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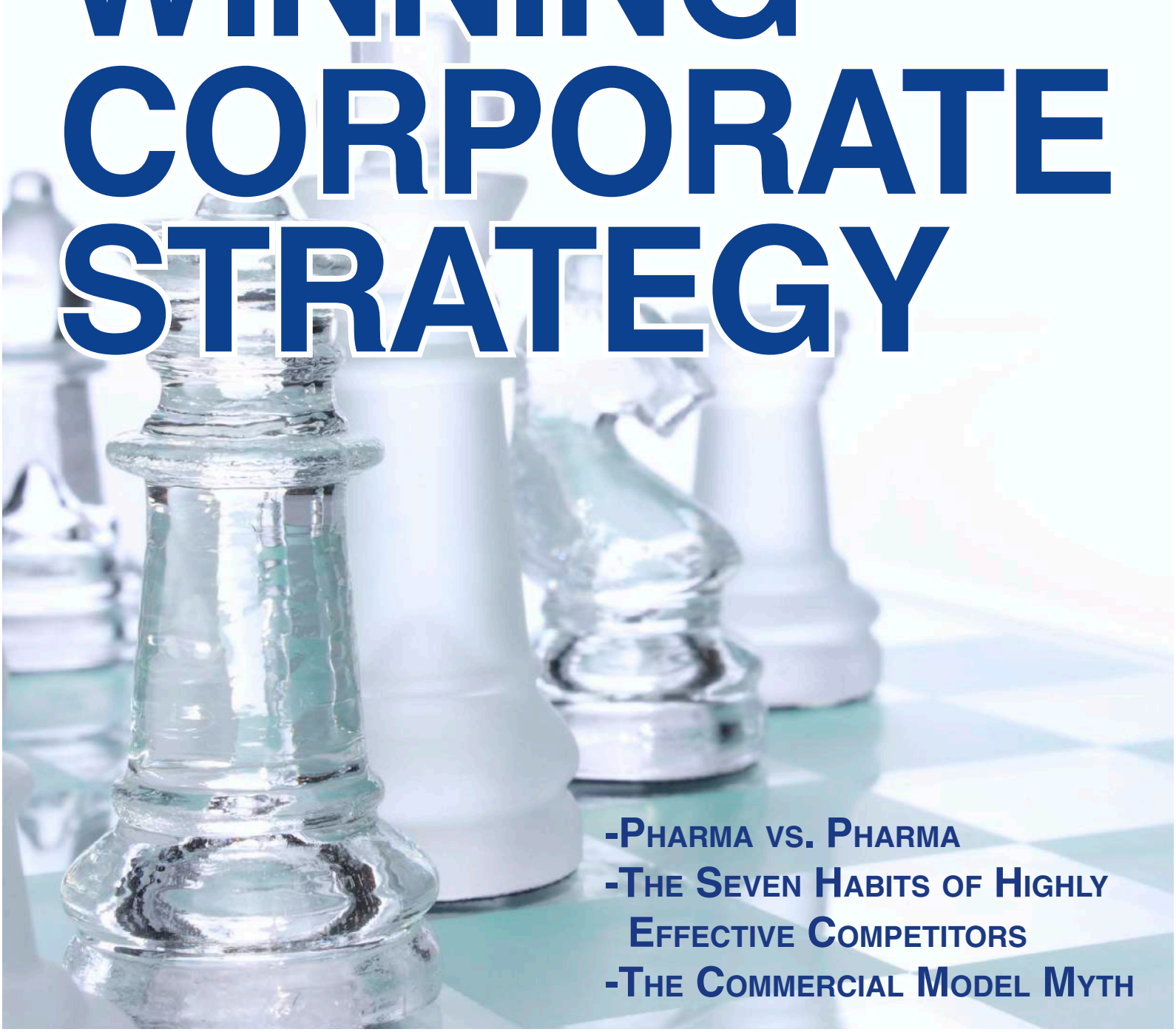

-Pharma vs. Pharma
-The Seven Habits of Highly Effective Competitors
-The Commercial Model Myth

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PHARMA VS. PHARMA

- Increasing numbers of low-cost and substitute products
- Intense cost pressures
- Falling prices and profits
- Dramatically higher R&D costs
- Fewer new, innovative products
- High-quality products with little differentiation
- Single-digit sales growth

These are characteristics of several key US industries: automobiles, telecommunications, manufacturing, apparel, airlines—and pharma. Like products, industries go through lifecycle phases, and in recent years, pharma like the others, has matured into the Competitive Stage of its lifecycle. Most pharmaceutical executives understand the importance of product lifecycles for brand planning. Similarly, they need to recognize the drivers and implications of industry lifecycle stages. Moreover, understanding industry lifecycles can help companies anticipate and benefit from industry changes, ultimately providing a competitive edge in an increasingly competitive field.

INDUSTRY LIFECYCLES

Most experts identify four industry lifecycle stages, though they vary a bit from industry to industry. For pharma, they can best be characterized as Commencement, Commercialization, Competition, and Commoditization.

