AN EXAMINATION OF THE PARK DOCTRINE AND PHARMACEUTICAL EXECUTIVE ACCOUNTABILITY FOR REGULATORY COMPLIANCE

by

MARIE FRANKLIN MATHEWS

(Under the Direction of Paul Brooks)

ABSTRACT

This paper investigates whether or not top officials face repercussions when their leadership results in serious violations of the Federal Food, Drug, and Cosmetic Act (FD&C) in the pharmaceutical manufacturing sector. This research studies if chief executive officers (CEOs) or chairman of the board (COB) of parent companies of pharmaceutical firms experience job turnover as a result FDA injunctions or consent decrees against their subsidiaries or primary unit. This research shows that while some CEOs did turnover in the study period, there were other reasons that contributed to the turnover such as mergers and acquisitions, the filing of criminal charges by FDA or another agency, and/or the filing of Securities and Exchange Commission (SEC) charges. A small number of the cases reviewed resulted in CEO turnover due to economic or other consequences of the FDA action, and also that a high number of the firms had CEO and COB positions combined.

AN EXAMINATION OF THE PARK DOCTRINE AND PHARMACEUTICAL EXECUTIVE ACCOUNTABILITY FOR REGULATORY COMPLIANCE

by

MARIE FRANKLIN MATHEWS

B.S., The University of Georgia, 1989

A Thesis Submitted to the Graduate Faculty of the University of Georgia in Partial Fulfillment of the Requirements for the Degree

MASTER OF SCIENCE

ATHENS, GEORGIA

2013

AN EXAMINATION OF THE PARK DOCTRINE AND PHARMACEUTICAL EXECUTIVE ACCOUNTABILITY FOR REGULATORY NONCOMPLIANCE

by

MARIE FRANKLIN MATHEWS

Major Professor: Paul Brooks

Committee: Frances Akelewicz
Randall Tackett

Electronic Version Approved

Maureen Grasso
Dean of the Graduate School
The University of Georgia
August 2013

.

TABLE OF CONTENTS

Page

CHAPTER

CHAPTER 1

INTRODUCTION

Purpose of the Study

This paper asserts that market and business forces do not result in personal accountability for chief executives of firms that exhibit dangerous or serious non-compliance with Food & Drug Agency (FDA) regulations. As a result, those who are in the ultimate authority for these firms may not face consequences for decisions that result in the firm being unable to produce drug products that have a high level of assurance to be safe and effective. Injunctions and or consent decrees are often the tool that the FDA uses for serious or recidivist violations of the manufacturing regulations, known as current Good Manufacturing Practices. The FDA may include options that include plant closure, third party auditor oversight, and fines. The use of fines and consent decrees do not always have a significant deterrent effect on the prohibited behaviors.[1] There is evolving opinion in the industry press that this is often seen as simply a cost of doing business.[2] This research examines the impact of FDA actions as they relate to the tenure of chief executive officer (CEO) and chairman of the board (COB). Noted quality management expert Juran defined quality as "the failure of a product or component to meet specifications".[3] For the purposes of this work, the term "quality" will strictly refer to product specifications that if not met, would negatively affect the potency, identity, safety of the product; or filth or contamination of the product. According to the Federal Food, Drug, and Cosmetic Act (FD&C), products are automatically considered illegal or "adulterated" if the manufacture of drug

products occurred where these conditions exist, such as in facilities that do not adequately adhere to current Good Manufacturing Practices (cGMPs). The term "compliance" will refer exclusively to adherence to FDA GMPs unless stated explicitly otherwise.

The American public often hears of cases of serious corporate wrongdoing that clearly involve violations of federal law by corporations. If charges are filed, they are most often against the corporation, and not against individuals in authority within the organization. The concept of pursuing individual accountability for corporate crimes has been well developed and studied in many different types of industries. Famous criminologist, John Braithwaite, suggests that pursuing legal action against a corporation can be sufficient, but only if the post action period involves close supervision and measures that provide assurance that the individuals within the corporation are internally held accountable. Braithwaite and his coauthor wrote when corporations are "sanctioned for offenses, in theory they are supposed to react by using their internal disciplinary systems to sheet *(drive)* home individual accountability, but the law now makes little or no attempt to ensure that such a reaction occurs." Failing to hold the guilty individuals responsible misses a valuable opportunity to provide disincentives to others in the same industries from committing these same crimes.[4] The FDA has not often used individual enforcement remedies in cases of serious manufacturing non-compliance. The FDA stands virtually alone as a federal agency in its ability to prosecute individuals for violations of law without showing that those individuals had any knowledge that the crimes were taking place. This research seeks to examine if the FDA is missing a valuable opportunity to encourage voluntary compliance through the occasional use of this unique enforcement power and to evaluate why individuals in power may not be held accountable under the current system.

In one recent example, the large bank HSBC was found to be knowingly engaged in money laundering for large Mexican drug cartels and violating American laws by engaging in banking business with the country of Iran. Although the bank was fined, no individual with the bank was charged with any crime. Popular press articles were written criticizing the government in their failure to indict the bank's executives.[5] The Department of Justice cites both expense of prosecuting corporate executives and the great difficulty of obtaining evidence of specific individual wrongdoing.[5] Some have suggested it had to do with concerns about the viability of the bank and the economic and job losses if the bank failed.[5] Failing to hold the guilty individuals responsible misses a valuable opportunity to provide a disincentive to others from committing these same crimes.[4-6] The concept of pursuing individual accountability for corporate crimes has been well developed and studied in many different types of industries, including FDA regulated corporations, which will be further described below. This paper seeks to expand on this topic by examining if the occasional use of the FDA's enforcement tool of strict liability, or Responsible Corporate Officer (RCO) Doctrine prosecutions might increase compliance in the pharmaceutical industry. This type of prosecution, at the federal level, is almost an exclusive enforcement tool to the FDA. This legal doctrine allows executives of the FDA regulated firms to be prosecuted without proof required that the individuals had intent to break the law, or even that they participated directly or had knowledge of the acts that resulted in the charges. This power was granted through a series of Supreme Court decisions, culminating in the case of the *United States v Park*, 421 U.S. 658 (1975), that presented that this power was intrinsic to the enforcement of the FD&C Act (FD&C Act) as a protection to the public.[7] Criminal convictions usually must show a "guilty mind", or criminal intent, but in this case, the court deemed the provisions of the FD&C Act were too important to conform to that legal standard. The court held

that simply failing to implement quality systems that would prevent violations of the FD&C Act, and ensure that food and drug products are properly made, is sufficient grounds for misdemeanor prosecution. Currently, these misdemeanors may result in jail time or large fines (up to $500,000 per count) if the person is found guilty. While this power is available to the FDA, it has been rarely used since the 1980s.[7] The agency used it in the prosecution of 4 corporate officials of a medical device company for conducting an unauthorized trial of a device that caused the deaths of 3 people in 2007.[8] FDA also prosecuted executives of a pharmaceutical company illegally promoting oxycontin and also in a case of owner operators illegally importing adulterated pet food ingredients. These charges were strictly based on their position within the company and not direct evidence of their knowledge of the crimes.[8]

The FDA has indicated a return to the use of this type of prosecution in some cases of the off-label promotion of approved drugs by companies when the company seeks to profit by promoting the drug for the use without proper FDA approval. This policy change has been attributed by FDA officials as due to the failure of large fines paid by corporate violators to act as a deterrent, but has not yet been applied in instances of failures to follow FDA regulations in pharmaceutical quality.[9] In some serious cases of manufacturing quality problems, the FDA has pursued felony criminal charges against executives involved, but this requires a higher level of evidentiary proof of the individual's role.[8] The agency has not pursued any strict liability cases to date solely for violations of FDA regulations pertaining to pharmaceutical manufacturing practices.

This document concludes that it is more appropriate to hold the top executives accountable as sociological and psychological research shows that those working underneath someone else are highly influenced to follow their instructions and directives, even if it is against their better

judgment. As a result, this gives the uppermost levels of management tremendous power of the decision-making and behavior of those below them. This research will include a review of sociological and psychological factors that can influence individuals and contribute to the organization's compliance failures. These theories include group risky shift phenomenon, which proposes that individual characteristics of those in power may offer critical behavioral influences.[10]

This work also considers factors that may be contributing to an even greater risk that leaders may engage in decisions that increase quality risk, or the risk that a product or process will not meet cGMP standards, as defined by economist John Gray in 2007. [11] Corporate governance expert Robert Monks writes that significant changes in the ownership models of corporations over the past seven years has changed management decision-making at the highest levels away from the model of maximizing benefit to the shareholders to maximizing benefit to themselves, personally.[12] Monks writes that this is due to the fact that 72% of all stock held in the U.S. is held by institutional investors on behalf of pension funds and 401(k) funds. The institutional investors exercise the voting rights on behalf of the shareholders, but according to Monks, they show little interest in going against the corporate leaders wishes. Monks proposes that the institutional trustees exhibit lack or no control over poor governance at major corporations when it exists. Often, shareholders no longer hold top managers for such conditions and these behaviors can go on essentially unchecked.[12] When federal law enforcement agencies fine a corporation for breaking the law, it often may be years after the violation has occurred, and the fine is essentially paid at the expense of the shareholders and not the responsible corporate official.

This work will evaluate how corporate compliance with FDA regulations is heavily dependent on, and can be disrupted by, decisions made by upper management. This research evaluates how quality is often dependent on financial decisions that involve funding capital and workforce expenditures, corporate culture, and staffing of corporate quality units. Enforcement actions taken at lower levels or strictly against a corporate entity may lack effectiveness in many cases.[13]

The infrequent use of the *Park* Doctrine or Responsible Corporate Officer (RCO) Doctrine in other types of violations of the FD&C Act may not just be available and effective tool, but also a necessary one in the current environment. The increasing globalization of this manufacturing sector adds tremendous difficulties, both in cost and logistics, in monitoring the compliance status of all points of the drug's lifecycle, including the conduct of clinical trials and manufacturing of drugs and drug components that may be performed overseas.[14] When FDA simply communicates the potential use of *Park* doctrine prosecutions, it receives wide attention from the trade press that serves this sector of regulated industry. [15-17] Thus, in addition to the individual deterrent effects that may come from its use, there is also a strong additional impact that may act as a deterrent to the industry at large.[18] This may be useful in that fines paid by corporations, that may also receive attention from the media, do not seem to act as a deterrent.

In one recent example, William Weldon presided over Johnson and Johnson (J&J) as both CEO and chairman of the board during a time when the company experienced serious quality problems in manufacturing in some of their companies, including headline-making quality failures in over-the-counter drugs made by McNeil that resulted in plant closures, the revelation of "fake recalls" and an FDA injunction. Soon after, J&J announced massive recalls of implantable hips by one its device subsidiaries, and additional recalls of products like contact

lenses, stents, and insulin pump cartridges. A shareholder lawsuit alleges that reckless cost cutting was a major cause of J&J's quality woes, but he retired one year past the typical age of retirement for J&J CEOs of 62, and stayed on as chairman of the board until the first quarter of 2013. [19, 20]

While there is increasing scrutiny of corporate governance due to high profile corporate snafus, there is not a corresponding rise in accountability. Some shareholders are objecting to what they perceive as lapsed corporate governance for significant regulatory violations, in the way of fines and other punitive measures.[21] In addition to shareholders feeling that their value may be diminished, it is possible that consumers could pay the bill if the price of the product rises to cover losses. Regardless of who pays for the losses, the cost of FDA injunctions and consent decrees are often very costly for companies and their shareholders.

CHAPTER 2

THE HISTORY OF STRICT LIABILITY PROSECUTION IN THE US

In 1975, Milton Friedman, the Nobel prize-winning economist from the University of Chicago, wrote an article in the *New York Times* that was shocking to many at that time. Friedman wrote the corporations could no more have social responsibilities to society than a building, and went further in suggesting that the concept of a corporation having social responsibilities was in opposition to the purpose of the formation of a corporation.[22] Friedman endorsed a laissez-faire approach to the government regulation of economic markets and firmly believed the power of corporations and free market forces to be the best protector of both the businesses and the consumers' vital interest in their economic markets. In this article, he wrote that it was inappropriate for a corporate executive to have social responsibilities, as the philosophy would be based on spending other people's money.[22] Dr. Friedman wrote this in response to those leaders who made demands upon businesses to have social responsibilities in a free enterprise system. Friedman points out that his responsibility is to his employers, and "that responsibility is to conduct the business in accordance with their desires, which generally will be to make as much money as possible while conforming to the basic rules of the society, both those embodied in law and those embodied in ethical custom." Dr. Friedman was famously opposed to government regulation, but in this essay he clearly points out that while the corporation has no responsibility to exceed standards that are set by law, they have a clear responsibility to follow them.[22] Dr. Friedman uses the example of making expenditures to reduce pollution "beyond the amount that is in the best interest of the corporation or that is required by law in order to contribute to the social objective of improving the environment"; while he opposed a corporate

executive substituting their own judgment for the minimum standards established by the government, he did not support the violations of those minimum standards. While he is recognized as a free market and strong anti-regulation proponent, Dr. Friedman believed that corporations should be held to reasonable standards for the protection of society. Dr. Friedman's famously quoted definition of the responsibility of the business, which he saw as the only appropriate social responsibility, was "to use its resources and engage in activities designed to increase its profits so long as it stays within the rules of the game, which is to say, engages in open and free competition without deception or fraud." Although Friedman did not believe that corporations should have social responsibilities outside of pursuing profit, he did recognize that if the corporation engages in fraud, deception, or otherwise violates "the rules," it not only endangers the owners of the corporation, it creates societal problems. The structure that provides the rules are legislators, and therefore the onus to pass proper laws and set proper standards to guide the corporations under Dr. Friedman's philosophies. In the U.S. system, our legislature tasks federal agencies with the enforcement of national standards. [23]

There are also many business arguments that support following appropriate regulations. For example, if only a portion of the corporations are following profits in an ethical manner, it would put those corporations at a competitive disadvantage. Obviously the playing field would become uneven, and thus compliant firms would be put at risk in a free market because they bear the costs that go along with meeting regulatory requirements while others are freed from those expenses through their evasion. In addition, it clearly could endanger a free-market system, as consumers may fail to trust corporations, which could also undermine the positive effects of the free market and lead to potentially more and overly restrictive regulations in the backlash. There is an additional risk to a corporation not following the rules, in that sometimes the rules are

designed in such a way so as to prevent problems. Following regulations can ensure that a firm is practicing risk management even if the firm's leaders fail to see the necessity on their own. Many of the FDAs requirements, as shown by case law, are intended to impose a duty upon corporate executives to understand their businesses' processes and to ensure that failures in those processes are prevented. The specifics of the regulations implemented to oversee manufacturing of drugs, medical devices, biological products, and higher risk foods—referred to as "Good Manufacturing Practices"—are all are based on a philosophy that the firm must implement preventive measures that are designed to predict and avoid failures in the firm's own processes.[24] There is a firm foundational belief that the expertise in determining what can fail in the process should be concentrated in the firm's own institutional knowledge.

If a corporation, as Dr. Friedman wrote, has no more social responsibilities than a building, who should be held responsible for not following the rules?[22] Theoretically, if the corporation pays a fine, it takes away from potential profits that would be distributed to the shareholders or owners. A review of the literature shows a strong legal history of the ability of the United States to hold responsible individuals criminally liable in cases of violations that endanger the public in the areas of food and drug laws, even if the individual could not be proven responsible for the decision to violate the law. In order to examine the history of individual accountability for violations of this type of statute, one must first understand the legal history of the United States and the strong respect in this country for an individual's rights to due process and freedom from prosecution for crimes in which one is innocent. This is a fundamental protection provided for in the founding of our legal system.[25]

One of the oldest principles in criminal law, going back as far as Plato's time, has been the establishment of the principal that for one to be held criminally liable for a crime it should be

established that the person had a "guilty mind" or *mens rea*.[26] Plato wrote that criminal punishment should be based on whether or not the accused acted "with a rightful spirit and in a rightful manner."[26] In fact, Plato proposed that if one acted with no intent, there should be no punishment imposed by society.[26] Jane Costello and Adrian Angold wrote in a 2000 that "Plato used the distinction between a good man and a criminal as one of disposition rather than action. He identifies three sources of criminal disposition: crime as ignorance (*e.g. Republic*); crime as psychic disorder or disorganization (*Laws*), and crime as disease (*Timaeus*)."[27]

English law over time adopted aspects of *mens rea* into the criminal code, particularly by the 17th century.[28] At times, however, cases would appear which challenged the court to hold individuals responsible for crimes due to their failure to prevent them, or due to the severity or impact of the crime to the public health. One of the earliest reported cases in Western law was the English case of Regina v Stephens, in which the owner of a rock quarry was prosecuted for his workers illegally dumping "rubbish" and slate into a river. The owner was charged for illegally obstructing the navigation of a public river. The court held the quarry owner liable as an individual even though he did not oversee the daily operations at the quarry.[29] This case has been described as the use of strict liability in a "criminal nuisance case."[6] As Steven Zipperman notes in his essay on strict liability, the court in Regina v Stephens references an even earlier case, Rex v Medley, in which individuals from the Equitable Gas Company were criminally charged for dumping hazardous waste into the river Thames.[29] Although the top managers declared complete ignorance of the acts, the prosecutor informed the jury that in his opinion the fact that the managers were not on site and were unaware was not important. The prosecutor stated "if persons for their own advantage employ servants to conduct works, they must be answerable for what is done by the servants."[29] The jury criminally convicted the plant's engineer and

superintendent as well as the deputy chairman, and chairman of the Equitable Gas Company. However, by the time the case went to court, enough corrections had been implemented that the judge did not issue a severe sentence.[29]

An early case of strict liability prosecution in the United States was the 1910 case United States v Mayfield.[30] In this case, corporate officers were individually tried for violations of the 1906 FD&C Act at an Alabama District Court. It was reported that the jury was instructed to only find if the defendant had been responsible for the introduction of a jug in interstate commerce that was later found to contain cocaine. The jury was not asked to determine if the defendant had been responsible for placing the cocaine into the jug.[30]

This concept was again adjudicated in the case of the United States v Balint, which was another narcotics case but with different charges. In this case, which occurred just a few years after Mayfield, the defendants were charged with violating the United States tax code as a form of tax evasion.[31] At that time a written permit from the IRS was required for the sale of narcotics, and only doctors could legally sell these drugs. This case was appealed to the Supreme Court, and the decision was written by Chief Justice Taft. The defendants claimed that they had no knowledge that the opium and cocoa leaf derivatives they were selling were illegal, and they did not know that the products were regulated as narcotics.[31] Chief Justice Taft specifically discussed the history and importance of *mens rea* (which he referred to as "scienter" in this case) as "a necessary element in the indictment and proof of every crime," even in the case of many statutory crimes. He continued, however, that there had been a "modification of this view in respect to prosecutions under statutes the purpose of which would be obstructed by such a requirement."[31] Justice Taft continued that in the interest of maintaining some important public policies it was necessary to dispense with the need for scienter. He wrote "many instances of this

are to be found in regulatory measures” in which the enforcement of the statute is based upon "achievement of some social betterment rather than the punishment of the crimes."[31] He then described the enforcement of the tax code provisions as an example of a law that must be enforced and prosecuted without the requirements of scienter. He continued: “Again where one deals with others and his mere negligence may be dangerous to them, as in selling diseased food or poison, the policy of the law may, in order to stimulate proper care, require the punishment of the negligent person though he be ignorant of the noxious character of what he sells.”[32] This Supreme Court decision on the criminal liability of individuals for tax code violations by their company expressly stated that even individuals without any intent could be held criminally accountable for violations that create harm to the public, even through negligence or ignorance. Justice Taft acknowledged that although some may have concerns that innocent people could be denied due process; the importance of the public interest protection in this type of statute outweighs those concerns.

