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Merck and Vioxx: An Examination of an Ethical Decision-Making Model

Erin Cavusgil

ABSTRACT. Marketing researchers have proposed various conceptual models of ethical decision-making to better clarify the steps in the decision-making process. However, lacking in the literature is comprehensive empirical validation of these models. This manuscript examines the ethical decision-making model proposed by Ferrell et al. [1989, *Journal of Macromarketing* **56**(Fall), 55–64] in the context of a real-world marketing situation. This model is a comprehensive synthesis of previously developed models in the literature. The events surrounding the withdrawal from the market of the pain reliever Vioxx, manufactured by Merck & Co., are detailed. The analysis provides insights into the decision-making process faced by Merck executives and sheds light onto the real-world applicability of the conceptual model. Furthermore, this study demonstrates how potential modifications to existing models can be developed by their examination in the context of real world events. It is hoped that this analysis, along with future examinations, aids marketing researchers in developing a better understanding of the ethical decision-making process in a business context.

KEY WORDS: Merck, Vioxx, ethical marketing decision-making, models of ethical marketing

Introduction

Ethical decision-making in an organizational context is important to marketing scholars and practitioners alike. A number of corporate examples of unethical behavior have been attempted in recent years. From the academic perspective, several ethical decision-making models have been put forth (Ferrell et al., 1989, Fritzsche, 1991, Hunt and Vitell, 1986, Jones, 1991, Malhotra and Miller, 1998) and to some extent, empirical tests of ethical decision-making have been conducted. Two recent reviews, that of Loe et al. (2000) and O'Fallon and Butterfield (2005), both summarize the empirical ethical decision-making literature. The various models represent frameworks for understanding the factors that affect an individual manager's ethical decision-making within the organization.

While these models can guide one's behavior in a theoretical situation, their overall applicability in *real-world* situations has not yet been demonstrated. In fact, researchers have touted the need for additional studies using industry samples to validate such models (Loe et al., 2000). The purpose of this paper is to address this concern. More specifically, this research attempts to apply a recent real-world ethical situation to an integrated ethical decision-making model. In doing so, I examine the following questions: (1) based on what is known about the ethical dilemma, how closely does this model adequately represent the decision-making process? and (2) can this model be modified or extended to better represent the ethical decision-making process? While it is not possible to exhaustively test a conceptualization by examining a single set of circumstances, by investigating a real-world situation, we can further our knowledge regarding the applicability of a particular conceptual model. Moreover, by scrutinizing a real-world ethical situation, we can demonstrate how potential modifications to an existing model may be developed. By combining a number of such studies, our understanding of the ethical decision-making process within a business context can be advanced.

Erin Cavusgil is a doctoral student at Michigan State University. She holds a BS in Chemical Engineering from the University of Michigan and an MS in Biomedical Engineering from the University of Minnesota. She spent 3 1/2 years working in the pharmaceutical industry as a chemical engineer. Her main area of research is new product development.

The ethical situation investigated here surrounds the withdrawal in September 2004 of the blockbuster drug Vioxx from the marketplace by its manufacturer, Merck & Co. Prior to withdrawal, Vioxx was one of Merck's top five most profitable drugs, generating $2.5 billion in sales per year. It accounted for more than 105 million prescriptions having been filled for approximately 20 million consumers since it first appeared on the market in August 1999 (Feder, 2004). Questions surrounding the drug's safety had plagued the company since 2000, due to studies that showed that patients taking Vioxx had an increased incidence of cardiovascular problems compared to an older drug. Yet, these studies were not entirely conclusive. Though Merck did not initiate any new studies to directly investigate these allegations of cardiovascular side effects, it continued to monitor ongoing studies. The health risks associated with Vioxx became apparent in September 2004, when evidence demonstrated an increased chance of heart attack or stroke in patients taking the drug. On September 28th, 2004, Merck executives then made the decision to withdraw this blockbuster drug from the market.

