

From **BLOCKBUSTER** to *Specialty Sales*



Specialty pharma companies that solely focus on drugs targeted to a specific group of patients are seizing the opportunity to make inroads into physician prescribing practices by carefully tailoring their sales and marketing activities.

It seems as if all aspects of the pharmaceutical industry are transitioning from a blockbuster to a micro or niche approach. Marketing is becoming more targeted; primary care sales forces are being diminished; and companies' pipelines are increasingly addressing more narrow diseases and specialty areas. The reasons for this transition are many and have been well-noted over the last year or so, but the two biggest factors are the number of small- and large-molecule blockbuster drugs losing patent protection and the continuing issue of diminishing access to primary-care physicians.

These factors, as well as a growing demand to address unmet medical needs, are turning the focus to specialty drugs. Specialty drugs are mainly prescribed by clinical specialists and aimed at defined patient groups. In many cases, specialty products address large unmet needs. Examples of specialty indications include infertility, gout, cystic fibrosis, pancreatic insufficiency, vitamin deficiencies, bipolar disorder, multiple sclerosis, and fibromyalgia.

"The area of specialty products should be in the vanguard of the pharmaceutical industry in making the transition from traditional relationship marketing to one that is defined by scientific and clinical value," says Bill Cooney, president and CEO of MedPoint Communications. "This is an area that is evolving and the main market for specialty products, the hospital market, is far ahead of physician offices and clinics.

FACT

THE GROWING U.S. SPECIALTY PHARMACEUTICALS MARKET IS COMPRISED OF MORE THAN 90 COMPANIES MARKETING MORE THAN 550 PRESCRIPTION PHARMACEUTICAL PRODUCTS.

Source: MCD Group

Hospitals are transforming themselves so that pharmaceutical reps can only gain access if they can bring value to the organization."

Consultant MCD Group has identified more than 80 companies actively participating in the specialty pharma space. These companies range in size, from very small (five employees) to very large (1,000-plus employees), but all are actively developing or marketing specialty pharmaceutical products.

The U.S. specialty pharmaceuticals market had an approximate value of \$21 billion in 2009, according to MCD Group. Companies active in the specialty pharma sector typically have small to medium-sized sales forces that promote products with annual sales of less than \$200 million, although there are exceptions.

And experts say these sales forces will re-

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quire a different type of marketing and sales rep — both of which will require a higher level of scientific and product knowledge.

"Specialty pharmaceutical companies are generally focused on only a few therapeutic categories, sometimes as few as one or two specialty indications," Mr. Cooney says. "These companies often have well-trained sales representatives who call on specialty physicians, such as allergists, psychiatrists, endocrinologists, or pain management physicians."

Currently, there are more than 550 specialty pharmaceutical products marketed in the United States, according to MCD Group. The categories with the largest number of marketed

products are women's health (about 90 products) and dermatology (about 130 products). Overall, the top-selling specialty pharmaceutical products in 2009 were products for pain, sleep disorders, opioid dependence, and ADHD. The top four therapeutic categories that generated the highest sales were pain management, CNS, ophthalmics, and dermatology.

James Datin, executive VP and managing director of Safeguard Scientifics, says because big pharmaceutical companies haven't been able to meet their pipeline, revenue, and financial guidances they are going to have to make further accretive acquisitions — a combination of specialty pharma companies along with biotech — to bring in marketed revenue-stage products." he says.

"There is also a growing field of midmarket pharma companies as well that have been fairly active in M&A," Mr. Datin says. "A lot of these companies are stock piling cash and with an improving economy, and they should be in a position to get capital or debt to acquire other companies."

