Penalties for Fraud in the Pharmaceutical Industry: A Financial and Reputational Analysis

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Abstract

In this study, we examined federal cases involving fraud by pharmaceutical manufacturers between 2000 and 2022, including only publicly held companies whose settlements were at least $1 million. 169 cases were identified. Our goal was to determine if the penalties would simply be a nuisance to the company or if they would have a significant financial impact. In addition, we discussed a private pharmaceutical company and included the findings from a content analysis of public sentiment to assess the lingering impact of fraud on a brand. For both the public and private firms, we found evidence of negative impact, both financial and reputational. We also highlighted the fact that the financial penalties were significant for only a portion of the companies analyzed and that many of the manufacturers continue to commit violations repeatedly, regardless of the penalties assessed.

Keywords: Corruption; fraud; public sentiment; Purdue Pharma; Oxycontin

Objectives

The objectives of this paper are twofold; one, to examine the financial impact of penalties for fraudulent behavior that are paid by pharmaceutical manufacturers in relation to their financial performance, and two, to assess the lingering reputational impact of fraudulent behavior. Penalties imposed on

pharmaceutical companies can arise from various factors including regulatory non-compliance, legal settlements, and fines resulting from unethical practices. Understanding the financial impact of these penalties is crucial for stakeholders, including investors, regulators, and industry participants. By conducting a comprehensive analysis of financial statements and relevant penalty data, this study aims to quantify and assess the significance of penalties on the financials of pharmaceutical companies. The research will contribute to the literature on the pharmaceutical manufacturing industry by highlighting the fiscal and reputational impact that ethical violations have on these firms.

Introduction

In recent years, there has been a growing concern about the ethical practices of pharmaceutical companies. These companies have been accused of engaging in a variety of unethical activities, including off-label marketing, providing kickbacks to doctors, and falsifying data. These activities have led to billions of dollars in fines and settlements against pharmaceutical manufacturers and have also damaged their reputations (Rajagopal et al., 2022). For example, in 2020, Johnson & Johnson agreed to pay $2.2 billion to settle allegations that it promoted the opioid painkiller Risperdal for uses that were not approved by the FDA (DOJ, 2013). In addition to fines and settlements, ethical infractions can impart other costs including legal fees, implementation of compliance programs, and need for damage control yielding a significant negative impact on a company's bottom line.

The long-term consequences of ethical infractions can be significant, even more so than the immediate financial penalties. These infractions can damage a company's reputation, erode public trust, and lead to decreased sales, loss of market share, and damage to brand value. In addition, ethical infractions can lead to regulatory consequences and increased scrutiny from regulatory authorities, potential limitations on product approvals, and additional compliance requirements which can have indirect financial impacts on the company's operations and future prospects.

By conducting a comprehensive analysis of financial statements and relevant penalty data, this study aims to quantify and assess the significance of penalties on the financials of pharmaceutical manufacturers. The research will contribute to the literature by highlighting the fiscal and reputational impact that ethical violations have on these corporations.

Background

There has been considerable research published on the topic of ethics. Liang, Huang, & Xiao (2023) used fraud triangle theory to analyze the relationship between financial risk and financial fraud, finding the greater the

financial risk to a firm, the greater the potential for financial fraud to occur among firms in the pharmaceutical industry. Andersen and Hong (2012) explored the impact that industry type has on the implementation of corporate social responsibility (CSR) practices. Their research focused on how firms' CSR strengths and concerns varied by industry. Stuebs and Sun (2011) concentrated on CSR and firm reputation. Utilizing stakeholder theory, they found that CSR activities can be utilized to improve financial performance.

According to Gaultier-Gaillard, et al (2009), reputation theory posits that an organization enjoys a good reputation when it consistently meets or exceeds the expectations of its stakeholders. A study of the factors that influence reputation risk in the pharmaceutical supply chain found quality risk and unethical governance are the most damaging to the reputations to firms in the pharmaceutical industry (Rajagopal et al., 2022). Combined, these risk factors lead to endangering the well-being of the end consumer and involve decisions and actions by leadership that are deemed unethical and contrary to balancing obligations to all stakeholders (Rajagopal et al., 2022).

