RISK ASSESSMENT AND ANALYSIS OF PHARMACEUTICAL INDUSTRY DUE TO RECALLS

by

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Abstract

RISK MANAGEMENT OF PHARMACEUTICAL INDUSTRY

DURING RECALLS

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In the past five years, there have been 5900 recalls of drugs by the U.S. Food and Drug Administration (FDA) which created distraught consumers and shareholders of pharmaceutical companies. In addition, recalls cause disruption in the supply chain making the pharmaceutical companies vulnerable to various types of risks. These risks include the potential for losing customers and investors as well as the huge financial losses from fines, penalties, lawsuits, revenue loss, market share and increased operations costs.

Purpose: The purpose of this research is to study the consequences of product recall on Pharmaceutical Company.

Methodology:

Event study methodology was used to study the financial impact of a product recall announcement. Multiple linear regression analysis was used to study the operational and reputation risk in terms of recall class (severity), recall reason, recall size, recall scope and size of the company. An interrupted time series design and segmented linear regression models were used to study regulation risk by examining the changes in Research & Development (R&D) expense and Operational expense, following the enforcement of Drug Quality and Security Act regulatory law passed on pharmaceutical companies following a Class I recall.

Findings: The findings indicate that the recall class and recall scope have significant impact on financial, operational and reputation risks compared to the reason of the recall, recall size and the size of the company. The financial and reputational risks increased with the severity of the recall but not the operational risk. Operational risk is high for most reputable companies. The enforcement of regulatory law did not have much effect on large cap companies compared to small cap companies.

Practical implication: The results from this study can be utilized to quickly determine which risks will require an immediate mitigation strategy based on the characteristics of the company and severity of the recall there by reducing significant damage to the company's reputation and financial cost.

Table of Contents

List of Illustrations

List of Tables

Chapter 1

Introduction

"In September 2012, the Centers for Disease Control and Prevention (CDC), in collaboration with state and local health departments and the Food and Drug Administration (FDA), began investigating a multistate outbreak of fungal meningitis and other infections among patients who received contaminated preservative-free MPA steroid injections from the New England Compounding Center in Framingham, Massachusetts (CDC, 2015). This outbreak across 20 states in U.S., which sickened more than 778 patients and ultimately led to 76 deaths, spurred the FDA to inspect compounding pharmacies and other sterile drug producers across the country. Inspection has led to recalls of potentially contaminated drugs"- Huffington Post (Sorscher, 2017).

The Pharmaceutical industry is a vital part of public's health and safety. Recalls have increased because of counterfeiting and tampering of drugs, as well as manufacturing and quality issues caused by increased globalization, outsourcing, and offshoring in the pharmaceutical supply chain. This is affecting the performance of almost all the entities of pharmaceutical supply chain economically and socially. The prevalence of recalls, apart from the health risk to patients, raises many questions:

- What are the risks faced by the pharmaceutical company following a recall?
- How are they affected by the size of the company?
- Will the severity of recall, the reason for the recall, the distribution of recalled product play any role in the risks faced by the pharmaceutical company?
- What effect the regulations have on the pharmaceutical company?

This research has addressed the above questions by identifying and analyzing the risks faced by the companies after a recall, and identifying the factors influencing those risks. It is intended to fill the gap in risk management /operations management by analyzing the risks involved and the operational disruption caused by the recall. Previous studies tell us currently there are standard procedures published by FDA for managing pharmaceutical recalls (FDA, CFR-Code of Federal Regulations Title 21, Chapter 7, 2016) and studies have been performed on methods to deal with drug counterfeiting. These include methods for tracing and tracking drug products across the supply chain. (Choi, Yang, & Cheung, 2015), (Wilcock & Kathryn, 2014), (Berman, 2008). With the rise in product recalls, there are few research articles examining the impacts of product recalls, focusing on the financial consequences of recalls i.e., analyzing the stock market fluctuations (Wowak & Boone, 2015). There is limited research done on overall risks from the recalls that capture the direct cost of recall, the effect of regulatory law because of a recall, the significance of the characteristics of the company in relation to the severity and scope of the recall. This research study takes comprehensive approach to quantify the effects of the recall on the different risks in relation to the characteristics of the company, the severity and scope of the recall.

The financial, operational and reputation risk analysis are based on the yearly sales data obtained from pharmaceutical companies for the Year 2012 and any recalls that occurred in the same year. The analysis of Regulation risk is based on the quarterly expense data reported by the companies from 2010 to 2016.

The dissertation is organized as follows. Chapter 2 describes the pharmaceutical industry, its forward and reverse supply chain, and the complexity of the supply chain. It also briefly describes product recalls, the severity and reasons for recalls, and the understanding of risks faced by the pharmaceutical companies. Chapter 3 describes how

the risks have been analyzed, how the data is collected, and the methodology used in the analysis of the risks. Chapter 4 discusses the results, strengths and limitations, recommendations. Chapter 5 ends with conclusion drawn and directions for future research.

Chapter 2

The Pharmaceutical Industry

The pharmaceutical sector is a highly regulated multi-billion-dollar industry. It encompasses complex processes & operational functions in manufacturing, research & development (R&D), delivery of a variety of drug & medicinal products. It is one of the most challenging industries because of the long time taken for drug discovery, high development cost and multi stage production. Per the Pharmaceutical Research and Manufacturers of America (PhRMA), only 12% of potential medicines investigated by America's research-based pharmaceutical companies' makes it through the research and development pipeline and is approved for patient use by the U.S. Food and Drug Administration. Winning approval for a single new product, on average, takes 15 years of R&D and costs more than $2 billion of private investment (PhRMA, 2016). The stringent regulation imposed by governments for the quality of drug and safety of public health is driving R&D costs even upward resulting in fewer drug releases. Once the winning drug is in the market, its life expectancy is limited due to short term patents which will lead to increase in manufacturing of generic drugs, in turn resulting in loss of market share. The US pharmaceutical industry, which accounts for 49 percent of the global market, is under stress due to competitive pressures, increasing use of generics, difficulty in replenishing their pipeline chains, and erosion of revenues as many blockbuster patents are expiring (Fraser, Heather E IBM Business Consulting Services, 2005). To maintain brand image and shareholder values, companies are adopting a range of strategies that include reaching untapped markets, outsourcing their non-core required competencies, extending drug shelf life, and developing strategic partnerships. This has increased counterfeiting and tampering of drugs, causing potentially fatal risks to public health and increased product recalls. Although the volumes returned (consisting of expired product,

overstocks, and voluntary or mandated product recalls) are low - around 1-2% of the forward supply chain, the cost can be onerous and beyond the economics issues are significant product-liability and regulatory-compliance issues (Shelley, 2010). While risk has always been present in the supply chain due to disruptions or disasters, the drug counterfeiting, and drug quality problems in the supply chain have increased the risks impacting the financial and legal aspects of a company

2.1 Pharmaceutical Supply Chain: Forward & Reverse

2.1.1 Forward Supply Chain

The pharmaceutical supply (see Figure 2-1) denotes the production and distribution of medicines at the right quantities, to the right location, at the right time to satisfy the patient's expectation. The medicinal products flow through manufacturers, warehouses, wholesalers, distributors, pharmacies and finally to the hospitals and patients.

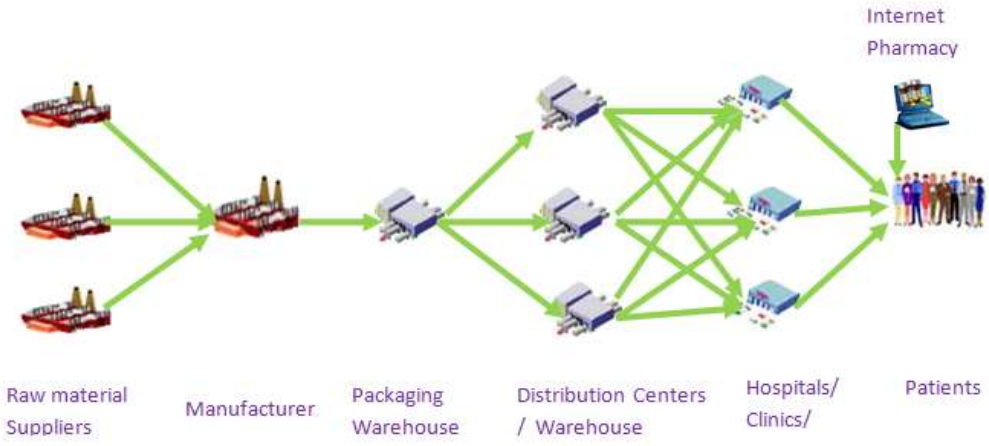


Figure 2-1 Forward Supply Chain of Pharmaceutical Industry

Pharmaceutical companies are struggling to recover their investments, especially with expiration of patents of high profile drugs and increase use of generic drugs. To

minimize cost and to be ahead of competitors, companies have been pressured to place more of their value chains in low cost destinations thereby making suppliers more responsible for a growing share of the extended value chain, diminishing visibility to and direct control over supply risks, and eliminating much of the margin for error because of leaving inventory out of the supply chain (Murphy, John WisdomNet, 2006). This makes the pharmaceutical supply chain a complex and sophisticated entity. For example, the pharmaceutical suppliers are based in a first country, manufacturing in a second country, packaging is in a third country, with the wholesale distributors located around the world (See Figure 2-2).

Figure 2-2 Complex nature of Pharmaceutical Supply Chain

The multi- manufacturing base and the global supply chain has decreased visibility across the supply and has led to the penetration of illicit trade into legitimate supply chain. This has exposed the pharmaceutical supply chain to quality issues associated with (1) ingredients, (2) counterfeiting, (3) packaging and (4) gray markets. Counterfeiting is strongest in countries where regulatory and enforcement systems for medicines are weak. Because the pharmaceutical supply chain is complex requiring

multiple movement of drugs between primary wholesalers, secondary wholesalers, and distributors, it is much easier for counterfeit drugs to penetrate the legitimate supply chain of developed countries. The counterfeit drugs have infiltrated the U.S. pharmaceutical supply chain through Internet pharmacies and a growing number of secondary distributors. The World Health Organization (WHO) states that (WHO, 2010):

> "In over 50% of cases, medicines purchased over the Internet from illegal sites that conceal their physical address have been found to be counterfeit".

2.1.2 Reverse flow of Pharmaceutical Products

Products can flow back to the supply chain due to recalls, returns/overstock, or expired products as shown in Figure 2-3. Unlike other business retailers that mainly operate seasonal returns and can stock up on their returns in waiting for the return period, the pharmaceutical supply chain should continuously move products back and forth between retailers and manufacturers or other processors of returned drugs. This happens because of the expiration dates attached to the drugs delivered to pharmaceuticals and hospitals, and in a pharmaceutical inventory, expiration dates occur randomly due to variability in dosage, formulation, stability, degradation, storage, and transportation (Atai & Mutushinda, 2010) (Swaroop & Varun, 2011). Likewise, the pharmaceutical products, once returned, cannot be reworked, or recycled. They can either be redistributed if it was an overstock return or disposed of if it was expired or recalled. This makes the pharmaceutical reverse supply chain (see Figure 2-3) different from other business reverse supply chains. Per the Healthcare Distribution Management Association (HDMA), the estimated value of pharmaceutical returns in the U.S. for which manufacturer credit is requested in 2007 is 2.6 – 4.2 billion U.S. dollars, which excluded recalls or overstock returns. In addition, there is handling, transportation and storage costs associated with these returns. The Reverse Logistics Executive Council (Reno,

NV), an association of practitioners and academics, estimates reverse logistics costs account for approximately one-half of 1% of the U.S. GDP.

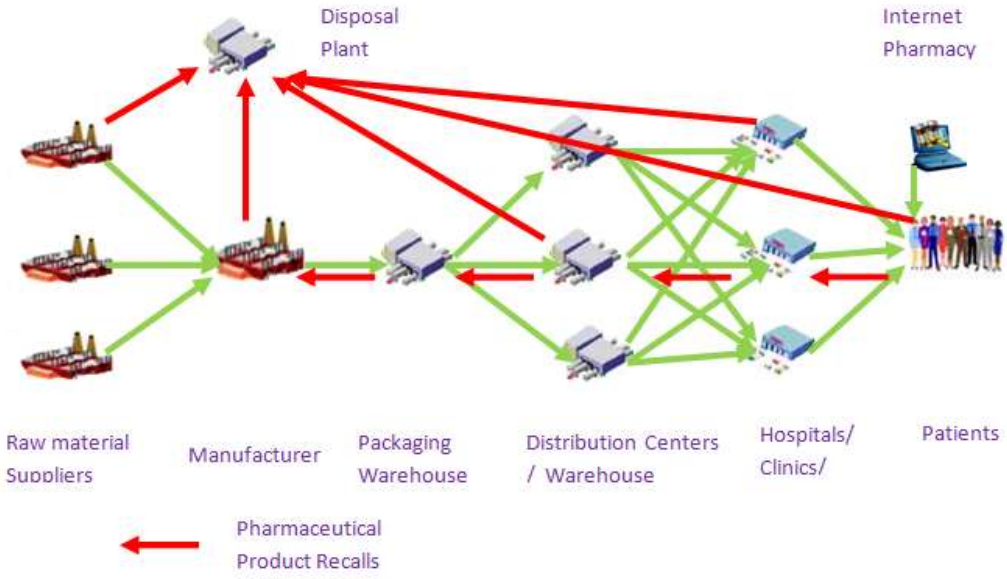


Figure 2-3 Reverse Supply Chain of Pharmaceutical Industry

The sudden inflow of products from various entities of supply chain requires companies to give priority to handling the reverse supply chain. “Manufacturers are looking at ways to minimize returns, match credits closer to actual value, expose inefficiencies in the returns process, and continue competitive return policies,” says Tom Marcellino, Inmar CLS MedTurn (Quinn, 2009). Companies who establish reverse logistics programs not only feel good about them for reducing the impact of their activities on the environment by eliminating waste, but also by strengthening customer loyalty and increasing profits (Melbin, 1995). Companies have outsourced their reverse logistics to third party providers, who manage the collecting and recycling of drug packages sent back to the manufacturer as a result of either recalls (where there is an FDA-mandated, or manufacturer-originated, retrieval of already shipped product) or returns (when out-of-

date product is sent back to the manufacturer by agreement) to ensure an environmentally safe method of recovery. Companies are offering drug take-back programs which will minimize the disposal of pharmaceutical wastes in the municipal waste facilities. When a controlled substance is recalled keeping safety concerns of patients, and in an industry where 100% recovery is rarely achieved even for highly unsafe products, there are the makings of a potentially painful hits to the essential point if recalls and returns are not handled adequately (Quinn, 2009).

Product recalls require organizations to be able to reverse the normal logistical flow from suppliers to customers so that inventory deemed unsuitable can be located by customers and returned to suppliers in a timely and cost-effective manner. This is particularly important in the case of pharmaceutical products where the health of the public may be put at risk if drugs are not withdrawn immediately (Bowersox & Closs, 1996) (Ritchie, Burnes, Whittle, & Hey, 2000). Since the drugs are stored in large number of locations, companies need to expedite the retrieval process resulting in complicated and time-consuming process. Once the drugs are retrieved, handling and disposal of hazardous products will be a costly exercise. Overall, recalls are on the rise, and yet there is limited knowledge and awareness about the true impact that a recall of any size can have on companies from both a liability and brand perspective, especially when there is no recall plan in place (Quinn, 2009). Companies need to look at their strategies and implement a recall plan which helps in minimizing the impact on their supply chain.

2.2 Drug Recalls

Despite the measures being taken by companies and government to maintain high quality and to stop the entrance of illicit drugs into the legitimate supply chain, the pharmaceutical companies will often undergo a recall of one of its products. If companies do not take action to these events in a timely and effective method, the consequences of

such event could prove catastrophic for the wellbeing of the consumers and company. In the recent years, product recalls in the pharmaceutical industry have become rampant and have increased dramatically (Dickinson, 2001). A recall occurs when a product is removed from the market because it is either defective or potentially harmful. Recalls may be conducted on a firm's own initiative, by a U.S. Food & Drug Administration (FDA) request, or by an FDA order under statutory authority (FDA, Drug Recalls, 2017).

2.2.1 Classification of Recalls

When a firm recalls a device, the FDA evaluates the degree of threat the recalled drug possesses to the patients and classifies into three types as in Table 2.1.

Table 2-1 Classification of Recalls and respective description

Classification	Description
Class I	Class I recall is for dangerous or defective products that predictably could cause serious health problems or death
Class II	Class II recall is for products which may cause a temporary health problem, or pose only a slight threat of a serious nature
Class III	Class III recall is for products that are unlikely to cause any adverse health reaction, but violate FDA labeling or manufacturing regulations

Source: (FDA, Drug Recalls, 2017)

2.2.2 Reasons for Recalls

The reasons to recall a pharmaceutical product may be due to quality of product not conforming to the registered specification during its shelf life, deterioration of packaging, counterfeit drugs, quality of dosage forms, container defects, questioned generic substitutions, questioned formulations, or labeling defects (Cheah, Chan, & Chieng, 2007). The FDA insists that the pharmaceutical companies should identify the reasons for recalls in the recall letter. This will help to determine the level of batch recall or product withdrawal in the distribution chain and the possible need for patient awareness and for the companies to avoid the recalls happening again. The reasons for recalls (see Figure 2-4) have been grouped into main categories for research purpose (FDA, 2017). (See Appendix A)

1. Health Hazard: Reports of Adverse events such as increase in health risks after prolonged intake of drug.
2. Contamination: The drugs can be contaminated with chemical, microbial or with other products. The drug may contain particulates like glass, stainless steel, charcoal, etc.
3. Manufacturing Defect: This type of defect is due to Good Manufacturing Practices (GMP) deviations, usage of non-approved component in the drug, or incorrect product formulation. The product lacking stability, super potent or sub potent of single ingredient or multiple ingredients, and drug related impurities exceeding the specification limits are manufacturing defects.
4. Labeling/Packaging Defect: These are due to defective containers such as broken bottles, seal breach on tamper evident foil seal, cracked vials; Miscalibrated and/or defective delivery system; Incorrect or Missing

Label; and short fills meaning some bottles contained less count than labeled claimed or under fill of vials.

5. Adulteration: The drug may contain adulterated presence of foreign substance.

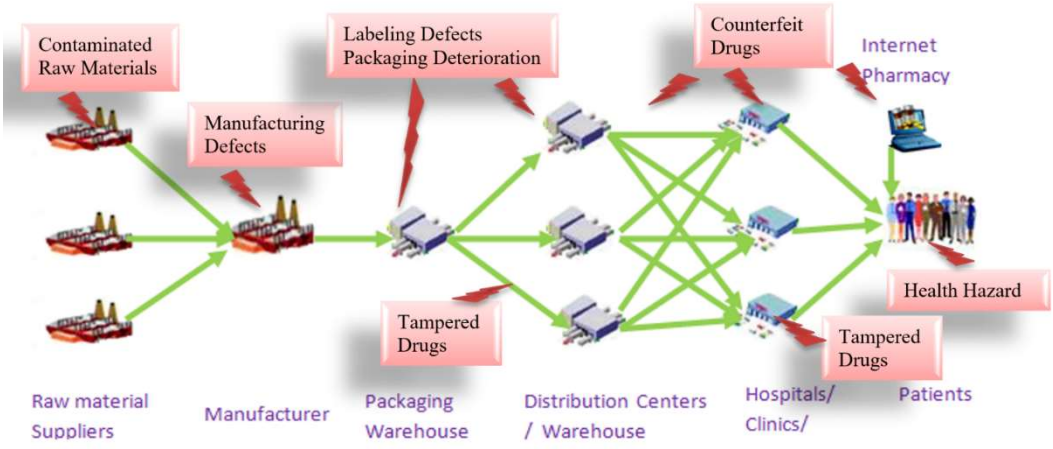


Figure 2-4 Reasons for Recalls w.r.t. supply chain entity

Recalling firms are responsible for notifying the customers about recalls and be in compliant with the FDA's recall plan. The FDA monitors the corrective actions implemented by the firms and terminates the recall after the necessary efforts been taken in accordance with the recall plan. The FDA publishes weekly Enforcement Reports that contain the recall date, name of the drug, the recalling firm, the manufacturer of the recalled drug, the quantity and location of the distribution of the recalled drug, and the method of notification used by the recalling firm (FDA, Drug Recalls, 2017).

2.3 Risks faced by Pharmaceutical Industry following a Recall

The pharmaceutical companies which are slow in reacting to product recalls can expose themselves to various types of risks. The impacts will be in terms of litigation costs, increased operational cost, losses, and long-term damage to their reputation.

Therefore, it is critical to company success and customer satisfaction that, if there is a recall, a risk management strategy is in place for an efficient uninterrupted flow of the pharmaceutical supply chain. The first step in the risk management process is identifying the risks which the company will likely face. The following risks in supply chain have been categorized into 4 major risks based on literature review of journals, articles, and books.

2.3.1 Financial Risk

On September 30, 2004, Merck announced withdrawal of one of its blockbuster drug Vioxx, which caused the company to lose a drug that accounted for $2.5 billion U.S. dollars in sales, accounting for about 11% of the company's total revenue in 2003. On the day of the withdrawal, Merck's shares dropped $12.07, a 27% decline in value, down to $33 per share, which was the company's lowest closing price in eight years (O'Rourke, 2006) (Freudenheim, Milt The New York Times, 2004). This event shows how a recall of a drug will affect the stock value of a company. Apart from the drop in stock price, Merck faced approximately 9,200 lawsuits, which include approximately 18,250 plaintiff groups alleging personal injuries resulting from the use of Vioxx, and in another 188 class actions alleging personal injuries and varying claims of economic loss (O'Rourke, 2006) (Feder, Barnaby J The New York Times, 2004) (Clemente, 2005). The company is exposed to legal risks in terms of litigation with individual lawsuits or class action lawsuits arising from customers, suppliers, shareholders, or employees. There will be an impact on future purchase intentions of the recalled drug or other drugs from that company resulting in loss of market share. The competitors will use the opportunity to improve their sales which will result in loss of market share of the recalled drug. Significant costs will be accrued from decline in stock value, litigations, loss in revenue, penalties and fines etc. following the announcement of recall causes financial risk to the company.

