Big pharma's market access mission

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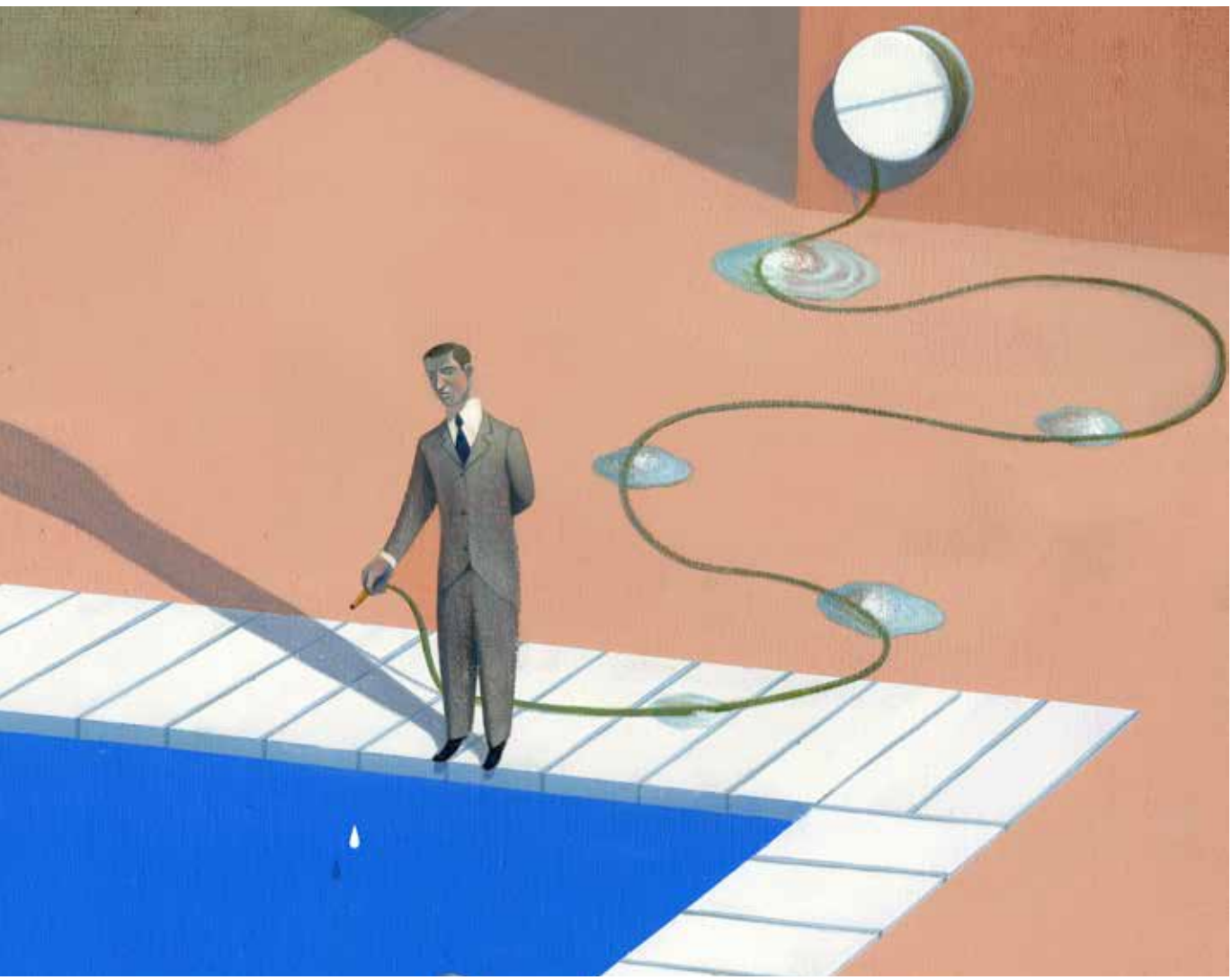
Executive summary

In the face of rising health care costs, payers (including insurers, pharmacy benefits managers, and government agencies) are exerting greater influence over pharmaceutical markets and demanding insight into a drug's cost effectiveness compared with alternative drugs and generics.