The Association of Certified Fraud Examiners (ACFE) is the largest fraud-fighting organization in the world with over 90,000 members across the globe. The Association works with industries by providing specialized training to prevent and deter fraud and unethical behavior. In an article published by the ACFE Fraud Magazine, Sebaugh (2023) discussed how the Department of Justice (DOJ) indicted 345 healthcare professionals for submitting $6 billion worth of fraudulent claims to federal programs. Sebaugh also examined the global pharmaceutical industry's long-standing problem with fraudulent activities.

Types of Pharmaceutical Ethics Infractions and Related Penalties

Pharmaceutical fraud has been a longstanding issue in the healthcare industry. Some of the most flagrant infractions of pharmaceutical ethics pertain to misleading advertising (Lober, 1993), fear-mongering of diseases (Navar, 2019), and escalating costs (Kirzinger et al., 2019). These infractions have been predominately executed by 'big pharma,' large pharmaceutical companies including those that are politically influential (Merriam-Webster, 2023).

Most of the marketing budgets of big pharma are targeted toward doctors with prescribing authority because the doctors are effectively the gatekeepers to drug sales. In 2019, big pharma collectively spent $20 billion to market to doctors and an additional $6 billion to market directly to consumers (Mole, 2019). To put this amount in perspective, big pharma went from spending $17.7 billion on medical marketing in 1997 to $29.9 billion in 2016 (Schwartz & Woloshin, 2019). An example of the efficacy of this type of marketing is evidenced by the actions of Purdue Pharma and their resultant

spike in sales. In the 1990s, Purdue Pharma launched aggressive awareness campaigns and pain education programs about opioid treatments for chronic, non-cancer pain. The result was that between 2000 and 2015, opioid prescriptions and overdose deaths quadrupled. In 2020, 44 people died each day from prescription opioid overdoses (CDC/NCHS, 2020). Drug manufacturers and distributors faced allegations of downplaying the addictive nature of their products and contributing to the widespread misuse and abuse of prescription opioids (United States Department of Justice, 2020).

Ethical misconduct has been a persistent problem throughout the history of the industry. Over the past 23 years, firms have been most often penalized for Off-Label Marketing and offenses against the False Claims Act. Table 1 indicates the violation type, the sum of the penalties for the specific violation types and the percentage of total violation charges each violation type represents. The data shows that over half of the fraud violations between 2000 – 2022 were due to off-label marketing or unapproved promotion of medical products.

Table 1. *Total Dollar Amount Paid Per Violation Type*

Violation Type	Sum of Penalty/Settlement (in $ millions)	Percentage of Total Violation Charges
Off-label or Unapproved Promotion of Medical Products	18,424	53.14
False Claims Act and related	12,061	34.78
Price-fixing or Anti-competitive Practices	1,563	4.51
Foreign Corrupt Practices Act	1,131	3.26
Kickbacks and Bribery	956	2.76
Fraud	306	0.88
Accounting Fraud or Deficiencies	233	0.67

Note. Data source: Violation Tracker, 2023

Off-label marketing refers to the practice of promoting or advertising a drug, a treatment, or a medical device for uses that have not been approved by the Food and Drug Administration (FDA). Off-label marketing may involve a pharmaceutical company promoting a product for unapproved uses, dosage forms, dosages, or patient populations. It can also involve providing unapproved product information to healthcare professionals or consumers.

There are a few reasons why drug or device manufacturers might engage in off-label marketing. One reason is the increase in sales driven partially by the influences of innovation and competition spurred by legislative protections of pharmaceutical manufacturers (Malerba & Oresnigo, 2015) and increased consumer pharmaceutical utilization (Tichy et al., 2022). If a drug or device is approved for a limited number of uses, the manufacturer may want to promote it for other uses to increase the number of prescriptions written.

