The Deterrent Effects of Corporate Punishment: Restoring the Broken Image of the Pharmaceutical Industry

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Introduction

Over three hundred million people live in the United States, home of the world’s largest healthcare industry. In the United States, $300 billion a year is spent on prescription drugs alone, and that number is rising. Despite the undisputed fact that pharmaceutical companies have made significant contributions to health care and in improving quality of life for patients, they are regularly critiqued as one of the least trusted industries, next to the nuclear industry, in public opinion surveys.² Numerous pharmaceutical companies commit crimes severe enough to be ranked in the top 100 corporate criminals list.³ However, when it comes time to prosecute them, their punishments are a mild reprimand for their crimes. Medications, and the industry that governs their development, the pharmaceutical industry, are human creations made to improve and extend our natural health boundaries and quality of life. However, what happens when too much power is extended to a technolog-

ical system* that holds control of our most basic and vital human rights, namely that of health and life? Pharmaceutical companies are often deemed as the “thugs” of the medical industry because, like giant banks on Wall Street, they are accepted as too big to fail.\(^4\) Like many pharmaceutical companies, Pfizer abuses the power granted by the structure of the healthcare system to illegally commercialize products at the expense of a patient’s wellbeing without taking full responsibility of their actions when caught. This injustice causes societal implications, and all participants that ought to be “winners” benefitting from this technological system (e.g. patients, doctors, pharmaceutical companies, and the healthcare industry) instead secure more losses, ultimately becoming “losers” of the system. However, solutions in restoring the image of the pharmaceutical industry can generate the necessary stubborn change.

This Investigation seeks to explore the negative societal implications of limited regulation in unethical criminal acts of pharmaceutical giants and potential solutions to increase public trust in Big Pharma. It does this by drawing on literature from medical history, philosophy, and sociology. This piece integrates ideas from these disciplines by utilizing the ideas of an experienced physician and health journalist, an emeritus sociology professor interested in socio-technological systems, and an interdisciplinary Harvard philosophy and technology studies professor to better understand the ramifications of America’s self-destructive health care system and generate potential solutions to remedy its grave impacts on society.

\(^5\)Pfizer Inc., “Pfizer Company History”, http://www.pfizer.com/about/history/all

*Note: the term technological system is used throughout this piece because medication and drugs are considered to be pieces of technology with the practical purpose of treatment, care, and promotion of health. The pharmaceutical industry is a system that employs drugs and medications, as is in large part a participant of the health care system.

**Background**

Pfizer researches, develops, and produces vaccines and medications over a range of medical disciplines, including the widely known little blue pill, Viagra. The global pharmaceutical giant was established and produced its first product in 1849\(^5\) and has since accumulated over $4 billion in fines.\(^6\) Pfizer’s fourth settlement over illegal marketing activities was the largest portion of the $4 billion. An historic $2.3 billion settlement resolved the civil and criminal allegations in fraudulent marking for the painkiller Bextra, and other drugs including the antipsychotic Geodon, the antibiotic Zyvox, and the antiepileptic Lyrica.\(^7\) As of 2009, this settlement was the largest criminal charge of any kind imposed in the United States.\(^8\)

Bextra was identified as part of a radical class of painkillers known as cyclooxygenase 2 (COX-2) inhibitors, at twenty times the price of ibuprofen, but intended to be safer than generic drugs.\(^9\) In 2001, Bextra was proposed to hit the market as an acute pain treatment after surgery. The U.S. Food and Drug Administration (FDA) approved Bextra for menstrual cramps and arthritis but deemed it unsafe at higher doses for acute surgical pain and for pa-
patients at high risk of heart attacks. With billions in profit at stake, Pfizer and its partner, Pharmacia, neglected the approval of the FDA and employed teams of sale managers across the country to market Bextra to health care professionals. To further incentivize prescription orders from doctors, a multimillion dollar budget intended for medical education was used instead to illegally pay doctors as promotional speakers and consultants for Bextra and other drugs.

The act of promoting drugs for unapproved uses is called “off-label marketing” and it is judged as a criminal offence because it can severely harm the lives of patients, especially those with dire health conditions. Even knowingly so, CNN Special Investigations Unit reported that a scripted sales pitch from Pfizer was emailed to sales representatives in Florida which condoned sales up to a 40 mg dose, twice what the FDA deemed to be safe. In court, Pfizer pleaded that, “the company’s intent was pure”. However, when Bextra was taken off the market in April 2005, “more than half of its $1.7 billion in profits had come from prescriptions written for uses the FDA had rejected.” Consequently, while the intent behind producing Bextra was to provide another alternative to improve the lives of patients suffering from pain, marketing Bextra at harmful unapproved dosages only harms these patients. If more than half of the earnings from Bextra came from off-label marketing, it is hard to believe Pfizer promoted Bextra with the patient’s best interest in mind.

