To Outperform In Pharma, Go Deep – Not Broad

The world's most successful pharma companies aren't winning on the basis of absolute scale; they succeed instead thanks to their leadership in a few clearly defined product categories. That approach delivers outsized returns, while helping firms navigate a changing health care landscape where payers and providers increasingly demand evidence of treatment efficacy.

BY NILS BEHNKE, MICHAEL RETTERATH AND TIM VAN BIESEN

- Category leaders are those firms that employ a common set of capabilities to develop products that serve a defined set of end-users and often exist within a common competitive class. The products are bought using a common purchasing process managed by common stakeholders.
- The key to understanding category leadership is to view categories through the eyes of the customer
 patients, prescribing physicians and payers.
- Current industry trends play to the strengths of category leaders. Payers and providers are demanding evidence of efficacy, creating new hurdles for drug approval, and category leaders are the best positioned to deliver compelling evidence.
- The rise of drugs prescribed by specialists instead of primary care physicians also favors pharma companies with deep networks and strong relationships within the specialty.

ey innovation, commercial strength and profitability in pharma are all closely linked to category leadership, analysis by Bain & Co. shows. Based on research over several years, Bain has found that companies that produce a higher share of revenue from category-leading positions have operating margins 13 percentage points higher than those that do not. Category leaders also achieved a success rate in Phase III clinical trials 27 percentage points higher than non-category leaders and peak sales from newly launched drugs are 36% higher. The combination is a powerful one, creating significant long-term competitive advantage. (See Exhibit 1.)

Why? Category leaders have a better understanding of the dynamics and evolution of the category. That's a built-in competitive advantage. Their product and regulatory divisions develop greater expertise and better insights into market needs, helping push innovations to market faster. They have greater ability to attract top talent and benefit from privileged access to all stakeholders in the category, including patients, key opinion leaders and clinical trial partners. Category leaders also have more resources to invest in product development, commercialization and acquisitions. And their ability to identify the best assets better and faster often gives them priority access.

Powerful industry trends play to the strengths of category leaders. Payers and providers are developing more sophisticated buying behaviors. Increasingly they are demanding evidence of efficacy, creating new hurdles for drug approval. Category leaders are the best positioned to deliver compelling evidence. The rise of drugs prescribed by specialists instead of primary care physicians also favors players with deep networks and strong relationships within the specialty.

Of course when it comes to winning, nothing trumps true innovation. But the bar for real scientific breakthroughs keeps rising. By concentrating on a category, companies enhance their ability to innovate and increase the odds of their success. The FDA approved 67% of category leaders' NMEs in Phase III, compared with 40% for non-category leaders. (See Exhibit 2). Category leaders also are bet-

Exhibit 1

Innovation, Commercial Strength, Profitability Linked To Category Leadership

The Strengths Of Category Leaders

...Deliver Competitive Advantage

 More efficient SG&A spend



• 13 percentage points higher operating margin

- Higher chance of success in development
- Improved launch of new products

- 27 percentage point greater Phase III success rates
- 36% higher **peak sales** from newly launched drugs
- Greater ability to attract top talent the most passionate scientific and commercial minds
- Deeper relationships with KOLs and biological expertise
- Improved BD&L opportunities the leader is the 'partner of choice'

SOURCE: Bain & Co.

ter positioned to identify and help create new pharma categories in adjacent fields - because they have privileged access to all stakeholders in the category, better insights into unmet needs in the market, and better access to new assets and technologies. As Goldman Sachs noted in a September 2014 equity research report, "five years down the road we could envision companies shifting to disease-based powerhouses that focus on only one or a few disease areas ... this model would allow for focus and innovation."

DEFINING CATEGORY LEADERSHIP

The definition of category leadership is critically important, and in our experience it is often misunderstood. A category is not just a product or technology platform. Nor is it a function of how companies are organized, for example, around therapeutic areas. Rather, a category is a group of products developed from a common set of capabilities and they are bought using a common purchasing process managed by common stakeholders. These products serve a defined set of end-users and often exist within a common competitive set.

