



PHARMA Marketing

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*New regulations, advancing medical science and increasing patient knowledge are creating an inhospitable environment for traditional pharmaceutical marketing strategies.
It's time to develop a new drug marketing model.*

The pharmaceutical marketplace isn't the easiest arena for marketers to play. The regulatory climate is tough, and getting tougher. The science behind new drugs is changing, prompting a shift in strategy, and the target audience can be brain surgeons—busy brain surgeons. It's enough to make you want a Zoloft.

Not long ago, the marketing model for pharmaceutical manufacturers was relatively straightforward: "A company invested in research and development. It uncovered a pathway and discovered a drug that produced a good outcome," says Mark Goldstone, president of DDB Worldwide Healthcare, the healthcare marketing practice of New York-based DDB Worldwide Communications Group Inc. "The agencies took the innovation and made it into a simple message, and the rep would call on the doctor and say, 'Here's the information; here's the clinical study.' She'd take the doctor to lunch, give him a pen and send his family to Disney."

Those days are gone, replaced by an era in which the Food and Drug Administration (FDA) is tightening its regulatory grip on manufacturers and how they market their drugs. The agency is demanding more transparency and greater risk management from everyone involved in producing and marketing drugs, experts say.

But the FDA might be the least of manufacturers' worries. In the last decade, the Department of Justice and Office of the Inspector General have pursued cases of off-label promotion, or instances in which a drug company promotes a drug as a remedy for a condition or ailment that the drug has not been specifically approved to treat. The logic: If a drug company promotes off-label use, prompting a physician to prescribe off-label, and if the government reimburses the pharmacy as part of an entitlement program such as Medicaid or Medicare, it amounts to fraud against the federal government.

"That threat is very worrisome to every drug company and has had serious consequences in terms of how products are marketed," says Wayne Pines, a healthcare advertising expert and a former chief spokesman for the FDA who now chairs the advisory committee of the Center for Communication Compliance, a New York-based consultancy that helps companies navigate risk communication and regulatory compliance. "It's a very challenging environment these days," Pines says.

In November, GlaxoSmithKline paid a \$3 billion fine—the largest in history—to settle a series of federal investigations. The U.S. government had filed criminal and civil complaints that accused the pharma giant of off-label marketing, defrauding Medicaid and hiding important information about the diabetes drug Avandia, which has been shown to increase the risk of heart attacks. Settling is preferable to going to trial because companies found guilty can face exclusion—that is, they can no longer sell to the government—and given the government's starring role in healthcare these days, that's a serious threat.

As if the regulatory shifts weren't enough, the nature of scientific innovations also is changing. "Pharma was more focused on blockbusters [drugs with sales of more than \$1 billion annually] even 10 years ago," says Allen Adamson, managing director of the New York office of global branding firm Landor Associates, which counts pharma companies such as Eli Lilly and Pfizer as clients. "There are fewer big opportunities and more niche opportunities": refined disease areas with smaller patient populations and perhaps less competition. Cancer drugs are an excellent example: As researchers learn more about genetic indicators for different types of cancer, drug developers can tailor formulas to respond to genetic mutations that cause some forms of cancer. A drug called vemurafenib and marketed as Zelboraf by Swiss pharma firm Roche, for instance, prevents a genetic mutation called BRAF present in some—but not all—melanoma patients.

