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# Conceptions of Crisis Management: The Analysis of Pharmaceutical Companies in Germany, Japan, and the United States

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*CONCEPTIONS OF CRISIS MANAGEMENT: THE ANALYSIS OF PHARMACEUTICAL  
COMPANIES IN GERMANY, JAPAN, AND THE UNITED STATES*

AN HONORS THESIS

College of St. Benedict/St. John's University

In Partial Fulfillment

of the Requirements for Distinction

in the Department of *Management*

by

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“Sooner or later comes a crisis in our affairs, and how we meet it determines our future happiness and success. Since the beginning of time, every form of life has been called upon to meet such crisis”

-Robert Collier, American motivational author, 1885-1950

Our use of technology created a world that can limitlessly distribute news if a catastrophic event transpires. Continental borders no longer obstruct intercultural communication. The result of increasing scientific advances leaves no organization impervious to both true problems and false rumors spread by the media, public or rivals. In an instant, an issue can erupt and leak into the public domain before a corporation can confer and manage the issue internally. Obliteration of a company’s reputation happens in only days, or in some cases just a few hours. The improved speed of communication has increased the vulnerability of a company being branded as ‘bad’ to the general population. The pharmaceutical industry is especially prone to the occurrence of a crisis because of its growing international operations in the healthcare sector. Businesses continue to expand into other world markets, however many firms hold on to their distinct national identities. If organizations strongly retain their cultural individuality, they may function in different manners. This can become an issue if a company’s values differ from those of the countries in which it operates. Although a universal set of crisis management guidelines is developing because of globalization, businesses still need to be sensitive to differing cultural values in other countries.

A pharmaceutical is often defined as, any chemical substance used to diagnose, cure, or prevent diseases and for restoring, correcting, or modifying organic functions (Geest, & Whyte, 1996). Pharmaceuticals are categorized by chemical groups, how they function within the body (pharmacological effect), and therapeutic use. Important pharmaceuticals created from natural

substances include antibiotics, vaccines, human blood-plasma fractions, and steroid hormones (“Drugs,” 2011).

From the above definition, one can conclude the manufacturing of medicinal drugs today relies heavily on systematic measures, such as manufacturing of the active ingredient and the conversion of active drugs into products suitable for administration (Geest, & Whyte, 1996). Pharmaceuticals were developed to combat ailments that have cast long shadows over human wellbeing. Throughout the existence of civilization, sickness and disease plagued humanity. Medications originated from the knowledge of which plants were effective to fight against a sickness. Today, medications, such as vaccines and antibiotics, are used to prevent illnesses from occurring. The refinement, or process of modifying drugs, diverted onto a more scientific route, such as the synthesizing of a medication (Geest, & Whyte, 1996).

However, some pharmaceutical companies still produce drugs obtained through natural products. It is important to note the idealistic approach to improve effectiveness and reduce harmful side effects of drugs through cutting-edge science is not always reachable. The iatrogenic phenomenon, such as drug side effects, occurs when companies try to develop drugs through systematic approaches rather than natural (Farson, 1996). With every new application of technology, a counterforce develops which is the exact opposite than what was intended. Some modern medications actually cause more harm than good. More than a thousand different diseases would not exist if not for the practice of medicine such as the use of digoxin, which intends to regulate heartbeats, but may cause heart toxicity (Farson, 1996).

Today, pharmaceutical corporations are scrutinized more so during a crisis than companies in other industries. This is due to the fact that their products affect “the health of yourself and your loved ones” (Koster, Politis-Norton, 2004, p. 608). People usually link crises

with the notion of danger and thus often perceive such events in a negative light. Nonetheless, not all recalls are received with the same magnitude of concern. For example, furniture recalls are much less threatening than a drug, with potential adverse side effects. Issues for drug recalls or withdrawals today relate to potency, tampering, dangerous reactions occurring, or lacking therapeutic effects (Cheah, Chan, & Chieng, 2007). Not all drug recalls are necessarily life threatening, but those which are receive far more publicity.

Regardless of whether or not a firm is international, the organization must comply within all laws of the geographical area it operates in. However, a number of scholars speculate that while businesses globalize, many keep their national distinctiveness (Thomas, 2004). In other words, the organization retains its national roots while functioning on a global frontier. Because cultures differ in what they deem as appropriate or responsible, firms respond in different management manners to reflect their society's culture. Nevertheless, a universal area of importance for corporate entities in the pharmaceutical industry stresses on immediate action to protect consumers.

The purpose of this analysis is to examine whether selected pharmaceutical firms in Germany, Japan, and the United States operate under a universal set of crisis management principles during a disaster situation, or if they are still influenced by the cultures in which they originated. At the present, there is no universal journal for ethics in pharmacy. In other words, there is not yet an official set standard of how to operate ethically in the pharmaceutical industry. Companies can differ in how they manage a crisis according to social responsibility perceptions in the locations they operate in even if it disagrees with other countries (Cheah et al., p. 429, 2007). Some countries value the long-term relationships between buyers and sellers, while others focus on short-term interactions. Consequently, how they respond may fluctuate to mirror

investors' or consumers' expectations. To gain a better understanding of an organizational crisis, the definition of a crisis needs to be explored. In addition, a crisis business model is used to determine whether organizations have handled the circumstances in the most productive way to save their company's reputation. Because businesses in the pharmaceutical industry have unique challenges regarding crises, a closer examination of the industries and their regulations must be investigated. For the sole discussion of this paper, the international pharmaceutical companies Bayer, Takeda, and Pfizer located in Germany, Japan, and the United States are examined to determine whether cultural aspects influence the organization's management decisions in events that can harm their reputation and competitiveness.

### **Organizational Crisis Defined**

Organizational crises not only damages the legitimacy of a company, but also harms stakeholders and the credibility of the company. Once a company is perceived pessimistically, the reputation and survival of the organization can be in jeopardy. Consumers may associate the firm and/or its products or services negatively, which will tarnish the company's status. Usually, senior corporate officials will attempt to communicate with the media, and key stakeholders, to appear as having controlled or contained the crisis (King, 2002). While proper management may help prevent a crisis, "external factors [still] have a huge influence" (Koster, Politis-Norton, 2004, p. 604). For instance, if the amount of news is low or if the organization holds a worldwide brand name, usually minimal issues can be amplified and attract a lot of media attention to the detriment of the company.

An organizational crisis is a vaguely defined concept and often has numerous definitions (Snyder et al., 2006). To this day, scholars struggle to find an adequate, universal definition. King (2002) describes a crisis as, "an unplanned event that has the potential of dismantling the

internal and external structure of an organization” (p. 237). Though this definition gives a rather generalized explanation of a crisis, it does not elaborate whether the cause of the event was under human error, natural disaster, or technology failure. Depending on the crisis, this distinction can make a large difference. According to Argenti (1998):

A crisis is a major catastrophe that may occur either naturally or as a result of human error. It can include tangible devastation, such as the destruction of lives or assets, or intangible devastation, such as the loss of an organization’s credibility. In the latter case, the loss of credibility may be the result of management’s response to tangible devastation or the result of human error (p. 214).

Here the origins of a crisis is better explained, however, the definition does not acknowledge the fact that technology now plays a large role in our lives today. Crises arising from technology malfunctions are just as prevalent as those from natural disasters or human mistakes.

Over time, the definition of a crisis appears to change in correlation with crisis management strategies. In the past, the organizational crisis classification just touched on what causes the event rather than what happens if management does not resolve or assuage the fallout after the incident. A universally accepted term of an organizational crisis is yet to be determined. The basic definition for a crisis is covered in each explanation; however, disagreement remains when it comes to the specific details of what clearly defines a crisis.

Definitions of a crisis appear to vary however, Koster and Politis-Norton (2004) state, “the most frequent are wordings which underline the inability of an organisation to have a major influence on its course and the speed with which the flow of events escalates during a crisis” (p. 604). By analyzing the above definitions, and for the purpose of this paper, a crisis will be define as an unexpected, detrimental event caused by natural terms (weather, natural disasters), human error, and/or technology failure, harming the reputation as well as the competitiveness of a company. The incident also negatively affects stakeholders and people external to the organization.

### **Crisis Management Business Model**

Crisis management is a managerial approach that emphasizes preventing crises and restoring or minimizing damages caused by an event. A company that responds in a swift, generous manner may find itself in a position to strengthen customer loyalty, and improve competitive standing; however, if a crisis is not controlled and escalates, the company's reputation may be under threat.

Some widely known corporate crises have developed into international events. For instance, the "TWA's flight 800, Texaco's racial discrimination suit, Exxon *Valdez*, Perrier's benzene problem, Morton-Thiokol's *Challenger* explosion, Tylenol's cyanide-laced pills, Union Carbide's Bhopal tragedy, and Metropolitan Edison's Three Mile Island disaster," were not only crises in media, but also for the corporations and stakeholders (Argenti, 1998). Every move the company made was in the eyes of a worldwide public. If the global populace perceives the company in a pessimistic light, it can forever tarnish the image of the firm. Some businesses can restore their reputation, but not all are successful. The scathed image of the company usually becomes a liability, which hurts the competitiveness of a firm. As a result, companies need to take preventative steps against any potential damaging event.

While it is not feasible to prepare for every accident, a corporation's responsibility is still to prepare for those that may happen to the best of their ability. Having a plan in place not only protects the company's status, but also those who consume their products. Crisis management is a necessity for every business and needs to be conducted with vigilant care. Organizations need to develop a crisis management plan with the mindset of 'when' a crisis would occur rather than 'if' (Koster, Politis-Norton, 2004). A crisis might not happen in the near future, but in time, some destructive event is bound to arise. Corporations need to either take preventative measures

or they need to respond proactively at the time of the incident rather than postponing a response. Consumers often believe if a company does not act immediately, it is self-serving and does not care about the welfare of others.

