

Applying the Potter Box to Merck's Actions Regarding the Painkiller Vioxx

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Abstract

In this paper we demonstrate how to focus an empirical application in reaching an ethical decision by working with the Potter Box, a model created by Ralph Potter as an analytical tool assessing the ethics of corporate decision-making. The facts emerging in news accounts regarding lawsuits against the pharmaceutical company Merck and its painkiller Vioxx are analyzed for ethical consideration. Utilizing the Potter Box model, the case against Merck can be interpreted and studied in light of ethical considerations. The results demonstrate not only how a decision is argued, but what is missing in the overall consideration for the decision.

Introduction

The mythos of freedom and responsibility in the United States is premised on the ethical actions of members of the society, particularly those in positions of power. And ethics in communication takes a place of preeminence since the words spoken by authorities are often all a public relies upon to pass judgment. How is the citizen or the communication analyst to evaluate the ethics of the utterances of others? And how does the communicator determine the ethical appropriateness of a planned message? This paper is an introduction to an accessible method of ethical decision-making in communication. The Potter Box allows both student and scholar to analyze the ethical responsibilities of communicators in terms that are both practical and theoretically grounded. The Potter Box's four primary dimensions--definition, values, principles, and loyalties--aid the communication analyst in locating the places where most misunderstanding occurs. It is along these lines that we construct action guides.

In this paper, we investigate the ethical considerations involving the law suites against Merck regarding its painkiller Vioxx. First, we provide background information regarding the case of Vioxx. We then describe the use of the Potter Box, as an analytical tool for assessing the ethics of corporate decision-making, by grounding the theoretical context and conceptualizing the four dimensions of the Potter Box. Finally, we demonstrate the analytically process using the Potter Box applied to the facts in the emerging cases against Merck.

The Case of Merck's Prescription Drug Vioxx

On the day this paper was being submitted for conference consideration, Merck, the pharmaceutical company which made the arthritis drug Vioxx, was defending itself in the penalty phase of a lawsuit brought against it. On April 5, 2006, a New Jersey jury found Merck concealed the dangers of Vioxx in a split verdict that gave one of two plaintiffs in the trial \$4.5 million in compensatory damages.

This trial was the sixth for Merck. The first one ended on August 19, 2005, when a jury in Angleton, Texas, awarded \$253 million to the widow of Robert Ernst, a 59-year-old Wal-Mart employee and marathon runner who died after taking Vioxx for eight months (the \$253 million award will be significantly reduced because Texas law limits punitive damages).

Merck's fortunes brightened on November 3, 2005, when a New Jersey jury absolved Merck of culpability in the case of Frederick "Mike" Humeston, 60. Humeston was an Idaho postal worker who survived a heart attack he said came after two months of Vioxx use. Just six weeks later (December 12, 2005), a mistrial was declared in Houston after a federal court jury couldn't reach a verdict in the case of Richard "Dicky" Irvin, 53, who died of a heart attack after taking the drug less than a month. The case was retried before a federal jury in New Orleans, and on February 18, 2006, the jury found that Merck wasn't responsible in Irvin's death. a trial over the death of Vioxx user Leonel Garza, 71, in state court in Rio Grande City, Texas, that began on January 25, 2006

The two Merck victories came about in cases where the use of Vioxx was short-term. The current New Jersey trial, the sixth over Merck's once-popular painkiller, was seen as a harbinger of things to come for many of the 9,650 pending lawsuits because it involved two men who said they took Vioxx for years. The company had previously admitted that people who take the drug for more than 18 months are at increased risk for heart attacks and strokes. Both plaintiffs in the case, John McDarby and Thomas Cona, had used Vioxx for a number of years. After two days of deliberations, the jury split, finding that Vioxx caused McDarby's heart attack but not Cona's. Cona was awarded only the cost of his Vioxx prescription. Jurors said the company also had failed to warn doctors and the public about risks associated with the drug.

Vioxx (formally known as rofecoxib) was approved by the FDA in 1999, after clinical trials of the drug conducted by Vioxx (and the results reported by Vioxx) revealed no significant adverse side effects. By 2004, the drug was making \$2.5 billion for Merck, its manufacturer. Then, suddenly, on September 30, 2004, Merck announced that it was pulling Vioxx off the market.

Merck's action came in the wake of results from its APPROVe (Adenomatous Polyp Prevention on VIOXX) study comparing Vioxx to a placebo for patients at risk for colon cancer. Results of the 34-month study revealed that the incidence of heart attacks (myocardial infarctions) was significantly higher than that of a control group, especially

among those patients who had been taking Vioxx for more than 18 months (Edwards, 2005).

