

The background of the entire page is an underwater scene. A large, dark silhouette of a shark is positioned vertically in the center, swimming downwards. The water is a deep blue with light rays filtering through from above, creating a shimmering effect. The overall mood is mysterious and powerful.

BERNARD

ASSOCIATES, LLC

—THE WINNING SERIES—

WINNING PRODUCT LAUNCHES

- PRODUCT LAUNCH 2.0
- SHARK-PROOF LAUNCHES

WWW.BERNARDASSOCIATESLLC.COM

BERNARD

ASSOCIATES, LLC

HELPING CLIENTS WIN



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 launch.

Product Launch 2.0

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 "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.

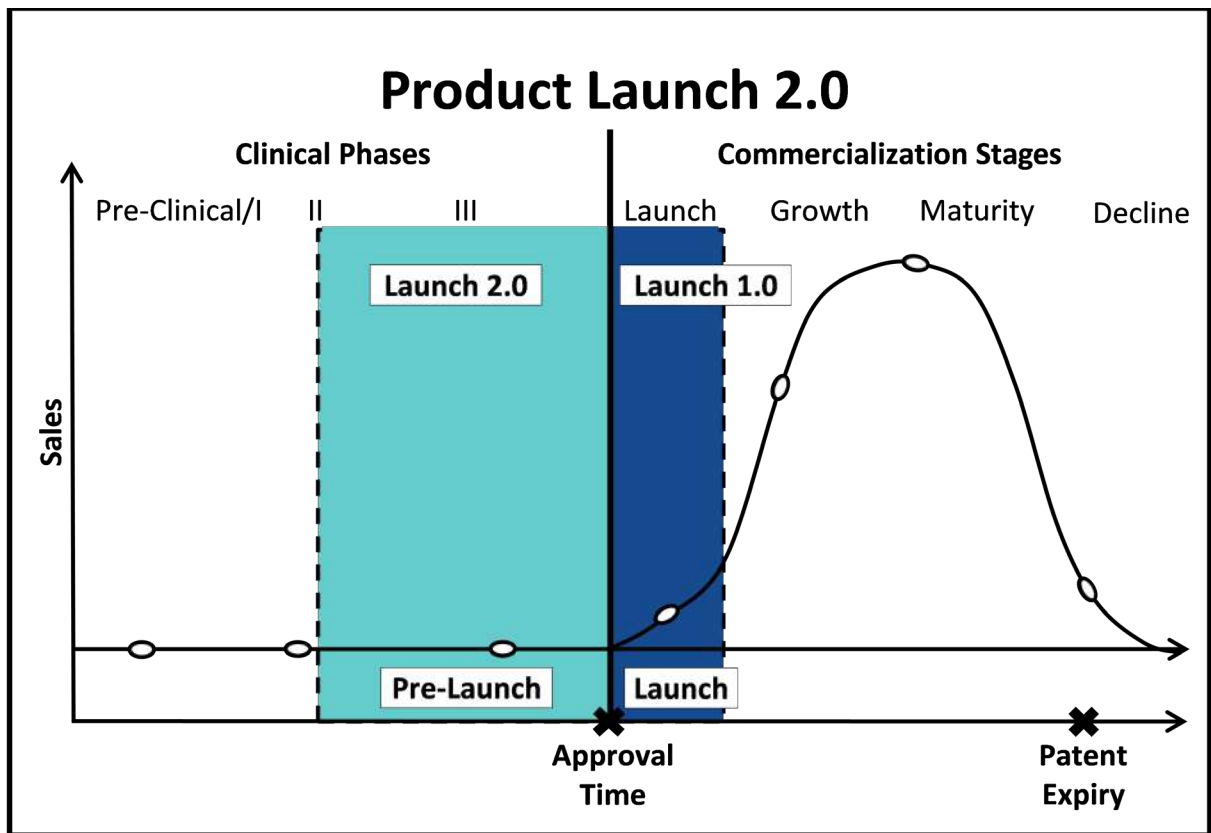
Two forces beginning in the late 1990s transformed product launches. The pharmaceutical industry in

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. In addition, the Internet and other information sources have empowered a larger, more diverse group of pharmaceutical stakeholders—including practicing physicians, patients, 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, Barak Obama and his campaign 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 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 his constituents. 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 election 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. 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 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 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.