The lifecycle curve typically takes the form of an S-curve (See Figure 1). The introductory stage is usually a relatively flat line, reflecting the challenges of gaining customer acceptance (Commencement). As customers appreciate and demand the product, explosive growth occurs (Commercialization). That growth eventually tapers off as customer segments become saturated (Competition). Ultimately, sales growth stops and begins to decline as cheaper substitutes and alternative products appear (Commoditization).

The US pharmaceutical industry—the world's largest, with more than $286 billion in sales—is in the Competitive Stage. The tell-tale indicator? A relatively consistent decline in sales growth over the past decade from solid double digits to single digits. In 2007, US pharma's annual growth rate hit 3.8 percent, the lowest rate since 1961, when the Commercialization Stage began. Other characteristics of the Competitive Stage: increasing marketing and R&D costs, more sophisticated buyers, greater competition, and decreasing profits.

DRIVING FORCES

Industries mature at different rates, depending on market- and industry-specific forces. Using Harvard professor Michael Porter's Competitive Structural Analysis Model we can identify five forces catalyzing pharma's transition to the Competitive Stage.

REDUCED R&D PRODUCTIVITY

The industry's impressive run of developing new products peaked in 1996, when FDA approved a record 53 new molecular entities (NMEs). Over the past decade, pharma's pipelines have dried up: In 2007, only 17 NMEs were approved, though the industry's R&D spend had doubled in the preceding decade. This past year, the US branded pharmaceutical industry launched fewer products than in any of the past 30 years. The lack of new, truly innovative products is the root cause of most of pharma's other difficulties,

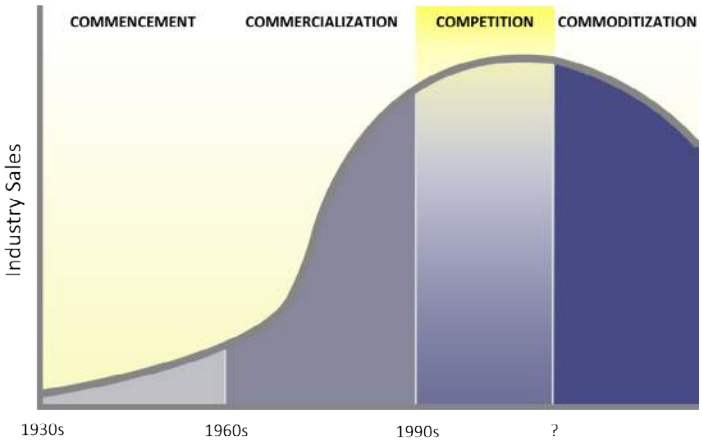

Figure 1: Four Lifecycle Stages

including greater generic penetration, higher cost pressures, slowing sales growth, and reduced profitability.

SOPHISTICATED PAYERS FOCUSED ON COSTS

The increasing power of managed markets in the US has accelerated the transition into the Competitive Stage. Private and public payers have dramatically influenced the prescribing, pricing, and perception of branded drugs, while employing techniques such as restricted formularies, product tiers, and prior authorization to control their use. By forcing companies to compete for reimbursement access, managed care companies have negotiated dramatically lower prices for pharmaceutical products. Moreover, managed market entities have highlighted to consumers the high costs of branded products by introducing higher co-pays and more out-of-pocket payments for non-reimbursed products, resulting in additional pressure on drug costs.

BRANDED AND GENERIC COMPETITION

Twenty years ago, it typically took years for a branded competitor with a similar mechanism of action to enter the market; now it is not unusual to have multiple same-class competitors in that same period of time. In addition, the explosive growth of generics has left branded products with less than one-third of the US prescription market. Generic intrusion has been hastened by generic companies that aggressively challenge patents and increasingly bring their products to market even at risk of lawsuits. According to Urch Publishing, new generics will threaten more than $100 billion of brand revenues in the United States and Europe in the period 2007 to 2011, with the most dramatic changes occurring in 2010–2012. The branded market has been further eroded by non-prescription options, including over-the-counter products and alternative therapies.

INTENSIFIED SCRUTINY AND CRITICISM OF THE INDUSTRY

No other US industry has as many stakeholders as pharma. Virtually every American uses ethical drugs at some point in his or her life. A variety of healthcare professionals and other entities are involved in assessing, prescribing, distributing, managing, and dispensing pharmaceutical products. Numerous regulatory agencies regulate and monitor most aspects of the industry. Other government officials, policy-makers, and payers have direct or indirect oversight and influence. These and numerous other stakeholders, such as the media, lawyers, and politicians, have forced pharmaceutical companies to spend enormous amounts of time, money, and other resources in responding to their demands, resulting in reduced efficiencies, sales, and profitability.

INTENSE COMPETITION FOR MARKET SHARE

The lack of new products compels companies to rely almost exclusively on existing markets and products. Regulatory restrictions have made it increasingly difficult to expand markets. Payers limit pharma's ability to raise prices, while patent challenges and generic products have reduced the duration of product exclusivity. Consequently, companies are left with only one real option to generate sales: grabbing market share from competitors.

