

STRATEGY THAT WORKS BEYOND 2020

WWW.PHARMEXEC.COM

Pharmaceutical Executive

ELECTRONICALLY REPRINTED FROM MARCH 2016

WHERE BUSINESS MEETS POLICY

VOLUME 36, NUMBER 3



Beyond 2020:

Building Strategic Coherence in the New Health Economy

Positioning for success in biopharma requires a self-critical analysis of the risk and rewards among four categories of value differentiation. The key question: How do you define yourself against the competition?

By Rick Edmunds, Jo Pisani, Douglas Strang, and Michael Swanick

The competitive landscape for life science companies around the world is changing rapidly. We are now in the “New Health Economy” in which drug pricing pressures, scientific breakthroughs, expanding global demand for healthcare access, and emerging digital and analytical capabilities are pushing the healthcare industry toward a new ecosystem defined by collaboration, quality, and consumer value.

Change requires a new strategic approach—one that enables companies to understand market trends and build the internal capabilities needed to execute. This article explores specific trends affecting pharmaceutical companies and provides clear guidance for how organizations can best respond.

The central thread running through our view of the New Health Economy is that strategy requires distinct capabilities to position a company ahead of its competitors. A capabilities-driven strategy requires three elements:

- » Coherent positioning that includes a clear “way to play.”
- » A set of underlying capabilities needed to differentiate the company from competitors.
- » An aligned portfolio and geographic focus.

Each of these elements warrants a closer look. The first element is a clear “way to play,” meaning a specific, well-defined means by which the company creates value for its customers. For example, in the automotive business, Mercedes-Benz and Kia both sell cars, but they have highly distinct ways to play. Mercedes sells expensive vehicles that emphasize performance, while Kia emphasizes value. The pharmaceutical industry clearly differs from the automotive industry, but the theme of creating a distinct value proposition for customers is relevant to both.

The second element is a set of differentiated capabilities that help the company execute its chosen “way to play.” By capabilities, we mean unique attributes that collectively differentiate a company from the competition. Each capability has underlying elements—people, processes, technology, competencies, behaviors, and operating models—that the company systematically acquires or builds up over time. Some capabilities may be similar across organizations, yet only those players that can execute the capabilities at a high level will outperform their peers. In consumer electronics, for example, Apple has strong capabilities in product design, intuitive user interfaces, and aggregating the rights to digital content.

The third element is the right mix of products, services, and geographic markets. Once a company has defined its way to play and has established the corresponding set of capabilities, some components of a company’s portfolio will natu-

FAST FOCUS

» Research has shown that organizations with a capabilities-based strategy deliver higher returns to shareholders. But to achieve this, management teams must go beyond traditional strategy development and ask themselves some tough questions: How does the company truly create value?

» An aging population, urbanization, and growth in emerging markets have increased the burden on healthcare systems worldwide. For biopharma, that has translated to new customers and greater demand for medicine.

» In the New Health Economy, portfolio management requires capturing synergies among multiple business units while still preserving the right level of autonomy.

rally align, while others may no longer fit.

Last, these elements must be consistent with market dynamics over time. A perfect strategy today will need to evolve tomorrow, as market conditions change and new risks and rewards emerge.

Our research has shown that across all industries, companies with a capabilities-based strategy deliver higher returns to shareholders.

But getting these elements right isn't easy. It forces management teams to go beyond traditional strategy development and ask themselves some tough questions: How does the company truly create value? How viable is such a way to play over the long term? Has the company identified and aligned its most critical capabilities, and can it leverage these capabilities in unison? Most important, are leaders willing to make difficult choices to ensure that everything the company does is coherent with its strategy?

New Health Economy: Emerging trends

Before looking more closely at each of the strategic options, it's worth discussing two "mega-trends" currently impacting pharma: the broadening demand for healthcare products and services, and severe cost pressures. An aging population, urbanization, and growth in emerging markets are all putting a greater strain on healthcare systems worldwide. For pharma, that means a huge influx of new customers and greater demand for medicine. But spending increases for drugs are triggering public and private efforts to reduce prices and tightly manage utilization.