In practical terms, the key to understanding category leadership is to view categories through the eyes of the customer – patients, of course, but also prescribing physicians, clinicians and payers. Category leaders have built a sustainable competitive advantage in a category, often by nurturing strong connections with customers and by using commercial insights to inform highly effective investments in R&D. Serving similar customers with similar technology helps develop strong capabilities.

To better understand the relationship between category leadership and value creation in pharma, we analyzed a dataset of 1.2 billion Medicare Part D prescriptions using prescriber overlap as a proxy for shared customers, cost and capabilities. We found that the US prescription market breaks down into at least 22 different customer-based categories that differ significantly from traditional therapeutic and disease areas. (See sidebar, "Customer-Based Therapeutic Categories.")

Our analysis also found that that leading category positions are highly predictive of profitability and value creation, measured in terms of total shareholder returns. To capture and track this trend, we created a Category Leadership Index (CLI) score. The CLI score is the revenue-weighted average of a company's relative market shares (RMS) in the categories in which it competes.

The CLI score showed a strong correlation between operating margins and weighted average RMS across the major pharma categories, using data from 2013. (See Exhibit 3.)

Category leaders benefit from scale economies in their category through significantly lower sales and general and administrative expenses. Even more striking, late-stage development programs from category leaders (RMS >0.75) were more than twice as likely to result in regulatory approval as similar programs from followers (p = 0.01).

That's partly because they picked the right molecules in earlier stages and partly due to a better understanding of the disease. Category leaders also typically design better clinical trials, with a keener understanding of what's possible from a regulatory perspective and what payers value most when deciding on reimbursement.

HOW CATEGORY LEADERSHIP WORKS

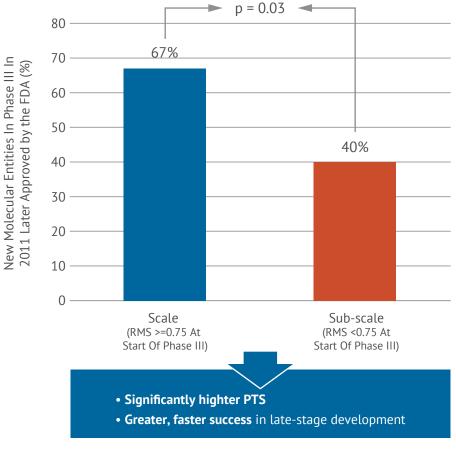
The pharma industry's leading long-term value creators refute the widely held assumption that serendipitous innovation is the key to success in pharma. They have prospered despite industry-wide trends such as declining R&D productivity and the demise of the primary care blockbuster model.

Most of these companies have focused on achieving leadership within specific categories rather than pursuing scale across the industry as a whole. Several, including Roche in oncology and Novo Nordisk AS in diabetes care, generated at least 50% of their revenues from one category. In two cases – Biogen Idec in neurology and Celgene Corp. in oncology – more than 90% of revenues came from a single category.

Category leaders are better positioned to deliver big breakthroughs as well as incremental innovation because they are better able to match ongoing product innova-

Exhibit 2

Category Leaders Innovate More, Have Better R&D Success Rates



SOURCE: Bain & Co.

CUSTOMER-BASED THERAPEUTIC CATEGORIES

Bain found that the US prescription market breaks down into at least 22 different customer-based categories that differ significantly from traditional therapeutic and disease areas.

- Cardiology
- Dermatology
- Dialysis
- Endocrinology
- Geriatrics
- Gynecology
- Hepatology
- HIV
- Inpatient infectious disease
- Neurology
- Oncology (treated as one category for the In Vivo analysis)

- Ophthalmology
- · Pain medicine
- Primary care
- Psychiatry
- Pulmonology
- Retina
- Rheumatology
- Transplant medicine
- Urology
- Vaccines
- · Orphan diseases

tions to market needs and communicate their value to stakeholders (payers, physicians, patients). Our data also show that category leaders earn higher rates of advocacy from customers and key opinion leaders, based on measures like the Net Promoter Score (NPS), Bain's key metric for customer loyalty. NPS tracks critical touch-points in the customer experience and helps companies harness that feedback to develop promoters who buy more, stay longer and recommend products and services to others. They also benefit from superior launch performance. In a study measuring average sales two years after launch between 2000 and 2010, category leaders' products averaged sales of \$500 million compared with an average \$400 million for products from subscale players.

