant in a crowded field? Can it demonstrate improvements in care delivery or reductions in cost of care?

Further complicating the picture, a payer’s attitude toward a product can, in turn, be influenced by other payers and opinion leaders. Payers actively look to each other in matters such as reference pricing, have formal and informal links with each other and are influenced by published studies.

We’re all payers now

The last factor contributing to the complexity of the payer landscape is the sheer number of payers, a number that’s rising even further thanks to the move to value-based health systems, which are making more entities into de facto payers.

The term “payer” is often used as shorthand to refer to what is in actuality a series of separate decisions, often made by different entities. These include:

- The **coverage** decision, determining whether a product is approved for insurance coverage, which may be influenced by analysis conducted by health technology assessment (HTA) agencies
- The **pricing** decision, which includes negotiating over the price paid for the product and, in Europe, may be influenced by reference pricing considerations
- The **prescription** decision, which determines whether the product is actually used by health care providers (since a positive coverage decision gives providers the option, but not necessarily the obligation, to actually prescribe the drug)

The disconnect between these decisions is illustrated by Mark Wilkinson of Barnsley Clinical Commissioning Group, who says: “In the UK, NHS funding isn’t automatically aligned with recommendations by NICE. Even after NICE produces a positive recommendation, doctors in the field may not get any additional budget to implement the recommendation – meaning that positive coverage decisions don’t necessarily translate into an uptick in prescriptions.”
Payer power in precision medicine

A rose is a rose is a rose, but a payer is not a payer is not a payer — especially in these early days of precision medicine.

When making coverage decisions about diagnostics, US payers segment roughly into one of three buckets: integrated delivery networks (IDNs), large national plans (both commercial and public) and small regional payers. These payer types have different appetites for risk, particularly regarding the adoption of new technologies. Moreover, they use different time horizons to judge a test’s cost-effectiveness. IDNs, for instance, typically retain their patients longer than commercial plans, and are thus better able to afford tests whose economic gains—in terms of cost offsets or improved outcomes—are not immediately realized.

The population make-up and turnover of a plan’s membership, as well as its internal analytic capabilities, drive specific payer behaviors. Although this seems intuitively obvious, this payer stratification has profound implications for test developers. When devising a reimbursement strategy, a life sciences company must develop its value story on a payer-by-payer basis, outlining the specific impact a given test will have on a payer’s member population.

Individualizing the message to a number of different customers adds complexity and uncertainty to the diagnostic business model. While there is no reimbursement shortcut, there are three common metrics all payers care about: clinical utility, clinical validity and cost-effectiveness.

Companies can best demonstrate clinical utility by showing their test changes clinical practice patterns in the patient populations that payers specifically care about. As is true for therapeutics, payers also want randomized, controlled trial data demonstrating an improvement relative to the standard of care; such data confirms the accuracy and validity of the test in question. Finally, prospective studies tracking health care costs with and without the new test provide a compelling economic reason for coverage. It’s admittedly difficult to come to market with such economic data in hand; models linking a potential reduction in health care costs to test use also help build a diagnostic’s value story.

From these three data sources, companies must then create a cohesive reimbursement package tailored to the payer in question and its specific clinical and economic concerns. Test developers should recognize that certain payer types can play a critical role in a diagnostic’s wider adoption. IDNs, some of which are the most progressive in adopting new tests, can be critical influencers. So, too, can for-profit, independent guideline developers (e.g., the National Comprehensive Cancer Network). It’s difficult for payers to deny coverage of tests that nationally recognized societies have espoused as medically necessary.

In the interim period between test launch and payer coverage, companies can accelerate the uptake of their tests—and build a more robust data package—by adopting smart commercial practices. These include creating self-pay or patient assistance options to enable coverage until payers issue official coverage decisions. In parallel, companies should also work with key opinion leaders to capture additional real-world data. These activities both broaden support for the test and further clinical utility arguments by deepening the pool of available evidence.

Recognize the US diagnostics market is in flux; in addition to clinical and economic evidence, coverage decisions are influenced by practical considerations. Certain tests, such as companion diagnostics, currently face little pushback from payers. Because payers direct the utilization of very expensive therapeutics to those most likely to respond, the clinical and economic calculus associated with companion tests is easier for payers to discern.

It’s a different story for diagnostics that aren’t directly tied to a therapeutic, especially multi-gene test panels employing new technology like next-generation sequencing. Although advances have been made in prenatal diagnostics, other examples of panel-based diagnostics in oncology have been harder to get reimbursed. Moreover, the current coding system doesn’t allow payers to easily link to specific tests, or link the results of such a test to a single clinical decision. Practically speaking, most payers just aren’t set up to process the information from such multi-gene tests.

However, the industry is making progress. Certain larger payers are piloting coverage with evidence programs that enable access to tests, while furthering real-world data collection. These same payers are also revising internal processes to better reflect the impact that diagnostics have on health outcomes. Other stakeholders have developed new pilot codes to help payers better define what they are paying for. Simultaneously, specific product companies are committing more resources to clearly proving the clinical utility and validity of their tests, while developing economic utility stories that are payer-specific. Over the next one to two years, we expect this strategy will become protocol. We believe that companies that strive to deliver the best clinical and economic outcomes for patients and the health system will continue to be rewarded.
Paying for personalization

The potential for personalized medicine has been around longer than many people realize. About 50–60 years ago, pharmacogenomics began to explore—and explain—how drugs work at the molecular level and why patients respond differently to the same drug. But personalized medicine has really become tangible over the past decade as a growing number of targeted therapeutics have been approved.

Most of the progress has been in a relatively small number of diseases, with oncology being most advanced in incorporating personalization into mainstream clinical practice. This is due partly to the complexity of many diseases—such as cardiovascular disease, diabetes, obesity and even neurological diseases—which makes it harder to identify specific and well-defined subgroups of patients, isolate variables for testing and derive conclusive results on why a particular therapy did or didn’t work. Perhaps also we have been expecting too much from genetics alone: personalizing medicine relies on a bigger, more complex set of data of which genetics is just one piece.

Pharma is increasingly interested in personalizing therapeutic interventions but is not in command of the entire decision process. Payers are gaining more influence with critical reimbursement decisions: extraordinarily effective new therapies are emerging that can be tailored to specific patient profiles, but many of these come at an extremely high cost, so inevitably payers are getting involved more deeply in coverage and reimbursement decisions in these types of new therapies and interventions.

Payers are asking not only for evidence that a product works but for evidence that it is significantly differentiated from existing treatments and, even further, that it improves the broader economics of health care. The challenge is to get smarter about collecting relevant information and design comprehensive studies that quantify the economic impact of interventions, preferably at the same time as pharma is thinking about the need to generate evidence for market registration of their products. This requires new strategies and approaches to clinical trials.

Drug companies aren’t alone in this challenge. Diagnostic companies have too long relied on a business model that was driven by “if you build it, they will come (pay).” But reimbursement pressures are changing this approach, and despite developing innovative products, few diagnostic companies have figured out how to make margins that lead to significant profitability. Here also, a re-evaluation of the approach to demonstrate clinical evidence and value needs to take place.

One of the keys to successfully developing new personalized medicine products and implementing them into clinical practice will be to forge creative relationships among the many stakeholders that drive innovation—pharma, diagnostics companies and payers, but also providers, patients, data management companies and others. Ideally, these partners would agree to pool their various sets of data, trying to find ways to match diverse and fragmented data sets so we can look at patients in a new, more holistic way.

The good news is that the increasingly urgent need to improve health outcomes in cost-effective ways is aligning interests like never before. Meanwhile, the science is progressing very rapidly and is bringing personalized medicine ever closer to widespread use.
As providers take on more financial risk via new delivery models, they are increasingly behaving like payers and focusing more closely on economic considerations. The US is witnessing a wave of payer-provider consolidation, largely driven by the move to outcomes and value. As a result of health care reform in the UK, 150 primary care trusts have been replaced by 240 clinical commissioning groups (CCGs) such as Mr. Wilkinson’s, each with its own budget.

In markets with employer-provided health insurance, escalating health care costs have become a competitive issue. More than ever, large employers are becoming actively involved in managing the health care costs of their employees. US grocery chain Safeway has launched a Healthy Measures initiative to focus on healthy behaviors and disease prevention. Meanwhile, Walmart’s Centers of Excellence program allows employees to incur no out-of-pocket travel or care expenses if they elect to have their surgeries at one of six leading hospital systems.

Lastly, patients themselves are becoming de facto payers thanks to two trends. The first is that reforms are tying patients more closely to the economic consequences of their decisions. French patients must now initially pay out of pocket for branded drugs if they refuse a generic equivalent. In the US, the shift toward high-deductible health plans and the rise of public and private insurance exchanges require patients to weigh the economic trade-offs associated with their treatment choices. Accompanying these shifts is a second trend that is empowering patients to behave like payers: increasing transparency into the quality and costs of different interventions (see discussion in Chapter 1).

The term “payer” is often used as shorthand to refer to what is in actuality a series of separate decisions, often made by different entities.
It’s no secret that achieving the triple aim – improved access to higher quality care delivered at a lower cost – requires the collaboration of all health care stakeholders: payers, providers, manufacturers and patients. This, in turn, requires new business models that can upend historically misaligned financial incentives and enable pay-for-success partnerships.

Enter the health impact bond (HIB). HIBs provide a market-based approach to finance evidence-based interventions that improve outcomes and/or lower costs. Rooted in the broader concept of social impact investing, HIBs work as follows. Financial stakeholders (e.g., investment banks) issue bonds to fund specific interventions (e.g., better care coordination). Governments and/or nonprofit entities guarantee the principal on the bonds. To the extent the interventions generate cost savings, a share of these savings provides a return to bondholders. By linking a potential return on investment to improved health outcomes, HIBs leverage future health care cost savings to pay for improvements today.