COMPETITIVE SUCCESS FACTORS

How should companies respond to this pharma-eat-pharma environment? Here are ten Competitive Success Factors for surviving and thriving in the Competitive Stage:

1. COMPETITIVE CULTURE

Companies in Competitive Stage industries such as consumer electronics and airlines must focus on competition and respond aggressively simply to survive. The vast majority of pharmaceutical companies have never experienced competition of this intensity and need to instill a much more competitive mindset in all levels of the organization. Executives should formulate and execute revised strategies for this new environment as soon as possible.

2. ORGANIZATIONAL COMPETITIVENESS

Increasing focus on competition requires changes in corporate structures, functions, and processes. Most pharma brand teams assign a single product manager, market researcher, or competitive intelligence professional, to be "in charge of" competition. More progressive companies, however, use multi-disciplinary groups, such as Competitive Centers of Excellence or full-time competitive teams, to handle such responsibilities. For example, some pharmaceutical companies deploy competitive counter-launch teams whose sole responsibility is to undermine and thwart competitive products up to two years prior to the competitor's launch. Companies should apply similar approaches to corporate competitive planning, with assigned, dedicated staff and regular meetings.

3. COMPETITIVE PLANNING

Most pharmaceutical product teams create only portions of competitive plans, such as competitive product market research and competitive product profiles. Relatively few brand teams conduct integrated, comprehensive competitive plans that synthesize findings and identify specific action steps based on competitive company and product profiles; competitive intelligence and research; customer analyses; stakeholder analyses; market and environmental analyses; and corporate profile relative to competitors. It is not enough just to prepare these plans: they need to be implemented, reviewed, revised, and regularly revisited.

Pharma executives should also prepare corporate competitive plans to anticipate and prepare for

changes in the broader environment. At minimum, executives should incorporate company competitive planning during annual strategic planning and budget review periods. Such plans help to identify potential competitive game-changers or wildcards, test market assumptions, and uncover potential blind spots.

4. LAUNCH/COUNTER-LAUNCH

The paucity of new products creates even greater pressure for a successful launch. Conversely, because of stagnating markets, competitors cannot afford to have a powerful new player penetrate their limited market space. Consequently, competitors will increasingly use counter-launch launch plans (CLPs) to preempt new competitors—particularly during the pre-launch phase when the new product is most vulnerable. For instance, Amgen to date has protected its multibillion-dollar anemia franchise in the United States by filing a patent infringement lawsuit to prevent Roche from introducing its new agent Cera. Similarly, Bristol-Myers Squibb, makers of the blockbuster anti-clotting agent Plavix, has aggressively tried to pre-position Lilly's new competitor Effient. "The way I see it, if and when it is approved, [Effient] will be a niche product," BMS CFO Lamberto Andriatti recently told analysts.

5. COMPETITIVE SIMULATIONS

Like sports teams, pharmaceutical companies should "scrimmage." Traditionally, pharma marketers have conducted business war games only when launching a product. In today's market, these exercises should be conducted at least annually. Companies should conduct a new version of war games called "competitive simulations." Competitive simulations are more realistic, engaging, and productive versions of war games that factor in not only physicians, payers, and consumers, but also other influential stakeholders.

Unlike traditional war games, which focus on physician promotions and detailing, competitive simulations are customized to test important strategic and tactical issues for a particular product and market. Simulations may be used to test the overall marketing plan or sections, such as payer strategies or communication plans. Most important, competitive simulations provide usable results, including specific action steps for going to market and winning.

6. COMPETITIVE DIFFERENTIATION

In the Competitive Stage, the sheer number, intensity, and diversity of competitors compels companies to create unique, sustainable product and corporate positioning along several dimensions. For example, to enhance its ability to negotiate with governments and other large payers, Novartis has repositioned itself as a full-line healthcare products company by offering branded and generic pharmaceuticals, vaccines, and consumer healthcare products.

Other companies will succeed in this competitive environment by focusing on a specific strategic market segment, geographic region, or disease state and serving that target more effectively and efficiently than its competitors. For example, Novo Nordisk achieves differentiation by focusing on all aspects of diabetes pharmacotherapy: a diverse portfolio of diabetes products, numerous product formulations, novel delivery systems, extensive diabetes education programs, strong stakeholder relationships, and global diabetes philanthropic initiatives.

7. COST COMPETITIVENESS

In the Competitive Stage, it is particularly important to focus on payers, sophisticated repeat buyers who have the advantage of deciding among multiple competing brands. In today's market that means that competition shifts toward greater emphasis on cost and service.

This means that pharmaceutical companies must move aggressively to identify substantive ways to reduce costs. Companies have implemented techniques such as rationalizing R&D and product portfolios, revising processes, and raising employees' financial consciousness. Companies in other industries, such as Dell and Nike, have become "virtual companies," essentially outsourcing most functions. Over the past decade, pharma companies have increasingly moved in this direction by outsourcing manufacturing, distribution, clinical development, sales, marketing, IT, and even discovery. This approach not only makes companies more cost-efficient but also more responsive to customers and competitors.