Another reason for off-label marketing is to bypass the FDA's approval process. which is lengthy and expensive, so manufacturers may want to promote a drug or device for off-label use to get it to market faster.

The False Claims Act (FCA) is a United States federal law that imposes liability on individuals and companies who defraud the federal government by submitting false or fraudulent claims for payment, including those pertaining to off-label marketing (Van Norman, 2023). The FCA also provides for treble damages requiring defendants found in violation to pay three times the monetary amount of damages sustained by the government because of the fraud. The ACFE warns that FCA violations can have serious consequences for pharmaceutical companies that include civil penalties of up to $10,000 per claim, criminal fines of up to $250,000 per violation up to five years in prison, and exclusion from any government healthcare programs (ACFE.com).

The impact of pharmaceutical companies' payments for violations on their bottom line can vary depending on several factors, including the size and financial strength of the company, the magnitude of the violations, and the specific circumstances surrounding the case. Overall, while the immediate financial impact of violations can vary, the long-term consequences such as reputational damage and regulatory consequences can significantly affect a pharmaceutical company's bottom line.

In addition to the financial penalties levied by the courts, companies found to be engaging in fraudulent behavior can suffer extensive damage to their brand (Ciesielka, 2021). Except for the oil industry, no other sector is more susceptible than the pharmaceutical industry to negative or positive changes in public opinion. Positive news about successful clinical trials or shared personal successes on social media might increase stock value while the inverse will have a negative impact on valuations (Moskowitz et al, 2007).

Materials and Methods

For the purposes of this paper, we utilized the database “Violation Tracker” which has been tracking corporate misconduct since 2000. It covers a wide range of cases resolved by federal regulatory agencies and all parts of the US Justice Department, plus cases involving state attorneys general and some selected state and local regulatory agencies. In total, they have 557,000 civil and criminal cases in their database from over 400 agencies with penalties of $930 billion (violationtracker.goodjobsfirst.org). Examples of other studies using Violation Tracker include wage theft (Raghunandan, 2021), the presence of external monitoring by the press (Heese et al., 2022), and the relationship between corporate misconduct and earnings restatements (Miller, 2022). Our research focused on fraud within the pharmaceutical manufacturing industry. We included all federal cases involving

pharmaceutical manufacturers through FCA violations, FCPA violations, kickbacks and bribery, off-label or unapproved promotion, price fixing, and accounting fraud cases that were prosecuted between 2000 and 2022. We focused on publicly held companies due to the availability of data. We included both civil and criminal cases in our analysis. All other federal and state cases were eliminated due to being immaterial in nature and the length of this study would be too great. All cases settled for less than $1 million were excluded for the same reason as stated previously. We focused not only on the top violators in dollar value but also on the number of violations over the 23-year time span. We also included available data on Purdue Pharma (a privately held company) in the Discussion section given that they were assessed the largest settlement in history.

Financial Analysis Methodology

Once the parameters of the sample were determined, we utilized the "advanced search" option in Violation Tracker. We selected the parameters that were previously indicated and ran the report. We then took the resulting data and sorted it to only include firms in the pharmaceutical industry and proceeded to examine the data in Excel. We identified the top violators in the industry and then accessed their annual report for the corresponding year of their violation payment/settlement. Finally, we examined the firms' violation penalty relative to their net income, current assets, and total assets.

Sentiment Analysis Methodology

Social media and blogs yield the opportunity to gauge public sentiment on a variety of topics. Sentiment analysis is the process of gathering and analyzing people's opinions, thoughts, and impressions on a specific company, product, subject, or service and is used by businesses, governments, and organizations (Sanchez-Rada & Iglesias, 2019). Examples include using hotel reviews to gain an understanding of consumer perceptions of their service experience (Valencia et al., 2019) and customer satisfaction in the healthcare industry (Baashar et al., 2020; Miotto et al., 2018).

