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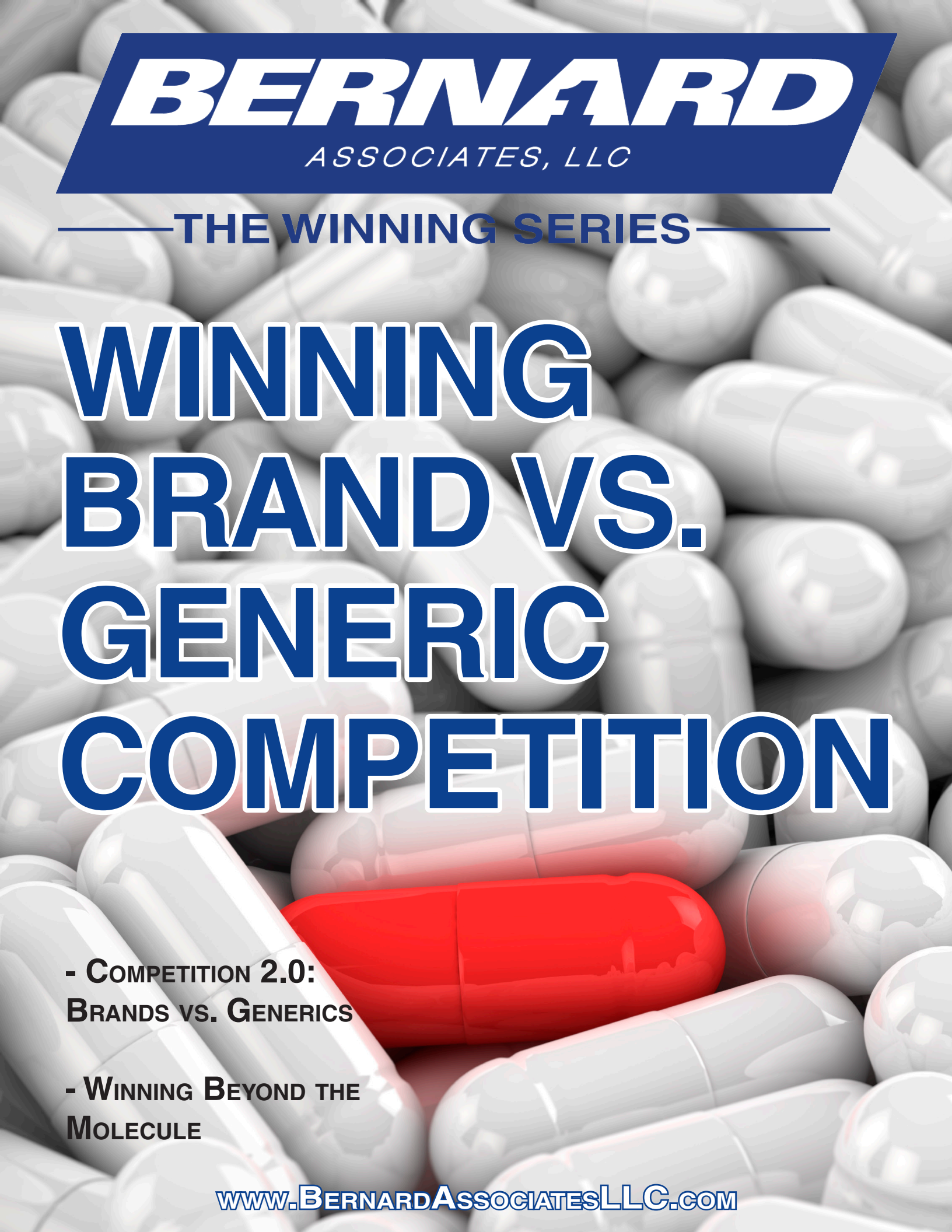
THE WINNING SERIES

WINNING BRAND VS. GENERIC COMPETITION



- Competition 2.0: Brands vs. Generics

- Winning Beyond the Molecule

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Innovator and generic companies are colliding as they invade each other's turf to compete more frequently and intensely.

Competition 2.0

Brands vs. Generics

Numerous articles have trumpeted the upcoming five-year patent cliff for innovative pharmaceutical companies during which 18 of the top twenty 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 bigger, 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. Generic companies have intensified their patent challenges, entered markets earlier, and targeted more off-patent blockbusters, including biosimilars, as well as smaller brands. In addition, generic 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. Generic companies are targeting not only mega-sellers like Lipitor and Plavix, but also smaller-selling agents, including some with less than $10 million in sales and 1% market share. According to a Thomson Reuters 2009 report, generic companies targeted as many U.S. products with sales less than $50 million dollars as they did blockbuster agents with sales over $1 billion. Over the past five years, generic companies have initiated 65% more U.S. patent lawsuits against branded pharmaceuticals and won 70% 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. For example, there are currently over 100 different generic competitors for a single anti-hypertensive agent in Korea.