It’s early days for HIBs. Still, leading life sciences companies should watch an unfolding experiment in Fresno, California, a municipality where the asthma and poverty rates hover, respectively, around 20% and 30%. A cost-benefit analysis by the health impact investment firm Collective Health and the University of California Berkeley School of Public Health estimated investments in education and home-based remediation of environmental factors could generate a return on investment of US$1.69 for every dollar spent on the intervention. In 2012, with backing from the California Endowment Fund, a consortium including Collective Health, local payers, providers and employers launched an HIB to prove that comprehensive asthma management could yield financial, as well as social, benefits.

If it’s successful, the Fresno HIB’s benefit to payers is obvious: significant savings tied to reduced emergency department and hospital usage. Providers, meantime, stand to create new revenue opportunities via the partnership while building bridges within the community that will drive practice growth. Employers should benefit from reduced worker absenteeism and, for those who are self-insured, additional savings via cost offsets. The potential to do well while doing good is significant enough that private-sector investors like Goldman Sachs and J.P. Morgan are also looking to commit capital to HIBs and other social impact investments. Outside asthma, groups like Collective Health believe HIBs could be used to develop diabetes risk reduction programs, in-home elder care plans and coordinated care initiatives to keep at-risk high health care utilizers out of the hospital.

Life sciences companies have largely remained on the sidelines of new social impact investing experiments. That may be a mistake, because they could benefit significantly from participating in HIBs. HIBs represent an opportunity to build deeper relationships and align pharma companies’ incentives with those of other health care stakeholders. Critically, these bonds could also allow pharma to collect additional real-world data to inform the development of both marketed and pipeline products. Drug companies already pay insurers for access to such data. Imagine if they were to reallocate part of this budget to partner around an HIB. In exchange for the monetary and educational support they could provide – drug companies have deep expertise in both structuring trials and patient education – companies could garner access to real-world data generated via the HIB. This data might be used in conversations with other payers and providers as part of the drug company’s justification for a given product’s value.

Drug companies have for the past several years been trying to move into the health outcomes business. But being a credible player in the new health care economy means more than just developing therapies to treat disease. It means enabling patient wellness and investing in preventive services. Some drug companies have tried to do this by creating new, independent business lines that improve health care delivery (e.g., Merck’s Vree Health). HIBs provide yet another mechanism for drug companies to enable prevention and wellness initiatives, while simultaneously earning a return on the money committed.

That seems like an experiment worth trying.
Changing the payer conversation

At a time when many European economies are dealing with austerity, payers are putting unprecedented pressure on life sciences companies. This pressure is often manifested in demands for discounts or rebates. For pharma companies, this is a challenge, but like all challenges, it also represents a potential opportunity. If a company studies the journey that the patient takes — and understands how its product affects this journey and the different unmet needs of the pathology in the context of the larger health care system — it can change the conversation with payers. Armed with such deep understanding, companies can have a conversation not about simple discounts, but rather about how they can help payers increase the efficiency of health care delivery and, more important, improve patient outcomes and quality of care.

We have guided several companies through this difficult journey. The experience of Anadial, the Portuguese association of privately run dialysis centers, in renal care provides an excellent example of this approach. In 2011, the Portuguese government announced that it planned to reduce its reimbursement rate for dialysis significantly. We helped Anadial by designing an innovative reimbursement model that included all necessary dialysis services, the deployment of dialysis-related products, laboratory services and other complementary medical tests. This allowed the association to work with the government to improve health outcomes, as the amount of this reimbursement directly depended on the fulfillment of certain treatment results and quality control parameters. Instead of being paid using the traditional fee-for-service approach, Anadial negotiated a bundled reimbursement agreement with the government, avoiding the direct fee reduction. The different companies this association represents are making care more efficient through the entire value chain of providers — not just in the hospital setting, but also in ambulatory and primary care. They are using disease management programs so that patients don’t need to come back to the hospital as frequently.

This is happening in other countries, such as Italy and Turkey. In both countries, companies have succeeded by understanding the context of the health care delivery system in the specific market, collecting and analyzing data, and working with technical teams from regional and national payers to explore different models for delivering and paying for care.

There is no reason why this approach could not be used more broadly for other diseases. Consider that more than half of health care costs are due to acute care provision of health care. There is a lot of money to be saved by keeping people out of hospitals and improving care pathways, particularly in chronic indications such as cardiovascular, respiratory diseases and diabetes, which drive the majority of health care costs.

The same sort of approach is very applicable when negotiating managed entry agreements — something that has become increasingly common in Europe. We recently helped a company that was negotiating access for an expensive new oncology drug. We started by analyzing patient pathways and clinical guidelines — which get even more complicated in oncology because of the way different drugs are used as first line, second line or third line treatments. We analyzed more than 300 sequences of treatment for the disease and prioritized them. We then developed a strategy based on a risk-sharing agreement to foster the use of six of the analyzed sequences that included the company’s product.

Once again, developing this sort of deep understanding is allowing the company to have a very different conversation with the payer. Instead of talking just about the launch of a new drug in Spain, for instance, the company has positioned itself as working with the payer on improving treatment protocols for different levels of the disease and with combinations of different lines of treatment to improve health outcomes across the value chain of the pathology. The payer loves it, and views the company as a partner with a deep understanding of patients and the health care system.

In Europe, austerity is here to stay for the foreseeable future. But even as pharma companies operate in this difficult environment, they should not lose sight of the fact that payers aren’t just looking to cut costs. They are also presiding over health care systems that have lots of inefficiency and plenty of room for improvement. By understanding the patient pathway for a particular disease in a specific market — from both a clinical and an economic perspective — companies can understand how to deploy their product, and potentially expand into services, in ways that make the health care system itself more efficient across the continuum of care. This helps shift the health system’s focus from reacting to the acute care needs of individuals to proactively engaging a population of patients and focusing on their health goals, needs and abilities — thereby improving health outcomes.

And that’s a conversation that payers are very interested in having.
In short, there is significant variation across payers. Perhaps it’s not surprising, then, that many of pharma companies’ efforts to engage differently with payers have been ad hoc pilots that never get scaled up. It’s hard to have a strategic and comprehensive approach if one lacks a strategic and comprehensive view of the market. Pharma companies need a process for understanding the overall payer market and setting strategic priorities in a systematic and consistent manner.

### Strategic payer engagement

- **Screening**
  - Where’s the market opportunity?
  - • “80/20 rule”
  - • Public, backward-looking data
  - • Specific to therapeutic/product category
  - • Geospatial analysis (incidence, specialist referrals, environmental factors, etc.)
  - • Influencers, network analysis
  - • Value leakages

- **Segmenting**
  - What do these payers want?
  - • Surveys, interviews
  - • Press releases, M&A, policies
  - • Segment by behavior, preferences

- **Sequencing**
  - Where next?
  - • Adapt approach to expand to other payers
  - • Forecast payer movement over time
  - • Health care reform timelines, forward-looking surveys

**Sustaining**

- • Develop customer-centric solutions
- • Develop data-driven insights and interventions
- • Increase transparency, restore trust
In the following pages, we present such a paradigm for approaching payers, something we refer to as strategic payer engagement (SPE). This process consists of four components — screening, segmenting, sequencing and sustaining — to identify the best priorities and markets for investing initially, develop a plan for scaling up approaches over time, and create ways to engage with payers that are more likely to be successful and sustainable. Many pharmaceutical companies are already using some elements of this process. But firms may often be using them in ways that are aligned with a fee-for-service world (e.g., identifying doctors for marketing efforts to drive prescriptions of existing brands) rather than with value-based health care (e.g., targeting the biggest cost drivers confronting payers or developing solutions that truly address payers’ biggest unmet needs). The real opportunity is in combining all of these competencies in a comprehensive way and redeploying existing tools to better align with the changing needs of health care systems and payers.

The strategic payer engagement process is relevant for both pharma’s traditional products businesses and the services and solutions into which a number of companies are now venturing. Regardless of corporate strategy — a gamut that runs from companies that are doubling down as pure drug R&D businesses to ones that are reinventing themselves as health solutions providers — payers are inescapably influential customers. The goal for any pharma company should therefore be to identify the most relevant customers for its offer — whether product or service — and then engage with these potential buyers in ways that are customer-centric and sustainable.

To succeed at strategic payer engagement, pharma companies will also need to reconsider how they are structured internally. Much of what we are recommending here involves a more centralized (or at least better coordinated) approach to sizing up market opportunities and interacting with payers. Of course, there is always tension between excessive centralization (which could inhibit flexibility and customer-centric experimentation in markets) and excessive decentralization (which could lead to interactions that are unfocused and inhibit the formation of a coherent, overarching strategy). Which functions should be conducted in a centralized location and which should be kept in the field? To what extent should teams conducting health economics outcomes research be better connected with, or even brought directly into, interactions with payers? Where should companies break down barriers between adjacent disease franchises to enable the development of more holistic, payer-centric solutions?

Companies are already exploring such issues and there are no universal “right” answers. Each company’s approach will need to be based on numerous factors: its legacy corporate structure, internal strengths, geographic footprint, disease focus and more. For that reason, we are not attempting to make any universally applicable recommendations here. But we do recognize that these issues are very timely and urge pharma firms to continue searching for corporate structures that enable, rather than inhibit, meaningful and comprehensive payer interactions.

Let’s now examine the four elements of strategic payer engagement: screening, segmenting, sequencing and sustaining.

1. Screening

If the challenge for pharmaceutical companies is that the payer landscape is overwhelmingly large and fragmented, then the immediate need is to quickly “narrow the funnel” and get to a manageable subset of targets. The first step of the SPE process is therefore to screen payers and, using the “80/20 rule,” identify the small percentage of targets that are most relevant for a particular offering.

