Pharma Marketing News

www.pharmamarketingnews.com

Mar 2005
Vol. 4, No. 3
•
Published by
VirSci Corp.
www.virsci.com

Contents

Articles

Marketing's Role in Limiting Physician Access and What to Do About It (p. 2)

Increase Prescription Sales with Smart Tools at the Point of Care (p. 4)

How to Sell a Drug Before it is Approved (p. 8)

Leverage Health Beliefs to Develop Effective Online Compliance Programs (p. 10)

Applying FDA Marketing Regulations to Internet Promotions (p. 13)

Pharma Cost-Cutting Strategies (p. 15)

Conference Calendar (p.18)

Experts and Resources Used (p.19)

Up Front

Give Docs What They Want

While attending the recent Gaining Physician Access conference I heard a lot of advice from consultants as well as physicians about how pharmaceutical companies need to change the number and kind of interactions between sales reps and physicians.

The article, "Marketing's Role in Limiting Physician Access and What to Do About It," for example, offers useful insight on how marketing can help sales reps communicate more effectively with physicians. The expert consultant cited in that article, Mr. Jerry Acuff, says that physicians want better relationships with sales reps and he cited a study showing that physicians ranked friendliness higher than scientific knowledge.

Physicians in a keynote panel at the same meeting, however, emphasized that they value a rep's product knowledge over the relationship with the rep. The panel moderator also cited a new, unpublished study that supported this preference (when asked "What do you like about sales reps?" respondents cited product knowledge first, relationship second, and samples third).

The docs on the panel worried that the impending downsizing of the pharma sales force (see "Pharma Cost-Cutting Strategies") will remove the highest paid and most knowledgeable reps and leave behind the younger, less knowledgeable ones and thus exacerbate the "dumb rep" problem.

What docs seem to want are pharma representatives that keep them informed about the product, talk to them without regulatory constraints, and maintain their sample closet. O yeah, they also want someone who talks like they do. In other words, they want another health professional and not a sales person at all! I've heard the same from other doctors at other industry meetings (see, for example, "A Crisis in Professional Detailing").

What if pharmaceutical companies actually listened to these physicians? Instead of talking about gaining "physician access" by sales reps, pharmaceutical companies might provide more access to the kind of representative physicians seem to want—the medical science liaison or MSL. Except let's drop the liaison part and just call them medical science representatives.

While I am not an expert on the current roles of MSLs and how often they are employed, I do sense a rivalry, let's say, between sales and marketing and the medical sciences department. MSLs play, at best, second fiddle to the sales reps. That situation should, IMHO, be turned on its head. The MSL should be the primary contact and call in the rep when the physician asks for samples. Sample delivery is the primary reason sales reps gain access to physicians anyway.

I think this idea could also save pharmaceutical companies money. Much fewer MSLs than sales reps would be needed. Docs would be more eager to see MSLs and not make them wait in the office or turn them away. Less time would be spent on unproductive calls and each MSL could service many more docs than a sales rep. The sales rep's time would also be better managed because the docs would request reps to deliver the samples. At that time, the rep can still make the pitch without having to explain the value of the product—the MSL would have already done that.

John Mack, Publisher, Editor
Pharma Marketing News

Feature Article

Marketing's Role in Limiting Physician Access and What to Do About It

By **John Mack**

In the 1950's and 1960's, the relationship among healthcare professionals and sales representatives was collegial, cordial and one where the pressures of time and economics were secondary to the quality of care, bedside manner, and professional interactions between pharma sales representatives and the healthcare community.

As manufacturers developed more products to fight more diseases and the competition between "blockbuster" drugs intensified, it became apparent to major pharmaceutical companies that they needed an expanded and better-trained sales force to generate market share and increased sales. Coupled with a steady drumbeat to accelerate profits and retain margins, senior executives embarked upon a road of "more reps equal more sales."

This expansion, however, negatively affected the quality of the sales call and the physician-rep relationship. The pharmaceutical sales interaction has lost much of its value over the last 10 years in the mind of the customer (i.e., physician). The data on this has been presented many times at various conferences and in this and other publications. One study often cited is the Accel Report ("Through Our Customers' Eyes"), which was based on proprietary research conducted by Accel, an Omnicom agency, in March 2003 (see chart on next page and below).

"The pharmaceutical industry has only itself to blame for limited physician access and two minute sales calls," claims Gerald J. Acuff Jr., Chief Executive Officer, Delta Point, a sales agency that enhances the effectiveness of sales representatives. He was speaking at the recent *Gaining Physician Access* conference hosted by the Center for Business Intelligence in Philadelphia, PA.

More Data from the Accel Report

Only 43% of pharma reps ever get past the receptionist

Only 7% of pharma rep visits last more than 2 minutes

Only 6% of physicians think representatives are very fair balanced

Only 8% of calls are remembered by the physician

56% of physicians think representatives are more aggressive today than in the past

Marketing's Role

Acuff emphasized that marketing departments have an opportunity to improve the impact of sales reps. He offered several useful insights about what marketers should do to change the negative perception that physicians have of pharma sales reps.

Marketing's role in limiting physician access could be due to either of the following two problems, according to Acuff:

1. Not truly understanding the difference between a marketing message and a sales message. The copy that accompanies sales aids, for example, is not written with an understanding of how sales are made.
2. Providing to the field suggested sales language that "closes down" customers. Examples of verbiage that signals the wrong thing include:
   - "Dr. If I could show you that……."
   - "Dr. Wouldn't you agree……."
   - "Dr. Today I am going to talk to you about……."
   - "Dr. Would you prescribe_____ for the next 5 patients you see with _____"
   - "Dr I want to talk to you about your patients with……."
   - "Dr. why do you prescribe a_____?"

Such classic detail verbiage, says Acuff, turns the doctor off. Marketing often uses superlative language and claims. If you listen to the way doctors talk, you will seldom hear superlatives. Instead, you hear phrases like "appears to" or "has some benefits." It's no wonder that 94% of doctors think sales reps are overly biased.

"Sales reps," says Acuff, "should stop talking like a drug rep and begin thinking like a physician. Being like every other sales rep just diminishes your credibility." The suggested sales verbiage offered by marketers does not resonate with the customer.

If the rep thinks the language won't work, he or she won't use it and will become convinced that marketing doesn't know what's going on! This drives a wedge between marketing and sales.

