STRATEGIC E-BOOKS TO MAKE YOUR JOB EASIER

Pharmaceutical Executive

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Global Launch

Branding Drugs In A Post-Blockbuster Era

Less than 1% of new brands excel in today's increasingly challenging launch environment

What You Need to Know...

Strategy

The golden years of easy profits are over for Pharma. Fewer and fewer products are being launched each year. So much rides on new-product approval that having a 100-percent issue-free launch is an imperative. The following articles from the industry's top strategists provide insights, anystist and good solid, DIY tactics on building a solid launch. We start with a short video (right) on why proactively establishing metrics, and closely monitoring performance both pre-and post-launch, are key to establishing an initial strong trajectory at launch, a long-term success.

Why A Launch is like a Presidential Campaign

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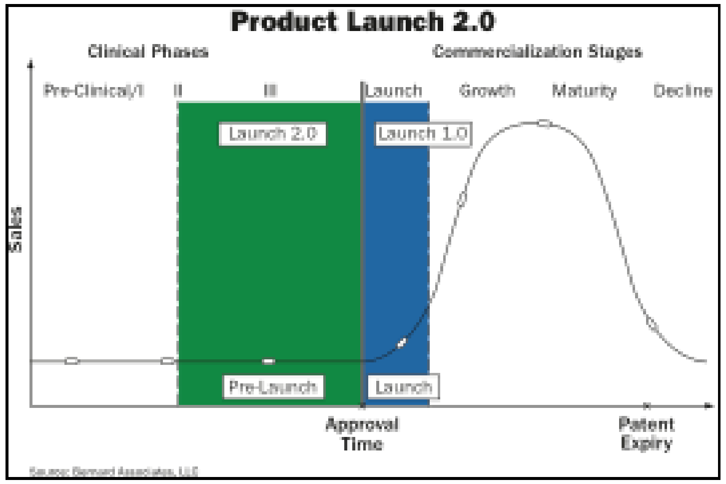
Historically pharmaceutical companies have modeled product launches after military campaigns. After extensive planning and product approval, waves of sales representatives would storm physicians' offices under heavy advertising air cover and promotional support to attack fortified competitors and their products. The outcome of the battle would typically become clear within a year.

In contrast, today's product launches are conducted more like election campaigns. Years before launch, companies position their drug candidates and lobby numerous influential constituencies. Early in the campaign, rival companies with incumbent marketed drugs pre-position and attack the new challenger seeking to steal their votes. Promising drug candidates are scrutinized by analysts and media professionals, who monitor and report each trial and tribulation. The drug election is won or lost soon after launch as patients go to pharmacies to cast their votes, heavily influenced by physicians, payers, and other constituencies.

In fact, an IMS study of 79 launch products and other analyses indicate that the ultimate success of a chronic care product launch is determined within the first 10 to 12 weeks after launch. Consequently, companies can no longer wait to battle during the benchmark ""launch year," but must seek to win the This paradigm shift from selection to election of drugs has fundamentally changed the timetable for



Today launch campaigns start early in pre-launch, while competitors with incumbent marketed products preemptively counterlaunch against the new threat. Brand competitions are increasingly won (or lost) during the pre-launch—rather than the actual the launch—phase.

product launches. Companies and professionals who grasp this shift and approach product launches like elections are demonstrating dramatic competitive advantages.

Two forces beginning in the late 1990s transformed product launches. The pharmaceutical industry in the US, Europe, and Japan transitioned from the growth stage to the competitive stage of its lifecycle, resulting in fewer new products, stagnant markets, pricing pressures, and greater brand and generic competition. Recognizing the threat of new products, companies with marketed products began attacking launch products preemptively during the pre-launch stage when these new agents were most vulnerable (see graph).

In addition, the Internet and other information sources have empowered a larger, more diverse group of pharmaceutical stakeholders—including practicing physicians, patients, and advocacy groups—who can readily access information and form opinions on new drugs long before they reach the market.

This is in stark contrast to past product launches where companies targeted an exclusive group of pre-launch influencers, namely key physician opinion leaders, payers, and the media.

Similar factors have shaped the most recent US presidential election campaigns. Regardless of one's political views, these campaigns provide valuable lessons for effectively launching—or counterlaunching against—pharmaceutical products.

Define Message, Agenda, Competitors

In election terms, a "message" is the core concept that a candidate wants to convey to voters. It is analogous to the "positioning" of a product. Obama's 2008 campaign message was clear and simple: "change." Using the slogan, "Change we can believe in," Obama incorporated the word change into nearly every speech, interview, press release, and debate, including 11 times in his last three debates with McCain. While the McCain campaign switched from message to message, the Obama campaign consistently stayed with the change message throughout the election. The Obama team positioned Obama as the agent of change in contrast to McCain and leveraged change to highlight his election agenda, including healthcare reform.

Obama's campaign demonstrated the power of owning a single word—change

—in the minds of the voters. Likewise, companies that position their drugs in stakeholders' minds with one or only a few key words are generally more successful in product launches. Moreover, Obama early in the campaign was able to define his opponent and the election on his terms. Defining or pre-positioning your competitor and establishing the criteria for product comparisons are particularly effective launch techniques.