At first, the decision by Merck was praised by Wall Street (Lublin, 2004, October 1). Pulling the drug off the market was bad enough for Merck. Not only was the company losing \$2.5 billion in annual sales from Vioxx, but it was faced with a number of popular drugs losing their patents in the next two years (like Pepcid and Prilosec). Estimates poured in that the litigation costs related to Vioxx would be over \$10 billion (Simons, et al., 2004).

The biggest blow to Merck, however, occurred when it was revealed that as early as the year 2000, Merck knew of a possible link between Vioxx and heart problems. Merck found in 2000 that more than twice as many patients had heart attacks when taking Vioxx than when given an older painkiller, naproxen. Merck reported incomplete results of this study (leaving out some data), and argued that difference was due to protective effects of naproxen, not the negative effects Vioxx. There was a problem with the logic of this explanation, however: Vioxx and naproxen are both COX-2 inhibitors, and help alleviate pain by reducing inflammation. Given that a major theory about heart disease is that reducing inflammation within coronary arteries should reduce risk for a heart attack, then Vioxx should have **reduced** the chances of a heart attack, not **increased** them. The

An investigation by reporters at the *Wall Street Journal* revealed e-mails that confirm Merck executives' knowledge of their drug's adverse cardiovascular profile—the risk was “clearly there”, according to one senior researcher. Merck's marketing literature included a document intended for its sales representatives which discussed how to respond to questions about Vioxx—it was labeled “Dodge Ball Vioxx” (Matthew & Martinez, 2004).

In the case of Vioxx, FDA was urged to mandate further clinical safety testing after a 2001 analysis suggested a “clear-cut excess number of myocardial infarctions” (Topol, 2004). It did not do so. Instead, the FDA did add a mild warning to the label, but that didn't stop the drug from being widely used (Casey & Barrett, 2004). Why? The FDA often sees the pharmaceutical industry as its customer—and a vital source of funding for its activities—and not as a sector of society in need of strong regulation.

For instance, the FDA's Office of Drug Safety co-exists in the same center—the Center for Drug Evaluation and Research (CDER)—as the Office of New Drugs, the part of the agency that works with the industry to license new medicines. The closeness of the two offices – both physically and psychically, makes it difficult for CDER to reverse itself once a licensing approval has been made. Thus, concerns about negative side effects about drugs often get downplayed, or outright ignored (Spake, 2004, December 13).

On Nov 2, 2004, the FDA belatedly tried to bolster its reputation as a regulator on November 2, 2004 when it posted on its website an early version of a recently completed study into the safety of Vioxx. Amid qualifications that the report “not been fully evaluated by the FDA and may not reflect the official views of the agency” the FDA

investigators estimate that over 27 000 excess cases of acute myocardial infarction and sudden cardiac death occurred in the U.S. between 1999 and 2003. The report suggested “These cases would have been avoided had celecoxib been used instead of rofecoxib”. Unfortunately, for many Vioxx users, the information came three years too late.

The Argument for Ethics in Business

In a broad sense, our culture may be suffering from a crisis in ethics. As we see our politicians, business leaders, and religious figures become entangled in self-woven webs of unethical behavior, natural questions arise as to which behaviors are “correct.” More specifically, we see a President impeached for lying, another President perhaps distorting the truth as a pretext for war, news bulletins about the latest Enron-like scandals, televangelists making public apologies for transgressions, and the Catholic church commenting (or not) on priest-child sexual abuse (Crane, 2004). We look to our leaders for moral and ethical guidance, but instead find humans as imperfect as ourselves. How, then, do we learn to behave and communicate ethically? Of course, there is no easy answer. Clark (2003, p. 18) offers a baseline for ethics training: “Business ethics should be an attempt to develop and apply basic principles of fair play to the area of human economic relations. Many problems in business are social problems, involving groups of individuals and dealing with relative positions rather than absolutes.”

It is reasonable to wonder if there is a crisis in ethics, particularly in business. The answer is a resounding “yes.” That there should be ethics training is without question, but current models are perceived to be inadequate (Crane, 2004). Although most businesses have explicit codes of ethics, very few employees follow such codes, and many are not familiar with the content of those codes (Carlson, 2003). The rise of the economic perspective in business, that is, making profit, appears to make teaching ethics a more difficult task (Gioia, 2002). In fact, Rothenburg (2003) questions the ability of anyone to teach ethics given capitalism’s profit motives. Those very profit motives, though, make the need for ethical behavior all the more compelling. Adler (2002) cites a lack of confidence in business due to recent ethics scandals. Furthermore, unethical behavior reduces a company’s ability to make a profit (Clark, 2003).