2.3.2 Operational / Supply Chain Risk

This risk affects a firm's internal ability to produce and supply goods/services resulting in loss in profits/revenues. Companies or their suppliers may have to close plants for short or long period, while the FDA conducts its investigation, or for the sanitization or other plant modifications depending on the nature of contamination (Belcastro, Denny and Alfonso, Bert GMA, Covington, Ernst & Young, 2011). On May 1, 2010, Johnson & Johnson recalled some 50 children's versions of non-prescription drugs, including Tylenol, Motrin and Benadryl, which was produced at Fort Washington, PA facility. The FDA charged the company that the plant does not maintain adequate laboratory facilities for the testing and approval (or rejection) of components of drug products, dusty and filthy conditions at the plant and the employees were not trained in current good manufacturing practices; resulting in temporary closure of the plant. The plant remained closed till the plant was sanitized and the FDA approved that plant was safe to reopen. This resulted in a 27.5% sales drop of the company's over-the-counter drugs in the United States. The Johnson & Johnson executives predicted the recalls and plant closure will reduce annual sales of its over-the-counter products by about $600 million U.S. dollars (Kavilanz, 2010). Other costs involved are recall execution cost consisting of technology and logistics investments. The technology risks expose the firm to invest in communication tools for effectively managing the inbound and outbound notification of product recalls, which includes how recall is notified, press release, phone or fax, or an automated system. This is necessary in response to misleading or inaccurate information published by the media. Logistics Risk affects company's ability to manage product retrieval, handling and disposal. The extra material handling, transportation personnel and equipment will drive the costs up for the company. When a controlled substance is recalled keeping safety concerns of patients, and in an industry

where 100% recovery is rarely achieved even for highly unsafe products, there is the makings of a potentially painful hit to the bottom line if recalls and returns are not handled adequately (Quinn, 2009). Recall execution cost will include another cost from forming a recall recovery team consisting of internal and/or external personnel from operations and supply chain, public relations, finance, accounting and risk management. In addition, a Recovery Leader, who has enough experience, knowledge, and gravity across the company to get things done should be appointed for faster recovery of losses (Belcastro, Denny and Alfonso, Bert GMA, Covington, Ernst & Young, 2011).

2.3.3 Reputation Risk

This risk will damage the company's reputation by costly litigations, inability to retain the investors and customers, resulting in negative brand image and decline in market share. Investor Relations is the term used to describe the communication between the companies and their investment community (Mitchell, 2010). The way a recall is handled or the consequences of a recall will affect the relationship of investors with the company. The sustainability of the firm may be at risk, since product recalls could destroy investor confidence in the firm leading either to decline in financial value of publicly traded firms or the unwillingness of investors to continue funding private firms (Chen, Ganesan, & Liu, 2009). Apart from losing investors, the company might lose current/potential employees who are not willing to work from an ethical point of view as well as financial stability resulting in loss of key talent. The financial loss from withdrawal of Vioxx, Merck may find it difficult to attract the finest scientists or form alliances with other firms to produce products that could make up for those losses (O'Rourke, 2006). Relationship Risk affects relationships between distributors / suppliers with manufacturers depending on where the defect has occurred in the supply chain.

Brand Image: The announcement of recall of a drug will create turmoil with the patients who will be using that drug. This raises the question within these patients whether to use the drug in future from the recalled company or not and whether to restrict using other products from the same company. The resulting impact will be loss of customers across all products of a company.

Johnson & Johnson lost sales of over- the- counter medicine by 19% in a year from recalling one of their Tylenol products in 1982. Marketers predicted the company cannot recover from the sabotage. But few months later, the Tylenol brand was back in market with the patented tamper-proof packaging for the over the counter medicines and with extensive media coverage. The market share of Tylenol, which had plunged to 7 percent from 37 percent following the poisoning, had climbed back to 30 percent in a year. This was possible because Johnson & Johnson placed its customers first by offering replacement product free of charge (Rehak & Tribune, 2002). Sometimes the impact might not be bad as assumed depending on how well the company manages the recall and thereby regaining its loyalty with the customers, as seen in the case of Tylenol recall in 1982.

2.3.4 Regulation Risk

Pharmaceuticals are a highly-regulated product in the world. To introduce a new drug to the market or for a smooth production of a drug, the companies need to follow good manufacturing practices (GMP) and certain regulations set by the government agency such as Food and Drug Administration (FDA) or EPA. And if there is a recall or the possibility of a recall, the company will be under investigation by the FDA. The FDA will penalize the companies which do not comply with the regulations.

Drug Approval/Production: Once there is a recall, the FDA will examine the cause for recall and impose a new set of procedures/ regulations for the companies to follow. This

will delay in obtaining approval for release of new drug in turn affecting the market share and getting new patents. For example: the FDA imposed new regulation for drug approval, which came after Merck recalled Vioxx in 2004, requiring companies to perform longer term studies on the drug before approval. This led to the postponement of the approval on Merck's Arcoxia, requesting additional data (O'Rourke, 2006). There will also be decline in production of the existing drug caused by reimplementation of new regulations. The FDA announced the packaging regulations specifying new over-the counter drug packaging requirements on Nov 5, 1982 following the Tylenol incident due to contamination by cyanide in 1982 (Kavilanz, 2010).

Environmental Regulation Fines: The US Environmental Protection Agency (USEPA) and Drug Enforcement Agencies (DEA) have implemented many rules and regulation for safe disposal of pharmaceutical products. Failure to comply with the regulations will lead to a fine up to $280,000 U.S. dollars per incident and the state regulations may be more stringent than federal regulations and may vary by state (Smith, 2008).

2.3.5 Summary of Risks

The severity of the recall, the reason for recall, the distribution pattern of recalled quantity, the recall magnitude and the retrieval time of the recalled drug will all play an important role in determining the complexity of the risks. The following Table 2.2 summarizes the risks as discussed above.

Table 2-2 Summary of Categorized Risks

Financial	Operational	Reputation	Regulation
Drop in Stock Price Value Decrease in Market Share Litigation / Legal Cost Fines / Penalties	Loss in Sales / Revenue Recall Notification Cost Recall Logistics Cost	Brand Image Investor Relations Retaining of Key Talent Relationship Risk	Difficulty in obtaining new drug approvals Decreased production of the existing drug

Chapter 3

Literature Review

Most product recall researchers have studied the stock market reaction to the announcement of recalls such as in Medical Device Industry (Thirumali & Sinha, 2011), Pharmaceuticals (Jarrell & Peltzman, 1985) (Dowdell, Govindaraj, & Jain, 1992) (Dranove & Olsen, 1994), Automotive Industry (Rupp, 2004), Meat and Poultry (Thomsen & McKenzie, 2001), and toy industry (Hora, Bapuji, & Roth, 2011) with mixed findings of significance of the abnormal returns with the announcement of recalls. The financial consequences from the announcement of recalls have been analyzed by Event Study Methodology, which has been applied across various fields such as in the field of law and economics, to measure the impact on the value of a firm when there is a change in the regulatory environment (Schwert, 1981), in legal liability cases and to assess the resulting damages (Mitchelle & Netter, 1994), in the field of accounting and finance to assess the retailer's financial value following a recall (Ni, Flynn, & Jacbos, 2014), and to study the effect of implementation of green supply chain management initiatives (Bose & Pal, 2012).

Dowdell et.al., (1992) examined the effect of packaging regulation from the Tylenol incident in 1982, on the stock prices of the firms in the pharmaceutical industry (Dowdell, Govindaraj, & Jain, 1992). Eger & Mahlich (2014) examined the effect of pharmaceutical regulation in Europe on corporate R&D., found that U.S. companies invest more on R&D than European companies (Eger & Mahlich, 2014) The effect of government regulation in the pharmaceutical industry has been used researched with respect to the drug price policy (Kaisrer, Mendez, & Ronde, 2014), (Jobjörnsson, Forster, Pertile, & Burman, 2016). Other researchers have examined the strategies and best practices for managing a recall and have created models to simulate the probability of a

recall and predict its size in food industry (Resende-Filho & Buhr, 2012). The operational risk have been researched with respect to quality risk (Gray, Roth, & Leiblein, 2011) outsourcing risk (Mokrini, Dafaoui, Berrado, & Mhamedi, 2016), and environmental risk (Mansour, Al-Hindi, Saad, & Salam, 2016) perspectives. Parker & Lahr (1999) have provided an overview of the involvement of the Food & Drug Administration (FDA) with the recall process and presented appropriate recall strategies. Table 3-1 illustrates some of the prior studies done.

Table 3-1 Prior Literature Review related to Pharmaceuticals and product recalls

Author	Methodology	Focus	Industry	Summary
(Resende-Filho & Buhr, 2012)	Simulation	Recall Cost, Traceability	Food	Developed conceptual and process simulation models to determine the probability of a recall and predict its size in food industry
(Thirumali & Sinha, 2011)	Event Study Methodology	Financial Consequences from Recall	Medical Devices	Assessed the financial implications of medical device recalls and found that at an aggregate level, the market penalties for medical device recalls are not significant.
(Dowdell, Govindaraj, & Jain, 1992)	Event Study Methodology	Financial Consequences from Packaging Regulation	Pharmaceuticals	Studied the effect of packaging regulation from the Tylenol incident in 1982, on the stock prices of pharmaceutical companies and found that the regulation had a significant negative effect on the common stock prices of firms in the pharmaceutical industry.
(Chen, Ganesan, & Liu, 2009)	Event Study Methodology	Financial Consequences from Recall	Consumer	Examined the impact of strategies used to manage recall on firm value and found proactive strategies have more negative effect on firm value than passive strategies.

Table 3.1 - Continued

(Ni, Flynn, & Jacbos, 2014)	Event Study Methodology	Retailer's financial consequences from recall	Consumer	Investigated the financial effect of a product recall announcement from the perspective of retailers and found negative impact for a private label product and refund remediation strategy.
(Bose & Pal, 2012)	Event Study Methodology	Financial Consequences of implementation of green initiatives	Multiple Industries	Studied the impact of green supply chain management initiatives on stock prices of firms and found manufacturing firms, firms with high R&D expense, and early adopters show strong increase in stock prices on the day of announcement.
(Tischer & Hildebrandt, 2013)	Event Study Methodology	Reputation	Multiple Industries	Linked corporate reputation and shareholder value using the publication of reputation rankings and found the publications of reputation rankings have an impact on shareholder value
(Enyinda, 2009)	Survey - Analytical Hierarchy Process (AHP)	Regulation Risk, Operational Risk, Reputation Risk	Pharmaceuticals	Applied AHP to choose optimal mitigation strategies to manage pharmaceutical global supply chain logistics risks
(Hsu, Ross-Degnan, Wagner, Zhang, & Lu, 2015)	Interrupted time series design and segmented linear regression models	FDA Actions on Market Shares	Pharmaceuticals - Prescription Drug	Found substantial reduction in the costs and use of the prescription drug rosiglitazone after the 2007 FDA actions, and use and costs of pioglitazone were substantially reduced after 2010 FDA actions regarding the drug's possible risk of bladder cancer.
(Horvath, 2005)	Model – Markov Chain	Reverse Logistics Risks		Modeling the expectations, risks, and potential shocks associated with cash flows stemming from retail reverse logistics activities.

Despite the importance given to the study of effect of recalls on stock market, price regulation, quality or outsourcing risk, and recall process aspect, there is limited research on overall risks from the recalls that capture the direct cost of recall, the effect of regulatory law because of a recall, the significance of the characteristics of the company in relation to the severity and scope of the recall. This research study takes a comprehensive approach to quantify the effects of the recall on the different risks in relation to the characteristics of the company and the severity and scope of the recall.

Chapter 4

Methodology and Data

In this study, statistical regression analysis was used to analyze the financial, operational and reputation risks based on the characteristics of the recall and the firm size. Event study methodology was employed in determining the dependent variables for Financial risk and a recall cost model was used to analyze the Operational Risk. Regulation risk was studied on the R&D and operational costs following the implementation of a new pharmaceutical regulation law using interrupted time series design, and segmented statistical regression analysis was performed on the firm's resulting characteristics/ performance metrics. The methods employed in these analysis studies are shown in Figure 4-1 and are explained as follows.

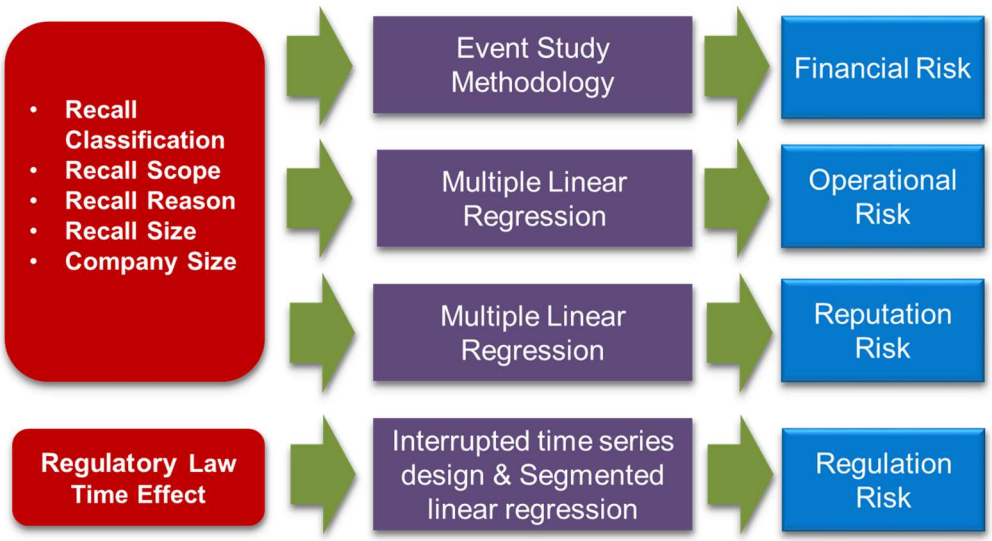


Figure 4-1 Methodology used in analyzing the Pharmaceutical Risks

4.1 Analysis of Financial Risk

Firms having drug recalls will face severe financial consequences directly or indirectly. The indirect costs include loss in firm's stock market value during and immediately following a product recall (Berman, 1999). Announcement of a recall will affect stock prices because of potential effects on future cash flows of the firms due to changing demand of their products, and the penalties or fines imposed by regulatory bodies (Hill & Schneewis, 1983). Previous studies have examined the stock market reaction to the announcement of product recalls in Medical Device Industry (Thirumali & Sinha, 2011), Pharmaceuticals (Jarrell & Peltzman, 1985) (Dowdell, Govindaraj, & Jain, 1992) (Dranove & Olsen, 1994), Automotive Industry (Rupp, 2004), Meat and Poultry (Thomsen & McKenzie, 2001), and Consumer Products (Chen, Ganesan, & Liu, 2009) with mixed findings of significance of the abnormal returns with the announcement of recalls. The research with Pharmaceutical Industry had a negative significant effect on abnormal returns whereas there was not much negative significance in the study of Medical Device recalls. The expected decrease in net cash flows from the recall is reflected in the changes in stock prices. Thus, we argue that a drug recall announcement is associated with negative abnormal return on stock price.

4.1.1 Event Study Methodology

Event study methodology was applied to examine the financial consequences of the recalls. Event study is a powerful tool used in measuring the impact of a specific unanticipated event on the value of the firm using the financial market data (MacKinlay, 1997). Monitoring changes in stock prices over a relatively short period around an event would effectively capture the financial impact of the event on firms' performance (McWilliams & Siegel, 1997) (MacKinlay, 1997).

The steps to perform an event study to determine the abnormal returns on stock prices associated with an unanticipated event, such as a drug recall announcement are described below.

1. Determining the time windows: There are three time windows required for the event studies – Estimation Window, Gap, and Event Window as shown in Figure 4-2.

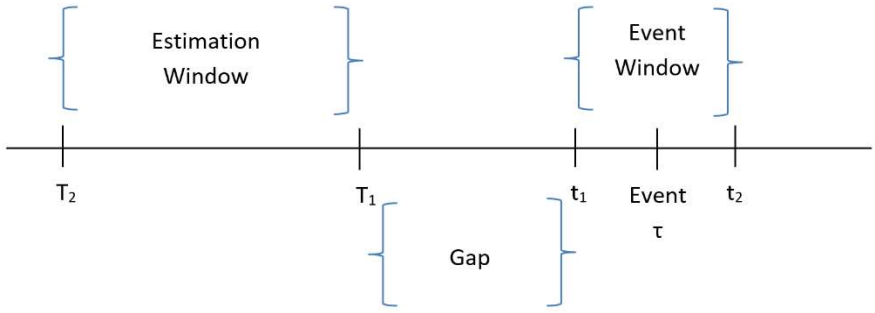


Figure 4-2 Timeline for Event Study

The most crucial research design issue is determining the length of the event window which is the short period surrounding the event of interest. Event windows used from previous studies include 2 -day windows (0, +1), (-1,0); a 3-day event window (-1, +1) to 21-day event window (-10, +10) to 180-day period. The short event window is more appropriate since the market price of a stock fully adjusts within 15 minutes of release of firm-specific information (Dann, Mayers, & Raab, 1977) and using long event window severely reduces the power of the test statistic (Brown & Warner, 1985). It should be long enough to capture the significant effect of the event, but short enough to exclude confounding effects (McWilliams & Siegel, 1997). Estimation window (T) is the length of the time period (in trading days) used to estimate the parameters of the

market model using ordinary least squares (OLS) regression and to determine the normal behavior of a stock's return with respect to a market. Other researchers have used 250 prior trading days or 120-day period with a gap of 21 days i.e., estimation period ends 21 days before the event of our estimation. One of the major assumption in the event study is the event windows and estimation windows do not overlap in calendar time (McWilliams & Siegel, 1997). Therefore, a Gap is established which is the number of trading days between the end of estimation window and the beginning of the event window. It is used to reduce the likelihood that the event-induced return variance affects risk model estimation (WRDS, Wharton School, University of Pennsylvania, 2017).

2. The standard approach for the event study is based on estimating a market model for each firm and then calculating abnormal returns, which are assumed to reflect the stock market's reaction to the recall announcement (McWilliams & Siegel, 1997). Market model is a linear function of market return of stock *i* at time *t*,

$$R_{it} = \alpha_i + \beta_i R_{mt} + \varepsilon_{it}$$

Where

R_{it} = Rate of return on the share price of firm *i* on day *t*,

R_{mt} = Rate of return on the market portfolio of stocks on day *t,*

α_i = Risk-free return of firm *i* or the intercept

β_i = Systematic risk of stock *i*

ε_{it} = Error term

3. The next step is derivations of estimates of daily abnormal returns (AR) for firm *i* on day *t* using the following equation,

$$AR_{it} = R_{it} - (\hat{\alpha}_i + \hat{\beta}_i R_{mt})$$

Where $\hat{\alpha}_i$ and $\hat{\beta}_i$ are the ordinary least squares (OLS) parameter estimates obtained from the regression of R_{it} on R_{mt} over an estimation period (T) preceding the event. The abnormal returns represent the rate of return on the stock is adjusted by subtracting the expected return from the actual return. The variance of the abnormal return is

$$Var(AR_{it}) = S_i^2 \left[1 + \frac{1}{T} + \frac{(R_{mt} - R_m)^2}{\sum_{t=1}^{T}(R_{mt} - R_m)^2}\right]$$

Where S_i^2 is the residual variance from the market model as computed for firm *i*, R_m is the mean return on the market portfolio calculated during the estimation period, and *T* is the number of days in the estimation period.

The mean of abnormal return $\overline{AR_t}$ on day *t* for all the sample firm and its variance is

$$\overline{AR_t} = \frac{\sum_{i=1}^{N} AR_{it}}{N}$$

$$Var(\overline{AR_t}) = \frac{\sum_{i=1}^{N} Var(AR_{it})}{N^2}$$

4. The last step is calculating the cumulative abnormal return (CAR) over the event window (t_1, t_2), and its variance,

$$CAR(t_1, t_2) = \sum_{t=t_1}^{t_2} AR_t$$

$$VAR_{CAR(t_1,t_2)} = \sum_{t=t_1}^{t_2} Var(AR_{it})$$

The test statistics is used to assess the significance of the abnormal returns is estimated as the ratio of the cumulative average abnormal return for

the sample over the event window and standard deviation of cumulative abnormal returns.

$$t_{CAR} = \sqrt{N} * \frac{CAAR(t_1, t_2)}{SD_{CAAR(t_1,t_2)}}$$

Where,

$$CAAR(t_1, t_2) = \sum_{t=t_1}^{t_2} \overline{AR_t}$$

and

$$SD_{CAAR(t_1,t_2)} = \sqrt{\sum_{t=t_1}^{t_2} Var(\overline{AR_t})}$$

The significance of the abnormal returns infers that the event had a significant impact on the values of the firm and is assumed to measure the average effect of the event on the value of the n firms (McWilliams & Siegel, 1997).

The event study was performed using Event Study Tool offered by Wharton Research Data Services (WRDS). The 3-day event window (-1, +1) was used to capture the information released before the reporting date. -1 represents one day before the event and +1 represents one day after the event. Estimation window used 120 trading days instead of 250 to avoid any acquisitions or mergers of the firms. We assumed there were no other significant events had happened during that period and shows the normal returns of the stock market. The Cumulative Abnormal Return, CAR (-1, +1) from the event study will be the dependent variable in performing regression analysis with the firm's performance, which represents our analysis for financial risk.

4.2 Analysis of Operational Risk

Operational Risk is the direct costs associated with the recall. These costs include expenses for communication, investigation cost, labor cost, transportation cost, storage and material handling costs associate with recovery and disposition of the recalled drug, proper disposal, incentives to the consumer or retailer, and diminished sales during and after the recall period (Berman, 1999). It is rather difficult to obtain the above costs, so the model developed by Moies A. Resende-Filho and Brian L. Buhr for the Food Industry was used to calculate the total direct recall cost. In their paper "Economics of traceability for mitigation of food recall costs", Moies A. Resende-Filho and Brian L. Buhr mention that "in 2000 the USDA reported, Economic Research Service estimates the food marketing cost on a consumer price basis and reported that the consumer expenditure on farm foods was $661.1 billion U.S. dollars. Of this $537.8 billion U.S. dollars was marketing costs, including approximately $75.6 billion U.S. dollars for advertising and transportation. Based on the above report, they consider advertising as a proxy for recall notification, and transportation as a proxy for transportation needs in case of a recall, they estimated that approximately four percent of the food marketing cost is toward advertising or recall notification. They also state that the Transportation and fuel costs would be directly related to the quantity recalled and total ten percent of the food marketing costs. The total direct cost of recall is equated as

$$C(Q_R) = P_r Q_R + 0.04\ P_r Q_R + 0.10\ P_r Q_R = 1.14\ P_r Q_R$$

Where P_r denotes the retail value of the product and Q_R is the quantity of product being recalled" (Resende-Filho & Buhr, 2012).

The pharmaceutical industry is like the food industry with similar manufacturing technologies, operating globally, compliance & labeling regulations, temperature

controlled storage and transportation, and consumer/patient safety (Boogaard, 2012). Therefore, the total direct cost of recall is used as a proxy for Operational Risk.