Merck executives faced tough decisions in 2000, when questions surrounding the safety of Vioxx first arose, and in 2004, when convincing evidence indicated health risks associated with the drug. These types of situations present a difficult conflict for decision-makers within an organization. Such decisions are generally guided by one's moral beliefs and values, which, of course, vary among individuals. Additionally, the culture of the organization likely plays a role in how decisions are made. And lastly, decisions must also be made in the best interest of the public (namely, the patients taking the drug) while keeping in mind their responsibility to the stakeholders of the organization, who are concerned with the firm's profits.

The remainder of this manuscript is organized as follows. First, the ethical decision-making model proposed by Ferrell, Gresham and Fraedrich (FGF) is described. Next, a detailed description of the events leading to the withdrawal of Vioxx is provided. Additional insight is offered by assessing the ethical issues surrounding the Merck executives. The situation is then applied to the ethical decision-making model. Possible modifications and extensions to the FGF model are discussed, and last, conclusions are provided.

A conceptualization of ethical decision-making

To evaluate the decision-making process faced by Merck executives, we adapt FGF's (1989) model of ethical decision-making. An adaptation of this conceptualization is proposed in Figure 1. This model, in turn, is a synthesis of:

(1) The Kohlberg Model of cognitive moral development (1969),
(2) Ferrell and Gresham's Contingency Model of Ethical Decision-Making (1985), and
(3) Hunt and Vitell Model depicting a ''General Theory of Marketing Ethics'' (1986). This comprehensive model provides a framework from which to structure the ethical decision-making process. While a number of models have been proposed in the literature, the FGF model synthesizes previous models, and therefore provides a ''richer and more complete understanding of the ethical decision process'' (Ferrell et al., 1989, p. 56). This model shares many similarities to subsequent models introduced in the literature. The advantage of this model is that it is comprehensive and robust, yet not overly complex, which would create difficulties in conducting the analysis. The model is briefly described as follows.

Of importance is the context, or situation, surrounding the issue at hand. Context plays an important role in the entire decision-making process.

1. The first stage is the identification of an ethical issue that has created a dilemma.

2. The second phase consists of the 'Stages of Cognitive Moral Development.' According to Kohlberg's model, there are three broad levels of cognitive moral development. An individual at the 'preconventional' level is concerned with ''concrete consequences, particularly external rewards and punishments (Ferrell et al., 1989, p. 58). At the 'conventional' level, ''right is that which conforms to the expectations of good behavior of the larger society or some significant referent group(s)'' (Ferrell et al., 1989, p. 58). At the 'principled' level, ''universal values or principles determine what is

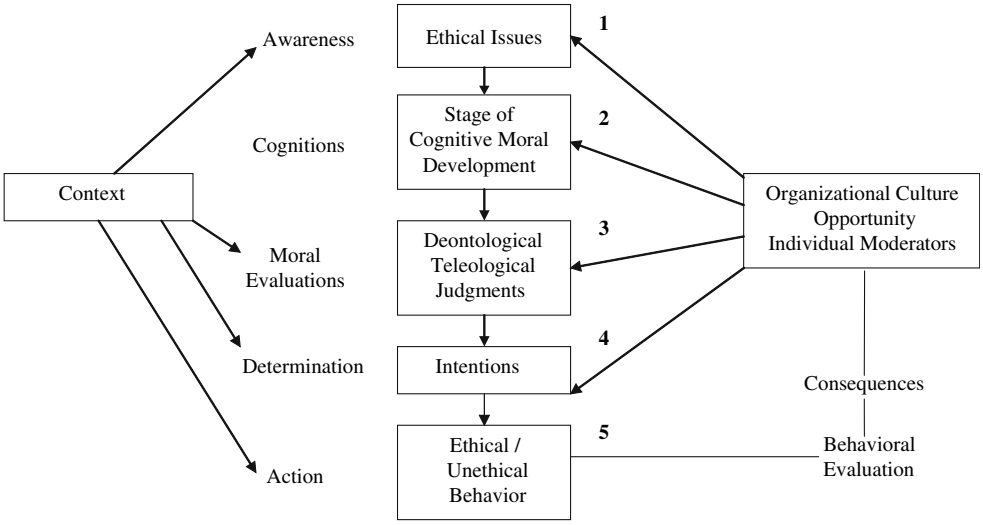

Figure 1. A synthesis: integrated model of ethical decision-making in business (adapted from Ferrell et al. (1989)).

right for individuals at the highest level of moral development'' (Ferrell et al., 1989, p. 58). This theory maintains that through the process of moral development, executives may change their values, which consequently affects their behavior.