There is a growing awareness of the need for ethics training, but the approaches are fragmented, heading in different directions. The Business Roundtable is planning ethics training for CEOs (Lavelle & Borrus, 2002). Accounting firms are offering ethics training for college accounting professors (Karr, 2004). However, “MBAs have given barely passing marks to Columbia Business School’s first required ethics course. Five ethics classes and extra lectures were woven into the core curriculum. But an informal tap of student opinion finds execution was uneven...” (Schneider & Sager, 2004, p. 16). The ineffectiveness of current approaches is highlighted in a 2002 NAS/Zogby poll: 84% of college students see the US as being in a business ethics crisis; only about 25% see ethics standards as “clear and uniform” (Ludlum & Mascaloinov, 2004).

Development of the Potter Box

During the tumult of the 1960s, Harvard University theology doctoral student Ralph Potter faced the ethical questions of his time with some degree of bewilderment. In particular, Potter (1999) observed the growing concerns over the build-up of nuclear weapons and saw an ethical quagmire. By asking the simple question of the ethics of nuclear weaponry, Potter began an arduous process of self-examination and inquiry that would form the basis of his doctoral dissertation (Potter, 1965) and lay the theoretical groundwork for what is now called the Potter Box. Just as Potter used this rubric to reach conclusions about nuclear weapons policy, we, too, can follow these steps to determine ethical courses of action as we communicate with others.

The Potter Box developed over the course of decades, reaching its present form through clarifications and modifications from a number of sources. Potter devised the Potter Box and was instrumental in its early development; others have applied the scheme to the analysis of the ethics of particular communication behavior. Potter's original task was to identify a Christian position on nuclear arms policy (1999). Rather than one position, Potter isolated myriad positions. Potter notes that, "Policy preferences could not be traced back simply to worldviews, religious belief, philosophical orientation, or any one factor. A number of elements of belief were coming together in the establishment of people's concrete decisions about what ought to be done. I set out to identify these ingredients" (1999, p. 2). Potter began this task by sorting his notes, eventually creating four piles of notes. The first pile concerned questions of fact. The next pile contained information on social responsibility for those affected by a policy. "[N]otes on traditional moral philosophy and ethics" (1999, p. 3) constituted the third pile. The final pile "dealt explicitly with underlying philosophical or quasi-theological perspective that gave a hue to all that was said" (1999, p. 3). After sorting his notes, Potter's next step offered the theoretical grounding for his analysis.

The Potter Box is about social ethics; it is not individualistic. As such, the model is as much about sociology as it is philosophy. Thus, it is not surprising that Potter detected strong similarities between his four stacks of notes and Talcott Parsons' Theory of Action. In particular, Potter saw parallels between his stacks and Parsons' Cultural Subsystem of the General Theory of Action (Parsons, 1961). Parsons identifies four elements of the cultural system: adaptation, goal-attainment, integration, and latent pattern maintenance. Parsons maintains that for a culture to survive, these imperatives must be met: a culture must change with changing times and conditions; a culture must create and meet objectives relevant to its functioning; the culture must bring together its diverse elements to form a coherent system; and a culture must provide guides or models reflective of the reality perceived. In narrowing the broad needs of society, Parsons focuses on these four factors in the Cultural Subsystem. Parsons operationalizes the factors as follows: adaptation takes the form of empirical ideas; goal attainment takes the form of communication; integration occurs through evaluation; and latent pattern management provides the grounding for meaning. And these explanations of Parsons' cultural subsystem parallel, strongly, the categories Potter identifies as essential qualities of any ethical debate.

Potter's four stacks reproduced his assessment of a particular issue, but reflect widely observed societal issues: empirical definition of the situation, loyalties rooted in preference, modes of ethical reasoning, and theological or quasi-philosophical religious worldviews (1999). Potter argues that, "any sustained argument, waged by alert, persistent interlocutors, would have, eventually, to deal with each of the four types of questions I had isolated" (1999, p. 4). That is, Potter's ideas are relevant to virtually any contentious issue. And, these four categories parallel Parsons' Cultural Subsystem categories. While the Potter Box moniker has been attributed to theologian Karen Lebacqz (Gillis, 2002), Potter himself claims that "waggish graduate students" first used the term (1999, p. 4).