The primary objective of crisis management necessitates on taking the appropriate steps to make sure the negative results of a crisis are controlled and limited as much as possible (Koster, Politis-Norton, 2004). According to Koster and Politis-Norton (2004), “Only a handful of pharmaceutical companies have learnt from the past of other organisations and their true character comes to light during a crisis” (p. 604). Though each situation differs, many experts agree that, “speedy, transparent communication...is more important than ever” (Grewal, & Levy, 2011, p. 8). In order to survive a crisis, organizations should be prepared, keep themselves in check, respond properly and follow the best practices (Levy, 2011).

Many aspects could provoke a crisis, such as, “a product-related disaster, like the under-reporting of adverse reactions during protocol 321 with triazolam (Halcion; Upjohn) and the cerivastatin (Baycol/Lipobay; Bayer) deaths due to severe rhabdomyolysis” (Koster, Politis-Norton, 2004, p. 605). Many, if not all, people take medications. Pharmaceuticals affect all of us. The jeopardy of one’s health or a loved one’s from a product related disaster often explodes into a crisis for all such as in the Merck & Co incident.

Merck & Co. is an example of how not to handle a crisis. In 2004, Merck withdrew an arthritis drug, Vioxx, because of evidence the medication increased the chance of heart attacks and strokes. In a study conducted four years prior, Vioxx had already shown an increase in cardiovascular problems, but the company did not issue a recall. The drug maker removed Vioxx from markets after serious health incidents increased. As a result, suddenly consumers needed to find new alternatives for arthritis treatment. Customers were upset because they were

left scrambling to find other medications. Merck's downfall was they did not immediately respond to problems nor initiate any new further in-depth studies, which could have avoided this recall (Grewal, & Levy, 2011).

On the other hand, the Tylenol cyanide-lacing scare in 1982 illustrates the other end of the spectrum. Top management did not hesitate to withdraw recalled medication and they provided the public with transparent communication and information (Aubato, 2008). Johnson and Johnson (J&J), the creators of Tylenol, pulled the medication off store shelves and for the time being, stopped product advertising. Even though J&J was not directly accountable for the tampering, they assumed liability. This action illustrated J&J as a company who took pride in responsible corporate practices. They exercised good corporate responsibility which did not just protect those within the organization, but also consumers. They restored consumer confidence and in doing so reclaimed their position as the leading pain reliever. Today, the Tylenol incident still stands as a golden model for effective crisis management execution. Recognition of J&J's actions cannot be ignored because people usually concentrate only on mistakes and faults. The fact that they are still renowned from the incident shows the degree of respect and approval toward J&J's practices. They salvaged the corporation's status by not only enduring the crisis, but also regaining their place as a market leader. J&J has a one-page Credo outlining the firm's obligations to various stakeholders (Grewal, & Levy, 2011). Several companies have mission statements including ethical guidelines or, "emergency response plans in place just in case they ever encounter a situation similar to the Tylenol tampering emergency or an industrial accident at a manufacturing plant" (Grewal & Levy p. 56, 2011). By creating these principles, companies present themselves as more ethical and socially responsible to consumers.

Below are guidelines recommended by Koster and Politis-Norton (2004) on how to prepare an organization for a crisis. These principles contain similarities to other crisis management business models suggested by different experts throughout the global economy. Commonalities from several models suggest these proposals are derived from past crisis incidents. The global overlap of guidelines means a universal set of crisis management principles is developing. In general, the models are linked with successful management from diverse organizations. Any corporation will benefit from the suggestions below.

- Define the real problem as soon as possible and solve them quickly
- Create focus
- Resist combative instinct
- Assume the worst
- Consider short-term sacrifice
- Necessitate clear communication and choose an articulate spokesperson
- Define the real problem as soon as possible and solve them quickly

To effectively manage an issue, those within the organization need to have a clear understanding of what exactly is going on, otherwise a proposed solution may only solve one part of a crisis. The problem needs to be documented as well; otherwise, it will continue to happen. If the root of the crisis is not identified immediately, valuable time will be wasted on other areas that may not be the true origin of an issue. The longer management or employees postpone defining the root of the problem the more chance they take that it could happen again.

- Create focus

Internal stakeholders within the organization need to pinpoint the problem and focus on solving it, instead of working broadly and trying to cover all aspects. Identifying the problem also helps motivate employees to develop an action plan. By encouraging others to focus on a positive goal instead of an ambiguous fear, they often begin devising a plan for success.

- Resist combative instinct

During a crisis, collaboration within the organization is crucial. Employees waste more time fighting amongst each other than using the energy to help solve the problem. In addition, disputing outside recommendations fogs the company's focus when the feedback may retain significant credibility. Combative instinct helps no one in the end.

- Assume the worst

Prepare for instances where everything that can go wrong does. A common fault is if a company believes nothing will happen or that they absolutely know how to handle every potential situation. For instance, when confronted with a serious crisis, consumer harm damages the reputation of a company beyond repair. When a business accounts for everything that could go wrong, they are better prepared to handle the issue from all angles.

- Consider short-term sacrifice

In most situations, the long-term survival of an organization greatly outweighs short-term loss. The battle to keep revenues may be won, but the war for the company's survival, lost. Preserving a business's reputation may allow it to rebound from an issue in the future.

- Necessitate clear communication and choose an articulate spokesperson

The most important tactic to successful crisis management requires articulate communication. Reducing the fallout of a crisis largely depends on how well the company corresponds and how the firm responds. Gene Grabowski, a senior vice president of Washington-based crisis communications firm Levick Strategic Communications elaborated, "Ninety-nine percent of handling a crisis correctly is communication: who is saying what to whom and what are they saying" (Levy, 2011, p. 8). Communication allows information to flow and gets everybody involved on the same page. It also helps when brainstorm diverse ideas during the planning

stage of how to manage a crisis event. Jim Lukaszewski, president of The Lukaszewski Group Inc., a crisis communications division of New Brighton, Minnesota-based Risdall McKinney Public Relations, adds that timing of the response is equally important (Levy, 2011, p. 8). Regardless of the country, many experts agree communication is the key to effectively handling a crisis. Choosing someone who excels in this area will help an organization reach out and connect with the public. On the other hand, sometimes businesses are reluctant to communicate for different reasons such as, a desire to avoid panic, fear of legal implications, or not all facts are yet available (Koster, & Politis-Norton 2004). While these issues may justify a company to withhold information, under most circumstances non-communication in crisis situations often evokes the wrong impression to the public.

These principles above reflect the ethical nature and consideration of the needs and obligations to an organization's stakeholders. Ethical rationality is the morally driven response to events (Snyder et al., 2006). By following these recommendations, an organization protects not only itself, but also its consumers and the public. If a company does not properly prepare, they are putting themselves at risk.

### **Pharmaceutical Industry: In-depth Perspectives**

The pharmaceutical industry develops, manufactures and markets licensed drugs for medications. This industry is subject to laws and regulations regarding the patenting, testing and ensuring the safety of marketed drugs. Debate concerns currently go on regarding whether drug regulations should be stricter to ensure patients' safety ("Pharmaceutical Industry," 2012).

Value in the human physical condition has increased in recent times. People are finding out they can lead a better lifestyle by taking antibiotics and getting the right amount of daily

nutritional content. More consumers purchase medications to ensure a longer, healthier life by averting and ameliorating sicknesses.

Demand for pharmaceuticals is motivated by the aspiration to cure diseases, prolong human life and to satisfy the natural curiosity to obtain knowledge. Medical researchers and scientists alike constantly work on finding new treatments to ailments that plague human life. The pharmaceutical industry strives to continuously create effective medicines through new scientific knowledge such as synthesizing through a biochemical procedure ("Pharmaceutical Industry," 2012).

In order to be profitable, each organization needs to develop and market new medications to solve both old and new health problems. Pharmaceutical companies can create both generic and brand medications. Conventionally, some small businesses produce generic drugs while larger organizations leverage their much larger resource bases to drive the innovation of new patented medications. Once a patent expires on the original brand name drug, it can be made into a generic. In order to be considered, the generic drug must have the exact same attributes [such as potency and effectiveness], as the brand name product (Synder et al., 2006). Large corporations benefit the most from extensive manufacturing, research, and marketing; while smaller corporations compete by specializing in drugs that target one or two particular ailments. Generic drugs give small companies a chance to compete successfully within the industry, whereas customers benefit by medications at a lower cost ("Industry Profile Biotechnology Research Services," 2011).

By centering on just a few focus groups, smaller companies utilize their resources to concentrate on quality rather than quantity. Therefore, the motivations of large and small businesses differ in the ways of developing and promoting medications. Nowadays, there is a

progressing shift in the operations of the pharmaceutical industry. For instance, traditional pharmaceutical manufacturers are becoming development and marketing companies that obtain new drugs from smaller research companies (“Pharmaceutical Industry,” 2012). Generally, larger firms do not focus as much in research and development; instead, they get the new drugs from smaller companies and then mass produce pharmaceuticals. Massive firms stretch broadly in their organizational activities, while smaller businesses tend to concentrate on one objective, such as the development of new drugs.

Through the revolutionary advances of modern medicine, pharmaceutical firms use biotechnology to produce new drugs. Biotechnology is a field of applied biology that entails, “the use of bioprocesses and living organisms in technology, engineering, medicine and other fields requiring bioproducts. Biotechnology also utilizes these products for manufacturing purposes” (Snyder et al., 2006, p. 377). Rather than relying solely on traditional pharmaceutical sciences, such as biochemistry, modern biotechnology utilizes tissue culture technologies [in vitro] and genetic engineering (Xia & Buccola, 2005). More specifically, within medicine, applications of biotechnology include gene therapy, genetic testing, drug production, and pharmacogenomics (“Pharmaceutical Industry,” 2012). In the past, physicians did not have a wide arsenal to combat diseases. As people discovered the link between pathogens and the spread of diseases, pharmaceutical companies started to develop and mass-produce medications to ensure the prevention of sickness. Previous generations did not have the relatively new science method of biotechnology and thus, were restricted to develop medications within the technology limitations of their time.