Just as the financial analysis was conducted to identify the top violators and the corresponding financial impact (penalties); a sentiment analysis was conducted on Purdue Pharma to gauge reputational impact. As explained by Saja, Teo, et al., surrogates are alternative measures to depict key facets of the target indicator (2020). Reputational data was gathered because, as a private company, financial statements for Purdue Pharma were not available so reputational impact was used as a surrogate indicator. Purdue Pharma was focused upon given the egregiousness of their infractions and the extensive publicity of the court judgement. A sentiment analysis was used to detect lingering hostility consumers have toward Purdue Pharma, the makers of

Oxycontin and Narcan and the enduring consequences of their actions: specifically, damage to their brand.

The sentiment analysis was conducted using Brand24, a firm that tracks and analyzes all public sources including social, news, blogs, videos, forums, podcasts, reviews, etc. The company uses proprietary data analytics tools to assign feelings like sadness, anger, frustration, and happiness by matching text to a list of words tagged with one of these emotions. Purdue Pharma was entered as the keyword and a dashboard was generated with all the mentions for the company, the source of the content (e.g., Facebook, blogs), the volume of mentions, and the nature of the sentiment: positive or negative from February 29 – March 29, 2023. The date range was selected given the announcement of Narcan being approved for over-the-counter sales on March 27, 2023. Narcan is used to counter opioid overdoses (including prescription opioid medications like Oxycontin). The release date is significant to gauge the public's lingering sentiment toward Purdue Pharma and the potential long-term damage to the brand's reputation.

Results

Our financial analysis of public companies found 471 total violations within the pharmaceutical industry between 2000 and 2022 for those cases that settled for more than $1 million with the total amount in fines being approximately $95.64 billion in the 23-year analytic period. The Purdue Pharma settlement of $8.3 billion in 2020 is the largest settlement in industry history. It is also the second highest civil litigation settlement in U.S. history, runner-up to the tobacco settlement in 1998. Purdue pleaded guilty to conspiracies to defraud the United States, violation of the Food, Drug, and Cosmetic Act, and violating the anti-kickback statute (USDOJ, 2020). Although the Purdue case was substantial, it will not be included in our financial analysis because it is not a publicly traded company, and its financial statements are not readily available. Also worth noting is TAP Pharmaceutical Products. They were also on our list of the top ten pharmaceutical fraud violators with a penalty of $875 million in 2001 (see Table 2). At the time of the violation, they were not a publicly traded company, so their financial statements were unavailable thus they too will not be included in our financial analysis.

As mentioned previously, our financial analysis included both civil and criminal cases impacting public companies from 2000-2022, resulting in a list of 169 violations, totaling $34.7 billion in penalties. We found it valuable to show the violators' ranking not only by the number of violations on record (see Table 2) but also by the total amount of penalties assessed (see Table 3). In both tables, Pfizer and Johnson & Johnson hold the top two spots in the

ranking as far as total penalty dollars paid and number of penalties. These findings illustrate the prevalence of repetitive infractions.

Table 2. *Top Pharmaceutical Fraud Violators, Ranked by Number of Violations*

Parent Company	Total Penalties Assessed (in $ millions)	Number of Violations on Record
Pfizer	4,357	15
Johnson & Johnson	3,319	12
Novartis	2,281	10
Abbott Laboratories	739	9
AbbVie	2,748	9
AstraZeneca	971	8
Sanofi	486	8
Bausch Health	183	7
Bristol-Myers Squibb	1,336	7
Teva Pharmaceutical Industries	2,193	7

Note. Data source: Violation Tracker, 2023; analytic period 2000 – 2022

Table 3.
Top 10 Pharmaceutical Fraud Violators, Ranked by Total Penalties Assessed

