

Merck & Co., Inc.: Communication Lessons from the Withdrawal of Vioxx

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On the afternoon of Friday, September 24, 2004, Joan Wainwright, Vice President of Public Affairs at Merck & Co., Inc., sat in the jury waiting room in a Baltimore, Maryland courthouse. "One last time," she thought, as she checked her Blackberry for e-mail, just to see if there were any last-minute issues to address before the weekend. It was 3:00 p.m., eastern daylight time.

An urgent message asked her to call Merck's General Counsel. Wainwright asked the court bailiff for permission to use the phone and quickly returned the call. What she learned wasn't good: the latest clinical study on Merck's blockbuster arthritis drug, Vioxx, had produced strongly unfavorable results. The Data and Safety Monitoring Board recommended stopping the Vioxx study with eight weeks remaining, citing an increased risk of heart attack and stroke in patients taking the drug.¹

Following the court's adjournment for the day, Wainwright rushed home to participate in a 5:00 p.m. conference call with other Merck executives. The conference call discussed scenario planning, leaving Merck with two viable options: leave Vioxx on the market with a "black box" warning or pull the drug.

While Wainwright spent the weekend contemplating the logistics of communicating the company's decision to many different audiences, Merck's Chief Executive Officer, Raymond Gilmartin, assigned Dr. Peter Kim, the company's Research and Development Chief, full authority to make a decision on Vioxx based on patient safety.² Regardless of the decision Dr. Kim would soon make, Joan Wainwright knew that life in the near term would change dramatically for the Public Affairs team at Merck.

Merck & Co., Inc.

With a lineage that can be traced as far back as 1668, Merck & Co., Inc. began as a modest chemical firm opened by Frederic Jacob Merck in Darmstadt, Germany. In 1891, George Merck brought the company to the United States and set up shop in New York. Originally established as a fine chemicals supplier, Merck began to conduct pharmaceutical research by the early 1930s.³

Today, Merck & Co., Inc. is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of human health products. They employ 70,000 people in 120 countries and 31 factories worldwide, and sell their products in more than 200 countries.⁴

What is Vioxx?

Developed in a Merck research facility in 1994, Vioxx (known generically as rofecoxib) is one among a class of drugs called Cox-2 inhibitors. This class of painkilling drugs was developed to reduce pain and inflammation in the human body. Cox-2 inhibitors compete with another class of drugs known as nonsteroidal anti-inflammatory drugs (NSAIDs) that are used as analgesics to reduce pain. Although Cox-2 inhibitors are also a part of the NSAID class, they were developed to reduce pain while eliminating the most common side effects of other NSAIDs, such as ulcers and gastrointestinal bleeding.⁵ Vioxx was approved in 1999 by the United States Food and Drug Administration (FDA) for the treatment of pain, inflammation, and stiffness caused by arthritis. The drug was later approved for use in the treatment of rheumatoid arthritis in both children and adults.⁶ Vioxx is the only Cox-2 inhibitor which is proven to have a benefit for ulcers and gastrointestinal bleeding.

The Withdrawal. After the initial notification of Vioxx risks by the Data and Safety Monitoring Board on September 24, 2004, Peter Kim had to decide what to do about the drug's future. With overwhelming results showing Vioxx's cardiovascular risks, Dr. Kim, in consultation with Merck Research Laboratories executives and outside experts, made the final decision to pull the drug from the market on Monday, September 27, citing patient safety as the motivation for the decision. For the next three days, Joan Wainwright and a team of 25 Merck officials assembled in a "war room" to discuss the communication of the withdrawal.

On September 30, 2004, Raymond Gilmartin, Merck's CEO, made an announcement that would change the face of Merck and the entire pharmaceutical industry. Gilmartin announced that Merck was voluntarily pulling its popular arthritis painkiller Vioxx from the worldwide market. At the time of the withdrawal, about two million people were taking Vioxx. Since the drug's approval in 1999, more than 100 million prescriptions had been written for the drug.⁷

