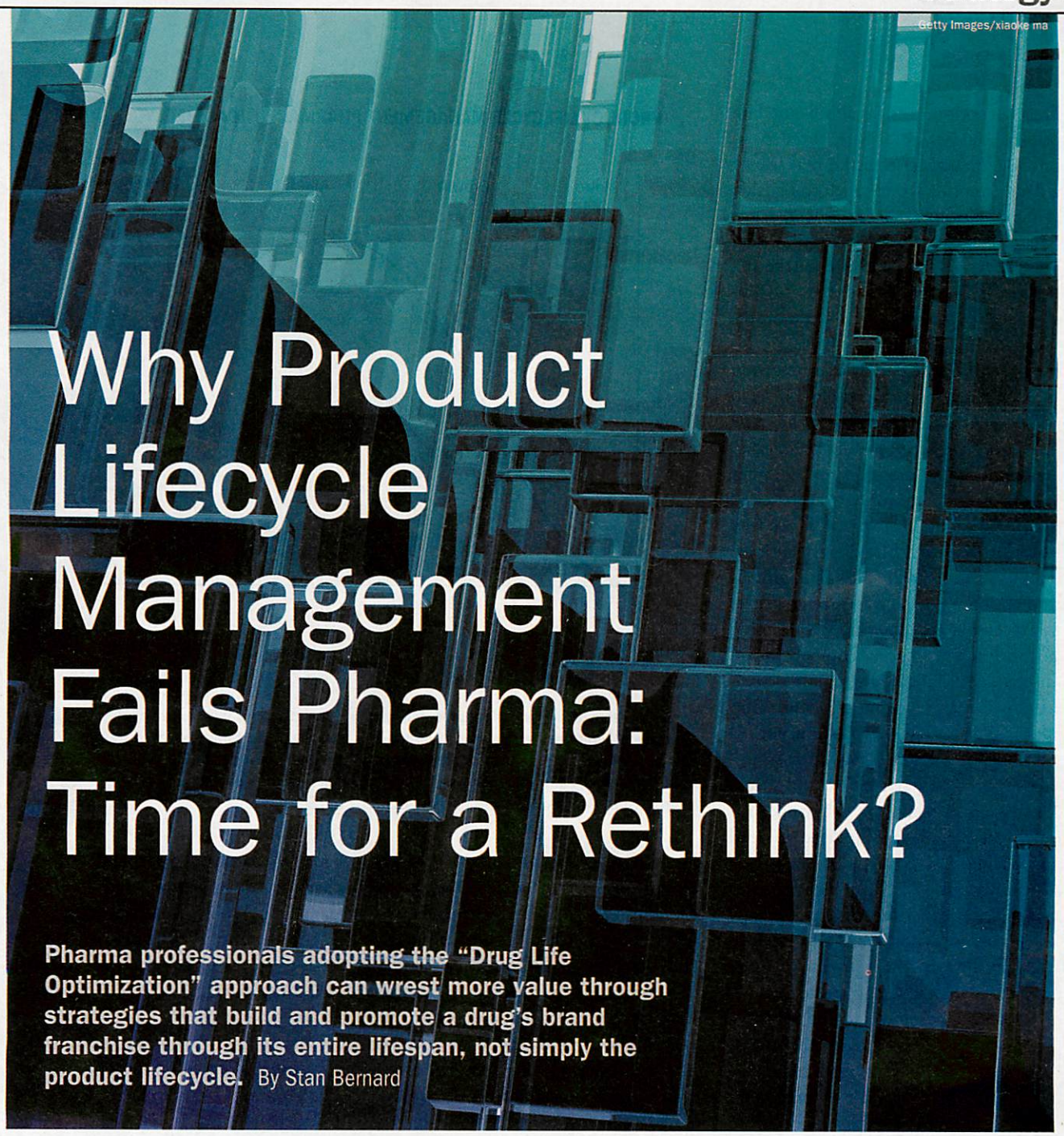

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Why Product Lifecycle Management Fails Pharma: Time for a Rethink?

