Pharma Marketing News

www.pharmamarketingnews.com

April 2008
Vol. 7, No. 4
•
Published by
VirSci Corp.
www.virsci.com

Feature Article

DTC Risk Communication

Is More or Less Needed?

By John Mack

Reprint #PMN74-01

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Comments to Editor, April 2008 Issue

This article is part of the April 2008 issue of *Pharma Marketing News*.

For other articles in this issue, see:
http://www.news.pharma-mkting.com/PMNissueApr08archive.htm

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On April 16, 2008, the FDA's DDMAC sent a letter to Pfizer CEO Jeff Kindler, instructing his company to "immediately cease dissemination of violative promotional materials for Viagra"—namely a video on the Viagra Web site that shows a group of men in a Nashville studio playing instruments and singing the "Viva Viagra" song.

"The video," said DDMAC in the letter to Kindler, "then ends with an audio voice over that states 'Talk to your doctor about Viagra, America's most prescribed treatment for erectile dysfunction.' This video is misleading because it makes representations and suggestions about the use of Viagra for erectile dysfunction, but fails to disclose any risk information for the drug."

Kindler, in a comment to Pharmalot, said "Due to a technical error by the website, the safety information contained in a companion banner complementing the video was not displayed as instructed. Pfizer discovered the error, notified the website of the error, and our understanding was that the website corrected its error immediately."

As of this writing (April 26, 2008) the violative Viagra video is still available on the www.viagra.com home page without the "companion banner" (see Figure 1).

Figure 1: Violative Viagra Video

And so it goes in the ongoing battle between pharmaceutical marketers and the FDA regarding the communication of risk vs. benefits in advertising.

But does it have to be that way?

Risk-First DTC

Although we can point to Pfizer as a culprit, we can also point to it as an innovator in communicating risk in direct-to-consumer (DTC) advertising.

For example, Pfizer was the first pharmaceutical company to produce what is called a "risk-first" DTC advertising. That ad is the 150-second Celebrex TV ad—as well as the 2-page print ad—that proclaims "Understand the risks. See the benefits" (see Figure 2, pg. 2).

The ad mentions the possibility of death as a side effect at least two times! You won't hear that word in many DTC ads. Several blog pundits and commenters to blogs thought this was a bad idea. An anonymous commenter to Pharma Marketing Blog, for example, had this to say:

"Those who make it through the two minutes or so of risk information finally get a tiny little coda of benefit message...conveying a tiny little package of benefits that 'in some patients...may outweigh the risks.'

"I can't even begin to imagine how much Pfizer is spending on this campaign at 150 seconds of airtime a pop. And by returning to the airwaves, they've just plastered a big 'Kick Me' sign on their back for Sidney Wolfe, Senator Grassley, Rep. Waxman, *et al*.

"Whoever sold this idea to Pfizer management must be one heck of a salesperson."

Although the Celebrex ad has been criticized for mentioning "death" several times, an article in *Pharmaceutical Executive Magazine* suggested that this "risk-first DTC" appears to be a new tactic—"to persuade the public about a drug's usefulness ... acknowledging the negative allows the product to gain credibility, mitigates resistance and counterarguing, and permits information that would normally 'hit a brick wall' to be viewed in a credible context."

The idea that being up front about communicating risk to consumers can actually increase credibility in a troubled brand is fascinating.

Expert Panel Discussion

This idea was also raised recently during a panel discussion I moderated at the **2nd Annual Pharmaceutical Sales & Marketing Executive Congress**, held in Rockville, MD in March, 2008. The panel—entitled "Communicating Risk: Key Issues at Hand"—included the following experts:

- **Scott M. Lassman**, Partner, FDA Group, WilmerHale LP
- **Hugo Stephenson**, President, iGUARD.org
- **Harry Sweeney**, CEO, SouthPennSquare Associates

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Figure 2: Celebrex "Risk-First" DTC Print Ad

The panel grappled with several issues, including

- Clarifying what we mean by "risk"
- Pharmaceutical industry responsibility to communicate risk under the "learned intermediary" doctrine
- FDA's Emerging Risk Communications
- The concept of Hazard vs. Outrage

The remainder of this article presents a summary of the panel's discussion. You can contribute your own opinions "Comments to Editor, April 2008 Issue" in the **Pharma Marketing Forums**.