Create a Winning Perception

In highly competitive launches, the overall perception of a new product is often more important to many pharmaceutical constituents than the details of a drug's clinical profile or data. Within regulatory constraints, launch teams should create and ensure an initial, positive perception of a pre-launch drug very early in the campaign. This can be achieved through a variety of approaches, including public relations and stakeholder management.

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In the 2008 election, the perception of Obama as the presidential agent of change was carefully crafted and cultivated in several ways. In the presidential debates, Obama appeared "presidential:" composed, calm, and sensible, while conveying optimism and hope. He regularly told stories about his upbringing, including the many changes in his personal life and how his grandparents, who raised him, gave him "hope." Obama's 2006 book, "The Audacity of Hope," highlighted his message of change in the form of Of election reform. His image was literally created in the ubiquitous "Hope and Change" portrait poster, one of the most widely recognized symbols of Obama's campaign.

In presidential elections, certain constituents base their vote primarily on the candidates' issues and facts. However, Obama's campaign team recognized that many undecided or swing voters, who often determine the outcome of close races, rely more on the character or perception of a candidate.

Anticipate, Counter, Respond

Pharmaceutical companies need to initiate their product launch campaigns much earlier than in the past. This is particularly important for new challengers, since incumbent products already have established brand-name recognition, clinical experience, and stakeholder relationships. While companies must remain compliant with commercial regulations, many companies make the mistake of waiting for most of their market research and clinical data before initiating late, traditional launch campaigns. This outmoded approach allows rivals to pre-position and create a negative initial perception of a company's launch product.

Increasingly, competitive companies and various stakeholders are criticizing or undermining developmental drugs during pre-launch period. Some competitors conduct counterlaunches to preempt and defeat new products months or years prior to their launch. These competitors will analyze the launch company and product, identify potential weaknesses, and directly (or indirectly, through supportive stakeholders) attack during the pre-launch phase when a new product is most vulnerable. This approach is akin to campaign teams who conduct background research on opponents to exploit an opponent's "skeletons" and to identify ways to get the opponent "off-message" by highlighting political or personal liabilities.

Counterlaunches are forcing product launch companies to conduct competitive intelligence and competitive simulations earlier in the pre-launch phase to anticipate and preempt such attacks in order to "inoculate" their new products.

Being the Best

As a 2004 senatorial candidate from Illinois, Barack Obama captivated the Democratic National Convention with a keynote address that catapulted him onto the national stage and later into presidential contention. Four years later, he helped secure the Democratic presidential nomination with a surprising victory in the Iowa Democratic presidential caucus, the first election of the primary season.

Early state caucuses are major indicators of front-runners, similar to professional medical society congresses for launch products. At the major medical conferences, launch and counterlaunch companies are trying to steal the show and create initial impressions for launch products and competitive products. Aggressive companies seek to dominate congresses through late-breaking abstracts or news, intensive face-to-face scientific outreach, and high-impact sponsorships

Execute Brand Promise

For both election and pre-launch campaign teams, it is essential to execute in the marketplace. As pre-launch competition is coming earlier, more intensely, and across a broader spectrum of better-informed stakeholders, traditional post-launch promotions, including field sales and advertising, have become less important, while pre-launch activities have become more critical.

Braneric Competition

By Stan Barnard MD

Innovator companies are either launching—or authorizing generics partners to launch—generic versions of their brands prior to patent expiry and before competitive generic entry. Originators also are now continuing brand promotion long after patent expiration in mature markets or giving them new life by launching into developing markets.

Numerous articles have trumpeted the upcoming five-year patent cliff for innovative pharmaceutical companies, during which 18 of the top 20 prescription best sellers—representing over $142 billion in global sales—will face generic competition in the leading developed markets. Unfortunately, these articles fail to tell the more important story: Over the past decade, the frequency and intensity of brand versus generic competition has grown dramatically and will surge globally as the industry continues its transition into the competitive stage of its lifecycle.

There are several reasons for increasing brand versus generic competition. Generics companies have intensified their patent challenges, entered markets earlier, and targeted more off-patent blockbusters, including biosimilars, as well as smaller brands. In addition, generics companies have taken advantage of more supportive laws, regulations, and policies in many markets. At the same time, innovator companies, with weaker pipelines and fewer new products, are trying to extract maximum sales from their existing brands by continuing post-patent promotions. Moreover, innovator companies have focused on emerging markets, where brand versus generic competition is more common.

Increasing generic competition cuts across most products, lifecycle stages, and markets. Generics companies are targeting not only megasellers such as Lipitor and Plavix, but also smaller-selling agents, including some with less than $10 million in sales and 1 percent market share. According to a 2009 Thomson Reuters report, generics companies targeted as many US products with sales less than $50 million dollars as they did blockbuster agents with sales over $1 billion. Over the past five years, generics companies have initiated 65 percent more US patent lawsuits against branded pharmaceuticals and won 70 percent of cases, often resulting in generic copies coming to market years before scheduled patent expirations. In addition, innovator companies are realizing that generic competition in emerging markets can be even more formidable, often with dozens of generic copies for a single brand. Consequently, most innovator company professionals, who are experienced in brand versus brand competition, need to transfer and enhance their skills to compete against generics companies. It is important for innovator professionals to understand the new dynamics of brand versus generic competition and the potential implications and actions for their companies.