3. The next stage involves moral evaluation. Deontological philosophies focus on moral obligations. In the deontological evaluation, the person assesses the inherent appropriateness of the actions required by each alternative. Teleological evaluation involves evaluating the outcomes or consequences of various behaviors in a situation. In the teleological evaluation, several constructs are entailed: ''the perceived consequences of each alternative for various stakeholder groups (such as customers, stockholders, or employees); the probability that each consequence will occur to each stakeholder group; the undesirability of each consequence; the importance of each consequence; and the importance of each stakeholder group'' (Ferrell et al., 1989, p. 59). These moral philosophies examine the content of the decision alternatives.

4. The subsequent stage is intention, which is ''the individual's subjective probability of behavior engagement'' (Ferrell et al., 1989, p. 61). The decision-maker's ethical beliefs, as well as the consequences of the decision alternatives both play a role in one's intentions.

5. The final step results in ethical or unethical behavior.

Other factors such as organizational culture, opportunity, and individual factors also influence the decision-making process.

Events leading to the withdrawal of Vioxx

During the late 1990s, Merck was known for being a leader in a very competitive industry where R&D spending requires millions of dollars and many years, yet successes are few and far between. Yet Merck managed to remain a leader, presenting 13 major new drugs between 1995 and 2001. One of these drugs was the blockbuster Vioxx, approved in May of 1999. Vioxx, part of the COX-2 class of anti-inflammatory pain medications, was competing with Pfizer's Celebrex and Bextra in a multi-million dollar market. This class of drugs was thought to be less harmful on the stomach compared to older drugs, though they were not shown to be any better in relieving pain.

In early 1999, Merck initiated the VIOXX Gastrointestinal Outcomes Research (VIGOR) trial to demonstrate that Vioxx was less damaging to the stomach compared to naproxen, known for causing gastrointestinal problems. In March 2000, the results from this study were revealed and findings showed evidence linking Vioxx to an increased heart risk. The heart attack rate in the Vioxx group appeared to

be four times as high as the naproxen group (Mathews and Martinez, 2004). Merck vehemently defended Vioxx, claiming that naproxen offered heart-protective effects. Merck officials insisted that firm conclusions could not be drawn from this study regarding potential heart risks from Vioxx. Yet the FDA forced Merck to revise the label for Vioxx to warn patients of cardiovascular risk.

It was clear at this stage that since a large clinical trial comparing Vioxx to placebo had not been conducted, definitive conclusions could not be drawn regarding the drug's safety profile. In May of 2000, executives at Merck met to consider whether to conduct a study directly to test if Vioxx posed an increased cardiovascular risk (Berenson et al., 2004). Merck decided not to conduct such a study, instead opting to monitor clinical trials that were currently being conducted, or were planned, to test Vioxx for other purposes. Merck officials decided that giving placebos and Vioxx to at-risk patients in order to compare side effects would be unethical. (Berenson et al., 2004) Yet, Merck was harshly criticized for not taking action to investigate the claims linking Vioxx to heart problems.

Some of Merck's most glaring critics were those within the medical community. In particular, Eric J. Topol, chairman of cardiology at the Cleveland Clinic, had for several years touted the risk of heart attacks from Vioxx. He was part of a team of doctors whose research had shown that patients taking Vioxx had a five times greater heart attack risk compared to those taking naproxen. On August 21, 2001, the Cleveland Clinic issued a warning concerning the safety of COX-2 inhibitors (Jennings and Moseley 2004). As such concerns were voiced, Merck continued to defend Vioxx. Dr. Topol claimed that before his report, published in the *Journal of the American Medical Association* (*JAMA*), came out, Merck scientists went to Cleveland to try to convince him not to publish it. Merck has denied these claims.