When using biotechnology, pharmaceutical companies [or biotech firms] have more ways to develop medications compared to companies in earlier decades. Technology allowed for the

chemical modifications of natural products to increase strength and potency in drugs. Scientists' desires to find solutions for medical issues influence the demand for this research technique in the field of medicine. Hence, developing medicines now rely on vast knowledge of biotech developments. The modern development of pharmaceuticals involves "gene-splicing to produce large quantities of drugs from bacterial fermentation, or the production of monoclonal antibodies using mouse or human cells" (Xia & Buccola, 2005, p. 235). For instance, pharmaceutical corporations develop new generic biotech drugs, called biosimilars, as an alternative way to generate revenues. Currently, generic biotechs are not allowed in the U.S., but are sold in Europe (Marcus, 2011). The U.S. bars biosimilars because "they were not part of the 1984 landmark Hatch-Waxman law, which allowed for cheaper generic drugs from chemically derived products" (Japsen, 2011 p. 1).

Given that biotechnology is another source to create new medicinal treatments, pharmaceutical manufacturing increasingly overlaps with the biotechnology industry (Maurer & Fischer, 2010). Analogous features between both markets influence the functions of organizations that create medicines using this technique. This synchronization allows for both industries to synergize their research and manufacturing efforts, providing consumers with potential high quality products. Because of the public's increasing reliance on medications, the demand for drugs continues to increase.

Annual revenue for the pharmaceutical industry is around \$200 billion, thus making the market highly lucrative worldwide. The industry is highly competitive for operating firms due to the opportunity to earn so much capital ("Pharmaceutical Industry," 2012). The pharmaceutical industry became a high profile industry because the potential for generating mass amounts of income worldwide. This high profile stems from the fact that drug recalls or withdrawals may

harm consumers' wellbeing. Most of all, the pharmaceutical industry is prone to greater crises because of its linkage with healthcare.

With increasing global awareness of maintaining one's health, this industry expands throughout the world, especially in the U.S. The entire size of the international pharmaceutical market experienced a "6-7% growth in 2006...with the size of the market around U.S. \$640-650 billion (Cheah et al., 2007, p. 427). Although organizations continue to compete in this industry, there are downsides to participating in this market. For example, investing large amounts of money into the development of a drug could prove to be a loss investment if the Food and Drug Administration (FDA) recalls it. Recalls cost millions and gives companies a bad if they mismanaged events.

The number of pharmaceutical withdrawals and recalls in the U.S. have generally increased since 1998 (Cheah et al., 2007). Some researchers speculate the recalls are due to the lacking of major restrictions of easily attainable prescription drugs. Despite the fact, other experts suggest the spike in recalls regarding generic or over-the counter pharmaceuticals are thought to be the result of low quality "raw materials, faulty labeling/packaging, and contamination" ("Drugs," 2011). These arguments, about regulations not being strict enough, propose that because of the high demand of pharmaceuticals, companies are rushing to manufacture and get their products out to consumers as quickly as possible. Therefore, corporations are not focusing as much on quality as they should. On the other hand, some authorities counter the FDA operates under stricter medication manufacturing guidelines. The tighter procedures do not allow poor performing drugs to pass into the public domain ("Drug Recall Surge," 2011).

Some pharmaceuticals, such as Baycol/Lipobay and Tysabri, were too hazardous for human use. Baycol/Lipobay, a cholesterol-lowering drug, was connected to fifty-two deaths and Tysabri [a medication for multiple sclerosis] patients developed progressive multifocal leukoencephalopathy, a rare brain disease (Young, 2001). Even though modern biological sciences developed the drugs, Baycol/Lipobay and Tysabri were not effective for public use. While biotech is a more scientific way to develop pharmaceuticals, it is not yet the key to eliminate all dangerous side effects in medicinal drugs. The Baycol/Tysabri event tail spun into a disaster for both consumers and the corporation.

Even though risks are not completely eliminated through use of biotech, several pharmaceutical companies all over the globe advance in technology at a rapid velocity to keep up with consumer demands. Swift manufacturing to meet consumer demand raises the issue as to whether the quality and effects of medications are being downgraded. As a result, some low quality drugs can endanger consumers' lives ("Drug Recall Surge," 2011). Is drug quality not emphasized enough just so they can be readily placed on store shelves? Doctors and patients alike become more concerned in recent years about the effectiveness of medications and the possibility patients will remain sick and need further prescriptions ("Drugs," 2011). Each drug can affect a patient differently, thus pharmaceutical regulations are installed to ensure a consumer's safety.

### **Regulators and Product Regulations**

In order to understand how well a pharmaceutical company managed a crisis, government drug regulations need to be examined. Experts conclude that crises tend to trigger moral beliefs in a way everyday proceedings do not (Snyder et al., 2006). A crisis can severely damage the reputation of a pharmaceutical company, because the health of oneself and others is so

interwoven with a culture's moral beliefs. The success of a corporation is usually parallel with how well it operated under governmental policies. Organizations cannot centralize actions solely on ethics because they must also abide by a country's laws. The three regulatory agencies for the countries in this analysis involve the Medicines and Healthcare products Regulatory Agency of the U.K., Federal Food and Drug Administration of the U.S. and the Pharmaceuticals and Medical Devices Agency of Japan. Below are major areas of concentrations for each regulatory agency based on the information provided on their websites.

The Medicines and Healthcare products Regulatory Agency (MHRA) regulate medications in the U.K. or other European companies. The MHRA works with manufactures and wholesalers on the most appropriate and timely action required to help solve quality or safety concerns when they arise ("How we regulate medicines," 2012). By law, manufactures need to report to the MHRA of any significant defects in both medicines and medical devices. According to European regulations, the criteria on which legislation to control human medicines includes safety, quality and efficacy. The MHRA stresses on taking this responsibility upon itself to maintain the sometimes difficult balance between safety and effectiveness. As a result of trying to regulate and protect consumers, the MHRA implements a system of inspection and testing that continues through the lifetime of the drug ("How we regulate medicines," 2012).

From the information, the MHRA operates under strict pharmaceutical regulations because once the agency approves a drug for public use, the medication still needs to go under rigorous testing throughout its life. The MHRA may impose such thorough regulations to act socially responsible for the protection of consumers. The recent heightened interest in corporate social responsibility in U.K. markets coincides with the MHRA's goals to act quickly if a

product issue arises (Cheah et al., 2007). In other words, regulators scrutinize pharmaceutical companies in order to prevent issues from developing.

Conversely, the Federal Food and Drug Administration (FDA), which regulates pharmaceuticals in the U.S., does not receive all adverse event reports that occur with a product. Many factors influence whether or not an event will be reported, such as the time a product was marketed and the publicity about the event. In addition, reporting adverse event from the point of care is voluntary in the U.S. regarding healthcare professionals and consumers. However, if a drug manufacturer receives an adverse event report, it is required to send the report to the FDA as specified by regulations ("Guidance Compliance Regulatory Information," 2012). According to this information, drug laws in the U.S. seem to be more lax comparing to the U.K. The emphasis appears to be placed on individual actions, such as consumers reporting about side effects rather than a business executing extensive research before the product launches on the market.

The Pharmaceuticals and Medical Devices Agency (PMDA) of Japan, focuses on three key areas of relief services for adverse health effects, product reviews, and post-marketing safety procedures. These areas create the PMDA's "safety triangle" system, which uniquely contributes to public health. Under this system, the PMDA hopes to commit its duties in line with the Japanese philosophy of maintaining a harmonious society ("PMDA," 2011). The PMDA conducts organizational operations under Japanese cultural values of harmony and philosophy. The agency strives to make decisions not only for the benefit of corporations, but for society overall.

Hofstede's cultural dimensions model can be used to help explain action deviations. Geert Hofstede was an industrial organizational psychologist in the Netherlands. He compiled

international data from IBM plants from 72 countries. Careful analysis shaped the six dimensions of values, such as, power, collectivism, uncertainty avoidance, masculinity, long/short term orientation and indulgence (Draguns, 2007). Hofstede's research information remains important and it has stood the test of time. Long-term oriented societies, such as Eastern cultures, stress the importance of the future. These cultures foster pragmatic values oriented towards rewards, including persistence, saving and capacity for adaptation. In contrast, short term-oriented societies value more immediate actions related to the past and the present, including steadiness and reciprocation (Draguns, 2007). Using just one of these dimensions, for instance long-term versus short-term orientation, explains how selected cultures diverge in creating and responding to regulations.

The most prevalent differences of Hofstede's dimensions are seen in the U.S. and Japanese regulations. The U.S. ranks very high in individuality (i.e. low in collectivism). Therefore, this could be why reporting adverse event from the point of care is voluntary in the U.S. regarding healthcare professionals and consumers ("Guidance Compliance Regulatory Information," 2012). Consumers in this sense need to act out and protect themselves individually. In other words, patients enact their own personal responsibility by reporting adverse side effects in pharmaceuticals. Japan on the other hand, illustrates its emphasis on high collectivism by stressing on the importance of the "safety triangle" to protect public health ("PMDA," 2011). Countries, such as Japan, that rank high on collectivism and long-term orientation concentrate on maintaining social harmony by protecting everyone. Hence, the needs of society greatly outweighs the needs of an individual (Hofstede, Hofstede, & Minkov, 2010).