8. TECHNOLOGY COMPETITION

In the Competitive Stage, companies have a much more difficult time discovering new products. Consequently, competition shifts from internal discovery to external licensing and partnering. Over the past decade, pharmaceutical companies have been forced not only to find new compounds but also to compete aggressively with their peers to gain access to those products. In a reversal from the Commercialization Stage, companies in this stage are now actively marketing to biopharmaceutical companies, academic institutions, and other organizations, sometimes participating in product "bake-offs" or auctions for attractive, often early-stage compounds. Companies are also competing for other types of technologies, such as genomics or nanotechnologies, to help expedite the discovery, development, or delivery of products.

9. STAKEHOLDER COMPETITION

Stakeholders other than physicians and patients—various healthcare professionals, regulators, consumers, the media, politicians, distributors, and patient advocacy groups—are increasingly influencing the adoption, utilization, pricing, and perception of

drugs. What's more, companies are competing among themselves for the influence and support of these key constituents. Forward-thinking companies have developed strategic stakeholder leader (SSL) plans, similar to those developed for key opinion leaders, to gain competitive advantage with these influencers.

10. COMPETITION TRAINING

Key staff members need to know how to analyze competitive products and companies, monitor competitive activities and signals, anticipate competitive moves, develop preemptive and defensive strategies, utilize best competitive practices, and take decisive action. Progressive companies have instituted competitive leadership forums, train-the-trainer programs, competitive case studies seminars, and a variety of other initiatives to provide professionals with the confidence and techniques to gain a competitive edge.

DELAYING PRODUCT COMMODITIZATION

The US pharmaceutical industry will remain in the Competitive Stage for the foreseeable future. Customer demand will remain high, especially with an aging population, but sales will peak in many established therapeutic areas as competitors and payers drive down prices and volume. While there is little chance of the industry reverting to the high-growth cycle of an earlier era, there are opportunities to delay the next stage, the Commoditization Stage. In this end stage, pharmaceutical products become nearly indistinguishable and customers buy primarily on price. Sales stagnate or decline as multiple competitors fight for shrinking branded markets. At this point, generic products could represent more than 80 percent of total prescription sales in the United States.

Slow-growing, price-constrained European markets are closer to this stage than the US market, while high-growth, emerging markets such as China, India, and Brazil remain in the Commercialization Stage. One of the best ways for the pharmaceutical industry to stave off the Commoditization Stage is by developing new technologies and technology platforms that ensure the development of new, patent-protected products. For example, biotechnology is the driving force behind a wave of novel, high-priced, and high-value products. In fact, biologics are growing at a rate of 13 percent, four times the rate of traditional small molecules. There is significant hope that biotechnologies, genomic technologies, nanotechnologies, and other future technologies can help keep the US. pharmaceutical industry in the Competitive Stage.

Pharmaceutical executives and their companies are at a critical juncture as the industry confronts its Competitive Stage. Executives who can recognize these changes, respond strategically, and take preemptive action have an opportunity to win in this new competitive landscape. The most successful companies will be those that can transform as the industry itself transforms.

CHARACTERISTICS OF THE FOUR STAGES OF THE PHARMA LIFE CYCLE

What's past and what's to come, as pharma moves from the Competition stage to the Commoditization stage

CHARACTERISTICS	COMMENCEMENT	COMMERCIALIZATION	COMPETITION	COMMODITIZATION
Stakeholder Demand	Needs to be created	Increasing	Very high	Decreasing as buyers seek substitutes
Sales	Low sales volume	Dramatic sales increase	Peak sales volume	Stagnant or declining sales
Growth rate	Minimal growth	Double-digit increases	Single-digit or stagnant growth	Declining growth rate
Costs	Significant startup costs	Increasing R&D and marketing costs	Heavy R&D and marketing costs	Reduced costs with decreasing investments
Competition	None/little	Increasing with established players	Fierce with numerous competitors	Overwhelming with low-cost/generic offerings

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THE 7 HABITS
OF HIGHLY EFFECTIVE COMPETITORS

Pharmaceutical Executive recently released its "12th Annual Pharmaceutical Industry Audit" which identifies how well companies advance shareholder value by evaluating eight benchmark corporate metrics. This audit ranked Novo Nordisk, Gilead Sciences, Biogen-Idec, Celgene, and Roche (in order) as the top five pharmaceutical companies. Bernard Associates conducted an analysis of these five industry stalwarts to identify seven habits that drive their success.

Biopharma's best companies provide valuable lessons for preparing, planning, and playing to win. Here's how:

1 Commit To and Execute a Specialty Mission

In 1961, President John F. Kennedy announced the aspirational goal of landing the first man on the moon and tasked NASA with this mission. While visiting NASA Space Center in 1962, he asked a janitor what he was doing. The janitor responded, "I'm helping put a man on the moon, Mr. President." While many biopharmaceutical companies focus on a specialty area, highly effective competitors ("HECs") focus on a specialty mission. Since 1923, Novo Nordisk's employees from top to bottom have fervently committed to "preventing, treating, and ultimately curing diabetes." Novo's CEO Lars Sørensen exemplifies the evangelical leadership and zeal that characterizes such companies and ensures employee alignment to and execution of this mission: "We attract people that want to work for a company that sees itself as part of a solution and are not just working for the money to reward the shareholders but to make a difference." Novo currently treats 20 million diabetics by manufacturing over 50% of the world's insulin, including generic insulin which is sold in emerging economies and extremely poor countries. Gilead Sciences, Biogen-Idec, and Roche are similarly passionate about overcoming viral diseases, multiple sclerosis, and cancer, respectively.

