Merck: Managing Vioxx (E)

Mr. Chairman, Merck believed wholeheartedly in Vioxx. I believed wholeheartedly in Vioxx.

Next Six Months

As Merck CEO Ray Gilmartin considered his options in the aftermath of Vioxx’s withdrawal, many factors—including reactions from competitors, Merck’s lagging stock price (Exhibit 1), FDA reviews, and lawsuits—made for a highly fluid and charged environment.

November - December 2004

In mid-November, Gilmartin was questioned before the U.S. Senate Finance Committee, which had jurisdiction over publicly funded health programs. He chose to face the committee alone, without a lawyer at his side. During the hearing—which was broadcast nationally over television network C-Span—a scientist testified that Vioxx may have caused more than 100,000 heart attacks since its release, with up to 40% being fatal—a claim Gilmartin responded was “just speculation.” “Mr. Chairman,” stated Gilmartin emphatically, “Merck believed wholeheartedly in Vioxx. I believed wholeheartedly in Vioxx.”

In the same week, CBS’s 60 Minutes aired a 15-minute segment on the Vioxx story. The bulk of the program focused on interviews with plaintiffs suing Merck following the death of loved ones who had been taking Vioxx, and with scientists and sales reps criticizing Merck for selling a drug that was known to have serious undisclosed cardiovascular risks.

For consumers yearning for Vioxx’s return, new evidence that other Cox-2 inhibitors might pose similar risks was disheartening. In November, results were published from a study alleging that Bextra, Pfizer’s second-generation Cox-2 inhibitor, posed similar cardiovascular risks to Vioxx. Worse news followed in December, when Pfizer announced a trial showing a 2.5 fold increase in cardiovascular events with Celebrex—the top-selling Cox-2 inhibitor—versus placebo. The news sent Pfizer’s stock plummeting: in a two-day period the company lost $35 billion in market value.

3 Schwab, “The CEO Calmly Tells Firm’s Side.”
the following weeks, prescriptions for Celebrex fell by half.\textsuperscript{7} In light of the evidence that cardiovascular risks appeared to be a problem shared by all Cox-2 inhibitors, a prominent cardiologist and pharmacologist stated simply: “This is a time bomb waiting to go off.”\textsuperscript{8}

\textbf{January 2005}

Although Henry McKinnell, Pfizer’s CEO, aggressively defended Celebrex’s safety, in January 2005 news arose that an earlier 1999 report had indicated that elderly patients taking Celebrex were four times as likely to experience cardiovascular problems as those taking placebo pills.\textsuperscript{9} The report was submitted to the FDA in June 2001, four months after the FDA finished a review of Vioxx and Celebrex. Pfizer acknowledged the report’s findings, but played down its importance. According to Pfizer’s medical team leader for Celebrex, “the study’s importance should not be overstated. Many other trials have shown that Celebrex is safe, and that the medicine is an important treatment for arthritis patients.”\textsuperscript{10}

Merck continued receiving letters pleading for Vioxx’s return. Many argued that the decision to take Vioxx was best left to those with severe pain who could weigh the risks versus the benefits for their individual circumstances.

A 47-year old woman afflicted with fibromyalgia, a chronic condition causing severe muscle and joint pain, wrote:

\begin{quote}
[Vioxx] was the best pain drug I had been on in 27 years. I felt good enough to do some exercise. Getting to work was not such a difficult thing. I would go back on it in a heartbeat . . . You’d have to present much higher numbers [of cardiovascular problems in the studies] to convince me not to take that risk again. It made so much difference in the quality of my life.\textsuperscript{11}
\end{quote}

Since Vioxx was withdrawn from the market, the woman explained, her pain had returned with such severity that simply readying for work in the morning often rendered her exhausted.