Government reforms vary widely, but often include efforts to improve the effectiveness of their healthcare spending by forcing pharma companies to demonstrate value, both for patients and for healthcare systems. Some governments are applying the blunt instrument of price freezes and drug spending caps. Others are using formal health technology assessment (HTA) organizations. And some developed markets like the US and UK are pushing control over budgets down to provider organizations (such as accountable care organizations, or ACOs), which are implementing tools like mandatory care protocols or strict formularies to manage the total cost of care within a set budget.

For chronic diseases, governments are also seeking more comprehensive treatment programs, including wellness and prevention, along with more advanced approaches to population management.

Finally, digitization and the explosion of data are rewriting the playbook for pharma. New technology—including cloud, mobile technology, analytics, and social media—can drive better patient education, engagement, and results. Wearables, biosensors, FDA-approved mobile apps and devices, and remote monitoring engage patients by providing the tools they need to receive treatment, and the feedback necessary to maximize drug effectiveness. Electronic health records (EHRs) and emerging digital technologies on the provider side are catalyzing new partnerships between health systems and pharma companies, with the goal of leveraging patient data to demonstrate health outcomes

and differentiate products in the real-world setting. Such technology can also transform the drug development process by improving patient recruiting and enhancing clinical trials.

Each of these evolving trends will have ramifications for a company's strategy in the New Health Economy. Management teams need to understand and act on new risks and rewards as they emerge by capitalizing on opportunities, or adapting their strategy and capabilities to reflect new developments in the market.

Four strategic options

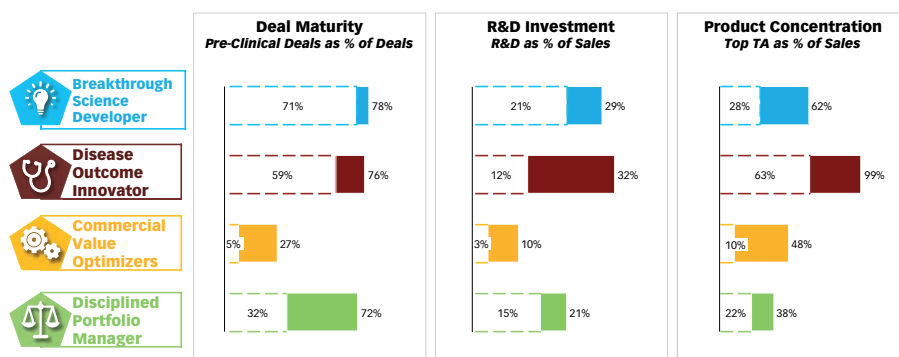
Every company will need to find its own "way to play," meaning its own value proposition that will distinguish it from competitors. In pharma, these value propositions generally fall into four broad categories:

1. Breakthrough Science Developers such as Celgene and Gilead create value by focusing on novel technologies and platforms that produce clearly differentiated products and lead to demonstrably better patient outcomes. They are able to leverage these technologies and platforms across a variety of diseases and therapeutic areas.

2. Disease Outcome Enablers, such as Shire in rare diseases, have historically differentiated themselves based on their expertise in specific diseases. Today, they are looking to take on a greater role through a focused product portfolio in ensuring optimal outcomes.

3. Commercial Value Optimizers create value by generating commercial and operational efficiencies that lead to cost advantages across large global networks. These companies rely

Profiling Different 'Ways To Play'



Source: Deals information from Evaluate Pharma WW Product Deals from January 2011 – November 2015. Financial Information from company annual reports for FY 2014.

Figure 1

heavily on inorganic growth through acquiring and integrating companies and other mature assets to fuel growth.

4. Disciplined Portfolio Managers, such as many of the larger legacy pharma companies, create value through commercial and financial discipline and by leveraging capabilities across a broad portfolio of diversified products in multiple global markets. This category includes many large incumbents that have historically been able to operate with a large, nonspecialized portfolio of business units and product areas.

These four options apply primarily to established pharma companies. New market entrants can pursue a fifth strategic option, in which they focus on a narrow portion of the value chain. Examples include players that enter through areas such as biologics manufacturing or commercializing smaller assets bought from big Pharma—with the potential to expand their role from such a base.

Each of the four approaches leads to a set of corresponding choices for a management team, such as its acquisition strategy, its level of investment—and focus—in R&D, and its degree of product

concentration (see Figure 1).

We looked at the historical market performance (defined as the annual total shareholder return, or TSR) of companies in all four categories, over the last three years. Critically, the results show that performance is not bound by strategy. The leaders in all four performed well in the market, with median annual returns ranging from 13% to 29% from 2013 through 2015 (see Figure 2 on facing page).