4.3 Analysis of Reputation Risk

Reputation Risk is a threat in meeting expectations of customers, employees, investors, or supply chain players, eventually may or may not damage the firm brand. Various approaches are available such as benchmarking, historical corporate profit and loss statements, corporate reputation rankings, employee turnover or stakeholder behaviors (Kossovsky, 2014). Sven and Lutz used reputation rankings from the German business periodical Manager Magazine (Tischer & Hildebrandt, 2013), in linking corporate reputation to shareholder value, while Marko et.al. studied and compared the commonly used reputation measures in terms of convergent validity and criterion validity (Sarstedt, Wilczynski, & Melewar, 2013). Chen, et.al. used reputation scores from Fortune Magazine for the year before a recall event, in analyzing the effect of Reputation on financial value of a company following a recall (Chen, Ganesan, & Liu, 2009). In this research, the brand image and investor relations are used as proxies for measuring Reputation Risk. The first proxy, brand image is measured by using the reputation rankings score from the Fortune 500 annual survey of “America’s Most Admired Companies”, now called “World’s Most Admired Companies”. The survey asks executives, directors, and analysts to rate companies in their own industry on nine criteria, from investment value and quality of management and products to social responsibility and ability to attract talent. An aggregate industry scores are then published (Fortune, 2017). The second proxy, investor relations reflects the stock market that sees companies interacting with existing shareholders, potential investors, analysts, and journalists (Mitchell, 2010). It is measured from the outcomes of the company’s success, one of is the P/E ratio in comparison to peer companies (Michaelson & Gilfeather, 2003)

or Earnings Per Share(EPS). EPS is the ratio of Net Earnings to Outstanding Shares and is the most common measure in assessing the company's profitability which reflects the number of investors. Lower EPS means less number of investors.

4.4 The Effect of Recall Characteristics and Firm Characteristics

Recall characteristics include the classification of recall, recall distribution, root cause of recall, recall size. Classification of recall refers to the severity of recall which is a potential to serious illness or death. A recall resulting in death or serious illness is likely be reported by the media because it is more dramatic and newsworthy (Barber & Odean, 2008). This eventually reduces investor's confidence, tarnish to reputation, depreciation of shareholder's wealth, and increase in operational costs and fines. Therefore, we expect the risks to be more severe for class I recalls than other class recalls.

Recall distribution refers to the geographic distribution of the drug in the market – local, national, and international. Recall Size is the quantity of recalled drug multiplied by the unit price of the drug. Recall size and Recall distribution captures the market share of the drug. If the recalled drug is distributed internationally in higher quantity, transportation and retrieval cost will increase along with damage to brand image. Overall recall size and the geographic distribution pattern will increase the risks.

The size of the firm will play a role in overcoming the negative impact of the recall. The sales or revenue will determine whether the firm is big or small. Firms with higher sales will cope with the losses accrued from recall and can better handle the recall, which might not be the situation with smaller firms. If the smaller firm faces recall, profitability will significantly reduce because the revenue is dependent on the fewer products. Thus, stock market reaction will be negative and operational risk will be more for small size firms or firms with lower sales. But it will be different with the reputation risk.

Firms with higher sales are more reputable and thus reputation risk will be higher for firms with high sales.

4.4.1 Regression Analysis

Full linear models for each risk were formulated using the Virtual SAS University Edition software.

Financial Risk:

$$CAR = \beta_0 + \sum_{i=1}^{3} \beta_{1i} Recall\_Classification_i + \sum_{j=1}^{5} \beta_{2j} Recal\_Scope_j + \sum_{k=1}^{5} \beta_{3k} Recall\_Reason_k + \beta_4 RecallSize \quad \beta_5 FirmSize + \beta_6 Brand\_Reputation \quad \beta_7 InvestorRelation \quad \varepsilon_i$$

Operational Risk:

$$OperationalCost = \beta_0 + \sum_{i=1}^{3} \beta_{1i} Recall\_Classification_i + \sum_{j=1}^{5} \beta_{2j} Recall\_Scope_j + \sum_{k=1}^{5} \beta_{3k} Recall\_Reason_k + \beta_4 FirmSize + \beta_5 Brand\_Reputation + \beta_6 InvestorRelations + \varepsilon_i$$

Reputation Risk:

$$Brand\_Reputation = \beta_0 + \sum_{i=1}^{3} \beta_{1i} Recall\_Classification_i + \sum_{j=1}^{5} \beta_{2j} Recall\_Scope_j + \sum_{k=1}^{5} \beta_{3k} Recall\_Reason_k + \beta_4 RecallSize \quad \beta_5 FirmSize + \varepsilon_i$$

$$InvestorRelations = \beta_0 + \sum_{i=1}^{3} \beta_{1i} Recall\_Classificat \quad _i + \sum_{j=1}^{5} \beta_{2j} Recall\_Scope + \sum_{k=1}^{5} \beta_{3k} Recall\_Reason_k + \beta_4 RecallSize + \beta_5 FirmSize + \varepsilon_i$$

4.5 Analysis of Regulation Risk

Following an outbreak in 2012 of an epidemic of fungal meningitis linked to a compounded steroid, the Drug Quality Safety and Security Act (DQSA) was signed into law by the Congress on November 27, 2013, which outlined the critical steps required to build an electronic, interoperable system to identify and trace prescription drugs in the supply chain. This law granted more authority to FDA to regulate and monitor the manufacturing of compounded drugs (FDA, 2014) (FDA, 2017). This regulation was intended to reduce recalls by preventing substandard, altered or counterfeit drugs entering the supply chain and benefit the pharmaceutical companies eventually in having an efficient system to track and trace down the recalled drug in a short time, and reducing the recall cost. But the immediate effect for the pharmaceutical companies was to implement this complex identification, track and trace system whose financial effect would show on innovation, operational expense, or reduction in inventory of finished goods. Dowdell et.al.(1992) investigated the Tylenol incident in 1982 which led to stringent packaging regulations for over the counter pharmaceutical drugs and studied the effect of regulation on the stock prices. They found that the regulation had a significant negative effect on stock prices and the share price decline occurred more around the subsequent packaging regulations than the Tylenol incident (Dowdell, Govindaraj, & Jain, 1992). Hsu et.al. (2015), examined the effects of multiple FDA actions on utilization and reimbursed costs of thiazolidinediones in state Medicad Programs. They found that the use and cost of the drug were substantially reduced after 2007 FDA actions and was rarely used after 2010 Risk Evaluation and Mitigation Strategy program. They used an interrupted time series design, which is a strong quasi-experimental method, to examine the effects of FDA actions on quarterly market shares according to use and costs of the above drug (Hsu, Ross-Degnan, Wagner, Zhang, & Lu, 2015). This

method provides evidence of casual effects by taking into consideration whether an intervention causes abrupt and measurable interruptions in the pre-existing trend (Shadish & Cook, 2002) (Wagner, Soumerai, Zhang, & Ross-Degnan, 2002).

Segmented time series linear regression model was used to study the effects of regulation on Research and Development (R&D) expense and Operational Expenses. Quarterly data for R&D expense and Operational expense was collected for the study period of 2010 to 2016 with regulation law passed on November of 2013. The study period was divided into 2 segments: (1) baseline period, from first quarter of 2010 to fourth quarter of 2016, and (2) post-2013 regulatory law, from fourth quarter of 2013 to fourth quarter of 2016. The linear regression models used were:

$$R\&D\ Expense = \beta_0 + \beta_1 Time + \beta_2 Regulation + \beta_3 Time\ after\ Regulation + \varepsilon_i$$

$$Operational\ Expense = \beta_0 + \beta_1 Time + \beta_2 Regulation + \beta_3 Time\ after\ Regulatio + \varepsilon_i$$

Where, *Time* is a continuous variable indicating time in quarters at time from the start of the study period, *Regulation* is an indicator of time occurring before (Regulation = 0) or after (Regulation = 1) the regulation law passed in 2013, *Time after regulation* is a continuous variable counting the number of quarters after the 2013 regulation law. In this model, β_0 estimates the baseline level intercept, $\beta_1$estimates baseline trend that occurs at each quarter, β_2 estimates the level change immediately after the 2013 regulation, and β_3 estimates change in trend after the 2013 regulation.

The above regression models were run for large and mid-cap companies to understand how the company handles following a regulation or immune to the regulatory effect.

4.6 Data

Analyzing the above risks requires data on drug recalls, market performance and the characteristics of the recalling firms. The data was gathered from: the FDA, the Compustat database, accessed through the Wharton Research Data Services, National Average Drug Acquisition Cost document, and Fortune 500 Magazine.

Information on drug recalls was collected from the weekly Enforcement Reports on the FDA website. The Enforcement Reports contain announcements of Drug Recalls, and each recall contains the date of recall, the description of the drug, the recalling firm and its address, the class of recall, the distribution of the drug being recalled, the method of notification (letter, press or email), and the quantity of the recalled drug. This information was collected for the YR 2012 and there were 426 recalls. The recalls were further filtered by the recalling firm type with focus on publicly traded manufacturers and eliminating recalls with missing data, 68 recalls were left for the study of risks. The unit price for the drug was obtained from National Average Drug Acquisition Cost, later used to calculate the Recall Size in dollars, which is a product of the units of recalled drug and the unit price. The score from the Fortune 500 Survey for World's Most Admired Companies in YR 2012 was used for measuring the Brand Reputation. The survey lists reputation scores for ten pharmaceutical companies, and hence an industry average was assigned to companies that were not in top 10. The sales in YR 2011 and the Earnings per share data was obtained from Compustat database which was used as a proxy for firm size and measuring Investor Relations respectively.

The Recall Class, Recall Scope, and Recall Reason was used as a continuous variable and as a categorical variable. To consider the above three variables as a continuous variable, weights were assigned. The weight for Class I is 3, meaning the severity is high followed by Class II as 2 and Class III as 1 with severity being low. The

weights for Recall scope was assigned as follows: Local-1, Nationwide-2 and Worldwide-3. This meant that the wider the geographical spread of the recalled drug is, the more the damage to the company leading to high overall cost. As the drug is widely accepted by people, any recall will have negative media coverage across the world leading to loss of sales. The weights for the Recall Reason was assigned solely based on the number of recalls caused by the defect in YR 2012: Manufacturing Defect – 5, Contamination – 4, Labeling/Packaging Defect – 3, Adulteration – 2, and Health Hazard - 1.

The categorical variables are analyzed using effect coding and coded as shown in Table 4.1.

Table 4-1 Effect Coding for Categorical Variables

	E1	E2		E3	E4	E5
Local	1	0	**Adulteration**	1	0	0
Nationwide	0	1	**Contamination**	0	1	0
Worldwide	-1	-1	**LabelingPackaging Defect**	0	0	1
			Manufacturing Defect	-1	-1	-1
	E6	**E7**				
Class I	1	0				
Class II	0	1				
Class III	-1	-1				

The list of variables used in regression analysis of the risks are described in Table 4.2, 4.3, 4.4.

Table 4-2 Dependent Variables used for Regression Analysis

Dependent Variables	Description	Proxy for Risk	Source
CAR	Cumulative Abnormal Returns from Event Study	Financial Risk	(WRDS, Wharton School, University of Pennsylvania, 2017)
Operational Cost	Consists of Recall Size Cost, notification cost and transportation cost	Operational Risk	(FDA, Drug Recalls, 2017); National Average Drug Acquisition Cost; (Resende-Filho & Buhr, 2012)
Brand Image	Reputation Score from America's Most Admired Companies List	Reputation Risk	(Fortune, 2017)
Investor Relations	Earnings per Share		(Compustat, WRDS, University of Pennsylvania, 2017)
R&D Expense	Research and Development Expense in each quarter from YR 2010 to YR 2016	Regulation Risk	(Compustat, WRDS, University of Pennsylvania, 2017)
Operational Expense	Operational Expense in each quarter from YR 2010 to YR 2016		(Compustat, WRDS, University of Pennsylvania, 2017)

Table 4-3 Categorical Variables used for Regression Analysis

Categorical Variables	Description	Source
Recall Classification	Class I, Class II, Class III	(FDA, Drug Recalls, 2017)
Recall Scope	Local, Nationwide, Worldwide	(FDA, Drug Recalls, 2017)
Recall Reason	Manufacturing Defect, Labeling/Packaging Defect, Contamination, Adulteration, Health Hazard	(FDA, Drug Recalls, 2017)

Table 4-4 Continuous Variables used for Regression Analysis

Continuous Variables	Description	Source
Recall Size	Quantity of recalled drug X Unit price of Drug	(FDA, Drug Recalls, 2017); National Average Drug Acquisition Cost;
Firm Size	Sales of the company in YR 2011 used as a proxy for Firm Size	(Compustat, WRDS, University of Pennsylvania, 2017)
Time	Count of time in quarters from YR 2010 to YR 2016	
Regulation	0 before fourth quarter of 2013 1 after fourth quarter of 2013	
Time after Regulation	Count of time in quarters after fourth quarter of 2013	

Chapter 5

Results

5.1 Descriptive Statistics for Data

Table 5.1 shows the descriptive statistics used for analyzing the risks and Figure 5-1, Figure 5-2, Figure 5-3 represents the percentage of frequencies of the drug recalls in Year 2012 by recall scope, reason for recall, and recall classification. The variable Firm Size is measured as the natural logarithmic of total sales, the natural logarithmic transformation of variables Recall_Size and Operational_Cost is used in the statistical analyzes.

Table 5-1 Descriptive Statistics and Frequencies

Variable	N	Mean	Std Dev	Minimum	Maximum
Recall_Size ($ Million)	68	4.43	12.80	0.0039	82.9
Firm_Size ($ Million)	68	18318.67	22774.9	670.95	82559
Operational_Cost ($ Million)	68	5.05	14.6	0.0044	94.50

Figure 5-1Frequencies of Drug Recalls in Year 2012 by Recall Scope (Distribution)

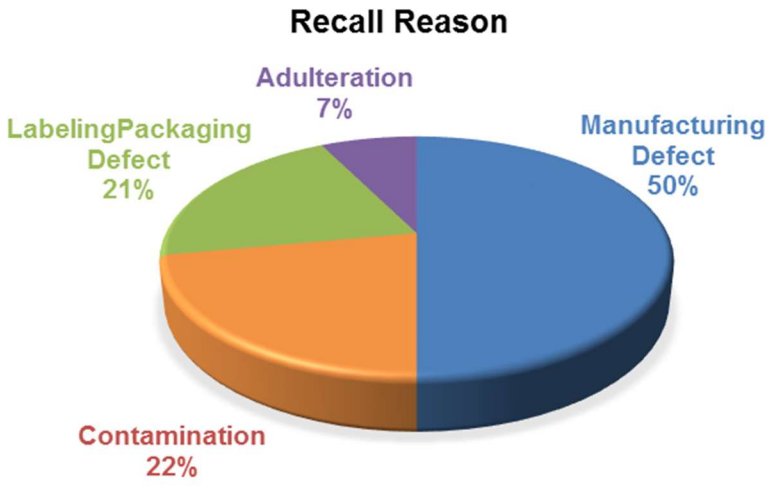


Figure 5-2 Frequencies of Drug Recalls in Year 2012 by Reason of Recall

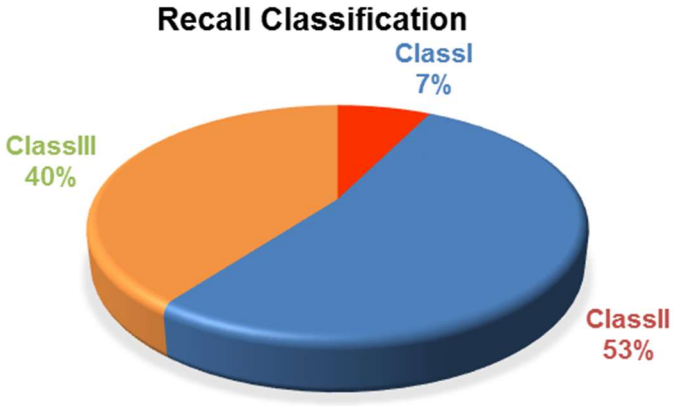


Figure 5-3 Frequencies of Drug Recalls in Year 2012 by Recall Classification

5.2 Financial Risk

5.2.1 Event Study Result

Table 5.2 provides the output from the event study of abnormal returns. The mean CAR (-1, +1) with a value of – 0.48 % indicates there is a negative abnormal return of stock price in Pharmaceutical companies following a drug recall. The significance of cumulative abnormal returns was tested using Patell Z- test (Patell, 1976) which is robust to potential bias caused by stocks with a large variance in abnormal returns, Cross-Sectional t and standardized cross – sectional t test which is robust to potential variances from changes in events as listed in Table 5.1. and the tests are significant supporting the abnormal behavior of the announcement of the drug recall.

Table 5-2 Abnormal Returns associated with Drug Recalls – Market Model

Variables	Number of Recalls	Mean Cumulative Abnormal Return (%)	Patell Z	Cross-Sectional t	Standardized Cross-Sectional t
(-1, +1)	68	-0.4833%	-1.4198*	-1.9467*	-1.6960*

*p<0.05

5.2.2 Main Effects

The next step in the analysis is to examine the influence of recall characteristics and firm characteristics on the financial consequences of the firm from the announcement of recall. Table 5.3 provides the results of cross-sectional regression of continuous variables with Cumulative Abnormal Returns and Table 5.4 shows results for regression model with categorical variables. The model showed significance in variables Recall_Scope ($\beta = 0.01367$, $p < 0.05$) and Recall_Classification ($\beta = -0.00651$, $p < 0.05$). The coefficient Recall_Classification is negative indicating more negative abnormal returns. This means, the market reaction is more severe with increase in the severity of recall class. The coefficient of Recall_Scope is positive indicating the stock market

reaction is less severe for the geographic distribution of the product. As mentioned earlier in the research, the bigger the size of the recall and the companies with higher sales might increase the financial risk of a company but the model does not show any significance for the variables Recall_Size and Firm_Size. The model may be more effective with the deletion of existing variables except Recall_Scope and Recall_Classification.

Table 5-3 Cross-Sectional Regression Analysis of Financial Risk

Independent Variable	Parameter Estimates	Std. Error	p	Standardized Estimates
Intercept	0.02943	0.04242	0.4905	0
Recall_Scope	0.01367*	0.00574	0.0204	0.29856
Recall_Reason	-0.00101	0.00178	0.5720	-0.06997
Recall_Classification	-0.00651*	0.00310	0.0401	-0.27535
Ln_Recall_Size	-0.00050368	0.00097911	0.6088	-0.07417
Ln_Firm_Size	-0.00209	0.00204	0.3099	-0.17875
Brand_Reputation	0.00141	0.00562	0.8021	0.04183
Investor_Relations	0.00144	0.00150	0.3399	0.15734
R-Squared	0.1406			
Adjusted R-Squared	0.0404			
P-Value	0.2212			
Dependent Variable	CAR (-1, +1)			
Dependent Mean	-0.00120			

Note: * p < 0.1, checked for heteroscedasticity

As shown in the Table 5.4, the linear regression with effect coding is

CAR = 0.039883 - 0.011271 (E1)** - 0.002196(E2) + 0.006155 (E3)** + 0.002819 (E4) - 0.004384 (E5)** - 0.000198 (E6) + 0.006580 (E7)* - 0.000267 Recall_Size - 0.002169 Firm Size + 0.002404 Brand_Reputation + 0.0022227 Investor_Relations

The variables E1, E3 and E5 are significant for heteroscedasticity and E7 is significant at p<0.1. The mean of cumulative abnormal returns for Recall_Scope_Worldwide is 0.05335 and mean for Recall_Scope_Local is 0.028612. This shows abnormal returns increases with increase in the geographic distribution of the recalled drug, which suggests the market reaction is less severe to the geographic distribution of the recalled drug. The mean of CAR for Class I is 0.039 compared to 0.046 for Class II. This supports the inference from Table 5.3 indicating, the stock market reaction is negative when the severity of the recall increases.

Table 5-4 Cross-Sectional Regression Analysis with Effect Coding of Financial Risk with Categorical Variables

Independent Variable	Parameter Estimates	Std. Error	p	Standardized Estimates
Intercept	0.039883	0.044175	0.3705	0
Recall_Scope E1	-0.011271**	0.009935	0.2614	-0.24614
Recall_Scope E2	-0.002196	0.005743	0.7037	-0.08835
Recall_Reason E3	0.006155**	0.005065	0.2294	0.26934
Recall_Reason E4	0.002819	0.004065	0.4910	0.15798
Recall_Reason E5	-0.004384**	0.003565	0.2240	-0.24128
Recall_Classification E6	-0.000198	0.004861	0.9676	-0.00839
Recall_Classification E7	-0.006580*	0.003644	0.0764	-0.43865
Ln_Recall_Size	-0.000267	0.000981	0.3121	-0.03937
Ln_Firm_Size	-0.002169	0.002126	0.7861	-0.18576
Brand_Reputation	0.002404	0.005720	0.6758	0.07116
Investor_Relations	0.0022227	0.001633	0.1782	0.24310
R-Squared	0.2135			
P-Value	0.2070			
Dependent Variable	CAR (-1, +1)			

Note: * p < 0.1, **p < 0.1 with heteroscedasticity

5.3 Operational Risk

Table 5.5 shows the regression analysis for the dependent variable- natural logarithmic of Operational cost with all continuous variables. The model is significant with a 32.67 % variance of operational cost indicating operational risk is present from a drug recall. The variables Recall_Classification ($\beta = -1.10607$, $p < 0.01$) and the Brand_Reputation ($\beta = 2.84413$, $p < 0.001$) are significant. The negative coefficient of Recall_Classification suggests the operational cost decreases with increase in severity of the recall class, contrary to initial assumption. This may be attributed to the cost of notification of Class I recalls being covered by media by way of negative publicity which affects reputation. This is shown from the significance of Brand_Reputation ($\beta = 2.69581$, $p < 0.05$) in the analysis suggesting operational cost increases for reputable companies.