### The Conviction and Settlement

The number of patient lives put at risk increased with every sale of Bextra. Considering this was Pfizer’s fourth settlement over fraudulent marketing, the punishments for their crimes should logically increase in severity to cripple the company enough such that they learn their lesson. However, with the following complicated legalities of the case, Pfizer escaped severe corporate punishment and even had difficulties bearing the requirements of their favorable resolution.

Any company convicted of serious health care fraud faces automatic exclusion from Medicare and Medicaid as the one of harshest forms of corporate punishment. Doing so will prevent a company from collecting compensation for the products it provides to Medicare and Medicaid. Prosecutors tried convicting Pfizer with the automatic exclusion clause that would lead to Pfizer’s collapse. However, Pfizer’s general counsel, Amy Schulman, urged: “the vast majority of our employees spend their lives dedicated to bringing truly important medications to patients and physicians in an appropriate manner.” Therefore, in consideration of the Pfizer employees not involved in fraudulent activity, patients relying on Pfizer products through Medicare and Medicaid, and the losses for Pfizer shareholders, Pfizer was given an exception from the automatic exclusion condition. For redemption for all prior cases of fraudulent marketing, Pfizer was given a fourth chance.

Instead of imparting a criminal charge upon Pfizer, prosecutors agreed to charge Pfizer

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through its subsidiary, Pharmacia & Upjohn Co. Inc. A subsidiary corporation is defined as one in which a generally larger company, known as the parent corporation owns all or most of its shares. As the owner of the subsidiary, the parent corporation controls the activities of the subsidiary. Instead of a merger, forming a subsidiary may be more beneficial to the parent company because the approval of the stockholders is not required and the parent owns a controlling interest with a smaller investment. The parent and subsidiary remains as separate legal entities and the subsidiary may produce goods and services completely different from those produced by the parent company. Pfizer owns Pharmacia & Upjohn Co. Inc. through inheritance in owning Pharmacia & Upjohn LLC which owns Pharmacia & Upjohn CO. LLC which then owns Pharmacia & Upjohn Co. Inc. If Pfizer was the parent, the company charged with the subsidiary is the greatgreat-grandson. Pharmacia & Upjohn Co. Inc. was incorporated on March 27, 2007 in Delaware. This was the same day when federal prosecutors and Pfizer lawyers battled it out, which led to Pfizer pleading guilty for a bribery case a few years prior to the Bextra case. Thus, Pharmacia & Upjohn Co. Inc., the protective bodyguard against criminal charges for Pfizer was born. The bribery case ended with Pharmacia & Upjohn Co Inc. pleading guilty for Pfizer, and Pharmacia was excluded from Medicare while Pfizer was free to commercialize through federally funded health programs. The same pattern was observed in the Bextra case. Pharmacia pleaded guilty without ever having sold a single pill or dosage of Bextra, while Pfizer was still permitted to sell its products to federally funded health programs. The subsidiary was nothing more than a shell company protecting Pfizer when it got caught in hot waters. Since Pharmacia’s sole function was to take criminal pleas for Pfizer, the impact of corporate punishment was severely minimized.

Pfizer paid almost $1.2 billion for Bextra but Pharmacia & Upjohn Co. Inc. was responsible for the rest. Together, the fees total to $2.3 billion, a record fine for any crime. Preceding the Bextra case, $1.2 billion was the largest sum the federal government has ever collected, until together, Pharmacia and Pfizer nearly doubled it. However, to put the money into perspective, even the total $2.3 billion collected amounts to less than three weeks of sales at Pfizer. Therefore, although $2.3 billion seems like devastating debt to pay, for a pharmaceutical giant like Pfizer, it may simply be spare pocket change. Harvard Medical School health science researcher and attorney, Aaron Kesselheim, worries that “settlements for fraud should do more than punish a particular company...it should send a message to the industry about what are-or are not-reasonable practices...there’s a big question as to whether these settlements actually do that.” Corporate punishment is meant to serve as a deterrent against criminal misconduct, but the punishment for Pfizer was essentially halved because they did not take full responsibility for their crime. Instead, Pfizer created an imaginary friend to take the fall for them.