Disciplined Portfolio Managers posted the lowest median TSR among the four groups, suggesting that firms with a single clear value proposition do better than those that combine several approaches. But top performers in that category still outperformed some of the laggards in other categories. The clear implication is that a company's "way to play" is only part of the answer; there is a wide range of performance within these alternatives based on whether a company is able to deliver through differential capabilities.

Shaping the four 'ways to play'

All four of the strategies we've analyzed require a clear understanding of their potential risks

and rewards—driven by changes underway in the market—along with a set of underlying capabilities that allow companies to better execute. The most important capabilities will vary from one company to the next, but the leading-edge companies will always have one thing in common: they will define and build out a set of strengths that others will have difficulty matching.

Breakthrough Science Developers

Breakthrough Science Developers create value through novel technology and deep, targeted innovation. They have built capabilities needed to win in the current market, such as a portfolio of first-in-class products that help them rapidly adapt existing products for additional therapeutic indications. Commercially, Breakthrough Science Developers have clinical tools and predictive analytics to help them identify and stratify patients, along with patient case-management models that allow them to reduce costs and increase the effectiveness of their products. And these companies have strong but focused R&D pipelines and the ability to validate targets across multiple disease states.

New trends are pointing to clear rewards for Breakthrough Science Developers. Clinical and scientific breakthroughs have helped them roll out innovative new drugs, and persistent demand for differentiated products supports premium pricing. In addition, analytics—for both individuals and populations—are allowing companies to identify potentially high-value products earlier in the R&D pipeline and target patient populations more effectively.

Yet Breakthrough Science Developers face risks as well. Pricing pressure from governments and payers is pushing pharma companies to make drugs more affordable (to varying degrees across markets), regardless of value. Attractive therapeutic areas can also become crowded, and an accelerated pace of technological advances can shorten the life cycle of innovative new therapies. For acquirers, highly desirable new technology assets draw extremely intense competition. There is a limited number of sustainable technology platforms (such as monoclonal antibodies, enzyme replacement therapies, and vaccines, among others).

In this environment, we believe Breakthrough Science Developers will need to be true market leaders in their capabilities across several core areas. For example, they need to establish and develop partnerships and collaborations with research centers. They also need to understand priority technology applications, including more complex and efficient platforms (such as delivery systems, drug-antibody conjugates, and bispecific antibodies). And Breakthrough Science Developers need capabilities in M&A, in order to acquire—or partner with—companies that have attractive new technology and pre-launch products.

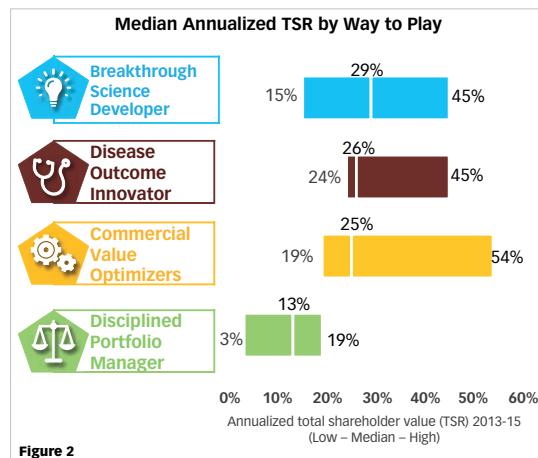
We also see the most innovative, research-based companies moving into a new frontier of drug discovery and product development that is fueled by analytics. For the last four decades, medical information has grown exponentially in terms of volume and variety, due to advancements in EHRs, high-resolution medical imaging, and

next-generation genomics. Yet integrating, aggregating, and analyzing medical data and information at an enterprise scale has not been possible due to technical limitations and high costs. Today, those constraints are disappearing, and advanced analytics capabilities are driving enhanced productivity.

In this example, a fundamental reorientation of internal and external data integration and insight generation is required, which demands new skills, technologies, and tools to develop advanced insights that are both scientific- and operations-based. These capabilities will be the key driver in unlocking the power of new data, and in determining the industry's path forward for the next decade of R&D.

