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Pharma Trends to Watch in 2006

By **John Mack**

This is the time of the year when we all look into our crystal balls and try to come up with predictions for the new year. In December, 2005, for example, Pharmaceutical Executive Magazine published their 2006 Forecast based on interviews with a few experts. Pharma Marketing News also hosted its "2006 Pharma Trend Survey" online beginning January 9, 2006. The Pharma Marketing Roundtable met by conference call on January 12 to discuss trends as well. This article summarizes the collective wisdom from these sources.

Survey Topline Results

The *Pharma Marketing Network 2006 Pharma Trend Survey* asked respondents how likely or unlikely were a number of possible pharmaceutical industry trends to unfold in 2006. Respondents could answer highly unlikely, somewhat unlikely, somewhat likely, or highly likely. The aggregated results from 75 respondents are summarized in FIGURE 1 (see page 3).

Increase in Generic Competition

Increasing competition from generics is near the top of the list of most likely trends. Fifty-five percent (55%) of respondents said increased competition was "highly likely" in 2006. A corollary of this trend is increased loss of patents and 31% of respondents felt this trend was highly likely to continue in 2006.

"For the first time in my lifetime there are drugs going generic that are more efficacious and have fewer side effects than was previously the case," said Harry Sweeney, member of the Pharma Marketing Roundtable and Chair of Dorland Healthcare Communications. There's no question that the generic pipeline is robust and generic utilization will increase in 2006. Currently, about 53% of prescriptions are generic drugs. "That's projected to increase by 15% to 18% in 2006," said Vince DeChellis, another member of the Pharma Marketing Roundtable and an independent healthcare consultant.

"The increasing power of formularies means that brand companies have to compete not only against their brand competitors, but also with generic versions of their competitor's patent-expired drugs," said Mario Cavallini, Manager, Competitive Intelligence at SimStar. "This will be a challenge for marketing people who have to look at more dimensions than one." He was speaking at the recent Pharma Marketing Roundtable conference call.

As consumers begin to pay more in co-pays for branded drugs, pharmaceutical brand marketers will be under pressure to communicate compelling reasons for them to pay a premium for brand products. "With the advent of consumer-directed healthcare, you have to convince the consumer that paying $50 for Lipitor vs. the cheaper generic version is worth it," said Jack Barrette, Category Development Officer at Yahoo!

Of course, the rollout of Medicare Part D makes the federal government an even bigger payor in the years ahead, which means more pressure to substitute generics for brand drugs. The pharma industry is bracing for this and, according to Henry McKinnell, CEO of Pfizer, has a plan. "…if the sole decision-maker was the government, we'd be really worried," said McKinnell. "…government puts cost before the interest of patients. And an all-generic and an absolutely minimal-cost formulary sounds pretty good. The competition we're focused on is not so much the competition at the PBM level. It's the competition at the plan-recruiting-patients level. That has all to do with choice and access. We believe," said McKinnell, "that we can convince the payors that our medicines not only produce better outcomes, they also lower cost."

Brands Caving-In to Generic Onslaught?

Interestingly, the brand industry may be accelerating the loss of patents by settling law suits brought by generic competitors (see "Branded Drugs Settling More Generic Suits", WSJ; 17-Jan-2006). According to the Wall Street Journal, "Instead of defending their patents in protracted and risky court proceedings, some companies are settling cases by agreeing to shorten the patent life of a drug—and to forgo hundreds of millions of dollars in potential revenue—in return for assurance that they can market it for a few years free of the pall cast over their share prices by litigation with their generic rivals."