19David Tippie, “Collapse of Drugs Due to Wellness” (Lulu Com, 2010), 12
While Pfizer was settling the improper marketing of Bextra and the three other medications involved, the company was also in the midst of bearing the expenses for marketing fraud with regards to the epilepsy drug, Neurontin, from 2004, and federal charges in illegal promotion of the growth hormone, Genotropin, from 2007. The Bextra scandal of 2009 was simply their fourth off-label marketing fraud, but it was not their last. In 2011, Pfizer was ordered to pay federal charges for illegally marketing the bladder drug Detrol. With the settlements of Detrol and Bextra being only 2 years apart, it is safe to conclude Pfizer did not learn their lesson from punishments prior to Bextra, and they certainly did not learn their lesson after, either. Illegal advertisement and marketing are the only crimes considered in this report, but Pfizer’s list of crimes under product safety, fixed pricing, bribery settlements, tax evasion, and more, are not short either. Mike Loucks, the federal prosecutor who oversaw the Bextra investigation worries that “the money is so great, dealing with the Department of Justice may be ‘just the cost of doing business.’”

As part of Pfizer’s Bextra settlement, and in exchange for continual participation in Medicare, Medicaid, and other federal health care programs, a five-year expansive corporate integrity agreement (CIA) was made between the U.S. Department of Health and Human Services to monitor future marketing activities. The CIA included ongoing review procedures and risk assessment. Pfizer pledged to create risk mitigation plans for every pharmaceutical product manufactured and an independent review organization (IRO) to evaluate product development and its promotions. Evidence of breach of the CIA can lead to the exclusion from participation of federal health programs which would most likely collapse the company. To cure an incompliance breach, Pfizer must comply to a firm monetary penalty at upwards of $5,000 per day the CIA agreement is broken. The government used the Bextra settlement to set forth an example of the rigorous government investigations and settlements for Pfizer’s peers in the pharmaceutical industry.

When the FDA tried to comply with Pfizer, warning them to report serious and unexpected side effects from produced drugs already on the market, Pfizer said they would collaborate with the FDA and “assured optimal surveillance and reporting of post marketing adverse events.” However, the FDA later cited several reporting lapses and even granted the company a waiver for 60 days to account for any complaints of Bextra which Pfizer simply ignored. Therefore, not only did Pfizer bear a minimal punishment in committing numerous fraudulent crimes, but they proved to have difficulty in adhering to their punishment as well. As a result, not only did other pharmaceutical companies learn how to evade drastic corporate punishment, they

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learned punishments do not have to be taken seriously.

Societal Consequences

When a Fortune 500 company with severe fraudulent activity escapes with minimal corporate punishment, negative outcomes can be anticipated. The following outlines arguments of how this injustice and the structure of the healthcare system causes all participants (e.g. patients, doctors, pharmaceutical companies, and even the healthcare industry at large) to become “losers” to this technological system.

The CIA agreement was designed to foster transparency of illegal medical promotions from health care professionals. However, without company compliance, monetary incentives are too numerous and complicated to track down. To capture a service fee like patient consulting is easy, but for travel fees ancillary to research services may only be stated in an expense report system or a logistics vendor. Pharmaceutical companies capitalize on the financial ambiguity to pay doctors under the table for promotional talks, speaker programs, research programs, and even to conduct unethical clinical trials. However, even doctors accepting bribes cannot bear all the faults of the corrupt industry either.

When a patient receives a prescription from a physician, they trust that the doctor has done extensive research about the drug. However, bad clinical trials are regularly erased from the report presented to doctors for the drug of interest. Doctors spread their time thinly, in between treating patients and updating themselves on the latest medical practices. They do their best in fulfilling the expectation to do in-depth research on every drug they prescribe but faulty research data makes this task difficult. When health care professionals promote a drug, they trust that their medical expertise conviction will provide more benefit or relief to the patient than harm, but sometimes the result cannot be all the fault of the doctor.

In a different perspective, pharmaceutical companies may not be exploiting power, instead the power is extended to them by the structure of the healthcare system. Thus, problems may lie in the structure of the healthcare system itself. The medical system is developed to nurture one’s health. Typically, participants of the system such as hospitals and pharmaceutical companies should also have the same chief commitment. However, pharmaceutical companies are structured and run as businesses. The purpose of the medical system conflicts with the purpose of a business. The intent of a business is to generate maximum profits by creating a product better than the competition. The pharmaceutical industry must juggle the responsibilities of the health care industry and its financial survival. In instances where the truth hinders product marketing, it may be of more interest to the company to prioritize the survival of the company and contemplate about the quality or harm of its products thereafter. Ideally, pharmaceutical companies try to fulfill the purpose of a business simultaneously with the purpose of medicine, but realistically, one may be prioritized over the other.