But did Merck suspect all along that Vioxx posed serious health risks? Rumors have emerged suggesting that internal company documents show that Merck had for years attempted to play down the drug's alleged risks (Mathews and Martinez, 2004). In particular, ''internal Merck e-mails and marketing materials as well as interviews with outside scientists show that the company fought forcefully for years to keep safety concerns from destroying the drug's commercial prospects'' (Mathews and Martinez, 2004, p. A1) For example, an e-mail written on March 9, 2000 by Merck's then research chief, Edward Scolnick, to his colleagues states that the cardiovascular events are clearly evident. In the same e-mail message, he also indicated that if the results of the VIGOR study were to become public, they should be presented in a manner so that it is apparent this was an effect of all COX-2 inhibitors, not only Vioxx.

In addition to these records, marketing documents suggest that sales representatives were trained to avoid questions from doctors who brought up concerns of the cardiovascular effects of Vioxx (Mathews and Martinez, 2004). Amid these accusations, Merck has offered various explanations for the claims. Nonetheless, investigations are being conducted concerning the company's handling of Vioxx.

In early 2000, Merck began a clinical trial, known as APPROVe, to examine whether Vioxx could prevent the recurrence of colon polyps. In late 2001, Merck appointed an external safety committee to monitor the drug's safety. Evidence of adverse cardiovascular events, such as heart attacks, strokes, and congestive heart failure, appeared early on. Minutes from the safety committee's meeting show that in May 2003, data indicated a 20% higher chance of heart attack or stroke in Vioxx patients compared to those taking placebos (Martinez, 2005). The risk grew to a 40% higher rate in November 2003, 80% higher in February 2004, and 120% in September 2004, at which point the results were statistically significant. During the trial, ''45 of the 1,287 patients taking Vioxx experienced heart attacks or strokes, compared with 25 patients out of 1,299 taking placebos'' (Martinez, 2005, p. A1). On September 17 2004, the committee decided to halt the trial.

On September 23rd 2004, Dr. Peter Kim, Merck's research chief, received news that the safety committee wanted to halt the trial due to the cardiovascular risk to patients taking Vioxx. The next morning, Dr. Kim informed the CEO of Merck, Ray Gilmartin, of the news. The Merck chief executive advised him to ''figure out what was the best thing to do in terms of patient safety'' (Kolata, 2004, p. 1). Dr. Kim and his aides extensively

reviewed the data collected from the trial. Numerous experts in various medical fields were consulted. Interestingly, some doctors advised keeping Vioxx on the market, since some of their patients had responded particularly well to Vioxx and could not easily switch to an alternative medication. Others recommended pulling Vioxx from the market. On September 28th, at an executive board meeting at the company's headquarters, it was ultimately decided to withdraw the drug. The Appendix provides a timeline of events regarding the Vioxx case.

The ethical dilemma

The ethical issues associated with the events at Merck are discussed within the context of the Merck executives, which represents the perspective of those closest to the central event.

Executives at Merck first became aware of the potential health risks associated with Vioxx in March of 2000. (See Table I for a list of dates and facts available to Merck executives). The results from these clinical trials served only to initiate speculation of these health risks; firm conclusion could not be drawn. Although the idea had been proposed and evaluated, Merck executives ultimately decided not to proactively seek answers to the question at hand: was Vioxx responsible for the increased risk of heart attack and stroke in these patients? They chose instead, citing ethical reasons, to monitor on-going studies in place that tested other effects of Vioxx. Consequently, the drug continued to be sold for over four years before it was ultimately withdrawn. Meanwhile, Merck continued to reap profits from this popular drug.

One can speculate about the ethical dilemma the executives at Merck may have faced over the course of events. When the potential dangers of Vioxx first became apparent, many issues had to be considered. What are the possible effects on patients taking the drugs? In this case, the consequences were quite serious, essentially life-threatening. Additionally, there were others that Merck had to answer to: the shareholders, whose main concern is the financial consequences. From a strictly financial point of view, withdrawing the drug from the market would be the worst option for the company. Merck invests billions of dollars and many years into its medical products. Vioxx was no exception. To withdraw the drug before its patent expires would mean forgoing billions of dollars, a huge financial loss to the company. Not to mention the effect on stock price they would suffer. Such an event would certainly severely damage their reputation. The decisions they faced had to be considered carefully with both the public's safety as well as the financial well-being of the company in mind. This situation demonstrates a unique aspect of business ethics – that firms are motivated to generate profits.