To achieve desired results, pharmaceutical executives should consider revamping the way they develop and market drugs—making market access planning an integral part of their organization—and balancing clinical and economic value in product development and commercialization decisions.

Executives at pharmaceutical companies should integrate the payer perspective throughout the suite of decisions they make. It is not sufficient to "bolt on" a new market access or payer plan to an existing set of brand strategies.



Payers growing in importance

FACING intense pressure to contain rising health care costs, payers—private insurance plans, pharmacy benefits managers, governments, and employers—are exerting much greater influence over pharmaceutical markets. They are demanding information on a drug's safety and efficacy, as well as its cost effectiveness compared to alternative treatments.

Executives at pharmaceutical companies are aware of the growing role of payers, but companies have usually responded to this new reality from the bottom up. Acknowledging the importance of payers and how they differ, many companies have developed regional account sales teams to cultivate closer ties with payers. Others have launched efforts aimed at collecting more data on payers and their decision-making processes. Some companies have experimented with performance-based contract provisions to better align their goals with payers. These efforts may have incremental benefits, but they are insufficient responses given the scope of the market access challenges pharmaceutical companies confront today.

Senior executives may consider major organizational changes to meet new market access challenges. Pharmaceutical executives should work to rebalance the time and attention they spend on payers and specifically commit to rebuilding the drug commercialization process to address a new market reality. They have to make market access planning an integral part of their organization, placing clinical and economic value at the center of product development and commercialization activities. To support this new approach, pharmaceutical companies may need to reallocate resources on a massive scale. It is not simply a question of determining how much payers will pay for drugs, but the value of and economic justification for a given drug. This question challenges today's commercialization processes and rules of thumb about how to invest across the physician, patient, and payer ecosystem. Navigating these challenges requires executive leadership; without such leadership, significant (and unpredictable) change is likely to bubble up.

It is not simply a question of determining how much payers will pay for drugs, but the value of and economic justification for a given drug.

The gap between GDP growth and rising health care costs (see figure 1) has created a situation in which health care eats into a larger portion of overall GDP. Even in the best of times, government payers had trouble affording these rising costs, but the recession that began in 2007 created a sense of urgency that gave both public and private payers an opening to expand their focus on medical costs. Faced with high unemployment, exploding debt, and falling tax revenue, government payers are urgently seeking to control health care spending. Private payers, under pressure to both turn a profit and keep a lid on costs, have followed the lead of government payers in looking beyond pure clinical efficacy to give greater

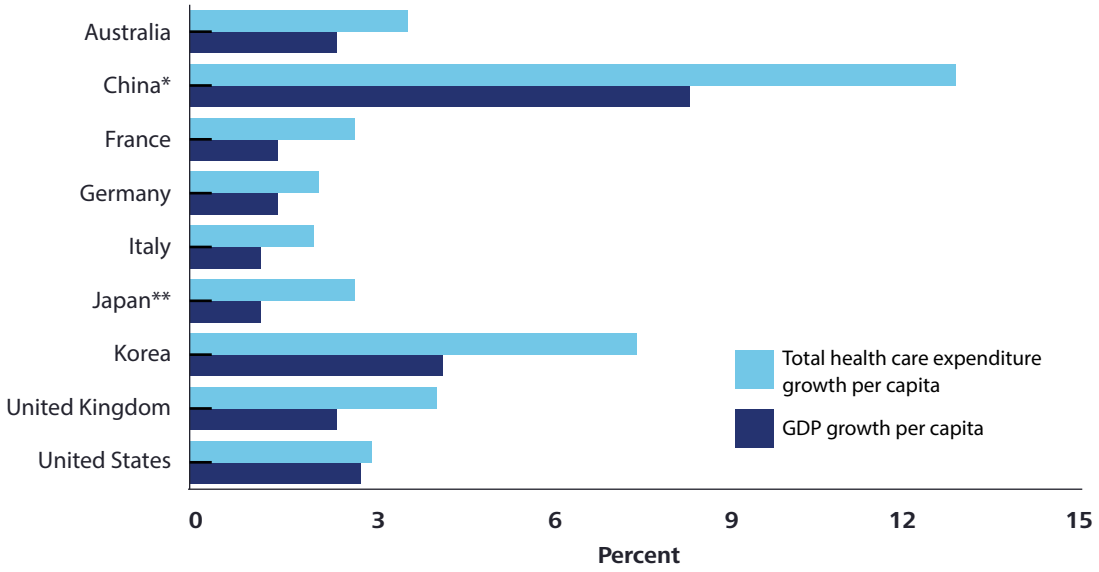
consideration to relative cost-benefit analyses when making formulary decisions.