2 Knowingly Pursue and Develop the Best Products

HECs cleverly hunt for the best internal and external drug candidates and efficiently develop these compounds. They demonstrate exceptional scientific acumen, clinical judgment, and R&D leadership, the three top traits of successful R&D organizations according to a recent BCG 10-year analysis of 842 developmental molecules. Moreover, HECs knowingly pursue compounds that their rivals might consider irrational gambles. For example, Gilead in 2011 took a seemingly huge risk by acquiring Pharmasset and its lead Hepatitis C ("HCV") antiviral compound sofosbuvir for $11 billion, the "largest deal ever for a company with no products in late stage development and valued at a 98% premium to its previous closing price," according to FirstWord Pharma. Sofosbuvir was considered particularly risky compound since previous NS5B polymerase inhibitors for HCV had failed clinical development.

In fact, Gilead's senior leadership – including three top executives with science Ph.D.'s and over twenty years' experience at the company – made a very shrewd scientific and strategic decision. The company relied on its leading anti-viral research experts and knowledge of nucleotides from its HIV research to place a huge bet that so far appears to have paid off. The FDA last month approved sofosbuvir under the brand name "Sovaldi," and FactSet Research Systems projects annual sales of the drug to reach $6.4 billion by 2017. Gilead exhibited the audit's highest "Enterprise Value Growth" measure for its unmatched operational efficiency.

Similarly, Celgene took a big strategic risk by developing a derivative of the notorious drug Thalidomide into the $4 billion blockbuster Revlimid for multiple myeloma. Not resting on its laurels, Celgene has emerged as "biotech's shrewdest, nimblest dealmaker" which is "fast building the biotech industry's best network of partnerships with innovators," proclaims Xconomy Biotech Editor Luke Timmerman. The company has acquired strategic players such as Pharmion and Abraxis Bioscience; partnered with many IPO companies such as Epizyme and Agios Pharmaceuticals; and invested in "some of the best venture-backed companies in the hottest areas of biomedicine," including epigenetics, immunotherapy, and regenerative medicine. According to Celgene's SVP Business Development George Golumbeski, "We tend to be looking for things that could be transformative, truly step-ahead therapies, not just incremental gains."

3 Win the Pre-Launch Phase

Once HECs find their products, they are experts at launching them. These top competitors conduct election-style – not military-style -- launch campaigns and seek to win the "Pre-Launch Years" versus the traditional but belated "Launch Year." Novo's launch of GLP-1 diabetes agent Victoza demonstrated such extensive pre-market preparation. At an analysts meeting in 2010, Novo SVP Jakob Riis said, "We've also been very conscious about early on opting our resources and our preparedness to engage in … 200,000 interactions last year of more than an hour's length with physicians globally explaining the science behind GLP-1" to maximize pre-launch awareness. Novo successfully counter-launched against Lilly's GLP-1 rivals Byetta and Bydureon, including stealing their thunder prior to the 2008 American Diabetes Association Meeting. The Journal of Managed Care Pharmacy highlighted Victoza's launch as a textbook case, saying the product "came to the market with unusually robust data demonstrating clinical comparative efficacy and safety," including head-to-head studies versus Byetta and other competitors. Despite being delayed by regulatory authorities, Victoza became a U.S. blockbuster within one year.

Biogen trumpeted its new MS therapy Tecfidera so much prior to its 2013 U.S. launch that analysts claimed there was "a bolus of patients in the queue ready to transition to therapy" with an estimated $100 million in pent up demand which the Wall Street Journal reported "overwhelmed some pharmacies." Called the "holy mother of all launches" by ISI analyst Mark Shoenebaum, Tecfidera doubled analysts' first quarter projections and is expected to reach blockbuster status in 2014 and exceed $5 billion annual global sales by 2018. FirstWord rates the launches of Tecfidera, Celgene's multiple myeloma agent Pomalyst, and Roche's breast cancer therapy Kadcyla as the top three 2013 product launches outperforming analysts' consensus projections.

4 Play Their Game

HECs shape their specialty markets to force rivals to play their game. For example, Gilead shaped the HIV market to be a drug combination game based predominantly on its compounds. A relatively late player in the HIV space, the company in 2004 launched the two-drug fixed-dose drug ("FDC") Truvada and two years later the three-drug FDC Atriplia, consisting of Truvada and Bristol-Myers Squibb's Sustiva (efavirenz). Preferring to use all Gilead ingredients, the company in 2012 launched a four-drug, once-daily single-tablet regimen nicknamed the "Quad" and branded as Stribild, which is projected to have 2015 sales exceeding $3 billion.

