

PHARMA

A close-up photograph of two hands, one from the left and one from the right, pulling on a thick, white rope with black flecks. The hands are positioned as if they are pulling the rope apart, with the fingers wrapped around it. The background is a plain, light blue color.

Like products, industries have life cycles.
And pharma's current stage is about
competition, competition, competition

BY STAN BERNARD

Increasing numbers of low-cost and substitute products. Intense cost pressures. Falling prices and profits. Dramatically higher R&D costs. Fewer new, innovative products. High-quality products with little differentiation. Single-digit sales growth.

These are characteristics of several key US industries: automobiles, telecommunications, manufacturing, apparel, airlines—and pharma. Like products, industries go through life cycle phases. And in recent years, just like others, pharma has matured into the Competitive stage of its life cycle. Most pharmaceutical executives understand the importance of product life cycles for brand planning. Similarly, they need to recognize the drivers and implications of industry life cycle stages. Moreover, understanding industry life cycles can help companies anticipate and benefit from market changes, ultimately providing a competitive edge in an increasingly competitive field.

The S-Curve

Experts identify four industry life cycle stages, though these vary from industry to industry. For pharma, the life cycle can best be characterized as Commencement, Commercialization, Competition, and Commoditization. (See “Pharma: A Life in Stages,” page 34.)

The life cycle typically takes the form of an S-curve. The introductory stage is a relatively flat line, reflecting the challenges

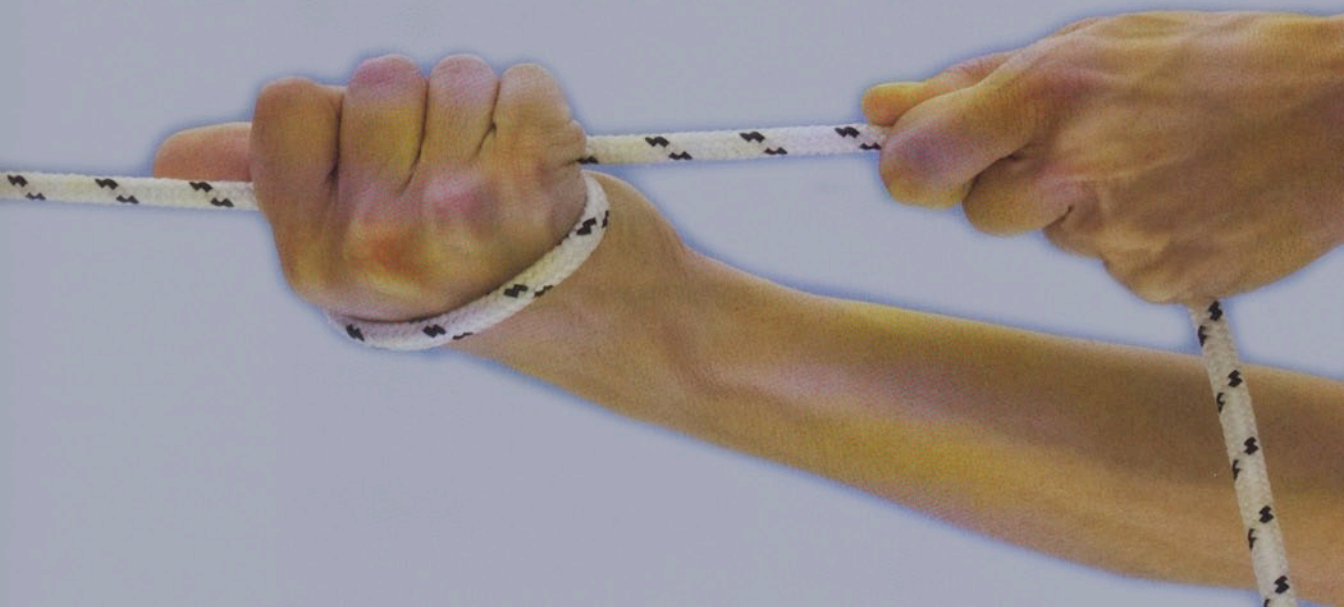
of gaining customer acceptance (Commencement). As customers appreciate and demand the product, explosive growth occurs (Commercialization). That growth eventually tapers off as customer segments become saturated (Competition). Ultimately, sales growth stops and begins to decline as cheaper substitutes and alternative products appear (Commoditization).

The US pharmaceutical industry—the world's largest, with more than \$286 billion in sales—is currently in the Competitive stage. What's the telltale indicator? A relatively consistent decline in sales growth over the past decade, from solid double digits to single digits. In 2007, US pharma's annual growth rate hit 3.8 percent, the lowest since 1961, when the Commercialization stage began. Other characteristics of the Competitive stage: increasing marketing and R&D costs, more sophisticated buyers, greater competition, and decreasing profits. (See “Characteristics of the Four Stages of the Pharma Life Cycle,” page 32.)