The decision to pull Vioxx from the worldwide market was based on data from a clinical trial that Merck had instituted to test whether Vioxx had alternative uses, principally the prevention of potentially cancerous growths in the human colon. With eight weeks left on the study, the Data and Safety Monitoring Board notified Merck officials that the preliminary results revealed that people who took the drug for more than 18 months had double the risk of heart attack or stroke than if they took a placebo. According to Dr. Kim, "Beginning after 18 months, there was a discernible and unexpected increase in cardiovascular disease rates."⁸ The preliminary results of Merck's study, along with the presence of two other competing Cox-2 inhibitors, Pfizer's Celebrex and Bextra, were the major factors that influenced Merck's ultimate decision to pull Vioxx from the market.⁹ Gilmartin defended Merck's decision saying that, "withdrawing the drug was going to be the responsible thing to do."¹⁰

Warning Signs. Merck had known about the possible serious risks associated with Vioxx years before the company withdrew the pain medication. In 2001, a research team at the Cleveland Clinic published a paper in *The Journal of the American Medical Association* that discussed the

serious increased heart attack risk of taking Vioxx.¹¹ The study found that Vioxx produces a risk of heart attack five times greater than naproxen sodium, a frequently used over-the-counter anti-inflammatory drug with comparable benefits.¹² Merck replied that early conclusions were inconsistent and that naproxen had an unproven protective effect.¹³

In another study called VIGOR (Vioxx Gastrointestinal Outcomes Research), Merck found similar results and submitted its findings to the FDA in June 2000.¹⁴ The VIGOR study found that Vioxx users had an increased risk of heart attacks and strokes compared to naproxen users.¹⁵ These results, along with findings of other Vioxx studies, forced the FDA to require Merck to implement labeling changes about the increased risk of heart attacks and strokes in April 2002.¹⁶ The fact that the FDA required a label change due to the overwhelming amount of data showing the risks of Vioxx, should have caused major concern for Merck and Vioxx users.

E-mails within the company suggest that Merck knew about the dangers of Vioxx even before the FDA approved the drug. In February 1997, Briggs Morrison, a Merck official, wrote that patients taking Vioxx would “get more thrombotic events” (blood clots) unless they took aspirin, as well.¹⁷ Another Merck research employee, Alise Reicin, responded in an e-mail, saying that Merck was in a “no-win situation” because taking aspirin and Vioxx together would increase cardiovascular events.¹⁸ With all of these internal and external warning signs, many people wonder why the drug was approved in the first place and why it took so long to pull the drug off the market.

Merck’s Study Backfires. With all of the negative studies pointing to Vioxx’s dangers, Merck attempted to prove the drug’s benefits to patients with colon polyps through its APPROVe [Adenomatous Polyp Prevention on VIOXX] trial. The company conducted this random trial of 2,600 patients with colon polyps, expecting to find that Vioxx helped their affliction. Much to Merck’s disappointment, the study found that 3.5% of Vioxx users in the study suffered heart attacks or strokes after taking the medicine for 18 months, compared to only 1.9% of the participants taking a placebo.¹⁹ This change appears to be small as it is only a 1.6% increase in the absolute risk of cardiovascular events. However, the relative risk increases by 84% from taking Vioxx, which means Vioxx almost doubles a person’s chance to suffer a heart attack.

The Role of the U.S. Food and Drug Administration

Complaints about the lack of long-term studies bombarded the FDA due to the quick approval process of Vioxx and other drugs. The pharmaceutical industry, according to observers and critics, routinely pressures the FDA for swift approval of new drugs, despite clinical trials that study too few patients for too short of a time for side effects to emerge.²⁰ “More than half of all drugs introduced have a new side effect after approval with the current system,” says Curt Furberg, a public health sciences professor at Wake Forest University School of Medicine.²¹ Crystal Rice, an FDA spokeswoman responded, “Our job is to appropriately balance our decisions, based on the risk-benefit profile for a drug and the societal need and desire for new drugs.”²² Richard Horton, editor of *The Lancet*, a British medical journal, claims the FDA is

accountable for failing to act after a 2001 study demonstrated Vioxx's dangers. Mr. Horton has requested a comprehensive renovation of the agency's process for reviewing drug safety.²³