Given that payers’ needs and attitudes vary from product to product and from one therapeutic segment to the next, this screening needs to be done separately for each new product or service. This requirement, combined with the sheer size of the overall payer landscape, also makes it important for the process to be relatively quick, inexpensive and replicable. Geospatial analysis has tremendous potential here. While creating such a tool requires up-front investment, once the platform has been built and populated with relevant data, it can be used fairly quickly and easily for different scenarios.

Daniel Fracas’ perspective on page 51 describes the geospatial mapping tool EY uses to help US pharma companies understand an increasingly complex payer and provider environment. Using geospatial mapping, a manufacturer preparing to launch a new diabetes drug could start by creating a couple of base layers — analyzing publicly available data on disease incidence to quickly home in on the regions where diabetes is most prevalent, and then identifying the payers and/or provider systems in those regions that have the most covered lives for this disease.
Mapping complex provider networks

As the US health care system moves to outcomes and value, significant numbers of independent doctors’ offices are being acquired by large hospital systems. Doctors who formerly had the freedom to make their own prescribing decisions are becoming employees of provider networks. And as these networks take on more financial risk and look for ways to reduce variation in care, they are exerting more influence over doctors’ prescribing behaviors.

For pharma companies, this means that the world of providers and payers has suddenly become much more complicated. Instead of talking to independent physicians, for instance, companies need to understand the interconnections and mechanics of complex provider networks. And this, in turn, requires sophisticated analytical techniques that can bring together vast amounts of disparate data and map the connections across a complex network.

Geospatial mapping can be invaluable in such situations. At EY, for instance, we have developed a geospatial mapping tool that combines several types of data – socio-demographic, payer, provider and structural (i.e., affiliations and alignments between institutions and individuals). The power of the tool is that it combines data from numerous best-in-class sources to build a complete picture: primary research (e.g., on socio-demographic variables); claims data from payers; and adjudication data from pharmacies.

Using geospatial techniques with this data allows for layers to be added or subtracted to give users an understanding of various dimensions and interconnections. For instance, the base layer in any analysis is the underlying cartographic characteristics of a particular region that have been pieced together from primary research: demographic composition, transportation infrastructure, etc. On top of this base layer, one can add a layer showing individual physicians, their prescribing behaviors, use of medical procedures and the types of patients that they see. On top of this, one could add a third layer showing provider facilities and networks, the connections between different facilities, and the relationships between individuals and facilities. A fourth layer could then map pharmacies, diet and exercise locations in the region. Being able to map all of these characteristics – and, more important, the interdependencies between these data points – is what allows one to identify the best points for engaging with other stakeholders.

For instance, we recently conducted an exercise in the Boston metropolitan statistical area where we identified important and influential neurologists that our pharma client had previously been ignoring. The pharma company was using only script-based data and was therefore unaware that these doctors see large numbers of relevant patients. When our geospatial tool gave them the full picture by adding in claims data and other interconnections, it became immediately apparent that these physicians were important users and influencers for their products, and needed to be engaged.
The real value of geospatial mapping is in the layers that can then be added or subtracted to the base layers. So far, this platform has been used primarily to boost sales and marketing efforts for pharmaceutical products, but it is very relevant for identifying the most promising markets for new payer-centric services and solutions. A pharma company expanding into disease management for a chronic indication, for instance, will need to be able to manage comorbidities. A tool that can map the relationships between different specialists – formal affiliations, referral patterns and more – could help identify the relevant subset of payers and providers. Similarly, a company looking to develop an offering in a disease where environmental factors play a big role, such as asthma or COPD, could use geospatial analysis to map the environmental risks in different regions, which could be very useful in determining which regions to target.

In Progressions 2011, we articulated the concept of the value pathway – the journey patients take through various stages of a disease (undiagnosed, at-risk, diagnosed, under treatment, etc.). In the movement from one stage to the next, there are potential value increases (improvements in health outcomes, timely diagnosis, adherence with treatment regimes, behavioral changes, etc.) and value leakages (where outcomes do not improve, or deteriorate, due to failure to diagnose, non-adherence, poor behaviors, etc.). This paradigm can provide additional context when companies are defining the payer universe during the screening phase. By looking for value leakages, companies can identify payers that may be more receptive to a new offering. For instance, if a company is developing a new product or service to improve drug adherence in a specific disease – say, an extended-release medication or a gamification-based service – the screening exercise should also aim to identify regions in which lack of adherence is a significant issue.

As mentioned above, payers are actively influenced by each other and this is an important dimension to account for in the screening stage. Pharma companies are interested in identifying not just payers and providers with the largest potential markets, but also organizations and individuals who have an outsize influence on others in a particular topic area. Geospatial analysis can be very relevant here, too. Thomas Gauthier of Biometis, for instance, has built a geospatial tool that maps the geographic distribution of key influencers in a certain disease space or other segment. Adding data on payer networks to geospatial mapping would allow for such analytics. This could include reference pricing (which other payer organizations does a payer look to when making pricing decisions?), formal relationships (which individuals or organizations advise other payers?) and informal networks (which individuals are very influential in a certain topic area because they publish and/or speak extensively on the topic?).
Advanced network analysis techniques are more appropriate to measure influence across a network. They involve measuring network features such as “betweenness centrality.” The betweenness centrality of Dr. Smith is the number of times that the shortest connections between any two KOLs go through Dr. Smith. Another important measure is the “small-world network” metric, which tells you how densely connected a community is. Lastly, network modularity metrics allow you to compute whether a broad network is naturally subdivided into smaller networks and ultimately how easily opinions and influence “travel” across the entire KOL network.

EY: Could this approach be used to map payer influence networks – individuals who influence payers as well as how payers influence each other?

Gauthier: It’s a good question. In recent years, there has been a huge increase in the amount of literature being published on health economics matters. There are now tens, if not hundreds of research centers publishing such studies, and I believe that much of this research is being read and carefully analyzed by payers such as the Centers for Medicare & Medicaid Services in the US and Social Security in France. So the potential is certainly there, and such an approach would be very timely.

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2. Segmenting

Once screening has been done to shrink the payer universe to a more manageable subset of high-opportunity targets, a company will want to get traction with these potential customers. Given the market fragmentation discussed earlier in this chapter, success at this stage requires understanding the behavioral drivers of different payers. Segmenting payers according to their values and behaviors helps a company understand which payers might be more receptive to a particular offering as well as how best to position the offering differently with different payers.

The sorts of data and processes used in this phase are quite different from those used in the screening phase, for a number of reasons. First, the objective of segmenting is to identify the preferences and value systems of payer organizations, which cannot always be divined from publicly available data. Therefore behavioral segmentation frequently relies on surveys and interviews to better understand payers’ worldviews. Second, given the rapidly changing payer environment, it is likely that the behaviors of payers and providers are themselves changing over time. So, while the screening phase used backward-looking data, the goal in the segmenting phase is to identify forward-looking “leading” indicators that offer some insight into the direction in which payers’ behaviors and preferences are moving. Lastly, the number of targets has been drastically reduced thanks to the screening process conducted earlier. Consequently, it is now feasible to use more personalized, resource- and time-intensive data collection methodologies such as surveys and interviews.

But segmentation is a two-way street. Even as pharma companies are segmenting payers, payers are segmenting pharma companies based on their behaviors. After all, payers are aware of the actions of individual pharmaceutical companies in the market and do perceive different companies differently. As a result, it is often useful for this phase of the analysis to be conducted by a third party. In the payer segmentation projects we have undertaken on behalf of pharma companies, for instance, we have uncovered situations in which payers perceived these firms in decidedly negative ways. This has often been surprising for our pharma clients – particularly in cases where they thought they had a strong relationship with the payer – and payers may not have been as forthcoming if the interviews had been conducted by the pharma companies themselves.

The accompanying case study by Alex Jung (see page 55) provides a recent example of behavioral segmentation conducted at a large medtech company. In this case, she and her team used a combination of primary and secondary data sources to segment 25 US payer and provider organizations into four behavioral archetypes.
Behavioral archetypes: a case study

We recently helped a large medical technology company that was facing significant reimbursement pressures from payers. The client found that its products were increasingly being commoditized in the minds of buyers, and it wanted to enhance its value proposition by expanding into services and solutions — initially, with a disease management service for heart disease. To succeed in this endeavor, the company needed to identify the payers and providers who would be most receptive to such a service. We helped them identify 25 high-potential targets out of thousands of payers and providers in the US.

To position the new service offering with these potential customers, we needed to segment targets according to their behaviors and preferences. In other words, we needed to understand not just what these potential customers bought, but why they made those purchasing decisions and the value systems that guided those decisions.

We did this by conducting primary and secondary research on these institutions.

The primary research consisted of a series of in-depth interviews (over 100 questions across nine dimensions) as well as observational research (embedding ourselves in the environment of these buyers to better understand what was driving their buying decisions). Of the people we interviewed in these organizations, 70% were C-suite executives — the real decision-makers.

The secondary research involved analyzing press releases and other information in the public domain. This helped us measure companies’ risk tolerance — an important criteria to identify companies that would be receptive to new types of services. Risk tolerance isn’t something you can easily divine from a survey; you have to look at actual behavior. We measured it by looking at the sorts of partnerships, alliances and acquisitions companies had actually undertaken over the last three years — not just what they were communicating to the market.

Four behavioral clusters

When we examined how the behaviors of these 25 institutions clustered, four behavioral archetypes emerged.

The first one was cash cow. These are institutions that tend to prioritize cost above any other decision criteria. They often go to market based on cost — emphasizing that they are the lowest-cost provider or have the ability to save customers money. To succeed with such buyers, a company’s value proposition had to be positioned in terms of savings generated.

The second behavioral cluster was one that we called data pop. And these are organizations that are very interested in data, intelligence and knowledge. Examples of such institutions include research hospitals or other organizations focused on leveraging and monetizing data. Cost is a driver for data-pop companies, but it isn’t their highest priority. When dealing with such customers, we therefore reworded the value proposition to lead with clinical outcomes.