What Is Risk?

Before you can communicate risk and determine who should communicate risk to whom, it is necessary to define what we mean by risk.

"We ought to clarify that risk is a lot more than odds and probability," said Sweeney. "You have to have a hazard. You have to be exposed to the hazard. Then there's proportion—the magnitude of the risk, which is not discussed in the pharmaceutical world. We are given tiny numbers upon which to make important major communications policy decisions."

Sweeney pointed out the need for a baseline of what consumers understand about drug risk before we can move the needle where it ought to be. He engaged the audience in a "parlor game" as a demonstration (see box, pg. 3).

Sweeney outlined the four elements to risk:

1. What's the hazard?
2. Are you exposed to it?
3. What is the likelihood of a negative outcome?
4. How risky is it? – how would you rate it on a scale of risks – death on one end and a rash on the other.

"Who answers these questions?"

Is there a legal definition of risk?
In answer to this question, Lassman stated "it depends on the context. If you look at FDA regulations, there are precise definitions of what they mean by things like 'contraindication,' 'precaution,' 'adverse event,' etc. All these are related to risk and that's as close as FDA gets to defining risk."

"I would add a 5th item to Harry's elements of risk: How certain do you need to be that whatever risk you are talking about is actually caused by the drug? Do you need 100% certainty or do you need something less? If you look at FDA regulations, they do not require 100% certainty to label something as an adverse event."

"When I think of risk communication," said Stephenson, "I imagine myself sitting with a patient in front of me. What is the objective of my

Continues…

Harry's Drug Risk Parlor Game

Imagine a scale in front of you with a zero at one end and a ten at the other. Zero is extremely risky (not safe) and ten is extremely safe. Put your finger somewhere on the scale in answer to the question: "How safe are prescription drugs?"

"Imagine doing this in a roomful of people more representative of the general public," said Sweeney. "If you don't have a baseline for what people's understanding of risk, how are you going to move the needle to where it ought to be?"

You are invited to play Harry's Drug Risk Parlor Game online here.

communication with that patient? I want that patient to have the best chance for the best possible outcome from the medication I am prescribing. Patients need enough information to do what is necessary to minimize THEIR risk. For example, if there is a cardiovascular risk, they need to know that is the reason why they need to have their cholesterol checked or do other tests periodically. In other words, I'd like to focus not just on numbers, but how patients interpret risk information in the context of their own care and use that information to improve their clinical outcomes."

Does DTC Negate the Learned Intermediary Doctrine?

According to the so-called "learned intermediary doctrine," pharmaceutical companies have the responsibility to warn doctors about drug safety information, but not patients. That is, historically this doctrine shielded pharmaceutical companies from any obligation to warn patients directly about their prescription products. Recently, however, this position has been brought into question due to DTC adve-tising, in which drug companies are communicating directly to consumers, bypassing the learned intermediary.

In Perez v Wyeth Laboratories Inc, the New Jersey Supreme Court recently argued that the learned intermediary doctrine does not apply when companies engage in direct-to-consumer (DTC) advertising.

Mark Cohen, executive director of the Government Account-ability Project—a 30-year-old nonprofit public interest group that promotes government and corporate accountability by advancing occupational free speech, defending whistleblowers, and empowering citizen activists -- said the learned intermediary doctrine made some sense until the appearance of the first DTC ad in 1981 and FDA's 1997 advertising guidance.

"Some states are trying to get around the learned intermediary doctrine by arguing that DTC advertising puts the drug industry outside of that doctrine and therefore they do have the responsibility to communicate risks to patients," noted Lassman. "Obviously, when pharma companies engage in DTC advertising they have responsibility under the federal food drugs and cosmetics act to communicate risk appropriately in accordance with FDA rules and regulations. So, when we talk about the learned intermediary doctrine, it's really just in the context of product liability laws."

There's some point to the argument that the learned intermediary doctrine cannot be abandoned simply because many drugs are not advertised directly to patients. Another argument is that many patients may not see these ads. That seems hardly likely. A recent USA Today/Kaiser Family Foundation/ Harvard School of Public Health Survey found that practically every American over 18 (ie, 91%) has seen or heard an advertisement for a prescription drug (see "What Americans Think About Drug Advertising"). Of course, not everyone has seen or recalled DTC ads for ALL Rx drugs.