Silence at the FDA? Perhaps the FDA, or at least officials within the agency, did try to act after learning of the cardiovascular dangers of Vioxx. Dr. David J. Graham, associate director for science in the FDA Drug Center's Office of Drug Safety, said he faced firm opposition within the agency to his findings that high doses of Vioxx tripled risks of heart attacks and stroke. Dr. Graham spoke with members of the Senate Finance Committee on Thursday, October 7, 2004. In a statement made after Finance Committee investigators interviewed the researcher, Senator Chuck Grassley, R-Iowa, said, "Dr. Graham described an environment where he was 'ostracized,' 'subjected to veiled threats' and 'intimidation.'"²⁴ Senator Grassley added, "Merck knew it had trouble on its hands and took action. At the same time, instead of acting as a public watchdog, the Food and Drug Administration was busy challenging its own expert and calling his work 'scientific rumor.'"²⁵

Wider Scrutiny of All Drugs. When knowledge of the dangers of a drug surface, other similar drugs face increased scrutiny. Vioxx is a Cox-2 inhibitor, part of the family of non-steroidal anti-inflammatory drugs (NSAIDs). Acting FDA Commissioner Dr. Lester M. Crawford stated that the FDA would closely monitor similar non-steroidal anti-inflammatory drugs. "All of the NSAID drugs have risks when taken chronically, especially of gastrointestinal bleeding, but also liver and kidney toxicity. They should only be used continuously under the supervision of a physician."²⁶ Two pain-relieving medicines in the same class as Vioxx that the FDA said they would re-examine data on are Pfizer's Celebrex and Bextra.²⁷ Pfizer says it will most likely add a "black-box" warning – the very strongest kind – to the label of Bextra.

Spurred by heavy advertising, COX-2 inhibitors took off faster than any other group of drugs after Celebrex and Vioxx went on sale in 1999. Critics say that these industry advertisements do not sufficiently emphasize the drugs' potential risks.²⁸ Vioxx's situation may result in a constriction of medical advertising rules, just as they stood to be relaxed.²⁹ Only weeks after Merck pulled Vioxx off the market, the FDA ordered Pfizer to pull certain Viagra ads that did not disclose any of its known risks.³⁰

Federal regulators are now more likely to require longer-term studies before approving Merck's new drug Arcoxia, which is considered a successor to Vioxx and is now available for sale by prescription in 47 other countries.³¹ The FDA has postponed approval on Merck's Arcoxia due to the Vioxx withdrawal and requested additional data.

Merck's Problems Go Beyond Vioxx

For seven consecutive years in the 1980's, Merck had been rated "Most Admired Company in American business" by a *Fortune* magazine corporate reputation survey. After the withdrawal of Vioxx, many people thought that this reputation would be tarnished, not knowing that Merck had already begun to run into problems before the withdrawal. For most of the company's existence,

Merck had an impeccable reputation and was perceived to be the “gold standard” in the pharmaceutical industry. Now that reputation is being questioned, and the Vioxx withdrawal is not the only reason.³²

As recently as 2003, Merck faced problems with two major new drugs that the company expected to be blockbusters. Under the direction of Merck’s former research chief, Edward Scolnick, Merck scientists were developing two new drugs for treatment of diabetes and depression. However, the company was forced to discontinue work on both drugs after unsuccessful animal studies and clinical trials. In addition, Merck’s popular anticholesterol drug Zocor, which accounts for roughly \$5 billion in annual revenues, twice that of Vioxx, loses patent protection in 2006, allowing generic anticholesterol drugs to flood the market.³³

Merck had also been experiencing problems financially since the year 2000. After the company’s stock price peaked in 2000 at \$95 per share, Merck watched its market capitalization fall by \$150 billion with the company’s shares losing just over half their value between 2001 and 2003. Merck’s earnings have been in decline since 2001 and the company saw one of its worst financial years ever in 2003. Even though sales grew by 5%, Merck experienced a decline in net income for the second straight year with a decrease of 4.5%. Merck, once the world’s largest pharmaceutical company, is now just number six on the list.³⁴

Financial Effects of the Withdrawal

The September 30, 2004 withdrawal of Vioxx caused Merck to lose a drug that accounted for \$2.5 billion in sales, accounting for about 11% of the company’s total revenue in 2003. According to analysts, Vioxx contributed even more to the company’s overall net income. Analysts estimate that sales of Vioxx contributed \$1.2 billion, or 18%, to Merck’s \$6.59 billion net income in 2003. The scene on Wall Street was even worse for the company. On the day of the withdrawal, Merck’s shares dropped \$12.07, a 27% decline in value, down to \$33 per share, which was the company’s lowest closing price in eight years.³⁵ Merck also caused Wall Street’s blue chip stocks to suffer a loss.