A third behavioral cluster is brand chip, which refers to payers or providers that perceive themselves as blue-chip brands and care most about protecting that reputation. With such customers, we therefore emphasized safety and security in the service being offered as well as our client’s own credentials and reputation, to drive home the message that partnering with our client would not hurt the brand of these institutions.

Lastly, we identified a fourth cluster of organizations for our client’s services strategy: channel partners. These aren’t payers or providers per se, but rather companies that are very influential in the buying decisions of payers and providers. One example of a channel partner is malpractice insurance companies. Most medtech companies wouldn’t typically think of malpractice insurance companies as natural partners, but they have considerable sway with payers and providers who, particularly in the US, are wary of any new product or service that could increase the risk of malpractice litigation. As such, malpractice insurance companies are well positioned to help in conversations with providers or payers that are very risk-averse. They are also good “first test” partners to verify that a product meets or exceeds customers’ expected safety standards — helping avoid potential malpractice issues such as recalls or adverse patient events. For such channel builders, the value proposition would not lead with costs and data, but rather with safety messages.
3. Sequencing

As discussed, the payer landscape is changing in fundamental ways. Across key markets, payers and providers are implementing health care reforms, experimenting with new models for delivering and paying for care, and entering new partnerships around data, among other changes.

With this in mind, a comprehensive payer strategy should include some measure of how things are changing and how the subset of payers identified and segmented in the first two phases can be expanded over time. In this third step, sequencing, companies might include considerations such as health care reforms in different markets and their implementation timelines. They might look even further out, at the evolution of the legislative debate to understand whether other changes might be imminent. Firms could conduct forward-looking surveys that gather data on how payers see their goals, needs, uses of data, methodological preferences and more changing over time.

With such inputs, pharma companies can begin to outline how different payers are changing, and whether specific payers might become more receptive to certain approaches at a later date. This would give companies a road map for expanding their approaches to other payers over time.

With the addition of sequencing, the three-step process described above provides an answer to two of the questions we identified at the outset of this report: How should companies invest now versus later? How can they move beyond pilots to larger-scale solutions?

The reason many of the business model innovations we have seen so far never progress beyond pilots is that the innovation that is occurring is typically random and ad hoc. A pharma company might identify an opportunity and develop a new service offering for a specific regional market based on the fact that it has a significant local presence or employs an executive with a strong relationship with a local payer. Even if that offering does well, there might never have been a vision for the larger opportunity, and without any basis for scaling it up to a larger service, the pilot typically runs its course and ends at some point.

The approach described above turns that model on its head. Strategic payer engagement replaces random experimentation with a deliberate process for identifying, segmenting and scaling up opportunities. By identifying the most significant markets and growth opportunities over time, companies can minimize the likelihood of wasting resources on one-off experimentation.

Strategic payer engagement replaces random experimentation with a deliberate process for identifying, segmenting and scaling up opportunities.
4. Sustaining

While the three steps described above provide a framework for identifying the most important payers, segmenting these targets and increasing the scale of solutions, they are not, by themselves, sufficient to get sustainable traction with payers in today’s market. A critical fourth component of any program for targeting payers – the foundation that enables the “engagement” in strategic payer engagement – is an emphasis on interacting with payers in ways that are fundamentally different from the ways in which pharma companies have handled payers in the past.

Specifically, payers are looking for interactions that are:

- **High-level.** Pharma companies need to give serious consideration to the question of who owns the payer relationship and ensure that appropriate senior executives are interfacing with important payers.

- **Collaborative.** While the interactions between pharma companies and payers have traditionally centered around negotiations, it is increasingly important for pharma firms to now build relationships that are collaborative rather than transactional. At a time when payers are preoccupied with significant challenges, companies that can demonstrate that they are interested in working together to solve these problems will get the best hearing.

- **Ongoing.** To engage with payers, these relationships also need to be ongoing rather than intermittent.

But to build relationships that are high-level, collaborative and ongoing, companies will need to take action on three fronts – what we refer to as the three pillars of sustainment. First, they should give serious consideration to expanding their offerings into services and solutions – and do so in ways that are customer-centric and address real customer problems. Second, to develop customer-centric solutions, companies need data and analytics for understanding the patient journey in the context of the health care system and identifying cost-effective, timely interventions. Third, pharma companies urgently need to restore trust in the pharmaceutical industry, without which their data is unlikely to be trusted and their attempts to develop customer-centric solutions are likely to founder. We turn to these three imperatives next.

To build relationships that are high-level, collaborative and ongoing, companies will need to take action.
Expanding into (customer-centric) solutions

We return now to a question we raised at the outset of this report — to what extent, and in what ways, do pharmaceutical companies need to move into services and solutions? For many companies, the answer to this question will depend on their management preferences, risk tolerance and overall strategy. Some companies see services as being outside their core competency and will continue to remain squarely in the business of being outside their core competency and will strategy. Some companies see services as preferences, risk tolerance and overall need to move into services and solutions? In what ways, do pharmaceutical companies outset of this report — to what extent, and We return now to a question we raised at the end of the story. In today’s market, companies don’t just have to win repeatedly; the pill should be based on comparisons with the drug business of today and tomorrow, rather than the drug business of yesteryear. Such decisions are sometimes influenced by an oft-repeated industry mantra: truly innovative drugs will always be paid for. While that statement is certainly true — and will always be true — the real question isn’t whether truly innovative products will be paid for, but rather whether the meaning of “truly innovative product” has itself changed in fundamental ways. What does it take to develop a product that is regarded as genuinely innovative in today’s payer environment? And, even if products satisfy the criteria for being recognized as truly innovative, will they get paid for at levels sufficient to provide a return on their R&D investments?

Drug R&D has always been an extraordinarily difficult enterprise, and it is now becoming even more so. We’re all familiar with the math. Out of thousands of candidates entering pre-clinical testing, only one will successfully make the journey to marketing approval. It is a journey that, for all the advances in new technologies and platforms, continues to be bedeviled by serendipity. The brightest minds in the labs of any pharma company cannot identify with certainty which candidates currently in clinical trials will succeed and which ones will fail.

With those odds, trying to develop a new product is, as we have pointed out in these pages before, like attempting to win the drug development lottery. And, to sustain growth with continued replenishment of the pipeline, companies have to win the lottery repeatedly. But even that, challenging as it is, isn’t the end of the story. In today’s market, companies don’t just have to win repeatedly; they also have to win decisively. To be differentiated in the market and satisfy payers’ demands, it isn’t enough for your product to work — it has to be demonstrably differentiated from other treatments. And then, companies have to hope that nobody else wins the lottery. Pharma is now operating in an environment in which the scrutiny of products never ends. You may have a breakthrough drug that is highly regarded by payers and investors — until a competitor comes along with a superior product, and your traction in the marketplace disappears overnight.

In making comparisons between services and drugs, therefore, it’s worth keeping in mind just how much more challenging that traditional business of pharma has now become. Much of this process has always involved risks that companies couldn’t completely control (e.g., the serendipity of drug development), but it now involves risks that are truly beyond a company’s influence (e.g., increased comparative scrutiny and the efficacy of products your competitors might develop).

In short, you can always remain in the drug business. But you can’t remain in the drug business you’ve always been in. This is now a very different game — with higher hurdles, unrelenting scrutiny, pricing pressure and heightened risks that aren’t entirely in your control. Even if innovative products are reimbursed, they may increasingly only be paid for at significantly lower price points. As that continues to happen, earnings and net margins, which haven’t yet shrunk meaningfully, could face significant compression.

Next, let’s consider what’s happening on the other side of the drug/service comparison. After all, drugs are only 10% of health care spending — what about the other 90%? This is an area with much opportunity, thanks to the move toward value and outcomes. While many of the goals of these reforms — for instance, harnessing the power of data analytics and care coordination to substantially improve outcomes and lower costs — might seem high, the starting point is low. For all the talk about big data, the reality is that in many markets, health care is only...
beginning to catch up with the computing revolution that has been sweeping through the rest of the economy since the 1980s. While digital documentation and workflows have been long established in most other industries, many health care providers are just starting to move out of the paper-and-pen era and implementing electronic health record systems. Industrialized processes and optimized supply chains have been squeezing out efficiencies in scores of industries, but health care's move to reduce variation in care is still in early days. As articulated in Chapter 2, payers are still figuring out many aspects of these transitions and could well be receptive to services and solutions that address their needs.

When comparing drugs and services, companies should consider how both sides of that equation are changing. Some companies may decide to expand into services and solutions; others may decide to remain squarely in the drug business. Either choice could be valid—as long as it's based on the right comparison.

**Being customer-centric**

As discussed in Chapter 1, there are many ways to expand into the outcomes business. The bare minimum in today's market is building value dossiers and adopting personalized medicine approaches. Beyond this, companies can expand into developing services and solutions (for instance, adherence, m-health and decision support) and, at the other end of the spectrum, even venture into care delivery itself.

Regardless of how far down this path companies choose to go, though, it will be critical to develop solutions that are customer-centric and truly aligned with payers' needs. So far, the services that companies are adding are typically developed from pharma's perspective rather than that of payers. The underlying goal is often a defensive one: to create an add-on service to increase the attractiveness of a product in the face of payer pressure, thereby protecting product sales. If pharma companies go in with that attitude, it's not surprising that when there is a conflict between the payer's goals and the pharma company's desire to sell more product, the product usually wins.

The gulf between payers' goals and pharma's interests is perhaps widest when it comes to payers' growing appetite for services that are broad and holistic—which often require companies to step outside their comfort zones and move beyond the silos in which they have historically functioned. As drug manufacturers, the primary focus of most pharma companies has been on treatment, but payers are interested in solutions that look holistically at the entire cycle of care. While drug companies tend to approach the world in terms of disease franchises, payers are interested in looking across diseases, both to target interections between ailments and to understand the impact of solutions on the total cost of care. (For more, see the perspective by David MacMurcy on page 68.) Lastly, while the idea of helping a competitor's products has historically been anathema to drug companies, moving into services may often require them to do precisely that, by being unbiased between the products of different manufacturers.