Gilead is determined to dominate the HCV space using the same game plan: leverage its new agent Sovaldi as the backbone for first-line HCV therapy and fixed-dosed combinations. As a testament to the company's competitiveness, Gilead has refused to collaborate with Bristol-Myers Squibb on co-development of a highly promising regimen featuring Sovaldi and BMS's drug daclatasvir; instead, Gilead has chosen to develop a similarly-effective HCV regimen featuring only Gilead products. Gilead's market-leading approach to drug combinations has transformed the HIV treatment paradigm and is likely to do the same in HCV.

5 Compete at Multiple Levels

HECs practice "Multi-Level Competition," the strategy of seeking to win not only with individual brands but also at the franchise, portfolio, and corporate levels. Roche wants to win with its HER2 breast cancer agent Herceptin, a $5 billion brand; its emerging HER2 franchise which includes recently launched agents Perjeta and Kadcyla; its overall oncology portfolio which includes blockbusters Avastin and Rituxan as well as biomarkers and diagnostics; and to further enhance its industry-leading oncology reputation.

Similarly, Novo's diabetes portfolio offers multiple brands and franchises including basal, rapid-acting, and premix insulins; GLP-1 agents including Victoza and soon other GLP-1 combinations; and a myriad of devices. For over two decades, Biogen has concentrated on Multiple Sclerosis, resulting in the industry's most robust MS franchise (Tysabri, Avonex, Fampyra, and Tecfidera) to help manage this debilitating disease across its continuum. Competing at multiple levels provides many advantages, including better stakeholder relationships, more product combination opportunities, and improved operating efficiencies. Not surprisingly, Novo and Roche held

the top two spots in the PE Industry Audit of sales-to-assets, a measure of corporate efficiency.

6 Mitigate the Impact of Payers and Generics

In the industry's Competitive Lifecycle Stage, both payers and generics represent significant threats. HECs realize that payers are not only customers but also potential "budget competitors," often fighting for the same funds as biopharmaceutical companies. These payers use numerous tactics to control the access, pricing, reimbursement, utilization, and perception of innovative drugs, including leveraging generic competition. Roche has relied on innovation to address payers and generics. The company recently launched 2nd generation follow-on products Gazyva and Kadcyla for its aging blockbusters Rituxan and Herceptin, respectively. Kadcyla, which links Herceptin's antibody with ImmunoGen chemotherapy agent DM1, is one of 25 antibody-drug conjugates in the company's pipeline.

Celgene has also emphasized new product development with a three-pronged strategy: expand Revlimid, its core $5 billion hematology-oncology agent, into new indications; develop new blockbusters such as apremilast for psoriasis and other indications; and build its early-stage pipeline through active deal-making. These efforts have provided Celgene with a 90% pricing margin, the highest in the PE Industry Audit.

7 Seek to Dominate Their Market

While many companies focus on specialty areas of unmet and growing therapeutic need, the most successful competitors seek to dominate and own their respective therapeutic areas. With an impressive portfolio of insulin and non-insulin products, Novo is the leading player in the burgeoning global diabetes market with a 27% global market share according to EvaluatePharma Research. Roche dominates oncology – the world's largest pharma market -- where it owns nearly one-third of all cancer product sales worldwide totaling $22 billion. Roche markets the industry's three best-selling cancer brands and is poised to have five of the six best cancer sellers by 2018. Gilead is expected to capture 43% of all anti-viral sales by 2018 by owning the HIV area while challenging the HCV arena. Catapulted by its recently launched Tecfidera, Biogen will cast an increasingly dominant shadow over the MS market. The company is expected to grow from a 34% to a 50% share of the projected $20 billion MS market by 2018.

In summary, highly effective competitors demonstrate three fundamental ways to win. They prepare to win by committing to a specialty market mission with the right people and products. They plan to win by shaping their market and competing at multiple levels. They play to win by mastering the Pre-Launch, countering payers and generics, and seeking to dominate their competitors.

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Pharma professionals need to find new competitive – not commercial – models to succeed in the Competitive Stage of the industry's lifecycle.

THE NEW COMMERCIAL MODEL MYTH

A recent Cegedim Relationship Management survey revealed that the number one concern of nearly three-quarters of pharmaceutical executives is the "Changing Commercial Business Model." Desperately seeking new commercial models, many executives have experimented with a myriad of approaches, including "corporate restructuring," "sales force realignments," "customer-centric account management," "multi-channel marketing," and "new emerging markets strategies." Unfortunately, these commercially-focused efforts were doomed to fail. Because the pharmaceutical industry has transitioned from the Commercial to the Competitive Stage of its lifecycle, companies seeking new commercial models in the Competitive Stage are fighting today's battles with yesterday's battle plans and weapons. Pharma companies need new competitive – not new commercial – models.