Representing 3.27% of the Dow Jones Industrial Average, Merck’s surprise withdrawal caused a 0.6% decrease in the Dow on September 30th.³⁶ As a result of Merck’s news, the New York Stock Exchange traded at 27 times its normal level, 144.5 million shares.³⁷ In addition, Merck had informed analysts that the company was likely to take a charge against earnings in the second half of 2004 of between \$700 and \$750 million because of the Vioxx withdrawal, causing Merck’s annual earnings to decline by 50-to-60 cents per share. The charge against earnings would be taken to account for the costs of customer returns of pills, lost future sales and obsolete inventory associated with the withdrawal.³⁸

Merck Faces Criminal Probe and Lawsuits

In a regulatory filing on November 8, 2004, Merck disclosed that the U.S. Department of Justice subpoenaed the company as part of a criminal investigation into Merck's handling of Vioxx. The company acknowledged that the Justice Department requested information from Merck regarding the company's research, marketing and selling activities for Vioxx as part of a federal healthcare investigation under criminal statutes.³⁹ The focus of the investigation could be centered on whether or not Merck misled regulators or even caused federal health programs to pay for Vioxx when its use was unwarranted.⁴⁰ The company also announced that the U. S. Securities and Exchange Commission was launching an informal inquiry into Merck concerning Vioxx. The inquiry is expected to investigate whether Merck properly informed investors about the results of clinical trials and other probing research that exposed the drug's risks.⁴¹

In addition to the U.S. Government investigations, Merck has begun to quantify litigation that the company already faces concerning Vioxx. Incentives for the litigation have been sparked by a report on the FDA website that concludes that over 27,000 deaths could be attributed to the use of the drug.⁴² As of December, 2005, the company has been served with or is aware that it has been named as a defendant in approximately 9,200 lawsuits, which include approximately 18,250 plaintiff groups alleging personal injuries resulting from the use of Vioxx, and in another 188 class actions alleging personal injuries and varying claims of economic loss.⁴³

Are Others at Fault?

Although Merck heavily marketed Vioxx and the FDA never recalled the drug despite many studies demonstrating its dangers, many people feel other parties are culpable. Some have blamed doctors, insurance companies, and the American health-care system for the number of heart attacks caused by Vioxx. Only a small portion, about 15%, of Vioxx users were benefiting from its lower incidence of stomach bleeding, which is the main benefit of the drug, as opposed to the use of common, over-the-counter naproxen.⁴⁴ Many patients were angry with their doctors for not informing them that Aleve or Advil would work just as well as Vioxx, if they were not susceptible to stomach bleeding from naproxen.⁴⁵

If so few people benefit from taking Vioxx over naproxen, why did the company spend \$100 million a year in direct-to-consumer advertising for the drug?⁴⁶ Some critics attribute the problem to a regulatory system that drives the cost of developing new drugs to exorbitant levels, which encourages large pharmaceutical firms to heavily market medicines to "over-insured baby boomers."⁴⁷

Patients may even be at fault for taking a drug with no significant benefits greater than an over-the-counter medicine. Even if doctors did offer patients not susceptible to stomach bleeding the option of over-the-counter naproxen, most patients would see the prescription drug as superior.

Doesn't an expensive prescription drug that insurance pays for somehow seem like a better treatment than an inexpensive over-the-counter drug that can be taken without a physician's approval?

Communication Response to the Withdrawal

As her team began organizing for whatever decision Dr. Kim and his review team would make, Wainwright knew that the attention of the pharmaceutical, medical, business, and financial worlds would be focused squarely on Merck the moment an announcement was made. "We began thinking about who we would have to notify, how we might go about that, and what resources would be available to us," she said, "so we prepared grids with the audiences and channels. But because we didn't yet have a decision, we couldn't begin preparing any of the message content."⁴⁸ On Monday, September 27, 2004, Wainwright assembled a team of 25 people, all experienced professionals from Merck public affairs, investor relations, U.S. and worldwide marketing, Merck research labs, and the Merck's corporate counsel. All would be responsible for helping to communicate the message, as soon as a decision regarding Vioxx was available to them.