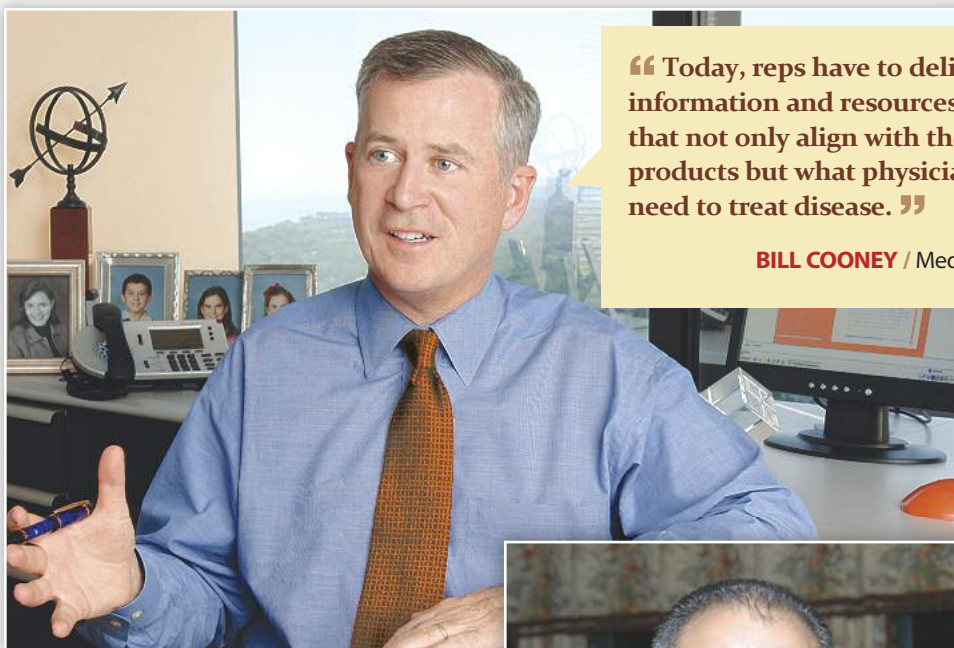
The biggest concern in the marketplace right now is the issue of the pipeline, and companies have to do something to perpetuate their five-year cycle of getting products through the pipeline, says Bill Abajian, senior executive advisor for global licensing and business development, at Genex Biotechnology.

"Big pharma companies have to evaluate smaller companies to supplement their back-office R&D development; they are looking to either acquire or license, as a way to move the pipeline forward," he says. "For example, we have a product called Oral-lyn, which is a buccal delivery of insulin through our RapidMist delivery system. This is not just a product; it's a platform technology that delivers molecules through the inner lining of the mouth. By adding a delivery technology platform, companies can enhance the sales viability of a new drug or a drug coming off patent."

The Specialty Sales Force

Biopharmaceutical sales forces focused on specialists and hospitals are expected to grow by about 10% to 20% in the next two years, according to a recent study by Cutting Edge Information. In recent years, there has been contraction that resulted in the cutting of thousands of reps from industry rosters, but highly targeted sales groups have ridden out the storm — and are poised to respond to the building momentum.

According to the report, 53% of hospital sales forces and 30% of specialty forces intend to expand, while only 5% plan any cutbacks.



“ Today, reps have to deliver information and resources that not only align with their products but what physicians need to treat disease. ”

BILL COONEY / MedPoint

FACT

THE U.S. SPECIALTY PHARMACEUTICALS MARKET WAS VALUED AT \$21 BILLION IN 2009.

Source: MCD Group

A handful of sales teams even plan to double in size.

Harris Kaplan, CEO of Healogix, points out that marketing to this space relative to marketing to primary care is a more recent proposition for pharma companies, and they are testing different approaches.

"One company has taken a portion of its representatives and trained them to be information specialists," he says. "Their job is to support the representative within a particular geographic area and act almost like an 'MSL lite.' Another approach is to move primary care reps to specialty products. Regardless of the approach, however, all the reps are going to need a higher level of medical and product knowledge. This creates an opportunity because if the rep really is knowledgeable, he or she can have a better dialogue with the physician and better understand how a particular product is going to meet that physician's needs and the needs of that patient."

Mr. Kaplan points out that this specialty sales model is different from the primary-care sales model.