Pharma professionals adopting the "Drug Life Optimization" approach can wrest more value through strategies that build and promote a drug's brand franchise through its entire lifespan, not simply the product lifecycle. By Stan Bernard

Imagine if physicians only treated people as if their lives began at age 18 and stopped treating them at age 65. This approach would essentially ignore the early development years of youth and the late maturity years of seniors, which also happen to be the peak periods of demand for the physicians' services. Sound preposterous? Not in the pharmaceutical industry. Pharmaceutical marketing professionals primarily focus on the middle years of a product's commercial life, commonly referred to as the "product lifecycle," which begins with regulatory approval and ends with expiration of the patent. The conventional practice is to apply a product lifecycle management (LCM) strategy that entails making critical investments corresponding to four commercial stages of a product's lifecycle: introduction; growth; maturity; and decline (Figure 1).

While LCM is adaptable to many types of manufactured products, it is not applicable to drugs. Drugs are unique products which have not one lifecycle but rather three different life periods: an extensive early development period; a highly competitive

mid-life period; and a significant late post-patent period. These three periods together constitute the real life of a drug, running from bench to bedside (Figure 2). Unlike most products, drugs have a lengthy, closely regulated, and complex developmental pre-marketing phase usually lasting a decade or longer. During this period of scale up toward commercialization, drugs are influenced by an extremely diverse group of customers and stakeholders, each of which can dramatically alter the conditions of access, utilization, pricing, and sales. And unlike most other products, pharmaceuticals are treated as a public good, usually financed by governments or third-party entities. This is reinforced by global, regional, and national intellectual property laws which frequently determine the timing and impact of generic competition in the product's later years.

Consequently, applying the limited LCM approach to pharmaceutical products can lead to flawed assumptions, unrealistic strategies, and value-destroying execution. Pharmaceutical professionals are advised instead to consider the concept of Drug Life Optimization (DLO), which enables pharmaceutical professionals to view the entire life—not just the lifecycle—of a product in order to make more appropriate, timely, and strategic decisions through each of a product's three life periods. DLO is an all-encompassing business approach to manage the complete set of product information, processes, and resources in order to maximize the longest, full life potential of a drug.

More life than you think

DLO is a disruptive innovation because it requires a transformational change in the mindset of every pharmaceutical professional. In contrast to LCM, DLO:

Incorporates early-stage development planning. The early period is a way to showcase not only the clinical but also the commercial market potential of a new product. During this foundational period, pharmaceutical planners are tasked with making crucial business planning decisions that will determine the ultimate sales, profitability, and therapeutic impact of the new agent, over a period of decades. The early period also requires a forward looking accounting of the full range of investments to position the drug for market success.

Includes the late generic period. Unlike the LCM curve, the DLO curve does not end with product patent expiration but includes the late period beginning with the loss of market exclusivity and initial generic competition. DLO recognizes that patent expiry is not necessarily the demarcation line for an abandonment of product support, since generic competitors are now entering the market to grab brand share prior to patent expiration. Moreover, there is no longer a single, primary patent or patent expiration date, even in the same market. Innovators utilize various types of patents (e.g., composition of matter, method, formulation, etc.), which generic companies can challenge in different markets.

Realizes cumulative product sales. DLO focuses on maximizing product sales throughout the entire life of the product, including the post-marketing exclusivity period. Consequently, the DLO approach assumes there is real business opportunity even for products facing generic competition, in contrast to the historical practice of withdrawing support from products as LOE approaches. A 2011 Leerink-Swann investor analysis reveals that innovative companies can capture as much as 20 to 30 percent of the total value of an innovative product after patent expira-