Indeed, the executives at Merck faced a very tough decision early in 2000. They chose to keep the drug on the market. They also continued to defend the drug, insisting that it was completely safe. They continued with their heavy direct-to-consumer advertising, still battling with their major competitor, Celebrex. They reluctantly changed the Vioxx label in 2002 (This was one battle with the FDA they could not win). Although there were possible disclosures amongst Merck insiders of the drug's potential risks, for the most part they strongly insisted to the public that the drug was indeed safe. That is, until that fateful day in 2004.

The role of the FDA

Governmental regulations have a significant influence on pharmaceutical firms' actions and behaviors. All activities must comply with FDA rules and regulations. When data from the VIGOR trial became available, FDA officials insisted that Merck prominently display warnings of cardiovascular risk on the drug's label. Merck resisted, arguing that the FDA was emphasizing the negative findings rather than the positive results from the study: that Vioxx seems to cause less gastrointestinal problems. Eventually, a compromise was reached. The revised Vioxx label first listed the benefits regarding fewer stomach problems, followed by two tables with the warnings of increased incidence of heart attacks and strokes.

Many have questioned whether or not the FDA acted aggressively enough when evidence of heart problems associated with Vioxx first surfaced five years prior. The agency was criticized for not early on insisting on additional studies to directly assess the drug's potential risks. This has brought to light the struggles felt by the regulatory watchdog: on the

TABLE I

Facts and dates available to Merck executives

Fact	Who knew?	Date
VIGOR trial initiated	Merck	Jan. 1999
APPROVe trial initiated	Merck	Jan. 2000
Preliminary results from VIGOR received	Merck	March 2000
Dr. Scolnick writes e-mail message to colleagues regarding data from trials for Vioxx, indicating that cardiovascular events are ''clearly there''(Mathews and Martinez, 2004, p. A1)	Dr. Edward Scolnick (Merck research chief)	March 9, 2000
Warning letter received from FDA stating that Merck engaged in ''a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings''(Martinez, 2004, p. B1)	Ray Gilmartin	Sep. 17, 2001
Committee decides to halt trial	External safety committee for APPROVe trial	Sep. 17, 2004
Receives news that the safety committee overseeing APPROVe trial wants to halt trial due to cardiovascular risk to patients	Dr. Peter Kim	Sep. 23, 2004
Dr. Peter Kim informs CEO of news regarding APPROVe trial	Ray Gilmartin	Sep. 24, 2004
Decision is made to withdraw Vioxx from market	Merck executive board members	Sep. 28, 2004
Merck officially withdraws Vioxx from market	Merck	Sep. 30, 2004

one hand, they are responsible for ensuring that new drugs are safe and effective. At the same time, they are there to help the pharmaceutical industry deliver needed medications to the public.

Application of the ethical decision-making model

This section examines the Vioxx case using the ethical decision-making model adopted from Ferrell et al. (1989). The ethical dilemma can be described from the perspective of the Merck executives, since it is these individuals who are involved in the decision-making process. These Merck executives faced significant decisions at two points in time (i) in 2000, when the potential health risks associated with Vioxx first surfaced, and executives had to decide whether or not to further investigate these risks, and (ii) in 2004, when executives had to decide whether or not to withdrawal Vioxx from the market. Even though it is not possible to know the exact thought processes these executives went through while making decisions, one can speculate on their experiences while facing the ethical dilemma.

As mentioned, context plays an important role in the entire decision-making process. For example, all pharmaceutical companies are under constant scrutiny by the FDA; Merck is no exception to this rule. They must behave within the guidelines set forth by this governmental regulatory agency. Additionally, they are under watch by the entire medical community. For example, physicians at the Cleveland Clinic conducted their own study involving COX-2 inhibitor drugs that showed a high incidence of harmful side effects with patients taking Vioxx. Over the years, doctors expressed their concerns over the drug's safety at various professional meetings and conferences in the medical field. Such activities occur which are completely out of the control of those within the company. Last, Merck executives must also make decisions based on the profit

objectives of the firm. These issues undoubtedly affect, to some extent, the deliberations confronted in the decision-making process.