What companies are up against and what they should do about it

For years, brand and generics companies have competed in virtually distinct worlds, separated by patent protection of branded products, a discrete corporate focus on a single product type, and a wide disparity in prices. However, over the past decade, these two worlds have collided to create a new space, which I term "Braneric Competition." Three competitive factors have catalyzed this fusion.

Competitive Duration Generics companies are no longer waiting for patent expiration to attack originators' products. Teva Pharmaceuticals, the world's largest generics company, has executed over a dozen "at-risk launches" of generic products while patent litigation is pending in the US. In international markets such as Russia, India, and China, some generics companies market brand copies before the originator's brand is launched. For example, there were generic versions of the rheumatoid arthritis biologic agent Enbrel in China prior to the launch of the original brand.

Innovator companies are either launching—or authorizing generics partners to launch—generic of their brands prior to patent expiry and before competitive generic entry. In addition, originators are now continuing brand promotion long after patent expiration in mature markets or giving them new life by launching into developing markets. According to IMS, innovators may be able to retain over 50 percent share in some markets and generate over 25 percent of a brand's total value after patent expiration. This combination of earlier generic entry and longer brand promotion has expanded and extended brand versus generic competition.

Corporate Convergence Previously, most innovator companies focused on commercializing original, branded products while generics companies exclusively sold generic copies. Increasingly, many large branded and generics companies are marketing both types of products. Novartis develops novel agents and sells generic products through its Sandoz division, one of the world's largest generics manufacturers. Sanofi-Aventis, an innovator company, has recently acquired generics manufacturers Zentiva (Czech Republic), Laboratorios Kendrick (Mexico), Medley (Brazil), and Helvepharm (Switzerland). Many other multinational brand companies, including Abbott, Pfizer, and GlaxoSmithKline have partnered with or purchased multiple generics companies. Conversely, generics maker Teva garners over 25 percent of its revenues from novel products, including Copaxone, the world's leading multiple sclerosis brand, and has new products in development for neurology, autoimmune diseases, and oncology.

Commercial Hybridization Perhaps the best example of commercial hybridization is the concept of "branded generics." Prominent innovator and generics companies both promote company-branded products, often stamped with their trusted name on product packages to convey authenticity and quality. For example, Glaxo- SmithKline has forged relationships with generics makers in India, South Africa, and other markets to sell branded generics. Similarly, Medley and EMS Sigma Pharma, Brazil's two largest generics makers, have standard corporate brand packaging to appeal to patients. Teva named its first biosimilar agent Tevagrastim, to compete with Amgen's brand drug Neupogen (filgrastim) for severe neutropenia. Some leading generics companies go even further by developing not only "me-too" products but also "me-betters" that are priced and promoted very much like their innovator brand rivals. For example, Sandoz specializes in differentiating complex generic products including injectibles, inhalables, patches, complex oral solids, and biosimilars, for which it has been a global leader.

Adopt These Approaches to Win Braneric competition is changing very quickly and dramatically. Recognizing the need to adapt to this dynamic landscape, successful innovator companies are adopting several approaches to help compete against generic competition:

Planning: The biggest mistake brand professionals make is waiting too long to plan for generic competition. According to a 2009 Thomson Reuters study, nearly half of surveyed pharmaceutical commercial professionals assume that generics companies begin their competitive planning against brands two years prior to patent expiry. In fact, generics companies often initiate competitive planning with targeting brands eight to 10 years earlier, beginning in Phase III or at the launch of an innovative product. The first sign of such competitive activities is a generics company's sourcing of active pharmaceutical ingredients, usually shortly after a brand's launch. Consequently, innovator professionals need to move beyond the relatively limited timeframe of traditional lifecycle management plans, which focus on extending the brand's patent life, and create more comprehensive, longer-term generic competitive plans that extend a brand's life. Innovators should develop these plans during a brand's prelaunch phase and update them as part of annual brand planning each year following launch.

Customization: Like their generics competitors who carefully select which brands to target, innovators need to analyze and prioritize potential markets, stakeholders, and competitors. Because every product, market, and competitor set is different, innovators should customize their approach for each situation to determine the appropriate timing, resources, and commitment.

Preparation: Prior to engaging generic competition, some companies utilize competitive simulations, war games, and other types of strategic planning exercises to role play and test strategies and tactics. These simulations can be used during brand versus brand exercises by adding a generics competitor; when competing against a generic copy of a rival brand; or when preparing to compete against the generic version of the company's brand.

Training: Innovator companies need to embed competitive mindsets, expertise, and capabilities throughout their organizations. Progressive brand companies are training not only members of their generic task forces and established brand groups but also a broader set of multidisciplinary professionals to compete with generics companies and products in fair and appropriate ways. These training sessions range from one- to two-day seminars and competition summits to simple lunch-and-learns or expert speaker presentations.