PHOTO: ISTOCK

NICHES TO RICHES

Specialty biopharma firms are using razor-sharp therapeutic focus to target "niche buster" categories. As **Noah Pines** discovers, their strategy is paying significant dividends

Gilead Sciences' corporate strategy under CEO John Martin looks more like that of General Electric during Jack Welch's tenure than that of a traditional life-science firm. Like Welch, who grew GE by tearing down many of its existing businesses, Gilead has taken a similarly relentless tack to growing its antiviral medicines business. Martin's no "Neutron Jack," but his California company is blowing up a traditional pharma paradigm.

Consider that in 2008, with Hepsera, its tablet for hepatitis B, enjoying a strong position behind Bristol-Myers Squibb's best-selling Baraclude, Gilead won approval for HIV drug Viread to treat hep. B. That approval put Gilead into direct competition with Hepsera—a full six years before Hepsera's patent is scheduled to expire. Gilead has been doing the same thing with its HIV franchise as well, launching Complera and filing the "Quad pill" for approval in 2011, despite the fact that it has Atripla exclusivity locked up until 2021.

"Gilead cannibalizes Gilead," explains Rick Wantiez, PhD, Gilead's director of market research for commercial operations, Americas. "Our CEO says it best: 'Come out with something better all the time, even if what's better is what you already have. Keep moving the ball forward.'"

Competing with themselves to build tomorrow's innovations, even years prior to patent expiry, is just one example of specialty biopharma firms' razor-sharp focus. In Gilead's case, adds Wantiez, the firm has "operationalized focus by continually improving the science."

Strategies like theirs are paying significant dividends. Specialty drug costs increased 15.2% in 2010, according to pharmacy benefits manager (PBM) informedRx, more than five times the increase for overall prescription drug spending. "With a full drug pipeline, increased utilization and relatively little generic competition, specialty medications are expected to garner an increasingly larger share of the overall drug market over the next decade," the PBM noted in a trend report.

Specialty medicines—defined simply as drugs that are predominantly for not-so-common diseases and treated by specialist physicians—may offer the bigger and nearer-term payoff as the industry weathers a period where drugs that are being discovered in the labs are not replacing the value of those medicines losing patent protection. The therapeutic categories they encompass include oncology, virology, neurology, as well as rare diseases, in contrast to mainstream PCP-treated ailments like hypertension, diabetes and asthma.

According to a 2011 review from the IMS Institute fof Healthcare Informatics cited by the Sanford Bernstein analyst Tim Anderson, only about 55% of total drug spending, or $170 billion out of $300 billion, went to primary care medicines. The specialty trend is being driven by breakthroughs in genomics, accelerated development of targeted therapeutics and improvements in genetic testing to facilitate personalized medicine approaches.

From Mercedes to Mini

So-called specialty pharma companies have no monopoly on the business, though. Big pharma companies have moved in, including Pfizer, which recently won approval for personalized lung cancer drug Xalkori (crizotinib), and Johnson & Johnson, which is co-marketing Incivek/Incivo (telaprevir) for hep. C.

"It would seem that the future of pharma and specialty drugs are

The specialty sell: meat-and-potatoes meets Madison Ave.

Companies that have successfully pioneered the specialty business recognize that providing thorough, comprehensive scientific knowledge trumps simply having a catchy, Madison-Ave. sound byte.

Specialty brands typically field smaller sales organizations and need to reach smaller target audiences. Personal interactions between customers and field reps remain of high value and are arguably more crucial considering how difficult it can be to reach a tight-knit group of specialists.


Jonathan Peischl

"Each and every interaction must carry high value to the customer and the brand, demanding innovation in the programs and tools utilized by the field team," says Jonathan Peischl, SVP, director of innovation & digital marketing, Giant Creative Strategy.

In targeting specialists, it is necessary for pharmaceutical companies to recognize that their reps will be standing in front of doctors who have more knowledge than they do, and who thus demand rigorous, evidence-based promotion. In this model of specialty-focused selling, the tenor of the conversation is likely to be far more clinically oriented, with reps needing to be equipped to answer complex questions about size and structure of clinical trials, study endpoints, and a wide spectrum of potential safety-related questions.

Reps often serve in a more consultative role, says Peischl. "It's less about 'closing the deal' and more about demonstrating commitment and support, often tailored to the needs of the individual patient."