For pharmaceutical companies, this drive for cost control represents a major change. In the past, market access for a drug depended almost exclusively on efficacy and safety. These factors are still critical. But in many instances, cost effectiveness—built on clinical differentiation—now matters just as much, and its importance is on the rise.

In the current health care environment, payers will make exceptions to their cost-control policies for truly revolutionary products, but exceptions will be rare. Pharmaceutical companies should be aware that many of the largest therapeutic areas (TAs) such as cardiovascular disease are already served by entrenched and demonstrated lipid-lowering and antihypertensive products, many of which are now (or soon will be) generic. As more blockbuster drugs lose patent protection and generic alternatives proliferate, pharmaceutical companies will have to absorb the double blow of lost revenue and greater scrutiny from payers who will have even more alternatives.

To achieve desired results in this new regulatory and market environment, pharmaceutical companies will have to consider the importance of market access and its place in the fabric of the organization. Making sure that the focus on payers is an ongoing concern—not just something done three to six months before a product launch—will be critical for efficacy.

Figure 1. Rising costs give payers power: Annual growth in total health spending and GDP, 1993-2008



* China statistics cover 1995-2006
** Japan statistics are through 2007
Sources: OECD, China Statistical Year Book

Graphic: Deloitte University Press | DUPress.com

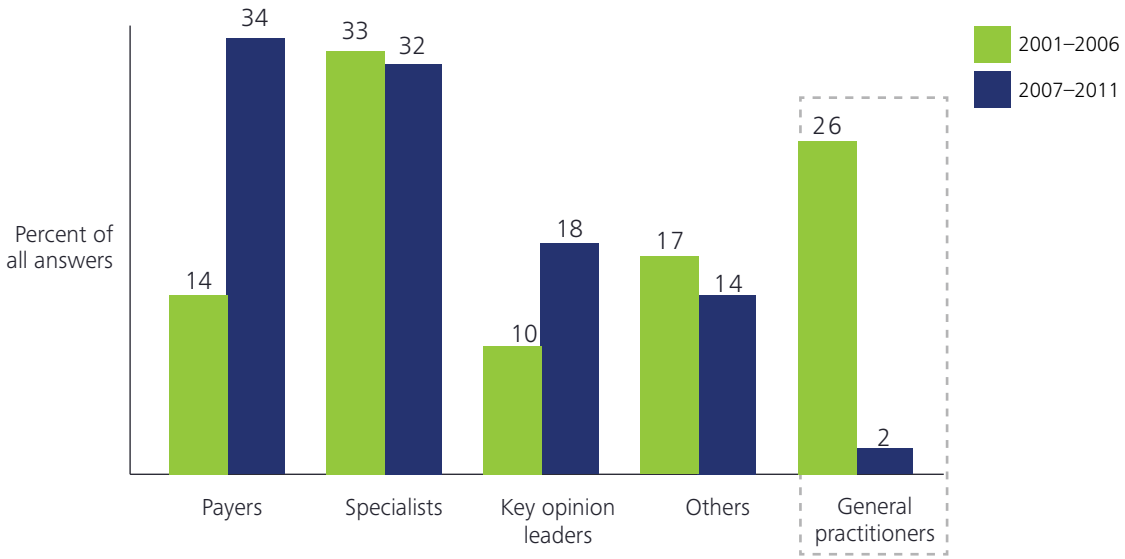
An emphasis on cost control *and* comparative effectiveness

PHARMACEUTICAL companies recognize that payers have gained power, but many have not yet grasped the extent to which payers have begun to dominate access decisions. A 2011 Monitor survey of more than 200 pharmaceutical company executives showed that payers have gained significant influence in health care in recent years. Meanwhile, the influence of general practitioners (GPs) has practically evaporated, calling into question the vast amounts of money and human resources pharmaceutical companies continue to invest in communicating with GPs (see figure 2).