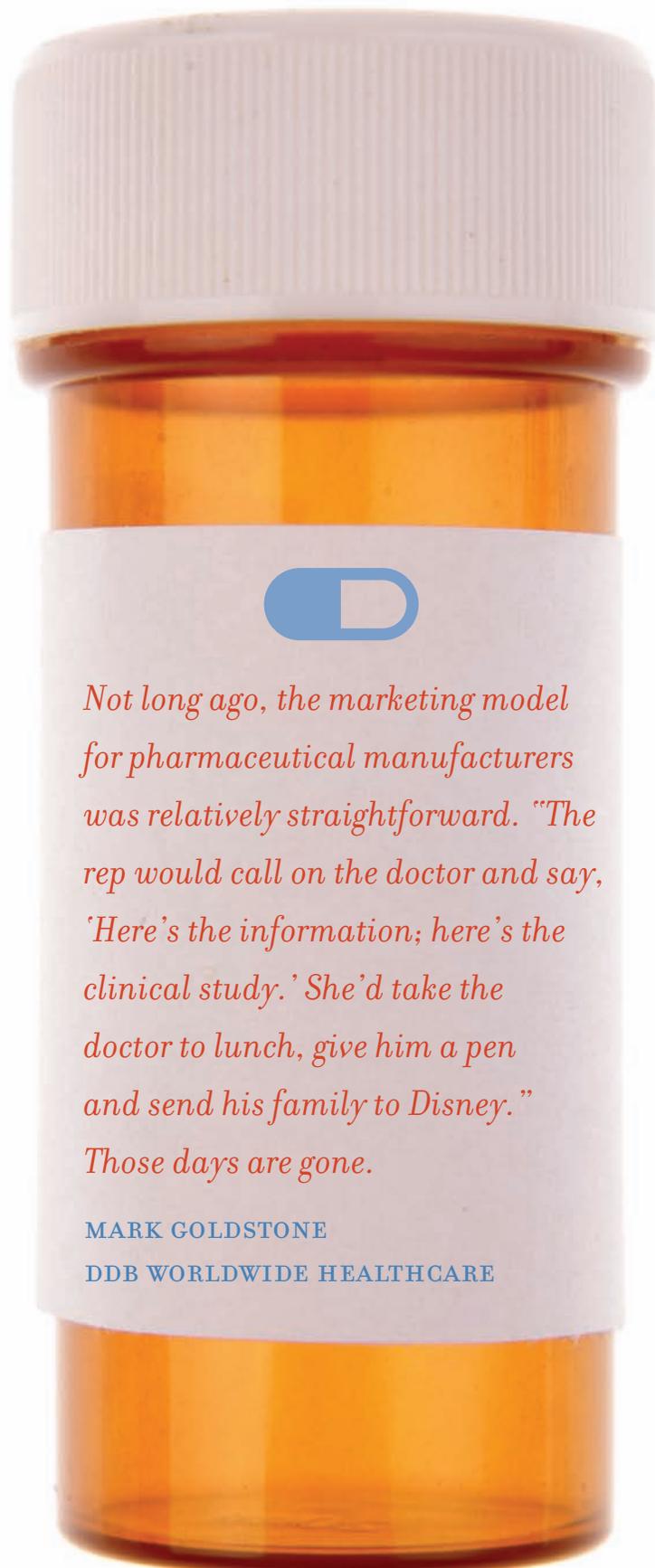
"Marketing [niche drugs] is a different skill set," Adamson says. "It's about building a relationship with a [small] segment. It's harder to market five niches than it is five big brands" because the audience is smaller and perhaps harder to reach, and the message might be more complicated.

Further upending the "old way" of marketing pharmaceutical products is the shift in how doctors deliver healthcare. "Governments and HMOs, as payers, are looking for better value from doctors. They're saying, 'I need you to see 12 patients a day, not the eight or nine you used to see,'" Goldstone says. That leaves less time for doctors to see a small army of sales reps, forcing pharma marketers to find novel ways to keep their brands in front of physicians and patients.

It all boils down to this: "Before, the brand value was the innovation created in the lab," Goldstone says. "What manufacturers are looking for now is how we can create more value above and beyond that innovation." Here are a few trends that marketers say represent that shift.

Starting early

In this complex and noisy marketplace, pharma marketers say, it's vital to make the most of the years leading up to a drug's launch. "What we're finding is that people are coming to us in early Phase II [of clinical trials] to help them define the hypothesis behind how their drug works," says R. John Fidelino, executive creative director at InterbrandHealth, the health



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and life sciences practice of the global branding consultancy Interbrand. Because studies at this point in the drug's development focus on safety and efficacy, the company can't make any direct claims about the drug's use. "What we're starting to do at this point is figure out how a drug is relevant to target audiences, how to describe how the product works based on what [the scientists] already know and what they anticipate," Fidelino says.

Consider Regorafenib, a drug under development at Bayer. "They talk about their drug as ... important for 'tumor deactivation,'" Fidelino says. "We believe that's a very interesting way of describing what the value or purpose is. It's a pretty innovative product and sometimes you're at a loss for words to describe the innovation."

But companies can't let the science speak for itself anymore, he warns. "You get compared to something that already exists in the marketplace because that's all the language that people have."

Finding patient-partners

As the FDA tightens its grip on how pharmaceutical companies can talk to target audiences, pharmaceutical marketers look to nonprofit patient advocacy organizations, such as the Arthritis Foundation or the American Heart Association, to launch important conversations about new drugs.