Later cases developed the United States' legal position for imposing individual criminal responsibility for actions taken by the corporation for which they work. The Supreme Court specifically indicated in the case of New York Central & Hudson River R.V. v United States that not only could individuals be criminally charged for the actions of their corporations, that the imposition of criminal liability for the acts of the individual could serve as both a "punishment and a deterrent."[9]

David J. Riley writes that wrongful actions performed "on behalf" of the corporation must be addressed.[33] Riley writes:

> *[A] theory, however, of criminal liability which stigmatizes all members of the organization, penalizing an innocent body of shareholders and having little deterrent effect on future misconduct, is not the answer. Rather, prosecutorial*

> *efforts must be directed at punishing responsible individuals, notwithstanding the argument that it is often difficult, if not impossible, to identify these persons.*

Later cases further developed the principles of strict liability in the United States and tested the circumstances in which the court would uphold its application. In one such case, the Supreme Court decided that a company president and general manager could be found guilty for violations that occurred at his facility when he was away for a month.[34] The evidence suggested that the conditions at the plant before the departure of the individual and after his return were the same as the conditions at the time the shipments for which the charges were based were made.[34]

The 1940s saw a significant solidifying of the Supreme Court's view of individual liability for corporations' violations of the pure Food and Drug Act of 1938, and demonstrated the court's respect for some of the stronger provisions that were included for the agency to protect consumers.[35] After the election of Franklin D Roosevelt, there was an effort on the part of the president and the head of the FDA to draft revisions to the 1906 Act, which had been found to be lacking in many important protection powers. The draft legislation was fiercely opposed by trade associations and advertising groups (the revisions closed loopholes such as the one that allowed manufacturers of fraudulent cures to go unpunished as long as they asserted that they believe in their own cures) and could not be passed for five years.[35] The legislation stalled as many strong and powerful groups opposed what they saw as more "New Deal" restrictions that challenged their view of capitalism. The use of strict liability prosecutions for FDA violations may have been accelerated due to a horrifying tragedy that fell under the FDA's jurisdiction, which also became one of the most pivotal milestones in FDA history.[35] In 1937, a Tennessee pharmaceutical manufacturer, S. E. Massengill Company, saw a need for a liquid dosage form of its popular sulfanilamide tablets and powder used for treatment of streptococcal infections, particularly for pediatric patients with strep throat.[36] Their products were popular with the public

in many states, and trusted by doctors who prescribed Massengill sulfanilamide for their patients.[36] The firm's chief chemist and pharmacist, Harold Watkins, found that sulfanilamide was difficult to dissolve, but that it would go easily into solution if added to diethylene glycol, to which raspberry flavoring was added.[36] Massengill's lab reportedly tested the mixture for flavor, appearance, and fragrance and immediately started production of its new product, "Elixir of Sulfanilamide".[36] Unfortunately, diethylene glycol is poisonous, and causes kidney failure with symptoms such as "stoppage of urine, severe abdominal pain, nausea, vomiting, stupor, and convulsions." [36] Many were shocked to learn that the only legal powers the FDA had to seize the shipments of this poisonous drug that caused the death of over 100 people, were due to a charge of misbranding: he product was called an "elixir" and did not contain alcohol, which is required if that name is used. The 1906 Act did not prohibit the sale of toxic drugs.[36] The public was even more shocked to hear the statement of the firm's president and owner, Samuel Evans Massengill, who stated: "My chemists and I deeply regret the fatal results, but there was no error in the manufacture of the product. We have been supplying a legitimate professional demand and not once could have foreseen the unlooked-for results. I do not feel that there was any responsibility on our part."[36] The firm's chief chemist, Mr. Watkins committed suicide prior to the case going to trial.[36] This event focused national attention on the dangerous omissions in the food and drug regulations of the time, as well as the potential risks that could result from a company's negligence. The revisions to the 1906 Food and Drug Act were quickly passed in 1938 due to the awareness of risks that could be presented to the public if a company fails to recognize health risks that can emanate from their products.[36] By the 1940s, the public was much more aware of the new stronger provisions in the 1938 Act, and expected more accountability from the manufacturers regulated by it.

United States v Dotterweich overturned a prior decision held by a Court of Appeals in the case of United States v Buffalo Pharmacal Company. The firm Buffalo Pharmacal, an own-label drug re-packager and distributor, purchased drugs made by a pharmaceutical manufacturer and repackaged them for distribution under their own label. Both the company and its president and general manager, Dotterweich, were charged with two counts of shipping misbranded drugs in interstate commerce and a third count for shipping an adulterated drug, which are all violations of Section 301 of the Act. Mr. Dotterweich was found guilty on all three counts; however, the jury was not in agreement as to the corporation, Buffalo Pharmacal.[37] Mr. Dotterweich appealed his personal conviction decision to the U.S. Circuit Court Of Appeals, which overturned his conviction because the court felt that the original decision represented an unsubstantiated interpretation of the 1938 Act as being more punitive than the 1906 Act.[37] They also felt that only one “person" could be subject to prosecution under this law. Unless Buffalo Pharmacal was only operated as a counterfeit screen for Mr. Dotterweich, both in the corporation and the individual officer could not both be held liable.[37]

The Supreme Court of the United States heard the government's appeal of the Circuit Court's opinion in 1943. According to trial transcripts, the Supreme Court justices actually reviewed congressional testimony from the debates held at the time of the passage of the 1938 Food, Drug, and Cosmetic Act.[37] In response to the prior appeals court’s opinion that the 1938 Act was improperly interpreted, the Supreme Court pointed out that the 1938 revisions to the Act were clearly intended to stiffen the penalties for those who introduce impure and adulterated food and drugs into commerce.[37] The opinion, delivered by Justice Frankfurter, famously included that "The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection."[37] The

opinion continued: "such legislation dispenses with the conventional requirements for criminal conduct – awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger."[37] The opinion stated that there not be a need for conscious fraud to secure a conviction in FDA cases due to the potential threats to public health by the actions of the regulated firms.[37]

The Supreme Court Justices also stated in the majority opinion that the original 1906 Act contained elaborate phrasing to show that criminal liability could be charged against corporations, for example “the act, omission, or failure of any officer, agent, or other person acting for or employee by any corporation, company, society, or association, within the scope of his employment or office, shall in every case also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person."[37] The Justices wrote that by the time of the 1938 revisions, legal understanding had increased the liability of corporations for violations of the law, and Congress felt that they did not need to go to such lengths to indicate that corporations could be legally liable for violations of the act. They wrote that the deletion of the wording was done in the interest of “brevity and good draftsmanship."[37] The Supreme Court held that the Circuit Court's opinion would essentially free all individuals, unless they are owners, from any liability for violations. To disprove the Circuit Court's opinion, the Supreme Court wrote that their reviews of both the House of Representatives and Senate committee testimonies specifically included statements of the Congress that their intention was to strengthen existing laws to protect the consumer, and that they did not wish to weaken the 1906 Food and Drug Act.[37] The Justices wrote that even a corporate officer with the intent to defraud or mislead could escape prosecution if the Court of Appeals opinion stood that only a corporation or a corporate officer could be prosecuted, but not both.[37]

In 1947 the Supreme Court heard the case of United States v Parfait Powder Puff Company, in which the Court found that a pharmaceutical executive could be held criminally liable for actions that were performed by a contract manufacturer, even if the actions were completely unknown to the individual being prosecuted. This case established the principle that delegation of the actions that caused the violation to occur does not relieve a regulated company from liability under the Act.[37]

Arguably, the most important and precedent-setting strict liability prosecution in the history of the United States was that of United States v *Park* in 1975.[38] In this case, the FDA developed a prosecution case against the chief executive officer and president of Acme Markets Incorporated. Acme operated as a large national retail food chain that owned approximately 874 retail outlets, 12 general warehouses, and four "special warehouses."[38] The FDA was responsible for inspecting and regulating the storage, transportation, and sale of the food items prior to arrival at the grocery stores. In April 1970, the FDA notified the firm that “unsanitary conditions" were found at the firm’s distribution warehouse in Philadelphia, Pennsylvania.[38] In late 1971, the FDA conducted a lengthy inspection of Acme's Baltimore warehouse and distribution center, in which the FDA inspectors documented significant evidence of rodent infestation and other serious unsanitary conditions. In January 1972, the FDA sent a strongly worded letter to Mr. Park advising him of the serious sanitation problems at the firm's Baltimore warehouse. The letter stated “such reprehensible conditions obviously existed for a prolonged period of time without any detection, or were completely ignored....”[38]

According to testimony provided at Mr. Park's trial, Mr. Park met with Acme's vice president for legal affairs, who assured him that the vice president who was in charge of the region in which the violations occurred would take action to correct the problems.[38] Both the

Baltimore warehouse and the Philadelphia warehouse were under the same vice president, which turned out to be significant in the course of evaluation of Mr. Park's responsibility. The FDA conducted a follow-up inspection of the Baltimore warehouse in March 1972, and found that there had been some improvement in the conditions, but there was still evidence of rodent activity in the building and in the warehouses. Worse still, the inspectors found pallets of food that had actually been eaten on by the rodents.[38]

The FDA brought charges against Acme for multiple counts of shipping of adulterated food in interstate commerce in violation of 21 U.S.C. Section 331(k), to which the firm pled guilty and paid fines. As previously mentioned, Mr. Park was also personally charged with multiple counts of causing adulterated food to be shipped in interstate commerce. Mr. Park pled not guilty, but was initially found guilty by a jury on all counts. Although the court only imposed a fine of $50 per count, Mr. Park appealed this decision. The Fourth Circuit reversed this decision; this appeals court found that Mr. Park had not engaged in wrongful conduct.[38] The government appealed the decision to the Supreme Court, which rendered its decision on June 9, 1975.[38] Chief Justice Warren Burger delivered the court's opinion in this landmark case in corporate executive liability. Mr. Park's defense included that he had delegated the responsibility to "dependable subordinates" for the sanitation and therefore also the corrective actions needed for the warehouses.[38] He contended that he could not possibly personally oversee the day-to-day operations of such a large company.[38] According to court records, Acme markets employed approximately 36,000 employees at that time. His defense also asserted that Mr. Park did not believe that there was anything he could have done "more constructively than what [he] found was being done." [38] The court disagreed, and upheld that Mr. Park could be found guilty strictly based on his position of ultimate authority for the company.

The *Park* case bestowed a somewhat unique prosecutorial stance upon the Food and Drug Administration, as this type of case does not appear frequently in violations of Federal law.[29] The state of California has used strict liability prosecution in different types of public welfare laws, including business fraud, hazardous waste, municipal code enforcement such as fire safety codes, and others.[29] Some have called for the use of strict liability prosecutions for violations of the Environmental Protection Act, as the violation of this law can also result in serious threats to the public health.[29] The federal courts, however, have been much more reluctant than the California state courts to uphold the use of strict criminal liability to federal agencies other than the FDA.[29]

FDA Use of the Park Doctrine

After the Supreme Court decision in U.S. v *Park*, the FDA utilized this enforcement tool in many cases, especially "sanitation cases," which are typically food warehouses that have insect or rodent infestations.[9] Reportedly, the Department of Justice did pursue a number of strict liability cases on behalf of the FDA from around 1974-1982.[9] All strict liability cases filed are for misdemeanor prosecutions only, in that legal policy in the United States requires that the government must prove *mens rea* to charge someone with a felony criminal violation of the FD&C Act.[9]

By the 1980s, the Department of Justice began to show a declining interest in pursuing these misdemeanor cases that did not yield much in way of penalties, in large part due to a serious staffing shortage on the part of the agency.[9] The enforcement strategy began to shift toward pursuing criminal prosecutions, known as "Title 18" charges, include fraud, lying to federal investigators, or racketeering. (The term "Title 18" refers the specific portion of the US criminal code that contains the actual prohibitions of the aforementioned activities.)[39] These

charges yielded greater penalties than the relatively minor misdemeanor charges, but they required the government to provide proof of intent to defraud or mislead during the commission of the violation.[9]

In 1984, significant changes were made to the meager penalties that could be provided for in these types of misdemeanor cases. As an example, the FDA spent a great deal of time and money in prosecuting Mr. Park, but he paid a grand total of $250 in fines, at $50 per guilty count.[9] These penalties were revised when Congress enacted the Sentencing Reform Act (SRA) of 1984.[9] The purpose of the SRA was to shift the primary goal of sentencing from "rehabilitation" to "retribution, education, deterrence and incapacitation" due to a perceived raise in federal crimes.[39] The law created sentencing guidelines and a commission to promulgate these guidelines.[39] When the SRA was implemented, misdemeanors could carry significant jail time and financial penalties, such as a year in prison and/or a maximum fine of $100,000 per count for an individual, with additional enhancements if the crime results in a death.[39] The maximum fine in those cases could reach as high as $250,000.[39] The corporation itself could be fined $200,000 per count and up to $500,000 per count if a death results from the violations.[39] The Sentencing Commission created by the SRA developed a separate guideline, Section 2N2.1 of the SRA, for misdemeanor violations.[39] This guideline includes enhancements in cases that involve fraud and intent to mislead either the government or the public. In 2008, the Sentencing Commission changed the guideline and allowed upward departures in cases that involved "a substantial risk of bodily injury or death." According to FDA guidance, many food and drug cases of serious non-compliance involve such a risk.[40]

Although the penalties increased, the FDA did not pursue strict liability prosecutions until May 2007, when Purdue Frederick, a division of Purdue Pharma, pled guilty to a felony

count of misbranding Oxycontin with the intent to defraud or mislead. In pleading guilty, the company's representatives admitted that its sales representatives had deliberately misled physicians about the safety of this powerful pain medication and its potential to cause addiction. In addition to charging the company with the felony counts, the FDA also charged individual executives of the company with misdemeanor counts of violating the Food, Drug, and Cosmetic Act. The Department of Justice prosecutors took the unusual step of also prosecuting the firm's president, former chief medical officer, and top attorney, charging them with criminal misdemeanors, to which they pled guilty.[41]

The criminal prosecution of the three executives of the Purdue Company reintroduced strict liability to the leaders of FDA regulated firms.[41] The Purdue case had generated strong interest from state prosecutors. In 2004, the attorney general of Virginia petitioned the FDA to take firm action against Purdue for what was seen as the irresponsible marketing of the drug Oxycontin.[42] Purdue had received approval from the FDA to market this powerful pain reliever in a time release formula. The firm, after receiving focus group feedback from physicians with concerns about addiction with this new formula, began marketing the drug as less addictive.[43] The government case claimed the sales force was even given reportedly fictitious charts to prove this claim. After the drug entered the marketplace, Purdue received numerous reports of the product being crushed and snorted so that users could receive a heroine-like high.[43] According to court records the firm did nothing to either warn the physicians or users of this risk.[43] The firm was fined $600 million, which included $160 million paid to state and federal healthcare programs.[43] The firm is also paying millions of dollars to resolve private lawsuits, which totaled approximately $130 million in 2007.[43]

Trade journals for the pharmaceutical industries reported on this case heavily, and it received considerable attention, although a literature review reveals that initially media outlets did not use the phrase "*Park Doctrine*" in conjunction with this case. While this move was seen as a more strong enforcement posture, it was not seen as the agency revitalizing this doctrine. The case received much more attention when the Office of Inspector General (OIG) for the Department of Health and Human Services filed charges against the three executives that would bar their participation in any company that produced products purchased by Medicare or other federal health programs.[8] Use of this legal provision effectively bars the employment of individuals from many or even most healthcare manufacturers. While the executives appealed the decision, the courts did uphold a 12 year ban against the men working in companies with any interest in federal healthcare programs.[8] OIG stated that anyone convicted of a felony violation of the FD&C Act falls under the mandatory exclusions in their policy.[44]

In March 2010, Margaret Hamburg, the Commissioner of the Food and Drug Administration, sent a letter to Senator Grassley to respond to a Government Accountability Office report that was critical of the FDA's conduct of criminal investigations.[45] The report focused on the performance and effectiveness of FDA's Office of Criminal Investigations.[46] As part of this response, Commissioner Hamburg stated that the agency planned to increase the use of misdemeanor prosecutions "to hold responsible corporate officials accountable."[45] She promised that criteria and policies would be developed on the appropriate use of these misdemeanor prosecutions. Commissioner Hamburg's announcement garnered a great deal of attention from all of those who followed Food and Drug Law enforcement.[8]

October 13, 2010, Eric Blumberg, then Deputy Chief for Litigation for the FDA, spoke at a Food and Drug Law institute conference and delivered a startling message. He said, "Unless

the government shows more resolve to criminally charge individuals at all levels in the company, we cannot expect to make more progress in deterring off-label promotion."[47] Mr. Blumberg brought up the then recent 2.3 billion fines levied against Pfizer for off-label marketing of multiple drugs. He continued, "It's clear we're not getting the job done with large, monetary settlements" and also stated that "the FD&C act is a strict liability statute".[47] Blumberg cited the fact that 27 major pharmaceutical companies had been cited for making unapproved drug claims in just the past few years.[47] Now that the FDA's top litigator, Eric Blumberg, had officially alluded to the increase of FDA's use of strict liability prosecution in the near future, Commissioner Hamburg's message became real: "*Park*" was back up for consideration.

CHAPTER 3

INDIVIDUAL VERSUS COLLECTIVE RESPONSIBILITY

"…..the latest and perhaps most formidable form of such dominion, bureaucracy, or the rule by an intricate system of bureaux in which no men, neither one nor the best, neither the few nor the many, can be held responsible, and which could be properly called the rule by Nobody"

H. Arendt[48]

Robert Monks wrote in 2008, that "the corporation is an odd and ancient beast", as he pointed out that the idea of a collective body that would be treated as a single entity was as old as clans, tribes, and medieval guilds.[49] He points out that such collective bodies can be enormously valuable, in that they can "pool individual wealth to achieve goals that no individual acting alone could've accomplished".[49] Sociological science has also shown that people when acting as a collective may behave differently than when acting independently. This phenomenon has been the subject of a large body of research to understand how and why these changes occur in human behavior.[50]

Ethicists, sociologists, criminologists and business scholars have written extensively on this topic, and revealed many surprising aspects of human nature when individuals become involved in group behaviors. One of the greatest concerns comes from diffusion or obfuscation of responsibility for consequential moral decisions, which can distort when in a collective.[48, 51, 52] An area which has been studied extensively in this category is that of war crimes and acts of genocide. Hannah Arendt wrote extensively on the cruel and murderous actions of the Nazi

regime against innocent civilians during World War II.[48] Ms. Arendt wrote that one such system in which tragic events can occur while the members of the responsible organization claim no fault as: "…the latest and perhaps most formidable form of such dominion, bureaucracy, or the rule by an intricate system of bureaux in which no men, neither one nor the best, neither the few nor the many, can be held responsible, and which could be properly called the rule by Nobody".[48] Diffusion of responsibility has also been shown to limit positive interruptive actions by those in a group who witness crimes or anti-social actions due to the premise that someone else will act, so they need not. [51] The story of the sexual assault and murder of a young woman in 1964 that supposedly took place over 30 minutes while 38 people watched spurred numerous studies and inquiries into this phenenomenon.[53] While the details of the "the 38" in this story, which was first reported in the New York Times, is in dispute, the research that resulted has been shown to be sound and reproducable.[53]

In addition to the identification of the effect of the diffusion of responsibility inhibiting socially responsible behaviors, researchers also identified the phenomenon of obedience to authority as a contributing factor. The most famous example of research into this area was by Stanley Milgram in what has come to be known simply as the "Milgram Obedience Experiments". Many variations of the same core experiment were examined: The study subject was told that they were going to participate in a learning experiment; they were told to teach another study participant (the learner) located in another room a series of word pairs for memorization, and to deliver an electric shock via a control panel to the unseen learner study participant when he or she made an error (the shock was not really delivered, but care was taken to make the situation seem quite real). The study participants were "supervised" by a confederate researcher, who wore a laboratory coat and represented a legitimate authority. The study subject

was referred to as “the teacher” in this study. The teachers were given a demonstration shock of 45 volts in the beginning of the experiment to demonstrate what it felt like to receive an electric shock. Despite this, the teachers virtually never refused to increase the level of the electric shock being delivered, all the way from a starting range of 15 volts to a maximum of 450 volts.[54] The higher voltage setting were marked as being in a red danger zone on the control board, and the highest levels were marked as potentially lethal.[54] While the teachers in many instances expressed dismay or doubt, they would still follow the researcher’s instructions to increase the shock level as directed.[54] Milgram wrote in his oft-quoted conclusion of his studies: “Ordinary people, simply doing their jobs, and without any particular hostility on their part, can become agents in a terrible destructive process.[54] Moreover, even when the destructive effects of their work become hotly clear, and they are asked to carry out actions incompatible with fundamental standards of morality, relatively few people have the resources needed to resist authority."[54] Milgram reported in subsequent variations that teachers were less likely to deliver the shocks if they could hear the participant’s screams, but strangely the majority did carry on to deliver the potentially lethal shocks. This was despite the fact, as Milgram reported, that “28% of the obedient subjects thought that the learner had probably died”.[54] Teachers were more likely to resist when the authority figure was not physically present in the same room, or alternatively when the learner was co-located in the same room with the teacher, without separation.[54]