Parent Company	Total Penalties Assessed (in $ millions)	Number of Violations on Record
Pfizer	4,357	15
Johnson & Johnson	3,319	12
GlaxoSmithKline	3,217	4
AbbVie	2,748	9
Merck	2,413	6
Novartis	2,281	10
Teva Pharmaceutical Industries	2,193	7
Eli Lilly	1,480	3
Viatris	1,347	5
Bristol-Myers Squibb	1,336	7

Note. Data source: Violation Tracker, 2023; analytic period 2000 – 2022

Next, we analyzed the net income (loss) of each company in the violation year to the penalty amount (Table 4). For example, Johnson & Johnson incurred an off-label promotion offense in 2013 for a total penalty payment of $2.20 billion. When compared to Johnson & Johnson's 2013 net income totaling $13.8 billion, the violation amounted to 15.9% of total net income. When looking at these results, one could conclude that the penalties were financially significant to the corporation.

Table 4. *Individual Corporate Penalties Compared to Net Income in Violation Year*

Parent Company	Year	Penalty Amount (in $ millions)	Total Net Income	Penalty as a Percentage of Net Income

GlaxoSmithKline	2012	3,000	7,543	39.77
Pfizer 2009	2009	2,300	8,635	26.64
Johnson & Johnson	2013	2,200	13,831	15.91
AbbVie	2012	1,500	5,275	28.44
Eli Lilly	2009	1,415	4,329	32.69
Teva Pharmaceutical Industries	2015	1,200	1,597	75.14
Merck	2011	950	6,392	14.86
Biogen	2022	900	2,962	30.38
Pfizer 2016	2016	785	7,215	10.87

Note. Data source: Violation Tracker, 2023; Company annual reports; analytic period 2000 – 2022

Our concern when comparing the penalty to the net income of a company is that depending on the year and the cycle of life the company is in, net income can be a fragile and difficult comparison. There are a variety of situations that can affect the net income of a corporation, such as going through a merger or IPO process, having research and development expenses greater than usual, or incurring the entire fraud violation expense in that year. Because net income tends to be highly volatile, we sought to assess the penalties' impact on the companies and chose to analyze each penalty as compared to the corporations' current assets and total assets in the year of penalty. Tables 5 and 6, along with Figure 1 reflect this assessment.

Table 5. *Individual Corporate Penalties Compared to Current Assets in Violation Year*

Parent Company	Year	Penalty Amount (in $ millions)	Current Assets in Year of Penalty (in $ millions)	Penalty as a Percentage of Current Assets
GlaxoSmithKline	2012	3,000	21,770	13.78
Pfizer	2009	2,300	61,670	3.73
Johnson & Johnson	2013	2,200	56,407	3.90
AbbVie	2012	1,500	15,354	9.77
Eli Lilly	2009	1,415	12,487	11.33
Teva Pharmaceutical Industries	2015	1,200	18,398	6.52
Merck	2011	950	33,181	2.86
Biogen	2022	900	9,791	9.19
Pfizer	2016	785	38,949	2.01

Note. Data source: Violation Tracker, 2023; analytic period 2000 – 2022

Table 5 shows the top 10 individual violations ranked by penalty amount along with the companies' current assets in the year of the penalty and the percentage that it represents.

Table 6. *Individual Corporate Penalties Compared to Total Assets in Violation Year*