"Mirrored sales forces are going away," he says. "In a mirrored sales force, one representative talks to Dr. Jones about Brand A, for example, and another product. A second rep will



“ The biggest concern in the marketplace right now is the pipeline. If pharma companies can use a different or a proven delivery platform, they can enhance their pipelines and the sales viability of their drugs. ”

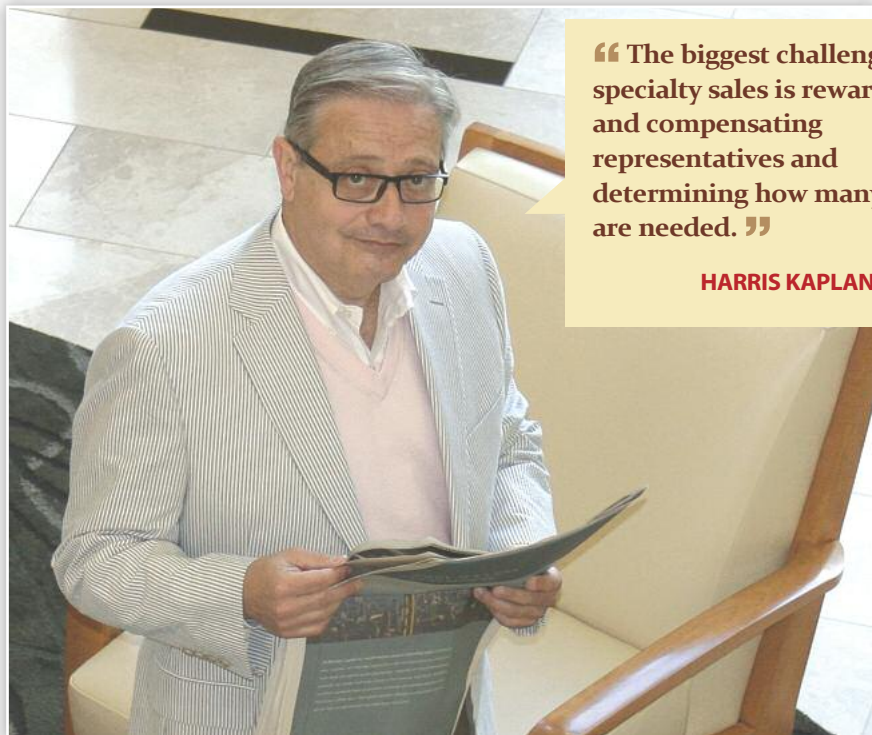
BILL ABAJIAN / Genex

come in to talk about Brand A but will also talk about a third product. This is referred to as a mirrored sales force, and the idea was to maximize the number of calls to one physician for Brand A by adding different second and third products into the detail. The beauty of the primary care model is that if reps got in front of the physician, they could talk to him about multiple drugs in multiple categories."

Mr. Kaplan says with a specialty sales force, there is more likely to be only one drug to amortize the cost of the sales call.

Mr. Cooney agrees, saying the marginal return on sales units may be smaller for many specialty drugs but a relatively small increase in units can be offset by high unit prices, making it a tenable business model.

"Companies may not be able to afford a specialty sales force for a true orphan drug," he says. "They will do the math to determine



“The biggest challenges with specialty sales is rewarding and compensating representatives and determining how many are needed.”

HARRIS KAPLAN / Healogix

whether the markets are big enough. There are plenty of specialty products where the markets and margins are big enough. In many cases, specialty sales reps can make a bigger contribution than traditional sales reps who don't have physician access.”

Mr. Kaplan says the bigger challenge is developing the right scale and compensation model for a specialty sales force.

“Companies need to figure out how they are going to reward and compensate specialty representatives and how many they need,” he says. “After about 12 to 18 months after a specialty product launch, a large specialty sales force may not be needed as the message has already been delivered to a more targeted and often smaller audience of specialists. Within primary care, there is a larger number of physicians who reps could continue to call on and they are detailed about many more products. It's more difficult to get a new product's message across.”

Creating Value

Experts agree the changing nature of sales forces provides an opportunity for pharmaceutical companies to bring scientific and clinical value to providers.

“Value can be defined in a lot of different ways,” Mr. Kaplan says. “For a physician, value may be in the form of pharmaceutical-provided materials to facilitate a dialogue with a patient. A second way to provide value is by answering questions physicians may have about the use of a drug in certain areas. A third scenario, might be helping physicians who are having problems getting a product

prescribed because managed markets or plans may have constraints.”

Large pharmaceutical companies have the national scale and scope to provide the value-added services providers might need, Mr. Cooney says.