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 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.

LESSON NO. 6: EFFECTIVELY EXECUTE THE BRAND PROMISE.

While the Obama team ran an 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. **B**

Stan Bernard, MD, MBA is President of Bernard Associates, LLC, the global pharmaceutical industry’s leading competition consulting firm for competitive simulations/war games 2.0, competitive product launches and counter-launches, competitive strategy and action planning, customized competitive workshops, and competitive training. He can be reached at SBernardMD@BernardAssociatesLLC.com.



Shark-Proof Launches

Swim with Competitors without Being Eaten Alive

Not so long ago, when you launched a new drug, you didn't have to worry about how your competitors already in the market would respond. For the most part, they'd give you a "free launch"—ignoring your product, typically not even mentioning it by name. Today, the free launch is gone. The industry has entered the competitive stage of its lifecycle; brands are fighting to maintain and extend their share in markets that are increasingly constrained by price consciousness and promotional regulations.

Today, your launch is likely to be met by a competitive counter-launch, perhaps one created by a cross-disciplinary counter-launch team that many companies are deploying. Companies have learned that the best time for aggressive market defense is when a competitor is still waiting for approval—when the product has the least corporate resources, market experience, and brand recognition—and when regulatory restrictions limit the manufacturer's ability to respond to attacks.

To borrow Harvey Mackay's metaphor, if you want to swim with the sharks, you need to execute a classic "shark launch," in which your product attacks the market, steals substantial share from rivals, and ultimately becomes a dominant beast. What you want to avoid is becoming shark bait. And the way to keep off the predators is to shark-proof your launch.

WHEN SHARKS ATTACK

Counter-launch comes in many forms. Here are case studies of three classic shark attacks:

CASE 1: PFIZER SHARK-BAITS CRESTOR

In 2003, AstraZeneca was preparing to launch Crestor (rosuvastatin), a cholesterol-lowering agent in the

same class as Pfizer's Lipitor (atorvastatin), but with greater cholesterol-lowering potency. Recognizing that Lipitor could not compete with Crestor on cholesterol-lowering efficacy, Pfizer changed the game and targeted the safety profile of Crestor, which appeared to have a slightly higher rate of muscle toxicity. Pfizer deployed a technique called "shark-baiting" in which it skillfully alerted key stakeholders about this potential safety issue. By putting some of Crestor's "blood" in the water, Pfizer created a virtual feeding frenzy among practicing physicians, the media, consumer advocacy groups, investment analysts, and even some regulatory professionals. Ultimately, Pfizer's shark-baiting tactic crippled Crestor's launch and ensured that the drug never became a serious competitive threat.

CASE 2: AMGEN SETS A SHARK NET

Since the approval of Epogen, Amgen's portfolio of erythropoietin (EPO) anti-anemia products has been the company's lifeline. In 2007, Roche launched competitive EPO product called NeoRecormon in Europe. For several years, Roche has tried to launch the same product (under the name "Cera") in the US market. Anticipating this move, Amgen prepared a "shark net" by filing patent infringement lawsuits to keep Cera off the market. Kevin Sharer, Amgen Chairman and CEO, has stated that "Amgen is working to win the peg-EPO trial and to keep Roche's product off the market until EPO patents in the United States expire some years from now." To date, Amgen has successfully countered the launch of Cera in the U.S.

