



## Death of a Drug: The Aftermath of Merck's Recall

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Wharton management professor [Michael Useem](#), director of the school's Center for Leadership and Change Management, notes that one of the key mantras in corporate crisis management is: "Hide nothing, tell all."



Less than a week after Merck & Co.'s voluntary withdrawal of its blockbuster arthritis pain medication Vioxx, following an extended clinical trial that linked the drug to heart attacks and strokes, the jury is still out on whether the pharmaceutical giant followed this cardinal rule.

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As headlines move past the company's initial announcement on Sept. 30 and begin to speculate on possible litigation, corporate liability and the financial implications of taking a drug used by more than 20 million people off the market, the spotlight has turned instead to previous suspicions about Vioxx, earlier FDA warnings about the drug's possible cardiovascular complications, and the drug company's own efforts to inform the public about possible risks since Vioxx was introduced in 1999.

What did Merck executives "know and when did they know it?" asks Wharton finance professor [Andrew Metrick](#). "Have they been aware and knowledgeable about this? Were they doing their best to prevent bad news from coming out? That's the crux of it. And this will get fought out in a lot of trials."

Merck's decision to immediately withdraw Vioxx was based on new three-year data from what the company called a "prospective, randomized, placebo-controlled clinical trial" designed to evaluate the efficacy of Vioxx in preventing the recurrence of colorectal polyps in patients with a history of this condition. During the trial, Merck also collected cardiovascular data on the 2,600 patients involved; half took 25 milligrams of Vioxx a day, half took a placebo. After 18 months, the patients taking Vioxx showed an increased risk of heart attacks and strokes. No increased risk was found in the first 18 months, the company reported, noting that these results "are similar to the results of two placebo-controlled studies described in the current U.S. labeling for Vioxx."

According to Robert E. Mittelstaedt, Jr., dean of the W.P. Carey School of Business at Arizona State University and former vice dean of executive education at Wharton, "one of the key factors in companies that succeed in managing a crisis vs. those that don't" is they understand that "the information being presented may not be to their liking ... Merck could have tried to rationalize the data as something that could turn out differently, but the company chose to believe it on its face and take action," says Mittelstaedt, author of a new book on crisis management called, *Will Your Next Mistake Be Fatal? Avoiding the Chain of Mistakes That Can Destroy your Organization*. "And that is the difference. The difference is the starting point."

### Red Flags Raised

For many, the ultimate issue may be in defining this "starting point," the moment when red flags were raised for Vioxx. Ever since the FDA first approved Vioxx for osteoarthritis and pain relief five years ago, researchers have warned that patients who take a class of drugs called COX-2 selective nonsteroidal anti-inflammatory drugs, or COX-2 inhibitors - Vioxx is in this class - had an increased risk of heart attack and stroke. A study reported in the press and conducted by the University of Pennsylvania's Garret A. FitzGerald, chairman of the Department of Pharmacology, first cautioned that COX-2 inhibitors

appeared to suppress the body's defense against blood clots, leading to the possibility of increased risk for heart attack and strokes.

When Vioxx was initially approved, Merck warned patients with heart trouble of possible complications. When the FDA approved Vioxx for rheumatoid arthritis in 2002, a new warning label noted that Vioxx is associated with a higher rate of heart attacks than competing COX-2 inhibitors like Celebrex or Bextra. In August 2004, the same year the FDA approved Vioxx for headache relief and for children over two years old, an FDA-Kaiser Permanente study announced that high-dosage Vioxx patients were more than three times as likely as non-Vioxx users to have heart problems. Citing the lack of a controlled, clinical trial, Merck strongly disagreed with the study's findings. However, in just a little over a month, Merck pulled Vioxx from the market, citing concerns from its own study.

"From an ethics standpoint, everything turns on the reason they did it," says [Thomas Donaldson](#), Wharton professor of legal studies and ethics. "And those are often highly submerged from the public eye. In other words, intent is always very difficult to fathom."

[Thomas W. Dunfee](#), Wharton professor of social responsibility in business and legal studies, agrees. "From just going back and looking at its actions, it does appear that Merck was a little uncertain internally about what to do. It came out not long ago supporting the product. Clearly, it was having some debates on this. In a broader framework," Dunfee adds, one way to position this discussion is to ask how it relates to the length of the FDA drug approval process and the question of continuing studies once a drug is approved.

Metrick gives Merck credit for conducting a study that, while designed to investigate Vioxx's efficacy in colon cancers, captured data on its cardiovascular effects. The fact that these studies were done "in daylight and not in secret" helps distance Vioxx from other corporate governance scandals, he says. "I don't think there is anything scandalous about this. These issues were known. There were some prominent people who said Vioxx has some problems. The information wasn't kept behind closed doors. The (Merck) study wasn't designed to pick up the cardiac issues but it did track them. If you really don't want this to be an issue, you do as little as you can. The company did not do that. It designed a study to see if Vioxx protected against polyps but looked at cardiac at the same time. The company was paying attention."