"Individuals differ in how they deal with information," pointed out Sweeney. "Societal rules must fit the least common denominator. And that is where the learned intermediary rule comes in—the physician makes the decision how much information a particular patient should get, not society."

"While we are focusing on communication with the learned intermediary, for various reasons—not the least of which is economic—these learned intermediaries are not communicating well with patients," said Stephenson. "Very few people have received a call from their pharmacist or doctor when there has been a drug recall, for example. Most people would actually like to have this kind of information communicated to them."

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Stephenson went on to point out that while we are a society of increasingly informed consumers and frequently receive communications from toaster manufacturers and car manufacturers about recalls of their products, we don't get this kind of information about the medicines we take.

Sweeny suggested "a good idea would be voluntary registration at a site like iGuard (see box, right), which will send users safety updates from drug companies to consumers who are taking their drugs." Presumably, consumers would then have been duly notified of risks and give up their right to sue the drug company.

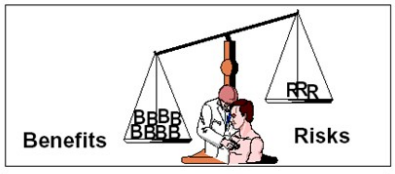
"The problem is," said Lassman, "if you believe in the merit of the learned intermediary doctrine, you may decide it's better to defend that wall than abandon the doctrine altogether and rely upon community websites like to communicate safety information to patients."

Sweeney brought up an idea from consumer-focused industries that may be applicable to the drug industry: "You buy a car and if there is a problem there may or may not be a mass recall. More often you get an individual piece of mail about your car. Same thing for many other products. If you register with the manufacturer, then you can get a targeted communication. It's such a simple idea."

This would avoid broadcasting risk problems that may not apply to every user of a drug. Such broadcast announcements may cause more problems than they solve. By analogy, patients at greater risk could be targeted with appropriate safety information when there is an issue relating to a drug they may be taking.

FDA
evaluates
benefits/risks
for the population

Provider
evaluates
benefits/risks
for a patient



Patient
evaluates
benefits/risks
in terms of
personal values

An Innovative System for Communicating Drug Risks to Patients

A Color-coded Risk Rating System That Delivers Personal Safety Alerts

Anyone who has tried reading a drug label knows how difficult it is to understand. It is especially difficult for consumers and patients to understand and evaluate the potential risks associated with the use of Rx drugs.

A study in the September 10, 2007, issue of the *Archives of Internal Medicine* found multiple problems with drug labels. The authors suggest that one way to improve readability and patient understanding of labels is for FDA to initiate a national standard for their format and content — much like it did with the "Nutrition Facts" labels required on food packaging.

In fact, the FDA recently invited food companies, trade groups, watchdog organizations, medical experts and its overseas counterparts to share how front-label symbols, like the "traffic light" system used in Britain, can improve public health. Shouldn't the FDA champion a similar system to rate risks on drug labels?

That's the idea behind iGuard's Risk Rating system, which converts medical jargon into simple, actionable information. It assigns color-coded risk labels to drugs to communicate the risk of developing serious side effects. This system is not intended for drug labels, however. It is an online solution that patients can customize for their own use depending on the drugs they are taking.

Listen to an audio podcast interview of Dr. Stephenson, Founder and President of iGuard.

FDA and Emerging Risk Communications

"For those of you who watch what the FDA has been doing," said Lassman, "you may have seen these 'early communications' that have come out about emerging risk issues. Several of these communications may come out within a single week. What they are doing is providing safety information about emerging risk even before they've identified any causal connection between the risk and the drug. They put disclaimers on the communications that basically say 'we want to let you know about this, we're looking into it, we don't know what it is, and we are not telling you to do anything about it.' "

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"My question is how useful is that? Does it provide information that physicians and patients will find helpful or does it just create a lot of noise in system? Obviously, FDA is getting a lot of criticism these days about how they deal with safety issues and they need to cover themselves. But is it really providing a public health benefit? Is it distracting people from important information that they can actually act on?"

Hazard vs. Outrage

Sweeney suggested that the audience think of plotting a BCG-type box where hazard is on one scale and outrage on the other. Outrage incorporates risk perception—how dangerous do people think the risks are. In one corner you have a high degree of hazard as judged by experts and a high degree of outrage as judged by the public. And so on.