Category leaders often get an earlier look at potential deals and can build deeper valuation insights based on their knowledge and experience. Category leaders typically have the perspective and wherewithal to place a higher value on assets, which in turn raises the profile of their dealmaking and partnerships. In late-stage development, category leaders attract the best scientific and clinical talent, are better able to identify and screen out inferior assets, and typically design better clinical endpoints and economic models.

When commercialization kicks in, category leaders again demonstrate advantages, with generally superior insights to guide marketing choices and both scale and quality in the infrastructure of their field forces, which can provide a cost advantage for incremental assets in a category. Their relationships with and access to key customers – key opinion leaders in a category, as well as payers, clinicians and patient bases – provide an additional edge.

Category leaders have privileged access to all stakeholders in the category. As a result, they are typically faster to spot unmet customer needs and deliver solutions, often at the intersection of science and marketing. **Gilead Sciences Inc.**, for example, built its success in HIV/AIDS therapies on the insight that a lower pill burden and fewer side effects were the keys to fostering better adherence in HIV patients and improving long-term outcomes. Gilead is now transferring its capabilities across product areas in virology by developing combination products for hepatitis C.

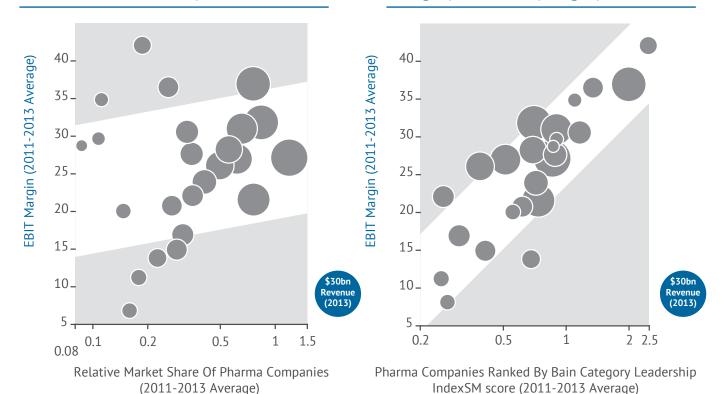
Better insights on customer needs and improved understanding of endpoints leads

Exhibit 3

Category Leadership More Correlated With Profitability Than Overall Scale

Overall Scale Weakly Correlated

Category Leadership Highly Correlated



Note: Includes branded pharmaceutical segments only; Bain Category Leadership IndexSM score is the revenue-weighted average of a company's relative market share in the categories in which it plays; category defined as overlap in prescribers, market access and development.

SOURCES: Bain & Co.; Company reports

to better asset sourcing and development, enabling category leaders to move from strength to strength and build sustainable advantage. Bain's 2015 "Front Line of Healthcare Report" underscores this point; this national survey of 632 physicians across specialties and 100 hospital procurement administrators in the US found that physicians are most likely to recommend the leader in a category and view that company as the innovation leader.

Category leaders benefit from greater growth opportunities because they are quick to spot emerging categories and invest in them. Genentech Inc.'s breakthrough B-cell technology was first used in treating Hodgkin's lymphoma. Deep understanding of the biological mechanisms underpinning the B-cell technology allowed the company's scientists to apply their learnings from oncology in two adjacent fields and develop breakthrough products to treat rheumatoid arthritis and

multiple sclerosis, with opportunities to build leadership in these categories as well.

THE PATH TO CATEGORY LEADERSHIP

As the pressure on growth and profits rises, pharma companies are reevaluating where to play and what it takes to win. One of the biggest organizational challenges is overcoming the traditional communication gap between R&D and commercial teams. A category view helps achieve corporate alignment by moving away from the industry's traditional R&D focus and redefining key markets through a customer lens.