Continued on next page…

What to Do About It
Acuff cited a variety of pharma sales practices that have lead to the current situation:

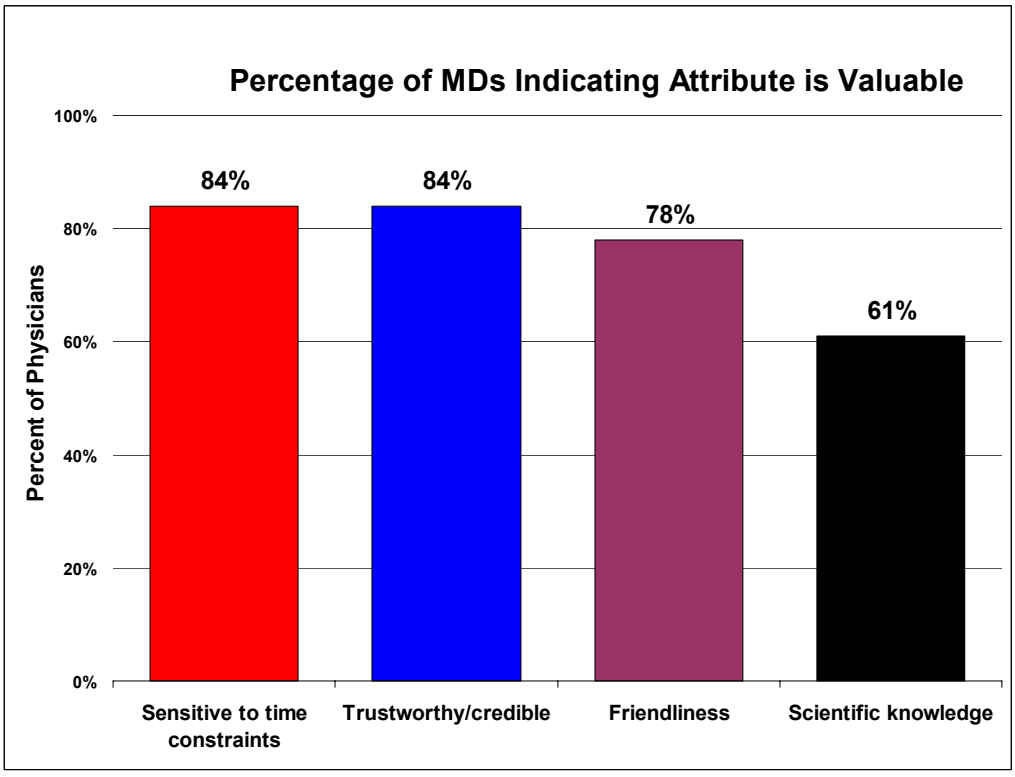
- Detailing won out over true "selling" in the early 90's
- A focus on activity over almost everything else
- Share of voice became royalty at the expense of share of mind
- Activity trumped accomplishment (and accomplishment became nearly impossible to measure)
- A unit is a unit mentality (thanks to some consultants)
- No one accountable or responsible for the relationship
- A lack of understanding of how customers buy
- Meetings more important than field time
- Follow the leader mentality in Big Pharma
- A lack of understanding that many, many physicians see your product as a commodity
- A Blind Eye—not leveraging what great people do

The last item, according to Acuff, holds the promise of the solution. "Great reps are islands of excellence in a sea of mediocrity," said Acuff. "This is an opportunity to exploit NOT to ignore! The great reps today have no major access problems, so let's do what they do."

Whether you hire an outside agency or do it yourself, the process begins with "picking the brains" of the very best reps. Marketers, unfortunately, are not in the field enough to get this kind of input from the sales force. Differences between these reps and others may be subtle, but the impact is great.

The goal is to break down the disconnect between marketing and sales and to realize how sales messages differ from marketing messages. While the marketing message drives the sales message, the latter is a verbal interpretation of the former. Sales messages should be designed to engage the physician in meaningful dialog, which is the most likely way to get customers to "Think Differently" about the product. Marketing/sales messages that change behavior must first be truthful, believable and compelling to become powerful, memorable and highly effective.

Pharma Marketing News



Representative attributes important to physicians (percent of MDs indicating attribute valuable; i.e., greater or equal to 8 on a scale of 1-10). Source: The Accel Report: Through Our Customers' Eyes.

Product Review

Increase Prescription Sales with Smart Tools at the Point of Care

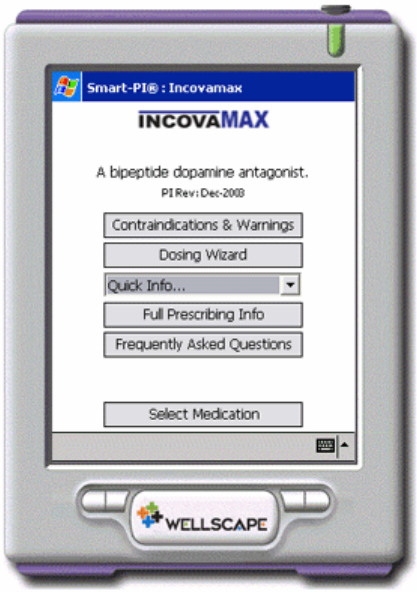
By **John Mack**

The limited time that sales representatives have with a physician is barely enough to drop off samples with a small-print size package insert and an occasional glossy printed sales aid with product information. This prescribing information is rarely read, and more than likely will get "filed away" and never accessed again.

"Physicians want information and tools that improve their ability to practice good medicine," says Stephen Kimberley, MD, Medical Director at Wellscape, a technology company that provides software solutions designed to improve patient care. "The FDA-approved package insert (PI) has all the information a physician needs to prescribe the drug," states Kimberley. "However, it is designed more as a legal or regulatory document than as a tool. The format is very poor for physician education and use at the point of care."

Smart-PI

Realizing the limitations of the printed PI, Wellscape has developed Smart-PI®, which distills complex prescribing information and packages it in portable, stand-alone real-time tools accessible from websites as well as deployable as a standalone application, available for desktop and Tablet PCs, and Palm OS®, Pocket PC and Smartphone PDAs.



Smart-PI utilizes a "layered" approach, which allows physicians to quickly access the information they need. The standard, non-layered approach of the official PI is difficult to scan and does not lend itself to rapid access to information. For example, the paper-based PI lumps together both "drug interactions" and "drug non-interactions" in the same section of the document. These can be confused by the busy physician attempting to quickly check his or her facts. In the Smart-PI layered approach, the two categories of "interactions" are separate line items in a drop-down list. All other sections of the PI are similarly indexed, searchable and intuitively organized.

Prescribing Information Wizards

Smart-PI also uses "wizards," which are interactive utilities that help the physician perform otherwise complex tasks. For instance, a dosing wizard leads the physician through the steps required to appropriately dose the drug, including all the relevant details such as medical status, diagnosis and drug regimen.

Smart-PI wizards follow simple, question-based paths through decision trees, covering indications and contraindications, pertinent product warnings and interactions. The contra-indications wizard, for example, is a series of questions that leads the physician to the proper information for a specific patient. If the patient is male, for example, it is not necessary to see the pregnancy contraindication warnings. By entering "male" for patient's sex in the wizard, the physician is taken down the appropriate pathway. Wizards help to ensure timely, correct and efficacious dosing of drugs with even complex dosing regimens.

"The Smart-PI wizards save time at the point of prescribing," says Kimberley. Saving time is important because if it takes too long to make a prescribing decision for a particular drug, a sale could be lost and quality of patient care jeopardized.

Although printed sales aids can be designed to help physicians make decisions without doing complicated calculations—e.g., use of dosing tables or sliding cards—using an interactive wizard on a handheld PDA is more convenient. Also, the PDA is automatically updated with the latest information about indications, dosage computation, warnings and interactions, whenever it is synchronized with an Internet-enabled PC. The delivery of comprehensive and current medication information is invaluable in reducing prescribing errors and associated liabilities for both physicians and the sponsoring pharmaceutical companies.