Consequently, most innovator company professionals, who are experienced in brand versus brand competition, need to transfer and enhance their skills to compete against generic companies. It is important for innovator professionals to understand the new dymamics of brand vs. generic competition and the potential implications and actions for their companies.

BRANERIC COMPETITION

For years, brand and generic 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 are colliding to create a new space which I term "Braneric Competition." Three competitive factors have catalyzed this fusion.

Competitive Duration: Historically, innovators promoted their products against other brands only until the patent expired, at which time multiple generic copies entered the market and often rapidly devoured the brand's market share. Over the past decade, the patent demarcation line has blurred as innovator and generic companies have entered earlier and more aggressively into each other's turf.

Generic 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 U.S. In international markets such as Russia, India, and China, some generic 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.

For their part, innovator companies are either launching or authorizing generic partners to launch generic versions 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. Many multi-national innovator companies have established mature products divisions specifically designed to market their off-patent brands. According to IMS, innovators may able to retain over 50% share in some markets and generate over 25% of a brand's total value after patent expiration. For example, Pfizer, which created an Established Products Division in 2008, has preserved a 60% market share in Spain following patent expiration of its cholesterol-lowering agent Lipitor. 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 generic 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 generic 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 generic companies. Pfizer and Merck have announced initiatives to develop biosimilars. Conversely, generic maker Teva Pharmaceuticals garners over 25% 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: As a result of corporate cross-breeding and intensifying competition, branded and generic companies have adopted many of each other's commercial approaches. For example, innovator companies are targeting and offering aggressive commercial terms to distributors and pharmacies, traditionally generic stakeholder strongholds. At the same time, generic companies in some countries are detailing physicians with sales forces that are larger than those of their innovative counterparts.

Perhaps the best example of commercial hybridization is the concept of "branded generics." Prominent innovator and generic companies both promote company-branded products, often stamped with their trusted name on product packages to convey authenticity and quality. For example, GlaxoSmithKline has forged relationships with generic makers in India, South Africa, and other markets to sell branded generics. GSK's Abbas Hussain stated in *The Economist* that this strategy aims to "build new product portfolios of quality branded medicines which we can combine with GSK's existing extensive sales and marketing." Similarly, Medley and EMS Sigma Pharma, Brazil's two largest generic 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 generic 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 injectables, inhalables, patches, complex oral solids, and biosimilars, for which it has been a global leader.

WINNING INNOVATOR APPROACHES

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 generic companies begin their competitive planning against brands two years prior to patent expiry. In fact, generic companies often initiate competitive planning with targeting brands 8-10 years earlier, beginning in Phase III or at the launch of an innovative product. The first sign of such competitive activities is a generic 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 pre-launch phase and update them as part of annual brand planning each year following launch.

Customization: Like their generic 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 generic 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 multi-disciplinary professionals to compete with generic companies and products in fair and appropriate ways. These training sessions range from 1-2 day seminars and competition summits to simple lunch-and-learns or expert speaker presentations.

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Winning Beyond the Molecule

It can take both a clinical and non-clinical approach to win the differentiation competition.

What would happen if you could not differentiate your brand based solely on its clinical profile? As the pharmaceutical industry transitions from the commercial to the competitive stage of its lifecycle (See "Pharma Vs. Pharma," *Pharmaceutical Executive*, January, 2009), it has become increasingly more difficult to compete primarily on the molecular differences among products. Many therapeutic areas, such as hypertension, rheumatoid arthritis, and diabetes, have numerous brands, presenting hurdles to establish unique product positioning. Many payers refuse to acknowledge brand differences, typically lumping brands within the same class, and often limiting or rejecting reimbursement for "me-too agents." Furthermore, brands are increasingly competing earlier and more often against generics, which renders clinical differentiation virtually irrelevant.

As a result, pharmaceutical professionals must learn to win beyond the molecule. Their new challenge is to find new competitive approaches beyond the molecular or clinical attributes of their products. Some progressive companies have already gained competitive advantages by applying this approach. Here are some examples of these innovative approaches.

CLINIC NETWORKS

When launching its rheumatoid arthritis drug Remicade in Canada, Schering-Plough (now Merck) found that when delivered via infusion versus injection like its competitors, the drug would not readily receive reimbursement in a hospital setting. To address this, Schering formed the "Remicade Infusion Network," a country-wide network of outpatient clinics, often conveniently located in or near physician offices. This approach enhanced patient reimbursement, compliance, and outcomes; financially incentivized specialty pharmacists; and excluded future infusion-administered biologic competitors. Remicade became the preferred biologic in Canada. Schering subsequently launched these clinics in several other countries.