Also, it is advantageous to spend more time with a physician over the course of fewer calls. This way, the rep can be more thorough and delve further into the scientific detail vs. skating over a series of superficial messages over more visits (as was the previous model). Not only that, the physician actually may give the rep more time when they are carrying scientific (vs. marketing) cargo—often using digital devices like the iPad.

Despite the need for high-minded promotions, clarity and simplicity in communication are still reigning principles. And while promotional concept takes a backseat to data during the sales call, visual identity is still a vital part of the mix.

"Brand promotion in a specialty market should also live up to the same fundamental principles we apply to primary care promotion," says AbelsonTaylor's Nancy Drescher, "in that it needs to be relevant, distinct, emotional, quick and campaignable, in order to establish a brand identity and differentiate from competitive products."


Nancy Drescher

Says Drescher, who is SVP, director of client services for the agency, the brand identity "is still necessary within the promotion to remind physicians, when they are experiencing the brand in other media, of the persuasive sales message they receive from their sales rep."

Smaller marketing and sales budgets are another differentiator. While the blockbuster brands of yesterday depended heavily on driving demand through expensive mass-media DTC promotion, more limited, often shoestring budgets are typically brought to bear for specialty products to effectively reach smaller target audiences of patients/caregivers.

There's an inherent paradox to having fewer marketing and sales dollars to promote what can be a very pricy product. Agency partners say the leaner budgets just make them more integral to the brand team.

"These types of restrictions require agencies to think about efficient [ways to] reach our customers where they are already going, so we are able to maximize reach with a lower spend," says Drescher. "It is also critical to identify the one or two core challenges we need to overcome with our customers, so that we can focus the more costly, innovative solutions on addressing those challenges."


Khawar Khokhar

Striking the right note in communications and ensuring the quality of MD-rep conversations are not the only areas of focus. Demonstrating the holistic value proposition of products to payer customers is no slam dunk, says Khawar Khokhar, chief access officer at Havas Worldwide Health. "In addition to smarter management of clients' ever shrinking budgets, agencies have to align their structure with the demands of the multi-stakeholder healthcare environment," says Khawar, a pharmacist in charge of advising clients on payer strategy. "Offering truly unified, not just integrated, services and industry-leading practices focused on HCPs, payers, and consumers is an absolute necessity."

really one and the same," notes Jim Heasley, PhD, principal, Evolution Marketing Research. "If nothing else, the increasing cost of healthcare is driving most non-specialty drugs toward generic use."

Indeed, the patent cliff of 2010-2013 is relocating the industry sweet spot toward building a portfolio of smaller products—whether through internal development or, more likely, acquisition. There are hundreds of innovative new specialty medicines coming to market in the next decade. Upwards of six in 10 of the more than 750 drug pipeline contenders are specialty medicines, many of which are focused on diseases of aging such as cancer and neurodegenerative diseases, as well as unmet treatment areas like multiple sclerosis, according to informedRx.

The global pharmaceutical industry is several years deep into this fundamental overhaul in strategy, from the Mercedes Benz of pharma—the PCP-prescribed small-molecule blockbuster brand for common ailments sold by vast armies of field representatives—to the Mini Cooper, the "niche buster" asset focused on a smaller patient population.

One big advantage of the shift is the opportunity to focus a company's marketing and sales efforts on a smaller provider audience. Companies can train, deploy and support fewer reps, and support them with lower marketing support expenditure.

As Wantiez points out, "From a strategic standpoint, [Gilead] can better meet unmet treatment needs when there is a more defined audience and patient population. We are better able to provide good science and good scientific discussion with customers—and we don't need a primary care salesforce of 600 reps. You can know your science and talk intelligently to doctors with 100 reps."

Add to that the benefit of lower R&D costs. Derek Fetzer, director, global strategic analytics/global strategic marketing & market access, at Janssen Pharmaceutical Services, says that this made it worthwhile for a big firm like J&J to make a move into the specialty arena: "Improving on the many good drugs on the market is a significant, technical challenge," he observes. "This is because demonstrating smaller, incremental benefits actually requires more patients in a clinical study, from a statistical point of view, and thus is more costly."

Compared to PCP-focused candidates, specialty medicine clinical development can be not only less expensive but offer a nearer-term opportunity for cashing-in on an investment. Specialty medicine

candidates typically are vetted by big pharma along the dimensions of demonstrating substantial innovation, where R&D efforts can require fewer patients and significant differences can be demonstrated over a shorter period of time.