Continued on next page…

Pharma Value Added Options

"Pharmaceutical companies that take advantage of our technology," says Kimberley, "can leverage it to increase prescription sales." Sales reps can distribute Smart-PIs to their physician clients via business card CDs, or the application can be downloaded from a product web site. Sponsoring company and/or product branding are displayed on the CD label and can be embedded in software—on the main screen—to reinforce the brand while avoiding intrusive promotional messaging at the point of care (POC).

Smart-PI is PhRMA compliant and is provided on a low cost per-license purchase for pharmaceutical companies and other customers. Smart-PI can be customized to include multiple medications, clinical guidelines, FAQs, and patient information, all of which are approved by the pharmaceutical sponsor. "The most important aspect," says Kimberley, "is that Smart-PI is based upon the complete, official package insert, which is always one click away."

Technology and Sources of Prescribing Information

According to a survey conducted by Lathian Systems, a provider of technology-based sales and marketing solutions, and commissioned by Wellscape, 58% of the cardiologist, emergency room doctor and internist survey respondents cited the package insert as a source they usually use to learn prescribing information (see the chart at right). Add to this the product web site, which is primarily considered labeling, the result is that 78% of physicians cite the package insert in one form or another as their usual source of Rx information.

Physicians in the survey indicated that Smart-PI would be helpful to them in prescribing medications with complex contraindications and warnings (92% of respondents), difficult to dose medications (86%), medications with new indications, labeling, or warnings (74%), and medications requiring communication of extensive patient information (72%).

A survey by Manhattan Research, LLC, a healthcare marketing information and services firm, found that 235,000 physicians in the U.S. were using PDAs in 2004 for professional purposes. Mark Bard, president of Manhattan Research, indicated that smartphones and tablet PCs were the fastest growing segments last year (personal communication).

Smart-PI can also provide feedback to the pharma sponsor through back-end reporting of tool usage for contraindications, warnings, and appropriate dosage. Such information may help provide post-surveillance monitoring, which is increasingly important in the post-Vioxx world.

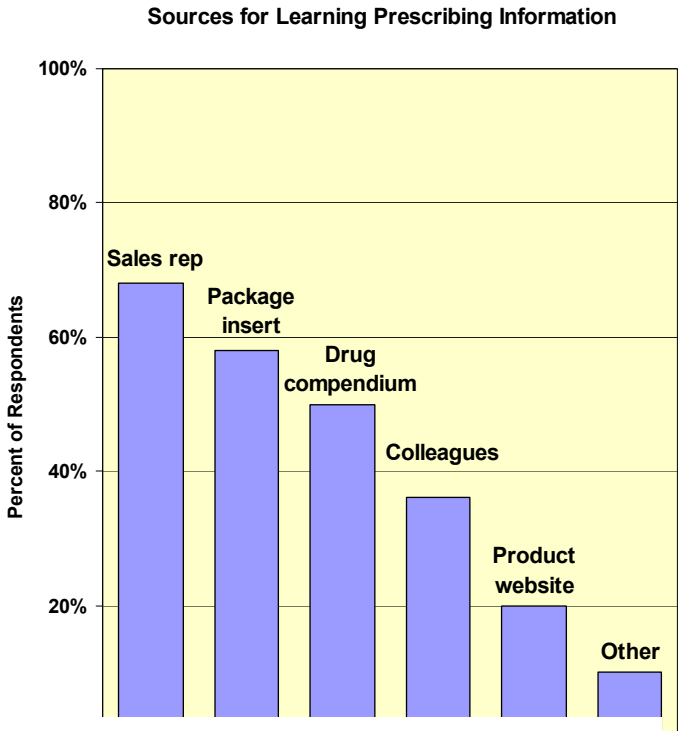
Physi-Calc

Another POC product offered by Wellscape is an electronic treatment guidelines tool called Physi-Calc, which uses the same "wizard" question-based approach as does Smart-PI.

"In recent years," says Kimberley, "the number of available clinical guidelines from various sources has increased exponentially. It's impossible for a busy physician to manually go through all the steps and decision trees of these guidelines, or to keep up on the changes as they are developed."

Wellscape's experienced medical staff identifies the latest clinically-relevant calculations, diagnostic and treatment guidelines, and risk assessments from authoritative medical sources, and distills these into easily-navigated tools within Physi-Calc. The results are improved patient care and better treatment decisions.

Continued on next page…

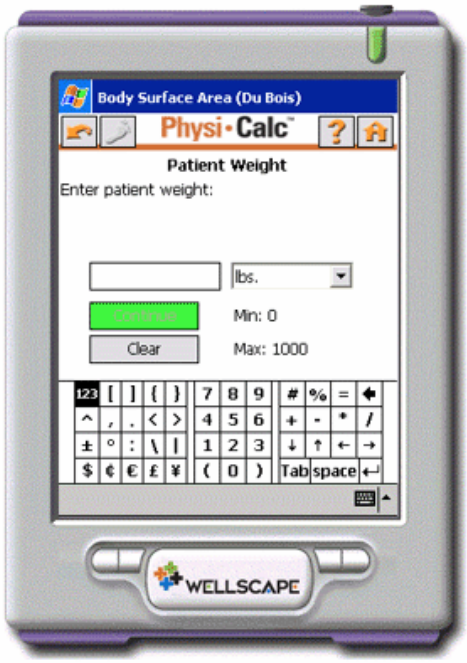


Source: Lathian Systems Survey: Prescribing Physicians Responses to Smart-PI®. March, 2004.

As with Smart-PI, Physi-Calc can be customized for the pharmaceutical sponsor. It can include, for example, science-based tools approved by the sponsor in a particular condition area. Sales reps can deliver the application to physicians on business card CDs with or without Smart-PI. Alternatively, the physician can download the full set of tools, or just the tools for a specific drug indication from the sponsor's web site.

Wellscape's tools present a great opportunity for pharmaceutical companies to assist and partner with physicians in improving patient care. Smart-PI is an innovative way to disseminate complex prescribing information and helps physicians prescribe new or unfamiliar medications safely and with more confidence. Physi-Calc complements Smart-PI by ensuring that the latest clinical information is easily accessible to medical professionals.

Pharma Marketing News



Article

How to Sell a Drug Before it is Approved

By **John Mack**

Pharmaceutical marketers can generate significant interest in a drug before it is officially launched. This is often done by supporting educational CME programs for physicians, employing key opinion leaders, sponsoring satellite symposia at major medical meetings, and publishing clinical trial results.

However, did you know that you can also sell a drug before it is launched? Dr. Gene Emmer, President of Med Services Europe B.V., an Amsterdam-based consultancy focused on sales, marketing, and business development for the medical industry, advises his start-up, cash hungry, biotech companies to consider if a European "named patient program" might be an option.

A named-patient program allows physicians and their patients access to drugs which have not yet received approval for marketing by national health authorities. The drug must be used to meet the needs of an individual patient where a licensed alternative therapy is not available or is not suitable for the patient.