In 1966, Charles Holfing and others publish the results of their field experiment in which they study the obedience of nurses to physician's orders. The study utilized the following scenario: a placebo drug was prescribed via telephone by a study confederate acting as a doctor.[55] The doctor, whose voice was unknown to the nurses, prescribed the drug at double the dosage recommended on the package; the nurses had never heard of this medicine; the drug was

not cleared for dispensing and placed on the ward's "stock list" per procedure; and prescribing of drugs via telephone was strictly against hospital policy.[55] Hofling reported that 95% of the nurses in the experiment administered the drug as prescribed, and did not request a written order or question the prescriber.[55]

In the 1960s, many researchers wished to study the risk-taking behaviors of individuals as compared to people acting in groups, with actual measurable data. Michael Wallach and Nathan Kogan designed a series of assessment tools which proved useful in providing such metrics.[52] In 1962, they developed a questionnaire which was given to study participants in which they asked study participants to predict their success in answering knowledge based questions based on the category and the group scores of previous test takers given as a percentile, such as 85% of those who answered this subset of questions answered them incorrectly.[52] This was to allow the study subjects to predict their own scores and to make choices on which sets of questions to choose. The study participants were told that they would receive added monetary rewards based on the level of difficulty that they would be willing to take in answering the questions, and asked to predict their performance.[52] Multiple studies of different groups of male students showed that they were more willing to take risks when working in groups as opposed to completing their choices as an individual.[52] The study showed that the increased risk-taking behaviors would occur even if the subjects were only privy to recordings of groups discussing strategy.[52] This phenomenon was titled "risky shift behaviors" by later researcher James Stoner, and has been reproduced in both genders and different cultures and nationalities. [50]

In 1977, Scott Armstrong published the shocking results of his experimental research in a journal article titled "Social Irresponsibility in Management". It is notable that Armstrong's research was published 7 years after Milton Friedman's New York Times editorial received

widespread attention for claiming that corporations have no social responsibilities other than to enrich its shareholders. Mr. Friedman stated that the corporations should follow the rules, but spoke out against having government oversight of corporations.[56] Armstrong did not cite Friedman in his papers, but he stated he intended his studies to examine the behaviors of business managers who existed under what he called the “current system” which he described by the term the “stockholder role”. Armstrong stated that in the U.S. legal system that “the duty of management is to be obedient and loyal to the stockholder”.[57] He continued that the outcome of the system is that the manager feels no responsibility to any other groups other than the shareholders, and that managers are trained that they should be concerned with other groups and stakeholders "only to the extent that they affect the well-being of the stockholder".[57] Armstrong wished to study a situation in which managers must make a decision which would allow a company’s stockholders to gain at the great expense of others, such as the company’s customers. He selected the case of the actions of the board of the Upjohn Company, who continued marketing the drug Panalba despite the knowledge that the drug was causing life-threatening side effects. Even worse the alternative drugs made by competitors offered no such side effects.[57] This drug was very profitable at the time to Upjohn, and reportedly sales were approximately 1.5 million dollars a month in 1968.[57] Upjohn sued the FDA to keep the drug on the market when FDA ordered sales of the drug to cease, which reportedly well after the time that the responsible corporate officials would have known the facts about the dangers of the drug.[57] Armstrong‘s study involved thousands of business school students who were asked to role-play as managers for a transnational pharmaceutical company. As part of the scenario the students were provided with the situation in which they were to make a decision about whether or not to withdraw a dangerous drug from the market. They were provided with a background

document which gave them their assigned role as manager and described the negative facts known about the drug. The participants were then asked to make a decision on whether or not to continue marketing the drug based on the information presented to them. Armstrong including in the case study the statement "it is extremely unlikely that bad publicity from this case would have any significant effect upon the long-term profits of any other products made by Upjohn". This is significant, as the students are presented with a situation in which the Corporation would not suffer adverse marketplace conditions due to the continuation of marketing of the dangerous product. Therefore, the decision would only be based on social responsibility, and not concern for economic consequences to the firm.

Armstrong reported that not only did none of the 57 control groups in the case demonstrate willingness to remove the dangerous drug from the market, 79% of these groups recommended that the fictional company take active steps to prevent the removal of the drug from the marketplace.[58] Armstrong concluded that social responsibilities were not given much weight in the business culture of that time, at least as perceived by his subjects.[58]

In the 1980's, Braithwaite and Fisse moved past the laboratory and conducted interviews with corporate executives from transnational companies around the world to study the organization structure as it relates to accountability and responsibility. Braithwaite & Fisse delved deeply into the crime of large corporations and failures of the current models to hold individual actors accountable for corporate wrongdoing in their book *Corporations, Crime and Accountability* and associated publications. Based on research performed in Japan, they postulated that there are 4 types of responsibility for the top officials in corporations: Noblese oblige, captain of the ship, nominated, and fault-based responsibility.[4] Noblesse oblige was described as cultural tradition of the top leader taking the blame regardless of the cause, with the

most notable and extreme examples being the Japanese tradition of the most responsible committing suicide when a terrible outcome befalls the organization. Braithwaite notes that this is “perverse” as Japanese leaders typically have less real power than their counterparts in the rest of the world due to corporate culture differences in Japan.[13] Braithwaite states that in Japanese business culture the decisions of the president are supposed to be reflective of the collective group below him.[13]

They wrote the captain of the ship “refers to the principle of holding the most senior executive officer who is on location at the time of the act of organization wrong doing as strictly accountable for it.” They wrote that this principle is widely used in Japan. Braithwaite notes that in this method the true initiator of the problem, if less senior, would not be held responsible by the organization. The accountability comes from serious social repercussions would result for the person who caused a “black mark” to fall on their supervisor by others on the team.

Nominated accountability is a system in which a person is held accountable based on the special responsibility that the person has in the area of concern. Braithwaite specifically names a quality control director of a pharmaceutical company as an example of a person “strictly” responsible for the supply of impure drugs. In the European Union, the creation of the "Qualified Person" makes a legal demarcation for this position gives them statutory legal responsibility.[59] Braithwaite states that this is the most familiar category to Westerners, and is the typical practice seen in Western culture when catastrophe strikes.[4] He describes this as the case in which an investigation is conducted into the individuals who caused a problem based on “intention, recklessness or negligence”.[13]

Braithwaite narrowed his focus in a body work described in the book “*Corporate Crime in the Pharmaceutical Industry*”, which he described as an “industry case study into corporate

crime". He based the book on 131 interviews with pharmaceutical executives, as well as review of court and congressional transcripts of investigations into wrongdoing by medical device and drugs companies. The areas studied in this work included bribery, negligent or fraudulent safety testing, unsafe manufacturing practices, antitrust, the "pushing" of unsafe drugs, unfair practices in the Third World, and fraudulent accounting practices. Although Braithwaite was Australian, he noted that a "disproportionate emphasis" would be placed on US products as not only the country that manufactured the largest amount of pharmaceutical products in the world at that time, but was home to half of the world's "top fifty" pharmaceutical companies at that time.[6]

In the book's introduction, Braithwaite described studies of public indignation of the seriousness of crimes comparing attitudes of 8 different countries by Scott and Al-thakeb, 1977. Braithwaite noted: "The US was the only country in which marketing a drug *[knowingly]* with harmful side-effects was judged as deserving less punishment than rape". Braithwaite writes that "the FDA is the world's premier regulatory agency, the United States can achieve more than any country in raising regulatory standards worldwide".[6] Braithwaite suggests that the U.S. FDA has a tremendous responsibility to get its approach to pharmaceutical crime "right", as the consequences to the rest of the world can be enormous.

Sociobiology, a term coined by E.O. Wilson, explains human sociological behavior by studying Darwinian human evolution.[60] The roots of why humans favor maintaining the collective and avoid conflict with leaders can be studied in sociobiology.[61] Wilson postulates that conformity to a group conveyed a genetic advantage to early humans that evolved this trait.[61] His theory is that belonging to a group conveyed specific benefits to members as it helped increase survival in a dangerous environment. Members had to ensure they were not ostracized from the group to maintain the benefits, so behaviors evolved to favor acceptance of conformity

which lowers conflict.[61] Conflict could destabilize the group, and if the group does not have sufficient conformity then the social bonds could weaken and the group could fall apart, thus ending the group advantage.[61] While genetic explanations of human behavior is controversial to some, many scientists accept that human social behaviors, both positive and negative, may have evolved in our ancestors via natural selection, and may provide some insight into ourselves.[61] Regardless of the origin of the behaviors that arise when people become part of a corporation, it is necessary for regulators to understand those behaviors to ensure that systems of accountability are properly designed for our current world. Accountability and responsibility should be given to those who are able to exercise it within an organizational system.

CHAPTER 4

THE FALLACY OF THE INVISIBLE HAND

In 1776, Adam Smith wrote *An Inquiry Into the Nature and Causes of the Wealth of Nations*, an incredibly influential book that has created much debate about the best structure for nations' economies and governance mechanisms. Smith covered many different groundbreaking areas, including concepts such as the division of labor and its limitations, the origin and use of money, real and nominal prices of commodities, natural and market prices of commodities, wages of labor, profits on stock, government economic policies, and international trade. Smith's work that has generated the most attention and controversy to date is his writing on the benefits of a free market. Smith theorized that people acting deliberately to make the world a better place was not effective. He believed that the best path for improvement for all was for each individual to act in their own "enlightened self-interest." He believed that there were unseen forces that were created when one person wished to sell another person something that they needed, and these unseen forces would force people to cooperate with one another, bringing about positive results for society. Smith wrote:

> "Every individual… Neither intends to promote the public interest, nor knows how much he is promoting it… he intends only his own security; and by directing that industry in such a manner as its produce may be of the greatest value, he intends only his own gain, and he is in this, as in many other cases, led by an invisible hand to promote an end which was no part of his intention."[62]

There is much debate among economists and scholars on whether or not Adam Smith believed that the market should operate completely unfettered and only guided by this "invisible hand." Some fervently suggest that Smith was not saying that government had no role, and several scholars have written that Smith was joking or simply being sardonic when he wrote of the invisible hand.[63-65]

During the 1970s, Smith's invisible hand theory became extremely influential in the United States among many economists and business scholars. During the rise of power of the USSR and America's ensuing fear of the rising tide of socialism and communism, Smith's treatise enjoyed a popular resurgence. But a large faction of economists,[66] including Milton Friedman, believed that Smith proposed that the market should only operate in a completely free and unregulated manner.[67] The only exception of note was that Friedman almost always advocated in his description of free markets that fraud and deception should be prohibited.[68] Friedman also asserted that "it is the responsibility of the rest of us to establish a framework of law such that an individual pursuing his own interest" would be able to participate in the market led by the invisible hand.[68]

The invisible hand theory later evolved into more general use, and free market "laissez-fare" proponents have extended the theory to the idea that the markets will not only produce a generalized beneficial outcome to the market participants, it will also provide disincentives to those who might not be operating in a socially responsible manner. Milton Friedman's ideal marketplace, which is primarily governed by minimal government intervention, and then only when dealing with fraud and deception, requires the enlightened self-interest of the executives to operate in a way that maximizes the value of the companies that they lead.

In 2003, Thomas Carson performed an interesting analysis of the free market theory as championed by Friedman, viewed through the lens of several corporate scandals that occurred at that time. In his work, *Self-Interest and Business Ethics: Some Lessons of the Recent Corporate Scandals*, Carson observes that several of the pillars upon which the theories of enlightened self-interest and the invisible hand rest are not holding.[69] Carson makes the assertion that Adam Smith's market model, which rests on enlightened self-interest, is predicated on the supposition that businesses are managed by business owners, as was the typical case in the 1700s.[69] Carson notes that most capitalism today is based on an ownership model in which the true ownership of the business is highly diffused among shareholders. He writes that "this gives considerable scope for high ranking executives to enrich themselves at the expense of shareholders and everyone else."[69] He continues that since managers and owners can have divergent interests, the selfish actions performed by executives will not act, as Smith hoped, to "promote the general welfare."[69]

Robert Monks has written extensively on the effects of changes in the way that corporations are managed and owned in the United States and the corresponding impact on the behavior of top corporate executives. Monks' primary treatise is that the way that American corporations (and most transnationals) are owned has changed significantly over the past 70 years. Monks wrote that the majority of all stock owned in the United States is held and managed by institutional investors on behalf of pension funds and 401(k). Monks has publicly shared many times the story of when his insight developed. He opens his book *Power and Accountability* with the story of when he noticed that the Penobscot River in Maine was covered with a large slick of thick foamy white bubbles due to discharge from the Great Northern Paper company plant upstream.[12] He wondered: "Who wants this to happen? Not the owners of the company, the shareholders. Not the managers or employees, who want to live in a healthy

environment. Not the Board of Directors, not the community, not the government. I cannot think of anyone connected with the company emitting the effluent who wanted the results I saw." He saw the plant's poor environmental practices as an "unintended consequence of the corporate structure."[12]

He wrote that he realized that he himself was part of the problem while he was the chairman of the board for a large bank, the Boston Safe Deposit and Trust Company. The bank was trustee for over 7 billion in assets which the bank oversaw for their investors.[12] Monks says he was going through the proxies on which he needed to vote as a trustee on behalf of the shareholders and was "about to do what he had always done", to simply vote for the board members that "management" supported, when he noticed that it was a proxy for Great Northern Paper.[12] In a 2002 interview, he states that he had an epiphany: "My God, it was the same company that was floating the foam."[70] He continues, "I understood that myself and maybe 50, 60 people like me owned enough of an interest that we could actually have an impact."[70] Monks realized that he was partially responsible for picking the leadership team that was making the decisions to allow the environmental damage to the river, and therefore was part of the problem.

While Carson writes that large corporations that are owned by large numbers of shareholders experience a diffusion of ownership and therefore also lose the positive influence and impact of owners on governance, Monks raises the alarm that the effect is much deeper. The shareholder impact is not just diffused; it is effectively removed when the shares are held by institutions such as banks and investment and pension funds. Monks became an outspoken activist on what came to be called "shareholder activism," which he believed was needed to draw attention to the many poor governance practices that not only hurt the value of their corporate investments/shares, but also the public by antisocial practices.

John Bogle, the famous investor who founded Vanguard and championed the propagation of “no-load” or no-commission mutual funds in the United States, also commented on the same phenomenon that concerned Monks. In 2007, Bogle wrote in his work “Reflections on ‘Toward Common Sense and Common Ground?’” that institutional ownership of stocks and equities is concentrated among a small number of firms.[71] Bogle calls the rise of the proportion of stocks that are owned by institutional investors a "veritable revolution in stock ownership." He writes that in 1950, institutional investors only held 8% of all US equities, with the other 92% held by individuals. In 2007, institutions held 74% of all stocks, with individual owners only holding 26%.[71] He also points out that due to the real value that individual investors realize from the benefits—such as the power of diversification, professional management, and the simple convenience of shared investments that come with mutual funds and pension plans—there is no reason that individuals will go back to the previous model.[71] Bogle asserts that with this radical change in the ownership model, new governance challenges have arisen. The massive size of the institutional investment companies is a challenge in and of itself. He points out that the five largest investors hold more than $500 billion worth of US stocks and that the 100 largest institutional investors own 57% of America's equities.[71] He also states that it is a problem that "to an important degree, corporate America now owns itself.”[71] Bogle describes the institutional managers’ approach in their participation in corporate governance as "docile as lambs", and that they do not wish to offend the leadership of corporations.[71] He writes that he knows of no instance personally in which a mutual fund or pension manager ever sponsored a proxy resolution that was opposed by a corporate board (a typical act that is performed as part of shareholder activism to bring a troubling corporate practice, culture, or person to accountability).[71] Bogle states that this new revolution of ownership in US corporations is "beset

by a series of profound conflicts of interest".[71] He goes on to make the following startling observation, that the current system has resulted in a "power vacuum which has been filled by corporate managers, virtually unconstrained in placing their own self-interest ahead of the long-term interests of their shareholders."[71]

In his research and commentary, Robert Monks frequently uses CEO compensation as a measure for whether or not a proper corporate governance system is functioning within a company. Monks points out that he has personally observed many instances in which CEOs are wildly overcompensated for the services which they perform. He writes that there is an observable lack of empowerment in many corporate boards which are supposed to be functioning as independent bodies that assert good governance practices on behalf of the shareholders. In addition to completely unjustifiable compensation, he also points to tremendous severance packages for CEOs who are relieved of their duties and the even more alarming fact that most CEOs are not fired for nonperformance. Monks purports that instead of creating an independent board, many board members are actually chosen to become part of the voting slates through the action of the CEO. Monks states that many support the large compensation packages for CEOs as reasonable, as some of the value comes from stock options that have been granted and are seen as part of an incentive to increase the value of the stock. In his book *Corpocracy,* Monks writes that CEO packages have become so inappropriately bloated–and accountability to the board so absent—that the system now creates some instances in which the CEO is better off triggering his or her “firing provision” than simply doing the job in such a way that ensures his or her continued employment.

Monks has written in great detail on the lack of accountability of US CEOs, and in his journal article “Redesigning Corporate Governance Structures and Systems for the 21st Century,"

he describes the gap between what most believe is occurring with CEO power and accountability and what is the "reality." A copy of a chart created by Monks, included as Appendix 4.1, describes many of the controls on CEO power that many people think exist contrasted with the reality that these executives operate relatively unchecked. Indeed, Bogle and Monks both point to legislation that was introduced to require corporations to release the details of CEO compensation packages that currently do not have to be disclosed, including information on the details of options and other types of incentives that are given to the CEOs outside of their salary.[49, 71] This measure was defeated in Congress, and Monks believes that it was largely due to the efforts of a powerful consortium of CEOs that operate as an organized group (The Business Roundtable). [49, 72] Monks sees this as evidence of the power of the few top managers of corporations operating at the expense of the corporations themselves and business interests.[49]

If CEOs need not fear retribution from corporate boards for poor governance and putting their own needs ahead of the corporation, then Adam Smith's invisible hand would indeed be unable to reach in and shape the decisions that are being made by these top stewards. In the case of issues of pharmaceutical and medical device companies, a lack of accountability can prove to be not just damaging for the corporation, but damaging to the people that are their customers. Monks and Bogle point out that the rise in large amounts of stock options given as CEO compensation has created an unfortunate emphasis on short-term value.[71, 72] In the case of pharmaceutical corporations, short-term value considerations can influence decisions that in turn can have serious consequences on the products made. These concepts will be explored further in following chapters.

Figure 4.1

Appearance versus reality of shareholder power in typical corporations

Appearance	Reality
1. Shareholders' interests are secured through the *election* of directors who protect their interests.	Shareholder action with respect to the election of directors can best be described as "coerced ratification". No matter how shareholders vote, those individuals listed on the management proxy are elected.
2. The preponderance of directors are "independent" according to the rules of the SEC, the New York Stock Exchange, the Council of Institutional Investors, GM, Campbell Soup, CalPERS and the Internal Revenue Service, among others.	Boards of directors are *self- perpetuating*. The CEO has at the least the power to veto nominees, but usually actively participates in the selection process. Membership is highly valued and those selected are conscious of benefit conferred on them.
3. Most boards have Compensation Committees, comprised entirely of "independent" directors	How can anyone be considered "independent" of someone to whom they are personally beholden?
4. Best practice requires the use of "professional" Compensation Consultants	The realities of a successful professional practice include not being perceived as insensitive to the needs of those in whose gift lies your selection.
5. The "free market" ensures that competitive factors control the levels of CEO pay.	There is no "free market" in top executive compensation. CEOs control the critical stages of the process, including government and professional accounting treatment.

Figure courtesy of Robert A. G. Monks [72]

CHAPTER 5

IS IT REASONABLE TO EXPECT TOP CORPORATE LEADERS TO BE RESPONSIBLE FOR ALL CORPORATE QUALITY?