1. Identification of the ethical issue was fairly easy in this particular case: evidence indicated that Vioxx was potentially responsible for causing harmful side effects in patients taking the drug. However, the facts surrounding the issue made the decision-making process difficult, at least early on. As early as 2000 there was evidence, though inconclusive, that Vioxx may be linked to heart problems. Certainly social, economic, and environmental issues came into play when faced with this issue. Any negative press associated with the drug would taint Merck's image, as well as hurt the company financially. Since there was no concrete evidence upon which to base a decision, executives at Merck took on a somewhat passive stance. They did not consider removal of the drug from the market or putting a warning label on the bottle (though they were forced to do the latter by the FDA). They continued to aggressively defend the product, insisting that it was a safe drug.

2. This phase involves examining the three broad levels of cognitive moral development: the preconventional, the conventional level, and the principled level. It is not possible to accurately assess which stage of cognitive moral development the Merck executives were in when facing a particular decision. Given the information known, however, it appears that in 2000 they tried to avoid having to make a decision altogether, essentially 'buying time,' while still profiting from the sales of Vioxx.

3. The concepts of deontological and teleological moral evaluations are introduced in this stage. As previously mentioned, both have been shown to play a role in ethical decision-making. Merck executives confronted several possible decision alternatives, each of which would produce considerable consequences for the company. The final decision to withdraw Vioxx from the market was made in the best interest of the customers, even though this decision negatively affected the company in many ways. The consequences of any other decision alternative would have continued to put patients' lives at risk, for which Merck did not want to be held accountable.

4/5. This stage involves intention, which is influenced by both the decision-maker's ethical beliefs as well as the consequences of the decision alternatives. This seems true for the present case study.

It appears that different paths were followed in 2000 and 2004, two points in Merck's history where critical decisions concerning Vioxx had to be made. In 2000, when the health risks associated with Vioxx first came to light, Merck vigorously denied these accusations. They also chose to not begin any new trials to investigate the claims. Their intention was to avoid exposure of this negative press. In retrospect, such behavior might be viewed as unethical. This path leading to an unethical decision may have been influenced by organizational culture and opportunities, as the model suggests. For example, at this point in time, Dr. Edward Scolnick was head of R&D at Merck, and very much involved with the issues surrounding Vioxx. As evident from the alleged e-mail messages he wrote, he did not want Vioxx to receive any harmful press. Dr. Scolnick was a stern fellow, the type of person no employee would dare dispute with, given his status within the company (Hawthorne, 2003). This aspect of Merck's organizational culture at the time might have played a role in leading to the final decision. Also, at this time no data was available comparing Vioxx to placebo – the only data that existed compared Vioxx to naproxen (from the VIGOR trial). This presented Merck with the opportunity to lay blame elsewhere (Merck suggested that the 'apparent' higher incidence of cardiovascular events in patients taking Vioxx was actually due to the heart protective effects on patients taking naproxen.)

In 2004, Merck faced another major decision point, one that led to different results compared to 2000. It appears that their intention was to behave ethically, even though it meant a huge financial loss for the company. When the data from the APPROVe trial showed that patients taking Vioxx had a higher incidence of cardiovascular side effects, Merck executives took action quickly. They *voluntarily* withdrew the drug from the market. At this time, Dr. Scolnick had retired from his position as head of R&D at Merck (although he was still somewhat involved in doing research there). Perhaps the organizational culture had changed by this time, with Dr. Scolnick

having a lesser influence and involvement in decision-making. Also, there were no opportunities as before to deny the health risks associated with Vioxx. These factors may have led to the resulting ethical decision to withdraw the drug from the market.

Modifications to the existing model

Based on the application described above, it appears that the adapted FGF model does a reasonable job of representing the ethical decision-making process. Though an outsider's knowledge of the situation is somewhat limited, assumptions can be made based on the facts observed. For example, it was noted how organizational culture as well as opportunity may have affected key decisions by Merck executives. Application of the set of events surrounding the withdrawal of Vioxx provides an ideal opportunity to investigate possible modifications to the FGF model. These modifications/extensions are described next.