Driving Forces

Industries mature at different rates, depending on market-

VS. PHARMA



and industry-specific forces. Using Harvard professor Michael Porter's Competitive Structural Analysis Model, we can identify five forces catalyzing pharma's transition to the Competitive stage.

Reduced R&D productivity The industry's impressive run of developing new products peaked in 1996, when FDA approved a record 53 new molecular entities (NMEs). But over the past decade, pharma's pipelines have dried up: In 2007, only 17 NMEs were approved, though R&D spend had doubled. This past year, the US branded pharmaceutical industry launched fewer products than in any of the past 30 years. The lack of new, truly innovative products is the root cause of most of pharma's other difficulties, including greater generic penetration, higher cost pressures, slowing sales growth, and reduced profitability.

Sophisticated payers focused on costs The increasing power of managed markets in the US has accelerated the transition into the Competitive stage. Private and public payers have dramatically influenced the prescribing, pricing, and perception of branded drugs, while employing techniques such as restricted formularies, product tiers, and prior authorization to control their use. By forcing companies to compete for reimbursement access, managed care companies have negotiated dramatically lower prices for pharmaceutical products. Moreover, managed market entities have high-

lighted to consumers the high costs of branded products by introducing higher copays and more out-of-pocket payments for non-reimbursed products, resulting in additional pressure on drug costs.

Branded and generic competition Twenty years ago, it typically took years for a branded competitor with a similar mechanism of action to enter the market; now it's not unusual to have multiple, same-class competitors at the same time. In addition, the explosive growth of generics has left branded products with less than one-third of the US prescription market. Generic intrusion has been hastened by generic companies that aggressively challenge patents and increasingly bring their products to market even at the risk of lawsuits. According to Urch Publishing, new generics will threaten more than \$100 billion of brand revenues in the US and Europe in the period from 2007 to 2011, with the most dramatic changes occurring in 2010–2012. The branded market has been further eroded by non-prescription options, including over-the-counter products and alternative therapies.

Intensified scrutiny and criticism of the industry No other US industry has as many stakeholders as pharma. Virtually every American uses ethical drugs at some point in his or her life. A variety of healthcare professionals and other entities are involved in assessing, prescribing, distributing, managing, and dispensing pharmaceutical products. Numer-

ous regulatory agencies regulate and monitor most aspects of the industry. Other government officials, policymakers, and payers have direct or indirect oversight and influence. These and numerous other stakeholders—such as the media, lawyers, and politicians—have forced pharmaceutical companies to spend enormous amounts of time, money, and other resources in responding to their demands, resulting in reduced efficiencies, sales, and profitability.

Intense competition for market share The lack of new products compels companies to rely almost exclusively on existing markets and products. Regulatory restrictions have made it increasingly difficult to expand markets. Payers limit pharma's ability to raise prices, while patent challenges and generic prod-

ary groups, such as Competitive Centers of Excellence, or full-time competitive teams to handle such responsibilities. For example, some pharmaceutical companies deploy competitive counter-launch teams whose sole responsibility is to undermine and thwart competitive products up to two years prior to the competitor's launch. Companies should apply similar approaches to corporate competitive planning, with assigned, dedicated staff and regular meetings.

3. Competitive planning Most pharmaceutical product teams create only portions of competitive plans, such as competitive product market research and competitive product profiles. Relatively few brand teams conduct integrated, comprehensive competitive plans that synthesize findings

and identify specific action steps based on competitive company and product profiles; competitive intelligence and research; customer analyses; stakeholder analyses; market and environmental analyses; and corporate profile relative to competitors. It is not enough just to prepare these plans: They need to

Characteristics of the Four Stages of the Pharma Life Cycle

What's past and what's to come, as pharma moves from the Competition stage to the Commoditization stage

CHARACTERISTICS	COMMENCEMENT	COMMERCIALIZATION	COMPETITION	COMMODITIZATION
Stakeholder Demand	Needs to be created	Increasing	Very High	Decreasing as buyers seek substitutes
Sales	Low sales volume	Dramatic sales increase	Peak sales volume	Stagnant or declining sales
Growth rate	Minimal growth	Double-digit increases	Single-digit or stagnant growth	Declining growth rate
Costs	Significant startup costs	Increasing R&D and marketing costs	Heavy R&D and marketing costs	Reduced costs with decreasing investments
Competition	None/little	Increasing with established players	Fierce with numerous competitors	Overwhelming with low-cost/generic offerings

SOURCE: Bernard Associates, LLC

ucts have reduced the duration of product exclusivity. Consequently, companies are left with only one real option to generate sales: grabbing market share from competitors.