Removing the power from owners of the corporation, *ie.* the shareholders, effectively eliminates the checks and balances that keep the tops levels of corporations in check. According to Robert Monks, the board may not operate independently or provide checks and balances when they are nominated and serve at the pleasure of the CEO. CEOs who operate without true checks from the board or the shareholders can become truly all-powerful. Monks wrote of times he has tried to introduce proxies for companies in which he owns a major share, he could get recognized to speak at shareholder meetings, much less present voting issues. Monks describes this type of CEO as an "emperor".[49]

Not all corporations are run by emperor-like CEOs some corporations have more effective governance models, such as an empowered board. An interview of Donald Rumsfeld, who has previously served as CEO, president and chairman of the board of the major pharmaceutical company G. D. Searle & Co., illustrates an interesting personal story of the power of the CEO and the ability of someone in this position to make decisions.[73] Journalist Stephen Dubner's story focused on the limitations of power on the role of the President of the United States, suggesting many of the powers the public imbues on this position do not exist in reality. Dubner asked Rumsfeld to comment on the parallels between the roles of the President and a CEO of a company:

> Well, they're really very, very different, and being good at one doesn't suggest that one would necessarily be good at the other. The political world is a thing of a

> different order because the powers are divided, a president has to spend a great deal of time dealing with the Congress and dealing with the media, because you communicate to the Congress and the public through the media. And almost anything that's proposed is going to be debated and discussed openly, immediately. In business conversely, I mean I can go into a corporation and decide that I want to freeze the dividends, and I could do it as CEO. I could decide I'm going to open a research facility in country X instead of country Y. I could decide I'm going to downsize or sell off the division, and I did it. And you can be wrong, as well as right, to be sure. But at least you were able to do it. You know in government, if we put something in place, in one of the departments or agencies, the Congress wants to have hearings on it, they want to pull the plant up by the roots every 5 min. to see if it's still growing and traumatize it, and the press wants to critique it even before it's even 15 min. old. It's enormously different.[74]

While only the experience of one CEO, Rumsfeld's account certainly supports what Monks purports: that some CEOs do not struggle very much with true interference or pressure influencing decisions that they make. The problem comes with the situation that Rumsfeld points out: CEOs can be wrong. In situations that simply deal with financial outcomes, that may be undesirable, but acceptable. In situations that negatively impact the safety of the people using the corporation's products, those mistakes may be less tolerable.

Rumsfeld served as the CEO and chairman of the board (COB) simultaneously while at Searle, so he likely would have enjoyed a great deal of automony.[75] Many scholars have pointed to positives and negatives of a divided leadership team when evaluating combining the CEO and COB. Advocates point out that a united CEO and board can accomplish great things from the synergy and elimination of needless controversy.[76] One researcher writes "while greater board involvement may increase the quality of management decisions, it may also complicate and lengthen the decision process. Consequently, board control may be advantageous under certain conditions (*e.g.*, assessing possible actions of competitors) but a hindrance in other conditions (*e.g.*, decision-making and high volatility environments)."[77] Noted corporate governance expert from the Dartmouth Tuck's School of Business, Sydney Finkelstein, also investigated this

phenomenon in 1994. He wrote of the tremendous formalized power enjoyed by a CEO who simultaneously served as COB, which he called "duality."[76] He found that duality could be a benefit in times that a corporation needs to act quickly and decisively, such as when a company is trailing competitors. He also found it could be very detrimental for a successful company, in that the CEO could become "entrenched" and unchallenged in his decision making. His empirical research concluded that the individual may also be granted large amounts of informal power, and that care must be exercised when a CEO is not checked by what he calls a "vigilant" board when making important decisions.

When analyzing who is responsible for critical decisions, it is important to understand that the person with a specific title at the top of a company may not be the actual person with the power. Many have described the complexity of trying to understand who is truly in power at the top. In 1992, Finkelstein analyzed this question empirically.[78] He points out that it is relatively simple to understand a situation where one person holds all the title, responsibility, and therefore power to make strategic choices. But he also points out that other factors come into play. He developed the following categories of "power dimensions":

Structural Power: Power that comes from formal organization and hierarchy. He measured this by the number of titles the person holds as a relational figure to the number of top managers, compensation as related to other top managers at the firm, and the number of titles (non-relational). [78]

Ownership Power: Power accrued by a manager from their "capacity as agents acting on behalf of shareholders." He measured this by the number of executive shares owned, the family shares owned (by the person's extended family), and if the person was a founder or relative of a founder. [78]

Expert Power: Manager with a great expertise in a critical component that is highly valued at the time due to challenges the organization is facing. Finkelstein analyzed this by comparing the areas in which the firm was in critical need with the number of functional areas in which the person had experience.[78]

Prestige Power: Power that comes from the manager's personal prestige or status, which others may value in association with their organization. This prestige may also give the person powerful friends and allies that help influence decisions. Finkelstein calculated power prestige based on the total number of corporate boards on which the person sat, the total number of non-profit boards on which the person sat, elite education, and the "average board rating."[78] This is the average stock rating from Standard & Poor's Stock Surveys for all companies for which a manager was an external director, or success of the corporations on which the person was a director (it is more prestigious to be on the board of a large successful corporation than a small struggling corporation).[78]

A more useful tool in examining the independence of the board would come from examining other factors. In 2004, Ryan and Wiggins published "Who is in whose pocket?: Director Compensation, Board Independence, and Barriers to Effective Monitoring" that provides an analysis of variables that are simpler to identify. Hermalin and Weisbach showed that a board becomes less effective as a governance control over time as the CEO gains more power over the board. In their model, directors will retain a CEO only if he or she is valuable to them. However, the CEO's value to the directors increases his or her bargaining power.[79] The model is that if a CEO is successful, he gains more power and longevity. The authors write that "over time, the CEO nominates new directors who are indebted for their appointments, which erodes board independence."[79] Studies have shown that the number of "outside" directors that sit

on the board are predictive of shorter tenure for their CEOs, and that when a CEO is involved in the selection process, firms choose fewer outside directors and more "gray directors (non-insiders with business ties to the firm or interlocking relationships with the CEO)."[79] Ryan and Wiggins find that companies with more powerful CEOs paid their directors less equity based pay, compensation that is sensitive to stock performance. They examine four variables that they determined could affect board independence: board size, board composition, CEO entrenchment and CEO/chair duality. Their study concludes that strong independent boards more closely correlate with the "shareholder's economic interests." Like many other studies, they find that bloated CEO compensation is evidence of entrenchment and the subsequent swelling of the CEO's power is at the expense of the board's power.[79]

Critics of systems that lack an empowered board have pointed to a lack of accountability and of proper checks and balances of the top leaders decisions.[12] Finkelstein continued his research into corporate governance but began to focus on individual decision making. In 2006, he co-wrote a book on strategic decision making in business and how the decisions of top executives can go terribly awry, titled *Think Again: Why Good Leaders Make Bad Decisions and How to Keep It from Happening to You*. Finkelstein and his co-authors, Whitehead and Campbell, systematically analyzed the types of errors in decision-making that may result in decisions with poor outcomes and then apply these to case studies of business and government failures. Finkelstein et al. studied 83 cases and coded them as to which of four types of decision making errors were involved. The case studies were based on publicly available information, but in 49 of the cases, interviews of involved parties were also conducted. The case studies were based on publicly available information, but in 49 of the cases, interviews of involved parties were also conducted. The authors indicate that they looked for cases that did not just have bad

outcomes, as in some cases negative outcomes could not be foreseen. The team looked for decisions that were flawed at the time they were made based on identifiable and known factors available to the decision maker at the time. The authors performed in-depth research into the scientific study of decision making, neuropsychology, corporate governance systems and corporate cultures to recommend measures that could be implemented to prevent such problems.

Finkelstein and his co-authors propose that there are four main sources of human decision-making error: misleading prejudgments, misleading experience, inappropriate self-interest, and inappropriate attachments. When evaluated in the context of the decision-making for an entire organization concentrated on one person's judgment, these errors can become quite significant.

The book delves into major decision making errors in non-business areas as well, including FEMA's handling of the Hurricane Katrina crisis, the Battle of Midway, and the Bay of Pigs. When evaluating Hurricane Katrina, the authors explain that the actions of Matthew Broderick, the Director of the Homeland Security Operations Center in Washington D.C. at the time delayed reporting of the breached levees to FEMA director by approximately 24 hours, thus delaying the government's actions and aid. Broderick was ordered to testify in front of Congress on this issue, and his testimony gave a great deal of information on what went wrong. The authors' analysis concludes that Broderick assumed that the hurricane in New Orleans would be similar to his experience with Florida hurricanes, but it was not. New Orleans was below sea level, which was a situation that was radically different than his prior dealings. He also had determined that the press often "overreacted" to hurricanes, based on his experience with Florida.[10] His prior military experience also led him to disbelieve sources of information that contradicted what his military sources provided, as he was inclined to believe those in military

service.[10] These misleading experiences and prejudgments resulted in terrible consequences for the people of New Orleans. This type of example helps illustrate how intelligent decision-makers can make poor decisions.

Without proper checks and balances, individual executives are left to make important decisions without proper reflection, evaluation and challenge. Decision making errors are important to understand and mitigate to properly protect the corporation, customers and stakeholders.[10] Finkelstein categorized specific error influencers, which he refers to as red flag conditions, which operate without the awareness of the decision-maker, and are therefore difficult to control.[10]

Finkelstein explains that misleading experiences are when decision-makers improperly generalize previous experiences to current issues, either because they misidentify the pattern or because they have an emotion attached to the pattern that leads to an "unsuitable action orientation." The authors describe this condition with the saying "Generals are usually fighting the last war."[10]

Misleading prejudgments are described as likely to "create distortions when we evaluate outcomes," as they lead decision-makers to commit to the wrong plans. They are also described as causing decision-makers to misjudge situations or fixate on one particular plan, often something that has worked in the past.[10]

Inappropriate self-interest and attachments are described as the most likely factors to manipulate the decision-making process, as they can subconsciously direct the decision-maker to support the wrong plan. The authors describe the situation as "it is hard to get a man to do something, when his salary depends on his not doing it." This factor is of the most concern when evaluating decisions that affect the quality of pharmaceuticals and medical devices, as many of

the decisions that deal with quality may adversely impact the immediate bottom line of the company. Examples include stopping sales of a product with quality problems, slowing down production to allow quality problems to be fixed, or reporting quality problems or side effects associated with a particular drug or device. All of these may have a short-term negative impact on the finances of the corporation and may be difficult decisions to make if the decision-maker is focused strictly on short-term finances.[80] Finkelstein points that humans will cheat if they perceive it will go undetected.[10] Dan Ariely, described this phenomenon in his book *Predictably Irrational*.[81] Ariely conducted a study to evaluate the propensity to cheat as correlated to threat of detection. He gave students a 50 item multiple choice test and then asked the students to transfer their answers from a worksheet to their scoring sheet.[81] The students were paid a small amount for each correct answer.[81] Ariely broke the students into different groups and gave the groups different opportunities to cheat. For example, one group had the correct answers given on the score sheet; therefore, the students could see if they missed the question and choose to fill in the correct answer instead of the incorrect one. Ariely found that the scores of the students who were allowed to cheat went up in a statistically significant way. What Ariely found the most interesting was that the results showed that it was not just a few people who cheated "a lot" but rather that most students cheated "a little".[10] Unfortunately, some cheat a bit more. For example, many blame corporate accounting scandals such as Enron, Worldcom and Globalcrossing on the fact that the top executives of these firms focused on stock options and attempted to preserve the value of those options at the expense of the proper governance of the firms.[82]

Stock options tie the manager's compensation and gains to the gains of the owners. Options also promote risk in managers, so that the manager will not avoid risk to keep his or her job. In business, most large gains require some level of risk.[83] Shareholders typically prefer risk-

taking CEOs because financial economics correlates risk with the size of returns. Sanders and Hambrick studied the types of risks that CEOs may take in business and evaluated the desirability of those risks by their outcomes. Sanders and Hambrick define risk as “the degree to which potential outcomes associated with the decision are consequential, vary widely, and include the possibility of extreme loss."[82] They explain that consequential refers to the ability of the event to positively or negatively alter the "health and vitality" of the corporation. The authors find that stock options encourage CEOs to invest more heavily in some "uncertain" categories, such as R&D, capital expenditures, and acquisitions.[82] They find that the stock options tend to result in more extremes in the corporation's performance, such as big wins and big losses. Most interestingly, the authors conclude that CEOs with large amounts of options delivered more big losses than big wins.[82]

In cases of pharmaceutical companies, this could be of great concern. For example, in 2004, Merck withdrew its blockbuster drug, Vioxx, for treatment of rheumatoid arthritis from the market due to an increase in the risk of cardiovascular problems in those who took the drug over other drugs in its category. It is estimated that over 38,000 people in the United States may have died from taking this drug. Slowly it was revealed that Merck began concealing information that the drug had negative cardiovascular effects as far back as 1996, when Merck scientists reportedly asked academic researchers to alter the wording of their results, which provided information on the possible risks, on a Merck-sponsored study of the drug.[84]

Since the early development of rofecoxib, the active ingredient of Vioxx, some scientists at Merck worried that the drug might adversely affect the cardiovascular system by altering the ratio of prostacyclin to thromboxane, which act in opposition, balancing blood flow and clotting. A study sponsored by Merck during 1996-97 reported that rofecoxib reduced urinary metabolites

of prostacyclin in healthy volunteers by about half. In internal emails made public through litigation, Merck officials sought to soften the academic authors' interpretation that cyclo-oxygenase-2 (COX 2) inhibition within the vascular endothelium may increase the propensity for thrombus formation, the basis of what became known as the FitzGerald hypothesis.[84] The academic authors changed the manuscript at Merck's request—for example, they changed "systemic biosynthesis of prostacyclin ... was decreased by [rofecoxib]" to "Cox-2 may play a role in the systematic biosynthesis of prostacyclin."[84] To the authors' credit, they continued to investigate the effects of COX 2 inhibition and ultimately provided much of the basic science knowledge that clarified the pathways by which rofecoxib probably leads to cardiovascular events.[84]

Even more egregious, internal records and emails released during the ensuing litigation against Merck showed that top Merck officials attempted to silence medical critics of the drug who brought up the potential cardiac side effects.[85] Vioxx was withdrawn after an FDA employee acting independently raised the alarm about the risk of Vioxx.[86]

Inappropriate attachment refers to the situation in which the decision-maker is overly emotionally attached to the corporation, product, or even unit that is involved in the decision. Examples include when a founder of a company makes unethical decisions to keep it afloat due to his pride and love of the entity rather than the money that it produces, or flawed decision-making in evaluating scientific data by the researcher who discovers a therapeutic compound—again due to the personal attachments of the individual to the object of the decision. Finkelstein also writes that this attachment may result when managers treat their part of a business as their personal "fiefdom" and become personally identified with the amount of capital expenditures or

success of their division.[10,87] This could also be a factor involved in the failure to properly deal with negative information, such as in the case of Vioxx.

There are critics of regulators who hold one top official, such as the CEO, strictly accountable for what happens on their watch. Jesse Vivian, an RPh and JD, wrote an article on the FDA's prosecutions of pharmaceutical executives for marketing their drugs for off-label uses. Vivian quotes Jackson Nickerson, a professor of organization and strategy at Washington University, as criticizing the FDA's prosecution of top executives as an example of "overregulation." Nickerson is quoted as saying "It's predicated on the assumption that if a company has done something wrong, it must mean that the senior executives have done something wrong. You are branded as being unethical if a subordinate makes a decision that turns out to be a bad one."[88] Bragg, Bentivoglia, and Colllins develop this position further in their work "Onus of Responsibility: The Changing Responsible Corporate Officer Doctrine."[17] These authors present several arguments against strict liability, including that a CEO who attempts to do things correctly could be unfairly implicated in the actions of subordinates. This could happen if regulators did not carefully select which situations warrant this type of prosecutorial pursuit. As the authors point out, *Park* and the sanitation cases that utilized the RCO doctrine involved misconduct on the part of the defendant, in that they knew that problems existed at their firms and did not take adequate steps to ensure that that they were corrected. This should not become the sole standard, as it may encourage top officials to engage in willful blindness where an official actually discourages subordinates from bringing problems to their attention if the problems involve regulatory or quality failures. The language of the *Park* decision said that Congress had imposed on responsible corporate officers a "positive duty to

seek and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations do not occur."[38]

This position would be more defensible if there were not simple mechanisms that executives can put into place to ensure that serious GMP and other FD&C Act violations do not occur—if they are empowered to do so. The recommendations on how a CEO, chairman of the board or other empowered official can avoid serious violations at their firm will be covered in a later chapter.

CHAPTER 6

CASE STUDIES: EVALUATION OF FDA INJUNCTIONS/CONSENT DECREES AND SUBSEQUENT CEO TURNOVER

Background on FDA Injunction Actions

When the FDA encounters what it defines as "continuing noncompliance" it may elect to pursue judicial remedies. Typically the agency will at first attempt to bring a violative firm into compliance by first pursuing advisory actions, including regulatory meetings and “Warning Letters”, although this is not a legal requirement.[40, 89] A regulatory meeting is when the agency asks the management of the company to come in to a district office or in multidistrict cases to The Center for Drug Evaluation and Research (CDER).[90] A regulatory meeting may be classified as either a “Voluntary Action Indicated” (VAI) or “Other Action Indicated” (OAI) in the FDA establishment inspection tracking database, FACTS.[91] If the district and CDER agree that the violations warrant, then a Warning Letter may be issued, which is considered always "Official Action Indicated” as a classification.[91] This is an official letter issued by the FDA which notifies the firm that significant violations have been found and often includes wording that the firm's propose corrections have not been sufficient and that the firm should take corrective actions were the agency may take further actions such as seizure, or injunctions without further notice.[89] The warning letters typically include wording that it is the responsibility of the firm to review their own practices and procedures and ensure that they are in compliance with all regulatory requirements.[89] FDA also has the ability to pursue administrative actions, depending on the type of category of some products.[90]

When the FDA determines that advisory or administrative sanctions have not been effective in achieving voluntary corrective actions by a company, or if the findings are serious enough without prior administrative or advisory actions, the agency may pursue judicial remedies.[40] In order for the FDA to pursue an action in court a case must be filed by the Department of Justice on behalf of the FDA. In cases of repeat violations of Good Manufacturing Practices the agency may seek civil court oversight by filing a Complaint for Injunction, as specified in 21 U.S.C. 332; Rule 65, Rules of Civil Procedure. This action represents FDA in court to stop or prevent a violation of the law from occurring.[40] The Complaint often contains specific requests to compel the firm to comply with FDA regulations and ensure proper oversight. The complaint may include some of the following:

- Requests for third-party audits, oversight, and certification to ensure that the firm is now properly complying with GMPs.
- Request that the third-party auditors or consultants supply reports directly to the FDA, so that information can be received directly and not be redacted by the company in question.
- Requests that manufacturing lines or entire facilities be shut down until they are brought into a state of compliance.
- Request that specific products be recalled
- Request that the firm pay costs associated with reinspection, and/or other specific financial provisions

Most injunction cases filed by the FDA result in a negotiated consent decree, a formal settlement agreement filed with the court. This is reflected in the outcomes of the case studies. The FDA

usually includes individuals by name in the complaint who are deemed to be in responsible positions in the corporation. According to the FDA's Regulatory Procedures Manual:

> Although there is no legal requirement to name individuals in complaints for injunction, the agency believes that by doing so, individuals not named in the complaint will be more inclined to prevent violations from occurring in the first instance (general deterrence) and that named individuals will be more inclined to take immediate and active interest in seeing that the violation ceases (specific deterrence). Also, the identification of the responsible persons will prevent their pretense that they were not subject to the injunction, and will help prevent circumvention of the injunction by changing the name of the corporation. Therefore, the individuals who have the authority and responsibility to correct or prevent the violations should be named as defendants.[40]

FDA compliance officers and attorneys are encouraged to identify individuals that hold responsible positions within the enjoined companies to name personally. In some cases CEOs are named in the original complaint for injunction. The naming of individual CEOs in the complaints indicates that they are deemed to be accountable for the failures in the firm's compliance and quality management systems that allowed the continuing and/or serious cGMP violations to occur.

The question to be answered in this research is there any corresponding disciplinary outcome for the CEO personally, other than being publically named in the complaint filed with the court. Negative outcomes for an individual would be defined as involuntary or forced

departure, a performance-based lowering of salary, bonus, or other form of compensation; or any other reported censure of the individual in question.