CASE 3: NOVO'S HAMMERHEAD ATTACK

Amylin and its partner Eli Lilly currently co-market the twice-daily drug Byetta (exenatide) for patients with type II diabetes. They are preparing to launch a once-weekly version of the drug called Exenatide

LAR in the US. Novo Nordisk is seeking to launch its own GLP-1 analogue with the brand name Victoza prior to the launch of Exenatide LAR. At the American Diabetes Association (ADA) meeting in June 2008, Amylin planned to present long-anticipated, new data for Exenatide LAR that had many physicians, investors, and media members excited.

On the eve of ADA, however, Novo conducted what I call a hammerhead attack: The company issued a press release stating that preliminary results in a head-to-head clinical trial revealed that Victoza was superior to Byetta in controlling blood sugar. Releasing preliminary data without any peer-review was a nearly unprecedented approach at such a high-level professional conference. Diabetes market analyst David Kliff wrote in the journal *Diabetic Investor*, "With their bush league tactics, Novo was deliberately trying to control the news flow, damage Amylin's share price, and steal Amylin's thunder." Amylin's stock price indeed plummeted 9 percent that day; the buzz among the meeting attendees focused on Victoza, not Exenatide LAR.

SHARK-PROOF YOUR LAUNCH

To keep your product launch out of the jaws of a wily competitor, I recommend six steps:

1. PREPARE THE CREW

Select a competitive planning team that is committed to developing and executing a comprehensive competitive launch plan. Many companies delegate a single brand team member to handle competitive issues; in contrast, the more successful companies dedicate an entire cross-functional counter-launch team and the necessary resources.

2. HIRE A SHARK EXPERT

Ironically, while pharmaceutical companies spend enormous effort and resources protecting corporate worksites and employee laptops, they often fail to protecting launch products, which typically take over a decade to develop and a billion dollars to bring to market. Engage a "competition consultant" -- different from a competitive intelligence professional or firm -- with the special expertise to lead the team through the competitive planning and protection process. This consultant should have extensive industry experience in both product launches and counter-launches. Importantly, do not rely on advertising agencies which focus on product launches, but not product protection.

3. ENGAGE IN SHARK DISCOVERY

The competitive consultant can lead the team through the development of comprehensive competitive analysis process. This process should incorporate assessments of competitive, corporate, product, stakeholder, and market factors.

4. CONDUCT SHARK SURVEILLANCE

Establish a shark surveillance network and process to identify competitive, stakeholder, or market signs of any impending attacks. This network can consist of field personnel, competitive intelligence experts, key opinion leaders, and other types of stakeholders. There should be a clear, expeditious process for identifying, assessing, and acting upon potential product threats.

5. SWIM IN A SHARK TANK

The best way to prepare to swim with the sharks is to practice, practice, and practice. Perform Competitive Simulation exercises, the new, improved version of war games. Competitive Simulations are custom-designed to be more realistic, engaging, and productive than traditional war games. Most importantly, Competitive Simulations lead to real results, including specific action steps which can be directly integrated into product launch plans.

6. PLAN THE FISHING EXPEDITION

Ultimately, the Competitive Planning Team needs to prepare and execute a winning Competitive Launch Plan that synthesizes the findings from the competitive analysis, surveillance, and simulation. Ideally, this plan will not only shark-proof the product launch, but also create a ferocious shark launch that overwhelms competitors and captures the market for years to come. **B**



BERNARD

ASSOCIATES, LLC

HELPING CLIENTS WIN



The #1 Global Competition Consulting Firm for the Pharmaceutical Industry

Headquartered in Morristown, N.J.

Founded in 1999

Mission: *Helping Clients Win*

Services:

- Competitive Simulations (Business War Games 2.0)
- Competitive Product Launches and Counter-Launches
- Customized Competitive Workshops
- Competitive Analysis, Strategy, and Planning Services
- Competitive Training Seminars

Scope: The firm works across health care products, therapeutic areas, product lifecycle stages, markets, stakeholders, and competitive landscapes.

Clients: Over 125 leading pharmaceutical and health care companies across five continents

Telephone: (908) 304-2888

Email: SBernardMD@BernardAssociatesLLC.com

Website: www.BernardAssociatesLLC.com