“Even the largest healthcare systems are local and regional,” he says. “Pharma companies can partner with service providers to bring scientific and clinical value through programs that improve care. They can provide programs that measure and improve the quality of care, and help specialists connect with their peers.”

Craig Kephart, president and CEO of Centric Health Resources, says the sales model of

the future for specialty drugs will provide a way for the manufacturer to get closer to the patient.

“To achieve this goal, essentially the distribution channel has to collapse; manufacturers will need to actively engage with a specialty provider to provide the services that are required to support that drug,” he says. “They can follow that patient and maintain a relationship over time.

“If the margin is taken out of the equation, the value of the service, whether it be pharmacy nursing, adherence, compliance, health management, is reimbursed at a fair market value and is independent of drug margins,” Mr. Kephart says “This is a key way to think about how specialty plays in a healthcare reform environment, and whatever reform looks like, there will be a clear focus on value and outcomes.”

Mr. Kephart says manufacturers have an opportunity to create programs that will help health systems decrease costs and help physician practices show that they are managing the health of patients better.

“There is a real opportunity to show that pharmaceutical manufacturers can be a part of the healthcare system instead of a vendor to the healthcare system,” he says.

Mr. Cooney says reimbursement is a huge issue for specialty drugs.

“They are often less well-understood by payers, and sometimes payers have practices that are out of touch with the latest medicine,” he says. “Pharmaceutical companies should provide payers with the latest evidenced-based medicine, as well as the support of recognized experts in the field.”

Mr. Datin says reimbursement is going to be such an important factor that his company is not investing capital in companies unless there is a clear pathway for reimbursement, either a CPT code, or the model is defined.

EXPERTS



BILL ABAJIAN. Senior Executive Advisor for Global Licensing and Business Development, Genex Biotechnology Corp., which is

engaged in the research, development, and commercialization of drug delivery systems and technologies. For more information, visit genex.com.



BILL COONEY. President and CEO, MedPoint Communications Inc., a global provider of diversified

communications services for pharmaceutical and biotechnology companies. For more information, visit medpt.com.



JAMES DATIN. Executive VP and Managing Director, Safeguard Scientifics, which provides growth capital for entrepreneurial and innovative

life-sciences and technology companies. For more information, visit safeguard.com.



HARRIS KAPLAN. CEO, Healogix, a global healthcare marketing research and consulting firm. For more information, visit healogix.com.



CRAIG KEPHART. President and CEO, Centric Health Resources, a patient-centered health management organization, serving patients with

rare, ultra-orphan disorders. For more information, visit centrichealthresources.com.


Five Trends in Specialty Sales Forces

- » Contraction is done and moderate expansion is on the horizon for specialty and hospital sales forces. While most companies intend to keep their hospital and specialty sales forces steady in the next two years, a sizeable group — 30% of specialty sales forces and 50% of hospital sales forces — plan to expand.
- » Companies are identifying new skill requirements and incorporating them into hiring and training practices. The impending healthcare overall could mean great changes for pharma sales forces over the next several years. These changes will likely mean a shift in the skill sets generally possessed by top-line pharma reps.
- » Companies are supplementing and enhancing field reps' activities with e-detailing activities. Access is the greatest concern facing pharma sales reps, and companies are seeking new ways of earning touches with top-line customers.
- » Companies are adding managed care and reimbursement services to next-generation reps' arsenals. The next-generation sales rep will shine by going beyond the typical level of service and providing managed care and reimbursement support to their targets.
- » New field force tactics can help maximize sales calls. Pharmaceutical companies' efforts to reduce sales force mirroring, lower their ratios of reps to district managers, seek out reps with new skill sets, and arm reps with better technologies are showing signs of success.

Source: Cutting Edge Information. For more information, visit cuttingedgeinfo.com.

"In the past, it was a foregone conclusion that a product would be reimbursed," he says. "Now before we make any investments, we're in touch with CMS and several insurance carriers just to make sure that the reimbursement model has been measured."

Mr. Datin says specialty pharmaceutical companies need to focus on niche markets.

"There are too many players," he says. "Inherently, the insurance companies are going to drive the market with a competitive bidding process and they are narrowing the categories. They are going to look for like-minded products, and the lowest cost will become the standard. A company can't enter a crowded market unless its product is very differentiated." 



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