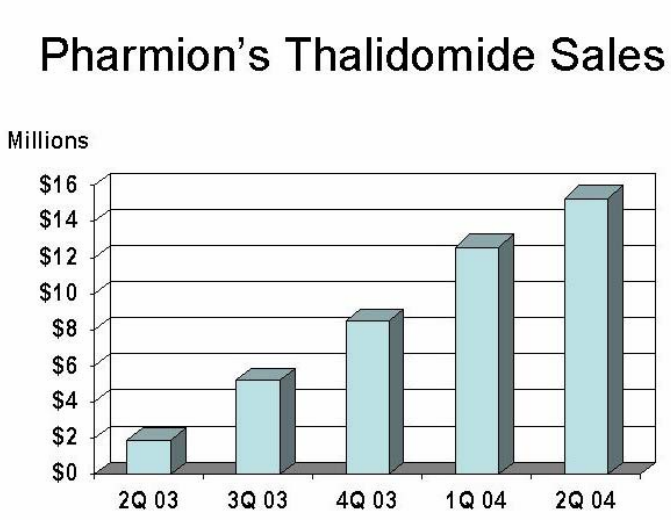
"European Named Patient Programs, like US compassionate use programs, offer physicians access to pharmaceuticals which have not yet been licensed" explained Dr. Emmer, "However, there is one important difference: in Europe an unlicensed drug is often purchased by National Health Systems." This presents drug-makers with an opportunity to generate revenues while development is still in-progress.

Most often, drugs that are commonly demanded by physicians and patients before they are approved for sale are those drugs that treat rare and/or fatal diseases. A case in point is Erbitux, the colon cancer drug developed by Imclone Therapeutics. Following reports in 2000 of the company's research, Imclone began receiving hundreds of calls a day requesting "compassionate use" the drug, which was then known as C225.

Generating pre-launch demand can help get your product off to a fast start after launch, but demand could be so high that it may upset your launch plans. If appropriate, a structured named patient access program may be a good way to manage the demand and make some sales as well.

Significant Revenues Are Possible

The additional revenues can be considerable. For example, a source at Pharmion, a US based company focusing on Oncology and Hematology reported dramatic increases in its Thalidomide sales from $1.9 million in 2Q '03 to $15.3 million in 2Q '04, primarily due to named patient sales in Europe for Multiple Myeloma (see Chart below).
Thalidomide sales accounted for approximately 75% of Pharmion's total revenues for the first half of 2004, according to company sources, and were generated while the product awaits marketing approval for this indication. Before receiving European Marketing Approval, Shire's Argylin® for essential thrombocythaemia generated about 5% of its total sales from its European named patient program.



"We are pleased with the compassionate use and named patient sales growth we experienced for thalidomide," said Patrick Mahaffy, Pharmion's president and chief executive officer. Net sales growth for the first quarter of 2004 was primarily driven by increased named patient sales of thalidomide, which have grown steadily since sales commenced in the second quarter of 2003.

Other Benefits of Named Patient Programs

A named patient program can speed uptake after official launch. Physicians, who have had experience before launch, via clinical trials or named patient programs, often become early adopters and references for other physicians once the drug is freely circulating.

Continued on next page…

Named patient programs, like US compassionate use programs, can increase good-will toward the company because they simplify the process of gaining access for patients in critical need. Smaller companies often can not afford the administrative time and costs of shipping drugs around the world before launch. This can lead to frustration and resentment towards a company that many physicians will remember long after a drug is officially on the market. Creating a formal channel eliminates the unfortunate need of denying requests and risking ill-will later.

A named patient program should be considered an important part of a pre-launch program. It increases awareness to a pharmaceutical's existence, creates excitement, generates good-will and speeds penetration of the product after launch. In this age of the Internet and patient empowerment, you cannot underestimate the power of the patient to drive awareness of and demand for your product.

A named patient management program also can provide valuable market research data including feedback from both physicians and patients. This vital pre-marketing data can be used to support the drug's approval.

Named patient and compassionate use programs also can help identify early adopters to target for post-launch marketing activities. In addition, information about the patients, including number of patients, can be helpful in forecasting.

Communication Yes, Marketing No

While physicians are used to simply writing a prescription and being done with it, named patient programs require paper-work that some find tedious. Therefore the pharmaceutical company needs to create an appropriate communication plan and work closely with the targeted medical community to keep them informed and simplify the process.

If one of the objectives is to generate revenues, setting up a named patient program is just the beginning. In order to achieve success, physicians need to be aware of the product and what they need to do to get it. Typical methods of informing physicians, such as detail aids and ads, may not be appropriate because a license is necessary to market a drug.

However, in many countries, a sales rep will be allowed to inform the doctor that the drug is available on compassionate use. In many cases, the rep will be able to give a scientific journal article and a telephone number to the doctor without it being considered promotion. In some countries, the rep can pre-market with an unbranded journal article. When asked by the doctor about availability, the rep will be able to give contact information or ask the doctor if he or she would like to receive a request form. "There are many approaches to this issue," suggests Dr. Emmer, "and it must be discussed in detail with a local medical advisor/regulatory expert."

European Marketing Expertise Required

Some companies may choose to hand the management of program over to a third party company that has experience with managing and handling named patient programs.

If you do not have an experienced European marketing group, an organization that is familiar in sales and marketing of pharmaceuticals in Europe can help you to maximize participation in the named patient program. A communication plan, if properly developed and implemented can increase product awareness, but communication concerning an unlicensed product must be done appropriately.

According to Dr. Emmer, your communication plan should ensure that your entire target group is fully aware of the product AND the program, knows what needs to be done to take advantage of the program, and has an advocate available to guide them through the process.

Pharma Marketing News

Conference Highlight

Leverage Health Beliefs to Develop Effective Online Compliance Programs

By **John Mack**

"Pharmaceutical marketers are itching to do something more sophisticated online, to go deeper," claims Monique Levy, an Analyst at Jupiter Research, a leading international research advisory organization. She was speaking at CBI's 4th Annual eMarketing for the Pharmaceutical Industry conference in Philadelphia, PA on March 16, 2005.