Table 5-5 Regression Analysis of Operational Risk

Independent Variable	Parameter Estimates	Std. Error	p	Standardized Estimates
Intercept	4.92412	5.51346	0.3753	0
Recall_Scope	0.35867	0.74927	0.6339	0.05319
Recall_Reason	0.10617	0.23241	0.6494	0.04987
Recall_Classification	-1.10607*	0.38013	0.0050	-0.31772
Ln_Firm_Size	-0.22466	0.26494	0.3998	-0.13068
Brand_Reputation	2.84413*	0.6376	<.0001	0.57162
Investor_Relations	-0.13439	0.19518	0.4937	-0.09961
R-squared		0.3109		
Adjusted R-Squared		0.2432		
P-Value		0.0007		
Dependent Variable		Ln(Operational_Cost)		
Dependent Mean		13.54764		

Note: * $p < 0.1$, Checked for heteroscedasticity

Table 5-6 Regression Analysis – Effect Coding of Operational Risk with Categorical Variables

Independent Variable	Parameter Estimates	Std. Error	p	Standardized Estimates
Intercept	2.843986	5.954877	0.6348	0
Recall_Scope E1	-1.168312**	1.332735	0.3844	-0.17327
Recall_Scope E2	0.603850	0.771481	0.4370	0.16500
Recall_Reason E3	-0.615517	0.679152	0.3686	-0.18292
Recall_Reason E4	0.053890	0.548949	0.9221	0.02051
Recall_Reason E5	0.256530	0.480300	0.5953	0.09587
Recall_Classification E6	-1.296107*	0.633568	0.0454	-0.37231
Recall_Classification E7	0.243232	0.491101	0.6223	0.11012
Ln_Firm_Size	-0.18424	0.28609	0.5222	-0.10717
Brand_Reputation	2.69581*	0.68502	0.0002	0.54181
Investor_Relations	-0.16568	0.21950	0.4535	-0.12281
R-Squared	0.3267			
P-Value	0.0075			
Dependent Variable	Ln (Operational Cost)			

Note: * p < 0.1, **p < 0.1 with heteroscedasticity

5.4 Reputation Risk

Table 5.7 and Table 5.8 shows the parameter estimates, standard error, and the p-value of regression coefficients for the dependent variables Brand Reputation and Investor Relations. The model is significant with 50.92 % of variation in Brand Reputation (p <.0001) and 55.75 % in Investor Relations (p <.0001), as explained by the linear regression model (See Table 5.8). The Recall_Classification (β = 0.15819, p < 0.05) is significant along with significance in Recall_Size (β = 0.08579, p < 0.001) and Firm_Size (β = 0.16868, p < 0.0001) for Brand Reputation. This infers the large cap companies with large recall size and severity of recalls attracts negative media coverage about the

company leading to loss of sales and customers. This will damage the brand image of the company. Variables Recall_Scope ($\beta = -0.88310$, $p < 0.1$) and Firm_Size ($\beta = 0.79815$, $p < 0.0001$) are significant for Investor Relations. The company will face huge loss in profitability when the recalled drug is widely accepted in the market. In addition, mean of earnings per share (proxy for Investors_Relations) is less for Class I (-16.922) compared to Class II (17.083) and Class III (16.06) recalls as shown in Table 5.8. This means that the investments will be lower with increase in the severity of the recall, since lower the EPS, less number of investors. Overall the cash flow of the company will get affected and all the negative information of the drug recall will deflect the investors from the future investments to the company.

Table 5-7 Regression Analysis of Reputation Risk

	Brand Reputation			Investor Relations		
Independent Variable	**Parameter Estimates**	**Std. Error**	**p**	**Parameter Estimates**	**Std. Error**	**p**
Intercept	0.23843	0.82791	0.7743	-14.37737	3.10262	<.0001
Recall_Scope	-0.17016	0.12549	0.1800	-0.88310*	0.47029	0.0651
Recall_Reason	0.00823	0.04004	0.8378	-0.16169	0.15003	0.2853
Recall_Classification	0.15819*	0.06723	0.0218	0.24386	0.25195	0.3369
Ln_Recall_Size	0.08579*	0.01929	<.0001	-0.02766	0.07229	0.7033
Ln_Firm_Size	0.16868*	0.03241	<.0001	0.79815*	0.12144	<.0001
R-Squared	0.4769			0.4598		
Adjusted R-Squared	0.4347			0.4163		
P-Value	<.0001			<.0001		
Dependent Variable	Brand_Reputation			Investor_Relations		
Dependent Mean	5.18676			1.58000		

Note: * p < 0.1, **p < 0.1 with heteroscedasticity

Table 5-8 Regression Analysis – Effect Coding of Reputation Risk with Categorical Variables

	Brand Image			Investor Relations		
Independent Variable	**Parameter Estimates**	**Std. Error**	**p**	**Parameter Estimates**	**Std. Error**	**p**
Intercept	0.322267	0.809589	0.6920	-16.22325*	2.83509	<.0001
Recall_Scope E1	-0.118210	0.227693	0.6056	-0.054368	0.79735	0.9459
Recall_Scope E2	0.165572**	0.127210	0.1982	0.753092*	0.44547	0.0963
Recall_Reason E3	0.044091	0.114879	0.7025	0.473567	0.40229	0.2439
Recall_Reason E4	-0.122375**	0.091345	0.1856	-0.307106	0.31987	0.3410
Recall_Reason E5	0.006800	0.081437	0.9337	-0.230914	0.28518	0.4214
Recall_Classification E6	0.105796	0.107505	0.3292	-0.699528*	0.37647	0.0682
Recall_Classification E7	0.072626	0.076804	0.3483	0.860428*	0.26896	0.0022
Ln_Recall_Size	0.078715*	0.019894	0.0002	-0.04912	0.06967	0.4836
Ln_Firm_Size	0.160728*	0.034015	<.0001	0.76745*	0.11912	<.0001
R-Squared	0.5092			0.5575		
P-Value	<.0001			<.0001		
Dependent Variable	Brand_Reputation			Investor_Relations		

Note: * p < 0.1, **p < 0.1 with heteroscedasticity

5.5 Regulation Risk

Segmented regression analyses of regulation risk with Operational Expense and Research & Development (R&D) expense as dependent variable was performed for three large companies with revenue in billion and three small companies with revenue in millions. Table 5.9 and Table 5.10 provides the parameter estimates, standard error, and the p-value from the regression models predicting changes in the Operational Expense following the 2013 regulation. Models for Large Firm 2 and Large Firm 3 are significant ($p < 0.01$) with 47.25% and 73.48% of variance in Operational Expense explained respectively. The parameter estimates for Large firm 2 as in Table 5.9 shows the significance in variable Time ($\beta = 0.0108$, $p < 0.01$) and Time after Regulation ($\beta = -0.0146$, $p < 0.05$). This suggests that there is change in Operational expense from baseline trend to the trend after the pharmaceutical regulation being passed in 2013. This is similar for Large Firm 3 with Time ($\beta = -0.0428$, $p < 0.01$) and Time after Regulation ($\beta = 0.0435$, $p < 0.01$) being significant.

Models for Small Firm 1, Small Firm 2, and Small Firm 3 are significant ($p < 0.0001$) with a variance of 84.42%, 95.27% and 66.32% respectively as shown in Table 5.10. The changes in trend of Operational expense is seen in the coefficients of variable Time ($\beta = -0.33441$, $p < 0.05$) and Time after Regulation ($\beta = 0.48453$, $p < 0.01$) for Small Firm1 and coefficients of variable Time ($\beta = 0.11787$, $p < 0.01$) and Time after Regulation ($\beta = -0.07404$, $p < 0.01$) for Small Firm 2. This is consistent with the results for the large firms.

Table 5-9 Regression Analysis of Regulation Risk with Operational Expense as dependent variable for Large companies

	Large Firm 1			Large Firm 2			Large Firm 3		
Variable	**Parameter Estimates**	**Std. Error**	**p**	**Parameter Estimates**	**Std. Error**	**p**	**Parameter Estimates**	**Std. Error**	**p**
Intercept	8.23279	0.04532	<.0001	9.24229*	0.03071	<.0001	8.89055	0.06727	<.0001
Time	0.00596	0.00498	0.2435	0.01082*	0.00338	0.0038	-0.04281*	0.00740	<.0001
Regulation	-0.10719	0.06394	0.1066	0.01979	0.04333	0.6521	0.02490	0.09492	0.7953
Time after regulation	-0.00112	0.00794	0.8885	-0.01460*	0.00538	0.0121	0.04355*	0.01179	0.0011
R-Square	0.1125			0.4725			0.7348		
P-Value	0.4036			0.0013			<.0001		
Dependent Variable	Ln (Operational Expense)								

Note: *p<0.1, checked for heteroscedasticity

Table 5-10 Regression Analysis of Regulation Risk Operational Expense as dependent variable for small companies

	Small Firm 1			Small Firm 2			Small Firm 3		
Variable	**Parameter Estimates**	**Std. Error**	**p**	**Parameter Estimates**	**Std. Error**	**p**	**Parameter Estimates**	**Std. Error**	**p**
Intercept	2.87257*	0.36032	<.0001	4.84844	0.10132*	<.0001	4.23986*	0.02645	<.0001
Time	-0.33441*	0.13157	0.0246	0.11787	0.01114*	<.0001	0.00546*	0.00291	0.0732
Regulation	0.13631	0.30091	0.6580	0.21204	0.14296**	0.1510	0.01636	0.03750	0.6667
Time after regulation	0.48453*	0.13336	0.0030	-0.07404	0.01775*	0.0003	0.00283	0.00463	0.5472
R-Square	0.8442			0.9527			0.6632		
P-Value	<.0001			<.0001			<.0001		
Dependent Variable	Ln (Operational Expense)								

Note: *p<0.1, **p<0.1 with heteroscedasticity

Table 5.11 and Table 5.12 provides the results from the regression models predicting changes in the R&D Expense following the 2013 regulation. The significant models for Large Firm 2 ($p < 0.05$) and Large Firm 3 ($p < 0.0001$) has a variance of 39.99% and 76.53% in R&D Expense respectively. The parameter estimates for Large firm 3 as in Table 5.11 shows the significance in variable Time ($\beta = -0.09648$, $p < 0.0001$) and Time after Regulation ($\beta = 0.10108$, $p < 0.001$). This suggests that there is change in R&D expense from baseline trend to the trend after the pharmaceutical regulation being passed in 2013. But the other two large firms do not show significance in Time after regulation rising the question whether the large companies are immune to new regulatory laws or is there other factors affecting the analysis.

Table 5-11 Regression Analysis of Regulation Risk R&D Expense as dependent variable for Large companies

	Large Firm 1			Large Firm 2			Large Firm 3		
Variable	**Parameter Estimates**	**Std. Error**	**p**	**Parameter Estimates**	**Std. Error**	**p**	**Parameter Estimates**	**Std. Error**	**p**
Intercept	7.10319	0.05483	<.0001	7.38656	0.07800	<.0001	7.29253*	0.14703	<.0001
Time	0.00902**	0.00603	0.1476	0.02218*	0.00858	0.0162	-0.09648*	0.01617	<.0001
Regulation	-0.09770	0.07737	0.2188	-0.04863	0.11006	0.6626	-0.02622	0.20746	0.9005
Time after regulation	-0.00428	0.00961	0.6598	-0.01440	0.01367	0.3026	0.10108*	0.02576	0.0006
R-Square	0.0992			0.3999			0.7653		
P-Value	0.4650			0.0059			<.0001		
Dependent Variable	Ln (R&D Expense)								

Note: *p<0.1, **p<0.1 with heteroscedasticity

The significant regression model for Small Firm 1 ($p < 0.05$) has a variance of 54.61% in R & D Expense followed by 41.73 % for Small Firm 2 ($p < 0.01$) and 79.14% for Small Firm 3 ($p < 0.0001$). The variable Time for Small Firm 1 is significant ($\beta = -0.60509$, $p < 0.05$) and the Time after Regulation ($\beta = 0.67403$, $p < 0.01$). This suggests there is change in R&D expense following a regulation.

The variable regulation which estimates the level change in regulation is significant in predicting R&D expense for Small Firm 1 but not significant in predicting the R&D expense and operational expense for the remaining firms. This infers there was an immediate effect in changes in R&D expense for one firm but overall there was gradual changes in R&D expense and operational expense for large and small firms.

Table 5-12 Regression Analysis of Regulation Risk R&D Expense as dependent variable for Small companies

	Small Firm 1			Small Firm 2			Small Firm 3		
Variable	**Parameter Estimates**	**Std. Error**	**p**	**Parameter Estimates**	**Std. Error**	**p**	**Parameter Estimates**	**Std. Error**	**p**
Intercept	2.70346*	0.57085	0.0004	3.10399*	0.36664	<.0001	1.99573*	0.08530	<.0001
Time	-0.60509*	0.20845	0.0123	0.06567	0.04033	0.1165	0.03628*	0.00938	0.0007
Regulation	0.90419*	0.47674	0.0803	0.13494	0.51735	0.7965	0.10392	0.12035	0.3964
Time after regulation	0.67403*	0.21129	0.0071	-0.01613	0.06425	0.8039	-0.01492	0.01495	0.3281
R-Square	0.5461			0.4173			0.7914		
P-Value	0.0139			0.0042			<.0001		
Dependent Variable	Ln (R&D Expense)								

Note: *p<0.1, Checked for heteroscedasticity

5.6 Discussion

The regression models were checked for multicollinearity among the regressors. The Variance inflation factors (VIF) were all below the limit of 3, suggesting that multicollinearity did not threaten the coefficient estimates. Heteroscedasticity analysis was conducted as few predictor variables showed nonrandom (U-shaped or inverted U) pattern of residual plots suggesting a better fit for a non-linear model, than a regression model.

5.6.1 Findings of the Analysis and Recommended Mitigation Strategies

The next important part after risk assessment is how to mitigate the risks. There are several research articles and reports on the methods available to minimize the recall cost. The Grocery Manufacturers Association (GMA) along with Covington & Burling, and Ernst & Young provided ten factors for recovery losses from recall and insurance coverages available for the U.S. based food and consumer industry. Figure 5-1 illustrates them. (Belcastro, Denny and Alfonso, Bert GMA, Covington, Ernst & Young, 2011).

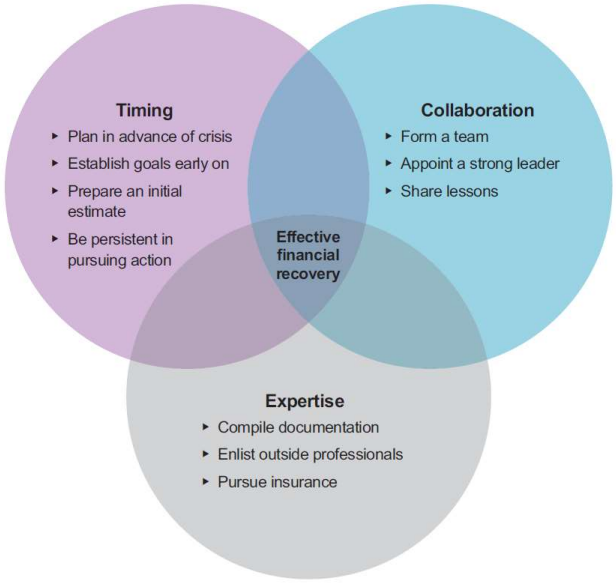


Figure 5-4 Ten Factors for Recovering Losses (Source: Capturing RecallCosts)

Craig Smith et.al., (1996) presented a User's Guide to Managing Product Recalls. (Smith, Thomas, & Quelch, 1996) . The observed outcome has been summarized and the appropriate recommendations for mitigation strategies of the risks have been mentioned based on above articles in Figure 5-2.

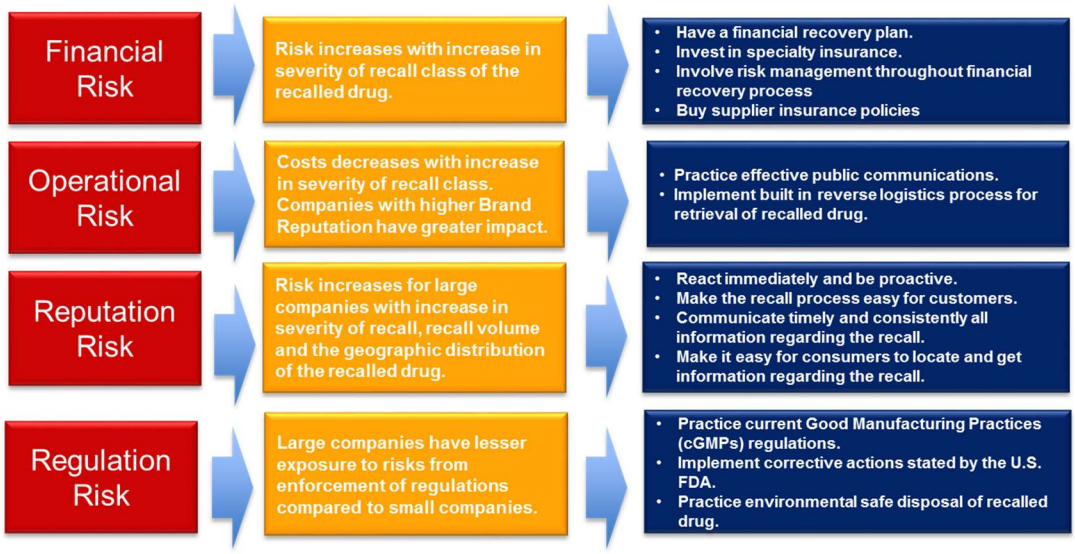


Figure 5-5 Recommended Mitigation Strategies for the Risks.

5.6.2 Examples of success/failure cases of Crisis Management:

5.6.2.1 Johnson & Johnson Tylenol Recall 1982: Starting Sep 29, 1982, seven people died in the Chicago area after taking cyanide-laced capsules of Extra Strength Tylenol resulting in recalling of 31 million bottles of Tylenol capsules. Johnson & Johnson put the consumers' safety first by taking control of the situation despite being aware that the capsules were replaced with cyanide by unknown personnel and not caused by them. Johnson & Johnson followed these steps in handling the recall crisis (Harris, Hart, Hibbard, Jurgensen, & Wells, 2002):

1. Formed a seven-member strategy team in reacting to the negative media coverage

2. Used media, both PR and paid advertising as well as national television feed to communicate their strategy during the crisis
3. Used toll free lines for customers and news organizations to respond to inquiries from customers and to provide updated statements about the crisis.
4. Communicated their new triple safety seal packaging in a press conference and Tylenol is the first product to use tamper resistant packaging as rectification strategy.
5. Johnson & Johnson provided counseling and financial assistance for victims' families as remediation strategy.

Judith Rehak (2002) mentioned the following in her report on Tylenol Recall: "Johnson & Johnson spent more than $100 million for the 1982 recall and relaunch of Tylenol. A much smaller recall in 1986, and a second relaunch also ran into millions of dollars. But Johnson & Johnson's shareholders were hurt only briefly. In 1982, the stock, which had been trading near a 52-week high just before the tragedy, see-sawed in panic selling but recovered to its highs only two months later. Investors have had little to complain about since then. If you had invested $1,000 in Johnson & Johnson shares on September 28, 1982, just before the first Tylenol episode, you would have $22,062 today, after four stock splits. The company has paid out increasing dividends for 39 years". (Rehak & Tribune, 2002)

This shows how the media can promote negative publicity to the public and large number of people will be aware of the situation within a week of an incident. The Tylenol recall happened when not much social media was used, now the situation will be amplified with increased use of social media in this digital era. Johnson & Johnson survived the recall crisis in 1982 by being proactive and transparent about their

investigation but it was not the case for Johnson & Johnson 2010 recall, Exxon crisis in 1989 and the Toyota Recall in 2010.

5.6.2.2 Johnson & Johnson 2010 Recall: Johnson & Johnson McNeil division recalled more than 135 million bottles of Tylenol, Mortin and Bendaryl products in 2010 because of musty smell caused by trace amounts of chemical, which is applied to wooden pallets that are used to transport and store packaging materials. The company had received complaints about moldy smelling bottles of Tylenol and temporary digestive problems, but delayed the recall by not conducting timely investigation, identifying the cause, and not notifying the authorities in a timely fashion (Singer, 2010). Upon investigation, the U.S. lawmakers unveiled documents that showed Johnson & Johnson conducted a clandestine recall of Motrin (Goldman, 2012). The slow response and failing to comply with federally-mandated manufacturing practice led to temporary closure of Ft. Washington PA plant costing the company $900 million U.S. dollars in lost sales for the year (Kavilanz, 2011).

5.6.2.3 Exxon Valdez Oil Spill 1989: In March1989, the tanker Exxon Valdez ran aground off the coast of Alaska, spilling 11 million gallons of crude oil into the waters of Prince William Sound and creating one of the worst oil spills in American history. (Fountain, 2013). The Exxon's corporation worsened the damage to its public standing by failing to take responsibility of the crisis, failing to take necessary actions for reducing the spread of spill and poor communications to the public. The Exxon's chairman sent a lower ranking executives to Alaska to deal with the spill instead of him, giving the impression that the company did not consider the spill as an environmental pollution problem. And then, the company did not update its media relations people elsewhere in the world, rather concentrating the news briefing to remote Alaskan town (Holusha, 1989). The oil spill caused the company to spend $2 billion U.S. dollars on the cleanup, $1.1 billion U.S.

dollars in settlements, punitive damages along with loss of market share (Schneider, 1991).

5.6.2.4 Toyota Recall 2009-2010: From late 2009 through 2010, Toyota recalled 16 million vehicles worldwide for various faults such as unintended and uncontrolled acceleration from sticky accelerator pedals and braking problems. The company representatives confused the consumers and the regulators by jumping into conclusions about the cause of failure and failed to disclose the information (Kalb, 2012). The uncertainty by the representative led to losing 59% of potential customers (Kelly, 2012) and $1.1 billion U.S. dollars class action lawsuit settlement (Kalb, 2012). Also the company delayed in accepting the responsibility and by the time company president Akio Toyoda apologized to the U.S.Congress, Toyota's stock price had declined by 20% - a $35 billion U.S. dollars loss of market value (Austen-Smith, Diermeier, & Zemel, 2009).

These case studies demonstrate that any company that does not systematically analyze and prioritize its risks can incur severe losses by not having a crisis-management plan in place and putting the public's safety first.

5.6.3 Limitations of the research

There were certain limitations to this study. The first limitation was that the study included only 12-month data set. Data was difficult to obtain due to confidentiality restrictions. There might be changes in the inferences if a larger data period was used. The study is restricted to publicly traded companies. An assumption was made that no other significant events happened to the company apart from the drug recall in analyzing the financial risk. The cost model used in the food industry was used to study the operational risk due to its similarity. Also, it might be possible that not all expenses were captured when the recall occurred. The regulatory impact on the operational expense and

R&D expense might be inconclusive because of the small data set used and a few companies considered for this analysis.

