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- THINK DIFFERENT:

COMPETITIVE GAME-CHANGERS

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OUTSIDE THE PILL BOX

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THINK DIFFERENT: COMPETITIVE GAME-CHANGERS

Here's to the crazy ones. The misfits. The rebels. The troublemakers. The round pegs in the square holes. The ones who see things differently. They're not fond of rules. And they have no respect for the status quo.... they change things. They push the human race forward. And while some may see them as the crazy ones, we see genius. Because the people who are crazy enough to think they can change the world, are the ones who do.

- Text from Apple's "Think Different" commercial (1997)

This advertisement accurately depicts Apple's game-changing mindset, culture, and execution. Apple's combination of the iPod digital music player and the iTunes digital download service has totally transformed the music industry landscape, propelling Apple to the dominant position in both the digital music and audio player categories. In less than five years, Apple has become the number one music retailer in America with over 5 billion music downloads; it commands over 70% share of the digital media player market by selling over 40 million iPod units annually. In June, 2009, Eli Harari, the CEO of rival SanDisk, effectively conceded that Apple's iPod has won the digital player competition, stating "You can't out-iPod the iPod."

Apple's approach to the digital music marketplace is a textbook example of game-changing, the process of re-defining an industry sector and/or product category to provide an unfair competitive advantage. Game-changing has tremendous implications for pharmaceutical companies and its professionals. As the U.S. and European pharmaceutical industry continues to transition through the mature or competitive stage of its lifecycle, it is more important than ever for companies to play the game at which they excel. Pharmaceutical professionals at every level of the company need to understand the types and techniques of game-changers in order to identify and execute their own game-changing strategies and tactics.

GAME-CHANGING INNOVATIONS

What is a "game-changer"? Game-changers like Apple are rule-breakers: they disrupt the industry's status

quo and conduct a market makeover in order to play a game they can win decisively. The best game-changers can evolve to become "game-makers." Game-makers dictate how business is done in their sector: they make the rules for other industry competitors to follow. Proctor & Gamble, Coke, and Microsoft were all once game-changers who have evolved to dominate their respective industries. Apple is seeking to become a game-maker in digital music by controlling the digital music format, ensuring its iPod is the only portable music player compatible with songs purchased from the company's iTunes music store, and by tightly managing its selected set of suppliers.

Apple was able to change the music industry game by combining two different types of innovations, product (iPod) and technology (digital music downloads). Most game-changing companies transform a market by using one of three types of innovations: product, technology, or business model innovations.

Pharmaceutical companies have traditionally focused on product and technology innovations. For example, GSK created the world's best-selling asthma agent and combination product Advair (fluticasone/salmeterol) by developing the diskus, a novel inhalation delivery device. Allergan has become a specialty pharmaceuticals market leader by adapting two therapeutic products into first-in-class cosmetic products: wrinkle-reducing agent Botox, initially used for the treatment of strabismus or crossed eyes, and eyelash enhancer Latisse, originally approved to manage glaucoma. Light Sciences Oncology is seeking to change the cancer treatment paradigm by using a drug that is only activated by a special light targeted

within a solid tumor. Its photo-therapy device Litx is currently undergoing Phase III trials for the treatment of metastatic colorectal cancer and hepatocellular carcinoma.

Genentech and Amgen have been leaders in the industry-changing biotechnologies of monoclonal antibodies and recombinant proteins, respectively. Roche was quick to invest in and ultimately acquire Genentech for its biotechnology expertise, which has resulted in the development of several blockbuster oncology products, including Avastin and Herceptin. By leveraging this acquisition and other capabilities, Roche is now poised to become a game-changer. It is the dominant player in the global oncology market, the largest market in the world. According to Decision Resources, Roche will be the only top ten pharmaceutical company with overall U.S. growth rates exceeding 3% during the next five years.

Despite the industry's emphasis on product and technology innovation, the most dramatic gamechanging pharmaceutical moves have actually resulted from business model innovation. Under the leadership of CEO Roy Vagelos, Merck & Co. in the early 1980's radically redesigned the industry's research development process by focusing resources on potential blockbusters, significantly reducing developmental times, and forging close relationships with industry regulators. By the late 1980's, Merck's new development model resulted in 8 products exceeding \$100 million in sales, twice that of its nearest competitors. Merck transformed the industry and became a true game-maker. As a result, the company was named America's most admired company by Fortune for a record seven years in a row.

Pfizer changed that game in the early 1990's using a blockbuster acquisition model. Pfizer acquired Warner-Lambert (2000) and Pharmacia (2003) to obtain the blockbusters Lipitor and Celebrex, and supported these products with the industry's largest and most aggressive sale force. These deals catapulted Pfizer from the industry's ninth largest company in 1990 to the world's largest pharmaceutical company in 2003. However, Pfizer's recent declining financial performance and its recent acquisition of Wyeth, predominantly for newer biologic technologies, signal that the industry is ripe for the next game-changer.