During the 'intention' stage of the decision-making process, the decision maker faces the dilemma of choosing to perform the ethical behavior or unethical behavior. This may cause an internal conflict within the decision-maker as he/she weighs the consequences of his/her actions. While the decision maker may perform a behavior that is considered unethical, he/she will be reluctant to admit doing so. This is certainty the case with corporations in the public eye. They are rarely willing to admit wrongdoing. In this case, Merck always maintained innocence throughout the entire set of events. Yet, some of the firm's actions are questionable. For example, Merck was reluctant to put a warning label on Vioxx at the FDA's request. Also, some evidence suggests that Merck was aware of the potential harmful risks of Vioxx long before it was pulled from the market.

The intention stage of the FGF model can be further developed by recognizing two types of behavioral intentions: (1) *observed intentions*, those observed based on the decision-maker's actions and (2) *unobserved intentions*, those based on the decision-maker's statements. An example of the former is Merck's reluctance to put a warning label on Vioxx, which appeared to be in the best interest of Merck, not the public. An example of the latter includes Merck's continual denial of any wrongdoing, maintaining their innocence. In their statements they claimed their actions were always in the best interest of the public, yet this may be suspect due to some questionable actions. In examining an ethical decision-making situation, one may observe both ethical and unethical behavior. This results from the internal conflict experienced by the decision-maker when weighing the consequences of his/her actions.

The ethical decision-making model presented by Ferrell et al. can be further extended to include the effects of escalation of commitment. Such a situation occurs when an individual or group of individuals pursue a course of action that is unlikely to be achieved. The individual(s) continue to remain committed to the objective, regardless of its likelihood of success. This may be due to sunk costs invested in the objective, or a feeling of being ''trapped'' in a particular course of action to justify earlier decisions.

Although researchers have examined the topic of escalation of commitment, few have investigated its effects on ethical decision-making. Street et al. (1997) propose that exposure to escalation situations moderates the relationship between 'intent' and 'behavior'. Street and Street (2006) find support for the assertion that exposure to an escalation situation increases one's unethical behavior. These authors suggest possible reasons for this relationship. For example, the unethical behavior may be a means of exiting an unfavorable escalation situation. Also, practical considerations such as opportunity or economic outcomes may be a greater influence on behavior than one's ethical belief system.

In examining the Merck case, it is possible that escalation of commitment may have played a part in key decisions made by Merck executives. By the time a drug has reached FDA approval, the pharmaceutical firm has already invested precious time and money into the development of the drug. Estimated costs of drug development exceed $400 million (DiMasi et al., 2003). Vioxx had been on the market for approximately 1 year when preliminary clinical trial data indicated potential health risks from the drug. This signaled bad news for Merck, since pharmaceutical firms count on the revenues from their drugs to support their costly R&D programs. Vioxx was one of Merck's top five most profitable drugs, generating $2.5 billion in sales

per year. Merck executives were aware that removing Vioxx from the market would result in a significant financial loss for the company. This perhaps is why Merck continued to sell the drug early on, even though the safety of Vioxx was questioned. In this case, the escalation of commitment – in the form of the financial investment the company had made in developing and advertising Vioxx – may have influenced the earlier decision (when suspicions arose of the drug's safety) to not immediately withdraw Vioxx from the marketplace.

A *slightly* modified model of ethical decision-making is shown in Figure 2, incorporating the stated changes to the model proposed by Ferrell et al. This model acknowledges (i) the possibility of observed and unobserved intentions as well as (ii) the possible moderating effects of escalation of commitment on the intention–behavior relationship. These modifications are based on an extensive examination of the ethical dilemma faced by Merck executives managing the difficulties associated with the pain reliever Vioxx. Further examinations applying ethical situations to the model are necessary to adequately test these modifications. Possible adjustments and extensions may result by combining a number of such studies, enhancing our understanding of the ethical decision-making process in a business context.

Conclusion

Various researchers have proposed conceptual models of ethical decision-making to provide a framework for the decision-making process. While some tests of these models have been conducted, there exist opportunities for further refinement. Therefore, the approach taken here has been to examine the effectiveness of a conceptual model in the context of a real-world situation in which business executives faced decisions involving ethical issues. This approach provides noteworthy insights into the validity of the model and points to potential refinements and extensions.