PRODUCT LIFECYCLE MANAGEMENT PHARMACEUTICAL LIFECYCLE CURVE

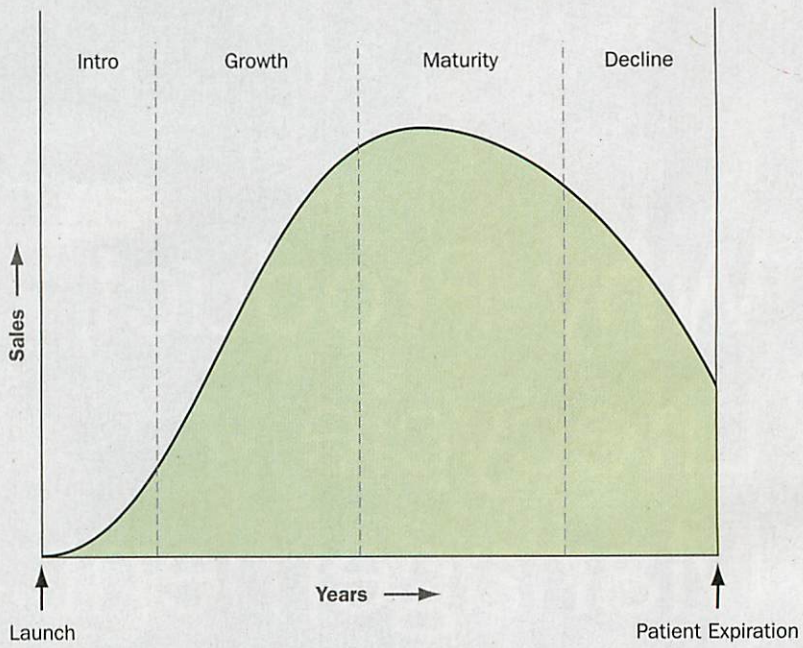

Figure 1: Many pharmaceutical professionals use the standard product lifecycle management approach to make important commercial choices. Unfortunately, this limited methodology focuses primarily on the middle years of a product's commercial life, commonly referred to as the product lifecycle, often resulting in flawed business decisions.
Source: Stan Bernard, Bernard Associates, LLC, 2013

Pharmaceutical professionals who apply DLO are demonstrating dramatically better commercial success and competitive advantages for their products and companies.

tion and the onset of generic competition, by considering a wide range of cost-effective actions.

Encourages a holistic business approach. LCM is preoccupied with winning during the middle years of the LCM curve; it relies on traditional marketing and sales promotion channel strategies to compete. However, DLO offers many other ways to win, involving the application of regulatory and legal tools; manufacturing, distribution, and formulation changes; partnerships, mergers and acquisitions; public policy, public relations, and stakeholder reputation advocacy; portfolio management; and other actions. Execution of DLO strategies thus demands an integrated, multi-disciplinary and cross-functional team approach to manage things through the entire life of the drug.

Like LCM, DLO has several limitations. Different types of products, such as acute care products or vaccines, will have different life curve "shapes." Because there are so many pharmaceutical stakeholders and market influences, the shape and duration of the life curve for any given product is highly unpredictable. For example, new clinical data, regulatory requirements, or market access can dramatically alter the drug's life. While the LCM and DLO curves are typically used cumulatively to reflect total sales across geographies, the curves for a particular drug can be applied to a specific market. Unlike LCM, the DLO curve includes the drug's pre-launch clinical and commercial investment, which represents only a relative estimation of actual costs.

Where to focus

Pharmaceutical professionals who apply DLO are demonstrating dramatically better commercial success and competitive advantages for their products and companies. The benefits of the DLO versus the LCM approach are highlighted in three critical events during a product's life:

Product launches. Pharmaceutical professionals using the LCM focus their efforts in succeeding during the launch year, the first year of the traditional product lifecycle. However, in today's highly competitive pharma industry, just winning the launch year is far too late. It's like a presidential candidate trying to win the election a year after it is held. In contrast, DLO users—like presidential campaign teams—realize that successful launches are actually won in the pre-launch years, usually in clinical Phases II and III, during the early period of a product's life.

In fact, IMS data has shown that the ultimate sales trajectory of a new chronic-care medicine is determined in the first 12 weeks as opposed to the first 12 months after launch. Applying DLO enables professionals to plan and execute pre-launch activities much earlier to position the product and generate stakeholder awareness and demand. Moreover, it enables the commercial launch team to preempt counter-launches, brand pre-positioning, and unfavorable messaging from competitors seeking to thwart the new product in the pre-launch years. It is analogous to a presidential candidate who begins the competitive campaign three to four years before the election by fixing an election strategy, communicating a platform, and establishing relationships with key constituencies before competitors can frame an alternative negative message about the candidate's platform and character.

