Bill McLean, VP of sales, Daiichi Sankyo

PHOTO: BILL BERNSTEIN

SP

Seeking a share of the primary care market, specialty and biotech firms are filling the void being vacated by Big Pharma. **Marc Iskowitz** on some of the strategies and tactics they employ to engage customers and maximize sales budgets

As pressure mounts to rein in selling costs, large pharma companies have sacrificed an old standby on the altar of bottom-line profitability—face-to-face time with primary care doctors. It's been well documented how firms like Pfizer, AstraZeneca and Bristol-Myers Squibb, among others, have slashed legions of sales reps once employed to call on general practitioners, as their mass-market brands approach, and fall over, the patent cliff.

As many in Big Pharma flee the market, in many cases toward specialty drugs, their smaller cousins—specialty pharma firms and some biotechs—are going in the opposite direction, expanding investment to engage generalists, medicine's front line treating everything from hypertension and metabolic disease to pain, osteoporosis, heartburn and other conditions.

Daiichi Sankyo Inc. (DSI) is a good example. The firm had about 450 reps in 2001 and, after a four-fold increase the last decade, today fields roughly 1,700 sales people to deliver product details about its cardiovascular portfolio. On the sales force scale, that puts DSI somewhere between a Merck and a tiny player. Indeed, DSI fits the classic profile of a specialty company yet has a big presence in primary care.

"We are never going to be as large as our com-

petition by pure numbers, ever," says Bill McLean, VP of sales at the New Jersey company. "And from the time that I've been here, we've always probably been undersized for the market that we've been into. But we've always been very successful because of one, the people we hire and two, the investment we make in training."

A formula for winning

Independent feedback from general practitioners and specialists suggests that this formula is working. DSI got very high marks in a survey in which the top sales forces were those that provided the highest-quality information, often to a smaller group of doctors. "It wasn't necessarily the biggest companies with the most feet on the street," says Jerry Maynor, US marketing and business development director, Cegedim Strategic Data, which ran the survey.

DSI's commercial operation beat out others based on the strength of information its reps deliver and their relationships with physicians and their staffs. "The companies that can bring value in and work very closely in those offices…are the ones that will win," explains McLean. "No longer will you be able to get overwhelmed and outgunned by larger companies."

That's an object lesson for a host of smaller firms looking to gain a foothold in the space. Map Pharmaceuticals has a migraine drug awaiting approval, the orally inhaled Levadex, as does NuPathe with its migraine patch Zelrix. Orexigen, which is partnered with Takeda, is knocking on FDA's door again, having reinitiated development of obesity drug Contrave in September. Among bigger biotechs, Roche/Genentech's dalcetrapib for raising "good" cholesterol and aleglitazar for diabetes are both in Phase III testing, while Amgen entered the primary care market in 2010 by launching Prolia for osteoporosis.

"The most effective sales forces weren't necessarily the biggest companies with the most feet on the street"

—Jerry Maynor, Cegedim Strategic Data

One of the challenges for Big Pharma has been its broad marketing and product focus. Since 2006, as many drugmakers have restructured and prepared for the loss of blockbuster business amid a productivity drought, the majors have been trying to determine the right mix of sales and marketing for their mature mass-market brands. Sales forces for the top 40 pharmas have shrunk 26%, from a peak of 101,734 in 2005 to 75,278 in 2010, according to SDI data. Industry has continued to trim commercial operations in 2011 and, considering the $50-billion patent cliff facing the industry over the next three years, don't look for the trend to come to an abrupt halt anytime soon.

Yet, even AstraZeneca's David Snow, VP of the firm's Cornerstone business unit—who has shown that the company can hold its own in primary care with less face-to-face detailing for one of its flagship brands, heartburn drug Nexium—acknowledged the power

ECIAL FORCE

of the in-person pitch. "In changing the model, the thing I want to emphasize," he said at a marketing conference in September, "is that there's still no significant commercial tool that we've got that's more impactful than personal selling. It's still a huge impact."

Considering his remarks on the potency of direct selling, and since biopharma cannot avoid primary care, the question has become how to grab a piece of this market with a budget that's often a shadow of what it was in the go-go 1990s.