Competitive Success Factors

How should companies respond to this pharma-versus-pharma environment? Here are 10 Competitive Success Factors for surviving and thriving in the Competitive stage:

1. Competitive culture Companies in Competitive stage industries, such as consumer electronics and airlines must focus on competition and respond aggressively simply to survive. The vast majority of pharmaceutical companies have never experienced competition of this intensity, and need to instill a much more competitive mindset in all levels of the organization. Executives should formulate and execute revised strategies for this new environment as soon as possible.

2. Organizational competitiveness Increasing focus on competition requires changes in corporate structures, functions, and processes. Most pharma brand teams assign a single product manager, market researcher, or competitive intelligence professional to be "in charge of" competition. More progressive companies, however, use multi-disciplin-

be implemented, reviewed, revised, and regularly revisited.

Pharma executives should also prepare corporate competitive plans to anticipate and prepare for changes in the broader environment. At minimum, executives should incorporate company competitive planning during annual strategic planning and budget review periods. Such plans help to identify potential competitive game-changers or wild cards, test market assumptions, and uncover potential blind spots.

4. Launch/counter-launch The paucity of new products creates even greater pressure for a successful launch. Conversely, because of stagnating markets, competitors cannot afford to have a powerful new player penetrate their limited market space. Consequently, competitors will increasingly use counter-launch plans to preempt new competitors—particularly during the pre-launch phase when the new product is most vulnerable. For instance, Amgen has, to date, protected its multibillion-dollar anemia franchise in the US by filing a patent infringement lawsuit to prevent Roche from introducing its new agent Cera. Similarly, Bristol-Myers Squibb, makers of the blockbuster anti-clotting agent Plavix, has aggressively tried to pre-position Lilly's new competitor Effient. "The way I see it, if and when it is approved, [Effient] will be a niche product," BMS CFO

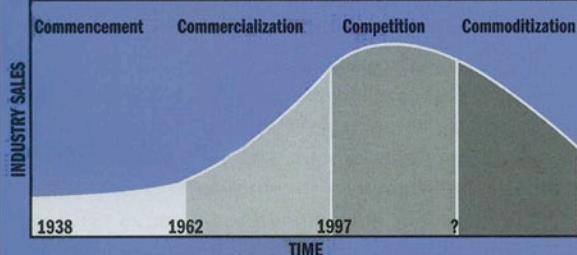
Pharma: A Life in Stages

The US Pharmaceutical Industry's **Commencement stage** began in 1938, with the passage of the Federal Food, Safety, and Cosmetics Act (FDCA), which established drug safety requirements, including the submission of a New Drug Application prior to commercial distribution of a drug. During this period, prescription and non-prescription drugs became legally distinguished from one another. Insulin and penicillin, two key discoveries of the 1920s and 1930s, became mass-manufactured and distributed in Europe and the US.

The industry began to experience significant growth in the 1960s due to the development of systematic scientific approaches, an understanding of human biology (including DNA), and sophisticated manufacturing techniques. The 1962 Kefauver-Harris Drug Amendment to the FDCA officially ushered in the **Commercialization stage**. This act required drug manufacturers to document the efficacy of pharmaceutical products prior to commercialization.

The Kefauver Amendment's influence on clinical, manufacturing, and marketing practices resulted in higher R&D and marketing investments and set the stage for the "blockbuster" phase of the US pharmaceutical industry. In 1963, Roche Labs launched Vallium (diazepam), which became the first true "blockbuster" product, with over one billion dollars in sales. For the next three decades, the US pharmaceutical industry thrived with numerous blockbuster products, double-digit growth rates, and dramatically increased customer demand for its innovative and life-enhancing products. The high-growth Commercialization stage of the US pharmaceutical industry gradually gave way to the more intense **Competitive stage** beginning in the late 1990's.

The U.S. Pharmaceutical Industry: Four Lifecycle Stages



SOURCE: Bernard Associates, LLC

Lamberto Andriatti recently told analysts.

5. Competitive simulations Like sports teams, pharmaceutical companies should "scrimmage." Traditionally, pharma marketers have conducted business "war gaming" only when launching a product. In today's market, these exercises should be conducted at least annually. Companies should conduct a new version of war games called "competi-

tive simulations." Competitive simulations are more realistic, engaging, and productive versions of war games that factor in not only physicians, payers, and consumers, but also other influential stakeholders.