"There are different communication techniques appropriate for each quadrant of the box," noted Sweeney. "Everything is not a crisis! You have to have the communication tailored to the magnitude of the problem as well as to the needs of the patient."

An FDA safety communications staffer in the audience said that the FDA is actively looking for new ideas on getting communications out to consumers. It typically puts out a press release that media pick up and report on. This is an effective way to reach consumers. However, the FDA has no control on how the media reports the event. If it is done too dramatically, then people will stop taking their medication even though that may not be appropriate and may cause more harm or scare other patients from taking the drug. Therefore, the FDA is constantly evaluating whether risk communications will cause too many people to stop taking medication. They evaluate how much information is disseminated and through which channels.

Patient Data and Actual Risk

"Another problem," said Sweeney, "is how to verify emerging risks. Vioxx is a case in point. Has anybody gone through a patient database—for example, Wellpoint's 28 million covered lives—to verify that the supposed hazard actually exists?"

"What the new FDA law passed last September is supposed to do is give the FDA authority to pull together information from all of these medical databases," noted Lassman, "including private insurers databases, so that when safety issues come up, they'll be able to run numbers on that population and try and get an answer."

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Understanding the difference between Hazard and Outrage

One of the challenges faced by risk communication is in how risks are perceived by target audiences. The perception of risk plays a major role in how well, or how poorly, messages which communicate risks and hazards are received by those the messages are intended for. This perception process can produce a wide range of outcomes from risk communication efforts, some of which may not have been intended by those who craft and disseminate those messages.

One approach to risk communication, known as the Hazard plus Outrage Approach, considers how messages related to risk are perceived. This process defined two separate measures of how risks are perceived and communicated:

Hazard, a technical and objective measure of risk which examined the possibility of the occurrence of a potential hazard, the potential consequences should it occur, how to manage the risk, as well as how to respond to an incident. This measure is primarily determined by experts who are knowledgeable about risks, and

Outrage, a subjective measure of risk which looks at how risks are perceived by those who are, or could be, exposed to them. While this method of assessment can involve factual information which has been presented by risk communicators, it is also influenced by more subjective measures, such as informal communication processes, social networks, and personal and cultural values.

The consideration of both is key in the effective transmission of messages related to risk communication, and the larger the difference between hazards being communicated and outrage by the recipients of those messages, the greater the potential for controversy and ineffective communication.

See http://earlcapps.blogspot.com/2007/09/risk-communication-understanding.html and

Lundgren, R., & McMakin, A. (2004). Understanding Risk Communication. In Risk Communication: A Handbook for Communicating Environmental Safety, and Health Risks (pp. 13-28). Columbus, OH: Batelle Press.

"When the FDA came up with its Drug Watch site a couple of years ago, one of the concerns of the pharmaceutical industry had was that there may not be any follow-up correction if it is subsequently determined that there really wasn't a safety problem. I was glad to see they posted a correction a few weeks ago to an early drug safety alert after determining that there was no causal connection."

Culture of Fear

The issue arose as to how to control the media, which may spin a story to make it more sensational and thereby instill a culture of fear among consumers.

"When we survey members of iGuard.org," said Stephenson, "85% feel that drugs are safe, but roughly the same percent also feel that the drug industry AND the FDA were actually holding back information. Every time there's a new safety issue reported in the press there is a culture of fear this feeds into. In my opinion, more and better communications is a very effective way of counteracting that."

"The key question is when does an emerging potential risk become a 'real' risk," said Sweeney. "Until that gets answered all risk communication is just throwing stuff up into the air."

Risk Communication and Adherence

"One of the things we are exploring is whether or not better communication about risk can improve compliance," said Stephenson. "Communicating risk should not be just about avoiding liability, but it could actually give patients a better experience with the product and result in better compliance. For example, if you know certain patients are more at risk to get nausea when taking a drug, you can communicate that risk along with tips on how to avoid the problem. This can reduce side effect dropouts. This can be supplemented by the sharing of patient information, which can help other patients put their risk in perspective."

Pfizer began airing it's "risk-first" Celebrex ads over a year ago and continues to do so today. That must mean that the ads are effective, considering the price of running them on TV. They just may be effective because putting risk first AND in perspective can keep patients from dropping their prescriptions, thereby improving compliance and adherence.

Pharma Marketing News

Experts Consulted

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

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