As another example, Celgene has been particularly adept at advanced research partnering and collaboration. The company excels as a Breakthrough Science Developer, particularly in its ability to strike deals for promising companies. Celgene has a clinical development team that works closely with the business development function to target and acquire—or partner with—VC-backed companies that have products in pre-clinical testing. Celgene focuses on rapidly emerging advances in biomedicine, including epigenetic-based drug development, cancer metabolism, antibody drugs, gene therapy, immunotherapy, and regenerative medicine. It has no strict deal template, instead working on a case-by-case basis to determine the right structure (such as strategic equity investments, option licensing deals, and structured acquisitions). Moreover, management has developed a corporate culture that puts science,

Performance in Each 'Way to Play'



and scientists, first, and allows younger and more nimble biotech wide leeway to control their own operations—making it more attractive to potential future partners. The company closed 10 acquisitions or partnerships in 2014, and it has 37 current active alliances.

Disease Outcome Enablers

Historically, Disease Outcome Enablers excelled by having the best understanding of a disease, developing a leading cohesive portfolio of products based on that understanding, and demonstrating leading expertise, credibility, and relationships in the market area of focus. These companies are often able to identify and segment patients at a highly granular level, and they can engage with patients and providers far more directly than their competitors due to their knowledge and focused disease portfolio. Similarly, they can design treatment pathways for better interventions, along with offering patient-support programs with services such as disease education, injection training, adherence support, and co-pay assistance. Last, they often benefit

Strategy & Planning

from an established network of academic and technology companies, which allows them to combine resources and insights.

Current trends in the market are pointing to clear rewards for Disease Outcome Enablers. Providers and payers are more focused on outcomes to create value, and increased data and analytics techniques are available that can generate more detailed patient insights and segmentation. Consumerism is a growing trend, with greater expectations for more coordinated, convenient and integrated care across healthcare sectors. Advanced technologies—often in the form of new digital tools—are helping patients measure, monitor, and manage their own health to achieve better outcomes.

Yet risks are emerging as well. Some market experts question whether pharma can truly add value in many disease areas. Regulatory hurdles could limit the ability to develop and offer integrated pharma offerings, as could challenges in working across healthcare sectors or patient populations. For example, some of the biggest opportunities from integrated care involve complex patient populations, where medical issues may be just one element of their needs. As with Breakthrough Science Incubators, pricing constraints put a greater priority on true product differentiation to obtain the premium pricing needed to support more advanced patient-care models.

As a result of these challenges, we believe that Disease Outcome Enablers will need to integrate drug, device, and technology platforms in order to better track needs and outcomes, adjust ther-

apies, monitor dosing compliance, and report data to both patients and providers. Disease Outcome Enablers will also need to design and implement treatment pathways across healthcare sectors to continuously improve patient outcomes. That will entail working with healthcare providers and other players across the value chain where they will need to assess and assume risk that ties their compensation to patient outcomes.

Although many organizations in this group tend to focus on a single disease area, Shire has built an emerging position in the broader rare disease space through a common set of capabilities needed to excel. As a result of seven acquisitions in recent years, the company has built a portfolio of highly valuable franchises such as *Cinryze* and *Firazyr* for hereditary angioedema (HAE), which require select capabilities for patients that need more personalized attention.

Shire has also created and scaled the US OnePath program, which designates a personalized case manager as a single contact that can coordinate patient care and access to therapy. Case managers use regional, field-based, patient access managers to work with nurses, genetic counselors, pharmacists, and physicians in order to prevent and address potential barriers. Beyond securing reimbursement, this team can help manage the transition to home care, coordinate with specialty pharmacies, and get critical information and resources to patients.

Commercial Value Optimizers

Commercial Value Optimizers thrive by generating efficiencies

through both organic and inorganic measures. Companies that adopt this strategy have built up capabilities in operational and commercial efficiency. For example, they typically have a portfolio of low-risk, established products and a strong focus on commercial operations, often through highly efficient infrastructure—including both supply chain and commercial aspects—along with targeted investment in the products with the greatest growth potential. Commercial Value Optimizers also tend to have strong operational networks and quality compliance in facilities around the world. An aggressive stance regarding M&A has allowed them to become adept at identifying acquisition candidates and smoothly integrating them.