COMBINATION PRODUCTS

In 2004, Gilead Sciences combined two of its HIV drugs, Viread and Emtriva, to form a best-selling drug Truvada. In 2006, the company added a third component, Sustiva from Bristol-Myers Squibb, to create the first, once-daily, triple-therapy Atripla, which become the world's biggest selling HIV compound in 2008. Gilead is collaborating with Johnson & Johnson to develop a single pill nicknamed "Btripla," combining Truvada with TMC-278 (rilpivirine hydrochloride) to improve patient tolerability and adherence. To further extend Gilead's AIDS cocktail franchise, Gilead is also developing a once-daily 'Quad' pill containing four different Gilead-owned HIV agents. Analysts project Quad sales to exceed $1.5 billion by 2015; Gilead's HIV franchise is expected to earn over $5 billion per year during the next decade.

In 2010, Jeff Taylor of the AIDS Treatment Activist Coalition (ATAC) declared that "Gilead revolutionized HIV care with its fixed dose combinations." Once-daily combination products have enabled Gilead to become so dominant in the HIV category that it compelled Pfizer and GSK to form a joint HIV venture ViiV Healthcare to try to compete with them

DELIVERY DEVICE

GlaxoSmithKline markets Advair (also known as Seretide), the world's third best-selling prescription with over $8 billion in annual sales. One reason for Advair's success is its unique inhalation device, the "Diskus." The Advair Diskus is favored by physicians and patients for its convenience and ease of use. A Decision Resources survey revealed that, despite increased competition from several emerging agents, the Advair Diskus will remain pulmonologists' and primary care physicians' favored fixed-dose long-acting beta2 agonist/inhaled corticosteroid combination inhaler through 2013 for asthma and chronic obstructive pulmonary disease.

The Diskus confers competitive advantages against both branded and generic competitors. Recognizing the significant influence of regulators on generic entries, GSK's Regulatory Affairs group worked closely with the FDA to ensure the agency understood the various complexities associated with the development and manufacture of the Advair Diskus. As a result, the FDA raised the standards for generic entry so high that generic companies wishing to launch a generic version of Advair must complete full clinical programs -- including long-term safety studies -- to gain access to the U.S. market. Consequently, Novartis/Sandoz backed out of its deal with Vectura for a generic version of Advair in the US. Teva, the world's largest generic manufacturer, will now be required to conduct a full clinical program for its "branded generic" before it can enter the U.S. market in approximately 2016. As a result, GSK will gain at least six more years of exclusivity for its blockbuster Advair in the world's largest pharmaceutical market.

ADVOCACY PARTNERSHIPS

Vertex Pharmaceuticals recently announced results of the Phase III STRIVE Study which demonstrated that the experimental drug VX-770 dramatically improved lung function in cystic fibrosis patients with the G551D genetic mutation, which affects about 4% of cystic fibrosis patients in the US. According to Mark Schoenebaum, an analyst at ISI Group, "These are potentially game-changing data in cystic fibrosis. VX-770 is the first drug to show good data in a Phase III trial that actually modifies the disease by binding to a defective protein and fixing it." Vertex is currently testing VX-770 in combination with VX-809, another drug in development for cystic fibrosis patients with a far more common gene mutation. If these drugs are approved, Sanford Bernstein analyst Geoffrey Porges estimates annual total sales of the two orphan drugs VX-770 and VX-809 to top $3 billion worldwide. The discovery and development of VX-770 and VX-809 would not have been possible without the novel collaboration between Vertex and the Cystic Fibrosis Foundation, a non-profit, donor-supported, patient advocacy organization. The Foundation helped identify the underlying genetic defect; characterize the biochemical process and its link to the disease; leveraged its clinical trial network to expedite patient enrollment in Vertex trials; and invested more than $75 million with Vertex for the drug's discovery phase. Presumably, once the products are approved, the Foundation, which receives a small royalty on product sales, will complement Vertex's product promotions with its own communication initiatives.

PATIENT SUPPORT PROGRAMS

Novartis is launching the first oral multiple sclerosis therapy, Gilenya, worldwide. While Gilenya has the advantage of oral administration versus injections for competitors, Novartis faces concerns regarding the product's relative efficacy, patient compliance rates, and higher pricing. According to Bloomberg News, Gilenya costs about $4,000 per month, nearly $1,000 more per month than competing drugs such as Teva's Copaxone.