On the other hand, the U.K. generally falls in between the U.S. and Japan in regards to long/short-term orientation and individualism/collectivism. The MHRA regulations concentrate

on maintaining the difficult balance between safety and effectiveness in drugs. The MHRA implements a system of inspection and testing that continues through the lifetime of the drug in order to protect consumers ("Guidance Compliance Regulatory Information," 2012). This statement highlights the importance of accounting for future events by persistently preserving long-term patient relationships (Hofstede, Hofstede, & Minkov, 2010). However, according to MHRA website, laws do not go as far as incorporating philosophy into regulations as does Japan, nor does it give consumers more freedom and responsibility when reporting adverse side effects ("Guidance Compliance Regulatory Information," 2012). As a result, MHRA regulations of the U.K. appear to be somewhere between the U.S. and Japan.

The regulatory websites of the MHRA, FDA and PMDA presents an overview of the agencies, however exact recall classification can be analyzed to give further operational insight of the organizations. Table I. below includes a summary of the pharmaceutical recall classifications in Japan, U.K. and the U.S.

<b>Table I. Japanese, United Kingdom, and the United States, Drug Recall Classifications</b>			
Classifications	Japan (Pharmaceuticals and Medical Devices Agency, PMDA)	U.K (Medicines and Healthcare Products Regulatory Agency, MHRA)	U.S (Food and Drug Administration, FDA)
Class I	Defect causes substantial effect on subjects	The defect presents a life-threatening or serious risk to health	Class I recalls are for dangerous or defective products that predictably could cause serious health problems or death
Class II	Defect raises low possibility of life threatening effect or serious injury	The defect may cause mistreatment or harm to the patient, but it is not life-threatening or serious	Class II recalls are for products which may cause a temporary health problem, or pose only a slight threat of a serious nature
Class III	Defect causes only minor effect on the human body	The defect is unlikely to cause harm to the patient, and the recall is carried out for other reasons, such as non-compliance with the marketing authorization or specification	Class III recalls are for products that are unlikely to cause any adverse health reaction, but violate FDA labeling or manufacturing regulations

(Source: Cheah et al., 2007 & PMDA website)

From these classifications, Japan and the U.K. appear to have a similar structures to the FDA in terms of classes. Their regulatory agencies collaborate with the FDA, even if they do not always reach the same conclusions or consensus (Cheah et al., 2007). In addition, product recall classes in each of these countries are approximately comparable with another, but they are not identical. In general, most appropriately deemed procedures in one culture are accepted in another. For instance, class I recalls, for each of the three countries are the most urgent; removing such medications for safety measures outweighs further promotions to improve a product's integrity. Any disregard of the above classifications would instantaneously explode into a crisis. Large corporations within the pharmaceutical industry experienced numerous crises over the last ten years and these issues continue to grow ("Pharmaceutical Industry," 2011). The information collected from the regulatory agencies' websites foreshadows how the selected companies may respond to a crisis. With this information, the specific firms can now be analyzed.

### **Bayer AG**

Bayer AG is a chemical and pharmaceutical company founded in Barmen, Germany in 1863. Its headquarters is located in Leverkusen, North Rhine-Westphalia, Germany. Bayer AG, also referred to as Bayer Group, is comprised of 315 operating businesses worldwide. The company, which created aspirin in 1897, makes health care products, pharmaceuticals, specialty materials such as plastics and high-performance materials, and agricultural products for crop protection and home garden care (Angelmar, 2007). It operates in the U.S. through Bayer Corporation. Aside from its line of Bayer aspirin, the company's best-known consumer brands include Aleve, Alka-Seltzer, and One-A-Day vitamins. Bayer's top selling medications include a multiple sclerosis treatment, Betaseron and the birth control pill, Yasmin. Although Bayer

produces some very effective and profitable products, the firm dealt a crippling reputational blow from a statin, or anti-cholesterol medicine, Baycol/Lipobay (Angelmar, 2007).

Bayer's Baycol originally launched in the U.K. in April 1997. Through several partnerships, Baycol entered other markets such as the U.S., France, Italy, Spain and Japan. The U.S. was the focus with over 60% of statin sales. In the U.S., Baycol had a label warning about rhabdomyolysis, which is the breakdown of muscle fibers resulting in the release of muscle fiber contents into the bloodstream. This often results in kidney damage (Angelmar, 2007). For a time, Bayer managed some seemingly inconsequential issues related to the drug such as adding gemfibrozil treatment to the Baycol warning label ("Bayer Corp. Restructuring Assists Recovery," 2010).

However, in the latter half of 2000, Bayer's Drug Safety division noticed a significant increase in the number of rhabdomyolysis reports associated with Baycol. Between September 2000 and February 2001, "eighteen cases of Baycol-associated fatal rhabdomyolysis were reported worldwide comparing to eight and two, respectively, for the preceding two six-month periods" (Angelmar, 2007, p. 81). This sudden increase flagged the safety and effectiveness of Baycol. For many, an increase from two cases to eighteen is alarming. What caused this sudden spike? After the studying reports, Bayer employees noted that the only one of the fatal cases involved gemfibrozil a drug, which is prescribed when diets change to assist the reduction of cholesterol and triglycerides in the blood of certain people who are at risk of pancreatic disease (Alperowicz, & Westervelt 2003). As a result, Bayer requested a change in U.S. prescribing information and stopped shipping 0.8mg dosage samples to U.S. doctors (Angelmar, 2007). A lower dosage, of 0.4mg entered the U.S. market, but the 0.8mg dosage soon launched in the U.K. Bayer's response to lower dosage reflects their tentativeness to modify their product. At first,

their response to lower dosage in the U.S. appears to be responsible; however, they should have postponed the release of the 0.8mg dosage in the U.K. or at least investigated Baycol more to prevent issues in the international market (Alperowicz, & Westervelt 2003). Their lack of further research soon deflected any responsible image they acquired from lowering dosages in the U.S. Over time, authorities in the U.K. also noted concern about fatal cases of rhabdomyolysis associated with Baycol and a push for lower dosages followed suit. The U.S. maintained the highest prescribed amount of 0.4mg while Japan took a stricter approach and only approved 0.15mg or lower (Angelmar, 2007).

On June 15 of 2000, Bayer publically revealed the results of a Bayer commissioned study on the relationship between Baycol and myopathy [muscle weakness] ("Bayer Corp. Restructuring Assists Recovery," 2010). Problems regarding myopathy cases eventually could interrelate with occurrences of rhabdomyolysis. Even though Bayer readily revealed the outcomes of the research, they had the opportunity to collect the same information earlier in the year. A comparable study was already proposed by Bayer Drug Safety/Epidemiology in March 2000, however the research was not carried out because an internal stakeholder at Bayer U.S. showed no enthusiasm about conducting such an analysis (Angelmar, 2007). Bayer believed the dangers of taking Baycol were not a significant threat to patients and the benefits outweighed the overall risks. However, in reality, confidence in Baycol's safety deteriorated and concern about patients' wellbeing spread throughout the world.

On June 26 of 2000, U.K. officials also restricted the maximum dosage of Baycol to 0.4mg. About the same time, Bayer voluntarily suspended the marketing and distribution of the 0.8mg dosage strength in the U.K. The deferral only happened two months after Baycol's launch ("Bayer Corp. Restructuring Assists Recovery," 2010). This deferment shows how dangerous

Baycol was in reality, even though those within Bayer believe potential issues were not statistically great enough to harm many consumers. Many people disapproved of Bayer's hesitation to inform regulators about possible problems that could arise from taking Baycol (Angelmar, 2007). Although Bayer willingly restricted the circulation of the 0.8mg dosage, regulators, such as the FDA, expressed disapproval towards Bayer's lack of a quick response.

During a meeting with Bayer, the FDA presented an analysis of spontaneous reports highlighting that, "The crude reporting rates for fatal rhabdomyolysis with Baycol 0.8mg alone or in combination with gemfibrozil were in market excess over reporting rates for this event in association with certain other marketed statins" (Angelmar, 2007, p. 83). This accusation shows the FDA absolutely did not condone Bayer's lack of action. Bayer's inadequacy to respond gave the perception they were irresponsible and failed to acknowledge Baycol's shortcomings. Rather than recognize failures, Bayer primarily dismissed them.

In reaction to the external pressures and the growing negative reception of Baycol, Bayer attempted to conduct clinical investigations to repair Baycol's reputation (Angelmar, 2007). Rather than focusing on restoring Baycol efficacy, Bayer should have started examining why dangerous side effects affected numerous consumers and then do something about it. Gathering accurate data from many credible sources could have helped Bayer pinpoint Baycol's issues at an early stage. Because the data suggested patients were exposed to undue health risks, Bayer could begin contemplating Baycol's withdrawal from markets.

In August 2001, Bayer finally concluded the threat of rhabdomyolysis was too great to keep Baycol in the market. They withdrew Baycol from all areas except Japan. The drug maker decided to keep selling Baycol in Japan because gemfibrozil was not available there so the threat

of fatal risks seemed minimal. However, Bayer eventually pulled Baycol from the market in late August after the approval of gemfibrozil use in Japan (Angelmar, 2007).

The backlash of Baycol's withdrawal from the market soon scathed all who were involved. Many condemned Bayer's decision to first notify investors about the possible issues with Baycol before regulatory agencies and healthcare professionals. By prioritizing investors before anyone else, people perceived Bayer as more concerned about short-term profits rather than health risks that may harm consumers ("Bayer Corp. Restructuring Assists Recovery," 2010). The self-serving attitudes of those within Bayer placed a heavy burden on consumers and exposed them to the unnecessary and avoidable risks of rhabdomyolysis. The president of the French Medical Association stated, "Bayer decided on the timing of the withdrawal based on stock market considerations, without providing prior information to the tens of thousands of physicians and pharmacists concerned" (Angelmar, 2007, p. 84). One must keep in mind however that in the U.K., most institutional investors concentrate on long-term perspectives. Companies strive to remain on good terms with their investors (Cheah et al., 2007).

Relationships between corporations and investors need to be maintained over the years. Taking this into consideration, Bayer may have been attempting to preserve their relations with investors by giving them advanced warnings on the issues that arose. However, Bayer failed to foresee the overall damage Baycol caused them by not considering everyone affected by the withdrawal. Bayer focused too narrowly on people directly involved with the company and did not consider all stakeholders. These actions made them appear egotistical and unconcerned about customers.