"We all know how to engage primary care when you have Lipitor, because it's easy—you target everyone, and the money's there," says Michael Luby, a former Merck marketing exec who is now CEO of BioPharma Alliance, a pharmaceutical consulting firm. "But how do you target primary care with a smaller drug where you don't have the prescribing density and the sheer volume? You have to make harder choices about where to engage and how to deploy your resources. That's the question that's perplexing the industry at all levels right now."

Smart and focused

Smaller companies like DSI think they have an answer: "It's being very smart and focused on who our customers are," explains McLean. In addition to ensuring it reaches the right physicians, DSI has evolved its sales model over the last few years to a bottom-up system that can be tweaked to react to changes in physician demographics. "If there's a market event that takes place in a local territory or district, we can quickly change the information or emphasis of the products we sell in those markets."

In addition to primary care docs, DSI reps call on cardiologists, interventional cardiologists, endocrinologists and nephrologists, and with the firm spending nearly $250 million a year to deliver details, they're expected to know their stuff. In 2008 the company completed its Learning and Conference Center, an impressive facility located near its main campus in Parsippany, NJ, designed to provide new hires with a solid foundation on the hypertension franchise: Benicar, Benicar HCT, Azor and Tribenzor. The company also markets Welchol to lower lipids as well as diabetes. (A separate specialty force promotes the antiplatelet medicine Effient through a co-promotion deal with Eli Lilly.) Pipeline drug edoxaban, a factor Xa inhibitor, could take DSI even further into the primary care arena.

"How do you target primary care with a smaller drug? Make harder choices about where to engage and deploy resources."

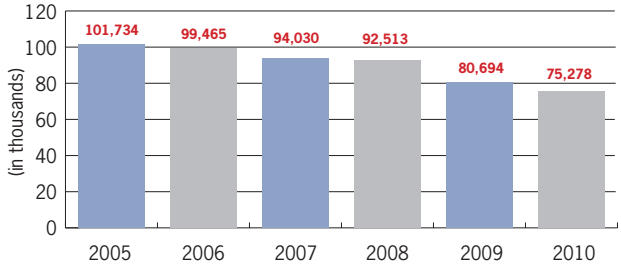
—Michael Luby, BioPharma Alliance

Experts from the American Society of Hypertension (ASH) are tapped to imbue a deep understanding, and DSI reps passing a written exam are minted as ASH-certified. Complementing new technology—iPads are standard issue for all its reps now—training adds the substance needed to carry on meaningful two-way conversations with physicians and their staff on products, disease state and healthcare as a whole.

McLean says his reps usually get a warm reception. As DSI's own customer surveys show, "we've had a lot of success in getting the message that Marketing wants us to get out to our customers."

Withering sales forces

US sales force counts for the top 40 pharmas are off 26% from their 2005 peak



Source: SDI's Sales Force Structures & Strategies

Putting an even greater premium on skill- and relationship-building is the added difficulty for reps to gain access to primary care physicians today. The most recent reading places 12% of physicians in the "highly restricted access" group. Six months ago that was 11%. Three years ago it was only 7%, according to data from ZS Associates' AccessMonitor. "At the aggregate level, we see a small but continued erosion in physician access," reports Chris Wright, managing principal for the firm.

Tiered selling and contract reps

That hasn't scared Somaxon Pharmaceuticals from entering the primary care fray. Countering the Big Pharma in-licensing model that has largely prevailed the last 10 years, the company took its Rx insomnia drug Silenor, approved in 2010, all the way through to commercialization, albeit with mixed results.

To overcome the challenges of selling its own product without a mature commercial infrastructure, Somaxon partnered with Procter & Gamble in a tiered approach. P&G's 105-strong primary care force helped out during year one of the launch, focusing on the retail side and also covering some lower-tier physicians that wouldn't have warranted a full-time rep. P&G helped obtain distribution of Silenor down to an individual retail pharmacy store level.