The next stage of development of the Potter Box came about as a result of the war in Vietnam. Potter, echoing the feelings of much of society, was deeply concerned about the morality of the war. Starting as an attempt to examine Just War doctrine, Potter expanded on his four ideas in *War and Moral Discourse* (1969). Potter examined the morality of the war through the lens of his category scheme, concluding that in the case of Vietnam, ethics demand action. As such, Potter takes ethics from being an intellectual exercise for philosophers and makes it a moral imperative.

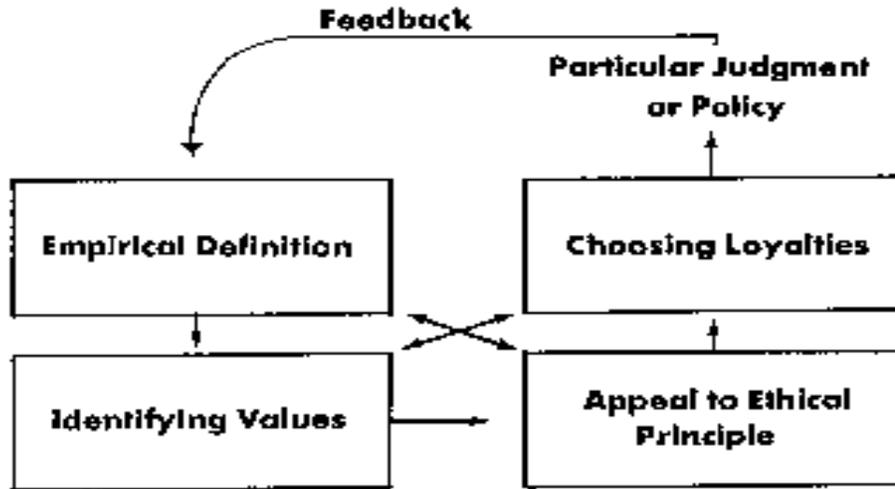
The Potter Box provides opportunities for the critic as well as the communicator. It has been used for scholarly analysis of decisions. Williams analyzes television news coverage decision making concerning AIDS using Potter's framework (1997). Park and Park utilize the model to assess Korean newspaper coverage of the Starr Report on the Clinton scandals (2000). Potter notes that, "The scheme can be used as a template or paradigm for content analysis" (1999, p. 5).

The rubric has also been employed in public relations (Christians, Fackler, Rotzoll, & McKee, 1998; Guth and Marsh, 2003). The Potter Box provides a method of making ethical decisions, regardless of context. To date, there appears to be no usage of the Potter Box in business communication outside public relations. Kienzler (2004) notes the complexity of ethical decision making, as well as the challenges posed by teaching ethics, for both teacher and student. Given the contemporary business atmosphere, business communication should investigate the use of this grounded and accessible tool.

Technique: The Potter Box

Christians, Fackler, Rotzoll, & McKee (2001) provide an effective introduction to the four dimensions of the Potter Box – definition, values, principles, loyalties – and construct action steps. The authors are careful to caution that the steps – usually applied in a systematic order – are a linked system, a circle, or an organic whole and not a random set of isolated questions. The action steps include: Providing an empirical definition, identifying values, appealing to ethical principles, choosing loyalties, making a particular judgment or policy, and finally, providing feedback.

The Potter Box



Guth and Marsh (2003) elaborate on the concept of the four dimensions of the Potter Box and provide clear definition to the action steps. The authors' clearly defined eight-step process, aided by the Potter Box model, is presented in a summarized form. We believe it to be a meaningful technique for communication researchers and practitioners.

Box One: Empirical Definition

Step 1: Define the situation as objectively as possible. This requires detailed information that is relevant to the ethical dilemma.

Box Two: Identifying Values

Step 2: State and compare the merits of the differing values. Each value influences our discourse and our reasoning on moral questions. These values represent our notions of rights, beliefs, notions of right and wrong that are in conflict, and questions of fact and values.

Box Three: Appeals to Ethical Principles

Step 3: State a principle that each value honors. That means, imagine each value as the basis for a categorical imperative. These principles are broader ideas of justice. For example:

a. Aristotle: The Golden Mean

The moral virtue is the appropriate location between two extremes.

b. Immanuel Kant: Categorical Imperative

Act on the maxim that you wish to have become a universal law.

c. John Stuart Mill: Principle of Utility
Seek the greatest happiness for the greatest number.

d. John Rawls: Veil of Ignorance
Justice emerges when negotiations are without social differentiation.

e. Hedonism: Personal Gain
The best option to take is the most pleasurable option

Step 4: Consider and compare other ethical principles. Do these ethical principles suggest new values to consider?