Additionally, the German health ministry accused Bayer of not informing the ministry soon enough of Baycol/Lipobay's side effects (Young, 2001). In the U.K., news of voluntary product recalls is the norm because of emphasis on corporate social responsibility. People

expect businesses in the U.K. to take accountability to ensure the maintainability of long-term relationships with investors and customers. Shareholders in the U.K. do not differentiate between the levels of severity of product recalls or withdrawals when expressing their dissatisfaction of product recalls or withdrawals (Cheah et al., 2007). Consequently, it is surprising Bayer did not respond by conducting more research into Baycol side effects and inform regulators instantaneously in the U.K., if European cultural norms rewarded firms who quickly act in the public's interest while greatly condemning negligent companies.

Bayer also did not appear to have effective crisis management policies that may help advert such issues. For instance, Bayer did have some data suggesting that Baycol usage [especially coupled with gemfibrozil] might have been associated with patient fatalities, but they did not conduct further tests due to a lack of enthusiasm ("Bayer Corp. Restructuring Assists Recovery," 2010). Rigorous testing should have been conducted, rather than assuming total confidence in the drug's effectiveness and/or that benefits outweighed the risks. This failure to take action resulted to Bayer's downfall. After acquiring more information on the dangers of taking Baycol, it is reasonably questionable as to why Bayer informed stockholders first before patients. The prioritization of investors downgraded Bayer's corporate image to profits first, patients later. Even if profit was not their first intention, their lack of action to inform consumers makes it appear so.

The press described Bayer's promotional practices as questionable. Patients became overtly apprehensive about the media reports. On average, U.K. industry participants, as well as other European markets, emphasize on corporate social responsibility than those in the U.S., and Bayer's reluctance to share information readily, shook consumers' faith in the pharmaceutical industry. For example, in an opinion poll in Italy, 73% of respondents claimed that, "drug

companies deserved criticism and disapproval because they disregard patient safety for profit” (Angelmar, 2007, p. 84). Although some unfavorably perceived companies inevitably fail because of their own deceitful practices or ignorance, this still sheds a negative light on other pharmaceutical companies who are trying to be ethically responsible. Nevertheless, in the end, businesses who take responsibility and swift action are more favorably received in the future than those firms who neglect such practices. Baycol’s forestalling of an immediate response and ‘irresponsible information provision’ soon hurt them not only reputation wise, but also financially (Angelmar, 2007).

The impact of Bayer’s withdrawal of Baycol caused a sharp decline in profits. Within just a week, Bayer’s share price dropped from €45 to only €33. The sharp decline of Bayer’s shock was the result of either the direct impact on Bayer’s profits from withdrawing Baycol or the cost of litigation, an estimated €10bn (Angelmar, 2007). Bayer became increasingly plagued by lawsuits associated with Baycol. Bayer’s CEO at the time, Werner Wenning, stated that Bayer faced 8,400 lawsuits. The company claimed to have already paid approximately \$150 million to settle 500 cases out of court (Alperowicz, & Westervelt, 2003). There is no doubt Bayer felt the negative repercussions of Baycol. The numerous lawsuits they were bombarded by caused many shareholders to lose confidence in Bayer, thus the slipping share prices. Product recalls and withdrawals placed more systematic risk on the company, which in turn caused stock valuation to decrease.

The highly publicized Baycol/Lipobay withdrawal produced a shadow of uncertainty on the rest of the pharmaceutical industry. The development of drugs and medical research are under scrutiny in recent years. Many people question whether the efforts to create medicines really benefit consumers, or perhaps such companies seek to be the largest profiteer and

customers are the ones who suffer the greatest if complications arise (Shah, 2010). Incidents, such as Baycol, further created worried customers and the confidence in pharmaceutical products.

Although Bayer was pessimistically looked upon due to the Baycol incident, they did cooperate with investigations and ultimately changed their tactics. Their openness to share information for investigations appears to be Bayer's last effort to save its status. Because of the emphasis on corporate social responsibility, Bayer still attempted to preserve their reputation by cooperating for the 'interest of patient health.' With all the unfavorable ramifications from Baycol's withdrawal, Bayer began to reassess its pharmaceutical strategies (Young, 2001). Their change of strategic thinking and adaption to external responses reflects Bayer's acknowledgement in their failures to maintain consumer confidence. Bayer recognized errors, such as not conducting more follow-up research and not informing regulators about risks sooner, could greatly harm the long-term survivability of the company. In the U.K., as well as the rest of Europe, more people focus on long run perspectives (Cheah et al., 2007). Failure to recognize this outlook and conform can eventually destroy the competitiveness of a corporation.

### **Takeda Pharmaceutical Company Limited**

The Japanese pharmaceutical company, Takeda, started back in 1781, when companies began selling traditional Japanese and Chinese remedies. Today, Takeda is one of Asia's largest pharmaceutical companies. The company produces branded prescription drugs they sell all over the world. Top-selling products include blood pressure treatment Blopress, diabetes drug Actos, and ulcer medication Prevacid. Takeda is also a leading maker of over-the-counter medications such as cold remedies and vitamins within its home country. In addition, the

company markets many products in the U.S. through its subsidiary, Takeda Pharmaceuticals North America and Millennium Pharmaceuticals Inc., (Mackenzie, 2012).

Historically, most of Takeda's sales came from Japan. However, in recent years, international sales grown to account for about half the company's total revenues, with North America as the firm's largest international market. Takeda's growth strategy includes advancing its market position in North America by cultivating sales of existing products, Actos and Prevacid, as well as promoting recently introduced products Uloric, a drug to help manage uric acid levels in patients with gout, and heartburn treatment Dexilant (Mackenzie, 2012). The North American market for Takeda continues to expand along with their innovative new products.

Millennium Pharmaceuticals Inc., which is owned by Takeda, in collaboration with J&J developed the drug Velcade. Drug usage includes treating people with multiple myeloma, a type bone marrow cancer and people with mantle cell lymphoma, a fast-growing cancer that begins in the cells of the immune system who already tried other medications for these diagnoses. Velcade works by killing cancer cells ("Bortezomib - PubMed Health," 2010). The FDA permitted the drug in 2003 as a second-line injection treatment for multiple myeloma. In 2008, the drug was approved as a front-line multiple myeloma treatment and as a second-line treatment for mantle cell lymphoma. However, the FDA cautioned patients with liver damage from taking the drug because Velcade can increase the risk of liver toxicity and liver damage. Patients who deal with liver problems were recommended to start with a low dose ("Velcade Recall Issued Due to Particle Contamination - AboutLawsuits.com," 2010). Around November of 2010, as a precautionary measure, Takeda voluntarily recalled a limited number of lots of Velcade (due to the possibility small white polyester particles found in vials).

The U.K. Medicines and Healthcare Products Regulatory Agency first announced the Velcade recall after polyester-like particles were found in vials from two different batches. Since then, the recall expanded to Japan and the U.S. Approximately 400,000 vials of the cancer drug were recalled worldwide after some contained the particles. Specifically, the recall affected about 195,000 vials distributed in the U.K., 200,000 vials in the U.S. and 22,300 vials sold in Japan ("Velcade Recall Issued Due to Particle Contamination - AboutLawsuits.com," 2010). The particles themselves may not have been particularly dangerous, but Takeda did not want to take the chance.

Takeda officials explained the problem was caused by a part of the manufacturing process contracted out to a third-party manufacturer. The companies received five complaints of the particles seen floating in vials in Europe and Japan after the powder form of the drug was reconstituted. However, no reports of particle contamination occurred in the U.S. ("Velcade Recall Issued Due to Particle Contamination - AboutLawsuits.com," 2010). The voluntary recall made by Takeda and J&J helped prevent patients from potential undesirable side effects because of the particles. Possible contamination results in placing consumers' wellbeing in jeopardy, thus making them sicker rather than healthier. Promptly recalling the drug eventually limited the scope of damage done to Takeda while also stopping more major issues from arising. Therefore, notifying consumers about possible contamination helped limit the severity of the impending crisis. The lack of numerous recall data or news articles suggests either the crisis was extinguished at the beginning, or perhaps cultural values played a part in the distribution of information.

For instance, in Japan, where Takeda's headquarters are located, the press restricts negative reports on companies to prevent shaming. Richard Bohr, a Director of Asian Studies at

the College of Saint Benedict/Saint John's University in Minnesota and the founding board chair of NEO Business College for Women in Tokyo, elaborated that in Japan, the media reports only on information companies disclose. The press does not want to pressure and single out corporations, instead they are discrete to promote 'saving face.' No respect is the first nail in the coffin to a falling out in relationships (R. Bohr, personal communication, February 2, 2012). Therefore, as long as no one points out errors to the people responsible, no 'face' is lost. It is also considered exceedingly impolite for anyone to bring attention to such mistakes in the Japanese culture (De, 1994).

Gathering specified information about the Velcade recall proved to be a challenge. There was not a lot of information other than statements that Takeda and J&J simply recalled the pharmaceutical. Although Takeda and J&J collaborated in the development of Velcade, the Japanese cultural values of Takeda influences how readily available information is to the public. In the Japanese society, leaders, or people who obtain significant power positions, are expected to work for the good of citizens. Collectivism in Eastern societies creates a hieratical nature of government and concentrates on society as whole rather than specific individuals (Nisbett, 2003). Therefore, collectivism societies try to prevent widespread panic by containing certain information. Nevertheless, what leaders perceive as suitable may not always be in the best interest of consumers. For instance, the Japanese government sets the pricing for doctor services. However, these regulations poorly compensate Japanese doctors for time spent with patients. The institutional norm for doctors consequently evolved into severely minimized patient time. As a result, less time interacting with patients reduces the amount of information transferred to their patients. Patients have little knowledge or understanding of product shifts, such as when doctors discontinue prescribing older products, therefore consumers have no real opportunity to

question medical professionals in the hierarchical medical culture in Japan (Thomas, 2004). A communication breakdown such as this hampers the development of good relations between corporations and consumers because misunderstandings can easily occur and escalate into a crisis. Lack of information on the Velcade recall perhaps is the result of companies directly controlling the amount of information the public receives. Many Japanese businesses still stay disinclined to release data.