Generic competition. A 2009 Thomson Reuters survey revealed most pharma professionals wait too late to prepare for generic competition, usually only a few years instead of the eight to 10 years before a product's patent expiration. Inno-

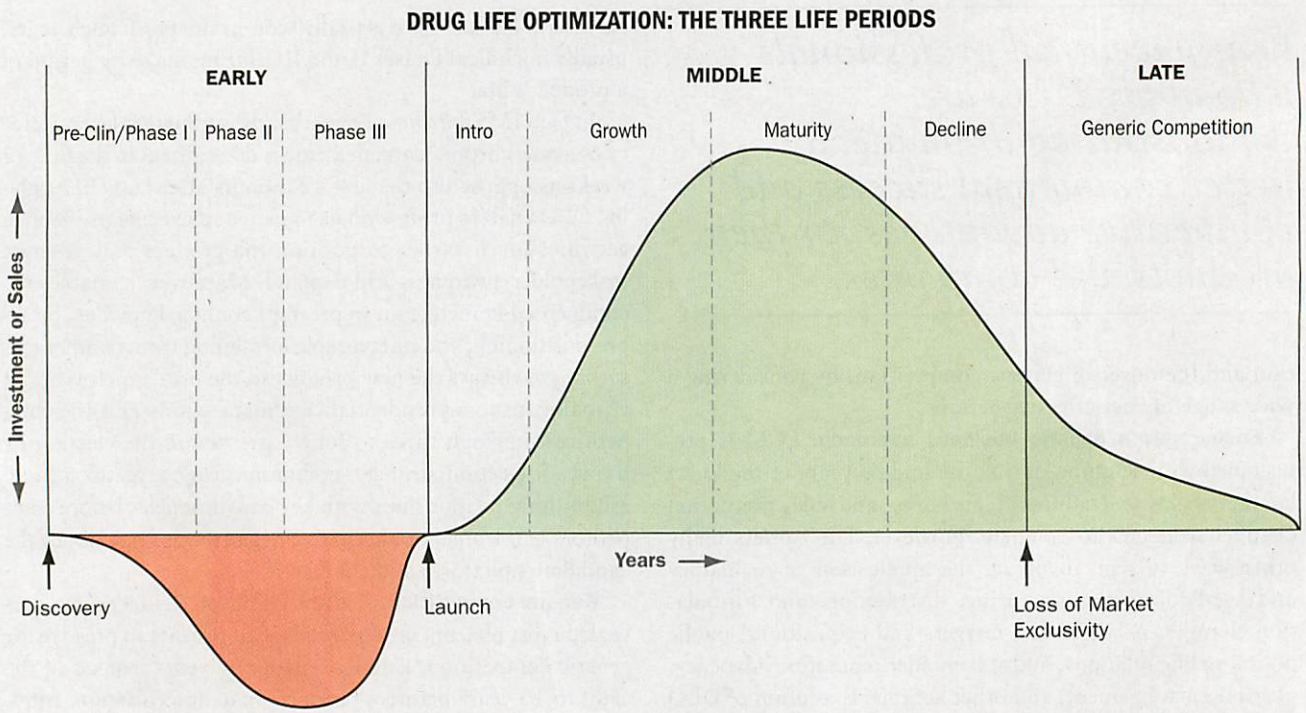

Figure 2: Drug Life Optimization enables pharmaceutical professionals to view the entire life—not just the lifecycle— of a product and to make more appropriate, timely, and strategic decisions to maximize cumulative, lifetime sales, represented as the area under the curve in green.

Source: Stan Bernard, Bernard Associates, LLC, 2013

vator professionals utilizing DLO initiate generic competitive planning prior to their brand's market launch, at the same time as generic companies typically start their planning by procuring the brand's active pharmaceutical ingredients. Earlier competitive planning is essential since increasingly aggressive generic companies are no longer waiting for patent expiration to enter the market. Teva has launched over a dozen products "at risk" in the United States prior to patent expiration. Many other generic companies have launched products prior to patent expiry in Europe and in some cases prior to the innovator's own product launch, as occurred with Amgen/Pfizer's rheumatoid arthritis agent Enbrel in China.

Recalculating product valuations. Business development professionals can utilize the DLO framework to properly value in-licensing and out-licensing opportunities by accounting for the full value of a product's life, not just during those middle years when the product stands front and center in the market. In fact, companies can use DLO to persuade payers on how innovative brand medicines can serve as a source of long-term value, setting prices in the context of a long duration of exposure to patients and the market. Stephen Whitehead, chief executive of the Association of the British Pharmaceutical Industry (ABPI), has used this DLO argument to expedite the adoption of novel products by payers in the UK healthcare system. He is determined to get the National Health Service authorities to stop thinking about the product lifecycle as the patent lifecycle, because the cumulative life of a product extends far beyond that—closer to 40 years. "The value of a medicine, starting from discovery to the point where it is replaced by something else is much greater than what is currently taken into account by regulators," he says.

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—Stephen Whitehead, ABPI

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