Chapter 6

Conclusion

The pharmaceutical industry is facing many challenges and risks due to increased globalization; one of them is product recall. As pharmaceutical companies are responsible for economic, social, and environmental needs; product recalls could significantly damage a Company's revenue, reputation, profitability, and brand image. Companies that are slow in reacting to product recalls could expose themselves to litigation costs and long-term damage to its reputation. Drug recalls could pose a threat to the manufacturing company and if not executed in a timely manner could pose a significant threat to the end user. Based on a sample of drug recalls in Year 2012 and the regulatory law passed in Year 2013, this study provides an assessment of the impacts of recalls on pharmaceutical companies and suggest the following:

- There will be a negative stock market reaction following the announcement of drug recall.
- The financial and reputation risks increase with increase in severity of the recall.
- The recall of a widely-accepted drug will increase the financial and operational risks.
- Operational Risk reduces with increase in severity of the recall and is more severe for reputable companies with good brand image.
- Reputation risk is higher for large companies than small companies.
- Large pharmaceutical companies have lesser exposure to risks from the enforcement of regulations compared to small companies.

This research differentiates itself from other research by the following:

- A systematic analysis of the major risks due to recalls was done at the organizational level.

- Data for multiple companies was used for the analysis that had recall in 2012.
- Event study methodology was used to analyze Financial Risks.
- Recall Cost model from the Food Industry was used to analyze Operational Risk.
- Fortune 500 Reputation score and Earnings per share where used to analyze Reputational Risk.
- Interrupted Time Series design was used to analyze Regulation Risk which was measured using R&D and Operational expense.

This study is a small step towards risk assessment and mitigation in the Pharmaceutical supply chain. Further research study can be done in the below areas:

- The effect of retrieval time can be further analyzed.
- Multivariate delta & Bootstrapping methods can be used to estimate confidence intervals around absolute and relative changes to the expenses related to regulation in an interrupted time series design study.
- Segmented time series regression analysis method can be applied to study multiple regulations
- A comparative study can be done across industries using this study as a reference
- Operational risk can be analyzed using actual cost of recall data
- Further study can also be done by sending survey questionnaire to supply chain managers from pharmaceutical companies to identify risks associated with product recalls at each element of the supply chain to determine the shortfalls of current the methodologies used to manage risks in reducing recall and overall company performance.

As the pharmaceutical supply chain gets even more complex, any company could face a recall and expose itself to different risks but companies with sound risk

mitigation strategy that focuses on the significant risks based on severity of the recall, geographical expanse, its size, and reputation can drastically reduce the reputation damage and the financial cost associated with the recall.

In conclusion, this research study adds value by assessing the major risks faced by Pharmaceutical Companies due to a recall holistically and prioritizing them to come up with a sound mitigation plan that will significantly reduce the impact of those risks.

Appendix A

Reasons of Recall in detail as cited in FDA.gov

The reasons for recall have been grouped into 5 categories for research purposes.

Health Hazard: Increase in health risks after consumption of drugs.
Manufacturing Defect:

1. cGMP Deviations
    a. does not meet in process specification requirements
    b. Product was made with an incorrect ingredient
    c. expired flavoring was used in the manufacturing of these lots
2. Product Lacks Stability
    a. failure to meet the particle size distribution specification
    b. Product does not meet stability to expiration date and exhibits low particle counts which could lead to a non-diagnostic scan.
3. Superpotent drug
4. Subpotent drug
5. Marketed Without An Approved NDA/ANDA
    a. contains undeclared drug ingredients making it an unapproved drug
6. Impurities/Degradation Products
    a. Out-of-specification results were obtained for a known impurities
    b. Potential for drug related impurities to exceed the specification limits
    c. An out of specification result for a known impurity of the product occurred during 12 month stability testing.
    d. Product may exhibit discoloration
7. Out of specification
8. Incorrect Product Formulation
9. Temperature abuse
    a. The affected product was stored below freezing conditions
    b. product had not been stored according to manufacturer's labeled temperature requirements prior to distribution
10. Tablet thickness
    a. presence of one slightly oversized tablet in a bottle of the identified lot
    b. Potential for some tablets not conforming to weight specifications (under and over weight)
11. Tablet Separation
    a. Possibility of cracked or split coating on the tablets.
    b. The manufacturer of Arthrotec had recalled the lots that were used, to re-package this product because they may contain broken tablets.
12. Failed PH Specifications
    a. out of specification low pH
13. Failed USP Dissolution Test Requirements
    a. Possible out-of-specification dissolution results at the 8 hour stability testing point
    b. do not meet the specification for dissolution
14. Crystallization
    a. Presence of crystals of Nimodipine within the capsule solution.
    b. Presence of crystalline particulates in a single vial

15. Lack of Assurance of Sterility
    a. Firm mistakenly released quarantined, non conforming material that failed sterility testing.
    b. environmental sampling revealed the presence of microorganisms and fungal growth in the clean room where sterile products were prepared
    c. The intravenous medication ondansetron is being recalled for lack of assurance of sterility because they may be contaminated with mold, fungus, and/or bacteria.
    d. Products were manufactured in conditions that compromised the sterility of the products.

Contamination:

1. Chemical Contamination
    a. complaints of an uncharacteristic odor identified as 2, 4, 6 tribromoanisole
    b. contain high levels of lead and arsenic
2. Microbial Contamination of Non-Sterile Products
    a. contaminated with mold, fungus, and/or bacteria
3. Cross Contamination w/Other Products
4. Presence of Particulate Matter
    a. Potential for charcoal particulates
    b. This is a subrecall of Amgen's Procrit due to glass delamination
    c. may contain small glass particulates
    d. visible crystalline particulates and the discovery of crystalline particulate in a retain sample
    e. presence of stainless steel particulates in the tablets

Labeling / Packaging Defect:

1. Label mix-up
    a. The affected units were labeled incorrectly describing the product as "ointment" instead of "solution."
    b. Product was incorrectly labeled "Tabs" instead of "Capsules."
    c. Product is labeled as sugar-free but it actually contains sugar
    d. A typographical error in the product form on the carton label incorrectly lists the configuration as 30 "Capsules" (3 x 10) rather than "Tablets"
    e. the label statement on the blister strip regarding the maximum number of capsules/caplets that should be taken within a 24-hour period, does not match the statement on the carton
2. incorrect or missing insert;
    a. Warnings portion of the Package Insert is missing the warning statement
    b. labels on outer containers do not match labels on vials
    c. Incorrect expiration date printed on the outer packaging
    d. incorrect manufacturer printed on the label
    e. Incorrect storage conditions
3. Labeling Illegible
    a. Portions of the product labeling in the area of the dosing directions, the warnings & other information sections is obscured.
    b. Some bottles labels have incomplete NDC numbers and missing strength.
4. Short Fill
    a. some bottles contained less than 120-count per labeled claim

b. The product is being recalled due to a potential underfill of the affected vials.

5. Miscalibrated and/or Defective Delivery System
    a. the dose knob spun slowly and the injection took longer than usual (slow dose delivery)
    b. Out of Specification results for mechanical peel force and/or the z-statistic value
6. Defective Container
    a. damaged bottles could allow moisture to get into the bottle and thus may impair the quality of the product
    b. Report of a vial containing visible particulate matter embedded in the glass wall which has the potential to dislodge resulting in the presence of particulate matter in the product.
    c. A number of bottles have a localized thin wall defect on the bottom which may potentially impact the stability of the tablets.
    d. Contraceptive Tablets Out of Sequence: This recall has been initiated due to the potential that some regimen packages may not contain placebo tablets.
    e. Contraceptive Tablets Out of Sequence: Patient complaint that inactive tablets were found in row 9 of a blister card instead of the appropriate row 13.
    f. small number of bottles have been punctured at the bottom edge during the packaging process
    g. seal breach on tamper evident foil seal
    h. Complaints of a loose crimp applied to the fliptop vial; and a missing stopper and flip cap were received and therefore sterility cannot be assured.
    i. A customer complaint reported some units had incomplete seals (open seals) on the Individual unit packaging.
    j. Product recalled due to displacement of the aluminum crimp cap during product usage.
    k. the firm's medical trays contain Hospira's 0.9% Sodium Chloride bags which were subject to recall due to leaking bags
    l. cracked vials

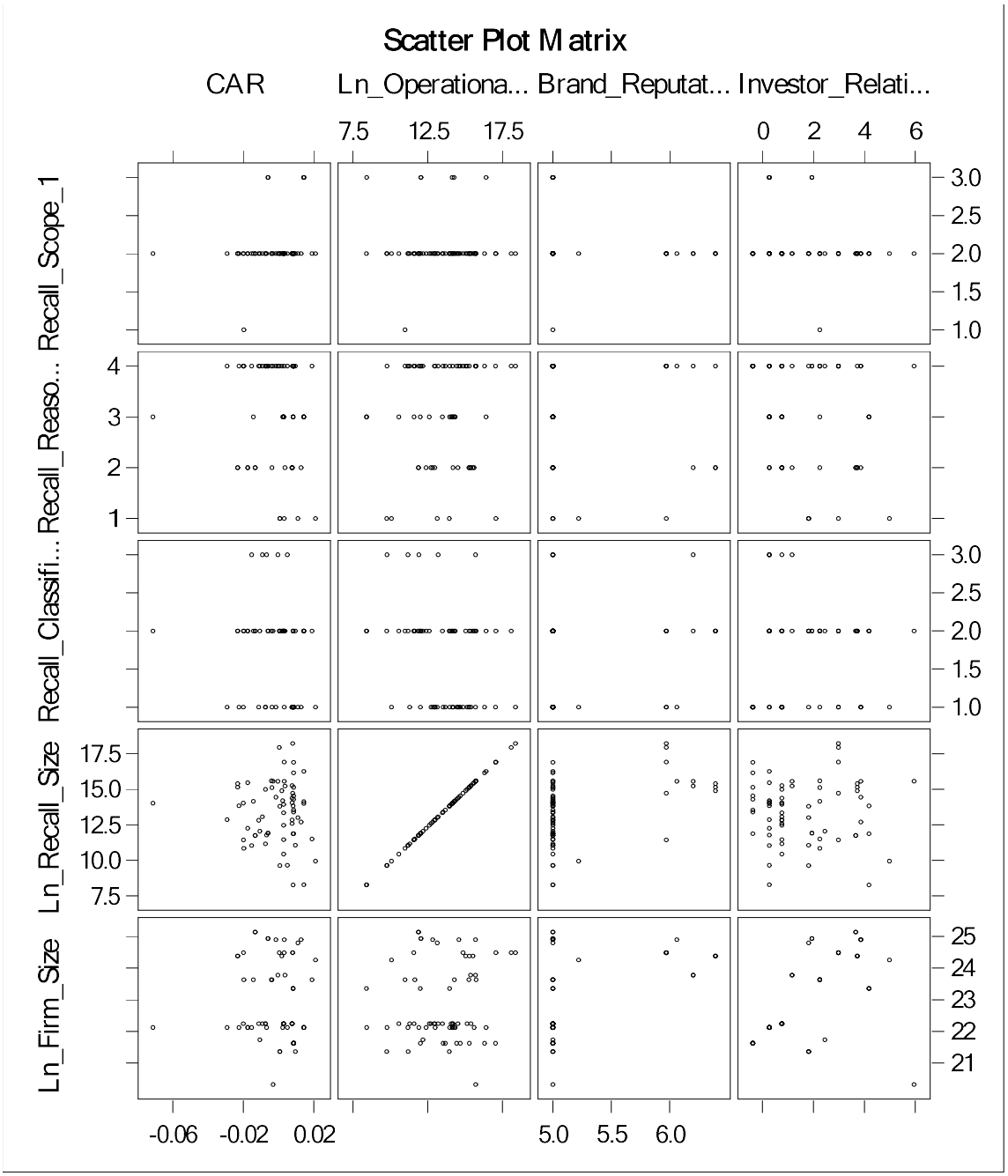
Adulteration: Adulterated Presence of Foreign Tablets

Appendix B

Correlation Analysis and Scatter Plots

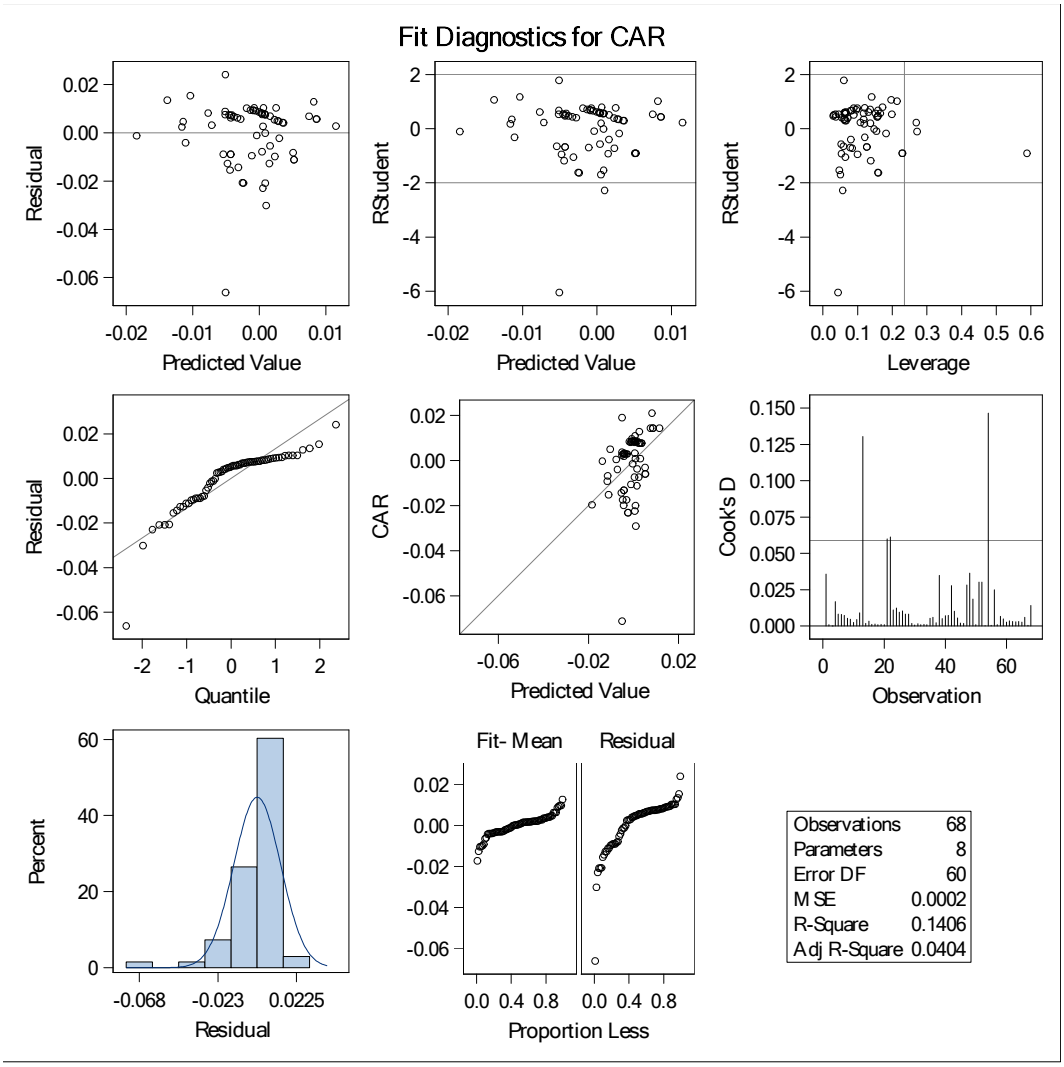
Pearson Correlation Coefficients, N = 68 Prob > |r| under H0: Rho=0				
	CAR	**Ln_Operational_ Cost**	**Brand_Reputation**	**Investor_Relations**
Recall_Scope Recall_Scope	0.23400 0.0548	-0.03172 0.7974	-0.10389 0.3992	-0.15657 0.2023
Recall_Reason Recall_Reason	-0.08424 0.4946	0.06818 0.5807	-0.02451 0.8428	-0.20460 0.0942
Recall_Classification Recall_Classification	-0.20651 0.0911	-0.25605 0.0351	0.11998 0.3298	0.10233 0.4063
Ln_Recall_Size Ln_Recall_Size	-0.01748 0.8875	1.00000 <.0001	0.41785 0.0004	-0.00698 0.9549
Ln_Firm_Size Ln_Firm_Size	-0.05761 0.6407	0.08926 0.4692	0.53010 <.0001	0.64066 <.0001

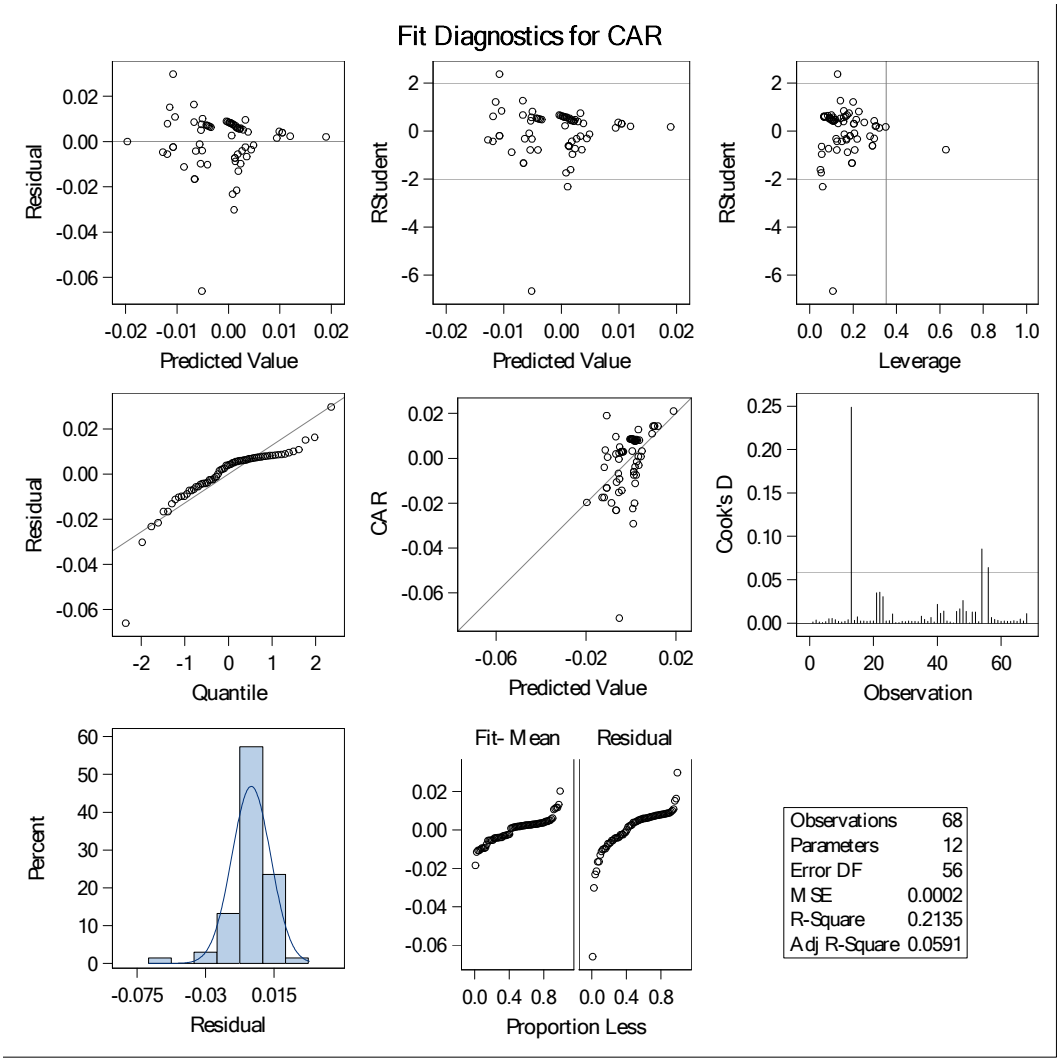
Spearman Correlation Coefficients, N = 68 Prob > |r| under H0: Rho=0				
	CAR	**Ln_Operational_ Cost**	**Brand_Reputation**	**Investor_Relations**
Recall_Scope Recall_Scope	0.28811 0.0172	0.00837 0.9460	-0.11129 0.3662	-0.17554 0.1522
Recall_Reason Recall_Reason	-0.08374 0.4972	0.05409 0.6613	-0.02368 0.8480	-0.21122 0.0838
Recall_Classification Recall_Classification	-0.28371 0.0190	-0.24366 0.0453	0.08135 0.5096	0.16183 0.1873
Ln_Recall_Size Ln_Recall_Size	0.01508 0.9029	1.00000 <.0001	0.38292 0.0013	-0.02081 0.8662
Ln_Firm_Size Ln_Firm_Size	-0.19266 0.1155	0.04863 0.6937	0.49869 <.0001	0.71255 <.0001