Some members of the medical community were also advocating that the benefits of taking Vioxx could outweigh the risks for some patients. Robert Bucholz, president of the American Academy of Orthopedic Surgeons, explained his view in a January 2005 \textit{USA Today} article:

\begin{quote}
I personally took Vioxx ever since it was released. It’s the one anti-inflammatory I can take that doesn’t upset my stomach . . . When that was taken off the market, I was personally disappointed. I’ve got my own personal supply of Vioxx, and I’m not about ready to destroy it . . . All life is a series of risks, and you’ve got to measure the risks versus the benefits. And that’s true of any drug.\textsuperscript{12}
\end{quote}

Other Vioxx takers echoed the sentiment that the decision to take Vioxx should be a personal one. A \textit{Wall Street Journal} article reported an interview with retired pharmacist Dave Ellis:

\begin{quote}
Dave Ellis dreads the day . . . when his Vioxx supply will run out. He doesn’t care that Merck . . . yanked it from the market and recommended that patients quit taking it. Instead, the 66-year-old from Edmond, Oklahoma, who has struggled with degenerative arthritis in his spine for 30 years, has
\end{quote}

\begin{itemize}
\item\textsuperscript{7} Ibid.
\item\textsuperscript{8} Harris, “New Study Links Pfizer’s Bextra, Similar to Vioxx, to Heart Attacks.”
\item\textsuperscript{9} Alex Berenson, “Pfizer Says 1999 Trials Revealed Risks with Celebrex,” \textit{New York Times}, February 1, 2005.
\item\textsuperscript{10} Ibid.
\item\textsuperscript{11} Julie Appleby and Anita Manning, “For Those in Pain, Relief Trumps Risk,” \textit{USA Today}, January 5, 2005.
\item\textsuperscript{12} Ibid.
\end{itemize}
continued to take his remaining pills. “If I look at the numbers, I just don’t feel I’m at risk,” said Mr. Ellis.13

The article went on to say that many patients were, “angered and frustrated by the limited range of alternative treatments, which for them have been unsuccessful or inferior to Vioxx, and can carry significant risks of their own.” According to an Atlanta-based rheumatologist, “If you live with intractable pain every day of your life, would you take a [small] chance that you would have a heart attack? A lot of my patients would.”14

February 2005

To further investigate the safety of Cox-2 inhibitors, the FDA announced it would convene two committees comprised mainly of independent experts: the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee. Though the committees’ recommendations were not binding,15 the FDA was under increasing public scrutiny for its failures in screening dangerous drugs, prompting press reports claiming that the public had lost confidence in the agency’s objectivity.

On February 16, 2005, the FDA hosted a three-day summit attended by the two committees, during which panels heard evidence about the safety and efficacy of the Cox-2 inhibitor class of drugs from representatives of pharmaceutical companies, professionals from the FDA’s Center for Drug Evaluation and Research, and independent experts. One expert, Dr. Garret FitzGerald, spoke about his theory of Cox-2 inhibitors and cardiovascular safety: “... Just as low dose aspirin affords cardioprotection and a small but absolute risk of serious GI bleeds... so do specific [Cox-2] inhibitors afford gastroprotection and a small but absolute risk of cardiovascular events.”16

In advance of the conference, the members of the advisory committees had been given a list of questions to consider while hearing the experts’ testimony. There were three categories of questions:

- Risk versus benefit analysis for non-selective NSAIDs and Cox-2 selective NSAIDs generally;
- Risk versus benefit analysis for the three approved Cox-2 inhibitors: Celebrex (Pfizer); Vioxx (Merck); and Bextra (Pfizer);
- Standards for approval of new NSAIDs, both non-selective and Cox-2 selective.17

Merck had a vested interest not only in the committees’ assessment of Vioxx, but also in their ruling on the standards for approval of new Cox-2 inhibitors. Merck had applied to the FDA in December 2003 for approval of Arcoxia, its next-generation Cox-2 inhibitor. The panel’s recommendation could affect the FDA’s decision.