The industry's Commercial or Growth Stage extended from the 1960's to the 1990's. During that period, there were significant unmet clinical needs; many new products and indications; expanding markets; pricing flexibility; and relatively little competition. Numerous companies, products, and brand teams experienced double-digit sales growth resulting in many pharma "winners." However, that changed in the 1990's when the European and the U.S. markets transitioned from the Commercial Stage to the Competitive Stage of their lifecycle. This stage has been characterized by brutal competition among a countless number of brands, generics, and substitute products; significantly reduced R&D productivity resulting in fewer new products; more sophisticated payers focused on cost minimization; and increasing industry consolidation and contraction.

The transition to the Competitive Stage in the U.S. was marked by two key indicators; the peak number of new molecular entities (NMEs) in 1996; and the end of double digit sales growth in the late 1990's. IMS projects that the U.S. and European markets will have low single-digit grow rates ranging from 3-6 % and 1-4%, respectively, through 2014. While emerging markets remain in the growth or Commercial Stage," companies are recognizing the competitive challenges these markets represent for innovative brands, especially biologics and other higher-priced medicines.

Several industry CEO's have acknowledged this important lifecycle transition. In a 2008 PharmaVoice interview, Andrew Witty, CEO of GlaxoSmithKline said, "The environment we find ourselves in as a pharmaceutical company is so different from seven or eight years ago that it is almost unrecognizable." In the same year, then-CEO of Merck Richard Clark stated in a corporate press release that, "Next year will continue to be a period of fundamental transformation that establishes Merck as a different competitor for the next decade....This new Merck will be built for the new era that our industry has entered."

In this environment, companies need a new competitive model to outperform rivals and thrive in these challenging conditions.

Here are five examples of such models that demonstrate winning approaches:

Technology Model: Beginning with its majority ownership of biotechnology pioneer Genentech in 1990, Roche has leveraged its leadership in biotechnology –specifically monoclonal antibodies– to become the world's largest oncology company, with its $20 billion in pharmaceutical sales representing one-third of the industry's total in this category. The company is the global leader in tissue-based cancer diagnostics and cancer therapeutics, including

blockbusters Herceptin (breast cancer), Avastin (colon and lung), and Rituxan (blood cancers). According to market research firm Evaluate Pharma, Roche is expected to dominant oncology, the industry's biggest therapeutic area, for at least the next five years.

Diversification Model: Beginning in the mid-1990s, Novartis adopted a "focused diversification portfolio" strategy by incorporating pharmaceuticals, vaccines, generics, and consumer health. Novartis invested in new areas of health care, such as generics and eye-care, highlighted by its $52 billion acquisition of US eye-care company Alcon. According to CEO Joseph Jimenez, "A broad, diversified portfolio is going to become increasingly important as more and more payers look for low-cost generics and preventive vaccines as complements to innovative pharmaceuticals." By leveraging this unique competitive model, Novartis will generate sales exceeding $60 billion and become the world's largest pharmaceutical company by 2017, according to First Word.

Specialization Model: Gilead Sciences (viral infections), Novo Nordisk (diabetes), and a number of other pharmaceutical companies have built dominating disease specialty companies. Gilead, the current leader in anti-HIV product sales, is expected to command over 40% share of the anti-viral market by 2018 by adding new Hepatitis C anti-viral agents. Similarly, Novo's insulin and non-insulin (Victoza) franchises will represent nearly 30% of the entire global diabetes market over the next five years. Such focused disease models offer numerous competitive advantages, including product portfolio co-positioning and segmentation; potential portfolio product combinations; enhanced corporate reputation and recognition; potential pricing and contracting leverage; substantive, longer-term relationships with key stakeholders, including regulators, thought leaders, and prescribers; and better business development and licensing opportunities. A 2011 Oliver Wyman study revealed that leading disease specialty companies complete 2.2 times more business development deals, achieve 70% higher development success rates, and generate 5.5 times more revenue than non-specialty companies.

Execution Model: Teva Pharmaceuticals has become the world's largest generic company by relentlessly focusing on better execution to outperform its rivals. Over the past fifteen years, the company has been the global leader in acquiring and integrating numerous generic manufacturers, including Taiya, Barr Pharmaceuticals, IVAX, Scios, Novopharma, Copley, and Ratiopharm, a pivotal European player for which Teva beat out Pfizer, the world's largest pharma company. In the U.S., Teva routinely beats its generic rivals to market by filing Abbreviated New Drug Applications ("ANDAs") for its generic products much earlier and with fewer revisions than competitors. Teva has been an implementation innovator in supply chain management, information technology, and research and development. For example, Teva effectively developed its branded Multiple Sclerosis blockbuster Copaxone for one-fifth of the average cost of innovative products. The company is increasingly leveraging its efficiency model for developing and commercializing other innovative products as demonstrated by its recent investments in Cephalon and CureTech. Execution excellence has catapulted Teva this year into the top ten of global pharma companies, according to Evaluate Pharma.