GAME-CHANGING TECHNIQUES

There are numerous ways to generate game-changing companies, products, and competitive moves, including:

Embed game-changing into the corporate culture: "The most successful game-changing companies -- from Apple to 3M -- encourage, highlight, and reward novel thinking and innovative ideas. These companies

also seek to engage employees at all levels of the organization to think creatively and competitively. For instance, one leading pharmaceutical company recently used "crowd sourcing" to elicit innovative ideas over the internet from over 15,000 global employees for a particular business opportunity.

Leverage game-changing analogues: Analyzing and adapting novel approaches from other companies or industries can expedite game-changing. For example, Light Sciences Oncology's application of light-activated cancer therapy builds upon similar models used in dermatology, such as DUSA Pharmaceuticals' Levulan® Photodynamic Therapy for the advanced treatment of actinic keratoses.

<u>Conduct "Game-changing Sessions":</u> Progressive companies utilize experienced consultants to facilitate brain-storming sessions at the intersection of competition and innovation. Relying on a variety of proprietary techniques, these sessions can help to identify, prioritize, and select game-changing solutions to gain unfair competitive advantages.

Create a separate business unit: Creating new business models can be problematic for established companies because it may conflict with their traditional ways of competing. Forming a separate business unit is one way to overcome this challenge. For example, Novartis established Sandoz as a generics company based in Munich, separated from the corporate headquarters in Basel. Novartis has built this division into the world's second largest generics manufacturer. According to Novartis CEO Daniel Vasella, this unit, combined with the company's branded products, vaccines, diagnostics, and consumer products divisions, enables the company to better serve large customers and "to offer greater benefits to patients and healthcare providers while creating a more competitive growth platform for our complementary businesses."

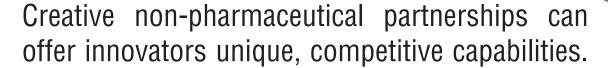
Establish game-changing partnerships: Merck and AstraZeneca recently announced a unique collaboration to study two early-stage, complementary cancer agents, MK-2206 and AZD6244, as a combination regimen for the treatment of solid cancer tumors. This approach could accelerate the products' development and approval process while enhancing patient clinical outcomes.

Acquire game-changers or game-changing technologies: Roche identified and acquired Genentech for its novel biotechnologies and products.

Perform Competitive Simulations: Competitive Simulations, the new version of war games, often incorporate game-changing exercises that help create, test, and validate game-changing ideas and competitive moves.



HELPING CLIENTS WIN



CREALLABORATIONS: PHARMA STARTS THINKING OUTSIDE THE PILL BOX

Despite the industry's transition into the Competitive Stage of its lifecycle, many companies continue to use old business models to compete, including "customercentric" regional sales realignments; hasty, belated initiatives to tap opportunities in emerging markets; and endless corporate level reorganizations. These attempts routinely fail because companies have been slow to recognize that new competitive models – not new commercial ones – are critical to winning in this time of market churn.

However, there are a few truly pioneering companies who are thinking outside of the (pill) box by initiating creative competitive collaborations, or what I term "creallaborations." Creallaborations can be defined as potential game-changing partnerships with non-pharmaceutical organizations that complement, enhance, or help a pharmaceutical company reshape its competitive landscape or achieve breakthrough results. These alliances confer unique competitive capabilities or advantages that the company could not obtain internally, through unique expertise in efficiencies, processes, relationships, or technologies.

The GlaxoSmithKline ("GSK") partnership with the McClaren Group and the Teva-Proctor & Gamble joint venture are two recent examples which highlight the benefits of such creallaborations. With dramatically increasing competition and payer pressures, GSK realized that it could no longer depend solely on its traditional marketing prowess to gain competitive advantage. The company identified three new "Winning Market Factors" (WMF's) essential to competing in the future: speed to market, market adaptability, and cost efficiencies. GSK then identified

a potential partner which excelled in all three areas: the McClaren Group, a leading global Formula One racing car company. In September, 2011, GSK CEO Andrew Witty announced a five-year partnership with McClaren to help GSK "innovate and rapidly respond to change and competitor activity...This partnership is another example of GSK looking outside its sector for inspiration and fresh perspectives on how we can achieve our strategic goals."

McClaren is recognized for high-speed, results-driven race car performance based on real-time monitoring, sophisticated system analytics, and flexible, just-in-time decision-making competencies. McClaren has used such engineering and technical expertise to simulate, monitor, assess, and enhance the performance of every single component within its cars during a race. In fact, McClaren's supercomputers can process telemetric data simultaneously from over 3000 Grand Prix car races.

GSK plans to apply this powerful technology to significantly improve its global efficiency, productivity, and adaptability in supply chain management and clinical research. To help facilitate this knowledge and technology transfer, the two companies will jointly build and leverage the "McClaren GSK Centre for Applied Performance." This facility will train GSK employees to deliver world-class results across its 2000 production lines in 80 global factories. In addition, the GSK Nutritionals division will construct an all-new Mission Control facility at its London headquarters modeled after McLaren Racing's own Formula 1 race-strategy Mission Control Centre. This facility will help expedite management and decision-making for

wholesaler stocking, inventory management, pricing, customer responses, and competitor activity. GSK will also evaluate how McLaren's system of in-car driver communications can be applied to modify and expedite clinical trials.