Appendix C

Diagnostics for Financial Risk

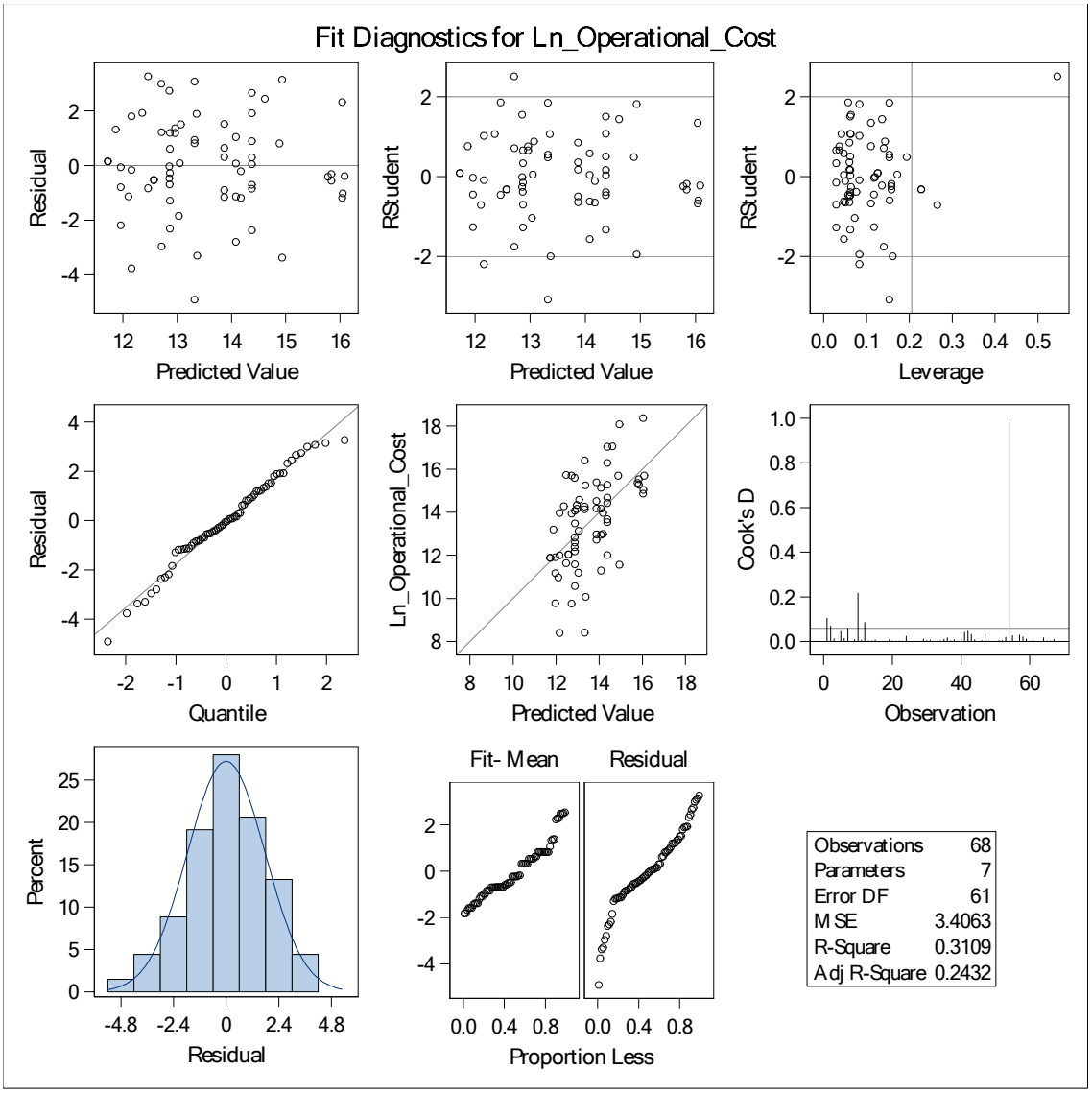


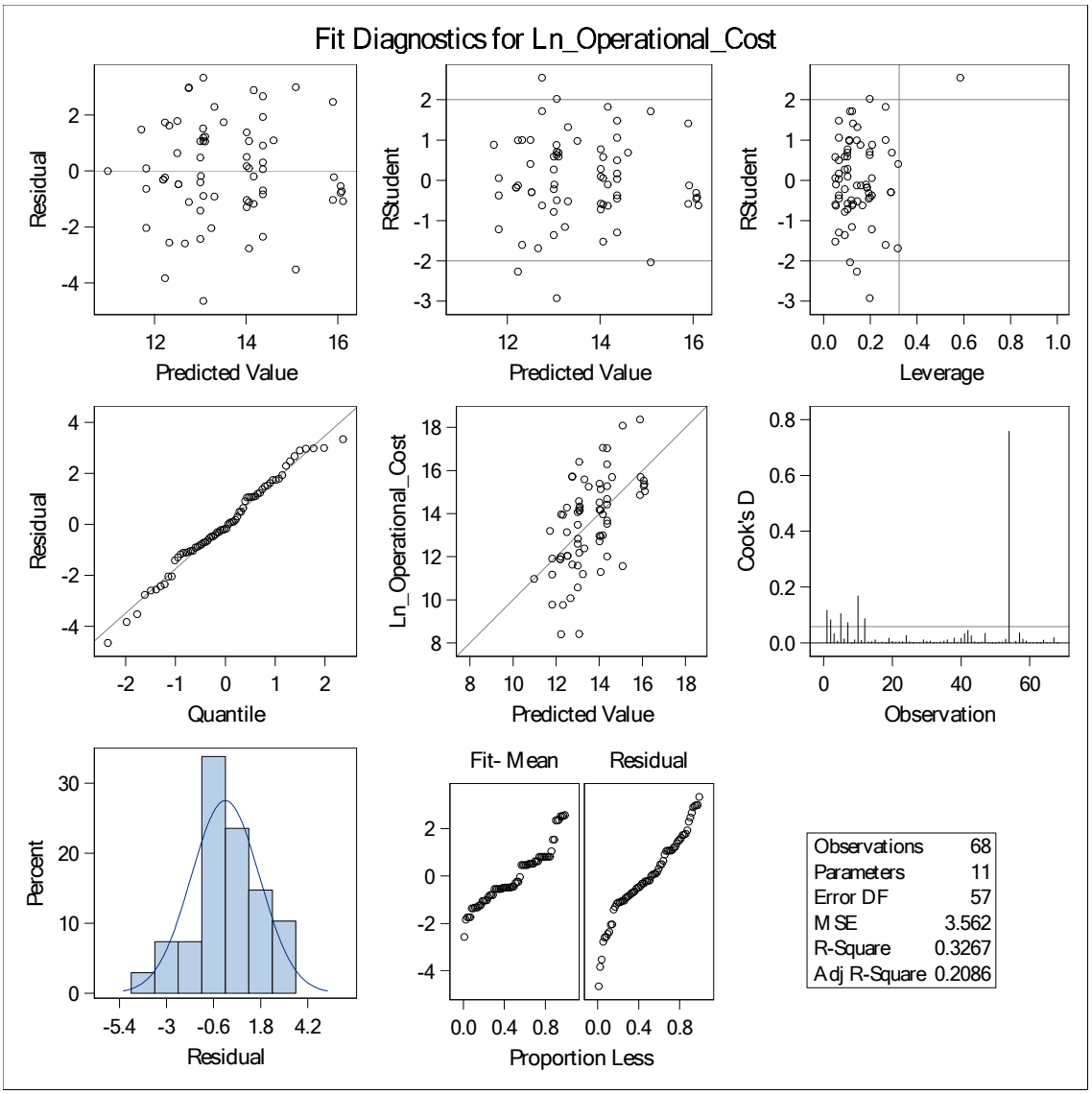


Diagnostics for Financial Risk with categorical variables

Appendix D

Diagnostics for Operational Risk

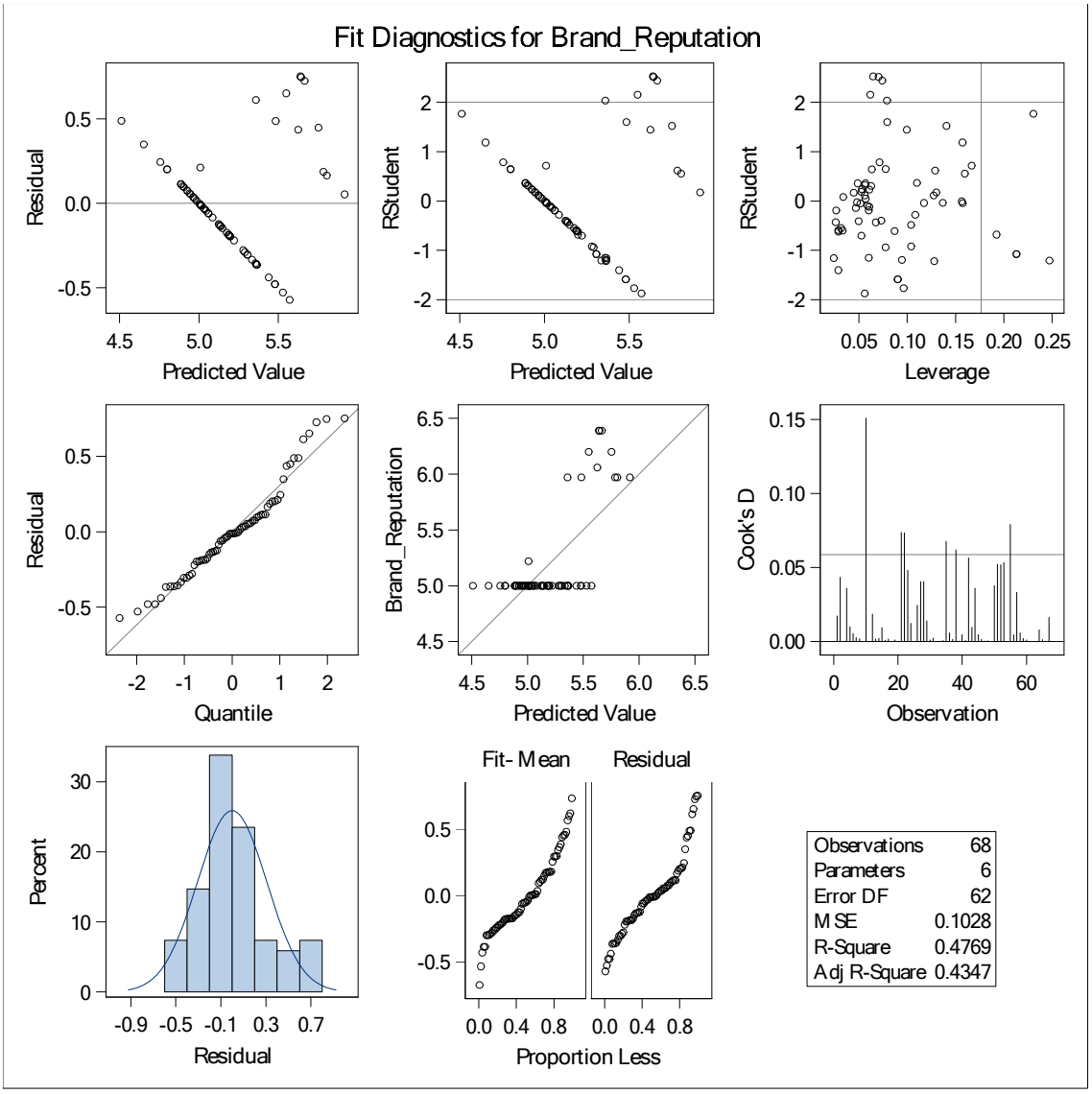


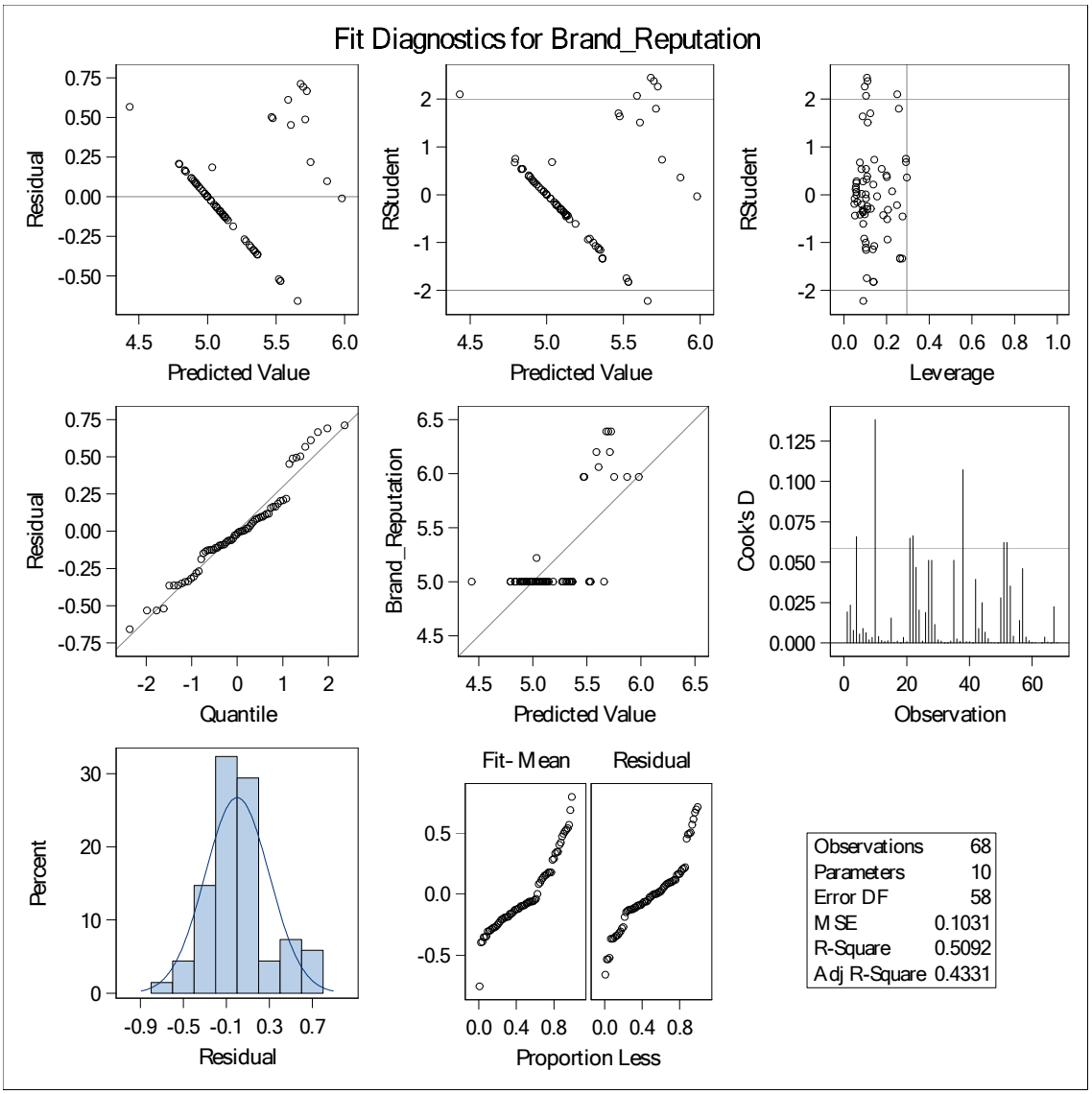


Diagnostics for Operational Risk with categorical variables

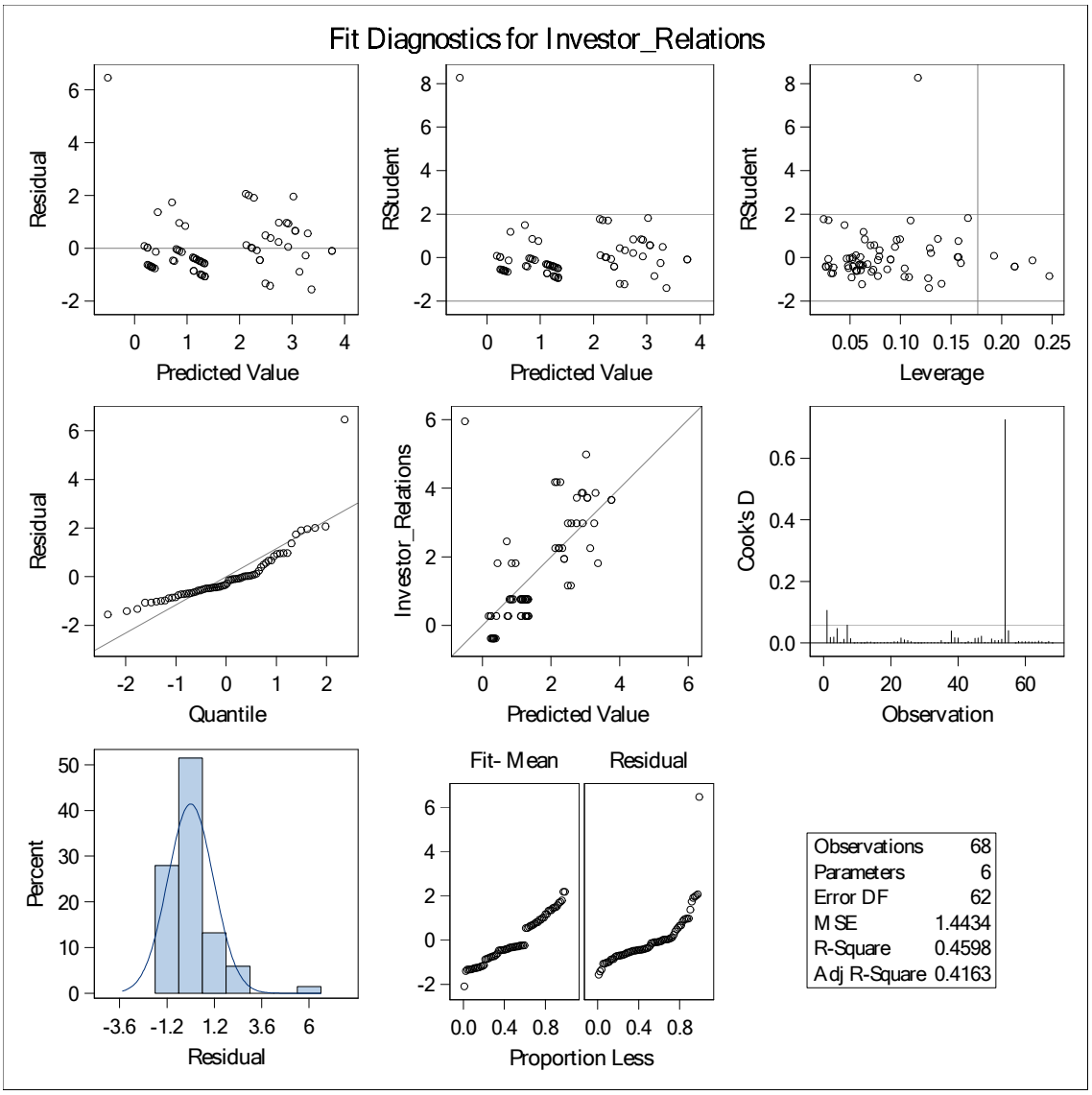
Appendix D

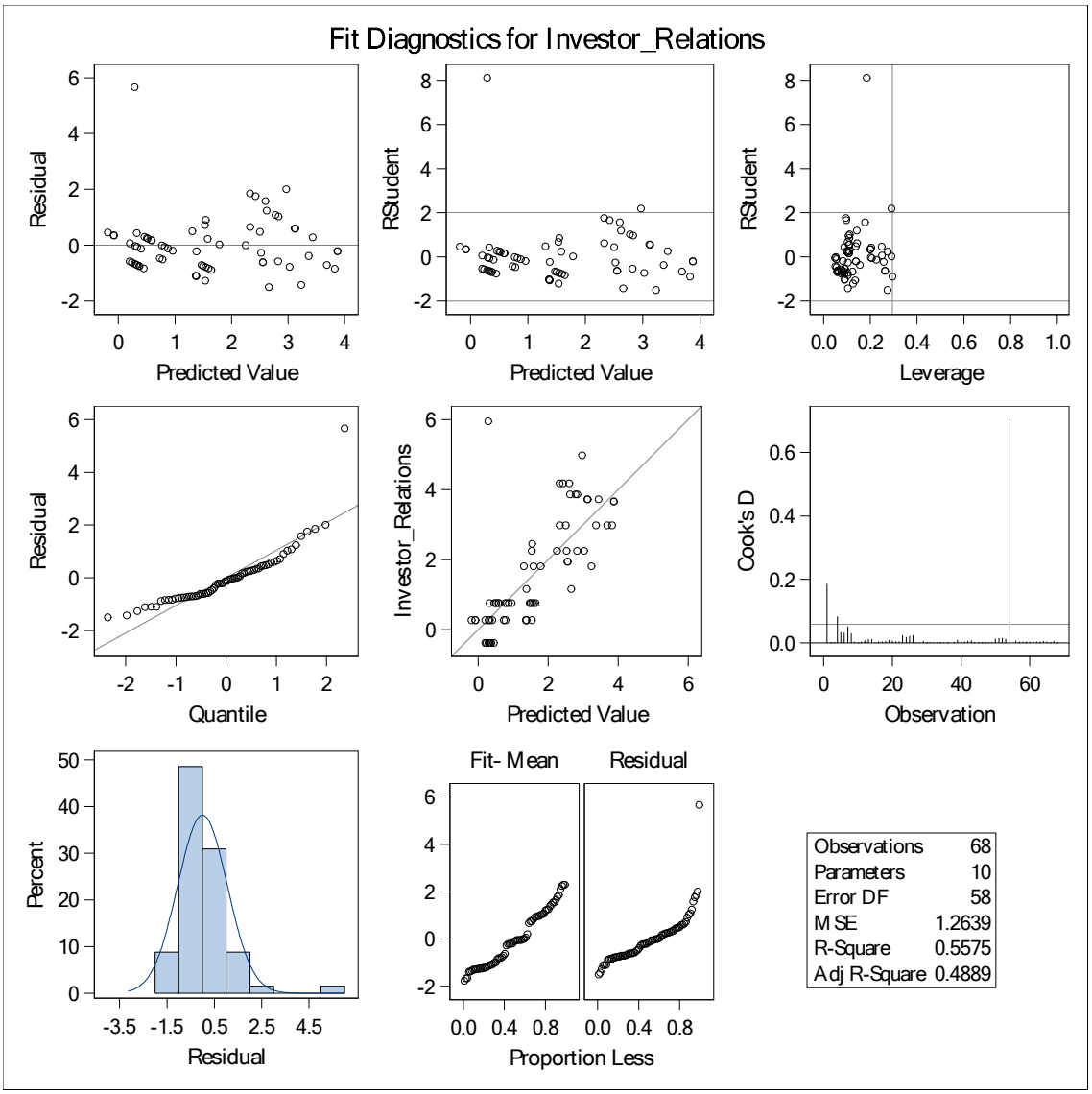
Diagnostics for Reputation Risk





Diagnostics for Brand Reputation with categorical variables