One may also argue there is only one winner in this corrupt system, Pfizer; it is the only member of this system securing profits. The power of the company is simply too large for lawsuits to affect their business. The profits the company earns from unethical activities such as off label marketing are only reimbursed fractionally from these settlements. However, the company does also bear social costs, especially the respect of their name. Undeniably, pharmaceutical companies have created numerous beneficial products devised to help improve the quality of life for patients. Yet, in public opinion surveys, they are regularly critiqued as one of the least trusted in-

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33 Ben Goldacre, “Bad Pharma How Drug Companies Mislead Doctors and Harm Patients”, February 2013, chapter 1 and 6
dustries next to the nuclear industry. Like any business, the public is the industry’s consumer and source of profit. If the public continually disproves of a company’s ethical conduct, there may be other companies that produce similar products which the public, as consumers, will naturally explore as alternatives, and eventually, Pfizer’s loyal customers will abandon the perilous company for products of a more honorable company.

Technological institutions, like the pharmaceutical industry, and inventions, like medications, are built with the intent of providing a better quality of life for society. However, in evading corporate punishment and harming millions, Pfizer is an example of how a technological system may exploit power within a society and warrants a re-evaluation of the true winners and losers of this technological system.

Ideally, all participants of this medical industry ought to benefit from one another. Pharmaceutical companies, like Pfizer, can commercialize medications aimed at improving a set of patient symptoms derived from the best recommendation of a doctor. Patients get better because their doctors prescribe a safe and suitable medication for their needs, and the pharmaceutical company can turn a profit from their reliable product. Everyone in the system wins. However, patients do not get the help they seek because doctors are prescribing harmful medications made by pharmaceutical companies with narrow financial concerns. Patients do not get better. The vow of a doctor practicing medicine, to provide the best care for their patient, is broken. The profits of the pharmaceutical company are returned in government settlements and their tarnished name. The reputation of the pharmaceutical industry sustains irreparable damage. Everyone in the system loses. Thus, in such a complex system of medicine, regulation and ethical reform should be established for pharmaceutical companies to restore the “winners and losers” imbalance of the healthcare system and public faith of the industry.

Solutions to Restoration

The pharmaceutical industry retains a bad reputation in the public eye, and often with reason, as exhibited from the events of the Bextra case. However, restoring this reputation can evoke necessary change in unethical corporate practices and still support the company’s bank account. A corporations reputation is an intangible asset as valuable as the company’s worth. With a good reputation, a company can fully capitalize on its commercial goods while satisfying consumer demands. A pharmaceutical company’s reputation would depend on the experience that patients have had with the company’s manufactured drugs and how the company is portrayed in media and by word of mouth. Only 34% of patient groups surveyed from Europe and North America believed major drug companies had good reputation. The drug industry has complicated and conflicting roles in improving the lives of patients while maximizing profits to fund further research and satisfy shareholders. Often, the pressure of how well their stock performs puts the needs of patients secondary. There is no cure-all to revitalize an industry’s reputation, it takes time and a collective effort towards change. The following offers some steps to take in repairing this image.

One method to rebuild the pharmaceutical industry’s reputation is to induce an ethical reform to put the needs of patients first. Medicine was primarily developed for patients, not profits. Major drug companies can collaborate with patient organizations to bridge the communication gap between patient needs and listen to ways to comply to them. Rather than promoting specific products, this fosters trust in the company. Programs that build bonds with patients and their physicians is a good place to start because physicians hear the patient’s needs directly. As an

Environment, 2015, 1-33.