This intensified focus on cost-effectiveness stems from data suggesting that many expensive new drugs have not always delivered significantly better results than their more affordable predecessors. For example, the monthly cost of cancer treatments has skyrocketed in recent decades, though five-year survival rates for cancer patients have barely budged during the same time frame (see figure 3).[1]

In many other therapeutic areas, there has been a steady parade of relatively undifferentiated "me too" products and product extensions that offer modest medical benefits and that have been priced at relative premiums. Consider the various new Type II oral diabetes medications that have delivered additional efficacy and safety, to be sure, but have done so at a premium price. This does not make economic sense and is even more problematic in a resource-constrained health care environment.

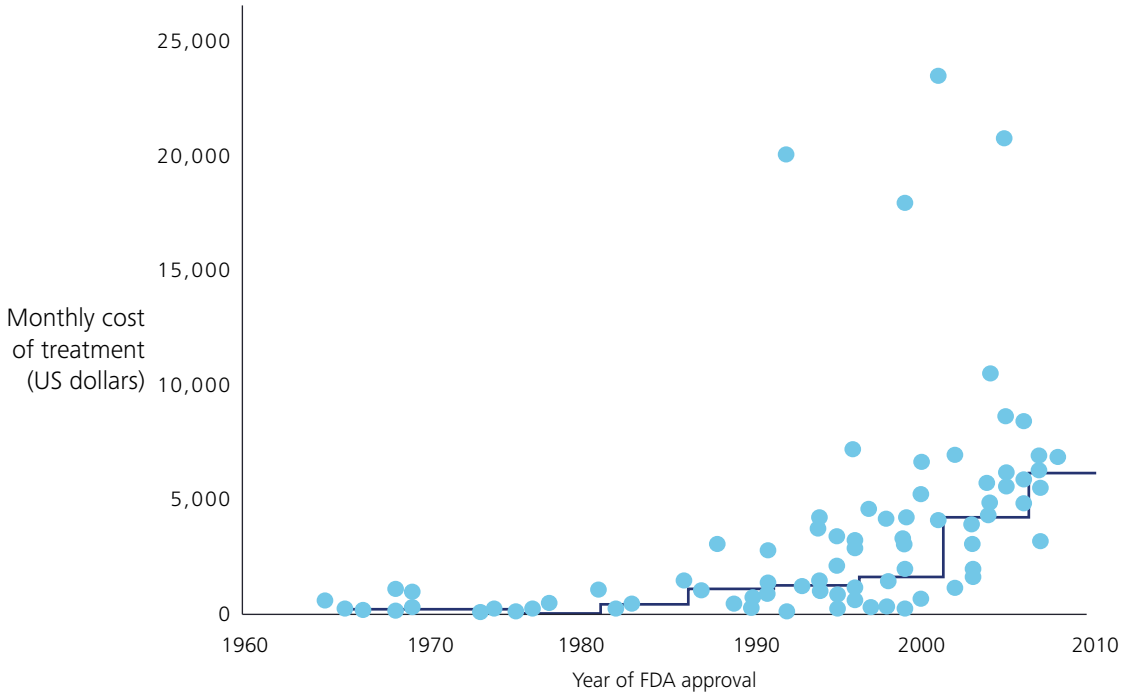
Figure 2. Payer influence on the rise



Source: Monitor survey of 236 executives from large and mid-sized pharmaceutical companies.