These advantages are generating potential rewards for Commercial Value Optimizers as several trends unfold. Growing global demand for effective healthcare across multiple types of customer channels and segments will likely boost their business. Continued pricing pressure supports mature players that have the operating efficiencies needed to reliably deliver high-quality, low-cost products. Similarly, consolidation among both payers and providers favors pharma companies with scale efficiencies. Innovative technologies have emerged to help fuel operational efficiencies as well, such as advanced manufacturing tools that help lean manufacturers accurately plan demand.

But this market segment is not without risk. Low product differentiation and intense pricing pressures are threatening reimbursement, and much of the potential value available through

acquisitions and incremental cost controls has already been captured, meaning that future gains in these areas may be more difficult.

In response, Commercial Value Optimizers will need to focus on several specific capabilities. Most important, they need to build a diverse portfolio of higher-priced, premium products along with lower-priced commodity products, with a strong focus on ROI management across the portfolio. Commercial Value Optimizers also need internal skills in deal-making and financial engineering. And they need to manage channels through a distinct combination of markets, customers, and products, using advanced analytics to make the right decisions to optimize profits.

Disciplined Portfolio Managers

Disciplined Portfolio Managers traditionally deliver value through a combination of commercial and financial efficiency, built on reasonably productive R&D sourcing. These are typically large incumbents that have built up diversified portfolios of business units and products. Accordingly, Disciplined Portfolio Managers have built up capabilities such as efficient product management across multiple therapeutic areas and distinct global geographies. These companies can also source and execute deals based on capacity in order to fill in gaps in their portfolios, along with forming strategic partnerships. They have strong market expertise at both the global and local level, and they can rapidly develop new markets by leveraging strong commercial operations.

Several market trends could support this strategy. Increasing demand for healthcare worldwide, along with larger customers (due to consolidation) both favor established pharma players with a range of products and global networks. Additionally, strategic data analysis can now help portfolio managers generate insights that allow them to expand products across multiple indications. And very broad product portfolios can generate leverage with major customers, potentially leading to data-sharing and other partnerships that focus on outcomes.


Perhaps most compelling, the highly dynamic market means that Disciplined Portfolio Managers may be better able to respond to market shifts, by reallocating resources among their various businesses (some companies in this category encourage competition for resources among various parts of the portfolio). A wide range of capabilities helps minimize downside risk to the company and its investors. And in terms of talent management, Disciplined Portfolio Managers can create a wider range of opportunities for high-potential managers and executives.

However, there are also clear risks for Disciplined Portfolio Managers in the current market. This strategy has not significantly advanced compared to the others discussed above—which likely explains why its shareholder returns are lower. It is simply harder for a company to differentiate itself from competitors, which limits the potential upside. Companies that have grown through acquisitions may struggle to maintain deal volume, as competition for

assets gets tougher. Even those that can may struggle to differentiate themselves in a sustainable way.

In a sense, Disciplined Portfolio Managers need to overcome longer odds to succeed. They need to apply the capabilities-driven approach to strategy—with a clear way to play, and an accompanying set of products and services—within individual business units. At the corporate level, they need to ensure they have the right portfolio in place and that they are funding business units appropriately. Disciplined Portfolio Managers also need to determine how to capture synergies among multiple business units while still preserving the right level of autonomy. One approach that could work is to borrow best practices from other industries, where management teams are highly skilled at managing a portfolio of products on an ROI basis and allocating resources accordingly.

Hold ground, adapt

In the New Health Economy, success requires staking out a clear and differentiated position. That means a strategy with a specific way to play; the underlying capabilities needed to execute; and a portfolio of products, services, and geographic markets that is aligned with those capabilities. Moreover, management teams need to understand how evolving trends will create new risks and new rewards—requiring that companies adapt their strategy accordingly. Many companies say they do these things, but the market will reward those who are able to do so in a truly differentiated way. 

RICK EDMUNDS is a partner with Strategy&PwC and leads the strategy group within the Pharma and Life Sciences practice. He can be reached at rick.edmunds@pwc.com. **JO PISANI** is a partner with Strategy&PwC and leads the UK Pharma and Life Sciences consulting practice. She can be reached at jo.pisani@strategyand.uk.pwc.com.

DOUGLAS STRANG is a partner with PwC and the advisory leader of PwC's Global Pharmaceuticals and Life Sciences practice. He can be reached at dstrang@pwc.com.

MICHAEL SWANICK is a partner with PwC and the leader of PwC's Global Pharmaceuticals and Life Sciences practice. He can be reached at michael.f.swanick@pwc.com.