The case studies focus on CEO turnover and not executive compensation. A literature review revealed difficulties associated with studying CEO compensation as related to performance. Studies have shown in many cases it is decoupled with performance measures, although some of the specific indicators have given mixed results.[92] More importantly, although some aspects of CEO pay are now openly reported, there are still many other "hidden" forms of CEO compensation that are unreported or difficult to calculate.[93] Finkelstein reports CEO compensation structures can even be misleading.[78] It has also been found that CEO compensation and correlation with performance can be altered by the type of ownership structure of the firm. Research has shown that firms that have an identifiable owner of as little as 5% of the shares reflect different levels of controls than those that don't, including in the area of CEO compensation.[94] Firms that lack a single equity owner, known as management controlled firms, tend to pay CEOs more and the pay is less correlated to firm performance.[94, 95]

CEO turnover has also not been shown to be predictably correlated to performance, in that some studies have shown correlations to performance measures that other studies do not.[96] Brickley in 2003 performed a review of much of the literature on CEO turnover to date, and concluded that the many different studies attempting to correlate CEO turnover to measures firm performance was inconclusive and of little predictive value.[96] Brickley found that the most positive and significant correlation to CEO turnover was that increasing age of the CEOs age, and not performance based variables.[96] Brickley did note that performance related CEO turnover was more possible in smaller firms than in larger ones.[96] Lehn and Zhao found, however, performance-related CEO turnover was correlated to CEO decisions to acquire other firms that

have poor financial outcomes.[97] Their findings indicated that this correlation was independent of the type of ownership structure present in the acquiring firm.[97] The authors proposed that this was an appropriate disciplinary action under these circumstances, as a bad merger can prove to have serious financial penalties for the acquiring firm.[97]

No studies could be located that examined the impact of FDA injunctions on the determination of CEO performance. Many studies have attempted to examine the correlation of CEO performance as measured by financial and economic measures. For issues not related to financial outcomes, the research is sparser. No research could be located on CEO turnover as correlated to FDA injunctive actions. The purpose of these case studies is to determine if there is market based or internal governance forces that may result in CEO turnover in cases of FDA noncompliance as indicated by the filing of FDA injunction actions. The specifics of the research questions will be specified below.

Research Questions and Method

This research utilizes the case study method to test the research questions. Case studies are valuable when the unit of analysis is at the organizational level and when experimental design is not critical.[97] The general procedure for conducting case study research is to select a sample set of cases relevant to the research questions, create a coding system for qualitative information to be studied so it can be quantified, and the use of multiple raters to code the cases so that greater reliability can be assessed. The final step is to perform statistical analysis on the data that has been coded.[98] In this case, the use of multiple raters is not necessary due to the simplicity of the hypothesis question, and the lack of subjectivity in the collection of the data to be reported. This will be further examined in the method description below.

Hypothesis 1: *Chairman of the Board and CEO's of medium and large corporations will not be removed from their position by the firm's Board of Directors as a primary result of costs and negative outcomes of an FDA injunction filed as a result of violations of Good Manufacturing Practices*.

Medium and large corporations for this study will include any corporation that is not defined as small in the methodology described below. Since many forced departures of CEOs may be announced as voluntary, any CEO departure that is announced within two years of the FDA action and does not meet the criteria of exclusion in hypothesis to will be coded as possibly related to the action. This is to prevent the subjective evaluation of CEO departures and the associated announcements for determination of cause.

Performance related financial sanctions: Other sanctions that may occur in lieu of CEO departure may be anecdotally included for additional information purposes. Performance related sanctions will include loss of merit salary increases the following year, reduction of bonus based on poor or nonperformance, or any other salary reduction that is not tied solely to the financial performance of the firm.

Definition of a turnover event: Departure of the chairman of the board or CEO within two years of the month and year of the FDA action will be considered potentially involuntary if the CEO is 64 years or under, unless the departure is related to death or illness. CEO retirement is much more common over the age of 64, and is used in other CEO turnover studies as a cutoff point. If the CEO is above 64 and announces retirement, it will be reported as CEO turnover but potentially retirement related. Business journals and press were reviewed for any performance

related factors that could be related CEO retirements of those above 64 that may indicate it was an involuntary retirement, in which case the coding will be classified as involuntary to cover the possibility. This is consistent with other classification schemes studying forced or voluntary (unforced) CEO turnover.

Hypothesis 2: *Those in CEO and chairman of the board positions at the time that the violations occur will most likely stay in power unless other specified conditions, that are not related to product quality, occur that may cause leadership changes. These conditions are the company being acquired were taken over by another company; serious poor financial outlooks by a analysts for reasons other than the decree, such as negative announcements about the firms R&D efforts/drug pipeline; the filing of criminal charges by FDA or another agency or charges filed by the securities and exchange commission for serious violations.*

When a company is merged with or acquired by a larger company, typically the CEO and chairman of the board will not serve as the top executives for the merged entity. While they may receive a position or title with the new company, it will not be at the same level as their prior position.

PFO: *Poor financial outlook by analysts for reasons other than decree, such as drug pipeline.* When CEO turnover occurs, a review of business trade press will be performed to determine if the turnover was linked to poor pipeline and new drug development. A search will be performed of major business information sources, including Wall Street Journal, Fortune and Forbes.

CC: *Criminal Charges filed, regardless of agency.* This information was obtained from a search on Lexis.com and other sources.

SEC*:* *Charges filed by SEC.* This information was obtained from searches of Lexis.com and other sources.

MT: *Merger/Takeover.* This information was obtained from searching business press trade sources.

Time Periods for Evaluation: For the purposes of this research, the top executives for each case study were reported for the time period five years prior to the filing of the consent decree/injunction ("action"), the time of the action, and 2 years after the action. The time periods will be coded as below:

Time of FDA action ($T_{FA)}$ – 5 years = Pre-action Time (T_P)

FDA Action Time-T_{FA}

T_{FA+} 2 years = T_{PFA}

The time preceding the action, ($T_{P)}$ was examined as injunctions are not filed unless continuing noncompliance is observed over several years. The responsible party for non-compliance would likely be presiding over the company in the time period before the action is filed. This information was collected for supplemental use. The five year period also to allows for the administrative lag time between the observation of the continuing noncompliance and the preparation and review of the case within FDA, the review of the FDA case with the Department of Justice (DOJ), and the subsequent filing of the case by DOJ.[40] This is the not utilized in the definition of reported turnover as this research is seeking turnover related to the consequences of the injunction being filed, which could not occur prior to the filing of the action.

Sources included were SEC filings obtained through Thomsons One and Wharton's Data Research Services databases for publically traded firms. For private companies, Dun & Brandstreet were utilized. Companies that do not list size in any of these research databases or directories were considered to have fewer than 500 employees.

Definition of a Turnover Event: A CEO turnover event that may be related to direct effect of the FDA action and associated fines will be defined as when a CEO or COB leaves for any reason, other than death or illness, within the Post-action Time period. The other potential associated causes were reported, coded and evaluated for potential greater relation to the turnover event.

Sample

This research examined all injunctions that the FDA filed against pharmaceutical corporations that are not small businesses, for violations of FDA Good Manufacturing Practices for the past 20 years.

Determination of Small Business - Small businesses are different in several ways from larger companies in ways that might present skewing information for the purposes of this study. Small businesses have ownership structures that may be more closely involved in the governance of the firms than large companies.[99] Small businesses also have different resources and capabilities than larger firms, and are described in academic literature. Please refer to Lepoutre and Heene's 2006 critical review of organizational characteristics of small businesses.[99] This research is interested in the impact of separation and diffusion of corporate ownership and the potential impact of this on accountability of top leaders. Therefore, this research excluded firms that are defined as small businesses.

The FDA Safe Medical Devices Act of 1990 and the Small Business Innovation Development Act of 1982 both define a small business as having no more than 500 employees including affiliates.

The Small Business Administration utilizes the number of employees as the sole criteria for classification of firms in the pharmaceutical manufacturing sector. The SBA methodology for determination that a business may qualify as a small business is usually based either solely on the number of employees, or the annual receipts of the firm. The agency prefers to use number of employees for manufacturing-based industries, and justifies this in its white paper titled "Size Standards Methodology", published April 2009.[100] The agency acknowledged that annual receipts are an easier measure to obtain, since they are usually available through tax returns and financial reporting documents.[100] SBA preferred to use the value of using number of employees for many sectors as it less likely to give skewed results.[100] Current SBA standards set specifications by the North American Industry Classification System (NAICS) code into which a firm falls. The most recently published standards showed that NAICS code 325412, Pharmaceutical Preparation Manufacturing, is allowed 750 employees or less to be qualified as a small business entity. In-Vitro Diagnostic Substance Manufacturers, NAICS CODE 325413, is allowed 500 employees or less to be qualified as a small business.[101]

This research used the more conservative number of employee standard, 500 employees or less, as the size criteria for determination that a firm is a small business. The number of employees was determined based on data available through the Thomson One database. Smaller companies were not included in this database, and other searches may be performed. If a company did not have employee numbers listed in Thomson One, Dun & Bradstreet or other references, it is not likely to be large enough to meet the criteria.

A review of trade and business publications and government official reports revealed approximately 30 FDA consent decrees and or injunctions that could potentially be pharmaceutical companies. Each FDA action was reviewed to determine if the action was based on pharmaceutical manufacturing violations. If the industry could not be determined, then the company was investigated to determine if the charges were related to pharmaceuticals, or another sector of the business, such as products regulated by the industry as medical devices, such as IVDs, or biologics, such as plasma derived products.

In order to be included in the study, information must be publically available about CEO turnover for the firm, a requirement used in other CEO turnover studies.[76] The main sources of CEO turnover information were SEC filings, company reports, newswires, and industry trade publications. Searches were conducted of company reports and proxy statements using Wharton's Data Research Services, Thompsons One and Lexis-nexis.

Reports of the filing of FDA injunctions or consent decrees were obtained by reviewing DOJ press releases, FDA announcements, newswires, SEC filing, industry trade publications and business news sources. Once a report was located of the FDA action, a copy of the DOJ filed a complaint or decree was obtained through the Lexis-nexis or DOJ sites.

A review of trade and business publications and government official reports revealed approximately 30 FDA consent decrees and or injunctions that could potentially be pharmaceutical companies. Each FDA action was reviewed to determine if the action was based on pharmaceutical manufacturing violations. If the industry could not be determined, then the company was investigated to determine if the charges were related to pharmaceuticals, or another sector of the business, such as products regulated by other FDA centers such as in vitro

diagnostics which are classified as medical devices or plasma derived products, which are regulated as biologics.

The firms that met the criteria were then evaluated for size at the time of the consent decree, and removed if they met the study definition of small business. The sample set resulted in a 14 firms to be included in the case study review. The turnover of the parent corporation will be examined, as the parent firm may control decisions such as cost cutting, outsourcing and offshoring and other key decisions.

Empirical Results

Sample Descriptive Statistics

CEO and COB Turnover

The parent corporation for each firm was determined, as the study was most focused on the ultimate responsibility. The results of the subsidiary and the parent corporation are listed in Table 6.1. For each of the 14 firms, the chief executive officer and chairman of the board were determined for each of the defined time period. Of the 14 cases, 5 did not experience a Turnover Event (TE). Of the cases experienced a TE of the CEO or the chairman of the board, or both, as shown in Table 6.1, five experienced a TE of both positions, two companies experienced a turnover event of the chairman of the board position only.

Descriptive Statistics for Turnover Events, by Potential Causes

Of the nine firms that experienced a turnover event the following cause cases were assigned as potentially associated with the executive's departure:

Mergers & Acquistions: Mergers and acquisitions were considered the primary cause of two CEO/CB turnovers. One of the acquisitions was deemed as financially positive (Genzyme being acquired by Sanofi). The other acquisition, the purchase of Schein Laboratories by

Watson, was considered partially prompted by the financial difficulties that Schein was encountering since the FDA action.

Pipeline: Pipeline was mentioned as one of the contributing factors in the turnover event of two of the nine, or 22% of the TE group. The first was Schering-Plough, as the FDA consent decree delayed the approval of one of the firm's products. Analysts indicated it may have contributed to that product's trouble in getting market traction. Poor pipeline outlook was cited less strongly as a factor in the TE at GlaxoSmithKline.

Criminal Charges: Criminal charges and associated additional enforcement measures taken by DOJ were contributing factors to the CEO, Marc Hermelin, stepping down in the case of KV pharmaceuticals. He remained on the board of directors and the chairman of the board, Terry Hatfield, resigned in protest. Hatfield, was considered a turnover event as chairman of the board, but was not due to his involvement of activities that resulted in criminal charges being filed. Hermelin did not resign from the board until DOJ disbarred him from participating in any future dealings with companies that sell healthcare products to the US government. J&J pled guilty to criminal charges filed by the SEC for Foreign Corrupt Practices Act violations, please see Chapter 7 for further explanation.

SEC Charges: SEC filed charges against three of the companies that experienced CEO/COB turnover, or 30% of the turnover sample. In one case, of the CEO/COB of Elan, the accounting inaccuracies that occurred under his tenure were described as quite serious. In the case of Schering, the CEO/COB was charged personally with SEC violations related to his disclosure of poor quarterly earnings results to selected analysts, portfolio managers and institutional investors, according to the SEC settlement documents. These individuals represented Schering's largest shareholders. The executive resigned after the charges were filed.

The SEC did file charges against Johnson & Johnson (J&J), but for violations of the Foreign Corrupt Practices Act (FCPA). April, 2011, DOJ and SEC announced a $70 million settlement agreement was reached with J&J surrounding charges that DePuy, a J&J subsidiary that manufactures surgical medical devices made illegal payments to Greek and Iraqi officials to ensure that their products entered those marketplaces in lieu of products made by their competitors.[102] The government claims that the illegal payments to Greece started prior to J&J's acquisition of DePuy, but once discovered, J&J officials consciously decided to continue the payment program.[102] Previously, in January, 2010, DOJ charged J&J with paying kickbacks to Omnicare Incorporated, the largest nursing home pharmacy in the United States.[103] This case was developed after two whistleblowers came forward with complaints involving these violations, which were of the False Claims Act.[103]

Duality of the CEO Position

One interesting result is of the 14 cases of FDA filing an injunction/consent decree for serious non-compliance with cGMPs, 12 of the 14, or 86% demonstrated duality of the leadership positions, ie the CEO and the COB were the same person. CEO duality is varies in prevalence according to industry. For example, it was found to be around 56% in the printing and publishing sector, 51% in computer firms and as high as 72% in chemical firms in the early 1990s.[76] Some have reported rates as high as 75% in general categories.[104]

The analysis of the reported Turnover Events (TE) is reported in Table 6.2. Other associated causes are coded and reported in this table.

All of the turnover events were strongly associated with one of the coded reasons, with the exception of one. This case involves the departure of Wyeth's chairman of the board/CEO,

who left within the turnover with none of the coded factors strongly associated. The departure was strongly associated, however, with a major settlement paid relating to health problems resulting from the use of the "Fen/Phen" combination.

Limitations: This study cannot draw comparative conclusions between firms that were the subject of FDA injunctions and those that did not, since the study was not comparative. The general rate of CEO turnover is estimated by other researchers. The primary cause for CEO turnover cannot be completely known, and is subject to speculation by outside analysts. The review of reports regarding CEO departure are subjective, and do not always reveal all the reasons for the departure.

The results have shown that CEOs do not experience performance related turnover unless other factors are involved such as SEC charges (22%), mergers or acquisitions (22%), or the filing of criminal charges by FDA or another agency (22%). Of the 14 cases of FDA injunctive actions in the study, only one CEO was turned over without the predefined concurrent causes present, or 7%. This research concludes that CEOs would not likely view the filing of an FDA injunction as a potential threat, since turnover is one of two potential performance related sanctions. The other sanction is rarely used, as CEOs are rarely financially penalized for performance related problems, as has been shown in other’s research. This work shows that chairmen of the board experienced even less performance related turnover than the CEO position. All COB turnovers were related to non-performance related retirement or because they were joint CEO/COB who experienced one of the concurrent causes.

Table 6.1

Analysis of CEO/COB of Parent Company

Most Responsible Firm	Action Date (Ta)	CEO or COB	Tp (Ta-5)	Ta	Tpa (Ta + 2)	Turnover Event
		CEO	Allen Chao, Ph.D.	Allen Chao, Ph.D.		
Watson	2002	COB	Allen Chao, Ph.D.	Allen Chao, Ph.D.	Allen Chao, Ph.D.	
		CEO	Richard Jay Cogan	Richard Jay Cogan	Fred Hassan	X
Schering	2002	COB	Richard Jay Cogan	Richard Jay Cogan	Fred Hassan	**X**
		CEO	Henri A. Termeer	Henri A. Termeer	David Meeker	
Genzyme	2010	COB	Henri A. Termeer	Henri A. Termeer	Christopher A. Viehbacher	X
		CEO	Melvin R. Goodes	Melvin R. Goodes	Melvin R. Goodes	X
Warner Lambert	1993	COB	Melvin R. Goodes	Melvin R. Goodes	Melvin R. Goodes	
		CEO	Bill Weldon	Bill Weldon	Alex Gorsky	
Johnson & Johnson (McNeil)	2011	COB	Bill Weldon	Bill Weldon	Bill Weldon	X
		CEO	Malvinder Singh	Joji Nakayama	Joji Nakayama	
Ranbaxy /Daiichi Sankyo	2012	COB	Malvinder Singh	Takashi Shoda	Takashi Shoda	
		CEO	Martin Sperber	Martin Sperber	Allen Chao	X
Schein (Steris Labs)	1998	COB	Martin Sperber	Martin Sperber	Allen Chao	X
		CEO	John R. Stafford	John R. Stafford	Robert A. Essner	X
Wyeth Ayerst	2000	COB	John R. Stafford	John R. Stafford	Robert A. Essner	X
		CEO	Donal J. Geaney	Donal J. Geaney	Kelly Martin	X
Elan	2001	COB	Donal J. Geaney	Donal J. Geaney	Garo Armen	X
		CEO	Israel Makov	Schlomo Yanai	Schlomo Yanai	X
Teva	2009	COB	Eli Hurvitz	Eli Hurvitz	Philip Frost	X
		CEO	Marc Hermelin	David Van Vliet	Gregory Divis	X
KV Pharmaceuticals	2009	COB	Marc Hermelin	Terry Hatfield	none named	X
		CEO	Jean Paul Garnier	Jean Paul Garnier	Andrew Witty	X
Glaxo Smith Kline	2005	COB	Sir Richard Sykes	Sir Christopher Gent (non-executive chairman)	Sir Chistopher Gent (non-executive chairman)	
		CEO	Dilip Shanghbi	Dilip Shanghbi	KalyanaSundaram Subramanian	X
CEO Sun Pharma (Curaco Pharmaceutical Laboratories)	2009	COB	Dilip Shanghvi	Dilip Shanghvi	Dilip Shanghvi	
		CEO	Allen Chao.	Paul Bisaro	Paul Bisaro	
Actavis Totowa	2009	COB	Allen Chao	Paul Bisaro	Paul Bisaro	

Table 6.2

Concurrent Causes of CEO/COB TE

Causes of Turnover									
Most Responsible Firm	**Action Date (Ta)**	**CEO or COB**	**M/A**	**PP**	**CC**	**SEC**	**Death or Illness**	**Resigned in Protest**	**FDA C/D Turnover**
Schering	2002	CEO/CB (same)		X		X			C/D influenced PP and SEC
Genzyme	2010	CEO/CB (same)	X						No
Johson & Johnson (McNeil)	2011	CEO (stayed on as COB)			X	X			No (see case) .
Schein (Steris Labs)	1998	CEO/CB (same)	X			*			FDA C/D contributed ot the firm's need to merge
Wyeth Ayerst	2000	CEO/CB (same)							Yes
Elan	2001	CEO COB				X			
Teva	2009	CEO n/a COB					X		N/A (death)
KV Pharmaceuticals	2009	CEO COB			X X			X	No - Resigned in protest.
Glaxo Smith Kline	2005	CEO COB							Doubtful. Claimed to be linked to poor financial outlook, excessive pay, and problems related to Avandia.
CEO Sun Pharma (Curaco	2009	CEO/COB							CEO stayed on as COB, not reported as related to FDA

CHAPTER 7

COSTS AND QUALITY

Who determines if there are sufficient funds today? Does a plant manager, a division CEO, chief operating officer, chief financial officer? If the quality control people do not believe they have the resources, whether it is a new tool, advanced technology in the production line or actual personnel, how is that done today so that we can know that those cost efficiencies are not being looked at by somebody far away and too many chains between them?

Darrell Issa, Congressional Hearing, McNeil

But I think that the regulatory environments have become somewhat risk averse, if you will, in trying to find out everything. And usually with patients, many times you don't find everything out because of the way somebody may use a product or what not. So, I think that it is in the area of cost control. I think that it is in the area of regulatory -- they are probably the two biggest. No matter where you look in the world, there are barriers that we have to overcome.