The team's work was aided by their experience a year earlier in which the company stopped the development of two very promising drugs that were in Stage III clinical trials. "We went back and reviewed the plans we used to announce the cessation of those two drugs," said Wainwright, "but because neither was on the market yet, we knew we would have additional audiences to reach with Vioxx."⁴⁹

Following an extensive review, with both internal and external panels of experts examining the data provided by the DSM Board, Dr. Kim met with Merck CEO Raymond Gilmartin on Monday afternoon and made the decision to pull the drug from the market. "You must do what is in the best interest of patient safety," Gilmartin said to Kim. "Don't worry about the financial or public relations issues. We'll address all of those later. Just do what's best for patients taking the drug."⁵⁰

Over the next two-and-a-half days, Wainwright and other senior Merck officials worked around the clock to prepare the announcement to multiple audiences, which was made public on Thursday, September 30th. "We were responsible," said Wainwright, "for developing more than 65 documents to notify investigators who were conducting the clinical trials, patients who were participating in the trials, physicians and patients worldwide, and numerous regulatory agencies." She also noted that, at that very moment, Merck had sales representatives worldwide who were calling on doctors and clinics to promote the beneficial effects of Vioxx, and they would each have to be contacted. They, among many others, would have questions and concerns that Wainwright and her team were only beginning to address.⁵¹

The public affairs team spent nearly 60 hours writing releases for the media, statements for physicians and patients worldwide, preparing a special website (<http://www.vioxx.com>), and a

toll-free number (1-888-368-4699) for medical professionals and the general public to call for answers to their questions.

Among Wainwright's concerns was that word of the withdrawal might prematurely leak to the news media before details of the announcement, scheduled for Thursday, were finalized. In response to those concerns, her public affairs team booked a hotel conference room and prepared to issue a fragmentary announcement on very short notice. On the 29th of September, a day before the announcement, Wainwright brought in an outside public relations crisis management firm to review her documents, examine the team's procedures, and offer advice based on the firm's experience with similar withdrawal announcements.⁵²

The Announcement

At 8:00 a.m., eastern standard time, on Thursday, September 30th, Merck issued a press release announcing the worldwide voluntary withdrawal of Vioxx, the company's \$2.5 billion dollar pharmaceutical. At 9:00 a.m., Wainwright held a press conference in New York at which CEO Raymond Gilmartin repeated the announcement and took questions from news media representatives. The company also conducted an investor relations teleconference at 10:00 a.m. that morning to explain the news to Wall Street and the financial community.⁵³ And, at the moment the press release was moving, Wainwright sent an e-mail to all Merck employees worldwide, explaining what had happened. A second e-mail sent each employee a link to view the Webcast of the press conference in New York.

For the balance of the day, Dr. Kim and Mr. Gilmartin spent the bulk of their time responding the press queries, physician concerns, and questions from regulatory agencies. "I was in the fortunate position," Wainwright said later, "that when I asked Dr. Kim and Mr. Gilmartin to make these announcements personally, and to make themselves available for press statements and interviews, I received complete cooperation from them and their staffs. They were more than willing to do whatever we asked of them."⁵⁴

On October 2nd, the Sunday following the announcement, Merck ran full-page advertisements in 25 major newspapers throughout the country, explaining the Data and Safety Monitoring Board's findings and the company's decision to withdraw Vioxx from the market. The advertisement was in the form of a letter to patients letting them know where they could find more information about the drug and the reason for the withdrawal.

Measurement of Communication Results

Wainwright's team knew that unless they could measure the results of their efforts, they would have no way to know how effective their communications had been, or which channels offered the greatest potential for reaching people with a stake in the Vioxx withdrawal. They discovered that about 65% of the general public were aware of the news within three days of the announcement. By early December, that figure rose to more than 75% of the general public.⁵⁵

During October and November of 2004, Merck's public affairs efforts generated more than four billion media impressions on the topic. The company's Vioxx Website traffic grew from about 4,000 daily visits on September 29th to 234,000 on October 1st. By early December, the vioxx.com Website had attracted more than two million visitors, while the company's merck.com Website had experienced an additional one million visitors. The team's toll-free telephone number received more than 120,000 calls in the first six days following the announcement. Additionally, the company reported issuing more than half-a-million refunds for Vioxx prescriptions worldwide.⁵⁶