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14 Ibid.
The committees’ votes and recommendations were as follows:

Table A  Advisory Committees’ Votes on Cox-2 Inhibitors

<table>
<thead>
<tr>
<th></th>
<th>Vioxx (Merck)</th>
<th>Celebrex (Pfizer)</th>
<th>Bextra (Pfizer)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do the available data support a conclusion that the drug significantly increases the risk of cardiovascular events?</td>
<td>YES 32  NO 0</td>
<td>YES 32  NO 0</td>
<td>YES 32  NO 0</td>
</tr>
<tr>
<td>Does the overall risk versus benefit profile for the drug support marketing in the US?</td>
<td>YES 17  NO 15</td>
<td>YES 31  NO 1</td>
<td>YES 32  NO 0</td>
</tr>
<tr>
<td>Black box warning?</td>
<td>YES* 24</td>
<td>YES 22</td>
<td>YES 22</td>
</tr>
<tr>
<td>Restrict direct to consumer advertising?</td>
<td>YES 22  NO 10</td>
<td>YES 19  NO 13</td>
<td></td>
</tr>
<tr>
<td>Restrict dose?</td>
<td>YES 5  NO 27</td>
<td>YES 3  NO 29</td>
<td></td>
</tr>
</tbody>
</table>

Source: Adapted from Minutes from “Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee,” February 16, 17, 18, 2005.

* The vote count was not tallied for the recommendations for Vioxx, as the drug had already been withdrawn from the worldwide market.

**FDA Ruling**  At the conclusion of the three-day summit, the FDA ruled that Vioxx could be relaunched in the U.S. market with a revised “black box” warning.

**Lawsuits**  On February 24, 2005, a Judicial Panel appointed New Jersey-based U.S. District Judge Stanley R. Chesler, a former federal prosecutor, to handle all lawsuits filed by Merck shareholders stemming from the recall of Vioxx. The lawsuits claimed Merck officers had made misleading statements about Vioxx, whose recall wiped out $25 billion in shareholder value as the stock plunged 27% when Merck pulled Vioxx from worldwide markets (see Exhibit 1).18

A week earlier, on February 16, the Judicial Panel had consolidated over 100 patient lawsuits charging that Vioxx harmed patients, and sent them to Judge Eldon E. Fallon of the U.S. District Court in New Orleans. Fallon, who had experience in major pharmaceutical litigation, would coordinate discovery and other pretrial proceedings.19 At the time, the press reported that, while Merck had set aside $675 million for legal costs stemming from the Vioxx withdrawal, the figure did not include any potential awards to shareholders or patients.20

Meanwhile, personal injury lawyers continued to run ads online, in newspapers, and on television canvassing for new Vioxx clients (see Exhibit 2 for a sample Internet advertisement).

**April 2005**

On April 7, the FDA announced that Pfizer’s second generation Cox-2 painkiller, Bextra, was to be pulled from the market, as it posed too many health risks for patients. Celebrex would remain on the market but would contain the most severe FDA “black box” warning on its packaging. Though Pfizer
complied with the FDA’s request to recall Bextra, the company noted that it “respectfully disagrees” with the FDA’s position.\textsuperscript{21}

Following the announcement of Bextra’s withdrawal and Celebrex’s label change, Moody’s, a credit rating firm, projected a drop of $1.5 to $2 billion for Pfizer’s yearly Cox-2 drug sales; Morningstar, another rating firm, forecast a year-over-year sales reduction of 85% for Bextra and 50% for Celebrex.\textsuperscript{22}

Later in April, Judge Fallon called for a postponement of state lawsuits against Vioxx so that he could obtain more control over the pretrial process.\textsuperscript{23} Judge Fallon also announced that he hoped to complete the Vioxx litigation process in a maximum of five years—a tall order, given a prominent attorney’s statement that he expected “100,000 cases in this litigation.”\textsuperscript{24}