Compare this response to the Firestone case, Metrick adds, referring to the massive tire recall by Firestone in 2000. "The story there is that Firestone knew about some of the issues with its tires, and kept them secret. Not until there was a big expose (did the company issue) a recall." In Merck's case, "there is no hint of fraud. The company didn't stifle the research. There is no question that its recent performance was exemplary. When its own interior people said there was a problem, the company pulled the drug from the market. The debate that will and should rage for years is: To what extent should they have been more aggressive in looking for [the problem] earlier? Should they have designed a different kind of study?"

## A Financial Crisis

According to Wharton deputy dean and marketing professor [David C. Schmittlein](#), the crisis surrounding Merck right now doesn't necessarily revolve around corporate ethics. Noting that Vioxx sales reached \$2.5 billion last year alone, Schmittlein believes that Merck is facing "a financial crisis - loss of revenue, loss of confidence in the product pipeline, loss of the company's ability to pursue product development. The (Merck) product line is not perceived as being as strong as it had been some years back," he says, adding that the patent for another popular Merck product, the cholesterol-lowering drug Zocor, expires in 2006. "But anyone who thinks this is a crisis of consumer confidence is just wrong. It's a crisis of financial confidence. Investors, business partners, suppliers, management, and employees - will they stick with the company?"

After Merck's decision to take Vioxx off the market, its stock price plunged from \$45.07 a share on September 30 to \$33 the next day and has hovered at that price ever since. Analysts quoted in *The Wall Street Journal* have already speculated that Vioxx litigation could create liability risks in excess of \$10 billion for the company, though other analysts have predicted much lower numbers. Nearly everyone seems to agree that the Vioxx liability issues will probably not approach the scale of suits associated with the failed diet-drug combination known as fen-phen, which resulted in 100,000 lawsuits against Wyeth and settlements to date in excess of \$16 billion.

[Patricia M. Danzon](#), Wharton professor of health care systems and insurance and risk management, points out that when it comes to liability, "drugs are different from other products in that they are regulated by the FDA and companies can only market drugs that are approved as safe and effective. To some extent, drug companies should be protected from liability because it is a government agency that has signed off on the data and the existing state of knowledge. The understanding when people take drugs is that there are risks, but that the approved benefits outweigh the risks." What happens in the courtroom, however, "is anybody's guess."

Merck's strong track record in taking the health interests of its customers seriously should work in its favor during a time of crisis, suggests Schmittlein. "If you look at Merck's decision, it contrasts significantly with the actions of companies that have marketed hormone replacement therapy drugs, companies that have kept the products on the market and are prepared to defend them even after there has been some evidence of increased heart attack risk. So Merck has clearly taken a conservative path here. And inasmuch as people are inclined to be Monday morning quarterbacks with respect to how companies are handling a crisis, Merck does have a stock of good will with patients, pharmacists and doctors. If you look at the brand of the company being put at risk, it's primarily with the investment community."

Donaldson points out that Merck was practically "lionized for the creation and free distribution of Mectizan, a drug that cures river blindness in the poorest parts of the world." Merck's corporate culture "has always emphasized, in effect, that the company 'puts the health of the customer first, and if we do that we will make money. If we ever just put making money first, we will lose our business,'" Donaldson says. "You can question the extent to which Merck follows this, but it's not something that just appears [once in a while]. It is repeated fairly consistently."

Indeed, after pulling Vioxx from the market, the company website's main story featured the press release announcing the company's decision, highlighting a quote from CEO Raymond V. Gilmartin: "We are taking this action because we believe it best serves the interest of patients." Four additional stories on the website clearly sought to position the pharmaceutical giant as being able to weather the crisis and retain the loyalty and trust of its customers: "Clinical Trials" (Merck's position on clinical trials), "Voluntary Withdrawal of Vioxx" (Information for U.S. Residents), "Our Values and Standards" (Our Values and Standards Form the Basis for Our Success), and "Ethical Business Practices" (We Believe our Emphasis on Ethics Benefits our Business).

Some wonder if Merck will become part of a larger political debate over whether pharmaceutical companies are making too much money, charging too much for medications and "not publishing result findings that don't go their way," says Donaldson. "This event is positioned at the center of a maelstrom, a storm of other hot-button issues. Because of these enormously strong currents of interest that are whirling around the Vioxx decision, my guess is that it's going to be very hard for a while to get to the bottom of exactly what happened."

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