For instance, the most recent issue of the Fukushima nuclear crisis in 2011 implies Japanese corporations remain reluctant to share information during major crises regardless if reports may lead to life threatening consequences to the public. The nuclear disaster is comparable to a pharmaceutical related crisis in a sense because both are sensitive and controversial issues. In other words, mistakes and results can be life threatening. One can conclude from the previous information that Japanese companies do not want people to receive news on such adversities (Burrett & Simmons, 2011). Regardless, people accused Tokyo Electric Power Company, or TEPCO, of making “opaque decision-making” and the information, which was released insufficiently, addressed citizens’ safety concerns. The quality and quantity of information coming out of Japan created gaping holes in experts’ understanding of the disaster (Vartabedian, 2011). Throughout the Fukushima disaster, a number of experts criticized TEPCO’s slow response to requests for information (Burrett & Simmons, 2011). According to Najmedin Meshkati, an USC engineering professor who advised federal agencies on nuclear safety issues, “Information sharing has not been in the culture of TEPCO or the Japanese government. This issue is larger than one utility and one country. It is an international crisis” (Vartabedian, 2011, p. 1). Because Japanese society retains a hierarchy set of characteristics,

they believe sharing sensitive information to inexperienced staff creates more public panic and reputation-damaging rumors.

In addition, Japanese media also does not want to promote the shaming of a company. In individualistic countries like the U.S., people feel guilt and in collectivistic societies, citizens feel shame (Hofstede, Hofstede, & Minkov, 2010). Reporting negative news creates the issue of 'losing face' and hurts not only the reputation of a company, but also employees. Although Japan regulates communication channels, social media and the internet has made it nearly impossible for businesses to completely contain such information (Vartabedian, 2011). In this perspective, as long as the amount of outflow of data and reports is controllable by a firm, they will do everything they can to keep calamity related information from the public.

Contrastingly, the lack of information is possibly because Japanese companies have high standards in maintaining product quality and their collaborator J&J already developed enough experience about crises through the Tylenol incident. Insufficient news reports could be the result of Takeda and J&J handling the recall swiftly and effectively. During the 1970s and 1980s, Japanese products were not of the highest quality. To construct a better image, the Edwards Demings award was created to benchmark and honor high quality products. The initial purpose of this award was to encourage the advancement of quality control activities in Japan (*The W. Edwards Deming Institute: The W. Edwards Deming Institute*, 2012). In recent years, the Demings award attracts non-Japanese companies. Rewarding firms' efforts to improve quality encourages others to benchmark their products to receive such a prestigious honor.

Additionally, J&J, Takeda's associate, already experienced how to properly respond in a crisis ("Velcade Recall Issued Due to Particle Contamination - AboutLawsuits.com," 2010). By quickly recalling Velcade, they did not express any strong intent to push for immediate profits or

the costs of withdrawing the drug; instead, they prepared themselves for short-term sacrifices. Furthermore, Takeda and J&J readily assumed the worst by assessing the costs of possible consumer harm and litigation.

Both Takeda and J&J did not believe financial ramifications of the Velcade recall were significant. Takeda's stock decreased 0.4 percent to 3,955 yen at the 3:00 p.m. close in Tokyo trading (Matsuyama, 2010). The insignificant reduction in stock prices conveys consumer confidence in the company. If shareholders were unsure or disapproved of Takeda's actions, they often sell their shares, which increases supply and thus, cause prices to drop. However, because stock prices did not considerably fall, investors must have decided Takeda's practices did not harm its overall profitability in the near future.

### **Pfizer Inc.**

Pfizer Inc. is a U.S. based corporation in New York City and the world's largest research-based pharmaceutical firm. Pfizer is most recognized for prescription products such as cholesterol-lowering Lipitor, pain management drugs Celebrex and Lyrica, pneumonia vaccine Prevnar, arthritis drug Enbrel and high blood pressure therapy Norvasc. Consumer health products include leading products as Advil, Centrum, and Robitussin. Currently, the U.S. is Pfizer's largest market, however, the company retains a strong global presence. More than half of Pfizer's sales come from international countries (Law, 2011).

Bextra is a COX-2 inhibitor or a pain medication, belonging to the same class of pharmaceuticals as Vioxx, a drug Merck Co. previously removed from pharmacy shelves after safety hazards, such an increase in strokes and heart attacks emerged. Since the late 1990s, prescription drugs, such as Bextra, are often used to help alleviate chronic pain conditions like arthritis and menstrual cramps. The FDA approved Bextra for public use in November 2001.

After the Vioxx recall, the safety of similar drugs came into question, and experts began to predict Bextra's recall ("Bextra Recall - Defective Drug Information," 2012).

In November 2004, Pfizer revealed the results of a Bextra cardiovascular study. The study was conducted to calculate the effects of Bextra treatment in pain management for patients recovering from coronary artery bypass grafting (McCoy, 2004). An analysis of several studies involving 8,000 heart-bypass recipients and arthritis patients showed Bextra doubled heart attacks and stroke risks in patients just like its predecessor, Vioxx. In these studies, patients were given either Bextra or a placebo. The study revealed trial participants treated with Bextra were two times more likely to suffer a heart attack, blood clot, stroke, or other adverse cardiovascular/thromboembolic event than participants in the control group. Bextra's risk was determined to be marginally higher than Vioxx ("Bextra Lawsuit: Bextra Side Effects, Bextra Recall, Drug Information," 2012). In the studies, the highest risk was seen in patients who had bypass operations, signifying that heart patients are particularly vulnerable to the threats.

Pfizer's compliance to share such information demonstrates the company promoted transparent communication with the public; however, Pfizer also contradicted themselves by not listening to external input. Transparent communication, such as letting the public know about recent findings is a positive action to avert future crises. Experts, and consumers determine for themselves whether Bextra was reasonably safe to take or not from the studies conducted. Nevertheless, Pfizer refuted the urgings of others to recall Bextra because of the increase in heart attacks and strokes. They insisted that Bextra was still not overtly dangerous in certain areas of use and the clinical trial did not adequately warrant a recall ("Bextra Recall - Defective Drug Information," 2012). In addition, a Pfizer spokesperson, Joseph Feczko, stated the report created "unsubstantiated conclusions" about Bextra's safety and was also "based on information that has

not been published in a medical journal or subject to independent scientific review” (McCoy, 2004). Pfizer’s dismissal of the study along with their insistence that no considerable risks existed when taking Bextra makes them appear recklessly overconfident that the issues would be overlooked. Although Pfizer provided adequate information to the public, they failed to uphold the necessary end for clear communication. They ignored external responses.

Compared to other countries like China or Japan, the U.S. government does not regulate the distribution of information as strictly. The U.S. necessitates the importance of two-way communication, which centers on receiving and responding to data. Western civilizations, such as the U.S., accentuate an individual’s right to receive and distribute news; however, the mass amount of media one collects may not be accurate or credible (Bell, 2000).

As a result, the researcher must take up the responsibility to analyze the information. On the other hand, in Eastern countries, governments tightly regulate news to ensure people hear the most precise, or approved information. Freedom of press is not necessarily an area of concern as this ideal ties in with Western individuality rather Eastern interdependence (Bell, 2000). Compared to Eastern countries, U.S. citizens believe more so that they have the right obtain data for their own personal needs whenever they see fit.

If a company conceals vital information from the public and this data is later exposed, the firm at fault will be associated with corruption and deceit. In the U.S., people often perceive companies who hid information as unwilling to share data that could amplify their shortcomings. As a result, this artificially skews the image of the company positively for the time being, however if other information proving otherwise is brought to attention, the efforts to hide negative data will backfire. Companies will either lose competitive advantage or sustain damages beyond repair (Marcus, 2011). This may be the reason why Pfizer readily provided the

results of their cardiovascular study to the public. In doing so, consumers can decide for themselves whether they should continue taking Bextra, and Pfizer could not be accused of concealing important research. However, a crucial component of two-way communication required Pfizer to listen to feedback from the results. If many requested Pfizer to recall Bextra, the company should have known the drug would soon be pulled from store shelves. A large outcry would warrant the recall of the drug regardless of Pfizer's assurance the drug was still safe. However, the corporation did not listen.

After evaluating safety information on a range of ant-inflammatory drugs, the FDA on April 7, 2005 requested Pfizer to remove Bextra from the market. The Bextra recall was ordered by the FDA after regulators concluded the potentially fatal risks associated with Bextra far outweigh projected benefits ("Bextra Recall - Defective Drug Information," 2012). The FDA singled out Bextra because it was determined to give no added benefits as a painkiller or in other words, it failed to demonstrate an advantage over other NSAID drugs, which are a family of chemicals produced by the cells of the body. These medications treat inflammation, pain, fever and support the blood clotting function of platelets ("Nonsteroidal Anti-inflammatory Drugs (NSAIDs) - drug class, medical uses, medication side effects, and drug interactions by MedicineNet.com," 2012).