It's important to point out that this isn't a zero-sum game. Putting payers' interests first through such holistic approaches does not have to be at the expense of pharma companies. As Silvia Ondategui-Parra points out in her perspective (page 48), customer-centric solutions allow companies to change the conversation they have with payers, from one that is defensive (trying to hold back price reductions or other forms of market erosion) to one that is constructive and collaborative (working together to save the system money and sharing the savings). In effect, this creates opportunities to expand into “the other 90%” in a somewhat different way—by increasing drugs’ share from the 10% of health care spending they command today. If companies could use their drugs to work with payers in lowering the total cost of care, there's no reason why drugs couldn't see their share of health care spending increase. As Silvia puts it, and as our survey results demonstrate, “that's a conversation that payers are very interested in having.”

Pharma-centric approaches may have worked so far, but our interviews suggest that payers may be less and less likely to go along with them in the future. Take, for instance, the experience of Eric Cannon of SelectHealth, who says: “A couple of years ago, we had a goal in diabetes that combined better A1C control, blood pressure control, lipid control, adherence to medications, etc. A pharma company was eager to work with us on this, but when it came down to it, they said that the only area in which they would help us was around adherence with their cholesterol medication. This meant that we had to drive adherence on every single one of the other measures. Working with a manufacturer on such a narrowly circumscribed goal simply wasn't worth it—especially given how long it took to get their legal, regulatory and compliance people to agree with ours. It would have been quicker and easier to just do it ourselves.”
Developing data-driven insights and interventions

The second pillar of the foundation underlying SPE is data-driven insights and interventions. To meaningfully engage in ways that meet payers’ needs, pharma companies will need to use large volumes of data to develop a comprehensive view of the patient journey and identify interventions to improve patient outcomes.

Buzzwords and opportunities

“Big data” has rapidly entered the public consciousness. The term appears to have gone from obscurity to omnipresence almost overnight. By now, we’ve all heard about the three V’s of big data – volume, velocity, variety – and seen the inevitable consultants’ presentations counseling companies about an all-important fourth V (value? viability? veracity? vulnerability?) that everyone else has supposedly missed.

Not surprisingly, the bandwagon has engendered an equal and opposite reaction, and the term “big data” is often greeted with a sizeable dose of skepticism. While this may be understandable, and while it’s certainly true that the champions of big data are often guilty of overstating their case, it’s also true that there is something real and consequential happening behind the hype.

For health care, big data is more than a buzzword – it’s a big opportunity. In short, it isn’t just the payer landscape that is complex and fragmented – those two adjectives apply to health care data as well. For companies looking to navigate this diverse landscape, it is therefore critical to focus on four key aspects of a structured approach to health data analytics. These activities do not necessarily have to be done in-house – indeed, most companies are proceeding with a combination of partnering, outsourcing, and/or building/ acquiring capabilities. But, regardless of how companies conduct these four aspects, it is critical that they are part of their data analytics strategies.

1. Pooling data

The first aspect of a structured approach is about going from lots of data to true big data, by pooling information from different sources. Companies across the health care spectrum are actively doing this. In some cases, firms are buying or acquiring data outright. In other instances, they are creating partnerships with other stakeholders to pool their data, contribute resources to analyze the pooled information, and share any lessons learned.

2. Creating the full picture

A critical goal in pooling data is generating a comprehensive picture of the patient journey. This involves not just increasing the volume of data, but also ensuring that it has sufficient variety, by bringing in data from EHRs, prescriptions, claims, registries and so on. Not surprisingly, many of the data analytics companies we profile in this report – GNS Healthcare, Symphony Health Solutions and others – have built algorithms for matching data from such disparate sources. It is becoming increasingly common for companies to be able to match data even if the underlying records have been stripped of personal identifier information. Over time, as mobile health technologies become increasingly ubiquitous, we expect to see...
The “big” that really matters in big data is not breadth, but depth—not more patients, but rather more variables covering the entirety of the patient experience.

Traditionally, statisticians have looked for causality using regression analysis—a relatively slow, labor-intensive process involving hypothesis generation followed by running repeated regressions until a statistically robust equation is estimated. With big data, however, it becomes possible to take this process to a whole other level. The vast quantities of data that organizations are now collecting have lots of variation in them. For instance, if one is looking to identify the best treatment for a particular disease from a range of different drugs and/or other interventions, big data makes it possible to analyze the millions of real-world experiments that are occurring every day. One could examine hundreds of combinations of different treatments, assess how efficacious these combinations have been on a subpopulation with a particular genetic profile, disease history, etc.—and with vast amounts of data, each of these thinly sliced experiments could still have robust sample sizes, allowing one to draw inferences and conduct backcasting to test the stability of any findings. Companies are already bringing these methodologies to health care. Using Bayesian methods and machine learning, GNS Healthcare reports it has developed the ability to “automate experiments within large data sets and extract causality from the variance that occurs every day in the natural world.” (For more, see the perspective by Colin Hill on page 62.)

4. Driving timely interventions

The ultimate goal of using predictive analytics to locate the most relevant subpopulations and identify cause-and-effect relationships is not merely to understand why things are happening, but to intervene in timely ways to improve health outcomes and increase the efficiency of care delivery. We refer to this as prescriptive analytics—the use of analytics to recommend one or more courses of action and show the likely outcome of each decision. Colin Hill of GNS Healthcare, for instance, talks about how his company is conducting “what-if” experiments to find optimal interventions.

This prescriptive element is where the real promise of data and analytics lies. As data sets become more comprehensive, and algorithms more robust, prescriptive analytics will enable prevention, behavioral change, disease management and more. The search for the most cost-efficient course of action will increasingly pit drugs against other interventions—from surgery to text message reminders and everything in between.

But to succeed at any of this, it is critical that pharma companies are trusted. Without trust, they will have a hard time being taken seriously as partners in data-driven initiatives and their insights will often be met with skepticism. So we turn next to the increasingly urgent issue of trust.
The most interesting opportunity for big data in health care is combining real-world data – electronic medical records (EMRs), claims, patient registries, etc. – with next-generation machine learning to create predictive models. Armed with such models, we can better match the right health care interventions to the right patients. This is the key to lowering costs and improving outcomes. Today, the US probably spends US$500 billion on health interventions that add no value. If we could fix this problem, we wouldn’t have a health care crisis.

At GNS Healthcare, we are working to achieve this potential. We are the first company to create a machine-learning analytics platform that can identify not just correlations but cause-and-effect relationships. We use Bayesian network inference – a branch of mathematics that has come into its own over the past three decades – to identify the directionality in the data.

To understand how this works, imagine you are an alien who lands on Earth and observes a rooster crowing every morning when the sun rises. What conclusion would you reach? Is the rooster causing the sun to rise, or is the sun causing the rooster to crow? To answer this question, you would need to break the symmetry between the two events, for instance by silencing the rooster one morning and seeing whether the sun still rises.

The methods we have built at GNS allow us to break the symmetry between correlated events on a much larger scale. We can automate experiments within large data sets and extract causality from the variance that occurs every day in the natural world. Our platform has been optimized to run on cloud-based supercomputers that have more than 100,000 processors. The system is able to automatically build comparable predictive models by matching disparate data sources – genetic sequencing data, clinical outcomes in electronic medical records, claims data, consumer data and more.

Identifying causality is a game changer for health. So far, health care delivery has been a messy, expensive, trial-and-error process in which nobody really knows what is going to work in a specific patient. Our platform turns this model on its head, by creating the ability to predict ahead of time what the optimal intervention is going to be for a specific individual, based on everything we know about that person. We can use the data to do what-if testing to predict ahead of time what the impact of different interventions will be for this individual.

This approach is being used by the pharmaceutical industry and others to address numerous questions. We work with pharma companies to improve clinical trial success by locating patients for clinical trials using predictive biomarkers. We help companies optimize sales and marketing efforts. And we are increasingly using our platform to help the pharma industry influence formulary placement decisions. This includes understanding which drugs are most effective for given patient subsets and how different types of patients fare on one drug versus another. We are currently working with about half of the top 30 pharma and biotech companies on these issues.

We also work with payer organizations. At a time when payers are being bombarded with data from all sides, we have emerged as an honest broker of sorts between payers, providers and pharma. We work with health insurance companies such as Aetna and Blue Cross Blue Shield. We also have the only contract with the Centers for Medicare & Medicaid Services to determine how well the quality measures in the Affordable Care Act are working and how their effectiveness varies across patient subpopulations.

The US spends US$300 billion a year on drugs – about 12% of total health care spending. But I think the positive value that drugs deliver to health outcomes across the system is more than 12%. Pharma needs to tell this story. To do so, companies need to investigate the full impact of their drugs on the system, by teasing out causality to understand improvements in health outcomes, the impact on the total cost of care and more.
The integrated dataverse

Big data has tremendous potential for reinventing health care as we know it. But data by itself is just data. It’s the insights that really make the difference.

To achieve the potential latent in big data, therefore, a couple of challenges have to be overcome. First, we need the ability to integrate across different data sets – effectively combining the patient view, the payer view, the prescriber view and the provider view to get the true big picture. Second, we need ways to translate this data into insights that can inform decisions, everything from health policy to health economics research to brand-related commercial decisions. Unfortunately, most drug companies – indeed, most stakeholders in the health care industry – don’t know how to take full advantage of the insights that are buried within these vast amounts of data.

Symphony Health Solutions was founded about 18 months ago to help fill this gap. Indeed, we created the company – combining unique capabilities through a series of acquisitions – because we recognized that integrating different sets of big data across the patient, provider, payer and prescriber is a potentially game-changing opportunity. We have invested tens of millions of dollars to create a comprehensive database, called the integrated dataverse, which combines data across these four dimensions and enables fast, on-the-fly analytics.

