## THIRTY YEARS of PHARM EXEC



In the accelerating battle for market share, the product launch has been transformed from a concentrated, all-out military assault to the subtle, persuasive art of electioneering, where the critical driver is what you do prior to registration

### By Stan Bernard

istorically, 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 candi-

dates 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 'pre-launch years." This paradigm shift—from selection to election of drugs—has fundamentally changed the timetable for 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, page 64). 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.

# Lesson No. 1: Start and Win the Campaign As Early As Possible

In the 2008 presidential race against Republican Senator John McCain, then-Democratic Senator Barak Obama and his team anticipated that Internet-empowered voters and other constituents, with ready access to all types of information, would make much earlier decisions about presidential candidates than in previous campaigns. According to media consultant Pete Snyder, the team believed that the traditional timetable for voters to select their candidate had

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fundamentally shifted from the traditional 72 hours before Election Day to weeks or even months prior to the election.

Using an unconventional approach, Obama conducted his most intensive campaigning very early in the cycle. For example, in the usually slow summer months preceding the election, Obama outspent McCain by nearly 10 to 1 and secured Virginia, a traditionally Republican state which allowed voting six weeks ahead of the election. In fact, over one-third of all votes cast in the 2008 presidential race arrived before Election Day, double the amount in 2000. By starting his campaign early and aggressively, Obama shaped early opinions, drove fundraising money and volunteers into his campaign, and ultimately won the election.

Similarly, 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.

#### Lesson No. 2: Define Your Message, Agenda, and 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.

#### **Lesson No. 3: Create a Winning Perception**

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 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. Similarly, 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.

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This can be achieved through a variety of approaches, including public relations and stakeholder management.

## Lesson No. 4: Anticipate, Counter, and Respond to Attacks

Presidential candidates often handle a variety of criticisms or attacks from campaign opponents or election constituents against their policies, actions, or character. For example, in the 2004 presidential campaign, the Swift Boat Veterans for

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

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.

## **Product Launch 2.0 Clinical Phases Commercialization Stages** Pre-Clinical/I ш Launch Growth Maturity Decline Launch 2.0 Launch 1.0 Sales Pre-Launch Launch Approval Patent Time Expiry Source: Bernard Associates, LLC

Truth, a political group of US war veterans, attacked Democratic presidential candidate John Kerry and his Vietnam war record. The Kerry team waited several weeks before responding to the allegations, but his campaign lost its momentum and ultimately the election. In contrast, when Obama was linked to the controversial Pastor Jeremiah Wright, he responded within days by giving an impassioned speech distancing himself from the pastor and his rhetoric.

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

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 pre-empt such attacks in order to "inoculate" their new products.

# Lesson No. 5: Be the Best on the Big Stage

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

## Lesson No. 6: Effectively Execute the Brand Promise

While the Obama team ran a archetypical campaign in many ways, many constituents believe that Obama has failed during his two years in office to deliver on several major campaign promises, including proposed Iraqi war policies and comprehensive healthcare reform. For both election and pre-launch campaign teams, it is essential to execute in the marketplace. Pharmaceutical stakeholders want products and companies to fulfill or exceed their expectations.

#### Implications for Pharmaceutical Professionals

Increasing competition and more empowered stakeholders have transformed the timing and approach to product launch campaigns. Pre-launch competition is coming earlier, more intensely, and across a broader spectrum of better-informed stakeholders. Consequently, traditional post-launch promotions, including field sales and advertising, have become relatively less important, while pre-launch activities have become more critical. Professionals who understand this paradigm shift and adapt to it will gain significant advantage in an increasingly competitive industry.

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