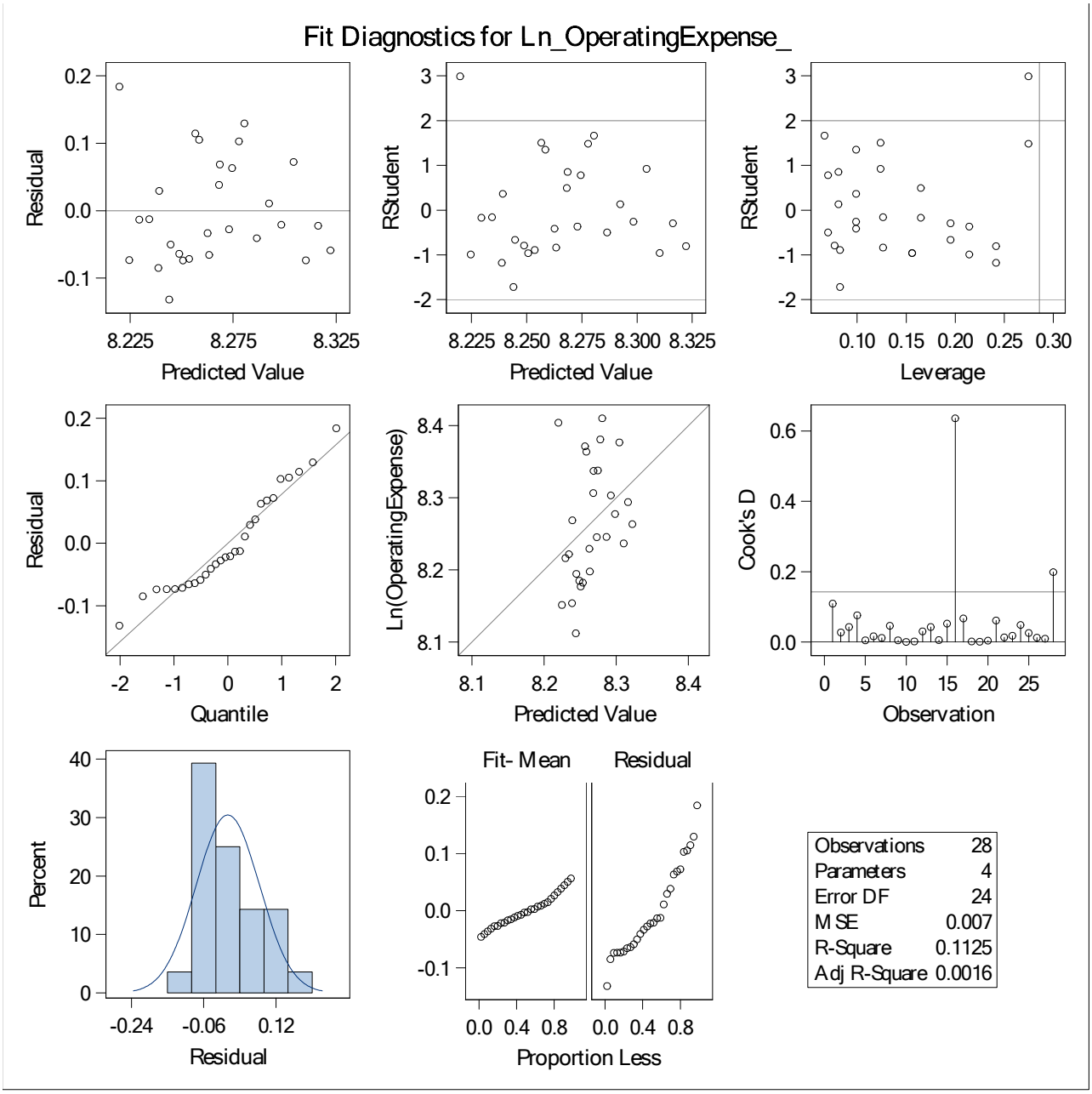




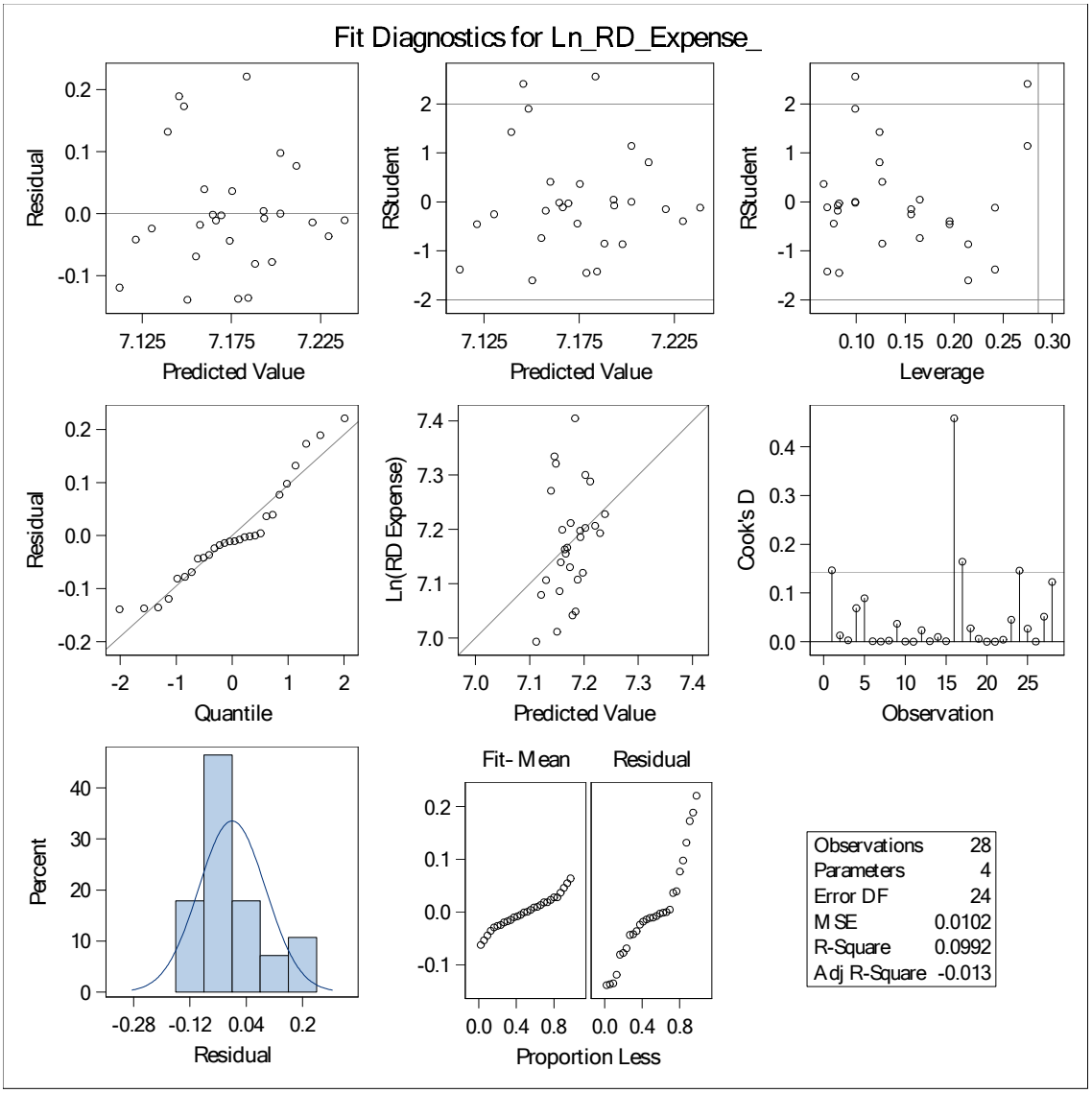
Diagnostics for Investor Relations with categorical variables

Appendix E

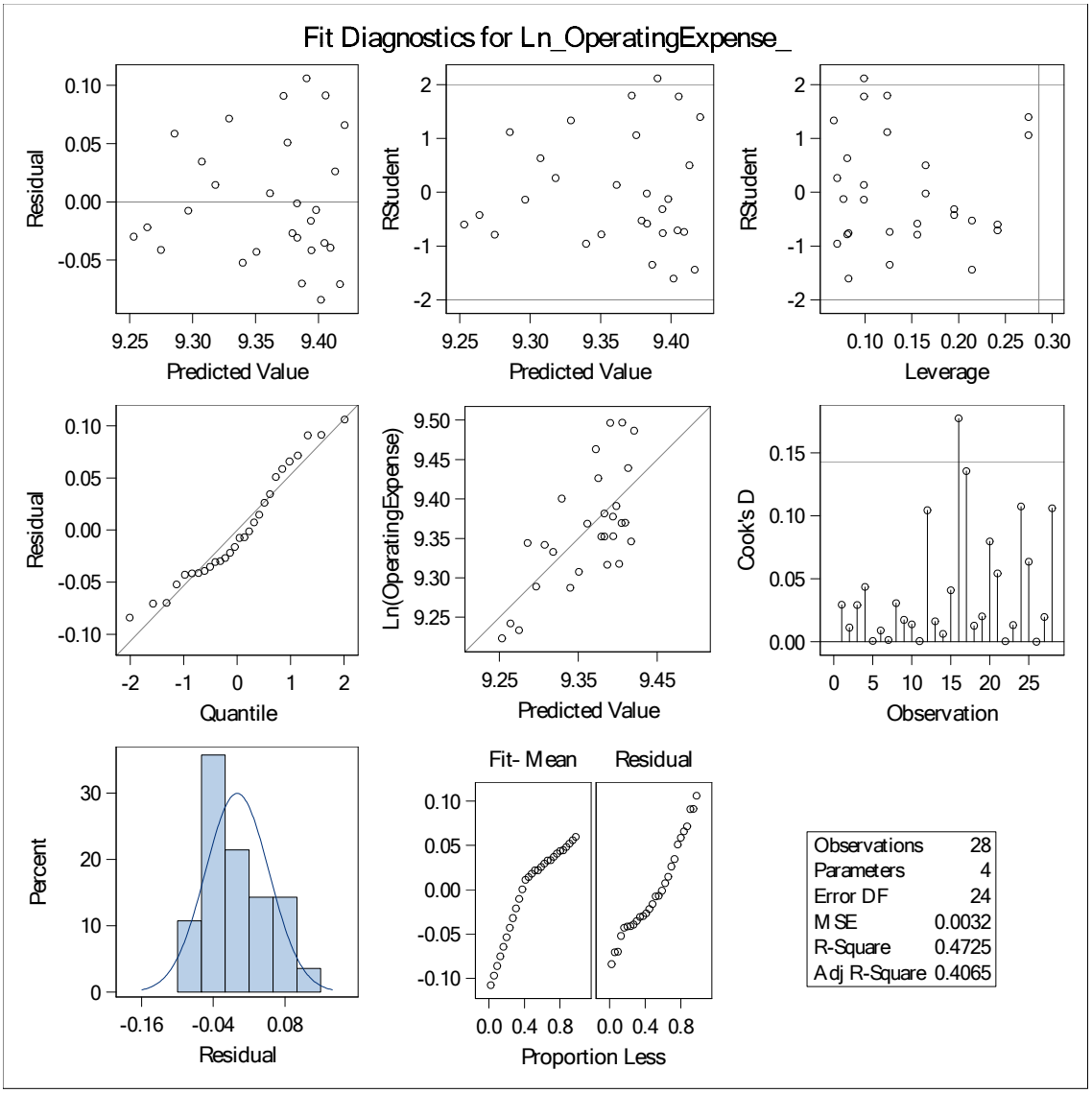
Diagnostics for Regulation Risk



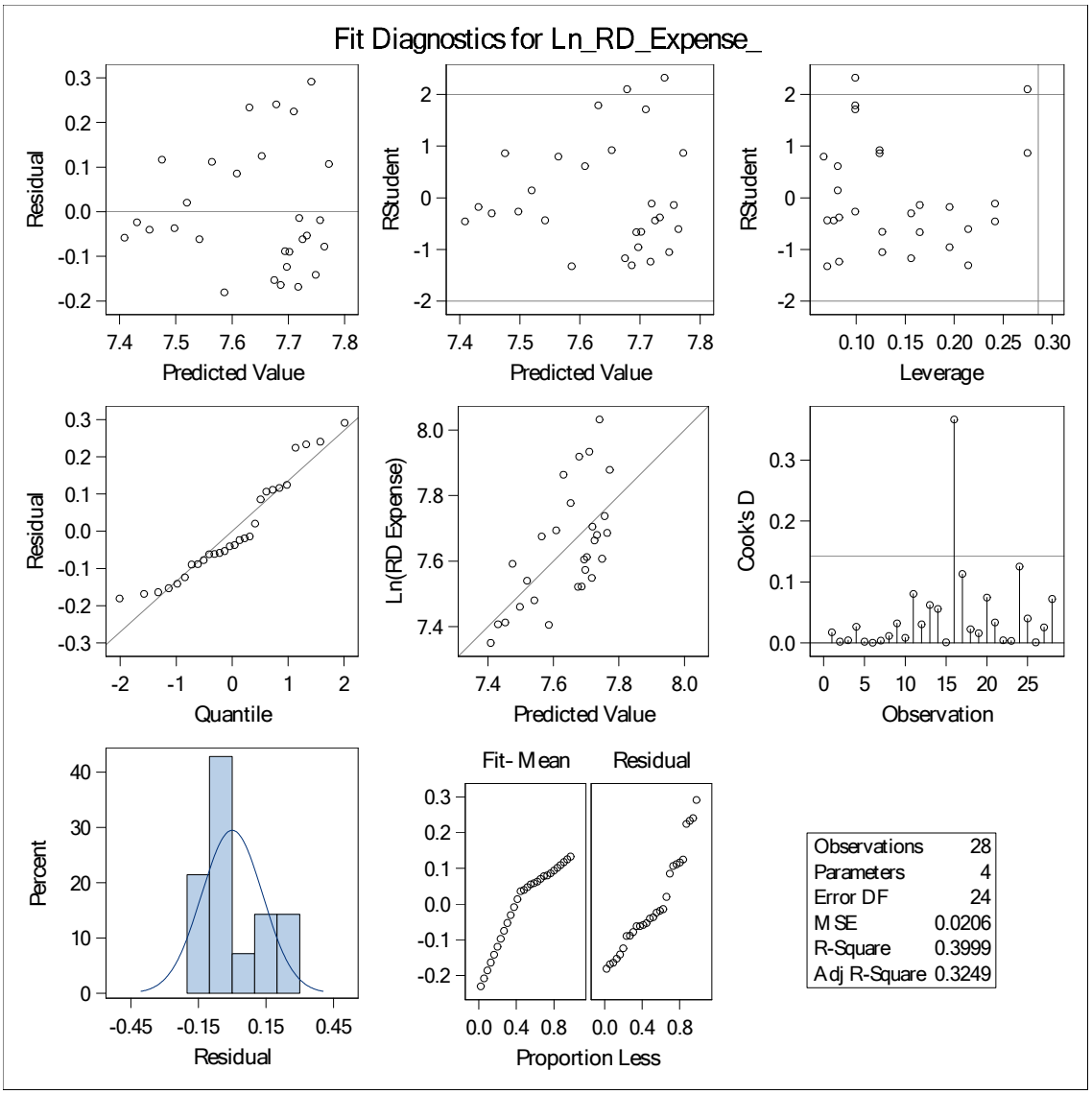
Diagnostics for Operational Expense of Large Firm 1



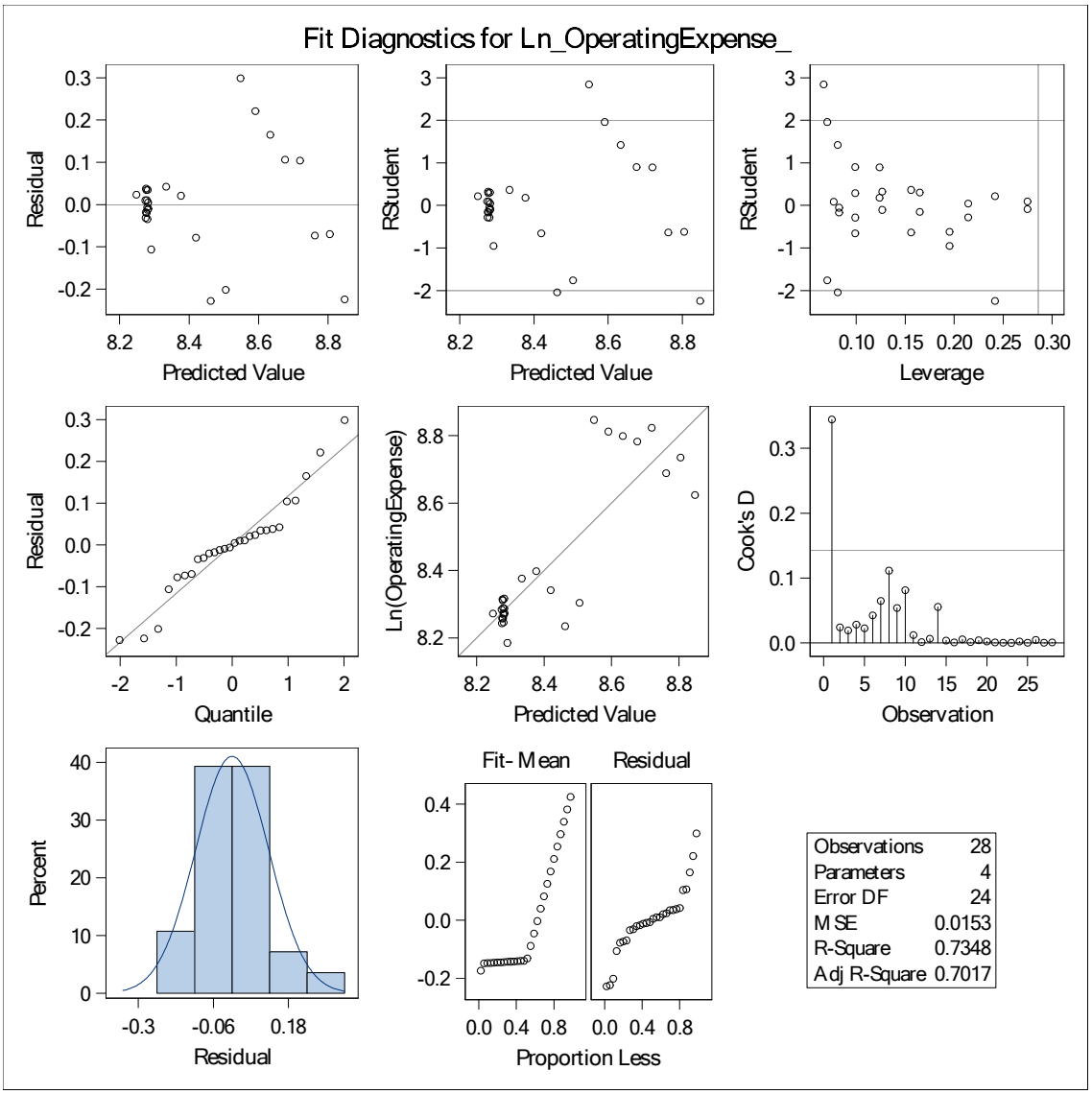
Diagnostics for R&D Expense of Large Firm 1



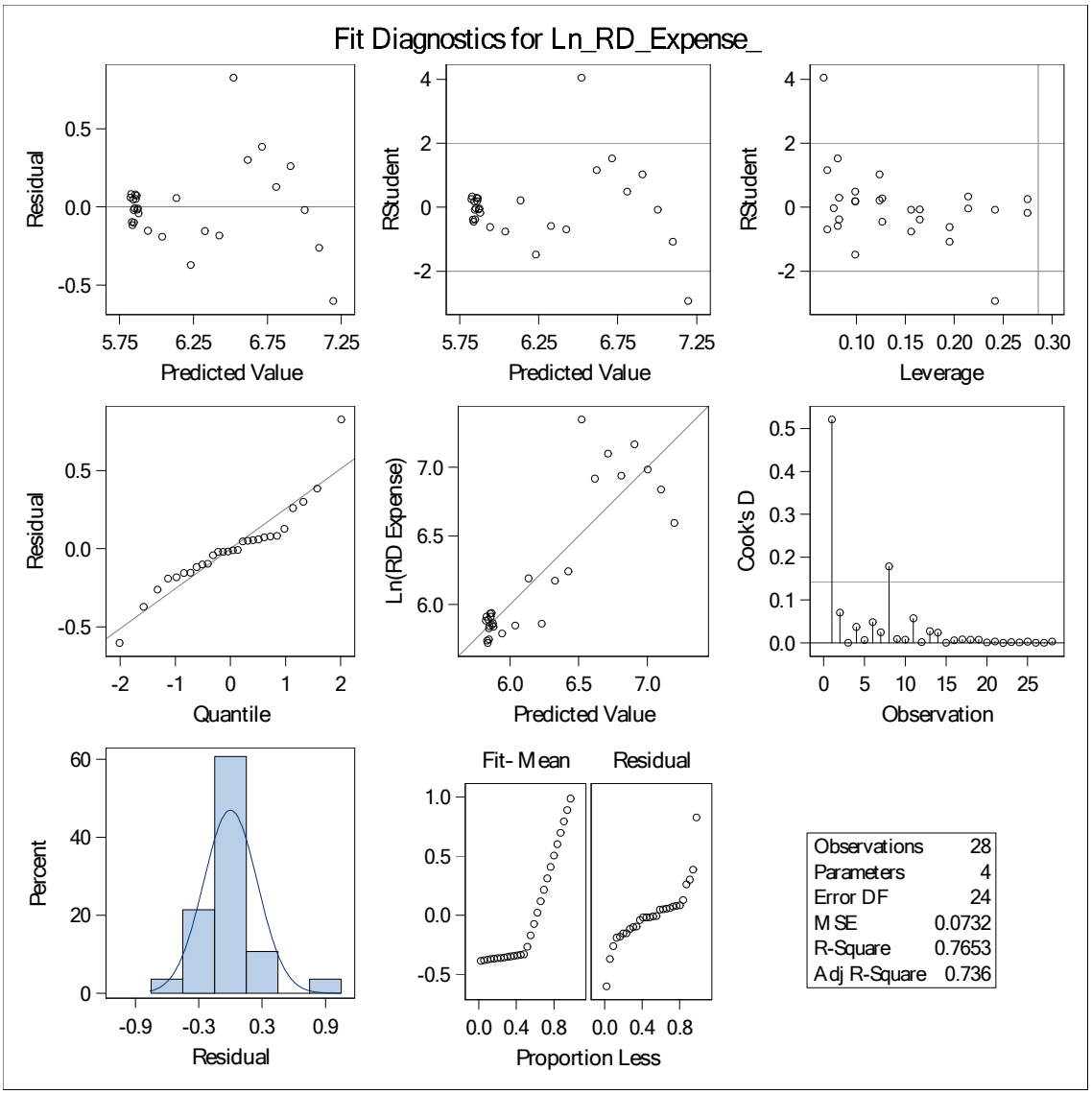
Diagnostics for Operational Expense of Large Firm 2