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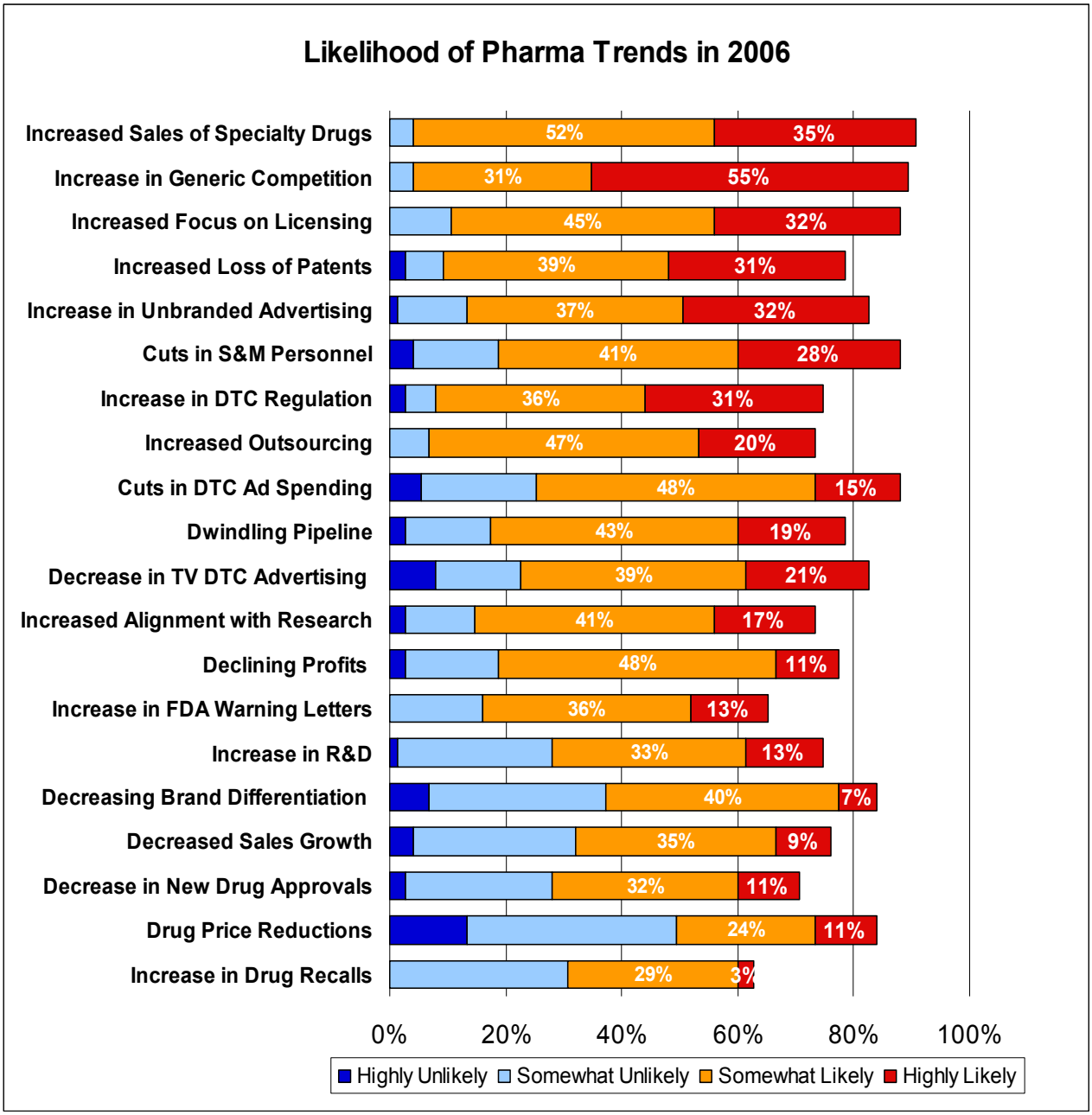


FIGURE 1: This is a summary of results of the Pharma Marketing Network 2006 Trend Survey. This snapshot was taken on 18-January-2006 (75 respondents). Respondents were asked to rate the likelihood of each trend by answering highly unlikely (dark blue), somewhat unlikely (light blue), somewhat likely (orange), or highly likely (red). The results are sorted according to the sum of the percent answering "somewhat likely" and "highly likely," with the most likely at the top and the least likely at the bottom..

The survey and current aggregated results can be found online at
http://www.pharma-mkting.com/surveys/surveys-hp.htm#2006trends

"Litigation as a marketing tool has been around for a long time," according to Sweeney. "As Medicare kicks in and fills [generic drug companies'] coffers, the generics will do things that they think will help them build their businesses. If they can grab more from branded drugs, they're going to do it."

At least one brand company is fighting back, however. Celebrating Pfizer's court victory over Ranbaxy's challenge to Lipitor, McKinnell offered this analogy: "If somebody is threatening to steal four tires off your car, it's not a good strategy to compromise and give them two." It depends. Does the person have a gun pointed at you? And is your family in the car?

As the WSJ article explains, there are advantages to settling and giving up a tire or two. "For the branded companies, settling has distinct advantages. They get a specific date when they know for sure they will lose a drug's revenue and can plan efforts to switch consumers to tweaked versions of the branded drug that still enjoy patent protection. Settlements also prevent generic makers from launching copycats before the courts decide patent cases, which has become increasingly common." In other words, this strategy could be good for the brand company's family (i.e., stockholders).