Online Marketing Issues and Plans

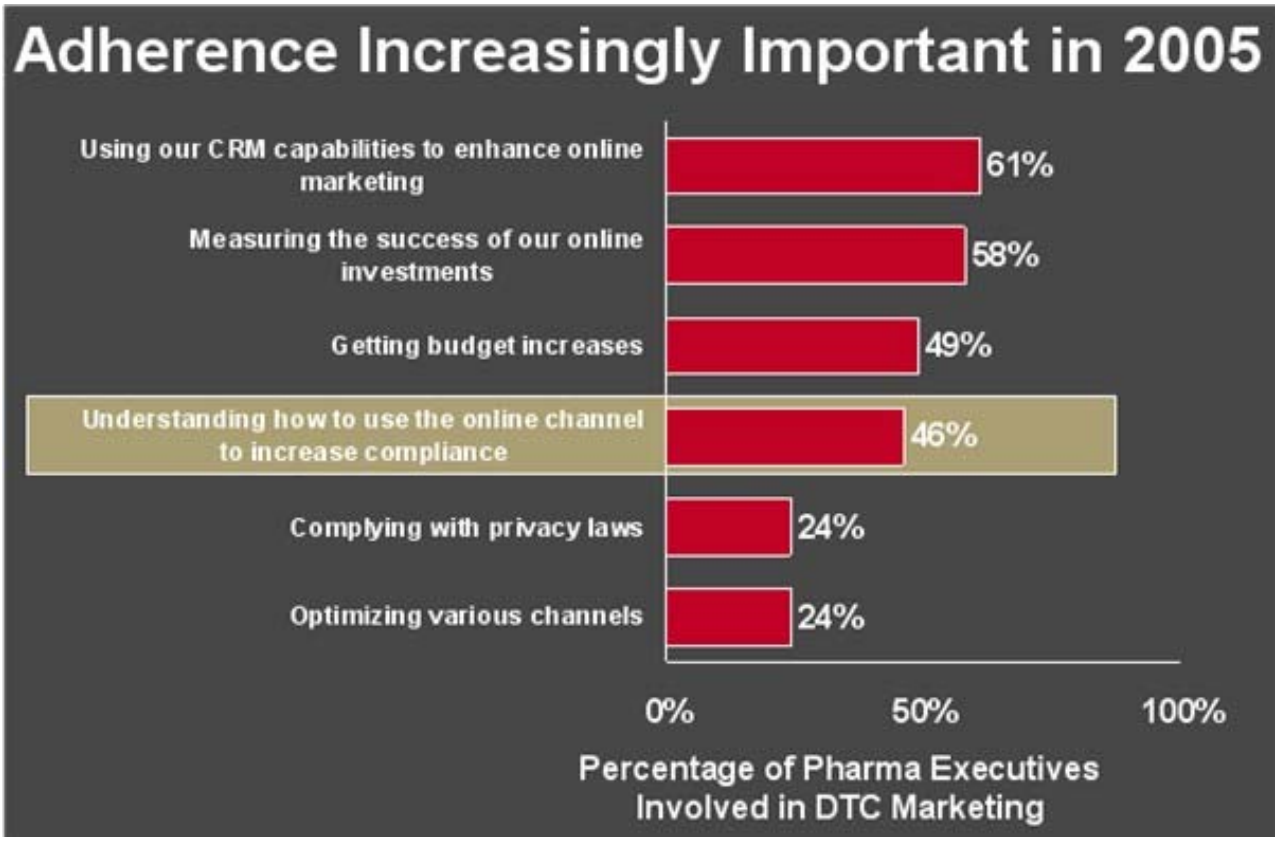
According to an August, 2004 JupiterResearch Executive Survey of 33 US pharma executives involved in DTC marketing, 46% of respondents said that understanding how to use the online channel to increase compliance was the most important issue they faced with regard to online marketing targeting consumers (see chart below).

The survey also showed that these executives plan to increase spending on adherence-related online tactics with 67% intending to increase spending on e-mail marketing in 2005 and a majority (58%) planning to increase spending on online patient support programs, web site redesign to improve usability, and online content sponsorships. Similar results were reported in the "2004 DTC Industry Checkup" survey (see PMN Reprint #42-03: "DTC in 2005: Can You Teach Old Dogs New Tricks?").

How Do Consumers Use the Internet for Health Purposes?

Before spending more money on Internet-based compliance programs, pharmaceutical marketers are keenly aware that (1) it will be a challenge to get increased funding, and (2) they need to be able to measure the success of their online investments. These issues have been discussed in several previous articles and OpEd pieces (see, for example, PMN Reprint #17-01, "The Absolute, Relative, and Incremental ROI of DTC e-Marketing" and "Product Web Sites: Are They Worth It?").

Consumer use of the Internet for health purposes spans a spectrum from accessing information only to using interactive tools to manage their health.



Question: What are the most important issues you are facing this year with regard to online marketing targeting consumers? (Select all). Source: JupiterResearch Executive Survey (8/04), n = 33 (pharma executives involved in DTC marketing, US only) © 2005 JupiterResearch.

Although it is widely known that almost three-quarters of online consumers use the Internet to find health information, many marketers don't realize that less than 10 percent of online consumers use online health resources to continuously manage their health conditions. According to a Jupiter survey, consumers don't manage their health online because they have low confidence in their ability to use online health resources to improve their health. Pharmaceutical marketers must leverage health beliefs and models to design comparatively more effective adherence-related online marketing programs.

A number of psychological models of health decision-making processes have been proposed to guide pharmaceutical marketers in designing effective consumer and patient marketing campaigns.

Responders and Non-responders

One such model talks of "responders" and "non-responders" in terms of health-related behaviors and treatment characteristics that drive DTC response (see PMN Reprint #27-03, "Understanding Drivers of Patient Behavior to Maximize DTC Effectiveness"). According to this model, responders are more likely to have condition and treatment-related concerns (severity of condition, management of symptoms, and satisfaction with medication), are more open to making changes in their lives, feel empowered within the patient-doctor relationship, and are more likely to already be Rx users. Non-responders, on the other hand, feel less vulnerable about their condition, describe themselves as being healthier, are more resistant to possible changes, and are less likely to ask for what they want in the doctor's office.

Proponents of this model suggest that pharmaceutical DTC advertisers should first determine if their intent is to motivate the responder or the non-responder and then tailor and personalize ads to specific target audiences to increase interest and motivation to respond.

Cycles of Change Model

In her presentation, Levy, who once provided health psychology expertise to eDiets.com, a diet web site, summarized Prochaska and DiClemente's "Cycles of Change" behavioral model (aka, "Transtheoretical Model") and its implications for pharmaceutical marketers.

STAGE 1: Precontemplation. This might be called the "Ignorance is bliss" stage in which there is a lack of awareness and the person is not currently considering change. The marketer's goal for people in this stage is to build awareness. DTC ads on TV are very good at this and much superior to the Internet.

STAGE 2: Contemplation. Let's call this the "Sitting on the fence" stage, which is characterized by an awareness of the problem and the person is thinking about a change. "Pharmaceutical marketers have a huge opportunity to use the Internet to build motivation at this stage," says Levy. This is when people access the Internet to do their research and are most receptive to advertising.

STAGE 3: Preparation. Sometimes referred to as the "testing the waters" stage, this is when action is imminent and when marketers can convert prospects into customers.

STAGE 4: Action, Maintenance. This is the stage that offers the biggest challenge to pharmaceutical marketers. Here's where people either commit to sustain the new behavior or suffer a relapse and revert to old behaviors. In health treatment terms, the challenge is maintaining compliance with treatment and improving retention.

Very few online consumers use compliance-building self-monitoring tools on the Internet. For example, only 10% of online consumers have used e-mail reminders in the past 12 months. "Given this low utilization of online compliance tools, pharmaceutical marketers face a huge challenge to leverage the Internet for compliance," says Levy.

Self-Efficacy

Pharmaceutical marketers that are really serious about compliance and who wish to increase consumers' adoption of online tools, need to understand the concept "self-efficacy" and how it influences online behavior. In this context, self-efficacy is a measure of a person's confidence and ability to use online tools to manage their health. According to Levy, only 15% of online consumers said they are confident they can manage their health condition online and that their actions will have a positive impact.