There are regulatory rewards, too. The most prominent "X-factor" in new drugs—the FDA—displays more love toward products that aspire to occupy salient treatment voids as opposed to those gaining incremental yardage vs. existing therapy. Indeed, this is an essential element of FDA's charter.

"One central factor FDA takes into account in determining the speed of review of a new product application is whether it addresses an unmet medical need, hence potentially translating into shorter time to market," says Wayne Pines, former FDA associate commissioner, who is now president of regulatory services and healthcare for APCO Worldwide. "A usual review is 10 months and a fast-track or priority review is six months or less."

Xalkori, the Pfizer lung cancer drug which earned accelerated approval, is a prime example of this. Even better, drugs for rare illnesses that can attain orphan drug status are granted seven years of marketing exclusivity in addition to being eligible for certain clinical-trial tax incentives.

According to PhRMA, there are over 450 medicines in development for the 25-30 million Americans who have been diagnosed with rare diseases (diseases of low incidence that affect <200,000 people), with key areas of research being rare cancers (e.g., tumors of the liver and thyroid, hematologic malignancies and melanoma).

As the negotiating power of insurance companies burgeons, developing new and novel therapies also helps to buttress the drug developers' pricing posture. In primary care markets, companies have seen themselves at risk or more vulnerable to pricing erosion.

"Smart companies recognize the challenges early and make sure that access is provided"

— Harris Kaplan

As Healogix CEO Harris Kaplan remarks, "Payers may also be less of a concern because the overall cost associated with treating a condition multiplied by the number of patients may not warrant the rigorous scrutiny that accompanies new and expensive therapies in more widespread conditions."

Yet drugmakers must still show value and work with payers to ensure access. As major non-specialty brand drugs become available as lower-cost generics, specialty plan spending is projected to grow from 18% of total pharmacy costs in 2010 to 43% of total costs by 2020, according to informedRx. Along the way, the rankings of specialty drugs, like Amgen/Pfizer's Enbrel and Amgen's Neulasta, are expected to grow from five of the top 16 drugs in 2009 to 11 of 16 by 2012.

Expanded indications for current biologic and small-molecule products could increase specialty utilization further, notes informedRx. This effectively expands the population of patients eligible for therapy with these agents. Many of the expanded indications can be significant because they represent novel and/or more convenient approaches to treatment of chronic conditions. Of course, new specialty entries may also boost utilization.

Given MCOs' growing awareness of the contribution of specialty medicines to prescription drug costs, the need to demonstrate the value of these therapies is becoming ever more salient.

With payers increasingly cordoning off specialty medicines, especially injectable biological therapies, to special formularies, making sure that access provisions are in place is paramount. Nothing frustrates a physician more than being detailed on an exciting and innovative new therapy, only to be hassled over or denied coverage for it by the patient's insurance carrier.

Says Kaplan: "Smart companies recognize the challenges early and make sure that access is provided, either through patient assistance programs or helping physicians navigate directly with payers to help their patients receive the product and care they want them to have."

The years ahead will bring specialty care pharmaceuticals to the forefront, both for companies that are in the trenches of specialty and those just breaching its borders. The massive land battles of primary care are long gone. Similar to the way modern warfare has progressed, from having the biggest firepower or arsenal to being able to intelligently deploy special forces and unmanned drones, the hot industry strategy is that of specialty medicines and innovative, targeted therapeutics to solve unmet medical needs and to address rare diseases. ■

Singular focus spurs deal-making frenzy

The imperative to maintain dominance in therapeutic markets is driving furious deal-making among specialty firms, such as that seen in the recent hepatitis C (HCV) feeding frenzy. Portfolio strategy within a given disease state is essential to these companies, especially in areas of rapid innovation like HCV.

Gilead's $11-billion dollar acquisition of Pharmasset and Bristol-Myers Squibb's $2.5-billion purchase of Inhibitex are being driven by companies' recognition that the opportunity is vast, the unmet need great and the winning candidates in short supply.

As Healogix CEO Harris Kaplan points out, "If having a portfolio of products to market to a singular audience is a path to financial leverage and profitability, then companies need to be very active in seeking out complementary product assets that can help diversify revenues and spread sales and marketing costs. In our experience, specialty pharma companies are often able to move more quickly, because they can spot the potential opportunity more quickly and the size of the opportunity doesn't have to be as large to make sense as it might for a big pharma."