Brand Differentiation

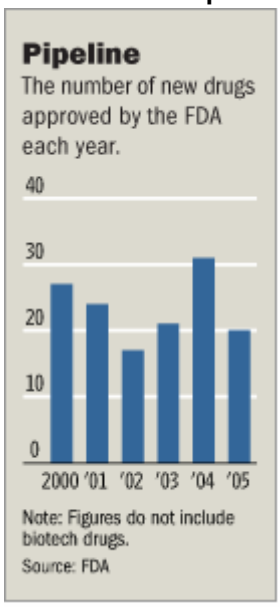
All this leads to brand differentiation, which I find means different things to different people. Unfortunately, the survey did not offer much in terms of defining what was meant by this term.

Harry Sweeney contended that brand differentiation refers to more than brand-specific messaging versus unbranded, disease-awareness messaging. "Whether there is an increase in unbranded ads or not, brand differentiation activities are going to increase," he said. "There's going to be more emphasis on distinguishing your brand to meet the generic competition." Sweeney voted, therefore, against any trend towards decreased brand differentiation whereas a higher percentage of survey respondents (47% vs. 38%) felt that decreased brand differentiation was somewhat or highly likely to be a trend in 2006.

Another option available to brands for combating generic competition is switching to over-the-counter (OTC). DeChellis warned that a trend in that direction would shift costs to the consumer, which might make the government happy since more drug costs coming out of consumers' pockets means less pressure on government budgets. Politically speaking, however, shifting costs of drugs to consumers may not be what the industry needs in 2006.

What I had in mind when I created the survey was not the problem of conveying distinctive brand messages to convince consumers to purchase the brand rather than the generic, but distinguishing your brand from the competitor's "me-too" brand. Take, for example, Viagra vs. Levitra vs. Cialis. Right now, I am finding it difficult to recall which brand—Viagra or Levitra—is promoting "Make the Call" vs. "Strike Up A Conversation." However, I *do* get the Cialis message: 36 hours, 36 hours, 36 hours!

R&D and the Pipeline of New Drugs



Another corollary to the increased generic competition trend is the brand drug pipeline issue. After all, if many more new drugs were on the immediate horizon, generics would only be a nuisance rather than a real threat. The consensus is hopeful. Only 19% of survey respondents, for example, felt it was highly likely that 2006 would see a continuing dwindling pipeline trend.

"2006 may be a rebuilding year," said Barrette. "You've got a trough in the pipeline—for the first time in years, there's been a drop rather than an increase in approvals compared to the previous year [see chart]. There's sure to be a ramp up in the years coming, but public opinion, generic growth, a lack of approval of new drugs, and pressure on marketing from physicians as well as consumers, means that 2006 will be a rebuilding year at best."

Only 20 new indications for drugs were approved in 2005 compared with 36 in 2004, despite $38 billion investment in drug development last year. Speaking of R&D investment, less than half (46%) of survey respondents felt that increased R&D expenditures—as a percent of sales—is likely to continue to be a trend in 2006. About a third said it was somewhat or highly unlikely. The subgroup of self-selected pharma company respondents was pretty divided on this issue with the largest percentage—35%—not knowing.

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The FDA recently announced new guidelines for the preliminary phases of drug development, which will, according to the FDA, "enable U.S. medical researchers to evaluate much more efficiently the promise of scientific advances discovered in their laboratories."

Roundtable members discounted the importance of this initiative, at least in the short term. "It would be a minimum of 5 to 10 years before this would impact the number of drugs coming out of the pipeline," said Barrette. "It's not a done deal," Cavallini pointed out. "There are human interest advocates who are complaining that this puts study participants at greater risk. This is another test of FDA's skittishness regarding risk."

Dreaded Precautionary Principle

Speaking of risk, FDA, and new drug approvals, DeChellis noted that "the projection for new drug approvals in 2006 looks to be about 36 or 37 new indications, but that depends on whether or not the FDA gets cold feet."

Sweeney referred to the "dreaded precautionary principle" concept attributed to Peter Pitts, former Associate Commissioner for External Relations at the FDA, and now a Senior Fellow in Health Care Studies at Pacific Research Institute (PRI). Pitts characterized the principle thusly: "unless you know everything you shouldn't do anything."

Whether or not precaution should be dreaded depends on your point of view. In any case, Pitts and other experts don't believe FDA is buying into this principle.

"The whole risk topic is ripe for robust discussion down in Washington," said Sweeney. "There are advocates—primarily consumer advocates—who are arguing for a zero risk approach. That's not the world that we live in. I think the FDA realizes this – the whole atmosphere is politicized and FDA is not sure what to do. The fact that the FDA does not have a true leader doesn't help."