"Pharmaceutical marketers must leverage these health beliefs and models to design comparatively more effective adherence-related online marketing programs," says Levy. She offers the following suggestions:

Involve healthcare professionals. Baxter has developed a sophisticated set of complementary online initiatives to manage patients with hemophilia, including an online patient-physician communications tool called Advoy (see PMN Reprint #41-06, "A Web-based Therapy Management Program") and a comprehensive patient support

program called Passport for Life. Ultimately, Baxter plans to coordinate data in both tools to increase patient adherence. At the very least, marketers unwilling to make this type of investment should emphasize patient online resources to physicians through various outlets, including office brochures and online detailing sessions.

Avoid long registrations up front. Jupiter-Research has continually advocated building consumers' profiles incrementally.

Reward long-term behavior. Several pharmas are having success using online coupons to drive compliance. However, this approach does not promote long-term behavior change. Marketers should consider offering increasingly substantial rewards for sustained consumer efforts.

Pharma Marketing News

Conference Highlight

Applying FDA Marketing Regulations to Internet Promotions

By **John Mack**

At the recent CBI *eMarketing for the Pharmaceutical Industry* conference held in Philadelphia, PA, Preeti Pinto, M.S., Senior Director Promotional Regulatory Affairs, AstraZeneca, gave the attendees some insight on the regulatory actions taken by the FDA with respect to online DTC marketing by pharmaceutical companies. She summarized the following most commonly cited violations found on pharmaceutical company web pages:

- Display of promotional information about investigational drugs
- Inclusion of outdated clinical research information
- Lack of fair balance
- Links to outdated PI
- Links to pages containing unapproved uses
- Use of unrepresentative graphical depiction
- Misleading presentation of clinical data

Ms. Pinto identified several specific regulatory citations by the FDA. The table on the next page is Ms. Pinto's current list of alleged violations, including companies, date cited, and URLs.

Be Careful With Web Site Names

Pfizer's use of "leavingpainbehind.com" as a web site name associated with Bextra and Celebrex is an interesting violation cited by the FDA. In a January 10, 2005, letter to Pfizer, FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) claimed that Pfizer's 27-minute TV infomercial "On the Road to Joint Pain Relief" ad on arthritis and joint pain relief is "a drug ad for Celebrex and Bextra that is misleading because it overstates its proven effectiveness and omits important information about the drugs' safety and effectiveness." The letter goes on to state: "In addition to the name of the website, testimonials promise that patients will 'leave pain behind,' and the infomercial features testimonials portraying dramatic efficacy results…"

Online Clinical Trial Registries

In September of 2004, the US industry trade group Pharmaceutical Research and Manufacturers' Association (PhRMA) launched a Clinical Study Results Database (ClinicalStudyResults.org) to provide a centralized repository where member companies have committed to register of all company-sponsored hypothesis-testing (non-exploratory) clinical trials.

In response to public demand, many pharmaceutical companies have started listing clinical trials that they sponsor on their own web sites. The FDA is likely to look closely at both the content and context of these online clinical trial registries associated with pharma corporate and/or product web sites.

Pinto offered a few clinical trial registry best practice suggestions, including:

- The presentation of clinical results should be non-promotional
- Both negative & positive trials should be included
- Data should be factual with all endpoints (not just favorable ones) included

Ms. Pinto recommended that registries "just state the facts and steer clear of conclusions and not be used as off-label promotional tools."

Pharma Marketing News

Table: Pharmaceutical Website Marketing Violations

Company	Date	Alleged Violation	Website
Pfizer Inc.	1/10/2005	Unsubstantiated Overstatement of Effectiveness	www.leavepainbehind.com
Bradley Pharm.	11/9/2004	Unsubstantiated Effectiveness claims; Omission of Risk Information; False/Misleading Safety Claims; Failure to Submit	www.bradpharm.com/pamine.htm
Ortho-McNeil Pharm.	9/15/2004	Omission of Material Risk Information	www.topamax.com
Cubist Pharm.	8/17/2004	Broadening of Indication; Misleading Superiority Claim	www.cubicin.com
Abbott Lab.	6/10/2004	Failure to Submit Updates to Website	www.norvir.com
Vivus Inc.	5/25/2004	Minimization of Risk Information; Unsubstantiated Effectiveness Claims	www.vivus.com
Pfizer Inc.	4/22/2004	Omission of Risk Information	www.zyrtec.com
King & Spaulding	6/18/2003	Unsubstantiated Safety/Efficacy Claim; Failure to Submit	www.Amnesteem.com
Novartis	6/18/2003	Unsubstantiated Superiority/Comparative Claims; Minimization of Risks	www.z-drops.com/ae; www.Zdrops.com; www.Zatidor.com
BMS	3/13/2002	Unapproved Uses / Broadened Indication; Failure to Submit	www.bms.com; www.ifex.com
Lilly ICOS, LLC	1/3/2002	Pre-approval Promotion	https://secure.lillyicos.com/news_lev2.cfm; www.icos.com; www.lilly.com
Merck & Co.	6/20/2001	Lack of Fair Balance	www.FOSAMAX.com
Supergen, Inc.	5/10/2001	Unapproved Uses	www.nipent.com/product/2_3.htm
Supergen, Inc.	5/10/2001	Pre-approval Promotion	www.supergen.com
Cubist Pharm.	11/22/2000	Pre-approval Promotion	www.cubist.com
Synsorb Bio.	9/5/2000	Pre-approval Promotion	www.synsorb.com
Hemispherx	7/7/2000	Pre-approval Promotion	www.hemispherx.com
Boehringer Ingelheim	6/27/2000	Use of Outdated Product Labeling	www.viramune.com
BMS	4/10/2000	Overstatement of Efficacy; Lack of Fair Balance	www.tequin.com
Ozelle	3/7/2000	Pre-approval Promotion	www.ozelle.com
Gel Tex Pharm.	10/23/1998	Pre-approval Promotion	www.geltex.com/ProductPipeline.html
Orphan Med.	9/17/1998	Pre-approval Promotion; Lack of Fair Balance	www.orphan.com/product_information.dbm
Hoffman-La Roche	6/4/1998	Lack of Fair Balance; Failure to Submit	www.roche.com/pharma/Products_Rx.htm
G.D. Searle	7/16/1997	Pre-approval Promotion	www.searlehealthnet.com
Immunex	2/14/1997	False, Misleading, Unsubstantiated Claims	N/A
Lipsome Co.	12/11/1996	Lack of Fair Balance	www.lipo.com
Schering	9/20/1996	Lack of Fair Balance	N/A

Source: Preeti Pint

Survey Results

Pharma Cost-Cutting Strategies

By **John Mack**

In February, reports circulated that Pfizer was poised to cut as much as 30% of its sales and marketing force (see "Pfizer to Slash 30% of its Sales & Marketing Staff"). This elicited a lively discussion among members of the PHARMA-MKTING listserv, including the following comments:

> "This could be the signal that starts the great pharma sales force massacre. On the other hand, I'll believe it when I see the blood in the streets. Seems I just saw McKinnel on record as saying PFE would stay the course. Of course, when the denials are strongest just before events belie them." -- Terry

> "I saw a segment on CNBC the other might where an industry analyst mentioned that there was a lot of buzz that pharma marketing and especially the sales forces are next to go (and soon). Pfizer could make the first move, but we can probably expect a much broader trend due to increasing financial pressures." -- Mark

> "We are just starting to witness the fat trimming that is about to take place mostly in sales force side then marketing. With 26% decline in sales rep productivity since 1996 when the industry started to fight for Share of Voice and doubled rep numbers to what we have today, something got to give when there is no ROI. This is not going to be pretty picture friends. I was speaking to a CEO of one of the top 5 multinational companies yesterday and he indicated that there is going to be significant adjustment taking place for the industry especially in sales and marketing." -- Mick

A recent *Philadelphia Inquirer article* ("Party may be over for Big Pharma") painted the following bleak picture for the industry as a whole:

> "Layoffs appear to be growing. Drug companies announced more than 8,700 job cuts nationwide in November, December and January, the biggest three-month figure for the sector since 2003.