The company also kept track of key measures related to reputation. "Prior to the withdrawal," said Joan Wainwright, "we had conducted an extensive amount of research to determine the drivers of reputation for Merck and the industry. This work guided what to measure and consumer perceptions established baseline metrics." Wainwright and her team measured company awareness; familiarity, including how it is derived from both positive and negative news accounts; company perceptions across a spectrum of attributes and how they form a reputation score; stated consumer behaviors related to key business goals and their ebb and flow based on perception change; and actual consumer behavior changes on those same measures. Those measures, according to a company spokesperson, were not specific to Vioxx, but were gathered across a range of company-wide issues.⁵⁷

Reorganization of the Vioxx Response Team

As the company's preparations for the withdrawal began on September 24th, Joan Wainwright's public affairs team took on the additional task of audience analysis, channel selection, message construction, press conferences, measurement and more, as additional duties. Each of the 25 people designated to work on the Vioxx withdrawal also had other duties to perform and, before long, the stress of the long hours, incessant demands of the press, and disappointments in the fairness and accuracy of some of the coverage began to take their toll.

"During the early weeks of our response," Wainwright said, "we typically came in at 7:30 in the morning and didn't leave until 11:30 or midnight." (The sentence that was deleted was not true.) "When you begin something like this," she explained, "you don't necessarily realize how big it will be or how long it will be. So, we've had to reorganize our staff, which now includes a Vioxx Management Team composed of people who are dedicated to this full-time. We've asked them to do this for a year before returning to their other jobs."⁵⁸

What's Next for Merck?

A New Chief Executive. On May 5, 2005, the company announced the retirement of Raymond Gilmartin, then 64 years old, Merck's chairman and CEO since June of 1994. Richard T. Clark, an insider who had been president of Merck's manufacturing division, was named to replace him as chief executive, but not as chairman. A newly formed three-member executive committee, led by retired Honeywell CEO Lawrence Bossidy, announced that they would "work closely with

Mr. Clark to provide support and continuity”but would not name a chairman for another 12 to 18 months.⁵⁹

Gilmartin’s retirement was not a complete surprise, since he had been planning to step down for some time, though he did depart 10 months earlier than expected. The choice of a long-time insider to replace him, along with an executive committee to run the board, signaled to investors that the company was more concerned with stability and continuity than innovation

Litigation Begins. Challenges for the chief executive weren’t long in coming. On July 11, 2005 the first Vioxx-related lawsuit went to trial in south Texas. The plaintiff was Mrs. Carol Ernst, the widow of Robert Charles Ernst, a 59-year-old triathlete who died suddenly in his sleep in May 2001. After weeks of complex and emotional testimony and reams of scientific evidence, it took the jury less than an hour to return a \$253 million guilty verdict against Merck. Although the award cannot exceed \$26.1 million under Texas law, it is still significant because of the message jurors appeared to be sending the company and the broader pharmaceutical industry. “I was amazed at the size of the verdict,” said Harry Sweeney, CEO of Dorland Global Health Communications. “It underscored . . . the industry’s failure to deflect and engage its critics. These were emotional issues,” he added, “not factual issues.”⁶⁰

A second trial in New Jersey held better news for the company. On November 3, 2005, Merck won a major victory in a case centered on the death of Frederick Humeston. After deliberating for less than eight hours over three days, a state jury cleared Merck of allegations that it failed to warn consumers about the drug’s risks and engaged in “unconscionable commercial practices” in marketing to doctors and their patients.⁶¹

A third trial, in the case of Plunkett v. Merck, ended in a mistrial when a federal judge in Houston declared the jury was “hopelessly deadlocked.” It was an unfortunate turn of events for Merck, as news reports indicated that the nine-member jury was prevented from reaching a verdict by a lone holdout.⁶²

The fallout from these verdicts, of course, has just begun. The sizable jury award in Texas will, doubtless, prompt a torrent of new lawsuits, even as the Justice Department criminal investigation continues. The larger unknown is whether Vioxx users have an increased risk of heart attacks even after they stop taking the drug. While many doctors have said that’s unlikely, data from a continuing Merck study could show otherwise, potentially ballooning the number of plaintiffs and even jeopardizing the company’s survival.⁶³