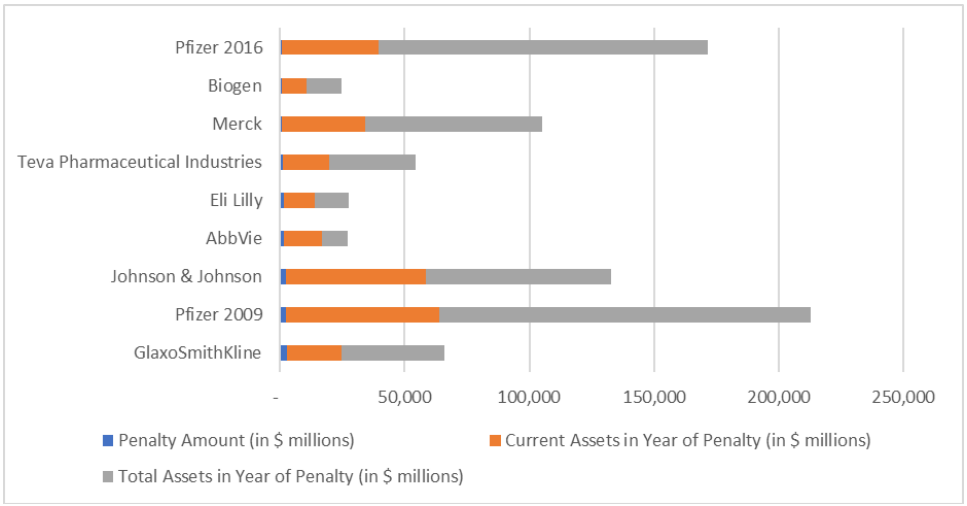
Parent Company	Year	Penalty Amount (in $ millions)	Total Assets in Year of Penalty (in $ millions)	Penalty as a Percentage of Total Assets
GlaxoSmithKline	2012	3,000	65,945	4.55
Pfizer	2009	2,300	212,949	1.08
Johnson & Johnson	2013	2,200	132,683	1.66
AbbVie	2012	1,500	27,008	5.55
Eli Lilly	2009	1,415	27,461	5.15
Teva Pharmaceutical Industries	2015	1,200	54,258	2.21
Merck	2011	950	105,128	0.90
Biogen	2022	900	24,554	3.67
Pfizer	2016	785	171,615	0.46

Note. Data source: Violation Tracker, 2023; analytic period 2000 - 2022

Table 6 shows the top 10 individual violations ranked by penalty amount along with the companies' total assets in the year of the penalty and the percentage that it represents. When comparing Johnson & Johnson's 2013 violation mentioned previously totaling $2.2 billion, as a percentage, that penalty represented 3.9% of the company's current assets, but a meager 1.7% of its total assets.

When looking at these results one could conclude that the overall violation penalties were not financially significant when compared to the current assets or the total assets. In a few of the cases, a 5% impact on total assets could be considered material, especially for a larger company. However, it is important to note that materiality is a subjective judgment and can vary depending on factors such as the size, nature, and industry of the company.

Figure 1. Individual Corporate Penalties Compared to Current Assets and Total Assets in Violation Year



Note. Data source: Violation Tracker, 2023; analytic period 2000 - 2022

Figure 1 represents the amount of the penalty paid, the current assets, and the total assets in the year of the penalty.

Discussion

Financial impact can be subjective in nature. The term "financially significant" generally refers to an item or event that has a material impact on a company's financial statements. It implies that the item or event is important or noteworthy enough to influence the financial condition or performance of the company. In the context of corporate financial statements, financial significance is often determined based on a combination of quantitative thresholds and qualitative judgments. The specific criteria for determining financial significance may vary from company to company, but it typically involves assessing the magnitude, frequency, and potential impact of the item or event.

While the analysis comparing the penalties to the companies' overall net income showed a significant percentage during that penalty year, it is hard to determine how much income was directly contributed to the violation before it was discovered. The analysis that is more telling is that of the comparison of the penalty amounts to total assets, the largest being 10% of total assets paid by Merck in 2007. Johnson & Johnson had two violations in 2021 and paid a mere 4.1% of their total assets in penalties.

When comparing penalty amounts to net income, the penalties paid would generally be considered significant in financial impact. However, when comparing the penalty amounts to current assets and total assets, some would be considered significant, while others were not. When we looked at the repeat

violators, it was clear the penalties had little to no effect on whether the companies repeated the offenses.