"The more patients are able to get online and research and get actively involved in their own care, the more they're going to flock to organizations that support them," says Tammy Russo, a Chicago-based independent healthcare marketing consultant who has directed advocacy relations programs for organizations such as Genentech, AstraZeneca, Searle, the Kidney Cancer Association and March of Dimes. What's more, physicians often sit on the boards of these organizations, giving pharmaceutical companies access to another important audience, Russo says. "As nonprofit organizations, patient advocacy groups are safer. ... They are another medium in and of themselves, and they can work in new media with a lot less restriction."

And as with most things, timing is everything. Like Fidelino, Russo says that clever pharma marketers help their clients engage early—once an Investigational New Drug application has been filed and a drug has been through pre-clinicals. "We find out what [patients] need, what's on

their minds," Russo says. "Ideally, there's a mutual education happening ... and once you have an established relationship, these groups can become pharma companies' advocates as well."

Adding value

Once upon a time, communication was just a medium for telling the scientific story. Now, "communication is the added value to the product itself," Goldstone says.

In the niche drug category, a very small company called Alexion has developed a remarkable drug for paroxysmal nocturnal hemoglobinuria, a disease that destroys red blood cells, Goldstone says. "But how do you find out about this drug [if you're a patient]? There's nothing about it on WebMD," he says. Turns out, these patients find each other and start communities online, and DDB Worldwide Healthcare helped the drug company establish Web-based platforms for engaging these communities. "When you see innovations like that—connecting people with the healthcare profession—it's quite exciting," he adds.

Other examples abound: Digitas Health, a unit of integrated branding firm Digitas, helped a client produce a site that helped doctors practice managed care, overseeing the finances and making a staffing plan. DDB Worldwide Healthcare built a support program for gastric-band patients; the client knew that the surgical outcomes would be good only if patients followed the post-op program. "The point is, don't just identify an audience. Identify *with* them," says Graham Mills, executive creative director and managing director of the New York office of Digitas Health.

Crowning content

It's no surprise, then, that savvy marketers "think like publishers, not marketers," Mills says. "We're thinking about marketing as content, as being more like magazines."

He characterizes this shift as "helping, not selling" because "you need to find a much deeper human connection. That makes some people freak out because we're still meant to be driving sales, but it's not a hard-core sales message [any longer]." This push to inform patients—to join the conversation, rather than scream above it—is born largely of patients'

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As health- or disease-based communities grow online, marketers have an opportunity to provide good information by aligning with credible people and organizations, Mills says. Digitas created the “Good to Share” campaign on behalf of MedImmune, makers of the FluMist vaccine. The campaign was an educational effort rather than a brand-specific promotional tactic, and Good to Share partnered with media channels such as Sesame Street and *Parents* magazine to give parents advice on how to help their kids share—and how to keep them from sharing the flu virus. The campaign’s website, GoodToShare.com, led visitors to MedImmune’s home page.

The digital opportunities for patient education are huge, Mills says. “Digital films, mini-sites for [doctors’] iPads—there’s a lot of over-the-shoulder learning going on [in doctors’ offices].” Pharma companies “almost have to be service brands as well as medication providers.”

Investing in compliance training

None of these innovations matter if agencies don’t understand the nuances of federal regulation because the stakes are high. Beyond fining pharmaceutical manufacturers, the FDA can charge individual executives with misdemeanors for industry violations, including the illegal promotion of prescription drugs, under the Responsible Corporate Officer (RCO) doctrine. If they’re found guilty, RCOs can face jail time and stiff fines.

As a result, “clients are demanding a higher level of accountability,” says Ilyssa Levins, president of the Center for Communication Compliance. She sees more agencies investing in more training, so everyone—sales reps, PR staff, marketing personnel and senior management—is aware of the rules of pharmaceutical promotion.

The benefits go beyond staying out of trouble. Being noncompliant with the federal regulations could cost a brand as much as \$200,000 in inefficiencies, according to the center. “The trend of looking at noncompliance through not only the risk lens, but also the cost-effectiveness lens will accelerate,” she says.

Levins sees another benefit to playing by the rules. “I’m excited about advances in relationship marketing, being able to really communicate with someone at the point of their disease progression. The right information gets to the right people at the right time with the right balance of benefits and risks. Get it right and that combination can actually change someone’s life.” **m**

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