> "The American Stock Exchange Pharmaceutical Index is currently down 31 percent from its high over five years and 11 percent over the last year.

> "Analysts are predicting a rise in mergers, partnerships and licensing deals as companies scour for profitable products and cost savings. Viren Mehta of Mehta Partners in New York projects that Big Pharma's sales growth will slow to 5 percent a year in coming years, half as fast as the last decade."

The pharmaceutical industry faces many challenges ahead including blockbusters going off patent, generic competition, collapsing sales due to product withdrawal, price pressures, etc. All this puts pressure on pharma profitability and Wall Street is clamoring for cost cutting measures. Now may be the time to end the pharmaceutical sales and marketing "arms race" and/or increase sales and marketing ROI.

Survey Results

With that as a backdrop, Pharma Marketing News hosted an online Pharma Cost Cutting Survey between February 22, 2005, and March 18, 2005. Respondents indicated how likely they thought pharma companies would adopt several cost-cutting strategies within the next six months. This article presents a summary of the results. You can also get an up-to-date interactive summary by clicking here.

The survey asked respondents to rank the likelihood of several cost-cutting strategies as highly unlikely, somewhat unlikely, somewhat likely, highly likely. Respondents could also choose "I don't know" for any strategy. The chart of results on page 17 assigns a relative score to measure the sense of respondents as a group by assigning a numerical value to each response (no opinion=0, highly likely=20, somewhat likely=10, somewhat unlikely=-10, highly unlikely=-20).

The three most likely cost-cutting strategies according to respondents were mergers, reductions in the number of sales representatives and a cut in direct-to-consumer (DTC) advertising.

Reduction in Sales Force

The vast majority of respondents (78%) felt that it was highly likely (31%) or somewhat likely (47%) that pharma companies would significantly reduce the number of sales reps in the next six months. No respondents sat on the fence—i.e., had no opinion—concerning this issue. Pharmaceutical company respondents were somewhat less enthusiastic about sales force reduction than agency respondents (see table on next page).

Respondent Group	Highly Likely	Somewhat Likely
All	31%	47%
Pharma	33%	33%
Agency	27%	50%

Mergers
Sixty-three percent (72%) of respondents felt that mergers were "highly likely" (33%) or "somewhat likely" (39%). A substantial percentage (22%) of respondents, however, had no opinion on the issue of mergers. A significantly greater percentage of pharma respondents anticipate mergers and acquisitions than do agency—marketing companies and advertising agencies—respondents (88% vs. 54%; see table).

Respondent Group	Highly Likely	Somewhat Likely
All	33%	39%
Pharma	44%	44%
Agency	18%	36%

Cut Back on DTC Advertising
Fifty-nine percent (62%) of respondents felt that pharmaceutical companies would cut back on DTC spending (21% thought it highly likely, 41% felt it somewhat likely). Pharma and agency respondents were pretty much in agreement on this cost-cutting option.

Respondent Group	Highly Likely	Somewhat Likely
All	21%	41%
Pharma	33%	33%
Agency	23%	45%

Cut Back in Physician Marketing
Cutting back on spending on physician marketing was not popular with respondents—only 6% of whom thought it was higher likely and only 12% saying it was somewhat likely. A substantial portion (44%) of pharma respondents, however, though it somewhat likely that there would be cutbacks in spending on physician marketing. A few respondents suggested that less samples would be distributed as a cost-saving tactic.

Respondent Group	Highly Likely	Somewhat Likely
All	6%	12%
Pharma	0%	44%
Agency	5%	0%

Impact on Agency Business
Fifty-four percent (54%) of agency respondents indicated that pharma cost-cutting strategies would have a somewhat negative impact on their business, although none predicted a highly negative impact. "In the short term," said one respondent, "it is a bad news to vendors. In the long run, more and more outsourcing opportunities will appear."

Mergers and acquisitions "bring everything to a halt in the involved companies, [including] decision-making," warns one respondent. A technology vendor thought that less spending in general also means less spending on technology. While some respondents suggested that pharmaceutical marketers use most cost-effective channels such as the Internet, print-based marketing and promotion vendors would suffer from such a strategy. Nevertheless, one vendor respondent said: "I do think though that there may be an increase in DTP as well as patient education materials either provided by doctor or sent directly by pharma."

The market research agency segment of the industry may continue to flourish regardless of what pharma does with its marketing budgets. If sales forces are reduced, for example, "those who are left will need to be more efficient at what they do and how they do it," suggested one respondent. "That efficiency is measured most often by market research, whether it's primary or secondary data. Remember, for the cost of just one specialty rep FTE -- $250,000 -- a pharma company can do a rigorous quantitative analysis of the effectiveness of its sales force. It's a relative bargain."

Other Suggestions and Comments
Several respondents suggested general expense containment options such as cutting salaries, commissions and bonuses, or improving ROI by process improvements or focusing on specific therapeutic categories.

Some specific comments included the following:

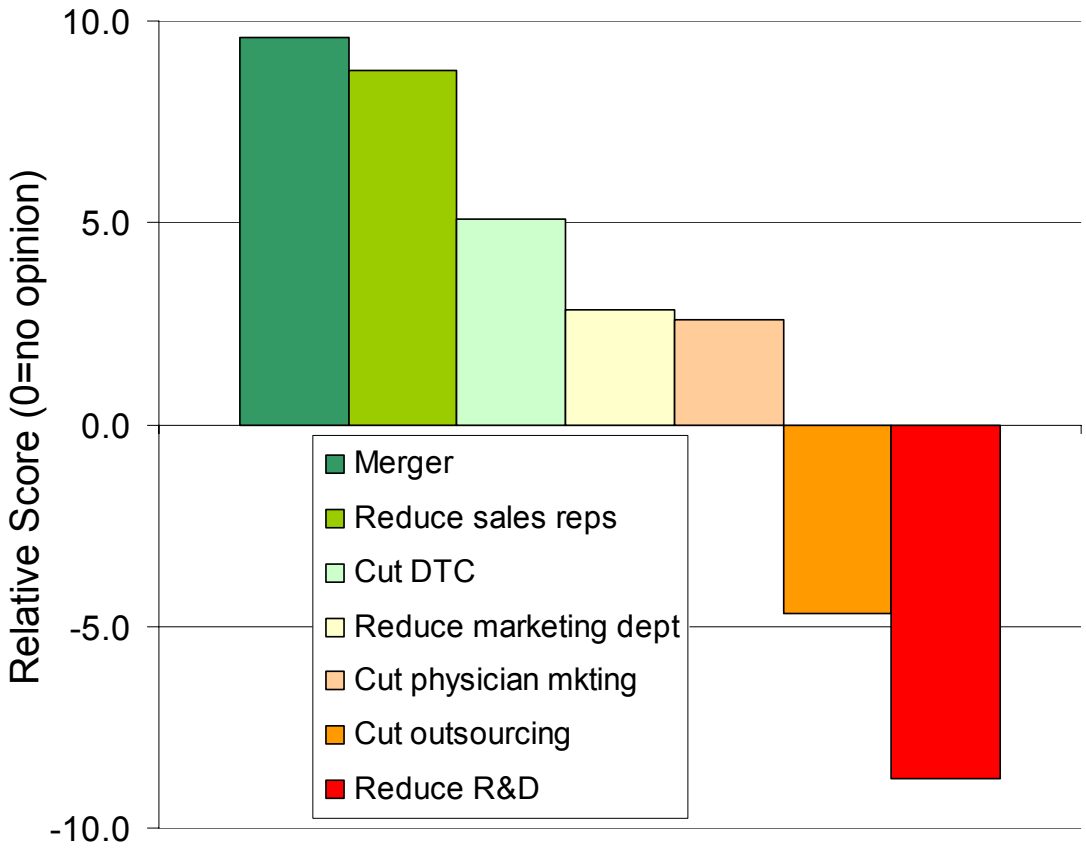
"Sales reps with 'programs' that improve GP efficacy in treating and educating patients provide

a very real service that will show a ROI. Spending $$$ Millions on logo pens and clipboards is a tragic waste of promotional spend that could serve a real purpose."

"One way out of this is employing pharmacists to be medical reps because they know the drugs and are very capable of convincing the doctors [without] any extra marketing expenses. Bring in the experts!"

"Even if sales forces size have to be reduced while their productivity and effectiveness are developed and monitored, there are important cost reduction opportunities lying within marketing activities: stop the 'nice to have' and concentrate on the 'necessary to do' with ROI evaluation."

Pharma Marketing News



Survey Results

Scoring assigns the following values to responses: highly likely=20, somewhat likely=10, somewhat unlikely=-10, highly unlikely=-20, no opinion=0

Conference Calendar

Access the complete up-to-date calendar at http://www.pharma-mkting.com/pm-mtgs.html

March/April 2005

International Pharmaceutical Compliance Summit on Medical Affairs, Clinical Trials, Safety and Publication
March 30 - April 1, 2005 • Inn at Penn, Philadelphia, PA
http://www.pharma-mkting.com/meetings/M141mtg131.htm

The Tenth National HIPAA Summit
April 6 - 8, 2005 • Baltimore, MD
http://www.hipaasummit.com/

4th Annual Patient Compliance
April 11 - 12, 2005 • Philadelphia, PA
http://www.pharma-mkting.com/meetings/M004mtg145.htm

Leveraging Longitudinal Patient Data for Segmentation, Targeting and Strategy Formation
April 11 - 12, 2005 • Princeton, NJ
http://www.pharma-mkting.com/meetings/M007Fmtg139.htm

Forum on Early Stage Commercialization Strategies for the Pharmaceutical Industry
April 21 - 22, 2005 • Philadelphia, PA
http://www.pharma-mkting.com/meetings/M004mtg129.htm

9th Annual China Pharmaceuticals Conference
April 25 - 26, 2005 • China World Hotel, Beijing
http://www.pharma-mkting.com/meetings/M187mtg140.htm

5th Annual Successfully Utilize Data Warehousing and Business Intelligence for Pharmaceutical Sales & Marketing
April 25 - 26, 2005 • Philadelphia, PA
http://www.pharma-mkting.com/meetings/M004mtg128.htm

Pharmaceutical Executive's Annual Marketing Summit
April 25 - 27, 2005 • Loews Hotel, Philadelphia, PA
http://www.pharma-mkting.com/meetings/M142Bmtg125.htm

May 2005

Identifying and Solving Risk Communication Problems
May 2 - 3, 2005 • Washington, DC
http://www.pharma-mkting.com/meetings/M006Emtg130.htm

Medical Education Congress
May 9 - 11, 2005 • Loews Philadelphia, Philadelphia, PA
http://www.pharma-mkting.com/meetings/M007Hmtg116.htm

3rd Annual USA Sales Force Effectiveness Summit
May 10 - 11, 2005 • Philadelphia, PA
http://www.pharma-mkting.com/meetings/M039mtg124.htm

PharmaDiscovery
May 10 - 12, 2005 • Washington, D.C. Convention Center
http://www.pharma-mkting.com/meetings/M204mtg119.htm

The Definitive Annual Forum on Field-Based Dissemination of Scientific Information
May 12 - 13, 2005
http://www.pharma-mkting.com/meetings/M004Emtg127.htm

5th Annual Sample Accountability
May 16 - 17, 2005 • Princeton, NJ
http://www.pharma-mkting.com/meetings/M004mtg134.htm

3rd Annual Publication Planning & Execution Excellence - USA
May 16 - 18, 2005 • Washington, DC
http://www.pharma-mkting.com/meetings/M006mtg146.htm

Experts Consulted and/or Cited In Articles

The following experts were mentioned or consulted in the preparation of articles for this issue.

- **Gerald J. Acuff Jr.**, Chief Executive Officer, Delta Point, 480-342-7113, jerryacuff@msn.com
- **Dr. Gene Emmer**, President, Med Services Europe B.V., +31 64 856 6707, info@medserviceseurope.com
- **Stephen Kimberley**, MD, Medical Director, Wellscape, LLC, 541-284-4700, skimberley@wellscape.com
- **Monique Levy**, Health Analyst, Jupiterresearch, (212) 389-2014, mlevy@jupitermedia.com
- **Preeti Pinto**, Sr. Dir. Head Promo Reg. Affairs, AstraZeneca Pharmaceuticals, 302-885-4408

Resource List

The following resources were consulted in the preparation of this issue or cited within this issue.

- **The Accel Report: Through Our Customers' Eyes**. The Accel Report is a document describing the state of the relationship between Physicians and Drug Reps. Based on proprietary research conducted by Accel in March 2003, it presents a fascinating glimpse into the problematic state of mind of MDs when it comes to drug company reps and their samples and points the way towards making realistic improvements. http://www.accelhealth.com/report1.htm
- **PhRMA Clinical Trial Registry Proposal**. http://www.phrma.org/publications/policy/06.01.2005.1111.cfm

Pharma Marketing News

Pharma Marketing News is an independent, free monthly electronic newsletter focused on issues of importance to pharmaceutical marketing executives. It is a service of the **Pharma Marketing Network** – The First Forum for Pharmaceutical Marketing Experts – which brings together pharmaceutical marketing professionals from manufacturers, communications companies, and marketing service providers for wide ranging discussions and education on a multitude of current topics.

Pharma Marketing Network & *Pharma Marketing News* provide executive-level content, professional networking & business development with permission-based emarketing opportunities.