Much of the original source data came through our acquisitions. We continue to collect data from a broad range of primary sources: prescription data, claims data, clinical data, etc. But this source data is not integrated in any way – in raw form, it is no better than the data that IMS produces. What differentiates our approach is that we have a sophisticated data integration operation that has managed to clean, organize and integrate all this disparate data.

The integrated dataverse we have developed is truly unique. As far as I can tell, there is nothing else like it in the industry. We now have data on 170 million US patients. For all of these individuals, we have their entire health care histories over the last 7-10 years – the progression of their diagnoses, the physicians treating them, the insurance plans they have been on, the drugs they have taken, etc.

We have also developed the tools for fast and flexible access to data from the integrated dataverse, the leading platform for predictive analytics, and a suite of cloud-based applications that deliver high-value commercial insights on the fly.

Having this sort of comprehensive view allows one to ask all sorts of questions. For instance, we can collate all patients who have a particular type of cardiovascular disease, look at what drugs are being prescribed for them, and examine whether they actually receive these drugs or whether payers and pharmacies are substituting other medications – valuable information for assessing the effectiveness of pharma companies’ commercial operations.

Similarly, we can look at whether a patient who has been prescribed medication for three months actually follows the prescribed course for this period of time. This is very important, because non-adherence imposes significant costs on health care systems, and it is a problem that payers and pharma companies are trying to solve.

At a time when payers are increasingly focused on the value and comparative effectiveness of medical interventions, the integrated dataverse is very useful in informing such questions. For instance, consider decisions about what drugs are included in formularies. While payers might attempt to make these decisions based on cost/benefit considerations, the reality is that they don’t have the full picture, because they don’t have all the relevant data. Payers have claims data for the patients they cover. But they don’t have any information about other patients and other parts of the health care system – all of which is relevant for making informed decisions.

So, we help pharma companies understand the effectiveness of their products across different cohorts of patients to see why certain drugs got unfavorable formulary treatment. We can help these companies provide more complete information to payers, so that payers can make informed decisions about how a particular drug should be treated on the formulary.

That’s better for pharma companies, payers – and ultimately, the entire health care system – because we can’t pay for value until we accurately measure it. And for that, we need the complete picture that only comes from applying technology and tools to fully integrated big data – enabling fast and flexible access, visualization and predictive analytics.
“Doing the right thing” is now the same as “doing the right thing for business.”

Restoring trust

It seems strange to imagine now, but the pharma industry was once one of the most highly regarded sectors around the world. Even into the 1990s, pharma firms topped Fortune magazine’s annual list of most respected companies with remarkable regularity.

Things have changed dramatically since then. Today, pharma regularly emerges as one of the least trusted sectors in numerous surveys. The image in the public’s mind has changed – from that of the scientist in the white lab coat toiling away to develop life-saving new medicines, to one of companies that are more interested in using aggressive means to boost drug sales. A number of trends have contributed to this change in perception. Armies of sales reps that add little value to physicians’ harried workdays have hurt pharma’s standing in the provider community. High-visibility lifestyle drugs, direct-to-consumer advertising and perceptions of high drug prices and “invented syndromes” have changed patients’ opinion of the industry. And numerous developments, such as a lack of transparency around clinical trial data and aggressive tactics to prevent generic competition, have lowered payers’ trust in pharma.

In recent months, the issue of trust and transparency has been in the headlines quite regularly. In late 2012, the publication of Ben Goldacre’s book, Bad Pharma, provided a detailed, damning and credible account of the industry’s transgressions. In the months that followed, a number of pharma companies have announced initiatives to increase the transparency of clinical trial data and boost trust in the industry.

These are timely moves. Restoring trust is perhaps the most urgent and important issue facing the industry today. To understand why, let’s consider another story that has made headlines in recent months: the decision by CVS, the largest pharmacy chain in the US, to stop selling tobacco products in its stores. The decision deservedly garnered praise in the media as an example of a company “doing the right thing” and putting the welfare of its customers above its own profits (the decision will cost CVS US$2 billion in annual tobacco sales). But the move was also a smart business decision, and the timing was no accident. After all, the public health consequences of tobacco consumption have been well known for decades. What changed to motivate action at this particular point in time?

The answer, at least in part, is that CVS is in two very different businesses, with very different growth prospects. As a pharmacy chain, the company is in the health care industry. But as a seller of numerous household and personal items in “the front of the store,” the company is also a convenience store and a member of the retail industry.

Retail trade, as we documented in Chapter 3 of Progressions 2012, is being disrupted by e-commerce, and CVS could well face increasing pressure from this trend in the months and years ahead. Amazon’s Prime service, in which the online giant offers free two-day delivery to subscribing customers, has already hurt the businesses of untold numbers of brick-and-mortar firms. The company is widely acknowledged to now be setting its sights even higher, by seeking to introduce same-day delivery in many metropolitan areas. That move, when it happens, could well be a game-changer for pharmacy chains’ convenience store business. For many customers, the offer of same-day, in-home delivery (possibly at a lower price point) may be more attractive than the prospect of trudging to the local drugstore in inclement weather.

Meanwhile, health care, CVS’ other business, presents opportunities for growth – because of many of the trends discussed in this report. With payers and health care systems moving toward outcomes and value, and with chronic diseases driving the lion’s share of costs, it will be increasingly important to improve patients’ health in the communities in which they live their daily lives (something we refer to as “health care everywhere” in Progressions 2012). Moreover, primary care physicians will be even more stretched in the new health care, thanks to greater emphasis on care coordination – increasing the need for others to share some of these responsibilities, and perhaps even expanding the definition of “provider.” With large numbers of retail locations and an integrated presence in communities, pharmacies could play a pivotal role here. (For perspectives on the pharmacy of the future, see the Progressions 2012 articles by Alex Jung, formerly of Walgreens, and Don Waugh of PharmaTrust, as well as the piece by Rita Shane of Cedars-Sinai in this report.)

But for CVS to be seen as a credible contributor to improving patients’ health outcomes, it couldn’t continue selling a product that is universally vilified for its harmful public health consequences. The decision to stop selling tobacco products is therefore not just good for patients – it’s also good for business. CVS realized that it could afford to walk away from US$2 billion in tobacco sales because there’s much more potential upside from positioning itself as a serious player in the health outcomes business. Saying no to tobacco was merely the price of entry.

This sort of calculation is strikingly similar to the choices before pharma with respect to trust and transparency – and we would argue that, much like the situation confronting CVS, the world has changed around pharma companies to the point where “doing the right thing” is now the same as “doing the right thing for business.”
Consider, for instance, the issue of clinical trial data. As Ben Goldacre documents, the industry has a long history of being less than forthcoming with data from unfavorable trials. So far, companies might have been motivated by what they perceived as the biggest risk in this issue — that unfavorable trial data would hurt the sales of their products. That may have been a valid, if somewhat cynical, calculation in the past, but in the new health care, the real risk is that such shortsighted tactics will ultimately hurt companies’ credibility as serious players in the outcomes business.

In the rapidly advancing world of value-driven health care, data is the currency. It is the driver of your enterprise value, the measure of your innovation, the determinant of your fate. Not surprisingly, we are seeing a flurry of activity in this space — everything from payers setting up their own analytics shops, to diverse stakeholders joining forces to pool data, to new start-ups emerging with creative algorithms for teasing out insights. (For more on these trends, see Chapter 1 and the discussion on analytics in this chapter.)

But if data is the currency of the new ecosystem, trust is the central bank. Without trust, you devalue your own data. We are now entering a world in which pharma companies will no longer have a monopoly over information about their products. Instead, payers will have access to competing studies from different sources. If pharma is the least trusted source of information, it’s inevitable that manufacturers will be handicapped in making the case for their products. Furthermore, any hopes of shielding payers from unflattering data about a product will be unrealistic in a world where pharma companies no longer have exclusive control over the information about their offerings.
The pharmacist of the future

As health care moves toward outcomes and value, hospital systems are focusing more closely on improving care coordination and continuity. Pharmacists have a vital role to play in this shift.

For instance, hospitals are focusing on care continuity during admission and post-discharge — ensuring they have a complete picture of patients when they arrive, as well as pre-discharge assessment and education, and post-discharge follow-up. The pharmacist plays a big role in these efforts, both because medication is such a large part of health care and because pharmacists are trained in evaluating the complete picture of the patient’s condition and history to determine if any changes are needed in medication therapy.

Even before electronic health records (EHRs), pharmacists looked through paper records to get this complete picture of the patient.

At Cedars-Sinai, pharmacists are helping improve continuity of care in multiple ways. We’re putting more effort into evaluating medication literacy (patients’ understanding of their medications) and adherence (whether patients are taking medications as prescribed) to identify patients who may be at risk for drug-related problems after discharge. Post-discharge, we’ve found that adherence improves significantly if we phone those who haven’t picked up their prescriptions, to remind them and to find out what questions they might have. We’re also forging relationships with post-discharge care providers — for example, our pharmacists review the medication records of discharged patients who are transferred to skilled nursing facilities to ensure that their medication lists are accurate.

US providers are moving to EHRs — a shift that has tremendous potential for improving outcomes. But data is only useful if it’s accurate, and pharmacists will play a vital role in ensuring that medication lists in the EHR are up-to-date. At Cedars-Sinai, we pay close attention to prior-to-admission medication lists, as a first step to ensuring safety and effectiveness of care. Do the medications make sense given the patient’s history, age, chronic conditions?

This evaluation has turned out to be a critical step, because medication lists are often flawed for several reasons. Patients sometimes provide inaccurate or incomplete medication histories. Many people, including medical assistants, can enter information into medication lists. Medication lists may not be systematically reviewed across health care settings to validate that the lists are current and accurate. Additionally, evidence supports that once the medication lists are in the EHR, confirmation bias creates the belief that the medications are correct and the medications are then prescribed. It is important to remember that a medication order is essentially a sentence, and that if any element is incomplete or inaccurate, this can lead to medication errors and adverse events. Just like the adoption of standard precautions to prevent infections in hospitalized patients (e.g., practices such as more frequent hand-washing), it’s time for a similar movement to develop ways of ensuring that medication lists, too, are regularly cleaned, and protected from recontamination. Pharmacists can play a key role in ensuring the accuracy of the medication list, especially for high-risk patients.