To address these concerns in the U.S., Novartis has one of the industry's most ambitious patient co-pay and support programs. The company is offering to pay out-of-pocket drug costs for non-Medicare patients. These costs include co-payments (up to $800) for those patients with insurance and full coverage of treatment costs for those without insurance who earn less than 500% of federal poverty levels. Novartis will also pay as much as $600 for FDA-required testing and monitoring. To expedite patient starts, Novartis is offering patients free starter product during the benefit's investigation period and "nurse navigators" to provide logistical support, educational materials, and a call-in hotline.

These cases represent a small sample of the many ways that companies can win beyond the molecule. Companies should think holistically and consider a wide range of competitive approaches, including technologies, regulations, manufacturing, distribution, pricing, reimbursement, public policies, partnerships, and legal actions. As pharmaceutical competition intensifies, savvy professionals are appreciating the need to differentiate their products using both clinical and non-clinical approaches.

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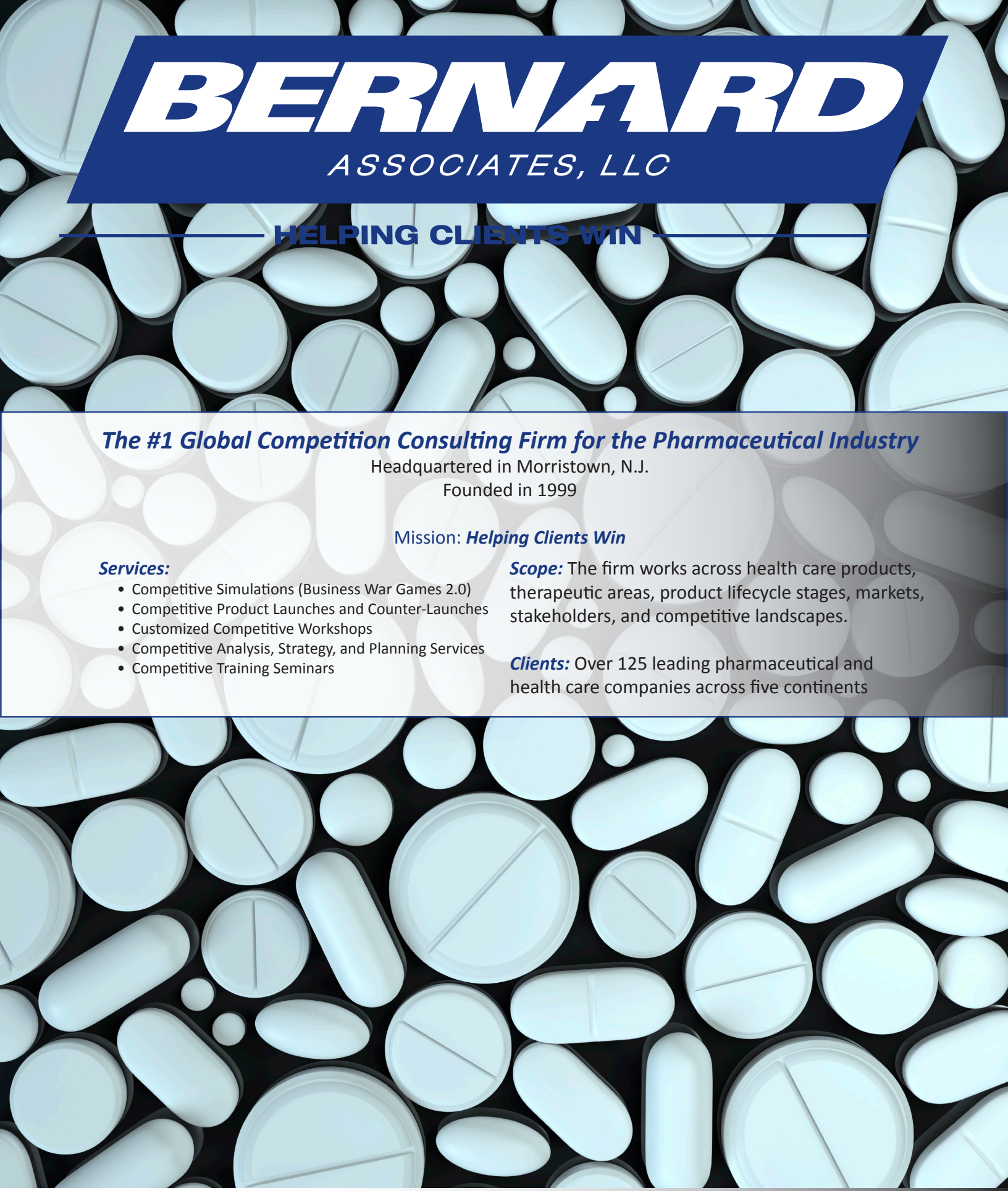

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