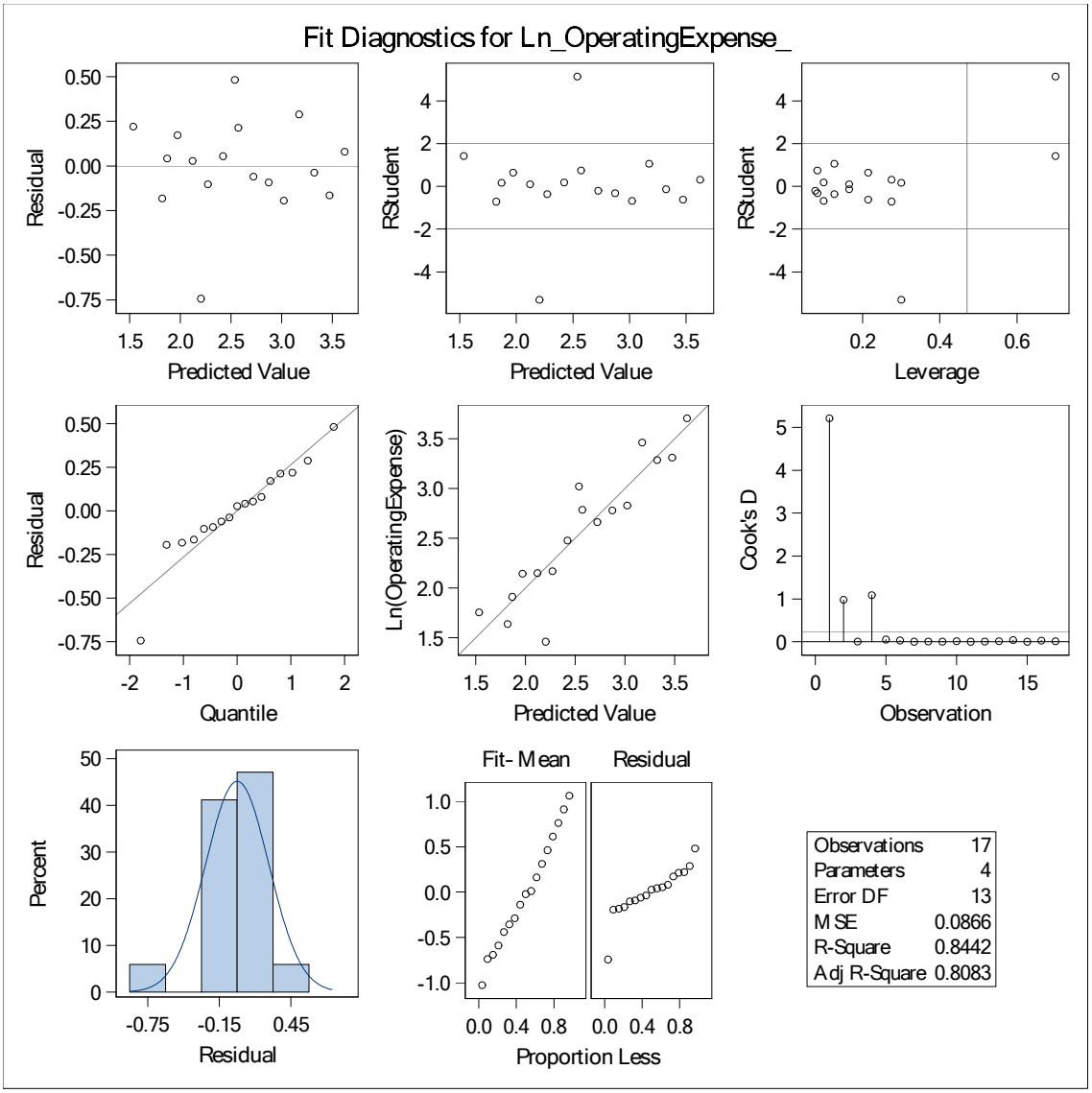
Diagnostics for R&D Expense of Large Firm 2



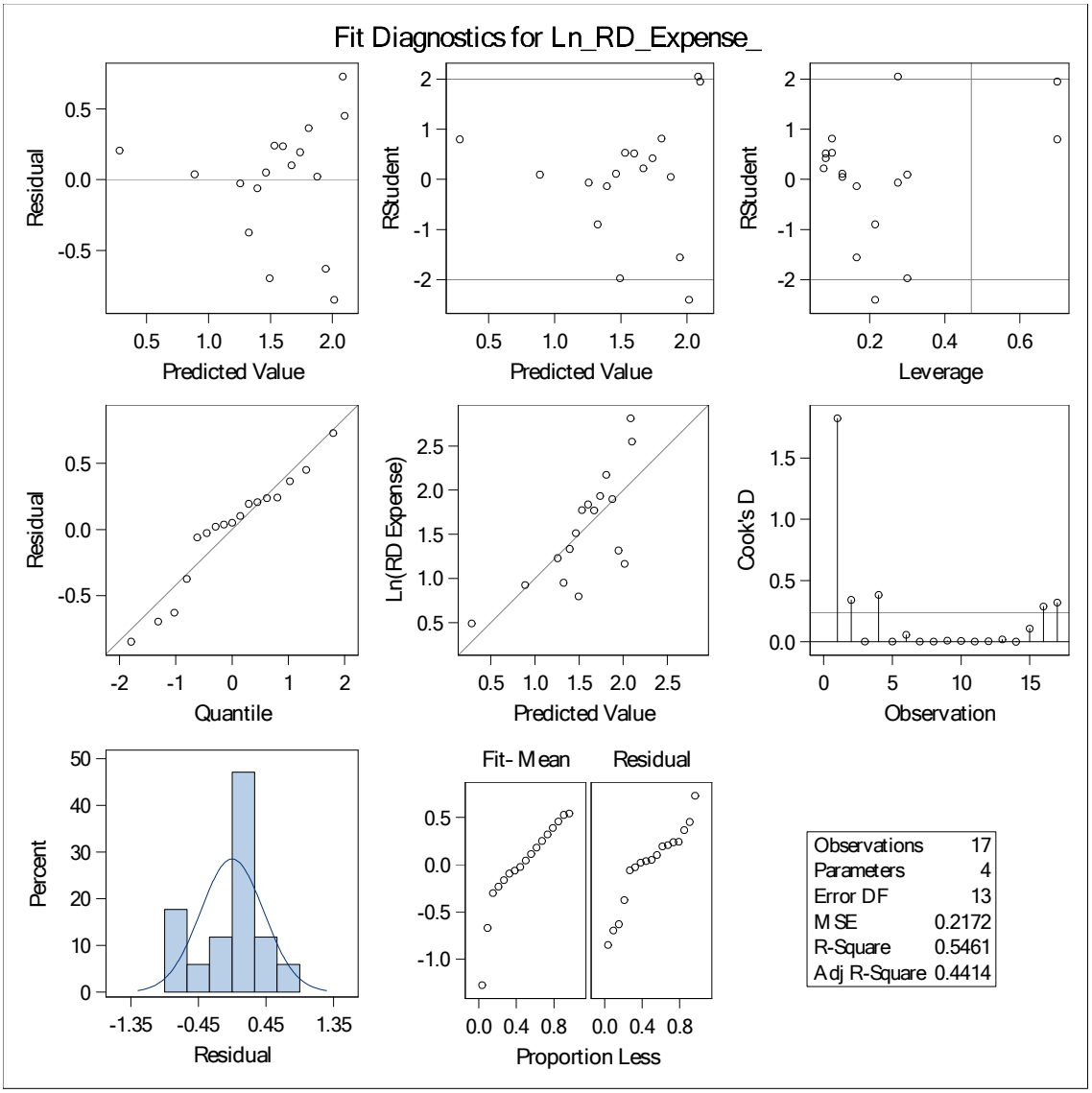
Diagnostics for Operational Expense of Large Firm 3



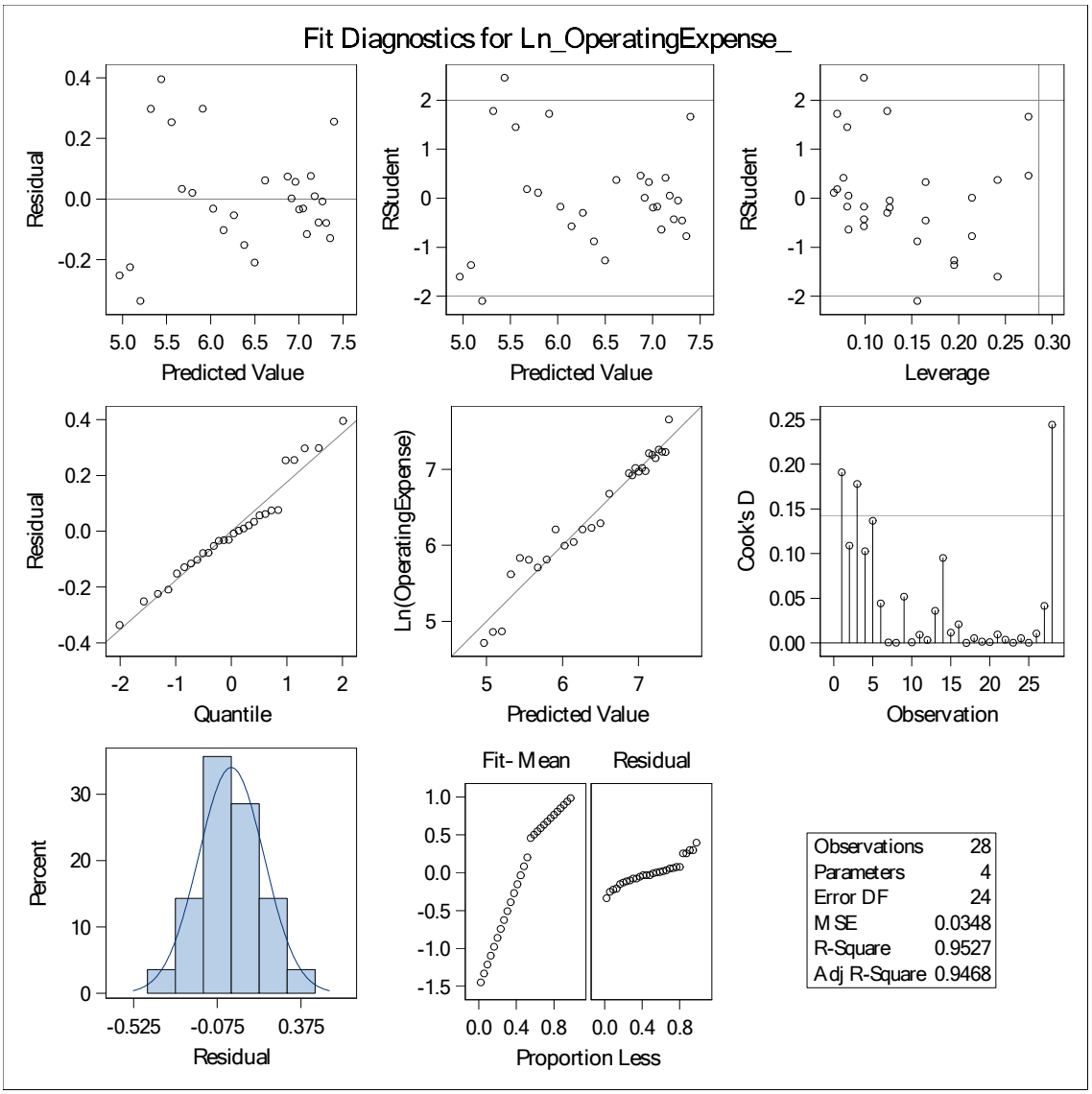
Diagnostics for R&D Expense of Large Firm 3



Diagnostics for Operational Expense of Small Firm 1



Diagnostics for R&D Expense of Small Firm 1



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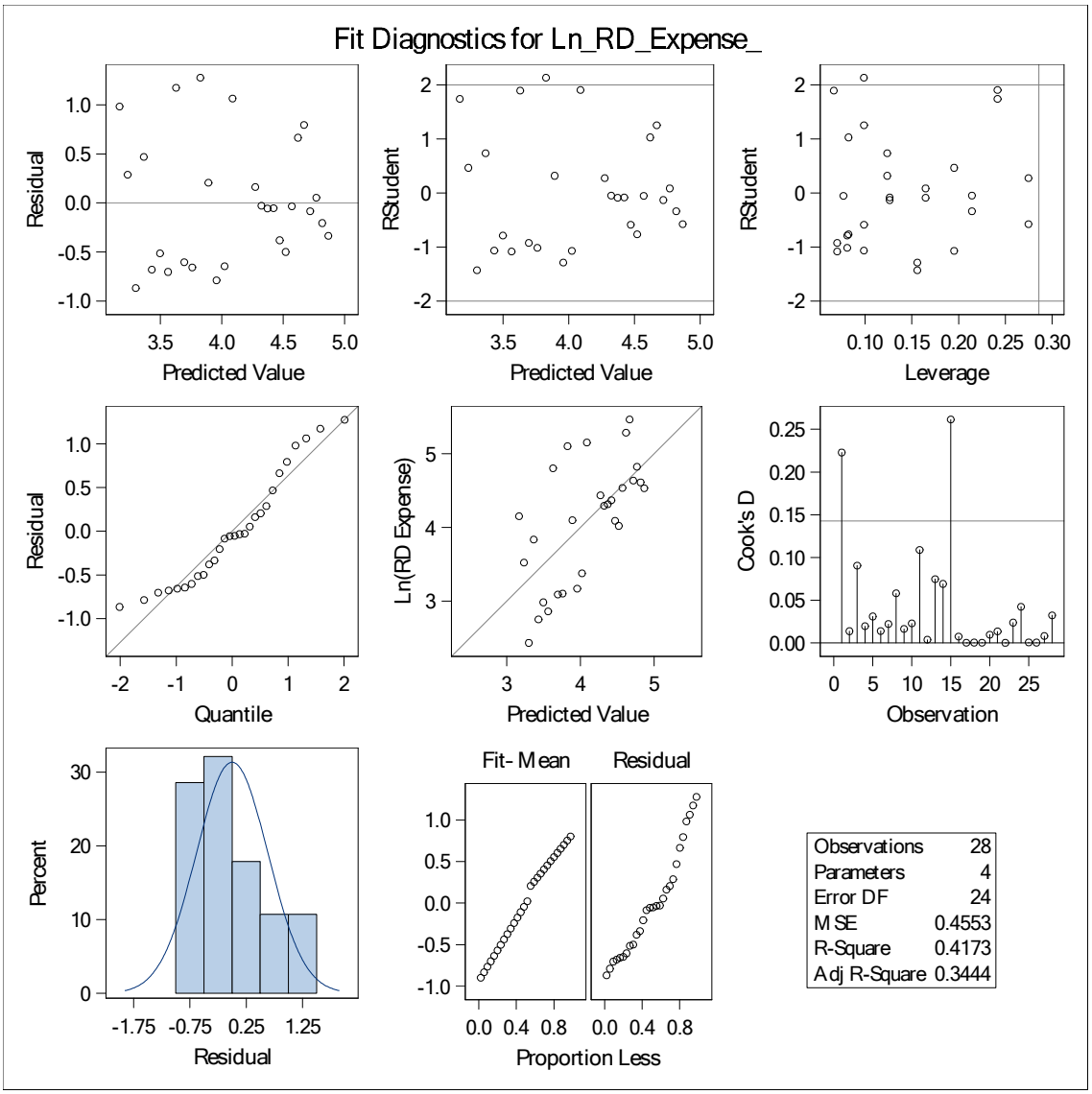

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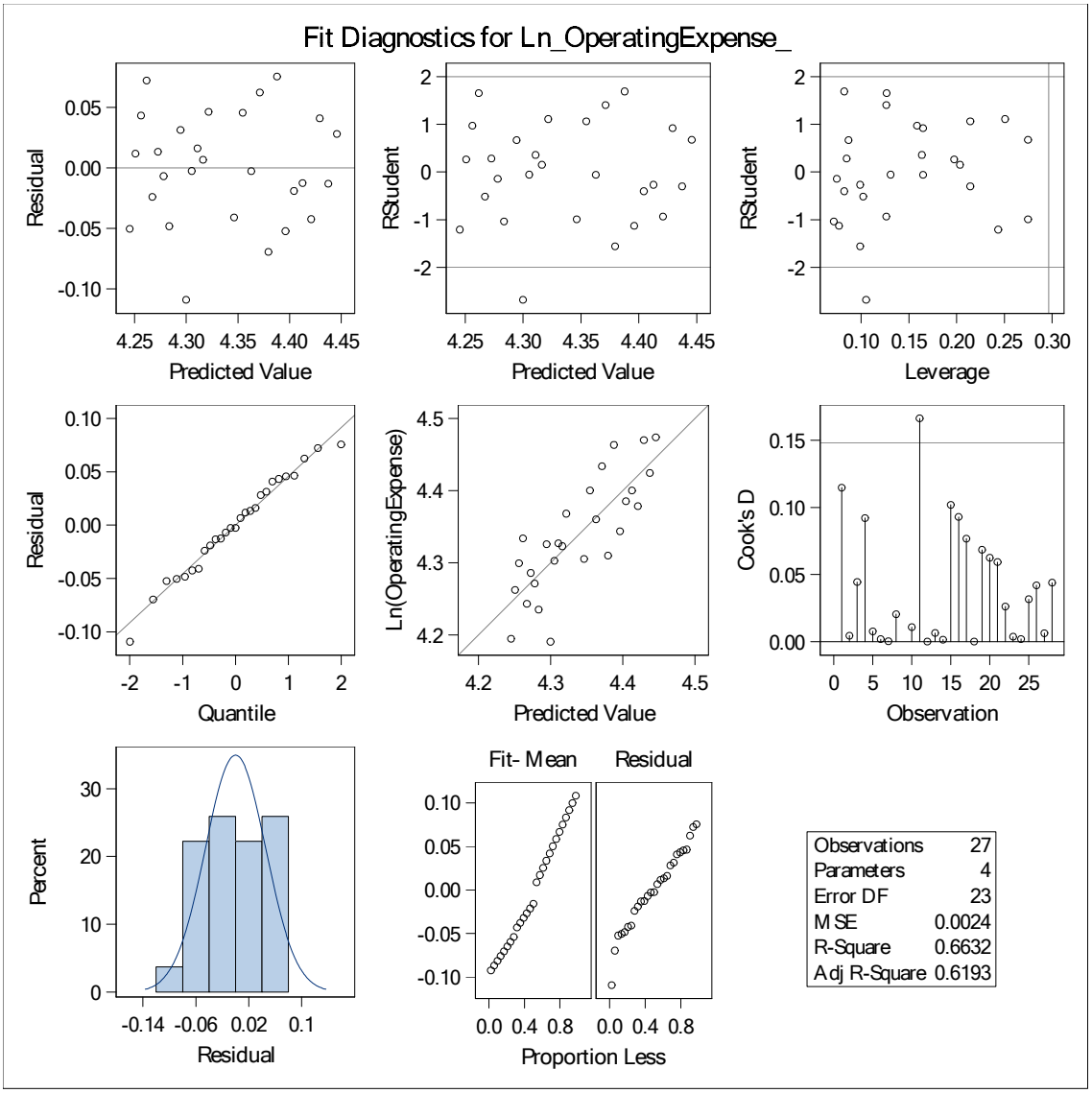
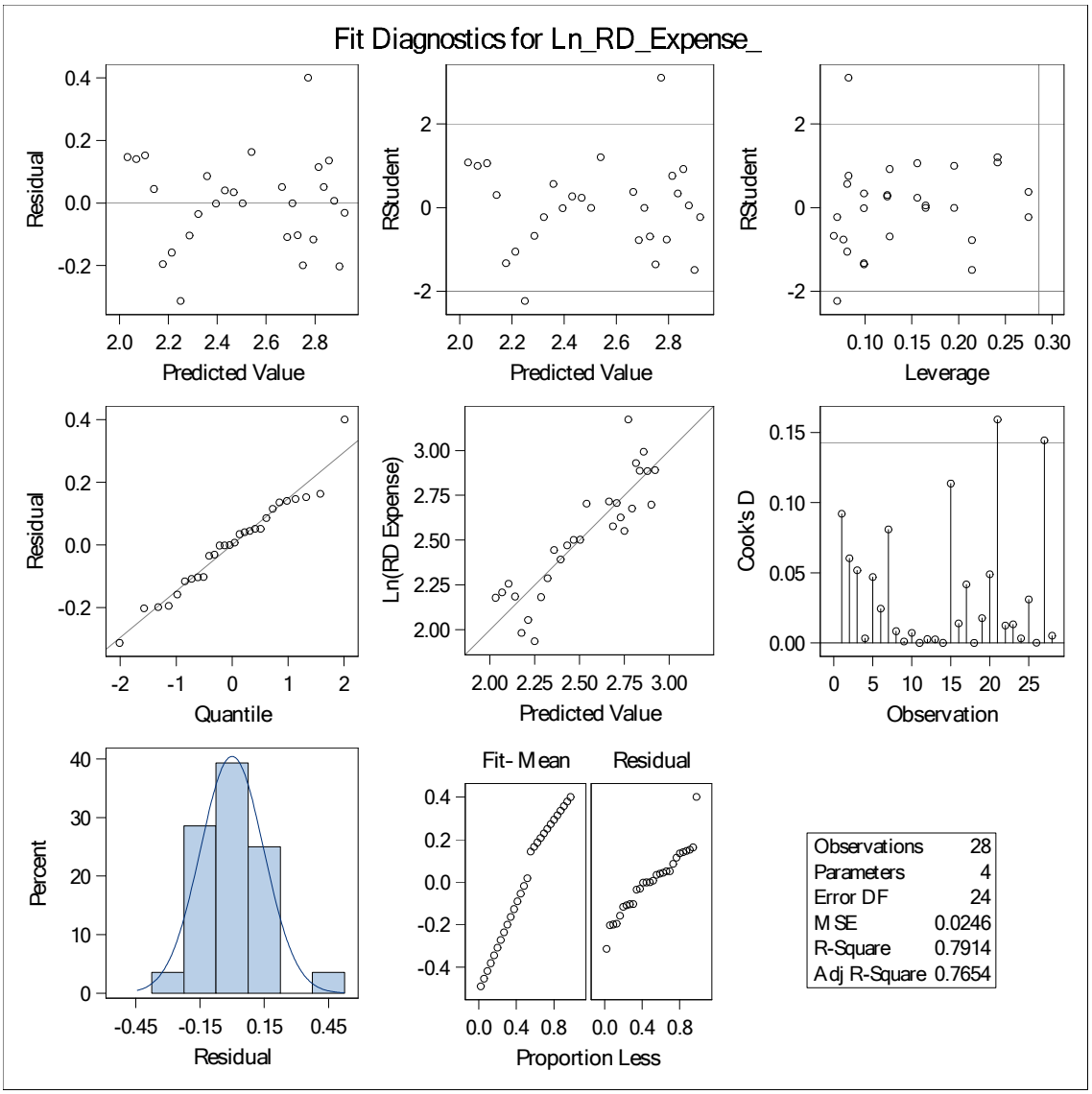


Diagnostics for Operational Expense of Small Firm 3



Diagnostics for R&D Expense of Small Firm 3

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The author Sowmya Dinamani Rao got her PhD in Industrial Engineering and Master's Degree in Electrical Engineering from the University of Texas at Arlington. Ms. Rao was inducted into the Tau Beta Phi Engineering Honor Society in 2010, and is a member of IISE (Institute of Industrial and Systems Engineering), recipient of Doctoral Dean Scholarship and STEM Doctoral Fellow. She has a Six Sigma Green Belt Certification from IISE.

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Ms. Rao briefly worked as International Supply Chain Analyst in The Hershey Company, one of the largest chocolate manufacturers in North America with its headquarters in Hershey, Pennsylvania. She worked as a Graduate Teaching Assistant in the Industrial, Manufacturing and Systems Engineering Department at the University of Texas at Arlington before graduating.

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