Three key steps can help companies map out a portfolio strategy to become a category leader. The first one is understanding the category's dynamics and attractiveness, including its size and growth potential, unmet market needs, the level of innovation and the intensity of competition. What are the

benefits of leading in a given category and what factors are critical to success?

Step two focuses on the point of departure - the company's current capability and its ability to win in a given category. How is the company positioned? Do its assets differentiate it from competitors? What are the company's core capabilities in the category, including both "hard" and "soft" capabilities? Finally, how do the firm's assets and capabilities align with the key success factors in target categories? Gilead first developed partnership capabilities so it could team up with firms that had the assets it needed to make a combination treatment for HIV. Later, the company learned to develop all of the components in-house.

Once a company has a solid understanding of a category and the company's relevant assets and capabilities, it can plot a path to leadership. This might include buying, selling or swapping assets to bolster its position and

Exhibit 4

A Virtuous Circle That Increases Odds Of Winning

Higher-quality assets with more compelling "evidence package"

Research

- Prominent category experts, backed by commitments
- Molecule library and associated IP
- Cumulative, integrated expertise
- "Partner of choice" for research community

Development

- Top talent in trial design for category
- Strong relationships with leading clinical centers and KOLs
- Leading pharmaco-economic capabilities in category
- Trusted relationships with policy makers

Market Access

- Deep knowledge of existing SoC across geographies
- Rich Phase III data set, including economic end points and comparators
- Strong relationship with payer-focused KoLs, payers and policy makers in major geographies

Customer Engagement

- Top marketing and medical talent in category
- Unique customer insights
- Scale and high-quality field infrastructure
- Reputation for expertise in category with KOLs and clinicians
- Expertise and infrastructure for patient engagement (where possible)

Superior insights on customer needs and key endpoints

SOURCE: Bain & Co.

free up capital. It might also include designing a new operating model to ensure a sharp focus on the pursuit of category leadership.

FINANCIAL MARKETS PRIZE FOCUS

Financial markets recognize the value of focus; they know that promising assets are not fully valued when the owner is not a category leader. As a result, more companies are pursuing M&A deals to help them achieve category leadership.

The 2014 asset swap between Novartis AG and GlaxoSmithKline PLC (GSK) left both companies with stronger positions in their target markets: Novartis in oncology, GSK in vaccines and consumer health. GSK's CLI score increased by nearly 9% as a result of the deal, share prices of both companies rose by 3% to 6% following the deal announcement and market cap increased by \$6 billion each. (See "GSK Vaccines: Injecting Visibility" — IN VIVO, May 2016.) Other examples include Bristol-Myers Squibb Co.'s sale of its diabetes division to AstraZeneca PLC, Novo Nordisk's exit from immunology and AstraZeneca's sale of its rare disease assets to

Sanofi's Genzyme Corp. division.

Category leaders also are a preferred partner for smaller biotech companies searching for an alliance to commercialize their assets. Celgene built a leading network of biotech start-ups to expand its oncology pipeline, acquiring six companies since 2002 and building strategic alliances with several others.

Category leadership is the single most important opportunity for pharma companies to build long-term profitability and shareholder value. It can help companies to define the business areas they want to be in tomorrow and grow successfully. Leaders benefit from a virtuous circle in the value chain that increases their odds of innovating and winning. (*See Exhibit 4.*) Once on top, companies can build multiple leadership engines by extending core capabilities to adjacent categories.

The biggest risk is taking no action. Pharma companies still operate in a high-margin environment. As a result, they often focus on defending their positions rather than doing things differently. Current leaders face a

particular dilemma: move too early and risk losing attractive cash flows from established business models; move too late and risk being overtaken by emerging competitors.

Although bigger may be better in some industries, the dynamics of the pharma industry are changing. Depth, not breadth, will be the key to success in the coming decade. Developing the leading value proposition within a category leads to superior clinical results and sustainable economic returns. That's a future worth investing in.

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