McClaren Group's Executive Chairman Rod Dennis summarized this approach by stating that "this allnew collaboration between McClaren Group and GSK – McClaren's first ever such association with a major pharmaceutical corporation – represents a strategic partnership that engages two great British companies at a variety of levels across a number of disciplines in a multi-faceted and ground-breaking way. Specifically, our intention is that GSK will harness McClaren's world-beating Formula-1 bred technology processes and operational dynamism, in order to enhance its performance across a wide variety of its divisions in a way that none of its competitors can match."

TEVA TAPS THE CONSUMER WORLD'S BIGGEST BRANDER

Despite being the world's leading generics company, Teva Pharmaceuticals also recognized the need to adapt its competitive business model. Teva is increasingly competing with not only generics but also branded products, which innovators are continuing to promote after patent expiry to supplement flagging sales. Brand versus generic battles are particularly fierce in the growing emerging markets, where price differentials are smaller than the U.S. and consumers have strong brand recognition and loyalty. Consequently, Teva needed to dramatically enhance its branding capabilities, product portfolio, and global reach.

Consequently, in November 2011 Teva formed a global joint venture called "PGT Healthcare" with Proctor & Gamble ("P&G"), the world's recognized leader in product branding. The two companies will combine their two global over-the-counter (OTC) businesses with plans to build a \$4 billion business leveraging P&G's strengths in consumer research and marketing with Teva's experience and relationships with regulators and pharmacies. Health News Daily reported that the joint venture will pool Teva's active pharmaceutical ingredients with P&G's recognized brands to create novel OTC products, such as new Vick's allergy relief combination products and line extensions.

Leaders of the two companies have publically emphasized PGT's competitive advantages, stating that their combined capabilities are "unmatched in the industry" with "one of the broadest and deepest OTC product portfolios and geographic footprints." However, Teva's primary underlying motive is to learn and apply P&G's best branding practices globally to its growing portfolio of branded generics and OTC products and, ultimately, its innovative products. "P&G has demonstrated it may be better than anyone... when it comes to branding, [which] increases the efficiency and the success," said Eli Shani, PGT's chief operational officer.

THE FIVE STEPS TO CREALLABORATIONS

These are only two high-profile examples of creallaborations being developed in the pharmaceutical industry. Pharmaceutical companies seeking to enhance their competitive models and positions should adopt a five-step "Creallaboration Framework" for creating innovative collaborations:

- (1) Creallaboration Analysis Identify and prioritize the Winning Market Factors in a particular competitive space to determine essential new corporate capabilities.
- (2) Creallaboration Brainstorming Brainstorm and broadly analyze potential non-pharmaceutical partners and their capabilities to select the best potential matches.
- (3) Creallaboration Contests Conduct scenario analyses, innovation tournaments, or competitive simulations to test potential company and competitor collaborations.
- (4) Creallaboration Actions Quickly explore and execute on selected creallaborations.
- (5) Creallaboration Monitoring Develop clear objectives and parameters for evaluating and refining such initiatives.

Pharmaceutical companies and professionals that recognize the importance of identifying and leveraging unique, first-in-class capabilities from other industries and partners will gain significant first-mover advantages, resulting in a much more competitive and timely business model.



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 counterlaunches, competitive strategy and action planning, customized competitive workshops, and competitive training. He can be reached at SBernardMD@BernardAssociatesLLC.com.

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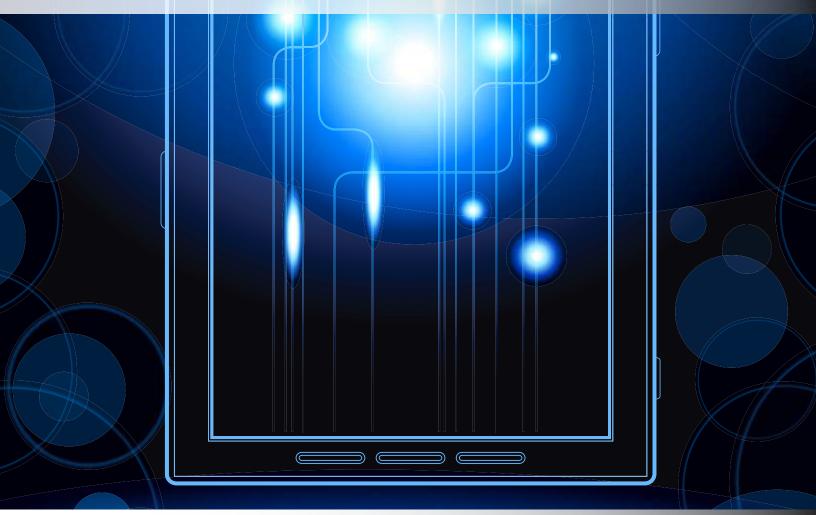
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Scope: The firm works across health care products, therapeutic areas, product lifecycle stages, markets, stakeholders, and competitive landscapes.

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



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