Virtual Outsourcing Model: Several biopharma companies have adopted a competitive model characterized by a small number of full-time employees directing a virtual network of support vendors responsible for core corporate functions. In 2006, NPS Pharmaceuticals was a floundering, nearly bankrupt biopharma company with over 400 employees, a failed lead development product, and four research and operational facilities. New CEO Francois Nader dramatically transformed NPS into a virtual pharma company by outsourcing most of its non-core functions to third-parties. NPS closed all but one of its facilities, including its research laboratories and original headquarters in Salt Lake City, effectively eliminating the firm's discovery, manufacturing, and commercial operations. Nader slashed the workforce to 40 people and focused on the development of two key orphan drugs. Today, NPS is a thriving competitor which recently gained FDA and European approval of Gattex, a treatment for short bowel syndrome, and is submitting a Biologic License Application (BLA) to the FDA in the 2nd half of 2013 for Natpara, a novel treatment of adult hypoparathyroidism. The company recently regained the worldwide rights to these two products from Takeda, making the company a global player in the orphan diseases space. Similarly, Ferrokin Biosciences was a virtual pharma company comprised of seven home-based employees who for several years directed an outsourced group of 60 vendors and contractors developing a novel, once-daily, oral iron chelator for treating transfusional iron overload. In March, 2013, Shire Pharmaceuticals bought the highly successful virtual biotech company in a deal valued potentially at over $300 million.

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The #1 Global Competition Consulting Firm for the Pharmaceutical Industry

Headquartered in Morristown, N.J.
Founded in 1999

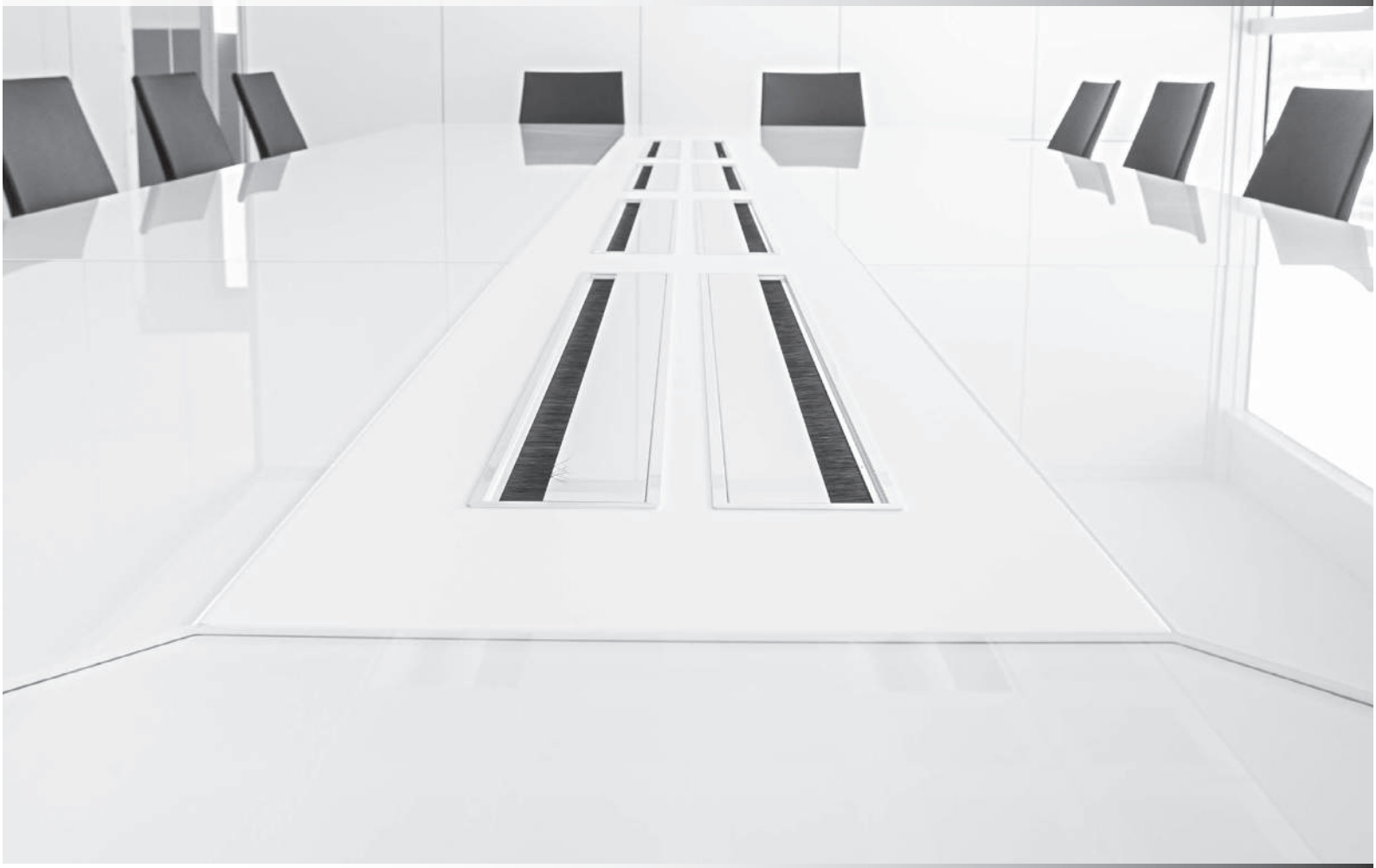
Mission: ***Helping Clients Win***

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



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