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Marketing in the Post-Vioxx Era

By **John Mack**

At the recent Pharmaceutical Executive (PE) Annual Marketing Summit in Philadelphia, a panel of experts moderated by Patrick Clinton, Editor-in-Chief of PE Magazine, discussed pharmaceutical marketing in the "post-Vioxx" Era. The panel, titled "The Post-Vioxx Era: Shedding New Light on Drug Safety, Risk Communications, and Advertising," examined shortcomings in the current regulatory system and discussed opportunities for improvement. Topics included:

- What can the industry learn from the experience and how can we respond?
- Does DTC advertising drive unnecessary drug use? If so, what are the implications for DTC advertising?
- How can we accommodate products with complex safety profiles?
- Can we inoculate products against this type of response?
- Is the problem drug safety, risk communications, doctor/patient education, the effects of advertising—or all of these?

Panel member Tom Albright, VP, Botox Global Marketing at Allergan, shared his vision of the future by looking at the promotional and strategic sides of pharmaceutical marketing. Albright defined a new vision of accelerated adoption of a drug within appropriately targeted populations. These markets would be smaller, but less risky than the typical market for which blockbusters aim their promotions.

Promotions to a smaller, targeted market can focus on open communication of better defined benefits to that specific population balanced by the risks. "Many times," said Albright, "benefits are emphasized and risks are just carried along rather than being openly discussed."

DTC Straight Talk

An example of a drug ad that uses a frank, open discussion about risk is the new ad for Ortho's Evra birth-control patch. As reported in the March 22, 2005 issue of the Wall Street Journal, the "new approach to TV and print campaigns … deals head-on with safety, putting drug risks on more-equal footing with drug benefits."

The "new" approach shows a split screen with a real doctor on one side and a woman actor-patient on the other. While the patient seems enthusiastic ("I'm in!" she says), the physician counters with a "Let's talk" response and goes on to talk about risks.

FIGURE: The Ortho Evra ad depicts a dialog on risk between the physician (left) and patient (right)

"The future of DTC advertising depends on its ability to inform, and the balance between persuasion and information is likely to shift towards information," said Richard Pounder, chief executive and president of Alchemy, a unit of Interpublic Group of Cos., which produced the Evra campaign. He wouldn't divulge details of focus-group tests for the new J&J ads, but said they were well-received and not off-putting, despite the frank talk about dangers.

Strategic Marketing Goals

Strategic marketing should be engaged early in the development cycle suggested Albright. Marketers need to better understand the needs and burdens of future patient populations, and early on, how the target profile of their product provides benefits to

these patients. Through early integration with clinical development teams, clinical trial protocols would be designed to effectively demonstrate those benefits.

In order to advance this idea internally, pharmaceutical executives should not promote "blockbuster" status for a drug if sufficient unmet need can not be demonstrated. Whether or not such a realistic view of a product can be maintained in the current competitive atmosphere is questionable given the pressure on pharma executives from Wall Street.

Quality of Revenue

Some experts argue that targeting a more appropriate market through evidence-based marketing leads to less income, but the income is of higher "quality." In this context, evidence-based marketing is marketing that bases its discussion of benefits and risks upon clinical evidence gleaned from trials or post-launch outcomes data and specifically targets a population having the highest benefit-to-risk ratio.

Quality revenue is a well-understood concept in the insurance industry, which typically carves out risky populations and denies them coverage.

The insurance industry analogy illustrates an important drawback of using evidence-based marketing techniques and settling for quality revenue in the pharmaceutical industry; namely, no one wants to be denied medical treatment even if the evidence suggests that the risks outweigh the benefits. The pharma industry should not make this decision, only the doctor and his or her own patient.

Another panel member, Russell Ellison, MD, Former Chief Medical Officer, Sanofi-Aventis, suggested that investors need to be educated as well as industry executives. "It's better for the industry in the long run," said Ellison. "Quality revenue will offer long term benefits and sustainable profitability," according to another expert responding to a recent PMN survey.

Arguing that one type of sales dollar is of higher quality than another, however, may be a hard sell to short-term thinkers prevalent on Wall Street. "There is no such thing as quality revenue," said a PMN survey respondent. "Profit is profit and you get it by generating revenue or managing expenses better."

Over Estimating the Market: What Our Survey Revealed

Seventy-five percent (75%) of respondents to our Evidence-based Marketing and Quality Revenue Survey believe that pharmaceutical marketers often overestimate the size of the potential market for drugs (e.g., by overestimating the number of people with the indication or by redefining the indication so that more people are likely to be included).

The urge to get a large market share quickly is difficult for marketing managers to resist. As one respondent said: "This is probably done for the same reason that other industries overestimate the potential market for products—to get a bigger share of corporate resources internally or to impress analysts externally and increase stock values."

Some other comments included:

"Often this is for internal consumption. That is, New Products Planners are competing with other internal compounds. To make their compound look [more] valuable and get more corporate resources, they often try to over estimate the market potential."

"They may not have accurate numbers, but if they overestimate they have to live with those consequences through an unrealistic forecast. It is too risky to overstate estimates today."