\textbf{June 2005}

The public controversy and media frenzy surrounding Cox-2 inhibitors continued. On June 24, Pfizer CEO Henry McKinnell appeared on PBS television show Charlie Rose to discuss Celebrex and the media’s responsibility in conveying medical information to the public. Defending his company’s decision to keep Celebrex on the market, McKinnell accused the media of overplaying the risks of the drug based on the results of a single study. He claimed that the media should tell patients to “consult your doctor, the person who understands the best treatment for you.” He went on to say, “most importantly, [patients] need to understand risk-benefit, which is what doctors do. They understand the benefits of these medicines for you, they will explain the risks, and then you make a fully informed decision.”\textsuperscript{25}

\begin{itemize}
\item \textsuperscript{21} Christopher Snowbeck, “Pfizer Pulls Pain Drug Bextra Removed Under Pressure Over Heart Risks,” \textit{Pittsburgh Post-Gazette}, April 8, 2005.
\item \textsuperscript{22} Anthony Cronin, “Bextra Woes Could Affect Pfizer Debt Ratings,” \textit{The Day}, April 9, 2005.
\item \textsuperscript{23} Alex Benenson, “Postponement Sought for First Vioxx Trial,” \textit{New York Times}, April 29, 2005.
\item \textsuperscript{24} “Judge Sees Vioxx Lawsuit Lasting Rest of Decade,” \textit{Reuters News}, April 28, 2005.
\end{itemize}
Exhibit 1  Merck versus the S&P 500, August 2004 - April 2005

Source: Data from Thomson ONE Banker, accessed October 14, 2008.
Exhibit 2  Personal Injury Lawyers’ Internet Advertisement Calling for Vioxx Plaintiffs

Get Your Million Dollars From Vioxx Lawsuit

Vioxx, taken by 1.3 million Americans, is used extensively for the treatment of many types of pain. Vioxx side effects include Heart Attack, Intestinal Bleeding, Kidney or Liver Impairment, Respiratory Infections, and Stroke. Launched in the United States in 1999, Vioxx was sold $2.5 billion in 2003, with estimated $8 billion profit in 4 years. Merck currently has $6.8 billion cash. (source: 1) That is enough to pay $5000 per Vioxx user. Experts estimate the class action lawsuit will award $5 billion, 60% of which will go to the top 1000 sufferers, or $2.5 million per person. Get your share. It is the easiest way to become a millionaire. (In 1997, the recall of a couple of diet therapies by Wyeth resulted in $16 billion so far paid out in claims.) If you have heard of Million Dollar Awards from Tobacco Lawsuit, Vioxx cases are easier to win. In tobacco cases, consumers were warned before purchase, while Vioxx recall is a combination of mismanagement and coverup. Merck ignored early warning signs (source: 2).

You need to take actions now. Following proper steps, you are guaranteed a Monetary Compensation. You need to have proof that you have taken Vioxx. The chance of winning is much greater if you have any heart attack in your medical record. Small heart attacks are untraceable. Many have this record without ever detected by doctors. If you win a case before class action, your reward will be much higher.

You will receive a document showing how an average person can benefit from this Once-in-a-LifeTime Opportunity to become a millionaire. We will show you how to prove you had taken Vioxx, to prove that you had related side effects, and to find a good lawyer to win your case. There are still places selling Vioxx after the recall, you can find them online. Merck is still 100% fully responsible for any side effect. If you purchase Vioxx now, not only can you sue Merck, you can also sue the pharmacy store for selling recalled products. The purchase is risk free, as Merck will pay you every penny you spend on Vioxx including tax and shipping fees. The top three executives of Merck, Raymond Gilman, Judy Lewent and David Amsic, made 13 million dollars (source: 3) last year from profits for positioning innocent people. It is time for consumers to fight back and hold big corporations accountable.

Many law firms want your information. Some even pay $200 per signup, regardless of the outcome of the class action lawsuit. Contact as many as possible using online form. Don’t miss the Opportunity!