Somaxon focused on high-decile doctors. Employing a strategy oft-used by companies for products later in their lifecycle, it contracted for another 140 reps from Publicis Touchpoint Solutions. In October the firm announced that most of the contracted reps would be converted to full-time Somaxon employees by the fourth quarter or early next year. Sales for Silenor, a branded version of the long-generic antidepressant doxepin, haven't exactly been on fire, though, and the firm is planning an Rx-to-OTC switch.

In the meantime, Somaxon, like DSI, has narrowly drawn its market, prioritized training and hired 25-year pharma veteran Michael Allen as SVP, sales and marketing. "The past year we've really refined our targeting," says Allen. "We understand who the primary care physicians are who are our target audience. Now it's about driving execution through the course of the product lifecycle."

Decisions on which subset of the national PCP market are detail-worthy must go beyond strictly the volume of prescriptions, Allen says. Other elements come into play: the type of practice, its location and "other healthcare market forces" unique to individual physicians. Reps should be geared to act as a resource for the entire office, from

the nursing staff to the people who handle billing questions.

"Overall those healthcare professionals working in physician offices... a rep certainly has to add real value for them and a big part of that is education about a product and the therapeutic category, and prescribing information, published data, etc., but also educational tools that they can use with patients, information and tools that can help them in the increasing amount of time they spend talking to payers. When you deliver that, you're seen as an allied part of that office. That's the goal for us."

Companies like Somaxon and DSI are boldly going into primary care, as a broader commercial shakeup plays out slowly across the industry. With a lack of new products to replace aging blockbusters, pharma is seeking to keep SG&A costs in line with lower revenue to help deliver bottom-line savings for Wall Street. That means most if not all of the majors now field a leaner sales corps, and many augment it with e-detailing and other non-personal promotion.

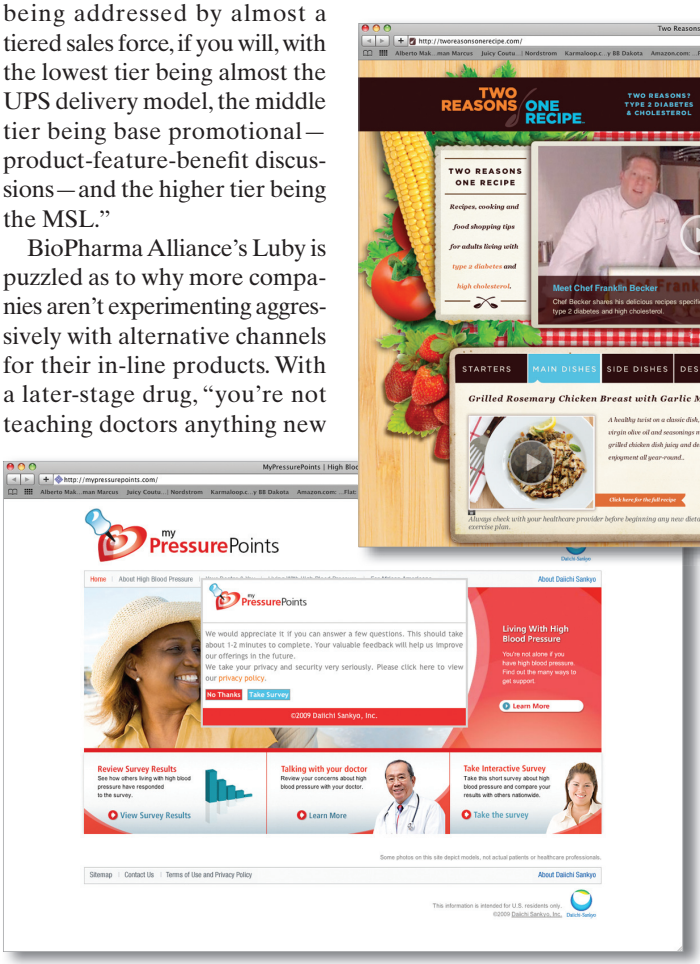
Flex forces, which can be ramped up or down as the need arises, are set to grow, as are tiered selling approaches, at least among Big Pharma, says Craig Robertson, partner and global lead for the life sciences market at consultancy Accenture. "There's a greater focus on medical science liaisons (MSLs) and a focus on specialists going forward, with the continued need for samples in the office being addressed by almost a tiered sales force, if you will, with the lowest tier being almost the UPS delivery model, the middle tier being base promotional—product-feature-benefit discussions—and the higher tier being the MSL."