Unlike traditional war games, which focus on physician promotions and detailing, competitive simulations are customized to test important strategic and tactical issues for a particular product and market. Simulations may be used to test the overall marketing plan or individual plan sections, such as payer strategies or communication plans. Most important, competitive simulations provide usable results, including specific action steps for going to market and winning.

6. Competitive differentiation In the Competitive stage, the sheer number, intensity, and diversity of competitors compels companies to create unique, sustainable product and corporate positioning along several dimensions. For example, to enhance its ability to negotiate with governments and other large payers, Novartis has repositioned itself as a full-line healthcare product company by offering branded and generic pharmaceuticals, vaccines, and consumer healthcare products.

Other companies will succeed in this competitive environment by focusing on a specific strategic market segment, geographic region, or disease state, and serving that target more effectively and efficiently than competitors. For example, Novo Nordisk achieves differentiation by focusing on all aspects of diabetes pharmacotherapy, including a diverse portfolio of diabetes products, numerous product formulations, novel delivery systems, extensive diabetes education programs, strong stakeholder relationships, and global diabetes philanthropic initiatives.

7. Cost competitiveness In the Competitive stage, it's particularly important to focus on payers, sophisticated repeat buyers who have the advantage of deciding among multiple competing brands. In today's market that means that competition shifts toward greater emphasis on cost and service.

Pharmaceutical companies must move aggressively to identify substantive ways to reduce costs. Companies have implemented techniques such as rationalizing R&D and product portfolios, revising processes, and raising employees' financial consciousness. Companies in other industries, such as Dell and Nike, have become "virtual companies," essentially outsourcing most functions. Over the past decade, pharma companies have increasingly moved in this direction by outsourcing manufacturing, distribution, clinical development, sales, marketing, IT, and even discovery. This approach not only makes companies more cost-efficient, but also more responsive to customers and competitors.

8. Technology competition In the Competitive stage, companies have a much more difficult time discovering new products. Consequently, competition shifts from internal discovery to external licensing and partnering. Over the past decade,

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pharmaceutical companies have been forced not only to find new compounds, but also to compete aggressively with their peers to gain access to those products. In a reversal from the Commercialization stage, pharmas in this stage are now actively marketing to biopharmaceutical companies, academic institutions, and other organizations, sometimes participating in product “bake-offs” or auctions for attractive, early-stage compounds. Companies are also competing for other types of technologies, such as genomics or nanotechnologies, to help expedite the discovery, development, or delivery of products.

9. Stakeholder competition Stakeholders other than physicians and patients—various healthcare professionals, regulators, consumers, the media, politicians, distributors, and patient advocacy groups—are increasingly influencing the adoption, utilization, pricing, and perception of drugs. What’s more, companies are competing among themselves for the influence and support of these key constituents. Forward-thinking companies have developed strategic stakeholder leader plans, similar to those developed for key opinion leaders, to gain competitive advantage with these influencers.

10. Competition training Key staff members need to know how to analyze competitive products and companies, monitor competitive activities and signals, anticipate competitive moves, develop preemptive and defensive strategies, utilize best competitive practices, and take decisive action. Progressive companies have instituted competitive leadership forums, train-the-trainer programs, competitive case studies seminars, and a variety of other initiatives to provide professionals with the confidence and techniques to gain a competitive edge.

Delaying Product Commoditization

The US pharmaceutical industry will remain in the Competitive stage for the foreseeable future. Customer demand will remain high, especially with an aging population, but sales will peak in many established therapeutic areas as competitors and payers drive down prices and volume. While there is little chance of the industry reverting to the high-growth cycle of an earlier era, there are opportunities to delay the next stage, Commoditization. In this end stage, pharmaceutical products become nearly indistinguishable, and customers buy primarily on price. Sales stagnate or decline as multiple competitors fight for shrinking branded markets. At this point, generic products could represent more than 80 percent of total prescription sales in the US.

Slow-growing, price-constrained European markets are closer to this stage than the US market, while high-growth, emerging markets such as China, India, and Brazil remain in the Commercialization stage. One of the best ways for the pharmaceutical industry to stave off Commoditization is by developing new technologies and technology platforms that ensure the development of new, patent-protected products. For example, biotechnology is the driving force behind a wave of novel, high-priced, high-value products. In fact, biologics are growing at a rate of 13 percent—four times the rate of traditional small molecules. There is significant hope that biotechnologies, genomic technologies, nanotechnologies, and other future technologies can help keep the US pharmaceutical industry in the Competitive stage.

Pharmaceutical executives and their companies are at a critical juncture as the industry confronts its Competitive stage. Executives who can recognize these changes, respond strategically, and take preemptive action have an opportunity to win in this new competitive landscape. The most successful companies will be those that can transform as the industry itself transforms. **DE**

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