Just as a company can experience financial impact for ethical infractions, a company can also experience lasting harm to its reputation as the public learns of a firm's wrongdoing. For example, the public took notice of Purdue Pharma when the company was found guilty of deceptive marketing that downplayed the risk of addiction to Oxycontin in 2019 (USDOJ, 2020). Shortly after the court verdict, a national outcry reverberated across social media. Such press is daunting for a firm to overcome. "The world has changed whereby a company or a person can be 'trialed and found guilty' by social media very quickly without any comeback" (O'Hagan, 2018) ultimately leading to shareholder losses, company closures, or buyouts.

To gauge the lasting effects of the Oxycontin scandal, a sentiment analysis was conducted to observe consumers' reactions to the FDA's approval of Purdue Pharma selling Naloxone without a prescription (branded as Narcan, an OTC therapeutic to address opioid overdoses) four years after the original scandal. A sentiment analysis was conducted on Purdue Pharma two days after the Narcan announcement, on March 29, 2023. The analysis revealed that the company received a staggering 4,350% increase in posts exhibiting a *negative* sentiment. Many of the tweets harkened back to Oxycontin and Purdue's influence on the opioid crisis (Davis, 2023). The public did not forgive Purdue Pharma for their unethical behavior in deceptively marketing the highly addictive drug.

With a global market value of $1.2 billion in 2023 and forecasted to be $11.9 billion by 2027 (Research and Markets, 2023), the pharmaceutical industry has taken steps to insulate itself from financial and reputational penalties due to fraud. Historically the industry has been shaped by a myriad of stakeholders each with their own individual purpose (Malerba & Oresnigo, 2015) and the industry is known for hiring former government employees to cultivate connections within the political arena. Examples include 36 former Congress members; 13 who used to work for federal agencies, 12 who were a part of a related congressional committee, two who worked for the White House, and one who was employed by the court system (Greenman & Greenman, 2017). These connections help shield firms from competitive threats via FDA protections, regulatory barriers, and intellectual property rights. The companies' fraudulent activities still yield substantial penalties. Our findings reveal that the financial penalties were financially significant for only a portion of the companies analyzed and that many of the manufacturers continue to commit violations repeatedly, regardless of the penalties assessed.

Limitations

Our analysis has limitations, principally in that we did not include all categories of violations, privately held companies, or those cases that were settled for less than $1 million. There are also non-financial consequences to the fraud settlements, with the growth of the healthcare industry and pharmaceutical needs, subsequent investigations are recommended. Reasons or motives leading to the penalized infractions are not included. Thus, the cause of the infractions is not clear (i.e., negligence, deviance, or anomalous errors in development and testing).

Conclusion

This study had two primary objectives. The first objective was to examine the financial impact of penalties for fraudulent behavior in relation to a company's financial performance. We examined this through the lens of total assets, net income, and current assets. We found violation impact most revealing when we compared a company's violation penalties to its total assets. We also found that financial impact could be considered significant when comparing penalty amounts to net income while a judgment of significance would be less concrete when comparing violation penalties to current assets or total assets. Observing the prevalence of repeat violations was disheartening, indicating that financial penalties had a seemingly negligible effect on discouraging fraudulent behavior.

The second primary objective was to assess the lingering reputational impact of fraudulent behavior. Using sentiment analysis, we found that negative public sentiment lingers and can inhibit the public's reception of a subsequent product. Pharmaceutical companies should be cognizant that sentiment analysis is being used by investors to inform their investment decisions. Hasselgren, Chrysoulas et al, found that social media sentiment is linked closely with stock market performance. They forecasted an increase in investors using brand reputation (sentiment) to inform their investment decisions (2022). While Purdue Pharma was focused upon sentiment analysis in this study, it would benefit pharmaceutical manufacturers throughout the industry to use sentiment analysis to gain insights into consumers' perceptions, and physicians' product opinions (not just behaviors) and to inform their communication strategy. Recognizing the influence of public sentiment and its capacity to negatively impact a company's reputation should further encourage businesses to act in an ethical manner.