Graphic: Deloitte University Press | DUPress.com

Figure 3a. The cost of cancer drugs and survival rates
Monthly and median costs of cancer drugs at the time of approval by the FDA, 1965–2008



Source: Peter B. Bach, MD, MAPP, "Limits on Medicare's ability to control rising spending on cancer drugs," *New England Journal of Medicine* 360 (February 5, 2009): p. 627.

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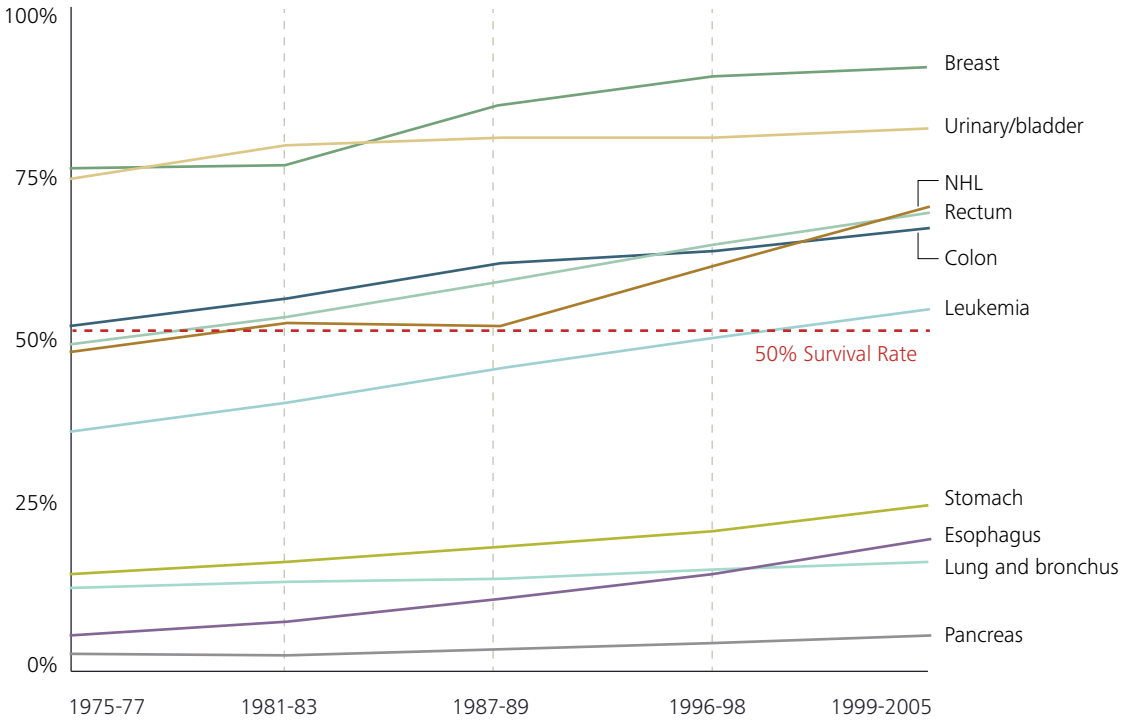
Figure 3b. The cost of cancer drugs and survival rates
Five-year cancer survival rates, 1975–2005



Source: Centers for Disease Control, "Cancer survival rates for selected cancer sites by sex and race" (2009).

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The costs of inaction

If pharmaceutical companies do not seize the initiative and lead the development of compelling cost-effectiveness arguments, payers may create their own potentially unfavorable narratives. This is already underway. For example, Wellpoint recently made its own comparative study of Genentech's Boniva product versus other osteoporosis drugs. Concluding that Boniva scored poorly on cost-effectiveness, Wellpoint required its members to try other products before they could obtain authorization for Boniva.[2] In another instance, the United Kingdom's National Institute for Clinical Health and Excellence (NICE)[3] approved AstraZeneca's lung cancer product Iressa after AstraZeneca agreed to offer the drug at a fixed price regardless of treatment duration and to provide Iressa at no charge for patients who used the drug for less than three months.[4]

Products with only modest clinical benefits and no supporting economic arguments will likely grossly underperform sales targets and/or force manufacturers to spend a huge amount on rebates.