37Mark Kessel, “Restoring the pharmaceutical industry’s reputation”, Nature Biotechnology 32 (2014): 983-990
example, teaching patients about health issues, like the harmful effects of when drug regimens are not followed, provides a more constructive educational experience than marketing products to patients. Companies can develop adherence programs for the drugs they produce to assist in educating patients. Pfizer developed a social media campaign in 2014 launching the hashtag #FOGO, “fear of getting old”, to nurture the Pfizer brand. Rather than promoting a product, Pfizer simply stimulated conversations with the public to listen to their worries. By refocusing on patient needs, the company caters to its biggest stakeholder, the consumers. A restaurant known for its great service will naturally attract more customers. If a pharmaceutical company is strongly committed to provide customers/patients exceptional care, generating profits will follow. Serving the needs of neglected patient groups, offering drugs with long term needs instead of short term health benefits, making drugs reasonably priced, and eliminating misleading marketing of drugs are a few demands the public has for the industry. To convince the public that pharmaceutical companies care about them is no easy task, but not impossible. It will require a sense of urgency on an industry-wide basis.38

The public also worries that drug companies have no regard for patient safety. Implementing data transparency to ensure patient safety and generate honest conversations between health care professionals and drug companies is one way to combat this fear. Pharmaceutical companies are known to only publish successful research data and deleting the negative clinical trials. Understandably company trade secrets in formulating their drugs must remain confidential to generate profits for their products, but there are no excuses in withholding patient safety data. Publishing all clinical data will drastically improve clinical decisions and ties back to the point of focusing on care of patients rather than marketing drugs to them. Transparency also changes behavior. ProPublica is a publicly accessible website that tracks promotional payments to health care professionals. Drug companies have been forced to enter their data into the database after numerous legal cases were lost. After industry payments to doctors have become more visible, such payments started to decline. Data transparency, such as annual financial reports and publishing negative clinical trial data, will promote patient safety, reduce unethical practices, and restore Big Pharma’s good name.39 Brand reputation is a valuable asset. If the pharmaceutical industry invests in its reputation with the same care as it does its other assets, positive change will certainly ensue.

No one individual, one patient, one doctor, one company, can induce this change in America’s healthcare system. A collected effort from all participants will only guarantee this stubborn but necessary restoration. It starts from the ground up: if pharmaceutical companies take initiatives towards ethical reforms to prioritize the needs of patients before their financial reports then patients and the public will be less skeptical of the drug industry, and trust and profits will naturally rise. The improvement of data transparency builds a stronger bridge of trust between health care professionals and pharmaceutical companies. Physicians can rely on the research of the drug and naturally further support a high-quality product without the extra illegal expenses of paying doctors as promotional speakers for the company. These potential solutions can restore the imbalance of “winners and losers”, and help reduce immoral practices within the healthcare system, an industry intended to support and improve the value of our lives.

Take Away

Drug companies, like Pfizer, have lost their prestige in the public eye due to numerous du-

38Mark Kessel, “Restoring the pharmaceutical industry’s reputation”, Nature Biotechnology 32 (2014): 983-990
39Ben Goldacre, “Bad Pharma How Drug Companies Mislead Doctors and Harm Patients”, February 2013, 334-379
bious practices. Questionable practices such as illegally marketing drugs at harmful dosages, bribing health care professionals, evading corporate punishment at the time of prosecution, and reluctance in adhering to the terms of corporate punishment, are some examples seen in the Bextra case that gave the pharmaceutical industry its bad name. Although drug companies have made many mistakes in the past, it is never too late to change. Steps in repairing the reputation of the pharmaceutical industry, like putting the needs of patients first and promoting data transparency, benefits both the public and the company. While listening to the demands of the public and fostering public safety, the company attracts more consumers by nurturing its brand and improving its relationship with the public. However, reputational change takes time and require industry wide effort. The public’s trust in big pharma will worsen if a collected effort to fix fundamental problems is not made which would continue to harm the health of the public and the industry.

About the Author

Hi I’m Emily! I recently graduated with a Bachelors of Science in Biochemistry Molecular Biology in Lyman Briggs at Michigan State University. My research interests align very closely to that of Briggs in fields such as history, philosophy, and sociology (HPS) of science and applying that to new technological systems and applications such as the highly controversial topic of CRISPR, artificial intelligence, and military drones. In the future, I would also like to delve into research in hard science fields such as DNA replication, cloning, and genetic epidemiology. I wrote my submission after an HPS class had exposed me to America’s broken healthcare system and the limitations of fixing dubious traditions within the system. It made me realize how little the public knows about what goes on behind the scenes of an industry intended to nurture and foster health. I wanted to publish my work in JIRR to inform others about what I had discovered and for others to use and build upon my ideas as well. I believe knowledge sharing is vital for all fields of research to continue to flourish and expand. I believe a journal like JIRR is a great initiative and I hope it continues for years to come to give undergraduates a voice and a chance to share our passions with one another.
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