The theory of corporate social responsibility highlights the importance of being mindful of all stakeholders, including customers, employees, stockholders, and channel partners. Our research raises concerns that despite the number of recoveries, significant changes are not yet occurring in the pharmaceutical industry. Until penalties are substantial enough to be a

deterrent, the industry will continue to see the violations as simply "a cost of doing business."

Some practical recommendations to the authorities responsible for enforcing the current laws to aid in deterring pharmaceutical corporations from committing these types of violations might include:

- Increase the amount of fines for manufacturers: Some experts suggest that more substantial fines for manufacturers under the False Claims Act could prevent fraudulent off-label marketing (Kesselheim, Mello, & Studdert, 2011).
- Strengthen enforcement of existing laws: The US government has a number of laws in place that prohibit pharmaceutical fraud, such as the False Claims Act and the Food, Drug, and Cosmetic Act. However, these laws are only effective if they are enforced vigorously. The government should increase funding for investigations and prosecutions of pharmaceutical fraud cases.
- Encourage transparency: Pharmaceutical companies should be required to disclose more information about their clinical trials, pricing, and marketing practices. This would make it more difficult for companies to engage in fraudulent activities without being caught and for consumers and practitioners to make better informed decisions.
- Provide better protection and compensation for whistleblowers: Protecting whistleblowers who report fraud and offering compensation will incentivize others to come forward and help prevent fraud.

In addition to these practical recommendations, some managerial recommendations to the pharmaceutical corporations would include:

- Implement strong internal controls: Pharmaceutical companies should have strong internal controls in place to prevent and detect fraud. These controls should include things like segregation of duties, regular audits, and anonymous reporting mechanisms.
- Provide education and training for employees: Pharmaceutical companies should educate their employees about fraud and how to prevent it. This training should be regular and ongoing. Training should include how to be transparent in crisis communications.
- Promote ethical leadership: Pharmaceutical companies should adopt strong ethical codes of conduct and hold their employees accountable for upholding those codes. Company leaders

should set a good example by being honest and transparent in their own business dealings.

- Create and maintain a culture of integrity: Pharmaceutical companies should create and maintain a culture of integrity where employees feel comfortable reporting fraud without fear of retaliation.

Other suggestions in deterring the pharmaceutical industry from continually committing
breaking these rules are:

- Increase competition in the pharmaceutical industry: Higher levels of competition would make it more difficult for pharmaceutical companies to engage in fraudulent activities without being punished by consumers and investors.
- Reduce the influence that pharmaceutical companies have on government policy: Pharmaceutical companies should not be allowed to have undue influence on government officials who are responsible for regulating the industry. This would help to ensure that government policies are in the best interests of the public, not the pharmaceutical industry.
- Increase support for alternative healthcare systems: The pharmaceutical industry is a very powerful industry, and it can be difficult to reform it from within. Therefore, it is important to support research into alternative healthcare systems that are not reliant on expensive and often dangerous pharmaceutical drugs.

Future research could focus on the correlation between the penalty amount and the number of fines over time; penalties and the timing of leadership change at the companies; and penalty amounts relative to the amount of income made from the product that caused the violation; and penalties and decisions to release products to the market. Future research could also look at the penalty amounts in comparison to the amounts paid in dividends to shareholders and to the effects on stock prices. Finally, future research could also examine the intersection of financial penalties and negative public sentiment to ascertain the negative synergistic impact on violating firms and their supply chain. Considering the tight connection between public trust, CSR, and the increased demand for pharmaceuticals, this work could be expanded to include consumer sentiments regarding the organizations and the amount and frequency of the penalties. In-kind, future studies can build upon this research by replicating the study in another industry that also has multiple violations for fraudulent behavior, such as mining and gas, transportation, or construction.

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