With payers newly empowered, pharmaceutical companies should grasp the fact that products with only modest clinical benefits and no supporting economic arguments will likely grossly underperform sales targets and/or force manufacturers to spend a huge amount on rebates. And even with rebates, success is not guaranteed.

This view from inside pharmaceutical companies presents an argument for action. Poor market access strategy decisions can lead to missed opportunities with devastating impact on a product's financial returns and can erode value at multiple stages of a product's life cycle: when a company pursues a new product opportunity that lacks sufficient commercial viability; when it fails to collect adequate economic outcomes data during the clinical development phase; when it defines a weak value proposition or selects the wrong payer targets when developing a market access strategy; or even when it pays too much for access because it has not succeeded in building a convincing, data-driven market access narrative. Leakage of value is a pervasive problem that many pharmaceutical companies face through the commercialization process (see figure 4).

Pharmaceutical companies can help reduce many of these value leakages by transforming their organizations to prioritize market access throughout a product's life cycle, from the earliest phases of exploratory clinical development to the post-launch period. For a billion-dollar product, plugging these value leaks could save or generate hundreds of millions of dollars in additional value over the product's lifetime.

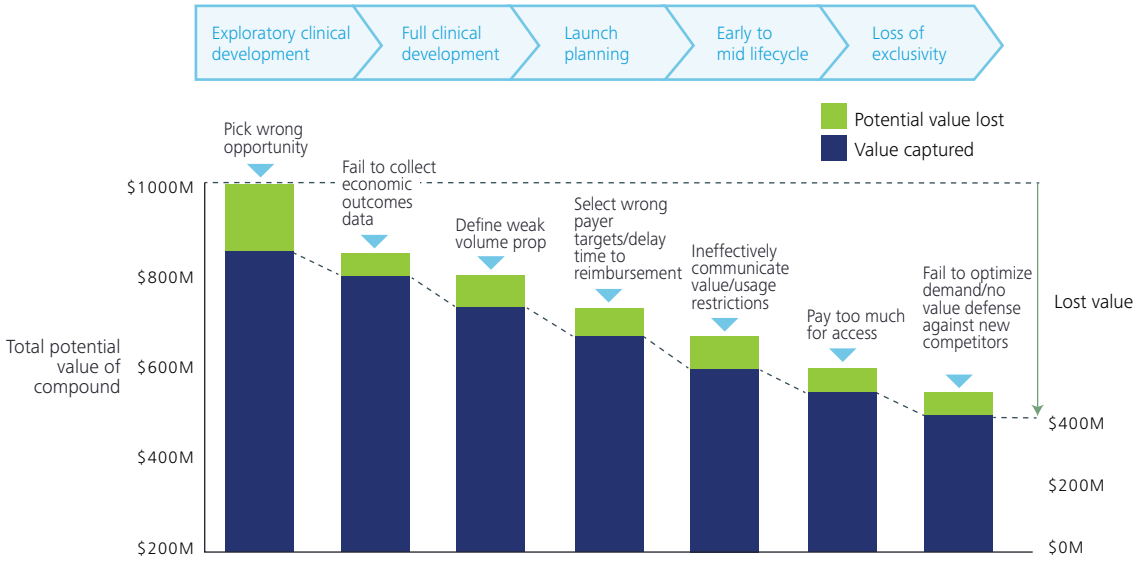
Yet many pharmaceutical companies face organizational challenges in even finding ways to have discussions on commercial

value and market access during a product's development phase.

Plugging these value leakages, making changes of this magnitude, is not to be taken lightly. While executives intuitively understand the rising influence of the payer, they are hard-wired to focus on getting a drug approved and then selling it to a physician. To thrive in an environment where payers dominate market access, pharmaceutical executives need to have a much clearer understanding of the payer as customer, their economics, and the patient populations and competitive context in which they serve. More to the point, pharmaceutical companies should invest the same effort to gain insight into payers today as they did to understand the motivations of physicians in the past.

Figure 4. Value decision points along the drug development life cycle (dollar values given for illustrative purposes only)

There are many decisions across the lifecycle that, when made without considering the value implications, can lead to significant loss of commercial potential.