Bextra was also associated with a deadly skin condition, Stevens Johnson syndrome ("Bextra Recall - Defective Drug Information," 2012). Prior to the Bextra recall, Stevens Johnson syndrome claimed the lives of some Bextra users. As a result, Pfizer ceased selling the drug both in the U.S. and the U.K. Bextra safety concerns came to the forefront of social awareness after the Vioxx recall in September 2004. Some would argue a Bextra recall has been in the making since the FDA first approved this drug in November 2001 ("Bextra Recall -

Defective Drug Information," 2012). Negligence, particularly in the healthcare sector, poses a great threat to patients who rely on the effectiveness and safety of a drug (Cheah et al., 2007). If Pfizer knowingly manufactured and distributed Bextra after gathering data on its potentially fatal risks, this brings up the issue of unethical behavior and corporate irresponsibility. Disregard of consumer wellbeing created the paradigm that Pfizer had ulterior motives rather than looking out for the welfare of customers.

Subsequent to the recall, there were numerous lawsuits, with many claiming Pfizer deliberately manufactured "this dangerous and defective drug" for years, while negligently putting patients' health and lives at risk without proper warning. Many law firms in the U.S. encouraged consumers to take action claiming that, "people who have been injured by Bextra side effects prior to the Bextra recall have the legal right to seek compensation for their losses through a Bextra lawsuit" (Area, 2010, p. 1). When Pfizer did not push for an immediate Bextra recall, many upset consumers felt as though the company's lack of concentration on customer relationships resulted in them not caring about additional health issues that can arise from taking the pharmaceutical. Pfizer's actions infringed on customers' belief that they should be informed about health risks as soon as they are found. To implement their individual and legal rights, many patients decided to take action and filed for lawsuits against Pfizer (Area, 2010).

Several of these lawsuits stated that Pfizer concentrated on shareholder wealth maximization by fraudulently promoting Bextra through aggressive marketing. According to these Bextra lawsuits, the ethical line kept moving in the wrong direction during the promotion of the drug (Mathews, & Hensley, 2005). In one lawsuit case, Pfizer was accused of having \$50 bounty paid to representatives when they got doctors to add Bextra to the standard care for patients. The care protocols directed patients to take Bextra in high dosages before operations

and afterwards to control pain (Mathews, & Hensley, 2005). Whether the claim is true or not, more Pfizer faced more even more pressure. They were accused of partaking in deceitful practices by not having Bextra come with proper warning labels.

The negative publicity of the recall and the growing number of lawsuits contributed to Pfizer's fall in share prices. Their shares fell to fifty-two cents, or 1.9%, to a close of \$27.47 on the New York Stock Exchange (Bloomberg, 2010). Bextra received a lot of negative press because of the serious circumstances. This eventually tainted consumers' trust in pharmaceutical companies and those who regulate the industry.

### **Summary**

Bayer's product Baycol, initially started as a very promising anti-cholesterol medicine, however safety issues that arose later on could not be ignored. Three years after Baycol's successful launch in the marketplace, a spike in rhabdomyolysis reports caused many to question the drug's safety. As a result, Bayer decided to lower dosages (Angelmar, 2007). In June of 2000, Bayer publicized a commissioned study about Baycol's link with myopathy. A similar study could have been conducted a few years earlier, but was not pursued because of unhinged confidence in the effectiveness of Baycol and little interest by internal stakeholders to start a study. Nevertheless, the assurance of Baycol's safety quickly eroded (Angelmar, 2007).

As a result, the FDA stepped in and expressed their disapproval on Bayer's reluctance to respond to a growing number of patient health problems. The FDA reported that they thought Bayer's lack of informing regulators as a direct threat to consumer safety (Angelmar, 2007). With this perception, Bayer insufficiently provided regulators and consumers enough information about the fatal rhabdomyolysis incidents.

The repercussions soon escalated and many condemned Bayer's futile responses to save their company's reputation. When Bayer recognized that they need to remove Baycol from the market, the company informed investors first rather than regulators. This move greatly stained the corporation's image because they presented themselves as cold and uncaring to customers directly harmed from the drug's side effects (Cheah et al., 2007). Patients became increasingly worried about cynical media reports on Bayer. Bad public reception led to a blow restricted to not only company image, but also financial reports.

Declining stock prices and a rising number of lawsuits soon forced Bayer to rethink their strategy. Bayer's headquarters location in Germany and extensive operations in the U.K., amplifies the importance of corporate responsibility operations (Young, 2001). The macroenvironmental influences, such as government regulations and consumer preference trends, determines the success of a company (Marcus, 2011). Eventual changes in pharmaceutical strategies propose that Bayer acknowledged their communication and indecisive movement failures and made new pharmaceutical strategies

Although Bayer received a lot of negative press because of Baycol, Takeda's quick action during their crisis helped them avoid going down the same path. Takeda instantaneously recalled Velcade after possible particle contamination occurred in a couple batches of vials. They pulled about 400,000 vials of the drug worldwide even though some countries such as the U.S. did not report any particle contamination. Takeda officials claimed that a third-party manufacturer was to blame ("Velcade Recall Issue Due to Particle Contamination – AboutLawsuits.com," 2010).

After the initial reporting, only sparse amounts of information were available. The lack of reports suggests Takeda stopped issues from escalating because of their concentration on

promoting quality benchmarks and protecting consumers. However, little data illustrates the regulation of press in Japanese society, or the company not willing to share information, whether for self-profiting or for reducing public panic (Vartabedian, 2011). Regardless, of real intentions, Takeda did not experience a terrible financial impact. Their stocks did not decrease significantly, nor did the public outcry like in the Baycol event.

Pfizer on the other hand, experienced the same magnitude of disapproval as Bayer, if not more so. Regulators and consumers alike accused Pfizer of promoting Bextra even though the company had information that the drug caused adverse side effects or in some instances, death. Despite the urgings of others to recall Bextra because of negative reports, Pfizer disputed recommendations. Pfizer did not listen to feedback from the reports. As a result, the FDA needed to step in and request Pfizer to remove Bextra from the market (“Bextra Recall – Defective Drug Information,” 2012).

Consumers, who felt they needed to take action, exercised their individual rights. Numerous lawsuits plagued Pfizer claiming they carelessly placed patients’ health at risk. Many lawsuits also asserted Pfizer as fraudulently promoting Bextra through aggressive marketing rather than doing more research on potential side effects (“Bextra Recall – Defective Drug Information,” 2012). The overwhelming amount of pessimistic publicity took a toll on consumers’ and investors’ confidence in Pfizer. The situation looked bleak, and as a result, Pfizer’s stock price considerably lowered along with the public’s ethical expectations in the company.

Koster and Politis-Norton’s guidelines are a good way to determine if the businesses managed crises to the best of their abilities. Table II. below illustrates in summary how well each evaluated business managed a crisis according to the crisis management model guidelines.

<b>Table II. Ratings Based on Crisis Management Guidelines</b>		
<b>Company</b>	<b>Guidelines</b>	<b>Rating (+ positive, - negative)</b>
Bayer	Define the real problem as soon as possible and solve them quickly	-
	Create focus	-
	Resist combative instinct	+
	Assume the worst	-
	Consider short-term sacrifice	-
	Necessitate clear communication and choose an articulate spokesperson	-
Takeda	Define the real problem as soon as possible and solve them quickly	+
	Create focus	+
	Resist combative instinct	+
	Assume the worst	+
	Consider short-term sacrifice	+
	Necessitate clear communication and choose an articulate spokesperson	+/-
Pfizer	Define the real problem as soon as possible and solve them quickly	-
	Create focus	-
	Resist combative instinct	-
	Assume the worst	-
	Consider short-term sacrifice	-
	Necessitate clear communication and choose an articulate spokesperson	+/-

(Based on Koster and Politis-Norton’s crisis management guidelines)

In accordance to the crisis management criteria from the model, Takeda operated the best and this is supported with the fact that after the Velcade incident, the firm’s stock was not significantly impacted. This could illustrate that investors did not lose faith in Takeda’s decisions. The only possible negative was perhaps Takeda restricted information about the incident due to the strict regulations in Japan (De, 1994).

The other two businesses, Bayer and Pfizer did not do well in most of the areas, thus showing there is a lot of room for improvement. In other words, both firms did not follow the crisis management model, resulting in the devaluation of their stock prices and the numerous

reports of expert and public disapproval. However, Pfizer had one +/- rating in common with Takeda, which regards transparent communication.

Takeda for instance received a positive rating because perhaps the company did report everything that was going on to the public as Pfizer also claimed by publishing a study done on Bextra. Where the companies diverged regards their negative ratings. Takeda may have withheld information because of the Japanese cultural influence and the country's strict regulations on information (De, 1994). Pfizer on the other hand, perhaps knowingly concealed negative data on Bextra from the public on their own accord ("Bextra Recall - Defective Drug Information," 2012).

### **Recommendations**

In some incidents such as the Enron scandal, employees can clearly discern the company committed both illegal and unethical acts, but the answers to all issues are not necessarily black and white. Crises habitually forces change, but do not necessarily make all organizations undergo a rigorous self-examination. Strong resistance is more likely to occur. As a result, some experts argue crises bring out either the best or worst qualities in business (Marcus, 2011). Companies are either keen on fixing their shortcomings or resistant to admit failures. In the marketplace, managers are rewarded for quick responses and heavily penalized for any delay. Events move swiftly and quickly spin out of control. If a firm is unable to stay ahead of a potential disaster as it unfolds, the business often becomes restricted to a reactive mode parameter. As a result, oftentimes corporations become victims of circumstances (Watkins & Blazerman, 2003).

In accord, the best actions these and other pharmaceutical companies need to take require both preventative and corrective actions. It is easier to avoid a crisis than handling one.

Therefore, improving an organization's processes to limit causes of undesirable outcomes or non-conformities are top priorities. Preventive actions are employed in response to the identification of potential sources of non-conformity ("Quality Systems Approach to Pharmaceutical CGMP Regulations," 2012).