BioPharma Alliance's Luby is puzzled as to why more companies aren't experimenting aggressively with alternative channels for their in-line products. With a later-stage drug, "you're not teaching doctors anything new anymore," he explains. "Pharmaceutical companies have a hard time admitting that. So, do I need an early 20-something, $200,000/year fully loaded person to go out and educate? No. You could have a very low-paid person go and drop off samples."

That thinking may pan out for a big pharma, but it's almost anathema to a company like DSI. "Unlike other pharmaceutical companies that may have products that they can put on the shelf, we promote all of ours," says McLean. "And actually, even in a mature market like hypertension, there's still a lot of activity in that space, and we need to make sure that we have the correct share of voice to drive sales."

Nevertheless, says Robertson, "We're seeing companies continue to look at the customer interactions as, 'We need to get as many touches as we can, whether through the sales force or remote personal detailing or e-detailing, or some other inbound or outbound call center capacity.' They are looking for that ability to continue to maintain the share of voice but to do so through alternate channels."

Robertson calls it multiple channel marketing as opposed to multichannel, because "the integration of the sales force into the promotional mix of non-sales force channels really isn't there yet," he says. "There's a missed opportunity in the industry to bring those together and get some incremental value from changing that customer experience, which every physician is looking for—does this company understand who I am and are they responding to my needs?"



DSI blankets customers using the sales force and other touches. Website from recent Welchol "Two Reasons/One Recipe" campaign (top) and My Pressure Points hypertension support site (bottom)

'Surround sound'

DSI is working on that problem, too. Making the touchpoints less disjointed is the province of its relationship marketing team. Originally, marketing campaigns were targeted toward customers, and data collected seemed siloed and focused in on only a few channels. Today, DSI says its approach is a synergistic, multi-channel "surround sound" deployment, which becomes a series of touches communicating key messages to customers. The key word there is "series," since it usually takes multiple touches for customers to recognize a message and respond.

These series of touches are tailored messages delivered by campaigns and channels (i.e., sales force, iPads coupled with interactive visual aids, e-mail, direct mail, tele-detailing and sampling, websites and speaker events using nationally known physicians). The company says differentiated and tailored customer experiences can generate growth. The data and management of the process is facilitated by its campaign management database.

For example, a patient-relationship marketing website for Welchol, called the Welchol My Progress Program, offers online registration, integrated with Welchol.com; real-time integration with co-pay card activation; real-time integration with WelcholTracker.com; and patient segmentation and a tailored communication stream.

The database uses technology and automation to segment

Real change comes slowly to pharma sales ops

Despite all the ink spilled about the broken state of the pharma commercial model and how leaders are scrambling to innovate, change is not coming as fast, as profoundly or as dramatically as some would think. A systemic review of changes undertaken or planned by industry in the US shows that only three of 21 companies have recently reorganized their strategy, structure or process substantially, according to a report from TGaS Advisors.

About half anticipate a change in their commercial model approaches or ways of working, and only a third foresee a completely reworked organization by 2012.

"Overall, for most companies, the imperative for radical transformation continues to be on the distant horizon," wrote TGaS's Anna McClafferty, a VP and author of the report.

Most change will occur in the marketing discipline, she notes. Of course, many firms have been laying off large swaths of sales reps, but a downsizing effort, while significant in terms of its impact on people, is not in and of itself a true change, the report says. Most of these organizational structures remain relatively stable, near term.

That said, virtually all companies fully expect to develop new approaches to leveraging non-personal selling, multiple alternative communications channels and sophisticated customer relationship management (CRM) capabilities within three years, TGaS found.

In a few cases, industry has done more than just downsize. In 2005, with its Pravachol lipid med teetering at the edge of expiry, Bristol-Myers Squibb halved sales calls for the drug and told reps to call only on existing prescribers. Prescription rates for the drug held steady. Pfizer, laying off thousands of reps ahead of megablockbuster Lipitor's patent sunset—scheduled for this month—has been exploring alternatives for its established products, including white-space targeting, or using a halo of non-personal touchpoints.