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Organizational transformation: Elevating market access

SOME pharmaceutical companies may not completely understand the differences within the US payer community and the factors that influence payers' formulary decisions. Even worse, they may end up sending payers mixed messages, since they typically have multiple groups within their organization (for example, market access, medical/health economics and outcomes research, policy) that communicate with payers. And each group communicates with payers in its own way, without first coordinating those communications.

Developing an effective strategy for negotiating with payers and getting on formularies begins with understanding how payers think and what motivates them. In the past, negotiations with payers were considered win-win, since there was little downside for a payer to put a new compound on formulary. However, as budgets have tightened and the ultimate financial sources behind payers (companies, government agencies, and patients) have grown more price-constrained, negotiations have become more antagonistic. Payers' business models have also become more varied. Some firms are focused on serving a specific type of customer (such as Medicare recipients), while others have expanded into other lines of business (such as pharmacy benefits management and specialty pharmaceuticals). These considerations should be factored into how pharmaceutical companies engage with payers.

> The market access function deserves more prominence as a professional position with its own path toward career advancement, recognition, and financial rewards.

The changing dynamic also explains why the old models of marketing communications and market access programs no longer get the best results. Pharmaceutical companies are spending large sums of money on payer rebates without investing the time or resources required to completely understand payer priorities, needs, and decision-making processes. Recent market research studies by CAM and IMS Health reveal that the vast majority of monitored promotion spending still goes toward detailing and samples for physicians, despite the fact that GPs in particular have lost considerable stakeholder influence over market access decisions.[5]

Once pharmaceutical companies understand the broader motivations of payers and acknowledge payers' constraints, they can start reconciling their organizations and processes with the realities of this payer-dominated market access environment. CEOs should consider focusing their energies on market access to help overcome organizational inertia and take

steps for necessary structural changes to be actually implemented.

This initiative requires elevating the stature of market access as a corporate function and placing it at the center of product strategy. Its leaders should report at the same level as leaders from commercial and medical organizations. The market access function deserves more prominence as a professional position with its own path toward career advancement, recognition, and financial rewards.

Based on experience with our clients, we have identified six requirements to help manage the increasingly complex market access environment:

1. **Decisions based on economic value begin in the development lab.** Early-stage drug development decisions should be informed by an understanding of the commercial potential of the compound, not just the ability to meet a medical endpoint. A new product should be pursued only when both clinical and economic value is strong; if not, this may need to be acknowledged early on so plans can be developed accordingly.

COMPARATIVE CLINICAL AND ECONOMIC VALUE (CCEV™)

In the United States, there are typically fewer than 30 important payers in each therapeutic area (TA). Pharmaceutical companies must understand the priorities and goals of the most important payers in their TAs and develop custom negotiation strategies for each of them.

Payers want to know:

- **What outcomes will actually be achieved for their patient population?**
- **What outcomes have already been achieved?**
- **What is the rationale for a product's price point?**
- **Which product attributes could justify a premium price?**

To answer these questions, pharmaceutical companies need a comparative clinical and economic value (CCEV™) position backed by unassailable data for each product. In constructing the case for a product's value, pharmaceutical companies should keep in mind that payers do not give equal weight to all types of data. For example, payers have grown skeptical of the real-world value of randomized controlled trials. To meet payer preferences for local outcome data, pharmaceutical companies should therefore:

- **Understand the current deployment of health resources for the relevant clinical condition**
- **Quantify the overall impact of a product intervention in terms of clinical outcomes and other resources required to manage the patient**
- **Identify the points of differentiation of a product vis-à-vis the existing standard of care or potential future competitors while prioritizing the value drivers that offer the most clinical and economic value**
- **Accurately and convincingly communicate product value both at launch and throughout a product's life cycle via an integrated value story**

No pharmaceutical company has yet mastered all these organizational and communications challenges, but some firms have taken the important step of routinely incorporating economic endpoints into all their Phase III trials.