Naturally, the application of a single situation to the model cannot definitively validate the model. However, it is a worthwhile step in this direction. A limitation of the current investigation surrounds the use of only qualitative data gathered from various news sources, whose objectivity may be uncertain. Additionally, one can only speculate on behalf of the Merck executives and the many influences upon their evaluations during the decision-making process. Nonetheless, this study demonstrates how examining real-world situations may lead to refinements in current models of ethical decision-making, improving our understanding of this process within a business context.

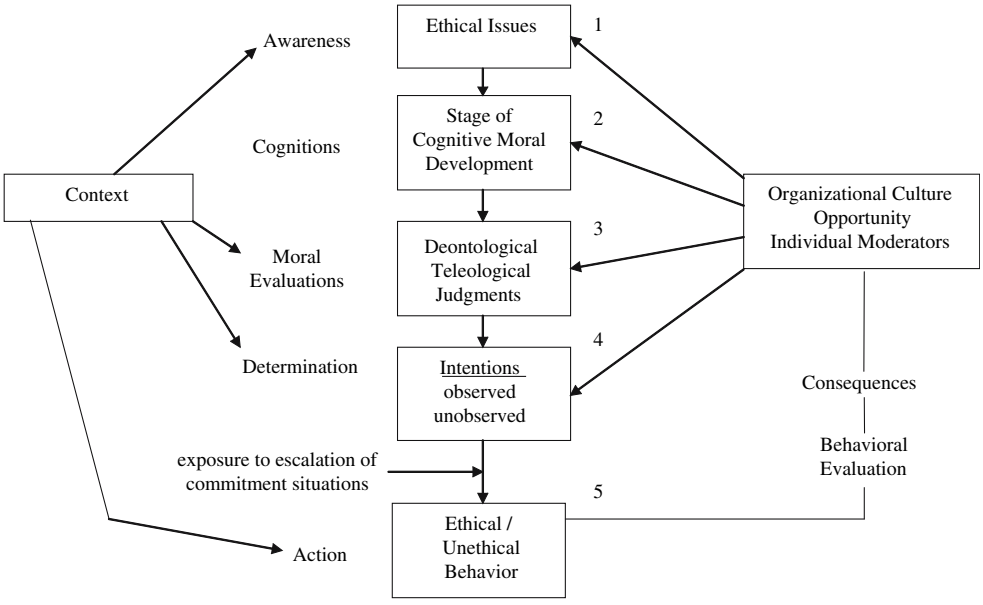

Figure 2. A *modified* integrated model of ethical decision-making in business.

It is hoped that similar studies conducted in the future, perhaps combined with empirical data, provide additional insight into the soundness and applicability of the ethical decision-making models proposed in the literature. Furthermore, additional research examining the role of escalation of commitment in ethical decision-making is warranted. Such studies would help researchers understand how business executives make decisions when faced with ethical dilemmas.

Appendix

Appendix: Timeline of important events

1999 January – VIOXX Gastrointestinal Outcomes Research (VIGOR) trial initiated
May – Vioxx approved by FDA

2000 January – APPROVe trial is initiated to determine whether Vioxx could prevent the recurrence of colon polyps
November – *New England Journal of Medicine* publishes results from VIGOR showing that patients taking Vioxx were four times as likely to have a heart attack or stroke as patients taking naproxen.

2001 August – Cleveland Clinic study (published in JAMA) shows association between Vioxx and increased risk for cardiovascular side effects
September – FDA issues warning letter to Merck regarding promotional campaign for Vioxx, scolding them for ''minimizing the potentially serious cardiovascular findings''

2002 April – FDA orders Merck to put precautionary label on Vioxx about cardiovascular risks

2004 September 24 – Merck CEO notified of halting of APPROVe clinical trial
September 30 – Vioxx is withdrawn from worldwide market

2005 May – Merck CEO Raymond Gilmartin is replaced

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Department of Marketing,
Michigan State University,
N 370 Business College, East Lansing,
MI, 48864, U.S.A.
E-mail: cavusgile@bus.msu.edu