Another hurdle to the pharmacists’ efforts to improve continuity of care is the different formularies between hospitals and prescription benefit managers. Patients with chronic conditions come into the hospital already on medications prescribed by others in the community. Then we have to switch them over to the hospital’s preferred drugs in the same class. This disrupts the continuity of care, is inefficient and increases risk to patients, because there’s a chance that both the preadmission drug and its replacement will stay on the medication list post-discharge.

There are other forces that interfere with ensuring the safe use of medication, such as the growth of restricted drug distribution channels, which require patients with complicated chronic diseases to get some medications from specialty pharmacies. This creates complexity for patients who often have to get medications from multiple pharmacies, as well as for health care providers, including health systems, which need to support elaborate prior authorization processes and ensure they have a complete list of specialty and traditional medications for each patient. But my hope, and my vision, is that the increasing need to improve value and outcomes will bring pharmaceutical companies, payers and hospitals together to explore innovative ways to lower these hurdles and make it easier for hospitals and pharmacists to ensure that patient care is high-quality across transitions, throughout the care continuum.
Guiding principles for restoring trust

So what can companies do to restore trust? The list of actions that have been responsible for the decline in the industry’s reputation includes everything from withholding clinical trial data to aggressive sales and marketing practices to direct-to-consumer advertising. The extent to which companies will want to address these trends or take other steps will vary from firm to firm. Rather than make universal recommendations about specific tactics, we point to four values or guiding principles that companies should seek to emphasize.

1. Transparency and openness

As discussed above, there is now an urgent call to become more transparent about clinical trial data. There seems to be growing momentum on this issue, with a few more firms taking actions in recent months. We urge companies to move as quickly and comprehensively as they can in this direction.

Because of its long history of announcing promises to fix this problem but not following through, the industry is now in the unfortunate position of being guilty until proven innocent. Hence firms should expect that every corrective action they take will be greeted with skepticism. It is imperative that they are open about everything they do and communicate transparently to ensure that their actions are not misconstrued.

For instance, the companies that have taken steps to open their trial data have also enacted safeguards to ensure that only researchers get access. This does make sense, since the risk that scientifically unsophisticated users could misinterpret the data and create unfounded fear and confusion is real. But companies need to make sure that this rationale is communicated clearly, and that their actions are seen as protecting the interests of patients rather than as more obstructionism. To minimize the perception that they are restricting access, it makes sense for a third party to make decisions about granting access (e.g., the Yale University Open Data Access project, or YODA, which has been a popular choice in recent initiatives). And while there may be a genuine need to ensure that researchers are the ones accessing the data, the bar should be set low. The gatekeeper’s job should be only to verify that there is a real research plan — not to make decisions about the merit or worthiness of the researcher’s agenda.

The same principles of transparency and openness extend beyond the issue of clinical trial data. In any area where there is the perception that companies are being opaque about their actions or intentions (e.g., paid relationships with physicians), companies should evaluate their policies, take corrective action to become more open and transparently communicate what they are doing.

Pharma companies sometimes protest that they all get tarred with the same brush, meaning that one company’s measures to rebuild trust can easily be undone by another firm’s missteps. That may have been true in the past, but we would argue that transparency and trust are going to draw increasing scrutiny going forward. Companies therefore have the opportunity to really differentiate themselves positively from their competitors by making proactive moves — and effectively communicating what they are doing.
To succeed in any customer-centric business, a company needs to understand how buyers make decisions, because what customers say they want isn't always what they buy. Most industries understand and operate by this principle, but so far it hasn't been broadly applied to the buyers of pharmaceutical products. There is very little understanding, for instance, about how payers make purchasing decisions.

The emotional component

To address this gap, we interviewed payers about how they really think. What we found was eye-opening. A key insight was that, even though payers are data-driven, there is a strong emotional component to their decisions. We interviewed a large number of payers — including many known to be very cost-driven — and 100% of the interviewees said they were emotionally engaged in every purchasing decision.

These difficult decisions aren’t about doing the “right” thing — there often may not even be a single “right” decision — but rather about doing the best thing for patients within payers’ budgetary and other constraints. A payer evaluating a new oncology drug may be informed about an elderly patient who is dying from cancer — the new treatment could give her a few more weeks of life and allow her to be present for the birth of her first grandchild. But the drug costs $250,000 — money that could otherwise buy life-changing treatments for 150 patients in another indication, or a year’s worth of statins for 200,000 patients with high cholesterol. Far from being dispassionate number crunchers, payers are well aware of the consequences of such trade-offs, and are emotionally engaged in them.

How pharma can help

So, what can pharma companies do to help? The payers we interviewed were very forthcoming with concrete steps that drug companies could take to help them in navigating these difficult decisions.

First, payers said it would be very useful if drug companies could help them articulate the “best” answer. This involves moving beyond individual therapeutic segments to analyze the best decision for an entire population. They are tremendously interested in any analyses that have population-level data and can help identify the trade-offs — from both a budgetary and a health-outcomes perspective — between different interventions.

Second — and this is where the emotional component becomes really relevant — payers reported that a big challenge for them was determining which data they could trust. Payers often feel like they are caught in the middle of a battle between governments or other funding bodies (who want them to be on budget) and drug companies (who want them to spend as much as possible on their products). Both sides have data supporting their case, and payers need to make sense of it all.

This implies, of course, that pharma companies need to do more to disclose all their data and increase the trustworthiness of their information. Pharma companies could also change their perception tremendously by building consistent and engaged payer relationships. Instead of interactions that occur only when there is a drug price to be negotiated, payers would like relationships with pharma companies that are more sustained. Payers see tremendous value in academics — even if explicitly identified as being paid by drug companies — who remain engaged with them through numerous situations. With that level of engagement, these individuals are no longer viewed as professional procurement people or negotiators, but rather as committed academics who are trying to help payers find the best answers.

To illustrate the power of trust and emotional engagement, consider the following quote from a payer: “We may be choosing between two identical products. The first has inferior rebates but is made by a manufacturer with which we have a good relationship. The second has better rebates but is made by a manufacturer with which we have a bad relationship. I’d still try to work with the company with which I have a better relationship.”

In other words, these decisions aren’t driven solely by data and costs. Payers are emotionally engaged in their decisions. Now, it’s time for pharma companies to emotionally engage with payers.
2. Patient centricity and proximity

To restore the trust that has been lost, pharma companies will also need to take more comprehensive measures to get closer to patients and operate in truly patient-centric ways. More than most other industries, health care is a sector in which constituents are motivated not just by financial reward but, more importantly, by a “social norm” – the desire to help patients. Payers and providers live by this core value every day. Physicians and nurses are on the front lines, actively improving the lives of patients. Payers grapple with difficult questions of ethics and social justice – trying to do the most good for the largest number – and, as articulated by David MacMurchy, are emotionally invested in the impact these decisions have on patients’ lives.

Pharma companies see themselves as living by the same values. The executives who contribute their insights in our annual reports frequently refer to how the industry improves the lives of patients. But while it’s certainly true that pharmaceuticals have made significant contributions to public health, it’s important to recognize that pharma companies’ connection to patients is not as immediate or well-aligned as that of payers and providers.

Payers and providers more directly improve health outcomes – by deciding how patients will be treated or by actually delivering care – than pharma companies, which affect outcomes more indirectly, by making products available to those who decide on and deliver care. And, since their immediate motivation is to sell drugs, any actions that appear to serve that end more than the interests of patients only damage their credibility.

To demonstrate that pharma lives by the same social norms as the rest of health care, it is therefore imperative that companies take steps to get closer to patients and more directly serve the needs of patients. There’s a lot that can be done here. For instance, companies would buy a lot of goodwill by moving boldly and visibly into segments where there are large public health needs, even if the economic incentives are poorly aligned (e.g., neglected tropical diseases, new generations of antibiotics).

But the most effective way of getting closer to patients and more directly serving their needs is probably through solutions that expand beyond the product and across the cycle of care. (For one payer’s perspective on how pharma companies can build trust by expanding into services, see the article by Mark Wilkinson on page 70.) Unfortunately, there’s also a paradox at play here. Services could demonstrate that pharma is being patient-centric, which would help rebuild trust. But, as we articulated earlier, the lack of trust hurting the industry’s credibility and acceptance as a service provider in the first place.

The way out of this Catch-22 is twofold. First, companies can take other initial steps to restore trust (e.g., measures to make clinical trial data more transparent), which would make it easier to move into services over time. Second, firms would go a long way toward overcoming trust by structuring services in the right way. As discussed earlier, an offering that genuinely solves customers’ needs, rather than just the cause of selling more pills, will be greeted with much less skepticism.

Lastly, at a time when patient-centricity has become a bit of an overused buzzword in health care, pharma companies will need to carefully define what it means – which brings us to a second paradox. One could argue, for instance, that direct-to-consumer advertising is patient-centric, since it helps companies connect directly with patients and educate them about health risks. Yet, this type of advertising is often recognized as a prime contributor to patients’ growing distrust of pharma companies.

The answer to this paradox is that it is possible for an organization to damage its reputation by giving consumers something they know is harmful at a societal level, even if they like it as individuals. We see this dynamic at play in many other arenas. Voters vehemently oppose any reductions in their entitlement benefits even as they censure politicians for profligate spending. Consumers love fatty, sugary foods, all the while castigating food companies for contributing to an obesity epidemic. By the same token, patients (and other health care stakeholders) are discerning enough to recognize what is truly in their interests. Rather than trying to justify existing actions as being patient-centric, companies should measure how these practices affect their reputations (e.g., through stakeholder surveys) and then correct practices that are not seen as serving the best interests of patients.
Mark Wilkinson
NHS Barnsley Clinical Commissioning Group
Chief Officer

Rebuilding trust through the five C’s

The UK’s National Health Service (NHS) is being reshaped by three major trends: continued austerity; an emphasis on care coordination and integrated service delivery; and an organizational overhaul that is putting clinicians in leadership positions.