William Weldon, CEO Johnson & Johnson 2005 (In answer to the question "What are the major challenges facing drug and healthcare companies, both in the U.S. and abroad?")

There are often economic benefits that corporations realize when making investments to improve their quality management systems. However, many researchers have studied and recommended cost cutting measures such as outsourcing, offshoring, layoffs, and plant closures as a means to increase economic benefits for shareholders. But these well-established and often recommended business practices may have an adverse effect on the firm's compliance with cGMPs. This chapter will examine the financial pressures that lead to cost-cutting in the pharmaceutical production sector and the impact of these measures on quality management. In addition, this chapter will explore the presumed "costs" of low quality which may not be as visible or widely considered in the pharmaceutical industry as they are in other sectors.

In the 1950's, Juran first published his influential work examining the economic benefits of improving quality, which he defined as the failure of a product or component to meet specifications.[3] As part of his conclusions, he described a model that he defined as the "Cost of Quality" (COQ).[3] Juran's model held that the relationship between the costs of poor quality products (internal and external) and the cost of achieving output of quality goods (appraisal and prevention costs) both escalate as overall quality goes down. This model has been refined over time to reflect some standard defined terminology. "Internal failure costs" refers to the costs associated with defects that are found prior to the product's release.[3] "External failure costs" are those associated with problems detected after its release to the marketplace. "Appraisal costs," also referred to as inspection costs, are costs incurred to evaluate the degree of conformance to specifications for quality prior to release. "Prevention costs" are those costs that are incurred in an effort to prevent quality failures, and could include education, training and auditing. Subsequent models, which are described in a critical research review by Plunkett and Dale, have included many other costs that can be considered related to quality.[105]

This chapter will explore factors of traditional COQ models that do not apply to some pharmaceutical manufacturers. Costs associated with quality failures or low quality, such as the cost of recalls, the cost of reworks or scrapping in process failures, have been widely studied and analyzed for decades.[105] Many quality management researchers assert that it makes good economic sense for a company to invest in quality systems in order to save money in the long run due to loss of market share and higher production costs. But most of these models operate with the basic assumption that the customers themselves can assess the quality of the product and make purchasing decisions based on the perceived quality.[105] Another assumption is that the manufacturer would have to recall and possibly replace poor quality products, thus incurring

additional costs from this activity. The external costs are typically more expensive since quality failures discovered externally can negatively impact customer retention.[106] Observed differences in the ability of the customers to switch to other firms' products will be discussed below, as well as difficulty for the customers to detect product quality failures.

A CEO that comes from another industry and takes over the helm of a large parenteral pharmaceutical manufacturer is faced with an interesting dichotomy: the products being manufactured require the highest level of quality assurance possible in order to safeguard the health of its customers, but once the product is approved there is no market reward for having a higher quality product than that of your competitors. The underlying factors of this statement are described by Janet Woodcock and a co-author in the 2012 published work "Economic and Technological Drivers of Generic Sterile Injectable Drug Shortages".[107] Woodcock, current director of the FDA Center for Drug Evaluation and Research, analyzed the potential economic and market causes of the many shortages that were occurring in the supply of generic drugs in the United States.[107] The majority, 56 percent, of all drug shortages in 2011 were caused by quality management problems at the finished dosage from manufacturing facilities, as opposed to other complications such as active ingredient supply chain problems. Woodcock asserts that the hospital and clinics who purchase injectable drugs assume that all FDA approved drugs that are on the market are essentially equal.[107] Based on this assumption, price is the only distinguishing factor on which the buyers representing healthcare facilities are making their purchasing decisions.

If the drug's price is the only purchasing determinant, then manufacturers are given no incentive from the marketplace to invest in quality improvements, as might occur in market situations where quality can be evaluated and rewarded by customers.[107] To complicate the

situation further, when quality problems do occur with injectables in the United States, few healthcare providers suspect that a commercially manufactured drug could be the cause of a patient's negative outcome.[107] Many adverse events, such as infections or variations in response to a medication, are common in a sick or hospitalized population. Even in the case of over-the-counter products, someone would not know if the lack of intended therapeutic effect of a drug is due to a quality problem or the normal variability of human-drug interactions. Even if a practitioner or customer suspects drug quality problems, it may be very difficult to tell if some issues, such as potency variation, occurred during manufacturing or handling after release.[107]

Woodcock points out that the FDA may no longer be able to simply shut down plants that do not demonstrate adequate levels of quality due to the ongoing and serious drug shortages of medically necessary drug products.[107] Plants that previously would have been the subject of an injunction and immediate closure now must stay open and work with the agency to mitigate quality problems while production is ongoing.[107] Woodcock states that the use of "regulatory flexibility" could have unintended consequences when coupled with a marketplace that does not necessarily discern or reward quality. She cites the cases of many generic injectable plants, where there is a lack of investment in the manufacturing lines and facilities.[107] Some of the plants that have been involved in the majority of drug shortages have been in operation continuously since the 1960s and have not had any major upgrades since.[108]

Woodcock states that executives who run sterile pharmaceutical companies are responsible for making decisions on many critical issues such as equipment, materials, maintenance, staff qualifications, supervision, process control and investigations into problems that can impact the confidence of sterility. Executives may make many other decisions that negatively impact quality as well. These include decisions on whether or not to outsource

production to contractors, offshore production plants, add new products to existing lines, or even simply shift the cultural empowerment of the quality unit towards production, which can significantly impact the compliance of the company in a negative way. These factors will be examined further below. Complicating the decision making of top pharmaceutical executives even further, much greater weight is placed on research and development in pharmaceutical companies than other industries. New product development is critical and competes for funding with other parts of the company. For companies that rely on developing new drug products (as opposed to generics), it is crucial that they develop new drugs to patent as their existing drug patents expire. Pharmaceutical manufacturers tend to spend far more on research and development than other most other types of manufacturers[109] Reportedly, R&D budgets have gone up since 1999, but the corresponding increase in the release of new drugs has not occurred commensurate with the spending.[110] In order to sustain the double digit growth that pharmaceutical companies have enjoyed over the last decade, it will be necessary for many new molecular compounds to be discovered. However, current trends do not support the same levels of successful discoveries going forward.[110] The insufficient completion rates of bringing new products to market, combined with the aging and expiry of patent exclusivity for many current products, has created a condition that some refer to as the "patent cliff".[111] The amount of promising new products in the more promising stages of the development process is referred to as a company's drug pipeline, and the contents of those pipelines receives a great deal of attention from investors.

The value of a pharmaceutical company is greatly influenced by how many new drugs are in the pipeline and development, and mathematical evaluations of the firm's profit margins.[112] FDA findings of serious non-compliance with cGMPs does not have a similarly direct impact on

a company's value, as reported anecdotally in some trade press accounts. For example, industry experts noted that despite the fact that the FDA filed an injunction against Genzyme in 2011, Sanofi paid a healthy and hefty price for the company a short time later.[113] A pharmaceutical sector industry analyst about the deal upon its announcement, and he stated that he felt is indicative of two trends. The first, he said, was that it shows the importance of "established" companies to invest in their product pipelines through mergers and acquisitions. The second, he said, "was that regulatory actions including consent decrees are increasingly part of the cost of business, and it is not the 'death knell' to a company's growth and acquisition options that it was in the past. [2]

Generic drug companies also devote time and man-hours to developing new generic products for their product line. While these manufacturers do not need to perform the initial research and development of creating these compounds, they must perform the initial development activities needed to obtain FDA approval of the Abbreviated New Drug Applications (ANDAs) needed. Generic drug companies also may develop novel delivery systems for existing products, and therefore some put research and development dollars into these efforts. These development activities can be seen as a greater investment in future profitability than investing in updating plants or other expenditures that may preserve or increase the assurance of quality at the plant, particularly the plants making less profitable drugs.[112] The profit margin of many generic drugs is very low, so many of these companies are expanding their product lines in order to pursue generic products with higher margins.[107] Many of these generic drug plants were operating at their full capacity prior to the companies bringing in new products on board.[107] This means that in order to manufacture these products, the manufacturing lines

must be rotated between products more frequently, which can create additional opportunities for quality and compliance problems.[107]

Investors and analysts typically do not know how to calculate the costs of compliance, and as previously referenced, even consent decrees have been seen simply as “a cost of doing business”. Institutional investors frequently have their own secret formulas for analyzing the value of a pharmaceutical company stock. They do not typically publish how they arrived at their buying decisions, but the stock market valuation of a firm as evidenced by share price may be observed at a gross level.

Pharmaceutical firms face more financial pressures to cut manufacturing costs or simply expand manufacturing output while controlling costs, which can put negatively impact product quality. There is very little research into the effects that decisions such as offshoring and outsourcing manufacturing has on quality, despite the large amount of growth in corporations employing these practices in order to save costs. James Cornelius, CEO of Bristol-Myers Squibb, was quoted in 2007 as saying "there are lots of people in India, China and Eastern Europe who can make products of the same quality as ours but at significantly less cost."[111] Cornelius at that time went on the record as being gravely concerned about the pending patent cliff and the lack of replacement novel drug compounds to take the place of blockbusters.[114] Outsourcing can reduce some types of costs, but may increase others. The primary reason that companies decide to outsource production is to save on labor costs.[115] Dr. John Gray, an economist at the University of Ohio, has studied business strategic decisions that have negative impacts on pharmaceutical companies' quality systems.[11] In 2009, Gray and his co-author reported that although there was a great deal of academic research on the savings and economics of outsourcing, there was little

scholarship on the impact of outsourcing production on production quality.[14] In 2011, Gray published an empirical analysis of matched pairs of drug manufacturing plants in the United States Versus Puerto Rico in order to assess the "quality risk" between them.[116] Quality risk was defined as the "propensity of a manufacturing establishment to fail to comply with good manufacturing practices."[116] The evidence of quality risk was determined through analysis of the results of FDA inspections of each selected site, as measured by a heuristic Gray's team developed. Puerto Rico was selected because its plants are inspected by the same regulator (FDA), thus controlling for variances among different regulatory agencies.[116] Although Puerto Rico is not as geographically distant as other common offshoring locations such as India and China, Gray points out the island has a different language and culture than the mainland US. Even though the matched pairs were controlled for in regards to plant age and size, the offshore manufacturing plants showed greater quality risk.[116] Gray reported that there was a significant increase of violations in Good Manufacturing Practices when a company utilized an offshore plant, even when the most significant potential contributing factors were controlled. Gray theorized that the cause for this was the difficulty in performing knowledge transfer and maintaining knowledge in an overseas location.[116] Consideration of the impact of offshoring on a company's quality management programs should be part of the decision making, otherwise the strategic analysis of offshoring would be incomplete.[117]

Pharmaceutical companies have often engaged in cost-cutting measures that shrink the production workforce through layoffs of personnel. Downsizing has been a popular trend in the industry. Between 2000 and the end of 2010 the pharmaceutical industry had cut about 300,000 jobs, and most of the large pharmaceutical companies had announced lay-offs by 2012.[118],[119] This figure includes sales staff and other areas as well as production. The manufacturing

employee counts have been dropping, and have included personnel lost from mergers and acquisitions, as well as plant closures and consolidations.[120] Downsizing is currently one of the strategies preferred by managers who are seeking to cut costs and improve economic performance measures.[121] The problem is that these perceived benefits come with a cost in other areas, and the economic improvements may not yield long-term benefits.[120] Research has shown that corporation's recognition and valuing of its workforce is extremely important to long-term growth and the success of the organization.[122] Not surprisingly, downsizing has been shown to negatively impact employee morale.[121] Downsizing has also been found to have serious detrimental effects on what has come to be called institutional or corporate "memory." This term refers to the loss of knowledge in an organization when experienced personnel leave and includes personal files, procedures, and policies that have not been proceduralized by the firm but are valuable to the success of the operation.[123] Institutional memory also includes the social learning structures and informal learning and training networks that allow organizational units to function at a higher level.[123] These can be extremely valuable to the organization but often are not valued since they are difficult to quantify and are somewhat intangible.[120, 123] Although they are often accounted for in strategic downsizing decisions, they can be extremely important to the firm's financial bottom-line, and are often cited as part of the cause when corporations fail to reap the long-term financial benefits that were predicted to come out of downsizing.[121, 124] Even if a firm is careful to retain its most valuable and knowledgeable employees, large or frequent rounds of layoffs can create an unstable retention environment in which the valuable employees may leave or become less productive.[121, 123] Pharmaceutical manufacturing is a knowledge intensive industry, and training can be very important to properly running these types of systems and facilities.[125]

Pharmaceuticals companies and investors often place a great deal of emphasis on the development of new products and R&D successes. Past research shows that these firms will reap great financial rewards when spending in this area versus making capital expenditures.[126] As previously discussed, current research indicates that pharmaceutical companies are receiving lower returns on investment for money spent developing new drugs, as more fail to come to fruition.[110] Companies must either spend more to get fewer R&D successes or pursue other means of expanding their product line, such as mergers and acquisitons.[2] As a result, pharmaceutical executives, who all as corporate leaders have a fiduciary duty to their shareholders, may elect to spend money in pursuit of new products overpaying to upgrade plants and systems. Pharmaceutical firms with older plants tend to have an increased risk of failure to comply with cGMPs.[116] This has been theorized to be due to waning interest from corporate officials, complacency, increasing layers of "bureaucracy" and lack of investments in the plant by the company.[116] Major upgrades to a facility or processing line may take more than just money: it also takes time to shut down. According to a recent government report on drug shortage, many generic pharmaceutical plants are running at capacity and have little time to shut down due to drug shortage situations or supply pressures.[108]

The case of McNeil Pharmaceuticals, a J&J subsidiary, serves as an interesting study in contributing factors that can lead to an FDA injunction. The injunction was filed due to recurring violative FDA inspections involving GMP failures at the firm's Fort Washington, PA and Puerto Rico plants. The product quality and compliance problems of McNeil received a great deal of attention by the public, which culminated in a congressional hearing on the breakdown of quality within the corporation. On March 3, 2011, a securities class action lawsuit was filed against J&J and some of the firm's top executives alleging that the firm withheld information from investors

on the true state of McNeil's quality systems when they had gone awry. [19] The Complaint asserted the moving of McNeil from the pharmaceutical group combined with aggressive cost-cutting negatively impacted quality control at J&J causing "embarrassing and alarming product defects, widespread recalls, the closure of a manufacturing plant in Fort Washington, Pennsylvania, a Congressional investigation and a permanent injunction…". [19] A settlement was announced for this case on July 15, in which J&J agreed to pay the shareholders in the class $22.9 million, but without admitting any wrongdoing. The company's spokesperson said that the claims in the lawsuit were without merit, and the company agreed to settle to "avoid the distraction, expense and time of a lawsuit".[127]

The history of both the FDA case and the shareholder lawsuit begins with a 2004 FDA inspection of the McNeil Fort Washington plant. The firm was cited for problems such as poor record-keeping, incomplete investigations into quality problems and incomplete and inadequate sampling practices. The Complaint claimed that a new director of quality, Bob Miller, was hired in 2005 who had previous pharmaceutical experience and had the proper knowledge and credentials for the job.[128]

In January 2007, J&J purchased the OTC division of Pfizer, which resulted in consolidation and restructuring to integrate the unit. [19] As part of this acquisition, J&J restructured and McNeil was moved from J&J's pharmaceutical unit to the J&J Consumer Products Group, which was also home to the firm's products such as baby bath and personal care products.[19] The responsibility for the quality assurance oversight of McNeil moved as well, in that they were no longer under the J&J pharmaceutical quality units oversight.[19, 129] The Pfizer product lines, which included OTC Zyrtec were placed with McNeil, now under the leadership of

Colleen Goggins, the “Worldwide Chairman” of the J&J Consumer Group.[19, 129] Ms. Goggins was also a member of the J&J Executive Committee, which consisted of nine members and was led by the firm's CEO, Bill Weldon.[19] According to the J&J annual report for 2007: "The Executive Committee of Johnson & Johnson is the principal management group responsible for operations and allocation of the resources of the company."[19] The annual report also stated that the committee was responsible for overseeing and coordinating the activities of all of the business segments.[19] The Complaint alleged that Colleen Goggins was responsible in her position for the quality control at McNeil and all of J&J's over-the-counter pharmaceutical products due to her position.[19] The Complaint further alleged that as a result of this shift, quality control and assurance at the McNeil facilities began to suffer.[19] A confidential witness named in the complaint as a former director of quality at McNeil, and responsible for all of the firm's North American manufacturing facilities, claimed Goggins did not understand pharmaceutical quality control.[19]

The Complaint stated that Johnson & Johnson aggressively began cost-cutting in pursuit of "unreasonable financial targets and then mandated aggressive cost-cutting" that contributed to recalls and quality problems.[19] The suit claimed that expiring patents in the pharmaceutical division "interfered" with the company's ability to continue previous growth and meet the predicted targets established as part of the Pfizer merger. In 2007, J&J laid off 4,000 workers, which was 7% of the company’s workforce.[129] The lawsuit alleged that the J&J executive committee created a "top-down" budget decrease for McNeil which negatively affected its quality control department according to one of the cooperating confidential witnesses.[19]

The complaint claimed that although Goggins and other top executives publically stated that the merger and cost-cutting was not disruptive to the day-to-day operations, the confidential witnesses claimed that the quality systems were suffering.[19] Specific reasons related were: experienced employees were laid off and replaced with new employees with no pharmaceutical experience; headcount reductions; and lack of funding for needed improvements to facilities and equipment.[19] The lawsuit claimed that the McNeil quality control unit's budget was cut by approximately 2.8 million to 2.9 million in both 2008 and again in 2009. [19] Confidential witness "CW1" claimed that since 80 to 90% of the quality unit's budget went to salaries, this necessitated reducing the number of employees in the unit by approximately 12 persons per year.[19] Weldon stated in his congressional testimony: "We have gone back and looked at the period between 2006 and 2009. And at best, the costs on quality at McNeil were flat. Actually, they increased during that period of time. And the head count was constant also. There was not a reduction."[128] Since this case was settled and did not go to court, there was no record of the resolution of these differing accounts.

An investigative article in *Fortune* magazine reportedly contains information obtained from several former McNeil employees. A former McNeil vice president described arguing with a high level executive in the Goggins division about the projected costs of moving the production lines of the Pfizer products to the Fort Washington plant.[129] This is a complex process that involves testing and validation to ensure that that the new lines can consistently and reliably produce the pharmaceutical within the proper quality standards, and not just rely on finished product testing which may miss problems.[35, 130] He stated that he told the executive it would cost about $600,000 per product. He was told that was far too expensive and he could only spend

$250,000 per product.[129] The vice president stated that they felt it would be "impossible to meet those demands without screwing the process up", but they gave in to avoid getting fired.[129]

Between 2009 and 2010, the FDA performed multiple inspections at McNeil's Fort Washington, Las Piedras, and Lancaster facilities and found serious violations that resulted in FDA recommendations for further action. High profile product problems, such as reported potential microbial and particle contamination of children's Motrin, chemical fungicide contamination of a Tylenol product, and potency variations that concerned both regulators and the public were also brought to light. The firm recalled several product lines and closed the Fort Washington plant. The FDA filed an injunction against McNeil and named the Consumer Healthcare Division's Vice President of Quality and the company's Vice President of Operations for OTC Products as defendants in the consent decree. McNeil's president at the time, Bob Luther, was not named. Colleen Goggins and William Weldon were also not named in the action, which was later settled via consent decree. While the naming of the individuals in a corporate action is not the same as charging the individuals, it can encourage the parties' attention to the corrections needed. [40]

Sydney Finkelstein later wrote that Weldon had been one of the worst CEOs of 2011 citing product quality problems and recalls among many disparate J&J products including "insulin pumps, syringes, hip implants, sutures, contact lenses, Tylenol …, Benadryl and Rolaids".[131] Finkelstein continued: "Johnson & Johnson is a highly decentralized organization, so it is unusual to see so many breakdowns in product quality and safety because they span such a wide range of businesses.[131] When this happens, responsibility must surely rest at the very top of the enterprise, with Mr. Weldon and the culture he has set in place." [131] The Johnson &

Johnson Board did not agree. They voted to give him a 55% raise to his performance bonus and a 3% raise to his base salary.[129] From some business metrics, this may be partially understandable. J&J reportedly has experienced monumental growth, acquiring many new corporations and product lines.[19] There are now 100 J&J subsidiaries located just in the United States, which is reportedly triple the amount in 1982.[19] Not only is J&J bigger and more decentralized it's also much more profitable. Its operating margin in 1990 was 17.7 percent; in 2010 it was 26.8 percent.[19]

But these subsidiaries, often referred to as the "sister companies" are not decentralized in one important way: financially. These subsidiaries receive instructions on financial issues, such as when to implement cost-cutting measures from the Chief Executive Team of J&J. When J&J announced the layoffs and cost-cutting measures they were announced by the CEO, and were not described as independent decisions of each separate subsidiary to make a changed contribution to the corporate entity at large. Mr. Weldon took responsibility for the decision, which is likely a difficult one, but in no way attempted to describe it as a decentralized decision. For example, there was certainly no information provided to investors that indicated that these decisions came from the subsidiaries who wish to make cost-cutting a priority and which did not. Weldon was given credit for these decisions and for the financial benefit reaped from them in his written review by his board of directors. Indeed, this is the role of the CEO, by any definition. They are to provide leadership in strategic business decisions for the group as a whole. The decisions for how to manage the impact of these measures would be squarely on the subsidiary if the corporation is truly decentralized.