One of the most visible examples of companies experimenting with changing their commercial model has been AstraZeneca's move, in late 2008, to start lowering the sales headcount for its $4.9 billion/year heartburn drug Nexium and replace it with a 300-person call center. By the end of 2009, virtually all detailing was eliminated, yet the company has been able to hold its sales line for Nexium through 2010.

The company also shifted a portion of its portfolio more toward bottom-line profitability. AZ created a late-stage, more mature product category called Cornerstone, where it could try alternatives to the large sales forces. The catalyst for the new unit was bringing Nexium, whose patent is due to expire in 2014, into the Cornerstone fold.

"While we continue to reduce the overall spending of Nexium, it didn't go away," said AstraZeneca's David Snow, VP of Cornerstone, in September at the DTC Performance-Based Marketing Summit. "We just changed the way we did it. A big part of it later on was how we resourced it from the large sales forces. We kept a lot of activity going on the marketing side but found a different way to represent the product in front of HCPs."

Why aren't there more examples of innovation involving flagship brands? Craig Robertson, partner and global lead for the life sciences market at consultancy Accenture, chalks it up to risk aversion. "The pain of not changing is not great enough to facilitate change yet," he says. More change is coming though, he predicts, as profits and operating income start to get squeezed and shareholders begin to demand it. Over the next 12-24 months, "I would speculate you will see significant, dramatic action… changing the customer-engagement model."

customers, provides tailored offerings and ultimately helps increase customer value and loyalty, hence builds a better relationship, says DSI.

As the use of alternate channels grows, and social media continues to be challenging for a regulated industry, e-detailing and closed-loop marketing capabilities are changing the game. "But what we are seeing is incremental change as opposed to transformative change," observes Robertson, "and that comes from a legacy of aversion to taking big risks in some of these areas."

Granted, branded leave-behinds have largely been left behind and "customer-centric" is now the rallying cry, perhaps most famously at GlaxoSmithKline, which decided to shift the criteria for rep bonuses from sales targets to service and value provided to customers.

Robertson says companies are taking a more deliberate approach to product-lifecycle planning, including Rx-to-OTC switches. "What we're seeing is this intent to actually think through that transition much earlier in the process to not miss the opportunities to maximize the value of particular products. Companies are now seeing mature brands as being part of a very strategic approach to extending revenue."

There have also been some new approaches to call patterns, direction and alignment for field selling teams; investment in digital marketing; and creation of special business units or groups to manage mature/end-of-lifecycle brands, says TGaS Advisors, which surveyed the extent of change in commercial models (see sidebar).

Wild cards, according to TGaS, are the extent and speed of new impact from payer pressure, health economics/outcomes research demands and comparative effectiveness hurdles. Some companies are interrogating their strategy, processes and investments in market access, asset valuation and pricing. Also unknown, says the benchmarking firm, is the extent to which the future regulatory and compliance environment will preclude today's vision of promotion and customer communication. "Some companies consider a scenario where regulatory and compliance factors will result in the dismantling of virtually all current approaches to promotion. These firms are proceeding cautiously with their investments in new promotion capabilities."

But, somewhat surprisingly, the model hasn't changed all that much. And as Big Pharma has significantly reduced its sales forces, a host of small- and mid-cap pharma and biotech firms are feeling newly emboldened to move into primary care. In some cases, TGaS found, "These companies' portfolios have been driving customer-focused strategies and tactics over time and have secured strong customer engagement by virtue of the products of value they offer. Their commercial models, particularly in the sales and reimbursement areas, have evolved over time to be fit for today and going into the future."

And two companies from the ranks of specialty pharma (the TGaS review included eight large-tier, eight mid-tier and five specialty firms) anticipate a highly stable period over the next three years with regard to their commercial model.

What does the future hold for DSI? "I don't see any significant [commercial] changes over the next three years, since we just changed our model," says McLean. He recognizes the changing landscape with regard to technology as well as the growing influence of payers but anticipates a stable period. That doesn't mean standing still. "We've been at this for a long time, grown a lot and never lost focus on what it takes to be successful." ■