Austerity is here to stay. Public finances are on a much slower recovery trajectory than initially forecast. The need to do more with the same, or even fewer, budgetary resources will continue for the foreseeable future. It’s a significant mind-set change and will result in continuing pressure on drug prices.

A bigger role for GPs

To make care delivery more efficient, the NHS is encouraging clinical care groups (CCGs; see footnote for definition) to work with local government authorities on initiatives to improve the health of individuals. We’re very interested in programs that allow the elderly to age in their homes rather than in nursing facilities; we’d also like to expand use of telehealth services and devices that move health care delivery from the hospital to the home. The good news for pharma is that NHS is now incentivized to prioritize products that deliver maximum health benefits for every pound the government spends on health.

In the UK, NHS funding isn’t automatically aligned with recommendations by the National Institute for Health and Care Excellence (NICE). Even after NICE produces a positive recommendation, doctors in the field may not get any additional budget to implement the recommendation – meaning that positive coverage decisions don’t necessarily translate into an uptick in prescriptions.

Product uptake ultimately depends also on endorsements by CCGs. As the NHS reorganizes its leadership structure, CCGs are increasingly being run by family doctors. In theory, this leadership change should benefit pharma companies, which can now engage with NHS executives who truly understand medicine. In practice, however, this change might be having the opposite effect. The main interaction these clinician leaders have previously had with the drug industry has been through sales reps, whose tactics have done little to engender trust.

In my earlier work as the NHS's Director of Life Sciences Innovation, I had the opportunity to work closely with pharma leadership. I know pharma is populated with smart, articulate individuals who are trying to move away from such heavy-handed methods. But my experience is sadly very different from that of a typical GP in my CCG.

Rebuilding trust

Pharmaceutical companies need to win back the trust of these family physicians. They can do so by investing in what I call the 5 C's: contact, collaboration, communication, clarity and celebration. Drug manufacturers need to contact and collaborate with physicians and government in new ways where communication is open and there are clearly defined benchmarks for what constitutes a benefit. It’s critical to celebrate early successes, recognizing opportunities exist where we can achieve more together than we can separately.

Two recent collaborations at Barnsley illustrate such approaches. In the first, we commissioned a pharmaceutical company to work with Barnsley primary care practices to improve the standard of diabetes care. Pharma companies have well-developed expertise in this arena and in principle they should be paid for their capabilities. This is also an attractive approach because payers and providers are less interested in medicines in isolation – our focus is the entire patient journey and solutions that address their specific challenges.

We’re also partnering with Daiichi Sankyo to develop an innovation boot camp for senior NHS officials. Together we funded a one-day workshop that brings industry and the NHS together to discuss business challenges my CCG faces. The pharmaceutical company understands it will gain insight into how this NHS group operates, as well as its challenges. We’ll benefit from their perspective and have a chance to interact with the company in a way that’s very different from the historical sales call model.

Such collaborations can help break down barriers between industry and NHS. As more NHS officials are exposed to senior pharmaceutical executives, this contact will build trust and be a catalyst for change.

The Barnsley Clinical Commissioning Group is one of 211 CCGs in the UK. These clinically led NHS groups plan and contract health care services in their communities, are measured on improved population outcomes and account for about 60% of the NHS budget.
3. Proactive leadership

When we talk to our clients about business model innovation, the one question that always comes up is, “what are our competitors doing in this space?” While being focused on the competition is usually a good thing, we see another dynamic in pharma: companies are often risk-averse about making innovative moves, and may only be willing to do something after another competitor has jumped in.

Whatever the supposed merits of this cautious approach may be on other topics, it is precisely the wrong strategy on the issue of trust and reputation. In this space, the goal is not just to do something, but to be recognized for doing it – to not just take corrective steps but also rebuild tarnished reputations. And when it comes to “do-the-right-thing” initiatives, the lion’s share of the recognition goes to the first mover. When GSK became the first pharma company to announce a new initiative to open clinical trial data, it garnered a lot of praise. The response to the companies that have taken similar steps since then, while positive, has been relatively muted. Similarly, it is quite possible that other drugstores may follow CVS’ lead and stop tobacco sales, but it is unlikely their initiatives will attract nearly as much attention or do as much to build trust.

On trust-building initiatives, pharma companies shouldn’t be waiting to follow the lead of competitors – they should be elbowing each other to be the first one out the door.

4. Consistency

Lastly, pharma companies need to make sure they are consistent in everything they do and say with respect to trust-building initiatives. As stated above, the industry is starting from the assumption that it is guilty until proven innocent. As such, any contradiction – intentional or otherwise – between stated policies and their implementation will immediately set firms back and reawaken stakeholders’ suspicions about their intentions. As in any relationship, trust, once destroyed, takes years of painstaking, consistent work to rebuild.

Given how potentially damaging missteps could be at this juncture, companies should implement controls to ensure that practices and procedures comply with stated policies. This should then be backed up with periodic audits to identify implementation gaps or weaknesses.

On trust-building initiatives, pharma companies shouldn’t be waiting to follow the lead of competitors – they should be elbowing each other to be the first one out the door.
# Five guiding principles for navigating the payer landscape

<table>
<thead>
<tr>
<th>1. Make the right comparisons</th>
<th>Are you trying to compete just with other pharma companies – or with disruptive new entrants? Are you comparing service opportunities to the drug business of yesteryear – or the drug business of tomorrow?</th>
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<tbody>
<tr>
<td>Payers and health care systems are changing rapidly. Focus on where the ball is going to be, not where it has been.</td>
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<td>2. Approach payers strategically and comprehensively</td>
<td>Is your approach to payers ad hoc and random – or structured and comprehensive?</td>
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<td>The time for dabbling is over. A complex, fragmented, rapidly changing payer environment demands a strategic and comprehensive approach for targeting and engaging with payers.</td>
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<td>3. Develop data-driven insights and interventions</td>
<td>How are you pooling data, accessing cutting-edge analytics and developing actionable insights?</td>
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<td>The big opportunity for engaging payers with big data is in building the complete picture and targeting the small percentage of patients who will drive the biggest percentage of costs.</td>
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<td>4. Create customer-centric solutions</td>
<td>Are you collaboratively trying to address payers’ biggest challenges – or are you using services defensively to try to sell more pills?</td>
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<td>Payers are interested in solutions that look across disease franchises, span the cycle of care and are unbiased between the products of different manufacturers.</td>
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<td>5. Rebuild trust through transparency</td>
<td>Are you being proactive on trust-building initiatives – or waiting for others to lead?</td>
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<td>If data is the currency of the new health care, trust is the central bank. Without trust, pharma’s data and solutions will get little traction with payers. Restoring trust is an urgent imperative – and the right thing to do for business.</td>
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Acknowledgments

Project development and creation
Patrick Flochel and Glen Giovannetti — EY's Global Pharmaceutical Leader and Global Life Sciences Leader, respectively — provided the overall sponsorship and strategic vision for this project. They guided the development of the report and provided valuable input on drafts.

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Data exhibit index and survey methodology

Chart 2.1. Payers’ business challenges

Chart 2.2. Importance of drug cost management strategies

Chart 2.3. Importance of comparative effectiveness measures

Chart 2.4. Importance of data types

Chart 2.5. Attitudes toward the pharmaceutical industry

Chart 2.6. Actions to build trust between pharma and payers

Survey methodology

For *Progressions 2014*, we surveyed 30 US payers, 30 European payers and 18 pharmaceutical company representatives from functions such as market access and managed markets. We asked payers about their business challenges, approaches for controlling costs, preferred data types/comparative effectiveness research methodologies and attitudes toward pharma. We asked pharma companies the same questions as payers, but with some important differences:

- On questions about business challenges and approaches for controlling costs, we asked pharma companies what they perceived payers’ business challenges and approaches to be. This allowed us to measure how well pharma companies understand payers.

- On questions about preferred data types and comparative effectiveness research methodologies, we asked pharma companies which data types and methodologies they use in their market access efforts. This allowed us to measure how much pharma companies are investing in the approaches that matter most to payers.

- On questions about attitudes toward the pharma industry, we asked pharma companies and payers the same questions. This allowed us to measure how well pharma companies’ perception of the industry matches that of payers.

On many questions, respondents were asked two sets of questions. For instance, with respect to business challenges, respondents were first asked to pick the five most important business challenges from a longer list. They were then asked to rank these five challenges based on their importance. To present the results more succinctly, we converted the answers to these two-part questions into a single score. In the example above, for instance, the challenge given top ranking by a particular respondent was assigned a score of 5, the second-most important challenge was assigned a score of 4, and so on. The challenges that were not picked to be in the top 5 were assigned a score of 0. We then calculated the average score across all respondents for each business challenge. These composite scores are presented in the charts in Chapter 2.
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How EY's Global Life Sciences Center can help your business
Life sciences companies – from emerging start-ups to multinational enterprises – face new challenges in a rapidly changing health care ecosystem. Payers and regulators are increasing scrutiny and accelerating the transition to value and outcomes. Big data and patient-empowering technologies are driving new approaches and enabling transparency and consumerism. Players from other sectors are entering health care, making collaborations increasingly complex.

These trends challenge every aspect of the life sciences business model, from R&D to marketing. Our Global Life Sciences Center brings together a worldwide network – more than 7,000 sector-focused assurance, tax, transaction and advisory professionals – to anticipate trends, identify implications and develop points of view on responding to critical issues. We can help you navigate your way forward and achieve success in the new ecosystem.

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