Merck’s most profitable drug – the cholesterol-lowering Zocor – registered 2005 sales of more than \$4.4 billion. Unfortunately for the company, Merck loses patent protection on Zocor in June of 2006, as well as protection for osteoporosis treatment Fosamax, it’s second biggest-selling drug, in 2008. With the additional management distractions and financial toll of settling Vioxx lawsuits for years to come, Clark, may find it difficult to attract the finest scientists or form alliances with other firms to produce products that could make up for those losses.⁶⁴

Merck has an enviable record of dividend distribution that may be jeopardized by the company's financial exposure in litigation and, possibly, criminal penalties and fines imposed by the federal government. The plan, according to company spokesmen is to continue to defend each case individually and not negotiate a global settlement. With as many as 60,000 or 70,000 potential plaintiffs lurking in the company's future, analyst David Moskowitz of Friedman Billings Ramsey thinks the increased likelihood of punitive damages could go as high as \$50 billion. And, if there is some ongoing risk to patients who took the drug, the pool of plaintiffs could expand alarmingly and, he says, "call into question the survival of the company."⁶⁵

The company continues to believe that each case can be defended on the merits, presumably because a number of early victories might well discourage the hoard of plaintiffs' lawyers waiting in the wings from pursuing their cases. At the very least, company officials now estimate that a satisfactory resolution of issues related to Vioxx may take another five years.

Restructuring Begins. In his first major move as Merck's new chief executive, Mr. Clark announced on November 29, 2005 that the company would cut its worldwide workforce by 11%, or 7,000 people. This will involve closing or selling five of its 31 manufacturing facilities, along with widespread improvements in the efficiency of the company's drug-making operations. Among other advances, the company pledged to reconfigure manufacturing operations to speed up production times and become responsive to changes in the market. In an interview, Clark said the changes represent the beginning of "a fundamental change in our business model." The job cuts will be completed by the end of 2008, with half of them coming from facilities in the U.S.⁶⁶

The Communication Lessons from Vioxx

A number of important lessons in communication strategy have emerged from the experience of withdrawing Vioxx from the market and defending the company against both litigation and continuing bad press. First, a crisis communication plan is genuinely helpful. "Yes," said Merck Sr. V.P. Joan Wainwright, "we had a crisis communication plan – a rapid response media plan – in place that worked very well. The plan allowed us to identify the key individuals who needed to be involved, their roles and responsibilities. It also helped us to establish a mechanism to enable them to start working together."⁶⁷

A second important lesson concerns persistence and a long-term view. "Essentially," said Wainwright, "the more we communicate, the better our positions are understood. We have employed a wide range of communication vehicles: press releases, corporate statements, teleconferences, Webcasts, paid advertising, letters to editors in response to misleading or inaccurate articles, frequent communication with employees, along with the development of internal and external Websites dedicated to Vioxx issues."⁶⁸

An important first step for the company was to identify which facts people needed to know about Merck and to address those needs in order to correct misconceptions. "We found," said Wainwright, "that if people understood the facts about Merck's actions with regard to Vioxx,

they had more favorable opinions of the company. We developed messaging around three major points that were frequently misunderstood by the public. Our strategy was to educate the public solely about the facts – the messages included no spin, no emotions.”⁶⁹

Those issues were particularly important to Merck’s global reputation, as well as its ability to defend itself, both in a court of law and in the court of public opinion. The public, as it turns out, incorrectly believed that the FDA forced Merck to remove Vioxx from the market. They also believed that Merck had information about the safety of Vioxx and somehow hid that information from doctors, the FDA, and the public. And, finally, the public did not seem to understand the extensive nature of drug testing prior to FDA approval, nor did they understand why drug companies continue testing medicines after they have been approved.

With that research in hand, Wainwright and her team were able to target their responses to those publications, audiences, and issues that would most affect consumer perceptions of the company. Those perceptions ultimately influence everything from stock price to employee morale to physician loyalty and more. If the Vioxx case has taught corporate executives anything, it is that no corporate strategy is viable without effective strategic communication, backed by current research on those issues that matter most to the company and its key stakeholders.

The lessons for Clark and his senior team would seem to be equally important: develop a long-term plan, despite near-term pressures for earnings performance; have faith in your decisions; and recognize that your employees – across the organization – are your greatest asset.

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