The class action security lawsuit discussed had named William Weldon and the firm's CFO as defendants in the lawsuit. The judge supported a J&J motion to dismiss the claims against Weldon and the CFO as the lawsuit failed to show sufficient evidence that the two men had a "wrongful state of mind" when making statements to the public that might have been misleading. The judge allowed the claims against Colleen Goggins to proceed, citing the evidence the plaintiffs claimed to possess such as her presence at meetings in which some of the quality issues were discussed.[19] This highlights the difficulty of pursuing individual cases without the use of strict liability.

Documents that J&J has filed with the SEC, the executive summary of the "Compensation Discussion and Analysis" clearly describes the criteria that the J&J Board is to use to evaluate their CEO's performance. The top executive is judged on financial metrics, such as "sales, earnings, cash flow and total shareholder return". Leadership measures are evaluated, which are described as retention of talent, leadership "pipeline" and employee engagement. The CEO is also to be evaluated on long-term growth measures such as "innovative products, robust pipelines" and "global presence". The summary includes provisions that the CEO may be evaluated on whether or not they had safeguarded the firm's reputation and upheld the J&J Credo, a mission statement created by the firm's founder that spells out the company's duties to its customers, its employees, and to its investors. The last two are the only two criteria that could be construed as relating to product quality. While the document does mentions the principles of excessive risk-taking versus appropriate risk-taking, but only in a section explaining that the executives 'incentives are designed in such a way so as to avoid incenting overly risky behavior. This typically refers to behaviors involving business risks, such as those involved in decisions dealing with mergers and acquisitions. While quality could be a factor that is examined when

performing due diligence of acquiring a subsidiary for example, it is not referring in a broad sense to patient risk. No evidence was found in reviewing the 2008-2011 CEO compensation discussion and analysis reports that this concept was invoked in any way in regards to business decisions that may have resulted in quality problems in the manufacturing plants. While some analysts suggested that the reputation of J&J had been harmed by the shortcomings associated with McNeil and other subsidiaries, the board made no mention of these issues as evidence that Mr. Weldon may not have succeeded in those two areas. The recalls and problems were summarized, but were presented simply as challenges that arose in Mr. Weldon's tenure, and as opportunities for him to demonstrate leadership in dealing with the crises. They were not used as a negative indicator of the CEO's performance. While may be within the board's prerogative, it may serve as an indicator, in this case it, whether or not a link was made by the board between any governance failure on the part of the CEO and the problems that resulted in the subsidiaries.

In the case of another type of regulatory compliance, the document has a very different approach. The expectations involved with accurate and reliable accounting reporting is much more clearly described to the board, the compensation committee and most importantly the CEO. Executive summary states: "*Executive Compensation Recoupment Policy:* The policy gives the Board the authority to recoup executive officers' past compensation in the event of a material restatement of the Company's financial results." This is laudable, but not surprising since the passing of the Sarbanes-Oxley (SOX) which requires certification by top officials of corporate financial results that are submitted to the SEC and additional powers granted in section 304 that gives the SEC the power to "clawback" CEO compensation derived from misreported financial numbers. It is notable in that it may be imposed even if the CEO is completely unaware of the misconduct that resulted in the incorrect statements provided, a form of strict liability for the

CEO.[132] This provision has been controversial to some, and has faced litigation objecting to its use.[132] Some boards have adopted policies that allow the board to have discretion over whether or not the clawback provision is to be utilized. which may undermine the effectiveness of this tool.[132] But even so, the fact that this provision is specifically addressed in the CEOs compensation evaluation, it is a valuable reminder is considered unacceptable. It is a reminder that the CEO could face serious, and most of all personal penalties for regulatory noncompliance.

A review of the compensation discussion and analysis shows no such equivalent form of accountability or warning when dealing with product safety and quality, which certainly could affect more than just financial harm. As previously discussed, the FDA does have the authority to pursue personal consequences in the case of a chief executive officer who does not take enough care to prevent adulterated pharmaceuticals from entering the marketplace.

By February 2012, Weldon announced that he planned to step down as CEO in April, but that he would stay on a bit longer as chairman of the board. He received a large severance package that reportedly contained no performance-based penalties, despite his many critics.[133,131] Such evaluations are subjective, but one may consider that Johnson & Johnson's board utilized measures that differed from those used by others, such as Finkelstein.[131] Finkelstein wrote that a series of product recalls that had occurred between 2010 -2011 were “a direct result of Weldon’s emphasis on cost-cutting.”[131]

Poor governance and leadership that results in a decline in product quality may result in problems not just to those that consume those products, but to other corporations. If a corporation cannot consistently and reliably produce the products that it is approved to make by its approved NDA and ANDAs, the company’s valuation may be incorrect. According to the

FD&C act, it is illegal to sell products made under such conditions. The events that are still unfolding surrounding Ranbaxy's serious regulatory non-compliance that has resulted in sanctions against the company by the FDA. The firm's prior head of research and development blew the whistle to both FDA and the Department of Justice involving Ranbaxy's submission of fraudulent data in support of numerous abbreviated new drug applications. Ranbaxy, the sixth largest generic drug company in US sales, with purchased by Daiichi Sankyo. In 2006 the FDA performed an inspection at one of Ranbaxy's plans, aided by information provided by the whistleblower. The inspection revealed that the firm was indeed discarding raw data, and was not performing stability testing or investigating patient complaints. The FDA sent a warning letter for months later, and notify the firm that approval of any new drug applications would be on hold until they could prove corrections were made. In 2007, FDA reportedly began on the criminal investigation into Ranbaxy, and executed a search warrant at the firm's US headquarters. Despite this, in June 2008, Daichii Sankyo announced that they planned to buy out the 34% stake in the company held by the then CEO, Malvinder Singh and his brother. They were the sons of Ranbaxy's founder. Malvinder, it was announced, would stay on as CEO, despite the revelations that were starting to come forward about quality concerns throughout the firm's plants the FDA found evidence of fraud during an inspection of another one of the company's plants. Just three months after Daiichi Sankyo bought Ranbaxy, FDA announced in importation ban of 30 products manufactured by Ranbaxy.

Additional internal employee whistleblower account claimed that Ranbaxy was substituting the innovator product in tests that were supposedly proving that their product was equivalent.[134] In February 2009 the FDA impose the application integrity policy requirements on Ranbaxy.[134] This requires a manufacturer to prove to the agency that the data submitted to

support product applications were not fraudulent.[134] Three months after this revelation, Singh finally step down as CEO.[134] In 2009, the FDA issued yet another warning letter to a Ranbaxy facility, but this time it was in the United States.[134] By 2012 the FDA had filed a complaint for injunction against Ranbaxy, and a consent agreement was negotiated that same year.[134] The company agreed to pay $500 million in fines to the government.[134]

The total cost of all of noncompliance with pharmaceutical regulatory requirements around the world by Ranbaxy cannot yet be determined. The first whistleblower estimates, for example, that of the approximately hundred and 63 drug products sold in Brazil since 2000, only eight have been properly tested. In May, 2013, Daichi Sankyo announced that it was suing "certain shareholders" for fraud, alleging that they misrepresented and concealed critical information involving Department of Justice and FDA investigations. When the costs of noncompliance are calculated, they are likely to include many expenses such as the cost of the many independent consultants that the firm was forced to retain as part of the consent decree, the cost of product recalls and the sales lost due to the FDA ban on US importation. There will also be additional costs which may not be measured by the company, such as the costs associated with additional regulatory scrutiny from many different country's regulators, for example. The MHRA, the body responsible for drug safety in the UK, reported that they have inspected Ranbaxy plants six times since 2006.

CHAPTER 8

CONCLUSION

The results have shown that CEOs do not experience performance related turnover unless other factors are involved such as SEC charges (22%), mergers or acquisitions (22%), or the filing of criminal charges by FDA or another agency (33%). Of the 14 cases of FDA injunctive actions reviewed in this study, only one CEO was turned over without the predefined concurrent causes present, or 7%. This research concludes that CEOs are not likely to view the filing of an FDA injunction as a potential threat, since this is one of two potential performance related sanctions. The other sanction is rarely used, as CEOs are rarely financially penalized for performance related problems, as has been shown in other's research. This study shows that chairmen of the board experienced even less performance related turnover than the CEO position. All COB turnovers were related to non-performance related retirement or because they were joint CEO/COB who experienced one of the concurrent causes.

The one CEO turned over without another predicted concurrent cause presided over Wyeth at a time that it was settling massive Fen-Phen lawsuit payouts. The costs associated with the settlements have run as high as $21.1 billion, with costs still climbing. This factor was considered a significant contributory cause to the CEOs departure. Some of the case study CEOs certainly experienced consequences, costs, and complications in performing their jobs as a result of the FDA injunctive action. None of the cases examined had a CEO turnover event caused soley due to an FDA injunction for manufacturing problems. This research does not intend to imply that any particular CEO should have been turned over, but rather to assess the CEO's

perceived risk of turnover. This work asserts that CEOs may consciously or unconsciously consider risk of personal consequences in strategic decision-making. One point of interest that may warrant further study is whether or not CEOs who preside over firms that are the subject of an FDA injunction/consent decree may have a greater propensity to engage in other risky behaviors, including violating SEC provisions. If research confirms this conclusion, investors and analysts may consider FDA violations as indicative of other important internal governance systems gone awry or poor decision making.

The limitations of this study include the fact that comparative conclusions cannot be drawn between CEO turnover rates of firms that were the subject of FDA injunctions and those that were not, since there was no comparative sample and analysis. Another limitation is the primary cause for CEO turnover cannot be completely known, and is subject to speculation by outside analysts, although consideration was given to this issue and conservative measures used. The small sample size limits the power of the results. In order to obtain a greater sample size, research could be expanded to include injunctions based on other types of firms such as medical device manufacturers.

Pharmaceutical manufacturers will continue to have to make hard choices in resource allocation and decisions that affect their financial earnings as future outlooks are less bright. It is more critical than ever that pharmaceutical chief executives understand the need for decision making that balances potential savings with appropriate evaluations of quality risk. Finkelstein and his co-authors recommend four types of sequential safeguards to protect against flawed decisions: experience, data and analysis; group debate and challenge; governance; and monitoring. These are described in detail in the previously discussed book, "Think Again", and are briefly described below. The authors give the example of a chairman of the board of a major

corporation in which the CEO is advocating strongly for a major strategic decision that may not be optimal. The first step they recommend to the fictional leader is to ask that the CEO explore new *experiences or data* that may give the person an opportunity to analyze and challenge their own preconceived ideas on the subject.[135] As previously presented in this work, the CEO may have strong notions on the subject based on their personal experiences that may not apply to the situation at hand.[135] Admittedly, this process alone may not be enough to dislodge deeply held opinions already in place.[135] The next step they recommended is "*debate and challenge*". Here, the authors recommend that the chairman ensure that the CEO actively seeks out someone with relevant experience who is sufficiently assertive so that they might challenge the CEOs preconceived concepts.[135] Another recommended alternative is an exploratory team that fits the same criteria.[135] In case the first two steps do not work as intended, they recommend the company ensure that corporate *governance* systems be set up in such a way that there would be a safety mechanism.[135] An example of such a mechanism is the establishment of a special subcommittee of the board that reviews the major proposals in detail, and could even include an individual consultant with special expertise.[135] Their final recommendation is that important decisions be properly *monitored* so that problems are caught and dealt with early. The book points out that negative outcomes and news may not reach the CEO and the board if the subordinates believe that the CEO (or chairman) is totally committed to a strategy and may not welcome "bad news".[135]

Even these types of safeguards may be rendered ineffective though if the top leaders do not embrace them. The authors give an example of a CEO, who when dealing with a committee analyzing an idea in which the CEO felt quite invested, gave very negative body language signs to anyone who challenged their proposal.[135] Thus, even well designed systems can be overcome

if subordinates or others are not encouraged to give pertinent feedback or share important information that may negatively impact a favorite project or strategic direction.[135] In the case of business decisions that may adversely affect quality risk in manufacturing units, these types of governance controls and challenges may be critical in ensuring that the potential negative outcomes are properly considered. In cases in which the CEO and chairman positions are combined, as in the vast majority of our cases - 86%, it would appear that Finkelstein's model would be less likely to be implemented. For example, in the case of J&J described in Chapter 7, William Weldon was chief executive officer, chairman of the board, and the chairman of the firm's executive committee. If such a CEO was inappropriately invested in cost cutting measures without concern for associated adverse impacts, there would be no equivalent level person to question his decisions. As presented previously in this work, the other members of the board and such executive committees may not challenge a top executive holding multiple top titles, or if the CEO is entrenched.

If CEOs do not experience turnover solely due to FDA injunctions even if large fines were involved, they are not likely to view this corporate sanction as a major personal deterrent. Regulators then must utilize additional measures to ensure that those most empowered to prevent quality risk have incentives to do so. Attorneys that advise pharmaceutical executives have presented strategies to avoid being the target of strict liability prosecution for cGMP violations.[7] While the intention is to help the individual avoid liability, the recommendations are helpful to the organization as a whole if implemented. From a review of the literature and case study findings from this research, there are specific measures that a CEOs and COB may consider to avoid strict liability prosecution for failure to comply with FDA regulations, which are presented below:

Effective compliance programs are essential. They can detect illegal or violative behavior early, and serve as a deterrent to the development of such behaviors.[136] These programs have to be properly implemented and all subordinates must understand the legal requirements and the risks properly in order for them to serve their purpose. Sydney Finkelstein describes an incident in which the new CEO of a large, transnational medical device company decides to make one his first actions to go into the field and interact with product users, which in this case was a cardiothoracic surgeon.[137, 137] As the surgeon located the stent within the patient, it broke into pieces.[137] The surgeon expressed frustration at what appeared to be a repeat occurrence and reportedly threw the broken pieces at the CEO. Finkelstein stated that the CEO then launched an inquiry and found out the same salesperson had filed 3 previous reports of the product breakages, but that no corrective action had been taken.[137] The CEO launched an inquiry which determined that the layers of management in between the original reporter, the salesperson, and the team responsible for determining the appropriate follow up were "watering down" the reports and minimizing the severity.[137] Finkelstein stated that some of the organizational sectors were "filtering" and "adjusting" the reported information. Finkelstein proposes that there may have been a personal interest for some that their own unit not be viewed as having a problem.[137] He stated that by the time the evaluation was completed the conclusion was that the problem was related to user error on the part of the surgeons.[137] A properly functioning medical device complaint investigation system with the adequate oversight should have prevented this from occurring, and is required by FDA regulations.[138] These regulations extend to reports received by medical device salespersons. A situation like this is not just a regulatory risk, but also a business risk, and compliance programs can protect against both. The CEO in Finkelstein's account was

fortunate to discover this problem first hand, but never should have had to discover such a problem in this way.

Rigorous, routine and effective audits are essential. They may be conducted by well-qualified external consultants combined with internal expertise, but are critical if compliance programs are going to be effective. While audits may detect problems after they have occurred, they may also serve to encourage adherence to quality systems. Production and quality unit employees and managers are more likely to properly adhere to the quality systems if they believe that effective audits will be conducted to ensure compliance, and lack of adherence would have consequences. The audits serve dual purposes, both the actual detection and the threat of detection. The threat of detection will not be effective; however, unless the top management team is supporting thorough audits and ensuring corrections are made appropriately when discovered. It may be tempting in today's culture for top leaders to limit their knowledge of quality problems to avoid being added to shareholder lawsuits for failure to properly correct such issues. This could result in these executives attempting to dissuade subordinates from sharing negative information in writing or not at all. Deliberate constriction of negative information flow to the corporate board and CEO is willful blindness. A corporation should have formal reporting requirements for specific types of quality information measures, metrics and outcomes to include audit results. The top management team should also be required to review documented proof that quality is prospectively designed into systems and products, so that problems do not have time to develop. Quality risks in an organization that have developed over time may be difficult and expensive to eradicate. Strict liability concepts are important as well to ensure that CEO and other top management team members have an incentive to overcome the potential instinct

towards willful blindness created by shareholder lawsuits or other blame based outcomes that depend on proof of individual knowledge.

Quality assurance, control and compliance employees must be empowered. If quality units are not empowered, they cannot properly function by statutory definition.[35] They will become less effective due to the sociological factors discussed previously, and may not properly advocate for quality management if social pressures are applied from superiors or peers. Most importantly, they must function as more than an advisory unit. They should have real ability to stop the release of products or components that do meet proper quality standards without any form of interference or retaliation. Business units should ensure that quality personnel are well qualified and trained, and allowed to advocate for their position without shaming. Shaming tactics could include behaviors such as negatively labeling the individual, such as calling them "alarmist", or suggesting they are not team-players. Discussions of proper outcomes when dealing with problems should remain fact based. Companies should also avoid placing external pressure on quality employees to release products. For example, companies should avoid providing bonuses to employees based on the number of lots released. This places a burden on quality unit employees who wish to withhold batch release, or could even provide incentive for inappropriate release of product.

Establish early warning systems and ensure they function. Employees often warn superiors of illegal or inappropriate behaviors before they result in catastrophic conditions. For example, several British Petroleum employees have claimed to have warned management of risky behavior that raised concerns for worker safety and equipment failure prior to the oil rig disaster in the Gulf of Mexico. BP has spent billions to clean up and monitor the spill, pay reparations to negatively impacted industries, to settle claims, and pay fines.[136] When

corporations fail to act upon a sincere concern about serious problems, it can not only be foolish, but also dangerous. Employees who attempt to alert higher levels of management often do so at the peril of their career, and can face retaliation. These decisions are not taken likely, and corporate officials should take them very seriously and not consider all such reports as without merit. It is far better for a corporation to investigate and remedy the conditions when warranted than to wait for the complainant to go to regulators. Companies should ensure that such reporting systems cannot be tampered with by lower levels of management attempting to conceal problems.

Lower level workers can provide important feedback on the state of a company's operations. Their input should be solicited, even if through anonymous surveys, as they may possess valuable knowledge of what systems are not functioning as intended. It should be recognized that some workers may not provide such input unless asked.

Budget and plan for predictable risks. Investors and executives must understand the risks associated with strategic business decisions that can have adverse impact to quality. As this work has shown, offshoring, outsourcing, downsizing, mergers, consolidation and lack of capital expenditures to maintain plants and equipment can have costly and potentially illegal outcomes in the case of FDA regulated firms This work contends that quality risks associated with business strategic decisions can be predicted and planned for, and failure to do so can represent dangerous or negligent behavior depending on the circumstances. One journalist claims, based on informant reports, that BP utilized a concept called "run-to-failure", a maintenance policy that allows a piece of equipment to run until it breaks, without maintenance or prevention.[139] Business decisions such as these must be examined for the associated risk, as in the case of pharmaceutical

firms not doing so should result in personal liability. This will ensure that those empowered to implement these controls will do so, and to educate themselves on potential negative outcomes.

CEOs and chairmen have tremendous challenges and responsibilities in their demanding positions. While their fiduciary duties to shareholders and increasing their firm's competitive position is important, it cannot be done at the expense of the public. Government regulators have a responsibility to ensure that such outcomes do not occur, and should strive to hold those most responsible also most accountable.

Note: This thesis represents the views of the author and should not be construed to represent FDA's views or policies.