FDA Regulation of DTC: To Be or Not To Be?

The most visible challenge to the pharmaceutical industry in 2006—one that if not handled deftly can affect the industry's public image the most—is direct-to-consumer (DTC) advertising. As Sweeney likes to say, DTC has become "a poster child for the industry and its marketing activities."

A large majority (67%) of respondents to the survey felt it was likely that there will be an increase in regulations of DTC by FDA in 2006 as opposed to only 8% who felt there will not be any increase. Roundtable members tended to favor the minority opinion on this point.

"The Bush administration is overextended with regard to political capital and it has to cut down the number of fronts it's fighting on," said Cavallini. "One of these is the battle of Bush appointees against government agency (e.g., FDA) professional staffers. Consequently, there's going to be a truce, at least until the end of mid-term elections."

Risk: I Say Relative, You Say Absolute

Most experts believe that if the FDA comes out with new DTC regulations, these will most likely focus on the communication of risk in consumer drug ads.

The industry, of course, has its own views on how risk should be communicated. Some industry proponents, for example, contend that risk should be presented in absolute terms rather than relative terms. Study data presented at a recent FDA public hearing suggest that consumers presented with drug risk information as an absolute risk were willing to accept a higher level of risk to achieve therapeutic benefit than those who were presented information as relative risk. That is, if I told you that your chances of getting a heart attack was 5 times higher if you took Vioxx than if you took Aleve, you would be less inclined to accept that risk than if I told you that your absolute risk was 0.25% with Vioxx vs. 0.05% with Aleve. Neither of the latter two numbers seems big enough to worry about, but a 5-times increase sounds terrible.

Sweeney expressed it this way: "Since most people are not interested in epidemiologic statistics, generally, but rather in a 'statistic of one'—themselves, or a loved one—wouldn't it make more sense to report risks in those terms as well as the ways favored by economists and epidemiologists?"

Not too many people have attempted to answer Sweeney's question. I only note here that many industry advocates want consumers to have a choice and to be able to make an informed choice. What better way to ensure that than to communicate relative benefits and risks of drugs? That way, consumers can make head-to-head comparisons just like they do when buying cars or margarine. If you are interested in reading further thoughts on this topic, see these Pharma Marketing Blog posts:

- Marketing "Acceptable Risk"
- Finally, Marketing Aligns with PR – Maybe

A future Pharma Marketing Roundtable discussion of this issue is planned.

Regardless of what the FDA may do, public opinion is the final court of appeals. "Public opinion and the consumer media are going to watchdog the PhRMA code closely in 2006," said Barrette. "Anyone who does a reminder ad or sends an ED ad to an inappropriate audience, for example, is going to be beaten up and stoned publicly. This public enforcement of the guidelines is going to be interesting to see."

New Directions Part 1: Alternative Media
Nearly two-thirds (63%) of survey respondents felt that there would be cuts in DTC ad spending in 2006 and 60% felt there would be less DTC on TV. Roundtable experts suggested that there would be a re-allocation of where DTC money is spent, not a dramatic cutback across the board. "I think that the channel spend is going to change," said DeChellis. "Medical communication, for example, is going virtual."

Some companies are already allocating sizeable chunks of their DTC ad budgets to online. "AstraZeneca said it is spending 8% of its consumer budget online," said Barrette. "which is about quadruple the industry average for the past several years. At Yahoo! we've already booked more for 2006 before the year has even started than we booked at the end of 2004. This move to up-front buying is a clear indication that the industry is moving in this direction."

New Directions Part 2: Unbranded DTC
More than two-thirds of survey respondents (69%) felt it was likely that there would be an increase in non-branded (unbranded) disease awareness advertising in 2006 as opposed to only 13% who felt there would not be an increase. Somewhat more pharma respondents (18%) agreed with the naysayers.

"Part 2 about the shift in how we reach consumers [part 1 being the channel mix – see New Directions Part 1: Alternative Media] is the creative that we reach them with," said Barrette. "There's no question that we are going to see more unbranded ads and a big shift in the way creative is done – it's already happening. You're going to see a flip to mensfacts.com and those types of programs."

Conclusion
There's enough collective wisdom here to get your brain cells working on ideas about how to align your business plan with the projected trends for 2006. The online Pharma Marketing Network 2006 Pharma Trend Survey will available for a bit longer and I invite you to look into your crystal ball and take the survey. Your comments are also welcome. If you are interested in joining the Pharma Marketing Roundtable, please go to the Web site (www.pharmamarketingroundtable.com) for more information and a link to the application form.

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