2. **Pricing and value propositions should be built around quantified economic value.** Many organizations fail to embed economic valuation early enough in the decision- and strategy-making process. This causes missed opportunities to collect the proper data during Phase II and III trials in support of value arguments. As a result, many of today's value propositions to payers are "message heavy" and "data light."

3. **Payer and market access strategy should be approached with the same rigor, process, and insight-driven analysis as traditional commercial strategy.** Too often, pharmaceutical companies set strategic goals to understand willingness to pay and to "optimize" price rather than to understand value drivers and influence willingness to pay. Typical payer strategies only scratch the surface, do not emphasize economic value, and do not think creatively enough about how to impact a payer's business.

4. **Companies should have insight into payers' decision making and the processes and criteria they use, as well as the skills to use these insights.** This is a challenging task for pharmaceutical companies skilled at communicating with doctors and patients. The questions required to better understand payers are different, as payers have more complicated decision-making processes. The information sources used to gain insight into these processes are dispersed and not always reliable. The analyses and analytical tools required are new (such as quantifiable data about the value of a drug).

5. **Market access strategy should be integrated with other aspects of bringing a drug to market.** In many organizations, market access strategy is developed separately from brand strategy and the two are combined at launch (often awkwardly and sometimes at cross-purposes). A disconnected approach will likely miss opportunities for collaboration and spending trade-offs across the brand. Furthermore, the lack of strong supporting capabilities and processes often leads to poor and episodic engagement with payers.

6. **Organizational structure should support market access insight generation, collaboration, and strategy development.** Market access is often a disconnected island, not part of the strategy development process. Pharmaceutical companies typically engage market access three to six months before a new drug launches, when contracting tactics are typically decided. That's too late to develop effective, data-supported, and value-driven insights for payers to evaluate.

To be effective, market access may need to have a seat at the table at several decision points in a drug's life cycle, from Phase I to product launch and through its life cycle management. Pharmaceutical companies should solicit input from their market access professionals from the earliest stages of research and development (R&D). Trials should have both clinical and economic endpoints, particularly in those countries judged important from a payer/sales perspective. Market access teams should be given the responsibility of making clinical trials strong enough to support economic arguments in future payer negotiations.

A precedent for change in big pharma

WHILE the changes in today's health care environment may be revolutionary, the industry has experienced and addressed revolution before. In 1997, the US Food and Drug Administration changed its policies to allow for increased use of direct communication between pharmaceutical companies and patients via broadcast advertising. Companies that invested in understanding their patients and brought their voices to commercialization decisions prevailed. In the process, industry leaders shifted from strategies that emphasized an R&D and sales orientation to strategies that encompassed R&D, marketing, and sales. And just as pharmaceutical companies built new skills and adapted to capture new opportunities in the direct-to-consumer marketing world, they can again develop new systems and processes to thrive in a world where payers take the lead on market access decisions and demand proof of cost-effectiveness as a condition for access. Those companies that step change, reorient, and commit to market access as a mindset—not an add-on—can achieve their desired outcomes.

Endnotes

1. Peter B. Bach, "Limits on Medicare's ability to control rising spending on cancer drugs," *New England Journal of Medicine* 360 (February 5, 2009): pp. 626-633.
2. "WellPoint's internal data led it to limit use of drug Boniva," *Wall Street Journal*, June 24, 2010, http://online.wsj.com/article/NA_WSJ_PUB:BT-CO-20100624-712623.html.
3. In 2012, the National Institute for Health and Clinical Excellence changed its name to the National Institute for Health and Care Excellence, see Bernard Murphy, "New NICE, new chair," *Clinica Medtech Intelligence*, April 2, 2013, http://www.clinica.co.uk/marketsector/New-NICE-new-chair-341685.
4. "UK's NICE backs Iressa after Astra sets fixed cost," *Reuters*, May 26, 2010.
5. Marc-André Gagnon and Joel Lexchin, "The cost of pushing pills: A new estimate of pharmaceutical promotion expenditures in the United States," *PLOS Medicine* 5, No. 1 (2008): e1, doi:10.1371/journal.pmed.0050001.

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