When managing a crisis, companies should not blindly dispute feedback. After investing so much time and money into the development of a drug, negative news about a medication often signifies the potential of a great loss. However, in order to stop further issues from developing, firms must research into it. Not all information may be credible, but in order to successfully discern what feedback is valid and noteworthy, an organization needs to follow up and investigate (Koster, & Politis-Norton, 2004). Pfizer spent so much time trying to dispute feedback and build up the efficacy of Bextra, that they could have used their energy to find out whether the input justified a recall. If so, they could have removed the drug from the market early on to prevent consumers from further harm, and highlight that their company partakes in responsible actions. If Pfizer critically contemplated feedback, they could have stopped the escalation of the issue.

Takeda avoided being in the same position as Pfizer altogether. For instance, they quickly recalled contaminated vials even though there was not an eruption of adverse or fatal cases. Takeda did not want to take a chance so they immediately removed the drug from the market and stopped the possibility of more problems arising ("Bortezomib – PubMed Health," 2010).

However, not all corporations can completely avoid every issue, hence the importance of companies needing to instantly inform both regulators and consumers about potential issues (Koster, & Politis-Norton, 2004). If corporations postpone communicating with the public about

issues, people usually condemn them in the future for not prioritizing customers' well fair.

Pharmaceutical businesses face two options in a crisis, either to publicize negative information, which may be incorrect because more tests need to be conducted, or delay the release and cause patients to possibly suffer irreversible harm. An early release of not thoroughly researched information hurts sales and may prevent some patients who could benefit from the product. Additionally, if it was a false alarm, the company's reputation would be harmed and nothing gained. In Bayer's case, they postponed the release of data too long and many patients suffered either fatal or adverse side effects.

Bayer is an example of how companies become surmounted under accusations that they put short-term profits ahead of patients' wellbeing. However, Bayer appeared to learn from their mistakes when they decided their strategies needed to be change ("Bayer Corp. Restructuring Assists Recovery," 2010). Businesses tenaciously refusing to acknowledge their mistakes and make no internal reforms are surely doomed to fail in the end.

After a crisis arises, corporations must quickly respond with corrective actions. Corrective actions are implemented as a response to consumer complaints, undesired levels of internal nonconformity, nonconformities identified during an internal audit or unstable trends in product and process monitoring ("Quality Systems Approach to Pharmaceutical CGMP Regulations," 2012). Quick responses need to be implemented to acknowledge issues and rectify damages. If corrective actions are instantly executed, the root of the crisis will be abruptly cut off before it can grow.

### **Conclusion**

Organizations operating in the pharmaceutical industry are becoming more frequent in the globalized economy. While corporations expand to different consumer bases, they need to be

more aware of not only their customers, but also their internal work environment to remain competitive (Marcus, 2011). As companies spread out into other world markets, their decisions are influenced by cultural identities spawned in the origin of their headquarters. Cultural values have deep roots within countries. Changes occur as the countries evolve in modern times, but their original beliefs and principles derived from previous generations remain just under the surface. Thus, companies need to be aware of both internal organizational, customer and investors' values.

Investors retain the influence to exercise a considerable role in the management of corporations. In previous years, individuals held the most stocks. However, nowadays, institutional investors, such as mutual funds and insurance companies, own the majority of stocks. These corporate investors speak with managers of a firm and make suggestions about how the business should be operated (Marcus, 2011). Public reception of Bayer, Takeda and Pfizer's management decisions of their crises were reflected by stock performance after the immediate incident. Therefore, it is vitally important companies pay close attention to the culture where they conduct operations, because not all investors uphold the same ideals. Although stockholders maintain a strong foothold in company operations, customers are the ones who buy the products.

Many businesses know consumers retain a vital role in the success of a company. Customers are the ones who ultimately demand and purchase a product or service. Without consumer need, products eventually become obsolete. If firms do not adapt, they lose any sustainable competitive advantage and flicker away into oblivion. Business managers must handle the needs of customers and their shareholders' expectations. In the marketplace, corporations are rewarded for taking quick action rather than waiting for the preeminent

compromise to emerge (Marcus, 2011). Mismanaging a crisis usually speeds up the process to a company's demise. However, corporate entities executing the right actions eventually outmaneuver their competition.

Responsible corporations set themselves apart from others competing in the same industry. Negative events gives a business publicity. Even though crises do place companies under public scrutiny, this is their chance to show a large audience a whether they care about patients or exercise self-serving attitudes.

A company must balance the interests of stakeholders. Concentration can be to work for the greater good for the greatest number, a utilitarianism belief, or focusing on social harmony and consensus. Japanese firms have a more balanced view of their responsibilities and the groups they serve than European, U.K. or U.S. firms do. With this mindset, European and U.S. companies affirm shareholders as their primary obligation, while Japanese businesses mention employees and society before shareholders (Marcus, 2011). Shareholder influence plays a vital role in both Europe and U.S. industries; however, firms failing to recognize the importance of customer support must survive the consequences.

Preventative and corrective actions are the best crisis management methods Pfizer, Takeda, Bayer and any other corporation can execute. It is easier for firms to avoid crisis than to manage them. However, businesses cannot circumvent all crises therefore; they need to respond swiftly in the public's interest. To retain a positive company image, firms should promote translucent communication with the public and not to indigently refute claims suggesting a drug is potentially dangerous (Koster, & Politis-Norton, 2004). If allegations are indeed correct, companies can focus on these issues and promptly withdraw the drug to prevent incurring irreversible harm to consumers.

Pfizer for instance, provided the public with information, but when people responded negatively to a clinical study, the company dismissed reports as inadequate. In the U.S., the ability to obtain a vast amount of information is the norm (Grewal, & Levy, 2011). If a company conceals results of a study, people automatically assume the entity partakes in deceitful and disingenuous actions. For this reason, Pfizer published data on a Bextra cardiovascular study. However, when Pfizer dismissed the recommendations to remove Bextra from the market in spite of the results, many consumers began to question the drug maker's motives ("Bextra Recall – Defective Drug Information," 2012).

Because Pfizer's headquarters originated in the U.S., they showed particular sensitivity to the needs of shareholders. One of management's goals was to satisfy investors. The company's reluctance to recall Bextra illustrates their concern about negatively affecting shareholders' trust in the business. The development of drugs demands a large investment on the firm's behalf and creates a massive loss when a medication does not perform as projected. In the immediate aftermath of a recall, shareholders tend to dump their stock as a way to escape quickly from the eroding situation (Marcus, 2011). Businesses do everything they can to maintain investors' confidence, but not acknowledging consumers' or society's influence usually leads to the firm's downfall like in Pfizer's case.

In contrast to Pfizer's failure to recall Bextra immediately, Takeda removed Veclade from the market before the drug would harm many more consumers ("Velcade Recall Issued Due to Particle Contamination – AboutLawsuits.com," 2010). By this action alone, they prevent any potential escalation of the situation. The Japanese culture emphasizes the importance of communication and the ardent affiliation between consumer and businesses; therefore, companies in Japan understand the significance of preserving long-term relationships (De, 1994).

Takeda expressed concern by responding quickly, even to what seemed like a minor incident of a few particles in vials (“Velcade Recall Issued Due to Particle Contamination – AboutLawsuits.com,” 2010). Recalling thousands of batches even though no significant amount of adverse threats were found, suggests the company did not want to expose several patients to irrevocable harm.

Takeda in joint with J&J, took the most responsible route in managing the Velcade crises, however their crises arose from external factors or ‘third parties.’ Even J&J’s Tylenol gold standard in crisis management resulted from cyanide tampering rather than centralized company mistakes (Aduvato, 2008). In contrast, Bayer and Pfizer’s cases were caused by internal faults, and they could not transfer the blame to anyone but themselves. Would Takeda, or even J&J, maintain a completely unscathed company image if they handled crises, which came from internal mistakes, like Bayer or Pfizer? On the other hand, would they try to hide the negative information or dismiss it to retain the efficacy of their drug that they invested so much capital in? This brings up another important question: is it easier to admit you were wrong because of your own decisions, or in instances where you relied on the decisions of others?

In the Baycol crisis, Bayer had no one to blame, but themselves. Like in the U.S., European firms also conduct operations with shareholders’ interests in mind (Marcus, 2011). Nevertheless, European companies do not place as much focus in this area as U.S. businesses do. On a scale, Japan would be on one side representing companies that place society over shareholders, and U.S. corporate entities on the other [shareholders above society]. U.K. firms and other European firms, such as Bayer, operate in the middle. Consequently, Bayer received a large outcry of disapproval when accused of informing shareholders about adverse side effects, before patients. Bayer’s actions were categorized out of the norm in the U.K. because of

regulations emphasizing on consumer wellbeing (Cheah et al., 2007). Nonetheless, Bayer recognized their faults and reshaped their strategies. If businesses cannot avoid a crisis, they must learn from the events.

While companies continue to function on a global scale, cultural roots and sheer physical distances still preserve the distinct national characteristics of societies. The Bayer, Takeda and Pfizer cases suggests firms still manage crises differently due to internal organizational cultural values and the external influence of consumer, and investor, expectations. The potential competitive advantage devastation to pharmaceutical companies during a crisis creates the incentive to have a general set of guidelines to follow.

Even though all corporations throughout the world should operate in accordance to a universal set of rules, they still need to adapt these principles to suit the cultural needs of the country in which they conduct operations. Two vital key points exist to help global firms succeed and preserve their reputation. These include, investing energy extensively in preventative actions and executing actions that maintains *all* relationships [either internally or externally]. First, preventing a crisis is much easier than handling a disaster burning out of control. Second, societies worldwide do not want to condone corporate psychopathy when a corporation's directors do what is best for the company, regardless of the harm created. People within businesses have the ability to think critically and distinguish between right and wrong (Achbar et. al., 2004). Organizations need to serve society rather than exploiting it. In the long run, companies who greatly value their relationships surpass profit driven firms whose image becomes tainted with greed and plagued with disaster events. “Sooner or later comes a crisis in our affairs...” but, international corporations appropriately executing rectifying actions to meet the needs of cultures, solidify a foundation to ensure their survival and ascendancy in the future.

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