REFERENCES

(1) Blumberg EM. Abbott Laboratories Consent Decree and Individual Responsibility Under the Federal Food, Drug, and Cosmetic Act. *Food & Drug LJ* 2000;55:145.

(2) Silverman, Ed. Sanofi Gobbles Up Genzyme: What The Wags Say. Pharmalot . 2-16-2013. 1-10-0013.

(3) Juran JM. Quality Control HandbookMcGraw-Hill. *New York* 1951.

(4) Fisse B, Braithwaite J. *Corporations, crime and accountability*. Cambridge University Press; 1994.

(5) Scura K. HSBC and Money Laundering: "Too Big to Indict". American Criminal Law Review . 4-5-2013. February 2, 2013.

(6) Braithwaite J. *Corporate crime in the pharmaceutical industry*. Routledge & Kegan Paul London; 1984.

(7) Abrams N. Criminal Liability of Corporate Officers for Strict Liability Offenses-A Comment on Dotterweich and Park. *UCLA L Rev* 1980;28:463.

(8) Cinquegrana RJ, Lloyd DK, Hall C. Liability Without Fault: New Enforcement Trends Against Corporate Executives. 2011. BLOOMBERG LAW REPORTS (Feb. 2011).

(9) Fleder JR. The Park Criminal Liability Doctrine: Is it Dead or is it Awakening? fdli.org . 2013. September/October 2009. 5-13-0013.

(10) Finkelstein S, Whitehead J. *Think Again: Why Good Leaders Make Bad Decisions and How to Keep It from Happeining to You*. Harvard Business School Press; 2009.

(11) Gray JV, Roth AV, Tomlin BT. Quality risk in outsourcing: Evidence from the us drug industry. Working Paper at the Wharton SchoolGÇÖs Mack Center for Technology Innovation. http://emertech. wharton. upenn. edu/TMiniPapers07/Gray_Roth_Tomlin_QualityRiskInOutsourcing. pdf; 2007.

(12) Monks RA, Minow N. *Power and accountability*. HarperCollins Publishers; 1991.

(13) Braithwaite J, Fisse B. Varieties of responsibility and organizational crime. *Law & Policy* 1985;7(3):315-343.

(14) Gray JV, Roth AV, Tomlin B. The Influence of Cost and Quality Priorities on the Propensity to Outsource Production*. *Decision sciences* 2009;40(4):697-726.

(15) Sethi SP, Katz RW. Expanding Scope of Personal Criminal Liability of Corporate Executives-Some Implications of United States v. Park, The. *Food Drug Cosm LJ* 1977;32:544.

(16) Block JG, Voisin NA. Responsible Corporate Officer Doctrine-Can You Go to Jail for What You Don't Know, The. *Envtl L* 1992;22:1347.

(17) Bragg J, Bentivoglio J, Collins A. Onus of Responsibility: The Changing Responsible Corporate Officer Doctrine. *Food & Drug LJ* 2010;65:525.

(18) Fisse B, Braithwaite J. *The impact of publicity on corporate offenders*. Suny Press; 1983.

(19) Monk v. Johnson & Johnson. [Civil Action No. 10-4841 (FLW)]. 2011. Dist. Court, D. New Jersey.

(20) Kines, Mina. Johnson & Johnson CEO Bill Weldon's painful year. Fortune Magazine . 10-7-2013. 5-11-0013.

(21) Bertoni Steven. Inside Icahn's Brain: How He Picks A Target And Pulls The Trigger. 3-11-2011.

(22) Friedman M. The Social Responsibility of Business is to Increase Its Profits. The New York Times Magazine . 9-13-1970.

(23) Tigar ME. It does the crime but not the time: corporate criminal liability in federal law. *Am J Crim L* 1989;17:211.

(24) Chesney DL. Management controls for GMP compliance. 2005.

(25) Finn CH. Responsible Corporate Officer, Criminal Liability, and Mens Rea: Limitations on the RCO Doctrine, The. *Am UL Rev* 1996;46:543.

(26) US v. Cordoba-Hincapie. F. Supp. 825[No. CR 92-650], 485. 1993. Dist. Court, ED New York.

(27) Hill J, Maughan B, Goodyer IM. *Conduct disorders in childhood and adolescence*. Cambridge University Press; 2000.

(28) Williams GL. *Criminal law: The general part*. Stevens; 1953.

(29) Zipperman S. Park Doctrine--Application of Strict Criminal Liability to Corporate Individuals for Violation of Environmental Crimes, The. *UCLA J Envtl L & Pol'y* 1991;10:123.

(30) United States v. Mayfield. F. 2d. 64[No. 746], 214. 1933. Circuit Court of Appeals, 10th Circuit.

(31) United States v. Balint. US. 258[No. 480], 250. 1922. Supreme Court.

(32) Hobbs v. Winchester Corporation. KB 2. 1910[19101], 471. 1910.

(33) Comment, Murder, Inc: The Criminal Liability of Corporations for Homicide. *Seton Hall Law Review* 1988;18:403-404.

(34) Golden Grain Macaroni Co. v. United States. F. 2d. 209[No. 13713], 166. 1953. Court of Appeals, 9th Circuit.

(35) Immel BK. A brief history of the GMPs for pharmaceuticals. *Pharmaceutical technology* 2001;25(7):44-53.

(36) Ballentine C. Taste of raspberries, taste of death: The 1937 elixir sulfanilamide incident. *FDA Consumer magazine* 1981;15:18-21.

(37) United States v. Dotterweich. US. 320[No. 5], 277. 1943. Supreme Court.

(38) United States v Park. US v Park. 658, 673-674. 1975.

(39) United States Sentencing Commission. *Federal sentencing guideline manual*. 3 ed. West Group; 2008.

(40) Regulatory Procedures Manual, Chapter Six Judicial Actions. Food and Drug Administration . 2-12-2010. 6-11-2013.

(41) Frederickson PD. Criminal Marketing: Corporate and Managerial Liability in the Prescription Drug Industry. *Midwest LJ* 2008;22:115.

(42) Purdue Pharma, executives plead guilty to Ms. branding OxyContin Fined. 5-15-2007.

(43) Comer B. Inspector General Puts Forest CEO in the Crosshairs. 3-15-2011.

(44) Cooper RM. Need for Oversight of Agency Policies for Settling Enforcement Actions, The. *Admin L Rev* 2007;59:835.

(45) Dr.Margaret A.Hamburg. Letter to Senator Charles E. Grassley, ranking Member, US Senate, Committee on Finance, March 2010, from Dr. Margaret A Hamburg, MD, Commissioner of Food and Drugs. 3-4-2010.

(46) General Accounting Office, Food and Drug Administration: Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal Misconduct Investigations. 3-1-2010.

(47) Blumberg E. Conference Remarks. 2010.

(48) Arendt H. *Eichmann in jerusalem*. ePenguin; 2006.

(49) Monks RA. *Corpocracy: how CEOs and the Business Roundtable hijacked the world's greatest wealth machine--and how to get it back*. Wiley; 2008.

(50) Stoner JA. Risky and cautious shifts in group decisions: The influence of widely held values. *Journal of Experimental Social Psychology* 1968;4(4):442-459.

(51) Guerin B. Diffusion of Responsibility. *The Encyclopedia of Peace Psychology*. Blackwell Publishing Ltd; 2011.

(52) Wallach MA, Kogan N, Bem DJ. Diffusion of responsibility and level of risk taking in groups. *The Journal of Abnormal and Social Psychology* 1964;68(3):263.

(53) Manning R, Levine M, Collins A. The Kitty Genovese murder and the social psychology of helping. *American Psychologist* 2007;62(6):555-562.

(54) Milgram S. Some conditions of obedience and disobedience to authority. *Human relations* 1965;18(1):57-76.

(55) Hofling CK, Brotzman E, Dalrymple S, Graves N, Pierce CM. An experimental study in nurse-physician relationships. *The Journal of nervous and mental disease* 1966;143(2):171-180.

(56) Feldman G. Putting Uncle Milton to Bed Reexamining Milton Friedman's Essay on the Social Responsibility of Business. *Labor Studies Journal* 2007;32(2):125-141.

(57) Mintz M. FDA and Panalba: A Conflict of Commercial, Therapeutic Goals? *Science* 1969;165(3896):875-881.

(58) Armstrong JS. Social irresponsibility in management. *Journal of Business Research* 1977;5(3):185-213.

(59) Brown EG. The Qualified Person for Pharmacovigilance for Europe. *International journal of pharmaceutical medicine* 2005;19(1):7-14.

(60) Wilson EO. What is sociobiology? *Society* 1978;15(6):10-14.

(61) Wilson EO. Sociobiology: the modern synthesis. *Cambridge, Massachusetts* 1975.

(62) Smith A. The Wealth of Nations (1776). *New York: Modern Library* 1937;740:456.

(63) Rothschild E. Adam Smith and the invisible hand. *The American Economic Review* 1994;84(2):319-322.

(64) Harrison P. Adam Smith and the history of the invisible hand. *Journal of the History of Ideas* 2011;72(1):29-49.

(65) Meeropol M. Another Distortion of Adam Smith: The Case of the" Invisible Hand". 2004.

(66) This school of thought, that included Friedman's, came to be known as neoliberalism or "the Chicago school".

(67) . Friedman went further to claim that government when attempting to act in the public's interest created a negative invisible hand that created counterproductive and antisocial outcomes due to the fact that government's proscriptions represented only "special interests" and not that of the public at large. Documentary series

(68) Friedman M. *Capitalism and freedom*. University of Chicago press; 2009.

(69) Carson TL. SelfGÇôinterest and business ethics: Some lessons of the recent corporate scandals. *Journal of Business Ethics* 2003;43(4):389-394.

(70) Gunther, Mark. Investors Of The World, Unite! It's up to institutional owners to fix corporate America, says the dean of shareholder activists. Fortune Magazine . 6-24-2002. 5-31-2013.

(71) Bogle JC. Reflections on toward Common Sense and Common Ground. *J Corp L* 2007;33:31.

(72) Monks RA. Redesigning corporate governance structures and systems for the twenty first century. *Corporate Governance: An International Review* 2001;9(3):142-147.

(73) uncredited. Bio About Donald Rumsfeld. 2013. 6-7-2013.

(74) Dubner, Stephen. It's Not the President, Stupid: A New Marketplace Podcast. 3-8-2012. 5-31-0013.

(75) Reader C. *Summary of Known and Unknown: A Memoir-Donald Rumsfeld*. PRIMENTO; 2013.

(76) Finkelstein S, D'Aveni RA. CEO duality as a double-edged sword: How boards of directors balance entrenchment avoidance and unity of command. *Academy of Management Journal* 1994;1079-1108.

(77) Boyd BK. Board control and CEO compensation. *Strategic Management Journal* 1994;15(5):342.

(78) Finkelstein S. Power in top management teams: Dimensions, measurement, and validation. *Academy of Management Journal* 1992;35(3):505-538.

(79) Ryan Jr HE, Wiggins III RA. Who is in whose pocket? Director compensation, board independence, and barriers to effective monitoring. *Journal of financial economics* 2004;73(3):497-524.

(80) Finkelstein S. *Why smart executives fail: And what you can learn from their mistakes*. Portfolio; 2004.

(81) Ariely D. *Predictably irrational, revised and expanded edition: The hidden forces that shape our decisions*. Harper; 2009.

(82) Sanders WG, Hambrick DC. SWINGING FOR THE FENCES: THE EFFECTS OF CEO STOCK OPTIONS ON COMPANY RISK TAKING AND PERFORMANCE. *Academy of Management Journal* 2007;50(5):1055-1078.

(83) Cohen RB, Hall BJ, Viceira LM. Do executive stock options encourage risk-taking. *Unpublished manuscript, Harvard University* 2000.

(84) Krumholz HM, Ross JS, Presler AH, Egilman DS. What have we learnt from Vioxx? *BMJ: British Medical Journal* 2007;334(7585):120.

(85) Horton R. Vioxx, the implosion of Merck, and aftershocks at the FDA. *Lancet* 2004;364(9450):1995.

(86) Lenzer J. FDA is incapable of protecting US GÇ£against another VioxxGÇ¥. *BMJ: British Medical Journal* 2004;329(7477):1253.

(87) Finkelstein S, Whitehead J, Campbell A. Think again: Why Good Leaders make bad decisions. *Business Strategy Review* 2009;20(2):62-66.

(88) Vivian JC. New FDA strategy: criminal charges against pharma executives. *US Pharm* 2011;36(6):58-62.

(89) Regulatory Procedures Manual, Chapter 4-1 Warning Letters. Food and Drug Administration . 8-1-2012. 6-11-2013.

(90) Regulatory Procedures Manual, Chapter 5 Administrative Actions. Food and Drug Administration . 3-19-2013. 6-11-2013.

(91) Field Management Directive 86 Establishment Inspection Report Conclusions and Decisions, Version 5.0. Food and Drug Administration . 10-17-2012. 7-5-2013.

(92) Bebchuk LA, Fried JM. Pay without performance: Overview of the issues. *Journal of Applied Corporate Finance* 2005;17(4):8-23.

(93) Finkelstein S, Hambrick DC. Chief executive compensation: A synthesis and reconciliation. *Strategic Management Journal* 1988;9(6):543-558.

(94) Tosi Jr HL, Gomez-Mejia LR. The decoupling of CEO pay and performance: An agency theory perspective. *Administrative Science Quarterly* 1989;169-189.

(95) Hambrick DC, Finkelstein S. The effects of ownership structure on conditions at the top: The case of CEO pay raises. *Strategic Management Journal* 1995;16(3):175-193.

(96) Brickley JA. Empirical research on CEO turnover and firm-performance: A discussion. *Journal of Accounting and Economics* 2003;36(1):227-233.

(97) Lehn KM, Zhao M. CEO turnover after acquisitions: Are bad bidders fired? *The Journal of Finance* 2006;61(4):1759-1811.

(98) Larsson R, Finkelstein S. Integrating strategic, organizational, and human resource perspectives on mergers and acquisitions: A case survey of synergy realization. *Organization Science* 1999;10(1):1-26.

(99) Lepoutre J, Heene A. Investigating the impact of firm size on small business social responsibility: a critical review. *Journal of Business Ethics* 2006;67(3):257-273.

(100) SBA Size Standards Methodology. Small Business Administration . 2013. 6-22-0013.

(101) Table of Small Business Size Standards Matched to North American Industry Classification System Codes. Small Business Administration . 1-7-2013. 6-22-2013.

(102) SEC Charges Johnson & Johnson With Foreign Bribery. U.S.Securities and Exchange Commission . 4-7-2013. 3-2-0013.

(103) Wang S, Bressman JO, Reidler JS. Recent Case Developments in Health Law. *The Journal of Law, Medicine & Ethics* 2010;38(3):708-716.

(104) Kim KH, Al-Shammari HA, Kim B, Lee SH. CEO duality leadership and corporate diversification behavior. *Journal of Business Research* 2009;62(11):1173-1180.

(105) Plunkett JJ, Dale BG. Quality costs: a critique of some GÇÿeconomic cost of qualityGÇÖmodels. *The International Journal Of Production Research* 1988;26(11):1713-1726.

(106) Freiesleben J. On the limited value of cost of quality models. *Total Quality Management & Business Excellence* 2004;15(7):959-969.

(107) Woodcock J, Wosinska M. Economic and technological drivers of generic sterile injectable drug shortages. *Clinical Pharmacology & Therapeutics* 2012;93(2):170-176.

(108) Haninger K, Jessup A, Koehler K. ASPE Issue Brief: Economic analysis of the causes of drug shortages. 2011. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services.

(109) *Pharmaceutical Research and Manufacturers Association 2003 Profile*. Washington, DC: PhRMA; 2003.

(110) Pammolli F, Magazzini L, Riccaboni M. The productivity crisis in pharmaceutical R&D. *Nature Reviews Drug Discovery* 2011;10(6):428-438.

(111) Martinez B, Goldstein J. Big Pharma Faces Grim Prognosis 000 Industry Fails to Find New Drugs to Replace Wonders Like Lipitor. 2007.

(112) Roberts PW. Product innovation, product-market competition and persistent profitability in the US pharmaceutical industry. *Strategic Management Journal* 1999;20(7):655-670.

(113) Carson KL. FDA crackdown on Genzyme. *Nature Biotechnology* 2010;28(5):388.

(114) Wang, Shirly. Bristol-Myers Cutting Jobs, Factories & Products. Wall Street Journal . 12-5-2007. 5-10-0013.

(115) Cecere L. So you want to outsource manufacturing. *Supply Chain Management Review* 2005;9(6):13-14.

(116) Gray JV, Roth AV, Leiblein MJ. Quality risk in offshore manufacturing: evidence from the pharmaceutical industry. *Journal of Operations Management* 2011;29(7):737-752.

(117) Gray JV, Roth AV, Leiblein MJ. Quality risk in offshore manufacturing: evidence from the pharmaceutical industry. *Journal of Operations Management* 2011;29(7):737-752.

(118) Herper M. A Decade in Drug Industry Layoffs. *Forbes com www forbes com/sites/matthewherper/2011/04/13/a-decade-in-drug-industry-layoffs* 2011.

(119) Carroll JD. Top 10 Pharma Layoffs of 2012. Fiercebiotech . 2-19-2013. 6-15-2013.

(120) Wilkinson A. Downsizing, rightsizing or dumbsizing? Quality, human resources and the management of sustainability. *Total Quality Management and Business Excellence* 2005;16(8-9):1079-1088.

(121) Mellahi K, Wilkinson A. Organizational failure: a critique of recent research and a proposed integrative framework. *International Journal of Management Reviews* 2004;5(1):21-41.

(122) Wilkinson A, Hill M, Gollan P. The sustainability debate. *International Journal of Operations & Production Management* 2001;21(12):1492-1502.

(123) Fisher SR, White MA. Downsizing in a learning organization: are there hidden costs? *Academy of Management Review* 2000;244-251.

(124) Wilkinson A. Downsizing, rightsizing or dumbsizing? Quality, human resources and the management of sustainability. *Total Quality Management and Business Excellence* 2005;16(8-9):1079-1088.

(125) Lowe NJ. Job creation and the knowledge economy: Lessons from North Carolina's life science manufacturing initiative. *Economic Development Quarterly* 2007;21(4):339-353.

(126) Hsieh PH, Mishra CS, Gobeli DH. The return on R&D versus capital expenditures in pharmaceutical and chemical industries. *Engineering Management, IEEE Transactions on* 2003;50(2):141-150.

(127) Voreacos D, Feeley J. J&J Agrees to Pay $22.9 Million to Settle on Drug Recalls. Bloomberg . 7-15-2013. 7-19-2013.

(128) JOHNSON & JOHNSON'S RECALL OF CHILDREN'S TYLENOL AND OTHER CHILDREN'S MEDICINES AND THE PHANTOM RECALL OF MOTRIN (PART 2): of the House Comm. on COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM, HR, JOHNSON & JOHNSON'S RECALL OF CHILDREN'S TYLENOL AND OTHER CHILDREN'S MEDICINES AND THE PHANTOM RECALL OF MOTRIN (PART 2), (Oct 30, 2013).

(129) Kimes M. Why J&J's headache won't go away. Cnn Money . 8-19-2010. 6-22-2013.

(130) World Health Organization. *Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials. Good Manufacturing Practices and Inspection*. World Health Organization; 2007.

(131) Adams S. The Biggest CEO Screwups of 2011. 12-22-2011. 7-22-2013.

(132) Fried J, Shilon N. Excess-pay clawbacks. *Journal of Corporation Law* 2011;36:722-751.

(133) Strauss L. Bringing J&J Back to Health. Barron's . 10-10-2011. 7-5-2013.

(134) Eban K. Dirty Medicine. Fortune . 5-15-2013. 7-4-2013.

(135) Finkelstein S, Whitehead J, Campbell A. Think again: Why Good Leaders make bad decisions. *Business Strategy Review* 2009;20(2):62-66.

(136) Webb DK, Molo SF, Hurst JF. Understanding and avoiding corporate and executive criminal liability. *The Business Lawyer* 1994;617-668.

(137) Finkelstein S. Classroom Discussion on Organizational Breakdowns, Video. Tucks School of Business . 10-10-2013.

(138) Basile EM. Medical device reporting: the good, the bad, and the ugly. *Food Drug Cosm LJ* 1987;42:83.

(139) Lustgarten A, Knutson R. Years of internal BP probes warned that neglect could lead to accidents. *ProPublica, June* 2010;7(10):00.