"Drug marketing shouldn't be like selling a car. Every action Product Managers take not to generate false expectations from patients should be worn like a [badge] of honor…"

"I believe that the size of any market is inversely proportional to the scale of therapeutic improvement over previous treatments. So an orphan drug has, by definition, a far greater market potential than another new antihypertensive that improves BP control by nanometers of Hg. The disturbing thing is that the industry appears obsessed with the low hanging fruit of major diseases (like hypertension, diabetes, hyperlipidemia) and assumes blockbuster potential for any new development in these areas, which are largely well treated."

Targeting a smaller audience may be appropriate for drugs with high risks, but respondents were divided on the issue of marketing strategy for a drug with a moderate side effect profile. About half of respondents felt that for this type of drug, marketing should focus on the widest possible population, regardless of the benefit/risk ratio as long as more risk awareness is included.

Some comments included:

"As long as risk awareness is provided to the population through effective source and with proper explanation, products with moderate side effects such as statins, which can do more good than harm, should focus on the widest possible population."

"Healthcare is a personal decision and as long as every possible effort is made to be brutally honest, then I think the patient should have the ultimate choice."

"Physicians should be made aware of the potential benefits -- as well as risks -- for the widest possible patient population. They have, or should have, the capability to make risk/benefit decisions. As for the population at large, people should be aware of drugs that can help them but also should know the downside risks."

The Role of the Physician

Panel member Keli R. Bennett, Consumer Marketing Director, Immunology Franchise, Abbott, asked "Where is the responsibility of the physician? Why are we putting all this burden on direct-to-consumer advertising (DTC)?" DTC may be wrongly accused as a driver of inappropriate use and overuse of drugs, claimed Bennett. "While DTC must provide balanced information regarding risks and benefits," said Bennett, "consumers cannot make treatment decisions without the support of a learned intermediary."

Some recent research reported in the literature, for example, claims to have proved that "marketing of prescription medications for depression may exert significant influence on treatment decisions." This may be so, but the research was misinterpreted in the press as proving that "Doctors are easily persuaded to prescribe antidepressants — often unnecessarily — when patients mention having seen them in television advertisements."

The study, which was published in JAMA, employed actor patients who visited physicians in 2 states, presented themselves with some medical complaints and asked (or did not ask as the case may be) for a specific drug by name. The problem is that in many cases, contrary to accepted medical practice guidelines, physicians prescribed an antidepressant inappropriately.

Dr. Richard L. Kravitz, lead investigator on the study said "Prescribing antidepressants for adjustment disorder, as presented in the study, is at the margin of clinical appropriateness."

For more on this, please read the Pharma Marketing Blog article "Blame the Doc, Not DTC!"

Patrick Clinton, the panel moderator, pointed out that the industry "cannot say it's not responsible for physicians' behavior. You can't have 80,000 to 100,000 representatives out there and say this.'

This was a subject at a recent hearing of the House Government Reform Committee analysis of confidential Merck documents revealed how Merck trained its sales staff to mislead doctors in an aggressive campaign to boost prescriptions for its painkiller Vioxx despite evidence that the drug increased heart attack risks.

"And when doctors asked about those risks," according to an AP story, "the Merck sales reps were to refer to a 'cardiovascular card' with data suggesting that Vioxx could be safer than other anti-inflammatory drugs. Yet the card…doesn't include the very study that raised the first warning signal that Vioxx could harm." A Merck memo to sales reps described the card as "an obstacle handling piece."

Between You and Your Doctor

In almost every DTC ad you hear or see the phrase "See your doctor" or "Only your doctor can determine if X is right for you" or "That's between you and your doctor." On the face of it, this sounds like the pharma industry is taking a neutral stand and defers to the doctor as the "learned intermediary." Ellison, however, suggested that the industry cannot assume that the appropriate risk-benefit discussion between a physician and patient takes place when the Rx is written.

Perhaps choosing the right doctors to market to is as important as choosing the right patients, suggested Clinton. Marketers should target physicians who know how to properly prescribe the drug. No one was sure how this could be done other than to market exclusively according to the labeled indications—i.e., do not market to drugs without a pediatric indication to pediatricians.

Evidence-Based Marketing and Compliance

However, it is possible to increase the "lifetime value of a drug even when marketing is based on evidence.

Currently, pharma brands spend 80% of the sales and marketing budget on acquisition of new patients and only 20% on retention of current patients. Much more effort should go into retaining patients and ensuring that they adhere to the treatment regime prescribed by the doctor. Evidence suggests that outcomes would be vastly improved with greater patient compliance. This is a great opportunity for evidence-based marketers to make a difference.

Bennett pointed out that by focusing on the "life-time value" of patients and increasing persistence, pharma companies can achieve more predictable revenue over time.

The Next Vioxx is Inevitable

Ellison pointed out that there is "nothing new here." He recalled the situation when Redux—an obesity

drug—was withdrawn from the market several years ago. There were similar calls for FDA reform.

By continuing to focus on the short-term capture of total market share, most emphasis is put on revenue from new prescriptions. Marketers are pressured to dig ever deeper into a pool of patients for whom the product is inappropriate, which increases the risk in the long term that the product will become the next Vioxx.

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