Box Four: Choosing Loyalties

Step 5: Decide to whom am I being loyal. For each principle, answer this question: If I base my action in this situation on this principle, to whom am I being loyal?

Step 6: Evaluate if there are others to whom I should feel loyal. If you identify new loyalties, do they suggest new principles and values you have not considered? Are there individuals or groups noted in the definition toward which you feel no loyalty?

Step 7: Select a course of action that embraces the most compelling values, principles and loyalties. Examine this course of action in light of your definition. If this course of action still seems to be the best choice, implement it. In each course of action you can now see which values, principles, and loyalties you are honoring.

Step 8: Evaluate the impact of your decision.

Application to Merck and Vioxx

The first step in applying the Potter Box is to empirically define the situation. In this case, the situation was: upon finding evidence in the year 2000 that Vioxx was linked to higher incidences of heart attacks, should that information been communicated to the Food and Drug Administration.

The next step is *to identify the applicable values*. One important value for a pharmaceutical company, like any company, is to make a profit, and to present a reasonable financial return to its investors. Corporations are not required to do good acts. They are required by law to make their investors money. On the other hand, while corporations are not in the business of doing good, doing good is good business. And, for pharmaceutical companies, an industry closest to the medical profession, the value of the medical profession – “do no harm” – should be followed. So, the dilemma here for Merck is one of completing underlying values. Revealing the information to the FDA that testing has revealed higher incidences of heart attacks will likely force Merck to drop a lucrative drug from the marketplace, resulting in substantially decreased profits. On the

other hand, telling the FDA about the tests will likely prevent future potential users of Vioxx from suffering the negative side effects of the drug.

The third step in the Potter Box model is to *link the ethical principle with its associated applicable value*. It might be too cynical to say that the maximization of profits for shareholders is linked with the principle of hedonism, but certainly an argument can be made that it is linked with Mill's principle of utility – that is taking a position where the outcome does the greatest good for the greatest number of people.

The dilemma here for Merck is that the conflicting value here – the medical professional axiom of “first, do no harm” operates from a deontological perspective – the Kantian perspective of the Categorical Perspective. In other words, you always report negative results in drug testing *just in case* the problem is a persistent and serious one. Consider the catastrophe that occurred in the 1960s when Chemie Grünenthal ignored trial results about the birth defects associated with its tranquilizer Thalidomide. The result was that 15,000 children were born without fully formed hands or feet. Had FDA reviewer Frances Oldham Kelsey not demanded further test data from U.S. thalidomide distributor Richardson-Merrell, a similar fate could have befallen thousands of babies in the United States.

The final step in the analysis is to *identify the principle stakeholders – to whom is the company or individual being loyal*. Merck was faced with the choice of potentially harming current and future **customers** with its drug Vioxx, or to lose literally billions of **dollars** if it chose the reveal information that would result in the drug being taken off the market, thereby resulting in financial harm to, and ill will from, your shareholders. If you are operating from a Categorical Imperative, the choice is clear – you report the results to the FDA and live with the consequences.

From a Millisian perspective, however, the choice is murkier. Suppose you take Vioxx off the market, and save potentially thousands of lives. You also risk billions of dollars in revenues. Could those billions be used to eliminate the harmful side effects of the new MK-0767 diabetes drug, and perhaps save even more people? What is the greatest good for the greatest number of people? The choice is not always so clearcut.

Conclusion: Using the Potter Box for Ethical Decision-making

In the end, Merck was loyal to its shareholders rather than to its customers. The results have been devastating to the company – a loss of over \$22 billion to its market capitalization, a potential \$10 billion worth of legal judgments against it, and a serious erosion of the public trust in the pharmaceutical giant. Worse still, people died because Merck withheld information. That loss is incalculable.

One implication of this study is that the Potter Box can be a useful tool for analyzing the ethics of any decision, specifically in cases of conflicting forces. While the Merck case presented here asks for an explicit discussion of the four boxes and eight steps, the Potter Box may also be used for less formal analysis. The ideas presented are excellent points

for discussion on any ethical issue. This technique may be used to analyze other case studies or ongoing examples from the front pages of the newspapers. Actual decisions may be examined to determine the motives of previous actors as well as to guide future actions.

As is true when utilizing most analytical communication tools, the process can be as significant as the results. An effective analytical result can aid in fine tuning the instrument and increasing the use of such an important analytical process.

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